

Clinical Development

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ET743SAR3007

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.
- Empty comments data will be submitted due to sensitivity of data.
- After removing sensitive information, dataset does not have any useful information for further analysis. Hence, dataset will not be submitted (eg. SUPPEG SUPPHB SUPPPE SUPPXZ).
- RFSTDTC will be used as Reference Date (referred as REF. DATE in the document) to derive relative days.

1.3. Data Files

The ET743SAR3007 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: BRTHDTC,INVNAM,DMDTC,INVID,RFSTDTC,RFENDTC

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 Siteid Assigned for De-identity		Randomly assigned Study Siteid for De-identity

Variable	Type	Label	Codes	Comments
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Age Units		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
ETHNIC	char	Ethnicity		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		Group element 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.

1.4.2. Supplemental Qualifiers for DM – SUPPDM

Dataset	SUPPDM
Creating program	dm.sas
Description	Supplemental Qualifiers for DM
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: IDVAR,IDVARVAL

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

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	STUDYID,DUSUBJID,AEDECOD,AESTDY,AESEQ
Sorted by	STUDYID,DUSUBJID,AEDECOD,AESTDY,AESEQ
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: AESTDTC,AEMODIFY,AESTDTC, AETERM,AEENDTC,AEENDTCD

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.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESER	char	Serious Event		Collected at CRF.
AEACN	char	Action Taken with Study Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 Trtmt Given		Collected at CRF.
AETOXGR	char	Standard Toxicity Grade		Collected at CRF.
AESTDY	num	Relative Start Day of Adverse Event		If AESTDTCD and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTCD less than REF.DATE then (AESTDTCD - REF.DATE). Else if AESTDTCD is greater than equal to REF.DATE then (AESTDTCD- REF.DATE) +1.
AEENDY	num	Relative End Day of Adverse Event		If AEENDTCD and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTCD less than REF.DATE then (AEENDTCD - REF.DATE). Else if AEENDTCD is greater than equal to REF.DATE then (AEENDTCD- 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.
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. Bio-Specimen – BE

Dataset	BE
Creating program	be.sas
Description	Bio-Specimen
Unique identifier	STUDYID,DUSUBJID,BEDECOD,BESEQ
Sorted by	STUDYID,DUSUBJID,BEDECOD,BESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BESTDTC,BEBODSYS,BEDTC

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
BESEQ	num	Sequence Number		Collected at CRF.
BESPID	char	Sponsor-Defined Identifier		Collected at CRF.
BETERM	char	BE Term		Collected at CRF.
BEDECOD	char	BE Dictionary-Derived Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
BECAT	char	BE Category		Collected at CRF.
BESTDY	num	Relative Start Day of DNA Consent		If BESTDTC and REF.DATE not missing then perform below logic to calculate BESTDY, If BESTDTC less than REF.DATE then (BESTDTC - REF.DATE). Else if BESTDTC is greater than equal to REF.DATE then (BESTDTC- REF.DATE) +1.

1.4.6. Clinical Events – CE

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

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

Variable	Type	Label	Codes	Comments
CESEQ	num	Sequence Number		Collected at CRF.
CESPID	char	Sponsor-Defined Identifier		Collected at CRF.
CETERM	char	CE Term		Collected at CRF.
CEDECOD	char	CE Dictionary-Derived Term		Collected at CRF.
CECAT	char	CE Category		Collected at CRF.
CETPTREF	char	Time Point Reference		Collected at CRF.
CESTTM	num	Start Time of Clinical Event		If CESTDTC contains time part then timepart(CESTDTC) else CESTTM equal to NULL.
CESTDY	num	Relative Start Day of Clinical Event		If CESTDTC and REF.DATE not missing then perform below logic to calculate CESTDY, If CESTDTC less than REF.DATE then (CESTDTC - REF.DATE). Else if CESTDTC is greater than equal to REF.DATE then (CESTDTC- REF.DATE) +1.

1.4.7. Supplemental Qualifiers for CE – SUPPCE

Dataset	SUPPCE
Creating program	ce.sas
Description	Supplemental Qualifiers for CE
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 (CESYSPEC) then drop. If QNAM in (CERFTDTC) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.8. Concomitant Medications – CM

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

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.
CMTRT	char	Reported Name of Drug, Med, or Therapy		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMOCCUR	char	CM Occurrence		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
CMDOSTOT	num	Total Daily Dose		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
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. 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.
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 (CMINDOTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.10. Comments – CO

Dataset	CO
Creating program	co.sas
Description	Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation.

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
COEVAL	char	Evaluator		Empty dataset will be submitted

1.4.11. Disposition – DS

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

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.
DSSCAT	char	Subcategory for Disposition Event		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
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.
DSDTHFL	char	Death Within 30 Days of Last Dose Flag		Collected at CRF.
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.

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

1.4.13. Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	STUDYID,DUSUBJID,DVSEQ
Sorted by	STUDYID,DUSUBJID,DVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
DVSPID	char	Sponsor-Defined Identifier		Collected at CRF.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.

1.4.14. Supplemental Qualifiers for DV – SUPPDV

Dataset	SUPPDV
Creating program	dv.sas
Description	Supplemental Qualifiers for DV
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.

1.4.15. ECG Test Results – EG

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

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
EGSEQ	num	Sequence Number		Collected at CRF.
EGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
EGTESTCD	char	ECG Test or Examination Short Name		Collected at CRF.
EGTEST	char	ECG Test or Examination Name		Collected at CRF.
EGCAT	char	Category for ECG		Collected at CRF.
EGORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGORNRLO	char	Institutional Lower Limit of Normal		Collected at CRF.
EGORRESU	char	Original Units		Collected at CRF.
EGSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
EGSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
EGSTRESU	char	Standard Units		Collected at CRF.
EGNAM	char	Vendor Name		Collected at CRF.
EGMETHOD	char	Method of ECG Test		Collected at CRF.
EGBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		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.

1.4.16. Exposure – EX

Dataset	EX
Creating program	ex.sas
Description	Exposure
Unique identifier	STUDYID,DUSUBJID,EXSTDY,EXSEQ
Sorted by	STUDYID,DUSUBJID,EXSTDY,EXSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
EXCAT	char	Category for Treatment		Collected at CRF.
EXDOSE	num	Dose per Administration		Collected at CRF.
EXDOSU	char	Dose Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXDOSFRM	char	Dose Form		Collected at CRF.
EXSTAT	char	Completion Status		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial 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	Start Time of Treatment		If EXSTDTC contains time part then timepart(EXSTDTC) else EXSTTM equal to NULL.
EXENTM	num	End Time of Treatment		If EXENDTC contains time part then timepart(EXENDTC) else EXENTM equal to NULL.

1.4.17. 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 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 (EXREAOTH) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.18. Prespecified Hepatobiliary Laboratory – HB

Dataset	HB
Creating program	hb.sas
Description	Prespecified Hepatobiliary Laboratory
Unique identifier	DUSUBJID,HBTEST,HB DY,HBSEQ
Sorted by	DUSUBJID,HBTEST,HB DY,HBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: HBBLFL,HBSTDTC,HBCAT

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
HBSEQ	num	Sequence Number		Collected at CRF.
HBSPID	char	Sponsor-Defined Identifier		Collected at CRF.
HBTESTCD	char	Assessment Short Name		Collected at CRF.
HBTEST	char	Assessment Name		Collected at CRF.
HBORRES	char	Result or Finding in Original Units		Collected at CRF.
HBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
HBSTDY	num	Relative Day of Pescfied Hepatobly Lab		If HBSTDTC and REF.DATE not missing then perform below logic to calculate HBSTDY, If HBSTDTC less than REF.DATE then (HBSTDTC - REF.DATE). Else if HBSTDTC is greater than equal to REF.DATE then (HBSTDTC- REF.DATE) +1.

1.4.19. Inclusion/Exclusion Exceptions – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions
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: IEDTC

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
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.
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.
EPOCH	char	Trial Epoch		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.

1.4.20. Laboratory Test Results – LB

Dataset	LB
Creating program	lb.sas
Description	Laboratory Test Results
Unique identifier	STUDYID,DUSUBJID,LBTEST,LBDY,VISIT,LBSEQ
Sorted by	STUDYID,DUSUBJID,LBTEST,VISIT,LBDY,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBFAST,LBNAM,LBSPCCND,LBRESND,LBDTC,LBSTAT,LBENDTC

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
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.

Variable	Type	Label	Codes	Comments
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.
LBSTNRC	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.
LBSTNRLO	num	Reference Range Lower Limit-Std Units		Collected at CRF.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBNRIND	char	Reference Range Indicator		Collected at CRF.
LBSPEC	char	Specimen Type		Collected at CRF.
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Trial Epoch		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.
LBSTRSND	num	Numeric Result in Standard Unit, Derived		Collected at CRF.

1.4.21. 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 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.

Variable	Type	Label	Codes	Comments
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. Microbiology Specimen – MB

Dataset	MB
Creating program	mb.sas
Description	Microbiology Specimen
Unique identifier	DUSUBJID,MBTEST,MBDY,MBSEQ
Sorted by	DUSUBJID,MBTEST,MBDY,MBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MBDTC,MBBLFL,MBMETHOD,MBRESCAT,MBGRPID

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
MBSEQ	num	Sequence Number		Collected at CRF.
MBSPID	char	Sponsor-Defined Identifier		Collected at CRF.
MBTESTCD	char	Microbiology Test or Finding Short Name		Collected at CRF.
MBTEST	char	Microbiology Test or Finding Name		Collected at CRF.
MBORRES	char	Result or Finding in Original Units		Collected at CRF.
MBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
MBSPEC	char	Specimen Type		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
MBTM	num	Time of Specimen Collection		If MBDTC contains time part then timepart(MBDTC) else MBTM equal to NULL.
MBDY	num	Relative Day of Specimen Collection		If MBDTC and REF.DATE not missing then perform below logic to calculate MBDY, If MBDTC less than REF.DATE then (MBDTC - REF.DATE). Else if MBDTC is greater than equal to REF.DATE then (MBDTC-REF.DATE) +1.

1.4.23. Medical History – MH

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

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.
MHCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory for Medical History		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOCH	char	Trial Epoch		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 MH 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.

1.4.24. 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		If QNAM in (MHPDTC) then will be converted to relative day.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.25. Physical Examinations – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Examinations
Unique identifier	DUSUBJID,PETESTCD,PEDY,PESEQ
Sorted by	DUSUBJID,PETESTCD,PEDY,PESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PEDTC,PEBLFL,PESTRESU,PESTRESN

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.
PEORRES	char	Verbatim Examination Finding		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESTRESC	char	Character Result/Finding in Std. Format		Collected at CRF.
PESTAT	char	Examination Status		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		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.

1.4.26. Questionnaires – QS

Dataset	QS
Creating program	qs.sas
Description	Questionnaires
Unique identifier	STUDYID,DUSUBJID,QSTEST,QSDY,QSSEQ
Sorted by	STUDYID,DUSUBJID,QSTEST,QSDY,QSSEQ
Notes	Below listed variables 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.
QSORRES	char	Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
QSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
QSSTRESN	num	Numeric Finding in Standard Units		Collected at CRF.
QSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		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.

1.4.27. Related Records – RELREC

Dataset	RELREC
Creating program	relrec.sas
Description	Related Records
Unique identifier	STUDYID,DUSUBJID,IDVAR,IDVARVAL,RELID
Sorted by	STUDYID,DUSUBJID,IDVAR,IDVARVAL,RELID
Notes	Below listed variables will be dropped from dataset 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.
IDNUM	num	Idnum		Collected at CRF.

1.4.28. Evaluation of Response – RS

Dataset	RS
Creating program	rs.sas
Description	Evaluation of Response
Unique identifier	STUDYID,DUSUBJID,RSTEST,RSDY,RSSEQ
Sorted by	STUDYID,DUSUBJID,RSTEST,RSDY,RSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RSDTC

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
RSSEQ	num	Sequence Number		Collected at CRF.
RSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
RSTESTCD	char	Assessment Short Name		Collected at CRF.
RSTEST	char	Assessment Name		Collected at CRF.
RSCAT	char	Category of Assessment		Collected at CRF.
RSORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
RSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
RSDY	num	Relative Day of Assessment		If RSDTC and REF.DATE not missing then perform below logic to calculate RSDY, If RSDTC less than REF.DATE then (RSDTC - REF.DATE). Else if RSDTC is greater than equal to REF.DATE then (RSDTC - REF.DATE) +1.

1.4.29. Supplemental Qualifiers for RS – SUPPRS

Dataset	SUPPRS
Creating program	rs.sas
Description	Supplemental Qualifiers for RS
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 (RSASREAS,RSNEREAS) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.30. Surgery – SG

Dataset	SG
Creating program	sg.sas
Description	Surgery
Unique identifier	STUDYID,DUSUBJID,SGSPID,SGSTDY
Sorted by	STUDYID,DUSUBJID,SGSPID,SGSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SGSTDTC,SGTRT

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
SGSEQ	num	Sequence Number		Collected at CRF.
SGSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SGCAT	char	Category for Surgery/Procedure		Collected at CRF.

Variable	Type	Label	Codes	Comments
SGOCCUR	char	Surgery/Procedure Occurrence		Collected at CRF.
SGDY	num	Study Day of Previous Surgery		Collected at CRF.
SGSTDY	num	Relative Start Day of Surgery/Procedure		If SGSTDTC and REF.DATE not missing then perform below logic to calculate SGSTDY, If SGSTDTC less than REF.DATE then (SGSTDTC - REF.DATE). Else if SGSTDTC is greater than equal to REF.DATE then (SGSTDTC- REF.DATE) +1.

1.4.31. Survival Status – SS

Dataset	SS
Creating program	ss.sas
Description	Survival Status
Unique identifier	STUDYID,DUSUBJID,SSTEST,SSDY
Sorted by	STUDYID,DUSUBJID,SSTEST,SSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SSDTC

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
SSSEQ	num	Sequence Number		Collected at CRF.
SSSPID	char	Sponsor-Defined Identifier		Collected at CRF.
SSTESTCD	char	Survival Status Short Name		Collected at CRF.
SSTEST	char	Survival Status Name		Collected at CRF.
SSCAT	char	Category of Survival Status		Collected at CRF.
SSORRES	char	Result or Finding in Original Units		Collected at CRF.
SSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		Collected at CRF.
SSDY	num	Relative Day of Survival Status		If SSDTC and REF.DATE not missing then perform below logic to calculate SSDY, If SSDTC less than REF.DATE then (SSDTC - REF.DATE). Else if SSDTC is greater than equal to REF.DATE then (SSDTC-REF.DATE) +1.

1.4.32. Supplemental Qualifiers for SS – SUPPSS

Dataset	SUPPSS
Creating program	ss.sas
Description	Supplemental Qualifiers for SS
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.

1.4.33. Subject Visits – SV

Dataset	SV
Creating program	sv.sas
Description	Subject Visits
Unique identifier	STUDYID,DUSUBJID,SVSTDY,VISIT
Sorted by	STUDYID,DUSUBJID,SVSTDY,VISIT
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.
EPOCH	char	Trial Epoch		Collected at CRF.
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.

1.4.34. Treatment Cycle Delayed – TD

Dataset	TD
Creating program	td.sas
Description	Treatment Cycle Delayed
Unique identifier	STUDYID,DUSUBJID,TDDECOD,TDDY
Sorted by	STUDYID,DUSUBJID,TDDECOD,TDDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TDDTC,TDTERM

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
TDSEQ	num	Sequence Number		Collected at CRF.
TDSPID	char	Sponsor-Defined Identifier		Collected at CRF.
TDDECOD	char	Standardized Trtmnt Cycle Delyd Term		Collected at CRF.
TDOCCUR	char	Treatment Cycle Delayed Occurrence		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

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

1.4.35. 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.
DOMAIN	char	Domain Abbreviation		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.36. Target/ Non-Target Lesion Assessments – TR

Dataset	TR
Creating program	tr.sas
Description	Target/ Non-Target Lesion Assessments
Unique identifier	STUDYID,DUSUBJID,TRTEST,TRDY,TRSEQ
Sorted by	STUDYID,DUSUBJID,TRTEST,TRDY,TRSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TRDTC

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

Variable	Type	Label	Codes	Comments
TRSEQ	num	Sequence Number		Collected at CRF.
TRSPID	char	Sponsor-Defined Identifier		Collected at CRF.
TRTESTCD	char	Test or Examination Short Name		Collected at CRF.
TRTEST	char	Test or Examination Name		Collected at CRF.
TRCAT	char	Category for TR Test		Collected at CRF.
TRORES	char	Result or Finding in Original Units		Collected at CRF.
TRORESU	char	Original Units		Collected at CRF.
TRSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
TRSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
TRSTRESU	char	Standard Units		Collected at CRF.
TRSTAT	char	Lesion Status		Collected at CRF.
TRREASND	char	Reason Test Not Done		Collected at CRF.
TRMETHOD	char	Method of Test or Examination		Collected at CRF.
TRBLFL	char	Baseline Flag		Collected at CRF.
TRDY	num	Relative Day of Specimen Collection		If TRDTC and REF.DATE not missing then perform below logic to calculate TRDY, If TRDTC less than REF.DATE then (TRDTC - REF.DATE). Else if TRDTC is greater than equal to REF.DATE then (TRDTC-REF.DATE) +1.

1.4.37. Supplemental Qualifiers for TR – SUPPTR

Dataset	SUPPTR
Creating program	tr.sas
Description	Supplemental Qualifiers for TR
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 (TRRSNEVL) then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

1.4.38. Tumor Identification – TU

Dataset	TU
Creating program	tu.sas
Description	Tumor Identification
Unique identifier	STUDYID,DUSUBJID,TUTEST,TUDY,TUSEQ
Sorted by	STUDYID,DUSUBJID,TUTEST,TUDY,TUSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: TUDTC,TUBLFL,TUORRESU

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
TUSEQ	num	Sequence Number		Collected at CRF.
TUSPID	char	Sponsor-Defined Identifier		Collected at CRF.
TUTESTCD	char	Test or Examination Short Name		Collected at CRF.
TUTEST	char	Test or Examination Name		Collected at CRF.
TUCAT	char	Category for TU Test		Collected at CRF.
TUORRES	char	Result or Finding in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
TULOC	char	Location Used for the Measurement		Collected at CRF.
TUMETHOD	char	Method of Test or Examination		Collected at CRF.
TUDY	num	Relative Day of Tumor Identification		If TUDTC and REF.DATE not missing then perform below logic to calculate TUDY, If TUDTC less than REF.DATE then (TUDTC - REF.DATE). Else if TUDTC is greater than equal to REF.DATE then (TUDTC-REF.DATE) +1.

1.4.39. Supplemental Qualifiers for TU – SUPPTU

Dataset	SUPPTU
Creating program	tu.sas
Description	Supplemental Qualifiers for TU
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.

1.4.40. Vital Signs – VS

Dataset	VS
Creating program	vs.sas
Description	Vital Signs
Unique identifier	STUDYID,DUSUBJID,VSTESTCD,VSDY,VSSEQ
Sorted by	STUDYID,DUSUBJID,VSTESTCD,VSDY,VSSEQ
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.
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.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
VSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
VSSTRESU	char	Standard Units		Collected at CRF.
VSBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EPOCH	char	Trial Epoch		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.

1.4.41. Supplemental Qualifiers for VS – SUPPVS

Dataset	SUPPVS
Creating program	vs.sas
Description	Supplemental Qualifiers for VS
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.

1.4.42. Sample Handling – XZ

Dataset	XZ
Creating program	xz.sas
Description	Sample Handling
Unique identifier	STUDYID,DUSUBJID,XZTESTCD,XZDY,XZSEQ
Sorted by	STUDYID,DUSUBJID,XZTESTCD,XZDY,XZSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: XZDTC

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
XZSEQ	num	Sequence Number		Collected at CRF.
XZSPID	char	Sponsor-Defined Identifier		Collected at CRF.
XZTESTCD	char	Test Short Name		Collected at CRF.
XZTEST	char	XZ Test		Collected at CRF.
XZCAT	char	XZ Category		Collected at CRF.
XZORRES	char	Results or Findings in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
XZORRESU	char	Original Units		Collected at CRF.
XZSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
XZSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
XZSTRESU	char	Standard Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
XZDY	num	Relative Day of Sample Handling		If XZDTC and REF.DATE not missing then perform below logic to calculate XZDY, If XZDTC less than REF.DATE then (XZDTC - REF.DATE). Else if XZDTC is greater than equal to REF.DATE then (XZDTC - REF.DATE) +1.