

Clinical Development

Golimumab

C0524T11

Anonymisation Data Derivation Specification Document

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

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided
- No pharmacogenetic data will be provided (specific IC)
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial
- Investigator Name will not be provided.
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.
- ECONOM, WQL datasets will not be submitted as it captures personal information of subject's economic status hence may lead to PII.
- Datasets ATRACK and CRESUL contain PK related information hence dropping the same.
- CLINPHONE data contains only date and time of Randomization, which is not needed for analysis. Hence, this data will not be submitted.
- Dataset CSU and NABRESUL does not contain subject level information. Hence dropping the same.
- PDRESUL contains sensitive immunogenicity data, will not be submitted.
- STUDYPAR Dataset will not be submitted because its data reconciliation data.

1.3. Data Files

The C0524T11 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0524T11 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demography – DEMO

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

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

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

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AEDECOD, AESTDY, AEENDY, AESEQ
Sorted by	DUSUBJID, AEDECOD, AESTDY, AEENDY, AESEQ
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>COUNTRY,PAG_NAME,AETERM,AEMODIFY,AESTDT,AEENDT,AGE,RACE,SEX,S AECONG,SAEDISAB,SAEDTH,SAELIFE,SAEOTH,SAEPHOS, AESTDTC,AEENDTC</p>

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		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.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AELOC	char	Adverse Event Location		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEPRSPEC	char	Related to Procedure Specify		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
SAERHOS	char	Hospitalization Required		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
AEENDY	num	Relative End Day of Event		If AEENDTC and IRLCNDTC not missing then perform below logic to calculate AEENDY, If AEENDTC less than IRLCNDTC then (AEENDTC - IRLCNDTC). Else if AEENDTC is greater than equal to IRLCNDTC then (AEENDTC - IRLCNDTC) +1.
AESTDY	num	Relative Start Day of Event		If AESTDTC and IRLCNDTC not missing then perform below logic to calculate AESTDY, If AESTDTC less than IRLCNDTC then (AESTDTC - IRLCNDTC). Else if AESTDTC is greater than equal to IRLCNDTC then (AESTDTC - IRLCNDTC) +1.

1.4.3. Past Medical History/Current Diagnosis – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Past Medical History/Current Diagnosis
Unique identifier	DUSUBJID,CHCONDD
Sorted by	DUSUBJID,CHCONDD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,CHOTHTYP,CHMALTYP,AGE,RACE,SEX,CHTYPE

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CHCOND	num	Condition		Collected at CRF.
CHSMCIG	num	Number of Cigarettes Per Day		Collected at CRF.
CHSMYRS	num	Number of Years of Smoking		Collected at CRF.
CHALUNWK	num	Number of Alcoholic Units Per Week		Collected at CRF.
CHALYRS	num	Number of Years of Alcohol Use		Collected at CRF.
CHEXNUM	num	Aerobic Exercise Units per Week		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CHCOND	char	Decode of CHCOND		Collected at CRF.
CHALSTAT	char	Status of Alcohol Use		Collected at CRF.
CHHIST	char	History of Condition		Collected at CRF.
CHSMSTAT	char	Status of Smoking		Collected at CRF.
CHTRT	char	Treated		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.4. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,CMDECOD,CMROUTE,CMSTDY,CMENDY, CMSEQ
Sorted by	DUSUBJID,CMDECOD,CMROUTE,CMSTDY,CMENDY, CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements COUNTRY,PAG_NAME,PAGE_SEQ,CMTERM,CMMODIFY,CMSTDT,CMENDT, AGE,RACE,SEX, DRECNO, SEQ1, SEQ2, CMSTDTC, CMENDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMDOSE	char	Dose		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMONGO	char	Ongoing Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
CMFREQ	char	Frequency		Collected at CRF.
CMUNIT	char	Dose Unit		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
CMSTDY	num	Relative Start Day of Medication		If CMSTDTC and IRLCNDTC not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than IRLCNDTC then (CMSTDTC - IRLCNDTC). Else if CMSTDTC is greater than equal to IRLCNDTC then (CMSTDTC - IRLCNDTC) +1.
CMENDY	num	Relative End Day of Medication		If CMENDTC and IRLCNDTC not missing then perform below logic to calculate CMENDY, If CMENDTC less than IRLCNDTC then (CMENDTC - IRLCNDTC). Else if CMENDTC is greater than equal to IRLCNDTC then (CMENDTC - IRLCNDTC) +1.

1.4.5.Prior Joint Procedures/Injections – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Prior Joint Procedures/Injections
Unique identifier	DUSUBJID, VISIT , VISITNUM, PROCDY
Sorted by	DUSUBJID, VISIT , VISITNUM, PROCDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,PROCDT,AGE,RACE,SEX,PRJOINT,PR_TYPED, PROCDTC, LINE_NO

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PR_TYPE	num	Procedure Code		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
PROCREL	char	Procedure Related		Collected at CRF.
PRTMSNC	char	Time Since Procedure		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.

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

1.4.6. Selection Criteria – CRITERIA

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

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

1.4.7. Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,DTDT,DTCAUSE,AGE,RACE,SEX, DTDC

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

Variable	Type	Label	Codes	Comments
DTAUTP	char	Autopsy Performed		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DTDY	num	Relative Day of Death		If DTDTC and IRLCNDTC not missing then perform below logic to calculate DTDY, If DTDTC less than IRLCNDTC then (DTDTC - IRLCNDTC). Else if DTDTC is greater than equal to IRLCNDTC then (DTDTC - IRLCNDTC) +1.

1.4.8. Classification of Rheumatoid Arthritis – DIAGINFO

Dataset	DIAGINFO
Creating program	diainfo.sas
Description	Classification of Rheumatoid Arthritis
Unique identifier	USUBJID, VISIT , DIFNCLAS
Sorted by	USUBJID, VISIT , DIFNCLAS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,DIAGDT,AGE,RACE,SEX,DIAGDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DIFNCLAS	char	Functional Class		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DIAGDY	num	Relative Day of Diagnosis		If DIAGDTC and IRLCNDTC not missing then perform below logic to calculate DIAGDY,If DIAGDTC less than IRLCNDTC then (DIAGDTC - IRLCNDTC).Else if DIAGDTC is greater than equal to IRLCNDTC then (DIAGDTC- IRLCNDTC) +1.

1.4.9. Patient and Physician Assessments – DIS_EVAL

Dataset	DIS_EVAL
Creating program	dis_eval.sas
Description	Patient and Physician Assessments
Unique identifier	USUBJID, VISIT, DEPCOR
Sorted by	USUBJID, VISIT, DEPCOR
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DEPCOR	num	Patient VAS Pain Score		Collected at CRF.
DEGDAPT	num	Patient VAS Score for GDA		Collected at CRF.
DEGDAPH	num	Physician VAS Score for GDA		Collected at CRF.
DEMORN	num	Morning Stiffness Duration in Minutes		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.10. Subcutaneous Study Agent Inj. Status II – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Subcutaneous Study Agent Injections Status II
Unique identifier	DUSUBJID, VISIT, DSDSCEND, DSREAS, DSTREAS, DSUNB
Sorted by	DUSUBJID, VISIT, DSDSCEND, DSREAS, DSTREAS, DSUNB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,DSTRSOTH,DSUNBDT,DSDSCDT, DRSOTH,AGE, RACE, SEX, DSUNBDTC, DSDSCDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DSDSCEND	char	Study Participation End		Collected at CRF.
DSEREAS	char	Reason for Study Participation End		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSTREAS	char	Reason for Treatment Discontinuation		Collected at CRF.
DSTWSTD	char	Worsening of Study Disease		Collected at CRF.
DSUNB	char	Treatment Unblinded		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DSDSCDY	num	Relative Day of Study Discontinuation		If DSDSCDTC and IRLCNDTC not missing then perform below logic to calculate DSDSCDY, If DSDSCDTC less than IRLCNDTC then (DSDSCDTC - IRLCNDTC). Else if DSDSCDTC is greater than equal to IRLCNDTC then (DSDSCDTC- IRLCNDTC) +1.
DSUNBDY	num	Relative Day of Treatment Unblinding		If DSUNBDTC and IRLCNDTC not missing then perform below logic to calculate DSUNBDY, If DSUNBDTC less than IRLCNDTC then (DSUNBDTC - IRLCNDTC). Else if DSUNBDTC is greater than equal to IRLCNDTC then (DSUNBDTC- IRLCNDTC) +1.

1.4.11. Prior Methotrexate Exposure – EXPHX

Dataset	EXPHX
Creating program	exphx.sas
Description	Prior Methotrexate Exposure
Unique identifier	DUSUBJID, VISIT
Sorted by	DUSUBJID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY, PAG_NAME, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
EHCDOS	char	Cumulative Methotrexate Dose in mg		Collected at CRF.
EHMAXDOS	num	Maximum Methotrexate Dose in mg/wk		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EHDUR	char	Duration of Therapy		Collected at CRF.
EHANY	char	Any Records Reported		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.12. Oral Study Agent Exposure – EXPOSURE

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

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

Variable	Type	Label	Codes	Comments
EXLCL	char	Exposure Locale		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXSAADM	char	Study Agent Administrator		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
EXSTDY	num	Relative Start Day of Dose		If EXSTDTC and IRLCNDTC not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than IRLCNDTC then (EXSTDTC - IRLCNDTC). Else if EXSTDTC is greater than equal to IRLCNDTC then (EXSTDTC - IRLCNDTC) +1.

1.4.13. FACIT-F Questionnaire – FACITFQ

Dataset	FACITFQ
Creating program	facitfq.sas
Description	FACIT-F Questionnaire
Unique identifier	DUSUBJID,VISITNUM
Sorted by	DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY, PAG_NAME, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
FFHI7	num	Fatigued		Collected at CRF.
FFHI12	num	Weak		Collected at CRF.
FFAN1	num	Listless		Collected at CRF.
FFAN2	num	Tired		Collected at CRF.
FFAN3	num	Trouble Starting Things		Collected at CRF.
FFAN4	num	Trouble Finishing Things		Collected at CRF.
FFAN5	num	Energy		Collected at CRF.
FFAN7	num	Usual Activities		Collected at CRF.

Variable	Type	Label	Codes	Comments
FFAN8	num	Sleep		Collected at CRF.
FFAN12	num	Too Tired to Eat		Collected at CRF.
FFAN14	num	Need Help		Collected at CRF.
FFAN15	num	Frustrated		Collected at CRF.
FFAN16	num	Limit Social Activity		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.14. Disability Index of the Health Ass Quest – HAQ

Dataset	HAQ
Creating program	haq.sas
Description	Disability Index of the Health Assessment Questionnaire
Unique identifier	DUSUBJID,VISITNUM
Sorted by	DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY, HAPFLG1, HASPEC1, HASPEC2, AGE, RACE, SEX, PAG_NAME

Variable	Type	Label	Codes	Comments
HATXT1	char	Use of other aids/devices - Category 1		Collected at CRF.
HATXT2	char	Use of other aids/devices - Category 2		Collected at CRF.
HATXT3	char	Use of other aids/devices - Category 3		Collected at CRF.
HATXT4	char	Use of other aids/devices - Category 4		Collected at CRF.
HATXT5	char	Use of other aids/devices - Category 5		Collected at CRF.

Variable	Type	Label	Codes	Comments
HATXT6	char	Use of other aids/devices - Category 6		Collected at CRF.
HATXT7	char	Use of other aids/devices - Category 7		Collected at CRF.
HATXT8	char	Use of other aids/devices - Category 8		Collected at CRF.
HAPFLG2	char	Adj. permanent devices flag - Category 2		Collected at CRF.
HAPFLG3	char	Adj. permanent devices flag - Category 3		Collected at CRF.
HAPFLG4	char	Adj. permanent devices flag - Category 4		Collected at CRF.
HAPFLG5	char	Adj. permanent devices flag - Category 5		Collected at CRF.
HAPFLG6	char	Adj. permanent devices flag - Category 6		Collected at CRF.
HAPFLG7	char	Adj. permanent devices flag - Category 7		Collected at CRF.
HAPFLG8	char	Adj. permanent devices flag - Category 8		Collected at CRF.
HANOADJ	char	Other aids/devices not requiring adjust.		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
HAQ1	num	HAQ Question 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
HAQ2	num	HAQ Question 2		Collected at CRF.
HAQ3	num	HAQ Question 3		Collected at CRF.
HAQ4	num	HAQ Question 4		Collected at CRF.
HAQ5	num	HAQ Question 5		Collected at CRF.
HAQ6	num	HAQ Question 6		Collected at CRF.
HAQ7	num	HAQ Question 7		Collected at CRF.
HAQ8	num	HAQ Question 8		Collected at CRF.
HAQ9	num	HAQ Question 9		Collected at CRF.
HAQ10	num	HAQ Question 10		Collected at CRF.
HAQ11	num	HAQ Question 11		Collected at CRF.
HAQ12	num	HAQ Question 12		Collected at CRF.
HAQ13	num	HAQ Question 13		Collected at CRF.
HAQ14	num	HAQ Question 14		Collected at CRF.
HAQ15	num	HAQ Question 15		Collected at CRF.
HAQ16	num	HAQ Question 16		Collected at CRF.
HAQ17	num	HAQ Question 17		Collected at CRF.
HAQ18	num	HAQ Question 18		Collected at CRF.
HAQ19	num	HAQ Question 19		Collected at CRF.
HAQ20	num	HAQ Question 20		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
HACAT1	char	HAQ Aid, Device/Help Category 1		Collected at CRF.
HACAT2	char	HAQ Aid, Device/Help Category 2		Collected at CRF.
HACAT3	char	HAQ Aid, Device/Help Category 3		Collected at CRF.
HACAT4	char	HAQ Aid, Device/Help Category 4		Collected at CRF.
HACAT5	char	HAQ Aid, Device/Help Category 5		Collected at CRF.
HACAT6	char	HAQ Aid, Device/Help Category 6		Collected at CRF.
HACAT7	char	HAQ Aid, Device/Help Category 7		Collected at CRF.
HACAT9	char	HAQ Aid, Device/Help Category 9		Collected at CRF.
HACAT10	char	HAQ Aid, Device/Help Category 10		Collected at CRF.
HACAT11	char	HAQ Aid, Device/Help Category 11		Collected at CRF.
HACAT12	char	HAQ Aid, Device/Help Category 12		Collected at CRF.
HACAT13	char	HAQ Aid, Device/Help Category 13		Collected at CRF.

Variable	Type	Label	Codes	Comments
HACAT14	char	HAQ Aid, Device/Help Category 14		Collected at CRF.
HACAT15	char	HAQ Aid, Device/Help Category 15		Collected at CRF.
HACAT16	char	HAQ Aid, Device/Help Category 16		Collected at CRF.
HACAT17	char	HAQ Aid, Device/Help Category 17		Collected at CRF.
HACAT19	char	HAQ Aid, Device/Help Category 19		Collected at CRF.
HACAT20	char	HAQ Aid, Device/Help Category 20		Collected at CRF.
HACAT21	char	HAQ Aid, Device/Help Category 21		Collected at CRF.
HACAT22	char	HAQ Aid, Device/Help Category 22		Collected at CRF.
HACAT23	char	HAQ Aid, Device/Help Category 23		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.15. IVRSDOSE

Dataset	IVRSDOSE
Creating program	ivrsdose.sas
Description	ivrsdose
Unique identifier	DUSUBJID,VISITNUM, IDSEQ, IDCLDY
Sorted by	DUSUBJID,VISITNUM, IDSEQ, IDCLDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>COUNTRY, IDCLDT, IDCTID3, IDCTID4, IDCTID5, IDCTID6, AGE, RACE, SEX, IDLTEDE, PAG_NAME, IDCTID1, IDCTID2, IDCLDTC</p>

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
IDSEQ	num	IVRS Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
IDJNTNE	num	Number of Joints Not Evaluable		Collected at CRF.
IDJNTTEN	num	Number of Tender Joints		Collected at CRF.
IDJNTSWL	num	Number of Swollen Joints		Collected at CRF.
IDEMRS	num	Emergency Re-Supply		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IDEARES	char	Early Escape		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
IDCLDY	num	Relative IVRS Dose Call Day		If IDCLDTC and IRLCNDTC not missing then perform below logic to calculate IDCLDY, If IDCLDTC less than IRLCNDTC then (IDCLDTC - IRLCNDTC). Else if IDCLDTC is greater than equal to IRLCNDTC then (IDCLDTC- IRLCNDTC) +1.

1.4.16. 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 non significant elements: COUNTRY,PAG_NAME,IRLCENDT,AGE, RACE,SEX, IRLCNDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TRTCD	num	Treatment Group		Collected at CRF.
IRSTRAT	char	Stratum		Collected at CRF.
TRTGRP	char	Decode of TRTCD		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.17. Upper Left Extremity Joint Evaluation – JNTSCORE

Dataset	JNTSCORE
Creating program	jntscore.sas
Description	Upper Left Extremity Evaluation
Unique identifier	DUSUBJID,VISITNUM,JOINTD
Sorted by	DUSUBJID,VISITNUM,JOINTD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,AGE,RACE,SEX

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
JOINTD	char	Decode of JOINT		Collected at CRF.
JTTEND	char	Joint Tenderness on Exam		Collected at CRF.
JTNE	char	Joint Not Evaluable		Collected at CRF.
JTSWELL	char	Joint Swelling on Exam		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.18. Laboratory Results – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Results
Unique identifier	DUSUBJID, VISITNUM, LBACTTM, LBCAT, LBTEST, LBDY
Sorted by	DUSUBJID, VISITNUM, LBACTTM, LBCAT, LBTEST, LBDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>PAG_NAME, LBLBLNUM, LBDT, RACE, SEX, LBCOM, LBID, LBKTTY, LBLOQL, LBUNTRV, COUNTRY, LBSEQ, AGE, LBDTC</p> <p>Note: Protocol unplanned tests will be removed; it may reveal participant information.</p>

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.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTHR	num	Hour of Collection		Collected at CRF.
LBACTMI	num	Minute of Collection		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBUNTCD	num	Unit Code		Collected at CRF.
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
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.
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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBEVQL	char	Event Qualifier		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBPTM	char	Planned Timepoint 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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and IRLCNDTC not missing then perform below logic to calculate LBDY, If LBDTC less than IRLCNDTC then (LBDTC - IRLCNDTC). Else if LBDTC is greater than equal to IRLCNDTC then (LBDTC - IRLCNDTC) +1.

1.4.19. Extra-Articular Manifestations – MANIFEST

Dataset	MANIFEST
Creating program	manifest.sas
Description	Extra-Articular Manifestations
Unique identifier	DUSUBJID, VISITNUM, MANIFEST
Sorted by	DUSUBJID, VISITNUM, MANIFEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY, PAG_NAME, MAOTHSP, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
MACURR	char	Currently Manifested		Collected at CRF.
MANIFEST	char	Manifestation		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.20. Baseline Medication Usage for RA – MEDRVIEW

Dataset	MEDRVIEW
Creating program	medrview.sas
Description	Baseline Medication Usage for RA
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,AGE,RACE,SEX,MRDCRSCS, MRDCRSIM, MRINCRIM,MRSTOPCS,MRSTOPIM

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

Variable	Type	Label	Codes	Comments
MRMTDOSE	num	Methotrexate Dose in mg/week		Collected at CRF.
MRSSDOSE	num	Sulfasalazine Dose in g/day		Collected at CRF.
MRHCQDOS	num	Hydroxychloroquine Dose in mg/day		Collected at CRF.
MRCODOSE	num	Oral Corticosteroid Dose in mg/day		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
MRCORTST	char	Oral Corticosteroids		Collected at CRF.
MRICORTS	char	Increase in Oral Corticosteroids Dose		Collected at CRF.
MRIMMUN	char	DMARD/Biologics/Systemic Immuno. Treatm.		Collected at CRF.
MRNEWCS	char	Treatment with Corticosteroids		Collected at CRF.
MRNSAIDS	char	NSAIDs		Collected at CRF.
MRHCQ	char	Subject Taking Hydroxychloroquine		Collected at CRF.
MRINHCQ	char	Increase in Hydroxychloroquine Dose		Collected at CRF.
MRINMTX	char	Increase in Methotrexate Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
MRMTX	char	Subject Taking Methotrexate		Collected at CRF.
MRINSULF	char	Increase in Sulfasalazine Dose		Collected at CRF.
MRSULPHA	char	Subject Taking Sulfasalazine		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.21. Reason Randomized But Never Treated – NOTTX

Dataset	NOTTX
Creating program	nottx.sas
Description	Reason Randomized But Never Treated
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,NTRSOTH,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
NTREAS	char	Reason Never Treated		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.22. Prior Medications for RA – RXHX

Dataset	RXHX
Creating program	rxhx.sas
Description	Prior Medications for RA
Unique identifier	DUSUBJID, VISITNUM, RXMED
Sorted by	DUSUBJID, VISITNUM, RXMED
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,RXDSCSP,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
RXMDOS	num	Maximum Dose		Collected at CRF.
RXMFQSP	char	Other Frequency of Maximum Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXLDOS	num	Amount of Last Dose		Collected at CRF.
RXLFRQSP	char	Other Frequency of Last Dose Received		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
RXDUR	char	Duration of Use		Collected at CRF.
RXMED	char	Medication Name		Collected at CRF.
RXLADM	char	Time of Last Administration		Collected at CRF.
RXDSC	char	Reason for Discontinuation		Collected at CRF.
RXLD SUN	char	Unit of Last Dose		Collected at CRF.
RXLFRQ	char	Frequency of Last Dose		Collected at CRF.
RXMDSUN	char	Units of Maximum Dose		Collected at CRF.
RXMFRQ	char	Frequency of Maximum Dose		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.23. Subject Status – SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY,PAG_NAME,SSDSCDT, SSRSOTH,AGE,RACE,SEX, SSDSCDTC, SSREAS

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
SSENT	char	Subject Entered Next Study Period		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.24. Screening for Tuberculosis – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Screening for Tuberculosis
Unique identifier	DUSUBJID, TBADMDY, TBCXRDY, TBRDDY
Sorted by	DUSUBJID, TBADMDY, TBCXRDY, TBRDDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>COUNTRY,PAG_NAME,TBOTHSP,TBADMDT,TBADMSP,TBRDDT,TBREADSP, TBCXRDT,AGE,RACE,SEX, TBRIFAM,TBRIFAB,TBPYRAZ, TBADMDTC,TBCXRDT, TBRDDTC</p>

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

Variable	Type	Label	Codes	Comments
TBSEQ	num	Sequence Number		Collected at CRF.
TBDURSMO	num	Total Duration of Treatment Start Month		Collected at CRF.
TBDURSYR	num	Total Duration of Treatment Start Year		Collected at CRF.
TBDUREMO	num	Total Duration of Treatment End Month		Collected at CRF.
TBDUREYR	num	Total Duration of Treatment End Year		Collected at CRF.
TBBCGYR	num	Year of Previous BCG Vaccination		Collected at CRF.
TBRSLT	num	PPD Result		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		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.

Variable	Type	Label	Codes	Comments
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.
TBRLTB	char	Complete Treatment Regimen		Collected at CRF.
TBISON	char	Isoniazid		Collected at CRF.
TBOTHTR	char	Other Treatment Regimen		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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
TBADMDY	num	Relative Day of PPD Administration		If TBADMDTC and IRLCNDTC not missing then perform below logic to calculate TBADMDY, If TBADMDTC less than IRLCNDTC then (TBADMDTC - IRLCNDTC). Else if TBADMDTC is greater than equal to IRLCNDTC then (TBADMDTC - IRLCNDTC) + 1.

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

1.4.25. Visit – VISITS

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.
VISITDY	num	Relative Visit Day		If VISITDTC and IRLCNDTC not missing then perform below logic to calculate VISITDY, If VISITDTC less than IRLCNDTC then (VISITDTC - IRLCNDTC). Else if VISITDTC is greater than equal to IRLCNDTC then (VISITDTC - IRLCNDTC) +1.

1.4.26. Weight – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Weight
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: COUNTRY, PAG_NAME, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
VSTEST	char	Vital Signs Test Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSTSTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSSTUNIT	char	Standard Units		Collected at CRF.
VSSTRES	char	Result in Standard Units		If VSTSTCD="WEIGHT" then Group element to protect PII.
EVENT_ID	char	Event Identifier		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.
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 Assigned for De-identity		Randomly Assigned Unique Subject ID for De-identity.