

Clinical Development

**Ustekinumab<sup>®</sup>**

CNTO1275PSA3002

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.
- Investigator Name will not be provided.
- 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+).
- 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, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- Lab Identifier information will not be provided.
- Lab Name information will not be provided.
- Empty datasets will not be submitted. (e.g. SUPPIF)
- Vendor specific information such as Vendor Name will not be provided. (e.g. LBNAM, XANAM, XINAM)
- Sponsor Identifier containing date will not be provided. (e.g. XISPID)
- PK data will be not be submitted due to sensitivity of the data. (e.g. PC, SUPPPC)
- Complete missing value variables will be removed
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- 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.
- Subject specific health economic assessment questionnaire will not be submitted to protect PII. (e.g. QSCAT = Health Economic Questionnaire)

### 1.3. Data Files

The CNT01275PSA3002 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the CNT01275PSA3002 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>	Subjects demographics information.
<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,DMDTC, ETHNIC

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 the Study 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>	suppdm.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-Identity
QNAM	char	Qualifier Variable Name		If QNAM = 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/Serious AEs
<b>Unique identifier</b>	DUSUBJID, AEBODSYS, AEDECOD, AESTDY, AESPID
<b>Sorted by</b>	DUSUBJID, AEBODSYS, AEDECOD, AESTDY, AESPID
<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-Identity
AESEQ	num	Sequence Number		Collected at CRF
AESPID	char	Sponsor-Defined Identifier		Collected at CRF
AEDECOD	char	Dictionary-Derived Term		Collected at CRF
AEBODSYS	char	Body System or Organ Class		Collected at CRF
AESEV	char	Severity/Intensity		Collected at CRF
AESER	char	Serious Event		Collected at CRF

Variable	Type	Label	Codes	Comments
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
AELOC	char	Location of the Reaction		Collected at CRF
AESTDY	num	Study Day of Start of Adverse Event		Collected at CRF
AEENDY	num	Study Day of End of Adverse Event		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: QEVAL

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

### 1.4.5. Clinical Findings– CF

<b>Dataset</b>	CF
<b>Creating program</b>	cf.sas
<b>Description</b>	Clinical Findings
<b>Unique identifier</b>	DUSUBJID, CFCAT ,CFTESTCD,CFSPID , CFLOC
<b>Sorted by</b>	DUSUBJID, CFCAT ,CFTESTCD,CFSPID, CFLOC
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values: CFORRESU,CFSTRESN,CFSTRESU,CFDTC,CFEVAL

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	Char 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,QNAM,IDVARVAL
<b>Sorted by</b>	DUSUBJID,QNAM,IDVARVAL
<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
USUBJID	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, CMSPID, CMCAT, CMDECOD , CMLOC
<b>Sorted by</b>	DUSUBJID, CMSPID, CMCAT, CMDECOD , CMLOC
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values: CMTRT, CMMODIFY, CMSCAT, CMSTAT, CMREASND, CMDOSE, CMDOSFRM, CMDOSFRQ, CMDOSRGM, 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



<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Codes</b>	<b>Comments</b>
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
CMSTDY	num	Study Day of Start of Medication		Collected at CRF
CMENDY	num	Study Day of End of Medication		Collected at CRF
CMLOC	char	Location of Dose Administration		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: 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 = CMRDSOTH then drop
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF
QORIG	char	Origin		Collected at CRF

### 1.4.9.Disease Characteristics – DC

<b>Dataset</b>	DC
<b>Creating program</b>	dc.sas
<b>Description</b>	Disease Characteristics
<b>Unique identifier</b>	DUSUBJID,DCSPID, DCCAT,DCTESTCD
<b>Sorted by</b>	DUSUBJID,DCSPID, DCCAT,DCTESTCD
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values: DCSCAT,DCSTRESN,DCDRVFL,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

Variable	Type	Label	Codes	Comments
DCCAT	char	Category for Disease Characteristic		Collected at CRF
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
DCBLFL	char	Baseline Flag		Collected at CRF
DCEVAL	char	Evaluator		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
DCDY	num	Study Day of Finding		Collected at CRF
DCREASND	char	Reason Not Done		Collected at CRF
DCLOC	char	Location		Collected at CRF
DCSTAT	char	Status		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,DSSPID, DSCAT,DSDECOD
<b>Sorted by</b>	DUSUBJID,DSSPID, DSCAT,DSDECOD
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values: 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
DSSCAT	char	Subcategory for Disposition Event		Collected at CRF

Variable	Type	Label	Codes	Comments
EPOCH	char	Epoch		Collected at CRF
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,QNAM,QVAL
<b>Sorted by</b>	DUSUBJID,QNAM,QVAL
<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 = DRSWC 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
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF
DVCAT	char	Category for Protocol Deviation		Collected at CRF
DVSCAT	char	Subcategory for Protocol Deviation		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
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

Variable	Type	Label	Codes	Comments
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>	suppex.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 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
IDVARVAL	char	Identifying Variable Value		Collected at CRF
QNAM	char	Qualifier Variable Name		If QNAM = EXCNTRID then drop
QLABEL	char	Qualifier Variable Label		Collected at CRF
QVAL	char	Data Value		Collected at CRF

Variable	Type	Label	Codes	Comments
QORIG	char	Origin		Collected at CRF

#### 1.4.15. Inclusion/Exclusion Exceptions – IE

<b>Dataset</b>	IE
<b>Creating program</b>	ie.sas
<b>Description</b>	Inclusion/Exclusion Criteria
<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 or due to repetition of the information or due missing values: 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

Variable	Type	Label	Codes	Comments
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF
IECAT	char	Inclusion/Exclusion Category		Collected at CRF
IESCAT	char	Inclusion/Exclusion Subcategory		Collected at CRF
IEORRES	char	I/E Criterion Original Result		Collected at CRF
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF
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,IFSPID,IFTESTCD
<b>Sorted by</b>	DUSUBJID,IFSPID,IFTESTCD
<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
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

Variable	Type	Label	Codes	Comments
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, LBDY, LBSEQ
<b>Sorted by</b>	DUSUBJID, LBTESTCD, LBDY, 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: LBREASND, LBNAM, LBDTC, LBENDTC, LBELTM, LBTPREF

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
LBORNRLHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF
LBSTNR0	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
LBSTNR0L0	num	Reference Range Lower Limit-Std Units		Collected at CRF
LBSTNR0HI	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 or due missing values: MHSTAT,MHREASND , MHDTC,MHSTDTC,MHENRF

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>	DMSUPPMH
<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: QEVAL

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

## 1.4.21. Questionnaires – QS

<b>Dataset</b>	QS
<b>Creating program</b>	qs.sas
<b>Description</b>	Questionnaires
<b>Unique identifier</b>	DUSUBJID,QSSPID,QSCAT,QSTESTCD, VISITNUM
<b>Sorted by</b>	DUSUBJID,QSSPID,QSCAT,QSTESTCD, 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: QSSTAT,QSDTC

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

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>	RDOMAIN, DUSUBJID, IDVAR, IDVARVAL, RELID
<b>Sorted by</b>	RDOMAIN, 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

## 1.4.23. Surgery – SG

<b>Dataset</b>	SG
<b>Creating program</b>	sg.sas
<b>Description</b>	Surgery
<b>Unique identifier</b>	DUSUBJID,SGCAT,SGDECOD,SGLOC,SGINDC,SGSPID
<b>Sorted by</b>	DUSUBJID,SGCAT,SGDECOD,SGLOC,SGINDC,SGSPID
<b>Notes</b>	Below listed variable 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
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 variable 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,SUSPID, SUTRT, SUCAT
<b>Sorted by</b>	DUSUBJID,SUSPID, SUTRT, SUCAT
<b>Notes</b>	

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

Variable	Type	Label	Codes	Comments
DUSUBJID	Char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-Identity
SUSEQ	Num	Sequence Number		Collected at CRF
SUSPID	Char	Sponsor-Defined Identifier		Collected at CRF
SUTRT	Char	Reported Name of Substance		Collected at CRF
SUCAT	Char	Category for Substance Use		Collected at CRF
SUOCCUR	Char	SU Occurrence		Collected at CRF
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 variable will be dropped from dataset due to missing values: QEVAL

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

## 1.4.27. 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>	IETESTCD
<b>Sorted by</b>	IETESTCD
<b>Notes</b>	

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



Variable	Type	Label	Codes	Comments
IETESTCD	Char	Inclusion/Exclusion Criterion Short Name		Collected at CRF
IETEST	Char	Inclusion/Exclusion Criterion		Collected at CRF
IECAT	Char	Inclusion/Exclusion Category		Collected at CRF

#### 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,VSTEST,VSTESTCD,VSDY,VSSPID
<b>Sorted by</b>	DUSUBJID,VSTEST,VSTESTCD,VSDY,VSSPID
<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
DUSUBJID	Char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
VSSEQ	Num	Sequence Number		Collected at CRF
VSSPID	Char	Sponsor-Defined Identifier		Collected at CRF
VSTESTCD	Char	Vital Signs Test Short Name		Collected at CRF
VSTEST	Char	Vital Signs Test Name		Collected at CRF
VSORRES	Char	Result or Finding in Original Units		Collected at CRF
VSORRESU	Char	Original Units		Collected at CRF
VSSTRESC	Char	Character Result/Finding in Std Format		Collected at CRF
VSSTRESN	Num	Numeric Result/Finding in Standard Units		Collected at CRF
VSSTRESU	Char	Standard Units		Collected at CRF
VSBLFL	Char	Baseline Flag		Collected at CRF
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,VISIT,XATEST,XATESTCD,XADY,XASEQ
<b>Sorted by</b>	DUSUBJID,VISIT,XATEST,XATESTCD,XADY,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,VISIT,XITEST,XITESTCD,XIDY,XISEQ
<b>Sorted by</b>	DUSUBJID,VISIT,XITEST,XITESTCD,XIDY,XISEQ
<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: XIGRPID,XIREFID,XISPID, XISTRESN, 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: QEQVAL

Variable	Type	Label	Codes	Comments
STUDYID	Char	Study Identifier		Collected at CRF
RDOMAIN	Char	Related Domain Abbreviation		Collected at CRF
DUSUBJID	Char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-Identity
IDVAR	Char	Identifying Variable		Collected at CRF
IDVARVAL	Char	Identifying Variable Value		Collected at CRF
QEQVAL	Char	Qualifier Variable Name		If QEQVAL = XIOOWIN then drop
QLABEL	Char	Qualifier Variable Label		Collected at CRF
QVAL	Char	Data Value		Collected at CRF

Variable	Type	Label	Codes	Comments
QORIG	Char	Origin		Collected at CRF