

Clinical Development

CNT0312

C0168T16

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 (i.e. COMMENTS) will be submitted due to sensitivity of data.
- Death dataset has zero observation in input, hence will not be submitted.
- CRITERIA.CONSDATE (Informed Consent Date) will be used as reference date to derive relative days (referred as REF.DATE in the document).

1.3. Data Files

The C0168T16 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demography – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demography
Unique identifier	DUNIQUE_P
Sorted by	DUNIQUE_P
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,INITIALS,DOB,RACE_OTH,DOB_MON,DOB_DAY,DOB_YR,STD_WGT,HOSPADT,HOSPAMON,HOSPADAY,HOSPAYR</p>

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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		Collected at CRF.
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.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.Dose Administration – ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Dose Administration
Unique identifier	DUNIQUE_P,STUDYSEG
Sorted by	DUNIQUE_P,STUDYSEG
Notes	<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>PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,ADM_MAT,PATGROUP,STARTDT,ENDDT,DOSE, DOSE_UN,WGT,TOTAL_MG,MIXED_MG,MIXED_ML,ROUTECD,RANDCODE, LOT_NUM,VIALS,VIAL_NUM,CONDOSE,EARLY_AE,TESTDT,TESTTIME, T_STDT,T_ENDDT,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,KIT_NUM,INTERRUP,AE,ADMIN, ADMIN_SP,OTH_REAS,RSN_SPEC,CONSENT,TOTAL_AD,A_VIAL,B_VIAL, UNBLDDAY,UNBLDMON,UNBLDYR,UNBLDDT,UNBLDHR,UNBLDMIN, UNBLDTIM,NOTTREAT,ILLNESS,ALT_THPY,UNBLMAT,ENROLDAY,ENROLMON, ENROLYR,ENROLDT,ENROLHR,ENROLMIN,ENROLTIM,LC_DAY,LC_MON, LC_YR,LC_ENRDT,LC_HR,LC_MIN,LC_ENRTM</p>

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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.
STOPTIM	num	Derived time infusion was interrupted		Collected at CRF.
RSTRTTIM	num	Derived time infusion was restarted		Collected at CRF.
ENDTIM	num	Derived time study material administrati		Collected at CRF.
TOTAL_ML	num	Total ml administrated (in ml)		Collected at CRF.
TEST_ND	char	Indicates test dose was not administered		Collected at CRF.

Variable	Type	Label	Codes	Comments
T_STTIM	num	Derived time test dose started		Collected at CRF.
T_ENDTIM	num	Derived time test dose ended		Collected at CRF.
TEST_ML	num	Test dose volume (in ml)		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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 Derv 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.

1.4.3.Ad_assessment - AD_ASSAY

Dataset	AD_ASSAY
Creating program	ad_assay.sas
Description	Ad_assessment
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD
Sorted by	DUNIQUE_P,STUDYSEG,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
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient ID for de-identity
STUDYSEG	char	Study segment of data collection		Collected at CRF.
C_PERIOD	char	Coded study period of data collection		Collected at CRF.
PERIOD	char	Study period of data collection		Collected at CRF.
SAMPLTIM	num	Time at which sample was collected		Collected at CRF.
C_OD	char	Character mean optical density		Collected at CRF.
C_CA2INH	char	% inhibition to cA2		Collected at CRF.
C_MA2INH	char	% inhibition to mA2		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_CD4INH	char	% inhibition to CD-4		Collected at CRF.
C_TITER	char	Titer ratio		Collected at CRF.
N_OD	num	Numeric mean optical density		Collected at CRF.
C_CA2	char	Character serum cA2 concentration		Collected at CRF.
N_CA2	num	Numeric serum cA2 concentration		Collected at CRF.
B_CA2	num	Baseline serum cA2 concentration		Collected at CRF.
B_OD	num	Baseline mean optical density		Collected at CRF.
SAMPRES	char	Sample HACA result		Collected at CRF.
P_POS	char	Potentially positive HACA sample		Collected at CRF.
INFER	char	Inferred HACA sample result		Collected at CRF.
MAX_TITR	char	Maximum titer for an infusion		Collected at CRF.
REASNE	char	Reason infusion result is not evaluable		Collected at CRF.
INF_RES	char	Infusion result		Collected at CRF.
HACACOMM	char	HACA related comments		Collected at CRF.
SAMPLDY	num	Relative Day at which sample collected		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.AE Occurrence - AEOCCUR

Dataset	AEOCCUR
Creating program	aeoccur.sas
Description	AE Occurrence
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,AE_OCCUR
Sorted by	DUNIQUE_P,STUDYSEG,PERIOD,AE_OCCUR
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
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
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	Derived Time deriv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day deriv item value(s)		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. Assessment – ASSESS

Dataset	ASSESS
Creating program	assess.sas
Description	Assessment
Unique identifier	DUNIQUE_P,STUDYSEG,DERIV_DY,STDYSTAT
Sorted by	DUNIQUE_P,STUDYSEG,DERIV_DY,STDYSTAT
Notes	<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>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,AUTOPSY,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,STDY_COM,PAGE_3,PAG_SEQ3,PAG_SEC3,PAGE_4,PAG_SEQ4,PAG_SEC4,COLECT,ELEC_COL,COL_REAS,COL_DATE,COL_MON,COL_DAY,COL_YR,VISIT_WK</p>

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.
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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
STDYSTAT	char	Indicates patient's further participatio		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.
DISCINIT	char	Code for study discontinuation initiator		Collected at CRF.
INITSPEC	char	Specifies 'Other' study discontinuation		Collected at CRF.

Variable	Type	Label	Codes	Comments
DERIV_TM	num	Derived Time deriv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day deriv item value(s)		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.

1.4.6.Atrack – ATRACK

Dataset	ATRACK
Creating program	atrack.sas
Description	Atrack
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY,ASSAY
Sorted by	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY,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,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,RCVD_MON,RCVD_DAY,RCVD_YR,RCVD_DT,ZWGT,ZWGT_UN,WGT</p>

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.

Variable	Type	Label	Codes	Comments
PERIOD	char	Data collection period		Collected at CRF.
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.

Variable	Type	Label	Codes	Comments
DERIV_DY	num	Relative Derived Day deriv item value(s)		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 Derv Day assay samp collected		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.

1.4.7.Cdeis - CDEIS

Dataset	CDEIS
Creating program	cdeis.sas
Description	Cdeis
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,DERIV_DY,SEGMENT
Sorted by	DUNIQUE_P,STUDYSEG,PERIOD,DERIV_DY,SEGMENT
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

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
SEGMENT	char	Code indicating segment of intestine		Collected at CRF.
SEG_ND	char	Indicates that segment was not evaluated		Collected at CRF.
TYPE0	char	Indicates no abnormalities		Collected at CRF.
TYPE1	char	Indicates pseudopolyp		Collected at CRF.
TYPE2	char	Indicates healed ulceration		Collected at CRF.
TYPE3	char	Indicates frank erythema		Collected at CRF.
TYPE4	char	Indicates frank swollen mucosa		Collected at CRF.
TYPE5	char	Indicates aphthoid ulceration		Collected at CRF.
TYPE6	char	Indicates superficial or shallow ulcerat		Collected at CRF.
TYPE7	char	Indicates deep ulceration		Collected at CRF.
TYPE8	char	Indicates non-ulcerated stenosis		Collected at CRF.
TYPE9	char	Indicates ulcerated stenosis		Collected at CRF.
SSD	num	Percentage of segment surface involved b		Collected at CRF.
SSU	num	Percentage of segment surface involved b		Collected at CRF.

Variable	Type	Label	Codes	Comments
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.

1.4.8.Cdeisc - CDEISC

Dataset	CDEISC
Creating program	cdeisc.sas
Description	Cdeisc
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,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

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
ASSESSND	char	Indicates that CDEIS assessment was not		Collected at CRF.
DERIV_TM	num	Derived Time deriv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day deriv item value(s)		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.Cfinal – CFINAL

Dataset	CFINAL
Creating program	cfinal.sas
Description	Cfinal
Unique identifier	DUNIQUE_P,ASSCODE,INJCODE,FINALRES,TINTERVAL
Sorted by	DUNIQUE_P,ASSCODE,INJCODE,FINALRES,TINTERVAL
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,ASSCOMM1,ASSCOMM2,LNK_PROT,LNK_SITE,LNK_PAT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.

1.4.10. Vital Signs – CLINF

Dataset	CLINF
Creating program	clinf.sas
Description	Vital Signs
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,PERIOD,DERIV_DY,TEMP,DIAS
Sorted by	DUNIQUE_P,STUDYSEG,C_PERIOD,PERIOD,DERIV_DY,TEMP,DIAS
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,DERIV_DT, VITAL_ND,BP_MTH,BPMED,RR,RR_ND,POSITION,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

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient ID for de-identity
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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.
WGT	num	Derived patient weight in kilograms		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.

1.4.11. Comments - COMMENTS

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

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Empty dataset will be submitted
C_PERIOD	char	Coded data collection period for chronol		Empty dataset will be submitted
STUDYSEG	char	Study segment identifier		Empty dataset will be submitted
PAGE	num	CRF page number		Empty dataset will be submitted
PAGE_SEQ	char	Qualifier for CRF page number (A,B,C)		Empty dataset will be submitted
PERIOD	char	Data collection period		Empty dataset will be submitted
PROTOCOL	char	Protocol number		Empty dataset will be submitted
DSITE	char	Site number assigned for de-identity		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Empty dataset will be submitted
FOR_PAGE	char	Number(s) of CRF page(s) to which commen		Empty dataset will be submitted
DERIV_TM	num	Derived Time derv item value(s)		Empty dataset will be submitted
DERIV_DY	num	Relative Derived Day derv item value(s)		Empty dataset will be submitted

1.4.12. Patient Seletion Criteria - CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Patient Seletion Criteria
Unique identifier	DUNIQUE_P
Sorted by	DUNIQUE_P
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,INC_1A,INC_1B,INC3A,INC3B,INC3C,INC3D,INC3E,INC3F,INC3G,INC3H,INC12A,INC12B,INC31,INC32,INC33,INC34,CONSDATE,CONSTIME,ENROLDT,ENROLTIM,CONS_MON,CONS_DAY,CONS_YR,CONS_HR,CONS_MIN,ENROLMON,ENROLDAY,ENROLYR,ENROLHR,ENROLMIN

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
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.
INC4	char	Criteria number 4		Collected at CRF.
INC4A	char	Criteria number 4a		Collected at CRF.
INC4B	char	Criteria number 4b		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.
INC17	char	Criteria number 17		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
INC27	char	Criteria number 27		Collected at CRF.
INC28	char	Criteria number 28		Collected at CRF.
INC29	char	Criteria number 29		Collected at CRF.
INC30	char	Criteria number 30		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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. Crohn's Disease – CROHNS

Dataset	CROHNS
Creating program	crohns.sas
Description	Crohn's Disease
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_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_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,NUM_CAT,HEMAT,HEMAT_U,WGT,ZWGT,ZWGT_UN, STD_WGT,STOOL_NA,DIARY_EX,ARTHRIT,ARTHRALG,IRITIS,UVEITIS, ERYTHEMA,PYODERMA,APHTHOUS,FISSURE,FISTULA,ABSCESS,OTHERFIS, FEVER</p>

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
ASSESSND	char	Indicates that assessment was not done		Collected at CRF.
NO_STOOL	char	Total number of liquid/soft stools in pa		Collected at CRF.
ABD_PAIN	char	Abdominal pain/cramps rating for past 7		Collected at CRF.
WELL_BE	char	Indicates general well being for past 7		Collected at CRF.
CAT_A	char	Indicates DAI category the patient now h		Collected at CRF.
CAT_B	char	Indicates DAI category the patient now h		Collected at CRF.
CAT_C	char	Indicates DAI category the patient now h		Collected at CRF.
CAT_D	char	Indicates DAI category the patient now h		Collected at CRF.
CAT_E	char	Indicates DAI category the patient now h		Collected at CRF.

Variable	Type	Label	Codes	Comments
CAT_F	char	Indicates DAI category the patient now h		Collected at CRF.
DRG_THER	char	Indicates antidiarrheal drug therapy dur		Collected at CRF.
DRG_THR2	char	Indicates opiates received daily for oth		Collected at CRF.
ABD_MASS	char	Indicates abdominal mass		Collected at CRF.
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.

1.4.14. Inflammatory Bowel Disease Questionnaire – IBDQC

Dataset	IBDQC
Creating program	ibdqc.sas
Description	Inflammatory Bowel Disease Questionnaire
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,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: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
ASSESSND	char	Indicates that IBD Questionnaire was not		Collected at CRF.
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time deriv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day deriv item value(s)		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. Ibdqscr - IBDQSCR

Dataset	IBDQSCR
Creating program	ibdqscr.sas
Description	Ibdqscr
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,QUESTION,DERIV_DY,SCORE
Sorted by	DUNIQUE_P,STUDYSEG,PERIOD,QUESTION,DERIV_DY,SCORE
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

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
QUESTION	char	Code representing question from IBD Ques		Collected at CRF.
SCORE	char	Score for IBD question		Collected at CRF.
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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. Laboratory - LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,DERIV_DY,COL_DY,TESTCODE
Sorted by	DUNIQUE_P,STUDYSEG,PERIOD,DERIV_DY,COL_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 or due to missing values: PAGE_SEQ,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,DERIV_DT, LAB_CODE,LABELNUM

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.
PROTOCOL	char	Protocol number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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	Lab units		Collected at CRF.
NORMAL_L	char	Lab normal low range		Collected at CRF.
NORMAL_H	char	Lab normal high range		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	Lab units (US)		Collected at CRF.
US_FLAG	char	Flag indicating US_RESULT's datatype or		Collected at CRF.

Variable	Type	Label	Codes	Comments
IS_RES	char	Test result converted to standard units		Collected at CRF.
IS_UNITS	char	Lab units (IS)		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.
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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. Ltrack – LTRACK

Dataset	LTRACK
Creating program	ltrack.sas
Description	Ltrack
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,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_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL, DERIV_DT,NOT_COLL,LABELNUM

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.
PROTOCOL	char	Protocol number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
BLD_SENT	char	Yes if blood sent to lab		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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. Medical History – MEDHX

Dataset	MEDHX
Creating program	medhx.sas
Description	Medical History
Unique identifier	DUNIQUE_P,RESPONSE,PAGE,HX_ITEM,HX_ONGO,DERIV_DY
Sorted by	DUNIQUE_P,RESPONSE,PAGE,HX_ITEM,HX_ONGO,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: STUDYSEG,PAGE_SEQ,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,HXONSET,HX_COMM,ONSETMON,ONSETDAY,ONSETYR, ONGOING

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient ID for de-identity
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.
PAGE	num	CRF page number		Collected at CRF.
PAGE_SEC	num	Number identifying the section of the CR		Collected at CRF.
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
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 enrollmen		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.
HXONSEDY	num	Relative Derv Day onset of spec condit		If HXONSET and REF.DATE not missing then perform below logic to calculate HXONSEDY, If HXONSET less than REF.DATE then (HXONSET - REF.DATE). Else if HXONSET is greater than equal to REF.DATE then (HXONSET - REF.DATE) +1.

1.4.19. Concomitant Medication - MEDS

Dataset	MEDS
Creating program	meds.sas
Description	Concomitant Medication
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,RX_CODE,ROUT_COD,DOSAGE,DERIV_DY, RXST_DY
Sorted by	DUNIQUE_P,STUDYSEG,C_PERIOD,RX_CODE,ROUT_COD,DOSAGE,DERIV_DY, RXST_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_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,CRX_NAME,DOSEFREQ,ROUTE,REAS_CHG,RXST_DT,RXST_TIM,RXENDDT,RXENDTIM,RX_REAS,RXST_MON,RXST_DAY,RXST_YR,RXST_HR,RXST_MIN,RXENDMON,RXENDDAY,RXENDYR,RXENDHR,RXENDMIN,PRIOR_EN

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
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.
RX_IND	char	Condition necessitating medication		Collected at CRF.
RX_CONT	char	Does patient continue to take concomitan		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.

Variable	Type	Label	Codes	Comments
DERIV_DY	num	Relative Derived Day deriv item value(s)		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 Derv Day patient start 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 Derv Day patient stop 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. Pharm - PHARM

Dataset	PHARM
Creating program	pharm.sas
Description	Pharm
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY,DOSE_SEQ
Sorted by	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY,DOSE_SEQ
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,RANDCODE,FORMULAT,PREPDATE,PREP_MON, PREP_DAY,PREP_YR,NOT_PREP,NOT_ADM

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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.
LOT_NUM	char	Number of inventory lot from which study		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.
PATGROUP	char	Indicates patient's dose group		Collected at CRF.
THERAPY	char	Indicates if patient is receiving cortic		Collected at CRF.

Variable	Type	Label	Codes	Comments
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.

1.4.21. Patient Experiences – PHCOND

Dataset	PHCOND
Creating program	phcond.sas
Description	Patient Experiences
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,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,ASSESSND,CHILLS,MYALGIA,HEADACHE,NAUSEA,STOOL, BLEEDING,PAIN,URGENCY,WELL_BE,SUFFER

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
FISTULA	char	Number of draining fistulas patient has		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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. Adverse Experiences – POSTAE

Dataset	POSTAE
Creating program	postae.sas
Description	Adverse Experiences
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,PREFTERM,CLASSDSC,PAGE_SEC,DERIV_DY,ONSETDY
Sorted by	DUNIQUE_P,STUDYSEG,C_PERIOD,PREFTERM,CLASSDSC,PAGE_SEC,DERIV_DY,ONSETDY
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,SERIOUS3,RELATION,AE_REL2,ACTION,AE_ACT2,DECHALL2,RECHALL2,ONSETMON,ONSETDAY,ONSETYR,ONSETHR,ONSETMIN,RESOLMON,RESOLDAY,RESOLYR,RESOLHR,RESOLMIN

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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.

Variable	Type	Label	Codes	Comments
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.
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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.
SERIOUS	char	Was A.E. Serious?		Collected at CRF.

Variable	Type	Label	Codes	Comments
SERIOUS1	char	AE severity code indicating fatal		Collected at CRF.
SERIOUS2	char	AE severity code indicating life threate		Collected at CRF.
SERIOUS4	char	AE severity code indicating severely/per		Collected at CRF.
SERIOUS5	char	AE severity code indicating initial/prol		Collected at CRF.
SERIOUS6	char	AE severity code indicating congenital a		Collected at CRF.
SERIOUS7	char	AE severity code indicating cancer		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_ACT	char	Code for initial action taken with study		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.
RECHALL	char	Code indicating AE recurrence after star		Collected at CRF.
AE_PREF	char	AE preferred term		Collected at CRF.
PREFTERM	char	Preferred term		Collected at CRF.
AE_CLASS	char	AE class		Collected at CRF.

Variable	Type	Label	Codes	Comments
CLASSDSC	char	Class description		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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 AE onset Day, derv frm onset mon		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 AE resolutn Day, derv from reso		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.

1.4.23. Procinf - PROCINF

Dataset	PROCONF
Creating program	procinf.sas
Description	Procinf
Unique identifier	DUNIQUE_P,STUDYSEG,C_PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,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: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,PROCDATE,PROCMON,PROCDAY,PROCYEAR,PROCND, SIG_EVAL,COL_EVAL

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
ECG_RES	char	Indicates ECG was normal or abnormal		Collected at CRF.
DERIV_TM	num	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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 of 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.

1.4.24. Ptrack - PTRACK

Dataset	PTRACK
Creating program	ptrack.sas
Description	Ptrack
Unique identifier	DUNIQUE_P,PAGE,NO_DATA,DERIV_DY
Sorted by	DUNIQUE_P,PAGE,NO_DATA,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: STUDYSEG,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,ANCLPAGE,COLLECTD

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity

Variable	Type	Label	Codes	Comments
NO_DATA	char	Indicates no data recorded on CRF page		Collected at CRF.
DERIV_TM	num	Derived Time deriv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day deriv item value(s)		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. Reasons – REASONS

Dataset	REASONS
Creating program	reasons.sas
Description	Reasons
Unique identifier	DUNIQUE_P,PAGE,REASCODE,DERIV_DY
Sorted by	DUNIQUE_P,PAGE,REASCODE,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_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT,REASSPEC,DATE_DIS,MON_DISC,DAY_DISC,YR_DISC, DISCINIT,INITSPEC,DOD,DOD_MON,DOD_DAY,DOD_YR,PAGE_1,P1_LINE, PAGE_2,P2_LINE,PAGE_3,P3_LINE,PAGE_4,P4_LINE

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient ID for de-identity
C_PERIOD	char	Coded data collection period for chronol		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.
PROTOCOL	char	Protocol number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.
DIS_DY	num	Relative Day of discontinuation		If DATE_DIS and REF.DATE not missing then perform below logic to calculate DIS_DY, 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.

1.4.26. Surgpr – SURGPR

Dataset	SURGPR
Creating program	surgpr.sas
Description	Surgpr
Unique identifier	DUNIQUE_P,PAGE,PROCTYPE,PROCRESP,DERIV_DY
Sorted by	DUNIQUE_P,PAGE,PROCTYPE,PROCRESP,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:STUDYSEG,PAGE_SEQ,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DERIV_DT,PROCSPEC,PROCDATE,PROCMON,PROCDA,PROCYEAR,STOMA,PROCTITI,RESECTIO

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient ID for de-identity
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.
PAGE	num	CRF page number		Collected at CRF.
PAGE_SEQ	num	Number identifying the section of the CR		Collected at CRF.
PROTOCOL	char	Protocol number		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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	Derived Time deriv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day deriv item value(s)		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.

1.4.27. Visits - VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visits
Unique identifier	DUNIQUE_P,STUDYSEG,PERIOD,NOT_COMP,DERIV_DY
Sorted by	DUNIQUE_P,STUDYSEG,PERIOD,NOT_COMP,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: PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,DERIV_DT

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.
DSITE	char	Site number assigned for de-identity		Randomly assigned site number for de-identity

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for de-identity		Randomly assigned patient number for de-identity
NOT_COMP	char	Indicates patient visit not completed		Collected at CRF.
TYPE_VIS	char	Indicates routine, final safety or final		Collected at CRF.
COL_DY	num	Relative Derived Day of data collection		If DATE_COL and REF.DATE not missing then perform below logic to calculate COL_DY, 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.

1.4.28. X-ray - XRAY

Dataset	XRAY
Creating program	xray.sas
Description	X-ray
Unique identifier	DUNIQUE_P,,STUDYSEG,PERIOD,DERIV_DY
Sorted by	DUNIQUE_P,,STUDYSEG,PERIOD,DERIV_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_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,KNEE_DT,KNEE_MON,KNEE_DAY,KNEE_YR</p>

Variable	Type	Label	Codes	Comments
DUNIQUE_P	char	Unique patient ID assign for de-identity		Randomly assigned unique patient 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		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned for de-identity		Randomly assigned site number 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	Derived Time derv item value(s)		If DERIV_DT contains time part then timepart(DERIV_DT) else DERIV_TM equal to NULL.
DERIV_DY	num	Relative Derived Day derv item value(s)		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.