

Clinical Development

**Infliximab**

C0168T32

Anonymisation Data Derivation Specification Document

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

Property of Janssen

Confidential

May not be used, divulged, published or otherwise disclosed  
without the consent of Janssen

## Table of contents

Clinical Development .....	1
1. Datasets .....	5
1.1. Specifications Introduction .....	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files.....	6
1.4. Data Domains.....	7
1.4.1. Demographics – DM.....	7
1.4.2. Study Infusion Administration – ADMIN.....	8
1.4.3. Adverse Events – AE.....	10
1.4.4. Childhood Health Assessment Questionnaire – CHAQ.....	12
1.4.5. Concomitant Procedures/Injections Affecting a Joint – CONPROC .....	15
1.4.6. Patient Selection Criteria– CRITERIA.....	16
1.4.7. Drug Accountability – DRUGACCT.....	17
1.4.8. Infection Summary– INFCTSUM.....	19
1.4.9. IVRSRAND – IVRSRAND .....	22
1.4.10. Pediatric Joint Assessment – Upper Extremities– JNTSCORE .....	23
1.4.11. Lab Test– LAB .....	24
1.4.12. Dipstick Urinalysis – LAB_ANCL.....	26
1.4.13. Extra-Articular Manifestations of JRA – MANIFST .....	27
1.4.14. Medication Review – MEDRVIEW .....	28
1.4.15. Concomitant Medications – MEDS .....	29
1.4.16. Medication Review – MEDSUMM.....	31
1.4.17. Medication History – MTX_HX.....	32
1.4.18. Methotrexate Toxicity – MTX_TOX.....	33
1.4.19. Prior Murine/Chimeric MAB Treatment – PRIORTX .....	34
1.4.20. Parent Response Parameters – RAEVAL .....	35
1.4.21. ACR/ILAR Classification – RAINFO.....	36
1.4.22. Reason Randomized but Never Treated – RANDCODE.....	37
1.4.23. Tuberculosis History and PPD Results – TB_INFO.....	38

1.4.24. Permanent Discontinuation of Study Infusions – TERMDOSE ..... 39

1.4.25. Study Termination – TERMSTDY ..... 41

1.4.26. Treatment extension – TX\_EXT ..... 43

1.4.27. Vaccination– VACCIN ..... 44

1.4.28. Visit Information – VISITS..... 45

1.4.29. Vital Signs – VITALS ..... 46

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

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

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

### 1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided.
- Investigator 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.
- Dataset used for data reconciliation, CRF page information will not be submitted (eg. ANY\_NONE, ATRACK, PAGE\_SEQ, LTRACK).
- Datasets CRESUL, DERVD\_PK and DERVD\_POPPK contain PK related information hence dropping the same.
- UNBLIND dataset will not be submitted to protect PII.
- TANNRSTG dataset will not be submitted as it captures very personal information of subject.
- Empty data set will not be submitted (eg. ATRACK2, COMTREAT, CRESUL21).
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.

### 1.3. Data Files

The C0168T32 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0168T32 CSR data from the following folders.

## 1.4. Data Domains

### 1.4.1. Demographics – DEMOG

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Group element to protect PII.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
TRTCD	num	Randomized Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRP	char	Decode of TRTCD		Collected at CRF.
TRTCDA	num	Actual Treatment Code		Collected at CRF.
TRTGRPA	char	Actual Treatment group		Collected at CRF.
AGE	char	Age in Years		Collected at CRF.

#### 1.4.2. Study Infusion Administration – ADMIN

<b>Dataset</b>	ADMIN
<b>Creating program</b>	admin.sas
<b>Description</b>	Study Infusion Administration
<b>Unique identifier</b>	DUSUBJID,EXSTDY,VISIT
<b>Sorted by</b>	DUSUBJID,EXSTDY,VISIT
<b>Notes</b>	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,EXSTDY,CRF_PAGE,UNIQUE_P, EXSTDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
EXSTTM	num	Administration start time		Collected at CRF.
EXENTM	num	Administration end time		Collected at CRF.
TOTAL_ML	num	Total ml administered		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
EXTVAE	char	Reason total vol not adm is AE		Collected at CRF.
EXPRPINF	char	Total dose administered		Collected at CRF.
EXPROP	char	Prophylactic medication given		Collected at CRF.



Variable	Type	Label	Codes	Comments
EXND	char	Administration not done		Collected at CRF.
EXINRPT	char	Infusion interrupted		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
EXSTDY	num	Relative Administration Start Day		If EXSTDTC and DMREFDT not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than DMREFDT then (EXSTDTC - DMREFDT).Else if EXSTDTC is greater than equal to DMREFDT then (EXSTDTC - DMREFDT) +1.

## 1.4.3. Adverse Events – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DUSUBJID, AEBODSYS, VISIT, AE_LINE, AESTDY, AEENDY
<b>Sorted by</b>	DUSUBJID, AEBODSYS, VISIT, AE_LINE, AESTDY, AEENDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY, PAG_NAME, PAGE_SEQ, AE_LINE, AETERM, AESTDT, AEENDT, CRF_PAGE, UNIQUE_P, SAEDTH, SAEOTH, SAEDISAB, SAEHOSP, SAELIFE, SAECONG, AESTDTC, AEENDTC

Variable	Type	Label	Codes	Comments
AECD	char	WHOART Adverse Event Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
AESTHR	num	Onset hour		Collected at CRF.
AESTMI	num	Onset minute		Collected at CRF.
AESTTM	num	Onset time		Collected at CRF.
AEENHR	num	Resolution hour		Collected at CRF.
AEENMI	num	Resolution minute		Collected at CRF.
AEENTM	num	Resolution time		Collected at CRF.
AETXCRT	num	Common toxicity criteria		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
AESERN	char	Not serious		Collected at CRF.

Variable	Type	Label	Codes	Comments
INFECT	char	AE infection		Collected at CRF.
AECTTRT	char	Action taken with study agent		Collected at CRF.
AEREL	char	Relationship to study agent		Collected at CRF.
AEONGO	char	Event continuing		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
AEENDY	num	Relative Resolution Day		If AEENDTC and DMREFDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than DMREFDT then (AEENDTC - DMREFDT).Else if AEENDTC is greater than equal to DMREFDT then (AEENDTC- DMREFDT) +1.
AESTDY	num	Relative Onset Day		If AESTDTC and DMREFDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than DMREFDT then (AESTDTC - DMREFDT).Else if AESTDTC is greater than equal to DMREFDT then (AESTDTC- DMREFDT) +1.

## 1.4.4. Childhood Health Assessment Questionnaire – CHAQ

<b>Dataset</b>	CHAQ
<b>Creating program</b>	chaq.sas
<b>Description</b>	Childhood Health Assessment Questionnaire
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,CHSPEC1,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CHAQ1	num	CHAQ question 1		Collected at CRF.
CHAQ2	num	CHAQ question 2		Collected at CRF.
CHAQ3	num	CHAQ question 3		Collected at CRF.
CHAQ4	num	CHAQ question 4		Collected at CRF.
CHAQ5	num	CHAQ question 5		Collected at CRF.
CHAQ6	num	CHAQ question 6		Collected at CRF.
CHAQ7	num	CHAQ question 7		Collected at CRF.
CHAQ8	num	CHAQ question 8		Collected at CRF.
CHAQ9	num	CHAQ question 9		Collected at CRF.
CHAQ10	num	CHAQ question 10		Collected at CRF.
CHAQ11	num	CHAQ question 11		Collected at CRF.
CHAQ12	num	CHAQ question 12		Collected at CRF.
CHAQ13	num	CHAQ question 13		Collected at CRF.
CHAQ14	num	CHAQ question 14		Collected at CRF.
CHAQ15	num	CHAQ question 15		Collected at CRF.
CHAQ16	num	CHAQ question 16		Collected at CRF.
CHAQ17	num	CHAQ question 17		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHAQ18	num	CHAQ question 18		Collected at CRF.
CHAQ19	num	CHAQ question 19		Collected at CRF.
CHAQ20	num	CHAQ question 20		Collected at CRF.
CHAQ21	num	CHAQ question 21		Collected at CRF.
CHAQ22	num	CHAQ question 22		Collected at CRF.
CHAQ23	num	CHAQ question 23		Collected at CRF.
CHAQ24	num	CHAQ question 24		Collected at CRF.
CHAQ25	num	CHAQ question 25		Collected at CRF.
CHAQ26	num	CHAQ question 26		Collected at CRF.
CHAQ27	num	CHAQ question 27		Collected at CRF.
CHAQ28	num	CHAQ question 28		Collected at CRF.
CHAQ29	num	CHAQ question 29		Collected at CRF.
CHAQ30	num	CHAQ question 30		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
CHND	char	None		Collected at CRF.
CHCAT8	char	CHAQ aid, device/help category 8		Collected at CRF.
CHCAT6	char	CHAQ aid, device/help category 6		Collected at CRF.
CHCAT4	char	CHAQ aid, device/help category 4		Collected at CRF.
CHCAT1	char	CHAQ aid, device/help category 1		Collected at CRF.
CHCAT10	char	CHAQ aid, device/help category 10		Collected at CRF.
CHCAT11	char	CHAQ aid, device/help category 11		Collected at CRF.
CHCAT12	char	CHAQ aid, device/help category 12		Collected at CRF.
CHCAT13	char	CHAQ aid, device/help category 13		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHCAT14	char	CHAQ aid, device/help category 14		Collected at CRF.
CHCAT15	char	CHAQ aid, device/help category 15		Collected at CRF.
CHCAT16	char	CHAQ aid, device/help category 16		Collected at CRF.
CHCAT17	char	CHAQ aid, device/help category 17		Collected at CRF.
CHCAT18	char	CHAQ aid, device/help category 18		Collected at CRF.
CHCAT19	char	CHAQ aid, device/help category 19		Collected at CRF.
CHCAT2	char	CHAQ aid, device/help category 2		Collected at CRF.
CHCAT20	char	CHAQ aid, device/help category 20		Collected at CRF.
CHCAT21	char	CHAQ aid, device/help category 21		Collected at CRF.
CHCAT22	char	CHAQ aid, device/help category 22		Collected at CRF.
CHCAT3	char	CHAQ aid, device/help category 3		Collected at CRF.
CHCAT5	char	CHAQ aid, device/help category 5		Collected at CRF.
CHCAT7	char	CHAQ aid, device/help category 7		Collected at CRF.
CHCAT9	char	CHAQ aid, device/help category 9		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.

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

#### 1.4.5. Concomitant Procedures/Injections Affecting a Joint – CONPROC

<b>Dataset</b>	CONPROC
<b>Creating program</b>	conproc.sas
<b>Description</b>	Concomitant Procedures/Injections Affecting a Joint
<b>Unique identifier</b>	DUSUBJID,PROCDY,VISIT,PRJOINT
<b>Sorted by</b>	DUSUBJID,PROCDY,VISIT,PRJOINT
<b>Notes</b>	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,PR_LINE,PRJNTSPC,PROCSPEC,PROCDT, CRF_PAGE,UNIQUE_P,PROCDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
PRSTRTPR	char	Prior to cutoff		Collected at CRF.
PROCRSN	char	Procedure reason		Collected at CRF.
PRJOINT	char	Joint		Collected at CRF.
PR_TYPE	char	Procedure code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.

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

#### 1.4.6. Patient Selection Criteria– CRITERIA

<b>Dataset</b>	CRITERIA
<b>Creating program</b>	criteria.sas
<b>Description</b>	Patient Selection Criteria
<b>Unique identifier</b>	DUSUBJID,VISIT,INCRIT
<b>Sorted by</b>	DUSUBJID,VISIT,INCRIT
<b>Notes</b>	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,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
INCRIT	char	Inclusion criterion not met		Collected at CRF.
EXCRIT	char	Exclusion criterion present		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.



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

#### 1.4.7. Drug Accountability – DRUGACCT

<b>Dataset</b>	DRUGACCT
<b>Creating program</b>	drugacct.sas
<b>Description</b>	Drug Accountability
<b>Unique identifier</b>	DUSUBJID,EXPDY,VISIT
<b>Sorted by</b>	DUSUBJID,EXPDY,VISIT
<b>Notes</b>	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,EXPDT,EXLOTNO1,EXLOTNO2,EXLOTNO3,CRF_PAGE,UNIQUE_P,EXPDTDC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PLANDOSE	num	Plan dose		Collected at CRF.
EXVWDRWN	num	Volume withdrawn (mL)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXVPREP	num	Total diluted volume (mL)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
EXND	char	Not done		Collected at CRF.
EXPLNDS	char	Decode of PLANDOS		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
EXPDY	num	Relative Day Prepared		If EXPDTC and DMREFDT not missing then perform below logic to calculate EXPDY, If EXPDTC less than DMREFDT then (EXPDTC - DMREFDT). Else if EXPDTC is greater than equal to DMREFDT then (EXPDTC - DMREFDT) +1.

## 1.4.8. Infection Summary– INFCTSUM

<b>Dataset</b>	INFCTSUM
<b>Creating program</b>	infctsum.sas
<b>Description</b>	Infection Summary
<b>Unique identifier</b>	DUSUBJID,VISIT,MEDSEQ,AELN
<b>Sorted by</b>	DUSUBJID,VISIT,MEDSEQ,AELN
<b>Notes</b>	<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, AEPG4, AESEQ4, AEOF4, AELN4,AEPG5,AESEQ5,AEOF5,AELN5, AEPG6, AESEQ6, AEOF6,AELN6,MEDPG5,MEDSEQ5,MEDOF5,MEDLN5, MEDPG6, MEDSEQ6, MEDOF6,MEDLN6,IFOCLTSP,IFOINFSP,CRF_PAGE, UNIQUE_P,IFWNDCLT,IFFUNGAL,IFGRMPOS,IFVIRAL</p>

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of series		Collected at CRF.
PAGE_OF	num	Total pages in series		Collected at CRF.
AEPG	num	AE CRF page		Collected at CRF.
AESEQ	num	AE page sequence		Collected at CRF.
AEOF	num	Number of AE pages in series		Collected at CRF.
AELN	num	AE CRF line number		Collected at CRF.
AEPG2	num	AE CRF page 2		Collected at CRF.
AESEQ2	num	AE page sequence 2		Collected at CRF.
AEOF2	num	Number of AE pages in series 2		Collected at CRF.
AELN2	num	AE CRF line number 2		Collected at CRF.
AEPG3	num	AE CRF page 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESEQ3	num	AE page sequence 3		Collected at CRF.
AEOF3	num	Number of AE pages in series 3		Collected at CRF.
AELN3	num	AE CRF line number 3		Collected at CRF.
MEDPG	num	Medication CRF page		Collected at CRF.
MEDSEQ	num	Medication page sequence		Collected at CRF.
MEDOF	num	Number of medication pages in series		Collected at CRF.
MEDLN	num	Medication CRF line number		Collected at CRF.
MEDPG2	num	Medication CRF page 2		Collected at CRF.
MEDSEQ2	num	Medication page sequence 2		Collected at CRF.
MEDOF2	num	Number of medication pages in series 2		Collected at CRF.
MEDLN2	num	Medication CRF line number 2		Collected at CRF.
MEDPG3	num	Medication CRF page 3		Collected at CRF.
MEDSEQ3	num	Medication page sequence 3		Collected at CRF.
MEDOF3	num	Number of medication pages in series 3		Collected at CRF.
MEDLN3	num	Medication CRF line number 3		Collected at CRF.
MEDPG4	num	Medication CRF page 4		Collected at CRF.
MEDSEQ4	num	Medication page sequence 4		Collected at CRF.
MEDOF4	num	Number of medication pages in series 4		Collected at CRF.
MEDLN4	num	Medication CRF line number 4		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
IFBLDCLT	char	Blood cultured		Collected at CRF.
IFCLTPOS	char	Cultures indicated infection		Collected at CRF.
IFCLT	char	Cultures performed		Collected at CRF.
IFGRMNEG	char	Gram negative		Collected at CRF.
IFHX	char	History of similar infections		Collected at CRF.
IFMYCBCT	char	Mycobacterial		Collected at CRF.
IFOTHCLT	char	Other cultured		Collected at CRF.

Variable	Type	Label	Codes	Comments
IFANTIMC	char	Antimicrobial tx given for infection		Collected at CRF.
IFSTREP	char	Streptococcus infection		Collected at CRF.
IFSTAPHA	char	Staph aureus infection		Collected at CRF.
IFSPUCLT	char	Sputum cultured		Collected at CRF.
IFOTHINF	char	Other infection		Collected at CRF.
IFPROTZ	char	Protozoal		Collected at CRF.
IFURICLT	char	Urine cultured		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

## 1.4.9.IVRS Data – IVRSRAND

<b>Dataset</b>	IVRSRAND
<b>Creating program</b>	ivrsrand.sas
<b>Description</b>	IVRS Data
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines : BIRTHDT,RAND_DT

Variable	Type	Label	Codes	Comments
TRTCD	num	Randomized treatment		Collected at CRF.
STRATUM	num	Age stratification		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

## 1.4.10. Pediatric Joint Assessment – Upper Extremities– JNTSCORE

<b>Dataset</b>	JNTSCORE
<b>Creating program</b>	jntscore.sas
<b>Description</b>	Pediatric Joint Assessment – Upper Extremities
<b>Unique identifier</b>	DUSUBJID,VISIT,JSJOINT
<b>Sorted by</b>	DUSUBJID,VISIT,JSJOINT
<b>Notes</b>	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,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
JSTENDR	char	Joint tenderness on exam		Collected at CRF.
JSPAIN	char	Joint pain on exam		Collected at CRF.
JSJNTNE	char	Joint not evaluable		Collected at CRF.
JSJOINT	char	Joint		Collected at CRF.
JSMTNLIM	char	Motion limitation		Collected at CRF.
JSSWELL	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 Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

## 1.4.11. Lab Results– LAB

<b>Dataset</b>	LAB
<b>Creating program</b>	lab.sas
<b>Description</b>	Lab Results
<b>Unique identifier</b>	DUSUBJID,LBTSTCD,VISIT,LBDY,LBACTTM, EVENT_ID
<b>Sorted by</b>	DUSUBJID,LBTSTCD,VISIT,LBDY,LBACTTM, EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,LBBLNUM,LBDT,LBID,CRF_PAGE,UNIQUE_P,LBCOM, LBDC Note: Protocol unplanned tests will be removed; it may reveal participant information.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LBEVNT	char	Lab event		Collected at CRF.
LBTSTCD	char	Test code		Collected at CRF.
LBACTHR	num	Hour of sample		Collected at CRF.
LBACTMI	num	Minute of sample		Collected at CRF.
LBACTTM	num	Time of sample		Collected at CRF.
LBORRES	char	Result		Collected at CRF.
LBORNRL0	char	Lower normal rng - test result		Collected at CRF.
LBORNRHI	char	Upper normal rng - test result		Collected at CRF.
LBSTRESC	char	Standardized test result		Collected at CRF.
LBSTNRLO	char	Lower normal rng - std result		Collected at CRF.
LBSTNRHI	char	Upper normal rng - std result		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
LBORUNIT	char	Units - test result		Collected at CRF.
LBPTM	char	Period		Collected at CRF.



Variable	Type	Label	Codes	Comments
LBNRIND	char	Out of range flag		Collected at CRF.
LBSTUNIT	char	Units - std result		Collected at CRF.
LBTEST	char	Decode of TESTCOD		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
LBDY	num	Relative Day of Sample		If LBDTC and DMREFDT not missing then perform below logic to calculate LBDY, If LBDTC less than DMREFDT then (LBDTC - DMREFDT).Else if LBDTC is greater than equal to DMREFDT then (LBDTC-DMREFDT) +1.

## 1.4.12. Dipstick Urinalysis – LAB\_ANCL

<b>Dataset</b>	LAB_ANCL
<b>Creating program</b>	lab_ancl.sas
<b>Description</b>	Dipstick Urinalysis
<b>Unique identifier</b>	DUSUBJID,URTSTCD,URDY,VISIT
<b>Sorted by</b>	DUSUBJID,URTSTCD,URDY,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,URDT,CRF_PAGE,UNIQUE_P,URCOM,URDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
URTSTCD	char	Test code		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
URRESCD	char	Test result code		Collected at CRF.
URTEST	char	Decode of TESTCOD		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

Variable	Type	Label	Codes	Comments
URDY	num	Relative Day of Sample		If URDTC and DMREFDT not missing then perform below logic to calculate URDY, If URDTC less than DMREFDT then (URDTC - DMREFDT). Else if URDTC is greater than equal to DMREFDT then (URDTC - DMREFDT) +1.

#### 1.4.13. Extra-Articular Manifestations of JRA – MANIFEST

<b>Dataset</b>	MANIFEST
<b>Creating program</b>	manifest.sas
<b>Description</b>	Extra-Articular Manifestations of JRA
<b>Unique identifier</b>	DUSUBJID,EMMANIFS
<b>Sorted by</b>	DUSUBJID,EMMANIFS
<b>Notes</b>	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,EMOETHMAN,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
EMRESPON	char	Any history		Collected at CRF.
EMMANIFS	char	Extra-articular manifestation		Collected at CRF.
EMONGO	char	Condition ongoing		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.

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

#### 1.4.14. Medication Review – MEDRVIEW

<b>Dataset</b>	MEDRVIEW
<b>Creating program</b>	medrview.sas
<b>Description</b>	Medication Review
<b>Unique identifier</b>	USUBJID , VISIT
<b>Sorted by</b>	USUBJID , VISIT
<b>Notes</b>	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,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MRMTXDOS	char	Methotrexate dose (mg/m/week)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
MRORALCO	char	Patient taking oral corticosteroids		Collected at CRF.
MRMTXINC	char	Methotrexate dose increase		Collected at CRF.
MRDCRRSN	char	Decrease reason		Collected at CRF.
MRCORTCH	char	Change in corticosteroid dose		Collected at CRF.
MRDMARD	char	Patient taking DMARDS?		Collected at CRF.
MRDMRDLE	char	DMARD for lack of efficacy		Collected at CRF.
MRDOSDCR	char	Dose decrease		Collected at CRF.

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

#### 1.4.15. Concomitant Medications – MEDS

<b>Dataset</b>	MEDS
<b>Creating program</b>	meds.sas
<b>Description</b>	Concomitant Medications
<b>Unique identifier</b>	DUSUBJID,CMSTDY,CMDECOD, CMIND,CMSTPR,CMROUTE,VISIT,CMSEQ
<b>Sorted by</b>	DUSUBJID,CMSTDY,CMDECOD, CMIND,CMSTPR,CMROUTE,VISIT,CMSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,CMTERM,CMRTE_V,CMIND_V,CMSTDT,CMENDT, DRECNO,SEQ1,SEQ2,CRF_PAGE,UNIQUE_P,CMENDTC,CMSTDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAGE_SEQ	num	Page of series		Collected at CRF.
CMSEQ	num	Line number		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
CMSTPR	char	Prior to cutoff		Collected at CRF.
CMONGO	char	Pt. continues taking medication		Collected at CRF.
CMIND	char	Medication indication		Collected at CRF.
CMROUTE	char	Decode of ROUTECD		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
CMSTDY	num	Relative Medication Start Day		If CMSTDTC and DMREFDT not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than DMREFDT then (CMSTDTC - DMREFDT).Else if CMSTDTC is greater than equal to DMREFDT then (CMSTDTC- DMREFDT) +1.
CMENDY	num	Relative Medication End Day		If CMENDTC and DMREFDT not missing then perform below logic to calculate CMENDY, If CMENDTC less than DMREFDT then (CMENDTC - DMREFDT).Else if CMENDTC is greater than equal to DMREFDT then (CMENDTC- DMREFDT) +1.

## 1.4.16. Medication Records Review – MEDSUMM

<b>Dataset</b>	MEDSUMM
<b>Creating program</b>	medsumm.sas
<b>Description</b>	Medication Records Review
<b>Unique identifier</b>	DUSUBJID, VISIT, MSCORTDS, CMDECOD
<b>Sorted by</b>	DUSUBJID, VISIT, MSCORTDS, CMDECOD
<b>Notes</b>	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,MSTERM,DRECNO,SEQ1,SEQ2,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MSCORTDS	char	Oral corticosteroid dose		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
MSNOTRX	char	Not prescribed		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

## 1.4.17. Medication History – MTX\_HX

<b>Dataset</b>	MTX_HX
<b>Creating program</b>	mtx_hx.sas
<b>Description</b>	Medication History
<b>Unique identifier</b>	DUSUBJID, VISIT
<b>Sorted by</b>	DUSUBJID, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,MXSTDT,CRF_PAGE,UNIQUE_P,MXSTDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
MXMOINTR	num	Number of months therapy was interrupted		Collected at CRF.
MXHIWKDS	char	Highest weekly dose (mg/m/week)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
MXCUMDOS	char	Cumulative 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 Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.



Variable	Type	Label	Codes	Comments
MXSTDY	num	Relative Onset Day		If MXSTDTC and DMREFDT not missing then perform below logic to calculate MXSTDY,if MXSTDTC less than DMREFDT then (MXSTDTC - DMREFDT).Else if MXSTDTC is greater than equal to DMREFDT then (MXSTDTC- DMREFDT) +1.

#### 1.4.18. Methotrexate Toxicity – MTX\_TOX

<b>Dataset</b>	MTX_TOX
<b>Creating program</b>	mtx_tox.sas
<b>Description</b>	Methotrexate Toxicity
<b>Unique identifier</b>	DUSUBJID,VISIT
<b>Sorted by</b>	DUSUBJID,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,DAEPG3,DAESEQ3,DAEOF3,DAELN3,DAEPG4,DAESEQ4,DAEOF4,DAELN4,DAEPG5,DAESEQ5,DAEOF5,DAELN5,DAEPG6,DAESEQ6,DAEOF6,DAELN6,MTRSNSPC,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DAEPG	num	Adverse event page		Collected at CRF.
DAESEQ	num	Adverse event page sequence		Collected at CRF.
DAEOF	num	Adverse event pages in series		Collected at CRF.
DAELN	num	Adverse event line number		Collected at CRF.
DAEPG2	num	Adverse event page 2		Collected at CRF.
DAESEQ2	num	Adverse event page sequence 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAEOF2	num	Adverse event pages in series 2		Collected at CRF.
DAELN2	num	Adverse event line number 2		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
MTDOSRSN	char	Reason for dose decrease or discontinue		Collected at CRF.
MTDECDOS	char	Dose decreased or discontinued		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

#### 1.4.19. Prior Murine/Chimeric MAB Treatment – PRIORTX

<b>Dataset</b>	PRIORTX
<b>Creating program</b>	priortx.sas
<b>Description</b>	Prior Murine/Chimeric MAB Treatment
<b>Unique identifier</b>	DUSUBJID, VISIT
<b>Sorted by</b>	DUSUBJID, VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,CRF_PAGE,UNIQUE_P

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

Variable	Type	Label	Codes	Comments
PTRCMAB	char	Patient received prior MAB tx		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

#### 1.4.20. Parent Response Parameters – RAEVAL

<b>Dataset</b>	RAEVAL
<b>Creating program</b>	raeval.sas
<b>Description</b>	Parent Response Parameters
<b>Unique identifier</b>	DUSUBJID,EVENT_ID,VISIT,REGOWPAR,REGDAEVL
<b>Sorted by</b>	DUSUBJID,EVENT_ID,VISIT,REGOWPAR,REGDAEVL
<b>Notes</b>	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,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
REPMPAR	num	Parent VAS score for pain		Collected at CRF.
REGOWPAR	num	Parent assessment of overall well-being		Collected at CRF.
RECMPPAR	num	Completed by same parent		Collected at CRF.

Variable	Type	Label	Codes	Comments
REMRNSTF	num	Morning stiffness duration-mins.		Collected at CRF.
REGDAEVL	num	Evaluator VAS score for GDA		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

#### 1.4.21. ACR/ILAR Classification – RAINFO

<b>Dataset</b>	RAINFO
<b>Creating program</b>	rainfo.sas
<b>Description</b>	ACR/ILAR Classification
<b>Unique identifier</b>	DUSUBJID, EVENT_ID, RIILACLS
<b>Sorted by</b>	DUSUBJID, EVENT_ID, RIILACLS
<b>Notes</b>	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,RIDIAGDT,CRF_PAGE,UNIQUE_P,RIDIADTC

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

Variable	Type	Label	Codes	Comments
RIILACLS	char	ILAR classification		Collected at CRF.
RIACRCLS	char	ACR classification		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
RIDIADY	num	Relative Day of Diagnosis		If RIDIADTC and DMREFDT not missing then perform below logic to calculate RIDIADY,if RIDIADTC less than DMREFDT then (RIDIADTC - DMREFDT).Else if RIDIADTC is greater than equal to DMREFDT then (RIDIADTC- DMREFDT) +1.

#### 1.4.22. Reason Randomized but Never Treated – RANDCODE

<b>Dataset</b>	RANDCODE
<b>Creating program</b>	randcode.sas
<b>Description</b>	Reason Randomized but Never Treated
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,DSNTRSOT,CRF_PAGE,UNIQUE_P

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

Variable	Type	Label	Codes	Comments
DSNTREAS	char	Reason not infused		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

#### 1.4.23. Tuberculosis History and PPD Results – TB\_INFO

<b>Dataset</b>	TB_INFO
<b>Creating program</b>	tb_info.sas
<b>Description</b>	Tuberculosis History and PPD Results
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,TBPPDDT,CRF_PAGE,UNIQUE_P,TBPPDNR,TBPPDDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TBPVACYR	num	Previous vaccination year		Collected at CRF.
TBPPDRES	char	PPD results (induration)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
TBTRREQ	char	Treatment required		Collected at CRF.
TBPTLTB	char	Prev completed treatment for latent TB		Collected at CRF.

Variable	Type	Label	Codes	Comments
TBPRVBCG	char	Previous BCG vaccination		Collected at CRF.
TBPTATB	char	Previously treated active TB		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
TBPPDDY	num	Relative PPD Day		If TBPPDDTC and DMREFDT not missing then perform below logic to calculate TBPPDDY, If TBPPDDTC less than DMREFDT then (TBPPDDTC - DMREFDT). Else if TBPPDDTC is greater than equal to DMREFDT then (TBPPDDTC - DMREFDT) +1.

#### 1.4.24. Permanent Discontinuation of Study Infusions – TERMDOSE

<b>Dataset</b>	TERMDOSE
<b>Creating program</b>	termdose.sas
<b>Description</b>	Permanent Discontinuation of Study Infusions
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,DSTRMDT,DAEPG5,DAEPGSQ5,DAEPGOF5,DAELN5, DAEPG6,DAEPGSQ6,DAEPGOF6,DAELN6,DSTRSOTH,CRF_PAGE,UNIQUE_P,DSTRMDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DAEPG	num	Adverse event page		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAEPGSEQ	num	Adverse event page sequence		Collected at CRF.
DAEPGOF	num	Number of AE pages in series		Collected at CRF.
DAELN	num	Adverse event line number		Collected at CRF.
DAEPG2	num	Adverse event page 2		Collected at CRF.
DAEPGSQ2	num	Adverse event page sequence 2		Collected at CRF.
DAEPGOF2	num	Number of AE pages in series 2		Collected at CRF.
DAELN2	num	Adverse event line number 2		Collected at CRF.
DAEPG3	num	Adverse event page 3		Collected at CRF.
DAEPGSQ3	num	Adverse event page sequence 3		Collected at CRF.
DAEPGOF3	num	Number of AE pages in series 3		Collected at CRF.
DAELN3	num	Adverse event line number 3		Collected at CRF.
DAEPG4	num	Adverse event page 4		Collected at CRF.
DAEPGSQ4	num	Adverse event page sequence 4		Collected at CRF.
DAEPGOF4	num	Number of AE pages in series 4		Collected at CRF.
DAELN4	num	Adverse event line number 4		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DSTREAS	char	Dosing termination reason code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.



Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DSTRMDY	num	Relative Dosing Termination Day		If DSTRMDTC and DMREFDT not missing then perform below logic to calculate DSTRMDY, If DSTRMDTC less than DMREFDT then (DSTRMDTC - DMREFDT). Else if DSTRMDTC is greater than equal to DMREFDT then (DSTRMDTC - DMREFDT) +1.

#### 1.4.25. Study Termination – TERMSTDY

<b>Dataset</b>	TERMSTDY
<b>Creating program</b>	termstdy.sas
<b>Description</b>	Study Termination
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: COUNTRY,PAG_NAME,DSDSCDT,DTDT,DTCAUSE,SAEPG2,SAEPGSQ2,SAEPGOF2,SAELN2,SAEPG3,SAEPGSQ3,SAEPGOF3,SAEPG4,SAEPGSQ4,SAEPGOF4,SAELN4,SAEPG5,SAEPGSQ5,SAEPGOF5,SAELN5,SAEPG6,SAEPGSQ6,SAEPGOF6,SAELN6,SAELN3,DSRSOTH,CRF_PAGE,UNIQUE_P,DSWCD,DTDTC,DSDSCDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
DTHR	num	Hour of death		Collected at CRF.
DTMI	num	Minute of death		Collected at CRF.
DTTM	num	Time of death		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAEPG	num	Adverse event page		Collected at CRF.
SAEPGSEQ	num	Adverse event page sequence		Collected at CRF.
SAEPGOF	num	Number of AE pages in series		Collected at CRF.
SAELN	num	Adverse event line number		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DSWCAE	char	Consent withdrawn due to AE		Collected at CRF.
DSREAS	char	Reason for study termination code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.
DSDSCDY	num	Relative Study Termination Day		If DSDSCDTC and DMREFDT not missing then perform below logic to calculate DSDSCDY,If DSDSCDTC less than DMREFDT then (DSDSCDTC - DMREFDT).Else if DSDSCDTC is greater than equal to DMREFDT then (DSDSCDTC- DMREFDT) +1.
DTDY	num	Relative Day of Death		If DTDTTC and DMREFDT not missing then perform below logic to calculate DTDY,If DTDTTC less than DMREFDT then (DTDTTC - DMREFDT).Else if DTDTTC is greater than equal to DMREFDT then (DTDTTC- DMREFDT) +1.

## 1.4.26. Treatment extension – TX\_EXT

<b>Dataset</b>	TX_EXT
<b>Creating program</b>	tx_ext.sas
<b>Description</b>	Treatment extension
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : PAG_NAME,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TX_EXT	char	Treatment extension		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

## 1.4.27. Vaccination– VACCIN

<b>Dataset</b>	VACCIN
<b>Creating program</b>	vaccin.sas
<b>Description</b>	Vaccination
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,CRF_PAGE,UNIQUE_P

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
VAIMMUN	char	Up to date immunization schedule		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

## 1.4.28. Visit Information – VISITS

<b>Dataset</b>	VISITS
<b>Creating program</b>	visits.sas
<b>Description</b>	Visit Information
<b>Unique identifier</b>	DUSUBJID,EVENT_ID
<b>Sorted by</b>	DUSUBJID,EVENT_ID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : COUNTRY,PAG_NAME,VISIT_DT,CRF_PAGE,UNIQUE_P,VISITDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
VISITND	char	None		Collected at CRF.
NONE	char	None		Collected at CRF.
MEDCHG	char	Change in medication		Collected at CRF.
DISCINF	char	Permanent discontinuation of infusions		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly Assigned Site ID for De-identity.
DSUBJID	char	Subject ID Assigned for De-identity		Randomly Assigned Subject ID for De-identity.
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly Assigned Site-Subject ID for De-identity.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly Assigned Unique Subject ID for De-identity.

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative Day of Patient Visit		If VISITDTC and DMREFDT not missing then perform below logic to calculate VISITDY,if VISITDTC less than DMREFDT then (VISITDTC - DMREFDT).Else if VISITDTC is greater than equal to DMREFDT then (VISITDTC- DMREFDT) +1.

#### 1.4.29. Vital Signs – VITALS

<b>Dataset</b>	VITALS
<b>Creating program</b>	vitals.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID,EVENT_ID
<b>Sorted by</b>	DUSUBJID,EVENT_ID
<b>Notes</b>	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,ZWGT,CRF_PAGE,UNIQUE_P,ZWGT_UN

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
WGT	char	Weight (kg)		Group element to protect PII.
ZHGT	num	Entered height		Collected at CRF.
HGT	num	Height (cm)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
ZHGT_UN	char	Units for entered height		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.

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