

Clinical Development

## **Bedaquiline**

### **TMC207-TiDP13-C209**

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

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

### 1.2. Guidelines for Preparing Data

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

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

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated.
- DA dataset will not be submitted as there is no information available for further analysis after removing sensitive information.
- Pharmacogenetics Data will not be submitted (eg. GT, SUPPGT).
- Pharmacokinetics dataset will not be submitted.(eg.PC and PP)
- SC Dataset will not be submitted as it contains sensitive information related to subject.
- For Screen failure subjects, the reference date has been used as Informed Consent Date.
- For subjects belonging to ITT population, the reference date has been used as Medication Start Date.
- Datasets, which after removing free text and sensitive information becomes empty, will not be submitted (eg. SUPPHO and SUPPMB)

### 1.3. Data Files

The Bedaquiline Clinical Study Report (CSR) data should be used for converting to de-identification. Use the TMC207-TiDP13-C209 CSR data from the following folders.

## 1.4. Data Domains

### 1.4.1. Demographics - DM

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

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	Study Subject Id Assign for De-identity		Randomly assigned Study 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.
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.
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

<b>Dataset</b>	SUPPDM
<b>Creating program</b>	suppdm.sas
<b>Description</b>	Supplemental Qualifiers for DM
<b>Unique identifier</b>	DUSUBJID,QNAM
<b>Sorted by</b>	DUSUBJID,QNAM
<b>Notes</b>	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.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
QNAM	char	Qualifier Variable Name		If QNAM = "PROTDTC" then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.3. Adverse Events - AE

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
AESEQ	num	Sequence Number		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AECAT	char	Category for Adverse Event		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESER	char	Serious Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
AETOXGR	char	Standard Toxicity Grade		Collected at CRF.
AEENRF	char	End Relative to Reference Period		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

<b>Dataset</b>	SUPPAE
<b>Creating program</b>	suppae.sas
<b>Description</b>	Supplemental Qualifiers for AE
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QVAL

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 (AEDTDC, AESBDC) then below mentioned logic will be performed to calculate relative day. If QVAL and REF.DATE not missing then perform below logic to QVAL. If QVAL less than REF.DATE then (QVAL - REF.DATE ).Else if QVAL is greater than equal to REF.DATE then (QVAL - REF.DATE ) +1..

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

#### 1.4.5. Concomitant Medications - CM

<b>Dataset</b>	CM
<b>Creating program</b>	cm.sas
<b>Description</b>	Concomitant Medications
<b>Unique identifier</b>	STUDYID,DUSUBJID,CMDECOD,CMCAT,CMSTDY,CMSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,CMDECOD,CMCAT,CMSTDY,CMSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CMTRT, CMINDC, CMSTDTC, CMENDTC, CMSTTPT

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.

Variable	Type	Label	Codes	Comments
CMGRPID	char	Group ID		Collected at CRF.
CMDECOD	char	Standardized Medication Name		Collected at CRF.
CMCAT	char	Category for Medication		Collected at CRF.
CMDOSTXT	char	Dose Description		Collected at CRF.
CMDOSU	char	Dose Units		Collected at CRF.
CMDOSFRM	char	Dose Form		Collected at CRF.
CMDOSFRQ	char	Dosing Frequency per Interval		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMADJ	char	Reason for Dose Adjustment		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
CMENRF	char	End Relative to Reference Period		Collected at CRF.
CMSTRTPT	char	Start Relative to Reference Time Point		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.

Variable	Type	Label	Codes	Comments
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.
CMSTPTDY	num	Relative Start Reference Day Time Point		If CMSTTPT and REF.DATE not missing then perform below logic to calculate , If CMSTTPT less than REF.DATE then (CMSTTPT - REF.DATE).Else if CMSTTPT is greater than equal to REF.DATE then (CMSTTPT- REF.DATE) +1.



## 1.4.6. Supplemental Qualifiers for CM – SUPPCM

<b>Dataset</b>	SUPPCM
<b>Creating program</b>	suppcm.sas
<b>Description</b>	Supplemental Qualifiers for CM
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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.
QEQVAL	char	Qualifier Variable Name		If QEQVAL in ("CMADJOTH"," ROUTEOTH"," FHAARTD") then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.7. Comments - CO

<b>Dataset</b>	CO
<b>Creating program</b>	co.sas
<b>Description</b>	Comments
<b>Unique identifier</b>	Not Applicable
<b>Sorted by</b>	Not Applicable
<b>Notes</b>	Comments data is sensitive data, contains free text information. Will be submitted as empty dataset.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		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
COSEQ	num	Sequence Number		Collected at CRF.
IDVAR	char	Identifying Variable		Collected at CRF.

Variable	Type	Label	Codes	Comments
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
CODY	num	Relative Day of Comment		If CODTC and REF.DATE not missing then perform below logic to calculate CODY, If CODTC less than REF.DATE then (CODTC - REF.DATE).Else if CODTC is greater than equal to REF.DATE then (CODTC-REF.DATE) +1.

#### 1.4.8. Diagnostic Procedures - DP

<b>Dataset</b>	DP
<b>Creating program</b>	dp.sas
<b>Description</b>	Diagnostic Procedures
<b>Unique identifier</b>	STUDYID,DUSUBJID,DPTESTCD,DPSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,DPTESTCD,DPSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DPDTC

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
DPSEQ	num	Sequence Number		Collected at CRF.
DPGRPID	char	Group ID		Collected at CRF.
DPTESTCD	char	Short Name of Test or Examination		Collected at CRF.
DPTEST	char	Name of Test or Examination		Collected at CRF.
DPCAT	char	Category		Collected at CRF.
DPSCAT	char	Subcategory		Collected at CRF.
DPORRES	char	Result or Finding in Original Units		Collected at CRF.
DPORRESU	char	Original Units		Collected at CRF.
DPSTRESC	char	Result or Finding in Standard Format		Collected at CRF.
DPSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
DPSTRESU	char	Standard Units		Collected at CRF.
DPLOC	char	Location Used for the Measurement		Collected at CRF.
DPBLFL	char	Baseline Flag		Collected at CRF.
DPDRVFL	char	Derived Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF.
DPTPT	char	Planned Time Point Name		Collected at CRF.
DPTPTNUM	num	Planned Time Point Number		Collected at CRF.
DPDY	num	Relative Day of Collection		If DPDTC and REF.DATE not missing then perform below logic to calculate DPDY, If DPDTC less than REF.DATE then (DPDTC - REF.DATE).Else if DPDTC is greater than equal to REF.DATE then (DPDTC-REF.DATE) +1.

#### 1.4.9. Disposition - DS

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

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
DSSEQ	num	Sequence Number		Collected at CRF.
DSTERM	char	Reported Term for the Disposition Event		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.
VISIT	char	Visit Name		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.

## 1.4.10. Protocol Deviations - DV

<b>Dataset</b>	DV
<b>Creating program</b>	dv.sas
<b>Description</b>	Protocol Deviations
<b>Unique identifier</b>	STUDYID,DUSUBJID,DVDECOD,DVSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,DVDECOD,DVSEQ
<b>Notes</b>	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.
DVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
DVCAT	char	Category for Protocol Deviation		Collected at CRF.
DVSCAT	char	Subcategory for Protocol Deviation		Collected at CRF.

## 1.4.11. Electrocardiogram Test Results - EG

<b>Dataset</b>	EG
<b>Creating program</b>	eg.sas
<b>Description</b>	Electrocardiogram Test Results
<b>Unique identifier</b>	STUDYID,DUSUBJID,EGTESTCD,EGSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,EGTESTCD,EGSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EGREFID, EGXFN, EGNAM, EGDTC

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.
EGGRPID	char	Group ID		Collected at CRF.
EGTESTCD	char	ECG Test or Examination Short Name		Collected at CRF.
EGTEST	char	ECG Test or Examination Name		Collected at CRF.
EGPOS	char	ECG Position of Subject		Collected at CRF.



Variable	Type	Label	Codes	Comments
EGORRES	char	Result or Finding in Original Units		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.
EGSTAT	char	Completion Status		Collected at CRF.
EGMETHOD	char	Method of ECG Test		Collected at CRF.
EGBLFL	char	Baseline Flag		Collected at CRF.
EGEVAL	char	Evaluator		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
EGTPT	char	Planned Time Point Name		Collected at CRF.
EGTPTNUM	num	Planned Time Point Number		Collected at CRF.
EGTPTREF	char	Time Point Reference		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.

## 1.4.12. Supplemental Qualifiers for EG – SUPPEG

<b>Dataset</b>	SUPPEG
<b>Creating program</b>	suppeg.sas
<b>Description</b>	Supplemental Qualifiers for EG
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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		If IDVAR = "EGREFID" then drop.
IDVARVAL	char	Identifying Variable Value		Collected at CRF.
QEQVAL	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. Exposure - EX

<b>Dataset</b>	EX
<b>Creating program</b>	ex.sas
<b>Description</b>	Exposure
<b>Unique identifier</b>	STUDYID,DUSUBJID,EXTRT,EXSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,EXTRT,EXSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EXDOSFRM, 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.
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.
EXDOSFRQ	char	Dosing Frequency per Interval		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXROUTE	char	Route of Administration		Collected at CRF.
EXADJ	char	Reason for Dose Adjustment		Collected at CRF.
EXTPT	char	Planned Time Point Name		Collected at CRF.
EXTPTNUM	num	Planned Time Point Number		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.

## 1.4.14. Supplemental Qualifiers for EX – SUPPEX

<b>Dataset</b>	SUPPEX
<b>Creating program</b>	supplex.sas
<b>Description</b>	Supplemental Qualifiers for EX
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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.
QEQVAL	char	Qualifier Variable Name		If QEQVAL="EXADJOTH" then drop.
QLABEL	char	Qualifier Variable Label		Collected at CRF.
QVAL	char	Data Value		Collected at CRF.
QORIG	char	Origin		Collected at CRF.

## 1.4.15. Hospitalization - HO

<b>Dataset</b>	HO
<b>Creating program</b>	ho.sas
<b>Description</b>	Hospitalization
<b>Unique identifier</b>	STUDYID,DUSUBJID,HOTERM,HOSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,HOTERM,HOSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HOSTDTC, HOENDTC

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
HOSEQ	num	Sequence Number		Collected at CRF.
HOTERM	char	Reported Term		Collected at CRF.
HOCAT	char	Category		Collected at CRF.
HOENRF	char	End Relative to Reference Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSTDY	num	Relative Start Day of Observation		If HOSTDTC and REF.DATE not missing then perform below logic to calculate HOSTDY, If HOSTDTC less than REF.DATE then (HOSTDTC - REF.DATE).Else if HOSTDTC is greater than equal to REF.DATE then (HOSTDTC- REF.DATE) +1.
HOENDY	num	Relative End Day of Observation		If HOENDTC and REF.DATE not missing then perform below logic to calculate HOENDY, If HOENDTC less than REF.DATE then (HOENDTC - REF.DATE).Else if HOENDTC is greater than equal to REF.DATE then (HOENDTC- REF.DATE) +1.

#### 1.4.16. Inclusion/ Exclusion Criterion not met - IE

<b>Dataset</b>	IE
<b>Creating program</b>	ie.sas
<b>Description</b>	Inclusion/ Exclusion Criterion not met
<b>Unique identifier</b>	STUDYID,DUSUBJID,IETESTCD
<b>Sorted by</b>	STUDYID,DUSUBJID,IETESTCD
<b>Notes</b>	

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
IESEQ	num	Sequence Number		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IEORRES	char	I/E Criterion Original Result		Collected at CRF.
IESTRESC	char	I/E Criterion Result in Std Format		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.



## 1.4.17. Intake of Investigational Medication - II

<b>Dataset</b>	II
<b>Creating program</b>	ii.sas
<b>Description</b>	Intake of Investigational Medication
<b>Unique identifier</b>	STUDYID,DUSUBJID,IITRT,IISEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,IITRT,IISEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IISTDTC, IIENDTC

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
IISEQ	num	Sequence Number		Collected at CRF.
IITRT	char	Name of Treatment		Collected at CRF.
IIDOSE	num	Dose		Collected at CRF.
IIDOSU	char	Dose Units		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
IITPT	char	Planned Time Point Name		Collected at CRF.
IITPTNUM	num	Planned Time Point Number		Collected at CRF.
IISTDY	num	Relative Start Day of Observation		If IISTDTC and REF.DATE not missing then perform below logic to calculate IISTDY, If IISTDTC less than REF.DATE then (IISTDTC - REF.DATE).Else if IISTDTC is greater than equal to REF.DATE then (IISTDTC- REF.DATE) +1.
IIENDY	num	Relative End Day of Observation		If IIENDTC and REF.DATE not missing then perform below logic to calculate IIENDY, If IIENDTC less than REF.DATE then (IIENDTC - REF.DATE).Else if IIENDTC is greater than equal to REF.DATE then (IIENDTC- REF.DATE) +1.

### 1.4.18. Supplemental Qualifiers for II – SUPPII

<b>Dataset</b>	SUPPII
<b>Creating program</b>	suppii.sas
<b>Description</b>	Supplemental Qualifiers for II
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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.

### 1.4.19. Laboratory Data - LB

<b>Dataset</b>	LB
<b>Creating program</b>	lb.sas
<b>Description</b>	Laboratory Data
<b>Unique identifier</b>	STUDYID,DUSUBJID,LBCAT,LBTESTCD,LBMETHOD,LBSPEC,VISITNUM, LBTPPTNUM,LBSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,LBCAT,LBTESTCD,LBMETHOD,LBSPEC,VISITNUM, LBTPPTNUM,LBSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBREFID, LBSCAT, LBNAM, LBSPCCND, LBDTC, LBSTDTC

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.
LBGRPID	char	Group ID		Collected at CRF.
LBTESTCD	char	Lab Test or Examination Short Name		Collected at CRF.
LBTEST	char	Lab Test or Examination Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBCAT	char	Category for Lab Test		Collected at CRF.
LBORRES	char	Result or Finding in Original Units		Collected at CRF.
LBORRESU	char	Original Units		Collected at CRF.
LBORNRLO	char	Reference Range Lower Limit in Orig Unit		Collected at CRF.
LBORNRHI	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.
LBSTNRHI	num	Reference Range Upper Limit-Std Units		Collected at CRF.
LBSTNRC	char	Reference Range for Char Rslt-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.

Variable	Type	Label	Codes	Comments
LBMETHOD	char	Method of Test or Examination		Collected at CRF.
LBBLFL	char	Baseline Flag		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
LBTPT	char	Planned Time Point Name		Collected at CRF.
LBTPTNUM	num	Planned Time Point Number		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.
LBTM	num	Relative Time of Specimen Collection		If LBDTC contains time part then timepart(LBDTC) else LBTM equal to NULL.
LBSTDY	num	Relative Start Day of Observation		If LBSTDTC and REF.DATE not missing then perform below logic to calculate LBSTDY, If LBSTDTC less than REF.DATE then (LBSTDTC - REF.DATE).Else if LBSTDTC is greater than equal to REF.DATE then (LBSTDTC- REF.DATE) +1.
LBSTTM	num	Relative Start Time of Observation		If LBSTDTC contains time part then timepart(LBSTDTC) else LBSTTM equal to NULL.

## 1.4.20. Supplemental Qualifiers for LB – SUPPLB

<b>Dataset</b>	SUPPLB
<b>Creating program</b>	supplb.sas
<b>Description</b>	Supplemental Qualifiers for LB
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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		If IDVAR = "LBREFID" then drop.
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.

## 1.4.21. Microbiology - MB

<b>Dataset</b>	MB
<b>Creating program</b>	mb.sas
<b>Description</b>	Microbiology
<b>Unique identifier</b>	STUDYID, DUSUBJID, MBTESTCD, MBSEQ
<b>Sorted by</b>	STUDYID, DUSUBJID, MBTESTCD, MBSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MBREFID, MBRESCAT, MBMETHOD, MBDTC

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 Identifier for De-identity
MBSEQ	num	Sequence Number		Collected at CRF
MBGRPID	char	Group ID		Collected at CRF
MBTESTCD	char	Microbiology Test or Finding Short Name		Collected at CRF
MBTEST	char	Microbiology Test or Finding Name		Collected at CRF



Variable	Type	Label	Codes	Comments
MBCAT	char	Category for Microbiology Finding		Collected at CRF
MBORRES	char	Result or Finding in Original Units		Collected at CRF
MBORRESU	char	Original Units		Collected at CRF
MBSTRESC	char	Character Result/Finding in Std Format		Collected at CRF
MBSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF
MBSTRESU	char	Standard Units		Collected at CRF
MBSPEC	char	Specimen Type		Collected at CRF
MBBLFL	char	Baseline Flag		Collected at CRF
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
MBTPT	char	Planned Time Point Name		Collected at CRF
MBTPTNUM	num	Planned Time Point Number		Collected at CRF
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.

## 1.4.22. Medical History - MH

<b>Dataset</b>	MH
<b>Creating program</b>	mh.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	STUDYID,DUSUBJID,VISITNUM,MHSCAT,MHSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,VISITNUM,MHSCAT,MHSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MHTERM, MHDTC, MHENTPT

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.
MHGRPID	char	Group ID		Collected at CRF.
MHSCAT	char	Category for Medical History		Collected at CRF.
MHSCAT	char	Subcategory 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.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
MHENRTPT	char	End Relative to Reference Time Point		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.
MHENPTDY	num	Relative End Reference Day Time Point		If MHENTPT and REF.DATE not missing then perform below logic to calculate , If MHENTPT less than REF.DATE then (MHENTPT - REF.DATE).Else if MHENTPT is greater than equal to REF.DATE then (MHENTPT- REF.DATE) +1.

## 1.4.23. Meal Data - ML

<b>Dataset</b>	ML
<b>Creating program</b>	ml.sas
<b>Description</b>	Meal Data
<b>Unique identifier</b>	STUDYID,DUSUBJID,MLTRT,MLSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,MLTRT,MLSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MLSTDTC, MLENDTC

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
MLSEQ	num	Sequence Number		Collected at CRF.
MLTRT	char	Name of Treatment		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
MLTPT	char	Planned Time Point Name		Collected at CRF.
MLTPTNUM	num	Planned Time Point Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
MLSTDY	num	Relative Start Day of Observation		If MLSTDTC and REF.DATE not missing then perform below logic to calculate MLSTDY, If MLSTDTC less than REF.DATE then (MLSTDTC - REF.DATE).Else if MLSTDTC is greater than equal to REF.DATE then (MLSTDTC- REF.DATE) +1.
MLSTTM	num	Relative Start Time of Observation		If MLSTDTC contains time part then timepart(MLSTDTC) else MLSTTM equal to NULL.
MLENDY	num	Relative End Day of Observation		If MLENDTC and REF.DATE not missing then perform below logic to calculate MLENDY, If MLENDTC less than REF.DATE then (MLENDTC - REF.DATE).Else if MLENDTC is greater than equal to REF.DATE then (MLENDTC- REF.DATE) +1.
MLENTM	num	Relative End Time of Observation		If MLENDTC contains time part then timepart(MLENDTC) else MLENTM equal to NULL.

## 1.4.24. Supplemental Qualifiers for ML – SUPPML

<b>Dataset</b>	SUPPML
<b>Creating program</b>	suppml.sas
<b>Description</b>	Supplemental Qualifiers for ML
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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. Microbiology Susceptibility - MS

<b>Dataset</b>	MS
<b>Creating program</b>	ms.sas
<b>Description</b>	Microbiology Susceptibility
<b>Unique identifier</b>	STUDYID,DUSUBJID,MSTESTCD,MSSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,MSTESTCD,MSSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MSGRPID, MSREFID, MSORRESU, MSSTRESU, MSRESCAT, MSNAM, MSDTC

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
MSSEQ	num	Sequence Number		Collected at CRF.
MSTESTCD	char	Microbiology Organism Finding Short Name		Collected at CRF.
MSTEST	char	Organism Test or Finding Name		Collected at CRF.
MSCAT	char	Category for Organism Findings		Collected at CRF.

Variable	Type	Label	Codes	Comments
MSORRES	char	Result or Finding in Original Units		Collected at CRF.
MSSTRESC	char	Character Result/Finding in Std Format		Collected at CRF.
MSSTRESN	num	Numeric Result/Finding in Standard Units		Collected at CRF.
MSSTAT	char	Completion Status		Collected at CRF.
MSREASND	char	Reason Test Not Done		Collected at CRF.
MSMETHOD	char	Method of Test or Examination		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
MSTPT	char	Planned Time Point Name		Collected at CRF.
MSTPTNUM	num	Planned Time Point Number		Collected at CRF.
MSDY	num	Relative Day of Test		If MSDTC and REF.DATE not missing then perform below logic to calculate MSDY, If MSDTC less than REF.DATE then (MSDTC - REF.DATE).Else if MSDTC is greater than equal to REF.DATE then (MSDTC-REF.DATE) +1.



## 1.4.26. Physical Examination - PE

<b>Dataset</b>	PE
<b>Creating program</b>	pe.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	STUDYID,DUSUBJID,PETESTCD,VISITNUM,PESEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,PETESTCD,VISITNUM,PESEQ
<b>Notes</b>	Below listed variables 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.
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.
PESTRESC	char	Character Result/Finding in Std Format		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESTAT	char	Completion Status		Collected at CRF.
PEBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
PETPT	char	Planned Time Point Name		Collected at CRF.
PETPTNUM	num	Planned Time Point Number		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.

## 1.4.27. Supplemental Qualifiers for PE – SUPPPE

<b>Dataset</b>	SUPPPE
<b>Creating program</b>	supppe.sas
<b>Description</b>	Supplemental Qualifiers for PE
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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.

## 1.4.28. Questionnaires - QS

<b>Dataset</b>	QS
<b>Creating program</b>	qs.sas
<b>Description</b>	Questionnaires
<b>Unique identifier</b>	STUDYID,DUSUBJID,QSTESTCD,QSSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,QSTESTCD,QSSEQ
<b>Notes</b>	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.
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.
QSBLFL	char	Baseline Flag		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.

#### 1.4.29. Related Records - RELREC

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

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

#### 1.4.30. References to Lab and Other Procedures - RF

<b>Dataset</b>	RF
<b>Creating program</b>	rf.sas
<b>Description</b>	References to Lab and Other Procedures
<b>Unique identifier</b>	STUDYID,DUSUBJID,RFTESTCD,RFSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,RFTESTCD,RFSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RFSTRESN, RFDC

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
RFSEQ	num	Sequence Number		Collected at CRF.
RFTESTCD	char	Short Name of Test or Examination		Collected at CRF.
RFTEST	char	Name of Test or Examination		Collected at CRF.
RFCAT	char	Category		Collected at CRF.
RFSCAT	char	Subcategory		Collected at CRF.
RFORRES	char	Result or Finding in Original Units		Collected at CRF.
RFSTRESC	char	Result or Finding in Standard Format		Collected at CRF.
RFBLFL	char	Baseline Flag		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
RFTPT	char	Planned Time Point Name		Collected at CRF.
RFTPTNUM	num	Planned Time Point Number		Collected at CRF.
RFDY	num	Relative Day of Collection		If RFDTC and REF.DATE not missing then perform below logic to calculate RFDY, If RFDTC less than REF.DATE then (RFDTC - REF.DATE).Else if RFDTC is greater than equal to REF.DATE then (RFDTC- REF.DATE) +1.

## 1.4.31. Survival Data - SD

<b>Dataset</b>	SD
<b>Creating program</b>	sd.sas
<b>Description</b>	Survival Data
<b>Unique identifier</b>	STUDYID,DUSUBJID,SDTESTCD,SDCAT,SDSEQ
<b>Sorted by</b>	STUDYID,DUSUBJID,SDTESTCD,SDCAT,SDSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SDDTC

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
SDSEQ	num	Sequence Number		Collected at CRF.
SDGRPID	char	Group ID		Collected at CRF.
SDTESTCD	char	Short Name of Test or Examination		Collected at CRF.
SDTEST	char	Name of Test or Examination		Collected at CRF.
SDCAT	char	Category		Collected at CRF.



Variable	Type	Label	Codes	Comments
SDSCAT	char	Subcategory		Collected at CRF.
SDORRES	char	Result or Finding in Original Units		Group element to protect PII.
SDSTRESC	char	Result or Finding in Standard Format		Group element to protect PII.
SDDY	num	Relative Day of Collection		If SDDTC and REF.DATE not missing then perform below logic to calculate SDDY, If SDDTC less than REF.DATE then (SDDTC - REF.DATE).Else if SDDTC is greater than equal to REF.DATE then (SDDTC-REF.DATE) +1.

## 1.4.32. Subject Elements - SE

<b>Dataset</b>	SE
<b>Creating program</b>	se.sas
<b>Description</b>	Subject Elements
<b>Unique identifier</b>	STUDYID,DUSUBJID,ETCD
<b>Sorted by</b>	STUDYID,DUSUBJID,ETCD
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SESTDTC, SEENDTC

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
SESEQ	num	Sequence Number		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.

Variable	Type	Label	Codes	Comments
SESTDY	num	Relative Start Day of Element		If SESTDTC and REF.DATE not missing then perform below logic to calculate SESTDY, If SESTDTC less than REF.DATE then (SESTDTC - REF.DATE).Else if SESTDTC is greater than equal to REF.DATE then (SESTDTC- REF.DATE) +1.
SEENDY	num	Relative End Day of Element		If SEENDTC and REF.DATE not missing then perform below logic to calculate SEENDY, If SEENDTC less than REF.DATE then (SEENDTC - REF.DATE).Else if SEENDTC is greater than equal to REF.DATE then (SEENDTC- REF.DATE) +1.

## 1.4.33. Subject Visits - SV

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

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.

#### 1.4.34. Trial Arms - TA

<b>Dataset</b>	TA
<b>Creating program</b>	ta.sas
<b>Description</b>	Trial Arms
<b>Unique identifier</b>	STUDYID,ARMCD,TAETORD
<b>Sorted by</b>	STUDYID,ARMCD,TAETORD
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: TATRANS

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

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain Abbreviation		Collected at CRF.
ARMCD	char	Planned Arm Code		Collected at CRF.
ARM	char	Description of Planned Arm		Collected at CRF.
TAETORD	num	Order of Element within Arm		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
TABRANCH	char	Branch		Collected at CRF.
EPOCH	char	Epoch		Collected at CRF.

### 1.4.35. Trial Elements - TE

<b>Dataset</b>	TE
<b>Creating program</b>	te.sas
<b>Description</b>	Trial Elements
<b>Unique identifier</b>	STUDYID,ETCD
<b>Sorted by</b>	STUDYID,ETCD
<b>Notes</b>	

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

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain Abbreviation		Collected at CRF.
ETCD	char	Element Code		Collected at CRF.
ELEMENT	char	Description of Element		Collected at CRF.
TESTRL	char	Rule for Start of Element		Collected at CRF.
TEENRL	char	Rule for End of Element		Collected at CRF.
TEDUR	char	Planned Duration of Element		Collected at CRF.

#### 1.4.36. Trial Inclusion/Exclusion Criteria - TI

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
IETESTCD	char	Incl/Excl Criterion Short Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
TIVERS	char	Protocol Criteria Versions		Collected at CRF.

#### 1.4.37. Trial Summary - TS

<b>Dataset</b>	TS
<b>Creating program</b>	ts.sas
<b>Description</b>	Trial Summary
<b>Unique identifier</b>	STUDYID,TSPARMCD,TSSEQ
<b>Sorted by</b>	STUDYID,TSPARMCD,TSSEQ
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
TSSEQ	num	Sequence Number		Collected at CRF.
TSGRPID	char	Group ID		Collected at CRF.
TSPARMCD	char	Trial Summary Parameter Short Name		Collected at CRF.



Variable	Type	Label	Codes	Comments
TSPARM	char	Trial Summary Parameter		Collected at CRF.
TSVAL	char	Parameter Value		Collected at CRF.
TSVAL1	char	Parameter Value		Collected at CRF.
TSVAL2	char	Parameter Value		Collected at CRF.

#### 1.4.38. Trial Visits - TV

<b>Dataset</b>	TV
<b>Creating program</b>	tv.sas
<b>Description</b>	Trial Visits
<b>Unique identifier</b>	STUDYID,VISITNUM
<b>Sorted by</b>	STUDYID,VISITNUM
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Identifier		Collected at CRF.
DOMAIN	char	Domain Abbreviation		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
ARMCD	char	Planned Arm Code		Collected at CRF.
TVSTRL	char	Visit Start Rule		Collected at CRF.

#### 1.4.39. Vital Signs - VS

<b>Dataset</b>	VS
<b>Creating program</b>	vs.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	STUDYID,DUSUBJID,VSTESTCD,VISITNUM
<b>Sorted by</b>	STUDYID,DUSUBJID,VSTESTCD,VISITNUM
<b>Notes</b>	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.
VSGRPID	char	Group ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSPOS	char	Vital Signs Position of Subject		Collected at CRF.
VSORRES	char	Result or Finding in Original Units		Collected at CRF.
VSORRESU	char	Original Units		Collected at CRF.
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.
VSTPT	char	Planned Time Point Name		Collected at CRF.
VSTPTNUM	num	Planned Time Point Number		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.

## 1.4.40. Supplemental Qualifiers for VS – SUPPVS

<b>Dataset</b>	SUPPVS
<b>Creating program</b>	suppvs.sas
<b>Description</b>	Supplemental Qualifiers for VS
<b>Unique identifier</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Sorted by</b>	DUSUBJID,IDVAR,IDVARVAL,QNAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: QEQVAL

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.