

Clinical Development

Infliximab

C0168T20

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

- Lab Identifier information will not be provided.
- 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.
- Dataset used for data reconciliation, CRF page information will not be submitted (eg. LTRACK, ATRACK , AEOCCUR,PGTRCK).
- Datasets CRESUL and CFINAL contain PK related information hence dropping the same.
- SURGPR dataset will not be submitted to protect PI.
- Data sets will not be submitted (eg. DEATH, MEDHX ,DUP_LIST,PHOTO,PRIORTX).

1.3. Data Files

The C0168T20 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0168T20 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demographics – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demography
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 non significant elements or due to missing values:</p> <p>STUDYSEG,PAGE,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,INITIALS,DOB,RACE_OTH,DOB_MON,DOB_DAY, DOB_YR,,STD_WGT,HOSPADT,HOSPAMON,HOSPADAY,HOSPAYR</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity for De-identity.
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
TRTMENT	char	Textual treatment group assignment		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.2. Administration – ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Administration
Unique identifier	DUNIQUEP ,STUDYSEG , DOSE_SEQ ,TEST_ND, TOTAL_AD ,UNBLMAT, NOTTREAT, INTERRUP
Sorted by	DUNIQUEP ,STUDYSEG , DOSE_SEQ ,TEST_ND, TOTAL_AD ,UNBLMAT, NOTTREAT, INTERRUP
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE, DATE_COL,TIME_COL,ADM_MAT,NOTDOSED,PATGROUP,DOSE,DOSE_UN, WGT,TOTAL_MG,TOTAL_ML,MIXED_MG,MIXED_ML,ROUTECD,RANDCODE, LOT_NUM,VIALS,VIAL_NUM,CONTDOSE,EARLY_AE,TESTDT,TESTTIME, T_STDT,T_ENDDT,FOREARM,REACTION,EXTRAVAS,STARTMON,STARTDAY, STARTYR,ENDMON,ENDDAY,ENDYR,TESTMON,TESTDAY,TESTYR,TESTHR, TESTMIN,T_STMON,T_STDAY,T_STYR,T_ENDMON,T_ENDDAY,T_ENDYR, KIT_NUM,ADMIN_SP,OTH_REAS,RSN_SPEC,CONSENT,UNBLDDAY, UNBLDMON,UNBLDYR,UNBLDDT,UNBLDHR,UNBLDMIN,UNBLDTIM,ILLNESS, ALT_THPY, ENROLDAY,ENROLMON,ENROLYR,LC_DAY,LC_MON,LC_YR</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
DOSE_SEQ	num	Number of dose within sequence of doses		Collected at CRF.
STARTTIM	num	Derived time study material administrati		Collected at CRF.
STOPTIM	num	Derived time infusion was interrupted		Collected at CRF.
RSTRTIM	num	Derived time infusion was restarted		Collected at CRF.
ENDTIM	num	Derived time study material administrati		Collected at CRF.
TEST_ND	char	Indicates test dose was not administered		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
STARTHR	char	Hour study material administration start		Collected at CRF.
STARTMIN	char	Minute portion of time study material ad		Collected at CRF.
STOPHR	char	Hour portion of time infusion was interr		Collected at CRF.
STOPMIN	char	Minute portion of time infusion was inte		Collected at CRF.
RSTRTHR	char	Hour portion of time infusion was restar		Collected at CRF.
RSTRTMIN	char	Minute portion of time infusion was rest		Collected at CRF.
ENDHR	char	Hour study material administration ended		Collected at CRF.
ENDMIN	char	Minute portion of time study material ad		Collected at CRF.
T_STHR	char	Hour test dose started		Collected at CRF.
T_STMIN	char	Minute portion of time test dose started		Collected at CRF.
T_ENDHR	char	Hour test dose ended		Collected at CRF.
T_ENDMIN	char	Minute portion of time test dose ended		Collected at CRF.
INTERRUP	char	Indicates if infusion was interrupted		Collected at CRF.

Variable	Type	Label	Codes	Comments
AE	char	Indicates adverse experience as reason		Collected at CRF.
ADMIN	char	Indicates administrative reason		Collected at CRF.
TOTAL_AD	char	Indicates total dose administered		Collected at CRF.
A_VIAL	num	Amount of drug withdrawn from the A vial		Collected at CRF.
B_VIAL	num	Amount of drug withdrawn from the B vial		Collected at CRF.
NOTTREAT	char	Indicates if patient was randomized but		Collected at CRF.
UNBLMAT	char	Indicates if study material unblinded		Collected at CRF.
ENROLHR	char	Hour portion of time of enrollment in st		Collected at CRF.
ENROLMIN	char	Minute portion of time of enrollment in		Collected at CRF.
ENROLTIM	num	Derived time of enrollment in study		Collected at CRF.
LC_HR	char	Hour portion of time of enrollment in st		Collected at CRF.
LC_MIN	char	Minute portion of time of enrollment in		Collected at CRF.

Variable	Type	Label	Codes	Comments
LC_ENRTM	num	Time of enrollment (site's time)		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.
STARTDY	num	Relative Derived Day study matl. admin		If STARTDT and RAND_DT not missing then perform below logic to calculate STARTDY, If STARTDT less than RAND_DT then (STARTDT - RAND_DT). Else if STARTDT is greater than equal to RAND_DT then (STARTDT- RAND_DT) +1.
ENDDY	num	Relative Derived Day study matl. admin		If ENDDT and RAND_DT not missing then perform below logic to calculate ENDDY, If ENDDT less than RAND_DT then (ENDDT - RAND_DT). Else if ENDDT is greater than equal to RAND_DT then (ENDDT- RAND_DT) +1.
ENROLDY	num	Relative Derived Day of enrollment		If ENROLDT and RAND_DT not missing then perform below logic to calculate ENROLDY, If ENROLDT less than RAND_DT then (ENROLDT - RAND_DT). Else if ENROLDT is greater than equal to RAND_DT then (ENROLDT- RAND_DT) +1.

Variable	Type	Label	Codes	Comments
LC_ENRDY	num	Relative Day of enrollment		If LC_ENRDT and RAND_DT not missing then perform below logic to calculate LC_ENRDY, If LC_ENRDT less than RAND_DT then (LC_ENRDT - RAND_DT). Else if LC_ENRDT is greater than equal to RAND_DT then (LC_ENRDT- RAND_DT) +1.

1.4.3. Assessment – ASSESS

Dataset	ASSESS
Creating program	assess.sas
Description	Assessment
Unique identifier	DUNIQUEP ,STUDYSEG ,PERIOD ,STDY_COM
Sorted by	DUNIQUEP ,STUDYSEG ,PERIOD ,STDY_COM
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,DATE_COL,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,STDYSTAT,PAGE_1,PAG_SEQ1,PAG_SEC1,PAGE_2,PAG_SEQ2,PAG_SEC2,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,INITSPEC,HOUR,MINUTE,TIME_COL</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PERIOD	char	Data collection period		Collected at CRF.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
STDY_COM	char	Indicates whether patient completed stud		Collected at CRF.
DISCINIT	char	Code for study discontinuation initiator		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.4. Crohn's Disease Activity Index – CDAIMEDS

Dataset	CDAIMEDS
Creating program	cdaimeds.sas
Description	Crohn's Disease Activity Index
Unique identifier	DUNIQUEP ,STUDYSEG ,PERIOD
Sorted by	DUNIQUEP ,STUDYSEG ,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,CRX_NAME,DOSEFREQ,ROUTE,RX_IND,RX_FREQ,CRX_NAME

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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.
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.
NO_MEDS	char	Indicates no medications were taken		Collected at CRF.
DAY_7	char	Number of doses on the 7th day prior to		Collected at CRF.
DAY_6	char	Number of doses on the 6th day prior to		Collected at CRF.
DAY_5	char	Number of doses on the 5th day prior to		Collected at CRF.
DAY_4	char	Number of doses on the 4th day prior to		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAY_3	char	Number of doses on the 3rd day prior to		Collected at CRF.
DAY_2	char	Number of doses on the 2nd day prior to		Collected at CRF.
DAY_1	char	Number of doses on the day prior to visi		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.5. Clinf – CLINF

Dataset	CLINF
Creating program	clinf.sas
Description	Clinf
Unique identifier	DUNIQUEP ,STUDYSEG ,PERIOD
Sorted by	DUNIQUEP ,STUDYSEG ,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,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,,WGT_ND,ZPEEP,ZPEEP_UN,ZPIP,ZPIP_UNI

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
HOUR	char	Hour part of time		Collected at CRF.
MINUTE	char	Minute part of time		Collected at CRF.

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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
ZWGT	num	Entered patient weight		Collected at CRF

Variable	Type	Label	Codes	Comments
ZWGT_UN	char	Units for entered patient weight		Collected at CRF
ZTEMP	num	Entered body temperature		Collected at CRF.
ZTEMPMTH	char	Method used to measure body temperature		Collected at CRF.
PE_PERF	char	Indicates if physical exam performed		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.6. Comments – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned 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.
PERIOD	char	Data collection period		Empty dataset will be submitted.
HOUR	char	Hour part of time		Empty dataset will be submitted.
MINUTE	char	Minute part of time		Empty dataset will be submitted.
PROTOCOL	char	Protocol number, derived from Unique_pat		Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Empty dataset will be submitted.
DPATIENT	char	Patient number assigned for De-identity		Empty dataset will be submitted.
TIME_COL	num	Derived time of data collection		Empty dataset will be submitted.
COMMENTS	char	Comment about patient to clarify any pre		Empty dataset will be submitted.
FOR_PAGE	char	Number(s) of CRF page(s) to which commen		Empty dataset will be submitted.
DERIV_DY	num	Relative Derived Day derived item value		Empty dataset will be submitted.

1.4.7. Ulcerative Colitis Surg/Proc – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Ulcerative Colitis Surg/Proc
Unique identifier	DUNIQUEP ,STUDYSEG ,PERIOD
Sorted by	DUNIQUEP ,STUDYSEG ,PERIOD
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,PROCSPEC,PROCMON,PROCDAY,PROCYEAR,PROCREAS, PROCDATE</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
PROCTYPE	char	Code for type of surgery/procedure		Collected at CRF.
PROC_RPT	char	Indicates if surgical/procedure report i		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.
PROCADAY	num	Relative Derived Day procedure		If PROCDATE and RAND_DT not missing then perform below logic to calculate , If PROCDATE less than RAND_DT then (PROCDATE - RAND_DT). Else if PROCDATE is greater than equal to RAND_DT then (PROCDATE- RAND_DT) +1.

1.4.8. Patient Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Patient Selection Criteria
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 non significant elements or due to missing values:</p> <p>STUDYSEG,PAGE,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,INC_1A,INC_1B,INC3C,INC3D,INC3E,INC3F,INC3G,INC3H,INC4A,INC4B,INC12A,INC12B,INC29,INC30,INC31,INC32,INC33,INC34,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 _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity for De-identity.
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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.

Variable	Type	Label	Codes	Comments
INC16	char	Criteria number 16		Collected at CRF.
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.
INC27	char	Criteria number 27		Collected at CRF.
INC28	char	Criteria number 28		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

Variable	Type	Label	Codes	Comments
CONSDADY	num	Relative Derived Day of informed consent		If CONSDATE and RAND_DT not missing then perform below logic to calculate CONSDADY, If CONSDATE less than RAND_DT then (CONSDATE - RAND_DT). Else if CONSDATE is greater than equal to RAND_DT then (CONSDATE - RAND_DT) +1.

1.4.9.Crohns – CROHNS

Dataset	CROHNS
Creating program	crohns.sas
Description	Crohns
Unique identifier	DUNIQUEP ,STUDYSEG, PERIOD
Sorted by	DUNIQUEP ,STUDYSEG, PERIOD
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,ASSESSND,NUM_CAT,CAT_A,CAT_B,CAT_C,CAT_D,CAT_E, CAT_F,DRG_THER,DRG_THR2,HEMAT,HEMAT_U,STD_WGT</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
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.
ABD_MASS	char	Indicates abdominal mass		Collected at CRF.
STOOL_NA	char	Indicates that patient has a stoma		Collected at CRF.
DIARY_EX	char	Indicates that the COMMENTS page contain		Collected at CRF.
ARTHRIT	char	Indicates if patient has arthritis		Collected at CRF.
ARTHRALG	char	Indicates that patient has arthralgia		Collected at CRF.
IRITIS	char	Indicates that the patient has iritis		Collected at CRF.
UVEITIS	char	Indicates that the patient has uveitis		Collected at CRF.

Variable	Type	Label	Codes	Comments
ERYTHEMA	char	Indicates patient has erythema nodosum		Collected at CRF.
PYODERMA	char	Indicates patient has pyoderma gangrenos		Collected at CRF.
APHTHOUS	char	Indicates patient has aphthous stomatiti		Collected at CRF.
FISSURE	char	Indicates patient has an anal fissure		Collected at CRF.
FISTULA	char	Indicates patient has an anal fistula		Collected at CRF.
ABSCCESS	char	Indicates patient has anal abscess		Collected at CRF.
OTHERFIS	char	Indicates other fistula		Collected at CRF.
WGT	num	Derived patient weight in kilograms		Collected at CRF.
ZWGT	num	Entered patient weight		Collected at CRF
ZWGT_UN	char	Units for entered patient weight		Collected at CRF
FEVER	char	Indicates that patient has or has had		Collected at CRF

Variable	Type	Label	Codes	Comments
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.10. Dzass – DZASS

Dataset	DZASS
Creating program	dzass.sas
Description	Dzass
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 non significant elements or due to missing values: PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PERIOD	char	Data collection period		Collected at CRF.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
ASSESSND	char	Indicates that assessment was not done		Collected at CRF.
PR_ASSES	char	Code for the severity of the fistula pro		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.11. Fistulas – FISTULAE

Dataset	FISTULAE
Creating program	fistulae.sas
Description	Fistulas
Unique identifier	DUNIQUEP ,C_PERIOD , STUDYSEG ,PERIOD, FIST_NUM ,FIST_LOC
Sorted by	DUNIQUEP ,C_PERIOD , STUDYSEG ,PERIOD, FIST_NUM ,FIST_LOC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,ONSETDAY,ONSETMON,ONSETYR,ONSETDT

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
FIST_NUM	num	Fistula number		Collected at CRF.
FIST_LOC	char	Code indicating the location of the fist		Collected at CRF.
PERI_STO	char	Indicates if fistula is peri-stoma		Collected at CRF.
TM_DRAIN	char	Code indicating how long the fistula has		Collected at CRF.
STATE	char	Code indicating whether fistula is drain		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.12. Laboratory Test Results – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Test Results
Unique identifier	DUNIQUEP , STUDYSEG ,PERIOD,TIME_COL,TESTCODE
Sorted by	DUNIQUEP , STUDYSEG ,PERIOD,TIME_COL,TESTCODE
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,LAB_CODE,NORM_ID, LABELNUM, DATE_COL</p> <p>Note: Protocol unplanned tests will be removed; it may reveal participant information.</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
HOURL	char	Hour part of time		Collected at CRF.

Variable	Type	Label	Codes	Comments
MINUTE	char	Minute part of time		Collected at CRF.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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			Collected at CRF.
NORMAL_L	char			Collected at CRF.
NORMAL_H	char			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.
US_RES	char	Test result converted to standard units		Collected at CRF.

Variable	Type	Label	Codes	Comments
US_UNITS	char			Collected at CRF.
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			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.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.13. Con Med for Crohn's Disease – MEDS

Dataset	MEDS
Creating program	meds.sas
Description	Con Med for Crohn's Disease
Unique identifier	DUNIQUEP ,C_PERIOD , STUDYSEG ,PERIOD
Sorted by	DUNIQUEP ,C_PERIOD , STUDYSEG ,PERIOD
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,CRX_NAME,DOSEFREQ,ROUTE,RX_IND,REAS_CHG,RXST_TIM, 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 _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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_CONT	char	Does patient continue to take concomitan		Collected at CRF.
PRIOR_EN	char	Indicates medication started prior to en		Collected at CRF.

Variable	Type	Label	Codes	Comments
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.
RXST_DY	num	Relative Derived Day patient started		If RXST_DT and RAND_DT not missing then perform below logic to calculate RXST_DY, If RXST_DT less than RAND_DT then (RXST_DT - RAND_DT). Else if RXST_DT is greater than equal to RAND_DT then (RXST_DT- RAND_DT) +1.
RXENDDY	num	Relative Derived Day patient stopped		If RXENDDT and RAND_DT not missing then perform below logic to calculate RXENDDY, If RXENDDT less than RAND_DT then (RXENDDT - RAND_DT). Else if RXENDDT is greater than equal to RAND_DT then (RXENDDT- RAND_DT) +1.

1.4.14. Immunomodulating Drug History – MEDSUMM

Dataset	MEDSUMM
Creating program	medsumm.sas
Description	Immunomodulating Drug History
Unique identifier	DUNIQUEP, C_PERIOD, STUDYSEG, PERIOD, RX_CAT, RXACSTAT
Sorted by	DUNIQUEP, C_PERIOD, STUDYSEG, PERIOD, RX_CAT, RXACSTAT
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,CRX_NAME,PREINF,WITHIN14,BEYOND14,METH_6MO, METH_3MO,MON_DISC,CUM_DOSE,CRX_NAME ,RX_NAME</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
RX_CAT	char	Code indicating medication category		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.
PREVIOUS	char	Indicates that medication was previously		Collected at CRF.
CUR_TAK	char	Indicates that medication is currently b		Collected at CRF.
NOT_ON	char	Indicates medication not administered to		Collected at CRF.
RESPONSE	char	Code for response to therapy		Collected at CRF.
TOXICITY	char	Indicates if medication was discontinued		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.15. Pdai – PDAI

Dataset	PDAI
Creating program	pdai.sas
Description	Pdai
Unique identifier	DUNIQUEP, C_PERIOD, STUDYSEG, PERIOD, PDAI_NA
Sorted by	DUNIQUEP, C_PERIOD, STUDYSEG, PERIOD, PDAI_NA
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
PDAI_NA	char	Indicates PDAI not done		Collected at CRF.
DISCHARG	char	Code for discharge		Collected at CRF.
PAIN_RES	char	Code for pain/restriction		Collected at CRF.
SEX_ACT	char	Code for restriction of sexual activity		Collected at CRF.
DIS_TYPE	char	Code for type of disease		Collected at CRF.
ANAL_CNL	char	Indicates anal canal ulceration		Collected at CRF.
DENUDAT	char	Indicates denudation of perianal skin		Collected at CRF.
INDURAT	char	Code for degree of induration		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.16. Pharm – PHARM

Dataset	PHARM
Creating program	pharm.sas
Description	Pharm
Unique identifier	DUNIQUEP, C_PERIOD, DOSE_SEQ, ADM_MAT, VIALS
Sorted by	DUNIQUEP, C_PERIOD, DOSE_SEQ, ADM_MAT, VIALS
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>STUDYSEG,PAGE,PAGE_SEQ,PAGE_SEC,PERIOD,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL,TIME_COL,DOSE_ML,MIXED_ML,LOT_NUM,RANDCODE,KIT_NUM,PREPDATE,PREP_MON,PREP_DAY,PREP_YR,NOT_PREP,NOT_ADM,PATGROUP,THERAPY,FORM_TYP, WGT,ZWGT,ZWGT_UN</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity for De-identity.
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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.
VIALS	num	Number of vials		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.17. Postae – POSTAE

Dataset	POSTAE
Creating program	postae.sas
Description	Postae
Unique identifier	DUNIQUEP, STUDYSEG, PERIOD, AEACSTAT, CONT, FREQ, SEVERITY
Sorted by	DUNIQUEP, STUDYSEG, PERIOD, AEACSTAT, CONT,FREQ, SEVERITY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,AE_CODE,CAE_DESC,AE_DESC,SERIOUS,SERIOUS1,SERIOUS2, SERIOUS3,SERIOUS6,SERIOUS7,RELATION,AE_REL2,ACTION,AE_ACT2, DECHALL2,RECHALL2,ONSETMON,ONSETDAY,ONSETYR,RESOLMON, RESOLDAY,RESOLYR, AE_LINE</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity for De-identity.
STUDYSEG	char	Study segment identifier		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 number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
WHOART	char	WHOART AE code generated by AE autoencod		Collected at CRF.
PRIMTERM	char			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.
SERIOUS5	char	AE severity code indicating initial/prol		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
ONSETHR	char	Hour portion of time of adverse event on		Collected at CRF.
ONSETMIN	char	Minute portion of time of adverse event		Collected at CRF.
RESOLHR	char	Hour portion of time of adverse event re		Collected at CRF.
RESOLMIN	char	Minute portion of time of adverse event		Collected at CRF.
C_PERIOD	char	Coded data collection period for chronol		Collected at CRF.
AE_PREF	char			Collected at CRF.
PREFTERM	char			Collected at CRF.

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

1.4.18. Procinf – PROCINF

Dataset	PROCONF
Creating program	procinf.sas
Description	Procinf
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 non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,PROCMON,PROCDAY,PROCYEAR,PROCND,SIG_EVAL,COL_EVAL, PROCDATE</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
ECG_RES	char	Indicates ECG was normal or abnormal		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.
PROCDADY	num	Relative Derived Day of procedure		If PROCDATE and RAND_DT not missing then perform below logic to calculate , If PROCDATE less than RAND_DT then (PROCDATE - RAND_DT). Else if PROCDATE is greater than equal to RAND_DT then (PROCDATE- RAND_DT) +1.

1.4.19. Reasons – REASONS

Dataset	REASONS
Creating program	reasons.sas
Description	Reasons
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 non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,TIME_COL, REASSPEC,DATE_DIS,MON_DISC,DAY_DISC,YR_DISC,DISCINIT,INITSPEC, DOD,DOD_MON,DOD_DAY,DOD_YR,PAG1,PAG1_SEQ,PAG1_LIN,PAGE_2, PAG2_SEQ,P2_LINE,PAGE_3,PAG3_SEQ,P3_LINE,PAGE_4,PAG4_SEQ, P4_LINE, DATE_COL</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
REASCODE	char	Code for reason patient did not complete		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.20. Visit – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visit
Unique identifier	DUNIQUEP ,C_PERIOD , STUDYSEG ,PERIOD
Sorted by	DUNIQUEP ,C_PERIOD , STUDYSEG ,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,TIME_COL, DATE_COL

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity 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.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.

1.4.21. Chest X-Ray – XRAY

Dataset	XRAY
Creating program	xray.sas
Description	Chest X-Ray
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 non significant elements or due to missing values:</p> <p>PAGE,PAGE_SEQ,PAGE_SEC,MONTH,DAY,YEAR,HOUR,MINUTE,DATE_COL, TIME_COL,CHEST_ND,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, CH_DATE</p>

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique _P assigned for De-identity		Randomly assigned Unique _P assigned for De-identity 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.
PROTOCOL	char	Protocol number, derived from Unique_pat		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITE	char	Site number assigned fo De-identity		Randomly assigned Site number assigned fo De-identity for De-identity.
DPATIENT	char	Patient number assigned for De-identity		Randomly assigned Patient number assigned for De-identity for De-identity.
CH_RSULT	char	Indicates chest x-ray was normal or abno		Collected at CRF.
DERIV_DY	num	Relative Derived Day derived item value		If DERIV_DT and RAND_DT not missing then perform below logic to calculate DERIV_DY, If DERIV_DT less than RAND_DT then (DERIV_DT - RAND_DT). Else if DERIV_DT is greater than equal to RAND_DT then (DERIV_DT- RAND_DT) +1.
CH_DATDY	num	Relative Derived Day of chest x-ray		If CH_DATE and RAND_DT not missing then perform below logic to calculate , If CH_DATE less than RAND_DT then (CH_DATE - RAND_DT). Else if CH_DATE is greater than equal to RAND_DT then (CH_DATE- RAND_DT) +1.