

Clinical Development

Infliximab

C0168T47

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	May 15, 2015

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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
- Date of birth will not be provided, only age
- Investigator Name will not be provided.
- No pharmacogenetic data will be provided (specific IC)
- Subject and site/center numbers will be assigned in a random manner so they are not matching the subject and site/center numbers that were used in the actual trial
- Subjects with ages above 89 will be assigned to 90+
- Remove the free text verbatim terms
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Lot/kit number will not be provided.
- Accession Number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Dataset used for data reconciliation, CRF page information will not be submitted (eg. ANY_NONE, ATRACK, PAGE_SEQ, LTRACK).
- Dataset which are redundant regarding analysis will not be provided (e.g. ZSTATAGE, CRFPAGES).
- Pharmacokinetic/Pharmacodynamic dataset will not be submitted (eg. CRESUL).
- Dataset which are empty will not be submitted (e.g. DEATH, SEVENT).
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.

1.3. Data Files

The C0168T47 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0168T47 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demography – DM

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Group element to protect PII.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
TRTGRP	char	Randomized Treatment Group		Collected at CRF.

1.4.2. Adverse Event – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event
Unique identifier	DUSUBJID,VISIT AEDECOD ,AESEQ
Sorted by	DUSUBJID,VISIT, AEDECOD ,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,PAGE_SEQ,AETERM,AEMODIFY,AESTDT,AEENDT,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P,AESTDTC,AEENDTDC,SAECONG,SAEDISAB,SAEDTH,SAEHOSP,SAELIFE,SAENS,SAEOTH

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

Variable	Type	Label	Codes	Comments
AESTTM	num	Start Time of Event		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
AECTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
AESTDY	num	Relative Start Day of Event		If AESTDTC and LCENR_DT not missing then perform below logic to calculate AESTDY,if AESTDTC less than LCENR_DT then (AESTDTC - LCENR_DT).Else if AESTDTC is greater than equal to LCENR_DT then (AESTDTC- LCENR_DT) +1.
AEENDY	num	Relative End Day of Event		If AEENDTC and LCENR_DT not missing then perform below logic to calculate AEENDY,if AEENDTC less than LCENR_DT then (AEENDTC - LCENR_DT).Else if AEENDTC is greater than equal to LCENR_DT then (AEENDTC- LCENR_DT) +1.

1.4.3. Bone Age – BONEAGE

Dataset	BONEAGE
Creating program	boneage.sas
Description	Bone Age
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,XRAY_DT,BONEAGEM,AGE,AGEM,RACE,SEX, CRF_PAGE,UNIQUE_P,XRAYDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
BONEAGEY	num	Bone age (years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
XRAYDY	num	Relative Day of X-ray		If XRAYDTC and LCENR_DT not missing then perform below logic to calculate XRAYDY,If XRAYDTC less than LCENR_DT then (XRAYDTC - LCENR_DT).Else if XRAYDTC is greater than equal to LCENR_DT then (XRAYDTC- LCENR_DT) +1.

1.4.4. 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 non significant elements: COUNTRY,PAG_NAME,DIAG_DT,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P, DIAGDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
SYMPTDUR	num	Duration of symptoms (years)		Collected at CRF.
SYMPTD_M	num	Duration of symptoms (months)		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
COLON	char	Indicates Colon Involvement		Collected at CRF.
GASINT	char	Indicates Gastro-intestinal Involvement		Collected at CRF.
ILEUM	char	Indicates Ileum Involvement		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DIAGDY	num	Relative Day of diagnosis		If DIAGDTC and LCENR_DT not missing then perform below logic to calculate DIAGDY,If DIAGDTC less than LCENR_DT then (DIAGDTC - LCENR_DT).Else if DIAGDTC is greater than equal to LCENR_DT then (DIAGDTC- LCENR_DT) +1.

1.4.5.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 non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

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

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

1.4.6. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,VISIT,DRECNO, CMSEQ, CMRTECD
Sorted by	DUSUBJID,VISIT, CMSEQ, CMRTECD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,PAGE_SEQ,CMTERM,CMMODIFY,CMRTE_V,DRECNO,SEQ1,SEQ2,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMPRD1	char	Time Period 1		Collected at CRF.
CMPRD2	char	Time Period 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMPRD3	char	Time Period 3		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.7. Crohn's Disease Surgeries – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Crohn's Disease Surgeries
Unique identifier	DUSUBJID, PROCTYPD
Sorted by	DUSUBJID, PROCTYPD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,PAGE_SEQ,PROCSPEC,PROCREAS,PROC_DT,AGE, AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P,PROCDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
LINE_NO	num	Line number		Collected at CRF.
PROCTYP	num	Procedure type		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
PROCTYPD	char	Procedure type decode		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROCDY	num	Relative Procedure Day		If PROCDTC and LCENR_DT not missing then perform below logic to calculate PROCDY, If PROCDTC less than LCENR_DT then (PROCDTC - LCENR_DT). Else if PROCDTC is greater than equal to LCENR_DT then (PROCDTC - LCENR_DT) +1.

1.4.8. Baseline Oral Corticosteroids – CORTSUM

Dataset	CORTSUM
Creating program	cortsum.sas
Description	Baseline Oral Corticosteroids
Unique identifier	DUSUBJID, VISIT, CSSEQ
Sorted by	DUSUBJID, VISIT, CSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,PAGE_SEQ,CSCHGDT,CMTERM,CMMODIFY,DRECNO,SEQ1,SEQ2,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P,CSCHGDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CSSEQ	num	Medication sequence number		Collected at CRF.
CSDOSE	num	Medication dose		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CSCHG	char	Reason for changing medication		Collected at CRF.

Variable	Type	Label	Codes	Comments
CSFREQ	char	Frequency of medication		Collected at CRF.
CSIND	char	Medication indication		Collected at CRF.
CSSTOP	char	Medication stopped		Collected at CRF.
CSUNIT	char	Code for units of medication		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
CSCHGDY	num	Relative Day of medication change		If CSCHGDTC and LCENR_DT not missing then perform below logic to calculate CSCHGDY, If CSCHGDTC less than LCENR_DT then (CSCHGDTC - LCENR_DT). Else if CSCHGDTC is greater than equal to LCENR_DT then (CSCHGDTC- LCENR_DT) +1.

1.4.9. Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Selection Criteria
Unique identifier	DSUBJID, VISIT, CRSEQ
Sorted by	DSUBJID, VISIT, CRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

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

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

1.4.10. Dose Profile – DOSEPFLE

Dataset	DOSEPFLE
Creating program	dosepfle.sas
Description	Dose Profile
Unique identifier	DSUBJID,VISIT
Sorted by	DSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
DOSADM	char	Dose Administered		Collected at CRF.
DOSINT	char	Dose Interval		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.11. Drug Preparation – DRUGPREP

Dataset	DRUGPREP
Creating program	drugprep.sas
Description	Drug Preparation
Unique identifier	DSUBJID,VISIT
Sorted by	DSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,EXPDT,EXLOTNO1,EXLOTNO2,EXLOTNO3,AGE,AGEM, RACE,SEX,CRF_PAGE,UNIQUE_P,EXPDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DPSEQ	num	Drug Preparation Sequence Number		Collected at CRF.
DPVWDRWN	num	Volume Withdrawn From Vial(s) in mL		Collected at CRF.
DPVPREP	num	Volume Prepared in Milliliters		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DPND	char	Drug Preparation Not Done		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
EXPDY	num	Relative Day Prepared		If EXPDTC and LCENR_DT not missing then perform below logic to calculate EXPDY,if EXPDTC less than LCENR_DT then (EXPDTC - LCENR_DT).Else if EXPDTC is greater than equal to LCENR_DT then (EXPDTC- LCENR_DT) +1.

1.4.12. Disposition – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Disposition
Unique identifier	DSUBJID, VISIT
Sorted by	DSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,DSDSCDT,DSRSOTH,AGE,AGEM,RACE,SEX,CRF_PAGE,U NIQUE_P,DSDSCDTC

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

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSDSCDY	num	Relative Day of Study Discontinuation		If DSDSCDTC and LCENR_DT not missing then perform below logic to calculate DSDSCDY,if DSDSCDTC less than LCENR_DT then (DSDSCDTC - LCENR_DT).Else if DSDSCDTC is greater than equal to LCENR_DT then (DSDSCDTC- LCENR_DT) +1.

1.4.13. Study Agent Administration – EXPOSURE

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
AMTADMU	char	Amount Administered Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXND	char	Dose 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
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 LCENR_DT not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than LCENR_DT then (EXSTDTC - LCENR_DT). Else if EXSTDTC is greater than equal to LCENR_DT then (EXSTDTC- LCENR_DT) +1.

1.4.14. Commercial Remicade Treatment – FUP

Dataset	FUP
Creating program	fup.sas
Description	Commercial Remicade Treatment
Unique identifier	DDUBJID,VISIT
Sorted by	DDUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

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

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

1.4.15. Subject Global Assessment – GLBASMT

Dataset	GLBASMT
Creating program	glbasmt.sas
Description	Subject Global Assessment
Unique identifier	DSUBJID, VISIT
Sorted by	DSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
GAND	char	Not done		Collected at CRF.

Variable	Type	Label	Codes	Comments
GAPARC	char	Parent/Guardian global assessment of chg		Collected at CRF.
GAPAR	char	Parent/Guardian global assessment		Collected at CRF.
GAPHYSC	char	Physician global assessment of chg		Collected at CRF.
GAPHYS	char	Physician global assessment		Collected at CRF.
GASUBJC	char	Subject global assessment of chg		Collected at CRF.
GASUBJ	char	Subject global assessment		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.16. Impact III Questionnaire – IMPACT3Q

Dataset	IMPACT3Q
Creating program	impact3q.sas
Description	Impact III Questionnaire
Unique identifier	DSUBJID,VISIT
Sorted by	DSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
BS1	num	Score for IMPACT question 1		Collected at CRF.
TI1	num	Score for IMPACT question 2		Collected at CRF.
BS2	num	Score for IMPACT question 3		Collected at CRF.
EF1	num	Score for IMPACT question 4		Collected at CRF.
EF2	num	Score for IMPACT question 5		Collected at CRF.
SS1	num	Score for IMPACT question 6		Collected at CRF.
BI1	num	Score for IMPACT question 7		Collected at CRF.
SF1	num	Score for IMPACT question 8		Collected at CRF.
SF2	num	Score for IMPACT question 9		Collected at CRF.

Variable	Type	Label	Codes	Comments
BS3	num	Score for IMPACT question 10		Collected at CRF.
EF3	num	Score for IMPACT question 11		Collected at CRF.
EF4	num	Score for IMPACT question 12		Collected at CRF.
EF5	num	Score for IMPACT question 13		Collected at CRF.
SF3	num	Score for IMPACT question 14		Collected at CRF.
BI2	num	Score for IMPACT question 15		Collected at CRF.
EF6	num	Score for IMPACT question 16		Collected at CRF.
SF4	num	Score for IMPACT question 17		Collected at CRF.
SF5	num	Score for IMPACT question 18		Collected at CRF.
BS4	num	Score for IMPACT question 19		Collected at CRF.
SF6	num	Score for IMPACT question 20		Collected at CRF.
BS5	num	Score for IMPACT question 21		Collected at CRF.
TI2	num	Score for IMPACT question 22		Collected at CRF.
SF7	num	Score for IMPACT question 23		Collected at CRF.
TI3	num	Score for IMPACT question 24		Collected at CRF.
BS6	num	Score for IMPACT question 25		Collected at CRF.
SF8	num	Score for IMPACT question 26		Collected at CRF.
SF9	num	Score for IMPACT question 27		Collected at CRF.
SS2	num	Score for IMPACT question 28		Collected at CRF.
EF7	num	Score for IMPACT question 29		Collected at CRF.
SF10	num	Score for IMPACT question 30		Collected at CRF.

Variable	Type	Label	Codes	Comments
BS7	num	Score for IMPACT question 31		Collected at CRF.
SS3	num	Score for IMPACT question 32		Collected at CRF.
BI3	num	Score for IMPACT question 33		Collected at CRF.
SF11	num	Score for IMPACT question 34		Collected at CRF.
SF12	num	Score for IMPACT question 35		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
NOTDONE	char	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
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.17. Infection Summary – INFCTSUM

Dataset	INFCTSUM
Creating program	infctsum.sas
Description	Infection Summary
Unique identifier	DSUBJID,AELN MEDOF, PROTOZL , SPUCULT ,HX_INF
Sorted by	DSUBJID, SPUCULT ,HX_INF
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>COUNTRY,PAG_NAME,PAGE_SEQ,PAGE_OF,AEPG,AEOF,AELN,AEPG2,AESEQ2,AEOF2,AELN2,AEPG3,AESEQ3,AEOF3,AELN3,MEDPG,MEDSEQ,MEDOF,MEDLN,MEDPG2,MEDSEQ2,MEDOF2,MEDLN2,MEDPG3,MEDSEQ3,MEDOF3,MEDLN3,MEDPG4,MEDSEQ4,MEDOF4,MEDLN4,MEDPG5,MEDSEQ5,MEDOF5,MEDLN5,OINFSPEC,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P,FUNGAL,MYCOBCT,PROTOZL</p>

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
ANTIMCR	char	Antimicrobial tx given for infection		Collected at CRF.

Variable	Type	Label	Codes	Comments
BLDCULT	char	Blood cultured		Collected at CRF.
CULTPOS	char	Cultures indicated infection		Collected at CRF.
CULTURE	char	Cultures performed		Collected at CRF.
GRAMNEG	char	Gram negative		Collected at CRF.
GRAMPOS	char	Other gram positive		Collected at CRF.
HX_INF	char	History of similar infections		Collected at CRF.
OTHCULT	char	Other cultured		Collected at CRF.
OTH_INF	char	Other infection		Collected at CRF.
SPUCULT	char	Sputum cultured		Collected at CRF.
STAPH_A	char	Staph aureus infection		Collected at CRF.
STREP	char	Streptococcus infection		Collected at CRF.
URICULT	char	Urine cultured		Collected at CRF.
VIRAL	char	Viral		Collected at CRF.
WNSDCULT	char	Wound or drainage cultured		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity

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

1.4.18. Ivrs – IVRS

Dataset	IVRS
Creating program	ivrs.sas
Description	Ivrs
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,OLENRDT,UNIQUE_P,AGE,AGEM,RACE,SEX,OLENRDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
OLETRCD	num	OLE Treatment Group Code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
OLENRDY	num	Relative OLE Day of Enrollment		If OLENRDTC and LCENR_DT not missing then perform below logic to calculate OLENRDY, If OLENRDTC less than LCENR_DT then (OLENRDTC - LCENR_DT). Else if OLENRDTC is greater than equal to LCENR_DT then (OLENRDTC- LCENR_DT) +1.

1.4.19. Laboratory – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory
Unique identifier	USUBJID ,LBTSTCD, LBEVNT
Sorted by	USUBJID, LBTSTCD,LBEVNT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,LBLBLNUM,LBDT,AGE,AGEM,RACE,SEX,CRF_PAGE, UNIQUE_P,LBDTC,LBID

Variable	Type	Label	Codes	Comments
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRL0	char	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBEVNT	char	Lab Event		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBTEST	char	Decode of LBTSTCD		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LBDY	num	Relative Day of Specimen Collection		If LBDTC and LCENR_DT not missing then perform below logic to calculate LBDY, If LBDTC less than LCENR_DT then (LBDTC - LCENR_DT). Else if LBDTC is greater than equal to LCENR_DT then (LBDTC - LCENR_DT) +1.

1.4.20. Change in Immunomodulator – MEDCHNG

Dataset	MEDCHNG
Creating program	medchng.sas
Description	Change in Immunomodulator
Unique identifier	USUBJID, VISIT
Sorted by	USUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,MCCHGDT,AGE,AGEM,RACE,SEX,CRF_PAGE, UNIQUE_P,MCCHGDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MCTYPE	char	Medication Type		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
MCCHNG	char	Medication Change		Collected at CRF.
MCINCR	char	Medication Increase		Collected at CRF.
MCRSN	char	Medication Reason For Change		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
MCCHGDY	num	Relative Medication Change Day		If MCCHGDTC and LCENR_DT not missing then perform below logic to calculate MCCHGDY,If MCCHGDTC less than LCENR_DT then (MCCHGDTC - LCENR_DT).Else if MCCHGDTC is greater than equal to LCENR_DT then (MCCHGDTC- LCENR_DT) +1.

1.4.21. Baseline Immunomodulator Dosage – MEDSUMM

Dataset	MEDSUMM
Creating program	medsumm.sas
Description	Baseline Immunomodulator Dosage
Unique identifier	DSUBJID,CMTERM
Sorted by	DSUBJID,CMTERM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,CMTERM,CMMODIFY,DRECNO,SEQ1,SEQ2,AGE,AGEM, RACE,SEX,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MSDOSE	num	Medication Dose		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
MSFREQ	char	Frequency		Collected at CRF.
MSRTE	char	Route Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
MSUNIT	char	Dose Units		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.22. Patrand – PATRAND

Dataset	PATRAND
Creating program	patrand.sas
Description	Patrand
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,LCENR_DT,ENROLLDT,CRSVRDT,UNIQUE_P,AGE,AGEM,RACE,SEX

Variable	Type	Label	Codes	Comments
TRTCD	num	Randomized treatment		Collected at CRF.
IVRSRESP	char	Responder/non-responder		Collected at CRF.
CROSOVER	char	Did the subject lose response		Collected at CRF.
CRSVRTRT	num	Crossover treatment group		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LCENR_DY	num	Relative Local Randomisation Day		If LCENR_DT and LCENR_DT not missing then perform below logic to calculate LCENR_DY,If LCENR_DT less than LCENR_DT then (LCENR_DT - LCENR_DT).Else if LCENR_DT is greater than equal to LCENR_DT then (LCENR_DT- LCENR_DT) +1.
ENROLLDY	num	Relative Enrollment Day		If ENROLLDT and LCENR_DT not missing then perform below logic to calculate ENROLLDY,If ENROLLDT less than LCENR_DT then (ENROLLDT - LCENR_DT).Else if ENROLLDT is greater than equal to LCENR_DT then (ENROLLDT- LCENR_DT) +1.
CRSVRDY	num	Relative Crossover Day		If CRSVRDT and LCENR_DT not missing then perform below logic to calculate CRSVRDY,If CRSVRDT less than LCENR_DT then (CRSVRDT - LCENR_DT).Else if CRSVRDT is greater than equal to LCENR_DT then (CRSVRDT- LCENR_DT) +1.

1.4.23. Pcdai – PCDAI

Dataset	PCDAI
Creating program	pcdai.sas
Description	Pcdai
Unique identifier	DSUBJID, VISIT
Sorted by	DSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PCABDPN	num	Abdominal pain rating		Collected at CRF.
PCSTOOL	num	Stools (per day)		Collected at CRF.
PCWELBE	num	General well being		Collected at CRF.
PCEIMAN	num	Extra-intestinal manifestations		Collected at CRF.
PCABD	num	Abdomen		Collected at CRF.
PCPRDIS	num	Perirectal disease		Collected at CRF.
PCWGT	num	Weight		Collected at CRF.
PCHGT	num	Height		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

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

1.4.24. Prophylactic Medication – PROMED

Dataset	PROMED
Creating program	propmed.sas
Description	Prophylactic Medication
Unique identifier	DSUBJID, VISIT
Sorted by	DSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

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

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

1.4.25. Drug History – RX_HX

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CODSTAT	char	Autoencoding Status		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.
TIMEUSD	char	PROCREAS		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.26. Open Label Extension – STDYEXT

Dataset	STDYEXT
Creating program	stdyext.sas
Description	Open Label Extension
Unique identifier	DSUBJID,VISIT
Sorted by	DSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P

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

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

1.4.27. Visits – VISITS

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

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

Variable	Type	Label	Codes	Comments
CROSOVR	char	Entering crossover phase		Collected at CRF.
VISITND	char	Visit 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
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITDY	num	Relative Day of patient visit		If VISITDTC and LCENR_DT not missing then perform below logic to calculate VISITDY,if VISITDTC less than LCENR_DT then (VISITDTC - LCENR_DT).Else if VISITDTC is greater than equal to LCENR_DT then (VISITDTC- LCENR_DT) +1.

1.4.28. Vitals – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vitals
Unique identifier	DSUBJID, VISIT
Sorted by	DSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,VSHISDT,AGE,AGEM,RACE,SEX,CRF_PAGE,UNIQUE_P, VSHISDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VSSEQ	num	Vital Signs Sequence		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSTSTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSSTUNIT	char	Vital Signs Standard Units		Collected at CRF.
VSORUNIT	char	Vital Signs Original Unit		Collected at CRF.
VSORRES	char	Vital Signs Result in Original Units		Collected at CRF.
VSSTRES	char	Vital Signs Results in Standard Units		Group element to protect PII.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VSHISDY	num	Relative Day of historic height & weight		If VSHISDTC and LCENR_DT not missing then perform below logic to calculate VSHISDY, If VSHISDTC less than LCENR_DT then (VSHISDTC - LCENR_DT). Else if VSHISDTC is greater than equal to LCENR_DT then (VSHISDTC- LCENR_DT) +1.