Clinical Development

Golimumab®

C0524T17

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 will not be submitted (eg. ATRACK, IVRSDOSE, RANDSTAT).
- Dataset CRESUL,IRESUL contains PK related information hence dropping the same.
- ECONOM dataset will not be submitted to protect PII.
- Dataset which is not having subject level information, will not be submitted.(eg. CSU, MEDCLASS)
- NABRESUL dataset will not be submitted as it contains Immunogenicity data.
- SUBSTDY dataset will not be submitted as it contains collection of informed consent data for a sub study and is not needed for analysis.
- PDRESUL contains sensitive immunogenicity data, will not be submitted.
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.

1.3. Data Files

The C0524T17 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0524T17 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demography – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demography
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,SUBJINIT,BIRTHDT,DMCONDT,DEMOG,BIRTHDTC,DMCONDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		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.
HEIGHT	char	Height in Centimeters		Group element to protect PII.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
RACE	char	Race		Group element to protect PII.
SEX	char	Sex		Collected at CRF.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AEDECOD, AESEQ, VISIT, AESTHR, AESTMI
Sorted by	DUSUBJID, AEDECOD, AESEQ, VISIT, AESTHR, AESTMI
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements. PAG_NAME,AETERM,AEMODIFY,AESTDT,AEENDT,AEPRSPEC,AELOCOTH,COUNTRY,AGE,RACE,SEX,AEENDTC,AESTDTC,AELOC,AEPROC,AERELPR,SAECONG,SAEDISAB,SAEDTH,SAELIFE,SAEOTH,SAEPHOS

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AESTHR	num	Start Hour of Event		Collected at CRF.
AESTMI	num	Start Minute of Event		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
AEENDY	num	Relative End Day of Event		If AEENDTC and IRLCNDTC not missing then perform below logic to calculate AEENDY,If AEENDTC less than IRLCNDTC then (AEENDTC - IRLCNDTC).Else if AEENDTC is greater than equal to IRLCNDTC then (AEENDTC- IRLCNDTC) +1.
AESTDY	num	Relative Start Day of Event		If AESTDTC and IRLCNDTC not missing then perform below logic to calculate AESTDY,If AESTDTC less than IRLCNDTC then (AESTDTC - IRLCNDTC).Else if AESTDTC is greater than equal to IRLCNDTC then (AESTDTC- IRLCNDTC) +1.

1.4.3. Past Medical History/Current Diagnoses – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Past Medical History/Current Diagnoses
Unique identifier	DUSUBJID, VISIT, CHCONDD
Sorted by	DUSUBJID, VISIT, CHCONDD
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CHCOND	num	Condition		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
CHCONDD	char	Condition		Collected at CRF.
CHHIST	char	History of Condition		Collected at CRF.
CHSMSTAT	char	Status of Smoking		Collected at CRF.

1.4.4. Concomitant Medication – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medication
Unique identifier	DUSUBJID, VISIT, CMSEQ
Sorted by	DUSUBJID, VISIT, CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,CMTERM,CMMODIFY,CMSTDT,CMENDT,DRECNO,SEQ1,SEQ2,COUNTRY,AGE,RACE,SEX,CMENDTC,CMSTDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMRTECD	num	Route Code		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
CMROUTE	char	Route Code		Collected at CRF.
CMONGO	char	Ongoing Medication		Collected at CRF.
CMREAS	char	Reason for Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMENDY	num	Relative End Day of Medication		If CMENDTC and IRLCNDTC not missing then perform below logic to calculate CMENDY,If CMENDTC less than IRLCNDTC then (CMENDTC - IRLCNDTC).Else if CMENDTC is greater than equal to IRLCNDTC then (CMENDTC- IRLCNDTC) +1.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and IRLCNDTC not missing then perform below logic to calculate CMSTDY,If CMSTDTC less than IRLCNDTC then (CMSTDTC - IRLCNDTC).Else if CMSTDTC is greater than equal to IRLCNDTC then (CMSTDTC- IRLCNDTC) +1.

1.4.5. Ulcerative Colitis Surgeries/Procedures – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Ulcerative Colitis Surgeries/Procedures
Unique identifier	DUSUBJID, VISIT, PRSEQ
Sorted by	DUSUBJID, VISIT, PRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements. PAG_NAME,PRSPEC,PRREASON,PRSTDT,PRENDT,COUNTRY,AGE,RACE,SEX,PRENDTC,PRSTDTC,PRTYPE, PRONGO

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PRSEQ	num	Sequence Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PRINOUT	char	In-Patient or Out-Patient		Collected at CRF.
PRENDY	num	Relative End Day		If PRENDTC and IRLCNDTC not missing then perform below logic to calculate PRENDY,If PRENDTC less than IRLCNDTC then (PRENDTC - IRLCNDTC).Else if PRENDTC is greater than equal to IRLCNDTC then (PRENDTC- IRLCNDTC) +1.
PRSTDY	num	Relative Procedure Day		If PRSTDTC and IRLCNDTC not missing then perform below logic to calculate PRSTDY,If PRSTDTC less than IRLCNDTC then (PRSTDTC - IRLCNDTC).Else if PRSTDTC is greater than equal to IRLCNDTC then (PRSTDTC- IRLCNDTC) +1.

1.4.6. Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Selection Criteria
Unique identifier	DUSUBJID, VISIT, INCRIT, EXCRIT
Sorted by	DUSUBJID, VISIT, INCRIT, EXCRIT
Notes	Below listed variables will be dropped from dataset due to non significant element. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CRSEQ	num	Criterion Sequence		Collected at CRF.
INCRIT	char	Inclusion Criterion Not Met		Collected at CRF.
EXCRIT	char	Exclusion Criterion Present		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.7. Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements. PAG_NAME,DTDT,DTSPEC,DTCAUSE,COUNTRY,AGE,RACE,SEX,DTDTC,DTAUTP

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.8. Ulcerative Colitis Disease History – DISEASEHX

Dataset	DISEASHX
Creating program	diseashx.sas
Description	Ulcerative Colitis Disease History
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,DHDXDT,COUNTRY,AGE,RACE,SEX,DHDXDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DHSYMPYR	num	Duration of Symptoms in Years		Collected at CRF.
DHSYMPMO	num	Duration of Symptoms in Months		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DHDXDY	num	Relative Day of Diagnosis		If DHDXDTC and IRLCNDTC not missing then perform below logic to calculate DHDXDY,If DHDXDTC less than IRLCNDTC then (DHDXDTC - IRLCNDTC).Else if DHDXDTC is greater than equal to IRLCNDTC then (DHDXDTC- IRLCNDTC) +1.

1.4.9. Study Participation Status – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Study Participation Status
Unique identifier	DUSUBJID, VISIT, DSDSC, DSTDC
Sorted by	DUSUBJID, VISIT, DSDSC, DSTDC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,DSTDCDT,DSTRSOTH,DSDSCDT,DSRSOTH,DSUNBDT,COUNTRY, AGE,RACE,SEX,DSDSCDTC,DSTDCDTC,DSUNBDTC,DSREAS,DSTREAS

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSDSC	char	Study Participation Discontinuation		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
DSDSCDY	num	Relative Day of Study Discontinuation		If DSDSCDTC and IRLCNDTC not missing then perform below logic to calculate DSDSCDY,If DSDSCDTC less than IRLCNDTC then (DSDSCDTC - IRLCNDTC).Else if DSDSCDTC is greater than equal to IRLCNDTC then (DSDSCDTC- IRLCNDTC) +1.
DSTDCDY	num	Relative Day of Treat. Discontinuation		If DSTDCDTC and IRLCNDTC not missing then perform below logic to calculate DSTDCDY,If DSTDCDTC less than IRLCNDTC then (DSTDCDTC - IRLCNDTC).Else if DSTDCDTC is greater than equal to IRLCNDTC then (DSTDCDTC- IRLCNDTC) +1.
DSUNBDY	num	Relative Day of Treatment Unblinding		If DSUNBDTC and IRLCNDTC not missing then perform below logic to calculate DSUNBDY,If DSUNBDTC less than IRLCNDTC then (DSUNBDTC - IRLCNDTC).Else if DSUNBDTC is greater than equal to IRLCNDTC then (DSUNBDTC- IRLCNDTC) +1.

1.4.10. Endoscopy – ENDOSCOP

Dataset	ENDOSCOP
Creating program	endoscop.sas
Description	Endoscopy
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,ENDT,COUNTRY,AGE,RACE,SEX,ENDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
ENMAYO	num	Endoscopy Findings		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
ENMAYOC	char	Endoscopy Findings		Collected at CRF.
ENDISEXT	char	Extent of Disease		Collected at CRF.
ENDY	num	Relative Day of Endoscopy		If ENDTC and IRLCNDTC not missing then perform below logic to calculate ENDY,If ENDTC less than IRLCNDTC then (ENDTC - IRLCNDTC).Else if ENDTC is greater than equal to IRLCNDTC then (ENDTC-IRLCNDTC) +1.

1.4.11. Endoscopy Type – ENDOTYPE

Dataset	ENDOTYPE
Creating program	endotype.sas
Description	Endoscopy Type
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
ENTYPE	char	Endoscopy Type		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.12. EQ-5D Health Questionnaire – EQ5D

Dataset	EQ5D
Creating program	eq5d.sas
Description	EQ-5D Health Questionnaire
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
EQ5DMB	num	EQ5D Mobility		Collected at CRF.
EQ5DSC	num	EQ5D Self Care		Collected at CRF.
EQ5DUA	num	EQ5D Usual Activities		Collected at CRF.

Variable	Type	Label	Codes	Comments
EQ5DPD	num	EQ5D Pain/Discomfort		Collected at CRF.
EQ5DAD	num	EQ5D Anxiety/Depression		Collected at CRF.
EQHSS	num	Health State Scale		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
EQ5DMBC	char	EQ5D Mobility		Collected at CRF.
EQ5DSCC	char	EQ5D Self Care		Collected at CRF.
EQ5DUAC	char	EQ5D Usual Activities		Collected at CRF.
EQ5DPDC	char	EQ5D Pain/Discomfort		Collected at CRF.
EQ5DADC	char	EQ5D Anxiety/Depression		Collected at CRF.
EQHSSND	char	Health State Scale Not Done		Collected at CRF.

1.4.13. Study Agent Administration – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Study Agent Administration
Unique identifier	DUSUBJID, VISIT, EXSEQ
Sorted by	DUSUBJID, VISIT, EXSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,EXCNTRID,EXSTDT,EXSITE_V,COUNTRY,AGE,RACE,SEX,EXSTDTC,EXTOTADM

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXSTHR	num	Start Hour of Dose, 24 Hour Clock		Collected at CRF.
EXSTMI	num	Start Minute of Dose, 24 Hour Clock		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
EXND	char	Dose Not Done		Collected at CRF.
EXSA	char	Study Agent		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXSTDY	num	Relative Start Day of Dose		If EXSTDTC and IRLCNDTC not missing then perform below logic to calculate EXSTDY,If EXSTDTC less than IRLCNDTC then (EXSTDTC - IRLCNDTC).Else if EXSTDTC is greater than equal to IRLCNDTC then (EXSTDTC- IRLCNDTC) +1.

1.4.14. UC Histological Response Biopsy Assessment – HISTOLGY

Dataset	HISTOLGY
Creating program	histolgy.sas
Description	UC Histological Response Biopsy Assessment
Unique identifier	DUSUBJID, VISIT, HISTRCHG, HICII, HIEOSLPA, HINPHLPB, HINPHEPI, HICRYPTD, HIERULC, NO_RSLT
Sorted by	DUSUBJID, VISIT, HISTRCHG, HICII, HIEOSLPA, HINPHLPB, HINPHEPI, HICRYPTD, HIERULC, NO_RSLT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,ACCNUM,SAMPNUM,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
HISTRCHG	char	Structural change		Collected at CRF.
HICII	char	Chronic Inflammatory Infiltrate		Collected at CRF.
HIEOSLPA	char	Eosinophil infltrtn in Lamina Propria(A)		Collected at CRF.
HINPHLPB	char	Neutrophil infltrtn in Lamina Propria(B)		Collected at CRF.
HINPHEPI	char	Neutrophils in Epithelium		Collected at CRF.
HICRYPTD	char	Crypt Destruction		Collected at CRF.

Variable	Type	Label	Codes	Comments
HIERULC	char	Presence of erosion/ulceration		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
HICIID	char	Chronic Inflammatory Infiltrate		Collected at CRF.
HICRYPDD	char	Crypt Destruction		Collected at CRF.
HIEOSLPD	char	Eosinophil infltrtn in Lamina Propria(A)		Collected at CRF.
HIERULCD	char	Presence of erosion/ulceration		Collected at CRF.
HINPHEPD	char	Neutrophils in Epithelium		Collected at CRF.
HINPHLPD	char	Neutrophil infltrtn in Lamina Propria(B)		Collected at CRF.

Variable	Type	Label	Codes	Comments
HISTRCHD	char	Structural change		Collected at CRF.
NO_RSLT	char	No results		Collected at CRF.

1.4.15. Hospitalization – HOSPIN

Dataset	HOSPIN
Creating program	hospin.sas
Description	Hospitalization
Unique identifier	DUSUBJID, VISIT, HOSEQ
Sorted by	DUSUBJID, VISIT, HOSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,HOADMDT,HODISDT,HODIAG,COUNTRY,AGE,RACE,SEX,HOADMDTC,HODISDTC,HONODSCH

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
HOSEQ	num	Hospitalization Sequence		Collected at CRF.
HOICUDYS	num	Total Number of Days in ICU		Collected at CRF.
HOTPNDYS	num	Number of Days TPN Received		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOTFDYS	num	Number of Days of Tube Feeding		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
HODRHOSP	char	Disease Related Hospitalization		Collected at CRF.
HOPRPERF	char	Surgery or Procedure Performed		Collected at CRF.
HOTFNA	char	Tube Feeding Not Applicable		Collected at CRF.
HOTPNNA	char	TPN Not Applicable		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOADMDY	num	Relative Hospital Admission Day		If HOADMDTC and IRLCNDTC not missing then perform below logic to calculate HOADMDY,If HOADMDTC less than IRLCNDTC then (HOADMDTC - IRLCNDTC).Else if HOADMDTC is greater than equal to IRLCNDTC then (HOADMDTC- IRLCNDTC) +1.
HODISDY	num	Relative Hospital Discharge Day		If HODISDTC and IRLCNDTC not missing then perform below logic to calculate HODISDY,If HODISDTC less than IRLCNDTC then (HODISDTC - IRLCNDTC).Else if HODISDTC is greater than equal to IRLCNDTC then (HODISDTC- IRLCNDTC) +1.

1.4.16. Quality of Life in Inflammatory Bowel Disease Questionnaire – IBDQSCR

Dataset	IBDQSCR
Creating program	ibdqscr.sas
Description	Quality of Life in Inflammatory Bowel Disease Questionnaire
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
IBDQ_1	num	Score for IBDQ Question 1		Collected at CRF.
IBDQ_2	num	Score for IBDQ Question 2		Collected at CRF.
IBDQ_3	num	Score for IBDQ Question 3		Collected at CRF.
IBDQ_4	num	Score for IBDQ Question 4		Collected at CRF.
IBDQ_5	num	Score for IBDQ Question 5		Collected at CRF.
IBDQ_6	num	Score for IBDQ Question 6		Collected at CRF.
IBDQ_7	num	Score for IBDQ Question 7		Collected at CRF.
IBDQ_8	num	Score for IBDQ Question 8		Collected at CRF.
IBDQ_9	num	Score for IBDQ Question 9		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQ_10	num	Score for IBDQ Question 10		Collected at CRF.
IBDQ_11	num	Score for IBDQ Question 11		Collected at CRF.
IBDQ_12	num	Score for IBDQ Question 12		Collected at CRF.
IBDQ_13	num	Score for IBDQ Question 13		Collected at CRF.
IBDQ_14	num	Score for IBDQ Question 14		Collected at CRF.
IBDQ_15	num	Score for IBDQ Question 15		Collected at CRF.
IBDQ_16	num	Score for IBDQ Question 16		Collected at CRF.
IBDQ_17	num	Score for IBDQ Question 17		Collected at CRF.
IBDQ_18	num	Score for IBDQ Question 18		Collected at CRF.
IBDQ_19	num	Score for IBDQ Question 19		Collected at CRF.
IBDQ_20	num	Score for IBDQ Question 20		Collected at CRF.
IBDQ_21	num	Score for IBDQ Question 21		Collected at CRF.
IBDQ_22	num	Score for IBDQ Question 22		Collected at CRF.
IBDQ_23	num	Score for IBDQ Question 23		Collected at CRF.
IBDQ_24	num	Score for IBDQ Question 24		Collected at CRF.
IBDQ_25	num	Score for IBDQ Question 25		Collected at CRF.
IBDQ_26	num	Score for IBDQ Question 26		Collected at CRF.
IBDQ_27	num	Score for IBDQ Question 27		Collected at CRF.
IBDQ_28	num	Score for IBDQ Question 28		Collected at CRF.
IBDQ_29	num	Score for IBDQ Question 29		Collected at CRF.
IBDQ_30	num	Score for IBDQ Question 30		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQ_31	num	Score for IBDQ Question 31		Collected at CRF.
IBDQ_32	num	Score for IBDQ Question 32		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.17. Ivrsmayo – IVRSMAYO

Dataset	IVRSMAYO
Creating program	ivrsmayo.sas
Description	Ivrsmayo
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,IMMYODT,COUNTRY,AGE,RACE,SEX,IMMYODTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
IMSTLFRQ	num	Stool Frequency		Collected at CRF.
IMRBLD	num	Rectal Bleeding		Collected at CRF.
IMPGA	num	Physician's Global Assessment		Collected at CRF.
IMENDFND	num	Endoscopy Score		Collected at CRF.
IMMAYOSC	num	IVRS Calculated Mayo Score		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
IMENDFNC	char	Endoscopy Score		Collected at CRF.
IMRBLDC	char	Rectal Bleeding		Collected at CRF.
IMSTLFRC	char	Stool Frequency		Collected at CRF.
IMPGAC	char	Physician's Global Assessment		Collected at CRF.
IM5ASAST	char	5-ASA Status		Collected at CRF.
IMMYODY	num	Relative Mayo Score Call Day		If IMMYODTC and IRLCNDTC not missing then perform below logic to calculate IMMYODY,If IMMYODTC less than IRLCNDTC then (IMMYODTC - IRLCNDTC).Else if IMMYODTC is greater than equal to IRLCNDTC then (IMMYODTC- IRLCNDTC) +1.

1.4.18. IVRS Randomization – IVRSRAND

Dataset	IVRSRAND
Creating program	ivrsrand.sas
Description	IVRS Randomization
Unique identifier	DUSUBJID, TRTCD
Sorted by	DUSUBJID, TRTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,IRSUBID1,IRLCNDT,IRLCENTM,IRSECNDS,IRIMB1,IRIMB2,IRIMB3,IRIMB4,IRPROB1,IRPROB2,IRPROB3,IRPROB4,IRRNDVAL,IRRNDVLC,IRRNDSD,IRTACRIT,COUNTRY,AGE,RACE,SEX,IRLCNDTC,IRPART,IRSEQ,IRDOSDEC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TRTCD	num	Treatment Group		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
TRTGRP	char	Decode of TRTCD		Collected at CRF.

1.4.19. Lab Results – LAB

Dataset	LAB
Creating program	lab.sas
Description	Lab Results
Unique identifier	DUSUBJID, VISIT, LBSEQ, LBCAT, LBSCAT, LBTSTCD, LBACTTM, LBSTRES
Sorted by	DUSUBJID, VISIT, LBSEQ, LBCAT, LBSCAT, LBTSTCD, LBACTTM, LBSTRES
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements. PAG_NAME,LBLBLNUM,LBDT,COUNTRY,AGE,RACE,SEX,LBDTC,LBCLNSG, LBCOM,LBID,LBKTTYP,LBLOQL

Variable	Type	Label	Codes	Comments
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTHR	num	Hour of Collection		Collected at CRF.
LBACTMI	num	Minute of Collection		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LBEVQL	char	Event Qualifier		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and IRLCNDTC not missing then perform below logic to calculate LBDY,If LBDTC less than IRLCNDTC then (LBDTC - IRLCNDTC).Else if LBDTC is greater than equal to IRLCNDTC then (LBDTC-IRLCNDTC) +1.

1.4.20. Mayo Diary – MAYODIAR

Dataset	MAYODIAR
Creating program	mayodiar.sas
Description	Mayo Diary
Unique identifier	DUSUBJID, VISIT, MDPLNTP
Sorted by	DUSUBJID, VISIT, MDPLNTP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,MDDIADT,COUNTRY,AGE,RACE,SEX,MDDIADTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MDNUMSTL	num	Number of Stools		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
MDAMTBS	char	Amount of Blood in Stools		Collected at CRF.
MDND	char	Not Done		Collected at CRF.
MDPLNTP	char	Planned Timepoint		Collected at CRF.
MDDIADY	num	Relative Diary Card Day		If MDDIADTC and IRLCNDTC not missing then perform below logic to calculate MDDIADY,If MDDIADTC less than IRLCNDTC then (MDDIADTC - IRLCNDTC).Else if MDDIADTC is greater than equal to IRLCNDTC then (MDDIADTC- IRLCNDTC) +1.

1.4.21. Screening Mayo Diary Card – MAYOSCR

Dataset	MAYOSCR
Creating program	mayoscr.sas
Description	Screening Mayo Diary Card
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MYSTL1	num	Stool Freq Day 1		Collected at CRF.
MYSTL2	num	Stool Freq Day 2		Collected at CRF.
MYSTL3	num	Stool Freq Day 3		Collected at CRF.
MYSTLSUM	num	Stool Frequency Sum		Collected at CRF.
MYSTLAVG	num	Average Stool Frequency		Collected at CRF.
MYSTLREM	num	Number of Stools in Remission		Collected at CRF.
MYSTLDIF	num	Stool Difference (remission - average)		Collected at CRF.
MYSTLNUM	num	Rounded Stool Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
MYSTLFRQ	num	Stool Frequency Score		Collected at CRF.
MYBLD1	num	Rectal Bleeding Day 1		Collected at CRF.
MYBLD2	num	Rectal Bleeding Day 2		Collected at CRF.
MYBLD3	num	Rectal Bleeding Day 3		Collected at CRF.
MYBLDSUM	num	Sum Rectal Bleeding Scores		Collected at CRF.
MYBLDAVG	num	Average of Rectal Bleeding Scores		Collected at CRF.
MYRBLD	num	Rectal Bleeding Score		Collected at CRF.
MYPGA	num	Physician Global Assessment		Collected at CRF.
MYPSCORE	num	Partial Mayo Score		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
MYPGAC	char	Physician Global Assessment		Collected at CRF.

1.4.22. 5-ASA Increase in Oral Dosage – MEDCHNG

Dataset	MEDCHNG
Creating program	medchng.sas
Description	5-ASA Increase in Oral Dosage
Unique identifier	DUSUBJID, VISIT, MCCAT, MCCHNG, MCINCR
Sorted by	DUSUBJID, VISIT, MCCAT, MCCHNG, MCINCR
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,MCCHGDT,COUNTRY,AGE,RACE,SEX,MCCHGDTC,MCRSN

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
MCCAT	char	Medication Type		Collected at CRF.
MCCHNG	char	Medication Change		Collected at CRF.
MCINCR	char	Medication Increase		Collected at CRF.
MCCHGDY	num	Relative Medication Change Day		If MCCHGDTC and IRLCNDTC not missing then perform below logic to calculate MCCHGDY,If MCCHGDTC less than IRLCNDTC then (MCCHGDTC - IRLCNDTC).Else if MCCHGDTC is greater than equal to IRLCNDTC then (MCCHGDTC- IRLCNDTC) +1.

1.4.23. Baseline Corticosteroid Medication Review – MEDREVIEW

Dataset	MEDRVIEW
Creating program	medrview.sas
Description	Baseline Corticosteroid Medication Review
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements. PAG_NAME,CMTERM,CMMODIFY,MRCDT,DRECNO,SEQ1,SEQ2,CODSTAT,COUNTRY,AGE,RACE,SEX,MRCDTC,MRTYPE

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MRSEQ	num	Medication Sequence Number		Collected at CRF.
MRDOSE	num	Dose		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
MRCAT	char	Medication Category		Collected at CRF.
MRDOSCH	char	Medication Reason for Change		Collected at CRF.
MRDUNIT	char	Dose Unit		Collected at CRF.
MRFREQ	char	Frequency		Collected at CRF.
MRPMST	char	Start Prohibited Medications		Collected at CRF.
MRROUTE	char	Medication Route		Collected at CRF.
MRCDY	num	Relative Medication Change Day		If MRCDTC and IRLCNDTC not missing then perform below logic to calculate MRCDY,If MRCDTC less than IRLCNDTC then (MRCDTC - IRLCNDTC).Else if MRCDTC is greater than equal to IRLCNDTC then (MRCDTC- IRLCNDTC) +1.

1.4.24. SF-36 Health Survey – QOL

Dataset	QOL
Creating program	qol.sas
Description	SF-36 Health Survey
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
QLGH1	num	Score for QOL question 1		Collected at CRF.
QLHT	num	Score for QOL question 2		Collected at CRF.
QLPF01	num	Score for QOL question 3A		Collected at CRF.
QLPF02	num	Score for QOL question 3B		Collected at CRF.
QLPF03	num	Score for QOL question 3C		Collected at CRF.
QLPF04	num	Score for QOL question 3D		Collected at CRF.
QLPF05	num	Score for QOL question 3E		Collected at CRF.
QLPF06	num	Score for QOL question 3F		Collected at CRF.
QLPF07	num	Score for QOL question 3G		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLPF08	num	Score for QOL question 3H		Collected at CRF.
QLPF09	num	Score for QOL question 3I		Collected at CRF.
QLPF10	num	Score for QOL question 3J		Collected at CRF.
QLRP1	num	Score for QOL question 4A		Collected at CRF.
QLRP2	num	Score for QOL question 4B		Collected at CRF.
QLRP3	num	Score for QOL question 4C		Collected at CRF.
QLRP4	num	Score for QOL question 4D		Collected at CRF.
QLRE1	num	Score for QOL question 5A		Collected at CRF.
QLRE2	num	Score for QOL question 5B		Collected at CRF.
QLRE3	num	Score for QOL question 5C		Collected at CRF.
QLSF1	num	Score for QOL question 6		Collected at CRF.
QLBP1	num	Score for QOL question 7		Collected at CRF.
QLBP2	num	Score for QOL question 8		Collected at CRF.
QLVT1	num	Score for QOL question 9A		Collected at CRF.
QLMH1	num	Score for QOL question 9B		Collected at CRF.
QLMH2	num	Score for QOL question 9C		Collected at CRF.
QLMH3	num	Score for QOL question 9D		Collected at CRF.
QLVT2	num	Score for QOL question 9E		Collected at CRF.
QLMH4	num	Score for QOL question 9F		Collected at CRF.
QLVT3	num	Score for QOL question 9G		Collected at CRF.
QLMH5	num	Score for QOL question 9H		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLVT4	num	Score for QOL question 9I		Collected at CRF.
QLSF2	num	Score for QOL question 10		Collected at CRF.
QLGH2	num	Score for QOL question 11A		Collected at CRF.
QLGH3	num	Score for QOL question 11B		Collected at CRF.
QLGH4	num	Score for QOL question 11C		Collected at CRF.
QLGH5	num	Score for QOL question 11D		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.25. Resection – RESECT

Dataset	RESECT
Creating program	resect.sas
Description	Resection
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,RSMO,RSYR,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
RSPROC	char	Procedure Type		Collected at CRF.
RSTYPE	char	Resection Type		Collected at CRF.

1.4.26. Drug History – RX_HX

Dataset	RX_HX
Creating program	rx_hx.sas
Description	Drug History
Unique identifier	DUSUBJID, VISIT, CMDECOD, RXCAT, RXTIMUSD
Sorted by	DUSUBJID, VISIT, CMDECOD, RXCAT, RXTIMUSD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,CMTERM,CMMODIFY,DRECNO,SEQ1,SEQ2,CODSTAT,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
RXSEQ	num	Medication Sequence Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
RXCAT	char	Medication Category		Collected at CRF.
RXTIMUSD	char	Length of Time Taken		Collected at CRF.

1.4.27. UC Medication History – RXCLASS

Dataset	RXCLASS
Creating program	rxclass.sas
Description	UC Medication History
Unique identifier	DUSUBJID, VISIT, RXUCART, RXUCB1
Sorted by	DUSUBJID, VISIT, RXUCART, RXUCB1
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,RXUCOSP1,RXUCOSP2,RXUCOSP3,COUNTRY,AGE,RACE,SEX,RXUCOTH1,RXUCOTH2,RXUCOTH3

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
RXUCART	char	Arthritis		Collected at CRF.
RXUCB1	char	Immunomodulators Adequate Treatment		Collected at CRF.
RXUCB2	char	Immunomodulators Response Failure		Collected at CRF.
RXUCB3	char	Immunomodulators Medical Complications		Collected at CRF.
RXUCC1	char	Oral Corticosteroids Adequate Treatment		Collected at CRF.
RXUCC2	char	Oral Corticosteroids Response Failure 1		Collected at CRF.
RXUCC3	char	Oral Corticosteroids Med Complications		Collected at CRF.
RXUCC4	char	Oral Corticosteroids Response Failure 2		Collected at CRF.
RXUCD1	char	5-Aminosaliscylates Adequate Treatment		Collected at CRF.
RXUCD2	char	5-Aminosaliscylates Response Failure		Collected at CRF.
RXUCD3	char	5-Aminosaliscylates Med Complications		Collected at CRF.
RXUCENZ	char	Liver Enzymes		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXUCHR	char	Hypersensitivity		Collected at CRF.
RXUCIN	char	Interstitial Nephritis		Collected at CRF.
RXUCLEU	char	Leukopenia		Collected at CRF.
RXUCOSN	char	Osteonecrosis		Collected at CRF.
RXUCOSP	char	Osteoporosis		Collected at CRF.
RXUCPAN	char	Pancreatitis		Collected at CRF.
RXUCPSY	char	Psychosis		Collected at CRF.
RXUCUDM	char	Uncontrolled diabetes mellitus		Collected at CRF.

1.4.28. Adverse Events Related to Final Blood Draw – SEVENT

Dataset	SEVENT
Creating program	sevent.sas
Description	Adverse Events Related to Final Blood Draw
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values or due to non significant elements. PAG_NAME,AETERM,AEMODIFY,SESTDT,SEENDT,COUNTRY,AGE,RACE,SEX,SEENDTC,SESTDTC,SECONG,SEDISAB,SEDTH,SELIFE,SEOTH,SEPHOS

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
SESEQ	num	Sequence Number		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
SECODE	char	Code for Reported Term		Collected at CRF.
SENS	char	Not Serious		Collected at CRF.
SEONGO	char	Ongoing Blood Draw Adverse Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEREL	char	Relationship		Collected at CRF.
SERHOS	char	Requires/Prolongs Hospitalization		Collected at CRF.
SEENDY	num	Relative End Day of Event		If SEENDTC and IRLCNDTC not missing then perform below logic to calculate SEENDY,If SEENDTC less than IRLCNDTC then (SEENDTC - IRLCNDTC).Else if SEENDTC is greater than equal to IRLCNDTC then (SEENDTC- IRLCNDTC) +1.
SESTDY	num	Relative Start Day of Event		If SESTDTC and IRLCNDTC not missing then perform below logic to calculate SESTDY,If SESTDTC less than IRLCNDTC then (SESTDTC - IRLCNDTC).Else if SESTDTC is greater than equal to IRLCNDTC then (SESTDTC- IRLCNDTC) +1.

1.4.29. Subject Status – SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,SSDSCDT,SSRSOTH,COUNTRY,AGE,RACE,SEX,SSDSCDTC,SSREAS

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
SSENT	char	Subject Entered Next Study Period		Collected at CRF.

1.4.30. Tuberculosis Testing – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Tuberculosis Testing
Unique identifier	DUSUBJID, VISIT, TBSSATB, TBBCGYR
Sorted by	DUSUBJID, VISIT, TBSSATB, TBBCGYR
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,TBADMDT,TBADMSP,TBRDDT,TBREADSP,TBCXRDT,COUNTRY,AGE,RACE,SEX,TBADMDTC,TBCXRDTC,TBRDDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TBSEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TBBCGYR	num	Year of Previous BCG Vaccination		Collected at CRF.
TBRSLT	num	PPD Result		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
TBADM	char	PPD Administrator		Collected at CRF.
TBATB	char	History of Active TB		Collected at CRF.
TBBCG	char	Previous BCG Vaccination		Collected at CRF.
TBCXRES	char	Chest X-Ray Result		Collected at CRF.
TBLTB	char	History of Latent TB		Collected at CRF.
TBRCATB	char	Recent Contact to Active TB		Collected at CRF.
TBREAD	char	PPD Reader		Collected at CRF.

Variable	Type	Label	Codes	Comments
TBRPN	char	PPD Test Result Positive or Negative		Collected at CRF.
TBSSATB	char	Signs or Symptoms of Active TB		Collected at CRF.
TBTRTRQ	char	Treatment Required		Collected at CRF.
TBADMDY	num	Relative Day of PPD Administration		If TBADMDTC and IRLCNDTC not missing then perform below logic to calculate TBADMDY,If TBADMDTC less than IRLCNDTC then (TBADMDTC - IRLCNDTC).Else if TBADMDTC is greater than equal to IRLCNDTC then (TBADMDTC- IRLCNDTC) +1.
TBCXRDY	num	Relative Chest X-Ray Day		If TBCXRDTC and IRLCNDTC not missing then perform below logic to calculate TBCXRDY,If TBCXRDTC less than IRLCNDTC then (TBCXRDTC - IRLCNDTC).Else if TBCXRDTC is greater than equal to IRLCNDTC then (TBCXRDTC- IRLCNDTC) +1.
TBRDDY	num	Relative Day PPD Read		If TBRDDTC and IRLCNDTC not missing then perform below logic to calculate TBRDDY,If TBRDDTC less than IRLCNDTC then (TBRDDTC - IRLCNDTC).Else if TBRDDTC is greater than equal to IRLCNDTC then (TBRDDTC- IRLCNDTC) +1.

1.4.31. Visit Information – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visit Information
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements. PAG_NAME,VISITDT,COUNTRY,AGE,RACE,SEX,VISITDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VIMAINST	char	Maintenance Study		Collected at CRF.
VISITDY	num	Relative Day of Subject Visit		If VISITDTC and IRLCNDTC not missing then perform below logic to calculate VISITDY,If VISITDTC less than IRLCNDTC then (VISITDTC - IRLCNDTC).Else if VISITDTC is greater than equal to IRLCNDTC then (VISITDTC- IRLCNDTC) +1.

1.4.32. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DUSUBJID, VISIT, VSTEST
Sorted by	DUSUBJID, VISIT, VSTEST
Notes	Below listed variables will be dropped from dataset due to non significant elements. PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSSEQ	num	Vital Signs Sequence		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSTSTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSSTRES	char	Result in Standard Units		Group element to protect PII.
VSSTUNIT	char	Standard Units		Collected at CRF.