

Clinical Development

Infliximab

C0168T29

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.
- 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.
- Dataset used for data reconciliation, CRF page information will not be submitted (e.g. ANY_NONE, ATRACK, PAGE_SEQ, PGSUMM, R2_CONT).
- Datasets CRESUL and PK_PHARM contain PK related information hence will be dropped.
- UNBLIND dataset will not be submitted to protect PII.
- CONPROC dataset will not submit to protect PII.
- Medical History data will not be submitted.
- ECONOM dataset will not be submitted as it captures personal information of subject's economic status hence may lead to PII.
- DATA_RVW, INFCTAE and INFCTMED will not be submitted as it contains non-significant data.
- Empty dataset will not be submitted (eg. ADMN_ERR)
- HAQDVC dataset contains HAQ device related information, will not be submitted as it contains non-significant data.
- LTRACK is a tracking record of laboratory samples for Central Laboratory, will not be submitted as it contains non-significant data.
- MCPHUMB, PIP, WRIST, XTRACK and XTRACK_22AUG02 will not be submitted, it may reveal PII.
- PHARMCOM dataset will not be submitted.
- SUBSTUDY dataset will not be submitted, since it contains subject information about sub study.
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.

1.3. Data Files

The C0168T29 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0168T29 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demographics – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,INITIALS,DOB_DY, DOB_MO,DOB_YR,DOB_DT, RACE_OTH, ZHGT,CRF_PAGE,ZHGT_UN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
HGT	num	Height (cm)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Group element to protect PII.
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.

1.4.2. Study Infusion Administration– ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Study Infusion Administration
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values or due to non significant elements: F_STATUS, PAG_NAME, START_DY,START_MO,START_YR,RSN_SPEC, CRF_PAGE,TVA_CNS,STP2_AD, START_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
START_HR	num	Administration start hour		Collected at CRF.
START_MI	num	Administration start minute		Collected at CRF.
START_TM	num	Administration start time		Collected at CRF.
END_HR	num	Administration end hour		Collected at CRF.

Variable	Type	Label	Codes	Comments
END_MI	num	Administration end minute		Collected at CRF.
END_TM	num	Administration end time		Collected at CRF.
STP1_HR	num	First admin stop hour		Collected at CRF.
STP1_MI	num	First admin stop minute		Collected at CRF.
STP1_TM	num	First admin stop time		Collected at CRF.
RST1_HR	num	First admin restart hour		Collected at CRF.
RST1_MI	num	First admin restart minute		Collected at CRF.
RST1_TM	num	First admin restart time		Collected at CRF.
STP2_HR	num	Second admin stop hour		Collected at CRF.
STP2_MI	num	Second admin stop minute		Collected at CRF.
STP2_TM	num	Second admin stop time		Collected at CRF.
RST2_HR	num	Second admin restart hour		Collected at CRF.
RST2_MI	num	Second admin restart minute		Collected at CRF.
RST2_TM	num	Second admin restart time		Collected at CRF.
TOTAL_ML	num	Total ml administered		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
TVA_AE	char	Reason total vol not adm is AE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TVA_ADM	char	Rsn total not adm administrative		Collected at CRF.
TESTADM	char	Test dose administered		Collected at CRF.
STP1_AD	char	First interrupt administrative		Collected at CRF.
PROPGIV	char	Prophylactic medication given		Collected at CRF.
ADMN_ND	char	Administration not done		Collected at CRF.
ANTIHT	char	Antihistamine prophylaxis		Collected at CRF.
C_ADMAT	char	Correct admin material used		Collected at CRF.
INTRRPT	char	Infusion interrupted		Collected at CRF.
OTHPROP	char	Other prophylactic med given		Collected at CRF.
PARACET	char	Paracetamol prophylaxis		Collected at CRF.
REAS_ND	char	Reason not done		Collected at CRF.
STP1_AE	char	First interruption reason is AE		Collected at CRF.
STP2_AE	char	Second interruption reason is AE		Collected at CRF.
TOT_ADM	char	Total dose administered		Collected at CRF.
START_DY	num	Relative Administration start Day		If START_DT and LCENR_DT not missing then perform below logic to calculate START_DY, If START_DT less than LCENR_DT then (START_DT - LCENR_DT).Else if START_DT is greater than equal to LCENR_DT then (START_DT- LCENR_DT) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUNIQUEP ,CLASSD ,PREFTRM ,ONSET_DY
Sorted by	DUNIQUEP ,CLASSD ,PREFTRM ,ONSET_DY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values or due to non significant elements:</p> <p>F_STATUS, PAG_NAME, PAGE_SEQ, AE_LINE, AE_DESC, ONSET_DY, ONSET_MO, ONSET_YR, RESOL_DY, RESOL_MO, RESOL_YR, CRF_PAGE, SER_5, SER_3, SER_1, SER_2, SER_4, RESOL_DT, ONSET_DT</p>

Variable	Type	Label	Codes	Comments
WHOART	char	WHOART AE code		Collected at CRF.
CLASS	char	System organ class code		Collected at CRF.
CLASSD	char	System organ class		Collected at CRF.
PREFTRM	char	Preferred term code		Collected at CRF.
PREFTRMD	char	Preferred term		Collected at CRF.
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
ONSET_HR	num	Onset hour		Collected at CRF.
ONSET_MI	num	Onset minute		Collected at CRF.
ONSET_TM	num	Onset time		Collected at CRF.
RESOL_HR	num	Resolution hour		Collected at CRF.
RESOL_MI	num	Resolution minute		Collected at CRF.
RESOL_TM	num	Resolution time		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
SEV	char	AE intensity		Collected at CRF.
SER_7	char	Not serious		Collected at CRF.
SER_6	char	Other serious		Collected at CRF.
ACT_TAK	char	Action taken with study agent		Collected at CRF.
ACT_TK2	char	Action taken w/ 2nd study agent		Collected at CRF.
AETREAT	char	Event treated		Collected at CRF.
AE_REL	char	Relationship to study agent		Collected at CRF.
AE_REL2	char	Relationship to 2nd study agent		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATEGORY	char	AE category		Collected at CRF.
CONT	char	Event continuing		Collected at CRF.
ONSET_DY	num	Relative Onset Day		If ONSET_DT and LCENR_DT not missing then perform below logic to calculate ONSET_DY, If ONSET_DT less than LCENR_DT then (ONSET_DT - LCENR_DT).Else if ONSET_DT is greater than equal to LCENR_DT then (ONSET_DT- LCENR_DT) +1.
RESOL_DY	num	Relative Resolution Day		If RESOL_DT and LCENR_DT not missing then perform below logic to calculate RESOL_DY, If RESOL_DT less than LCENR_DT then (RESOL_DT - LCENR_DT).Else if RESOL_DT is greater than equal to LCENR_DT then (RESOL_DT- LCENR_DT) +1.

1.4.4.Allergies – ALLERGY

Dataset	ALLERGY
Creating program	allergy.sas
Description	Allergies
Unique identifier	DUNIQUEP ,POLLEN
Sorted by	DUNIQUEP ,POLLEN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS, PAG_NAME, DRUGSPEC, FOODSPEC, POLLSPEC, OTHRSPEC, CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
POLLEN	char	History of pollen allergies		Collected at CRF.

Variable	Type	Label	Codes	Comments
OTHER	char	History of other allergies		Collected at CRF.
DRUG	char	History of drug allergies		Collected at CRF.
FOOD	char	History of food allergies		Collected at CRF.

1.4.5. Comments-COMMENTS

Dataset	COMMENT
Creating program	comment.sas
Description	Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Empty dataset will be submitted.
DCNO	char	Center ID Assigned for De-identity		Empty dataset will be submitted.
DPATNO	char	Patient Number Assigned for De-identity		Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
VISIT	char	Study Visit		Empty dataset will be submitted.
DPATID	char	Patid Assigned for De-identity		Empty dataset will be submitted.
DUNIQUEP	char	Unique_P Assigned for De-identity		Empty dataset will be submitted.

1.4.6. Prior Procedures/Inj. Affecting a Joint – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Prior Procedures/Inj. Affecting a Joint
Unique identifier	DUNIQUEP, JOINT, PR_TYPE, VISIT
Sorted by	DUNIQUEP, JOINT, PR_TYPE, 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: F_STATUS, PAG_NAME, PAGE_SEQ, LINE_NO, JNTSPEC, PROCSPEC, RSN_SPEC, PROC_DY, PROC_MO, PROC_YR, CRF_PAGE, PROC_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
JOINT	num	Joint		Collected at CRF.
PR_TYPE	num	Procedure code		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
STARTPR	char	Prior		Collected at CRF.
IN_OUT	char	Site of care		Collected at CRF.
PROCRSN	char	Procedure reason		Collected at CRF.
REPORT	char	Report attached		Collected at CRF.
PR_TYPED	char	Decode of PR_TYPE		Collected at CRF.
JOINTD	char	Decode of JOINT		Collected at CRF.
PROC_DY	num	Relative Procedure start Day		If PROC_DT and LCENR_DT not missing then perform below logic to calculate PROC_DY ,If PROC_DT less than LCENR_DT then (PROC_DT - LCENR_DT).Else if PROC_DT is greater than equal to LCENR_DT then (PROC_DT- LCENR_DT) +1.

1.4.7. Patient Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Patient Selection Criteria
Unique identifier	DUNIQUEP, CONS_DY
Sorted by	DUNIQUEP, CONS_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values or due to non significant elements: F_STATUS, PAG_NAME, CONS_DY, CONS_MO, CONS_YR, XCRIT_4, RSNENROL, RSNSPEC, CRF_PAGE, CONS_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
ICRIT_1	char	First incl. criterion not met		Collected at CRF.
ICRIT_2	char	Second incl. criterion not met		Collected at CRF.
ICRIT_3	char	Third incl. criterion not met		Collected at CRF.
ICRIT_4	char	Fourth incl. criterion not met		Collected at CRF.

Variable	Type	Label	Codes	Comments
XCRIT_1	char	First exclusion criterion met		Collected at CRF.
XCRIT_2	char	Second exclusion criterion met		Collected at CRF.
XCRIT_3	char	Third exclusion criterion met		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity.
CRITMET	char	All criteria met		Collected at CRF.
CNS_SGN	char	Consent signed		Collected at CRF.
CONS_DY	num	Relative Informed consent Day		If CONS_DT and LCENR_DT not missing then perform below logic to calculate CONS_DY, If CONS_DT- less than LCENR_DT then (CONS_DT- LCENR_DT).Else if CONS_DT is greater than equal to LCENR_DT then (CONS_DT- LCENR_DT) +1.

1.4.8. Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS, PAG_NAME, DOD_DY, DOD_MO, DOD_YR, CRF_PAGE, DOD_DT, PROBCAUS

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
TOD_HR	num	Hour of death		Collected at CRF.
TOD_MI	num	Minute of death		Collected at CRF.
TOD_TM	num	Time of death		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
AUTOPSY	char	Autopsy performed		Collected at CRF.
DOD_DY	num	Relative Day of death		If DOD_DT and LCENR_DT not missing then perform below logic to calculate DOD_DY, If DOD_DT less than LCENR_DT then (DOD_DT - LCENR_DT).Else if DOD_DT is greater than equal to LCENR_DT then (DOD_DT- LCENR_DT) +1.

1.4.9. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,ECG_DY,ECG_MO, ECG_YR, CRF_PAGE, ECG_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
ECGRSLT	char	ECG result		Collected at CRF.
ECG_DY	num	Relative ECG Day		If ECG_DT and LCENR_DT not missing then perform below logic to calculate ECG_DY, If ECG_DT less than LCENR_DT then (ECG_DT - LCENR_DT).Else if ECG_DT is greater than equal to LCENR_DT then (ECG_DT- LCENR_DT) +1.

1.4.10. Disability Index of Health Assess. Quest - HAQ

Dataset	HAQ
Creating program	haq.sas
Description	Disability Index of Health Assess. Quest
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values or due to non significant elements: PERMFLG1,PERMFLG3,PERMFLG4,PERMFLG6,PERMFLG8,F_STATUS,PAG_NAME,SPEC1,SPEC2,CRF_PAGE

Variable	Type	Label	Codes	Comments
TXT_1	char	Use of other aids/devices - Category 1		Collected at CRF.
TXT_2	char	Use of other aids/devices - Category 2		Collected at CRF.
TXT_3	char	Use of other aids/devices - Category 3		Collected at CRF.
TXT_4	char	Use of other aids/devices - Category 4		Collected at CRF.
TXT_5	char	Use of other aids/devices - Category 5		Collected at CRF.

Variable	Type	Label	Codes	Comments
TXT_6	char	Use of other aids/devices - Category 6		Collected at CRF.
TXT_7	char	Use of other aids/devices - Category 7		Collected at CRF.
TXT_8	char	Use of other aids/devices - Category 8		Collected at CRF.
PERMFLG2	char	Adj. permanent devices flag - Category 2		Collected at CRF.
PERMFLG5	char	Adj. permanent devices flag - Category 5		Collected at CRF.
PERMFLG7	char	Adj. permanent devices flag - Category 7		Collected at CRF.
NOTTOADJ	char	Other aids/devices not requiring adjust.		Collected at CRF.
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Unique Center ID for De-identity
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
Q1	num	HAQ question 1		Collected at CRF.
Q2	num	HAQ question 2		Collected at CRF.
Q3	num	HAQ question 3		Collected at CRF.
Q4	num	HAQ question 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q5	num	HAQ question 5		Collected at CRF.
Q6	num	HAQ question 6		Collected at CRF.
Q7	num	HAQ question 7		Collected at CRF.
Q8	num	HAQ question 8		Collected at CRF.
Q9	num	HAQ question 9		Collected at CRF.
Q10	num	HAQ question 10		Collected at CRF.
Q11	num	HAQ question 11		Collected at CRF.
Q12	num	HAQ question 12		Collected at CRF.
Q13	num	HAQ question 13		Collected at CRF.
Q14	num	HAQ question 14		Collected at CRF.
Q15	num	HAQ question 15		Collected at CRF.
Q16	num	HAQ question 16		Collected at CRF.
Q17	num	HAQ question 17		Collected at CRF.
Q18	num	HAQ question 18		Collected at CRF.
Q19	num	HAQ question 19		Collected at CRF.
Q20	num	HAQ question 20		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
HAQ_ND	char	HAQ not done		Collected at CRF.

Variable	Type	Label	Codes	Comments
CAT8	char	HAQ aid, device/help category 8		Collected at CRF.
CAT6	char	HAQ aid, device/help category 6		Collected at CRF.
CAT4	char	HAQ aid, device/help category 4		Collected at CRF.
CAT23	char	HAQ aid, device/help category 23		Collected at CRF.
CAT21	char	HAQ aid, device/help category 21		Collected at CRF.
CAT2	char	HAQ aid, device/help category 2		Collected at CRF.
CAT1	char	HAQ aid, device/help category 1		Collected at CRF.
CAT10	char	HAQ aid, device/help category 10		Collected at CRF.
CAT11	char	HAQ aid, device/help category 11		Collected at CRF.
CAT12	char	HAQ aid, device/help category 12		Collected at CRF.
CAT13	char	HAQ aid, device/help category 13		Collected at CRF.
CAT14	char	HAQ aid, device/help category 14		Collected at CRF.

Variable	Type	Label	Codes	Comments
CAT15	char	HAQ aid, device/help category 15		Collected at CRF.
CAT16	char	HAQ aid, device/help category 16		Collected at CRF.
CAT17	char	HAQ aid, device/help category 17		Collected at CRF.
CAT18	char	HAQ aid, device/help category 18		Collected at CRF.
CAT19	char	HAQ aid, device/help category 19		Collected at CRF.
CAT20	char	HAQ aid, device/help category 20		Collected at CRF.
CAT22	char	HAQ aid, device/help category 22		Collected at CRF.
CAT3	char	HAQ aid, device/help category 3		Collected at CRF.
CAT5	char	HAQ aid, device/help category 5		Collected at CRF.
CAT7	char	HAQ aid, device/help category 7		Collected at CRF.
CAT9	char	HAQ aid, device/help category 9		Collected at CRF.

1.4.11. Hospitalization – HOSPIN

Dataset	HOSPIN
Creating program	hospin.sas
Description	Hospitalization
Unique identifier	DUNIQUEP ,VISIT, HADM_DY, HDIS_DY
Sorted by	DUNIQUEP ,VISIT, HADM_DY, HDIS_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,PAGE_SEQ,PAGE_OF,HADM_DY,HADM_MO,HADM_YR,HDIS_DY,HDIS_MO,HDIS_YR,DIAGNOS,CRF_PAGE, HADM_DT, HDIS_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
ICU_DAYS	num	Total number of days in ICU		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.

Variable	Type	Label	Codes	Comments
NODSCHG	char	Not discharged		Collected at CRF.
NJTPROC	char	Non-joint surg/procs performed		Collected at CRF.
ARTHREL	char	Arthritis related hosp.		Collected at CRF.
HADM_DY	num	Relative Hospital admission Day		If HADM_DT and LCENR_DT not missing then perform below logic to calculate HADM_DY, If HADM_DT less than LCENR_DT then (HADM_DT - LCENR_DT).Else if HADM_DT is greater than equal to LCENR_DT then (HADM_DT- LCENR_DT) +1.
HDIS_DY	num	Relative Hospital discharge Day		If HDIS_DT and LCENR_DT not missing then perform below logic to calculate HDIS_DY ,if HDIS_DT less than LCENR_DT then (HDIS_DT - LCENR_DT).Else if HDIS_DT is greater than equal to LCENR_DT then (HDIS_DT- LCENR_DT) +1.

1.4.12. Immunization – IMMUN

Dataset	IMMUN
Creating program	immun.sas
Description	Immunization
Unique identifier	DUNIQUEP, INJSITE ,VAC_ADM ,VISIT
Sorted by	DUNIQUEP, INJSITE ,VAC_ADM ,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: F_STATUS,PAG_NAME,ABOBT_SP,CORINT_S,VACADM_S,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
VAC_ADM	char	Vaccine administered		Collected at CRF.
INJSITE	char	Injection site		Collected at CRF.

Variable	Type	Label	Codes	Comments
COR_INT	char	AB drawn at correct interval		Collected at CRF.
AB_OBT	char	Antibody obtained/sent		Collected at CRF.

1.4.13. Infection Summary– INFCTSUM

Dataset	INFCTSUM
Creating program	infctsum.sas
Description	Infection Summary
Unique identifier	DUNIQUEP, INF_DUR, INF_OUT, VISIT
Sorted by	DUNIQUEP, INF_DUR, INF_OUT, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values or due to non significant elements: F_STATUS,PAG_NAME,PAGE_SEQ,PAGE_OF,OINFSPEC,PROCSPEC,CRF_PAGE,PROTOZL

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
INF_OUT	num	Infection outcome code		Collected at CRF.
INF_DUR	num	Duration of infection value		Collected at CRF.
DUR_UN	num	Duration units		Collected at CRF.
DUR_COD	num	Duration code		Collected at CRF.
SIMCHRAC	num	Similar chronic/acute infections		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
UNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity.
WNDCULT	char	Wound or drainage cultured		Collected at CRF.
STAPH_A	char	Staph aureus infection		Collected at CRF.
SIMINFS	char	History of similar infections		Collected at CRF.
BX_HST	char	Biopsy/histology performed		Collected at CRF.
CT_US	char	CT scan or ultrasound performed		Collected at CRF.
CULTPOS	char	Cultures indicated infection		Collected at CRF.
CULTURE	char	Cultures performed		Collected at CRF.
CXR	char	Chest X-ray performed		Collected at CRF.
FUNGAL	char	Fungal		Collected at CRF.

Variable	Type	Label	Codes	Comments
GRAMNEG	char	Gram negative		Collected at CRF.
GRAMPOS	char	Other gram positive		Collected at CRF.
MYCOBCT	char	Mycobacterial		Collected at CRF.
ANTIMCR	char	Antimicrobial tx given for inf.		Collected at CRF.
BLDCULT	char	Blood cultured		Collected at CRF.
OTHCULT	char	Other cultured		Collected at CRF.
OTHDXPR	char	Other diagnostic procs performed		Collected at CRF.
OTHPROC	char	Other procedure performed		Collected at CRF.
OTH_INF	char	Other infection		Collected at CRF.
R_ANTIM	char	Resolved w/ antimicrobial tx		Collected at CRF.
R_SPONT	char	Resolved spontaneously		Collected at CRF.
R_SURG	char	Resolved with surgical treatment		Collected at CRF.
SPUCULT	char	Sputum cultured		Collected at CRF.
STREP	char	Streptococcus infection		Collected at CRF.
VIRAL	char	Viral		Collected at CRF.
URICULT	char	Urine cultured		Collected at CRF.
SURGERY	char	Surgery performed		Collected at CRF.

1.4.14. Ivrsrand-IVRSRAND

Dataset	IVRSRAND
Creating program	ivrsrand.sas
Description	Ivrsrand
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SITENO PATIENT

Variable	Type	Label	Codes	Comments
TRTGRP	char	Randomized treatment code		Collected at CRF.
RANDTRT	char	Randomized treatment		Collected at CRF.
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity .
DPATID	char	Patid Assigned for De-identity		Randomly assigned Unique Patid for De-identity .

1.4.15. Upper Extremity Joint Evaluation – JNTSCORE

Dataset	JNTSCORE
Creating program	jntscore.sas
Description	Upper Extremity Joint Evaluation
Unique identifier	DUNIQUEP, VISIT, JOINT
Sorted by	DUNIQUEP, VISIT, JOINT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.

Variable	Type	Label	Codes	Comments
JOINT	num	Joint		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity .
SWELL	char	Joint swelling on exam		Collected at CRF.
JNT_NE	char	Joint not evaluable		Collected at CRF.
PAIN	char	Joint pain/tenderness on exam		Collected at CRF.
JOINTD	char	Decode of JOINT		Collected at CRF.

1.4.16. Local Lab Results– LAB

Dataset	LAB
Creating program	lab.sas
Description	Local Lab Results
Unique identifier	DUNIQUEP, TESTCOD, VISIT, STDRES, LAB_DY, LAB_TM
Sorted by	DUNIQUEP, TESTCOD, VISIT, STDRES, LAB_DY, LAB_TM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,LABELNUM,LAB_DY,LAB_MO,LAB_YR,CRF_PAGE,TEST COM, LAB_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Unique Center ID for De-identity .
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Unique Patient Number for De-identity .
PAG_NAME	char	Page		Collected at CRF.
TESTCOD	char	Test code		Collected at CRF.
LAB_HR	num	Hour of sample		Collected at CRF.
LAB_MI	num	Minute of sample		Collected at CRF.
LAB_TM	num	Time of sample		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAB_CODE	char	Prtcl/site specific code for lab		Collected at CRF.
ENT_RES	char	Test result		Collected at CRF.
NORM_LOW	char	Lower normal rng - test result		Collected at CRF.
NORM_HI	char	Upper normal rng - test result		Collected at CRF.
UNITS	char	Units - test result		Collected at CRF.
STDRES	char	Standardized test result		Collected at CRF.
STDUNIT	char	Units - std result		Collected at CRF.
STDNRMLO	char	Lower normal rng - std result		Collected at CRF.
STDNRMHI	char	Upper normal rng - std result		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
UNITSD	char	Decode of UNITS		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly assigned Unique Patid for De-identity .
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
HILOFLG	char	Out of range flag		Collected at CRF.
TESTCODD	char	Decode of TESTCOD		Collected at CRF.
LAB_DY	num	Relative Day of sample		If LAB_DT and LCENR_DT not missing then perform below logic to calculate LAB_DY, If LAB_DT less than LCENR_DT then (LAB_DT - LCENR_DT Else if LAB_DT is greater than equal to LCENR_DT then (LAB_DT- LCENR_DT) +1.

1.4.17. Dipstick Urinalysis – LAB_ANCL

Dataset	LAB_ANCL
Creating program	lab_ancl.sas
Description	Dipstick Urinalysis
Unique identifier	DUNIQUEP, VISIT, TESTCOD ,LAB_DY
Sorted by	DUNIQUEP, VISIT, TESTCOD ,LAB_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements : F_STATUS,PAG_NAME,LAB_DY,LAB_MO,LAB_YR,CRF_PAGE, LAB_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Unique Center ID for De-identity .
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number Assigned for De-identity
TESTCOD	char	Test code		Collected at CRF.
RESCODE	num	Test result code		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly assigned Unique Patid for De-identity .
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.

Variable	Type	Label	Codes	Comments
TESTCOM	char	Test comment		Collected at CRF.
TESTCODD	char	Decode of TESTCOD		Collected at CRF.
LAB_DY	num	Relative Day of sample		If LAB_DT and LCENR_DT not missing then perform below logic to calculate LAB_DY, If LAB_DT less than LCENR_DT then (LAB_DT - LCENR_DT).Else if LAB_DT is greater than equal to LCENR_D T then (LAB_DT- LCENR_DT) +1.

1.4.18. Extra- Articular Manifestations of RA – MANIFST

Dataset	MANIFST
Creating program	manifst.sas
Description	Extra-Articular Manifestations of RA
Unique identifier	DUNIQUEP, VISIT, RESPONS, MANIFST
Sorted by	DUNIQUEP, VISIT, RESPONS, MANIFST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,OTHMANIF,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
RESPONS	char	Any history		Collected at CRF.
ONGOING	char	Condition ongoing		Collected at CRF.
MANIFEST	char	Extra-articular manifestation		Collected at CRF.

1.4.19. Concomitant Medications – MEDS

Dataset	MEDS
Creating program	meds.sas
Description	Concomitant Medications
Unique identifier	DUNIQUEP, RX_NAME, RXEND_DY, REASCHG
Sorted by	DUNIQUEP, RX_NAME, RXEND_DY, REASCHG
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,PAGE_SEQ,LINE_NO,RX_IND,RXST_DY,RXST_MO,RXST_YR,RXEND_DY,RXEND_MO,RXEND_YR,DRECNO,SEQ1,SEQ2,CRF_PAGE, RXST_DT, RXEND_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Unique Center ID for De-identity .
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
RX_NAME	char	Name of medication		Collected at CRF.
ROUTECD	num	Route Code		Collected at CRF.
ROUTE_V	char	Route specified on the CRF		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSAGE	char	Dose of concomitant medication		Collected at CRF.
DOSEUNT	num	Code for units of medication		Collected at CRF.
D_UNITV	char	Dose unit specified on the CRF		Collected at CRF.
RX_FREQ	num	Frequency of medication		Collected at CRF.
FREQ_V	char	Frequency specified on CRF		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
PREFTERM	char	Preferred name		Collected at CRF.
ROUTECD	char	Decode of ROUTECD		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly assigned Unique Patid for De-identity .
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
STARTPR	char	Prior		Collected at CRF.
REASCHG	char	Reason for dose change		Collected at CRF.
RX_CONT	char	Pt. continues taking medication		Collected at CRF.
RX_FREQD	char	Decode of RX_FREQ		Collected at CRF.
DOSEUNTD	char	Decode of DOSEUNT		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXST_DY	num	Relative Medication start Day		If RXST_DT and LCENR_DT not missing then perform below logic to calculate RXST_DY, If RXST_DT less than LCENR_DT then (RXST_DT - LCENR_DT).Else if RXST_DT is greater than equal to LCENR_DT then (RXST_DT- LCENR_DT) +1.
RXEND_DY	num	Relative Medication end Day		If RXEND_DT and LCENR_DT not missing then perform below logic to calculate RXEND_DY, If RXEND_DT less than LCENR_DT then (RXEND_DT - LCENR_DT).Else if RXEND_DT is greater than equal to LCENR_DT then (RXEND_DT- LCENR_DT) +1.

1.4.20. DMARD History – MEDSUMM

Dataset	MEDSUMM
Creating program	medsumm.sas
Description	DMARD History
Unique identifier	DUNIQUEP, PREFTERM
Sorted by	DUNIQUEP, PREFTERM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,RX_NAME,DRECNO,SEQ1,SEQ2,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
PREFTERM	char	Preferred name		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.

1.4.21. Methotrexate Summary – MTXSUM

Dataset	MTXSUM
Creating program	mtxsum.sas
Description	Methotrexate Summary
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,RAEPG,RAESEQ,RAEOF,RAELN,RSPEC,MAEPG,MAESEQ, ,MAELN,MSPEC,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
MAEOF	num	Not maintained AE pgs. in series		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
R_RSN	char	Reason target dose not reached		Collected at CRF.
M_RSN	char	Rsn target dose not maintained		Collected at CRF.
MAINTND	char	Target MTX dose maintained		Collected at CRF.
REACHED	char	Target MTX dose reached		Collected at CRF.

1.4.22. Pharmacy Records – PHARM

Dataset	PHARM
Creating program	pharm.sas
Description	Pharmacy Records
Unique identifier	DUNIQUEP, WEEK
Sorted by	DUNIQUEP, WEEK
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: LOTUSED,PHRMPAGE, DATEPREP, DOSEWGT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Protocol Identifier-Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEEK	char	Week		Collected at CRF.
PHRMDOSE	char	Dose in mg/kg		Collected at CRF.
X_ML	num	mL (per kg weight)		Collected at CRF.
VOLTOUSE	num	Volume to use (mL)		Collected at CRF.
NUMVIALS	num	Number of vials reconstituted		Collected at CRF.
VOLDRAWN	num	Volume withdrawn from vial(s) (mL)		Collected at CRF.
TOTALVOL	num	Total diluted volume (mL)		Collected at CRF.
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DATEPRDY	num	Relative Day prepared		If DATEPREP and LCENR_DT not missing then perform below logic to calculate DATEPRDY ,if DATEPREP less than LCENR_DT then (DATEPREP - LCENR_DT).Else if DATEPREP is greater than equal to LCENR_DT then (DATEPREP- LCENR_DT) +1.

1.4.23. Prior Murine/Chimeric MAB Treatment – PRIORTX

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

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
RCVDMAB	char	Patient received prior MAB tx		Collected at CRF.

1.4.24. Health Survey – QOL

Dataset	QOL
Creating program	qol.sas
Description	Health Survey
Unique identifier	DUNIQUEP, GH1, RP2 ,VISIT
Sorted by	DUNIQUEP, GH1, RP2 ,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: F_STATUS,PAG_NAME,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
GH1	num	Score for QOL question 1		Collected at CRF.
HT	num	Score for QOL question 2		Collected at CRF.
PF01	num	Score for QOL question 3A		Collected at CRF.
PF02	num	Score for QOL question 3B		Collected at CRF.
PF03	num	Score for QOL question 3C		Collected at CRF.

Variable	Type	Label	Codes	Comments
PF04	num	Score for QOL question 3D		Collected at CRF.
PF05	num	Score for QOL question 3E		Collected at CRF.
PF06	num	Score for QOL question 3F		Collected at CRF.
PF07	num	Score for QOL question 3G		Collected at CRF.
PF08	num	Score for QOL question 3H		Collected at CRF.
PF09	num	Score for QOL question 3I		Collected at CRF.
PF10	num	Score for QOL question 3J		Collected at CRF.
RP1	num	Score for QOL question 4A		Collected at CRF.
RP2	num	Score for QOL question 4B		Collected at CRF.
RP3	num	Score for QOL question 4C		Collected at CRF.
RP4	num	Score for QOL question 4D		Collected at CRF.
RE1	num	Score for QOL question 5A		Collected at CRF.
RE2	num	Score for QOL question 5B		Collected at CRF.
RE3	num	Score for QOL question 5C		Collected at CRF.
SF1	num	Score for QOL question 6		Collected at CRF.
BP1	num	Score for QOL question 7		Collected at CRF.
BP2	num	Score for QOL question 8		Collected at CRF.
VT1	num	Score for QOL question 9A		Collected at CRF.
MH1	num	Score for QOL question 9B		Collected at CRF.
MH2	num	Score for QOL question 9C		Collected at CRF.
MH3	num	Score for QOL question 9D		Collected at CRF.

Variable	Type	Label	Codes	Comments
VT2	num	Score for QOL question 9E		Collected at CRF.
MH4	num	Score for QOL question 9F		Collected at CRF.
VT3	num	Score for QOL question 9G		Collected at CRF.
MH5	num	Score for QOL question 9H		Collected at CRF.
VT4	num	Score for QOL question 9I		Collected at CRF.
SF2	num	Score for QOL question 10		Collected at CRF.
GH2	num	Score for QOL question 11A		Collected at CRF.
GH3	num	Score for QOL question 11B		Collected at CRF.
GH4	num	Score for QOL question 11C		Collected at CRF.
GH5	num	Score for QOL question 11D		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
QOL_ND	char	QOL survey not done		Collected at CRF.

1.4.25. Patient Response Parameters – RAEVAL

Dataset	RAEVAL
Creating program	raeval.sas
Description	Patient Response Parameters
Unique identifier	DUNIQUEP, VISIT, ASSESSOR, MORNSTIF
Sorted by	DUNIQUEP, VISIT, ASSESSOR, MORNSTIF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Unique Center ID for De-identity
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
ASSESSOR	char	Initials of joint assessor		Collected at CRF.
PAINSCOR	num	Patient VAS pain score		Collected at CRF.
TIRESCOR	num	Patient VAS tiredness score		Collected at CRF.
GDA_PAT	num	Patient VAS score for GDA		Collected at CRF.
MORNSTIF	num	Morning stiffness duration-mins.		Collected at CRF.

Variable	Type	Label	Codes	Comments
GDA_EVAL	num	Evaluator VAS score for GDA		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
UNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
TS_SWEL	char	Swelling in tendon sheaths		Collected at CRF.

1.4.26. RA Diagnosis – RAINFO

Dataset	RAINFO
Creating program	rainfo.sas
Description	RA Diagnosis
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,DIAG_DY,DIAG_MO,DIAG_YR,CRF_PAGE, DIAG_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
ANASTAGE	num	Anatomical stage of RA		Collected at CRF.
FUNCLASS	num	Functional class		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
DIAG_DY	num	Relative Day of diagnosis		If DIAG_DT and LCENR_DT not missing then perform below logic to calculate DIAG_DY, If DIAG_DT less than LCENR_DT then (DIAG_DT - LCENR_DT).Else if DIAG_DT is greater than equal to LCENR_DT then (DIAG_DT- LCENR_DT) +1.

1.4.27. Randomization – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: F_STATUS,PAG_NAME,LCENR_DY,LCENR_MO,LCENR_YR,RSN_SPEC,CRF_PAG E,NT_AE,ALT_TX,WC_ADM,OTH_RSN, LCENR_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Unique Patient Number for De-identity .
LCENR_HR	num	Local enrollment hour		Collected at CRF.
LCENR_MI	num	Local enrollment minute		Collected at CRF.
LCENR_TM	num	Local enrollment time		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
WC_STDY	char	Cons wthdrwn for study particip.		Collected at CRF.
NT_ILL	char	Not treated rsn illness		Collected at CRF.
TREATED	char	Treated		Collected at CRF.

1.4.28. Tuberculosis History and PPD Results – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Tuberculosis History and PPD Results
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,PVAC_YR,PPD_DY,PPD_MO,PPD_YR,CRF_PAGE PPD_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Unique Center ID for De-identity .
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Unique Patient Number for De-identity .
PPD_RES	char	PPD results (induration)		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity .

Variable	Type	Label	Codes	Comments
TRT_REQ	char	Treatment required		Collected at CRF.
PRV_BCG	char	Previous BCG vaccination		Collected at CRF.
PPD_NR	char	PPD test not required		Collected at CRF.
PT_ATB	char	Previously treated active TB		Collected at CRF.
PT_LTB	char	Prev completed treatment for latent TB		Collected at CRF.
PPD_DY	num	Relative PPD Day		If PPD_DT and LCENR_DT not missing then perform below logic to calculate PPD_DY ,if PPD_DT less than LCENR_DT then (PPD_DT - LCENR_DT).Else if PPD_DT is greater than equal to LCENR_DT then (PPD_DT- LCENR_DT) +1.

1.4.29. Study Infusion Termination – TERMDOSE

Dataset	TERMDOSE
Creating program	termdose.sas
Description	Study Infusion Termination
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,DTRM_DY,DTRM_MO,DTRM_YR,DAEPG,DAEPGSEQ,D AEPGOF,DAEPGLN,DRSNSPEC,COMMENT,CRF_PAGE, DTRM_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.

Variable	Type	Label	Codes	Comments
DRSNCOD	char	Dosing termination rsn code		Collected at CRF.
DTRM_DY	num	Relative Dosing termination Day		If DTRM_DT and LCENR_DT not missing then perform below logic to calculate DTRM_DY, If DTRM_DT less than LCENR_DT then (DTRM_DT - LCENR_DT).Else if DTRM_DT is greater than equal to LCENR_DT then (DTRM_DT- LCENR_DT) +1.

1.4.30. Methotrexate Termination – TERMMTX

Dataset	TERMMTX
Creating program	termmtx.sas
Description	Methotrexate Termination
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the or due to non significant elements or due to non significant elements: F_STATUS,PAG_NAME,DTRM_DY,DTRM_MO,DTRM_YR,DAEPG,DAEPGSEQ,D AEPGOF,DAEPGLN,DRSNSPEC,COMMENT,CRF_PAGE, DTRM_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Unique Patient Number for De-identity .
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
DRSNCOD	char	Dosing termination rsn code		Collected at CRF.
DTRM_DY	num	Relative Dosing termination Day		If DTRM_DT and LCENR_DT not missing then perform below logic to calculate DTRM_DY, If DTRM_DT less than LCENR_DT then (DTRM_DT - LCENR_DT).Else if DTRM_DT is greater than equal to LCENR_DT then (DTRM_DT- LCENR_DT) +1.

1.4.31. Study Termination – TERMSTDY

Dataset	TERMSTDY
Creating program	termstdy.sas
Description	Study Termination
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: F_STATUS,PAG_NAME,STRM_DY,STRM_MO,STRM_YR,SAEPG,SAEPGSEQ,SAE PGOF,SAEPGLN,SRSNSPEC,COMMENT,CRF_PAGE, STRM_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.

Variable	Type	Label	Codes	Comments
SRSNCOD	char	Reason for study term code		Collected at CRF.
STRM_DY	num	Relative Study termination Day		If STRM_DT and LCENR_DT not missing then perform below logic to calculate STRM_DY, If STRM_DT less than LCENR_DT then (STRM_DT - LCENR_DT).Else if STRM_DT is greater than equal to LCENR_DT then (STRM_DT- LCENR_DT) +1.

1.4.32. Visit Information– VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visit Information
Unique identifier	DUNIQUEP,VISIT_DY, VISIT
Sorted by	DUNIQUEP,VISIT_DY, 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: F_STATUS,PAG_NAME,VISIT_DY,VISIT_MO,VISIT_YR,RSN_SPEC,CRF_PAGE, VISIT_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
VISITND	char	Indicates visit not done		Collected at CRF.
REAS_ND	char	Reason not done		Collected at CRF.
VISIT_DY	num	Relative Day of patient visit		If VISIT_DT and LCENR_DT not missing then perform below logic to calculate VISIT_DY ,If VISIT_DT less than LCENR_DT then (VISIT_DT - LCENR_DT).Else if VISIT_DT is greater than equal to LCENR_DT then (VISIT_DT- LCENR_DT) +1.

1.4.33. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DUNIQUEP ,VISIT
Sorted by	DUNIQUEP ,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the or due to non significant elements: F_STATUS,PAG_NAME,ZWGT,CRF_PAGE,ZWGT_UN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
SYST	num	Systolic BP (mmHg)		Collected at CRF.
DIAS	num	Diastolic BP (mmHg)		Collected at CRF.
HR	num	Heart rate in beats/minute		Collected at CRF.
ZTEMP	num	Entered body temperature		Collected at CRF.
WGT	char	Weight (kg)		Grouping the element to protect PII

Variable	Type	Label	Codes	Comments
VISIT	Char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
PE_PERF	char	Physical exam performed		Collected at CRF.
ZTMPMTH	char	Method to measure body temp.		Collected at CRF.

1.4.34. Chest X-ray– XRAY

Dataset	XRAY
Creating program	xray.sas
Description	Chest X-ray
Unique identifier	DUNIQUEP, XRAY_DY, XRYTYPE
Sorted by	DUNIQUEP, XRAY_DY, XRYTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the or due to non significant elements: F_STATUS,PAG_NAME,XRAY_DY,XRAY_MO,XRAY_YR,CRF_PAGE, XRAY_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly Assigned Unique Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly Assigned Unique Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
DPATID	char	Patid Assigned for De-identity		Randomly Assigned Unique Patid for De-identity.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly Assigned Unique_P for De-identity.
XRYTYPE	char	X-ray type		Collected at CRF.

Variable	Type	Label	Codes	Comments
XRYRSLT	char	X-ray result		Collected at CRF.
GHON	char	Ghons/calcfid grans/apical scar.		Collected at CRF.
EROS_RA	char	Evidence of erosive RA		Collected at CRF.
XRAY_DY	num	Relative Day of X-ray		If XRAY_DT and LCENR_DT not missing then perform below logic to calculate XRAY_DY ,If XRAY_DT less than LCENR_DT then (XRAY_DT - LCENR_DT).Else if XRAY_DT is greater than equal to LCENR_DT then (XRAY_DT- LCENR_DT) +1.