

Clinical Development

Infliximab

C0168T72

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
- No pharmacogenetic data will be provided
- 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
- Subjects with ages above 89 will be assigned to 90+
- 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.
- lot,kit number will not be provided.
- Accession 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 which are redundant regarding analysis will not be provided (e.g. ZSTATAGE, DOSPFLE).
- Pharmacokinetic/Pharmacodynamic dataset will not be submitted (eg. CRESUL, DERVDAUC, DERVDPK, PDRESULT).
- Dataset which are empty will not be submitted (e.g. DEATH, SCRNDTH, and PRESENT).
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.
- Screen failure data sets will not be submitted (e.g. SCRNAE, SCRNATRK, SCRNCRIT, SCRNDEMO, SCRNHIST, SCRNNIMCH, SCRNLAB, SCRNVIS)
- BIOMARKER datasets will not be submitted (e.g. BBMSRESL, BBMURES)
- Surgery dataset will not be submitted (e.g. CONPROC)
- Dataset used for data reconciliation, CRF page information will not be submitted (e.g. ATRACK, LSCNA).

1.3. Data Files

The C0168T72 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0168T72 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
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,AGEM,DMCONDT,BIRTHDTC,DMCONDTC, DEMOG

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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	Deidentify 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		Element will be grouped to protect PII:
SEX	char	Sex		Collected at CRF.
DMCONDY	num	Relative Day of Informed Consent		If DMCONDTC and IRLCNDTC not missing then perform below logic to calculate DMCONDY, If DMCONDTC less than IRLCNDTC then (DMCONDTC - IRLCNDTC). Else if DMCONDTC is greater than equal to IRLCNDTC then (DMCONDTC- IRLCNDTC) +1.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AECD
Sorted by	DUSUBJID, AECD
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>PAG_NAME, AETERM, AEMODIFY, AESTDT, AEENDT, AEPRSPEC, CODSTAT, MDAE CD, COUNTRY, AGE, AGEM, RACE, SEX, AEPROC, SAECONG, SAEDISAB, SAEDTH, SA ELIFE, SAEOTH, SAEPHOS, SAERHOS, AEENDTC, AESTDTC</p>

Variable	Type	Label	Codes	Comments
AECD	char	WHOART Adverse Event Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
MDV	char	MEDDRA Version		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.
AECTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECT	char	Infection		Collected at CRF.

Variable	Type	Label	Codes	Comments
INFECTRT	char	Infection Treated		Collected at CRF.
SAENS	char	Not Serious		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. Bone Age-Wrist X-Ray – BONEAGE

Dataset	BONEAGE
Creating program	boneage.sas
Description	Bone Age - Wrist X-Ray
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,BADT,COUNTRY,AGE,AGEM,RACE,SEX, BADTC, BAAGEM

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
BAAGEY	Num	Bone age (years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
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.
BADY	num	Relative Day of X-ray		If BADTC and IRLCNDTC not missing then perform below logic to calculate BADY, If BADTC less than IRLCNDTC then (BADTC - IRLCNDTC). Else if BADTC is greater than equal to IRLCNDTC then (BADTC - IRLCNDTC) +1.

1.4.4. Medical History – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Medical History
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,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.

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.
CHCONDD	char	Condition		Collected at CRF.
CHHIST	char	History of Condition		Collected at CRF.
CHSMSTAT	char	Status of Smoking		Collected at CRF.

1.4.5. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE, AGEM,RACE,SEX, CMENDTC, CMSTDT, PAGE_SEQ

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.

1.4.6. Inclusion/Exclusion Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Inclusion/Exclusion Criteria
Unique identifier	DUSUBJID, EVENT_ID, INCRIT
Sorted by	DUSUBJID, EVENT_ID, INCRIT
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,COUNTRY,AGE,AGEM,RACE,SEX, EXCRIT

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.
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.

1.4.7. Disease History – DISEASHX

Dataset	DISEASHX
Creating program	diseashx.sas
Description	Disease History
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,DHDXDT,COUNTRY,AGE,AGEM,RACE,SEX, DHDXDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DHSYMYR	num	Duration of symptoms (years)		Collected at CRF.
DHSYMMO	num	Duration of symptoms (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.
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.
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.

1.4.8. Discontinuation Status – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Discontinuation Status
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,RACE,SEX,DSTWSTD, DSDSCDTC, DSTDCDTC

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.
DSEREAS	char	Rsn for Study Participation Termination		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
DSTREAS	char	Reason for 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 Study Trt Discont		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.

1.4.9. Endoscopy Information – ENDOSCOP

Dataset	ENDOSCOP
Creating program	endoscop.sas
Description	Endoscopy Information
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,AGEM,RACE,SEX, ENDC

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.

1.4.10. Study Agent Administration – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Study Agent Administration
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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: PAG_NAME,EXLOTNO1,EXLOTNO2,EXLOTNO3,EXSTDTC,COUNTRY,AGE,AGEM, RACE,SEX, EXSTDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXVWDRWN	num	Volume Withdrawn From Vial(s) in mL		Collected at CRF.
EXVPREP	num	Volume Prepared in Milliliters		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.

Variable	Type	Label	Codes	Comments
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
EXENHR	num	End Hour of Dose, 24 Hour Clock		Collected at CRF.
EXENMI	num	End Minute of Dose, 24 Hour Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
AMTADM	num	Amount Administered		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.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
EXINRPT	char	Infusion Interrupted		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXSA	char	Study Agent		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.

1.4.11. Follow Up – FUP

Dataset	FUP
Creating program	fup.sas
Description	Follow Up
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,COUNTRY,AGE,AGEM,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.
FPCMTRT	char	Commercial treatment		Collected at CRF.

1.4.12. Global Assessment – GLBASMT

Dataset	GLBASMT
Creating program	glbasmt.sas
Description	Global Assessment
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,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.

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.
GAPAR	char	Parent/Guardian global assessment		Collected at CRF.
GAPARC	char	Parent/Guardian global assessment of chg		Collected at CRF.
GAPHYSC	char	Physician global assessment of chg		Collected at CRF.
GASUBJ	char	Subject global assessment		Collected at CRF.
GASUBJC	char	Subject global assessment of chg		Collected at CRF.

1.4.13. Histological Biopsy Assessment – HISTOLGY

Dataset	HISTOLGY
Creating program	histolgy.sas
Description	Histological Biopsy Assessment
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,AGEM,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.

1.4.14. Impact - III Questionnaire – IMPACT3Q

Dataset	IMPACT3Q
Creating program	impact3q.sas
Description	Impact - III Questionnaire
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
IQBS1	num	Score for IMPACT question 1		Collected at CRF.
IQT11	num	Score for IMPACT question 2		Collected at CRF.
IQBS2	num	Score for IMPACT question 3		Collected at CRF.
IQEF1	num	Score for IMPACT question 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
IQEF2	num	Score for IMPACT question 5		Collected at CRF.
IQSS1	num	Score for IMPACT question 6		Collected at CRF.
IQBI1	num	Score for IMPACT question 7		Collected at CRF.
IQSF1	num	Score for IMPACT question 8		Collected at CRF.
IQSF2	num	Score for IMPACT question 9		Collected at CRF.
IQBS3	num	Score for IMPACT question 10		Collected at CRF.
IQEF3	num	Score for IMPACT question 11		Collected at CRF.
IQEF4	num	Score for IMPACT question 12		Collected at CRF.
IQEF5	num	Score for IMPACT question 13		Collected at CRF.
IQSF3	num	Score for IMPACT question 14		Collected at CRF.
IQBI2	num	Score for IMPACT question 15		Collected at CRF.
IQEF6	num	Score for IMPACT question 16		Collected at CRF.
IQSF4	num	Score for IMPACT question 17		Collected at CRF.
IQSF5	num	Score for IMPACT question 18		Collected at CRF.
IQBS4	num	Score for IMPACT question 19		Collected at CRF.
IQSF6	num	Score for IMPACT question 20		Collected at CRF.
IQBS5	num	Score for IMPACT question 21		Collected at CRF.
IQT12	num	Score for IMPACT question 22		Collected at CRF.
IQSF7	num	Score for IMPACT question 23		Collected at CRF.
IQT13	num	Score for IMPACT question 24		Collected at CRF.
IQBS6	num	Score for IMPACT question 25		Collected at CRF.

Variable	Type	Label	Codes	Comments
IQSF8	num	Score for IMPACT question 26		Collected at CRF.
IQSF9	num	Score for IMPACT question 27		Collected at CRF.
IQSS2	num	Score for IMPACT question 28		Collected at CRF.
IQEF7	num	Score for IMPACT question 29		Collected at CRF.
IQSF10	num	Score for IMPACT question 30		Collected at CRF.
IQBS7	num	Score for IMPACT question 31		Collected at CRF.
IQSS3	num	Score for IMPACT question 32		Collected at CRF.
IQBI3	num	Score for IMPACT question 33		Collected at CRF.
IQSF11	num	Score for IMPACT question 34		Collected at CRF.
IQSF12	num	Score for IMPACT question 35		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.

1.4.15. Immunohistochemistry – IM_CHEM

Dataset	IM_CHEM
Creating program	im_chem.sas
Description	Immunohistochemistry
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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, AGEM, RACE, SEX, IMCOMM

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
IMTSTCD	char	Test Code		Collected at CRF.
IMRESLT1	num	Test Result		Collected at CRF.
IMRESLT2	num	Test Result		Collected at CRF.
IMRESLT3	num	Test Result		Collected at CRF.
IMRESLT4	num	Test Result		Collected at CRF.
IMRESLT5	num	Test Result		Collected at CRF.
IMUNITS	char	Test Result Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
IMTEST	char	Lab Test Name		Collected at CRF.
IMCAT	char	Category for Lab Test		Collected at CRF.
IMSCAT	char	Subcategory for Lab Test		Collected at CRF.
IMTSTORD	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.
IMCORES	char	Coded Test Result		Collected at CRF.
IMNORES	char	No results		Collected at CRF.

1.4.16. Randomisation – IVRSRAND

Dataset	IVRSRAND
Creating program	ivrsrand.sas
Description	Randomisation
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,IRLCENDT,IRENRTD,IRSTPDT,COUNTRY,AGE,AGEM,RACE,SEX,IRLCNDTC,IRENRDTC,IRSTPDC,IRNOEND,IRRESP,IRSTPUP,IRSTRAT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TRTCD	num	Randomized Treatment		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.
IRSTPTRT	char	Step-up Treatment		Collected at CRF.
IENRDY	num	Relative Enrollment Day		If IENRDTC and IRLCNDTC not missing then perform below logic to calculate IENRDY, If IENRDTC less than IRLCNDTC then (IENRDTC - IRLCNDTC). Else if IENRDTC is greater than equal to IRLCNDTC then (IENRDTC - IRLCNDTC) +1.
IRSTPDY	num	Relative Step-up Day		If IRSTPDTC and IRLCNDTC not missing then perform below logic to calculate IRSTPDY, If IRSTPDTC less than IRLCNDTC then (IRSTPDTC - IRLCNDTC). Else if IRSTPDTC is greater than equal to IRLCNDTC then (IRSTPDTC - IRLCNDTC) +1.

1.4.17. Laboratory Test Results – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Test Results
Unique identifier	DUSUBJID, LBCAT, LBSCAT, LBTSTCD, LBTSTORD, LBSTRES, EVENT_ID, LBDY
Sorted by	DUSUBJID, LBCAT, LBSCAT, LBTSTCD, LBTSTORD, LBSTRES, EVENT_ID, LBDY
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: PAG_NAME,LBLBLNUM,LBDT,COUNTRY,AGE,AGEM,RACE,SEX,LBID,LBLOQL,LBORCOD, LBDTC,LBCOM

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.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRL0	char	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRI	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.
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.

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.
LBFAST	char	Fasting		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBPTM	char	Planned Timepoint Name		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.

1.4.18. Mayo Score – MAYOSCR

Dataset	MAYOSCR
Creating program	mayoscr.sas
Description	Mayo Score
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,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.

1.4.19. Medication Change – MEDCHNG

Dataset	MEDCHNG
Creating program	medchng.sas
Description	Medication Change
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,AGEM,RACE,SEX, MCCHGDT

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.
MCCHNG	char	Medication Change		Collected at CRF.
MCINCR	char	Medication Increase		Collected at CRF.
MCRSN	char	Medication Reason for Change		Collected at CRF.
MCTYPE	char	Medication Type		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.

1.4.20. Medication Review – MEDRVIEW

Dataset	MEDRVIEW
Creating program	medview.sas
Description	Medication Review
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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: PAG_NAME,CMTERM,CMMODIFY,MRCDT,DRECNO,CODSTAT,COUNTRY,AGE, AGEM,RACE,SEX, MRCBTC

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.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
MRCAT	char	Medication Category		Collected at CRF.
MRDOSCH	char	Dose Change Reason		Collected at CRF.
MRDUNT	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.
MRSTAT	char	Current Medication Status		Collected at CRF.
MRTYPE	char	Route Type		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.

1.4.21. Prophylactic Medication – PROMED

Dataset	PROPMED
Creating program	propmed.sas
Description	Prophylactic Medication
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PROPSEQ	num	Prophylactic Medication 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.

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.
PROPGIV	char	Prophylactic Medication Given		Collected at CRF.

1.4.22. Pediatric Ulcerative Colitis Index (PUCAI) – PUCAI

Dataset	PUCAI
Creating program	pucai.sas
Description	Pediatric Ulcerative Colitis Activity Index (PUCAI)
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,COUNTRY,AGE,AGEM,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PUABDPN	num	Abdominal Pain		Collected at CRF.

Variable	Type	Label	Codes	Comments
PURBLD	num	Rectal Bleeding		Collected at CRF.
PUSTLCNS	num	Stool Consistency of Most Stools		Collected at CRF.
PUNUMSTL	num	Number of Stools per 24 Hours		Collected at CRF.
PUNOCTBM	num	Nocturnal Bowel Movement		Collected at CRF.
PUACTLVL	num	Activity Level		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.
PUABDPNC	char	Abdominal Pain		Collected at CRF.
PURBLDC	char	Rectal Bleeding		Collected at CRF.
PUSTLCNC	char	Stool Consistency of Most Stools		Collected at CRF.

Variable	Type	Label	Codes	Comments
PUNMSTLC	char	Number of Stools per 24 Hours		Collected at CRF.
PUNOCBMC	char	Nocturnal Bowel Movement		Collected at CRF.
PUACTLVC	char	Activity Level		Collected at CRF.

1.4.23. Subject Population – RXCLASS

Dataset	RXCLASS
Creating program	rxclass.sas
Description	Subject Population
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,COUNTRY,AGE,AGEM,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.

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.
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		Collected at CRF.
RXUCC3	char	Oral Corticosteroids Med Complications		Collected at CRF.
RXUCD1	char	5-ASA Adequate Treatment		Collected at CRF.
RXUCD2	char	5-ASA Failed Response		Collected at CRF.
RXUCD3	char	5-ASA Medical Complications		Collected at CRF.

1.4.24. Drug History – RX_HX

Dataset	RX_HX
Creating program	rx_hx.sas
Description	Drug History
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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: PAG_NAME,CMTERM,CMMODIFY,DRECNO,CODSTAT,COUNTRY,AGE,AGEM,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
RXSEQ	num	Medication Sequence Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		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.

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.
RXCAT	char	Medication Category		Collected at CRF.
RXTIMUSD	char	Length of time taken		Collected at CRF.

1.4.25. SEVENT – SEVENT

Dataset	SEVENT
Creating program	sevent.sas
Description	SEVENT
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
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>PAG_NAME,AETERM,AEMODIFY,SESTDT,SEENDT,CODSTAT,MDAECD,MDCDS T,MDV,COUNTRY,AGE,AGEM,RACE,SEX,SECONG,SEDISAB,SEDTH,SELIFE,SENS, SEOTH,SEPHOS,SERHOS, SEENDTC, SESTDTC</p>

Variable	Type	Label	Codes	Comments
AECD	char	WHOART Adverse Event Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
SESEQ2	num	Sequence Number		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.
SECODE	char	Code for Reported Term		Collected at CRF.
SEONGO	char	Ongoing Blood Draw Adverse Event		Collected at CRF.
SEREL	char	Relationship		Collected at CRF.
SEREL2	char	AE Related to		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.26. Subject Status – SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
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,SSDSCDT,SSRSOTH,COUNTRY,AGE,AGEM,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.

1.4.27. Visits – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visits
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,VISIT_DT,COUNTRY,AGE,AGEM,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.

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.
VISSTEP	char	Entering Step-Up Phase		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.

1.4.28. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
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,VSDT,COUNTRY,AGE,AGEM,RACE,SEX, VSDTC

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

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