

Clinical Development

## **Ustekinumab**

CNTO1275PSA3001

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

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

### 1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided
- 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.

- PK data will be not be submitted due to sensitivity of the data. (e.g. PC, SUPPPC)
- Complete missing value variables will be removed.
- DNA (Genetic) information will not be submitted to protect PII. (e.g. GE)
- Subject characteristics data (SC) contains only Subject Initials which is sensitive information. Hence it will not be submitted.
- Empty data set will not be submitted (e.g. SUPPIF)
- Subject specific health economic assessment questionnaire will not be submitted to protect PII. (e.g. QSCAT = Health Economic Questionnaire)

### 1.3. Data Files

The CNT01275PSA3001 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the CNT01275PSA3001 CSR data from the following folders.

## 1.4. Data Domains

### 1.4.1. Demographics – DM

<b>Dataset</b>	DM
<b>Creating program</b>	dm.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RFSTDTC,RFENDTC,INVNAM,BRTHDTC,ETHNIC,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.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DMDY	num	Study Day of Collection		Collected at CRF.
RFENDY	num	Relative Subject Reference End Day		If RFENDTC and RFSTDTC not missing then perform below logic to calculate RFENDY,if RFENDTC less than RFSTDTC then (RFENDTC - RFSTDTC).Else if RFENDTC is greater than equal to RFSTDTC then (RFENDTC- RFSTDTC) +1.



## 1.4.2. Supplemental Qualifiers for DM – SUPPDM

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

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

## 1.4.3. Adverse Events – AE

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

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

Variable	Type	Label	Codes	Comments
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
AESTDY	num	Study Day of Start of AE		Collected at CRF.
AEENDY	num	Study Day of End of AE		Collected at CRF.

## 1.4.4. Supplemental Qualifiers for AE – SUPPAE

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

## 1.4.5. Clinical Findings – CF

<b>Dataset</b>	CF
<b>Creating program</b>	cf.sas
<b>Description</b>	Clinical Findings
<b>Unique identifier</b>	DUSUBJID, CFTESTCD, CFSEQ
<b>Sorted by</b>	DUSUBJID, CFTESTCD, CFSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CFDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
CFSEQ	num	Sequence Number		Collected at CRF.
CFSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CFTESTCD	char	Clinical Findings Test/Exam Short Name		Collected at CRF.
CFTEST	char	Clinical Findings Test/Examination Name		Collected at CRF.
CFCAT	char	Category for Clinical Finding		Collected at CRF.

Variable	Type	Label	Codes	Comments
CFLOC	char	Location of surgery findings/Procedure		Collected at CRF.
CFORRES	char	Result or Finding in Original Units		Collected at CRF.
CFSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CFDY	num	Study Day of Collection		Collected at CRF.
CFBLFL	char	Baseline Flag		Collected at CRF.

## 1.4.6. Supplemental Qualifiers for CF – SUPPCF

<b>Dataset</b>	SUPPCF
<b>Creating program</b>	suppcf.sas
<b>Description</b>	Supplemental Qualifiers for CF
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, IDVARVAL, QNAM
<b>Notes</b>	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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.7. Concomitant Medications – CM

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

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



Variable	Type	Label	Codes	Comments
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMLOC	char	Location of Dose Administration		Collected at CRF.
CMSTDY	num	Study Day of Start of Medication		Collected at CRF.
CMENDY	num	Study Day of End of Medication		Collected at CRF.

## 1.4.8. Supplemental Qualifiers for CM – SUPPCM

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

## 1.4.9. Disease Characteristics – DC

<b>Dataset</b>	DC
<b>Creating program</b>	dc.sas
<b>Description</b>	Disease Characteristics
<b>Unique identifier</b>	DUSUBJID, DCCAT, DCTESTCD, DCSEQ
<b>Sorted by</b>	DUSUBJID, DCCAT, DCTESTCD, DCSEQ
<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: DCSTRESN,DCDTC

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

Variable	Type	Label	Codes	Comments
DCORRES	char	Result or Finding in Original Units		Collected at CRF.
DCORRESU	char	Original Units		Collected at CRF.
DCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
DCSTRESU	char	Standard Units		Collected at CRF.
DCEVAL	char	Evaluator		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCREASND	char	Reason Not Done		Collected at CRF.
DCLOC	char	Location		Collected at CRF.
DCSTAT	char	Status		Collected at CRF.
DCDY	num	Study Day of Finding		Collected at CRF.
DCBLFL	char	Baseline Flag		Collected at CRF.

## 1.4.10. Disposition – DS

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

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

Variable	Type	Label	Codes	Comments
DSSTDY	num	Study Day of Start of Disposition Event		Collected at CRF.
DSDY	num	Relative Day of Collection		If DSDTC and RFSTDTC not missing then perform below logic to calculate DSDY, If DSDTC less than RFSTDTC then (DSDTC - RFSTDTC). Else if DSDTC is greater than equal to RFSTDTC then (DSDTC - RFSTDTC) +1.

#### 1.4.11. Supplemental Qualifiers for DS – SUPPDS

<b>Dataset</b>	SUPPDS
<b>Creating program</b>	suppds.sas
<b>Description</b>	Supplemental Qualifiers for DS
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, 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.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QNAM	char	Qualifier Variable Name		If QNAM in (DSRSWC) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.12. Protocol Deviations – DV

<b>Dataset</b>	DV
<b>Creating program</b>	dv.sas
<b>Description</b>	Protocol Deviations
<b>Unique identifier</b>	DUSUBJID, DVCAT, DVSCAT, DVDECOD, DVSEQ
<b>Sorted by</b>	DUSUBJID, DVCAT, DVSCAT, 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.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DVSEQ	num	Sequence Number		Collected at CRF.
DVCAT	char	Category for Protocol Deviation		Collected at CRF.



Variable	Type	Label	Codes	Comments
DVSCAT	char	Subcategory for Protocol Deviation		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

#### 1.4.13. Exposure – EX

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

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

Variable	Type	Label	Codes	Comments
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.
EXDOSTXT	char	Dose Description		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EXSTAT	char	Completion Status		Collected at CRF.
EXSTDY	num	Study Day of Start of Treatment		Collected at CRF.

## 1.4.14. Supplemental Qualifiers for EX – SUPPEX

<b>Dataset</b>	SUPPEX
<b>Creating program</b>	supplex.sas
<b>Description</b>	Supplemental Qualifiers for EX
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, IDVARVAL, QNAM
<b>Notes</b>	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.
QNAM	char	Qualifier Variable Name		If QNAM in (EXCNTRID) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.15. Inclusion/Exclusion Exceptions – IE

<b>Dataset</b>	IE
<b>Creating program</b>	ie.sas
<b>Description</b>	Inclusion/Exclusion Exceptions
<b>Unique identifier</b>	DUSUBJID, IETEST
<b>Sorted by</b>	DUSUBJID, IETEST
<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.

Variable	Type	Label	Codes	Comments
IEORRES	char	I/E Criterion Original Result		Collected at CRF.
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IEDY	num	Study Day of Collection		Collected at CRF.

#### 1.4.16. Intervention Findings – IF

<b>Dataset</b>	IF
<b>Creating program</b>	if.sas
<b>Description</b>	Intervention Findings
<b>Unique identifier</b>	DUSUBJID, IFTESTCD, IFSEQ
<b>Sorted by</b>	DUSUBJID, IFTESTCD, IFSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IFDTC

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
IFSEQ	num	Sequence Number		Collected at CRF.
IFSPID	char	Sponsor-Defined Identifier		Collected at CRF.
IFTESTCD	char	Body System Examined Short Name		Collected at CRF.
IFTEST	char	Body System Examined		Collected at CRF.
IFCAT	char	Category for Examination		Collected at CRF.
IFORRES	char	Verbatim Examination Finding		Collected at CRF.
IFORRESU	char	Original Units		Collected at CRF.
IFSTRESC	char	Character Result/Finding in Std. Format		Collected at CRF.
IFSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
IFSTRESU	char	Standard Units		Collected at CRF.
IFBLFL	char	Baseline Flag		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IFDY	num	Study Day of Collection		Collected at CRF.

## 1.4.17. Laboratory Test Results – LB

<b>Dataset</b>	LB
<b>Creating program</b>	lb.sas
<b>Description</b>	Laboratory Test Results
<b>Unique identifier</b>	DUSUBJID, LBTESTCD, LBSEQ
<b>Sorted by</b>	DUSUBJID, 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: LBNAM,LBDTC,LBENDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
LBSEQ	num	Sequence Number		Collected at CRF.
LBSPID	char	Sponsor-Defined Identifier		Collected at CRF.
LBTESTCD	char	LAB Test or Examination Short Name		Collected at CRF.
LBTEST	char	LAB Test or Examination Name		Collected at CRF.
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.
LBSTNRC	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.



Variable	Type	Label	Codes	Comments
LBBLFL	char	Baseline Flag		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBDY	num	Study Day of Specimen Collection		Collected at CRF.

#### 1.4.18. Supplemental Qualifiers for LB – SUPPLB

<b>Dataset</b>	SUPPLB
<b>Creating program</b>	supplb.sas
<b>Description</b>	Supplemental Qualifiers for LB
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, 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.

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

## 1.4.19. Medical History – MH

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

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

Variable	Type	Label	Codes	Comments
MHOCCUR	char	Medical History Occurrence		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
MHDY	num	Study Day of History Collection		Collected at CRF.
MHSTDY	num	Relative Start Day of Medical Hist Event		If MHSTDTC and RFSTDTC not missing then perform below logic to calculate MHSTDY,if MHSTDTC less than RFSTDTC then (MHSTDTC - RFSTDTC).Else if MHSTDTC is greater than equal to RFSTDTC then (MHSTDTC- RFSTDTC) +1.

## 1.4.20. Supplemental Qualifiers for MH – SUPPMH

<b>Dataset</b>	SUPPMH
<b>Creating program</b>	suppmh.sas
<b>Description</b>	Supplemental Qualifiers for MH
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, IDVARVAL, QNAM
<b>Notes</b>	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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.21. Questionnaires – QS

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

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

Variable	Type	Label	Codes	Comments
QSORRES	char	Finding in Original Units		Collected at CRF.
QSORRESU	char	Original Units		Collected at CRF.
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
QSSTRESU	char	Standard Units		Collected at CRF.
QSBLFL	char	Baseline Flag		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
QSDY	num	Study Day of Finding		Collected at CRF.

## 1.4.22. Related Records – RELREC

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

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



## 1.4.23. Surgery – SG

<b>Dataset</b>	SG
<b>Creating program</b>	sg.sas
<b>Description</b>	Surgery
<b>Unique identifier</b>	DUSUBJID, SGCAT, SGDECOD, SGSEQ
<b>Sorted by</b>	DUSUBJID, SGCAT, SGDECOD, SGSEQ
<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: 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.
SGDECOD	char	Standardized Surgery/Procedure Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.
SGINDC	char	Indication		Collected at CRF.
SGLOC	char	Location of Surgery/Procedure		Collected at CRF.
SGSTDY	num	Study Day of Surgery		Collected at CRF.

#### 1.4.24. Supplemental Qualifiers for SG – SUPPSG

<b>Dataset</b>	SUPPSG
<b>Creating program</b>	suppsg.sas
<b>Description</b>	Supplemental Qualifiers for SG
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, 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

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

#### 1.4.25. Substance Use – SU

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

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Codes</b>	<b>Comments</b>
SUSEQ	num	Sequence Number		Collected at CRF.
SUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUCAT	char	Category for Substance Use		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.
SUDOSE	num	Substance Use Consumption		Collected at CRF.
SUDOSU	char	Consumption Units		Collected at CRF.
SUDOSFRQ	char	Use Frequency Per Interval		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
SUDUR	char	Duration of Substance Use		Collected at CRF.

## 1.4.26. Supplemental Qualifiers for SU – SUPPSU

<b>Dataset</b>	SUPPSU
<b>Creating program</b>	suppsu.sas
<b>Description</b>	Supplemental Qualifiers for SU
<b>Unique identifier</b>	DUSUBJID, IDVARVAL, QNAM
<b>Sorted by</b>	DUSUBJID, IDVARVAL, QNAM
<b>Notes</b>	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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.27. Subject Visits – SV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
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 RFSTDTC not missing then perform below logic to calculate SVSTDY, If SVSTDTC less than RFSTDTC then (SVSTDTC - RFSTDTC). Else if SVSTDTC is greater than equal to RFSTDTC then (SVSTDTC - RFSTDTC) +1.
SVENDY	num	Relative End Day of Visit		If SVENDTC and RFSTDTC not missing then perform below logic to calculate SVENDY, If SVENDTC less than RFSTDTC then (SVENDTC - RFSTDTC). Else if SVENDTC is greater than equal to RFSTDTC then (SVENDTC - RFSTDTC) +1.

1.4.28. 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>	IECAT, IETESTCD
<b>Sorted by</b>	IECAT, IETESTCD
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.

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

### 1.4.29. Vital Signs – VS

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

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



Variable	Type	Label	Codes	Comments
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		Group element to protect PII.
VSORRESU	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result/Finding in Std Format		Group element to protect PII.
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VSSTAT	char	Vitals Status		Collected at CRF.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VSDY	num	Study Day of Vital Signs		Collected at CRF.

## 1.4.30. 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>	DUSUBJID, XATESTCD, XASEQ
<b>Sorted by</b>	DUSUBJID, XATESTCD, XASEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: XANAM,XADTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
XASEQ	num	Sequence Number		Collected at CRF.
XASPID	char	Sponsor-Defined Identifier		Collected at CRF.
XATESTCD	char	Short Name of Measurement		Collected at CRF.
XATEST	char	Name of Measurement		Collected at CRF.
XAORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XAORRESU	char	Original Units		Collected at CRF.
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.
XASTAT	char	Status		Collected at CRF.
XASPEC	char	Specimen Type		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
XATPT	char	Planned Timepoint Name		Collected at CRF.
XATPTNUM	num	Planned Time point Number		Collected at CRF.
XADY	num	Study Day of Specimen Collection		Collected at CRF.
XABLFL	char	Baseline Flag		Collected at CRF.

## 1.4.31. Imaging – XI

<b>Dataset</b>	XI
<b>Creating program</b>	xi.sas
<b>Description</b>	Imaging
<b>Unique identifier</b>	DUSUBJID, XITESTCD, XISPID, XISEQ
<b>Sorted by</b>	DUSUBJID, XITESTCD, XISPID, XISEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: XIGRPID,XIREFID,XISTRESN, XISPID ,XINAM,XIDTC

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

Variable	Type	Label	Codes	Comments
XIORRES	char	Result or Finding in Original Units		Collected at CRF.
XISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XISTAT	char	XI Status		Collected at CRF.
XIREASND	char	Reason XI Not Performed		Collected at CRF.
XILOC	char	Location of Imaging Test		Collected at CRF.
XIMETHOD	char	Method of XI Test		Collected at CRF.
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	Study Day of Imaging Collection		Collected at CRF.

#### 1.4.32. Supplemental Qualifiers for XI – SUPPXI

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