

Clinical Development

CNT0312

C0168T51

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided.
- Investigator 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.
- Completely missing variables those are not annotated in CRF will not be included in the De-identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset with zero observation and zero variable will not be submitted (ex. DEXA,DEXTRACK and INVSIG).
- Dataset with zero observation will not be submitted (ex. UNBLIND).
- Remove OASISDEM dataset, since it does not belongs to this study.
- IVRSRAND.RAND_DT (Local Randomization Date) will be used as Reference Date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files

The C0168T51 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMO

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

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

1.4.2. 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: COUNTRY,AETERM,AEMODIFY,AESTDY,AESTMO,AESTYR,AESTDT,AEENDY,AEENMO,AEENYR,AEENDT,UNIQUE_P,AGE,RACE,SEX,AEENDTC,AESTDTC

Variable	Type	Label	Codes	Comments
AECD	char	WHOART Adverse Event Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
LINE_NO	num	Line Number		Collected at CRF.
AESTTM	num	Onset Time		Collected at CRF.
AEENTM	num	Resolution Time		Collected at CRF.
AESEV	char	AE Intensity		Collected at CRF.
SAECONG	char	Congenital Anomaly		Collected at CRF.
SAEDISAB	char	Significant Disability		Collected at CRF.
SAEOTH	char	Other Serious		Collected at CRF.
AESER7	char	Not Serious		Collected at CRF.
SAEHOSP	char	Hospitalization		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.

Variable	Type	Label	Codes	Comments
SAELIFE	char	Life-threatening		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AEENDY	num	Relative End Day of Event		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 Start Day of Event		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.

1.4.3. Atrack – ATRACK

Dataset	ATRACK
Creating program	atrack.sas
Description	Atrack
Unique identifier	DUSUBJID,PERIOD,ASSAY,LABEVNT,SAMP_DY
Sorted by	DUSUBJID,PERIOD,ASSAY,LABEVNT,SAMP_DY
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,COLLNUM,ACCNUM,SAMP_DY,SAMP_MO,SAMP_YR,SAMP_DT, SAMP_HR,SAMP_MI,UNIQUE_P,AGE,SEX,RACE,SAMP_DTC

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LABEVNT	char	Lab Event		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
SAMP_TM	num	Sample Time		Collected at CRF.
NOT_COL	char	Sample Not Collected		Collected at CRF.
ASSAY	char	Assay 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

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 Subject ID for De-identity
SAMP_DY	num	Relative Sample Day		If SAMP_DTC and REF.DATE not missing then perform below logic to calculate SAMP_DY, If SAMP_DTC less than REF.DATE then (SAMP_DTC - REF.DATE). Else if SAMP_DTC is greater than equal to REF.DATE then (SAMP_DTC- REF.DATE) +1.

1.4.4. Bath Ankylosing Spondylitis Disease Activity Index – BASDAI

Dataset	BASDAI
Creating program	basdai.sas
Description	Bath Ankylosing Spondylitis Disease Activity Index
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
BDTIRED	num	Fatigue/tiredness Score		Collected at CRF.
BDNBHPN	num	Neck, Back or Hip Pain Score		Collected at CRF.
BDOTHPN	num	Other Pain/swelling Score		Collected at CRF.
BDDISC	num	Overall Level of Discomfort to Touch		Collected at CRF.
BDMSTIFF	num	Overall Level of Morning Stiffness Score		Collected at CRF.
BDSTFDUR	num	Morning Stiffness (cm)		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

1.4.5. Bath Ankylosing Spondylitis Functional Index – BASFI

Dataset	BASFI
Creating program	basfi.sas
Description	Bath Ankylosing Spondylitis Functional Index
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
BFDRESS	num	Unassisted Dressing		Collected at CRF.

Variable	Type	Label	Codes	Comments
BFBEND	num	Unassisted Bending Forward		Collected at CRF.
BFREACH	num	Unassisted Reaching		Collected at CRF.
BFSEAT	num	Unassisted Rising from a Seated Position		Collected at CRF.
BFFLOOR	num	Unassisted Rising from a Lying Position		Collected at CRF.
BFSTAND	num	Standing Without Discomfort		Collected at CRF.
BFCLIMB	num	Unassisted Climbing		Collected at CRF.
BFLOOK	num	Looking Without Turning the Body		Collected at CRF.
BFPHYACT	num	Physical Activity		Collected at CRF.
BFDAYACT	num	Full Days Activity		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

1.4.6. Bath Ankylosing Spondylitis Metrology Index – BASMI

Dataset	BASMI
Creating program	basmi.sas
Description	Bath Ankylosing Spondylitis Metrology Index
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
BMTRAWAL	num	Tragus to Wall		Collected at CRF.
BMLMFLX	num	Lumbar Flexion		Collected at CRF.
BMCRVROT	num	Cervical Rotation		Collected at CRF.
BMLMSFLX	num	Lumbar Side Flexion		Collected at CRF.
BMIMDIST	num	Intermalleolar Distance		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

1.4.7. Chest Expansion – CHESTEX

Dataset	CHESTEX
Creating program	chestex.sas
Description	Chest Expansion
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CXMAXIN	num	Max. Inspiration Chest Circumference(cm)		Collected at CRF.
CXMAXEXP	num	Max. Expiration Chest Circumference(cm)		Collected at CRF.

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

1.4.8. Concomitant Medication – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medication
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: COUNTRY,CMTERM,CMMODIFY,CMSTDY,CMSTMO,CMSTYR,CMSTDT,CMENDY,CMENMO,CMENYR,CMENDT,UNIQUE_P,AGE,RACE,SEX,CMSTDTC,CMENDTC

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

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
CMONGO	char	Ongoing Medication		Collected at CRF.
CMROUTE	char	Route 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
CMSTDY	num	Relative Start Day of Medication		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 End Day of Medication		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.

1.4.9. Prior Joint Procedures/Injections – CONPROC

Dataset	CONPROC
Creating program	conproc.sas
Description	Prior Joint Procedures/Injections
Unique identifier	DUSUBJID,PR_TYPE,JOINTD,PRRELAT,VISIT,PRDY
Sorted by	DUSUBJID,PR_TYPE,JOINTD,PRRELAT,VISIT,PRDY
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, PRJNTSP ,PRPRSPEC,PRDT,UNIQUE_P,AGE,RACE,SEX

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

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
LINE_NO	num	Line Number		Collected at CRF.
JOINT	num	Joint		Collected at CRF.
PRTMSINC	char	Time Since Procedure		Collected at CRF.
PRRELAT	char	Related Procedure		Collected at CRF.
PRINOUT	char	Site of Care		Collected at CRF.
PR_TYPE	char	Procedure Code		Collected at CRF.
JOINTD	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
PRDY	num	Relative Procedure Day		If PRDT and REF.DATE not missing then perform below logic to calculate PRDY, If PRDT less than REF.DATE then (PRDT - REF.DATE). Else if PRDT is greater than equal to REF.DATE then (PRDT - REF.DATE) +1.

1.4.10. Cresul – CRESUL

Dataset	CRESUL
Creating program	cresul.sas
Description	Cresul
Unique identifier	DUSUBJID,CPRESCAT,CPTTEST,CPPERIOD,CPRESC
Sorted by	DUSUBJID,CPRESCAT,CPTTEST,CPPERIOD,CPRESC
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: CPLABEL ,UNIQUE_P

Variable	Type	Label	Codes	Comments
CPLABID	char	CPLABID		Collected at CRF.
CPPERIOD	char	CPPERIOD		Collected at CRF.
CPASYCD	char	CPASYCD		Collected at CRF.
CPASY	char	CPASY		Collected at CRF.
CPTTESTCD	char	CPTTESTCD		Collected at CRF.
CPTTEST	char	CPTTEST		Collected at CRF.
CPRESCAT	char	CPRESCAT		Collected at CRF.
CPRESC	char	CPRESC		Collected at CRF.
CPUNIT	char	CPUNIT		Collected at CRF.
CPLLOQ	num	CPLLOQ		Collected at CRF.

Variable	Type	Label	Codes	Comments
CPCMT1CD	char	CPCMT1CD		Collected at CRF.
CPCMT1	char	CPCMT1		Collected at CRF.
CPCMT2CD	char	CPCMT2CD		Collected at CRF.
CPCMT2	char	CPCMT2		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.11. Subject Selection Criteria – CRITERIA

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

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
ICRIT_1	char	First Inclusion Criterion Not Met		Collected at CRF.
ICRIT_2	char	Second Inclusion Criterion Not Met		Collected at CRF.
ICRIT_3	char	Third Inclusion Criterion Not Met		Collected at CRF.
ICRIT_4	char	Fourth Inclusion Criterion Not Met		Collected at CRF.
XCRIT_1	char	First Exclusion Criterion Present		Collected at CRF.
XCRIT_2	char	Second Exclusion Criterion Present		Collected at CRF.
XCRIT_3	char	Third Exclusion Criterion Present		Collected at CRF.
XCRIT_4	char	Fourth Exclusion Criterion Present		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRITMET	char	All Criteria 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
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. Dexacor – DEXACOR

Dataset	DEXACOR
Creating program	dexacor.sas
Description	Dexacor
Unique identifier	DUSUBJID,DCIMLOCD,VISIT
Sorted by	DUSUBJID,DCIMLOCD,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: COUNTRY,DCEXDT,DCSSCDT,DCCOMNT,UNIQUE_P,DCSSCDTC,DCEXDT

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

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
DCIMLOC	num	Image Location		Collected at CRF.
DCCORBMD	num	Corrected BMD		Collected at CRF.
DCPCTDIF	num	Percentage Difference		Collected at CRF.
DCIMLOCD	char	DCIMLOC Decode		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
DCSSCDY	num	Relative IQC Shift/Scanner Change Day		If DCSSCDTC and REF.DATE not missing then perform below logic to calculate DCSSCDY, If DCSSCDTC less than REF.DATE then (DCSSCDTC - REF.DATE). Else if DCSSCDTC is greater than equal to REF.DATE then (DCSSCDTC- REF.DATE) +1.
DCEXDY	num	Relative Exam Day		If DCEXDTC and REF.DATE not missing then perform below logic to calculate DCEXDY, If DCEXDTC less than REF.DATE then (DCEXDTC - REF.DATE). Else if DCEXDTC is greater than equal to REF.DATE then (DCEXDTC- REF.DATE) +1.

1.4.13. Dexafemr – DEXAFEMR

Dataset	DEXAFEMR
Creating program	dexafemr.sas
Description	Dexafemr
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 or due to missing values: COUNTRY,DFEXDT,DFBCOM1,DFBCOM2,DFSCOM1,DFSCOM2,UNIQUE_P, DFEXDTC

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DFEXTM	num	Exam Time		Collected at CRF.
DFNBMC	num	Femoral Neck BMC		Collected at CRF.
DFNAREA	num	Femoral Neck Area		Collected at CRF.
DFNBMD	num	Femoral Neck BMD		Collected at CRF.
DFNTSCR	num	Femoral Neck T-score		Collected at CRF.
DFNZSCR	num	Femoral Neck Z-score		Collected at CRF.
DFWBMC	num	Femoral Ward BMC		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFWAREA	num	Femoral Ward Area		Collected at CRF.
DFWBMD	num	Femoral Ward BMD		Collected at CRF.
DFWTSCR	num	Femoral Ward T-score		Collected at CRF.
DFWZSCR	num	Femoral Ward Z-score		Collected at CRF.
DFTBMC	num	Trochanter BMC		Collected at CRF.
DFTAREA	num	Trochanter Area		Collected at CRF.
DFTBMD	num	Trochanter BMD		Collected at CRF.
DFTTSCR	num	Trochanter T-score		Collected at CRF.
DFTZSCR	num	Trochanter Z-score		Collected at CRF.
DFSBMC	num	Shaft/Intertroch BMC		Collected at CRF.
DFSAREA	num	Shaft/Intertroch Area		Collected at CRF.
DFSBMD	num	Shaft/Intertroch BMD		Collected at CRF.
DFSTSCR	num	Shaft/Intertroch T-score		Collected at CRF.
DFSZSCR	num	Shaft/Intertroch Z-score		Collected at CRF.
DFHTSCR	num	Total Hip T-score		Collected at CRF.
DFHZSCR	num	Total Hip Z-score		Collected at CRF.
DFTHBMC	num	Total Analyzable Hip - BMC		Collected at CRF.
DFTHAREA	num	Total Analyzable Hip - Area		Collected at CRF.
DFTHBMD	num	Total Analyzable Hip - BMD		Collected at CRF.
DFEXPNUM	num	Export Number		Collected at CRF.
DFWADEQ	char	Femoral Ward Adequate		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFNADEQ	char	Femoral Neck Adequate		Collected at CRF.
DFSADEQ	char	Shaft/Intertroch Adequate		Collected at CRF.
DFTADEQ	char	Trochanter Adequate		Collected at CRF.
DFSIDE	char	Body Side		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
DFEXDY	num	Relative Exam Day		If DFEXDTC and REF.DATE not missing then perform below logic to calculate DFEXDY, If DFEXDTC less than REF.DATE then (DFEXDTC - REF.DATE). Else if DFEXDTC is greater than equal to REF.DATE then (DFEXDTC- REF.DATE) +1.

1.4.14. Dexaspin – DEXASPIN

Dataset	DEXASPIN
Creating program	dexaspin.sas
Description	Dexaspin
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 or due to missing values: COUNTRY,DXEXDT,DXBCOM1,DXBCOM2,DXSCOM1,DXSCOM2,UNIQUE_P, DXEXDTC

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DXEXTM	num	Exam Time		Collected at CRF.
DXL1BMC	num	L1 BMC		Collected at CRF.
DXL1AREA	num	L1 Area		Collected at CRF.
DXL1BMD	num	L1 BMD		Collected at CRF.
DXL1TSCR	num	L1 T-score		Collected at CRF.
DXL1ZSCR	num	L1 Z-score		Collected at CRF.
DXL2BMC	num	L2 BMC		Collected at CRF.

Variable	Type	Label	Codes	Comments
DXL2AREA	num	L2 Area		Collected at CRF.
DXL2BMD	num	L2 BMD		Collected at CRF.
DXL2TSCR	num	L2 T-score		Collected at CRF.
DXL2ZSCR	num	L2 Z-score		Collected at CRF.
DXL3BMC	num	L3 BMC		Collected at CRF.
DXL3AREA	num	L3 Area		Collected at CRF.
DXL3BMD	num	L3 BMD		Collected at CRF.
DXL3TSCR	num	L3 T-score		Collected at CRF.
DXL3ZSCR	num	L3 Z-score		Collected at CRF.
DXL4BMC	num	L4 BMC		Collected at CRF.
DXL4AREA	num	L4 Area		Collected at CRF.
DXL4BMD	num	L4 BMD		Collected at CRF.
DXL4TSCR	num	L4 T-score		Collected at CRF.
DXL4ZSCR	num	L4 Z-score		Collected at CRF.
DXL1L4TS	num	L1 - L4 T-score		Collected at CRF.
DXL1L4ZS	num	L1 - L4 Z-score		Collected at CRF.
DXTOTBMC	num	Total Analyzable Vertebrae - BMC		Collected at CRF.
DXTOTARE	num	Total Analyzable Vertebrae - Area		Collected at CRF.
DXTOTBMD	num	Total Analyzable Vertebrae - BMD		Collected at CRF.
DXEXPNUM	num	Export Number		Collected at CRF.
DXL4ADEQ	char	L4 Adequate		Collected at CRF.

Variable	Type	Label	Codes	Comments
DXL1ADEQ	char	L1 Adequate		Collected at CRF.
DXL2ADEQ	char	L2 Adequate		Collected at CRF.
DXL3ADEQ	char	L3 Adequate		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
DXEXDY	num	Relative Exam Day		If DXEXDTC and REF.DATE not missing then perform below logic to calculate DXEXDY, If DXEXDTC less than REF.DATE then (DXEXDTC - REF.DATE). Else if DXEXDTC is greater than equal to REF.DATE then (DXEXDTC- REF.DATE) +1.

1.4.15. Diagnosis Information – DIAGINFO

Dataset	DIAGINFO
Creating program	diaginfo.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: COUNTRY,CHDY,CHMO,CHYR,CHDT,UNIQUE_P,AGE,RACE,SEX,CHDTC

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

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

1.4.16. Patient Global Assessment – DIS_EVAL

Dataset	DIS_EVAL
Creating program	dis_eval.sas
Description	Patient Global Assessment
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PGGDAPAT	num	Patient VAS Score for GDA		Collected at CRF.

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

1.4.17. Drug Preparation – DRUGPREP

Dataset	DRUGPREP
Creating program	drugprep.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 or due to missing values: COUNTRY,DPDT,DPLOTNO1,DPLOTNO2,DPLOTNO3,UNIQUE_P,DPDTC

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DPSEQ	num	Drug Preparation Sequence Number		Collected at CRF.
DPVWDRWN	num	Volume Withdrawn from Vial(s) in mL		Collected at CRF.
DPVPREP	num	Volume Prepared in Milliliters		Collected at CRF.
DPND	char	Drug Preparation 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

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 Subject ID for De-identity
DPDY	num	Relative Day Prepared		If DPDTC and REF.DATE not missing then perform below logic to calculate DPDY, If DPDTC less than REF.DATE then (DPDTC - REF.DATE). Else if DPDTC is greater than equal to REF.DATE then (DPDTC-REF.DATE) +1.

1.4.18. Health Economic Questionnaire – ECONOM

Dataset	ECONOM
Creating program	econom.sas
Description	Health Economic Questionnaire
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
HEFPVIS	num	Disease-related Family Physician Visits		Collected at CRF.
HESPVIS	num	Disease-related Specialist Visits		Collected at CRF.
HEERVIS	num	Disease-related Emergency Room Visits		Collected at CRF.
HEPSVIS	num	Disease-related Physiotherapist Visits		Collected at CRF.
HENRVIS	num	Disease-related Nursing Visits		Collected at CRF.
HEHRSWK	num	Number of Hours Worked		Collected at CRF.

Variable	Type	Label	Codes	Comments
HEMISSDY	num	Days Pt Missed Due to Illness		Collected at CRF.
HEPROD	num	Productivity Scale (Vas 0-10 cm)		Collected at CRF.
HEHAVIS	num	Household Assistance Visits		Collected at CRF.
HEHAHRS	num	Household Assistance Hours Per Visit		Collected at CRF.
HECGMISS	num	Caregiver Missed Days		Collected at CRF.
HEWRKING	char	Patient Currently Actively Employed		Collected at CRF.
HECANWRK	char	Could Work if Job Available		Collected at CRF.
HESCHOOL	char	School Attendance		Collected at CRF.
HERETIRE	char	Retired		Collected at CRF.
HEPSND	char	Productivity Scale Not Done		Collected at CRF.
HEDISAB	char	Receiving Disability Compensation		Collected at CRF.
HERLHAV	char	Disease Related Household Assist. Visits		Collected at CRF.
HESTUDNT	char	Subject Currently Attending School		Collected at CRF.
HEWRKFP	char	Working Full or Part-time		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

1.4.19. Enthesis Index – ENTHIDX

Dataset	ENTHIDX
Creating program	enthidx.sas
Description	Enthesis Index
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EILGRTUB	num	Greater Tuberosity of the Humerus Left		Collected at CRF.
EIRGRTUB	num	Greater Tuberosity of the Humerus Right		Collected at CRF.

Variable	Type	Label	Codes	Comments
EILMEDEH	num	Medial Epicondyles Humerus Left Side		Collected at CRF.
EIRMEDEH	num	Medial Epicondyles Humerus Right Side		Collected at CRF.
EILLATEH	num	Lateral Epicondyles Humerus Left Side		Collected at CRF.
EIRLATEH	num	Lateral Epicondyles Humerus Right Side		Collected at CRF.
EILILCR	num	Iliac Crest Left Side		Collected at CRF.
EIRILCR	num	Iliac Crest Right Side		Collected at CRF.
EILASIS	num	Anterior Superior Iliac Spine Left Side		Collected at CRF.
EIRASIS	num	Anterior Superior Iliac Spine Right Side		Collected at CRF.
EILGTF	num	Greater Trochanter of Femur Left Side		Collected at CRF.
EIRGTF	num	Greater Trochanter of Femur Right Side		Collected at CRF.
EILMDCDF	num	Medial Condyles of Femur Left Side		Collected at CRF.
EIRMDCDF	num	Medial Condyles of Femur Right Side		Collected at CRF.
EILLTCDF	num	Lateral Condyles of Femur Left Side		Collected at CRF.
EIRLTCDF	num	Lateral Condyles of Femur Right Side		Collected at CRF.

Variable	Type	Label	Codes	Comments
EILCIPFA	num	Caleaneal Ins Plantar Fascia Left Side		Collected at CRF.
EIRCIPFA	num	Caleaneal Ins Plantar Fascia Right Side		Collected at CRF.
EILCIACT	num	Caleaneal Ins Achilles Tendon Left Side		Collected at CRF.
EIRCIACT	num	Caleaneal Ins Achilles Tendon Right Side		Collected at CRF.
EILIT	num	Ischial Tuberosity Left Side		Collected at CRF.
EIRIT	num	Ischial tuberosity Right side		Collected at CRF.
EILPSIS	num	Posterior Superior Iliac Spine Left		Collected at CRF.
EIRPSIS	num	Posterior Superior Iliac Spine Right		Collected at CRF.
EIMSJNT	num	Manubriosternal Joint		Collected at CRF.
EINUCRST	num	Nuchal Crests		Collected at CRF.
EICOSJNT	num	Costochondral Joints		Collected at CRF.
EICRVREG	num	Cervical Region		Collected at CRF.
EITHOREG	num	Thoracic Region		Collected at CRF.
EILUMREG	num	Lumbar Region		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

1.4.20. Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure
Unique identifier	DUSUBJID,VISIT,EXSTDY
Sorted by	DUSUBJID,VISIT,EXSTDY
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,EXSTDY,UNIQUE_P,AGE,RACE,SEX,EXSTDTC

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 Hour Clock		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMTADM	num	Amount Administered		Collected at CRF.
EXND	char	Dose Not Done		Collected at CRF.
AMTADMU	char	Amount Administered 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 Subject ID for De-identity
TRTGRP	char	Treatment Group		Collected at CRF.
EXSTDY	num	Relative Start Day of Dose		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.

1.4.21. Hospitalization – HOSPIN

Dataset	HOSPIN
Creating program	hospin.sas
Description	Hospitalization
Unique identifier	DUSUBJID,VISIT,HOADM DY
Sorted by	DUSUBJID,VISIT,HOADM DY
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,HOADM DT,HODISDT,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
HOICUDYS	num	Total Number of Days in ICU		Collected at CRF.
HONODSCH	char	Not Discharged		Collected at CRF.
HODISREL	char	Disease Related Hospitalization		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
HOADMDY	num	Relative Hospital Admission Day		If HOADMDT and REF.DATE not missing then perform below logic to calculate HOADMDY, If HOADMDT less than REF.DATE then (HOADMDT - REF.DATE). Else if HOADMDT is greater than equal to REF.DATE then (HOADMDT- REF.DATE) +1.
HODISDY	num	Relative Hospital Discharge Day		If HODISDT and REF.DATE not missing then perform below logic to calculate HODISDY, If HODISDT less than REF.DATE then (HODISDT - REF.DATE). Else if HODISDT is greater than equal to REF.DATE then (HODISDT- REF.DATE) +1.

1.4.22. 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 due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
AESEQ	num	Ae Page Sequence		Collected at CRF.
AELN	num	Ae CRF Line Number		Collected at CRF.
AESEQ2	num	Ae Page Sequence 2		Collected at CRF.
AELN2	num	Ae CRF Line Number 2		Collected at CRF.
AESEQ3	num	Ae Page Sequence 3		Collected at CRF.
AELN3	num	Ae CRF Line Number 3		Collected at CRF.
MEDSEQ	num	Medication Page Sequence		Collected at CRF.

Variable	Type	Label	Codes	Comments
MEDLN	num	Medication CRF Line Number		Collected at CRF.
MEDSEQ2	num	Medication Page Sequence 2		Collected at CRF.
MEDLN2	num	Medication CRF Line Number 2		Collected at CRF.
MEDSEQ3	num	Medication Page Sequence 3		Collected at CRF.
MEDLN3	num	Medication CRF Line Number 3		Collected at CRF.
IFOINFSP	char	Other Infection Specify		Collected at CRF.
IFWNDCLT	char	Wound or Drainage Cultured		Collected at CRF.
IFSTREP	char	Streptococcus Infection		Collected at CRF.
IFSTAPHA	char	Staph Aureus Infection		Collected at CRF.
IFURICLT	char	Urine Cultured		Collected at CRF.
IFVIRAL	char	Viral		Collected at CRF.
IFSPUCLT	char	Sputum Cultured		Collected at CRF.
IFOCLT	char	Other Culture		Collected at CRF.
IFANTIMC	char	Antimicrobial tx Given For Infection		Collected at CRF.
IFBLDCLT	char	Blood Cultured		Collected at CRF.
IFCLTPOS	char	Cultures Indicated Infection		Collected at CRF.
IFCLT	char	Cultures Performed		Collected at CRF.
IFFUNGAL	char	Fungal		Collected at CRF.
IFGRMNEG	char	Gram Negative		Collected at CRF.
IFGRMPOS	char	Other Gram Positive		Collected at CRF.

Variable	Type	Label	Codes	Comments
IFHX	char	History of Similar Infections		Collected at CRF.
IFMYCBCT	char	Mycobacterial		Collected at CRF.
IFPROTZ	char	Protozoal		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. Ivrsdose – IVRSDOSE

Dataset	IVRSDOSE
Creating program	ivrsdose.sas
Description	Ivrsdose
Unique identifier	DSUBJID,DOSE,EVENT_ID
Sorted by	DSUBJID,DOSE,EVENT_ID
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: REC_ID,SCTRY

Variable	Type	Label	Codes	Comments
R_DRUG	char	Program Identifier - Drug		Collected at CRF.
TAREA	char	Program Identifier - Therapeutic Area		Collected at CRF.
PNO	char	Protocol Identifier - Number		Collected at CRF.
F_STATUS	char	Record Status		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
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
IVRS_SQ	num	Sequence		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASDAI	num	BASDAI		Collected at CRF.
DOSE	num	Dose (mg/kg)		Collected at CRF.

1.4.24. 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 repetition of the information: SCTRY,RAND_DT

Variable	Type	Label	Codes	Comments
REC_ID	char	Record Identifier		Collected at CRF.
R_DRUG	char	Program Identifier - Drug		Collected at CRF.
TAREA	char	Program Identifier - Therapeutic Area		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
EVENT_ID	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.

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

1.4.25. Lower Left Extremity Joint Evaluation – JNTSC_LL

Dataset	JNTSC_LL
Creating program	jntsc_ll.sas
Description	Lower Left Extremity Joint Evaluation
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 or due to repetition of the information: COUNTRY,JTEVAL,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
JOINT	num	Joint		Collected at CRF.
VISIT	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.
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

1.4.26. Lower Right Extremity Joint Evaluation – JNTSC_LR

Dataset	JNTSC_LR
Creating program	jntsc_lr.sas
Description	Lower Right Extremity Joint Evaluation
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
JOINT	num	Joint		Collected at CRF.
VISIT	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.

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

1.4.27. Upper Left Extremity Joint Evaluation – JNTSC_UL

Dataset	JNTSC_UL
Creating program	jntsc_ul.sas
Description	Upper Left Extremity Joint Evaluation
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
JOINT	num	Joint		Collected at CRF.

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

1.4.28. Upper Right Extremity Joint Evaluation – JNTSC_UR

Dataset	JNTSC_UR
Creating program	jntsc_ur.sas
Description	Upper Right Extremity Joint Evaluation
Unique identifier	DUSUBJID,JOINTD,VISIT
Sorted by	DUSUBJID,JOINTD,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
JOINT	num	Joint		Collected at CRF.
VISIT	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.
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. 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: COUNTRY, LBLBLNUM, LBDY, LBMO, LBYR, LBDT, LBACTHR, LBACTMI, UNIQUE_P, RACE, LBDTC, LBID

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
VISIT	char	Lab Event		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	Original Units		Collected at CRF.
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTUNIT	char	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.
LBSTUSET	char	Lab Standard Unit Set		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.
SEX	char	Sex		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBCOM	char	Lab Comment		Collected at CRF.
LBTEST	char	Decode of LBTSTCD		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LBDY	num	Relative Day of Specimen Collection		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.

1.4.30. Lab_ancl – LAB_ANCL

Dataset	LAB_ANCL
Creating program	lab_ancl.sas
Description	Lab_ancl
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
AG_RES	char	Antigen Result		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

1.4.31. Ltrack – LTRACK

Dataset	LTRACK
Creating program	ltrack.sas
Description	Ltrack
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
SAMPOBT	char	Lab Sample Obtained/sent		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

1.4.32. Medclass – MEDCLASS

Dataset	MEDCLASS
Creating program	medclass.sas
Description	Medclass
Unique identifier	ATC_CODE,SEQ1
Sorted by	ATC_CODE,SEQ1
Notes	

Variable	Type	Label	Codes	Comments
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
LEVEL1	char	1st Level, ATC Class		Collected at CRF.
LEVEL2	char	2nd Level, ATC Class		Collected at CRF.
LEVEL3	char	3rd Level, ATC Class		Collected at CRF.
LEVEL4	char	4th Level, ATC Class		Collected at CRF.
ATC_CODE	char	ATC Code		Collected at CRF.

1.4.33. Medical History – MEDHX

Dataset	MEDHX
Creating program	medhx.sas
Description	Medical History
Unique identifier	DUSUBJID,UVEITIS,ANKSPON
Sorted by	DUSUBJID,UVEITIS,ANKSPON
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
UVEITIS	char	Uveitis		Collected at CRF.
ANKSPON	char	Ankylosing Spondylitis		Collected at CRF.
PSORIAS	char	Psoriasis		Collected at CRF.
IBD	char	Inflammatory Bowel Disease		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

1.4.34. Mri – MRI

Dataset	MRI
Creating program	mri.sas
Description	Mri
Unique identifier	DUSUBJID,MRREADD,MRRND,MREXDY
Sorted by	DUSUBJID,MRREADD,MRRND,MREXDY
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, MRBLNUM ,MREXDT,UNIQUE_P

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
MRREAD	num	MRI Read		Collected at CRF.
MRRANDTP	char	Random Timepoint		Collected at CRF.
MRREADER	num	Reader Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
MRQ1OSP	char	Timepoint A Other Reason Specify		Collected at CRF.
MRQ2A	char	Timepoint A Updated Vertebrae ID		Collected at CRF.
MRQ3OSP	char	Timepoint B Other Reason Specify		Collected at CRF.
MRQ4A	char	Timepoint B Updated Vertebrae ID		Collected at CRF.
MRAC2C3	char	Activity Score C2/C3		Collected at CRF.
MRAC3C4	char	Activity Score C3/C4		Collected at CRF.
MRAC4C5	char	Activity Score C4/C5		Collected at CRF.
MRAC5C6	char	Activity Score C5/C6		Collected at CRF.
MRAC6C7	char	Activity Score C6/C7		Collected at CRF.
MRAC7T1	char	Activity Score C7/T1		Collected at CRF.
MRAT1T2	char	Activity Score T1/T2		Collected at CRF.
MRAT2T3	char	Activity Score T2/T3		Collected at CRF.
MRAT3T4	char	Activity Score T3/T4		Collected at CRF.
MRAT4T5	char	Activity Score T4/T5		Collected at CRF.
MRAT5T6	char	Activity Score T5/T6		Collected at CRF.
MRAT6T7	char	Activity Score T6/T7		Collected at CRF.
MRAT7T8	char	Activity Score T7/T8		Collected at CRF.
MRAT8T9	char	Activity Score T8/T9		Collected at CRF.
MRAT9	char	Activity Score T9/T10		Collected at CRF.
MRAT10	char	Activity Score T10/T11		Collected at CRF.
MRAT11	char	Activity Score T11/T12		Collected at CRF.

Variable	Type	Label	Codes	Comments
MRAT12	char	Activity Score T12/L1		Collected at CRF.
MRAL1L2	char	Activity Score L1/L2		Collected at CRF.
MRAL2L3	char	Activity Score L2/L3		Collected at CRF.
MRAL3L4	char	Activity Score L3/L4		Collected at CRF.
MRAL4L5	char	Activity Score L4/L5		Collected at CRF.
MRAL5S1	char	Activity Score L5/S1		Collected at CRF.
MRCC2C3	char	Chronicity Score C2/C3		Collected at CRF.
MRCC3C4	char	Chronicity Score C3/C4		Collected at CRF.
MRCC4C5	char	Chronicity Score C4/C5		Collected at CRF.
MRCC5C6	char	Chronicity Score C5/C6		Collected at CRF.
MRCC6C7	char	Chronicity Score C6/C7		Collected at CRF.
MRCC7T1	char	Chronicity Score C7/T1		Collected at CRF.
MRCT1T2	char	Chronicity Score T1/T2		Collected at CRF.
MRCT2T3	char	Chronicity Score T2/T3		Collected at CRF.
MRCT3T4	char	Chronicity Score T3/T4		Collected at CRF.
MRCT4T5	char	Chronicity Score T4/T5		Collected at CRF.
MRCT5T6	char	Chronicity Score T5/T6		Collected at CRF.
MRCT6T7	char	Chronicity Score T6/T7		Collected at CRF.
MRCT7T8	char	Chronicity Score T7/T8		Collected at CRF.
MRCT8T9	char	Chronicity Score T8/T9		Collected at CRF.
MRCT9	char	Chronicity Score T9/T10		Collected at CRF.

Variable	Type	Label	Codes	Comments
MRCT10	char	Chronicity Score T10/T11		Collected at CRF.
MRCT11	char	Chronicity Score T11/T12		Collected at CRF.
MRCT12	char	Chronicity Score T12/L1		Collected at CRF.
MRCL1L2	char	Chronicity Score L1/L2		Collected at CRF.
MRCL2L3	char	Chronicity Score L2/L3		Collected at CRF.
MRCL3L4	char	Chronicity Score L3/L4		Collected at CRF.
MRCL4L5	char	Chronicity Score L4/L5		Collected at CRF.
MRCL5S1	char	Chronicity Score L5/S1		Collected at CRF.
MRRND	char	MRI Round		Collected at CRF.
MRQ3A2	char	Timepoint B Patient Motion		Collected at CRF.
MRQ1A1	char	Timepoint A Missing Slices/Images		Collected at CRF.
MRQ1A2	char	Timepoint A Patient Motion		Collected at CRF.
MRQ1A3	char	Timepoint A Improper Contrast		Collected at CRF.
MRQ1A4	char	Timepoint A Inadequate Signal		Collected at CRF.
MRQ1A5	char	Timepoint A Poor Copy Film		Collected at CRF.
MRQ1A6	char	Timepoint A Other Reason		Collected at CRF.
MRQ2	char	Timepoint A Vertebrae ID Agreement		Collected at CRF.
MRQ3	char	Timepoint B Images Technically Adequate		Collected at CRF.
MRQ3A1	char	Timepoint B Missing Slices/Images		Collected at CRF.

Variable	Type	Label	Codes	Comments
MRQ1	char	Timepoint A Images Technically Adequate		Collected at CRF.
MRQ3A3	char	Timepoint B Improper Contrast		Collected at CRF.
MRQ4	char	Timepoint B Vertebrae ID Agreement		Collected at CRF.
MRQ3A6	char	Timepoint B Other Reason		Collected at CRF.
MRQ3A5	char	Timepoint B Poor Copy Film		Collected at CRF.
MRQ3A4	char	Timepoint B Inadequate Signal		Collected at CRF.
MRREADD	char	Decode of MRREAD		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
MREXDY	num	Relative Exam Day		If MREXDT and REF.DATE not missing then perform below logic to calculate MREXDY, If MREXDT less than REF.DATE then (MREXDT - REF.DATE). Else if MREXDT is greater than equal to REF.DATE then (MREXDT- REF.DATE) +1.

1.4.35. Pkparameters – PKPARMS

Dataset	PKPARMS
Creating program	pkparms.sas
Description	Pkparameters
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: NMID,AGE,RACE,SEX,UNIQUE_P,COUNTRY

Variable	Type	Label	Codes	Comments
CL	num	CL (mL/day/kg)		Collected at CRF.
VSS	num	Vss (mL/kg)		Collected at CRF.
THALF	num	t1/2 (day)		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID 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

1.4.36. Prophylactic Medication – PROPMED

Dataset	PROPMED
Creating program	propmed.sas
Description	Prophylactic Medication
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
PMSEQ	num	Prophylactic Medication Sequence Number		Collected at CRF.
PROPGIV	char	Prophylactic Medication 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 Subject ID for De-identity

1.4.37. Questionnaires – QOL

Dataset	QOL
Creating program	qol.sas
Description	Questionnaires
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
QLGH1	num	Score for QOL Question 1		Collected at CRF.
QLHT	num	Score for QOL Question 2		Collected at CRF.
QLPF01	num	Score for QOL Question 3A		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLPF02	num	Score for QOL Question 3B		Collected at CRF.
QLPF03	num	Score for QOL Question 3C		Collected at CRF.
QLPF04	num	Score for QOL Question 3D		Collected at CRF.
QLPF05	num	Score for QOL Question 3E		Collected at CRF.
QLPF06	num	Score for QOL Question 3F		Collected at CRF.
QLPF07	num	Score for QOL Question 3G		Collected at CRF.
QLPF08	num	Score for QOL Question 3H		Collected at CRF.
QLPF09	num	Score for QOL Question 3I		Collected at CRF.
QLPF10	num	Score for QOL Question 3J		Collected at CRF.
QLRP1	num	Score for QOL Question 4A		Collected at CRF.
QLRP2	num	Score for QOL Question 4B		Collected at CRF.
QLRP3	num	Score for QOL Question 4C		Collected at CRF.
QLRP4	num	Score for QOL Question 4D		Collected at CRF.
QLRE1	num	Score for QOL Question 5A		Collected at CRF.
QLRE2	num	Score for QOL Question 5B		Collected at CRF.
QLRE3	num	Score for QOL Question 5C		Collected at CRF.
QLSF1	num	Score for QOL Question 6		Collected at CRF.
QLBP1	num	Score for QOL Question 7		Collected at CRF.
QLBP2	num	Score for QOL Question 8		Collected at CRF.
QLVT1	num	Score for QOL Question 9A		Collected at CRF.
QLMH1	num	Score for QOL Question 9B		Collected at CRF.

Variable	Type	Label	Codes	Comments
QLMH2	num	Score for QOL Question 9C		Collected at CRF.
QLMH3	num	Score for QOL Question 9D		Collected at CRF.
QLVT2	num	Score for QOL Question 9E		Collected at CRF.
QLMH4	num	Score for QOL Question 9F		Collected at CRF.
QLVT3	num	Score for QOL Question 9G		Collected at CRF.
QLMH5	num	Score for QOL Question 9H		Collected at CRF.
QLVT4	num	Score for QOL Question 9I		Collected at CRF.
QLSF2	num	Score for QOL Question 10		Collected at CRF.
QLGH2	num	Score for QOL Question 11A		Collected at CRF.
QLGH3	num	Score for QOL Question 11B		Collected at CRF.
QLGH4	num	Score for QOL Question 11C		Collected at CRF.
QLGH5	num	Score for QOL Question 11D		Collected at CRF.
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

1.4.38. Randcode – RANDCODE

Dataset	RANDCODE
Creating program	randcode.sas
Description	Randcode
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
RSN_SPEC	char	Not Treated Reason Specify		Collected at CRF.
RSNOINF	char	Reason Not Infused		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.39. Tuberculosis Information – TB_INFO

Dataset	TB_INFO
Creating program	tb_info.sas
Description	Tuberculosis 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: COUNTRY,TBPVACYR,TBPPDDT,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
TBPPDRES	char	PPD Results (Induration)		Collected at CRF.
TBPRVBCG	char	Previous BCG Vaccination		Collected at CRF.
TBPPDNR	char	PPD Test Not 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

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

1.4.40. 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: COUNTRY,DSTRM_DT,DSTRSOTH,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DAEPGSEQ	num	Adverse Event Page Sequence		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAELN	num	Adverse Event Line Number		Collected at CRF.
DAEPGSQ2	num	Adverse Event Page Sequence 2		Collected at CRF.
DAELN2	num	Adverse Event Line Number 2		Collected at CRF.
DAEPGSQ3	num	Adverse Event Page Sequence 3		Collected at CRF.
DAELN3	num	Adverse Event Line Number 3		Collected at CRF.
DSTREAS	char	Dosing Termination Reason Code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSTRM_DY	num	Relative Dosing Termination Day		If DSTRM_DT and REF.DATE not missing then perform below logic to calculate DSTRM_DY, If DSTRM_DT less than REF.DATE then (DSTRM_DT - REF.DATE). Else if DSTRM_DT is greater than equal to REF.DATE then (DSTRM_DT- REF.DATE) +1.

1.4.41. 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: COUNTRY, DSDSCDT, DTTM, DSRSOH, UNIQUE_P, AGE, RACE, SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
DTTM	num	Time of Death		Collected at CRF.
DTCAUSE	char	Stated Cause of Death		Collected at CRF.
SAEPGSEQ	num	Adverse Event Page Sequence		Collected at CRF.
SAELN	num	Adverse Event Line Number		Collected at CRF.
SAEPGSQ2	num	Adverse Event Page Sequence 2		Collected at CRF.
SAELN2	num	Adverse Event Line Number 2		Collected at CRF.
SAEPGSQ3	num	Adverse Event Page Sequence 3		Collected at CRF.
SAELN3	num	Adverse Event Line Number 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSWCAE	char	Consent Withdrawn Due to AE		Collected at CRF.
DSREAS	char	Reason for Study Termination Code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSDSCDY	num	Relative Study Termination Day		If DSDSCDT and REF.DATE not missing then perform below logic to calculate DSDSCDY, If DSDSCDT less than REF.DATE then (DSDSCDT - REF.DATE). Else if DSDSCDT is greater than equal to REF.DATE then (DSDSCDT- REF.DATE) +1.
DTDY	num	Relative Day of Death		If DTDY and REF.DATE not missing then perform below logic to calculate DTDY, If DTDY less than REF.DATE then (DTDY - REF.DATE). Else if DTDY is greater than equal to REF.DATE then (DTDY- REF.DATE) +1.

1.4.42. Subject Visits – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Subject Visits
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: COUNTRY,VISIT_DT,UNIQUE_P,AGE,RACE,SEX

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

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

1.4.43. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: COUNTRY,UNIQUE_P,AGE,RACE,SEX

Variable	Type	Label	Codes	Comments
VISIT	char	Event Identifier		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
VSWEIGHT	num	Weight in Kilograms		Collected at CRF.

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

1.4.44. Xr10pct – XR10PCT

Dataset	XR10PCT
Creating program	xr10pct.sas
Description	Xr10pct
Unique identifier	DUSUBJID,READER,TPDESC
Sorted by	DUSUBJID,READER,TPDESC
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: BITI_ID,EXDATE,UNIQUE_P

Variable	Type	Label	Codes	Comments
READER	char	Reader Number		Collected at CRF.
TRUETP	char	True Timepoint		Collected at CRF.

Variable	Type	Label	Codes	Comments
TPDESC	char	Timepoint Descriptor		Collected at CRF.
RANDTP	char	Random Timepoint		Collected at CRF.
REREAD	char	Intra ReRead		Collected at CRF.
Q1	char	Cervical Spine - Technically Adequate?		Collected at CRF.
Q1A_01	char	RO or NR - Poor Coverage		Collected at CRF.
Q1A_02	char	RO or NR - Poor Technique		Collected at CRF.
Q1A_03	char	RO or NR - Patient Motion		Collected at CRF.
Q1A_04	char	RO or NR - Site Image Sizing		Collected at CRF.
Q1A_05	char	RO or NR - Poor Positioning, etc.		Collected at CRF.
Q1A_06	char	RO or NR - Other		Collected at CRF.
Q1ACOM	char	RO or NR - Other, Comments		Collected at CRF.
Q2_C2_B	char	mSASSS Score - Cerv Spine, Bot Ant C2		Collected at CRF.
Q2_C3_B	char	mSASSS Score - Cerv Spine, Bot Ant C3		Collected at CRF.
Q2_C4_B	char	mSASSS Score - Cerv Spine, Bot Ant C4		Collected at CRF.
Q2_C5_B	char	mSASSS Score - Cerv Spine, Bot Ant C5		Collected at CRF.
Q2_C6_B	char	mSASSS Score - Cerv Spine, Bot Ant C6		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q2_C7_B	char	mSASSS Score - Cerv Spine, Bot Ant C7		Collected at CRF.
Q2_C3_T	char	mSASSS Score - Cerv Spine, Top Ant C3		Collected at CRF.
Q2_C4_T	char	mSASSS Score - Cerv Spine, Top Ant C4		Collected at CRF.
Q2_C5_T	char	mSASSS Score - Cerv Spine, Top Ant C5		Collected at CRF.
Q2_C6_T	char	mSASSS Score - Cerv Spine, Top Ant C6		Collected at CRF.
Q2_C7_T	char	mSASSS Score - Cerv Spine, Top Ant C7		Collected at CRF.
Q2_T1_T	char	mSASSS Score - Cerv Spine, Top Ant T1		Collected at CRF.
Q3	char	Lumbar Spine - Technically Adequate?		Collected at CRF.
Q3A_01	char	RO or NR - Poor Coverage		Collected at CRF.
Q3A_02	char	RO or NR - Poor Technique		Collected at CRF.
Q3A_03	char	RO or NR - Patient Motion		Collected at CRF.
Q3A_04	char	RO or NR - Site Image Sizing		Collected at CRF.
Q3A_05	char	RO or NR - Poor Positioning, etc.		Collected at CRF.
Q3A_06	char	RO or NR - Other		Collected at CRF.
Q3ACOM	char	RO or NR - Other, Comments		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q4_T12_B	char	mSASSS Score - Lumbar Spine, Bot Ant T12		Collected at CRF.
Q4_L1_B	char	mSASSS Score - Lumbar Spine, Bot Ant L1		Collected at CRF.
Q4_L2_B	char	mSASSS Score - Lumbar Spine, Bot Ant L2		Collected at CRF.
Q4_L3_B	char	mSASSS Score - Lumbar Spine, Bot Ant L3		Collected at CRF.
Q4_L4_B	char	mSASSS Score - Lumbar Spine, Bot Ant L4		Collected at CRF.
Q4_L5_B	char	mSASSS Score - Lumbar Spine, Bot Ant L5		Collected at CRF.
Q4_L1_T	char	mSASSS Score - Lumbar Spine, Top Ant L1		Collected at CRF.
Q4_L2_T	char	mSASSS Score - Lumbar Spine, Top Ant L2		Collected at CRF.
Q4_L3_T	char	mSASSS Score - Lumbar Spine, Top Ant L3		Collected at CRF.
Q4_L4_T	char	mSASSS Score - Lumbar Spine, Top Ant L4		Collected at CRF.
Q4_L5_T	char	mSASSS Score - Lumbar Spine, Top Ant L5		Collected at CRF.
Q4_S1_T	char	mSASSS Score - Lumbar Spine, Top Ant S1		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
VISIT	char	Event Identifier		Collected at CRF.
EXDY	num	Relative Exam Day		If EXDATE and REF.DATE not missing then perform below logic to calculate EXDY, If EXDATE less than REF.DATE then (EXDATE - REF.DATE). Else if EXDATE is greater than equal to REF.DATE then (EXDATE- REF.DATE) +1.

1.4.45. Xrayscor – XRAYSCOR

Dataset	XRAYSCOR
Creating program	xrayscor.sas
Description	Xrayscor
Unique identifier	DUSUBJID,READER,TPDESC
Sorted by	DUSUBJID,READER,TPDESC
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: BITI_ID,EXDATE,Q1ACOM,Q3ACOM,UNIQUE_P

Variable	Type	Label	Codes	Comments
READER	char	Reader Number		Collected at CRF.
TRUETP	char	True Timepoint		Collected at CRF.
TPDESC	char	Timepoint Descriptor		Collected at CRF.
RANDTP	char	Random Timepoint		Collected at CRF.
REREAD	char	Intra ReRead		Collected at CRF.
Q1	char	Cervical Spine - Technically Adequate?		Collected at CRF.
Q1A_01	char	RO or NR - Poor Coverage		Collected at CRF.
Q1A_02	char	RO or NR - Poor Technique		Collected at CRF.
Q1A_03	char	RO or NR - Patient Motion		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q1A_04	char	RO or NR - Site Image Sizing		Collected at CRF.
Q1A_05	char	RO or NR - Poor Positioning, etc.		Collected at CRF.
Q1A_06	char	RO or NR - Other		Collected at CRF.
Q2_C2_B	char	mSASSS Score - Cerv Spine, Bot Ant C2		Collected at CRF.
Q2_C3_B	char	mSASSS Score - Cerv Spine, Bot Ant C3		Collected at CRF.
Q2_C4_B	char	mSASSS Score - Cerv Spine, Bot Ant C4		Collected at CRF.
Q2_C5_B	char	mSASSS Score - Cerv Spine, Bot Ant C5		Collected at CRF.
Q2_C6_B	char	mSASSS Score - Cerv Spine, Bot Ant C6		Collected at CRF.
Q2_C7_B	char	mSASSS Score - Cerv Spine, Bot Ant C7		Collected at CRF.
Q2_C3_T	char	mSASSS Score - Cerv Spine, Top Ant C3		Collected at CRF.
Q2_C4_T	char	mSASSS Score - Cerv Spine, Top Ant C4		Collected at CRF.
Q2_C5_T	char	mSASSS Score - Cerv Spine, Top Ant C5		Collected at CRF.
Q2_C6_T	char	mSASSS Score - Cerv Spine, Top Ant C6		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q2_C7_T	char	mSASSS Score - Cerv Spine, Top Ant C7		Collected at CRF.
Q2_T1_T	char	mSASSS Score - Cerv Spine, Top Ant T1		Collected at CRF.
Q3	char	Lumbar Spine - Technically Adequate?		Collected at CRF.
Q3A_01	char	RO or NR - Poor Coverage		Collected at CRF.
Q3A_02	char	RO or NR - Poor Technique		Collected at CRF.
Q3A_03	char	RO or NR - Patient Motion		Collected at CRF.
Q3A_04	char	RO or NR - Site Image Sizing		Collected at CRF.
Q3A_05	char	RO or NR - Poor Positioning, etc.		Collected at CRF.
Q3A_06	char	RO or NR - Other		Collected at CRF.
Q4_T12_B	char	mSASSS Score - Lumbar Spine, Bot Ant T12		Collected at CRF.
Q4_L1_B	char	mSASSS Score - Lumbar Spine, Bot Ant L1		Collected at CRF.
Q4_L2_B	char	mSASSS Score - Lumbar Spine, Bot Ant L2		Collected at CRF.
Q4_L3_B	char	mSASSS Score - Lumbar Spine, Bot Ant L3		Collected at CRF.
Q4_L4_B	char	mSASSS Score - Lumbar Spine, Bot Ant L4		Collected at CRF.
Q4_L5_B	char	mSASSS Score - Lumbar Spine, Bot Ant L5		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q4_L1_T	char	mSASSS Score - Lumbar Spine, Top Ant L1		Collected at CRF.
Q4_L2_T	char	mSASSS Score - Lumbar Spine, Top Ant L2		Collected at CRF.
Q4_L3_T	char	mSASSS Score - Lumbar Spine, Top Ant L3		Collected at CRF.
Q4_L4_T	char	mSASSS Score - Lumbar Spine, Top Ant L4		Collected at CRF.
Q4_L5_T	char	mSASSS Score - Lumbar Spine, Top Ant L5		Collected at CRF.
Q4_S1_T	char	mSASSS Score - Lumbar Spine, Top Ant S1		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
VISIT	char	Event Identifier		Collected at CRF.
EXDY	num	Relative Exam Day		If EXDATE and REF.DATE not missing then perform below logic to calculate EXDY, If EXDATE less than REF.DATE then (EXDATE - REF.DATE). Else if EXDATE is greater than equal to REF.DATE then (EXDATE- REF.DATE) +1.

1.4.46. Xrgb – XRGB

Dataset	XRGB
Creating program	xrgb.sas
Description	Xrgb
Unique identifier	DUSUBJID,READER
Sorted by	DUSUBJID,READER
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: BITI_ID,BCODE,Q1ACOM1,Q1ACOM2,UNIQUE_P

Variable	Type	Label	Codes	Comments
READER	char	Reader Number		Collected at CRF.
Q1	char	Time point Review		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