

Clinical Development

CNTO148

C0524T16

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset with zero observation will not be submitted. (ex. DEATH, SCRNDTH and SEVENT).
- For Randomized subjects, DEMO.DMCONDTC("Date of Informed Consent") will be used as Reference Date (referred as REF. DATE in the document) to derive relative day. For Screen Failure subjects, SCRNDEMO.DMCONDTC("Date of Informed Consent") will be used as a Reference date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The C0524T16 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SUBJINIT,BIRTHDT,DMCONDT,DEMOG,BIRTHDTC,DMCONDTC</p> <p>Below listed variables were not part of the Raw dataset. These have been added to retain the treatment related information in the de-identified datasets:</p> <p>TRTCDA (Source: PKATSA_3 dataset) TRTGRPA (Source: PKATSA_3 dataset)</p>

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.

Variable	Type	Label	Codes	Comments
HEIGHT	num	Height in Centimeters		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
TRTCDA	num	Actual Treatment Code		Collected at CRF.
TRTGRPA	char	Actual Treatment Group		Collected at CRF.

1.4.2. Adverse Events – AE

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

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.
AESTHR	num	Start Hour of Event		Collected at CRF.
AESTMI	num	Start Minute of Event		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

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

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
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.
SAENS	char	Not Serious		Collected at CRF.
SAEOTH	char	Other Medically Important		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.

1.4.3.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	

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

1.4.4. Concomitant Medications – CONMEDS

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

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
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
CMROUTE	char	Route Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMONGO	char	Ongoing Medication		Collected at CRF.
CMREAS	char	Reason for Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
CMENDY	num	Relative End Day of Medication		If CMENDTC and 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.

1.4.5.Crohn's Disease Related Surgeries – CONPROC

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PRSEQ	num	Sequence Number		Collected at CRF.
PRREASON	char	Procedure Reason		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
PRINOUT	char	In-Patient or Out-Patient		Collected at CRF.
PRONGO	char	Ongoing		Collected at CRF.
PRTYPE	char	Procedure Type		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.

1.4.6. Inclusion Criteria/Exclusion Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Inclusion Criteria/Exclusion Criteria
Unique identifier	DUSUBJID, EXCRIT
Sorted by	DUSUBJID, EXCRIT
Notes	

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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

1.4.7.CSU – CSU

Dataset	CSU
Creating program	csu.sas
Description	Csu
Unique identifier	STUDYID,ACTTRT,CSSEQ
Sorted by	STUDYID,ACTTRT,CSSEQ
Notes	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.

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

1.4.8. DISEASHX – DISEASHX

Dataset	DISEASHX
Creating program	diseashx.sas
Description	Diseashx
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DHDXDT,DHDXDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DHSYMPYR	num	Duration of Symptoms in Years		Collected at CRF.
DHSYMPMO	num	Duration of Symptoms in Months		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
DHDXDY	num	Relative Day of Diagnosis		If DHXDTC and REF.DATE not missing then perform below logic to calculate DHDXDY, If DHXDTC less than REF.DATE then (DHXDTC - REF.DATE). Else if DHXDTC is greater than equal to REF.DATE then (DHXDTC - REF.DATE) +1.

1.4.9. Drug Preparation – DRUGPREP

Dataset	DRUGPREP
Creating program	drugprep.sas
Description	Drug Preparation
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DPDT, DPLOTNO1, DPLOTNO2, DPLOTNO3, DPDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		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.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
DPND	char	Drug Preparation Not Done		Collected at CRF.
DPSA	char	Study Agent		Collected at CRF.
DPDY	num	Relative Day Prepared		If DPDTC and REF.DATE not missing then perform below logic to calculate DPDY, If DPDTC less than REF.DATE then (DPDTC - REF.DATE). Else if DPDTC is greater than equal to REF.DATE then (DPDTC - REF.DATE) + 1.

1.4.10. Disposition Status – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Disposition Status
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: DSDSCDT,DSRSOTH,DSUNBDT,DSDSCDTC,DSUNBDTC

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

1.4.11. Health Economic Questionnaire – ECONOM

Dataset	ECONOM
Creating program	econom.sas
Description	Health Economic Questionnaire
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

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.
ECHOSP	num	Number of Hospitalizations		Collected at CRF.
ECHOSDYS	num	Number of Days Hospitalized		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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
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.
ECSTUFP	char	Full or Part-time Student		Collected at CRF.
ECWORK	char	Currently Working		Collected at CRF.
ECWRKFP	char	Working Full or Part-time		Collected at CRF.

1.4.12. Endoscopy Findings – ENDOSCOP

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

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
ENMAYO	num	Endoscopy Findings		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
ENMAYOC	char	Endoscopy Findings		Collected at CRF.
ENDISEXT	char	Extent of Disease		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.

1.4.13. EQ-5D Health Questionnaire – EQ5D

Dataset	EQ5D
Creating program	eq5d.sas
Description	EQ-5D Health Questionnaire
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.

1.4.14. Oral/Subcutaneous Study Agent Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Oral/Subcutaneous Study Agent Exposure
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXSTDT,EXSTDTC

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.
EXSTHR	num	Start Hour of Dose, 24 Hour Clock		Collected at CRF.
EXSTMI	num	Start Minute of Dose, 24 Hour Clock		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
EXENHR	num	End Hour of Dose, 24 Hour Clock		Collected at CRF.
EXENMI	num	End Minute of Dose, 24 Hour Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
AMTADM	num	Amount Administered		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
EXINRPT	char	Infusion Interrupted		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXSA	char	Study Agent		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXTOTADM	char	Total Dose Administered		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.

1.4.15. Hospitalization – HOSPIN

Dataset	HOSPIN
Creating program	hospin.sas
Description	Hospitalization
Unique identifier	DUSUBJID,VISIT,HOSEQ
Sorted by	DUSUBJID,VISIT,HOSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: HOADMDT,HODISDT,HODIAG,HOTFDYS,HOADMDTC,HODISDTC

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.

Variable	Type	Label	Codes	Comments
HOTPNNDYS	num	Number of Days TPN Received		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.
HOTPNNA	char	TPN Not Applicable		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
HODIS DY	num	Relative Hospital Discharge Day		If HODIS DTC and REF.DATE not missing then perform below logic to calculate HODIS DY, If HODIS DTC less than REF.DATE then (HODIS DTC - REF.DATE). Else if HODIS DTC is greater than equal to REF.DATE then (HODIS DTC - REF.DATE) +1.

1.4.16. IBDQSCR – IBDQSCR

Dataset	IBDQSCR
Creating program	ibdqscr.sas
Description	ibdqscr
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

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
IBDQ_1	num	Score for IBDQ Question 1		Collected at CRF.
IBDQ_2	num	Score for IBDQ Question 2		Collected at CRF.
IBDQ_3	num	Score for IBDQ Question 3		Collected at CRF.
IBDQ_4	num	Score for IBDQ Question 4		Collected at CRF.
IBDQ_5	num	Score for IBDQ Question 5		Collected at CRF.
IBDQ_6	num	Score for IBDQ Question 6		Collected at CRF.
IBDQ_7	num	Score for IBDQ Question 7		Collected at CRF.
IBDQ_8	num	Score for IBDQ Question 8		Collected at CRF.
IBDQ_9	num	Score for IBDQ Question 9		Collected at CRF.
IBDQ_10	num	Score for IBDQ Question 10		Collected at CRF.
IBDQ_11	num	Score for IBDQ Question 11		Collected at CRF.
IBDQ_12	num	Score for IBDQ Question 12		Collected at CRF.
IBDQ_13	num	Score for IBDQ Question 13		Collected at CRF.
IBDQ_14	num	Score for IBDQ Question 14		Collected at CRF.
IBDQ_15	num	Score for IBDQ Question 15		Collected at CRF.
IBDQ_16	num	Score for IBDQ Question 16		Collected at CRF.
IBDQ_17	num	Score for IBDQ Question 17		Collected at CRF.
IBDQ_18	num	Score for IBDQ Question 18		Collected at CRF.
IBDQ_19	num	Score for IBDQ Question 19		Collected at CRF.
IBDQ_20	num	Score for IBDQ Question 20		Collected at CRF.
IBDQ_21	num	Score for IBDQ Question 21		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
IBDQ_31	num	Score for IBDQQuestion 31		Collected at CRF.
IBDQ_32	num	Score for IBDQQuestion 32		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

1.4.17. IRESUL – IRESUL

Dataset	IRESUL
Creating program	iresul.sas
Description	Iresul
Unique identifier	CPTTEST, CPTTESTCD, CPLLOQ, CPCMT1, CPCMT2
Sorted by	CPTTEST, CPTTESTCD, CPLLOQ, CPCMT1, CPCMT2
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CPLABID, CPLABEL, CPCMT2CD

Variable	Type	Label	Codes	Comments
CPPERIOD	char	CPPERIOD		Collected at CRF.
CPASYCD	char	CPASYCD		Collected at CRF.
CPASY	char	CPASY		Collected at CRF.
CPTTESTCD	char	CPTTESTCD		Collected at CRF.
CPTTEST	char	CPTTEST		Collected at CRF.

Variable	Type	Label	Codes	Comments
CPRESCAT	char	CPRESCAT		Collected at CRF.
CPRESC	char	CPRESC		Collected at CRF.
CPUNIT	char	CPUNIT		Collected at CRF.
CPLLOQ	num	CPLLOQ		Collected at CRF.
CPCMT1CD	char	CPCMT1CD		Collected at CRF.
CPCMT1	char	CPCMT1		Collected at CRF.
CPCMT2	char	CPCMT2		Collected at CRF.

1.4.18. IVRSDOSE – IVRSDOSE

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

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
IDSEQ	num	Sequence Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.

1.4.19. IVRSMAYO – IVRSMAYO

Dataset	IVRSMAYO
Creating program	ivrsmayo.sas
Description	Ivrsmayo
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: IMMYODT,IMMYODTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
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	IVRS Calculated Mayo Score		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.
IM5ASAST	char	5-ASA Status		Collected at CRF.
IMMYODY	num	Relative Mayo Score Call Day		If IMMYODTC and REF.DATE not missing then perform below logic to calculate IMMYODY, If IMMYODTC less than REF.DATE then (IMMYODTC - REF.DATE). Else if IMMYODTC is greater than equal to REF.DATE then (IMMYODTC - REF.DATE) +1.

1.4.20. IVRSRAND – IVRSRAND

Dataset	IVRSRAND
Creating program	ivrsrand.sas
Description	Ivrsrand
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: IRLCNDT,IRRNDVAL,IRRNDVLC,IRRNDSD,IRLCNDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IRLCENTM	num	Time of Randomization		Collected at CRF.
IRSECNDS	num	Seconds		Collected at CRF.
TRTCD	num	Treatment Group		Collected at CRF.
IRPART	num	Study Schema Part Number		Collected at CRF.
IRSEQ	num	Randomization Sequence		Collected at CRF.
IRIMB1	num	Imbalance if Assigned Tx 1		Collected at CRF.
IRIMB2	num	Imbalance if Assigned Tx 2		Collected at CRF.
IRIMB3	num	Imbalance if Assigned Tx 3		Collected at CRF.
IRIMB4	num	Imbalance if Assigned Tx 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
IRPROB4	num	Prob. of Tx 4 Allocation		Collected at CRF.
IRTACRIT	char	Criterion for Treatment Assignment		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
TRTGRP	char	Decode of TRTCD		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRDOSDEC	char	Study Schema Prior to Dose Decision		Collected at CRF.
IRLCNDY	num	Relative Day of Randomization		If IRLCNDTC and REF.DATE not missing then perform below logic to calculate IRLCNDY, If IRLCNDTC less than REF.DATE then (IRLCNDTC - REF.DATE). Else if IRLCNDTC is greater than equal to REF.DATE then (IRLCNDTC - REF.DATE) +1.

1.4.21. Laboratory Tests – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Tests
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRES,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRES,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBLBLNUM,LBDT,LBDTC,LBCLNSG,LBID,LBLOQL

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.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTHR	num	Hour of Collection		Collected at CRF.
LBACTMI	num	Minute of Collection		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.
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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
LBNRIND	char	Normal Range Indicator		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.

1.4.22. MAYODIAR – MAYODIAR

Dataset	MAYODIAR
Creating program	mayodiar.sas
Description	Mayodiar
Unique identifier	DUSUBJID,VISIT,MDDIADY,MDAMTBS,MDND,MNUMSTL
Sorted by	DUSUBJID,VISIT,MDDIADY,MDAMTBS,MDND,MNUMSTL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MDDIARDY,MDDIARMO,MDDIADT,MDDIADTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MDDIARYR	num	Diary Card Year		Collected at CRF.
MNUMSTL	num	Number of Stools		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
MDAMTBS	char	Amount of Blood in Stools		Collected at CRF.
MDND	char	Not Done		Collected at CRF.
MDPLNTP	char	Planned Timepoint		Collected at CRF.
MDDIADY	num	Relative Diary Card Day		If MDDIADTC and REF.DATE not missing then perform below logic to calculate MDDIADY, If MDDIADTC less than REF.DATE then (MDDIADTC - REF.DATE). Else if MDDIADTC is greater than equal to REF.DATE then (MDDIADTC - REF.DATE) +1.

1.4.23. MAYOSCR – MAYOSCR

Dataset	MAYOSCR
Creating program	mayoscr.sas
Description	Mayoscr
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

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.
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.

Variable	Type	Label	Codes	Comments
MYBLD2	num	Rectal Bleeding Day 2		Collected at CRF.
MYBLD3	num	Rectal Bleeding Day 3		Collected at CRF.
MYBLDSUM	num	Sum Rectal Bleeding Scores		Collected at CRF.
MYBLDAVG	num	Average of Rectal Bleeding Scores		Collected at CRF.
MYRBLD	num	Rectal Bleeding Score		Collected at CRF.
MYPGA	num	Physician Global Assessment		Collected at CRF.
MYPSCORE	num	Partial Mayo Score		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
MYPGAC	char	Physician Global Assessment		Collected at CRF.

1.4.24. MEDCHNG – MEDCHNG

Dataset	MEDCHNG
Creating program	medchng.sas
Description	Medchng
Unique identifier	DUSUBJID,VISIT,MCCAT,MCCHNG,MCINCR,MCCHGDY
Sorted by	DUSUBJID,VISIT,MCCAT,MCCHNG,MCINCR,MCCHGDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: MCCHGDT,MCCHGDTTC

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

1.4.25. MEDCLASS – MEDCLASS

Dataset	MEDCLASS
Creating program	medclass.sas
Description	Medication Class
Unique identifier	ATC_CODE,SEQ1
Sorted by	ATC_CODE,SEQ1
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DRECNO

Variable	Type	Label	Codes	Comments
SEQ1	char	Drug Sequence 1		Collected at CRF.
LEVEL1	char	1st 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.

1.4.26. Medication Review – MEDRVIEW

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

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.
CMMODIFY	char	Modified Reported Term		Collected at CRF.
MRDOSE	num	Dose		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
CODSTAT	char	Autoencoding Status		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
MRTYPE	char	Route Type		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.

1.4.27. Pharmacokinetic and ATSA (recoded) data – PKATSA_3

Dataset	PKATSA_3
Creating program	pkatsa_3.sas
Description	Pharmacokinetic and ATSA (recoded) data
Unique identifier	DUSUBJID,VISIT,PKRESCAT,PKRESC,PKACTDY,PKLLOQ
Sorted by	DUSUBJID,VISIT,PKRESCAT,PKRESC,PKACTDY,PKLLOQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: PKDT,PKDTC,CPLABEL,PKNOTCOL,PKCMT1CD,PKCMT1,PKCMT2CD,PKCMT2

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

Variable	Type	Label	Codes	Comments
PKACTDY	num	Actual Study Day of Visit		Collected at CRF.
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCD	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Decode of TRTCD		Collected at CRF.
TRTCDA	num	Actual Treatment Code		Collected at CRF.
TRTGRPA	char	Actual Treatment Group		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
POPRAND1	char	Subject randomized in part 1		Collected at CRF.
POPRAND2	char	Subject randomized in part 2.		Collected at CRF.
POPRAND	char	Subject randomized.		Collected at CRF.
POP_TRT	char	Subject Treated		Collected at CRF.
POP16PLA	char	Subject had 16w PLA visit		Collected at CRF.
PKW6	char	Through Week 6 visit flag		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PKACTTM	num	Time of sample		Collected at CRF.
PKREFLG	num	Relative to Baseline Indicator		Collected at CRF.

Variable	Type	Label	Codes	Comments
PKRELBAS	char	Relative to Baseline Description		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PKSMPINC	char	Sample Included in PK/PD Analysis		Collected at CRF.
PKRESCAT	char	PK Result Category		Collected at CRF.
PKTESTCD	char	PK Test Code		Collected at CRF.
PKTEST	char	PK Test		Collected at CRF.
PK_RESN	num	PK Numeric Results		Collected at CRF.
PKRESC	char	PK Characteristic Result		Collected at CRF.
PKUNIT	char	PK Unit		Collected at CRF.
PKLLOQ	num	PK Lower Limit of Quantification		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
PKDY	num	Relative Day of Sample		If PKDTC and REF.DATE not missing then perform below logic to calculate PKDY, If PKDTC less than REF.DATE then (PKDTC - REF.DATE). Else if PKDTC is greater than equal to REF.DATE then (PKDTC-REF.DATE) +1.

1.4.28. SF-36 Health Survey – QOL

Dataset	QOL
Creating program	qol.sas
Description	SF-36 Health Survey
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

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.
QLPF08	num	Score for QOL question 3H		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
QLVT4	num	Score for QOL question 9I		Collected at CRF.

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

1.4.29. RANDSTAT – RANDSTAT

Dataset	RANDSTAT
Creating program	randstat.sas
Description	Randstat
Unique identifier	DCNO,DPATNO
Sorted by	DCNO,DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REC_ID,R_DRUG,IRSUBID2,IRSUBID3,IRSUBID4,IRLCENDT,IRRNDVAL, IRRNDVLC,IRRNDSD

Variable	Type	Label	Codes	Comments
TAREA	char	Program Identifier - Therapeutic Area		Collected at CRF.
PNO	char	Protocol Identifier - Number		Collected at CRF.
DSCTRY	char	De-identify Study Country		Group element to protect PII.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
DIRSBID1	char	Subid Rep 1st Time Assign for Deidentity		Randomly assigned Subid Rep 1st Time for Deidentity
DIREMNID	char	Sub ID Entr Maint Assign for Deidentity		Randomly assigned Sub ID Entr Maint for Deidentity
IRLCENTM	num	Time of Randomization		Collected at CRF.
IRSECNDS	num	Seconds		Collected at CRF.
IRTRTGRP	num	Treatment Group		Collected at CRF.
IRPART	num	Study Schema Part Number		Collected at CRF.
IRSEQ	num	Randomization Sequence		Collected at CRF.
IRDOSDEC	num	Study Schema Prior to Dose Decision		Collected at CRF.
IRIMB1	num	Imbalance if Assigned Tx 1		Collected at CRF.
IRIMB2	num	Imbalance if Assigned Tx 2		Collected at CRF.
IRIMB3	num	Imbalance if Assigned Tx 3		Collected at CRF.
IRIMB4	num	Imbalance if Assigned Tx 4		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.
IRPROB4	num	Prob. of Tx 4 Allocation		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRTACRIT	char	Criterion for Treatment Assignment		Collected at CRF.
IRLCENDY	num	Relative Day of Randomization		If IRLCENDT and REF.DATE not missing then perform below logic to calculate IRLCENDY, If IRLCENDT less than REF.DATE then (IRLCENDT - REF.DATE). Else if IRLCENDT is greater than equal to REF.DATE then (IRLCENDT - REF.DATE) +1.

1.4.30. Resection – RESECT

Dataset	RESECT
Creating program	resect.sas
Description	Resection
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
RSMO	num	Resection Month		Collected at CRF.
RSYR	num	Resection Year		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

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

1.4.31. RXCLASS – RXCLASS

Dataset	RXCLASS
Creating program	rxclass.sas
Description	Rxclass
Unique identifier	DUSUBJID,RXUCLEU,VISIT,RXUCOSP3,RXUCC1
Sorted by	DUSUBJID,RXUCLEU,VISIT,RXUCOSP3,RXUCC1
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RXUCOSP1,RXUCOSP2,RXUCIN,RXUCPSY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
RXUCOSP3	char	Other Specify		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RXUCART	char	Arthritis		Collected at CRF.
RXUCB1	char	Immunomodulators Adequate Treatment		Collected at CRF.
RXUCB2	char	Immunomodulators Response Failure		Collected at CRF.
RXUCB3	char	Immunomodulators Medical Complications		Collected at CRF.
RXUCC1	char	Oral Corticosteroids Adequate Treatment		Collected at CRF.
RXUCC2	char	Oral Corticosteroids Response Failure 1		Collected at CRF.
RXUCC3	char	Oral Corticosteroids Med Complications		Collected at CRF.
RXUCC4	char	Oral Corticosteroids Response Failure 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXUCD1	char	5-Aminosalicylates Adequate Treatment		Collected at CRF.
RXUCD2	char	5-Aminosalicylates Response Failure		Collected at CRF.
RXUCD3	char	5-Aminosalicylates Med Complications		Collected at CRF.
RXUCENZ	char	Liver Enzymes		Collected at CRF.
RXUCHR	char	Hypersensitivity		Collected at CRF.
RXUCLEU	char	Leukopenia		Collected at CRF.
RXUCOSN	char	Osteonecrosis		Collected at CRF.
RXUCOSP	char	Osteoporosis		Collected at CRF.
RXUCOTH1	char	Other		Collected at CRF.
RXUCOTH2	char	Other		Collected at CRF.
RXUCOTH3	char	Other		Collected at CRF.
RXUCPAN	char	Pancreatitis		Collected at CRF.
RXUCUDM	char	Uncontrolled diabetes mellitus		Collected at CRF.

1.4.32. Prior Medication for Rheumatoid Arthritis – RX_HX

Dataset	RX_HX
Creating program	rx_hx.sas
Description	Prior Medi. for Rheumatoid Arthritis
Unique identifier	DUSUBJID,RXCAT,CMDECOD
Sorted by	DUSUBJID,RXCAT,CMDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CMTERM,DRECNO

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
RXSEQ	num	Medication Sequence Number		Collected at CRF.
CMMODIFY	char	Modified Reported Term		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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
CMDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RXCAT	char	Medication Category		Collected at CRF.
RXTIMUSD	char	Length of Time Taken		Collected at CRF.

1.4.33. Adverse Events for Screen Failures – SCRNAE

Dataset	SCRNAE
Creating program	scrnae.sas
Description	Adverse Events for Screen Failures
Unique identifier	DUSUBJID,AEBODSYS,AEDECOD,AELLT,AESTDY,AESEQ
Sorted by	DUSUBJID,AEBODSYS,AEDECOD,AELLT,AESTDY,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AETERM,AESTDT,AEENDT,AEPRSPEC,AEENDTC,AESTDTC,SAECONG,SAEDISAB,SAEDTH,SAELIFE

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.
AEMODIFY	char	Modified Reported Term		Collected at CRF.
AESTHR	num	Start Hour of Event		Collected at CRF.
AESTMI	num	Start Minute of Event		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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.
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 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
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.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
AECTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
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.
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.

Variable	Type	Label	Codes	Comments
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.

1.4.34. SCR NATRK – SCR NATRK

Dataset	SCR NATRK
Creating program	scrnatrk.sas
Description	Scrnatrk
Unique identifier	DUSUBJID, VISIT, ATPTM
Sorted by	DUSUBJID, VISIT, ATPTM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ATKITNUM, ATDT, ATDTC, ATKTTYP

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
ATHR	num	Assay Tracking Hour		Collected at CRF.
ATMI	num	Assay Tracking Minute		Collected at CRF.
ATTM	num	Sample Collection Time		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
ATEVQL	char	Event Qualifier		Collected at CRF.
ATNTCOL	char	Sample Not Collected		Collected at CRF.
ATPTM	char	Planned Timepoint (Period)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATSMTYP	char	Sample Type		Collected at CRF.
ATDY	num	Relative Sample Collection Day		If ATDTC and REF.DATE not missing then perform below logic to calculate ATDY, If ATDTC less than REF.DATE then (ATDTC - REF.DATE). Else if ATDTC is greater than equal to REF.DATE then (ATDTC - REF.DATE) +1.

1.4.35. SCRNCMED – SCRNCMED

Dataset	SCRNCMED
Creating program	scrncmed.sas
Description	Scrncmed
Unique identifier	DUSUBJID,CMRTECD,VISIT,CMDECOD,CMSEQ
Sorted by	DUSUBJID,CMRTECD,VISIT,CMDECOD,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CMTERM,CMSTDT,CMENDT,DRECNO,CMENDTC,CMSTDTC

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.

Variable	Type	Label	Codes	Comments
CMRTECD	num	Route Code		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
CMROUTE	char	Route Code		Collected at CRF.
CMONGO	char	Ongoing Medication		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMREAS	char	Reason for Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
CMENDY	num	Relative End Day of Medication		If CMENDTC and 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.

1.4.36. SCRNCOMP – SCRNCOMP

Dataset	SCRNCOMP
Creating program	scrncomp.sas
Description	Scrncomp
Unique identifier	DUSUBJID,VISIT,PRSTDY
Sorted by	DUSUBJID,VISIT,PRSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: PRSPEC,PRSTDT,PRENDT,PRENDTC,PRSTDTC,PRONGO

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PRSEQ	num	Sequence Number		Collected at CRF.
PRREASON	char	Procedure Reason		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
PRINOUT	char	In-Patient or Out-Patient		Collected at CRF.
PRTYPE	char	Procedure Type		Collected at CRF.
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.

1.4.37. Selection Criteria for Screen Failures – SCRNCRIT

Dataset	SCRNCRIT
Creating program	scrncrit.sas
Description	Selection Criteria for Screen Failures
Unique identifier	DUSUBJID,EXCRIT,CRSEQ
Sorted by	DUSUBJID,EXCRIT,CRSEQ
Notes	

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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

1.4.38. Demographics for Screen Failures – SCRNDemo

Dataset	SCRNDemo
Creating program	scrndemo.sas
Description	Demographics for Screen Failures
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SUBJINIT, BIRTHDT, DMCONDT, DEMOG, BIRTHDTC, DMCONDTC

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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HEIGHT	num	Height in Centimeters		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.

1.4.39. SCRNHOSP – SCRNHOSP

Dataset	SCRNHOSP
Creating program	scrnhosp.sas
Description	Scrnhosp
Unique identifier	DUSUBJID,VISIT,HOSEQ
Sorted by	DUSUBJID,VISIT,HOSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: HOADMDT,HODISDT,HOADMDTC,HODISDTC

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.
HODIAG	char	Diagnosis		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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.
HOTPNNA	char	TPN Not Applicable		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
HODIS DY	num	Relative Hospital Discharge Day		If HODIS DTC and REF.DATE not missing then perform below logic to calculate HODIS DY, If HODIS DTC less than REF.DATE then (HODIS DTC - REF.DATE). Else if HODIS DTC is greater than equal to REF.DATE then (HODIS DTC - REF.DATE) +1.

1.4.40. Lab Data for Screen Failures – SCRNLAB

Dataset	SCRNLAB
Creating program	scrnlab.sas
Description	Lab Data for Screen Failures
Unique identifier	DUSUBJID,VISIT,LBACTTM,LBSTRES,LBKTTYP,LBSEQ
Sorted by	DUSUBJID,VISIT,LBACTTM,LBSTRES,LBKTTYP,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBLBLNUM,LBDT,LBDTC,LBCLNSG,LBHIQL,LBID,LBLOQL

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.
LBACTHR	num	Hour of Collection		Collected at CRF.
LBACTMI	num	Minute of Collection		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRL0	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
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.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
LBCOM	char	Lab Comment		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBKTYP	char	Kit Type		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDT and REF.DATE not missing then perform below logic to calculate LBDY, If LBDT less than REF.DATE then (LBDT - REF.DATE). Else if LBDT is greater than equal to REF.DATE then (LBDT - REF.DATE) +1.

1.4.41. SCRNMAYO – SCRNMAYO

Dataset	SCRNMAYO
Creating program	scrnmayo.sas
Description	Scrnmayo
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

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.
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.

Variable	Type	Label	Codes	Comments
MYBLD2	num	Rectal Bleeding Day 2		Collected at CRF.
MYBLD3	num	Rectal Bleeding Day 3		Collected at CRF.
MYBLDSUM	num	Sum Rectal Bleeding Scores		Collected at CRF.
MYBLDAVG	num	Average of Rectal Bleeding Scores		Collected at CRF.
MYRBLD	num	Rectal Bleeding Score		Collected at CRF.
MYPGA	num	Physician Global Assessment		Collected at CRF.
MYPSCORE	num	Partial Mayo Score		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
MYPGAC	char	Physician Global Assessment		Collected at CRF.

1.4.42. SCRN Visit – SCRNVIS

Dataset	SCRNVIS
Creating program	scrnvis.sas
Description	SCRN Visit
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISITDT,VISITDTC,VIMAINST

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

1.4.43. Subject Status – SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SSDSCDT,SSRSOTH,SSDSCDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SSENT	char	Subject Entered Next Study Period		Collected at CRF.
SSREAS	char	Reason for Discontinuation		Collected at CRF.
SSDSCDY	num	Relative Day of Study Discontinuation		If SSDSCDTC and REF.DATE not missing then perform below logic to calculate SSDSCDY, If SSDSCDTC less than REF.DATE then (SSDSCDTC - REF.DATE). Else if SSDSCDTC is greater than equal to REF.DATE then (SSDSCDTC- REF.DATE) +1.

1.4.44. SUBSTDY – SUBSTDY

Dataset	SUBSTDY
Creating program	substdy.sas
Description	Substdy
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SPDMICDY,SPDMICMO,SPDMICYR,SPDMCDT,SPBICDT,SPBICDTC,SPDMCDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SPBIOPSY	char	Biopsy Substudy		Collected at CRF.
SPDNA	char	DNA Substudy		Collected at CRF.
SPDNAST	char	DNA Storage		Collected at CRF.
SPMRNA	char	mRNA Substudy		Collected at CRF.
SPBICDY	num	Relative Biopsy Informed Consent Day		If SPBICDTC and REF.DATE not missing then perform below logic to calculate SPBICDY, If SPBICDTC less than REF.DATE then (SPBICDTC - REF.DATE). Else if SPBICDTC is greater than equal to REF.DATE then (SPBICDTC - REF.DATE) +1.
SPDMCDY	num	Relative DNA/mRNA Informed Consent Day		If SPDMCDTC and REF.DATE not missing then perform below logic to calculate SPDMCDY, If SPDMCDTC less than REF.DATE then (SPDMCDTC - REF.DATE). Else if SPDMCDTC is greater than equal to REF.DATE then (SPDMCDTC - REF.DATE) +1.

1.4.45. Tuberculosis Testing Data – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Tuberculosis Testing Data
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: TBBCGYR,TBADMDT,TBADMSP,TBRDDT,TBCXRD,TBADMDTC,TBCXRDC,TBRDDTC

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.
TBREADSP	char	Specification of PPD Reader		Collected at CRF.
TBRSLT	num	PPD Result		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
TBADM	char	PPD Administrator		Collected at CRF.
TBATB	char	History of Active TB		Collected at CRF.
TBBCG	char	Previous BCG Vaccination		Collected at CRF.
TBCXRES	char	Chest X-Ray Result		Collected at CRF.
TBLTB	char	History of Latent TB		Collected at CRF.
TBRCATB	char	Recent Contact to Active TB		Collected at CRF.
TBREAD	char	PPD Reader		Collected at CRF.
TBRPN	char	PPD Test Result Positive or Negative		Collected at CRF.
TBSSATB	char	Signs or Symptoms of Active TB		Collected at CRF.
TBTRTRQ	char	Treatment Required		Collected at CRF.

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

1.4.46. Subject Visits – VISITS

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

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

1.4.47. Vital Signs – VITALS

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

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 Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
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.