

Clinical Development

**CNTO148**

CNTO148\_P07642

Anonymization Data Derivation Specification Document

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## Table of contents

Clinical Development.....	1
1. Datasets.....	4
1.1. Specifications Introduction .....	4
1.2. Guidelines for Preparing Data.....	4
1.3. Data Files .....	5
1.4. Data Domains .....	6
1.4.1. Demographics – DM.....	6
1.4.2. Adverse Events – AE .....	8
1.4.3. Clinical Findings – CF .....	15
1.4.4. Concomitant Medications – CM .....	20
1.4.5. Comments – CO .....	23
1.4.6. Drug Accountability – DA.....	25
1.4.7. Disposition – DS.....	27
1.4.8. Exposure – EX.....	29
1.4.9. Family Event – FE .....	32
1.4.10. Healthcare Encounters – HO.....	35
1.4.11. Inclusion/Exclusion Criterion Not Met – IE.....	37
1.4.12. Laboratory Test Results – LB.....	39
1.4.13. Medical History – MH.....	43
1.4.14. ORIGAE – ORIGAE .....	45
1.4.15. Procedures – PR.....	52
1.4.16. Questionnaires – QS .....	55
1.4.17. Related Records – RELREC.....	57
1.4.18. Subject Elements – SE.....	58
1.4.19. Subject Visits – SV .....	60
1.4.20. Trial Arms – TA.....	61
1.4.21. Trial Elements – TE.....	62
1.4.22. Trial Inclusion/Exclusion Criteria – TI.....	63
1.4.23. Trial Visits – TV .....	64
1.4.24. Vital Signs – VS .....	65
1.4.25. Biomedical Research Consent – ZE.....	67
1.4.26. Specimen Collection Status – ZF .....	69

Status and Version	Release Date	Summary of Key Changes

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

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

### 1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty comments data will be submitted due to sensitivity of data.
- Due to sensitive information FF, PY and SC datasets will be removed.
- Dataset with zero observation from input will not be submitted (ex. CE,IF,PX).
- For Randomized subjects, DM.RFSTDTC ("Subject Reference Start Date") will be used as Reference Date (referred as REF. DATE in the document) to derive relative day. For Non-Randomized subjects, SV.SVSTDTC ("Start Date/Time of Visit") having SV.VISIT="visit 1" will be used as a Reference date (referred as REF. DATE in the document) to derive relative day.

### 1.3. Data Files

The CNT0148\_P07642 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 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>	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 repetition of the information or due to missing values: RFSTDTC,RFENDTC,INVID,INVNAM,BRTHDTC,DMDTC,DMDY,AGEDAYS, AGEMOS,AGEWEEKS,AGEYEARS,BRTHDTI,CNTRYNAM,DISCNDTC,DMCAGE, DMCAGEU,RACEWHITE,RACENHPI,RACEBKA,RACEASN,RACEAIAN,RACEASIA

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 in AGEU at		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.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
ACTARMCD	char	Actual Arm Code		Collected at CRF.
ACTLARM	char	Description of Actual Arm		Collected at CRF.
DAYOFDC	num	Relative Day of Discontinuance		Collected at CRF.
DSITENUM	char	Study Site Number Assign for De-Identity		Randomly assigned Study Site Number for De-Identity
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.
DISCNTM	num	Time of Discontinuance		If DISCNDTC contains time part then timepart(DISCNDTC) else DISCNTM equal to NULL.

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

### 1.4.2. Adverse Events – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	STUDYID,DUSUBJID,AEBOBSYS,AEDECOD,AESTDY,AESEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,AEBOBSYS,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: AETERM,VISITDY,AESTDTC,AEENDTC,AECLCRS1,AECLCRS2, AECRSFU1,AECRSFU2,AECRSFU3,AECRSTRT,AEDTHAF1,AEDTHAF2,AEDTHAF3, AEDTHAUT,AEDTHDTC,AEDTHNOT,AEHODDGS,AEHODDTC,AEHOSDTC, AEOCEVID,AERELSM,AESEU,AESS1,AESS2,AESRCH4,AEWRSNDT

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
AESEQ	num	Sequence Number		Collected at CRF.
AEGRPID	char	Group ID		Collected at CRF.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AECAT	char	Category for Adverse Event		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.
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AERELNST	char	Relationship to Non-Study Treatment		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AESCAN	char	Involves Cancer		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.

Variable	Type	Label	Codes	Comments
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESOD	char	Occurred with Overdose		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmt Given		Collected at CRF.
AETOXGR	char	Standard Toxicity Grade		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC - REF.DATE) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC - REF.DATE) +1.
AEDUR	char	Duration of Adverse Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEENRF	char	End Relative to Reference Period		Collected at CRF.
AEACNCD	char	Action Taken with Study Treatment Code		Collected at CRF.
AEAGE	char	Age At AE Onset		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AEAGEU	char	Age At AE Onset Unit		Collected at CRF.
AECLINT	char	Clinical Interest		Collected at CRF.
AEDOSTOX	char	Dose Limiting Toxicity		Collected at CRF.
AEDURDD	num	Duration of Adverse Event Diff of Dates		Collected at CRF.
AEDURDDU	char	Duration Units		Collected at CRF.
AELLT	char	Dictionary Term LLT		Collected at CRF.
AERELCD	char	Causality Code		Collected at CRF.
AESDCH	char	AE Diminish Aft Stopping EXTRT Dechallng		Collected at CRF.
AESEVCD	num	Intensity Code		Collected at CRF.
AESIZE	num	Maximum Size		Collected at CRF.
AESRCH	char	AE Reappear Aft Restarting EXTRT Rechal		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
SPDYRLEP	num	Stop Day Rel to Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
ACN1	char	Action Taken with SM1		Collected at CRF.
ACN2	char	Action Taken with SM2		Collected at CRF.
ACN3	char	Action Taken with SM3		Collected at CRF.
ACN4	char	Action Taken with SM4		Collected at CRF.
ACN5	char	Action Taken with SM5		Collected at CRF.
ACN6	char	Action Taken with SM6		Collected at CRF.
AESDCH1	char	AE Diminish Aft Stopping SM1 Dechallng		Collected at CRF.
AESDCH2	char	AE Diminish Aft Stopping SM2 Dechallng		Collected at CRF.
AESDCH3	char	AE Diminish Aft Stopping SM3 Dechallng		Collected at CRF.
AESDCH4	char	AE Diminish Aft Stopping SM4 Dechallng		Collected at CRF.
AESDCH5	char	AE Diminish Aft Stopping SM5 Dechallng		Collected at CRF.
AESDCH6	char	AE Diminish Aft Stopping SM6 Dechallng		Collected at CRF.
AESRCH1	char	AE Reappear Aft Stopping SM1 Rechallng		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESRCH2	char	AE Reappear Aft Stopping SM2 Rechallng		Collected at CRF.
AESRCH3	char	AE Reappear Aft Stopping SM3 Rechallng		Collected at CRF.
AESRCH5	char	AE Reappear Aft Stopping SM5 Rechallng		Collected at CRF.
AESRCH6	char	AE Reappear Aft Stopping SM6 Rechallng		Collected at CRF.
REL1	char	Causality SM1		Collected at CRF.
REL2	char	Causality SM2		Collected at CRF.
REL3	char	Causality SM3		Collected at CRF.
REL4	char	Causality SM4		Collected at CRF.
REL5	char	Causality SM5		Collected at CRF.
REL6	char	Causality SM6		Collected at CRF.
RELPR	char	Relationship to Study Procedure		Collected at CRF.
SM1	char	Study Medication 1		Collected at CRF.
SM2	char	Study Medication 2		Collected at CRF.
SM3	char	Study Medication 3		Collected at CRF.
SM4	char	Study Medication 4		Collected at CRF.
SM5	char	Study Medication 5		Collected at CRF.
SM6	char	Study Medication 6		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAECRYEV	char	De-Identify Country Where Event Occur		Group element to protect PII.
AEPQCA	char	Product Quality Complaint Attached		Collected at CRF.
AEDOSDUR	char	Time Since Last Dose		Collected at CRF.
AESTTM	num	Start Time of Adverse Event		If AESTDTC contains time part then timepart(AESTDTC) else AESTTM equal to NULL.
AEWRSNDY	char	Relative Day Adverse Event Worsened		If AEWRSNDT and REF.DATE not missing then perform below logic to calculate AEENDY, If AEWRSNDT less than REF.DATE then (AEENDY - REF.DATE). Else if AEWRSNDT is greater than equal to REF.DATE then (AEWRSNDT - REF.DATE) +1.

### 1.4.3.Clinical Findings – CF

<b>Dataset</b>	CF
<b>Creating program</b>	cf.sas
<b>Description</b>	Clinical Findings
<b>Unique identifier</b>	STUDYID,DUSUBJID,CFTEST,CFDY,CFSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,CFTEST,CFDY,CFSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>CFREFID,CFMODIFY,CFXFN,CFNAM,CFDTC,CFSTDTC,CFENDTC,CFEVLINT,SPDYRLEP,CFROUTE,AADJEVDT,OUTCOME,SAABNFTG,SADROWSY,SASLEEPY,SALKCONC,SASUDROW,SAOTHER,DZABNFTG,DZDROWSY,DZSLEEPY,DZLKCONC,DZSUDROW,DZOTHER,CLAMPTYP,CFEVLINX,SRCACCEX,SRCACPNT,SRCCURIV,SRCPSTIV,SRCINASU,SRUNSEQ,SRCSRGY,SRCPOTH,CFLOCHD,CFLOCFC,CFLOCOM,CFLOCCHS,CFLOCSTM,CFLOCBCK,CFLOCARM,CFLOCHND,CFLOCLEG,CFLOCFT,CFLOC GT,CFLOCIS,CFLOCOTH,CFDERMSD,CFPRIMRY,CFREAND1,CFREAND2,CFREAND3,SUPP1,SUPP2,SUPP3,SUPP4,SUPP5,SUPP6,SUPP7,SUPP8,SUPP9,SUPP10,HLADTC,CFNAMSEQ,ADJREAS,CFAEMHSQ,WEEKNMB,MONTHNMB,ATTCKNMB,DTHREAS,DTHDTC</p>

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.

Variable	Type	Label	Codes	Comments
CFGRPID	char	Group ID		Collected at CRF.
CFSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CFTESTCD	char	Test Short Name		Collected at CRF.
CFTEST	char	Test		Collected at CRF.
CFCAT	char	Category for Clinical Findings		Collected at CRF.
CFSCAT	char	Subcategory for Clinical Findings		Collected at CRF.
CFPOS	char	Clinical Finding Position of Subject		Collected at CRF.
CFBODSYS	char	Body System or Organ Class		Collected at CRF.
CFORRES	char	Result or Finding in Original Units		Collected at CRF.
CFORRESU	char	Original Units		Collected at CRF.
CFORNRL0	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
CFORNRLH	char	Reference Range Upper Limit in Orig Unit		Collected at CRF.
CFSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
CFSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
CFSTRESU	char	Standard Units		Collected at CRF.
CFSTNRL0	num	Reference Range Lower Limit-Std Units		Collected at CRF.
CFSTNRLH	num	Reference Range Upper Limit-Std Units		Collected at CRF.



Variable	Type	Label	Codes	Comments
CFSTNRC	num	Reference Range for Char Rslt-Std Units		Collected at CRF.
CFNRIND	char	Reference Range Indicator		Collected at CRF.
CFRESCAT	char	Result Category		Collected at CRF.
CFSTAT	char	Completion Status		Collected at CRF.
CFREASND	char	Reason Not Performed		Collected at CRF.
CFLOINC	char	LOINC Code		Collected at CRF.
CFSPEC	char	Specimen Type		Collected at CRF.
CFSPCCND	char	Specimen Condition		Collected at CRF.
CFLOC	char	Location of the Clinical Finding		Collected at CRF.
CFMETHOD	char	Method of Test or Examination		Collected at CRF.
CFBLFL	char	Baseline Flag		Collected at CRF.
CFFAST	char	Fasting Status		Collected at CRF.
CFEVAL	char	Evaluator		Collected at CRF.
CFTOX	char	Toxicity		Collected at CRF.
CFTOXGR	char	Standard Toxicity Grade		Collected at CRF.
CFSEV	char	Severity		Collected at CRF.
CFDTHREL	char	Relationship to Death		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
CFDY	num	Relative Day of Collection		If CFDTDC and REF.DATE not missing then perform below logic to calculate CFDY, If CFDTDC less than REF.DATE then (CFDTDC - REF.DATE). Else if CFDTDC is greater than equal to REF.DATE then (CFDTDC-REF.DATE) +1.
CFTPT	char	Planned Time Point Name		Collected at CRF.
CFTPTNUM	num	Planned Time Point Number		Collected at CRF.
CFTPTREF	char	Time Point Reference		Collected at CRF.
CFOBJ	char	Object of the Observation		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
VSTTYP	char	Vendor-Provided Visit Type		Collected at CRF.
CFSIDE	char	Side		Collected at CRF.
SM1	char	Study Medication 1		Collected at CRF.
SM2	char	Study Medication 2		Collected at CRF.
SM3	char	Study Medication 3		Collected at CRF.
SM4	char	Study Medication 4		Collected at CRF.
SM5	char	Study Medication 5		Collected at CRF.

Variable	Type	Label	Codes	Comments
SM6	char	Study Medication 6		Collected at CRF.
SM7	char	Study Medication 7		Collected at CRF.
SM8	char	Study Medication 8		Collected at CRF.
VSTNUM	char	Vendor-Provided Visit Number		Collected at CRF.
VSTNAME	char	Vendor-Provided Visit Name		Collected at CRF.
CFBLNDFL	char	Blinding Flag		Collected at CRF.
HLADY	num	Relative Day of HLA B27		If HLADTC and REF.DATE not missing then perform below logic to calculate HLADY, If HLADTC less than REF.DATE then (HLADTC - REF.DATE). Else if HLADTC is greater than equal to REF.DATE then (HLADTC - REF.DATE) +1.

### 1.4.4. 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: CMTRT,VISITDY,CMSTDTC,CMENDTC,CMADSFPM,CMAROUTE,CMCLAS3,CMCLSCD1,CMCLSCD2,CMCLSCD3,CMDCDOSU,CMDRUG,CMENDTI,CMSTDTI,CMVDOSU,CMVDSFRM,INDCDOSU,INDDOSU,CMLNTHPY,CMLOCTX,CMSYSTX,CMVACTX,CMSKNDTX,CMDISRES,CMTOTCYC,BESTRES

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
CMSEQ	num	Sequence Number		Collected at CRF.
CMGRPID	char	Group ID		Collected at CRF.
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMMODIFY	char	Modified Reported Name		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCAT	char	Category for Medication		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSE	num	Dose per Administration		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRM	char	Dose Form		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency Per Interval		Collected at CRF.
CMDOSTOT	num	Total Daily Dose using CMDOSU		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMLOC	char	Location of Dose Administration		Collected at CRF.
CMADJ	char	Reason for Dose Adjustment		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC - REF.DATE) +1.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.
CMBRTRM	char	Broader Therapy		Collected at CRF.
CMCLAS1	char	Therapeutic Class 1		Collected at CRF.
CMCLAS2	char	Therapeutic Class 2		Collected at CRF.
CMDURDD	num	Duration of Medication Diff of Dates		Collected at CRF.
CMDURDDU	char	Duration Units		Collected at CRF.
CMVROUTE	char	Route of Administration Verbatim		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
INDDOS	num	Individual Dose		Collected at CRF.
INDVDOSU	char	Individual Dose Units Verbatim		Collected at CRF.
SPDYRLEP	num	Stop Day Rel to Epoch		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
CMENIDY	num	Relative End Day of Medication Imputed		If CMENDTI and REF.DATE not missing then perform below logic to calculate CMENIDY, If CMENDTI less than REF.DATE then (CMENDTI - REF.DATE). Else if CMENDTI is greater than equal to REF.DATE then (CMENDTI- REF.DATE) +1.
CMSTIDY	num	Relative Start Day of Medication Imputed		If CMSTDTI and REF.DATE not missing then perform below logic to calculate CMSTIDY, If CMSTDTI less than REF.DATE then (CMSTDTI - REF.DATE). Else if CMSTDTI is greater than equal to REF.DATE then (CMSTDTI- REF.DATE) +1.

### 1.4.5. Comments – CO

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Empty dataset will be submitted
DOMAIN	char	Domain Abbreviation		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
RDOMAIN	char	Related Domain Abbreviation		Empty dataset will be submitted
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Empty dataset will be submitted
COSEQ	num	Sequence Number		Empty dataset will be submitted
IDVAR	char	Identifying Variable		Empty dataset will be submitted
IDVARVAL	char	Identifying Variable Value		Empty dataset will be submitted
COREF	char	Comment Reference		Empty dataset will be submitted
DSUBJID	char	Subject Id Assigned for De-Identity		Empty dataset will be submitted
CODY	char	Relative Day of Comment		Empty dataset will be submitted



## 1.4.6. Drug Accountability – DA

<b>Dataset</b>	DA
<b>Creating program</b>	da.sas
<b>Description</b>	Drug Accountability
<b>Unique identifier</b>	STUDYID,DUSUBJID,DATESTCD,DADY,DASEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,DATESTCD,DADY,DASEQ
<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: DAREFID,DASTNRLO,DASTAT,DAREASND,VISITDY,DADTC,SPDYRLEP

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
DASEQ	num	Sequence Number		Collected at CRF.
DAGRPID	char	Group ID		Collected at CRF.
DASPID	char	Sponsor ID		Collected at CRF.
DATESTCD	char	Test Short Name		Collected at CRF.
DATEST	char	Test		Collected at CRF.
DACAT	char	Category for Clinical Findings		Collected at CRF.
DASCAT	char	Subcategory for Clinical Findings		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAORRES	char	Result or Finding in Original Units		Collected at CRF.
DAORRESU	char	Original Units		Collected at CRF.
DASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
DASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
DASTRESU	char	Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
DADY	num	Relative Day of Collection		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
DAPERPRO	char	Study Medication Taken as per Protocol		Collected at CRF.

## 1.4.7.Disposition – DS

<b>Dataset</b>	DS
<b>Creating program</b>	ds.sas
<b>Description</b>	Disposition
<b>Unique identifier</b>	STUDYID,DUSUBJID,DSDECOD,DSSTDY,DSSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,DSDECOD,DSSTDY,DSSEQ
<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: DSSPID,DSTERM,VISITDY,DSDTC,DSSTDTC,SPDYRLEP

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.
DSGRPID	char	Group ID		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.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
DSDY	num	Relative Day of Collection		If DSDTC and REF.DATE not missing then perform below logic to calculate DSDY, If DSDTC less than REF.DATE then (DSDTC - REF.DATE). Else if DSDTC is greater than equal to REF.DATE then (DSDTC - REF.DATE) +1.
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDTC and REF.DATE not missing then perform below logic to calculate DSSTDY, If DSSTDTC less than REF.DATE then (DSSTDTC - REF.DATE). Else if DSSTDTC is greater than equal to REF.DATE then (DSSTDTC - REF.DATE) +1.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

### 1.4.8.Exposure – EX

<b>Dataset</b>	EX
<b>Creating program</b>	ex.sas
<b>Description</b>	Exposure
<b>Unique identifier</b>	STUDYID,DUSUBJID,EXTRT,EXSTDY,EXSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,EXTRT,EXSTDY,EXSEQ
<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: EXDECOD,EXDOSTXT,EXDOSRGM,EXLOT,VISITDY,EXSTDTC,EXENDTC,EXTPT,EXTPTNUM,EXDOSPRP,EXDOSPRU,EXDOSSTR,EXFSTDTC,EXLSTDTC,EXRPADJ,EXRPDTC,EXVACNUM,EXVOLPRP,EXVOLPRU,WGHTPRE,WGHTPREU,WGHTPSTU

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EXSEQ	num	Sequence Number		Collected at CRF.
EXGRPID	char	Group ID		Collected at CRF.
EXREFID	char	Reference ID		Collected at CRF.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXTRT	char	Name of Actual Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXMODIFY	char	Modified Reported Term		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.
EXDOSFRQ	char	Dosing Frequency Per Interval		Collected at CRF.
EXDOSTOT	num	Total Daily Dose Using EXDOSU		Collected at CRF.
EXROUTE	char	Route of Administration		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.
EXADJ	char	Reason for Dose Adjustment		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
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.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
EXDOSSEQ	char	Dose Number		Collected at CRF.
EXDURDD	num	Duration of Treatment Diff of Dates		Collected at CRF.
EXDURDDU	char	Duration Units		Collected at CRF.
EXNUMDOS	num	Number of Daily Doses		Collected at CRF.
EXRATE	num	Infusion Rate		Collected at CRF.
EXRATEU	char	Infusion Rate Unit		Collected at CRF.
EXSPID2	char	Vial or Component ID		Collected at CRF.
PRDFLAG	char	Period Flag		Collected at CRF.
SPDYRLEP	num	Stop Day Rel to Epoch		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
WGHTINF	num	Apparatus Weight Infused		Collected at CRF.
WGHTINFU	char	Apparatus Weight Infused Units		Collected at CRF.
WGHTPST	num	Apparatus Weight Postdose		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXSTTM	num	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.
EXENTM	num	End Time of Treatment		If EXENDTC contains time part then timepart(EXENDTC) else EXENTM equal to NULL.

### 1.4.9. Family Event – FE

<b>Dataset</b>	FE
<b>Creating program</b>	fe.sas
<b>Description</b>	Family Event
<b>Unique identifier</b>	STUDYID,DUSUBJID,FEDECOD,FESTDY,FESEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,FEDECOD,FESTDY,FESEQ
<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: FEREFID,FETERM,FEMODIFY,FESCAT,FECCUR,FESTAT,FEREASND,FEBODSYS, FELOC,FEOUT,VISITDY,FEDTC,FESTDTC,FEENDTC,FEENDY,FEDUR,FEENRF, FEDURDD,FEDURDDU,FELLT,SPDYRLEP,RELATIVE,FEINDV,FEPRDDSC

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
FESEQ	num	Sequence Number		Collected at CRF.
FEGRPID	char	Group ID		Collected at CRF.
FESPID	char	Sponsor ID		Collected at CRF.
FEDECOD	char	Dictionary-Derived Term		Collected at CRF.
FECAT	char	Category for Family Event		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
FEDY	num	Relative Day of Collection		If FEDTC and REF.DATE not missing then perform below logic to calculate FEDY, If FEDTC less than REF.DATE then (FEDTC - REF.DATE). Else if FEDTC is greater than equal to REF.DATE then (FEDTC - REF.DATE) +1.
FESTDY	num	Relative Start Day of Family Event		If FESTDTC and REF.DATE not missing then perform below logic to calculate FESTDY, If FESTDTC less than REF.DATE then (FESTDTC - REF.DATE). Else if FESTDTC is greater than equal to REF.DATE then (FESTDTC - REF.DATE) +1.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
FEINDBMT	char	Indication Breech Malpresentn Transv Lie		Collected at CRF.
FEINDCD	char	Indication Cephalopelvic Disproportion		Collected at CRF.
FEINDCPP	char	Indication Cord Prolapse Placenta Previa		Collected at CRF.
FEINDFPD	char	Indication Failure to Progress Dystocia		Collected at CRF.
FEINDFD	char	Indication Fetal Distress		Collected at CRF.
FEINDPDM	char	Indication Premat Delivery Multiple Gestn		Collected at CRF.
FEINDRES	char	Indication Repeat or Elective Section		Collected at CRF.
FEMODE	char	Mode of Delivery		Collected at CRF.
FEPRDEXM	char	Products of Conception Examined		Collected at CRF.

## 1.4.10. Healthcare Encounters – HO

<b>Dataset</b>	HO
<b>Creating program</b>	ho.sas
<b>Description</b>	Healthcare Encounters
<b>Unique identifier</b>	STUDYID,DUSUBJID,HODECOD,HOSTDY,HOSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,HODECOD,HOSTDY,HOSEQ
<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: HOREFID,HOSPID,HOTERM,HOMODIFY,HOCAT,HOSCAT,HOSTAT,HOREASND, VISITDY,HODTC,HOSTDTC,HOENDTC,HODY,HODUR,HOENRF

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.
HOGRPID	char	Group ID		Collected at CRF.
HODECOD	char	Dictionary-Derived Term		Collected at CRF.
HOCCUR	char	Hospitalization Event Occurrence		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSTDY	num	Relative Start Day of Hospitalization		If HOSTDTC and REF.DATE not missing then perform below logic to calculate HOSTDY, If HOSTDTC less than REF.DATE then (HOSTDTC - REF.DATE). Else if HOSTDTC is greater than equal to REF.DATE then (HOSTDTC - REF.DATE) +1.
HOENDY	num	Relative End Day of Hospitalization		If HOENDTC and REF.DATE not missing then perform below logic to calculate HOENDY, If HOENDTC less than REF.DATE then (HOENDTC - REF.DATE). Else if HOENDTC is greater than equal to REF.DATE then (HOENDTC - REF.DATE) +1.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
HODURDD	num	Duration of Hosp Diff of Dates		Collected at CRF.
HODURDDU	char	Duration Units		Collected at CRF.
SPDYRLEP	num	Stop Day Rel to Epoch		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
HOSAE	char	Hospitalization due to SAE		Collected at CRF.
HOER	char	Hospitalization due to ED Visit		Collected at CRF.
HOSTTM	num	Start Time of Hospitalization		If HOSTDTC contains time part then timepart(HOSTDTC) else HOSTTM equal to NULL.

Variable	Type	Label	Codes	Comments
HOENTM	num	End Time of Hospitalization		If HOENDTC contains time part then timepart(HOENDTC) else HOENTM equal to NULL.

#### 1.4.11. Inclusion/Exclusion Criterion Not Met – IE

<b>Dataset</b>	IE
<b>Creating program</b>	ie.sas
<b>Description</b>	Inclusion/Exclusion Criterion Not Met
<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 or due to missing values: IESTRESN,IESTRESU,VISITDY,IETDC,SPDYRLEP

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.
IEGRPID	char	Group ID		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IETEST1	char	Inclusion/Exclusion Criterion 1		Collected at CRF.
IETEST2	char	Inclusion/Exclusion Criterion 2		Collected at CRF.
IETEST3	char	Inclusion/Exclusion Criterion 3		Collected at CRF.
IETEST4	char	Inclusion/Exclusion Criterion 4		Collected at CRF.
IETEST5	char	Inclusion/Exclusion Criterion 5		Collected at CRF.
IETEST6	char	Inclusion/Exclusion Criterion 6		Collected at CRF.
IETEST7	char	Inclusion/Exclusion Criterion 7		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IEORRES	char	I/E Criterion Original Result		Collected at CRF.
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDTC and REF.DATE not missing then perform below logic to calculate IEDY, If IEDTC less than REF.DATE then (IEDTC - REF.DATE). Else if IEDTC is greater than equal to REF.DATE then (IEDTC - REF.DATE) + 1.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
IEPROTV	char	Protocol Version		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
IETM	num	Time of Collection		If IEDTC contains time part then timepart(IEDTC) else IETM equal to NULL.

#### 1.4.12. 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,LBTEST,LBDY,LBSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,LBTEST,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: LBSTAT,LBREASND,LBNAM,LBSPCCND,LBBLFL,VISITDY,LBDTC,LBENDTC, LBENDY,LTPTNUM,LBNAMSEQ,LBNRDTC,LBNRERR,SPDYRLEP,TSTDTC, LBBODLOC

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
LBSEQ	num	Sequence Number		Collected at CRF.
LBGRPID	char	Group ID		Collected at CRF.
LBREFID	char	Specimen ID		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.
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.
LBORNRLH	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.



Variable	Type	Label	Codes	Comments
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTOX	char	Toxicity		Collected at CRF.
LBTOXGR	char	Standard Toxicity Grade		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial 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.
LBTPT	char	Planned Time Point Name		Collected at CRF.
BLNDFL	char	Blinding Flag		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
LBCONC	char	Character Rslt/Finding in Convntl Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBCONN	num	Numeric Result/Finding in Convntl Units		Collected at CRF.
LBCONRHI	num	Ref Range Upper Limit - Convntl Units		Collected at CRF.
LBCONRLO	num	Ref Range Lower Limit - Convntl Units		Collected at CRF.
LBCONU	char	Conventional Units		Collected at CRF.
LBDICTU	char	Unit Dictionary Term		Collected at CRF.
LBINDTYP	char	Laboratory Result Indicator Type		Collected at CRF.
LBSIFL	char	LAB Standard International Unit Flag		Collected at CRF.
LBTESTV	char	LAB Test or Examination Name Verbatim		Collected at CRF.
LBVORESU	char	Original Units Verbatim		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
VSTNUM	char	Vendor-Provided Visit Number		Collected at CRF.
VSTTYP	char	Vendor-Provided Visit Type		Collected at CRF.
VSTNAME	char	Vendor-Provided Visit Name		Collected at CRF.
LBINDTYN	char	Numeric Result Type		Collected at CRF.
LBINDTYC	char	Character Result Type		Collected at CRF.
LBTM	num	Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.

## 1.4.13. Medical History – MH

<b>Dataset</b>	MH
<b>Creating program</b>	mh.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	STUDYID,DUSUBJID,MHDECOD,MHSTDY,MHSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,MHDECOD,MHSTDY,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: MHTERM,MHSCAT,MHLOC,VISITDY,MHDTC,MHSTDTC,MHDUR,MHEVLINT, MHRCTDTC,SPDYRLEP,MHRECUR,MHCAUSE,MHLOCBON,MHLOCESO, MHLOCEXT,MHLOCHD,MHLOCLIV,MHLOCLUN,MHLOCLN,MHLOCOPH, MHLOCKN,MHLOCSPE,MHLOCSPE,MHLOCTRK,MHLOCOTH,MHMETLOC, MHTYPE,MHBONMET,MHCNSMET,MHLIVMET,MHLUNMET,MHDURUN, MHLMETOT

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.
MHGRPID	char	Group ID		Collected at CRF.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHCAT	char	Category for Medical History		Collected at CRF.
MHDECOD	char	Dictionary-Derived Term		Collected at CRF.
MHBODSYS	char	Body System or Organ Class		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
MHDY	num	Relative Day of History Collection		If MHDTDC and REF.DATE not missing then perform below logic to calculate MHDY, If MHDTDC less than REF.DATE then (MHDTDC - REF.DATE). Else if MHDTDC is greater than equal to REF.DATE then (MHDTDC - REF.DATE) +1.
MHSTDY	num	Relative Start Day of Medi History Event		If MHSTDTC and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than REF.DATE then (MHSTDTC - REF.DATE). Else if MHSTDTC is greater than equal to REF.DATE then (MHSTDTC - REF.DATE) +1.
MHENRF	char	End Relative to Reference Period		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
MHLLT	char	Dictionary-Derived Term LLT		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
MHTM	num	Time of History Collection		If MHDTDC contains time part then timepart(MHDTDC) else MHTM equal to NULL.

#### 1.4.14. ORIGAE – ORIGAE

<b>Dataset</b>	ORIGAE
<b>Creating program</b>	origae.sas
<b>Description</b>	ORIGAE
<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: AETERM,VISITDY,AESTDTC,AEENDTC,AECLCRS1,AECLCRS2,AECRSFU1,AECRSFU2,AECRSFU3,AECRSTRT,AEDOSDUR,AEDTHAF1,AEDTHAF2,AEDTHAF3,AEDTHAUT,AEDTHDTC,AEDTHNOT,AEHODDGS,AEHODDTC,AEHOSDTC,AEOCEVID,AERELSM,AESIZEU,AESS1,AESS2,AESRCH4,AEWRSNDT

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

Variable	Type	Label	Codes	Comments
AEGRPID	char	Group ID		Collected at CRF.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AECAT	char	Category for Adverse Event		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.
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AERELNST	char	Relationship to Non-Study Treatment		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AESCAN	char	Involves Cancer		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
AESOD	char	Occurred with Overdose		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
AETOXGR	char	Standard Toxicity Grade		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC - REF.DATE) + 1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC - REF.DATE) + 1.
AEDUR	char	Duration of Adverse Event		Collected at CRF.
AEENRF	char	End Relative to Reference Period		Collected at CRF.
AEACNCD	char	Action Taken with Study Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEGE	char	Age At AE Onset		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AEGEU	char	Age At AE Onset Unit		Collected at CRF.
AECLINT	char	Clinical Interest		Collected at CRF.
AEDOSTOX	char	Dose Limiting Toxicity		Collected at CRF.
AEDURDD	num	Duration of Adverse Event Diff of Dates		Collected at CRF.
AEDURDDU	char	Duration Units		Collected at CRF.
AELLT	char	Dictionary Term LLT		Collected at CRF.
AERELCD	char	Causality Code		Collected at CRF.
AESDCH	char	AE Diminish Aft Stopping EXTRT Dechallng		Collected at CRF.
AESVCD	num	Intensity Code		Collected at CRF.
AESIZE	num	Maximum Size		Collected at CRF.
AESRCH	char	AE Reappear Aft Restarting EXTRT Rechal		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
SPDYRLEP	num	Stop Day Rel to Epoch		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity



Variable	Type	Label	Codes	Comments
ACN1	char	Action Taken with SM1		Collected at CRF.
ACN2	char	Action Taken with SM2		Collected at CRF.
ACN3	char	Action Taken with SM3		Collected at CRF.
ACN4	char	Action Taken with SM4		Collected at CRF.
ACN5	char	Action Taken with SM5		Collected at CRF.
ACN6	char	Action Taken with SM6		Collected at CRF.
AESDCH1	char	AE Diminish Aft Stopping SM1 Dechallng		Collected at CRF.
AESDCH2	char	AE Diminish Aft Stopping SM2 Dechallng		Collected at CRF.
AESDCH3	char	AE Diminish Aft Stopping SM3 Dechallng		Collected at CRF.
AESDCH4	char	AE Diminish Aft Stopping SM4 Dechallng		Collected at CRF.
AESDCH5	char	AE Diminish Aft Stopping SM5 Dechallng		Collected at CRF.
AESDCH6	char	AE Diminish Aft Stopping SM6 Dechallng		Collected at CRF.
AESRCH1	char	AE Reappear Aft Stopping SM1 Rechallng		Collected at CRF.
AESRCH2	char	AE Reappear Aft Stopping SM2 Rechallng		Collected at CRF.
AESRCH3	char	AE Reappear Aft Stopping SM3 Rechallng		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESRCH5	char	AE Reappear Aft Stopping SM5 Rechallng		Collected at CRF.
AESRCH6	char	AE Reappear Aft Stopping SM6 Rechallng		Collected at CRF.
REL1	char	Causality SM1		Collected at CRF.
REL2	char	Causality SM2		Collected at CRF.
REL3	char	Causality SM3		Collected at CRF.
REL4	char	Causality SM4		Collected at CRF.
REL5	char	Causality SM5		Collected at CRF.
REL6	char	Causality SM6		Collected at CRF.
RELPR	char	Relationship to Study Procedure		Collected at CRF.
SM1	char	Study Medication 1		Collected at CRF.
SM2	char	Study Medication 2		Collected at CRF.
SM3	char	Study Medication 3		Collected at CRF.
SM4	char	Study Medication 4		Collected at CRF.
SM5	char	Study Medication 5		Collected at CRF.
SM6	char	Study Medication 6		Collected at CRF.
DAECRYEV	char	De-Identify Country Where Event Occur		Group element to protect PII.
AEPQCA	char	Product Quality Complaint Attached		Collected at CRF.

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

### 1.4.15. Procedures – PR

<b>Dataset</b>	PR
<b>Creating program</b>	pr.sas
<b>Description</b>	Procedures
<b>Unique identifier</b>	STUDYID,DUSUBJID,PRBODSYS,PRDECOD,PRSTDY,PRSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,PRBODSYS,PRDECOD,PRSTDY,PRSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>PRTRT,PRCAT,PRDOSE,PRDOSTOT,PRDOSU,VISITDY,PRDTC,PRSTDTC,PRENDTC,PRDY,PRTPT,PRTPTNUM,PRDTC_TP,PRCHNGBL,PRCHNGPP,PRCONT,PRBODLOC,PRLNTHPY,PRAPLAST,PRDRYTAP,PRDYSPLA,PRERTHRD,PRFIBROT,PRHYPERP,PRHYPOPL,PRMEGAKC,PRMERAT,PRMYELO,PROTHER,PRTUMOR,PRTRTOTH,PRLOCBON,PRLOCCU,PRLOCEPH,PRLOCEXT,PRLOCHD,PRLOCLIV,PRLOCLUN,PRLOCLN,PRLOCOPH,PRLOCSKI,PRLOCSPI,PRLOCSPE,PRLOCTBI,PRLOCTRK,PRLOCOTH,BESTRES,PRALLTYP,PRHRVDCT,PRSPECBM,PRSPECCB,PRSPECPB,PRCYTOSL</p>

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

Variable	Type	Label	Codes	Comments
PRSPID	char	Sponsor-Defined Identifier		Collected at CRF.
PRMODIFY	char	Modified Reported Name		Collected at CRF.
PRDECOD	char	Dictionary-Derived Term		Collected at CRF.
PRINDC	char	Indication		Collected at CRF.
PRLOC	char	Location of Procedure		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
PRSTDY	num	Relative Start Day of Procedure		If PRSTDTC and REF.DATE not missing then perform below logic to calculate PRSTDY, If PRSTDTC less than REF.DATE then (PRSTDTC - REF.DATE). Else if PRSTDTC is greater than equal to REF.DATE then (PRSTDTC - REF.DATE) +1.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
PRDURDD	num	Duration of Treatment Diff of Dates		Collected at CRF.
PRDURDDU	char	Duration Units		Collected at CRF.
SPDYRLEP	num	Stop Day Rel to Epoch		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
PRLLT	char	Dictionary Term LLT		Collected at CRF.
PRSIDE	char	Side		Collected at CRF.
PRRESULT	char	Procedure Result		Collected at CRF.
PRRELSAE	char	Procedure Related to SAE		Collected at CRF.
PRBODSYS	char	Body System or Organ Class		Collected at CRF.
PRENDY	num	Relative End Day of Procedure		If PRENDTC and REF.DATE not missing then perform below logic to calculate PRENDY, If PRENDTC less than REF.DATE then (PRENDTC - REF.DATE). Else if PRENDTC is greater than equal to REF.DATE then (PRENDTC - REF.DATE) +1.

## 1.4.16. Questionnaires – QS

<b>Dataset</b>	QS
<b>Creating program</b>	qs.sas
<b>Description</b>	Questionnaires
<b>Unique identifier</b>	STUDYID, DUSUBJID, QSTEST, QSDY, QSSEQ
<b>Sorted by</b>	STUDYID, DUSUBJID, QSTEST, QSDY, 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: QSREFID, QSSPID, QSSCAT, QSSTAT, QSREASND, QSBFL, QSDRVFL, VISITDY, QSDTC, QSENDTC, QSENDY, QSTPT, QSTPTNUM, QSELTM, QSTPTREF, SPDYRLEP, RATER

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.
QSTESTCD	char	Question Short Name		Collected at CRF.
QSTEST	char	Question Name		Collected at CRF.
QSCAT	char	Category of Question		Collected at CRF.
QSORRES	char	Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
QSTM	num	Time of Finding		If QSDTC contains time part then timepart(QSDTC) else QSTM equal to NULL.



## 1.4.17. Related Records – RELREC

<b>Dataset</b>	RELREC
<b>Creating program</b>	relrec.sas
<b>Description</b>	Related Records
<b>Unique identifier</b>	STUDYID,DUSUBJID,RDOMAIN,IDVARVAL,RELID
<b>Sorted by</b>	STUDYID,DUSUBJID,RDOMAIN,IDVARVAL,RELID
<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.
RELTYPE	char	Relationship Type		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

## 1.4.18. Subject Elements – SE

<b>Dataset</b>	SE
<b>Creating program</b>	se.sas
<b>Description</b>	Subject Elements
<b>Unique identifier</b>	STUDYID,DUSUBJID,ETCD,SESTDY
<b>Sorted by</b>	STUDYID,DUSUBJID,ETCD,SESTDY
<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: SESTDTC,SEENDTC,SEUPDES,EPENDTC,EPSTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
SESEQ	num	Sequence Number		Collected at CRF.
ETCD	char	Subject Element Code		Collected at CRF.
ELEMENT	char	Description of Subject Element		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
EPOCH	char	Trial Epoch		Collected at CRF.
SESTTM	num	Start Time of Element		If SESTDTC contains time part then timepart(SESTDTC) else SESTTM equal to NULL.

Variable	Type	Label	Codes	Comments
SESTDY	num	Relative Start Day of Element		If SESTDTC and REF.DATE not missing then perform below logic to calculate SESTDY, If SESTDTC less than REF.DATE then (SESTDTC - REF.DATE). Else if SESTDTC is greater than equal to REF.DATE then (SESTDTC- REF.DATE) +1.
SEENTM	num	End Time of Element		If SEENDTC contains time part then timepart(SEENDTC) else SEENTM equal to NULL.
SEENDY	num	Relative End Day of Element		If SEENDTC and REF.DATE not missing then perform below logic to calculate SEENDY, If SEENDTC less than REF.DATE then (SEENDTC - REF.DATE). Else if SEENDTC is greater than equal to REF.DATE then (SEENDTC- REF.DATE) +1.
EPENTM	num	Trial Epoch End Time		If EPENDTC contains time part then timepart(EPENDTC) else EPENTM equal to NULL.
EPENDY	num	Relative Trial Epoch End Day		If EPENDTC and REF.DATE not missing then perform below logic to calculate EPENDY, If EPENDTC less than REF.DATE then (EPENDTC - REF.DATE). Else if EPENDTC is greater than equal to REF.DATE then (EPENDTC- REF.DATE) +1.
EPSTTM	num	Trial Epoch Start Time		If EPSTDTC contains time part then timepart(EPSTDTC) else EPSTTM equal to NULL.
EPSTDY	num	Relative Trial Epoch Start Day		If EPSTDTC and REF.DATE not missing then perform below logic to calculate EPSTDY, If EPSTDTC less than REF.DATE then (EPSTDTC - REF.DATE). Else if EPSTDTC is greater than equal to REF.DATE then (EPSTDTC- REF.DATE) +1.

## 1.4.19. 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,SVSTDY
<b>Sorted by</b>	STUDYID,DUSUBJID,VISITNUM,SVSTDY
<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: VISITDY,SVSTDTC,SVENDTC,SVSF,SVTYPE,ERRVISIT

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.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
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.

## 1.4.20. Trial Arms – TA

<b>Dataset</b>	TA
<b>Creating program</b>	ta.sas
<b>Description</b>	Trial Arms
<b>Unique identifier</b>	STUDYID,ARMCD,ETCD,ELEMENT,EPOCH
<b>Sorted by</b>	STUDYID,ARMCD,ETCD,ELEMENT,EPOCH
<b>Notes</b>	

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

## 1.4.21. Trial Elements – TE

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

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

## 1.4.22. 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	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IETEST1	char	Inclusion/Exclusion Criterion 1		Collected at CRF.
IETEST2	char	Inclusion/Exclusion Criterion 2		Collected at CRF.
IETEST3	char	Inclusion/Exclusion Criterion 3		Collected at CRF.
IETEST4	char	Inclusion/Exclusion Criterion 4		Collected at CRF.
IETEST5	char	Inclusion/Exclusion Criterion 5		Collected at CRF.
IETEST6	char	Inclusion/Exclusion Criterion 6		Collected at CRF.
IETEST7	char	Inclusion/Exclusion Criterion 7		Collected at CRF.

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

#### 1.4.23. Trial Visits – TV

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITDY	num	Planned Study Day of Visit		Collected at CRF.



## 1.4.24. Vital Signs – VS

<b>Dataset</b>	VS
<b>Creating program</b>	vs.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	STUDYID,DUSUBJID,VSTESTCD,VSDY,VSSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,VSTESTCD,VSDY,VSSEQ
<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: VSREFID,VSSPID,VSCAT,VSNAM,VSBLFL,VISITDY,VSDTC,VSTPT,VSTPTNUM, SPDYRLEP,VSAXLEQC,VSAXLEQF,VSORLEQC,VSORLEQF,VSRECEQC,VSRECEQF

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

Variable	Type	Label	Codes	Comments
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.
VSLOC	char	Location of Vital Signs Measurement		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE). Else if VSDTC is greater than equal to REF.DATE then (VSDTC - REF.DATE) +1.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
STDYRLEP	num	Start Day Rel to Epoch		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
VSTM	num	Time of Measurements		If VSDTC contains time part then timepart(VSDTC) else VSTM equal to NULL.

### 1.4.25. Biomedical Research Consent – ZE

<b>Dataset</b>	ZE
<b>Creating program</b>	ze.sas
<b>Description</b>	Biomedical Research Consent
<b>Unique identifier</b>	STUDYID,DUSUBJID,ZEDECOD,ZEDY,ZESEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,ZEDECOD,ZEDY,ZESEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>ZESPID,ZETERM,ZEMODIFY,ZECAT,ZESCAT,ZESTAT,ZEREASND,ZEBODSYS,ZELOC,ZESEV,ZESER,ZEACN,ZEACNOTH,ZEREL,ZERELNST,ZEPATT,ZEOUT,ZESCAN,ZESCONG,ZESDISAB,ZESDTH,ZESHOSP,ZESLIFE,ZESOD,ZESMIE,ZECONTRT,ZETOXGR,VISITDY,EPOCH,ZEDTC,ZESTDTC,ZEENDTC,ZESTDY,ZEENDY,ZEDUR,ZETPT,ZETPTNUM,ZEELTM,ZETPTREF,ZERFTDTC,ZESTRF,ZEENRF,ELEMENT,ETCD,SPDYRLEP,STDYRLEP,STOREDUR,ZEDURDD,ZEDURDDU</p>

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
ZESEQ	num	Sequence Number		Collected at CRF.
ZEGRPID	char	Group ID		Collected at CRF.
ZEREFID	char	Reference ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZEDECOD	char	Dictionary-Derived Term		Collected at CRF.
ZEOCCUR	char	Occurrence		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
ZEDY	num	Relative Day of Collection		If ZEDTC and REF.DATE not missing then perform below logic to calculate ZEDY, If ZEDTC less than REF.DATE then (ZEDTC - REF.DATE). Else if ZEDTC is greater than equal to REF.DATE then (ZEDTC - REF.DATE) +1.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity

## 1.4.26. Specimen Collection Status – ZF

<b>Dataset</b>	ZF
<b>Creating program</b>	zf.sas
<b>Description</b>	Specimen Collection Status
<b>Unique identifier</b>	STUDYID,DUSUBJID,ZFTEST,ZFDY,ZFSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,ZFTEST,ZFDY,ZFSEQ
<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: ZFREPID,ZFSPID,ZFMODIFY,ZFCAT,ZFSCAT,ZFPOS,ZFBODSYS,ZFORRESU, ZFORNRLO,ZFORNRHI,ZFSTRESN,ZFSTRESU,ZFSTNRLO,ZFSTNRHI,ZFSTNRC, ZFNRIID,ZFRESCAT,ZFREASND,ZFXFN,ZFNAM,ZFLOINC,ZFSPCCND,ZFLOC, ZFMETHOD,ZFBLFL,ZFFAST,ZFDRVFL,ZFEVAL,ZFTOX,ZFTOXGR,ZFSEV, ZFDTHREL,VISITDY,ZFDTC,ZFENDTC,ZFENDY,ZFELTM,ZFTPTREF,ZFOBJ

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
ZFSEQ	num	Sequence Number		Collected at CRF.
ZFGRPID	char	Group ID		Collected at CRF.
ZFTESTCD	char	Test Short Name		Collected at CRF.
ZFTEST	char	Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZFORRES	char	Result or Finding in Original Units		Collected at CRF.
ZFSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
ZFSTAT	char	Completion Status		Collected at CRF.
ZFSPEC	char	Specimen Type		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
ZFDY	num	Relative Day of Measurement		If ZFDTC and REF.DATE not missing then perform below logic to calculate ZFDY, If ZFDTC less than REF.DATE then (ZFDTC - REF.DATE). Else if ZFDTC is greater than equal to REF.DATE then (ZFDTC-REF.DATE) +1.
ZFTPT	char	Planned Time Point Name		Collected at CRF.
ZFTPTNUM	num	Planned Time Point Number		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
DSUBJID	char	Subject Id Assigned for De-Identity		Randomly assigned Subject Id for De-Identity
ZFTM	num	Time of Measurement		If ZFDTC contains time part then timepart(ZFDTC) else ZFTM equal to NULL.