

Clinical Development

JNJ54767414

MMY2002

Anonymization Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	27 NOV 2018

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. Supplemental Qualifiers for DM – SUPPDM	10
1.4.3. Adverse Events – AE	11
1.4.4. Supplemental Qualifiers for AE – SUPPAE	15
1.4.5. Biospecimen Events – BE.....	16
1.4.6. Clinical Events – CE.....	17
1.4.7. Supplemental Qualifiers for CE – SUPPCE.....	19
1.4.8. Concomitant Medications – CM	20
1.4.9. Supplemental Qualifiers for CM – SUPPCM	23
1.4.10. Comments – CO	24
1.4.11. Death Diagnosis – DD	25
1.4.12. Disposition – DS.....	26
1.4.13. Supplemental Qualifiers for DS – SUPPDS	28
1.4.14. Protocol Deviations – DV.....	29
1.4.15. ECG Test Results – EG.....	30
1.4.16. Supplemental Qualifiers for EG – SUPPEG.....	32
1.4.17. Exposure – EX.....	33
1.4.18. Supplemental Qualifiers for EX – SUPPEX.....	35
1.4.19. Findings About Events or Interventions – FA	36
1.4.20. Supplemental Qualifiers for FA – SUPPFA	38
1.4.21. Inclusion/Exclusion Criteria Not Met – IE.....	39
1.4.22. Laboratory Test Results – LB.....	41
1.4.23. Supplemental Qualifiers for LB – SUPPLB.....	44
1.4.24. Medical History – MH.....	45
1.4.25. Pharmacokinetic Concentrations – PC.....	47

1.4.26.	Pharmacokinetic Parameters – PP	50
1.4.27.	Supplemental Qualifiers for PP – SUPPPP	52
1.4.28.	Procedure – PR	53
1.4.29.	Supplemental Qualifiers for PR – SUPPPR	55
1.4.30.	Questionnaire – QS	56
1.4.31.	Respiratory System Findings – RE	58
1.4.32.	Related Records – RELREC.....	60
1.4.33.	Disease Response – RS.....	61
1.4.34.	Supplemental Qualifiers for RS – SUPPRS.....	63
1.4.35.	Subject Characteristics – SC.....	64
1.4.36.	Subject Elements – SE.....	65
1.4.37.	Subject Status – SS	67
1.4.38.	Subject Visits – SV	69
1.4.39.	Trial Arms – TA.....	71
1.4.40.	Trial Elements – TE.....	72
1.4.41.	Trial Inclusion/Exclusion Criteria – TI.....	73
1.4.42.	Tumour Results – TR.....	74
1.4.43.	Supplemental Qualifiers for TR – SUPPTR.....	76
1.4.44.	Trial Summary – TS.....	77
1.4.45.	Tumor Identification – TU.....	79
1.4.46.	Supplemental Qualifiers for TU – SUPPTU.....	81
1.4.47.	Trial Visits – TV	82
1.4.48.	Vital Signs – VS	83
1.4.49.	Antibodies to study Agent – XA	85
1.4.50.	Cytogenetics Findings – XC	88
1.4.51.	Sample Handling – XZ	90
1.4.52.	Randomization – ZR.....	92

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- 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, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- 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.
- Empty CO (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 MMY2002 CSR 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: INVNAM,RFSTDTC,DTHDTC,INVID,RFICDTC,DMDTC,RFXENDTC,RFPENDTC,RFENDTC,RFXSTDTC,BRTHDTC

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

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

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

1.4.2. Supplemental Qualifiers for DM – SUPPDM

Dataset	SUPPDM
Creating program	dm.sas
Description	Supplemental Qualifiers for DM
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: IDVAR,IDVARVAL,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
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.

1.4.3. Adverse Events – AE

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

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
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.
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.
AESOC	num	Primary System Organ Class Code		Collected at CRF.
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEREL	char	Causality		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
AETOXGR	char	Standard Toxicity Grade		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.

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

1.4.4. Supplemental Qualifiers for AE – SUPPAE

Dataset	SUPPAE
Creating program	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 (AESBDTC) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.5. 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, BETERM

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

Variable	Type	Label	Codes	Comments
BESTDY	num	Relative Start Day of 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.

1.4.6. Clinical Events – CE

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

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

Variable	Type	Label	Codes	Comments
CEGRPID	char	Group ID		Collected at CRF.
CESPID	char	Sponsor-Defined Identifier		Collected at CRF.
CEDECOD	char	Dictionary-Derived Term		Collected at CRF.
CECAT	char	Category for Clinical Event		Collected at CRF.
CEPRESP	char	Clinical Event Pre-Specified		Collected at CRF.
CEOCCUR	char	Clinical Event Occurrence		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CESTDY	num	Relative Start Day of Clinical Event		If CESTDTC and REF.DATE not missing then perform below logic to calculate CESTDY, If CESTDTC less than REF.DATE then (CESTDTC - REF.DATE). Else if CESTDTC is greater than equal to REF.DATE then (CESTDTC - REF.DATE) +1.

1.4.7. Supplemental Qualifiers for CE – SUPPCE

Dataset	SUPPCE
Creating program	ce.sas
Description	Supplemental Qualifiers for CE
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CECNFDTC, CESTDTC1, CESTDTC2, CESTDTC3

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 (CECNFDTC, CESTDTC1, CESTDTC2, CESTDTC3) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.

Variable	Type	Label	Codes	Comments
QORIG	char	Origin		Collected at CRF.
QEVAL	char	Evaluator		Collected at CRF.

1.4.8. 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,CMSTTPT,CMENTPT

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.
CMGRPID	char	Group ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSE	num	Dose per Administration		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.
CMDOSTOT	num	Total Daily Dose		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.

Variable	Type	Label	Codes	Comments
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC - REF.DATE) +1.
CMENRF	char	End Relative to Reference Period		Collected at CRF.
CMSTRTPT	char	Start Relative to Reference Time Point		Collected at CRF.
CMENRTPT	char	End Relative to Reference Time Point		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.
CMSTPTY	char	Relative Day of Start Ref Time Point		If CMSTTPT and REF.DATE not missing then perform below logic to calculate CMSTPTY, If CMSTTPT less than REF.DATE then (CMSTTPT - REF.DATE). Else if CMSTTPT is greater than equal to REF.DATE then (CMSTTPT - REF.DATE) +1.
CMENPTY	char	Relative Day of End Ref Time Point		If CMENPTPT and REF.DATE not missing then perform below logic to calculate CMENPTY, If CMENPTPT less than REF.DATE then (CMENPTPT - REF.DATE). Else if CMENPTPT is greater than equal to REF.DATE then (CMENPTPT - REF.DATE) +1.

1.4.9. 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: QEQVAL

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

1.4.10. Comments – CO

Dataset	CO
Creating program	co.sas
Description	Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

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

1.4.11. Death Diagnosis – DD

Dataset	DD
Creating program	dd.sas
Description	Death Diagnosis
Unique identifier	STUDYID, DUSUBJID, DDTEST, DDSEQ
Sorted by	STUDYID, DUSUBJID, DDTEST, DDSEQ
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
DDSEQ	num	Sequence Number		Collected at CRF.
DDSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DDTESTCD	char	Death Detail Assessment Short Name		Collected at CRF.
DDTEST	char	Death Detail Assessment		Collected at CRF.
DDORRES	char	Result or Finding as Collected		Collected at CRF.
DDSTRESC	char	Standardized Result in Character Format		Collected at CRF.

1.4.12. Disposition – DS

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

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

1.4.13. Supplemental Qualifiers for DS – SUPPDS

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

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

1.4.14. Protocol Deviations – DV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DVSEQ	num	Sequence Number		Collected at CRF.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
DVCAT	char	Category for Protocol Deviation		Collected at CRF.

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

1.4.15. ECG Test Results – EG

Dataset	EG
Creating program	eg.sas
Description	ECG Test Results
Unique identifier	STUDYID,DUSUBJID,EGTEST,EGSEQ
Sorted by	STUDYID,DUSUBJID,EGTEST,EGSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EGDTC

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

Variable	Type	Label	Codes	Comments
EGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EGTESTCD	char	ECG Test or Examination Short Name		Collected at CRF.
EGTEST	char	ECG Test or Examination Name		Collected at CRF.
EGORRES	char	Result or Finding in Original Units		Collected at CRF.
EGSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
EGSTAT	char	Completion Status		Collected at CRF.
EGREASND	char	Reason ECG Not Performed		Collected at CRF.
EGMETHOD	char	Method of ECG Test		Collected at CRF.
EGBLFL	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.
EGDY	num	Relative Day of ECG		If EGDTC and REF.DATE not missing then perform below logic to calculate EGDY, If EGDTC less than REF.DATE then (EGDTC - REF.DATE). Else if EGDTC is greater than equal to REF.DATE then (EGDTC - REF.DATE) + 1.
EGTM	num	Time of ECG		If EGDTC contains time part then timepart(EGDTC) else EGTM equal to NULL.

1.4.16. Supplemental Qualifiers for EG – SUPPEG

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

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

1.4.17. 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: EXENDTC,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.
EXGRPID	char	Group ID		Collected at CRF.
EXREFID	char	Reference ID		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXTRT	char	Name of Actual Treatment		Collected at CRF.
EXDOSE	num	Dose per Administration		Collected at CRF.

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

1.4.18. Supplemental Qualifiers for EX – SUPPEX

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

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

1.4.19. Findings About Events or Interventions – FA

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

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.
FAOBJ	char	Object of the Observation		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.

Variable	Type	Label	Codes	Comments
FAORRES	char	Result or Finding in Original Units		Collected at CRF.
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
FASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
FASTRESU	char	Standard Units		Collected at CRF.
FABLFL	char	Baseline Flag		Collected at CRF.
FAEVAL	char	Evaluator		Collected at CRF.
FAEVALID	char	Evaluator Identifier		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		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.
FATM	num	Time of Collection		If FADTC contains time part then timepart(FADTC) else FATM equal to NULL.

1.4.20. 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	

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

1.4.21. Inclusion/Exclusion Criteria 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.

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

1.4.22. 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: LBDTC,LBENDTC,LBNAM,LBSPID

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.
LBGRPID	char	Group ID		Collected at CRF.
LBREFID	char	Specimen ID		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.

Variable	Type	Label	Codes	Comments
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.
LBORNRL0	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF.
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Completion Status		Collected at CRF.
LBREASND	char	Reason Test Not Done		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
LBFAS	char	Fasting Status		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.
LBENDY	num	Relative End Day of Specimen Collection		If LBENDTC and REF.DATE not missing then perform below logic to calculate LBENDY, If LBENDTC less than REF.DATE then (LBENDTC - REF.DATE). Else if LBENDTC is greater than equal to REF.DATE then (LBENDTC - REF.DATE) + 1.
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.
LBTPT	char	Planned Time Point Name		Collected at CRF.
LBTPTNUM	num	Planned Time Point Number		Collected at CRF.
LBELTM	char	Planned Elapsed Time from Time Point Ref		Collected at CRF.
LBTPTREF	char	Time Point Reference		Collected at CRF.

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

1.4.23. 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.

Variable	Type	Label	Codes	Comments
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.

1.4.24. 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: MHTERM,MHSTDTC,MHENTPT

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.
MHDECOD	char	Dictionary-Derived Term		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.
MHBODSYS	char	Body System or Organ Class		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
MHTOXGR	char	Standard Toxicity Grade		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
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.
MHENRTPT	char	End Relative to Reference Time Point		Collected at CRF.
MHENPTDY	num	Relative Day of End Ref Time Point		If MHENTPT and REF.DATE not missing then perform below logic to calculate MHENPTDY, If MHENTPT less than REF.DATE then (MHENTPT - REF.DATE). Else if MHENTPT is greater than equal to REF.DATE then (MHENTPT - REF.DATE) +1.

1.4.25. Pharmacokinetic Concentrations – PC

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
PCSEQ	num	Sequence Number		Collected at CRF.
PCREFID	char	Reference ID		Collected at CRF.
PCTESTCD	char	Pharmacokinetic Test Short Name		Collected at CRF.
PCTEST	char	Pharmacokinetic Test Name		Collected at CRF.
PCCAT	char	Test Category		Collected at CRF.
PCSCAT	char	Test Subcategory		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
PCSTAT	char	Completion Status		Collected at CRF.
PCREASND	char	Reason Test Not Done		Collected at CRF.
PCSPEC	char	Specimen Material Type		Collected at CRF.
PCBLFL	char	Baseline Flag		Collected at CRF.
PCMETHOD	char	Method of Test or Examination		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.
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.

Variable	Type	Label	Codes	Comments
PCTPT	char	Planned Time Point Name		Collected at CRF.
PCTPTNUM	num	Planned Time Point Number		Collected at CRF.
PCTPTREF	char	Time Point Reference		Collected at CRF.
PCTM	num	Time of Specimen Collection		If PCDTC contains time part then timepart(PCDTC) else PCTM equal to NULL.
PCRFTTM	num	Time of Reference Point		If PCRFTDTC contains time part then timepart(PCRFTDTC) else PCRFTTM equal to NULL.
PCRFTDY	num	Relative Day of Reference Point		If PCRFTDTC and REF.DATE not missing then perform below logic to calculate PCRFTDY, If PCRFTDTC less than REF.DATE then (PCRFTDTC - REF.DATE). Else if PCRFTDTC is greater than equal to REF.DATE then (PCRFTDTC - REF.DATE) +1.

1.4.26. Pharmacokinetic Parameters – PP

Dataset	PP
Creating program	pp.sas
Description	Pharmacokinetic Parameters
Unique identifier	STUDYID,DUSUBJID,PPCAT,PPTTESTCD,PPSEQ
Sorted by	STUDYID,DUSUBJID,PPCAT,PPTTESTCD,PPSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PPNAM,PPRFTDTC

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
PPSEQ	num	Sequence Number		Collected at CRF.
PPGRPID	char	Group ID		Collected at CRF.
PPTTESTCD	char	Parameter Short Name		Collected at CRF.
PPTTEST	char	Parameter Name		Collected at CRF.
PPCAT	char	Parameter Category		Collected at CRF.
PPSCAT	char	Parameter Subcategory		Collected at CRF.

Variable	Type	Label	Codes	Comments
PPORRES	char	Result or Finding in Original Units		Collected at CRF.
PPORRESU	char	Original Units		Collected at CRF.
PPSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
PPSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
PPSTRESU	char	Standard Units		Collected at CRF.
PPSTAT	char	Completion Status		Collected at CRF.
PPREASND	char	Reason Test Not Done		Collected at CRF.
PPSPEC	char	Specimen Material Type		Collected at CRF.

1.4.27. Supplemental Qualifiers for PP – SUPPPP

Dataset	SUPPPP
Creating program	pp.sas
Description	Supplemental Qualifiers for PP
Unique identifier	STUDYID RDOMAIN DUSUBJID IDVAR IDVARVAL QNAM
Sorted by	STUDYID RDOMAIN DUSUBJID IDVAR IDVARVAL QNAM
Notes	

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

1.4.28. 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: PRENDTC,PRSTDTC,PRTRT

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.
PRGRPID	char	Group ID		Collected at CRF.
PRSPID	char	Sponsor-Defined Identifier		Collected at CRF.
PRCAT	char	Category for Procedure		Collected at CRF.
PRSCAT	char	Subcategory for Procedure		Collected at CRF.
PRPRESP	char	Procedure Pre-specified		Collected at CRF.

Variable	Type	Label	Codes	Comments
PROCCUR	char	Procedure Occurrence		Collected at CRF.
PRINDC	char	Indication		Collected at CRF.
PRDOSE	num	Dose		Collected at CRF.
PRDOSU	char	Dose Units		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
VISITNUM	num	Visit Number		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.
VISIT	char	Visit Name		Collected at CRF.
PRENDY	num	Relative End Day of Procedure		If PRENDTC and REF.DATE not missing then perform below logic to calculate PRENDY, If PRENDTC less than REF.DATE then (PRENDTC - REF.DATE). Else if PRENDTC is greater than equal to REF.DATE then (PRENDTC - REF.DATE) +1.
PRLOC	char	Location of Procedure		Collected at CRF.

1.4.29. Supplemental Qualifiers for PR – SUPPPR

Dataset	SUPPPR
Creating program	pr.sas
Description	Supplemental Qualifiers for PR
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. 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: QSDTC

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

Variable	Type	Label	Codes	Comments
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
QSBFL	char	Baseline Flag		Collected at CRF.
QSEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		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.

1.4.31. Respiratory System Findings – RE

Dataset	RE
Creating program	re.sas
Description	Respiratory System Findings
Unique identifier	STUDYID,DUSUBJID,RETESTCD,RESEQ
Sorted by	STUDYID,DUSUBJID,RETESTCD,RESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: REDTC

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
RESEQ	num	Sequence Number		Collected at CRF.
RESPID	char	Sponsor-Defined Identifier		Collected at CRF.
RETESTCD	char	Test or Examination Short Name		Collected at CRF.
RETEST	char	Test or Examination Name		Collected at CRF.
REORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
REORRESU	char	Original Units		Collected at CRF.
RESTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
RESTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
RESTRESU	char	Standard Units		Collected at CRF.
RESTAT	char	Completion Status		Collected at CRF.
REMETHOD	char	Method of Test or Examination		Collected at CRF.
REBLFL	char	Baseline Flag		Collected at CRF.
REEVAL	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.
REDY	num	Relative Day of Measurements		If REDTC and REF.DATE not missing then perform below logic to calculate REDY, If REDTC less than REF.DATE then (REDTC - REF.DATE). Else if REDTC is greater than equal to REF.DATE then (REDTC - REF.DATE) + 1.

1.4.32. 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	

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.
RELTYPE	char	Relationship Type		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.33. Disease Response – RS

Dataset	RS
Creating program	rs.sas
Description	Disease Response
Unique identifier	STUDYID,DUSUBJID,RSSEQ,RSDY
Sorted by	STUDYID,DUSUBJID,RSSEQ,RSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RSSPID,RSDTC

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
RSSEQ	num	Sequence Number		Collected at CRF.
RSTESTCD	char	Response Assessment Short Name		Collected at CRF.
RSTEST	char	Response Assessment Name		Collected at CRF.
RSCAT	char	Category for Response Assessment		Collected at CRF.

Variable	Type	Label	Codes	Comments
RSORRES	char	Response Assessment Original Result		Collected at CRF.
RSSTRESC	char	Response Assessment Result in Std Format		Collected at CRF.
RSEVAL	char	Evaluator		Collected at CRF.
RSEVALID	char	Evaluator Identifier		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
RSDY	num	Relative Day of Response Assessment		If RSDTC and REF.DATE not missing then perform below logic to calculate RSDY, If RSDTC less than REF.DATE then (RSDTC - REF.DATE). Else if RSDTC is greater than equal to REF.DATE then (RSDTC - REF.DATE) + 1.

1.4.34. Supplemental Qualifiers for RS – SUPPRS

Dataset	SUPPRS
Creating program	rs.sas
Description	Supplemental Qualifiers for RS
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	

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

1.4.35. Subject Characteristics – SC

Dataset	SC
Creating program	sc.sas
Description	Subject Characteristics
Unique identifier	STUDYID,DUSUBJID,SCTESTCD,SCSEQ
Sorted by	STUDYID,DUSUBJID,SCTESTCD,SCSEQ
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
SCSEQ	num	Sequence Number		Collected at CRF.
SCSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SCTESTCD	char	Subject Characteristic Short Name		Collected at CRF.
SCTEST	char	Subject Characteristic		Collected at CRF.
SCORRES	char	Result or Finding in Original Units		Collected at CRF.
SCSTRESC	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.
EPOCH	char	Epoch		Collected at CRF.

1.4.36. Subject Elements – SE

Dataset	SE
Creating program	se.sas
Description	Subject Elements
Unique identifier	STUDYID,DUSUBJID,ETCD,SESTDY
Sorted by	STUDYID,DUSUBJID,ETCD,SESTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SEENDTC,SESTDTC

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
SESEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
ETCD	char	Element Code		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
TAETORD	num	Planned Order of Element within Arm		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
SEUPDES	char	Description of Unplanned Element		Collected at CRF.
SESTTM	num	Start Time of Element		If SESTDTC contains time part then timepart(SESTDTC) else SESTTM equal to NULL.
SESTDY	num	Relative Start Day of Element		If SESTDTC and REF.DATE not missing then perform below logic to calculate SESTDY, If SESTDTC less than REF.DATE then (SESTDTC - REF.DATE). Else if SESTDTC is greater than equal to REF.DATE then (SESTDTC - REF.DATE) +1.
SEENTM	num	End Time of Element		If SEENDTC contains time part then timepart(SEENDTC) else SEENTM equal to NULL.
SEENDY	num	Relative End Day of Element		If SEENDTC and REF.DATE not missing then perform below logic to calculate SEENDY, If SEENDTC less than REF.DATE then (SEENDTC - REF.DATE). Else if SEENDTC is greater than equal to REF.DATE then (SEENDTC - REF.DATE) +1.

1.4.37. Subject Status – SS

Dataset	SS
Creating program	ss.sas
Description	Subject Status
Unique identifier	STUDYID,DUSUBJID,SSSEQ
Sorted by	STUDYID,DUSUBJID,SSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SSDTC

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
SSSEQ	num	Sequence Number		Collected at CRF.
SSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SSTESTCD	char	Status Short Name		Collected at CRF.
SSTEST	char	Status Name		Collected at CRF.
SSORRES	char	Verbatim Result or Finding		Collected at CRF.
SSSTRESC	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.
SSDY	num	Relative Day of Test		If SSDTC and REF.DATE not missing then perform below logic to calculate SSDY, If SSDTC less than REF.DATE then (SSDTC - REF.DATE). Else if SSDTC is greater than equal to REF.DATE then (SSDTC - REF.DATE) +1.

1.4.38. 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: SVUPDES,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.

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.

1.4.39. Trial Arms – TA

Dataset	TA
Creating program	ta.sas
Description	Trial Arms
Unique identifier	STUDYID,ARMCD,ETCD
Sorted by	STUDYID,ARMCD,ETCD
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
TABRANCH	char	Branch		Collected at CRF.
TATRANS	char	Transition Rule		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

1.4.40. Trial Elements – TE

Dataset	TE
Creating program	te.sas
Description	Trial Elements
Unique identifier	STUDYID,ETCD
Sorted by	STUDYID,ETCD
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
TESTRL	char	Rule for Start of Element		Collected at CRF.
TEENRL	char	Rule for End of Element		Collected at CRF.

1.4.41. 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.
TIVERS	char	Protocol Criteria Versions		Collected at CRF.

1.4.42. Tumour Results – TR

Dataset	TR
Creating program	tr.sas
Description	Tumour Results
Unique identifier	STUDYID,DUSUBJID,TRDY,TRSEQ
Sorted by	STUDYID,DUSUBJID,TRDY,TRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: TREVAL,TRDTC

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
TRSEQ	num	Sequence Number		Collected at CRF.
TRSPID	char	Sponsor ID		Collected at CRF.
TRLNKID	char	Link ID		Collected at CRF.
TRTESTCD	char	Tumor Assessment Short Name		Collected at CRF.
TRTEST	char	Tumor Assessment Test Name		Collected at CRF.
TRCAT	char	Category		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRSCAT	char	Subcategory		Collected at CRF.
TRORES	char	Result or Finding in Original Units		Collected at CRF.
TRORESU	char	Original Units		Collected at CRF.
TRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
TRSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
TRSTRESU	char	Standard Units		Collected at CRF.
TRSTAT	char	Completion Status		Collected at CRF.
TRREASND	char	Reason Tumor Measurement Not Performed		Collected at CRF.
TRMETHOD	char	Method Used to Identify the Tumor		Collected at CRF.
TRDY	num	Relative Day of Tumor Measurement		If TRDTC and REF.DATE not missing then perform below logic to calculate TRDY, If TRDTC less than REF.DATE then (TRDTC - REF.DATE). Else if TRDTC is greater than equal to REF.DATE then (TRDTC - REF.DATE) + 1.
TRBLFL	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
TRLOC	char	Location Used for the Measurement		Collected at CRF.

1.4.43. Supplemental Qualifiers for TR – SUPPTR

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

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

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

1.4.44. Trial Summary – TS

Dataset	TS
Creating program	ts.sas
Description	Trial Summary
Unique identifier	STUDYID,TSPARMCD,TSSEQ
Sorted by	STUDYID,TSPARMCD,TSSEQ
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
TSSEQ	num	Sequence Number		Collected at CRF.
TSGRPID	char	Group ID		Collected at CRF.
TSPARMCD	char	Trial Summary Parameter Short Name		Collected at CRF.
TSPARM	char	Trial Summary Parameter		Collected at CRF.

Variable	Type	Label	Codes	Comments
TSVAL	char	Parameter Value		Collected at CRF.
TSVAL1	char	Parameter Value		Collected at CRF.
TSVAL2	char	Parameter Value		Collected at CRF.
TSVAL3	char	Parameter Value		Collected at CRF.
TSVALNF	char	Parameter Null Flavor		Collected at CRF.
TSVALCD	char	Parameter Value Code		Collected at CRF.
TSVCDREF	char	Name of the Reference Terminology		Collected at CRF.
TSVCDVER	char	Version of the Reference Terminology		Collected at CRF.

1.4.45. Tumor Identification – TU

Dataset	TU
Creating program	tu.sas
Description	Tumor Identification
Unique identifier	STUDYID,DUSUBJID,VISIT,TUDY,TUSEQ
Sorted by	STUDYID,DUSUBJID,VISIT,TUDY,TUSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: TUDTC,TUEVAL

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
TUSEQ	num	Sequence Number		Collected at CRF.
TUSPID	char	Sponsor ID		Collected at CRF.
TUTESTCD	char	Tumor Identification Short Name		Collected at CRF.
TUTEST	char	Tumor Identification Test Name		Collected at CRF.
TUCAT	char	Category		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUORRES	char	Tumor Identification Result		Collected at CRF.
TUSTRESC	char	Tumor Identification Result Std Format		Collected at CRF.
TULOC	char	Location of the Tumor		Collected at CRF.
TUMETHOD	char	Method of Identification		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.
TUDY	num	Relative Day of Tumor Identification		If TUDTC and REF.DATE not missing then perform below logic to calculate TUDY, If TUDTC less than REF.DATE then (TUDTC - REF.DATE). Else if TUDTC is greater than equal to REF.DATE then (TUDTC - REF.DATE) + 1.
TULNKID	char	Link ID		Collected at CRF.
TUBLFL	char	Baseline Flag		Collected at CRF.

1.4.46. Supplemental Qualifiers for TU – SUPPTU

Dataset	SUPPTU
Creating program	tu.sas
Description	Supplemental Qualifiers for TU
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.

1.4.47. Trial Visits – TV

Dataset	TV
Creating program	tv.sas
Description	Trial Visits
Unique identifier	STUDYID,VISITNUM
Sorted by	STUDYID,VISITNUM
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		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.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
TVSTRL	char	Visit Start Rule		Collected at CRF.
TVENRL	char	Visit End Rule		Collected at CRF.

1.4.48. 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, VSRFTDTC

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

Variable	Type	Label	Codes	Comments
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VSSTAT	char	Completion Status		Collected at CRF.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
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.
VSTPT	char	Planned Time Point Name		Collected at CRF.
VSTPTNUM	num	Planned Time Point Number		Collected at CRF.
VSELTM	char	Planned Elapsed Time from Time Point Ref		Collected at CRF.
VSTPTREF	char	Time Point Reference		Collected at CRF.
VSTM	num	Relative Time of Measurements		If VSDTC contains time part then timepart(VSDTC) else VSTM equal to NULL.

Variable	Type	Label	Codes	Comments
VSRFTTM	num	Time of Reference Time Point		If VSRFTDTC contains time part then timepart(VSRFTDTC) else VSRFTTM equal to NULL.
VSRFTDY	num	Day of Reference Time Point		If VSRFTDTC and REF.DATE not missing then perform below logic to calculate VSRFTDY, If VSRFTDTC less than REF.DATE then (VSRFTDTC - REF.DATE). Else if VSRFTDTC is greater than equal to REF.DATE then (VSRFTDTC - REF.DATE) +1.

1.4.49. 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: XARFTDTC,XADTC,XANAM,XASPID,XAREFID

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
XASEQ	num	Sequence Number		Collected at CRF.
XATESTCD	char	Measurement Test Short Name		Collected at CRF.
XATEST	char	Measurement Test Name		Collected at CRF.
XACAT	char	Test Category		Collected at CRF.
XASCAT	char	Test Subcategory		Collected at CRF.
XAORRES	char	Result or Finding in Original Units		Collected at CRF.
XAORRESU	char	Original Units		Collected at CRF.
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.
XAREASND	char	Reason Test Not Done		Collected at CRF.
XASPEC	char	Specimen Type		Collected at CRF.
XAMETHOD	char	Method of Test or Examination		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.
XADY	num	Relative Day of 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.
XATPTREF	char	Time Point Reference		Collected at CRF.
XATM	num	Time of Collection		If XADTC contains time part then timepart(XADTC) else XATM equal to NULL.
XARFTTM	num	Relative Time of Reference Point		If XARFTDTC contains time part then timepart(XARFTDTC) else XARFTTM equal to NULL.
XARFTDY	num	Relative Day of Reference Point		If XARFTDTC and REF.DATE not missing then perform below logic to calculate XARFTDY, If XARFTDTC less than REF.DATE then (XARFTDTC - REF.DATE). Else if XARFTDTC is greater than equal to REF.DATE then (XARFTDTC - REF.DATE) +1.

1.4.50. Cytogenetics Findings – XC

Dataset	XC
Creating program	xc.sas
Description	Cytogenetics Findings
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: XCNAM,XCDTC

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
XCSEQ	num	Sequence Number		Collected at CRF.
XCSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XCTESTCD	char	Cytogenetics Test Short Name		Collected at CRF.
XCTEST	char	Cytogenetics Test Name		Collected at CRF.
XCCAT	char	Cytogenetics Test Category		Collected at CRF.
XCORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XCSPEC	char	Specimen Material Type		Collected at CRF.
XCMETHOD	char	Method of Test or Examination		Collected at CRF.
XCBLFL	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.
XCDY	num	Relative Day of Specimen Collection		If XCDTC and REF.DATE not missing then perform below logic to calculate XCDY, If XCDTC less than REF.DATE then (XCDTC - REF.DATE). Else if XCDTC is greater than equal to REF.DATE then (XCDTC - REF.DATE) +1.

1.4.51. Sample Handling – XZ

Dataset	XZ
Creating program	xz.sas
Description	Sample Handling
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: 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	Test or Examination Short Name		Collected at CRF.
XZTEST	char	Test or Examination Name		Collected at CRF.
XZCAT	char	Category		Collected at CRF.
XZSCAT	char	Subcategory		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
XZSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XZSTRESU	char	Standard Units		Collected at CRF.
XZSPEC	char	Specimen Material Type		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 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.
XZTPT	char	Planned Time Point Name		Collected at CRF.
XZTPTNUM	num	Planned Time Point Number		Collected at CRF.
XZELTM	char	Planned Elapsed Time from Time Point Ref		Collected at CRF.
XZTPTREF	char	Time Point Reference		Collected at CRF.

1.4.52. Randomization – ZR

Dataset	ZR
Creating program	zr.sas
Description	Randomization
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: ZRDTTC,ZRNAM,ZRSPID

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
ZRSEQ	num	Sequence Number		Collected at CRF.
ZRTESTCD	char	Randomization Test Short Name		Collected at CRF.
ZRTEST	char	Randomization Test Name		Collected at CRF.
ZRCAT	char	Category for Randomization Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZRSCAT	char	Subcategory for Randomization Test		Collected at CRF.
ZRORRES	char	Result or Finding in Original Units		Collected at CRF.
ZRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
ZRSTRESN	num	Numeric Result/Finding in 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.
ZRTM	num	Time of Randomization		If ZRDTC contains time part then timepart(ZRDTC) else ZRTM equal to NULL.