

Clinical Development

CNTO1275

C0379T07

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset with zero observation from input will not be submitted (ex. NOTTX).
- Completely missing value variables will be removed.
- DM.DMCONDTC("Date of Informed Consent") will be used as Reference Date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The C0379T07 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,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: SUBJINIT,BIRTHDT,DMCONDT,DMCONDTC,BIRTHDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HEIGHT	num	Height in Centimeters		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEMOG	char	Demographics (Age Race Sex)		Collected at CRF.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	STUDYID,DUSUBJID,AEDECOD,AESTDY,AESEQ
Sorted by	STUDYID,DUSUBJID,AEDECOD,AESTDY,AESEQ
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: AETERM,AEMODIFY,AESTDT,AEENDT,AESTDTC,AEENDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEDECOD	char	Dictionary Term		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SAEOTH	char	Other Medically Important		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.
SAEHOSP	char	Requires Hospitalization		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
ASR	char	Administration Site Reaction		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AEADMST	char	Administration Site		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treat		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
INFECT	char	Infection		Collected at CRF.
SAECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF.
SAEDISAB	char	Permanent/Serious or Disable /Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.Crohn's Disease History – CD_HX

Dataset	CD_HX
Creating program	cd_hx.sas
Description	Crohn's Disease History
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,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: CXDXDT,CXDXDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
CXILEUM	char	Ileum Involvement		Collected at CRF.

Variable	Type	Label	Codes	Comments
CXCOLON	char	Colon Involvement		Collected at CRF.
CXGASINT	char	Gastro-intestinal Involvement		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
CXDXY	num	Relative Diagnosis day		If CXDXDTC and REF.DATE not missing then perform below logic to calculate CXDXY, If CXDXDTC less than REF.DATE then (CXDXDTC - REF.DATE). Else if CXDXDTC is greater than equal to REF.DATE then (CXDXDTC - REF.DATE) +1.

1.4.4.Crohn's Disease Activity Index – CDAI

Dataset	CDAI
Creating program	cdai.sas
Description	Crohn's Disease Activity Index
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CDSTOOL	num	Number of Liquid or Soft Stools		Collected at CRF.
CDABDPN	num	Abdominal Pain Rating		Collected at CRF.
CDWELL	num	General Well Being Rating		Collected at CRF.
CDCOMP	num	Days Patient Completed Diary Card		Collected at CRF.
CDDIARR	num	Patient Receive Antidiarrheal Therapy		Collected at CRF.
CDOPIAT	num	Patient Received Opiate Therapy		Collected at CRF.
CDABMAS	num	Abdominal Mass		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
CDUVEIT	char	Uveitis		Collected at CRF.
CDFISTU	char	Anal Fistula		Collected at CRF.
CDFEVER	char	Fever		Collected at CRF.
CDABSCE	char	Anal Abscess		Collected at CRF.
CDARTHR	char	Arthritis		Collected at CRF.
CDARTLG	char	Arthralgia		Collected at CRF.
CDERYTH	char	Erythema Nodosum		Collected at CRF.
CDFISSU	char	Anal Fissure		Collected at CRF.
CDIRITS	char	Iritis		Collected at CRF.
CDSTOMA	char	Aphthous Stomatitis		Collected at CRF.
CDPYDER	char	Pyoderma Gangrenosum		Collected at CRF.
CDOTHFI	char	Other Fistula		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.5. Endoscopy – CDEIS

Dataset	CDEIS
Creating program	cdeis.sas
Description	Endoscopy
Unique identifier	STUDYID, DUSUBJID, EISEGMT, VISIT
Sorted by	STUDYID, DUSUBJID, EISEGMT, VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EISSD	num	Segment Involved All Lesions		Collected at CRF.
EISSU	num	Segment Involved Ulcerations		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
EITYPE9	char	Indicates Ulcerated Stenosis		Collected at CRF.
EITYPE1	char	Indicates Pseudopolyp		Collected at CRF.
EISEGMT	char	Endoscopy Segment		Collected at CRF.
EISEGNE	char	Reason Segment Not Evaluated		Collected at CRF.
EITYPE0	char	Indicates No Abnormalities		Collected at CRF.
EITYPE2	char	Indicates Healed Ulceration		Collected at CRF.
EITYPE7	char	Indicates Deep Ulceration		Collected at CRF.
EITYPE5	char	Indicates Aphthoid Ulceration		Collected at CRF.
EITYPE4	char	Indicates Frankly Swollen Mucosa		Collected at CRF.
EITYPE3	char	Indicates Frank Erythema		Collected at CRF.
EITYPE6	char	Indicates Superficial Shallow Ulcer		Collected at CRF.
EITYPE8	char	Indicates Non-ulcerated Stenosis		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.6.Date of Endoscopy – CDEIS_DT

Dataset	CDEIS_DT
Creating program	cdeis_dt.sas
Description	Date of Endoscopy
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,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: EIDT,EIDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EIDY	num	Relative Day of Endoscopy		If EIDTC and REF.DATE not missing then perform below logic to calculate EIDY, If EIDTC less than REF.DATE then (EIDTC - REF.DATE). Else if EIDTC is greater than equal to REF.DATE then (EIDTC - REF.DATE) +1.

1.4.7.Past Medical History/Current Diagnoses – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Past Medical History/Current Diagnoses
Unique identifier	STUDYID,DUSUBJID,CHCONDD,VISIT
Sorted by	STUDYID,DUSUBJID,CHCONDD,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CHCOND	num	Condition		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SMSTAT	char	Status of Smoking		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHHIST	char	History of Condition		Collected at CRF.
CHCONDD	char	Condition		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.8. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	STUDYID, DUSUBJID, CMDECOD, CMSTDY, CMSEQ
Sorted by	STUDYID, DUSUBJID, CMDECOD, CMSTDY, CMSEQ
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: CMTERM, CMMODIFY, CMSTDT, CMENDT, CMSTDTC, CMENDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

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

Variable	Type	Label	Codes	Comments
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.

1.4.9. Crohn's Disease Surgeries – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Crohn's Disease Surgeries
Unique identifier	STUDYID, DUSUBJID
Sorted by	STUDYID, 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: PRREASON, PRSTDT, PRSTDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
LINE_NO	num	Line number		Collected at CRF.
PROCTYP	num	Procedure type		Collected at CRF.
PRSPEC	char	Procedure specify		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
PROCTYPD	char	Decode of procedure type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
PRSTDY	num	Relative Start day of procedure		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.

1.4.10. Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Selection Criteria
Unique identifier	STUDYID,DUSUBJID,CRSEQ
Sorted by	STUDYID,DUSUBJID,CRSEQ
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CRSEQ	num	Criterion Sequence		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCRIT	char	Inclusion Criterion Not Met		Collected at CRF.
EXCRIT	char	Exclusion Criterion Present		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.11. Derived PK Parameters – DERVD_PK

Dataset	DERVD_PK
Creating program	dervd_pk.sas
Description	Derived PK Parameters
Unique identifier	STUDYID,DUSUBJID,DPTTESTCD
Sorted by	STUDYID,DUSUBJID,DPTTESTCD
Notes	

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.
TRTCD	num	Treatment Code		Collected at CRF.
TRTGRP	char	Randomized Treatment Group		Collected at CRF.
TRTCDA	num	Actual Treatment Code		Collected at CRF.
TRTGRPA	char	Actual Treatment Group		Collected at CRF.
POP_RAND	char	Subject randomized		Collected at CRF.

Variable	Type	Label	Codes	Comments
POP_TRT	char	Subject treated		Collected at CRF.
POP_POP	char	Population category		Collected at CRF.
POP_ASA	char	Sub received active study agent		Collected at CRF.
DPLABEL	char	PK parameter estimate label		Collected at CRF.
DPTEST	char	PK parameter estimate description		Collected at CRF.
DPTESTCD	char	PK parameter estimate test code		Collected at CRF.
DPRESC	char	PK parameter estimate result		Collected at CRF.
DPRESN	num	PK parameter estimate result		Collected at CRF.
DPUNIT	char	PK parameter estimate unit		Collected at CRF.
DPINC	char	PK parameter estimate inclusion flag		Collected at CRF.
DPRSNINC	char	Comments		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity

1.4.12. Drug Preparation – DRUGPREP

Dataset	DRUGPREP
Creating program	drugprep.sas
Description	Drug Preparation
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,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: EXPDT,EXLOTNO1,EXPDT, EXLOTNO2, EXLOTNO3

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DPSEQ	num	Drug Preparation Sequence Number		Collected at CRF.
EXVWDRWN	num	Volume Withdrawn From Vial in mL		Collected at CRF.
EXVPREP	num	Volume Prepared in Milliliters		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
EXND	char	Drug Preparation Not Done		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.13. Subject Status for Week 0 - 54 – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Subject Status for Week 0 - 54
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,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: DSTRSOTH,DSDSCDT,DSRSOTH,DSDSCDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
DSUNBDTC	char	Day of Treatment Unblinding		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUNB	char	Treatment Unblinded		Collected at CRF.
DSTREAS	char	Reason for Treatment Disconti		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSDSC	char	Study Discontinuation		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.14. Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,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
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXSTTM	num	Start Time of Dose 24 Hour Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
AMTADM	num	Amount Administered		Collected at CRF.
EXSITE_V	char	Expo Site Speci as Other on CRF		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXINRPT	char	Infusion Interrupted		Collected at CRF.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.15. Baseline Fistulas – FISTULA

Dataset	FISTULA
Creating program	fistula.sas
Description	Baseline Fistulas
Unique identifier	STUDYID,DUSUBJID,VISIT,FISEQ
Sorted by	STUDYID,DUSUBJID,VISIT,FISEQ
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
FISEQ	num	Sequence Number		Collected at CRF.
FINUM	num	Fistula Number		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
FILOC	char	Fistula Location		Collected at CRF.
FISTAT	char	Fistula Status		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.16. GI Histological Response Biopsy Assess – GIHIST

Dataset	GIHIST
Creating program	gihist.sas
Description	GI Histological Response Biopsy Assess
Unique identifier	STUDYID,DUSUBJID,GISEGMT,VISIT
Sorted by	STUDYID,DUSUBJID,GISEGMT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACCNUM,SAMPNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
GIEPIDMG	num	Epithelial Damage		Collected at CRF.
GIARCH	num	Architectural Changes		Collected at CRF.
GIMONO	num	Infiltration of Mononuclear Cell		Collected at CRF.
GIPOLYLP	num	Infiltration of Polymorphs in Lamina		Collected at CRF.
GIPOLYEP	num	Polymorphonuclear Cells in Epithelium		Collected at CRF.
GIEROSIN	num	Presence of Erosion/Ulcer		Collected at CRF.

Variable	Type	Label	Codes	Comments
GIGRANLA	num	Presence of Granuloma		Collected at CRF.
GIBIOP	num	Number of Biopsies Affected		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.
SEX	char	Sex		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
GISEGMT	char	Endoscopy Segment		Collected at CRF.
GIND	char	Not Done		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.17. Inflammatory Bowel Disease Questionnaire – IBDQSCR

Dataset	IBDQSCR
Creating program	ibdqscr.sas
Description	Inflammatory Bowel Disease Questionnaire
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IBDQ_1	num	Score for IBDQ Question 1		Collected at CRF.
IBDQ_2	num	Score for IBDQ Question 2		Collected at CRF.
IBDQ_3	num	Score for IBDQ Question 3		Collected at CRF.
IBDQ_4	num	Score for IBDQ Question 4		Collected at CRF.
IBDQ_5	num	Score for IBDQ Question 5		Collected at CRF.
IBDQ_6	num	Score for IBDQ Question 6		Collected at CRF.
IBDQ_7	num	Score for IBDQ Question 7		Collected at CRF.
IBDQ_8	num	Score for IBDQ Question 8		Collected at CRF.
IBDQ_9	num	Score for IBDQ Question 9		Collected at CRF.

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

Variable	Type	Label	Codes	Comments
IBDQ_31	num	Score for IBDQQuestion 31		Collected at CRF.
IBDQ_32	num	Score for IBDQQuestion 32		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.18. Inflammatory Markers_Biopsy Sample – IM_BIOSM

Dataset	IM_BIOSM
Creating program	im_biosm.sas
Description	Inflammatory Markers_Biopsy Sample
Unique identifier	STUDYID,DUSUBJID,IMBIOSM,VISIT
Sorted by	STUDYID,DUSUBJID,IMBIOSM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACCNUM,SAMPNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		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.
SEX	char	Sex		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
IMBIOSM	char	Location of Biopsy Sample		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.19. Inflammatory Markers_Chemistry – IM_CHEM

Dataset	IM_CHEM
Creating program	im_chem.sas
Description	Inflammatory Markers_Chemistry
Unique identifier	STUDYID,DUSUBJID,IMBIOSM,IMTEST,VISIT,IMSEQ
Sorted by	STUDYID,DUSUBJID,IMBIOSM,IMTEST,VISIT,IMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACCNUM,SAMPNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IMSEQ	num	Test Sequence		Collected at CRF.
IMTSTCD	char	Test Code		Collected at CRF.
IMRESLT	char	Test Result		Collected at CRF.
IMUNITS	char	Test Result Units		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
SEX	char	Sex		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IMBIOSM	char	Location of Biopsy Sample		Collected at CRF.
IMCOMM	char	Test Comment		Collected at CRF.
IMCORES	char	Coded Test Result		Collected at CRF.
IMTEST	char	Test Code Decode		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.20. Intravenous Administration – IVRS

Dataset	IVRS
Creating program	ivrs.sas
Description	Intravenous Administration
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RAACTDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
POPULAT	char	Population		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
RAACTDY	num	Relative Day of Randomization		If RAACTDT and REF.DATE not missing then perform below logic to calculate RAACTDY, If RAACTDT less than REF.DATE then (RAACTDT - REF.DATE). Else if RAACTDT is greater than equal to REF.DATE then (RAACTDT - REF.DATE) +1.

1.4.21. Laboratory Test – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Test
Unique identifier	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,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: LBDT,LBDTC,LBID,LBLBLNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRL0	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRLHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRLC	char	Normal Range for Char Reslt in Orig Unit		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Unit		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Unit		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Unit		Collected at CRF.
LBSTDNRLC	char	Normal Range for Char Result Std Unit		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		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.
SEX	char	Sex		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.22. Lab Sequence – LSCNA

Dataset	LSCNA
Creating program	lscna.sas
Description	Lab Sequence
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LSSEQ	num	Lab Sequence		Collected at CRF.
LSPTM	char	Planned Time point Name		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.23. Medication Review – MEDRVIEW

Dataset	MEDRVIEW
Creating program	medview.sas
Description	Medication Review
Unique identifier	STUDYID,DUSUBJID,MRCAT,VISIT,MRSEQ
Sorted by	STUDYID,DUSUBJID,MRCAT,VISIT,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: CMTERM,CMMODIFY,MRCDT,MRCDC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MRSEQ	num	Medication Sequence Number		Collected at CRF.
MRDOSE	num	Dose		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		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.
SEX	char	Sex		Collected at CRF.
MRTYPE	char	Route Type		Collected at CRF.
MRSTAT	char	Current Medication Status		Collected at CRF.
MRFREQ	char	Frequency		Collected at CRF.
MRDOSCH	char	Dose Change Reason		Collected at CRF.
MRCAT	char	Medication Category		Collected at CRF.
MRDUNT	char	Dose Unit		Collected at CRF.
MRROUTE	char	Medication Route		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.24. Perianal Disease Activity Index – PDAI

Dataset	PDAI
Creating program	pdai.sas
Description	Perianal Disease Activity Index
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PEDISCH	num	Discharge		Collected at CRF.

Variable	Type	Label	Codes	Comments
PEPAIN	num	Pain/Restriction of Activities		Collected at CRF.
PESEXAC	num	Restriction of Sexual Activity		Collected at CRF.
PERIDIS	num	Type of Perianal Disease		Collected at CRF.
PEINDUR	num	Degree of Induration		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.25. Sample Atsa – PK_ATSA

Dataset	PK_ATSA
Creating program	pk_atsa.sas
Description	Sample Atsa
Unique identifier	STUDYID,DUSUBJID,PKRELBAS,PKDTC,VISIT
Sorted by	STUDYID,DUSUBJID,PKRELBAS,PKDTC,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,CPLABEL,PKNOTCOL,PKINH,PKTITER,PKTTRLQ,PKATSCD2,PKATSCD3,PKATSCM2,PKATSCM3,PKINHNN,PKTITERN

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 Speci Collect		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
TRTCD	num	Treatment Code		Collected at CRF.
TRTGRP	char	Randomized Treatment Group		Collected at CRF.
TRTCDA	num	Actual Treatment Code		Collected at CRF.
TRTGRPA	char	Actual Treatment Group		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
POP_TRT	char	Subject treated		Collected at CRF.
POP_RAND	char	Subject randomized		Collected at CRF.
POP_ASA	char	Sub received active study agent		Collected at CRF.
POP_POP	char	Population category		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PKACTTM	num	Time of sample		Collected at CRF.
PKREFLG	num	Relative to Baseline Indicator		Collected at CRF.
PKRELBAS	char	Relative to Baseline Description		Collected at CRF.
DOSENUM	num	Sequential dose number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
CPPERIOD	char	Period (Clinparm)		Collected at CRF.
PKCONC	char	Serum concentration (char)		Collected at CRF.
PKCONCLQ	num	Lower Limit of Quantitation		Collected at CRF.
PKOD	char	Mean optical density (char)		Collected at CRF.
PKATSCD1	char	CPCMT1CD/2CD for ATSA result		Collected at CRF.
PKATSCM1	char	CPCMT1/2 for ATSA result		Collected at CRF.

Variable	Type	Label	Codes	Comments
PKCONCD1	char	CPCMT1CD/2CD for PK result		Collected at CRF.
PKCONCD2	char	CPCMT1CD/2CD for PK result		Collected at CRF.
PKCONCM1	char	CPCMT1CD/2CD for PK result		Collected at CRF.
PKCONCM2	char	CPCMT1/2 for PK result		Collected at CRF.
PKSMPINC	char	Sample included PK/PD analysis		Collected at CRF.
PKUNDET	char	Serum concentration undetectable		Collected at CRF.
PKCONCN	num	Serum concentration (numeric)		Collected at CRF.
PKODN	num	Mean optical density (numeric)		Collected at CRF.
PKRESULT	char	Sample ATSA Result		Collected at CRF.
PKASAEM	char	Active study agent emergent PK		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
PKDY	num	Relative Day of Sample		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.

1.4.26. Intestinal Resections – RESECT

Dataset	RESECT
Creating program	resect.sas
Description	Intestinal Resections
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
RESECT	num	Have Intestines Been Resected		Collected at CRF.
REDUODEN	num	Duodenum		Collected at CRF.
REJEJUN	num	Jejunum		Collected at CRF.
REILEUM	num	Ileum		Collected at CRF.
RECECUM	num	Cecum		Collected at CRF.
REASCOLN	num	Ascending Colon		Collected at CRF.
RETRCOLN	num	Transverse Colon		Collected at CRF.
REDECOLN	num	Descending Colon		Collected at CRF.
RESIGM	num	Sigmoid		Collected at CRF.

Variable	Type	Label	Codes	Comments
RERECTUM	num	Rectum		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.27. Drug History – RX_HX

Dataset	RX_HX
Creating program	rx_hx.sas
Description	Drug History
Unique identifier	STUDYID,DUSUBJID,VISIT,CMSEQ
Sorted by	STUDYID,DUSUBJID,VISIT,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CMTERM,CMMODIFY

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD1	char	Dictionary Preferred Term		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.
SEX	char	Sex		Collected at CRF.
RXTIMUSD	char	Length of time taken		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.28. Crohn's Disease Subject Population – RXCLASS

Dataset	RXCLASS
Creating program	rxclass.sas
Description	Crohn's Disease Subject Population
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
RXCP1A	num	Pop1 Unable to Taper Corticosteroids		Collected at CRF.
RXCP1B	num	Pop1 Freq. Intermit Corticosteroids		Collected at CRF.
RXCP1C	num	Pop1 - Inadequate Response to 5ASA		Collected at CRF.
RXCP1D	num	Pop1 - Inadequate Response to 6-MP		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RXCP2	char	Pop2 - Nonresponders to Infliximab		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.29. Crohn's Disease Subject Population – RXCLASS2

Dataset	RXCLASS2
Creating program	rxclass2.sas
Description	Crohn's Disease Subject Population
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RXCP2	char	Pop2 - Nonresponders to Infliximab		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXCP1C1	char	Pop1 - Recev Othr Immunomodulators		Collected at CRF.
RXCP1B2	char	Pop1 - Duration of 6-MP, AZA, MTX		Collected at CRF.
RXCP1A2	char	Pop1 - Respond 5-ASA, Antibiotics, Cort		Collected at CRF.
RXCP1A1	char	Pop1 - Received 5-ASA, Antibiotics, Cort		Collected at CRF.
RXCP1B1	char	Pop1 - Received 6-MP, AZA, MTX		Collected at CRF.
RXCP1B3	char	Pop1 - Respond 6-MP, AZA, MTX		Collected at CRF.
RXCP1C2	char	Pop1 - Respd Othr Immunomodulators		Collected at CRF.
RXCP1D1	char	Pop1 - Received Infliximab		Collected at CRF.
RXCP1D2	char	Pop1 - Respond Infliximab		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.30. Adverse Events For Screen Failures – SCRNAE

Dataset	SCRNAE
Creating program	scrnae.sas
Description	Adverse Events For Screen Failures
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,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: AETERM,AEMODIFY,AESTDT,AEENDT,AESTDTC,AEENDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SAEOTH	char	Other Medically Important		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.
SAEHOSP	char	Requires Hospitalization		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
ASR	char	Administration Site Reaction		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AEADMST	char	Administration Site		Collected at CRF.
AEACTTRT	char	Action Taken for Study Treatment		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
SAECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF.
SAEDISAB	char	Permanent/Serious or Disable /Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.31. Assay Tracking For Screen Failures – SCRNRCK

Dataset	SCRNRCK
Creating program	scrnrck.sas
Description	Assay Tracking For Screen Failures
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ATKITNUM,ATDY,ATMO,ATYR,ATDT,ATHR,ATMI

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
ADEVQL	char	Event Qualifier		Collected at CRF.
ATKTTYP	char	Kit Type		Collected at CRF.
ATPTM	char	Planned Time point		Collected at CRF.
ATTM	num	Assay Tracking Time		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
ATNTCOL	char	Sample Not Collected		Collected at CRF.
ATSMTYP	char	Sample Type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
ATDY	num	Relative Assay Tracking Day		If ATDT and REF.DATE not missing then perform below logic to calculate ATDY, If ATDT less than REF.DATE then (ATDT - REF.DATE). Else if ATDT is greater than equal to REF.DATE then (ATDT - REF.DATE) +1.

1.4.32. Selection Criteria For Screen Failures – SCRNCRIT

Dataset	SCRNCRIT
Creating program	scrncrit.sas
Description	Selection Criteria For Screen Failures
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
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.
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.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.33. Demographics For Screen Failures – SCRNDemo

Dataset	SCRNDemo
Creating program	scrndemo.sas
Description	Demographics For Screen Failures
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,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: SUBJINIT,BIRTHDT,DMCONDT,DMCONDTC,BIRTHDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HEIGHT	num	Height in Centimeters		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DEMOG	char	Demographics (Age Race Sex)		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.34. GI Histological Resp for Screen Failure – SCRNHIST

Dataset	SCRNHIST
Creating program	scrnhist.sas
Description	GI Histological Resp for Screen Failure
Unique identifier	STUDYID,DUSUBJID,GISEGMT,VISIT
Sorted by	STUDYID,DUSUBJID,GISEGMT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACCNUM,SAMPNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
GIEPIDMG	num	Epithelial Damage		Collected at CRF.
GIARCH	num	Architectural Changes		Collected at CRF.
GIMONO	num	Infiltration of Mononuclear Cell		Collected at CRF.
GIPOLYLP	num	Infiltration of Polymorphs in Lamina		Collected at CRF.
GIPOLYEP	num	Polymorphonuclear Cells in Epithelium		Collected at CRF.
GIEROSIN	num	Presence of Erosion/Ulcer		Collected at CRF.

Variable	Type	Label	Codes	Comments
GIGRANLA	num	Presence of Granuloma		Collected at CRF.
GIBIOP	num	Number of Biopsies Affected		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.
SEX	char	Sex		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
GISEGMT	char	Endoscopy Segment		Collected at CRF.
GIND	char	Not Done		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.35. IM_Biopsy Sample for Screen Failure – SCRNBISM

Dataset	SCRNBISM
Creating program	scrnbism.sas
Description	IM_Biopsy Sample for Screen Failure
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACCCNUM,SAMPNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		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.
SEX	char	Sex		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
IMBIOSM	char	Location of Biopsy Sample		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.36. IM_Chemistry for Screen Failure – SCRNCHEM

Dataset	SCRNCHEM
Creating program	scrnchem.sas
Description	IM_Chemistry for Screen Failure
Unique identifier	STUDYID,DUSUBJID,IMBIOSM,IMTEST,VISIT,IMSEQ
Sorted by	STUDYID,DUSUBJID,IMBIOSM,IMTEST,VISIT,IMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ACCCNUM,SAMPNUM,IMCOMM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IMSEQ	num	Test Sequence		Collected at CRF.
IMTSTCD	char	Test Code		Collected at CRF.
IMRESLT	char	Test Result		Collected at CRF.
IMUNITS	char	Test Result Units		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
SEX	char	Sex		Collected at CRF.
CRF_PAGE	char	CRF Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IMBIOSM	char	Location of Biopsy Sample		Collected at CRF.
IMCORES	char	Coded Test Result		Collected at CRF.
IMTEST	char	Test Code Decode		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.37. Lab Data For Screen Failures – SCRNLAB

Dataset	SCRNLAB
Creating program	scrnlab.sas
Description	Lab Data For Screen Failures
Unique identifier	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,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: LBDT,LBDTC,LBID,LBLBLNUM

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRL0	char	Normal Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Unit		Collected at CRF.
LBORNRC	char	Normal Range for Char Reslt in Orig Unit		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Unit		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Unit		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Unit		Collected at CRF.
LBSTDNRC	char	Normal Range for Chr Result Std Unit		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
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
SEX	char	Sex		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
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.

1.4.38. Lab Sequence for Screen Failure – SCRLSCNA

Dataset	SCRLSCNA
Creating program	scriscna.sas
Description	Lab Sequence for Screen Failure
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LSSEQ	num	Lab Sequence		Collected at CRF.
LSPTM	char	Planned Time point Name		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

1.4.39. Visit Data For Screen Failures – SCRNVIS

Dataset	SCRNVIS
Creating program	scrnvis.sas
Description	Visit Data For Screen Failures
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_DT,VISITDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VISITDY	num	Relative Visit Day		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.

1.4.40. Subject Status – SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,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: SSDSCDT,SSRSOTH,SSDSCDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SSREAS	char	Reason for Discontinuation		Collected at CRF.

Variable	Type	Label	Codes	Comments
SSENT	char	Sub Entered Next Study Period		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
SSDSCDY	num	Relative Day of study discontinuation		If SSDSCDTC and REF.DATE not missing then perform below logic to calculate SSDSCDY, If SSDSCDTC less than REF.DATE then (SSDSCDTC - REF.DATE). Else if SSDSCDTC is greater than equal to REF.DATE then (SSDSCDTC- REF.DATE) +1.

1.4.41. Subject Visits – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Subject Visits
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_DT,VISITDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VISITDY	num	Relative Visit Day		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.

1.4.42. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	STUDYID,DUSUBJID,VISIT
Sorted by	STUDYID,DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VSSEQ	num	Vital Signs Sequence		Collected at CRF.
EXWEIGHT	num	Weight in Kilograms		Collected at CRF.
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-Identity		Randomly assigned Study 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 Assign for De-Identity		Randomly assigned Site-Subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity