

Clinical Development

CNTO312

CNTO312C0168T14

Anonymisation Data Derivation Specification Document

| | |
|------------------|--------------------|
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| 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.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty comments data will be submitted due to sensitivity of data.
- Dataset having zero observations will not be submitted. (eg. DEATH)
- CRITERIA.CONSDATE ("Derived Date of Informed Consent") will be used as Reference Date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The CNT0312C0168T14 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMOG

| | |
|--------------------------|--|
| Dataset | DEMOG |
| Creating program | demog.sas |
| Description | Demographics |
| Unique identifier | DUNIQUEP |
| Sorted by | DUNIQUEP |
| Notes | <p>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:</p> <p>PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,INITIALS,DOB,RACE_OTH,DOB_MON,DOB_DAY, DOB_YR,STD_WGT,HOSPADT,HOSPAMON,HOSPADAY,HOSPAYR</p> <p>Below listed variables were not part of the Raw dataset. These have been added to retain age, treatment related information and race in the de-identified datasets:</p> <p>AGE TRTGRP (Source: RANDCODE dataset) RACEC (Source: DEMOG dataset)</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| SEX | char | Sex | | Collected at CRF. |
| RACE | char | Race | | Group element to protect PII. |
| HGT | num | Derived height in centimeters | | Collected at CRF. |
| ZHGT | num | Entered height | | Collected at CRF. |
| ZHGT_UN | char | Units for entered height | | Collected at CRF. |
| AGE | char | Age in Years | | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules. |
| TRTGRP | char | Treatment | | Collected at CRF. |
| RACEC | char | Racec | | Group element to protect PII. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |

1.4.2.Admin – ADMIN

| | |
|--------------------------|---|
| Dataset | ADMIN |
| Creating program | admin.sas |
| Description | Admin |
| Unique identifier | DUNIQUEP,STUDYSEG |
| Sorted by | DUNIQUEP,STUDYSEG |
| Notes | <p>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:</p> <p>PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,ADM_MAT,PATGROUP,STARTDT,STOPTIM,RSTRTTIM, ENDDT,DOSE,DOSE_UN,TOTAL_MG,MIXED_MG,ROUTECD,RANDCODE, LOT_NUM,VIAL_NUM,CONTDOSE,EARLY_AE,TEST_ND,TESTDT,TESTTIME, T_STDT,T_STTIM,T_ENDDT,T_ENDTIM,FOREARM,REACTION,EXTRAVAS, STARTMON,STARTDAY,STARTYR,STARTHR,STARTMIN,STOPHR,STOPMIN, RSTRTHR,RSTRTMIN,ENDMON,ENDDAY,ENDYR,ENDHR,ENDMIN,TESTMON, TESTDAY,TESTYR,TESTHR,TESTMIN,T_STMON,T_STDAY,T_STYR,T_STHR, T_STMIN,T_ENDMON,T_ENDDAY,T_ENDYR,T_ENDHR,T_ENDMIN</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| DOSE_SEQ | num | Number of dose within sequence of doses | | Collected at CRF. |
| NOTDOSED | char | Yes if study material was not administer | | Collected at CRF. |
| STARTTIM | num | Derived time study material administrati | | Collected at CRF. |
| ENDTIM | num | Derived time study material administrati | | Collected at CRF. |
| WGT | num | Patient weight (in kg) | | Collected at CRF. |
| TOTAL_ML | num | Total ml administrated (in ml) | | Collected at CRF. |
| MIXED_ML | num | Total volume drug mixed (in ml) | | Collected at CRF. |
| VIALS | num | Number of vials | | Collected at CRF. |
| TEST_ML | num | Test dose volume (in ml) | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |
| STARTDY | num | Relative Derivd day study material admin | | If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1. |
| ENDDY | num | Relative Derivd day study material admin | | If ENDDT and REF.DATE not missing then perform below logic to calculate ENDDY, If ENDDT less than REF.DATE then (ENDDT - REF.DATE). Else if ENDDT is greater than equal to REF.DATE then (ENDDT - REF.DATE) +1. |

1.4.3.AD_PK – AD_PK

| | |
|--------------------------|--|
| Dataset | AD_PK |
| Creating program | ad_pk.sas |
| Description | AD_PK |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLDT |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| SAMPLTIM | num | Derived time assay sample was collected | | Collected at CRF. |
| DPAT_NO | char | Site/Pat number Assigned for De-identity | | Randomly assigned Site/Pat number for De-identity |
| C_CA2 | char | Character cA2 serum level (ug/ml) | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| N_CA2 | num | Numeric cA2 serum level (ug/ml) | | Collected at CRF. |
| SAMPLDY | num | Relative Derivd day assay sample collect | | If SAMPLDT and REF.DATE not missing then perform below logic to calculate SAMPLDY, If SAMPLDT less than REF.DATE then (SAMPLDT - REF.DATE). Else if SAMPLDT is greater than equal to REF.DATE then (SAMPLDT- REF.DATE) +1. |

1.4.4.AEOCCUR – AEOCCUR

| | |
|--------------------------|---|
| Dataset | AEOCCUR |
| Creating program | aeoccur.sas |
| Description | AEOCCUR |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| AE_OCCUR | char | Yes if adverse event(s) occurred; No if | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.5.ASSESS – ASSESS

| | |
|--------------------------|---|
| Dataset | ASSESS |
| Creating program | assess.sas |
| Description | ASSESS |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | <p>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:</p> <p>PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,ASSESSND,GN_BACT,GN_FOCAL,GP_FOCAL,GP_BACT, FUNGAL,VIRAL,NEG_CULT,NOT_INFC,OTH_AGT,A_STATUS,DOD,TOD, CAUS_DTH,PROBCAUS,LTF_DT,LTF_REAS,HOSPDDT,NOTDHOSP,DIS_REAS, DISOTHER,CIDISDT,NOTDICU,DOD_MON,DOD_DAY,DOD_YR,TOD_HR, TOD_MIN,LTF_MON,LTF_DAY,LTF_YR,HOSPDMON,HOSPDDAY,HOSPDYR, CIDISMON,CIDISDAY,CIDISYR,EFF_PAT,EFF_EVAL,STDYSTAT,COLECT, ELEC_COL,COL_REAS,COL_DATE,COL_MON,COL_DAY,COL_YR,VISIT_WK, DISCINIT,INITSPEC</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| AUTOPSY | char | Indicates if autopsy was performed | | Collected at CRF. |
| STDY_COM | char | Indicates whether patient completed stud | | Collected at CRF. |
| PAGE_1 | num | Page number of first AE | | Collected at CRF. |
| PAG_SEQ1 | char | Qualifier for first AE page number (A, B | | Collected at CRF. |
| PAG_SEC1 | num | Line number of first AE | | Collected at CRF. |
| PAGE_2 | num | Page number of second AE | | Collected at CRF. |
| PAG_SEQ2 | char | Qualifier for second AE page number (A, | | Collected at CRF. |
| PAG_SEC2 | num | Line number of second AE | | Collected at CRF. |
| PAGE_3 | num | Page number for third AE | | Collected at CRF. |
| PAG_SEQ3 | char | Qualifier for third AE page number (A, B | | Collected at CRF. |
| PAG_SEC3 | num | Line number of third AE | | Collected at CRF. |
| PAGE_4 | num | Page number for fourth AE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| PAG_SEQ4 | char | Qualifier for fourth AE page number (A, | | Collected at CRF. |
| PAG_SEC4 | num | Line number of fourth AE | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |
| LTF_DY | num | Relative Derivd day patient lost follow | | If LTF_DT and REF.DATE not missing then perform below logic to calculate LTF_DY, If LTF_DT less than REF.DATE then (LTF_DT - REF.DATE). Else if LTF_DT is greater than equal to REF.DATE then (LTF_DT - REF.DATE) +1. |

1.4.6.ATRACK – ATRACK

| | |
|--------------------------|--|
| Dataset | ATRACK |
| Creating program | atrack.sas |
| Description | ATRACK |
| Unique identifier | DUNIQUEP,C_PERIOD,ASSAY |
| Sorted by | DUNIQUEP,C_PERIOD,ASSAY |
| Notes | <p>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:</p> <p>PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,LABELNUM,SAMPLMON,SAMPLDAY,SAMPLYR, SAMPLHR,SAMPLMIN,SAMPLDT,SENT_MON,SENT_DAY,SENT_YR,SENT_DT, RCVD_MON,RCVD_DAY,RCVD_YR,RCVD_DT,ZWGT,ZWGT_UN,WGT</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| ASSAY | char | Code for type of assay | | Collected at CRF. |
| NOT_COLL | char | Yes if laboratory specimen not collected | | Collected at CRF. |
| SAMPLTIM | num | Derived time assay sample was collected | | Collected at CRF. |
| SENT | char | Was assay sample sent to laboratory by c | | Collected at CRF. |
| RCVD | char | Was assay sample received by laboratory? | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |
| SAMPLDY | num | Relative Derivd day assay sample collect | | If SAMPLDT and REF.DATE not missing then perform below logic to calculate SAMPLDY, If SAMPLDT less than REF.DATE then (SAMPLDT - REF.DATE). Else if SAMPLDT is greater than equal to REF.DATE then (SAMPLDT- REF.DATE) +1. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| SENT_DY | num | Relative Derivd day assay sample sent | | If SENT_DT and REF.DATE not missing then perform below logic to calculate SENT_DY, If SENT_DT less than REF.DATE then (SENT_DT - REF.DATE). Else if SENT_DT is greater than equal to REF.DATE then (SENT_DT - REF.DATE) +1. |
| RCVD_DY | num | Relative Derivd day assay sample receivd | | If RCVD_DT and REF.DATE not missing then perform below logic to calculate RCVD_DY, If RCVD_DT less than REF.DATE then (RCVD_DT - REF.DATE). Else if RCVD_DT is greater than equal to REF.DATE then (RCVD_DT - REF.DATE) +1. |

1.4.7.CFINAL – CFINAL

| | |
|--------------------------|---|
| Dataset | CFINAL |
| Creating program | cfinal.sas |
| Description | CFINAL |
| Unique identifier | DUNIQUEP,ASSCODE,INJCODE |
| Sorted by | DUNIQUEP,ASSCODE,INJCODE |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LAB_ID,ASSCOMM2,LNK_PROT,LNK_SITE,LNK_PAT |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| PROTOCOL | char | PROTOCOL | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| ASSCODE | char | ASSCODE | | Collected at CRF. |
| INJCODE | char | INJCODE | | Collected at CRF. |
| TESTCODE | char | TESTCODE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------|-------|-------------------|
| FINALRES | char | FINALRES | | Collected at CRF. |
| TITERVAL | num | TITERVAL | | Collected at CRF. |
| ASSCOMM1 | char | ASSCOMM1 | | Collected at CRF. |

1.4.8.CLINF – CLINF

| | |
|--------------------------|---|
| Dataset | CLINF |
| Creating program | clinf.sas |
| Description | CLINF |
| Unique identifier | DUNIQUEP,C_PERIOD,COLDY,TIME_COL |
| Sorted by | DUNIQUEP,C_PERIOD,COLDY,TIME_COL |
| Notes | <p>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:</p> <p>PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,DERIV_DT, VITAL_ND,BP_MTH,BPMED,RR,RR_ND,ON_VENT,INTUB,ON_PACE,PEEP, PEEP_ND,PIP,PIP_ND,TIDAL,TIDAL_ND,SHOCK,SHOCK_ND,ARDS,ARDS_ND, ZPEEP,ZPEEP_UN,ZPIP,ZPIP_UNI</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| TIME_COL | num | Derived time of data collection | | Collected at CRF. |
| TEMP | num | Derived body temperature in degrees Cent | | Collected at CRF. |
| TEMP_ND | char | Temperature not measured | | Collected at CRF. |
| SYST | num | Systolic blood pressure measurement in m | | Collected at CRF. |
| DIAS | num | Diastolic blood pressure measurement in | | Collected at CRF. |
| BP_ND | char | Blood pressure not measured | | Collected at CRF. |
| HR | num | Heart rate in beats/minute | | Collected at CRF. |
| HR_ND | char | Heart rate not measured | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| POSITION | char | Code for position of patient as vitals o | | Collected at CRF. |
| WGT | num | Derived patient weight in kilograms | | Collected at CRF. |
| ZTEMP | num | Entered body temperature | | Collected at CRF. |
| ZTEMPMTH | char | Method used to measure body temperature | | Collected at CRF. |
| ZWGT | num | Entered patient weight | | Collected at CRF. |
| ZWGT_UN | char | Units for entered patient weight | | Collected at CRF. |
| WGT_ND | char | Weight not measured | | Collected at CRF. |
| PE_PERF | char | Indicates if physical exam performed | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL- REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.9.COMMENTS – COMMENTS

| | |
|--------------------------|--|
| Dataset | COMMENTS |
| Creating program | comments.sas |
| Description | COMMENTS |
| Unique identifier | Not Applicable |
| Sorted by | Not Applicable |
| Notes | Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|----------------------------------|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Empty Datasets will be submitted |
| C_PERIOD | char | Coded data collection period for chronol | | Empty Datasets will be submitted |
| STUDYSEG | char | Study segment identifier | | Empty Datasets will be submitted |
| PAGE | num | CRF page number | | Empty Datasets will be submitted |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Empty Datasets will be submitted |
| PERIOD | char | Data collection period | | Empty Datasets will be submitted |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Empty Datasets will be submitted |
| DSITE | char | Site ID Assigned for De-identity | | Empty Datasets will be submitted |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|----------------------------------|
| DPATIENT | char | Patient Number Assigned for De-identity | | Empty Datasets will be submitted |
| FOR_PAGE | char | Number(s) of CRF page(s) to which commen | | Empty Datasets will be submitted |
| DERIV_TM | num | Derivd Time derived item values | | Empty Datasets will be submitted |
| DERIV_DY | num | Relative Derivd day derived item values | | Empty Datasets will be submitted |

1.4.10. CRESUL – CRESUL

| | |
|--------------------------|--|
| Dataset | CRESUL |
| Creating program | cresul.sas |
| Description | CRESUL |
| Unique identifier | DUNIQUEP,TESTCODE,FLDNAME |
| Sorted by | DUNIQUEP,TESTCODE,FLDNAME |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LAB_ID,LABEL_NU,CV,LNK_PROT,LNK_SITE,LNK_PAT |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------------------------------|-------|---|
| PROTOCOL | char | PROTOCOL | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| ASSCODE | char | ASSCODE | | Collected at CRF. |
| INJCODE | char | INJCODE | | Collected at CRF. |
| TESTCODE | char | TESTCODE | | Collected at CRF. |
| FLDNAME | char | FLDNAME | | Collected at CRF. |
| RESTYPE | char | RESTYPE | | Collected at CRF. |
| RESULT | char | RESULT | | Collected at CRF. |
| UNITS | char | UNITS | | Collected at CRF. |
| ASSCOMM1 | char | ASSCOMM1 | | Collected at CRF. |
| ASSCOMM2 | char | ASSCOMM2 | | Collected at CRF. |
| PERIOD | char | PERIOD | | Collected at CRF. |

1.4.11. CRITERIA – CRITERIA

| | |
|--------------------------|---|
| Dataset | CRITERIA |
| Creating program | criteria.sas |
| Description | CRITERIA |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | <p>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:</p> <p>STUDYSEG,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,INC_1A,INC_1B,INC3C,INC3D,INC3E,INC3F,INC3G,INC3H,INC4A,INC4B,INC12A,INC12B,INC27,INC28,INC29,INC30,INC31,INC32,INC33,INC34,CONSDATE,CONSTIME,ENROLDT,ENROLTIM,CONS_MON,CONS_DAY,CONS_YR,CONS_HR,CONS_MIN,ENROLMON,ENROLDAY,ENROLYR,ENROLHR,ENROLMIN</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| INC1 | char | Criteria number 1 | | Collected at CRF. |
| INC2 | char | Criteria number 2 | | Collected at CRF. |
| INC3 | char | Criteria number 3 | | Collected at CRF. |
| INC3A | char | Criteria number 3a | | Collected at CRF. |
| INC3B | char | Criteria number 3b | | Collected at CRF. |
| INC4 | char | Criteria number 4 | | Collected at CRF. |
| INC5 | char | Criteria number 5 | | Collected at CRF. |
| INC6 | char | Criteria number 6 | | Collected at CRF. |
| INC7 | char | Criteria number 7 | | Collected at CRF. |
| INC8 | char | Criteria number 8 | | Collected at CRF. |
| INC9 | char | Criteria number 9 | | Collected at CRF. |
| INC10 | char | Criteria number 10 | | Collected at CRF. |
| INC11 | char | Criteria number 11 | | Collected at CRF. |
| INC12 | char | Criteria number 12 | | Collected at CRF. |
| INC13 | char | Criteria number 13 | | Collected at CRF. |
| INC14 | char | Criteria number 14 | | Collected at CRF. |
| INC15 | char | Criteria number 15 | | Collected at CRF. |
| INC16 | char | Criteria number 16 | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| INC17 | char | Criteria number 17 | | Collected at CRF. |
| INC18 | char | Criteria number 18 | | Collected at CRF. |
| INC19 | char | Criteria number 19 | | Collected at CRF. |
| INC20 | char | Criteria number 20 | | Collected at CRF. |
| INC21 | char | Criteria number 21 | | Collected at CRF. |
| INC22 | char | Criteria number 22 | | Collected at CRF. |
| INC23 | char | Criteria number 23 | | Collected at CRF. |
| INC24 | char | Criteria number 24 | | Collected at CRF. |
| INC25 | char | Criteria number 25 | | Collected at CRF. |
| INC26 | char | Criteria number 26 | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |

1.4.12. CULTURE – CULTURE

| | |
|--------------------------|--|
| Dataset | CULTURE |
| Creating program | culture.sas |
| Description | CULTURE |
| Unique identifier | DUNIQUEP,COLDY |
| Sorted by | DUNIQUEP,COLDY |
| Notes | 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: PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL, DERIV_DT,LAB_NUM,SSPECIFY,PATHNAME,CAT_NAME,AT_NAME,ANTIBIOT, RXACSTAT,SENSITIV,MICCOMM,ENT_MIC,MIC |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| SPECSITE | char | Code for site of culture specimen | | Collected at CRF. |
| PATHOGEN | char | Code for culture pathogen | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL- REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.13. DUP_LIST – DUP_LIST

| | |
|--------------------------|--------------|
| Dataset | DUP_LIST |
| Creating program | dup_list.sas |
| Description | DUP_LIST |
| Unique identifier | FILENAME |
| Sorted by | FILENAME |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------|-------|-------------------|
| FILENAME | char | Filename | | Collected at CRF. |
| VER | num | Version | | Collected at CRF. |

1.4.14. HAQ – HAQ

| | |
|--------------------------|---|
| Dataset | HAQ |
| Creating program | haq.sas |
| Description | HAQ |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | 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: PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL, DERIV_DT,CAT23,SPEC1,SPEC2 |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| Q1 | char | Question 1 | | Collected at CRF. |
| Q2 | char | Question 2 | | Collected at CRF. |
| Q3 | char | Question 3 | | Collected at CRF. |
| Q4 | char | Question 4 | | Collected at CRF. |
| Q5 | char | Question 5 | | Collected at CRF. |
| Q6 | char | Question 6 | | Collected at CRF. |
| Q7 | char | Question 7 | | Collected at CRF. |
| Q8 | char | Question 8 | | Collected at CRF. |
| Q9 | char | Question 9 | | Collected at CRF. |
| Q10 | char | Question 10 | | Collected at CRF. |
| Q11 | char | Question 11 | | Collected at CRF. |
| Q12 | char | Question 12 | | Collected at CRF. |
| Q13 | char | Question 13 | | Collected at CRF. |
| Q14 | char | Question 14 | | Collected at CRF. |
| Q15 | char | Question 15 | | Collected at CRF. |
| Q16 | char | Question 16 | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|-------------------|
| Q17 | char | Question 17 | | Collected at CRF. |
| Q18 | char | Question 18 | | Collected at CRF. |
| Q19 | char | Question 19 | | Collected at CRF. |
| Q20 | char | Question 20 | | Collected at CRF. |
| CAT1 | char | Aid, device or help category 1 | | Collected at CRF. |
| CAT2 | char | Aid, device or help category 2 | | Collected at CRF. |
| CAT3 | char | Aid, device or help category 3 | | Collected at CRF. |
| CAT4 | char | Aid, device or help category 4 | | Collected at CRF. |
| CAT5 | char | Aid, device or help category 5 | | Collected at CRF. |
| CAT6 | char | Aid, device or help category 6 | | Collected at CRF. |
| CAT7 | char | Aid, device or help category 7 | | Collected at CRF. |
| CAT8 | char | Aid, device or help category 8 | | Collected at CRF. |
| CAT9 | char | Aid, device or help category 9 | | Collected at CRF. |
| CAT10 | char | Aid, device or help category 10 | | Collected at CRF. |
| CAT11 | char | Aid, device or help category 11 | | Collected at CRF. |
| CAT12 | char | Aid, device or help category 12 | | Collected at CRF. |
| CAT13 | char | Aid, device or help category 13 | | Collected at CRF. |
| CAT14 | char | Aid, device or help category 14 | | Collected at CRF. |
| CAT15 | char | Aid, device or help category 15 | | Collected at CRF. |
| CAT16 | char | Aid, device or help category 16 | | Collected at CRF. |
| CAT17 | char | Aid, device or help category 17 | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| CAT18 | char | Aid, device or help category 18 | | Collected at CRF. |
| CAT19 | char | Aid, device or help category 19 | | Collected at CRF. |
| CAT20 | char | Aid, device or help category 20 | | Collected at CRF. |
| CAT21 | char | Aid, device or help category 21 | | Collected at CRF. |
| CAT22 | char | Aid, device or help category 22 | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL-REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT-REF.DATE) +1. |

1.4.15. JNTEVAL – JNTEVAL

| | |
|--------------------------|---|
| Dataset | JNTEVAL |
| Creating program | jnteval.sas |
| Description | JNTEVAL |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| JNT_EVAL | char | Yes if joints were evaluated, no if not | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.16. JNTSCORE – JNTSCORE

| | |
|--------------------------|---|
| Dataset | JNTSCORE |
| Creating program | jntscore.sas |
| Description | JNTSCORE |
| Unique identifier | DUNIQUEP,C_PERIOD,JOINT |
| Sorted by | DUNIQUEP,C_PERIOD,JOINT |
| Notes | 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: PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL, DERIV_DT,SWELLING,NOTEVALA,NOTEVALB |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| JOINT | char | Code indicating joint | | Collected at CRF. |
| PAIN | char | Pain score for joint | | Collected at CRF. |
| SWEL_SEV | char | Swelling severity score for joint | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL - REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |

1.4.17. LAB – LAB

| | |
|--------------------------|--|
| Dataset | LAB |
| Creating program | lab.sas |
| Description | LAB |
| Unique identifier | DUNIQUEP,C_PERIOD,COLDY,DERIV_DY,TESTCODE |
| Sorted by | DUNIQUEP,C_PERIOD,COLDY,DERIV_DY,TESTCODE |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,DERIV_DT,LAB_CODE |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |
| PAGE_SEC | num | Number identifying the section of the CR | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| TIME_COL | num | Derived time of data collection | | Collected at CRF. |
| TESTCODE | char | Code for lab test | | Collected at CRF. |
| NORM_VAR | char | Code for variation of normal range assoc | | Collected at CRF. |
| ENT_RES | char | Quantitative or qualitative lab test res | | Collected at CRF. |
| UNITS | char | Units | | Collected at CRF. |
| NORMAL_L | char | NORMAL_L | | Collected at CRF. |
| NORMAL_H | char | NORMAL_H | | Collected at CRF. |
| TESTCOMM | char | Code for flagging test not performed or | | Collected at CRF. |
| HILOFLAG | char | Flag indicating normal or abnormal labor | | Collected at CRF. |
| NORM_ID | char | ID of normal range record containing res | | Collected at CRF. |
| US_RES | char | Test result converted to standard units | | Collected at CRF. |
| US_UNITS | char | US Units | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| US_FLAG | char | Flag indicating US_RESULT's datatype or | | Collected at CRF. |
| IS_RES | char | Test result converted to standard units | | Collected at CRF. |
| IS_UNITS | char | IS units | | Collected at CRF. |
| IS_FLAG | char | Flag indicating IS_RESULT's datatype or | | Collected at CRF. |
| UNIT_SET | char | Standard unit set containing units for U | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL- REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.18. MEDHX – MEDHX

| | |
|--------------------------|---|
| Dataset | MEDHX |
| Creating program | medhx.sas |
| Description | MEDHX |
| Unique identifier | DUNIQUEP,DERIV_DY,HX_ITEM,HX_ONGO |
| Sorted by | DUNIQUEP,DERIV_DY,HX_ITEM,HX_ONGO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STUDYSEG,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE, DATE_COL,TIME_COL,DERIV_DT,HXONSET,HX_COMM,ONSETMON, ONSETDAY,ONSETYR |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| HX_ITEM | char | Specific Body System/Condition | | Collected at CRF. |
| RESPONSE | char | Specifies No History, Prior, Concurrent, | | Collected at CRF. |
| HX_ONGO | char | Indicates condition present at enrollment | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |

1.4.19. MEDS – MEDS

| | |
|--------------------------|--|
| Dataset | MEDS |
| Creating program | meds.sas |
| Description | MEDS |
| Unique identifier | DUNIQUEP,C_PERIOD,DERIV_DY,RX_CODE,RXST_DY |
| Sorted by | DUNIQUEP,C_PERIOD,DERIV_DY,RX_CODE,RXST_DY |
| Notes | <p>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:</p> <p>PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,DOSEFREQ,RXST_DT,RXST_TIM,RXENDDT,RXENDTIM,RX_REAS,RXST_MON,RXST_DAY,RXST_YR,RXST_HR,RXST_MIN,RXENDMON,RXENDDAY,RXENDYR,RXENDHR,RXENDMIN</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| CRX_NAME | char | Name of medication | | Collected at CRF. |
| RX_NAME | char | Derived name of medication for reporting | | Collected at CRF. |
| RX_CODE | char | Code for concomitant medication | | Collected at CRF. |
| RXACSTAT | char | Code for status of most recent Rx autoen | | Collected at CRF. |
| RX_FREQ | char | Code for frequency of concomitant medica | | Collected at CRF. |
| DOSAGE | char | Dose of concomitant medication | | Collected at CRF. |
| DOSEUNTS | char | Code for units of concomitant medication | | Collected at CRF. |
| ROUT_COD | char | Code for route of concomitant medication | | Collected at CRF. |
| ROUTE | char | Route of concomitant medication administ | | Collected at CRF. |
| RX_IND | char | Condition necessitating medication | | Collected at CRF. |
| REAS_CHG | char | Reason for change in medication | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| RX_CONT | char | Does patient continue to take concomitan | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |
| RXST_DY | num | Relative Derivd day patient started conc | | If RXST_DT and REF.DATE not missing then perform below logic to calculate RXST_DY, If RXST_DT less than REF.DATE then (RXST_DT - REF.DATE). Else if RXST_DT is greater than equal to REF.DATE then (RXST_DT- REF.DATE) +1. |
| RXENDDY | num | Relative Derivd day patient stopped conc | | If RXENDDT and REF.DATE not missing then perform below logic to calculate RXENDDY, If RXENDDT less than REF.DATE then (RXENDDT - REF.DATE). Else if RXENDDT is greater than equal to REF.DATE then (RXENDDT- REF.DATE) +1. |

1.4.20. MEDSUMM – MEDSUMM

| | |
|--------------------------|--|
| Dataset | MEDSUMM |
| Creating program | medsumm.sas |
| Description | MEDSUMM |
| Unique identifier | DUNIQUEP,C_PERIOD,DERIV_DY,RX_CODE |
| Sorted by | DUNIQUEP,C_PERIOD,DERIV_DY,RX_CODE |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,RX_CAT,WITHIN14,BEYOND14,METH_6MO,METH_3MO |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| CRX_NAME | char | Name of medication | | Collected at CRF. |
| RX_NAME | char | Derived name of medication for reporting | | Collected at CRF. |
| RX_CODE | char | Code for specific drug | | Collected at CRF. |
| RXACSTAT | char | Code for status of most recent Rx autoen | | Collected at CRF. |
| PREINF | char | Indicates patient on medication prior to | | Collected at CRF. |
| NOT_ON | char | Indicates medication not administered to | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.21. PGTRCK – PGTRCK

| | |
|--------------------------|--|
| Dataset | PGTRCK |
| Creating program | pgtrck.sas |
| Description | PGTRCK |
| Unique identifier | DUNIQUEP,C_PERIOD,DERIV_DY |
| Sorted by | DUNIQUEP,C_PERIOD,DERIV_DY |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,ANCLPAGE,COLLECTD,REQ_PAGE,NUM_PGS |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| NO_DATA | char | Indicates no data recorded on CRF page | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.22. PHARM – PHARM

| | |
|--------------------------|---|
| Dataset | PHARM |
| Creating program | pharm.sas |
| Description | PHARM |
| Unique identifier | DUNIQUEP,STUDYSEG |
| Sorted by | DUNIQUEP,STUDYSEG |
| Notes | 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: PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,LOT_NUM,RANDCODE,PREPDATE,PREP_MON, PREP_DAY,PREP_YR,PATGROUP,THERAPY |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| DOSE_SEQ | num | Number of dose within sequence of doses | | Collected at CRF. |
| ADM_MAT | char | Code for administered study material | | Collected at CRF. |
| DOSE | num | Dose of study material administered | | Collected at CRF. |
| DOSEUNTS | char | Code for units of dose administered | | Collected at CRF. |
| DOSE_ML | num | Dose in ml of study material | | Collected at CRF. |
| MIXED_ML | num | Total volume drug mixed (in ml) | | Collected at CRF. |
| WGT | num | Derived patient body weight in kilograms | | Collected at CRF. |
| ZWGT | num | Entered patient weight | | Collected at CRF. |
| ZWGT_UN | char | Units for entered weight | | Collected at CRF. |
| VIALS | num | Number of vials | | Collected at CRF. |
| NOT_PREP | char | Indicates that drug was not prepared | | Collected at CRF. |
| NOT_ADM | char | Indicates that drug was prepared but not | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |
| PREPDY | num | Relative Derived day drug was prepared | | If PREPDATE and REF.DATE not missing then perform below logic to calculate PREPDY, If PREPDATE less than REF.DATE then (PREPDATE - REF.DATE). Else if PREPDATE is greater than equal to REF.DATE then (PREPDATE - REF.DATE) +1. |

1.4.23. POSTAE – POSTAE

| | |
|--------------------------|--|
| Dataset | POSTAE |
| Creating program | postae.sas |
| Description | POSTAE |
| Unique identifier | DUNIQUEP,WHOART,DERIV_DY,ONSETDY,RESOLDY |
| Sorted by | DUNIQUEP,WHOART,DERIV_DY,ONSETDY,RESOLDY |
| Notes | 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: MONTH, DAY, YEAR, HOUR, MINUTE, DATE_COL, TIME_COL, DERIV_DT, AE_CODE, CAE_DESC, AE_DESC, AE_LINE, PRIMTERM, ONSETDT, RESOLDT, SERIOUS, SERIOUS1, SERIOUS2, SERIOUS3, SERIOUS6, SERIOUS7, AE_REL, RELATION, ACT_TAK, ACTION, AE_TREAT, CLASS, INFECT, ONSETMON, ONSETDAY, ONSETYR, ONSETHR, ONSETMIN, RESOLMON, RESOLDAY, RESOLYR, RESOLHR, RESOLMIN |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PAGE_SEC | num | Number identifying the section of the CR | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| WHOART | char | WHOART AE code generated by AE autoencod | | Collected at CRF. |
| AEACSTAT | char | Code for status of most recent AE autoen | | Collected at CRF. |
| ONSETTIM | num | Time of AE onset, derived from onset hou | | Collected at CRF. |
| RESOLTIM | num | Time of AE resolution, derived from resol | | Collected at CRF. |
| CONT | char | Yes if adverse event continued (i.e., wa | | Collected at CRF. |
| FREQ | char | Code for frequency of adverse event | | Collected at CRF. |
| SEVERITY | char | Code for severity of adverse event | | Collected at CRF. |
| SERIOUS4 | char | AE severity code indicating severely/per | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|-------------------|
| SERIOUS5 | char | AE severity code indicating initial/prol | | Collected at CRF. |
| SERIOUS8 | char | AE severity code indicating none of the | | Collected at CRF. |
| AE_RELAT | char | Code for relationship of adverse event t | | Collected at CRF. |
| AE_REL2 | char | Code for relationship of AE to second dr | | Collected at CRF. |
| AE_ACT | char | Code for initial action taken with study | | Collected at CRF. |
| AE_ACT2 | char | Code for initial action taken with secon | | Collected at CRF. |
| OUTCOME | char | Code for outcome of adverse event | | Collected at CRF. |
| DECHALL | char | Code indicating AE resolution after stop | | Collected at CRF. |
| DECHALL2 | char | Code indicating AE resolution after stop | | Collected at CRF. |
| RECHALL | char | Code indicating AE recurrence after star | | Collected at CRF. |
| RECHALL2 | char | Code indicating AE recurrence after star | | Collected at CRF. |
| AE_PREF | char | AE_PREF | | Collected at CRF. |
| PREFTERM | char | PREFTERM | | Collected at CRF. |
| AE_CLASS | char | AE_CLASS | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| CLASSDSC | char | CLASSDSC | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |
| ONSETDY | num | Relative Day of AE onset | | If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT - REF.DATE) +1. |
| RESOLDY | num | Relative Day of AE resolution | | If RESOLDT and REF.DATE not missing then perform below logic to calculate RESOLDY, If RESOLDT less than REF.DATE then (RESOLDT - REF.DATE). Else if RESOLDT is greater than equal to REF.DATE then (RESOLDT - REF.DATE) +1. |

1.4.24. RAEVAL – RAEVAL

| | |
|--------------------------|--|
| Dataset | RAEVAL |
| Creating program | raeval.sas |
| Description | RAEVAL |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | 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: PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL, DERIV_DT,NOT_PERF,EFF_PAT,EFF_EVAL |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEQ | char | Qualifier for CRF page number (A,B,C) | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| SWELL | char | Indicates soft tissue swelling in tendon | | Collected at CRF. |
| GRIP_R1 | num | Grip strength - Right side, first measur | | Collected at CRF. |
| GRIP_R2 | num | Grip strength - Right side, second measu | | Collected at CRF. |
| GRIP_R3 | num | Grip strength - Right side, third measur | | Collected at CRF. |
| RIGHT_ND | char | Indicates right side grip strength not d | | Collected at CRF. |
| GRIP_L1 | num | Grip strength - Left side, first measure | | Collected at CRF. |
| GRIP_L2 | num | Grip strength - Left side, second measur | | Collected at CRF. |
| GRIP_L3 | num | Grip strength - Left side, third measure | | Collected at CRF. |
| LEFT_ND | char | Indicates left side grip strength not do | | Collected at CRF. |
| GRIPUNIT | char | Units of grip strength values | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| MORNSTIF | num | Duration of morning stiffness (in minute) | | Collected at CRF. |
| SCORUNIT | char | Units used for scoring items | | Collected at CRF. |
| STIFSCOR | num | Morning stiffness score | | Collected at CRF. |
| PAINSCOR | num | Pain score | | Collected at CRF. |
| TIRESCOR | num | Tiredness score | | Collected at CRF. |
| GDA_PAT | num | Patient's score for global disease asses | | Collected at CRF. |
| GDA_EVAL | num | Evaluator's score for global disease ass | | Collected at CRF. |
| RSP_PAT | num | Patient's score for global response to p | | Collected at CRF. |
| RSP_EVAL | num | Evaluator's score for global response to | | Collected at CRF. |
| SEV_PAT | char | Code for patient's assessment of disease | | Collected at CRF. |
| SEV_EVAL | char | Code for evaluator's assessment of disea | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL - REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |

1.4.25. RAINFO – RAINFO

| | |
|--------------------------|---|
| Dataset | RAINFO |
| Creating program | rainfo.sas |
| Description | RAINFO |
| Unique identifier | DUNIQUEP |
| Sorted by | DUNIQUEP |
| Notes | 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: STUDYSEG,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE, DATE_COL,TIME_COL,DERIV_DT,DIAG_DT,DIAG_MON,DIAG_DAY,DIAG_YR, CRIT1,CRIT2,CRIT3,CRIT4,CRIT5,CRIT6,CRIT7 |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| PATTERN | char | Code indicating past pattern of disease | | Collected at CRF. |
| ANASTAGE | char | Classification of anatomical stage | | Collected at CRF. |
| FUNCLASS | char | Classification of functional capacity | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |
| DIAG_DY | num | Relative Derivd day initial diagnosis RA | | If DIAG_DT and REF.DATE not missing then perform below logic to calculate DIAG_DY, If DIAG_DT less than REF.DATE then (DIAG_DT - REF.DATE). Else if DIAG_DT is greater than equal to REF.DATE then (DIAG_DT- REF.DATE) +1. |

1.4.26. RANDCODE – RANDCODE

| | |
|--------------------------|---|
| Dataset | RANDCODE |
| Creating program | randcode.sas |
| Description | RANDCODE |
| Unique identifier | ADM_MAT,ADM_MAT2 |
| Sorted by | ADM_MAT,ADM_MAT2 |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDCODE,LOT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|-------------------|
| PROTOCOL | char | Protocol for randomization code | | Collected at CRF. |
| ADM_MAT | char | Code for administered study material | | Collected at CRF. |
| ADM_MAT2 | char | Code for second administered study mater | | Collected at CRF. |
| DOSE | num | Dose of study material administered | | Collected at CRF. |
| DOSEUNTS | char | Code for units of dose administered | | Collected at CRF. |

1.4.27. REASONS – REASONS

| | |
|--------------------------|--|
| Dataset | REASONS |
| Creating program | reasons.sas |
| Description | REASONS |
| Unique identifier | DUNIQUEP,C_PERIOD,DERIV_DY,REASCODE |
| Sorted by | DUNIQUEP,C_PERIOD,DERIV_DY,REASCODE |
| Notes | 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: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,REASSPEC,DATE_DIS,MON_DISC,DAY_DISC,YR_DISC, DOD,DOD_MON,DOD_DAY,DOD_YR |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| REASCODE | char | Code for reason patient did not complete | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |
| DISCNTDY | num | Relative Day of discontinuation | | If DATE_DIS and REF.DATE not missing then perform below logic to calculate DISCNTDY, If DATE_DIS less than REF.DATE then (DATE_DIS - REF.DATE). Else if DATE_DIS is greater than equal to REF.DATE then (DATE_DIS - REF.DATE) +1. |

1.4.28. SURGPR – SURGPR

| | |
|--------------------------|--|
| Dataset | SURGPR |
| Creating program | surgpr.sas |
| Description | SURGPR |
| Unique identifier | DUNIQUEP,C_PERIOD,DERIV_DY |
| Sorted by | DUNIQUEP,C_PERIOD,DERIV_DY |
| Notes | 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: STUDYSEG,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,PROCSPEC,PROCDATE,PROCMON,PROCDAY,PROCYEAR |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| PROCTYPE | char | Code for type of surgery/procedure | | Collected at CRF. |
| PROCRESP | char | Specifies No History, Prior, Concurrent, | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT- REF.DATE) +1. |
| PROCDY | num | Relative Derived day surgery/procedure | | If PROCDATE and REF.DATE not missing then perform below logic to calculate PROCDY, If PROCDATE less than REF.DATE then (PROCDATE - REF.DATE). Else if PROCDATE is greater than equal to REF.DATE then (PROCDATE- REF.DATE) +1. |

1.4.29. XRAY – XRAY

| | |
|--------------------------|--|
| Dataset | XRAY |
| Creating program | xray.sas |
| Description | XRAY |
| Unique identifier | DUNIQUEP,C_PERIOD |
| Sorted by | DUNIQUEP,C_PERIOD |
| Notes | 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: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,CHEST_ND,CH_DATE,CH_TIME,CH_MONTH,CH_DAY, CH_YEAR,CH_HOUR,CH_MIN,QUADRANT,HF_ND,HF_DATE,HF_MONTH, HF_DAY,HF_YEAR |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|-----------|------|--|-------|---|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| CH_RESULT | char | Indicates chest x-ray was normal or abno | | Collected at CRF. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |
| CH_DY | num | Relative Derived day of chest x-ray | | If CH_DATE and REF.DATE not missing then perform below logic to calculate CH_DY, If CH_DATE less than REF.DATE then (CH_DATE - REF.DATE). Else if CH_DATE is greater than equal to REF.DATE then (CH_DATE - REF.DATE) +1. |
| HF_DY | num | Relative Derivd day hands and feet x-ray | | If HF_DATE and REF.DATE not missing then perform below logic to calculate HF_DY, If HF_DATE less than REF.DATE then (HF_DATE - REF.DATE). Else if HF_DATE is greater than equal to REF.DATE then (HF_DATE - REF.DATE) +1. |

1.4.30. XRAYSC – XRAYSC

| | |
|--------------------------|--|
| Dataset | XRAYSC |
| Creating program | xraysc.sas |
| Description | XRAYSC |
| Unique identifier | DUNIQUEP,C_PERIOD,DERIV_DY,BODYPART,JOINT |
| Sorted by | DUNIQUEP,C_PERIOD,DERIV_DY,BODYPART,JOINT |
| Notes | 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: PAGE_SEQ,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,RAND_NO |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| DUNIQUEP | char | Unique Subject Id Assign for De-identity | | Randomly assigned Unique Subject Id for De-identity |
| C_PERIOD | char | Coded data collection period for chronol | | Collected at CRF. |
| STUDYSEG | char | Study segment identifier | | Collected at CRF. |
| PAGE | num | CRF page number | | Collected at CRF. |
| PAGE_SEC | num | Number identifying the section of the CR | | Collected at CRF. |
| PERIOD | char | Data collection period | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| PROTOCOL | char | Protocol number, derived from Unique_pat | | Collected at CRF. |
| DSITE | char | Site ID Assigned for De-identity | | Randomly assigned Site ID for De-identity |
| DPATIENT | char | Patient Number Assigned for De-identity | | Randomly assigned Patient Number for De-identity |
| BODYPART | char | Indicates body part xrayed | | Collected at CRF. |
| SCORE_ND | char | Indicates scoring not done | | Collected at CRF. |
| JOINT | char | Code indicating joint | | Collected at CRF. |
| SCORE | char | Score of X-ray | | Collected at CRF. |
| SCORETYP | char | Code indicating type of xray score | | Collected at CRF. |
| COLDY | num | Relative Derived day of data collection | | If DATE_COL and REF.DATE not missing then perform below logic to calculate COLDY, If DATE_COL less than REF.DATE then (DATE_COL - REF.DATE). Else if DATE_COL is greater than equal to REF.DATE then (DATE_COL - REF.DATE) +1. |
| DERIV_TM | num | Derivd Time derived item values | | Collected at CRF. |
| DERIV_DY | num | Relative Derivd day derived item values | | If DERIV_DT and REF.DATE not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than REF.DATE then (DERIV_DT - REF.DATE). Else if DERIV_DT is greater than equal to REF.DATE then (DERIV_DT - REF.DATE) +1. |