

Clinical Development

CNT0148

C0524T08

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	08OCT2015

Property of Janssen

Confidential

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

Table of contents

Clinical Development	1
1. Datasets	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data	5
1.3. Data Files	6
1.4. Data Domains	7
1.4.1. Demography - Demo	7
1.4.2. Adverse Events – AE	9
1.4.3. Body Surface Area Covered by Disease - BSA	13
1.4.4. Past Medical History/Current Diagnoses - CONDHIST	14
1.4.5. Concomitant Medications - CONMEDS	16
1.4.6. Prior Joint Procedures/Injections - CONPROC	19
1.4.7. Selection Criteria - CRITERIA	21
1.4.8. Dactylitis - DACTYL	22
1.4.9. Death - DEATH	25
1.4.10. Psoriasis Diagnosis Information - DIAGINFO	27
1.4.11. Patient and Physician Assessments - DIS_EVAL	29
1.4.12. Disposition Status - DSTATUS	31
1.4.13. Enthesis Evaluation - ENTHES	33
1.4.14. Subcutaneous Study Agent Exposure - EXPOSURE	34
1.4.15. Health Assessment Questionnaire - HAQ	37
1.4.16. Ivrsdose - IVRSDOSE	42
1.4.17. Ivrsrand - IVRSRAND	44
1.4.18. Joint Evaluation - JNTSCORE	46
1.4.19. Laboratory Tests - LAB	48
1.4.20. Lesion Assessment - LESASMNT	51
1.4.21. Medication Review - MEDRVIEW	52
1.4.22. Nail Physician Global Assessment - NAILPGA	55
1.4.23. Nail Psoriasis Severity Index - NAPSI	56

1.4.24. Psoriasis Area and Severity Index - PASI 58

1.4.25. SF-36 Health Survey - QOL 60

1.4.26. Prior Medications - RXHX 63

1.4.27. Subject Status - SUBSTAT 64

1.4.28. Tuberculosis - TB_INFO 66

1.4.29. Pneumococcal Vaccination - VACCIN 69

1.4.30. Visit - VISITS 71

1.4.31. Vital Signs - VITALS 72

1.4.32. Xrscore - XRSCORE 74

1.4.33. Xrtrack - XRTRACK 77

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

- 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.
- Partial date's relative day cannot be calculated.
- Dataset which do not have subject level information will not be submitted. (e.g. CLABCONV, CNTYDICT, CSU, DF_FORM, HAQDVC, LABDICT, NABRESULT, UNITDICT, VISPER, WHO_DD)
- Biomarker dataset will not be submitted to protect PII. (e.g. STUDYPAR)
- Dataset which do not have any significant information for analysis will be dropped. (e.g. DSATTRIB)
- Dataset which are used for reconciliation purpose will not be submitted. (e.g. ATRACK)
- Dataset which have sensitive information at subject level will not be submitted to protect PII. (e.g. ECONOM)
- Dataset which have no records will not be submitted. (e.g. NOTTX)
- Dataset which have information related to pharmacokinetics will not be submitted to protect PII. (e.g. CRESUL, PC)
- Datasets which have information about screen failure subjects will not be submitted. (e.g. SCRNAE, SCRNATRACK, SCRNCRIT, SCRNDEMO, SCRNDST, SCRNDTH, SCRNLAB, SCRNTBI, SCRNVIS)

1.3. Data Files

The C0524T08 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0524T08 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demography - Demo

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

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

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID 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 Subj ID for De-identity
DMCONDY	num	Relative Day of Informed Consent		If DMCONDTC and IRLCNDTC not missing then perform below logic to calculate DMCONDY, If DMCONDTC less than IRLCNDTC then (DMCONDTC - IRLCNDTC). Else if DMCONDTC is greater than equal to IRLCNDTC then (DMCONDTC- IRLCNDTC) +1.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID, AESEQ, AEDECOD
Sorted by	DUSUBJID, AESEQ, AEDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information or due to missing values: AETERM,AEMODIFY,AEENDTC,AESTDTC,PAG_NAME,AESTHR,AESTMI,AESTTM ,COUNTRY,AGE,RACE,SEX,AESTDT,AEENDT,SAECONG

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
SAEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.
MDV	char	MEDDRA Version		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAEOTH	char	Other Medically Important		Collected at CRF.
SAEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AELOC	char	Adverse Event Location		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEPRSPEC	char	Related to Procedure Specify		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
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 Subj ID for De-identity

Variable	Type	Label	Codes	Comments
AEENDY	num	Relative End Day of Event		If AEENDTC and IRLCNDTC not missing then perform below logic to calculate AEENDY, If AEENDTC less than IRLCNDTC then (AEENDTC - IRLCNDTC).Else if AEENDTC is greater than equal to IRLCNDTC then (AEENDTC- IRLCNDTC) +1.
AESTDY	num	Relative Start Day of Event		If AESTDTC and IRLCNDTC not missing then perform below logic to calculate AESTDY,if AESTDTC less than IRLCNDTC then (AESTDTC - IRLCNDTC).Else if AESTDTC is greater than equal to IRLCNDTC then (AESTDTC- IRLCNDTC) +1.

1.4.3. Body Surface Area Covered by Disease - BSA

Dataset	BSA
Creating program	bsa.sas
Description	Body Surface Area Covered by Disease - BSA
Unique identifier	DUSUBJID, VISITNUM, BSBSA
Sorted by	DUSUBJID, VISITNUM, BSBSA
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information : PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
BSBSA	char	Body Surface Area Covered by Disease		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

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 Subj ID for De-identity

1.4.4. Past Medical History/Current Diagnoses - CONDHIST

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CHCOND	num	Condition		Collected at CRF.
CHSMCIG	num	Number of Cigarettes Per Day		Collected at CRF.
CHSMYRS	num	Number of Years of Smoking		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHALUNWK	num	Number of Alcoholic Units Per Week		Collected at CRF.
CHALYRS	num	Number of Years of Alcohol Use		Collected at CRF.
CHEXNUM	num	Aerobic Exercise Units per Week		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CHCONDD	char	Decode of CHCOND		Collected at CRF.
CHALSTAT	char	Status of Alcohol Use		Collected at CRF.
CHTYPE	char	Condition Type		Collected at CRF.
CHHIST	char	History of Condition		Collected at CRF.
CHSMSTAT	char	Status of Smoking		Collected at CRF.
CHTRT	char	Treated		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity

1.4.5. Concomitant Medications - CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID, CMDECOD1, CMCLASCD, VISITNUM, CMROUTE, CMONGO, CMSTPR, CMFREQ, CMSEQ
Sorted by	DUSUBJID, CMDECOD1, CMCLASCD, VISITNUM, CMROUTE, CMONGO, CMSTPR, CMFREQ, CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information: CMTERM, CMMODIFY, CMDECOD, DRECNO, PAG_NAME, PAGE_SEQ, CMENDTC, CMSTDTC, COUNTRY, AGE, RACE, SEX, CMSTDT, CMENDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMDOSE	char	Dose		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.
CMONGO	char	Ongoing Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
CMFREQ	char	Frequency		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity

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

1.4.6. Prior Joint Procedures/Injections - CONPROC

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
LINE_NO	num	Line Number		Collected at CRF.
PR_TYPE	num	Procedure Code		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
PRJOINT	char	Joint		Collected at CRF.
PROCREL	char	Procedure Related		Collected at CRF.
PRTMSNC	char	Time Since Procedure		Collected at CRF.
PR_TYPED	char	Decode of PR_TYPE		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 Subj ID for De-identity
PROCDY	num	Relative Day of Procedure		If PROCDTC and IRLCNDTC not missing then perform below logic to calculate PROCDY, If PROCDTC less than IRLCNDTC then (PROCDTC - IRLCNDTC). Else if PROCDTC is greater than equal to IRLCNDTC then (PROCDTC - IRLCNDTC) +1.

1.4.7. Selection Criteria - CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Selection Criteria
Unique identifier	DUSUBJID, INCRIT
Sorted by	DUSUBJID, INCRIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

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

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

1.4.8. Dactylitis - DACTYL

Dataset	DACTYL
Creating program	dactyl.sas
Description	Dactylitis
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

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

Variable	Type	Label	Codes	Comments
DARHDIG1	num	Right Hand Digit 1		Collected at CRF.
DARHDIG2	num	Right Hand Digit 2		Collected at CRF.
DARHDIG3	num	Right Hand Digit 3		Collected at CRF.
DARHDIG4	num	Right Hand Digit 4		Collected at CRF.
DARHDIG5	num	Right Hand Digit 5		Collected at CRF.
DALHDIG1	num	Left Hand Digit 1		Collected at CRF.
DALHDIG2	num	Left Hand Digit 2		Collected at CRF.
DALHDIG3	num	Left Hand Digit 3		Collected at CRF.
DALHDIG4	num	Left Hand Digit 4		Collected at CRF.
DALHDIG5	num	Left Hand Digit 5		Collected at CRF.
DARFDIG1	num	Right Foot Digit 1		Collected at CRF.
DARFDIG2	num	Right Foot Digit 2		Collected at CRF.
DARFDIG3	num	Right Foot Digit 3		Collected at CRF.
DARFDIG4	num	Right Foot Digit 4		Collected at CRF.
DARFDIG5	num	Right Foot Digit 5		Collected at CRF.
DALFDIG1	num	Left Foot Digit 1		Collected at CRF.
DALFDIG2	num	Left Foot Digit 2		Collected at CRF.
DALFDIG3	num	Left Foot Digit 3		Collected at CRF.
DALFDIG4	num	Left Foot Digit 4		Collected at CRF.
DALFDIG5	num	Left Foot Digit 5		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
DACTYL	char	Subject has Dactylitis		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 Subj ID for De-identity

1.4.9. Death - DEATH

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DTAUTP	char	Autopsy Performed		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

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

1.4.10. Psoriasis Diagnosis Information - DIAGINFO

Dataset	DIAGINFO
Creating program	diaginfo.sas
Description	Psoriasis 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 non significant elements or due to repetition of the information: PAG_NAME,DIAGDTC,DIAGPDT,COUNTRY,AGE,RACE,SEX,DIAGDT,DIAGPDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DISPSA	char	Subset of Psoriatic Arthritis		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 Subj ID for De-identity
DIAGDY	num	Relative Day of Diagnosis		If DIAGDTC and IRLCNDTC not missing then perform below logic to calculate DIAGDY,If DIAGDTC less than IRLCNDTC then (DIAGDTC - IRLCNDTC).Else if DIAGDTC is greater than equal to IRLCNDTC then (DIAGDTC- IRLCNDTC) +1.
DIAGPDY	num	Relative Day of Psoriasis Diagnosis		If DIAGPDTC and IRLCNDTC not missing then perform below logic to calculate DIAGPDY,If DIAGPDTC less than IRLCNDTC then (DIAGPDTC - IRLCNDTC).Else if DIAGPDTC is greater than equal to IRLCNDTC then (DIAGPDTC- IRLCNDTC) +1.

1.4.11. Patient and Physician Assessments - DIS_EVAL

Dataset	DIS_EVAL
Creating program	dis_eval.sas
Description	Patient and Physician Assessments
Unique identifier	DUSUBJID, EVENT_ID, DEMORN
Sorted by	DUSUBJID, EVENT_ID, DEMORN
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

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

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 Subj ID for De-identity

1.4.12. Disposition Status - DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Disposition Status
Unique identifier	DUSUBJID, EVENT_ID, DSDSCEND, DSUNB
Sorted by	DUSUBJID, EVENT_ID, DSDSCEND, DSUNB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information: PAG_NAME, DSTRSOTH, DSR SOTH, DSDSCDTC, DSUNBDTC, COUNTRY, AGE, RACE, SEX, DSUNBDT, DSDSCDT

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

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

1.4.13. Enthesis Evaluation - ENTHES

Dataset	ENTHES
Creating program	enthes.sas
Description	Enthesis Evaluation
Unique identifier	DUSUBJID, EVENT_ID, ENSITE
Sorted by	DUSUBJID, EVENT_ID, ENSITE
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
ENTENDER	num	Tender		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
ENSITE	char	Enthesis Site		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 Subj ID for De-identity

1.4.14. Subcutaneous Study Agent Exposure - EXPOSURE

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

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

Variable	Type	Label	Codes	Comments
EXSTHR	num	Start Hour of Dose, 24 Hour Clock		Collected at CRF.
EXSTMI	num	Start Minute of Dose, 24 Hour Clock		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
EXLCL	char	Exposure Locale		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
EXSAADM	char	Study Agent Administrator		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity
EXSTDY	num	Relative Start Day of Dose		If EXSTDTC and IRLCNDTC not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than IRLCNDTC then (EXSTDTC - IRLCNDTC). Else if EXSTDTC is greater than equal to IRLCNDTC then (EXSTDTC - IRLCNDTC) +1.

1.4.15. Health Assessment Questionnaire - HAQ

Dataset	HAQ
Creating program	haq.sas
Description	Health Assessment Questionnaire
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information or due to missing values:: PAG_NAME,HASPEC1,HASPEC2,HAPFLG1,HAPFLG3,HAPFLG6,COUNTRY,AGE, RACE,SEX

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

Variable	Type	Label	Codes	Comments
HATXT6	char	Use of other aids/devices - Category 6		Collected at CRF.
HATXT7	char	Use of other aids/devices - Category 7		Collected at CRF.
HATXT8	char	Use of other aids/devices - Category 8		Collected at CRF.
HAPFLG2	char	Adj. permanent devices flag - Category 2		Collected at CRF.
HAPFLG4	char	Adj. permanent devices flag - Category 4		Collected at CRF.
HAPFLG5	char	Adj. permanent devices flag - Category 5		Collected at CRF.
HAPFLG7	char	Adj. permanent devices flag - Category 7		Collected at CRF.
HAPFLG8	char	Adj. permanent devices flag - Category 8		Collected at CRF.
HANOADJ	char	Other aids/devices not requiring adjust.		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
HAQ1	num	HAQ Question 1		Collected at CRF.
HAQ2	num	HAQ Question 2		Collected at CRF.
HAQ3	num	HAQ Question 3		Collected at CRF.
HAQ4	num	HAQ Question 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
HAQ5	num	HAQ Question 5		Collected at CRF.
HAQ6	num	HAQ Question 6		Collected at CRF.
HAQ7	num	HAQ Question 7		Collected at CRF.
HAQ8	num	HAQ Question 8		Collected at CRF.
HAQ9	num	HAQ Question 9		Collected at CRF.
HAQ10	num	HAQ Question 10		Collected at CRF.
HAQ11	num	HAQ Question 11		Collected at CRF.
HAQ12	num	HAQ Question 12		Collected at CRF.
HAQ13	num	HAQ Question 13		Collected at CRF.
HAQ14	num	HAQ Question 14		Collected at CRF.
HAQ15	num	HAQ Question 15		Collected at CRF.
HAQ16	num	HAQ Question 16		Collected at CRF.
HAQ17	num	HAQ Question 17		Collected at CRF.
HAQ18	num	HAQ Question 18		Collected at CRF.
HAQ19	num	HAQ Question 19		Collected at CRF.
HAQ20	num	HAQ Question 20		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
HACAT1	char	HAQ Aid, Device/Help Category 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
HACAT2	char	HAQ Aid, Device/Help Category 2		Collected at CRF.
HACAT3	char	HAQ Aid, Device/Help Category 3		Collected at CRF.
HACAT4	char	HAQ Aid, Device/Help Category 4		Collected at CRF.
HACAT5	char	HAQ Aid, Device/Help Category 5		Collected at CRF.
HACAT6	char	HAQ Aid, Device/Help Category 6		Collected at CRF.
HACAT7	char	HAQ Aid, Device/Help Category 7		Collected at CRF.
HACAT9	char	HAQ Aid, Device/Help Category 9		Collected at CRF.
HACAT10	char	HAQ Aid, Device/Help Category 10		Collected at CRF.
HACAT11	char	HAQ Aid, Device/Help Category 11		Collected at CRF.
HACAT12	char	HAQ Aid, Device/Help Category 12		Collected at CRF.
HACAT13	char	HAQ Aid, Device/Help Category 13		Collected at CRF.
HACAT14	char	HAQ Aid, Device/Help Category 14		Collected at CRF.

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

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

1.4.16. Ivrsdose - IVRSDOSE

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

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

Variable	Type	Label	Codes	Comments
IDJNTNE	num	Number of Joints Not Evaluable		Collected at CRF.
IDJNTTEN	num	Number of Tender Joints		Collected at CRF.
IDJNTSWL	num	Number of Swollen Joints		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
IDEARES	char	Early Escape		Collected at CRF.
IDLTEDE	char	Long Term Extension Dose Escalation		Collected at CRF.
IDLTEDD	char	Long Term Extension Dose Decrease		Collected at CRF.
IDEMRS	char	Emergency Re-Supply		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity
IDCLDY	num	Relative IVRS Dose Call Day		If IDCLDTC and IRLCNDTC not missing then perform below logic to calculate IDCLDY, If IDCLDTC less than IRLCNDTC then (IDCLDTC - IRLCNDTC). Else if IDCLDTC is greater than equal to IRLCNDTC then (IDCLDTC- IRLCNDTC) +1.

1.4.17. Ivrsrand - IVRSRAND

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

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

Variable	Type	Label	Codes	Comments
TRTCD	num	Treatment Group		Collected at CRF.
IRSTRAT	char	Stratum		Collected at CRF.
TRTGRP	char	Decode of TRTCD		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
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 Subj ID for De-identity

1.4.18. Joint Evaluation - JNTSCORE

Dataset	JNTSCORE
Creating program	jntscore.sas
Description	Joint Evaluation
Unique identifier	DUSUBJID, EVENT_ID, JOINTD
Sorted by	DUSUBJID, EVENT_ID, JOINTD
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
JOINT	num	Joint		Collected at CRF.
JTTEND	num	Joint Tenderness on Exam		Collected at CRF.
JTSWELL	num	Joint Swelling on Exam		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
JOINTD	char	Decode of JOINT		Collected at CRF.
JTNE	char	Joint Not Evaluable		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 Subj ID for De-identity

1.4.19. Laboratory Tests - LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Tests
Unique identifier	DUSUBJID, LBTEST, VISITNUM, LBTSTORD, LBSTDNRC, LBDY, LBSEQ
Sorted by	DUSUBJID, LBTEST, VISITNUM, LBTSTORD, LBSTDNRC, LBDY, LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information or due to missing values: LBLBLNUM,LBCOM,LBID,LBKTTYP,PAG_NAME,LBLOQL,LBDTC,COUNTRY,AGE,RACE,SEX,LBDT

Variable	Type	Label	Codes	Comments
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTHR	num	Hour of Collection		Collected at CRF.
LBACTMI	num	Minute of Collection		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRL0	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRLHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBPTM	char	Planned Timepoint Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity
LBDY	num	Relative Day of Specimen Collection		If LBDTC and IRLCNDTC not missing then perform below logic to calculate LBDY, If LBDTC less than IRLCNDTC then (LBDTC - IRLCNDTC). Else if LBDTC is greater than equal to IRLCNDTC then (LBDTC - IRLCNDTC) +1.

1.4.20. Lesion Assessment - LESASMNT

Dataset	LESASMNT
Creating program	lesasmnt.sas
Description	Lesion Assessment
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
LES_ERY	num	Lesion Erythema		Collected at CRF.
LES_SCL	num	Lesion Scale		Collected at CRF.
LES_IND	num	Plaque Induration		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LESBT	char	Baseline Target Lesion		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity

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

1.4.21. Medication Review - MEDRVIEW

Dataset	MEDRVIEW
Creating program	medview.sas
Description	Medication Review
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

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

Variable	Type	Label	Codes	Comments
MRMTDOSE	num	Methotrexate Dose in mg/week		Collected at CRF.
MRCODOSE	num	Oral Corticosteroid Dose in mg/day		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
MRCORTST	char	Oral Corticosteroids		Collected at CRF.
MRDCRSCS	char	Decreased Dose of Corticosteroids		Collected at CRF.
MRDCRSIM	char	Decreased Dose of Immunosuppressives		Collected at CRF.
MRICORTS	char	Increase in Oral Corticosteroids Dose		Collected at CRF.
MRIMMUN	char	DMARD/Biologics/Systemic Immuno. Treatm.		Collected at CRF.
MRINCRIM	char	Increase in Immunosuppressives		Collected at CRF.
MRNEWCS	char	Treatment with Corticosteroids		Collected at CRF.
MRNSAIDS	char	NSAIDs		Collected at CRF.
MRSTOPCS	char	Stopped Oral Corticosteroids		Collected at CRF.
MRSTOPIM	char	Stopped Immunosuppressives		Collected at CRF.

Variable	Type	Label	Codes	Comments
MRINMTX	char	Increase in Methotrexate Dose		Collected at CRF.
MRMTX	char	Subject Taking Methotrexate		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 Subj ID for De-identity

1.4.22. Nail Physician Global Assessment - NAILPGA

Dataset	NAILPGA
Creating program	nailpga.sas
Description	Nail Physician Global Assessment
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
NGPGA	num	Nail Physician Global Assessment		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
NGPGAD	char	Decode of NGPGA		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 Subj ID for De-identity

1.4.23. Nail Psoriasis Severity Index - NAPSI

Dataset	NAPSI
Creating program	napsi.sas
Description	Nail Psoriasis Severity Index
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset to due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
NANMNAIL	num	Number of Finger Nails Involved		Collected at CRF.
NAMPSCOR	num	Matrix Psoriasis Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
NANBSCOR	num	Nail Bed Psoriasis Score		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
NATGNAIL	char	Target Fingernail at Baseline		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 Subj ID for De-identity

1.4.24. Psoriasis Area and Severity Index - PASI

Dataset	PASI
Creating program	pasi.sas
Description	Psoriasis Area and Severity Index
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
PAERHEAD	num	Erythema of the Head		Collected at CRF.
PAERTRNK	num	Erythema of the Trunk		Collected at CRF.
PAERULMB	num	Erythema of the Upper Limbs		Collected at CRF.
PAERLLMB	num	Erythema of the Lower Limbs		Collected at CRF.
PAINHEAD	num	Induration of the Head		Collected at CRF.
PAINTRNK	num	Induration of the Trunk		Collected at CRF.
PAINULMB	num	Induration of Upper Limbs		Collected at CRF.
PAINLLMB	num	Induration of Lower Limbs		Collected at CRF.
PASCHEAD	num	Scaling of the Head		Collected at CRF.

Variable	Type	Label	Codes	Comments
PASCTRNK	num	Scaling of the Trunk		Collected at CRF.
PASCULMB	num	Scaling of Upper Limbs		Collected at CRF.
PASCLLMB	num	Scaling of Lower Limbs		Collected at CRF.
PAASHEAD	num	Area Score for the Head		Collected at CRF.
PAASTRNK	num	Area Score for the Trunk		Collected at CRF.
PAASULMB	num	Area Score for the Upper Limbs		Collected at CRF.
PAASLLMB	num	Area Score for the Lower Limbs		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity

1.4.25. SF-36 Health Survey - QOL

Dataset	QOL
Creating program	qol.sas
Description	SF-36 Health Survey
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: PAG_NAME,COUNTRY,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
QLGH1	num	Score for QOL question 1		Collected at CRF.
QLHT	num	Score for QOL question 2		Collected at CRF.
QLPF01	num	Score for QOL question 3A		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
QLPF08	num	Score for QOL question 3H		Collected at CRF.
QLPF09	num	Score for QOL question 3I		Collected at CRF.
QLPF10	num	Score for QOL question 3J		Collected at CRF.
QLRP1	num	Score for QOL question 4A		Collected at CRF.
QLRP2	num	Score for QOL question 4B		Collected at CRF.
QLRP3	num	Score for QOL question 4C		Collected at CRF.
QLRP4	num	Score for QOL question 4D		Collected at CRF.
QLRE1	num	Score for QOL question 5A		Collected at CRF.
QLRE2	num	Score for QOL question 5B		Collected at CRF.
QLRE3	num	Score for QOL question 5C		Collected at CRF.
QLSF1	num	Score for QOL question 6		Collected at CRF.
QLBP1	num	Score for QOL question 7		Collected at CRF.
QLBP2	num	Score for QOL question 8		Collected at CRF.
QLVT1	num	Score for QOL question 9A		Collected at CRF.
QLMH1	num	Score for QOL question 9B		Collected at CRF.
QLMH2	num	Score for QOL question 9C		Collected at CRF.
QLMH3	num	Score for QOL question 9D		Collected at CRF.
QLVT2	num	Score for QOL question 9E		Collected at CRF.
QLMH4	num	Score for QOL question 9F		Collected at CRF.
QLVT3	num	Score for QOL question 9G		Collected at CRF.
QLMH5	num	Score for QOL question 9H		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLVT4	num	Score for QOL question 9I		Collected at CRF.
QLSF2	num	Score for QOL question 10		Collected at CRF.
QLGH2	num	Score for QOL question 11A		Collected at CRF.
QLGH3	num	Score for QOL question 11B		Collected at CRF.
QLGH4	num	Score for QOL question 11C		Collected at CRF.
QLGH5	num	Score for QOL question 11D		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID 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 Subj ID for De-identity

1.4.26. Prior Medications - RXHX

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
RXDUR	char	Duration of Use		Collected at CRF.
RXMED	char	Medication Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

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 Subj ID for De-identity

1.4.27. Subject Status - SUBSTAT

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

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
SSENT	char	Subject Entered Next Study Period		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
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 Subj ID for De-identity

1.4.28. Tuberculosis - TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Tuberculosis
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information: PAG_NAME, TBADMSP, TBREADSP, COUNTRY, AGE, RACE, SEX, TBADMDC, TBCXRDT, TBRDDTC, TBADMDC, TBRDDT, TBCXRDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
TBSEQ	num	Sequence Number		Collected at CRF.
TBBCGYR	num	Year of Previous BCG Vaccination		Collected at CRF.
TBRSLT	num	PPD Result		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
TBADM	char	PPD Administrator		Collected at CRF.

Variable	Type	Label	Codes	Comments
TBATB	char	History of Active TB		Collected at CRF.
TBBCG	char	Previous BCG Vaccination		Collected at CRF.
TBCXRES	char	Chest X-Ray Result		Collected at CRF.
TBLTB	char	History of Latent TB		Collected at CRF.
TBRCATB	char	Recent Contact to Active TB		Collected at CRF.
TBREAD	char	PPD Reader		Collected at CRF.
TBRPN	char	PPD Test Result Positive or Negative		Collected at CRF.
TBSSATB	char	Signs or Symptoms of Active TB		Collected at CRF.
TBTRTRQ	char	Treatment Required		Collected at CRF.
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 Subj ID for De-identity

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

1.4.29. Pneumococcal Vaccination - VACCIN

Dataset	VACCIN
Creating program	vaccin.sas
Description	Pneumococcal Vaccination
Unique identifier	DUSUBJID, EVENT_ID
Sorted by	DUSUBJID, EVENT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information: PAG_NAME,VCNGOTH,COUNTRY,AGE,RACE,SEX,VCVACDTC,VCVACDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VCNGRSN	char	Reason Vaccination Not Given		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 Subj ID for De-identity
VCVACDY	num	Relative Day of Vaccination		If VCVACDTC and IRLCNDTC not missing then perform below logic to calculate VCVACDY, If VCVACDTC less than IRLCNDTC then (VCVACDTC - IRLCNDTC). Else if VCVACDTC is greater than equal to IRLCNDTC then (VCVACDTC- IRLCNDTC) +1.

1.4.30. Visit - VISITS

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

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity
VISITDY	num	Relative Visit Day		If VISITDTC and IRLCNDTC not missing then perform below logic to calculate VISITDY, If VISITDTC less than IRLCNDTC then (VISITDTC - IRLCNDTC). Else if VISITDTC is greater than equal to IRLCNDTC then (VISITDTC - IRLCNDTC) +1.

1.4.31. Vital Signs - VITALS

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

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

Variable	Type	Label	Codes	Comments
VSTSTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSSTUNIT	char	Standard Units		Collected at CRF.
VSSTRES	char	Result in Standard Units		Group element to protect PII.
EVENT_ID	char	Event Identifier		Collected at CRF.
VSSEQ	num	Vital Signs Sequence		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subj ID for De-identity
VSDY	num	Relative Visit Day		If VSDTC and IRLCNDTC not missing then perform below logic to calculate VSDY, If VSDTC less than IRLCNDTC then (VSDTC - IRLCNDTC). Else if VSDTC is greater than equal to IRLCNDTC then (VSDTC - IRLCNDTC) +1.

1.4.32. Xrscore - XRSCORE

Dataset	XRSCORE
Creating program	xrscore.sas
Description	Xrscore
Unique identifier	DUSUBJID, EVENT_ID, XRJOINT, XRRDDY, XRDY, XRSEQ
Sorted by	DUSUBJID, EVENT_ID, XRJOINT, XRRDDY, XRDY, XRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information: XRBLNDPT,PAG_NAME,COUNTRY,AGE,RACE,SEX,XRRDDT,XRDTC,XRDT

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
XRSEQ	num	Sequence Number		Collected at CRF.
XRRANDTP	char	Random Timepoint		Collected at CRF.
XRRDNME	num	Reader Name		Collected at CRF.
XRREGN	num	Extremity Region		Collected at CRF.
XRTYP	char	Score Type		Collected at CRF.
XRSIDE	num	Side		Collected at CRF.
XRSCORE	num	Score		Collected at CRF.
XRRERED	num	Re-Read Record Indicator		Collected at CRF.

Variable	Type	Label	Codes	Comments
XRRDSESN	num	Reading Session		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
XRINRSN	char	Inadequate Reason		Collected at CRF.
XRJOINT	char	Joint Evaluated		Collected at CRF.
XRTCADQ	char	Technical Adequacy		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 Subj ID for De-identity
XRDY	num	Relative Exam day		If XRDTC and IRLCNDTC not missing then perform below logic to calculate XRDY, If XRDTC less than IRLCNDTC then (XRDTC - IRLCNDTC). Else if XRDTC is greater than equal to IRLCNDTC then (XRDTC - IRLCNDTC) +1.

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

1.4.33. Xrtrack - XRTRACK

Dataset	XRTRACK
Creating program	xrtrack.sas
Description	Xrtrack
Unique identifier	DUSUBJID, EVENT_ID, XRMISIMG, XROOWIN, XRTYPE, XRSEQ
Sorted by	DUSUBJID, EVENT_ID, XRMISIMG, XROOWIN, XRTYPE, XRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to repetition of the information: XRBLNDPT,PAG_NAME,XRMISCM1,XRMISCM2,XROOWCM1,XROOWCM2,COUNTRY,AGE,RACE,SEX,XRDT,XRDTC

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event Identifier		Collected at CRF.
XRSEQ	num	Sequence Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
XRMISIMG	char	Missing Image		Collected at CRF.
XROOWIN	char	Image Out of Window		Collected at CRF.
XRTYPE	char	Anatomical Location of Image		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 Subj ID for De-identity
XRDY	num	Relative Exam day		If XRDTTC and IRLCNDTC not missing then perform below logic to calculate XRDY,if XRDTTC less than IRLCNDTC then (XRDTTC - IRLCNDTC).Else if XRDTTC is greater than equal to IRLCNDTC then (XRDTTC-IRLCNDTC) +1.