

Clinical Development

**CNT0148**

C0524T18

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 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, if not collected on CRF.
- Partial date's relative day cannot be calculated.
- Empty comments data will be submitted due to sensitivity of data.
- Due to sensitive information CNTYDICT datasets will be removed.
- DEMO.DMCONDTC will be used as Reference Date to derive relative days (referred as REF. DATE in the document).

### 1.3. Data Files

The C0524T18 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics – DEMO

<b>Dataset</b>	DEMO
<b>Creating program</b>	demo.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	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, BIRTHDTC, DMCONDTC, DEMOG

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.
HEIGHT	num	Height in Centimeters		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity



## 1.4.2. Adverse Events – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DUSUBJID, AEDECOD, AESTDY, VISIT, AESEQ
<b>Sorted by</b>	DUSUBJID, AEDECOD, AESTDY, VISIT, AESEQ
<b>Notes</b>	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, COUNTRY, AEENDTC, AESTDTC, AELOC, SAECONG, AGE, RACE, SEX, AESTHR, AESTMI

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AEPRSPEC	char	Related to Procedure Specify		Collected at CRF.
AELOCOTH	char	Other Adverse Event Location		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AELOC	char	Adverse Event Location		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEPROC	char	Trial Procedure		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
SAEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
SAEOTH	char	Other Medically Important		Collected at CRF.
SAEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
AESTDY	num	Relative Start Day of Event		If AESTDT and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDT less than REF.DATE then (AESTDT - REF.DATE). Else if AESTDT is greater than equal to REF.DATE then (AESTDT- REF.DATE) +1.

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

### 1.4.3. Assay Tracking – ATRACK

<b>Dataset</b>	ATRACK
<b>Creating program</b>	atrack.sas
<b>Description</b>	Assay Tracking
<b>Unique identifier</b>	DUSUBJID,ATSMTYP,ATPTM,ATEVQL,ATKTTYP,ATDY,ATTM,VISIT
<b>Sorted by</b>	DUSUBJID,ATSMTYP,ATPTM,ATEVQL,ATKTTYP,ATDY,ATTM,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ATKITNUM,ATDT,COUNTRY,ATDTC,AGE,RACE,SEX,ATHR,ATMI

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
ATTM	num	Sample Collection Time		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
ADEVQL	char	Event Qualifier		Collected at CRF.
ATKTTYP	char	Kit Type		Collected at CRF.
ATNTCOL	char	Sample Not Collected		Collected at CRF.
ATPTM	char	Planned Timepoint (Period)		Collected at CRF.
ATSMTYP	char	Sample Type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
ATDY	num	Relative Sample Collection 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.

## 1.4.4.Lab Conversion – CLABCONV

<b>Dataset</b>	CLABCONV
<b>Creating program</b>	clabconv.sas
<b>Description</b>	Lab Conversion
<b>Unique identifier</b>	CATEGORY,TSTNAME,STUNTTYP,STUNIT
<b>Sorted by</b>	CATEGORY,TSTNAME,STUNTTYP,STUNIT
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
TESTCD	char	Lab Test Code		Collected at CRF.
TSTNAME	char	Lab Test Name		Collected at CRF.
RESTYP	char	Result Type		Collected at CRF.
STUNTTYP	char	Starting Unit Type		Collected at CRF.
STUNIT	char	Starting Unit		Collected at CRF.
TRUNTTYP	char	Target Unit Type		Collected at CRF.
TRUNIT	char	Target Unit		Collected at CRF.
CONV_EQ	char	Conversion Equation		Collected at CRF.
BASISCD	char	Basis Lab Test Code		Collected at CRF.
CATEGORY	char	Category		Collected at CRF.

## 1.4.5. Concomitant Medications – CONMEDS

<b>Dataset</b>	CONMEDS
<b>Creating program</b>	conmeds.sas
<b>Description</b>	Concomitant Medications
<b>Unique identifier</b>	DUSUBJID,CMROUTE,CMDECOD1,CMSTDY,VISIT,CMSEQ
<b>Sorted by</b>	DUSUBJID,CMROUTE,CMDECOD1,CMSTDY,VISIT,CMSEQ
<b>Notes</b>	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,CMSTDT,CMENDT,COUNTRY,CMENDTC,CMSTDTC,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMMODIFY	char	Modified Reported Term		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		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.

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



Variable	Type	Label	Codes	Comments
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.
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.

## 1.4.6. Concomitant Procedures – CONPROC

<b>Dataset</b>	CONPROC
<b>Creating program</b>	conproc.sas
<b>Description</b>	Concomitant Procedures
<b>Unique identifier</b>	DUSUBJID, PRTYPE, PRSTDY, VISIT
<b>Sorted by</b>	DUSUBJID, PRTYPE, PRSTDY, VISIT
<b>Notes</b>	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: PRREASON, PRSTDY, PRENDT, COUNTRY, PRENDTC, PRSTDTC, PRONGO, AGE, RACE, SEX

	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PRSEQ	num	Sequence Number		Collected at CRF.
PRSPEC	char	Procedure Specify		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity

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

## 1.4.7.Results – CRESUL

<b>Dataset</b>	CRESUL
<b>Creating program</b>	cresul.sas
<b>Description</b>	Results
<b>Unique identifier</b>	DUSUBJID, CPPERIOD, CPRESCAT, CPTTEST, CPRESC
<b>Sorted by</b>	DUSUBJID, CPPERIOD, CPRESCAT, CPTTEST, CPRESC
<b>Notes</b>	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: CPLABID, CPLABEL, CPCMT1, CPCMT2CD, CPCMT2, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
CPPERIOD	char	Planned Timepoint (Period)		Collected at CRF.
CPASYCD	char	Assay Code		Collected at CRF.
CPASY	char	Assay		Collected at CRF.
CPTTESTCD	char	Test Code		Collected at CRF.
CPTTEST	char	Test		Collected at CRF.
CPRESCAT	char	Result Category		Collected at CRF.
CPRESC	char	Result (character)		Collected at CRF.
CPUNIT	char	Result Unit		Collected at CRF.
CPLLOQ	num	Lower Limit of Quantitation		Collected at CRF.
CPCMT1CD	char	Comment Code 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
STUDYID	char	Study ID		Collected at CRF.

## 1.4.8. Inclusion/Exclusion Criteria – CRITERIA

<b>Dataset</b>	CRITERIA
<b>Creating program</b>	criteria.sas
<b>Description</b>	Inclusion/Exclusion Criteria
<b>Unique identifier</b>	DUSUBJID, INCRIT, EXCRIT
<b>Sorted by</b>	DUSUBJID, INCRIT, EXCRIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
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		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
STUDYID	char	Study ID		Collected at CRF.

#### 1.4.9.Substance Use – CSU

<b>Dataset</b>	CSU
<b>Creating program</b>	csu.sas
<b>Description</b>	Substance Use
<b>Unique identifier</b>	ACTTRT,EXPLNDS,CSSEQ
<b>Sorted by</b>	ACTTRT,EXPLNDS,CSSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXKITNO,EXLOTNO,EXCNTRID

Variable	Type	Label	Codes	Comments
CSSEQ	num	Sequence Number		Collected at CRF.
EXVPREP	num	Volume in Container in mL		Collected at CRF.
EXPLNDS	num	Treatment Dose		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTTRT	char	Treatment		Collected at CRF.
CSDRFORM	char	Drug Formulation		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

#### 1.4.10. Death – DEATH

<b>Dataset</b>	DEATH
<b>Creating program</b>	death.sas
<b>Description</b>	Death
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DTDT,DTSPEC,COUNTRY,DTDTC,AGE,SEX

Variable	Type	Label	Codes	Comments
ISTUDYID	char	Source study ID		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DTCAUSE	char	Primary Cause of Death		Collected at CRF.



Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		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 Number Assigned for De-Identity		Randomly assigned Subject Number 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
DTAUTP	char	Autopsy Performed		Collected at CRF.
DTDY	num	Relative Day of Death		If DTDTCC and REF.DATE not missing then perform below logic to calculate DTDY, If DTDTCC less than REF.DATE then (DTDTCC - REF.DATE). Else if DTDTCC is greater than equal to REF.DATE then (DTDTCC - REF.DATE) + 1.

## 1.4.11. Normal – DF\_NORM

<b>Dataset</b>	DF_NORM
<b>Creating program</b>	df_norm.sas
<b>Description</b>	Normal
<b>Unique identifier</b>	CNO,NRTSTCD,NRSEQ
<b>Sorted by</b>	CNO,NRTSTCD,NRSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: NREFDY,NREFMO,NREFYR

Variable	Type	Label	Codes	Comments
NRUNIT	char	Normal Range Unit		Collected at CRF.
CNO	char	Normal Range Type		Collected at CRF.
NRSEQ	num	Sequence Number		Collected at CRF.
NRTSTCD	char	Test Code		Collected at CRF.
NRAGELO	num	Lowest Age Applicable		Collected at CRF.
NRLOUNT	num	Lowest Age Applicable Unit		Collected at CRF.
NRAGEHI	num	Highest Age Applicable		Collected at CRF.
NRHIUNT	num	Highest Age Applicable Unit		Collected at CRF.
NRLOQL	char	Lower Bound Qualifier		Collected at CRF.
NRLO	char	Lower Bound of Normal Range		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRHIQL	char	Upper Bound Qualifier		Collected at CRF.
NRHI	char	Upper Bound of Normal Range		Collected at CRF.
NRGR	num	Gender Restriction		Collected at CRF.
NRFAS	num	Fasting		Collected at CRF.
NRCHAR	char	Normal Range for Character Result		Collected at CRF.
NREFDT	num	Effective Date		Collected at CRF.

#### 1.4.12. Patient Status – DSTATUS

<b>Dataset</b>	DSTATUS
<b>Creating program</b>	dstatus.sas
<b>Description</b>	Patient Status
<b>Unique identifier</b>	DUSUBJID, DSDSC, DSTDSC, VISIT
<b>Sorted by</b>	DUSUBJID, DSDSC, DSTDSC, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DSTDCDT, DSDSCDT, DSUNBDT, DSRELDT, COUNTRY, DSDSCDTC, DSRELDTC, DSTDCDTC, DSUNBDTC, AGE, RACE, SEX

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

Variable	Type	Label	Codes	Comments
DSTRSOTH	char	Other Reason for Tx Disc. Details		Collected at CRF.
DSRSOTH	char	Other Reason for Non-Completion Details		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		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 Number Assigned for De-Identity		Randomly assigned Subject Number 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
DSDSC	char	Study Participation Discontinuation		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
DSTREAS	char	Reason for Treatment Discontinuation		Collected at CRF.
DSDSCDY	num	Relative Day of Study Discontinuation		If DSDSCDTC and 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.

Variable	Type	Label	Codes	Comments
DSRELDY	num	Relative Day Release of 1-Year Follow-Up Signed		If DSRELDTC and REF.DATE not missing then perform below logic to calculate DSRELDY, If DSRELDTC less than REF.DATE then (DSRELDTC - REF.DATE). Else if DSRELDTC is greater than equal to REF.DATE then (DSRELDTC - REF.DATE) +1.
DSTDCDY	num	Relative Study Treatment Discont. Day		If DSTDCDTC and REF.DATE not missing then perform below logic to calculate DSTDCDY, If DSTDCDTC less than REF.DATE then (DSTDCDTC - REF.DATE). Else if DSTDCDTC is greater than equal to REF.DATE then (DSTDCDTC - REF.DATE) +1.
DSUNBDY	num	Relative Day of Treatment Unblinding		If DSUNBDTC and REF.DATE not missing then perform below logic to calculate DSUNBDY, If DSUNBDTC less than REF.DATE then (DSUNBDTC - REF.DATE). Else if DSUNBDTC is greater than equal to REF.DATE then (DSUNBDTC - REF.DATE) +1.

## 1.4.13. Economic Status – ECONOM

<b>Dataset</b>	ECONOM
<b>Creating program</b>	econom.sas
<b>Description</b>	Economic Status
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
ECFPMC	num	Family Physician Medical Care Visits		Collected at CRF.
ECSPMC	num	Specialist Medical Care Visits		Collected at CRF.
ECERMC	num	Emergency Room Medical Care Visits		Collected at CRF.
ECNRVIS	num	Nursing Visits		Collected at CRF.
ECHRSWK	num	Average Number of Hours Worked		Collected at CRF.
ECDYSAB	num	Days of Absence		Collected at CRF.
ECPSCLE	num	Productivity Scale (cm)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECCGMSDY	num	Days Caregivers Missed		Collected at CRF.
ECHAVIS	num	Household Assistance Visits		Collected at CRF.
ECHAHRS	num	Household Assistance Avg Hours Per Visit		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
ECCNWRK	char	Could Work If Job Available		Collected at CRF.
ECDISAB	char	Receiving Disability Compensation		Collected at CRF.
ECERTRE	char	Early Retirement		Collected at CRF.
ECILRSN	char	Illness Reason For Not Working		Collected at CRF.
ECPSND	char	Productivity Scale Not Done		Collected at CRF.
ECRETRE	char	Retired		Collected at CRF.
ECSTUD	char	Student		Collected at CRF.
ECSTUFF	char	Full or Part-time Student		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECWORK	char	Currently Working		Collected at CRF.
ECWRKFP	char	Working Full or Part-time		Collected at CRF.
ECHOSP	num	Number of Hospitalizations		Collected at CRF.
ECHOSDYS	num	Number of Days Hospitalized		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

#### 1.4.14. Endoscopy Information – ENDOSCOP

<b>Dataset</b>	ENDOSCOP
<b>Creating program</b>	endoscop.sas
<b>Description</b>	Endoscopy Information
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ENDT,COUNTRY,ENDTC,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
ENMAYO	num	Endoscopy Findings		Collected at CRF.



Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
ENMAYOC	char	Endoscopy Findings		Collected at CRF.
ENDISEXT	char	Extent of Disease		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
ENDY	num	Relative Day of Endoscopy		If ENDTC and REF.DATE not missing then perform below logic to calculate ENDY, If ENDTC less than REF.DATE then (ENDTC - REF.DATE). Else if ENDTC is greater than equal to REF.DATE then (ENDTC - REF.DATE) +1.

## 1.4.15. EQ-5D Health Questionnaire Data – EQ5D

<b>Dataset</b>	EQ5D
<b>Creating program</b>	eq5d.sas
<b>Description</b>	EQ-5D Health Questionnaire Data
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EQ5DMB	num	EQ5D Mobility		Collected at CRF.
EQ5DSC	num	EQ5D Self Care		Collected at CRF.
EQ5DUA	num	EQ5D Usual Activities		Collected at CRF.
EQ5DPD	num	EQ5D Pain/Discomfort		Collected at CRF.
EQ5DAD	num	EQ5D Anxiety/Depression		Collected at CRF.
EQHSS	num	Health State Scale		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source 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 Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
EQ5DMBC	char	EQ5D Mobility		Collected at CRF.
EQ5DSCC	char	EQ5D Self Care		Collected at CRF.
EQ5DUAC	char	EQ5D Usual Activities		Collected at CRF.
EQ5DPDC	char	EQ5D Pain/Discomfort		Collected at CRF.
EQ5DADC	char	EQ5D Anxiety/Depression		Collected at CRF.
EQHSSND	char	Health State Scale Not Done		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

## 1.4.16. Exposure – EXPOSURE

<b>Dataset</b>	EXPOSURE
<b>Creating program</b>	exposure.sas
<b>Description</b>	Exposure
<b>Unique identifier</b>	DUSUBJID, EXSITE, EXSTDY, VISIT, EXSEQ
<b>Sorted by</b>	DUSUBJID, EXSITE, EXSTDY, VISIT, EXSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EXCNTRID, EXSTDT, EXSTHR, EXSTMI, COUNTRY, EXSTDTC, EXENHR, EXENMI, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
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.
EXSITE_V	char	Exposure Site Specified as Other on CRF		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source 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 Number Assigned for De-Identity		Randomly assigned Subject Number 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
EXLCL	char	Exposure locale		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXSA	char	Study Agent		Collected at CRF.
EXSAADM	char	Study Agent Administrator		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
AMTADM	num	Amount Administered		Collected at CRF.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
EXINRPT	char	Infusion Interrupted		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
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.

## 1.4.17. Serious Adverse Events – FUPEVENT

<b>Dataset</b>	FUPEVENT
<b>Creating program</b>	fupevent.sas
<b>Description</b>	Serious Adverse Events
<b>Unique identifier</b>	DUSUBJID,AEDECOD
<b>Sorted by</b>	DUSUBJID,AEDECOD
<b>Notes</b>	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,MDCDST,AESTDT,AEENDT,AEENDTC,AESTDTC, COUNTRY, AEMODIFY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTC	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
SAECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF.
SAEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAEOTH	char	Other Medically Important		Collected at CRF.
SAEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
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.
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.



## 1.4.18. Hospitalization Data – HOSPIN

<b>Dataset</b>	HOSPIN
<b>Creating program</b>	hospin.sas
<b>Description</b>	Hospitalization Data
<b>Unique identifier</b>	DUSUBJID,HODRHOSP,HOADMMDY,VISIT,HOSEQ
<b>Sorted by</b>	DUSUBJID,HODRHOSP,HOADMMDY,VISIT,HOSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: HOADMMDT,HODISDT,HODIAG,HOADMMDTC,HODISDTC,AGE,RACE,SEX, COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
HOSEQ	num	Hospitalization Sequence		Collected at CRF.
HOICUDYS	num	Total Number of Days in ICU		Collected at CRF.
HOTPNDYS	num	Number of Days TPN Received		Collected at CRF.
HOTFDYS	num	Number of Days of Tube Feeding		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source 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 Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
HODRHOSP	char	Disease Related Hospitalization		Collected at CRF.
HONODSCH	char	Not Discharged		Collected at CRF.
HOPRPERF	char	Surgery or Procedure Performed		Collected at CRF.
HOTFNA	char	Tube Feeding Not Applicable		Collected at CRF.
HOTPNA	char	TPN Not Applicable		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
HOADM DY	num	Relative Hospital Admission Day		If HOADM DTC and REF.DATE not missing then perform below logic to calculate HOADM DY, If HOADM DTC less than REF.DATE then (HOADM DTC - REF.DATE). Else if HOADM DTC is greater than equal to REF.DATE then (HOADM DTC - REF.DATE) +1.
HODISDY	num	Relative Hospital Discharge Day		If HODISDTC and REF.DATE not missing then perform below logic to calculate HODISDY, If HODISDTC less than REF.DATE then (HODISDTC - REF.DATE). Else if HODISDTC is greater than equal to REF.DATE then (HODISDTC - REF.DATE) +1.

## 1.4.19. Inflammatory Bowel Disease Questionnaire Score – IBDQSCR

<b>Dataset</b>	IBDQSCR
<b>Creating program</b>	ibdqscr.sas
<b>Description</b>	Inflammatory Bowel Disease Questionnaire Score
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: AGE,RACE,SEX, COUNTRY

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

Variable	Type	Label	Codes	Comments
IBDQ_10	num	Score for IBDQQuestion 10		Collected at CRF.
IBDQ_11	num	Score for IBDQQuestion 11		Collected at CRF.
IBDQ_12	num	Score for IBDQQuestion 12		Collected at CRF.
IBDQ_13	num	Score for IBDQQuestion 13		Collected at CRF.
IBDQ_14	num	Score for IBDQQuestion 14		Collected at CRF.
IBDQ_15	num	Score for IBDQQuestion 15		Collected at CRF.
IBDQ_16	num	Score for IBDQQuestion 16		Collected at CRF.
IBDQ_17	num	Score for IBDQQuestion 17		Collected at CRF.
IBDQ_18	num	Score for IBDQQuestion 18		Collected at CRF.
IBDQ_19	num	Score for IBDQQuestion 19		Collected at CRF.
IBDQ_20	num	Score for IBDQQuestion 20		Collected at CRF.
IBDQ_21	num	Score for IBDQQuestion 21		Collected at CRF.
IBDQ_22	num	Score for IBDQQuestion 22		Collected at CRF.
IBDQ_23	num	Score for IBDQQuestion 23		Collected at CRF.
IBDQ_24	num	Score for IBDQQuestion 24		Collected at CRF.
IBDQ_25	num	Score for IBDQQuestion 25		Collected at CRF.
IBDQ_26	num	Score for IBDQQuestion 26		Collected at CRF.
IBDQ_27	num	Score for IBDQQuestion 27		Collected at CRF.
IBDQ_28	num	Score for IBDQQuestion 28		Collected at CRF.
IBDQ_29	num	Score for IBDQQuestion 29		Collected at CRF.
IBDQ_30	num	Score for IBDQQuestion 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		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
STUDYID	char	Study ID		Collected at CRF.

## 1.4.20. IVRS Dose – IVRSDOSE

<b>Dataset</b>	IVRSDOSE
<b>Creating program</b>	ivrsdose.sas
<b>Description</b>	IVRS Dose
<b>Unique identifier</b>	DUSUBJID, IDCLDY, VISIT, IDSEQ
<b>Sorted by</b>	DUSUBJID, IDCLDY, VISIT, IDSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: IDKITNUM, IDCNTRID, IDCLDT, IDCLDTC, AGE, RACE, SEX, COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IDSEQ	num	IVRS Sequence Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
STUDYID	char	Study ID		Collected at CRF.
IDCLDY	num	Relative IVRS Dose Call Day		If IDCLDTC and REF.DATE not missing then perform below logic to calculate IDCLDY, If IDCLDTC less than REF.DATE then (IDCLDTC - REF.DATE). Else if IDCLDTC is greater than equal to REF.DATE then (IDCLDTC - REF.DATE) + 1.

#### 1.4.21. IVRS Mayo – IVRSMAYO

<b>Dataset</b>	IVRSMAYO
<b>Creating program</b>	ivrsmayo.sas
<b>Description</b>	IVRS Mayo
<b>Unique identifier</b>	DUSUBJID, IMPGAC, IMCLDY, VISIT
<b>Sorted by</b>	DUSUBJID, IMPGAC, IMCLDY, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: IMCLDT, IMCLDTC, AGE, RACE, SEX, COUNTRY

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

Variable	Type	Label	Codes	Comments
IMSTLFRQ	num	Stool Frequency		Collected at CRF.
IMRBLD	num	Rectal Bleeding		Collected at CRF.
IMPGA	num	Physician's Global Assessment		Collected at CRF.
IMENDFND	num	Endoscopy Score		Collected at CRF.
IMMAYOSC	num	Calculated Mayo Score		Collected at CRF.
IMCLTM	num	IVRS Call Time		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
IMENDFNC	char	Endoscopy Score		Collected at CRF.
IMRBLDC	char	Rectal Bleeding		Collected at CRF.
IMSTLFRC	char	Stool Frequency		Collected at CRF.
IMPGAC	char	Physician's Global Assessment		Collected at CRF.
IMCCR	char	Calculated Clinical Response		Collected at CRF.
IMCCRM	char	Calculated Clinical Remission		Collected at CRF.



Variable	Type	Label	Codes	Comments
IMCORT	char	Corticosteroids Currently Used		Collected at CRF.
IMDOSADJ	char	Dose Adjusted		Collected at CRF.
IMINDOSE	char	Induction Dosage		Collected at CRF.
IMLOR	char	Loss of Clinical Response		Collected at CRF.
IM5ASAST	char	5-ASA Status		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
IMCLDY	num	Relative IVRS Call Day		If IMCLDTC and REF.DATE not missing then perform below logic to calculate IMCLDY, If IMCLDTC less than REF.DATE then (IMCLDTC - REF.DATE). Else if IMCLDTC is greater than equal to REF.DATE then (IMCLDTC - REF.DATE) + 1.

## 1.4.22. IVRS Randomization – IVRSRAND

<b>Dataset</b>	IVRSRAND
<b>Creating program</b>	ivrsrand.sas
<b>Description</b>	IVRS Randomization
<b>Unique identifier</b>	DUSUBJID, TRTGRP
<b>Sorted by</b>	DUSUBJID, TRTGRP
<b>Notes</b>	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: IRSUBID1,IRSUBID2,IRSUBID3,IRSUBID4,IRLCNDT,IRCHGDT,IRPA3DT,IRLCNDTC,AGE,RACE,SEX,COUNTRY,IRENMNID,IRADJID,IRRNDVAL,IRRNDVLC,IRRNDSD,IRSEQ,IRSEQ2

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IRLCENTM	num	Time of Treatment Assignment		Collected at CRF.
IRSUBORD	num	Subject Treatment Assignment Order		Collected at CRF.
TRTCD	num	Treatment Group		Collected at CRF.
IRFCTR1	char	Stratification Factor 1		Collected at CRF.
IRIMB1	num	Imbalance if Assigned Tx 1		Collected at CRF.
IRIMB2	num	Imbalance if Assigned Tx 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRIMB3	num	Imbalance if Assigned Tx 3		Collected at CRF.
IRPROB1	num	Prob. of Tx 1 Allocation		Collected at CRF.
IRPROB2	num	Prob. of Tx 2 Allocation		Collected at CRF.
IRPROB3	num	Prob. of Tx 3 Allocation		Collected at CRF.
IRTACRIT	char	Criterion for Treatment Assignment		Collected at CRF.
IRCHGTM	num	Time of First Algorithm Correction		Collected at CRF.
IRPA3TM	num	Time of Protocol Amendment 3		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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	Treatment Group		Collected at CRF.
IRBCOUSE	char	Baseline Corticosteroid Use		Collected at CRF.
IRCREMSB	char	Clinical Remission Status at Baseline		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRCRESSB	char	Clinical Response Status at Baseline		Collected at CRF.
IRDOSCHG	char	Treatment Group After Protocol Amndmnt 3		Collected at CRF.
IRFCTR2	char	Stratification Factor 2		Collected at CRF.
IRFCTR3	char	Stratification Factor 3		Collected at CRF.
IRPHASE	char	Phase of Treatment Assignment		Collected at CRF.
IRSECNDS	num	Seconds		Collected at CRF.
IRPART	num	Study Schema Part Number		Collected at CRF.
IRIMB4	num	Imbalance if Assigned Tx 4		Collected at CRF.
IRPROB4	num	Prob. of Tx 4 Allocation		Collected at CRF.
IRDOSDEC	char	Study Schema Prior to Dose Decision		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
IRCHGDY	num	Relative First Algorithm Correction Day		If IRCHGDT and REF.DATE not missing then perform below logic to calculate IRCHGDY, If IRCHGDT less than REF.DATE then (IRCHGDT - REF.DATE). Else if IRCHGDT is greater than equal to REF.DATE then (IRCHGDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
IRPA3DY	num	Relative Day of Protocol Amendment 3		If IRPA3DT and REF.DATE not missing then perform below logic to calculate IRPA3DY, If IRPA3DT less than REF.DATE then (IRPA3DT - REF.DATE). Else if IRPA3DT is greater than equal to REF.DATE then (IRPA3DT- REF.DATE) +1.
IRLCNDY	num	Relative Day of Treatment Assignment		If IRLCNDTC and REF.DATE not missing then perform below logic to calculate IRLCNDY, If IRLCNDTC less than REF.DATE then (IRLCNDTC - REF.DATE). Else if IRLCNDTC is greater than equal to REF.DATE then (IRLCNDTC- REF.DATE) +1.

## 1.4.23. Laboratory Tests – LAB

<b>Dataset</b>	LAB
<b>Creating program</b>	lab.sas
<b>Description</b>	Laboratory Tests
<b>Unique identifier</b>	DUSUBJID,LBCAT,LBSCAT,LBTEST,LBDY,LBKTTY,VISIT
<b>Sorted by</b>	DUSUBJID,LBCAT,LBSCAT,LBTEST,LBDY,LBKTTY,VISIT
<b>Notes</b>	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: LBLBLNUM,LBDT,LBACTHR,LBACTMI,LBDTC,LBCLNSG,LBID,LBLOQL,AGE,RACE,SEX,COUNTRY

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.
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.

Variable	Type	Label	Codes	Comments
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		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.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
LBCOM	char	Lab Comment		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC - REF.DATE) +1.



## 1.4.24. Lab Dictionary – LABDICT

<b>Dataset</b>	LABDICT
<b>Creating program</b>	labdict.sas
<b>Description</b>	Lab Dictionary
<b>Unique identifier</b>	CATEGORY,SUB_CAT,TESTNAME,UPDDY
<b>Sorted by</b>	CATEGORY,SUB_CAT,TESTNAME,UPDDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABID

Variable	Type	Label	Codes	Comments
TESTCD	char	Testcd		Collected at CRF.
CATSEQ	num	Catseq		Collected at CRF.
SUBSEQ	num	Subseq		Collected at CRF.
TESTNAME	char	Testname		Collected at CRF.
CATEGORY	char	Category		Collected at CRF.
STANDFLG	char	Standflag		Collected at CRF.
OBSFLG	char	Obsflg		Collected at CRF.
VALFLG	char	Valflg		Collected at CRF.
UPDDATE	num	Trunc(Upddate)-To_date('01-01-1960',		Collected at CRF.
UPDUSRID	num	Updusrid		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUB_CAT	char	Sub_cat		Collected at CRF.
APPROVED	char	Approved		Collected at CRF.
RESTYP	num	Restyp		Collected at CRF.
PRCSN	num	Prcsn		Collected at CRF.

#### 1.4.25. Mayo Score – MAYOSCR

<b>Dataset</b>	MAYOSCR
<b>Creating program</b>	mayoscr.sas
<b>Description</b>	Mayo Score
<b>Unique identifier</b>	DUSUBJID,MYPGAC,VISIT
<b>Sorted by</b>	DUSUBJID,MYPGAC,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: AGE,RACE,SEX, COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MYSTL1	num	Stool Freq Day 1		Collected at CRF.
MYSTL2	num	Stool Freq Day 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
MYSTL3	num	Stool Freq Day 3		Collected at CRF.
MYSTLSUM	num	Stool Frequency Sum		Collected at CRF.
MYSTLAVG	num	Average Stool Frequency		Collected at CRF.
MYSTLREM	num	Number of Stools in Remission		Collected at CRF.
MYSTLDIF	num	Stool Difference (remission - average)		Collected at CRF.
MYSTLNUM	num	Rounded Stool Number		Collected at CRF.
MYSTLFRQ	num	Stool Frequency Score		Collected at CRF.
MYBLD1	num	Rectal Bleeding Day 1		Collected at CRF.
MYBLD2	num	Rectal Bleeding Day 2		Collected at CRF.
MYBLD3	num	Rectal Bleeding Day 3		Collected at CRF.
MYBLDSUM	num	Sum Rectal Bleeding Scores		Collected at CRF.
MYBLDAVG	num	Average of Rectal Bleeding Scores		Collected at CRF.
MYRBLD	num	Rectal Bleeding Score		Collected at CRF.
MYPGA	num	Physician Global Assessment		Collected at CRF.
MYPSCORE	num	Partial Mayo Score		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source 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 Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
MYPGAC	char	Physician Global Assessment		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

#### 1.4.26. Medication Change – MEDCHNG

<b>Dataset</b>	MEDCHNG
<b>Creating program</b>	medchng.sas
<b>Description</b>	Medication Change
<b>Unique identifier</b>	DUSUBJID,MCCHNG,MCINCR,MCRSN,VISIT
<b>Sorted by</b>	DUSUBJID,MCCHNG,MCINCR,MCRSN,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MCCHGDT,MCCHGDTC,AGE,RACE,SEX,COUNTRY

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

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
MCCAT	char	Medication Category		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.
MCCHGDY	num	Relative Medication Change Day		If MCCHGDTC and REF.DATE not missing then perform below logic to calculate MCCHGDY, If MCCHGDTC less than REF.DATE then (MCCHGDTC - REF.DATE). Else if MCCHGDTC is greater than equal to REF.DATE then (MCCHGDTC - REF.DATE) +1.

## 1.4.27. Medication Class – MEDCLASS

<b>Dataset</b>	MEDCLASS
<b>Creating program</b>	medclass.sas
<b>Description</b>	Medication Class
<b>Unique identifier</b>	ATC_CODE,SEQ1
<b>Sorted by</b>	ATC_CODE,SEQ1
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
LEVEL1	char	4th Level, ATC Class		Collected at CRF.
LEVEL2	char	2nd Level, ATC Class		Collected at CRF.
LEVEL3	char	3rd Level, ATC Class		Collected at CRF.
LEVEL4	char	4th Level, ATC Class		Collected at CRF.
ATC_CODE	char	ATC Code		Collected at CRF.

## 1.4.28. Medication Review Data – MEDRVIEW

<b>Dataset</b>	MEDRVIEW
<b>Creating program</b>	medrview.sas
<b>Description</b>	Medication Review Data
<b>Unique identifier</b>	MRCAT,MRROUTE,CMDECOD1,MRCDY,VISIT,MRSEQ
<b>Sorted by</b>	MRCAT,MRROUTE,CMDECOD1,MRCDY,VISIT,MRSEQ
<b>Notes</b>	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,AGE,RACE,SEX,COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MRSEQ	num	Medication Sequence Number		Collected at CRF.
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.
CODSTAT	char	Autoencoding Status		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
MRCAT	char	Medication Category		Collected at CRF.
MRDOSCH	char	Medication Reason for Change		Collected at CRF.
MRDUNIT	char	Dose Unit		Collected at CRF.
MRFREQ	char	Frequency		Collected at CRF.
MRPMST	char	Start Prohibited Medications		Collected at CRF.
MRROUTE	char	Medication Route		Collected at CRF.
MRTYPE	char	Route Type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
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.



## 1.4.29. Nabresult – NABRESUL

<b>Dataset</b>	NABRESUL
<b>Creating program</b>	nabresul.sas
<b>Description</b>	Nabresult
<b>Unique identifier</b>	DUSUBJID, CPPERIOD, CPRESC
<b>Sorted by</b>	DUSUBJID, CPPERIOD, CPRESC
<b>Notes</b>	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: CPLABID, CPLABEL, CPCMT1CD, CPCMT1, CPCMT2CD, CPCMT2, AGE, RACE, SEX, COUNTRY

Variable	Type	Label	Codes	Comments
CPPERIOD	char	Planned Timepoint (Period)		Collected at CRF.
CPASYCD	char	Assay Code		Collected at CRF.
CPASY	char	Assay		Collected at CRF.
CPTTESTCD	char	Test Code		Collected at CRF.
CPTTEST	char	Test		Collected at CRF.
CPRESCAT	char	Result Category		Collected at CRF.
CPRESC	char	Result (character)		Collected at CRF.
CPUNIT	char	Result Unit		Collected at CRF.
CPLLOQ	num	Lower Limit of Quantitation		Collected at CRF.

Variable	Type	Label	Codes	Comments
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
STUDYID	char	Study ID		Collected at CRF.

## 1.4.30. Questionnaires Data – QOL

<b>Dataset</b>	QOL
<b>Creating program</b>	qol.sas
<b>Description</b>	Questionnaires Data
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: AGE,RACE,SEX, COUNTRY

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

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

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

## 1.4.31. Sevent – SEVENT

<b>Dataset</b>	SEVENT
<b>Creating program</b>	sevent.sas
<b>Description</b>	Sevent
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	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,SESTDT,SEENDT,MDCDST,SEENDTC,SESTDTC,AGE,RACE,SEX, COUNTRY

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

Variable	Type	Label	Codes	Comments
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
SECODE	char	Code for Reported Term		Collected at CRF.
SECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF.
SEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF.
SEDTH	char	Results in Death		Collected at CRF.
SELIFE	char	Is Life-Threatening		Collected at CRF.

Variable	Type	Label	Codes	Comments
SENS	char	Not Serious		Collected at CRF.
SEONGO	char	Ongoing Blood Draw Adverse Event		Collected at CRF.
SEOTH	char	Other Medically Important		Collected at CRF.
SEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SEREL	char	Relationship		Collected at CRF.
SERHOS	char	Requires/Prolongs Hospitalization		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
SEENDY	num	Relative End Day of Event		If SEENDTC and REF.DATE not missing then perform below logic to calculate SEENDY, If SEENDTC less than REF.DATE then (SEENDTC - REF.DATE). Else if SEENDTC is greater than equal to REF.DATE then (SEENDTC - REF.DATE) +1.
SESTDY	num	Relative Start Day of Event		If SESTDTC and REF.DATE not missing then perform below logic to calculate SESTDY, If SESTDTC less than REF.DATE then (SESTDTC - REF.DATE). Else if SESTDTC is greater than equal to REF.DATE then (SESTDTC - REF.DATE) +1.



## 1.4.32. Tuberculosis Testing Data – TB\_INFO

<b>Dataset</b>	TB_INFO
<b>Creating program</b>	tb_info.sas
<b>Description</b>	Tuberculosis Testing Data
<b>Unique identifier</b>	DUSUBJID, TBADM, TBATB, TBADMDY, VISIT
<b>Sorted by</b>	DUSUBJID, TBADM, TBATB, TBADMDY, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: TBADMDT, TBADMSP, TBRDDT, TBREADSP, TBCXRDT, TBADMDC, TBCXRDC, TBRDDTC, AGE, RACE, SEX, COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
TBSEQ	num	Sequence Number		Collected at CRF.
TBRSLT	num	PPD Result		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
TBADM	char	PPD Administrator		Collected at CRF.
TBCXRES	char	Chest X-Ray Result		Collected at CRF.
TBREAD	char	PPD Reader		Collected at CRF.
TBRPN	char	PPD Test Result Positive or Negative		Collected at CRF.
TBTRTRQ	char	Treatment Required		Collected at CRF.
TBBCGYR	num	Year of Previous BCG Vaccination		Collected at CRF.
TBATB	char	History of Active TB		Collected at CRF.
TBBCG	char	Previous BCG Vaccination		Collected at CRF.
TBLTB	char	History of Latent TB		Collected at CRF.
TBRCATB	char	Recent Contact to Active TB		Collected at CRF.
TBSSATB	char	Signs or Symptoms of Active TB		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
TBADMDY	num	Relative Day of PPD Administration		If TBADMDC and REF.DATE not missing then perform below logic to calculate TBADMDY, If TBADMDC less than REF.DATE then (TBADMDC - REF.DATE). Else if TBADMDC is greater than equal to REF.DATE then (TBADMDC - REF.DATE) + 1.

Variable	Type	Label	Codes	Comments
TBCXRDY	num	Relative Chest X-Ray Day		If TBCXRDTc and REF.DATE not missing then perform below logic to calculate TBCXRDY, If TBCXRDTc less than REF.DATE then (TBCXRDTc - REF.DATE). Else if TBCXRDTc is greater than equal to REF.DATE then (TBCXRDTc - REF.DATE) +1.
TBRDDY	num	Relative Day PPD Read		If TBRDDTc and REF.DATE not missing then perform below logic to calculate TBRDDY, If TBRDDTc less than REF.DATE then (TBRDDTc - REF.DATE). Else if TBRDDTc is greater than equal to REF.DATE then (TBRDDTc - REF.DATE) +1.

#### 1.4.33. Unit Dictionary –UNITDICT

<b>Dataset</b>	UNITDICT
<b>Creating program</b>	unitdict.sas
<b>Description</b>	Unit Dictionary
<b>Unique identifier</b>	UNITUC
<b>Sorted by</b>	UNITUC
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
UNITID	num	Unitid		Collected at CRF.

Variable	Type	Label	Codes	Comments
UNITCD	num	Unitidcd		Collected at CRF.
UNITUC	char	Unituc		Collected at CRF.
UNITMC	char	Unitmc		Collected at CRF.
UNITCL	char	Unitcl		Collected at CRF.
OBSFLG	char	Obsflg		Collected at CRF.
UPDDATE	num	Trunc(Upddate)-To_date('01-01-1960',		Collected at CRF.
UPDUSRID	num	Updusrid		Collected at CRF.

## 1.4.34. Visit Information – VISITS

<b>Dataset</b>	VISITS
<b>Creating program</b>	visits.sas
<b>Description</b>	Visit Information
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: VISITDT,VISITDTC,AGE,RACE,SEX,COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number 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
VISITEXT	char	Study Extension		Collected at CRF.
VIMAINST	char	Maintenance Study		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
VISITDY	num	Relative Day of Subject Visit		If VISITDTC and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDTC less than REF.DATE then (VISITDTC - REF.DATE). Else if VISITDTC is greater than equal to REF.DATE then (VISITDTC - REF.DATE) +1.

#### 1.4.35. Visper – VISPER

<b>Dataset</b>	VISPER
<b>Creating program</b>	visper.sas
<b>Description</b>	Visper
<b>Unique identifier</b>	EVENT_ID,MOD_NAME,VISIT
<b>Sorted by</b>	EVENT_ID,MOD_NAME,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: LBEVNTD,LBEVNT,CRF_PAGE,PHASE,PHASENUM,VPERIOD,VPERIODN

Variable	Type	Label	Codes	Comments
PNO	char	Pno		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Pag_Name		Collected at CRF.
MOD_NAME	char	Mod_Name		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visitnum		Collected at CRF.

#### 1.4.36. Vital Signs – VITALS

<b>Dataset</b>	VITALS
<b>Creating program</b>	vitals.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: AGE,RACE,SEX, COUNTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VSSEQ	num	Vital Signs Sequence		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visitnum		Collected at CRF.
ISTUDYID	char	Source Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DSITESBJ	char	Site-subject ID Assigned for De-Identity		Randomly assigned Site-subject ID for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSTSTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSSTRES	num	Result in Standard Units		Collected at CRF.
VSSTUNIT	char	Standard Units		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.



## 1.4.37. Who\_dd – WHO\_DD

<b>Dataset</b>	WHO_DD
<b>Creating program</b>	who_dd.sas
<b>Description</b>	Who_dd
<b>Unique identifier</b>	CMDECOD1,ATC1_TXT,ATC2_TXT,ATC3_TXT,ATC4_TXT,SEQ1,SEQ2
<b>Sorted by</b>	CMDECOD1,ATC1_TXT,ATC2_TXT,ATC3_TXT,ATC4_TXT,SEQ1,SEQ2
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
ATC1_TXT	char	1st Level, ATC Class		Collected at CRF.
ATC2_TXT	char	2nd Level, ATC Class		Collected at CRF.
ATC3_TXT	char	3rd Level, ATC Class		Collected at CRF.
ATC4_TXT	char	4th Level, ATC Class		Collected at CRF.
ATC1_CDE	char	1st Level, ATC Code		Collected at CRF.
ATC2_CDE	char	2nd Level, ATC Code		Collected at CRF.
ATC3_CDE	char	3rd Level, ATC Code		Collected at CRF.
ATC4_CDE	char	4th Level, ATC Code		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEQ2	char	Drug Sequence 2		Collected at CRF.
DD_VER	char	Dd_ver		Collected at CRF.