

Clinical Development

CNTO312

C0168T41

Anonymisation Data Derivation Specification Document

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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. Demography – DEMOG.....	7
1.4.2. Dose Administration – ADMIN	9
1.4.3. Adverse Events – AE	11
1.4.4. Any_none – ANY_NONE.....	14
1.4.5. Commercial Anti-TNF Therapy – COMTRSUM.....	15
1.4.6. Prior Joint Procedures/Injections – CONPROC	16
1.4.7. Patient Selection Criteria – CRITERIA.....	18
1.4.8. Drug Preparation – DRUGACCT	19
1.4.9. Drugacct_scram – DRGACSCR	21
1.4.10. Health Assessment Questionnaire – HAQ	23
1.4.11. Infection Summary – INFCTSUM.....	26
1.4.12. IVRS – IVRS.....	31
1.4.13. IVRS Randomization – IVRSRAND.....	32
1.4.14. Lower Extremity Joint Evaluation Left Side – JNTSC_LL.....	33
1.4.15. Lower Extremity Joint Evaluation Right Side – JNTSC_LR	35
1.4.16. Upper Extremity Joint Evaluation Left Side – JNTSC_UL.....	36
1.4.17. Upper Extremity Joint Evaluation Right Side – JNTSC_UR	38
1.4.18. Laboratory Tests – LAB.....	39
1.4.19. Extra-Articular Manifestations of RA – MANIFEST	42
1.4.20. Medical History – MEDHX.....	44
1.4.21. Concomitant Medications – MEDS.....	46
1.4.22. Medication Review – MEDSUMM.....	48
1.4.23. Page Sequence – PAGE_SEQ.....	52
1.4.24. Pharmacokinetic and ATSA – PK_ATSA	53
1.4.25. Questionnaires – QOL	57

1.4.26.	Patient Assessment – RAEVAL.....	60
1.4.27.	Diagnosis Information – RAINFO.....	61
1.4.28.	Randcode – Randcode	63
1.4.29.	Tuberculosis History and PPD Results – TB_INFO	64
1.4.30.	Permanent Discontinuation of Study Infusions – TERMDOSE.....	66
1.4.31.	Study Termination – TERMSTDY.....	69
1.4.32.	Study Treatment Unblinding – UNBLIND.....	71
1.4.33.	Visit Information – VISITS.....	73
1.4.34.	Vital Signs – VITALS.....	75

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset with zero observation will not be submitted (ex. INVSIG).
- IVRSRAND.RAND_DT (Local Randomization Date) will be used as Reference Date (referred as REF. DATE in the document) to derive relative days.

1.3. Data Files

The C0168T41 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demography – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demography
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BIRTHDT,SUBJINIT,BIRTHDTC</p> <p>Below listed variables were not part of the Raw dataset. These have been added to retain the demographic and treatment related information in the de-identified datasets:</p> <p>AGE (Source: PK_ATSA dataset) TRTGRP (Source: IVRSRAND and PK_ATSA datasets)</p>

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.

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

1.4.2. Dose Administration – ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Dose Administration
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EXSTDT,EXSTDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EXENTM	num	Administration End Time		Collected at CRF.
EXSTTM	num	Administration Start Time		Collected at CRF.
TOTAL_ML	num	Total mL Administered		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EXTVAEE	char	Reason Total Vol Not Adm Is AE		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXPRPINF	char	Total Dose Administered		Collected at CRF.
EXPROP	char	Prophylactic Medication Given		Collected at CRF.
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 REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE). Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC - REF.DATE) +1.

1.4.3. Adverse Events – AE

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
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.
PAG_NAME	char	Page		Collected at CRF.
AE_LINE	num	Line Number		Collected at CRF.
AESTHR	num	Onset Hour		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESTMI	num	Onset Minute		Collected at CRF.
AESTTM	num	Onset Time		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
AEENHR	num	Resolution Hour		Collected at CRF.
AEENMI	num	Resolution Minute		Collected at CRF.
AEENTM	num	Resolution Time		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
AESEV	char	AE Intensity		Collected at CRF.
SAEDTH	char	Fatal		Collected at CRF.
AEACTTRT	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.
INFECT	char	AE Infection		Collected at CRF.
SAELIFE	char	Life-Threatening		Collected at CRF.
AESERN	char	Not Serious		Collected at CRF.
SAEDISAB	char	Significant Disability		Collected at CRF.
SAEHOSP	char	Hospitalization		Collected at CRF.
SAEOTH	char	Other Serious		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
AEENDY	num	Relative Resolution Day		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC - REF.DATE) +1.
AESTDY	num	Relative Onset Day		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC - REF.DATE) +1.

1.4.4. Any_none – ANY_NONE

Dataset	ANY_NONE
Creating program	any_none.sas
Description	ANY_NONE
Unique identifier	DUNIQUEP,VISIT
Sorted by	DUNIQUEP,VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: ANYRECS

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity
PNO	char	Protocol Identifier - Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
NONE	char	No Records Reported		Collected at CRF.

1.4.5. Commercial Anti-TNF Therapy – COMTRSUM

Dataset	COMTRSUM
Creating program	comtrsum.sas
Description	Commercial Anti-TNF Therapy
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CTSPECTH	char	Specify Therapy		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
CTTHERTK	char	Therapy Taken		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

1.4.6. Prior Joint Procedures/Injections – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Prior Joint Procedures/Injections
Unique identifier	DUSUBJID,PR_TYPED,PRJOINTD,VISIT
Sorted by	DUSUBJID,PR_TYPED,PRJOINTD,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: PROC_DT,PROC_DY,PROC_MO,PROC_YR

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PRJNTSPC	char	Joint Specify		Collected at CRF.
PRJOINT	num	Joint		Collected at CRF.
LINE_NO	num	Line Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGE_SEQ	num	Page of Series		Collected at CRF.
PROCSPEC	char	Procedure Specify		Collected at CRF.
PR_TYPE	num	Procedure Code		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
PRTIMESN	char	Time Since Procedure		Collected at CRF.
PR_TYPED	char	Decode of Pr_Type		Collected at CRF.
PRJOINTD	char	Decode of Joint		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
PROC_DY	num	Relative Procedure Day		If PROC_DT and REF.DATE not missing then perform below logic to calculate PROC_DY, If PROC_DT less than REF.DATE then (PROC_DT - REF.DATE). Else if PROC_DT is greater than equal to REF.DATE then (PROC_DT- REF.DATE) +1.

1.4.7. Patient Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Patient Selection Criteria
Unique identifier	DUSUBJID,INCRIT,EXCRIT,VISIT
Sorted by	DUSUBJID,INCRIT,EXCRIT,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
INCRIT	char	Inclusion Criterion Not Met		Collected at CRF.
EXCRIT	char	Exclusion Criterion Present		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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

1.4.8. Drug Preparation – DRUGACCT

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DPVWDRWN	num	Volume Withdrawn (mL)		Collected at CRF.
DPVPREP	num	Total Diluted Volume (mL)		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPPLNDS	char	Plan Dose		Collected at CRF.
DPND	char	Not Done		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
DPDY	num	Relative Day Prepared		If DPDT and REF.DATE not missing then perform below logic to calculate DPDY, If DPDT less than REF.DATE then (DPDT - REF.DATE). Else if DPDT is greater than equal to REF.DATE then (DPDT - REF.DATE) +1.

1.4.9. Drugacct_scram– DRGACSCR

Dataset	DRGACSCR
Creating program	drugacct_scram.sas
Description	DRUGACCT_SCRAM
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DPDY,DPMO,DPYR,DPDT,DPLOTNO1,DPLOTNO2,DPLOTNO3

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPND	char	Not Done		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
DPVWDRWN	num	Volume Withdrawn (mL)		Collected at CRF.
DPVPREP	num	Total Diluted Volume (mL)		Collected at CRF.
DPPLNDS	char	Plan Dose		Collected at CRF.
DPDY	num	Relative Day Prepared		If DPDT and REF.DATE not missing then perform below logic to calculate DPDY, If DPDT less than REF.DATE then (DPDT - REF.DATE). Else if DPDT is greater than equal to REF.DATE then (DPDT - REF.DATE) +1.

1.4.10. Health Assessment Questionnaire – HAQ

Dataset	HAQ
Creating program	haq.sas
Description	Health Assessment Questionnaire
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HASPEC1,HASPEC2

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
HAQ1	num	HAQ Question 1		Collected at CRF.
HAQ10	num	HAQ Question 10		Collected at CRF.
HAQ11	num	HAQ Question 11		Collected at CRF.
HAQ12	num	HAQ Question 12		Collected at CRF.
HAQ13	num	HAQ Question 13		Collected at CRF.
HAQ14	num	HAQ Question 14		Collected at CRF.
HAQ15	num	HAQ Question 15		Collected at CRF.
HAQ16	num	HAQ Question 16		Collected at CRF.

Variable	Type	Label	Codes	Comments
HAQ17	num	HAQ Question 17		Collected at CRF.
HAQ18	num	HAQ Question 18		Collected at CRF.
HAQ19	num	HAQ Question 19		Collected at CRF.
HAQ2	num	HAQ Question 2		Collected at CRF.
HAQ20	num	HAQ Question 20		Collected at CRF.
HAQ3	num	HAQ Question 3		Collected at CRF.
HAQ4	num	HAQ Question 4		Collected at CRF.
HAQ5	num	HAQ Question 5		Collected at CRF.
HAQ6	num	HAQ Question 6		Collected at CRF.
HAQ7	num	HAQ Question 7		Collected at CRF.
HAQ8	num	HAQ Question 8		Collected at CRF.
HAQ9	num	HAQ Question 9		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
NOTDONE	char	Not Done		Collected at CRF.
HACAT9	char	HAQ Aid, Device/Help Category 9		Collected at CRF.
HACAT7	char	HAQ Aid, Device/Help Category 7		Collected at CRF.
HACAT5	char	HAQ Aid, Device/Help Category 5		Collected at CRF.
HACAT3	char	HAQ Aid, Device/Help Category 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
HACAT1	char	HAQ Aid, Device/Help Category 1		Collected at CRF.
HACAT10	char	HAQ Aid, Device/Help Category 10		Collected at CRF.
HACAT11	char	HAQ Aid, Device/Help Category 11		Collected at CRF.
HACAT12	char	HAQ Aid, Device/Help Category 12		Collected at CRF.
HACAT13	char	HAQ Aid, Device/Help Category 13		Collected at CRF.
HACAT14	char	HAQ Aid, Device/Help Category 14		Collected at CRF.
HACAT15	char	HAQ Aid, Device/Help Category 15		Collected at CRF.
HACAT16	char	HAQ Aid, Device/Help Category 16		Collected at CRF.
HACAT17	char	HAQ Aid, Device/Help Category 17		Collected at CRF.
HACAT19	char	HAQ Aid, Device/Help Category 19		Collected at CRF.
HACAT2	char	HAQ Aid, Device/Help Category 2		Collected at CRF.
HACAT20	char	HAQ Aid, Device/Help Category 20		Collected at CRF.
HACAT21	char	HAQ Aid, Device/Help Category 21		Collected at CRF.
HACAT22	char	HAQ Aid, Device/Help Category 22		Collected at CRF.
HACAT23	char	HAQ Aid, Device/Help Category 23		Collected at CRF.
HACAT4	char	HAQ Aid, Device/Help Category 4		Collected at CRF.
HACAT6	char	HAQ Aid, Device/Help Category 6		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

1.4.11. Infection Summary – INFCTSUM

Dataset	INFCTSUM
Creating program	infctsum.sas
Description	Infection Summary
Unique identifier	DUSUBJID, IFHX, IFANTIMC, VISIT
Sorted by	DUSUBJID, IFHX, IFANTIMC, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: IFOCLTSP, IFOINFSP, IFPROTZ

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AELN	num	AE CRF Line Number		Collected at CRF.
AELN2	num	AE CRF Line Number 2		Collected at CRF.
AELN3	num	AE CRF Line Number 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEOF	num	Number of AE Pages In Series		Collected at CRF.
AEOF2	num	Number of AE Pages In Series 2		Collected at CRF.
AEOF3	num	Number of AE Pages In Series 3		Collected at CRF.
AEPG	num	AE CRF Page		Collected at CRF.
AEPG2	num	AE CRF Page 2		Collected at CRF.
AEPG3	num	AE CRF Page 3		Collected at CRF.
AESEQ	num	AE Page Sequence		Collected at CRF.
AESEQ2	num	AE Page Sequence 2		Collected at CRF.
AESEQ3	num	AE Page Sequence 3		Collected at CRF.
MEDLN	num	Medication CRF Line Number		Collected at CRF.
MEDLN2	num	Medication CRF Line Number 2		Collected at CRF.
MEDLN3	num	Medication CRF Line Number 3		Collected at CRF.
MEDLN4	num	Medication CRF Line Number 4		Collected at CRF.
MEDLN5	num	Medication CRF Line Number 5		Collected at CRF.
MEDLN6	num	Medication CRF Line Number 6		Collected at CRF.
MEDLN7	num	Medication CRF Line Number 7		Collected at CRF.
MEDLN8	num	Medication CRF Line Number 8		Collected at CRF.
MEDLN9	num	Medication CRF Line Number 9		Collected at CRF.
MEDOF	num	Number of Medication Pages In Series		Collected at CRF.

Variable	Type	Label	Codes	Comments
MEDOF2	num	Number of Medication Pages In Series 2		Collected at CRF.
MEDOF3	num	Number of Medication Pages In Series 3		Collected at CRF.
MEDOF4	num	Number of Medication Pages In Series 4		Collected at CRF.
MEDOF5	num	Number of Medication Pages In Series 5		Collected at CRF.
MEDOF6	num	Number of Medication Pages In Series 6		Collected at CRF.
MEDOF7	num	Number of Medication Pages In Series 7		Collected at CRF.
MEDOF8	num	Number of Medication Pages In Series 8		Collected at CRF.
MEDOF9	num	Number of Medication Pages In Series 9		Collected at CRF.
MEDPG	num	Medication CRF Page		Collected at CRF.
MEDPG2	num	Medication CRF Page 2		Collected at CRF.
MEDPG3	num	Medication CRF Page 3		Collected at CRF.
MEDPG4	num	Medication CRF Page 4		Collected at CRF.
MEDPG5	num	Medication CRF Page 5		Collected at CRF.
MEDPG6	num	Medication CRF Page 6		Collected at CRF.
MEDPG7	num	Medication CRF Page 7		Collected at CRF.

Variable	Type	Label	Codes	Comments
MEDPG8	num	Medication CRF Page 8		Collected at CRF.
MEDPG9	num	Medication CRF Page 9		Collected at CRF.
MEDSEQ	num	Medication Page Sequence		Collected at CRF.
MEDSEQ2	num	Medication Page Sequence 2		Collected at CRF.
MEDSEQ3	num	Medication Page Sequence 3		Collected at CRF.
MEDSEQ4	num	Medication Page Sequence 4		Collected at CRF.
MEDSEQ5	num	Medication Page Sequence 5		Collected at CRF.
MEDSEQ6	num	Medication Page Sequence 6		Collected at CRF.
MEDSEQ7	num	Medication Page Sequence 7		Collected at CRF.
MEDSEQ8	num	Medication Page Sequence 8		Collected at CRF.
MEDSEQ9	num	Medication Page Sequence 9		Collected at CRF.
PAGE_OF	num	Total Pages In Series		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
IFWNDCLT	char	Wound or Drainage Cultured		Collected at CRF.
IFSPUCLT	char	Sputum Cultured		Collected at CRF.
IFMYCBCT	char	Mycobacterial		Collected at CRF.
IFANTIMC	char	Antimicrobial tx Given for Infection		Collected at CRF.

Variable	Type	Label	Codes	Comments
IFBLDCLT	char	Blood Cultured		Collected at CRF.
IFCLTPOS	char	Cultures Indicated Infection		Collected at CRF.
IFCLT	char	Cultures Performed		Collected at CRF.
IFFUNGAL	char	Fungal		Collected at CRF.
IFGRMNEG	char	Gram Negative		Collected at CRF.
IFGRMPOS	char	Other Gram Positive		Collected at CRF.
IFHX	char	History of Similar Infections		Collected at CRF.
IFSTAPHA	char	Staph Aureus Infection		Collected at CRF.
IFVIRAL	char	Viral		Collected at CRF.
IFURICLT	char	Urine Cultured		Collected at CRF.
IFSTREP	char	Streptococcus Infection		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

1.4.12. IVRS – IVRS

Dataset	IVRS
Creating program	ivrs.sas
Description	IVRS
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LCENR_DT,CRF_PAGE

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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
LCENR_DY	num	Relative Local Enrollment Day		If LCENR_DT and REF.DATE not missing then perform below logic to calculate LCENR_DY, If LCENR_DT less than REF.DATE then (LCENR_DT - REF.DATE). Else if LCENR_DT is greater than equal to REF.DATE then (LCENR_DT - REF.DATE) + 1.

1.4.13. IVRS Randomization – IVRSRAND

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

Variable	Type	Label	Codes	Comments
STRATUM	num	CRP Stratification - Prednisone Eq Use		Collected at CRF.
TRTCD	num	Randomized Treatment Code		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

1.4.14. Lower Extremity Joint Evaluation Left Side – JNTSC_LL

Dataset	JNTSC_LL
Creating program	jntsc_ll.sas
Description	Lower Extremity Joint Evaluation Left Side
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EVALUATR

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
JOINT	num	Joints		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
JOINTD	char	Joints Decode		Collected at CRF.
JTNE	char	Joints Not Evaluable		Collected at CRF.
JTSWELL	char	Joints Swelling		Collected at CRF.
JTPAIN	char	Joints Pain/Tenderness		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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. Lower Extremity Joint Evaluation Right Side – JNTSC_LR

Dataset	JNTSC_LR
Creating program	jntsc_lr.sas
Description	Lower Extremity Joint Evaluation Right Side
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
JOINT	num	Joints		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
JOINTD	char	Joints Decode		Collected at CRF.
JTNE	char	Joints Not Evaluable		Collected at CRF.
JTSWELL	char	Joints Swelling		Collected at CRF.
JTPAIN	char	Joints Pain/Tenderness		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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

1.4.16. Upper Extremity Joint Evaluation Left Side – JNTSC_UL

Dataset	JNTSC_UL
Creating program	jntsc_ul.sas
Description	Upper Extremity Joint Evaluation Left Side
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
JOINT	num	Joints		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
JOINTD	char	Joints Decode		Collected at CRF.

Variable	Type	Label	Codes	Comments
JTNE	char	Joints Not Evaluable		Collected at CRF.
JTSWELL	char	Joints Swelling		Collected at CRF.
JTPAIN	char	Joints Pain/Tenderness		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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. Upper Extremity Joint Evaluation Right Side – JNTSC_UR

Dataset	JNTSC_UR
Creating program	jntsc_ur.sas
Description	Upper Extremity Joint Evaluation Right Side
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
JOINT	num	Joints		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
JOINTD	char	Joints Decode		Collected at CRF.
JTNE	char	Joints Not Evaluable		Collected at CRF.
JTSWELL	char	Joints Swelling		Collected at CRF.
JTPAIN	char	Joints Pain/Tenderness		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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

1.4.18. Laboratory Tests – LAB

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORRES	char	Test Result		Collected at CRF.
LBEVNT	char	Lab Event		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.
LBORNRHI	char	Upper Normal Range - Test Result		Collected at CRF.
LBORNRLO	char	Lower Normal Range - Test Result		Collected at CRF.
LBSTNRHI	char	Upper Normal Range - Standard Result		Collected at CRF.
LBSTNRLO	char	Lower Normal Range - Std Result		Collected at CRF.
LBSTRES	char	Standardized Test Result		Collected at CRF.
LBTSTCD	char	Test Code		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
LBORUNIT	char	Units - Test Result		Collected at CRF.
LBPTM	char	Period		Collected at CRF.
LBNRIND	char	Out of Range Flag		Collected at CRF.
LBSTUNIT	char	Units - Standard Result		Collected at CRF.
LBCOM	char	Test Comment		Collected at CRF.
LBTEST	char	Decode of TESTCOD		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
LBDY	num	Relative Day of Sample		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE). Else if LBDTC is greater than equal to REF.DATE then (LBDTC - REF.DATE) +1.

1.4.19. Extra-Articular Manifestations of RA – MANIFEST

Dataset	MANIFEST
Creating program	manifest.sas
Description	Extra-Articular Manifestations of RA
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MASPEC1	char	Specify Other Manifestation 1		Collected at CRF.
MASPEC2	char	Specify Other Manifestation 2		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
MAVASCUL	char	Vasculitis		Collected at CRF.
MAPERICR	char	Pericarditis		Collected at CRF.
MAAMYLOI	char	Amyloidosis		Collected at CRF.
MAFELTYS	char	Feltys Syndrome		Collected at CRF.

Variable	Type	Label	Codes	Comments
MAILUNGF	char	Interstitial Lung Fibrosis		Collected at CRF.
MALYMPHA	char	Lymphadenopathy		Collected at CRF.
MAOTHER1	char	Other Manifestation 1		Collected at CRF.
MAOTHER2	char	Other Manifestation 2		Collected at CRF.
MAPERNEU	char	Peripheral Neuropathy		Collected at CRF.
MASPLENO	char	Splenomegaly		Collected at CRF.
MASCLERI	char	Scleritis		Collected at CRF.
MARHEUNO	char	Rheumatoid Nodules		Collected at CRF.
MAPLEURI	char	Pleuritis		Collected at CRF.
MASICCSY	char	Sicca Syndrome		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. Medical History – MEDHX

Dataset	MEDHX
Creating program	medhx.sas
Description	Medical History
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
MHOSTEOM	char	Osteomyelitis		Collected at CRF.
MHCHR_CI	char	Chr Chest Infection with Bronchiectasis		Collected at CRF.
MHCHR_RF	char	Chronic Renal Failure		Collected at CRF.
MHDIAB	char	Diabetes		Collected at CRF.
MHCHR_SI	char	Chronic Sinusitis		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHCHR_RI	char	Chronic Renal Infection		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. Concomitant Medications – MEDS

Dataset	MEDS
Creating program	meds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,CMROUTE,CMDECOD,VISIT,CMSTDY,CMSEQ
Sorted by	DUSUBJID,CMROUTE,CMDECOD,VISIT,CMSTDY,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CMENDT,CMENDY,CMENDMO,CMENDYR,CMIND_V,CMSTDT,CMSTDY,CMSTMOT,CMSTYR,CMTERM,CMSTDTC,CMENDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
CMSEQ	num	Line Number		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
CMRTE_V	char	Route Specified on The CRF		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRF_PAGE	num	CRF Page		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.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
CMSTPR	char	Prior Start of Medication		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

Variable	Type	Label	Codes	Comments
CMSTDY	num	Relative Medication Start Day		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.
CMENDY	num	Relative Medication End Day		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.

1.4.22. Medication Review – MEDSUMM

Dataset	MEDSUMM
Creating program	medsumm.sas
Description	Medication Review
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: MSPEN_SI,MSPENCIL,MSCYC_LE,MSCYC_SI,MSPEN_LE

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
MSBETDOS	char	Betamethasone Dose		Collected at CRF.
MSCLODOS	char	Cloprednol Dose		Collected at CRF.
MSCORDOS	char	Cortisone (Acetate) Dose		Collected at CRF.
MSDEFDOS	char	Deflazacort Dose		Collected at CRF.
MSDEXDOS	char	Dexamethasone Dose		Collected at CRF.
MSFLUDOS	char	Fluprednisolone Dose		Collected at CRF.
MSHYDDOS	char	Hydrocortisone Dose		Collected at CRF.
MSMETDOS	char	Methylprednisolone Dose		Collected at CRF.
MSMTXDOS	char	Methotrexate Dose		Collected at CRF.
MSOMDOSE	char	Other Medication Dose		Collected at CRF.
MSOTHMED	char	Other Medication		Collected at CRF.
MSPARDOS	char	Paramethasone Acetate Dose		Collected at CRF.
MSPRDDOS	char	Prednisone Dose		Collected at CRF.
MSPREDOS	char	Prednisolone Dose		Collected at CRF.
MSTRIDOS	char	Triamcinolone Dose		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
MSSULFSI	char	Sulfasalazine Start or Increase		Collected at CRF.

Variable	Type	Label	Codes	Comments
MSMTXUNT	char	Methotrexate Unit		Collected at CRF.
MSAZATHI	char	Azathioprine		Collected at CRF.
MSAZA_LE	char	Azathioprine Lack of Efficacy		Collected at CRF.
MSAZA_SI	char	Azathioprine Start or Increase		Collected at CRF.
MSCHLORO	char	Chloroquine		Collected at CRF.
MSCHL_LE	char	Chloroquine Lack of Efficacy		Collected at CRF.
MSCHL_SI	char	Chloroquine Start or Increase		Collected at CRF.
MSHYD_SI	char	Hydroxychloroquine Start or Increase		Collected at CRF.
MSIMGOLD	char	IM-Gold		Collected at CRF.
MSIMG_LE	char	IM-Gold Lack of Efficacy		Collected at CRF.
MSIMG_SI	char	IM-Gold Start or Increase		Collected at CRF.
MSINCDOS	char	Dose Increased		Collected at CRF.
MSLEFLUN	char	Leflunomide		Collected at CRF.
MSLEF_LE	char	Leflunomide Lack of Efficacy		Collected at CRF.
MSLEF_SI	char	Leflunomide Start or Increase		Collected at CRF.
MSMTXFRQ	char	Methotrexate Frequency		Collected at CRF.
MSCORTCH	char	Change In Corticosteroid Dose		Collected at CRF.
MSCORFRQ	char	Oral Corticosteroid Frequency		Collected at CRF.
MSCORUNT	char	Oral Corticosteroid Unit		Collected at CRF.
MSCYCLOS	char	Cyclosporine		Collected at CRF.

Variable	Type	Label	Codes	Comments
MSDMARDS	char	Start a New DMARD or Increase Dose		Collected at CRF.
MSHYDROX	char	Hydroxychloroquine		Collected at CRF.
MSHYD_LE	char	Hydroxychloroquine Lack of Efficacy		Collected at CRF.
MSNODMAR	char	No DMARDs Being Taken		Collected at CRF.
MSSULFAS	char	Sulfasalazine		Collected at CRF.
MSSULFLE	char	Sulfasalazine Lack of Efficacy		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. Page Sequence – PAGE_SEQ

Dataset	PAGE_SEQ
Creating program	page_seq.sas
Description	Page Sequence
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_OF	num	Total Pages In Series		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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

1.4.24. Pharmacokinetic and ATSA – PK_ATSA

Dataset	PK_ATSA
Creating program	pk_atsa.sas
Description	Pharmacokinetic and ATSA
Unique identifier	DUSUBJID,PERIOD,VISIT
Sorted by	DUSUBJID,PERIOD,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: PKDT,PKDTC,CPLABEL,PKNOTCOL,PKATSCD3,PKATSCM3,PKCONCD2,PKCONCM2,PKDEVDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Event Identifier		Collected at CRF.
PKACTDY	num	Actual Study Day of Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
TRTGRP	char	Randomized Treatment Group		Collected at CRF.
TRTCDA	num	Actual Treatment Code		Collected at CRF.
TRTGRPA	char	Actual Treatment Group		Collected at CRF.
POP_EFF	char	Included In The Efficacy Population		Collected at CRF.
POP_SAF	char	Included In Safety Population		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DBLNDPAT	char	Blinded Pat Num Assigned for De-identity		Randomly assigned Blinded Pat Num for De-identity
PAG_NAME	char	Page Id		Collected at CRF.
PKACTTM	num	Time of Sample		Collected at CRF.
PKREFLG	num	Relative to Baseline Flag		Collected at CRF.
PKRELBAS	char	Relative to Baseline Indicator		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
CPPERIOD	char	Period (ClinparM)		Collected at CRF.
DOSENUM	num	Sequential Dose Number		Collected at CRF.
PKCONC	char	Serum Concentration (Char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
PKCONCLQ	num	Lower Limit of Quantitation (PKCONC)		Collected at CRF.
PKINH	char	Inhibition to Study Agent (Char)		Collected at CRF.
PKOD	char	Mean Optical Density (Char)		Collected at CRF.
PKTITER	char	Antibodies to Study Agent Titer (Char)		Collected at CRF.
PKTTRLQ	num	Lower Limit of Quantitation (PKTITER)		Collected at CRF.
PKCONCN	num	Serum Concentration (Numeric)		Collected at CRF.
PKINHNN	num	% Inhibition to Study Agent (Numeric)		Collected at CRF.
PKODN	num	Mean Optical Density (Numeric)		Collected at CRF.
PKTITERN	num	Antibodies to Study Agent Titer(Numeric)		Collected at CRF.
PKRESULT	char	Sample ATSA Result		Collected at CRF.
PKATSCD1	char	CPCMT1CD/2CD for ATSA Result		Collected at CRF.
PKATSCD2	char	CPCMT1CD/2CD for ATSA Result		Collected at CRF.
PKATSCM1	char	CPCMT1/2 for ATSA Result		Collected at CRF.
PKATSCM2	char	CPCMT1/2 for ATSA Result		Collected at CRF.
PKCONCD1	char	CPCMT1CD/2CD for PK Result		Collected at CRF.
PKCONCM1	char	CPCMT1CD/2CD for PK Result		Collected at CRF.
PKSMPINC	char	Sample included in PK/PD Analysis		Collected at CRF.

Variable	Type	Label	Codes	Comments
PKUNDET	char	Serum Concentration Undetectable		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
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
PKDY	num	Relative Day of Sample		If PKDTC and REF.DATE not missing then perform below logic to calculate PKDY, If PKDTC less than REF.DATE then (PKDTC - REF.DATE). Else if PKDTC is greater than equal to REF.DATE then (PKDTC - REF.DATE) +1.
PKDEVY	num	Relative Infus Deviat/Dose Terminat Day		If PKDEVDT and REF.DATE not missing then perform below logic to calculate PKDEVY, If PKDEVDT less than REF.DATE then (PKDEVDT - REF.DATE). Else if PKDEVDT is greater than equal to REF.DATE then (PKDEVDT - REF.DATE) +1.

1.4.25. Questionnaires – QOL

Dataset	QOL
Creating program	qol.sas
Description	Questionnaires
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
QLBP1	num	Score for QOL Question 7		Collected at CRF.
QLBP2	num	Score for QOL Question 8		Collected at CRF.
QLGH1	num	Score for QOL Question 1		Collected at CRF.
QLGH2	num	Score for QOL Question 11A		Collected at CRF.
QLGH3	num	Score for QOL Question 11B		Collected at CRF.
QLGH4	num	Score for QOL Question 11C		Collected at CRF.
QLGH5	num	Score for QOL Question 11D		Collected at CRF.
QLHT	num	Score for QOL Question 2		Collected at CRF.
QLMH1	num	Score for QOL Question 9B		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLMH2	num	Score for QOL Question 9C		Collected at CRF.
QLMH3	num	Score for QOL Question 9D		Collected at CRF.
QLMH4	num	Score for QOL Question 9F		Collected at CRF.
QLMH5	num	Score for QOL Question 9H		Collected at CRF.
QLPF01	num	Score for QOL Question 3A		Collected at CRF.
QLPF02	num	Score for QOL Question 3B		Collected at CRF.
QLPF03	num	Score for QOL Question 3C		Collected at CRF.
QLPF04	num	Score for QOL Question 3D		Collected at CRF.
QLPF05	num	Score for QOL Question 3E		Collected at CRF.
QLPF06	num	Score for QOL Question 3F		Collected at CRF.
QLPF07	num	Score for QOL Question 3G		Collected at CRF.
QLPF08	num	Score for QOL Question 3H		Collected at CRF.
QLPF09	num	Score for QOL Question 3I		Collected at CRF.
QLPF10	num	Score for QOL Question 3J		Collected at CRF.
QLRE1	num	Score for QOL Question 5A		Collected at CRF.
QLRE2	num	Score for QOL Question 5B		Collected at CRF.
QLRE3	num	Score for QOL Question 5C		Collected at CRF.
QLRP1	num	Score for QOL Question 4A		Collected at CRF.
QLRP2	num	Score for QOL Question 4B		Collected at CRF.
QLRP3	num	Score for QOL Question 4C		Collected at CRF.
QLRP4	num	Score for QOL Question 4D		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLSF1	num	Score for QOL Question 6		Collected at CRF.
QLSF2	num	Score for QOL Question 10		Collected at CRF.
QLVT1	num	Score for QOL Question 9A		Collected at CRF.
QLVT2	num	Score for QOL Question 9E		Collected at CRF.
QLVT3	num	Score for QOL Question 9G		Collected at CRF.
QLVT4	num	Score for QOL Question 9I		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
NOTDONE	char	Not Done		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

1.4.26. Patient Assessment – RAEVAL

Dataset	RAEVAL
Creating program	raeval.sas
Description	Patient Assessment
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
REGDAEVL	num	Evaluator Vas Score for Gda		Collected at CRF.
REGDAPAT	num	Patient Vas Score for Gda		Collected at CRF.
REPAINSC	num	Patient Vas Pain Score		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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

1.4.27. Diagnosis Information – RAINFO

Dataset	RAINFO
Creating program	rainfo.sas
Description	Diagnosis Information
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: RIDIAGDT,RIDIAGDY,RIDIAGMO,RIDIAGYR

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
FUNCLAS	char	Functional Class		Collected at CRF.
ANASTAG	char	Anatomical Stage of RA		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
RIDIAGDY	num	Relative Day of Diagnosis		If RIDIAGDT and REF.DATE not missing then perform below logic to calculate RIDIAGDY, If RIDIAGDT less than REF.DATE then (RIDIAGDT - REF.DATE). Else if RIDIAGDT is greater than equal to REF.DATE then (RIDIAGDT - REF.DATE) +1.

1.4.28. Randcode – Randcode

Dataset	RANDCODE
Creating program	randcode.sas
Description	Randcode
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DSNTRSOT	char	Not Treated Reason Specify		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
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

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

1.4.29. Tuberculosis History and PPD Results – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Tuberculosis History and PPD Results
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: TBPPDDT, TBPPDDY, TBPPDMO, TBPPDYR, TBPVACYR, TBPPDDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
TBPPDRES	char	PPD Results (Induration)		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
TBTRREQ	char	Treatment Required		Collected at CRF.
TBPPDNR	char	PPD Test Not Required		Collected at CRF.
TBPTLTB	char	Prev Completed Treatment for Latent TB		Collected at CRF.
TBPTATB	char	Previously Treated Active Tb		Collected at CRF.
TBPRVBCG	char	Previous Bcg Vaccination		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 REF.DATE not missing then perform below logic to calculate TBPPDDY, If TBPPDDTC less than REF.DATE then (TBPPDDTC - REF.DATE). Else if TBPPDDTC is greater than equal to REF.DATE then (TBPPDDTC - REF.DATE) +1.

1.4.30. Permanent Discontinuation of Study Infusions – TERMDOSE

Dataset	TERMDOSE
Creating program	termdose.sas
Description	Permanent Discontinuation of Study Infusions
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DSTRSOTH,DSTRMDT,DSTRM_DY,DSTRM_MO,DSTRM_YR,DSTRMDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DAELN	num	Adverse Event Line Number		Collected at CRF.
DAELN2	num	Adverse Event Line Number 2		Collected at CRF.
DAELN3	num	Adverse Event Line Number 3		Collected at CRF.
DAELN4	num	Adverse Event Line Number 4		Collected at CRF.
DAELN5	num	Adverse Event Line Number 5		Collected at CRF.
DAELN6	num	Adverse Event Line Number 6		Collected at CRF.
DAEPG	num	Adverse Event Page		Collected at CRF.
DAEPG2	num	Adverse Event Page 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAEPG3	num	Adverse Event Page 3		Collected at CRF.
DAEPG4	num	Adverse Event Page 4		Collected at CRF.
DAEPG5	num	Adverse Event Page 5		Collected at CRF.
DAEPG6	num	Adverse Event Page 6		Collected at CRF.
DAEPGOF	num	Number of AE Pages In Series		Collected at CRF.
DAEPGOF2	num	Number of AE Pages In Series 2		Collected at CRF.
DAEPGOF3	num	Number of AE Pages In Series 3		Collected at CRF.
DAEPGOF4	num	Number of AE Pages In Series 4		Collected at CRF.
DAEPGOF5	num	Number of AE Pages In Series 5		Collected at CRF.
DAEPGOF6	num	Number of AE Pages In Series 6		Collected at CRF.
DAEPGSEQ	num	Adverse Event Page Sequence		Collected at CRF.
DAEPGSQ2	num	Adverse Event Page Sequence 2		Collected at CRF.
DAEPGSQ3	num	Adverse Event Page Sequence 3		Collected at CRF.
DAEPGSQ4	num	Adverse Event Page Sequence 4		Collected at CRF.
DAEPGSQ5	num	Adverse Event Page Sequence 5		Collected at CRF.
DAEPGSQ6	num	Adverse Event Page Sequence 6		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DSTREAS	char	Dosing Termination Reason Code		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
DSTRMDY	num	Relative Dosing Termination Day		If DSTRMDTC and REF.DATE not missing then perform below logic to calculate DSTRMDY, If DSTRMDTC less than REF.DATE then (DSTRMDTC - REF.DATE). Else if DSTRMDTC is greater than equal to REF.DATE then (DSTRMDTC - REF.DATE) +1.

1.4.31. Study Termination – TERMSTDY

Dataset	TERMSTDY
Creating program	termstdy.sas
Description	Study Termination
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: DTDT, DTDY, DTMO, DTYR, SAEPG3, SAEPGOF3, DSR SOTH, DSDSCDT, DSDSCDY, DSDSCMO, DSDSCYR, DSDSCDTC, DTDTTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DTCAUSE	char	Stated Cause of Death		Collected at CRF.
SAELN	num	Adverse Event Line Number		Collected at CRF.
SAELN2	num	Adverse Event Line Number 2		Collected at CRF.
SAELN3	num	Adverse Event Line Number 3		Collected at CRF.
SAEPG	num	Adverse Event Page		Collected at CRF.
SAEPG2	num	Adverse Event Page 2		Collected at CRF.
SAEPGOF	num	Number of AE Pages In Series		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAEPGOF2	num	Number of AE Pages In Series 2		Collected at CRF.
SAEPGSEQ	num	Adverse Event Page Sequence		Collected at CRF.
SAEPGSQ2	num	Adverse Event Page Sequence 2		Collected at CRF.
SAEPGSQ3	num	Adverse Event Page Sequence 3		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.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DSWCD	char	Use of Data Permitted		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

Variable	Type	Label	Codes	Comments
DSDSCDY	num	Relative Study Termination Day		If DSDSCDTC and REF.DATE not missing then perform below logic to calculate DSDSCDY, If DSDSCDTC less than REF.DATE then (DSDSCDTC - REF.DATE). Else if DSDSCDTC is greater than equal to REF.DATE then (DSDSCDTC - REF.DATE) +1.
DTDY	num	Relative Day of Death		If DTDTTC and REF.DATE not missing then perform below logic to calculate DTDY, If DTDTTC less than REF.DATE then (DTDTTC - REF.DATE). Else if DTDTTC is greater than equal to REF.DATE then (DTDTTC - REF.DATE) +1.

1.4.32. Study Treatment Unblinding – UNBLIND

Dataset	UNBLIND
Creating program	unblind.sas
Description	Study Treatment Unblinding
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
UAELN	num	Adverse Event Line Number		Collected at CRF.
UAELN2	num	Adverse Event Line Number 2		Collected at CRF.
UAELN3	num	Adverse Event Line Number 3		Collected at CRF.
UAEPG	num	Adverse Event Page		Collected at CRF.
UAEPG2	num	Adverse Event Page 2		Collected at CRF.
UAEPG3	num	Adverse Event Page 3		Collected at CRF.
UAEPGOF	num	Number of AE Pages In Series		Collected at CRF.
UAEPGOF2	num	Number of AE Pages In Series 2		Collected at CRF.
UAEPGOF3	num	Number of AE Pages In Series 3		Collected at CRF.
UAEPGSEQ	num	Adverse Event Page Sequence		Collected at CRF.
UAEPGSQ2	num	Adverse Event Page Sequence 2		Collected at CRF.
UAEPGSQ3	num	Adverse Event Page Sequence 3		Collected at CRF.
UNBLD_DT	num	Date Unblinded		Collected at CRF.
UNBLD_DY	num	Day Unblinded		Collected at CRF.
UNBLD_MO	num	Month Unblinded		Collected at CRF.
UNBLD_YR	num	Year Unblinded		Collected at CRF.
URSNSPEC	char	Reason for Unblinding Specify		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity

Variable	Type	Label	Codes	Comments
UNBLRSN	char	Reason for Unblinding		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

1.4.33. Visit Information – VISITS

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
VISITND	char	Visit Not Done		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
VISITDY	num	Relative Day of Patient Visit		If VISITDTC and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDTC less than REF.DATE then (VISITDTC-REF.DATE). Else if VISITDTC is greater than equal to REF.DATE then (VISITDTC-REF.DATE)+1.

1.4.34. Vital Signs – VITALS

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

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
HGT	num	Height (cm)		Collected at CRF.
WGT	num	Weight (kg)		Collected at CRF.
ZHGT	num	Entered Height		Collected at CRF.
ZWGT	num	Entered Weight		Collected at CRF.
CRF_PAGE	num	CRF Page		Collected at CRF.
VISIT	char	Study Visit		Collected at CRF.
DUNIQUEP	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
ZWGT_UN	char	Units for Entered Weight		Collected at CRF.
ZHGT_UN	char	Units for Entered Height		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