Clinical Development

Golimumab

C0524T12

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 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+).
- 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, Bottle, lot, kit 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.
- Dataset used for data reconciliation will not be submitted (e.g. ATRACK, STUDYPAR).
- Datasets CRESUL will not be submitted as it contains PK related information.
- ECONOM dataset will not be submitted as it captures personal information of subject's economic status hence may lead to PII.
- Dataset which is not having subject level information will not be submitted (e.g. MEDCLASS).
- Dataset PDRESUL will not be submitted as it does not contain subject level information.
- CSU dataset will not be submitted as it does not contain any subject level information.

1.3. Data Files

The C0524T12 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0524T12 CSR data from the following folders.

1.4.   Data Domains

1.4.1.   Demographics – DEMO

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

Variable	Type	Label	Codes	Comments
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.
WEIGHT	char	Weight in Kilograms		Group element to protect PII.
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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
RACE	char	Race		Group element to protect PII.
SEX	char	Sex		Collected at CRF.

1.4.2. Adverse Events – AE

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

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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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
AEACTTRO	char	Action Taken with Other Study Treatment		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		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.
AERELO	char	Causality (Relation to Other 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.

Variable	Type	Label	Codes	Comments
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 MH / Current Diag / Smoking History – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Past Medical History / Current Diagnoses / Smoking History
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: PAG_NAME,CHOTHTYP,CHMALTYP,COUNTRY,RACE,SEX,AGE

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.
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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
CHCONDD	char	Condition		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.
CHTYPE	char	Condition Type		Collected at CRF.

1.4.4. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID, CMDECOD, VISIT, CMSTDY, CMSEQ
Sorted by	DUSUBJID, CMDECOD, VISIT, CMSTDY, 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 or due to missing values: PAG_NAME,CMTERM,CMMODIFY,CMSTDT,CMENDT,DRECNO,SEQ1,SEQ2,COUNTRY,RACE,SEX,CMREAS,AGE, CMSTDTC,CMENDTC, PAGE_SEQ

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
CMROUTE	char	Route Code		Collected at CRF.
CMONGO	char	Ongoing Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
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.
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.

1.4.5. Prior/Conc Joint Procs /Inj. – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Prior/Concomitant Joint Procedures/Injections
Unique identifier	DUSUBJID, PR_TYPE, VISIT, PRJOINT, PRTMSNC, PROCDY
Sorted by	DUSUBJID, PR_TYPE, VISIT, PRJOINT, PRTMSNC, 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: PAG_NAME,LINE_NO,PROCDT,COUNTRY,RACE,SEX,AGE, PROCDTC

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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
PR_TYPED	char	Procedure Code		Collected at CRF.
PRJOINT	char	Joint		Collected at CRF.
PROCREL	char	Procedure Related		Collected at CRF.
PRTMSNC	char	Time Since Procedure		Collected at CRF.
PROCDY	num	Relative Procedure Day		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, INCRIT
Sorted by	DUSUBJID, INCRIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,COUNTRY,RACE,SEX,AGE

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.

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

1.4.7. Cardiovascular Disease Information – CVINFO

Dataset	CVINFO
Creating program	cvinfo.sas
Description	Cardiovascular Disease Information, Events and/or Procedures
Unique identifier	DUSUBJID, CVEVENT, VISIT, CVEVNDY, CVSEQ
Sorted by	DUSUBJID, CVEVENT, VISIT, CVEVNDY, CVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,CVEVNTSP,CVEVNDT,COUNTRY,RACE,SEX,AGE, CVEVNDTC

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
CVEVENT	char	Event		Collected at CRF.
CVEVNDY	num	Relative Day of Event		If CVEVNDTC and IRLCNDTC not missing then perform below logic to calculate CVEVNDY, If CVEVNDTC less than IRLCNDTC then (CVEVNDTC - IRLCNDTC).Else if CVEVNDTC is greater than equal to IRLCNDTC then (CVEVNDTC- IRLCNDTC) +1.

1.4.8. 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: PAG_NAME,DTDT,DTCAUSE,COUNTRY,RACE,SEX, AGE, DTDTC

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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
DTAUTP	char	Autopsy Performed		Collected at CRF.
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.

1.4.9. Classification of Rheumatoid Arthritis – DIAGINFO

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

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DIANSTAG	char	Anatomical Stage of RA		Collected at CRF.
DIFNCLAS	char	Functional Class		Collected at CRF.
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.

1.4.10. Morning Stiffness/ Patient & Phy. Ass. – DIS_EVAL

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DEPSCOR	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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

1.4.11. Study Agent Preparation – DRUGPREP

Dataset	DRUGPREP
Creating program	drugprep.sas
Description	Study Agent Preparation
Unique identifier	DUSUBJID, VISIT, DPVWDRWN, DPDY, DPSEQ
Sorted by	DUSUBJID, VISIT, DPVWDRWN, DPDY, DPSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,DPDT,DPCNTRID,COUNTRY,RACE,SEX,AGE, DPDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DPSEQ	num	Drug Preparation Sequence Number		Collected at CRF.
DPVWDRWN	num	Volume Withdrawn From Vial(s) in mL		Collected at CRF.
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 Assigned for De-identity.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DPND	char	Drug Preparation Not Done		Collected at CRF.
DPPRD	char	Drug Preparation Period		Collected at CRF.
DPDY	num	Relative Day Prepared		If DPDTC and IRLCNDTC not missing then perform below logic to calculate DPDY,If DPDTC less than IRLCNDTC then (DPDTC - IRLCNDTC).Else if DPDTC is greater than equal to IRLCNDTC then (DPDTC-IRLCNDTC) +1.

1.4.12. Study Agent & Participation Status – DSTATUS

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

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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
DSDSCEND	char	Study Participation End		Collected at CRF.
DSEREAS	char	Rsn for Study Participation Termination		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
DSTREAS	char	Reason for Treatment Discontinuation		Collected at CRF.
DSTWSTD	char	Worsening of Study Disease		Collected at CRF.
DSUNB	char	Treatment Unblinded		Collected at CRF.
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.

1.4.13.　　　Methotrexate: Prior Expo & Screen Dose – EXPHX

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

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.
EHSCRDOS	num	Screening Methotrexate Dose in mg/wk		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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
EHDUR	char	Duration of Therapy		Collected at CRF.

1.4.14.   Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure
Unique identifier	DUSUBJID, VISIT, EXSTDY, EXSTTM, EXSEQ
Sorted by	DUSUBJID, VISIT, EXSTDY, EXSTTM, 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 or due to missing values: PAG_NAME,EXSTDT,EXCNTRID,EXVWDRWN,COUNTRY,RACE,SEX,EXSITE,AGE, 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.
EXENHR	num	End Hour of Dose, 24 Hour Clock		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXENMI	num	End Minute of Dose, 24 Hour Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
EXINTHR	num	Hour of Interruption, 24 Hour Clock		Collected at CRF.
EXINTMI	num	Minute of Interruption, 24 Hour Clock		Collected at CRF.
EXINTTM	num	Time of Interruption, 24 Hour Clock		Collected at CRF.
EXRSHR	num	Hour of Resumption, 24 Hour Clock		Collected at CRF.
EXRSMI	num	Minute of Resumption, 24 Hour Clock		Collected at CRF.
EXRSTM	num	Time of Resumption, 24 Hour Clock		Collected at CRF.
AMTADM	num	Amount Administered		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
EXINRPT	char	Infusion Interrupted		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXPRD	char	Exposure Period		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
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.

1.4.15. Exposure PK – EXPOSUREPK

Dataset	EXPOSUREPK
Creating program	exposurepk.sas
Description	Exposure PK
Unique identifier	DUSUBJID, VISIT, EXSTDY, EXSTTM, EXSEQ
Sorted by	DUSUBJID, VISIT, EXSTDY, EXSTTM, 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 or due to missing values: PAG_NAME,EXSTDT,EXCNTRID,EXVWDRWN,COUNTRY,RACE,SEX, EXSITE,AGE, 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.
EXENHR	num	End Hour of Dose, 24 Hour Clock		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXENMI	num	End Minute of Dose, 24 Hour Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.
EXINTHR	num	Hour of Interruption, 24 Hour Clock		Collected at CRF.
EXINTMI	num	Minute of Interruption, 24 Hour Clock		Collected at CRF.
EXINTTM	num	Time of Interruption, 24 Hour Clock		Collected at CRF.
EXRSHR	num	Hour of Resumption, 24 Hour Clock		Collected at CRF.
EXRSMI	num	Minute of Resumption, 24 Hour Clock		Collected at CRF.
EXRSTM	num	Time of Resumption, 24 Hour Clock		Collected at CRF.
AMTADM	num	Amount Administered		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.

Variable	Type	Label	Codes	Comments
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
AMTADMU	char	Amount Administered Unit		Collected at CRF.
EXINRPT	char	Infusion Interrupted		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXPRD	char	Exposure Period		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
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.

1.4.16.   Health Assessment Questionnaire – HAQ

Dataset	HAQ
Creating program	haq.sas
Description	Disability Index of the Health Assessment Questionnaire
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 or due to missing values: HAPFLG1,HAPFLG6,HAPFLG8,PAG_NAME,COUNTRY,HASPEC1,HASPEC2,RACE, SEX,AGE

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.
HAPFLG7	char	Adj. permanent devices flag - Category 7		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.
HAQ2	num	HAQ Question 2		Collected at CRF.
HAQ3	num	HAQ Question 3		Collected at CRF.
HAQ4	num	HAQ Question 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.

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

Variable	Type	Label	Codes	Comments
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.
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.

1.4.17. Medications for Infusion Reaction – IFRTX

Dataset	IFRTX
Creating program	ifrtx.sas
Description	Medications for Infusion Reaction
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: PAG_NAME,COUNTRY,RACE,SEX,AGE

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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
IFTXDUR	char	Treatment During Infusion		Collected at CRF.
IFTXPR	char	Prophylaxis		Collected at CRF.
IFTXPST	char	Treatment After Infusion		Collected at CRF.

1.4.18.   IVRSDOSE – IVRSDOSE

Dataset	IVRSDOSE
Creating program	ivrsdose.sas
Description	IVRSDOSE
Unique identifier	DUSUBJID, VISIT, IDEMRS, IDSEQ
Sorted by	DUSUBJID, VISIT, IDEMRS, IDSEQ
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: PAG_NAME,IDCLDT,IDCTID1,IDCTID2,IDCTID3,IDCTID4,IDCTID5,IDCTID6,IDCTID7,IDCTID8,IDBTID1,IDBTID2,IDBTID3,IDBTID4,IDBTID5,IDBTID6,COUNTRY,RACE,SEX, AGE, IDWEIGHT, IDCLDTC

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

Variable	Type	Label	Codes	Comments
IDSEQ	num	IVRS Sequence Number		Collected at CRF.
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.
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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
IDDRA	char	Dose Regimen Adjustment		Collected at CRF.
IDEARES	char	Early Escape		Collected at CRF.

Variable	Type	Label	Codes	Comments
IDEMRS	char	Emergency Re-Supply		Collected at CRF.
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.

1.4.19.   IVRSRAND – IVRSRAND

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TRTCD	num	Treatment Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
TRTGRP	char	Decode of TRTCD		Collected at CRF.
IRSMTXD	char	Methotrexate dose in mg		Collected at CRF.
IRSTRAT	char	Stratum		Collected at CRF.

1.4.20. Joint Evaluation Score – JNTSCORE

Dataset	JNTSCORE
Creating program	jntscore.sas
Description	Joint Evaluation Score
Unique identifier	DUSUBJID, JOINT, VISIT
Sorted by	DUSUBJID, JOINT, 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: PAG_NAME,COUNTRY,RACE,SEX,AGE

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.
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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
JOINTD	char	Joint		Collected at CRF.
JTNE	char	Joint Not Evaluable		Collected at CRF.
JTSWELL	char	Joint Swelling on Exam		Collected at CRF.
JTTEND	char	Joint Tenderness on Exam		Collected at CRF.

1.4.21. Laboratory Tests – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Tests
Unique identifier	DUSUBJID, LBCAT, LBSCAT, LBTEST, VISIT, LBDY
Sorted by	DUSUBJID, LBCAT, LBSCAT, LBTEST, VISIT, LBDY
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: PAG_NAME ,LBLBLNUM, LBDT, COUNTRY, RACE, SEX, LBCOM, LBID, LBLOQL, AGE, LBDTC Note: Protocol unplanned tests will be removed; it may reveal participant information.

Variable	Type	Label	Codes	Comments
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
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.
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.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBFAST	char	Fasting		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBPTM	char	Planned Timepoint Name		Collected at CRF.
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.

1.4.22. Extra-Articular Manifestations of RA – MANIFST

Dataset	MANIFST
Creating program	manifst.sas
Description	Extra-Articular Manifestations of RA
Unique identifier	DUSUBJID, MANIFEST
Sorted by	DUSUBJID, 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: PAG_NAME,COUNTRY,RACE,SEX,AGE

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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
MACURR	char	Currently Manifested		Collected at CRF.
MANIFEST	char	Manifestation		Collected at CRF.

1.4.23.   Medication Review – MEDRVIEW

Dataset	MEDRVIEW
Creating program	medrview.sas
Description	Medication Review
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 or due to missing values: PAG_NAME,MRMTXDOS,COUNTRY,RACE,SEX,MRDCCORT,MRDCRMTX,AGE

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MRCODOSE	num	Oral Corticosteroid Dose in mg/day		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
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.
MRINMTX	char	Increase in Methotrexate Dose		Collected at CRF.
MRNEWCS	char	Treatment with Corticosteroids		Collected at CRF.
MRNSAIDS	char	NSAIDs		Collected at CRF.

1.4.24. Reason Randomized But Never Treated – NOTTX

Dataset	NOTTX
Creating program	nottx.sas
Description	Reason Randomized But Never Treated
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 or due to missing values: PAG_NAME,NTRSOTH,COUNTRY,RACE,SEX,AGE

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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
NTREAS	char	Reason Never Treated		Collected at CRF.

1.4.25.   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	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,COUNTRY,RACE,SEX,AGE

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		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.

Variable	Type	Label	Codes	Comments
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.
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.

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

1.4.26.   Prior Med. for Rheumatoid Arthritis – RXHX

Dataset	RXHX
Creating program	rxhx.sas
Description	Prior Medications for Rheumatoid Arthritis Other than Methotrexate
Unique identifier	DUSUBJID, VISIT, RXMED
Sorted by	DUSUBJID, VISIT, 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: PAG_NAME,RXDSCSP,COUNTRY,RACE,SEX, AGE

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 Assigned for De-identity.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
RXDSC	char	Reason for Discontinuation		Element is grouped to protect PII.
RXDUR	char	Duration of Use		Collected at CRF.
RXMED	char	Medication Name		Collected at CRF.

1.4.27.   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: PAG_NAME,SSDSCDT,SSRSOTH,COUNTRY,RACE,SEX,AGE, 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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
SSENT	char	Subject Entered Next Study Period		Collected at CRF.

1.4.28. Screening/ Testing for Tuberculosis – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Screening/ Testing for Tuberculosis
Unique identifier	DUSUBJID, VISIT, TBRCATB, TBADMDY
Sorted by	DUSUBJID, VISIT, TBRCATB, TBADMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,TBADMDT,TBADMSP,TBRDDT,TBREADSP,TBCXRDT,COUNTRY, RACE,SEX,AGE, TBADMDTC, TBCXRDTC, TBRDDTC

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

Variable	Type	Label	Codes	Comments
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.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
TBADM	char	PPD Administrator		Collected at CRF.
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.
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.
TBCXRDY	num	Relative Chest X-Ray Day		If TBCXRDTC and IRLCNDTC not missing then perform below logic to calculate TBCXRDY, If TBCXRDTC less than IRLCNDTC then (TBCXRDTC - IRLCNDTC).Else if TBCXRDTC is greater than equal to IRLCNDTC then (TBCXRDTC- 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.

1.4.29. Visits – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visits data
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: PAG_NAME,VISITDT,COUNTRY,RACE,SEX,AGE, 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 Assigned for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID Assigned for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID Assigned 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.
VISITDY	num	Relative Day of Subject Visit		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.

1.4.30.   Vital Signs – VITALS

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

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

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