Clinical Development

Ustekinumab

C0743T26

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	1 JUN 2017

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- DEATH (Death) and NOTTX (Reason Randomized But Never Treated) datasets will not be submitted as it has 0 observation at source.
- DEMO.DMCONDTC (referred as REF. DATE in the document) will be used as Reference Date to derive relative days.

1.3.   Data Files

The C0743T26 Clinical Study Report (CSR) data should be used for converting to de-identification.

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 repetition of the information: DMCONDT,DMCONDTC,DEMOG,SUBJINIT,BIRTHDT,BIRTHDTC,REGION

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
HEIGHT	num	Height in Centimeters		Collected at CRF.
BWEIGHT	num	Baseline Weight		Collected at CRF.
B_BCS	char	Baseline Budesonide use		Collected at CRF.
BAMINO	char	Baseline Aminosalicylates use		Collected at CRF.
BANTIBIO	char	Baseline Antibiotics use		Collected at CRF.
BAZAMP	char	Baseline 6-MP/Azathioprine use		Collected at CRF.
BCMED	char	Baseline Concomitant CD Med Use		Collected at CRF.
BCORT	char	Baseline Corticosteroid use(excl. budes)		Collected at CRF.
BCSBDOSE	num	Baseline budesonide dose		Collected at CRF.
BCSDOSE	num	Baseline CS P.eq dose (no budesonnide)		Collected at CRF.
BIMM	char	Baseline Immunomodulator use		Collected at CRF.
BMETHO	char	Baseline Methotrexate use		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AEBODSYS,AEDECOD,AELLT, VISIT, AEACTSDY
Sorted by	DUSUBJID, AEBODSYS,AEDECOD,AELLT, VISIT, AEACTSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AESTDT,AEENDT,AESTDTC,AEENDTC,AESTHR,AESTMI,AETERM,SAEDTH, SAELIFE,SAEDISAB,SAECONG,AEMODIFY,AELOCOTH

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
AEACTSDY	num	Actual Study Day of Start of Event		Collected at CRF.
AEACTEDY	num	Actual Study Day of End of Event		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
SAEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SAEOTH	char	Other Medically Important		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.
AEPROC	char	Trial Procedure		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
AECD	char	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.

Variable	Type	Label	Codes	Comments
AEDECOD	char	Dictionary Term		Collected at CRF.
AEPRSPEC	char	Related to Procedure Specify		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AELOC	char	Adverse Event Location		Collected at CRF.
AELOINJ	num	Most Recent Injection at Admin Site		Collected at CRF.
AELODOSE	num	Most Recent Dose at Admin Site		Collected at CRF.
AELOAGNT	char	Most Recent Study Agent at Admin Site		Collected at CRF.
AERELATE	char	Reasonably Related to Study Treatment		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AEDUR	num	Duration of Event (in Days)		Collected at CRF.
AETRTEM	char	Treatment Emergent		Collected at CRF.
AEEXSDY	num	Study Day of Dose Prior to AE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEDOSE	num	Dose Prior to AE		Collected at CRF.
AEDOSUN	char	Unit of Dose Prior to AE		Collected at CRF.
DOSENUM	num	Sequential Dose Number		Collected at CRF.
AESTAGNT	char	Study agent prior to AE		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
INFREAC	char	Infusion reaction		Collected at CRF.
SSANAPH	char	Anaphylaxis/Serum Sickness of Interest		Collected at CRF.
W22FLAG	char	Up to and including Week 22 analysis		Collected at CRF.
WA36FLAG	char	After Week 36 date		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
AESTDY	num	Relative Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.

1.4.3. Endoscopy Results – BIOPSY

Dataset	BIOPSY
Creating program	biopsy.sas
Description	Endoscopy Results
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 repetition of the information: BIDT,BIDTC,BIOACC1,BIOACC2

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
BIRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
BIRELBAS	char	Relative to Baseline Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
BIOULCER	char	Biopsy Ulceration		Collected at CRF.
BIOILEUM	num	Was terminal ileum visualized?		Collected at CRF.
BIOLOC	num	location of visible ulceration		Collected at CRF.
BICOL	char	Was Biopsy Collected		Collected at CRF.
MUCOSAL	char	Subjects with Mucosal Healing		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
BIDY	num	Relative Day of Biopsy		If BIDTC and REF.DATE not missing then perform below logic to calculate BIDY, If BIDTC less than REF.DATE then (BIDTC - REF.DATE). Else if BIDTC is greater than equal to REF.DATE then (BIDTC-REF.DATE) +1.

1.4.4. Crohn's Disease Activity Index Score – CDAI

Dataset	CDAI
Creating program	cdai.sas
Description	Crohn's Disease Activity Index Score
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 repetition of the information: CDDT,CDDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
CDACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
CDRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
CDRELBAS	char	Relative to Baseline Description		Collected at CRF.
CDSTOOL	num	Total Stools		Collected at CRF.
CDPAIN	num	Abdominal Pain/Cramps		Collected at CRF.
CDWELLBE	num	Sum Well-Being		Collected at CRF.
CDDAYS	num	Diary Days		Collected at CRF.
CDHEMAT	num	Hematocrit		Collected at CRF.
CDWEIGHT	num	Weight		Collected at CRF.
CDSTWEIG	num	Standard weight		Collected at CRF.
CDSC	num	Calculated CDAI Score		Collected at CRF.
CDABSCES	char	Anal abscess		Collected at CRF.
CDAMASS	num	Abdominal Mass		Collected at CRF.
CDARALGA	char	Arthralgia		Collected at CRF.
CDARTHR	char	Arthritis		Collected at CRF.
CDDIARRH	char	Antidiarrheal		Collected at CRF.
CDERYTHE	char	Erythema nodosum		Collected at CRF.
CDFEVER	char	Fever		Collected at CRF.
CDFISSUR	char	Anal Fissure		Collected at CRF.
CDFISTUL	char	Anal fistula		Collected at CRF.
CDIRIT	char	Iritis		Collected at CRF.
CDOPIATE	char	Opiates		Collected at CRF.

Variable	Type	Label	Codes	Comments
CDOTFIST	char	Other fistula		Collected at CRF.
CDPYODER	char	Pyoderma gangrenosum		Collected at CRF.
CDSEX	char	Sex		Collected at CRF.
CDSTOMAT	char	Aphthous stomatitis		Collected at CRF.
CDUVEIT	char	Uveitis		Collected at CRF.
EI_MANIF	char	Extra-intestinal manifestations of CD		Collected at CRF.
CDPAINM	num	Abdominal pain rating (lvcf if missing)		Collected at CRF.
CDAMASSM	num	Abdominal mass (lvcf if missing)		Collected at CRF.
CDABSCEM	char	Abscess present (lvcf if missing)		Collected at CRF.
CDWEIGHM	num	CDAI weight (kg)(lvcf if missing)		Collected at CRF.
CDSTOMAM	char	Aphthous stomatitis (lvcf if missing)		Collected at CRF.
CDARALGM	char	Arthralgia (lvcf if missing)		Collected at CRF.
CDARTRTM	char	Arthritis (lvcf if missing)		Collected at CRF.
CDDRGM	char	Antidiarrheal/opiates(lvcf if missing)		Collected at CRF.
CDERYTHM	char	Erythema nodosum (lvcf if missing)		Collected at CRF.
CDFEVERM	char	Fever (lvcf if missing)		Collected at CRF.
CDFISTUM	char	Anal fistula (lvcf if missing)		Collected at CRF.
CDFISURM	char	Anal fissure (lvcf if missing)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CDHCT	num	Hematocrit Result for CDAI		Collected at CRF.
CDHCTM	num	Hematocrit for CDAI (lvcf if missing)		Collected at CRF.
CDOTFISM	char	Other fistula present (lvcf if missing)		Collected at CRF.
CDPYODEM	char	Pyoderma gangrenosum (lvcf if missing)		Collected at CRF.
CDSTOOLM	num	Nbr liquid/soft stools (lvcf if missing)		Collected at CRF.
CDUVEITM	char	Uveitis (lvcf if missing)		Collected at CRF.
CDWELBEM	num	General well being (lvcf if missing)		Collected at CRF.
CDAI	num	CDAI Total Score		Collected at CRF.
CDAICG	num	CDAI change from baseline		Collected at CRF.
CDAIPCG	num	Percent change from b/l in CDAI score		Collected at CRF.
STDWGT	num	Standard weight (Kg)		Collected at CRF.
CDIRITM	char	Iritis (lvcf if missing)		Collected at CRF.
CDAMASSD	char	Abdominal Mass		Collected at CRF.
CDAI70NA	char	Reduction >=25% & >=70 point(no TF/LVCF)		Collected at CRF.
REMISSNA	char	Clinical remission (no TF & LVCF)		Collected at CRF.
RESPNA	char	Clinical response (no TF & LVCF)		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
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
CDDY	num	Relative Visit Day		If CDDTC and REF.DATE not missing then perform below logic to calculate CDDY, If CDDTC less than REF.DATE then (CDDTC - REF.DATE). Else if CDDTC is greater than equal to REF.DATE then (CDDTC-REF.DATE) +1.

1.4.5. Crohn's Disease History – CD_HX

Dataset	CD_HX
Creating program	cd_hx.sas
Description	Crohn's 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 repetition of the information: DIAG_DT,DIAG_DTC,CXDT,CXDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
CXACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
COLON	char	Colon Involvement		Collected at CRF.
GASINT	char	Gastro-intestinal Involvement		Collected at CRF.
ILEUM	char	Ileum Involvement		Collected at CRF.
DIS_DUR	num	Duration of Crohn's disease (years)		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
DIAG_DY	num	Relative Day of Diagnosis		If DIAG_DTC and REF.DATE not missing then perform below logic to calculate DIAG_DY, If DIAG_DTC less than REF.DATE then (DIAG_DTC - REF.DATE). Else if DIAG_DTC is greater than equal to REF.DATE then (DIAG_DTC- REF.DATE) +1.
CXDY	num	Relative Visit Day		If CXDTC and REF.DATE not missing then perform below logic to calculate CXDY, If CXDTC less than REF.DATE then (CXDTC - REF.DATE). Else if CXDTC is greater than equal to REF.DATE then (CXDTC-REF.DATE) +1.

1.4.6. Past Medical History/Current Diagnoses – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Past Medical History/Current Diagnoses
Unique identifier	DUSUBJID,VISIT,CHCOND
Sorted by	DUSUBJID,VISIT,CHCOND
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CHDT,CHDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
CHACTDY	num	Actual Study Day of Condition History		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHCONDD	char	Condition		Collected at CRF.
CHHIST	char	History of Condition		Collected at CRF.
CHSMSTAT	char	Status of Smoking		Collected at CRF.
CHSTSTAT	char	Stoma Status		Collected at CRF.
CHCOND	num	Condition		Collected at CRF.
ASCVD	char	Subject if had current or past ASCVD		Collected at CRF.
CARDIO1	char	Subject if had cardiovascular risk		Collected at CRF.
CARDIO2	char	Subject if had two or more cardio risk		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
CHDY	num	Relative Visit Day		If CHDTC and REF.DATE not missing then perform below logic to calculate CHDY, If CHDTC less than REF.DATE then (CHDTC - REF.DATE). Else if CHDTC is greater than equal to REF.DATE then (CHDTC-REF.DATE) +1.

1.4.7. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,CMDECOD,CMREAS,VISIT ,CMACTSDY,CMACTEDY
Sorted by	DUSUBJID,CMDECOD,CMREAS,VISIT ,CMACTSDY,CMACTEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CMSTDT,CMSTDTC,CMENDT,CMENDTC,CMTERM,CMMODIFY, DRECNO

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
CMACTSDY	num	Actual Study Day of Start of Medication		Collected at CRF.
CMACTEDY	num	Actual Study Day of End of Medication		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		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.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
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.
IRRESP	char	Achieving clinical response at Week 6		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
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.

1.4.8. Crohn's Disease Related Surgeries – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Crohn's Disease Related Surgeries
Unique identifier	DUSUBJID,VISIT,PRTYPE,PRINOUT,W6FLAG,PRSTDY
Sorted by	DUSUBJID,VISIT,PRTYPE,PRINOUT,W6FLAG,PRSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: PRSTDT,PRSTDTC,PRSPEC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
PRACTDY	num	Actual study day of procedure		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PRSEQ	num	Sequence Number		Collected at CRF.
PRTYPE	char	Surgery Type		Collected at CRF.
PRINOUT	char	In-Patient or Out-Patient		Collected at CRF.
W6FLAG	char	Up to and including Week 6 analysis		Collected at CRF.
W8FLAG	char	Up to and including Week 8 analysis		Collected at CRF.
W16FLAG	char	Up to and including Week 16 analysis		Collected at CRF.
W22FLAG	char	Up to and including Week 22 analysis		Collected at CRF.
W28FLAG	char	Up to and including Week 28 analysis		Collected at CRF.
W36FLAG	char	Up to and including Week 36 analysis		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
PRSTDY	num	Relative Surgery Day		If PRSTDTC and REF.DATE not missing then perform below logic to calculate PRSTDY, If PRSTDTC less than REF.DATE then (PRSTDTC - REF.DATE). Else if PRSTDTC is greater than equal to REF.DATE then (PRSTDTC- REF.DATE) +1.

1.4.9. Inclusion CriteriaIn/Exclusion Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Inclusion CriteriaIn/Exclusion Criteria
Unique identifier	DUSUBJID,VISIT,CRCAT,CRSEQ,INCRIT
Sorted by	DUSUBJID,VISIT,CRCAT,CRSEQ,INCRIT
Notes	

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		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.
CRCAT	char	Selection criteria category		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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

1.4.10. Cardiovascular AEs (Adjudicated) – CVADJ

Dataset	CVADJ
Creating program	cvadj.sas
Description	Cardiovascular AEs (Adjudicated)
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 repetition of the information or due to missing values: DOSSIER,EVENTID,EVENTDT,EVENTDTC,COD,CVDEATH,OTHCV,ISCTYP,MITYP,STRKETYP,AETERM

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
EVENT	char	Type of Suspected Event		Collected at CRF.
CECASS	char	CEC Assessment		Collected at CRF.
NEURTYP	char	Type of Neurological Event		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELLT	char	Low Level Term Name		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
DOSENUM	num	Sequential Dose Number		Collected at CRF.
CPFLAG	char	Event occured during controlled portion		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
EVENTDY	num	Relative Event Day		If EVENTDTC and REF.DATE not missing then perform below logic to calculate EVENTDY, If EVENTDTC less than REF.DATE then (EVENTDTC - REF.DATE). Else if EVENTDTC is greater than equal to REF.DATE then (EVENTDTC- REF.DATE) +1.

1.4.11.   Cardiovascular Adverse Events (Thrombot) – CVAETHMB

Dataset	CVAETHMB
Creating program	cvaethmb.sas
Description	Cardiovascular Adverse Events (Thrombot)
Unique identifier	DUSUBJID,AEBODSYS,AEDECOD,AEACTTRT,VISIT
Sorted by	DUSUBJID,AEBODSYS,AEDECOD,AEACTTRT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AESTDT,AEENDT,AESTDTC,AEENDTC,AETERM,SAEDTH,SAELIFE,SAEPHOS, SAEDISAB,SAECONG,SAEOTH,MI,ISCOTH,ISC,CARDTHMB

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
AEACTSDY	num	Actual Study Day of Start of Event		Collected at CRF.
AEACTEDY	num	Actual Study Day of End of Event		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AECD	char	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.
AERELATE	char	Reasonably Related to Study Treatment		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AETRTEM	char	Treatment Emergent		Collected at CRF.
AEEXSDY	num	Study Day of Dose Prior to AE		Collected at CRF.
AEDOSE	num	Dose Prior to AE		Collected at CRF.
AEDOSUN	char	Unit of Dose Prior to AE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSENUM	num	Sequential Dose Number		Collected at CRF.
AESTAGNT	char	Study agent prior to AE		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
EMBTHVEN	char	Flg embolic/thrombotic events, venous		Collected at CRF.
EMBTHART	char	Flg embolic/thrombotic events, arterial		Collected at CRF.
CERETHMB	char	Poss. cerebrovascular thrombotic event		Collected at CRF.
PERVASC	char	Possible peripheral vascular events		Collected at CRF.
RMJ	char	Requires Medical Judgment		Collected at CRF.
INCLUDE	char	Include in Analysis		Collected at CRF.
W22FLAG	char	Up to and including Week 22 analysis		Collected at CRF.
WA36FLAG	char	After Week 36 date		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
AESTDY	num	Relative Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.

1.4.12.   Disposition – DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition
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 repetition of the information: DSDT,DSDTC,DSDSCDT,DSDSCDTC,DSTDT,DSTDTC,DSTDCDT,DSTDCDTC, DSUNBDT,DSUNBDTC,DSRSOTH,DSTRSOTH,DSIATDT,DSIATDTC,DSITDT, DSITDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DSACTDY	num	Actual Study Day of Disposition		Collected at CRF.
DSTACTDY	num	Actual Study Day of Final Treatment		Collected at CRF.
DSUACTDY	num	Actual Study Day of Unblinding		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DSDSCEND	char	Study Participation End		Collected at CRF.
DSEREAS	char	Reason for Study Participation End		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSTREAS	char	Reason for Treatment Discontinuation		Collected at CRF.
DSTWSTD	char	Worsening of Study Disease		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
DSUNB	char	Treatment Unblinded		Collected at CRF.
DSLSTVIS	char	Last Scheduled Study Treatment Visit		Collected at CRF.
DSLSVIS	char	Last Scheduled Visit		Collected at CRF.
DSLSUVIS	char	Last Sched Visit on or prior to Unblding		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
DSDY	num	Relative Day of Disposition Status		If DSDTC and REF.DATE not missing then perform below logic to calculate DSDY, If DSDTC less than REF.DATE then (DSDTC - REF.DATE). Else if DSDTC is greater than equal to REF.DATE then (DSDTC-REF.DATE) +1.
DSDSCDY	num	Relative Day of Study Discontinuation		If DSDSCDTC and REF.DATE not missing then perform below logic to calculate DSDSCDY, If DSDSCDTC less than REF.DATE then (DSDSCDTC - REF.DATE). Else if DSDSCDTC is greater than equal to REF.DATE then (DSDSCDTC- REF.DATE) +1.
DSTDY	num	Relative Day of Final Treatment		If DSTDTC and REF.DATE not missing then perform below logic to calculate DSTDY, If DSTDTC less than REF.DATE then (DSTDTC - REF.DATE). Else if DSTDTC is greater than equal to REF.DATE then (DSTDTC- REF.DATE) +1.
DSTDCDY	num	Relative Day of Study Trt Discontination		If DSTDCDTC and REF.DATE not missing then perform below logic to calculate DSTDCDY, If DSTDCDTC less than REF.DATE then (DSTDCDTC - REF.DATE). Else if DSTDCDTC is greater than equal to REF.DATE then (DSTDCDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DSUNBDY	num	Relative Day of Treatment Unblinding		If DSUNBDTC and REF.DATE not missing then perform below logic to calculate DSUNBDY, If DSUNBDTC less than REF.DATE then (DSUNBDTC - REF.DATE). Else if DSUNBDTC is greater than equal to REF.DATE then (DSUNBDTC- REF.DATE) +1.
DSIATDY	num	Relative Day of Initial Active Treatment		If DSIATDTC and REF.DATE not missing then perform below logic to calculate DSIATDY, If DSIATDTC less than REF.DATE then (DSIATDTC - REF.DATE). Else if DSIATDTC is greater than equal to REF.DATE then (DSIATDTC- REF.DATE) +1.
DSITDY	num	Relative Day of Initial Treatment		If DSITDTC and REF.DATE not missing then perform below logic to calculate DSITDY, If DSITDTC less than REF.DATE then (DSITDTC - REF.DATE). Else if DSITDTC is greater than equal to REF.DATE then (DSITDTC- REF.DATE) +1.

1.4.13.   Major protocol deviation – DV

Dataset	DV
Creating program	dv.sas
Description	Major protocol deviation
Unique identifier	DUSUBJID,DVDECOD
Sorted by	DUSUBJID,DVDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DVSEQ,DVSEQE,DVTERM,DVCAT,DVSCAT,EPOCH,DVSTDTC,DVSTDT,DVSTTM, DVENDTC,DVENDT,DVENTM

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned subject ID for De-identity
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned site 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
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.

1.4.14.   Health Economic Questionnaire – ECONOM

Dataset	ECONOM
Creating program	econom.sas
Description	Health Economic Questionnaire
Unique identifier	DUSUBJID,DVDECOD
Sorted by	DUSUBJID,DVDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ECDT,ECDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
ECACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
ECSURG	char	Surgeries		Collected at CRF.
ECSRGNUM	num	Number of Surgeries		Collected at CRF.
ECHOSP	char	Hospitalized		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECHOSPTM	num	Times Hospitalized		Collected at CRF.
ECHOSPDY	num	Days Hospitalized		Collected at CRF.
ECWORK	char	Currently Working		Collected at CRF.
ECWRKFP	char	Working Full or Part-time		Collected at CRF.
ECHRSWK	num	Average Number of Hours Worked		Collected at CRF.
ECDYSAB	num	Days of Absence		Collected at CRF.
ECILRSN	char	Illness Reason For Not Working		Collected at CRF.
ECCNWRK	char	Could Work If Job Available		Collected at CRF.
ECRETRE	char	Retired		Collected at CRF.
ECERTRE	char	Early Retirement		Collected at CRF.
ECDISAB	char	Receiving Disability Compensation		Collected at CRF.
ECSTUD	char	Student		Collected at CRF.
ECSTUFP	char	Full or Part-time Student		Collected at CRF.
ECPSCLE	num	Productivity Scale (cm)		Collected at CRF.
ECPSND	char	Productivity Scale Not Done		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
ECRELBAS	char	Relative to Baseline Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
ECPSCG	num	productivity scales change from baseline		Collected at CRF.
ECPSPCG	num	precent change from bl In prod scale		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
ECDY	num	Relative Day of health economic quest.		If ECDTC and REF.DATE not missing then perform below logic to calculate ECDY, If ECDTC less than REF.DATE then (ECDTC - REF.DATE). Else if ECDTC is greater than equal to REF.DATE then (ECDTC-REF.DATE) +1.

1.4.15.   Study Agent Administration/Drug Preparat – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Study Agent Administration/Drug Preparat
Unique identifier	DUSUBJID,VISIT,EXSITE,EXISR
Sorted by	DUSUBJID,VISIT,EXSITE,EXISR
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: EXSTDT,EXSTHR,EXSTMI,EXSTDTC,EXCNTRID,EXKITNO,EXSITE_V,EXENHR, EXENMI,EXINTHR,EXINTMI,EXRSHR,EXRSMI,EXPDT,EXPDTC,EXLOT1OS, EXLOTNO1,EXLOTNO2, EXLOTNO3,EXLOTNO

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EXACTSDY	num	Actual Study Day of Start Dose		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
EXINTTM	num	Time of Interruption, 24 Hour Clock		Collected at CRF.
EXRSTM	num	Time of Resumption, 24 Hour Clock		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
AMTADM	num	Amount Administered		Collected at CRF.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
EXINRPT	char	Infusion Interrupted		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 in Container in mL		Collected at CRF.
EXWEIGHT	num	Weight in kg		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXDSDSC	char	Dose Descriptor		Collected at CRF.
EXDRFORM	char	Drug Formulation		Collected at CRF.
ACTTRT	char	Treatment		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
DOSEFREQ	char	Frequency of Dosing		Collected at CRF.
DOSE	num	Dose Received		Collected at CRF.
DOSENUM	num	Sequential Dose Number		Collected at CRF.
EXROUTE	char	Route of administration		Collected at CRF.
PREPDOSE	num	Dose prepared per IV infusion (mg/kg)		Collected at CRF.
EXDOSGRP	char	IV Dose received group (mg/kg)		Collected at CRF.
EXINFRCT	char	At Least One Infusion Reaction Occurred		Collected at CRF.
EXSER	char	Serious Infusion Reaction		Collected at CRF.
EXSEV	char	Severity of Infusion Reaction		Collected at CRF.
EXISR	char	At least one ISR occurred		Collected at CRF.
EXSERSC	char	Serious Injection Site Reaction		Collected at CRF.
EXSEVSC	char	Severity of ISR		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
EXSTDY	num	Relative Start Day of Dose		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC- REF.DATE) +1.
EXPDY	num	Relative Day Prepared		If EXPDTC and REF.DATE not missing then perform below logic to calculate EXPDY, If EXPDTC less than REF.DATE then (EXPDTC - REF.DATE). Else if EXPDTC is greater than equal to REF.DATE then (EXPDTC- REF.DATE) +1.

1.4.16. Fistula Status and Information – FISTULA

Dataset	FISTULA
Creating program	fistula.sas
Description	Fistula Status and Information
Unique identifier	DUSUBJID,VISIT,FIACTDY
Sorted by	DUSUBJID,VISIT,FIACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: FIDT,FIDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
FIACTDY	num	Actual Study Day of End of Event		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
FIRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
FIRELBAS	char	Relative to Baseline Description		Collected at CRF.
FSASSESS	char	Fistulas Assessed		Collected at CRF.
FISTNC	char	Fistulas Not Closed		Collected at CRF.
FSNEW	char	New Fistulas		Collected at CRF.
FSCHNG	char	Fistula Change		Collected at CRF.
FSNUM	num	Fistula Number		Collected at CRF.
FSLOC	char	Fistula Location		Collected at CRF.
FSEVNT	char	Fistula Visit		Collected at CRF.
FSSTAT	char	Fistula Status		Collected at CRF.
FSFIS	num	Fistula Form Iteration		Collected at CRF.
FSSEQ	num	Sequence 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
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
FIDY	num	Relative Visit Day		If FIDTC and REF.DATE not missing then perform below logic to calculate FIDY, If FIDTC less than REF.DATE then (FIDTC - REF.DATE). Else if FIDTC is greater than equal to REF.DATE then (FIDTC-REF.DATE) +1.

1.4.17.   Crohn's Disease Related Hospitalizations – HOSPIN

Dataset	HOSPIN
Creating program	hospin.sas
Description	Crohn's Disease Related Hospitalizations
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 repetition of the information: HOADMDT,HOADMDTC,HODISDT,HODISDTC,HODIAG

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
HOSEQ	num	Hospitalization Sequence		Collected at CRF.
HOICUDYS	num	Total Number of Days in ICU		Collected at CRF.
HONODSCH	char	Not Discharged		Collected at CRF.
HOSPDUR	num	Duration of Event (in Days)		Collected at CRF.
W6FLAG	char	Up to and including Week 6 analysis		Collected at CRF.
W8FLAG	char	Up to and including Week 8 analysis		Collected at CRF.
W16FLAG	char	Up to and including Week 16 analysis		Collected at CRF.
W22FLAG	char	Up to and including Week 22 analysis		Collected at CRF.
W28FLAG	char	Up to and including Week 28 analysis		Collected at CRF.

Variable	Type	Label	Codes	Comments
W36FLAG	char	Up to and including Week 36 analysis		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
HOADMDY	num	Relative Hospital Admission Day		If HOADMDTC and REF.DATE not missing then perform below logic to calculate HOADMDY, If HOADMDTC less than REF.DATE then (HOADMDTC - REF.DATE). Else if HOADMDTC is greater than equal to REF.DATE then (HOADMDTC- REF.DATE) +1.
HODISDY	num	Relative Hospital Discharge Day		If HODISDTC and REF.DATE not missing then perform below logic to calculate HODISDY, If HODISDTC less than REF.DATE then (HODISDTC - REF.DATE). Else if HODISDTC is greater than equal to REF.DATE then (HODISDTC- REF.DATE) +1.

1.4.18.   IBDQ questionnaire – IBDQSCR

Dataset	IBDQSCR
Creating program	ibdqscr.sas
Description	IBDQ questionnaire
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 repetition of the information or due to missing values: IBDT,IBDTC,IBDQEXCL

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
IBACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
IBRELBAS	char	Relative to Baseline Description		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.
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.

Variable	Type	Label	Codes	Comments
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.
IBDQ_31	num	Score for IBDQ Question 31		Collected at CRF.
IBDQ_32	num	Score for IBDQ Question 32		Collected at CRF.
IBDQD1	char	Score for IBDQ Question 1		Collected at CRF.
IBDQD2	char	Score for IBDQ Question 2		Collected at CRF.
IBDQD3	char	Score for IBDQ Question 3		Collected at CRF.
IBDQD4	char	Score for IBDQ Question 4		Collected at CRF.
IBDQD5	char	Score for IBDQ Question 5		Collected at CRF.
IBDQD6	char	Score for IBDQ Question 6		Collected at CRF.
IBDQD7	char	Score for IBDQ Question 7		Collected at CRF.
IBDQD8	char	Score for IBDQ Question 8		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQD9	char	Score for IBDQ Question 9		Collected at CRF.
IBDQD10	char	Score for IBDQ Question 10		Collected at CRF.
IBDQD11	char	Score for IBDQ Question 11		Collected at CRF.
IBDQD12	char	Score for IBDQ Question 12		Collected at CRF.
IBDQD13	char	Score for IBDQ Question 13		Collected at CRF.
IBDQD14	char	Score for IBDQ Question 14		Collected at CRF.
IBDQD15	char	Score for IBDQ Question 15		Collected at CRF.
IBDQD16	char	Score for IBDQ Question 16		Collected at CRF.
IBDQD17	char	Score for IBDQ Question 17		Collected at CRF.
IBDQD18	char	Score for IBDQ Question 18		Collected at CRF.
IBDQD19	char	Score for IBDQ Question 19		Collected at CRF.
IBDQD20	char	Score for IBDQ Question 20		Collected at CRF.
IBDQD21	char	Score for IBDQ Question 21		Collected at CRF.
IBDQD22	char	Score for IBDQ Question 22		Collected at CRF.
IBDQD23	char	Score for IBDQ Question 23		Collected at CRF.
IBDQD24	char	Score for IBDQ Question 24		Collected at CRF.
IBDQD25	char	Score for IBDQ Question 25		Collected at CRF.
IBDQD26	char	Score for IBDQ Question 26		Collected at CRF.
IBDQD27	char	Score for IBDQ Question 27		Collected at CRF.
IBDQD28	char	Score for IBDQ Question 28		Collected at CRF.
IBDQD29	char	Score for IBDQ Question 29		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQD30	char	Score for IBDQ Question 30		Collected at CRF.
IBDQD31	char	Score for IBDQ Question 31		Collected at CRF.
IBDQD32	char	Score for IBDQ Question 32		Collected at CRF.
IBDQ_B	num	Total IBDQ score - Bowel		Collected at CRF.
IBDQ_E	num	Total IBDQ score - Emotional		Collected at CRF.
IBDQ_SF	num	Total IBDQ score - Social		Collected at CRF.
IBDQ_SY	num	Total IBDQ score - Systemic		Collected at CRF.
IBDQ_TOT	num	Total IBDQ score		Collected at CRF.
IBDQ_COM	char	Comments concerning IBDQ score		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
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
IBDY	num	Relative Visit Day		If IBDTC and REF.DATE not missing then perform below logic to calculate IBDY, If IBDTC less than REF.DATE then (IBDTC - REF.DATE). Else if IBDTC is greater than equal to REF.DATE then (IBDTC-REF.DATE) +1.

1.4.19.   IVRS-CDAI – IVRSCDAI

Dataset	IVRSCDAI
Creating program	ivrscdai.sas
Description	IVRS-CDAI
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 repetition of the information: IVRSCDT,IVRSCDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IVCDAISC	num	Calculated Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRRESP	char	Achieving clinical response at Week 6		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
IVRSCDY	num	Relative Calculated Score Day		If IVRSCDTC and REF.DATE not missing then perform below logic to calculate IVRSCDY, If IVRSCDTC less than REF.DATE then (IVRSCDTC - REF.DATE). Else if IVRSCDTC is greater than equal to REF.DATE then (IVRSCDTC- REF.DATE) +1.

1.4.20. IVRS - Dosing – IVRSDOSE

Dataset	IVRSDOSE
Creating program	ivrsdose.sas
Description	IVRS - Dosing
Unique identifier	DUSUBJID,VISIT,IDSEQ
Sorted by	DUSUBJID,VISIT,IDSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: IDCLDT,IDCLDTC,IDKITNUM,IDCNTRID

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IDSEQ	num	Sequence Number		Collected at CRF.
IDWEIGHT	num	Week 0 Weight		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRRESP	char	Achieving clinical response at Week 6		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
IDCLDY	num	Relative IVRS Dose Call Day		If IDCLDTC and REF.DATE not missing then perform below logic to calculate IDCLDY, If IDCLDTC less than REF.DATE then (IDCLDTC - REF.DATE). Else if IDCLDTC is greater than equal to REF.DATE then (IDCLDTC- REF.DATE) +1.

1.4.21.   IVRS - Randomization – IVRSRAND

Dataset	IVRSRAND
Creating program	ivrsrand.sas
Description	IVRS - Randomization
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 repetition of the information: IRLCENDT,IRLCNDTC,IRRNDVAL,IRSUBORD

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCD	num	Treatment Group		Collected at CRF.
TRTGRP	char	Decode of TRTCD		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IRLCENTM	num	Time of Treatment Assignment		Collected at CRF.
IRFCTR1	char	Stratification Factor 1		Collected at CRF.
IRFCTR2	char	Stratification Factor 2		Collected at CRF.
IRFCTR3	char	Stratification Factor 3		Collected at CRF.
IRIMB1	num	Imbalance Measure 1		Collected at CRF.
IRIMB2	num	Imbalance Measure 2		Collected at CRF.
IRIMB3	num	Imbalance Measure 3		Collected at CRF.
IRIMB4	num	Imbalance Measure 4		Collected at CRF.
IRPROB1	num	Probablility Assignment 1		Collected at CRF.
IRPROB2	num	Probability Assignment 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRPROB3	num	Probability Assignment 3		Collected at CRF.
IRPROB4	num	Probability Assignment 4		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRLCNDY	num	Relative Day of Randomization		If IRLCNDTC and REF.DATE not missing then perform below logic to calculate IRLCNDY, If IRLCNDTC less than REF.DATE then (IRLCNDTC - REF.DATE). Else if IRLCNDTC is greater than equal to REF.DATE then (IRLCNDTC- REF.DATE) +1.

1.4.22. Jenkins Sleep Questionnaire – JENKINSQ

Dataset	JENKINSQ
Creating program	jenkinsq.sas
Description	Jenkins Sleep Questionnaire
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 repetition of the information: JEDT,JEDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
JEACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
JERELFLG	num	Relative to baseline indicator		Collected at CRF.
JERELBAS	char	Relative to Baseline Description		Collected at CRF.
JSASL	num	Trouble Falling Asleep		Collected at CRF.
JSSTASL	num	Trouble Staying Asleep		Collected at CRF.
JSTWO	num	Wake up Feeling Tired and Worn Out		Collected at CRF.
JSWAKE	num	Wake up Several Times		Collected at CRF.
JSASLD	char	Trouble Falling Asleep		Collected at CRF.
JSSTASLD	char	Trouble Staying Asleep		Collected at CRF.
JSTWOD	char	Wake up Feeling Tired and Worn Out		Collected at CRF.
JSWAKED	char	Wake up Several Times		Collected at CRF.
JSEQ_TOT	num	Total JSEQ score		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
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
JEDY	num	Relative Visit Day		If JEDTC and REF.DATE not missing then perform below logic to calculate JEDY, If JEDTC less than REF.DATE then (JEDTC - REF.DATE). Else if JEDTC is greater than equal to REF.DATE then (JEDTC-REF.DATE) +1.

1.4.23. Laboratory Results- Chemistry – LABCHEM

Dataset	LABCHEM
Creating program	labchem.sas
Description	Laboratory Results- Chemistry
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBDT,LBDTC,LBLBLNUM,LBACTHR,LBACTMI,LBSTDNRC,LBORNRC,LBLOQL, LBHIQL,LBID

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBACTDY	num	Actual Study Day of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
LBRELBAS	char	Relative to Baseline Description		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBTSTCD	char	Lab Test Code		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.
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF.
LBSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF.
LBSTUNIT	char	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.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
STDCHGBL	num	Change from Baseline in Standard Units		Collected at CRF.
LBABNCRT	char	Markedly Abnormal Criteria		Collected at CRF.
LBABNFLG	char	Markedly Abnormal Indicator		Collected at CRF.
LBINCL	char	Lab Result Included in By-Time Analyses		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.

1.4.24.   Laboratory Results- Fecal – LABFECL

Dataset	LABFECL
Creating program	labfecl.sas
Description	Laboratory Results- Fecal
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBDT,LBDTC,LBLBLNUM,LBACTHR,LBACTMI,LBSTDNRC,LBORNRC,LBLOQL, LBHIQL,LBID,LBABNCRT,LBABNFLG

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBACTDY	num	Actual Study Day of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBFCLFLG	num	Baseline Fecal Indicator		Collected at CRF.
LBFCLBAS	char	Baseline Fecal Description		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBTSTCD	char	Lab Test Code		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.
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF.
LBSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSTUNIT	char	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.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	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.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
STDCHGBL	num	Change from Baseline in Standard Units		Collected at CRF.
LBINCL	char	Lab Result Included in By-Time Analyses		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.

1.4.25. Laboratory Results- Hematology – LABHEM

Dataset	LABHEM
Creating program	labhem.sas
Description	Laboratory Results- Hematology
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBDT,LBDTC,LBLBLNUM,LBACTHR,LBACTMI,LBSTDNRC,LBORNRC,LBLOQL, LBHIQL,LBID

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBACTDY	num	Actual Study Day of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
LBRELBAS	char	Relative to Baseline Description		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBTSTCD	char	Lab Test Code		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.
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF.
LBSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF.
LBSTUNIT	char	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.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
STDCHGBL	num	Change from Baseline in Standard Units		Collected at CRF.
LBABNCRT	char	Markedly Abnormal Criteria		Collected at CRF.
LBABNFLG	char	Markedly Abnormal Indicator		Collected at CRF.
LBINCL	char	Lab Result Included in By-Time Analyses		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.

1.4.26.   Laboratory Results- Hormone – LABHORM

Dataset	LABHORM
Creating program	labhorm.sas
Description	Laboratory Results- Hormone
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBDT,LBDTC,LBLBLNUM,LBACTHR,LBACTMI,LBSTRESN,LBSTNRLO,LBSTNRHI, LBORNRLO,LBORNRHI,LBLOQL,LBHIQL,LBID,STDCHGBL,LBABNCRT,LBABNFLG

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBACTDY	num	Actual Study Day of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
LBRELBAS	char	Relative to Baseline Description		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBTSTCD	char	Lab Test Code		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.
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	Original Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBINCL	char	Lab Result Included in By-Time Analyses		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.

1.4.27.   Laboratory Results- Immunology – LABIMM

Dataset	LABIMM
Creating program	labimm.sas
Description	Laboratory Results- Immunology
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBDT,LBDTC,LBLBLNUM,LBACTHR,LBACTMI,LBLOQL,LBHIQL,LBID,LBABNCRT, LBABNFLG

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBACTDY	num	Actual Study Day of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
LBRELBAS	char	Relative to Baseline Description		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBTSTCD	char	Lab Test Code		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.
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF.
LBSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSTUNIT	char	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.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	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.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
STDCHGBL	num	Change from Baseline in Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBINCL	char	Lab Result Included in By-Time Analyses		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.

1.4.28. Laboratory Results- Other Labs – LABOTH

Dataset	LABOTH
Creating program	laboth.sas
Description	Laboratory Results- Other Labs
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRESC,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBDT,LBDTC,LBLBLNUM,LBACTHR,LBACTMI,LBSTRESN,LBSTNRLO,LBSTNRHI, LBORNRLO,LBORNRHI,LBLOQL,LBHIQL,LBID,STDCHGBL,LBABNCRT,LBABNFLG

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBACTDY	num	Actual Study Day of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBRELFLG	num	Relative to Baseline Indicator		Collected at CRF.
LBRELBAS	char	Relative to Baseline Description		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBTSTCD	char	Lab Test Code		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.
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	Original Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBTSTORD	num	Lab Test Order		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBINCL	char	Lab Result Included in By-Time Analyses		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC-REF.DATE) +1.

1.4.29. Pyoderma Gangrenosum Information – LESASMT

Dataset	LESASMT
Creating program	lesasmt.sas
Description	Pyoderma Gangrenosum Information
Unique identifier	DUSUBJID,VISIT,LASEQ
Sorted by	DUSUBJID,VISIT,LASEQ
Notes	

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LASEQ	num	Lesion Assessment Sequence		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAVISIT	char	Visit		Collected at CRF.
LALESNUM	num	Number of Lesions		Collected at CRF.
LAMSR1	num	Diameter of Primary Lesion in cm		Collected at CRF.
LALOCTN	char	Location of Lesion		Collected at CRF.
LARESOLV	char	Resolved		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

1.4.30. Medication Review – MEDRVIEW

Dataset	MEDRVIEW
Creating program	medrview.sas
Description	Medication Review
Unique identifier	DUSUBJID,VISIT,MRCAT,MRSEQ
Sorted by	DUSUBJID,VISIT,MRCAT,MRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: MRCDT,MRCDTC,CMTERM,CMMODIFY,MRRTE_V,DRECNO,CODSTAT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
MRACTDY	num	Actual Study Day of Med change		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MRSEQ	num	Medication Sequence Number		Collected at CRF.
MRROUTE	num	Medication Route		Collected at CRF.
MRDOSE	num	Dose		Collected at CRF.
MRFRQSP	char	Frequency Specify		Collected at CRF.
MRDOSCH	num	Medication Reason for Change		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
MRCAT	char	Medication Category		Collected at CRF.
MRCHANGE	char	Medication Change		Collected at CRF.
MRDUNIT	char	Dose Unit		Collected at CRF.
MRFREQ	char	Frequency		Collected at CRF.
MRINCR	char	Medication Initiation Increase		Collected at CRF.
MRPMST	char	Start Prohibited Medications		Collected at CRF.
MRDOSCHD	char	Medication Reason for Change		Collected at CRF.
MRROUTED	char	Medication Route		Collected at CRF.
PEDOSE	num	Corticosteroid PE equivalent dose (mg)		Collected at CRF.

Variable	Type	Label	Codes	Comments
AZADOSE	num	AZA/6-MP equivalent dose		Collected at CRF.
IMMUDOSE	num	Total daily dose of immunomodulator (mg)		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
MRCDY	num	Relative Medication Change Day		If MRCDTC and REF.DATE not missing then perform below logic to calculate MRCDY, If MRCDTC less than REF.DATE then (MRCDTC - REF.DATE). Else if MRCDTC is greater than equal to REF.DATE then (MRCDTC- REF.DATE) +1.

1.4.31. Pharmacokinetic and ATSA – PDRESUL

Dataset	PDRESUL
Creating program	pdresul.sas
Description	Pharmacokinetic and ATSA
Unique identifier	DUSUBJID,VISIT,CPRESCAT
Sorted by	DUSUBJID,VISIT,CPRESCAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: ATDT,ATDTC,CPLABEL,ATNTCOL,CPPERIOD,CPLABID

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
ATTM	num	Time of sample		Collected at CRF.
CPRESCAT	char	PD Result Category		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATPTM	char	Planned Timepoint(Period)		Collected at CRF.
CPTEST	char	PD test code Description		Collected at CRF.
CPTESTCD	char	PD Test Code		Collected at CRF.
CPRESC	num	PD Characteric result		Collected at CRF.
CPUNIT	char	PD Unit		Collected at CRF.
CPLLOQ	num	PD Low of Quantity		Collected at CRF.
ATEVQL	char	Event Qualifier		Collected at CRF.
ATKTTYP	char	Kit Type		Collected at CRF.
ATSMTYP	char	Sample Type		Collected at CRF.
CPASY	char	Assay Description		Collected at CRF.
CPASYCD	char	Assay Description		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
ATDY	num	Relative Day of Sample (Char.)		If ATDTC and REF.DATE not missing then perform below logic to calculate ATDY, If ATDTC less than REF.DATE then (ATDTC - REF.DATE). Else if ATDTC is greater than equal to REF.DATE then (ATDTC-REF.DATE) +1.

1.4.32. Pharmacokinetic and ATSA – PKATSA

Dataset	PKATSA
Creating program	pkatsa.sas
Description	Pharmacokinetic and ATSA
Unique identifier	DUSUBJID,VISIT,PKRESCAT,PKRESC,PKDY
Sorted by	DUSUBJID,VISIT,PKRESCAT,PKRESC,PKDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: PKDT,PKDTC,PKCMT2CD,PKNOTCOL

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
PKACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
PKACTTM	num	Time of sample		Collected at CRF.
PKRELFLG	num	Relative to baseline indicator		Collected at CRF.
PKRELBAS	char	Relative to baseline description		Collected at CRF.
PKRESCAT	char	PK Result Category		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PKTEST	char	PK test		Collected at CRF.
PKTESTCD	char	PK Test Code		Collected at CRF.
PKRESN	num	PK Numeric Results		Collected at CRF.
PKRESC	char	PK Characteric result		Collected at CRF.
PKUNIT	char	PK Unit		Collected at CRF.
PKCMT1	char	PK Comment 1		Collected at CRF.
PKCMT1CD	char	PK Comment Code 1		Collected at CRF.
PKCMT2	char	PK Comment 2		Collected at CRF.
PKLLOQ	num	PK Low of Quantity		Collected at CRF.
PKSMPINC	char	Sample included in PK analysis		Collected at CRF.
SERUMCAT	char	PK Concentration Category		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
PKDY	num	Relative Day of Sample (Char.)		If PKDTC and REF.DATE not missing then perform below logic to calculate PKDY, If PKDTC less than REF.DATE then (PKDTC - REF.DATE). Else if PKDTC is greater than equal to REF.DATE then (PKDTC-REF.DATE) +1.

1.4.33.   Neutralizing Antibody – PKNAB

Dataset	PKNAB
Creating program	pknab.sas
Description	Neutralizing Antibody
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 repetition of the information or due to missing values: PKDT,PKDTC,PKRESN,PKCMT1,PKCMT1CD,PKCMT2,PKCMT2CD,PKNOTCOL

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
PKACTDY	num	Actual Study Day of Visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PKACTTM	num	Time of sample		Collected at CRF.
PKRELFLG	num	Relative to baseline indicator		Collected at CRF.
PKRELBAS	char	Relative to baseline description		Collected at CRF.
PKRESCAT	char	PK Result Category		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PKTEST	char	PK test		Collected at CRF.
PKTESTCD	char	PK Test Code		Collected at CRF.
PKRESC	char	PK Characteric result		Collected at CRF.
PKUNIT	char	PK Unit		Collected at CRF.
PKLLOQ	num	PK Low of Quantity		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
PKDY	num	Relative Day of Sample (Char.)		If PKDTC and REF.DATE not missing then perform below logic to calculate PKDY, If PKDTC less than REF.DATE then (PKDTC - REF.DATE). Else if PKDTC is greater than equal to REF.DATE then (PKDTC-REF.DATE) +1.

1.4.34. Crohn's disease medication history – RXCLASS

Dataset	RXCLASS
Creating program	rxclass.sas
Description	Crohn's disease medication history
Unique identifier	DUSUBJID,VISIT,RXSEQ,RXDRUG,RXDOS1
Sorted by	DUSUBJID,VISIT,RXSEQ,RXDRUG,RXDOS1
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: RXDS1DT,RXDS1DTC,RXDS2DT,RXDS2DTC,RXDS3DT,RXDS3DTC,RXHXCAT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXSEQ	num	RX Sequence Number		Collected at CRF.
RXDRUG	char	Drug Name		Collected at CRF.
RXDOS1	char	Dose 1		Collected at CRF.
RXDOS1SP	num	Dose 1 Specify		Collected at CRF.
RXDOS2	char	Dose 2		Collected at CRF.
RXDOS2SP	num	Dose 2 Specify		Collected at CRF.
RXDOS3	char	Dose 3		Collected at CRF.
RXDOS3SP	num	Dose 3 Specify		Collected at CRF.
RXSTFRQ	char	Worsening Stool Frequency		Collected at CRF.
RXABPAIN	char	Worsening Abdominal Pain		Collected at CRF.
RXFEVER	char	CD Related Fever		Collected at CRF.
RXDRAIN	char	Draining		Collected at CRF.
RXRCBLD	char	Rectal Bleeding		Collected at CRF.
RXDIARR	char	Antidiarrheal Medication		Collected at CRF.
RXSAIR	char	Significant Acute Infusion Reaction		Collected at CRF.
RXFEVAC	char	Acute Fever		Collected at CRF.
RXCHILL	char	Chill/Rigor		Collected at CRF.
RXITCH	char	Itching		Collected at CRF.
RXRASH	char	Rash		Collected at CRF.
RXFLUSH	char	Flushing		Collected at CRF.
RXURTIC	char	Urticaria/Angioedema		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXBREATH	char	Breathing Difficulties		Collected at CRF.
RXHYPOT	char	Hypotension		Collected at CRF.
RXSDIR	char	Significant Delayed Infusion Reaction		Collected at CRF.
RXMYALGI	char	Myalgias		Collected at CRF.
RXARTHAL	char	Arthralgias		Collected at CRF.
RXFEVDEL	char	Delayed Fever		Collected at CRF.
RXMALAIS	char	Malaise		Collected at CRF.
RXDELRAS	char	Delayed Rash		Collected at CRF.
RXSSIR	char	Significant Injection Site Reaction		Collected at CRF.
RXBRUISE	char	Bruising		Collected at CRF.
RXERYTHE	char	Erythema		Collected at CRF.
RXHEMORR	char	Hemorrhage		Collected at CRF.
RXIRR	char	Irritation		Collected at CRF.
RXPAIN	char	Pain		Collected at CRF.
RXPRITUS	char	Pruritus		Collected at CRF.
RXINJST	char	Injection Site Reaction		Collected at CRF.
RXCCST	char	Corticosteroid		Collected at CRF.
RXSTDEP	char	Corticosteroid Dependent		Collected at CRF.
RXCORTFU	char	Corticosteroid Full Course		Collected at CRF.
RXCORREF	char	Corticosteroid Refractory		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXIMMFU	char	Immunomodulator Full Course		Collected at CRF.
RXIMMREF	char	Immunomodulator Refractory		Collected at CRF.
RXTNF	char	Inadeq resp or loss resp or intol to TNF		Collected at CRF.
RXINADEQ	char	Subj had an inadequate initial response		Collected at CRF.
RXLORESP	char	Subj had resp. followed by loss of resp.		Collected at CRF.
RXINTOLE	char	Subj experienced intolerance		Collected at CRF.
RXIQTNF1	char	Inadequate initial resp. to 1 TNF drug		Collected at CRF.
RXIQTNF2	char	Inadequate initial resp. to 2 TNF drugs		Collected at CRF.
RXIQTNF3	char	Inadequate initial resp. to 3 TNF drugs		Collected at CRF.
RXLOTNF1	char	Loss resp to 1 TNF drug		Collected at CRF.
RXLOTNF2	char	Loss resp to 2 TNF drugs		Collected at CRF.
RXLOTNF3	char	Loss resp to 3 TNF drugs		Collected at CRF.
RXTOTNF1	char	Intolerance to 1 TNF drug		Collected at CRF.
RXTOTNF2	char	Intolerance to 2 TNF drugs		Collected at CRF.
RXTOTNF3	char	Intolerance to 3 TNF drugs		Collected at CRF.
RXTNF1	char	Inadeq resp/loss resp/intole to 1 TNF		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXTNF2	char	Inadeq resp/loss resp/intole to 2 TNF		Collected at CRF.
RXTNF3	char	Inadeq resp/loss resp/intole to 3 TNF		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
RXDS1DY	num	Relative Dose 1 Day		If RXDS1DTC and REF.DATE not missing then perform below logic to calculate RXDS1DY, If RXDS1DTC less than REF.DATE then (RXDS1DTC - REF.DATE). Else if RXDS1DTC is greater than equal to REF.DATE then (RXDS1DTC- REF.DATE) +1.
RXDS2DY	num	Relative Dose 2 Day		If RXDS2DTC and REF.DATE not missing then perform below logic to calculate RXDS2DY, If RXDS2DTC less than REF.DATE then (RXDS2DTC - REF.DATE). Else if RXDS2DTC is greater than equal to REF.DATE then (RXDS2DTC- REF.DATE) +1.
RXDS3DY	num	Relative Dose 3 Day		If RXDS3DTC and REF.DATE not missing then perform below logic to calculate RXDS3DY, If RXDS3DTC less than REF.DATE then (RXDS3DTC - REF.DATE). Else if RXDS3DTC is greater than equal to REF.DATE then (RXDS3DTC- REF.DATE) +1.

1.4.35.   Subject level efficacy data – SUBJEF

Dataset	SUBJEF
Creating program	subjef.sas
Description	Subject level efficacy data
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 repetition of the information: REGION,ITFDT,MTFDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
RESPWK4	char	Clinical response at week 4		Collected at CRF.
RESPWK6	char	Clinical response at week 6		Collected at CRF.
RESPSA1	char	Clinical response at week 6, sens anal 1		Collected at CRF.
REMWK6	char	Clinical remission at week 6		Collected at CRF.
REMWK4	char	Clinical remission at week 4		Collected at CRF.
CDAI70W6	char	With reduct. in CDAI of >=70 at W6		Collected at CRF.

Variable	Type	Label	Codes	Comments
BFIST	char	Subject had 1 or more fistula at bl.		Collected at CRF.
BWEIGHT	num	Baseline Weight		Collected at CRF.
IBDQEXCL	char	Excluded from IBDQ analysis flag.		Collected at CRF.
IBDQST22	char	Sustained improved IBDQ thr wk22 TF rule		Collected at CRF.
IBDQST36	char	Sustained improved IBDQ thr wk36 TF rule		Collected at CRF.
RACE_C	char	Race Category (caucasian/non_caucasian)		Collected at CRF.
AGE_C	char	Baseline age category		Collected at CRF.
AGEM_C	char	responder age category		Collected at CRF.
BWGT_C	char	Baseline body weight category		Collected at CRF.
BWGT_Q	char	Baseline body weight quartile		Collected at CRF.
DISDUR_C	char	Disease duration category.		Collected at CRF.
GI_INVOL	char	Involved gastrointertinal area		Collected at CRF.
BCDAI_C	char	Baseline CDAI score category		Collected at CRF.
BCRP_C	char	Baseline CRP category		Collected at CRF.
BCDAIM_C	char	Baseline Median CDAI cat for responders		Collected at CRF.
BRSP_TNF	char	Initial response to TNF antagonist tx.		Collected at CRF.
BWGTM_C	char	Baseline responder body weight category		Collected at CRF.

Variable	Type	Label	Codes	Comments
BWGTM_Q	char	Baseline responder body weight quartile		Collected at CRF.
RXTNF	char	Inadeq resp or loss resp or intol to TNF		Collected at CRF.
RXTNF1	char	Inadeq resp/loss resp/intole to 1 TNF		Collected at CRF.
RXTNF2	char	Inadeq resp/loss resp/intole to 2 TNF		Collected at CRF.
RXTNF3	char	Inadeq resp/loss resp/intole to 3 TNF		Collected at CRF.
RXINADEQ	char	Subj had an inadequate initial response		Collected at CRF.
RXLORESP	char	Subj had resp. followed by loss of resp.		Collected at CRF.
RXINTOLE	char	Subj experienced intolerance		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
RESPST22	char	Sustained responses through wk22 TF rule		Collected at CRF.
RESPST28	char	Sustained responses through wk28 TF rule		Collected at CRF.
RESPST36	char	Sustained responses through wk36 TF rule		Collected at CRF.

Variable	Type	Label	Codes	Comments
REMST22	char	Sustained remission through wk22 TF rule		Collected at CRF.
REMST28	char	Sustained remission through wk28 TF rule		Collected at CRF.
REMST36	char	Sustained remission through wk36 TF rule		Collected at CRF.
W8CORTYN	char	Corticosteroid received at Wk 8		Collected at CRF.
WK8CORT	num	Corticosteroid total daily use at Wk 8		Collected at CRF.
ITFFLG	char	Trt fail flg - subj level (induction)		Collected at CRF.
MTFFLG	char	Trt fail flg - subj level (maintenance)		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
ITFDY	num	Relative Trt failure Day (induction)		If ITFDT and REF.DATE not missing then perform below logic to calculate ITFDY, If ITFDT less than REF.DATE then (ITFDT - REF.DATE). Else if ITFDT is greater than equal to REF.DATE then (ITFDT-REF.DATE) +1.
MTFDY	num	Relative Trt failure Day (maintenance)		If MTFDT and REF.DATE not missing then perform below logic to calculate MTFDY, If MTFDT less than REF.DATE then (MTFDT - REF.DATE). Else if MTFDT is greater than equal to REF.DATE then (MTFDT-REF.DATE) +1.

1.4.36. Subject level safety data – SUBJSF

Dataset	SUBJSF
Creating program	subjsf.sas
Description	Subject level safety data
Unique identifier	DUSUBJID,TXPHASCD
Sorted by	DUSUBJID,TXPHASCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TXSTDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
TXSTTM	num	Treatment Phase Start Time		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
DURFUP	num	Wks of Follow-up (Phase)		Collected at CRF.
OVRFUP22	num	Wks of Follow-up thru Wk22		Collected at CRF.

Variable	Type	Label	Codes	Comments
OVRFUP	num	Wks of Follow-up		Collected at CRF.
DURTRT	num	Wks of Treatment (Phase)		Collected at CRF.
OVRTRT22	num	Wks of Treatment thru Wk22		Collected at CRF.
OVRTRT	num	Wks of Treatment		Collected at CRF.
TADM	num	Total Administrations (Phase)		Collected at CRF.
TAADM	num	Total Active Administrations (Phase)		Collected at CRF.
OVRADM22	num	Total Administrations Thru Week 22		Collected at CRF.
OVRAAD22	num	Total Active Administrations thru Wk 22		Collected at CRF.
OVRADM	num	Total Administrations		Collected at CRF.
OVRAADM	num	Total Active Administrations		Collected at CRF.
TDOSE	num	Total Dose (Phase)		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
DOSERTE	char	Dose Route (Phase)		Collected at CRF.
BWEIGHT	num	Baseline Weight		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
TXSTDY	num	Relative Treatment Phase Start Day		If TXSTDT and REF.DATE not missing then perform below logic to calculate TXSTDY, If TXSTDT less than REF.DATE then (TXSTDT - REF.DATE). Else if TXSTDT is greater than equal to REF.DATE then (TXSTDT- REF.DATE) +1.

1.4.37.   Substudy info - DNA/mRNA and Biopsy – SUBSTDY

Dataset	SUBSTDY
Creating program	substdy.sas
Description	Substudy info - DNA/mRNA and Biopsy
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 repetition of the information: SPDMCDT,SPDMCDTC,SSDT,SSDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
SSACTDY	num	Actual study day of visit		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
SPBIOCOL	char	Colonoscopy Substudy		Collected at CRF.
SPBIOPSY	char	Colonoscopy Biopsy		Collected at CRF.
SPBIORE	char	Colonoscopy Recording		Collected at CRF.
SPDNA	char	DNA Substudy		Collected at CRF.
SPDNAST	char	DNA Storage		Collected at CRF.
SPDNAST2	char	DNA Storage 2		Collected at CRF.
SPMRNA	char	RNA Substudy		Collected at CRF.
SPMRNAST	char	RNA Storage		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
SPDMCDY	num	Relative DNA Informed Consent Day		If SPDMCDTC and REF.DATE not missing then perform below logic to calculate SPDMCDY, If SPDMCDTC less than REF.DATE then (SPDMCDTC - REF.DATE). Else if SPDMCDTC is greater than equal to REF.DATE then (SPDMCDTC- REF.DATE) +1.
SSDY	num	Relative Day of visit		If SSDTC and REF.DATE not missing then perform below logic to calculate SSDY, If SSDTC less than REF.DATE then (SSDTC - REF.DATE). Else if SSDTC is greater than equal to REF.DATE then (SSDTC-REF.DATE) +1.

1.4.38.   Screening for Tuberculosis /Tuberculosis – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Screening for Tuberculosis /Tuberculosis
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 repetition of the information: TBLTRDT,TBLTRDTC,TBCXRDT,TBCXRDTC,TBBCGYR

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
TBACTADY	num	Acutal Study Day of Latent TB Treatment		Collected at CRF.
TBACTXDY	num	Acutal Study Day of Chest X-ray		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.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
TBSEQ	num	Sequence Number		Collected at CRF.
TBCXRES	char	Chest X-Ray Result		Collected at CRF.
TBLTB	char	History of Latent TB		Collected at CRF.
TBLTRT	char	Latent TB Treatment		Collected at CRF.
TBTRTRQ	char	Treatment Required		Collected at CRF.
TBBCG	num	Previous BCG Vaccination		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
TBLTRDY	num	Relative Latent TB Treatment Day		If TBLTRDTC and REF.DATE not missing then perform below logic to calculate TBLTRDY, If TBLTRDTC less than REF.DATE then (TBLTRDTC - REF.DATE). Else if TBLTRDTC is greater than equal to REF.DATE then (TBLTRDTC- REF.DATE) +1.
TBCXRDY	num	Relative Chest X-Ray Day		If TBCXRDTC and REF.DATE not missing then perform below logic to calculate TBCXRDY, If TBCXRDTC less than REF.DATE then (TBCXRDTC - REF.DATE). Else if TBCXRDTC is greater than equal to REF.DATE then (TBCXRDTC- REF.DATE) +1.

1.4.39.   Treatment Failures in induction phase – TRTFAILI

Dataset	TRTFAILI
Creating program	trtfaili.sas
Description	Treatment Failures in induction phase
Unique identifier	DUSUBJID,TFIMCAT,TFACTDY
Sorted by	DUSUBJID,TFIMCAT,TFACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: TFIDT,TFIDTC,TFIREAS

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
TFACTDY	num	Actual study day of Treatment failure		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
TFICRIT	char	Treatment failure criteria (W0 to W8)		Collected at CRF.
TFIMCAT	char	Treatment failure med sub-cat (W0 to W8)		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
TFIDY	num	Relative Trt failure Day (W0-W8 char)		If TFIDTC and REF.DATE not missing then perform below logic to calculate TFIDY, If TFIDTC less than REF.DATE then (TFIDTC - REF.DATE). Else if TFIDTC is greater than equal to REF.DATE then (TFIDTC- REF.DATE) +1.

1.4.40. Treatment Failures in maintenance phase – TRTFAILM

Dataset	TRTFAILM
Creating program	trtfailm.sas
Description	Treatment Failures in maintenance phase
Unique identifier	DUSUBJID,TF22MCAT,TFMMCAT,TFACTDY
Sorted by	DUSUBJID,TF22MCAT,TFMMCAT,TFACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: TF22DT,TF22DTC,TF22REAS,TF36DT,TF36DTC,TF36REAS,TFMDT,TFMDTC, TFMREAS

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
TFACTDY	num	Actual study day of Treatment failure		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
TF22CRIT	char	Treatment failure criteria (W8 to W22)		Collected at CRF.

Variable	Type	Label	Codes	Comments
TF22MCAT	char	Treatment fail med sub-cat (W8 to W22)		Collected at CRF.
TF36CRIT	char	Treatment failure criteria (W22 to W36)		Collected at CRF.
TF36MCAT	char	Treatment fail med sub-cat (W22 to W36)		Collected at CRF.
TFMCRIT	char	Treatment failure criteria (W8 to W36)		Collected at CRF.
TFMMCAT	char	Treatment fail med sub-cat (W8 to W36)		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
TF22DY	num	Relative Trt failure Day (W8-W22 char)		If TF22DTC and REF.DATE not missing then perform below logic to calculate TF22DY, If TF22DTC less than REF.DATE then (TF22DTC - REF.DATE). Else if TF22DTC is greater than equal to REF.DATE then (TF22DTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TF36DY	num	Relative Trt failure Day (W22-W36 char)		If TF36DTC and REF.DATE not missing then perform below logic to calculate TF36DY, If TF36DTC less than REF.DATE then (TF36DTC - REF.DATE). Else if TF36DTC is greater than equal to REF.DATE then (TF36DTC- REF.DATE) +1.
TFMDY	num	Relative Trt failure Day (W8-W36 char)		If TFMDTC and REF.DATE not missing then perform below logic to calculate TFMDY, If TFMDTC less than REF.DATE then (TFMDTC - REF.DATE). Else if TFMDTC is greater than equal to REF.DATE then (TFMDTC- REF.DATE) +1.

1.4.41. Administration Level IV/SC Exposure – VISADM

Dataset	VISADM
Creating program	visadm.sas
Description	Administration Level IV/SC Exposure
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 repetition of the information: EXSTDT,EXSTDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EXACTSDY	num	Actual Study Day of Start Dose		Collected at CRF.
SEX	char	Sex		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.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE	num	Dose Received		Collected at CRF.
EXROUTE	char	Route of administration		Collected at CRF.
EXDEV2	char	Subject had a legcy admini deviation		Collected at CRF.
EXINCORT	char	Received incorrect study agent or dose		Collected at CRF.
EXMISS	char	Skipped an administration		Collected at CRF.
EXOUTWD2	char	Received an admin. outside window		Collected at CRF.
EXINFDEV	char	Duration of admin less than 30 minutes		Collected at CRF.
EXDUR	num	Duration of this Exposure		Collected at CRF.
EXDURU	char	Units of time for this exposure		Collected at CRF.
TXPHASCD	num	Study Phase Code		Collected at CRF.
TXPHASE	char	Study Phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
EXSTDY	num	Relative Start Day of Dose		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC- REF.DATE) +1.

1.4.42.   Visit level CDAI summary – VISCDAI

Dataset	VISCDAI
Creating program	viscdai.sas
Description	Visit level CDAI summary
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 repetition of the information: EVALDT,EVALDTC,MTFDT,MTFDTC,ITFDT,ITFDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
RELFLG	num	Relative to baseline indicator		Collected at CRF.
RELBAS	char	Relative to baseline descriptor		Collected at CRF.
CDAI	num	CDAI Total Score		Collected at CRF.
CDAICG	num	CDAI change from baseline		Collected at CRF.
CDAIPCG	num	Percent change from b/l in CDAI score		Collected at CRF.
CDAIL	num	CDAI score LVCF		Collected at CRF.
CDAILCG	num	Bl change CDAI (LVCF)		Collected at CRF.
CDAILPCG	num	CDAI pct change from b/l (LVCF)		Collected at CRF.
CDAILTF	num	CDAI score LVCF and TF rule in I/M phase		Collected at CRF.
CDAITCG	num	CDAI change from b/l (LVCF+TF)		Collected at CRF.
CDAITPCG	num	CDAI pct change from b/l (LVCF+TF)		Collected at CRF.
CDAILM	num	CDAI score LVCF in maintenance phase		Collected at CRF.
CDAILTFM	num	CDAI score LVCF and TF rule in M phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
CDAI70	char	Reduction >=25% &>= 70point (primary)		Collected at CRF.
REMISS	char	Clinical remission (primary rules)		Collected at CRF.
RESPONSE	char	Clinical response (primary rules)		Collected at CRF.
RSPSENS1	char	Clinical response, sens analysis 1		Collected at CRF.
CDAI70RE	char	Reduction >= 70point (primary)		Collected at CRF.
MTFFLGV	char	Trt fail flg - visit level (maintenance)		Collected at CRF.
ITFFLGV	char	Trt fail flg - visit level (induction)		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
EVALDY	num	Relative Evaluation Day		If EVALDTC and REF.DATE not missing then perform below logic to calculate EVALDY, If EVALDTC less than REF.DATE then (EVALDTC - REF.DATE). Else if EVALDTC is greater than equal to REF.DATE then (EVALDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MTFDY	num	Relative Trt failure Day (mantence char)		If MTFDTC and REF.DATE not missing then perform below logic to calculate MTFDY, If MTFDTC less than REF.DATE then (MTFDTC - REF.DATE). Else if MTFDTC is greater than equal to REF.DATE then (MTFDTC- REF.DATE) +1.
ITFDY	num	Relative Trt failure Day (inductn-char)		If ITFDTC and REF.DATE not missing then perform below logic to calculate ITFDY, If ITFDTC less than REF.DATE then (ITFDTC - REF.DATE). Else if ITFDTC is greater than equal to REF.DATE then (ITFDTC-REF.DATE) +1.

1.4.43. Visit level corticosteroids summary – VISCORT

Dataset	VISCORT
Creating program	viscort.sas
Description	Visit level corticosteroids summary
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 repetition of the information: EVALDT,EVALDTC,MTFDT,MTFDTC,ITFDT,ITFDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
RELFLG	num	Relative to baseline indicator		Collected at CRF.
RELBAS	char	Relative to baseline descriptor		Collected at CRF.
PEAVDD	num	Avg Daily Prednisone Eq. Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
PEAVDDLM	num	Avg Daily Prednisone Eq. LVCF in M phase		Collected at CRF.
PEAVDMTF	num	Avg Daily cort Eq. Dose TF/LVCF in M		Collected at CRF.
BUAVDD	num	average daily dose of budesonide		Collected at CRF.
BUAVDDLM	num	Avg Daily Budesonide LVCF in M phase		Collected at CRF.
BUAVDMTF	num	Avg Daily Budesonide Dose TF/LVCF in M		Collected at CRF.
MTFFLGV	char	Trt fail flg - visit level (maintenance)		Collected at CRF.
ITFFLGV	char	Trt fail flg - visit level (induction)		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned subject ID for De-identity
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned site ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned site-subject ID for De-identity
EVALDY	num	Relative Evaluation Day		If EVALDTC and REF.DATE not missing then perform below logic to calculate EVALDY, If EVALDTC less than REF.DATE then (EVALDTC - REF.DATE). Else if EVALDTC is greater than equal to REF.DATE then (EVALDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MTFDY	num	Relative Trt failure Day (mantence char)		If MTFDTC and REF.DATE not missing then perform below logic to calculate MTFDY, If MTFDTC less than REF.DATE then (MTFDTC - REF.DATE). Else if MTFDTC is greater than equal to REF.DATE then (MTFDTC- REF.DATE) +1.
ITFDY	num	Relative Trt failure Day (inductn-char)		If ITFDTC and REF.DATE not missing then perform below logic to calculate ITFDY, If ITFDTC less than REF.DATE then (ITFDTC - REF.DATE). Else if ITFDTC is greater than equal to REF.DATE then (ITFDTC-REF.DATE) +1.

1.4.44. Visit level productivity (VAS) summary – VISECON

Dataset	VISECON
Creating program	visecon.sas
Description	Visit level productivity (VAS) summary
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 repetition of the information: EVALDT,EVALDTC,ITFDT,ITFDTC,MTFDT,MTFDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
RELFLG	num	Relative to baseline indicator		Collected at CRF.
RELBAS	char	Relative to baseline descriptor		Collected at CRF.

Variable	Type	Label	Codes	Comments
VAS	num	Productivity Scale (cm)		Collected at CRF.
VASLTF	num	VAS score TF rule in I/M phase		Collected at CRF.
VASLTFM	num	VAS score with TF rule in M phase		Collected at CRF.
VASCG	num	VAS change from baseline		Collected at CRF.
VASTCG	num	VAS change from b/l (TF)		Collected at CRF.
VASTCGM	num	VAS change from b/l (TF) in m phas		Collected at CRF.
ITFFLGV	char	Trt fail flg - visit level (induction)		Collected at CRF.
MTFFLGV	char	Trt fail flg - visit level (maintenance)		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
EVALDY	num	Relative Evaluation Day		If EVALDTC and REF.DATE not missing then perform below logic to calculate EVALDY, If EVALDTC less than REF.DATE then (EVALDTC - REF.DATE). Else if EVALDTC is greater than equal to REF.DATE then (EVALDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ITFDY	num	Relative Trt failure Day (inductn-char)		If ITFDTC and REF.DATE not missing then perform below logic to calculate ITFDY, If ITFDTC less than REF.DATE then (ITFDTC - REF.DATE). Else if ITFDTC is greater than equal to REF.DATE then (ITFDTC-REF.DATE) +1.
MTFDY	num	Relative Trt failure Day (mantence char)		If MTFDTC and REF.DATE not missing then perform below logic to calculate MTFDY, If MTFDTC less than REF.DATE then (MTFDTC - REF.DATE). Else if MTFDTC is greater than equal to REF.DATE then (MTFDTC- REF.DATE) +1.

1.4.45. Visit level fistula summary – VISFIST

Dataset	VISFIST
Creating program	visfist.sas
Description	Visit level fistula summary
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 repetition of the information: EVALDT,EVALDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
RELFLG	num	Relative to baseline indicator		Collected at CRF.
RELBAS	char	Relative to baseline descriptor		Collected at CRF.
FSTNUM	num	Number of draining fistulas at the visit		Collected at CRF.
FSTNUMPC	num	Pct chg from b/l in draining fistula		Collected at CRF.
FSTRSP50	char	>= 50% fistula response		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
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
EVALDY	num	Relative Evaluation Day		If EVALDTC and REF.DATE not missing then perform below logic to calculate EVALDY, If EVALDTC less than REF.DATE then (EVALDTC - REF.DATE). Else if EVALDTC is greater than equal to REF.DATE then (EVALDTC- REF.DATE) +1.

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1.4.46.   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 repetition of the information: VISITDT,VISITDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

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Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		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
VISITDY	num	Relative Day of Subject Visit		If VISITDTC and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDTC less than REF.DATE then (VISITDTC - REF.DATE). Else if VISITDTC is greater than equal to REF.DATE then (VISITDTC- REF.DATE) +1.

1.4.47. Visit level lab efficacy summary – VISLABEF

Dataset	VISLABEF
Creating program	vislabef.sas
Description	Visit level lab efficacy summary
Unique identifier	DUSUBJID,VISIT,CRPTCFM
Sorted by	DUSUBJID,VISIT,CRPTCFM
Notes	

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
RELFLG	num	Relative to baseline indicator		Collected at CRF.
RELBAS	char	Relative to baseline descriptor		Collected at CRF.
FLACT	num	Fecal Lactoferrin Concentration		Collected at CRF.
FLACTLOG	num	Fecal lactoferrin log value		Collected at CRF.
FLACTLCF	num	FecalLactoferrin log LVCF in I/M		Collected at CRF.

Variable	Type	Label	Codes	Comments
FLACTTCF	num	Fecal lactoferrin log LVCF/TF in I/M		Collected at CRF.
LACTCFCH	num	Fecal Lacto log Change from bl LVCF/TF		Collected at CRF.
FCALP	num	Fecal Calprotectin Concentration		Collected at CRF.
FCALPLOG	num	Fecal calprotectin log value		Collected at CRF.
FCALPLCF	num	fecal calprotectin log LVCF in I/M		Collected at CRF.
FCALPTCF	num	Fecal calprotectin log LVCF/TF in I/M		Collected at CRF.
CALPCFCH	num	fecal calp log chang from bl LVCF/TF		Collected at CRF.
CRP	num	CRP Concentration		Collected at CRF.
CRPLCF	num	CRP Concentration with LVCF in I/M		Collected at CRF.
CRPTCF	num	CRP Concentration LVCF/TF in I/M phase		Collected at CRF.
CRPCFCH	num	CRP change from baseline with LVCF/TF		Collected at CRF.
CRPNORM	char	Normal CRP flag		Collected at CRF.
CRPLFNOR	char	Normal CRP with LVCF flag		Collected at CRF.
CRPTFNOR	char	Normal CRP with TF flag		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRPTCFM	num	CRP Concentration LVCF/TF in M phase		Collected at CRF.
CRPLCFM	num	CRP Concentration with LVCF in M phase		Collected at CRF.
FCALPTFM	num	Fecal calprotectin log LVCF/TF in M		Collected at CRF.
FCALPLM	num	fecal calprotectin log LVCF in M		Collected at CRF.
FLACTTFM	num	Fecal lactoferrin log LVCF/TF M phas		Collected at CRF.
FLACTLM	num	Fecal Lactoferrin log LVCF in M phase		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

1.4.48.   Visit level BDQ,JSEQ summary – VISQOL

Dataset	VISQOL
Creating program	visqol.sas
Description	Visit level BDQ,JSEQ summary
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 repetition of the information: EVALDT,EVALDTC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned unique subject Id for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCDI	num	Randomized trt Code induction phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPI	char	Decode of TRTCDI		Collected at CRF.
TRTCDM	num	Re-randed Trt Code in maintenance phase		Collected at CRF.
TRTGRPM	char	Decode of TRTCDM		Collected at CRF.
TRTCDAI	num	Actual trt Code induction phase		Collected at CRF.
TRTGRPAI	char	Decode of TRTCDAI		Collected at CRF.
TRTCDAM	num	Actual trt Code in maintenance phase		Collected at CRF.
TRTGRPAM	char	Decode of TRTCDAM		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRANDI	char	Subjects Randomized in induction phase		Collected at CRF.
POPTRTI	char	Subjects Treated in induction phase		Collected at CRF.
POPENTM	char	Subjects in the maintenance phase		Collected at CRF.
POPRANDM	char	Subjects Randomized in maintenance phase		Collected at CRF.
POPTRTM	char	Subjects Treated in maintenance phase		Collected at CRF.
RELFLG	num	Relative to baseline indicator		Collected at CRF.
RELBAS	char	Relative to baseline descriptor		Collected at CRF.
IBDQ_TOT	num	Total IBDQ score		Collected at CRF.
IBDQ_B	num	Total IBDQ score - Bowel		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQ_E	num	Total IBDQ score - Emotional		Collected at CRF.
IBDQ_SF	num	Total IBDQ score - Social		Collected at CRF.
IBDQ_SY	num	Total IBDQ score - Systemic		Collected at CRF.
IBDQTCF	num	Total IBDQ score TF+wLVCF I/M phase		Collected at CRF.
IBDBOTCF	num	IBDQ Bowel score w LVCF/TF in I/M phase		Collected at CRF.
IBDEMTCF	num	IBDQ emotion score wLVCF/TF in I/M phase		Collected at CRF.
IBDSFTCF	num	IBDQ social score w LVCF/TF in I/M phase		Collected at CRF.
IBDSYTCF	num	IBDQ systemic score w LVCF/TF in I/M pha		Collected at CRF.
IBDQCH	num	IBDQ Total score change from baseline		Collected at CRF.
IBDQCFCH	num	Total IBDQ chang from baseline, TF+BLVCF		Collected at CRF.
IBBOCFCH	num	Change from bl in IBDQ bowel score		Collected at CRF.
IBEMCFCH	num	Change from bl in IBDQ emotional score		Collected at CRF.
IBSFCFCH	num	Change from bl in IBDQ social score.		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBSYCFCH	num	Change from bl in IBDQ systemic score		Collected at CRF.
JSEQ_TOT	num	Total JSEQ score		Collected at CRF.
JSEQTCF	num	Total JSEQ score, TF+LVCF in I/M phase		Collected at CRF.
JSEQCFCH	num	Total JSEQ chang from baseline, TF+BLVCF		Collected at CRF.
IBDQEXCL	char	Excluded from IBDQ analysis flag.		Collected at CRF.
IBDQIMPF	char	>= 16 pts. improve in IBDQ (TF)		Collected at CRF.
IBDQIMPV	char	More than 16 pts. improvement in IBDQ		Collected at CRF.
IRRESP	char	Achieving clinical response at Week 6		Collected at CRF.
IBDBOLM	num	IBDQ Bowel score LVCF in M phase		Collected at CRF.
IBDBOTFM	num	IBDQ Bowel score LVCF/TF in M phase		Collected at CRF.
IBDSYTFM	num	IBDQ systemic score w LVCF/TF in M phase		Collected at CRF.
IBDSYLM	num	IBDQ systemic score LVCF in M phase		Collected at CRF.
IBDSFLM	num	IBDQ social score LVCF in M phase		Collected at CRF.
IBDSFTFM	num	IBDQ social score w LVCF/TF in M phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDEMLM	num	IBDQ emotional score LVCF in M phase		Collected at CRF.
IBDEMTFM	num	emotional score LVCF/TF in M phase		Collected at CRF.
IBDQLM	num	total IBDQ score LVCF in M phase		Collected at CRF.
IBDQTFM	num	total IBDQ score LVCF/TF in M phase		Collected at CRF.
JSEQLM	num	total JSEQ score LVCF in M phase		Collected at CRF.
JSEQTFM	num	total JSEQ score LVCF/TF in M phase		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
EVALDY	num	Relative Evaluation Day		If EVALDTC and REF.DATE not missing then perform below logic to calculate EVALDY, If EVALDTC less than REF.DATE then (EVALDTC - REF.DATE). Else if EVALDTC is greater than equal to REF.DATE then (EVALDTC- REF.DATE) +1.