

Clinical Development

Golimumab

C0524T28

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Datasets PC contains PK related information hence dropping the same.
- SG and MH dataset will not be submitted to protect PII.
- Data set CS contains lot number hence not submitted.
- SUPP Domains will not be submitted as same information is present in the parent dataset.
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.

1.3. Data Files

The C0524T28 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0524T28 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demographics – DM

Dataset	DM
Creating program	dm.sas
Description	Demographics
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>RFSTDTC,RFENDTC,INVID,INVNAM,BRTHDTC,ETHNIC,ARMCD,ARM,RFSTDT,RFSTTM,RFSTDTM,RFENDT,RFENTM,RFENDTM,BRTHDT,BRHTM,BRTHDTM,RA CEA,RACEIAN,RACEBA,RACENHOP,RACEOTH,RACEOTHR,RACEW, AGEU</p>

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity

DSITEID	char	Study Site ID assigned for De-identity		Randomly assigned Study Site ID for De-identity
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.

1.4.2. Adverse Event -AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event
Unique identifier	DUSUBJID, AESEQ, AEDECOD, AEBODSYS, AESEV
Sorted by	DUSUBJID, AESEQ, AEDECOD, AEBODSYS, AESEV
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:</p> <p>AEREFID,AESPID,AETERM,AEMODIFY,AESDISAB,AESDTH,AESCONG,AESHOSP, AESLIFE,AESMIE,AESTDTC,AEENDTC,AESTDT,AESTDTM,AEENDT,AEENTM,AEE NDTM,AESHOSPP,AESHOSPR,AELOC,AELOCOTH</p>

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
AESEQ	num	Sequence Number		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESEV	char	Severity/Intensity		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.
AEREL	char	Causality		Collected at CRF.
AEOUT	char	Outcome of Adverse Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.
AESTTM	num	Start Time of Adverse Event		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLT	char	Higher Level Term		Collected at CRF.
AELLT	char	Lower Level Term		Collected at CRF.
AELLTCD	char	Lower Level Term Code		Collected at CRF.
AEINF	char	Infection		Collected at CRF.
AEINFTX	char	Infection Treated with Antibiotics		Collected at CRF.
AEINJRR	char	Related to Injection Reaction		Collected at CRF.
AEINJSAR	char	Study Agent Injection Site Reaction		Collected at CRF.
AETRLPRC	char	Related to Trial Procedure		Collected at CRF.
AEDICTVS	char	Dictionary Version		Collected at CRF.

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

1.4.3. Concomitant Medication-CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medication
Unique identifier	DUSUBJID, CMSEQ, CMSPID, CMDECOD, CMCAT
Sorted by	DUSUBJID, CMSEQ, CMSPID, CMDECOD, CMCAT
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 missing values: CMTRT, CMMODIFY, CMSTDTC, CMENDTC, CMSTDT, CMSTD TM, CMENDT, CMEN DTM, CMINDOTH, CMSTTM, CMENTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
CMSEQ	num	Sequence Number		Collected at CRF.
CMSPID	char	Sponsor-Defined Identifier		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMSCAT	char	Subcategory for Medication		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMINDC	char	Indication		Collected at CRF.
CMCLAS	char	Medication Class		Collected at CRF.
CMCLASCD	char	Medication Class Code		Collected at CRF.
CMDOSE	num	Dose per Administration		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency Per Interval		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMLOC	char	Location of Medication		Collected at CRF.
CMLVL1	char	Preferred ATC Text for ATC Level 1		Collected at CRF.
CMLVL1CD	char	Preferred ATC Code for ATC Level 1		Collected at CRF.
CMLVL2	char	Preferred ATC Text for ATC Level 2		Collected at CRF.
CMLVL2CD	char	Preferred ATC Code for ATC Level 2		Collected at CRF.
CMLVL3	char	Preferred ATC Text for ATC Level 3		Collected at CRF.
CMLVL3CD	char	Preferred ATC Code for ATC Level 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMLVL4	char	Preferred ATC Text for ATC Level 4		Collected at CRF.
CMLVL4CD	char	Preferred ATC Code for ATC Level 4		Collected at CRF.
CMONGO	char	Treatment Ongoing at End of Study		Collected at CRF.
CMPRIOR	char	Treatment Began Prior to Entry		Collected at CRF.
CMDUROTH	char	Duration of Methotrexate		Collected at CRF.
CMMAXDOS	num	Maximum dose of Methotrexate		Collected at CRF.
CMDOSTWK	num	Screening Methotrexate Dose		Collected at CRF.
CMTMINJ	char	Time Since Injection		Collected at CRF.
CMDURUSE	char	Duration of Use of RA		Collected at CRF.
COMPRES	char	Previously Taken		Collected at CRF.
CMINDRA	char	Therapy for RA		Collected at CRF.
CMDICTVS	char	Dictionary Version		Collected at CRF.

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

1.4.4. Disease Characteristic- DC

Dataset	DC
Creating program	dc.sas
Description	Disease Characteristic
Unique identifier	DUSUBJID, DCSEQ, DCTESTCD, DCTEST
Sorted by	DUSUBJID, DCSEQ, DCTESTCD, DCTEST
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 missing values: DCSPID,DCSTRESN,DCREASND,DCEVAL,DCDTC,DCDT,DCTM,DCDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DCSEQ	num	Sequence Number		Collected at CRF.
DCTESTCD	char	Disease Characteristic Short Name		Collected at CRF.
DCTEST	char	Disease Characteristic Name		Collected at CRF.
DCCAT	char	Category for Disease Characteristic		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCORRES	char	Result or Finding in Original Units		Collected at CRF.
DCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
DCSTAT	char	Disease Characteristic Status		Collected at CRF.
DCLOC	char	Location of Disease Characteristic Measu		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCDY	num	Relative Day of Collection		If DCDTC and RASTDTC not missing then perform below logic to calculate DCDY, If DCDTC less than RASTDTC then (DCDTC - RASTDTC). Else if DCDTC is greater than equal to RASTDTC then (DCDTC - RASTDTC) +1.

1.4.5. Disposition-DS

Dataset	DS
Creating program	ds.sas
Description	Disposition
Unique identifier	DUSUBJID, DSSEQ, DSDECOD
Sorted by	DUSUBJID, DSSEQ, DSDECOD
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 missing values: DSSPID,DSTERM,DSSTDTC,DSSTDT,DSSTTM,DSSTD TM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSSEQ	num	Sequence Number		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.
DSCAT	char	Category for Disposition Event		Collected at CRF.
DSSCAT	char	Subcategory for Disposition Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Trial Epoch		Collected at CRF.
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDTC and RASTDTC not missing then perform below logic to calculate DSSTDY, If DSSTDTC less than RASTDTC then (DSSTDTC - RASTDTC). Else if DSSTDTC is greater than equal to RASTDTC then (DSSTDTC - RASTDTC) +1.

1.4.6. Protocol Deviations- DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	DUSUBJID,DVSEQ,DVDECOD
Sorted by	DUSUBJID,DVSEQ,DVDECOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DVSPID,DVTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DVSEQ	num	Sequence Number		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

1.4.7. Exposure -EX

Dataset	EX
Creating program	ex.sas
Description	Exposure
Unique identifier	DUSUBJID, EXSEQ, EXCAT, VISITNUM
Sorted by	DUSUBJID, EXSEQ, EXCAT, VISITNUM
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 missing values: EXSPID,EXTRT,EXDOSE,EXDOSU,EXSTAT,EXSTDTC,EXSTD,EXSTD,EXSTD,EXSYRIN,EXADMIN

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
EXSEQ	num	Sequence Number		Collected at CRF.
EXCAT	char	Category for Treatment		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.
EXLOC	char	Location of Dose Administration		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EXSTTM	num	Start Time of Treatment		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		If EXSTDTC and RASTDTC not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than RASTDTC then (EXSTDTC - RASTDTC). Else if EXSTDTC is greater than equal to RASTDTC then (EXSTDTC - RASTDTC) +1.

1.4.8. Finding About Event or Intervention -FA

Dataset	FA
Creating program	fa.sas
Description	Finding About Event or Intervention
Unique identifier	DUSUBJID,FASEQ,FASPID,FATESTCD
Sorted by	DUSUBJID,FASEQ,FASPID,FATESTCD
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 missing values: FATEST,FAEVAL,FADTC,FADT,FATM,FADTM,FADATADM,FAOBJ,FAADMIN,FACMLL4,FACMLL5,FACMLL6

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
FASEQ	num	Sequence Number		Collected at CRF.
FASPID	char	Sponsor-Defined Identifier		Collected at CRF.
FATESTCD	char	Findings About Test Short Name		Collected at CRF.
FACAT	char	Category for Findings About		Collected at CRF.

Variable	Type	Label	Codes	Comments
FASCAT	char	Subcategory for Findings About		Collected at CRF.
FAORRES	char	Result or Finding in Original Units		Collected at CRF.
FAORRESU	char	Original Units		Collected at CRF.
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
FASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
FASTRESU	char	Standard Units		Collected at CRF.
FARESCAT	char	Result Positive or Negative		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
FACMLL1	num	Concomitant Therapy Log Line Number		Collected at CRF.
FACMLL2	num	Concomitant Therapy Log Line Number		Collected at CRF.
FACMLL3	num	Concomitant Therapy Log Line Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
FADY	num	Relative Day of Collection		If FADTC and RASTDTC not missing then perform below logic to calculate FADY,If FADTC less than RASTDTC then (FADTC - RASTDTC).Else if FADTC is greater than equal to RASTDTC then (FADTC- RASTDTC) +1.
FADYADY	num	Relative Day PPD Administered		If FADATADM and RASTDTC not missing then perform below logic to calculate ,If FADATADM less than RASTDTC then (FADATADM - RASTDTC).Else if FADATADM is greater than equal to RASTDTC then (FADATADM- RASTDTC) +1.

1.4.9. Inclusion/Exclusion Criteria Not Met -IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Criteria Not Met
Unique identifier	DUSUBJID,IESEQ,IETESTCD
Sorted by	DUSUBJID,IESEQ,IETESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IESPID

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
IESEQ	num	Sequence Number		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IEORRES	char	I/E Criterion Original Result		Collected at CRF.

Variable	Type	Label	Codes	Comments
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

1.4.10. Laboratory Test Result -LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Result
Unique identifier	DUSUBJID, LBSEQ, LBTESTCD
Sorted by	DUSUBJID, LBSEQ, LBTESTCD
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 missing values: LBGRPID, LBSPID, LBSCAT, LBREASND, LBNAM, LBBLFL, LBDTC, LBDT, LBDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LBSEQ	num	Sequence Number		Collected at CRF.
LBTESTCD	char	LAB Test or Examination Short Name		Collected at CRF.
LBTEST	char	LAB Test or Examination Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.
LBORNRL0	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRLHI	char	Reference Range Upper Limit in Orig Unit		Collected at CRF.
LBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
LBSTNR0	char	Reference Range for Char Rslt-Std Units		Collected at CRF.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNR0L0	num	Reference Range Lower Limit-Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSTAT	char	Lab Status		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBSPCCND	char	Specimen Condition		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBFASST	char	Fasting Status		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBTM	num	Time of Specimen Collection		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and RASTDTC not missing then perform below logic to calculate LBDY, If LBDTC less than RASTDTC then (LBDTC - RASTDTC). Else if LBDTC is greater than equal to RASTDTC then (LBDTC - RASTDTC) +1.

1.4.11. Questionnaire - QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaire
Unique identifier	DUSUBJID, QSSEQ, QSTESTCD
Sorted by	DUSUBJID, QSSEQ, QSTESTCD
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 missing values: QSSPID, QSDTC, QSDT, QSBLFL, QSTM, QSDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
QSSEQ	num	Sequence Number		Collected at CRF.
QSTESTCD	char	Question Short Name		Collected at CRF.
QSTEST	char	Question Name		Collected at CRF.
QSCAT	char	Category of Question		Collected at CRF.
QSSCAT	char	Subcategory for Question		Collected at CRF.

Variable	Type	Label	Codes	Comments
QSORRES	char	Finding in Original Units		Collected at CRF.
QSORRESU	char	Original Units		Collected at CRF.
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
QSSTRESU	char	Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
QSDY	num	Relative Day of Finding		If QSDTC and RASTDTC not missing then perform below logic to calculate QSDY, If QSDTC less than RASTDTC then (QSDTC - RASTDTC). Else if QSDTC is greater than equal to RASTDTC then (QSDTC - RASTDTC) +1.

1.4.12. Randomisation -RA

Dataset	RA
Creating program	ra.sas
Description	Randomisation
Unique identifier	DUSUBJID,RASEQ
Sorted by	DUSUBJID,RASEQ
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 missing values: RASPID,RANUM,RAORIG,RASTDTC,RAORDER,RATRTPN,RATRTP,RASTDY,RAST TM,RASTDYTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	char	Study Site ID assigned for De-identity		Randomly assigned Study Site ID for De-identity
RASEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
DRASTRA1	char	Stratifctn fctr 1 assign for De-identity		Randomly assigned Stratifctn fctr 1 for De-identity
RASTRA2	char	Stratification factor 2		Collected at CRF.
RARESP1	char	Total Back Pain Score		Collected at CRF.
RARESP2	char	Overall Level of Morning Stiffness		Collected at CRF.
RARESP3	char	Duration of Morning Stiffness		Collected at CRF.
RARESP4	char	Early Escape		Collected at CRF.

1.4.13. Related Records -RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	DUSUBJID,RDOMAIN,IDVAR,IDVARVAL,RELID
Sorted by	DUSUBJID,RDOMAIN,IDVAR,IDVARVAL,RELID
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 missing values: RELTYPE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
IDVAR	char	Identifying Variable		Collected at CRF.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.14. Subject Characteristic -SC

Dataset	SC
Creating program	sc.sas
Description	Subject Characteristic
Unique identifier	DUSUBJID,SCSEQ,SCTESTCD
Sorted by	DUSUBJID,SCSEQ,SCTESTCD
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 missing values: SCSPID,SCSTRESN,SCDTC,SCDT,SCTM,SCDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
SCSEQ	num	Sequence Number		Collected at CRF.
SCTESTCD	char	Subject Characteristic Short Name		Collected at CRF.
SCTEST	char	Subject Characteristic		Collected at CRF.
SCCAT	char	Category for Subject Characteristic		Collected at CRF.

Variable	Type	Label	Codes	Comments
SCORRES	char	Result or Finding in Original Units		Collected at CRF.
SCSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
SCAVGHR	num	Average number of Hours		Collected at CRF.
SCDY	num	Relative Day of Collection		If SCDTC and RASTDTC not missing then perform below logic to calculate SCDY, If SCDTC less than RASTDTC then (SCDTC - RASTDTC). Else if SCDTC is greater than equal to RASTDTC then (SCDTC - RASTDTC) +1.

1.4.15. Substance Use -SU

Dataset	SU
Creating program	su.sas
Description	Substance Use
Unique identifier	DUSUBJID,SUSEQ,SUTRT
Sorted by	DUSUBJID,SUSEQ,SUTRT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUSPID

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
SUSEQ	num	Sequence Number		Collected at CRF.
SUTRT	char	Reported Name of Substance		Collected at CRF.
SUCAT	char	Category for Substance Use		Collected at CRF.
SUSCAT	char	Subcategory for Substance Use		Collected at CRF.
SUOCCUR	char	SU Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUDOSE	num	Substance Use Consumption		Collected at CRF.
SUDOSU	char	Consumption Units		Collected at CRF.
SUDOSFRQ	char	Use Frequency Per Interval		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
SUDUR	char	Duration of Substance Use		Collected at CRF.
SUSMSTAT	char	Smoking Status		Collected at CRF.
SUALSTAT	char	Alcohol Status		Collected at CRF.

1.4.16. Subject Visit -SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visit
Unique identifier	DUSUBJID,VISITNUM
Sorted by	DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SVSTDT,SVSTDTM,SVSTDTM,SVSTDTM,SVENDT,SVENDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
SVSTTM	num	Start Time of Visit		Collected at CRF.
SVENTM	num	End Time of Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
SVSTDY	num	Relative Start Day of Visit		If SVSTDTC and RASTDTC not missing then perform below logic to calculate SVSTDY, If SVSTDTC less than RASTDTC then (SVSTDTC - RASTDTC). Else if SVSTDTC is greater than equal to RASTDTC then (SVSTDTC - RASTDTC) +1.
SVENDY	num	Relative End Day of Visit		If SVENDTC and RASTDTC not missing then perform below logic to calculate SVENDY, If SVENDTC less than RASTDTC then (SVENDTC - RASTDTC). Else if SVENDTC is greater than equal to RASTDTC then (SVENDTC - RASTDTC) +1.

1.4.17. Trial Inclusion/Exclusion Criteria-TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	STUDYID,IETESTCD,IECAT
Sorted by	STUDYID,IETESTCD,IECAT
Notes	NOT APPLICABLE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.

1.4.18. Vital Signs-VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	DUSUBJID,VISITNUM,VSTESTCD
Sorted by	DUSUBJID,VISITNUM,VSTESTCD
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 missing values: VSSPID,VSBLFL,VSDTC,VSDT,VSTM,VSDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VSSEQ	num	Sequence Number		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		If VSTESTCD in (HEIGHT WEIGHT) then group element to protect PII.
VSORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSSTRESC	char	Character Result/Finding in Std Format		If VSTESTCD in (HEIGHT WEIGHT) then group element to protect PII.
VSSTRESN	num	Numeric Result/Finding in Standard Units		If VSTESTCD in (HEIGHT WEIGHT) then group element to protect PII.
VSSTRESU	char	Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VSDY	num	Relative Day of Measurements		If VSDTC and RASTDTC not missing then perform below logic to calculate VSDY,If VSDTC less than RASTDTC then (VSDTC - RASTDTC).Else if VSDTC is greater than equal to RASTDTC then (VSDTC- RASTDTC) +1.

1.4.19. Xa-XA

Dataset	XA
Creating program	xa.sas
Description	Xa
Unique identifier	DUSUBJID,XASEQ,XATESTCD
Sorted by	DUSUBJID,XASEQ,XATESTCD
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 missing values: XASPID,XASTAT,XANAM,XABLFL,XADTC,XADY,XADT,XADTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
XASEQ	num	Sequence Number		Collected at CRF.
XATESTCD	char	Antibodies Short Name		Collected at CRF.
XATEST	char	Antibodies Name		Collected at CRF.
XAORRES	char	Result or Finding in Original Units		Collected at CRF.
XAORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XASTRESU	char	Standard Units		Collected at CRF.
XASPEC	char	Specimen Type		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
XATM	num	Time of Collection		Collected at CRF.
XADY	num	Relative Day of Collection		If XADTC and RASTDTC not missing then perform below logic to calculate XADY, If XADTC less than RASTDTC then (XADTC - RASTDTC). Else if XADTC is greater than equal to RASTDTC then (XADTC - RASTDTC) +1.

1.4.20. Xi -XI

Dataset	Xi
Creating program	xi.sas
Description	Xi
Unique identifier	DUSUBJID,XISEQ,XISPID,XITESTCD
Sorted by	DUSUBJID,XISEQ,XISPID,XITESTCD
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 missing values: XISTRESN,XIBLFL,XIEVAL,XIDTC,XIDT,XITM,XIDTM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject ID assign for De-identity		Randomly assigned Unique Subject ID for De-identity
XISEQ	num	Sequence Number		Collected at CRF.
XISPID	char	Sponsor-Defined Identifier		Collected at CRF.
XITESTCD	char	Imaging Test or Examination Short Name		Collected at CRF.
XITEST	char	Imaging Test or Examination Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
XICAT	char	Category for imaging		Collected at CRF.
XIORRES	char	Result or Finding in Original Units		Collected at CRF.
XISTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
XIDY	num	Relative Day of imaging		If XIDTC and RASTDTC not missing then perform below logic to calculate XIDY, If XIDTC less than RASTDTC then (XIDTC - RASTDTC). Else if XIDTC is greater than equal to RASTDTC then (XIDTC - RASTDTC) +1.