

Clinical Development

**Ustekinumab**

CRD3001

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	23 MAR 2017

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 .....	14
1.4.5. Bio-Specimen – BE .....	15
1.4.6. Clinical Events – CE.....	17
1.4.7. Supplemental Qualifiers for CE – SUPPCE.....	18
1.4.8. Concomitant Medications – CM .....	19
1.4.9. Supplemental Qualifiers for CM – SUPPCM .....	21
1.4.10. Disposition – DS.....	22
1.4.11. Supplemental Qualifiers for DS – SUPPDS .....	23
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.....	33
1.4.19. Inclusion/Exclusion Exceptions – IE .....	34
1.4.20. Laboratory Test Results – LB.....	36
1.4.21. Supplemental Qualifiers for LB – SUPPLB.....	39
1.4.22. Microbiology Specimen – MB.....	40
1.4.23. Medical History – MH.....	42
1.4.24. Supplemental Qualifiers for MH – SUPPMH .....	44
1.4.25. Pharmacokinetic Concentrations – PC.....	45

1.4.26.	Questionnaires – QS .....	47
1.4.27.	Supplemental Qualifiers for QS – SUPPQS .....	49
1.4.28.	Related Records – RELREC .....	50
1.4.29.	Surgery – SG .....	51
1.4.30.	Supplemental Qualifiers for SG – SUPPSG .....	52
1.4.31.	Substance Use – SU .....	54
1.4.32.	Supplemental Qualifiers for SU – SUPPSU .....	55
1.4.33.	Subject Visits – SV .....	56
1.4.34.	Trial Inclusion/Exclusion Criteria – TI .....	57
1.4.35.	Antibodies to Study Agent – XA .....	58
1.4.36.	Imaging – XI .....	60
1.4.37.	Sample Handling – XZ .....	62

Status and Version	Release Date	Summary of Key Changes

## 1. Datasets

### 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.

### 1.1. 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.
- For Randomized subjects, "Subject Reference Start Date" (RFSTDTC) will be used as Reference Date (Referred as REF.DATE in the document) to derive relative day. For Screen Failure subjects, "Date of Informed Consent" (RFICDTC) from DM dataset will be used as a reference date (Referred as REF.DATE in the document) to derive relative days.

## 1.2. Data Files

The CRD3001 Clinical Study Report (CSR) data should be used for converting to de-identification.

### 1.3. Data Domains

#### 1.3.1. Demographics – DM

<b>Dataset</b>	DM
<b>Creating program</b>	dm.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	STUDYID,DUSUBJID
<b>Sorted by</b>	STUDYID,DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DTHFL,DTHDTC,RFICDTC,RFXENDTC,RFXSTDTC,RFSTDTC,RFENDTC,RFPENDTC, BRTHDTC,DMDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned subject ID for De-identity
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned study site ID for De-identity

Variable	Type	Label	Codes	Comments
AGE	char	Age		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Age Units		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
ACTARMCD	char	Actural Arm Code		Collected at CRF.
ACTARM	char	Description of Actural 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.
RFENTM	num	Subject Reference End Time		If RFENDTC contains time part then timepart(RFENDTC) else RFENTM equal to NULL.
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.



Variable	Type	Label	Codes	Comments
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.

## 1.3.2. Supplemental Qualifiers for DM – SUPPDM

<b>Dataset</b>	SUPPDM
<b>Creating program</b>	dm.sas
<b>Description</b>	Supplemental Qualifiers for DM
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,QNAM
<b>Notes</b>	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.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
QNAM	char	Qualifier Variable Name		If QNAM in ( RACEW,RACEOTH, RACEBA,RACEAIAN,RACEA) then drop. If QNAM in (DMRESCDT) 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.

## 1.3.3. Adverse Events – AE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
AESEQ	num	Sequence Number		Collected at CRF.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
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.

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

## 1.3.4. Supplemental Qualifiers for AE – SUPPAE

<b>Dataset</b>	SUPPAE
<b>Creating program</b>	ae.sas
<b>Description</b>	Supplemental Qualifiers for AE
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	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.

## 1.3.5.Bio-Specimen – BE

<b>Dataset</b>	BE
<b>Creating program</b>	be.sas
<b>Description</b>	Bio-Specimen
<b>Unique identifier</b>	STUDYID,DUSUBJID,BEDECOD,BESEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,BEDECOD,BESEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BEBODSYS,BEDTC,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
BEDY	num	Relative Day of Specimen Collection		If BEDTC and REF.DATE not missing then perform below logic to calculate BEDY, If BEDTC less than REF.DATE then (BEDTC - REF.DATE). Else if BEDTC is greater than equal to REF.DATE then (BEDTC - REF.DATE) +1.
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.



## 1.3.6.Clinical Events – CE

<b>Dataset</b>	CE
<b>Creating program</b>	ce.sas
<b>Description</b>	Clinical Events
<b>Unique identifier</b>	STUDYID,DUSUBJIC,CECAT,CESEQ
<b>Sorted by</b>	STUDYID,DUSUBJIC,CECAT,CESEQ
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: CESTAT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
CESEQ	num	Sequence Number		Collected at CRF.
CESPID	char	Sponsor-Defined Identifier		Collected at CRF.
CETERM	char	Reported Term for the Clinical Event		Collected at CRF.
CECAT	char	Category for Clinical Event		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CEPRESP	char	Clinical Event Pre-Specified		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
CEOCCUR	char	Clinical Event Occurrence		Collected at CRF.

### 1.3.7. Supplemental Qualifiers for CE – SUPPCE

<b>Dataset</b>	SUPPCE
<b>Creating program</b>	ce.sas
<b>Description</b>	Supplemental Qualifiers for CE
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	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 ( CEOTHSPC ) then drop.

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.

### 1.3.8. Concomitant Medications – CM

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

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.

Variable	Type	Label	Codes	Comments
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.
CMPRESP	char	CM Pre-Specified		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMROUTE	char	Route of Administration		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.

## 1.3.9. Supplemental Qualifiers for CM – SUPPCM

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

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.

## 1.3.10. Disposition – DS

<b>Dataset</b>	DS
<b>Creating program</b>	ds.sas
<b>Description</b>	Disposition
<b>Unique identifier</b>	STUDYID,DUSUBJID,DSDECOD,DSSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,DSDECOD,DSSEQ
<b>Notes</b>	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.
EPOCH	char	Epoch		Collected at CRF.

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

### 1.3.11. Supplemental Qualifiers for DS – SUPPDS

<b>Dataset</b>	SUPPDS
<b>Creating program</b>	ds.sas
<b>Description</b>	Supplemental Qualifiers for DS
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QEVAL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
IDVAR	char	Identifying Variable		Collected at CRF.

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

### 1.3.12. Protocol Deviations – DV

<b>Dataset</b>	DV
<b>Creating program</b>	dv.sas
<b>Description</b>	Protocol Deviations
<b>Unique identifier</b>	STUDYID,DUSUBJID,DVDECOD,DVSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,DVDECOD,DVSEQ
<b>Notes</b>	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.



Variable	Type	Label	Codes	Comments
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.

### 1.3.13. Exposure – EX

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

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

Variable	Type	Label	Codes	Comments
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.
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.

## 1.3.14. Supplemental Qualifiers for EX – SUPPEX

<b>Dataset</b>	SUPPEX
<b>Creating program</b>	ex.sas
<b>Description</b>	Supplemental Qualifiers for EX
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	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 ( EXVL16, EXVL15, EXVL14, EXVL13, EXVL12, EXVL11, EXVL10, EXVWDOT, EXVL1, EXVL9, EXVL8, EXVL7, EXVL6, EXVL5, EXVL4, EXVL3, EXVL24, EXVL23, EXVL22, EXVL21, EXVL20, EXVL2, EXVL19, EXVL18, EXVL17, EXLOTA) then drop. If QNAM in (EXDTP) then will be converted to relative day.

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

### 1.3.15. Findings About Events or Interventions – FA

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

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

Variable	Type	Label	Codes	Comments
FASPID	char	Sponsor-Defined Identifier		Collected at CRF.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FATEST	char	Findings About Test Name		Collected at CRF.
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.
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
FASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
FADY	num	Relative Day of Collection		If FADTC and REF.DATE not missing then perform below logic to calculate FADY, If FADTC less than REF.DATE then (FADTC - REF.DATE). Else if FADTC is greater than equal to REF.DATE then (FADTC-REF.DATE) +1.

## 1.3.16. Supplemental Qualifiers for FA – SUPPFA

<b>Dataset</b>	SUPPFA
<b>Creating program</b>	fa.sas
<b>Description</b>	Supplemental Qualifiers for FA
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	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.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in ( PRDTC,MAINDTC,FNLDTC,DOSE2DTC,DOSE3DTC,DOSE1DTC) 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.

## 1.3.17. Hospitalization – HO

<b>Dataset</b>	HO
<b>Creating program</b>	ho.sas
<b>Description</b>	Hospitalization
<b>Unique identifier</b>	STUDYID,DUSUBJID,HOTERM,HOSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,HOTERM,HOSEQ
<b>Notes</b>	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.

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



## 1.3.18. Supplemental Qualifiers for HO – SUPPHO

<b>Dataset</b>	SUPPHO
<b>Creating program</b>	ho.sas
<b>Description</b>	Supplemental Qualifiers for HO
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	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.

## 1.3.19. Inclusion/Exclusion Exceptions – IE

<b>Dataset</b>	IE
<b>Creating program</b>	ie.sas
<b>Description</b>	Inclusion/Exclusion Exceptions
<b>Unique identifier</b>	STUDYID,DUSUBJID,IETESTCD,IESEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,IETESTCD,IESEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:  IEDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
IESEQ	num	Sequence Number		Collected at CRF.
IESPID	char	Sponsor-Defined Identifier		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IEORRES	char	I/E Criterion Original Result		Collected at CRF.

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

## 1.3.20. Laboratory Test Results – LB

<b>Dataset</b>	LB
<b>Creating program</b>	lb.sas
<b>Description</b>	Laboratory Test Results
<b>Unique identifier</b>	STUDYID,DUSUBJID,LBCAT,LBTESTCD,LBSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,LBCAT,LBTESTCD,LBSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBSPID,LBGRPID,LBREFID,LBSCAT,LBTPTNUM,LBTOXGR,LBDTC,LBTPTRF, LBFAST,LBENDTC,VISITDY,LBTOX,LBNAM,LBELTM,LBTPT

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.

Variable	Type	Label	Codes	Comments
LBORRESU	char	Original Units		Collected at CRF.
LBORNRL0	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRLHI	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.

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.
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.

## 1.3.21. Supplemental Qualifiers for LB – SUPPLB

<b>Dataset</b>	SUPPLB
<b>Creating program</b>	lb.sas
<b>Description</b>	Supplemental Qualifiers for LB
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	

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.
QEQVAL	char	Evaluator		Collected at CRF.

### 1.3.22. Microbiology Specimen – MB

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

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.



Variable	Type	Label	Codes	Comments
MBCAT	char	Category for Microbiology Finding		Collected at CRF.
MBORRES	char	Result or Finding in Original Units		Collected at CRF.
MBSTRESC	char	Character Result/Finding in Std Format		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.
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.

## 1.3.23. Medical History – MH

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
MHSEQ	num	Sequence Number		Collected at CRF.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MHTERM	char	Reported Term for the Medical History		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHPRESP	char	Medical History Event Pre-Specified		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
MHOCCUR	char	Medical History Occurrence		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 Strt Day of Medicl History Evt		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.

## 1.3.24. Supplemental Qualifiers for MH – SUPPMH

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

## 1.3.25. Pharmacokinetic Concentrations – PC

<b>Dataset</b>	PC
<b>Creating program</b>	pc.sas
<b>Description</b>	Pharmacokinetic Concentrations
<b>Unique identifier</b>	STUDYID,DUSUBJID,PCTESTCD,PCSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,PCTESTCD,PCSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PCENDTC,PCDTC,PCNAM,PCSTAT,PCSPID,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.
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.
PCSPEC	char	Specimen Type		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 Start Day of Specimn 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.
PCTPTNUM	num	Planned Time Point Number		Collected at CRF.
PCTM	num	Start Time of Specimn Collection		If PCDTTC contains time part then timepart(PCDTTC) else PCTM equal to NULL.

## 1.3.26. Questionnaires – QS

<b>Dataset</b>	QS
<b>Creating program</b>	qs.sas
<b>Description</b>	Questionnaires
<b>Unique identifier</b>	STUDYID,DUSUBJID,QSTESTCD,VISITNUM,QSSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,QSTESTCD,VISITNUM,QSSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: QSDTC,QSREASND

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.
QSGRPID	char	Group ID		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.

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



## 1.3.27. Supplemental Qualifiers for QS – SUPPQS

<b>Dataset</b>	SUPPQS
<b>Creating program</b>	qs.sas
<b>Description</b>	Supplemental Qualifiers for QS
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	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.

## 1.3.28. Related Records – RELREC

<b>Dataset</b>	RELREC
<b>Creating program</b>	relrec.sas
<b>Description</b>	Related Records
<b>Unique identifier</b>	STUDYID,DUSUBJID,IDVAR,IDVARVAL,RELID
<b>Sorted by</b>	STUDYID,DUSUBJID,IDVAR,IDVARVAL,RELID
<b>Notes</b>	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.

## 1.3.29. Surgery – SG

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
SGSEQ	num	Sequence Number		Collected at CRF.
SGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SGTRT	char	Reported Name of Surgery/Procedure		Collected at CRF.
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.
SGSCAT	char	Subcategory for Surgery/Procedure		Collected at CRF.
SGPRESP	char	Surgery/Procedure Pre-Specified		Collected at CRF.

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

### 1.3.30. Supplemental Qualifiers for SG – SUPPSG

<b>Dataset</b>	SUPPSG
<b>Creating program</b>	sg.sas
<b>Description</b>	Supplemental Qualifiers for SG
<b>Unique identifier</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEVAL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
IDVAR	char	Identifying Variable		Collected at CRF.

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

## 1.3.31. Substance Use – SU

<b>Dataset</b>	SU
<b>Creating program</b>	su.sas
<b>Description</b>	Substance Use
<b>Unique identifier</b>	STUDYID,DUSUBJID
<b>Sorted by</b>	STUDYID,DUSUBJID
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned unique subject ID for De-identity
SUSEQ	num	Sequence Number		Collected at CRF.
SUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUCAT	char	Category for Substance Use		Collected at CRF.
SUPRESP	char	SU Pre-Specified		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

## 1.3.32. Supplemental Qualifiers for SU – SUPPSU

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

## 1.3.33. Subject Visits – SV

<b>Dataset</b>	SV
<b>Creating program</b>	sv.sas
<b>Description</b>	Subject Visits
<b>Unique identifier</b>	STUDYID,DUSUBJID,VISITNUM
<b>Sorted by</b>	STUDYID,DUSUBJID,VISITNUM
<b>Notes</b>	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.
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.

### 1.3.34. Trial Inclusion/Exclusion Criteria – TI

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

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.

## 1.3.35. Antibodies to Study Agent – XA

<b>Dataset</b>	XA
<b>Creating program</b>	xa.sas
<b>Description</b>	Antibodies to Study Agent
<b>Unique identifier</b>	STUDYID,DUSUBJID,XATESTCD,VISITNUM
<b>Sorted by</b>	STUDYID,DUSUBJID,XATESTCD,VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: XAENDTC,XADTC,XASTAT,XASPID,XAREFID, 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.
XATESTCD	char	Short Name of Measurement		Collected at CRF.
XATEST	char	Name of Measurement		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 Std Units		Collected at CRF.
XASTRESU	char	Standard Units		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.
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.

## 1.3.36. Imaging – XI

<b>Dataset</b>	XI
<b>Creating program</b>	xi.sas
<b>Description</b>	Imaging
<b>Unique identifier</b>	STUDYID,DUSUBJID,XITESTCD,VISITNUM
<b>Sorted by</b>	STUDYID,DUSUBJID,XITESTCD,VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
XISPID	char	Sponsor-Defined Identifier		Collected at CRF.
XITESTCD	char	Imaging Test or Examination Short Name		Collected at CRF.
XITEST	char	Imaging Test or Examination Name		Collected at CRF.
XICAT	char	Category for imaging		Collected at CRF.
XIORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XIMETHOD	char	Method of Test or Examination		Collected at CRF.
XIBLFL	char	Baseline Flag		Collected at CRF.
XIEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
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.

## 1.3.37. Sample Handling – XZ

<b>Dataset</b>	XZ
<b>Creating program</b>	xz.sas
<b>Description</b>	Sample Handling
<b>Unique identifier</b>	STUDYID,DUSUBJID,XZTESTCD,XZSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,XZTESTCD,XZSEQ
<b>Notes</b>	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.

Variable	Type	Label	Codes	Comments
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.
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.