

Clinical Development

Infliximab[®]

REMICADEUCO3001

Anonymisation Data Derivation Specification Document

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Table of contents

Clinical Development	1
1. Datasets	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files.....	6
1.4. Data Domains.....	7
1.4.1. Demographics - DM	7
1.4.2. Supplemental Qualifiers for DM - SUPPDM.....	9
1.4.3. Adverse Events - AE	11
1.4.4. Supplemental Qualifiers for AE- SUPPAE.....	13
1.4.5. Clinical Events - CE	15
1.4.6. Concomitant Medications - CM	16
1.4.7. Supplemental Qualifiers for CM - SUPPCM	18
1.4.8. Comments - CO	20
1.4.9. Disposition - DS	21
1.4.10. Supplemental Qualifiers for DS - SUPPDS.....	23
1.4.11. Protocol Deviations - DV	24
1.4.12. ECG Test Results - EG	25
1.4.13. Supplemental Qualifiers for EG - SUPPEG.....	27
1.4.14. Exposure - EX.....	28
1.4.15. Supplemental Qualifiers for EX - SUPPEX	30
1.4.16. Findings About Events or Interventions - FA.....	31
1.4.17. Inclusion/Exclusion Criteria Not Met - IE	33
1.4.18. Laboratory Tests Results - LB	34
1.4.19. Supplemental Qualifiers for LB - SUPPLB.....	37
1.4.20. Medical History - MH	38
1.4.21. Supplemental Qualifiers for MH - SUPPMH.....	40
1.4.22. Physical Examinations - PE.....	41
1.4.23. Questionnaires - QS	43
1.4.24. Supplemental Qualifiers for QS - SUPPQS.....	45
1.4.25. Related Records - RELREC	46

1.4.26. Subject Visits - SV 47

1.4.27. Trial Inclusion/Exclusion Criteria - TI..... 48

1.4.28. Vital Signs - VS..... 49

1.4.29. Randomization Findings - ZR..... 51

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	Code list 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.
- Partial date's relative day cannot be calculated
- Dataset having no subject level information will not be submitted. (eg. CD, COMPMETH, DATADEF, STUDYDEF, VALDEF, VARDEF)
- Comments dataset will be submitted with zero observation due to sensitivity of data.
- For Randomized subjects, RFSTDTC used as the reference date and for Non-Randomized subjects, informed Consent Date used as the reference date. It will be referred as REF.DATE in the document.

1.3. Data Files

The REMICADEUCO3001 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics - DM

Dataset	DM
Creating program	dm.sas
Description	Demographics
Unique identifier	STUDYID,DUSUBJID
Sorted by	STUDYID,DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RFSTDTC,RFENDTC,RFXSTDTC,RFXENDTC,INVID,BRTHDTC,DMDTC

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

Variable	Type	Label	Codes	Comments
AGE	char	Age		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Age Units		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
DCOUNTRY	char	De-identify Country		Element will be grouped to protect PII.
DMDY	num	Relative Day of Collection		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE). Else if DMDTC is greater than equal to REF.DATE then (DMDTC- REF.DATE) +1.
RFENDY	num	Relative Subject Reference End Day		If RFENDTC and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDTC less than REF.DATE then (RFENDTC - REF.DATE). Else if RFENDTC is greater than equal to REF.DATE then (RFENDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFXENTM	num	Relative Time of Last Study Treatment		If RFXENDTC contains time part then timepart(RFXENDTC) else RFXENTM equal to NULL.
RFXENDY	num	Relative Day of Last Study Treatment		If RFXENDTC and REF.DATE not missing then perform below logic to calculate RFXENDY, If RFXENDTC less than REF.DATE then (RFXENDTC - REF.DATE). Else if RFXENDTC is greater than equal to REF.DATE then (RFXENDTC- REF.DATE) +1.

1.4.2. Supplemental Qualifiers for DM - SUPPDM

Dataset	SUPPDM
Creating program	dm.sas
Description	Supplemental Qualifiers for DM
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID, QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: IDVAR, IDVARVAL, QEVAL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
RDOMAIN	char	Related 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
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.3. Adverse Events - AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	STUDYID,DUSUBJID,AEDECOD,AESTDY
Sorted by	STUDYID,DUSUBJID,AEDECOD,AESTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AETERM,AESTDTC,AEENDTC, AEMODIFY

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.
AESPID	char	Sponsor-Defined Identifier		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AECAT	char	Category for Adverse Event		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.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medically Important Serious Event		Collected at CRF.
AECONTRT	char	Concomitant or Additional Trtmnt Given		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESTDY	num	Relative Start Day of Adverse 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.
AEENDY	num	Relative End Day of Adverse 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.

1.4.4. Supplemental Qualifiers for AE- SUPPAE

Dataset	SUPPAE
Creating program	ae.sas
Description	Supplemental Qualifiers for AE
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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

Variable	Type	Label	Codes	Comments
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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.5. Clinical Events - CE

Dataset	CE
Creating program	ce.sas
Description	Clinical Events
Unique identifier	STUDYID,DUSUBJID,CESPID
Sorted by	STUDYID,DUSUBJID,CESPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CEDTC

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
CESEQ	num	Sequence Number		Collected at CRF.
CESPID	char	Sponsor-Defined Identifier		Collected at CRF.
CETERM	char	Reported Term for the Clinical Event		Collected at CRF.
CECAT	char	Category for Clinical Event		Collected at CRF.
CEPRESP	char	Clinical Event Pre-Specified		Collected at CRF.
CEOCCUR	char	Clinical Event Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
CESTAT	char	Completion Status		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
CEDY	num	Relative Day of Event Collection		If CEDTC and REF.DATE not missing then perform below logic to calculate CEDY, If CEDTC less than REF.DATE then (CEDTC - REF.DATE). Else if CEDTC is greater than equal to REF.DATE then (CEDTC - REF.DATE) +1.

1.4.6. Concomitant Medications - CM

Dataset	CM
Creating program	cm.sas
Description	Concomitant Medications
Unique identifier	STUDYID,DUSUBJID,CMDECOD,CMSPID
Sorted by	STUDYID,DUSUBJID,CMDECOD,CMSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CMTRT,CMSTDTC,CMENDTC, CMMODIFY

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
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.
CMSCAT	char	Subcategory for Medication		Collected at CRF.
CMRESP	char	CM Pre-Specified		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.
CMINDC	char	Indication		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.
CMSTRF	char	Start Relative to Reference Period		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.
CMSTRTPT	char	Start Relative to Reference Time Point		Collected at CRF.
CMSTTPT	char	Start Reference Time Point		Collected at CRF.

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.

1.4.7. Supplemental Qualifiers for CM - SUPPCM

Dataset	SUPPCM
Creating program	cm.sas
Description	Supplemental Qualifiers for CM
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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

Variable	Type	Label	Codes	Comments
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.
QNAM	char	Qualifier Variable Name		If QNAM in ("CMAE", "CMINDOTH", "RXHXOTHS", "RXIND") then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.8. Comments - CO

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Empty dataset will be submitted.
DOMAIN	char	Domain Abbreviation		Empty dataset will be submitted.
RDOMAIN	char	Related Domain Abbreviation		Empty dataset will be submitted.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty dataset will be submitted.
COSEQ	num	Sequence Number		Empty dataset will be submitted.
IDVAR	char	Identifying Variable		Empty dataset will be submitted.
IDVARVAL	char	Identifying Variable Value		Empty dataset will be submitted.
COREF	char	Comment Reference		Empty dataset will be submitted.

1.4.9. Disposition - DS

Dataset	DS
Creating program	ds.sas
Description	Disposition
Unique identifier	STUDYID,DUSUBJID,DSCAT,DSSPID
Sorted by	STUDYID,DUSUBJID,DSCAT,DSSPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DSTERM,DSDTC,DSSTDTC

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.
DSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DSDECOD	char	Standardized Disposition Term		Collected at CRF.
DSCAT	char	Category for Disposition Event		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSSTDY	num	Relative Start Day of Disposition Event		If DSSTDTC and REF.DATE not missing then perform below logic to calculate DSSTDY, If DSSTDTC less than REF.DATE then (DSSTDTC - REF.DATE). Else if DSSTDTC is greater than equal to REF.DATE then (DSSTDTC- REF.DATE) +1.
DSDY	num	Relative Day of Collection		If DSDTC and REF.DATE not missing then perform below logic to calculate DSDY, If DSDTC less than REF.DATE then (DSDTC - REF.DATE). Else if DSDTC is greater than equal to REF.DATE then (DSDTC- REF.DATE) +1.
DSSTTM	num	Relative Start Time of Disposition Event		If DSSTDTC contains time part then timepart(DSSTDTC) else DSSTTM equal to NULL.

1.4.10. Supplemental Qualifiers for DS - SUPPDS

Dataset	SUPPDS
Creating program	ds.sas
Description	Supplemental Qualifiers for DS
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		If QNAM in (“RANUM”, “AESEQE”) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.11. Protocol Deviations - DV

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

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.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
DVCAT	char	Category for Protocol Deviation		Collected at CRF.

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

1.4.12. ECG Test Results - EG

Dataset	EG
Creating program	eg.sas
Description	ECG Test Results
Unique identifier	STUDYID,DUSUBJID,EGDY
Sorted by	STUDYID,DUSUBJID,EGDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EGSTAT,EGDTC

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
EGSEQ	num	Sequence Number		Collected at CRF.
EGTESTCD	char	ECG Test or Examination Short Name		Collected at CRF.
EGTEST	char	ECG Test or Examination Name		Collected at CRF.
EGORRES	char	Result/Finding in Original Units		Collected at CRF.
EGSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
EGMETHOD	char	Method of ECG Test		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EGDY	num	Relative Day of ECG		If EGDTC and REF.DATE not missing then perform below logic to calculate EGDY, If EGDTC less than REF.DATE then (EGDTC - REF.DATE). Else if EGDTC is greater than equal to REF.DATE then (EGDTC-REF.DATE) +1.

1.4.13. Supplemental Qualifiers for EG - SUPPEG

Dataset	SUPPEG
Creating program	eg.sas
Description	Supplemental Qualifiers for EG
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.14. Exposure - EX

Dataset	EX
Creating program	ex.sas
Description	Exposure
Unique identifier	STUDYID,DUSUBJID,EXSTDY
Sorted by	STUDYID,DUSUBJID,EXSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EXADJ,EXSTDTC,EXENDTC

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.
EXSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EXTRT	char	Name of Actual Treatment		Collected at CRF.
EXDOSE	num	Dose per Administration		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.
EXDOSFRM	char	Dose Form		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXROUTE	char	Route of Administration		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.
EXSTDY	num	Relative Start Day of Treatment		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.
EXENDY	num	Relative End Day of Treatment		If EXENDTC and REF.DATE not missing then perform below logic to calculate EXENDY, If EXENDTC less than REF.DATE then (EXENDTC - REF.DATE). Else if EXENDTC is greater than equal to REF.DATE then (EXENDTC- REF.DATE) +1.
EXSTTM	num	Relative Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.
EXENTM	num	Relative End Time of Treatment		If EXENDTC contains time part then timepart(EXENDTC) else EXENTM equal to NULL.

1.4.15. Supplemental Qualifiers for EX - SUPPEX

Dataset	SUPPEX
Creating program	ex.sas
Description	Supplemental Qualifiers for EX
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variable will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.16. Findings About Events or Interventions - FA

Dataset	FA
Creating program	fa.sas
Description	Findings About Events or Interventions
Unique identifier	STUDYID,DUSUBJID,VISITNUM,FAOBJ,FATESTCD
Sorted by	STUDYID,DUSUBJID,VISITNUM,FAOBJ,FATESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: FAREASND,FADTC

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.
FATEST	char	Findings About Test Name		Collected at CRF.
FAOBJ	char	Object of the Observation		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.
FASTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
FASTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
FASTAT	char	Completion Status		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
FADY	num	Relative Day of Collection		If FADTC and REF.DATE not missing then perform below logic to calculate FADY, If FADTC less than REF.DATE then (FADTC - REF.DATE). Else if FADTC is greater than equal to REF.DATE then (FADTC-REF.DATE) +1.

1.4.17. Inclusion/Exclusion Criteria Not Met - IE

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

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.
IESPID	char	Sponsor-Defined Identifier		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.
IEDY	num	Relative Day of Collection		If IEDTC and REF.DATE not missing then perform below logic to calculate IEDY, If IEDTC less than REF.DATE then (IEDTC - REF.DATE). Else if IEDTC is greater than equal to REF.DATE then (IEDTC-REF.DATE) +1.

1.4.18. Laboratory Tests Results - LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Tests Results
Unique identifier	STUDYID,DUSUBJID,LBCAT,LBSPEC,VISITNUM,LBTESTCD
Sorted by	STUDYID,DUSUBJID,LBCAT,LBSPEC,VISITNUM,LBTESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LB DTC

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

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
LBSEQ	num	Sequence Number		Collected at CRF.
LBSPID	char	Sponsor-Defined Identifier		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.
LBSCAT	char	Subcategory 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.
LBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
LBSTRESU	char	Standard Units		Collected at CRF.
LBSTNRLO	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	Completion Status		Collected at CRF.
LBREASND	char	Reason Test Not Done		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
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.

1.4.19. Supplemental Qualifiers for LB - SUPPLB

Dataset	SUPPLB
Creating program	lb.sas
Description	Supplemental Qualifiers for LB
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variable will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.20. Medical History - MH

Dataset	MH
Creating program	mh.sas
Description	Medical History
Unique identifier	STUDYID,DUSUBJID,MHSPID,MHDECOD,MHSEQ
Sorted by	STUDYID,DUSUBJID,MHSPID,MHDECOD,MHSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MHTERM,MHSTAT,MHDTC,MHSTDTC, MHMODIFY

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
MHSEQ	num	Sequence Number		Collected at CRF.
MHSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MHMODIFY	char	Modified Reported Term		Collected at CRF.
MHDECOD	char	Dictionary-Derived Term		Collected at CRF.
MHCAT	char	Category for Medical History		Collected at CRF.
MHPRESP	char	Medical History Event Pre-Specified		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHOCCUR	char	Medical History Occurrence		Collected at CRF.
MHBODSYS	char	Body System or Organ Class		Collected at CRF.
MHENRF	char	End Relative to Reference Period		Collected at CRF.
MHDY	num	Relative Day of History Collection		If MHDTC and REF.DATE not missing then perform below logic to calculate MHDY, If MHDTC less than REF.DATE then (MHDTC - REF.DATE). Else if MHDTC is greater than equal to REF.DATE then (MHDTC- REF.DATE) +1.
MHSTDY	num	Relative Start Day of Medical History Event		If MHSTDTC and REF.DATE not missing then perform below logic to calculate MHSTDY, If MHSTDTC less than REF.DATE then (MHSTDTC - REF.DATE). Else if MHSTDTC is greater than equal to REF.DATE then (MHSTDTC- REF.DATE) +1.

1.4.21. Supplemental Qualifiers for MH - SUPPMH

Dataset	SUPPMH
Creating program	mh.sas
Description	Supplemental Qualifiers for MH
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.22. Physical Examinations - PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examinations
Unique identifier	STUDYID,DUSUBJID,PETESTCD,VISITNUM
Sorted by	STUDYID,DUSUBJID,PETESTCD,VISITNUM
Notes	Below listed variable will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PEDTC

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
PESEQ	num	Sequence Number		Collected at CRF.
PESPID	char	Sponsor-Defined Identifier		Collected at CRF.
PETESTCD	char	Body System Examined Short Name		Collected at CRF.
PETEST	char	Body System Examined		Collected at CRF.
PECAT	char	Category for Examination		Collected at CRF.
PEORRES	char	Verbatim Examination Finding		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESTRESC	char	Character Result in Std Format		Collected at CRF.
PESTAT	char	Completion Status		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
PEDY	num	Relative Day of Examination		If PEDTC and REF.DATE not missing then perform below logic to calculate PEDY, If PEDTC less than REF.DATE then (PEDTC - REF.DATE). Else if PEDTC is greater than equal to REF.DATE then (PEDTC - REF.DATE) +1.

1.4.23. Questionnaires - QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	STUDYID,DUSUBJID,QSTESTCD,QSCAT,VISITNUM,QSSEQ
Sorted by	STUDYID,DUSUBJID,QSTESTCD,QSCAT,VISITNUM,QSSEQ
Notes	Below listed variable will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QSDTC

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.
QSSPID	char	Sponsor-Defined Identifier		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.
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
QSSTAT	char	Completion Status		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 REF.DATE not missing then perform below logic to calculate QSDY, If QSDTC less than REF.DATE then (QSDTC - REF.DATE). Else if QSDTC is greater than equal to REF.DATE then (QSDTC - REF.DATE) +1.

1.4.24. Supplemental Qualifiers for QS - SUPPQS

Dataset	SUPPQS
Creating program	qs.sas
Description	Supplemental Qualifiers for QS
Unique identifier	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Sorted by	STUDYID,RDOMAIN,DUSUBJID,IDVAR,IDVARVAL,QNAM
Notes	Below listed variables will be dropped from dataset due to missing values: QEVAL

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.
QNAM	char	Qualifier Variable Name		Collected at CRF.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.25. Related Records - RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,DUSUBJID,RDOMAIN,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,DUSUBJID,RDOMAIN,IDVAR,IDVARVAL,RELID
Notes	

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.
RELTYPE	char	Relationship Type		Collected at CRF.
RELID	char	Relationship Identifier		Collected at CRF.

1.4.26. Subject Visits - SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visits
Unique identifier	STUDYID,DUSUBJID,VISITNUM
Sorted by	STUDYID,DUSUBJID,VISITNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SVSTDTC,SVENDTC

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.

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

1.4.27. Trial Inclusion/Exclusion Criteria - TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion/Exclusion Criteria
Unique identifier	STUDYID,IETESTCD
Sorted by	STUDYID,IETESTCD
Notes	

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

Variable	Type	Label	Codes	Comments
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.

1.4.28. Vital Signs - VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	STUDYID,DUSUBJID,VISITNUM,VSTESTCD
Sorted by	STUDYID,DUSUBJID,VISITNUM,VSTESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VSDTC

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
VSSEQ	num	Sequence Number		Collected at CRF.
VSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSCAT	char	Category For Vital Signs		Collected at CRF.
VSPOS	char	Vital Signs Position of Subject		Collected at CRF.
VSORRES	char	Result in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result in Std Format		Collected at CRF.
VSSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VSSTAT	char	Completion Status		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 REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE). Else if VSDTC is greater than equal to REF.DATE then (VSDTC-REF.DATE) +1.

1.4.29. Randomization Findings - ZR

Dataset	ZR
Creating program	zr.sas
Description	Randomization Findings
Unique identifier	STUDYID,DUSUBJID,VISITNUM,ZRTESTCD
Sorted by	STUDYID,DUSUBJID,VISITNUM,ZRTESTCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ZRGRPID,ZRORRESU,ZRSTRESU,ZRNAM,EPOCH,ZRDTC

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
ZRSEQ	num	Sequence Number		Collected at CRF.
ZRTESTCD	char	Randomization Test Short Name		Collected at CRF.
ZRTEST	char	Randomization Test Name		Collected at CRF.
ZRCAT	char	Category for Randomization Test		Collected at CRF.
ZRSCAT	char	Subcategory for Randomization		Collected at CRF.
ZRORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
ZRSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VISITNUM	char	Visit Number		Collected at CRF.
VISIT	num	Visit Name		Collected at CRF.
ZRTM	num	Relative Time of Randomization		If ZRDTC contains time part then timepart(ZRDTC) else ZRTM equal to NULL.
ZRDY	num	Relative Day of Randomization		If ZRDTC and REF.DATE not missing then perform below logic to calculate ZRDY, If ZRDTC less than REF.DATE then (ZRDTC - REF.DATE). Else if ZRDTC is greater than equal to REF.DATE then (ZRDTC - REF.DATE) +1.