

Clinical Development

**Trabectedin**

ET743-OVC-1001

Anonymisation Data Derivation Specification Document

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## Table of contents

Clinical Development .....	1
1. Datasets .....	4
1.1. Specifications Introduction .....	4
1.2. Guidelines for Preparing Data.....	4
1.3. Data Domains .....	6
1.3.1. DEMOGRAPHICS – DEMOG .....	6
1.3.2 ADVERSE EVENT - AE.....	8
1.3.3 CHEMISTRY DATA - CHEM.....	10
1.3.4 CONMED RELATED AE – CMAE.....	12
1.3.5 CONCOMITANT MEDICATIONS – CONMED .....	13
1.3.9. DEATH - DEATH .....	16
1.3.10.DIAGNOSIS – DIAGNOS .....	17
1.3.11. DISPOSITION ADVERSE EVENTS – DISPAE .....	18
1.3.12. DISPOSITION – DISPOSIT.....	19
1.3.13. ELECTROCARDIOGRAM – ECG .....	21
1.3.14. ELECTROCARDIOGRAM - CRF – ECGSAM .....	23
1.3.15. ECOG PERFORMANCE STATUS - ECOG.....	24
1.3.16. EXPOSURE DETAILS RELATED AE – EDAE .....	25
1.3.17. EVALUATION OF RESPONSE – EVALRES .....	26
1.3.18.EXPOSURE – EXPOSURE .....	27
1.3.19. LABORATORY TEST RESULTS - HEMAT.....	29
1.3.20. INCLUSION/EXCLUSION EXCEPTIONS – IE.....	31
1.3.21. RESULTS OF AE RELATED TESTS – LABSAE.....	32

1.3.22. LEFT VENT EJECT FRACTION – LVEF .....	33
1.3.23. MEAL – MEAL.....	34
1.3.24. MEDICAL HISTORY – MEDHIST .....	35
1.3.25. MEDICATION VIAL NUMBERS – MEDVIAL.....	36
1.3.26. PC CONCENTRATIONS – PCCNC .....	37
1.3.27. PHYSICAL EXAM – PE .....	39
1.3.28. TOTAL PRIOR ANTHRACYCLINE – PRANTCYC.....	40
1.3.29. RADIOTHERAPY – PRERADIA.....	41
1.3.30. PREVIOUS CANCER SURGERY – PRESURG .....	42
1.3.31. PREVIOUS THERAPY – PRETHER.....	43
1.3.32. PROTOCOL DESCRIPTION – PROTDESC.....	45
1.3.33. PROTOCOL DEVIATION – PROTDEV .....	46
1.3.34. SURGERY – SURGERY .....	47
1.3.35. TUMOR LESIONS – TUMMEAS .....	48
1.3.36. TRIAL INCLUSION/EXCLUSION CRITERIA – TI.....	50
1.3.37. VISIT – VISIT.....	50
1.3.38. VITAL SIGNS – VITAL.....	51

## 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
Description	Short description
Unique Identifier	Unique key

#### Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
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 be masked.
- Investigator Information will be masked.
- Date of birth will not be provided to protect PII as per HIPAA rules.
- Age at subject start date will be calculated and grouped in intervals to protect PII as per HIPAA rules. A deidentified age variable will be created in which a new age is randomly selected within the original interval.
- Patient identification numbers will be assigned in a random manner so they are not matching the patient identification numbers that were used in the actual trial. Site and location information will not be preserved.

- Site number will be masked to reduce re-identification risk.
- Country will be masked to reduce re-identification risk.
- Race will be masked to reduce re-identification risk.
- Free text verbatim terms will be masked.
- Free text summary terms will be masked.
- “Other” free text terms will be masked.
- Drug Record Number will be masked.
- Drug Sequence Number will be masked.
- Accession Number will be masked.
- Vial and Bottle number will be masked.
- Central Lab Sample Identifier will be masked.
- Central Lab Batch Identifier will be masked.
- Vendor Panel Comments will be masked.
- Vendor Test Specific Comments will be masked.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a relative study day will be provided which is the number of days from a randomly sampled reference date (REF.DATE) to the original date.
- 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.
- The following dataset will not be provided: COMMENTS, EVALRES (0 rows)

### 1.3.Data Domains

#### 1.3.1. DEMOGRAPHICS – DEMOG

<b>Dataset</b>	DEMOG
<b>Description</b>	DEMOGRAPHICS
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
SUBJINIT	character	Subject Initials	Suppressed all records to protect PII.
IVID	character	Investigator ID	Suppressed all records to protect PII.
IVNAME	character	Investigator Name	Suppressed all records to protect PII.
RACESPEC	character	Race Other	Suppressed all records to protect PII.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
CIVNAME	character	Co-Investigator Name	Suppressed all records to protect PII.
ETHNICC	double	Ethnicity Code	Collected at CRF.
ETHNIC	character	Ethnicity	Collected at CRF.
DAY	character	Day	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.

DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification.
DSEX	character	De-identified Sex	Suppressed selected records to protect PII.
DSEXC	double	De-identified Sex Code	Suppressed selected records to protect PII.
DCOUNTRY	character	De-identified Country	Grouped by continental region and suppressed selected records to protect PII.
DRACE	character	De-identified Race	Replaced low frequency race groups with 'OTHER' and suppressed selected records to protect PII.
DRACEC	double	De-identified Race Code	Replaced low frequency race groups with '4' and suppressed selected records to protect PII.
DAGEGROUP	character	De-identified Age Group	Aggregated age to 10-year age groups and suppressed selected records to protect PII.
DAGE	double	De-identified Age	Randomly sampled within age group and suppressed selected records to protect PII.
DDMACTDT	double	De-identified Actual Date of Demography	Relative day of actual date of demography from randomly assigned reference date (DMACTDT-REF.DATE).
DDMSCRDT	double	De-identified Date of of First Trial Related Procedure	Relative day of first trial related procedure from randomly assigned reference date (DMSCRDT-REF.DATE).
DDMINFDT	double	De-identified Date of Signature on Informed Consent	Relative day of signature on informed consent from randomly assigned reference date (DMINFDT-REF.DATE).

### 1.3.2 ADVERSE EVENT - AE

<b>Dataset</b>	AE
<b>Description</b>	ADVERSE EVENT
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAY	character	Day	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
AESEQ	double	AE Sequence Number	Collected at CRF.
AETERM	character	Reported Term	Suppressed all records to protect PII.
AEMODIFY	character	Modified Reported Term	Suppressed all records to protect PII.
AECTTRC	character	Action Taken with Treatment Code	Collected at CRF.
AECTTRT	character	Action Taken with Treatment	Collected at CRF.
AEOUTC	character	Outcome of Event Code	Collected at CRF.
AEOUT	character	Outcome of Event	Collected at CRF.



AERELC	character	Relationship to Treatment Code	Collected at CRF.
AEREL	character	Relationship to Treatment	Collected at CRF.
AESERC	character	Seriousness Criteria Code	Collected at CRF.
AESER	character	Seriousness Criteria	Collected at CRF.
AESHOSPR	character	Requires Hospitalization	Collected at CRF.
AESHOSPP	character	Prolonged Hospitalization	Collected at CRF.
AESDTH	character	Results in Death	Applied subject specific randomly sampled offset to protect PII
AESLIFE	character	Is Life Threatening	Collected at CRF.
AESDISAB	character	Persist or Signif Disability/Incapacity	Collected at CRF.
AESCONG	character	Congenial Anomaly or Birth Defect	Collected at CRF.
AESMIE	character	Other Medicaly Important Serious Event	Collected at CRF.
AECONTRC	character	Concomitant/Additional Treatment Code	Collected at CRF.
AECONTRT	character	Concomitant/Additional Treatment	Collected at CRF.
AEREPRTC	double	Were any AEs Reported Code	Collected at CRF.
AEREPRT	character	Were Any Aes Reported	Collected at CRF.
AEDICTDM	character	Adverse Events Dictionary	Collected at CRF.
SOC1	character	AE System Organ Class 1	Collected at CRF.
SOC2	character	AE System Organ Class 2	Collected at CRF.
SOC3	character	AE System Organ Class 3	Collected at CRF.
AESERREF	character	Serious AE Reference Number	Collected at CRF.
AETOX	character	AE Toxicity Grade	Collected at CRF.
AETOXC	character	AE Toxicity Grade Code	Collected at CRF.

DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DAEBODSYC	Double	De-identified Body System or Organ Class Code	Suppressed selected cells to protect PII.
DAEBODSYS	character	De-identified Body System or Organ Class	Suppressed selected cells to protect PII.
DAEDECOD	character	De-identified Dictionary-Derived Term	Suppressed selected cells to protect PII.
DAEDECOD1	character	De-identified Dictionary-Derived Lower Level Term	Suppressed selected cells to protect PII.
DAECODE	numeric	AE Dictionary Code	Suppressed selected cells to protect PII.
DAESTDT	numeric	De-identified Actual Start Date of Event	Relative day of actual start of event from randomly assigned reference date (AESTDT-REF.DATE).
DAEENDT	numeric	De-identified End Date of Event	Relative day of first trial related procedure from randomly assigned reference date (AEENDT-REF.DATE).

### 1.3.3 CHEMISTRY DATA - CHEM

<b>Dataset</b>	CHEM
<b>Description</b>	CHEMISTRY DATA
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
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STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
LBPRVIDC	character	CHEM oratory ID Code	Suppressed all records to protect PII.
LBPRVID	character	CHEM oratory ID	Suppressed all records to protect PII.
LBSEQ	character	Sample Sequence Number	Collected at CRF.
LBVTYPEC	character	CHEM Visit Type Code	Collected at CRF.
LBVTYPE	character	CHEM Visit Type	Collected at CRF.
LBTESTC	double	CHEM Test Code	Collected at CRF.
LBTEST	character	CHEM Test Name	Collected at CRF.
LBDESCR	character	Full Test Description	Collected at CRF.
LBABBR	character	CHEM Test Abbreviation	Collected at CRF.
ORGRES	character	Character Result in Original Units	Suppressed all records to protect PII.
ORGRESN	double	Numeric Result in Original Units	Suppressed all records to protect PII.
REPUNIT	character	Reported Unit	Collected at CRF.
ORGUNIT	character	Original Units	Suppressed all records to protect PII.
ORGNRLO	double	Normal Range Lower Limit in Orig Units	Suppressed all records to protect PII.
ORGNRHI	double	Normal Range Upper Limit in Orig Units	Suppressed all records to protect PII.
NRIND	character	Normal Range Indicator	Collected at CRF.
STDUNIT	character	Standard Units	Collected at CRF.
STDRESN	double	Numeric Result in Standard Units	Collected at CRF.
STDRESC	character	Character Result in Standard Units	Collected at CRF.
STDNRLO	double	Normal Range Lower Limit in Std Units	Collected at CRF.

STDNRHI	double	Normal Range Upper Limit in Std Units	Collected at CRF.
LBSIFACT	double	Std. Intl. Conversion Factor	Collected at CRF.
LBSIGLO	character	Significant Range Low	Collected at CRF.
LBSIGHI	character	Significant Range High	Collected at CRF.
STDNRC	character	Normal Range in Char Result in Std Units	Collected at CRF.
LBTYPE	character	CHEM Type	Collected at CRF.
LBTYPEC	double	CHEM Type Code	Collected at CRF.
LBSIG	character	Clinically Significant	Collected at CRF.
DUSUBJID	character	Deidentified Short subject ID	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DLBACTDT	numeric	Deidentified Actual Date of Sample	Relative day of sample from randomly assigned reference date (LBACTDT-REF.DATE).

#### 1.3.4 CONMED RELATED AE – CMAE

<b>Dataset</b>	CMAE
<b>Description</b>	Conmed Related AE
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.

VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
AESEQ	double	AE Sequence Number for conmed	Collected at CRF.
CMSEQ	double	Conmed Sequence Number	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

### 1.3.5 CONCOMITANT MEDICATIONS – CONMED

<b>Dataset</b>	CONMED
<b>Description</b>	Concomitant Medications
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.

DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
CMSEQ	double	Conmed Sequence Number	Collected at CRF.
CMTERM	character	Reported Name of Drug/Medication/Therapy	Suppressed all records to protect PII.
CMCODE	character	Medication Dictionary Code	Collected at CRF.
CMMODIFY	character	Modified Report Name	Suppressed all records to protect PII.
CMDECOD	character	Medication Generic Term	Collected at CRF.
CMDECOD1	character	Medication Specified Term	Collected at CRF.
CMREAS	character	Reason for Medication	Suppressed all records to protect PII.
CMCLASC	character	ATC Code	Collected at CRF.
CMCLAS	character	ATC Text	Collected at CRF.
CMCLASC0	character	ATC Code 0	Collected at CRF.
CMCLASC1	character	ATC Code 1	Collected at CRF.
CMCLASC2	character	ATC Code 2	Collected at CRF.
CMCLASC3	character	ATC Code 3	Collected at CRF.
CMCLASC4	character	ATC Code 4	Collected at CRF.
CMCLASC5	character	ATC Code 5	Collected at CRF.
CMCLASC6	character	ATC Code 6	Collected at CRF.
CMCLASC7	character	ATC Code 7	Collected at CRF.
CMCLASC8	character	ATC Code 8	Collected at CRF.
CMCLASC9	character	ATC Code 9	Collected at CRF.
CMCLAS0	character	ATC Text 0	Collected at CRF.
CMCLAS1	character	ATC Text 1	Collected at CRF.
CMCLAS2	character	ATC Text 2	Collected at CRF.
CMCLAS3	character	ATC Text 3	Collected at CRF.
CMCLAS4	character	ATC Text 4	Collected at CRF.
CMCLAS5	character	ATC Text 5	Collected at CRF.
CMCLAS6	character	ATC Text 6	Collected at CRF.
CMCLAS7	character	ATC Text 7	Collected at CRF.

CMCLAS8	character	ATC Text 8	Collected at CRF.
CMCLAS9	character	ATC Text 9	Collected at CRF.
CMTYPEC	double	Prior/Concomitant Medication Code	Collected at CRF.
CMTYPE	character	Prior/Concomitant Medication	Collected at CRF.
CMREGIM	character	Regimen ( Dose + Frequency )	Collected at CRF.
CMROUTE	character	Route of Administration	Collected at CRF.
CMREPRC	double	Were Any Meds Administered Code	Collected at CRF.
CMREPR	character	Were Any Meds Administered	Collected at CRF.
CMCONTC	character	Medication Continuing Code	Collected at CRF.
CMCONT	character	Medication Continuing	Collected at CRF.
CMCAUSC	character	Given for AE Code	Collected at CRF.
CMCAUS	character	Given for AE	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
CMPRIOR	character	Med Started Prior to Trial	Collected at CRF.
CMPRIORC	character	Med Started Prior to Trial Code	Collected at CRF.
CMDICTVS	character	Dictionary version	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DCMSTDTC	numeric	Deidentified Actual Start Date of Medication	Relative day of start day of medication from randomly assigned reference date (CMSTDTC-REF.DATE).
DCMENDTC	numeric	Deidentified Actual End Date of Medication	Relative day of end day of medication from randomly assigned reference date (CMENDTC-REF.DATE).

### 1.3.9. DEATH - DEATH

<b>Dataset</b>	DEATH
<b>Description</b>	Death
<b>Unique identifier</b>	None

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DTCAUSEC	character	Cause of Death Code	Collected at CRF.
DTCAUSE	character	Cause of Death	Collected at CRF.
DTPDSPEC	character	Progressive Disease - Specify	Collected at CRF.
DTPROGC	character	Evidence of PD been documented Code	Collected at CRF.
DTPROG	character	Evidence of PD been documented	Collected at CRF.
DTOTH	character	Other Reason, Specify	Suppressed all records to protect PII.
DUSUBJID	character	De-identified Unique Subject ID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Subject ID	Suppressed all records to protect PII.
DDTACTDT	numeric	De-identified Date of Death	Relative day of death from randomly assigned reference date (DTACTDT-REF.DATE)



### 1.3.10.DIAGNOSIS – DIAGNOS

<b>Dataset</b>	DIAGNOS
<b>Description</b>	Diagnosis
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
DIAGNOSC	double	Diagnosis Code	Collected at CRF.
DIAGNOS	character	Diagnosis	Collected at CRF.
DGSCMSPC	character	Specify Type of Sarcoma	Collected at CRF.
DGOTHSPC	character	Specify Type of Other	Suppressed all records to protect PII.
DGSTGDSC	double	Stage of Disease Code	Collected at CRF.
DGSTGDS	character	Stage of Disease	Collected at CRF.
DGLSNFWC	double	Is Lesion Being Followed (Code)?	Collected at CRF.
DGLSNFW	character	Is Lesion Being Followed	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

DDGTMYPC	double	De-identified Tumor Type Code	Grouped small counts to protect PII.
DDGTMYPE	character	De-identified Tumor Type	Grouped small counts to protect PII.
DDGACTDT	numeric	De-identified Actual Date of Diagnosis	Relative day of diagnosis from randomly assigned reference date (DGACTDT-REF.DATE)
DDGLPDDT	numeric	De-identified Date of Latest Disease Progression	Relative day of latest disease progression from randomly assigned reference date (DGLPDDT-REF.DATE)

### 1.3.11. DISPOSITION ADVERSE EVENTS – DISPAE

<b>Dataset</b>	DISPAE
<b>Description</b>	Disposition Adverse Events
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DATYPEC	double	Disposition Type Code	Collected at CRF.

DATYPE	character	Disposition Type	Collected at CRF.
AESEQ	character	Adverse Event Sequence Number	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

### 1.3.12. DISPOSITION – DISPOSIT

<b>Dataset</b>	DISPOSIT
<b>Description</b>	Disposition
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DSTYPEC	double	End of Treatment or Trial Code	Collected at CRF.
DSTYPE	character	End of Treatment or Trial	Collected at CRF.
DSREASC	character	Reason for Withdrawal/Termination Code	Collected at CRF.
DSREAS	character	Reason for Withdrawal/Termination	Collected at CRF.

DSSTATC	double	Subject Completed Treatment/Trial Code	Collected at CRF.
DSSTAT	character	Subject Completed Treatment/Trial	Collected at CRF.
DSRSOTH	character	Other Reason - Specify	Suppressed all records to protect PII.
DSRSSOTH	character	Subject Choice, Other Specify	All records blank in original data
PREGDUDT	character	Pregnancy Due Date	All records were suppressed in original data.
DSSUFUC	character	Subject agree to Survival Follow-Up Code	Suppressed all records to protect PII.
DSSUFU	character	Subject agree to Survival Follow-Up	Suppressed all records to protect PII.
DSCYCNUM	character	Completed Cycle Number	Collected at CRF.
DSOLEXTC	double	Subject enter Open-label Extension Code	Collected at CRF.
DSOLEXT	character	Subject enter Open-label Extension	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DDSACTDT	character	De-identified Actual Date Trial Completion/Withdrawal	Relative day of trial completion/withdrawal from randomly assigned reference date (DDSACTDT-REF.DATE)

### 1.3.13. ELECTROCARDIOGRAM – ECG

<b>Dataset</b>	ECG
<b>Description</b>	Electrocardiogram
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
EGSEQ	double	ECG Sequence Number	Collected at CRF.
EGPRVIDC	double	ECG Provider Name Code	Suppressed all records to protect PII.
EGPRVID	character	ECG Provider Name	Suppressed all records to protect PII.
EGREADC	double	ECG Reader Code	Collected at CRF.
EGREAD	character	ECG Reader	Collected at CRF.
EGINTPC	character	Interpretation Code	Collected at CRF.
EGINTP	character	Interpretation	Collected at CRF.
EGINTOTH	character	ECG Interpretation, Specify	Suppressed all records to protect PII.
EGORUNIT	character	Original Units	Collected at CRF.
EGORRESN	character	Numeric Result in Original Units	Suppressed all records to protect PII.
EGTEST	character	ECG Test	Collected at CRF.
EGTESTCD	character	ECG Test Short Name	Collected at CRF.
EGSTRESN	character	Numeric Result in Standard Units	Collected at CRF.

EGSTUNIT	character	Standard Units	Collected at CRF.
EGSTRESC	character	Character Result in Standard Units	Collected at CRF.
EGPOS	character	Position	Collected at CRF.
EGQUAL	character	Qualifier	Collected at CRF.
EGLEAD	character	Lead Used for Measurement	Collected at CRF.
EGCHGC	character	Sig Change from Prev/Baseline ECG Code	Collected at CRF.
EGCHG	character	Sig Change from Prev/Baseline ECG	Collected at CRF.
EGCHGOTH	character	Change, Specify	Suppressed all records to protect PII.
EGACTTM	double	Actual Time of ECG	Collected at CRF.
EGREF	character	ECG Reference Number	Collected at CRF.
EGND	character	ECG Not Done	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
EGVTYPEC	double	ECG Visit Type Code	Collected at CRF.
EGVTYPE	character	ECG Visit Type	Collected at CRF.
EGPTM	character	Planned Time Point Name	Collected at CRF.
EGPTMNUM	double	Planned Time Point Number	Collected at CRF.
BATCHID	character	Central batch identifier	Collected at CRF.
EGVENCOM	character	Comments from External Vendor	Suppressed all records to protect PII.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DEGDT	character	De-identified Actual Date of ECG	Relative day of ECG from randomly assigned reference date (EGDT -REF.DATE)

### 1.3.14. ELECTROCARDIOGRAM - CRF – ECGSAM

<b>Dataset</b>	ECGSAM
<b>Description</b>	Electrocardiogram - CRF
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAY	character	DAY	Collected at CRF.
DAYNUM	character	DayNumber	Collected at CRF.
EGSTRPT	character	Rest 1 hour prior to Predose ECG Asmnt	Collected at CRF.
EGSTRPTC	character	Rest 1 hour prior to Predose ECG Asmnt	Collected at CRF.
EGENRPT	character	Rest 1 hour prior to 24 hr ECG Asmnt	Collected at CRF.
EGENRPTC	character	Rest 1 hour prior to 24 hr ECG Asmnt	Collected at CRF.
EGPTM	character	Planned Time Point Name	Collected at CRF.
EGPTMNUM	double	Planned Time Point Number	Collected at CRF.
EGINTRP	character	ECG Interpretation	Collected at CRF.
EGINTRPC	character	ECG Interpretation Code	Collected at CRF.
EGINOTH	character	Clinically Significant Specify	Suppressed all records to protect PII.

DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

### 1.3.15. ECOG PERFORMANCE STATUS - ECOG

<b>Dataset</b>	ECOG
<b>Description</b>	ECOG Performance Status
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
ECECOGC	double	ECOG Performance Status Code	Collected at CRF.
ECECOG	character	ECOG Performance Status	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification



DECACTDT	character	De-identified ECOG Actual Date	Relative day of ECOG from randomly assigned reference date (ECACTDT-REF.DATE)
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### 1.3.16. EXPOSURE DETAILS RELATED AE – EDAE

<b>Dataset</b>	EDAE
<b>Description</b>	Exposure Details Related AE
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
ACTTRT	character	Drug/Therapy	Collected at CRF.
AESEQ	double	AE Sequence Number	Collected at CRF.
EDSEQ	double	Exposure Details Sequence Number	Collected at CRF.

DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

### 1.3.17. EVALUATION OF RESPONSE – EVALRES

<b>Dataset</b>	EVALRES
<b>Description</b>	Evaluation of Response
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Id	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
ERMETHAC	double	Method of Assessment Code	Collected at CRF.
ERMETHA	character	Method of Assessment	Collected at CRF.
ERRESPC	Double	Evaluation of Response Code	Collected at CRF.
ERRESP	Character	Evaluation of Response	Collected at CRF.
ERCPSPEC	character	Clinical Progression, Specify	Suppressed all records to protect PII.
ERRESPEC	character	Evaluation of Response, Specify	Suppressed all records to protect PII.
DAYNUM	double	Day Number	Collected at CRF.
DAY	Character	Day	Collected at CRF.
DSUBJID	character	Deidentified Long subject ID	Randomly assigned patient number for de-identification

DUSUBJID	character	Deidentified Short subject ID	Randomly assigned patient number for de-identification
DERDT	double	Deidentified Date of Evaluation	Relative day of evaluation from randomly assigned reference date (ERDT -REF.DATE)

### 1.3.18.EXPOSURE – EXPOSURE

<b>Dataset</b>	EXPOSURE
<b>Description</b>	Exposure
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
EXSEQ	double	Exposure Sequence Number	Collected at CRF.
EDSTTM	double	Start Time	Collected at CRF.
EDENDTM	character	End Time	Collected at CRF.
ACTTRT	character	Drug/Therapy	Collected at CRF.
ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
EXPRETRT	character	Pre-Treatment Given	Collected at CRF.

EXPREDOS	character	Pre-Treatment Dose	Collected at CRF.
ROUTE	character	Route of Administration	Collected at CRF.
DOSE	character	Dose per Administration	Collected at CRF.
DOSEUNIT	character	Dose Unit	Collected at CRF.
EXDOSPRE	character	Prescribed Dose	Collected at CRF.
EXPRUNIT	character	Prescribed Dose Unit	Collected at CRF.
EDRSNOTH	character	Temp. Interrupted Other Reason, Specify	Suppressed all records to protect PII.
EXTMLBL	character	Label of Planned Administration Time	Collected at CRF.
EXSTATC	character	Exposure Status Code	Collected at CRF.
EXSTAT	character	Exposure Status	Collected at CRF.
DAY	character	Day	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
EXRSITP	character	Reason for Interruption	Collected at CRF.
EXRSITPC	character	Reason for Interruption Code	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DEXSTDT	numeric	De-identified Start Date of Exposure	Relative day of start of exposure from randomly assigned reference date (EXSTDT-REF.DATE)

### 1.3.19. LABORATORY TEST RESULTS - HEMAT

<b>Dataset</b>	HEMAT
<b>Description</b>	Laboratory Test Results
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
LBPRVIDC	character	HEMAToratory ID Code	Suppressed all records to protect PII.
LBPRVID	character	HEMAToratory ID	Suppressed all records to protect PII.
LBSEQ	character	Sample Sequence Number	Collected at CRF.
LBVTYPEC	character	HEMAT Visit Type Code	Collected at CRF.
LBVTYPE	character	HEMAT Visit Type	Collected at CRF.
LBTESTC	double	HEMAT Test Code	Collected at CRF.
LBTEST	character	HEMAT Test Name	Collected at CRF.
LBDESCR	character	Full Test Description	Collected at CRF.
LBABBR	character	HEMAT Test Abbreviation	Collected at CRF.

ORGRES	character	Character Result in Original Units	Suppressed all records to protect PII.
ORGRESN	double	Numeric Result in Original Units	Suppressed all records to protect PII.
REPUNIT	character	Reported Unit	Collected at CRF.
ORGUNIT	character	Original Units	Suppressed all records to protect PII.
ORGNRLO	character	Normal Range Lower Limit in Orig Units	Suppressed all records to protect PII.
ORGNRHI	character	Normal Range Upper Limit in Orig Units	Suppressed all records to protect PII..
NRIND	character	Normal Range Indicator	Collected at CRF.
STDUNIT	character	Standard Units	Collected at CRF.
STDRESN	double	Numeric Result in Standard Units	Collected at CRF.
STDRESC	character	Character Result in Standard Units	Collected at CRF.
STDNRLO	character	Normal Range Lower Limit in Std Units	Collected at CRF.
STDNRHI	character	Normal Range Upper Limit in Std Units	Collected at CRF.
LBSIFACT	double	Std. Intl. Conversion Factor	Collected at CRF.
LBSIGLO	character	Significant Range Low	Collected at CRF.
LBSIGHI	character	Significant Range High	Collected at CRF.
STDNRC	character	Normal Range in Char Result in Std Units	Collected at CRF.
LBTYPE	character	HEMAT Type	Collected at CRF.
LBTYPEC	double	HEMAT Type Code	Collected at CRF.
LBSIG	character	Clinically Significant	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DLBACTDT	numeric	De-identified Actual Date of Sample	Relative day of sample from randomly assigned reference date (LBACTDT-REF.DATE)

### 1.3.20. INCLUSION/EXCLUSION EXCEPTIONS – IE

<b>Dataset</b>	IE
<b>Description</b>	Inclusion/Exclusion Exceptions
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
IECAT	character	Inclusion/Exclusion Category	Collected at CRF.
IESPID	character	Sponsor-defined Identifier	Suppressed all records to protect PII.
IETEST	character	Inclusion/Exclusion Criterion	Collected at CRF.
IETESTCD	character	Inclusion/Exclusion Criterion Short Name	Collected at CRF.
IEORRES	character	Exception Criterion Original Result	Suppressed all records to protect PII.
IESTRESC	character	Exception Criterion Result in Std Format	Collected at CRF.
IEMETC	double	Overall Criteria Met Code	Collected at CRF.
IEMET	character	Overall Criteria Met	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

DIEDT	numeric	De-identified Date of Collection	Relative day of collection from randomly assigned reference date (IEDT - REF.DATE)
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### 1.3.21. RESULTS OF AE RELATED TESTS – LABSAE

<b>Dataset</b>	LABSAE
<b>Description</b>	Results of AE Related Tests
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAY	character	Day	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
LBPRVID	character	Laboratory ID	Suppressed all records to protect PII.
LBTEST	character	Lab Test Name	Collected at CRF.
ORGRES	character	Character Result in Original Units	Suppressed all records to protect PII.
ORGUNIT	character	Original Units	Collected at CRF.



LBSEQ	character	Sample Sequence Number	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DLBACTDT	numeric	De-identified Actual Date of Sample	Relative day of sample from randomly assigned reference date (LBACTDT- REF.DATE)

### 1.3.22. LEFT VENT EJECT FRACTION – LVEF

<b>Dataset</b>	LVEF
<b>Description</b>	Left Vent Eject Fraction
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
LVMETHC	double	Method Code	Collected at CRF.

LVMETH	character	Method	Collected at CRF.
LVNRLO	double	Lower Limit of Normal	Collected at CRF.
LVRESN	double	Test of Result	Collected at CRF.
LVUNIT	character	Unit	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DLVACTDT	character	De-identified Date of Sample Testing	Relative day of sample testing from randomly assigned reference date (LVACTDT-REF.DATE)

### 1.3.23.MEAL – MEAL

<b>Dataset</b>	MEAL
<b>Description</b>	Meal
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.

MLPDSNKC	double	Pre-dose Snack Code	Collected at CRF.
MLPDSNK	character	Pre-dose Snack	Collected at CRF.
MLSTTM	character	Start Time of a Meal	Collected at CRF.
MLENDTM	character	End Time of a Meal	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DMLACTDT	character	De-identified Date of a Meal	Relative day of meal from randomly assigned reference date (MLACTDT-REF.DATE)

### 1.3.24. MEDICAL HISTORY – MEDHIST

<b>Dataset</b>	MEDHIST
<b>Description</b>	Medical History
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
MHBODSYC	double	Body System Code	Collected at CRF.
MHBODSYS	character	Body System	Collected at CRF.

MHTERM	character	Reported Term for Condition	Suppressed all records to protect PII.
MHSEQ	double	MH Sequence Number	Collected at CRF.
MHSTATC	character	Condition Code	Collected at CRF.
MHSTAT	character	Condition	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Applied subject specific randomly sampled offset to protect PII
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DMHACTDT	numeric	De-identified Actual Date of Collection	Relative day of collection from randomly assigned reference date (MHACTDT- REF.DATE)

### 1.3.25. MEDICATION VIAL NUMBERS – MEDVIAL

<b>Dataset</b>	MEDVIAL
<b>Description</b>	Medication Vial Numbers
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.

VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
MVNUM	double	Medication Vial Number	Collected at CRF.
MVSEQ	double	Medication Vial Sequence Number	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

### 1.3.26. PC CONCENTRATIONS – PCCNC

<b>Dataset</b>	PCCNC
<b>Description</b>	PC Concentrations
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
PCPRVIDC	double	Result Provider Name Code	Suppressed all records to protect PII.
PCPRVID	character	Result Provider Name	Suppressed all records to protect PII.

TPT	character	Planned Time Point Name	Collected at CRF.
TPTNUM	double	Planned Time Point Number	Collected at CRF.
PCSTTM	double	Start Time of Specimen Collection	Collected at CRF.
SAMMAT	character	Sample Material	Collected at CRF.
SPPRVIDC	double	Sample Provider Name Code	Suppressed all records to protect PII.
SPPRVID	character	Sample Provider Name	Suppressed all records to protect PII.
PCSEQ	double	Sample Sequence Number	Collected at CRF.
ACQREF	character	Acquisition Reference Number	Collected at CRF.
SAMREF	character	Sample Reference Number	Collected at CRF.
PCTEST	character	Test Name	Collected at CRF.
PCORRES	character	Result in Original Units	Suppressed all records to protect PII.
PCORUNIT	character	Original Units	Suppressed all records to protect PII.
PCORRESN	double	Numeric Result in Original Units	Suppressed all records to protect PII.
PCSTRESC	character	Character Result in Standard Units	Collected at CRF.
PCSTUNIT	character	Standard Units	Collected at CRF.
PCSTRESN	double	Numeric Result in Standard Units	Collected at CRF.
PCPRMTYP	character	Parameter Type	Collected at CRF.
PCVTYPEC	double	PK/PD Sample Visit Type Code	Collected at CRF.
PCVTYPE	character	PK/PD Sample Visit Type	Collected at CRF.
PCCAT	character	Category for Test or Examination	Collected at CRF.
PCSTATC	double	Sample Collection Status Code	Collected at CRF.
PCSTAT	character	Sample Collection Status	Collected at CRF.
PCSPCOM	character	Comments on Sample	Suppressed all records to protect PII.
PCSPCOM2	character	Comments on Sample from Central Lab	Suppressed all records to protect PII.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DPCSTDT	numeric	De-identified Start Date of Specimen Collection	Relative day of start of specimen collection from randomly assigned reference date (PCSTDT- REF.DATE)

### 1.3.27. PHYSICAL EXAM – PE

<b>Dataset</b>	PE
<b>Description</b>	Physical Exam
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
PEBODSYC	double	Body System Code	Collected at CRF.
PEBODSYS	character	Body System	Collected at CRF.
PESEQ	character	Phys Sequence Number	Collected at CRF.
PESTATC	double	Exam Result Code	Collected at CRF.
PESTAT	character	Exam Result	Collected at CRF.
PEFIND	character	Description of Exam Findings	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PEVTYPEC	character	PE Visit Type Code	Collected at CRF.
PEVTYPE	character	PE Visit Type	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification

DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DPEACTDT	numeric	De-identified Actual Date of Physical Exam	Relative day of physical exam from randomly assigned reference date (PEACTDT-REF.DATE)

### 1.3.28. TOTAL PRIOR ANTHRACYCLINE – PRANTCYC

<b>Dataset</b>	PRANTCYC
<b>Description</b>	Total Prior Anthracycline
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PADOSE	character	Cumulative dose of prior anthracycline	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification



### 1.3.29. RADIOTHERAPY – PRERADIA

<b>Dataset</b>	PRERADIA
<b>Description</b>	Radiotherapy
<b>Unique identifier</b>	DUSUBJID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
PRSEQ	double	Radiotherapy Site Sequence Number	Collected at CRF.
PRTERM	character	Radiotherapy Site Term	Suppressed all records to protect PII.
PRDECOD	character	Radiotherapy Site	Collected at CRF.
PRDOSE	character	Total Dose	Collected at CRF.
PRREPRT	character	Had previous radiation for malignancy?	Collected at CRF.
PRREPRTC	double	Had previous radiation for malignancy?	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PRUNIT	character	Dose Unit	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

DPRENDT	numeric	De-identified End Date of Radiotherapy	Relative day of end of radiotherapy from randomly assigned reference date (PRENDT-REF.DATE)
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### 1.3.30. PREVIOUS CANCER SURGERY – PRESURG

<b>Dataset</b>	PRESURG
<b>Description</b>	Previous Cancer Surgery
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PSREPTC	double	Had previous surgery for malignancy?	Collected at CRF.
PSREPT	character	Had previous surgery for malignancy?	Collected at CRF.
PSTERM	character	Surgery/Procedure Term	Suppressed all records to protect PII
PSDECOD	character	Surgery/Procedure	Collected at CRF.
PSSEQ	double	Surgery/Procedure Sequence Number	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.

CYCLE	character	Cycle	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DPSACTDT	numeric	De-identified Actual Date of Surgery	Relative day of surgery from randomly assigned reference date (PSACTDT- REF.DATE)

### 1.3.31. PREVIOUS THERAPY – PRETHER

<b>Dataset</b>	PRETHER
<b>Description</b>	Previous Therapy
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PTSEQ	double	Sequence Number	Collected at CRF.

PFTERM	character	Reported Name of Previous Therapy	Suppressed all records to protect PII.
PTDECOD1	character	Previous Therapy Specified Term	Collected at CRF.
PTTHPHC	character	Therapeutic Phase Code	Collected at CRF.
PTTHPH	character	Therapeutic Phase	Collected at CRF.
PTBRESPC	character	Best Response Code	Collected at CRF.
PTBRESP	character	Best Response	Collected at CRF.
PTREPRTC	double	Did Subject receive systemic treatment?	Collected at CRF.
PTREPRT	character	Did Subject receive systemic treatment?	Collected at CRF.
PTDICTVS	character	Dictionary version	Collected at CRF.
PTMODIFY	character	Modified Reported Name	Suppressed all records to protect PII.
PTCODE	character	Previous Therapy Dictionary Code	Collected at CRF.
PTDECOD	character	Previous Therapy Generic Term	Collected at CRF.
PTCLAS	character	Medication Class	Collected at CRF.
PTCLASC	character	Medication Class Code	Collected at CRF.
PTCLAS0	character	ATC Text 0	Collected at CRF.
PTCLAS1	character	ATC Text 1	Collected at CRF.
PTCLAS2	character	ATC Text 2	Collected at CRF.
PTCLAS3	character	ATC Text 3	Collected at CRF.
PTCLAS4	character	ATC Text 4	Collected at CRF.
PTCLAS5	character	ATC Text 5	Collected at CRF.
PTCLAS6	character	ATC Text 6	Collected at CRF.
PTCLAS7	character	ATC Text 7	Collected at CRF.
PTCLAS8	character	ATC Text 8	Collected at CRF.
PTCLAS9	character	ATC Text 9	Collected at CRF.
PTCLASC0	character	ATC Code 0	Collected at CRF.
PTCLASC1	character	ATC Code 1	Collected at CRF.
PTCLASC2	character	ATC Code 2	Collected at CRF.
PTCLASC3	character	ATC Code 3	Collected at CRF.

PTCLASC4	character	ATC Code 4	Collected at CRF.
PTCLASC5	character	ATC Code 5	Collected at CRF.
PTCLASC6	character	ATC Code 6	Collected at CRF.
PTCLASC7	character	ATC Code 7	Collected at CRF.
PTCLASC8	character	ATC Code 8	Collected at CRF.
PTCLASC9	character	ATC Code 9	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DPTSTDT	numeric	De-identified Previous Therapy Start Date	Relative day of start of previous therapy from randomly assigned reference date (PTSTDT-REF.DATE)
DPTENDT	numeric	De-identified Previous Therapy End Date	Relative day of end of previous therapy from randomly assigned reference date (PTENDT-REF.DATE)

### 1.3.32. PROTOCOL DESCRIPTION – PROTDESC

<b>Dataset</b>	PROTDESC
<b>Description</b>	Protocol Description
<b>Unique identifier</b>	STUDYID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
COMPND	character	Compound Name	Collected at CRF.
COMPND	character	Compound Name	Collected at CRF.
BLINDING	character	Blinding Level	Collected at CRF.

ACTCONTR	character	Active Control	Collected at CRF.
PLACONTR	character	Placebo Control	Collected at CRF.
DESIGN	character	Trial Design	Collected at CRF.
MULTCENT	character	Multi Center	Collected at CRF.
INDICAT	character	Indication	Collected at CRF.
DEVPROID	character	Development Program Id	Suppressed all records to protect PII.
AGEGRP	character	Age Group	Collected at CRF.
SPECPOP	character	Special Population	Collected at CRF.
SUBJTYPE	character	Subject Type	Collected at CRF.
PROCSTUD	character	Preceding Study Id	Collected at CRF.
STUDPHAS	character	Phase of Study	Collected at CRF.
CRDMVR	character	CRDM Version Number	Collected at CRF.

### 1.3.33. PROTOCOL DEVIATION – PROTDEV

<b>Dataset</b>	PROTDEV
<b>Description</b>	Protocol Deviation
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	character	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.

PVTERM	character	Protocol Deviation Term	Suppressed all records to protect PII.
PVDECOD	character	Protocol Deviation Coded Term	Collected at CRF.
PVSEQ	double	Protocol Deviation Seq Number	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

### 1.3.34. SURGERY – SURGERY

<b>Dataset</b>	SURGERY
<b>Description</b>	Surgery
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
SGSEQ	double	Sequence Number	Collected at CRF.
SGPROC	character	Surgery/Procedure	Suppressed all records to protect PII.
SGINDIC	character	Indication for Surgery/Procedure	Suppressed all records to protect PII.

SGREPRTC	double	Are any Surg/Proc. Planned Code	Collected at CRF.
SGREPRT	character	Are any Surg/Proc. Planned	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DSGPLNDT	numeric	De-identified Date of Planned Surgery/Procedure	Relative day of planned surgery/procedure from randomly assigned reference date (SGPLNDT- REF.DATE)
DSGBODYSYS	character	De-identified Surgery Body System	Replaced surgery body systems with low frequency with 'other'
DSGBODYSYC	character	De-identified Surgery Body System Code	Replaced surgery body system codes with low frequency with '99'

### 1.3.35. TUMOR LESIONS – TUMMEAS

<b>Dataset</b>	TUMMEAS
<b>Description</b>	Tumor Lesions
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.



PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
TMSEQ	double	Tumor Measurement Sequence Number	Collected at CRF.
TMTERM	character	Site of Metastatic Disease Term	Suppressed all records to protect PII.
TMDECOD	character	Site of Metastatic Disease	Collected at CRF.
TMTEMSPC	character	Other Site of Metastatic Disease Specify	Suppressed all records to protect PII.
TMMETHC	double	Method Code	Collected at CRF.
TMMETH	character	Method	Collected at CRF.
TMMETSPC	character	Other Method Specify	Suppressed all records to protect PII.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DTMTSTDT	numeric	De-identified Date of Test	Relative day of test from randomly assigned reference date (TMTSTDT-REF.DATE)

### 1.3.36. TRIAL INCLUSION/EXCLUSION CRITERIA – TI

<b>Dataset</b>	TI
<b>Description</b>	Trial Inclusion/Exclusion Criteria
<b>Unique identifier</b>	IESPID

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Comments</b>
SUBJID	character	Subject Number	Actual SUBJID not present in original dataset.
IESPID	character	Sponsor-defined Identifier	Collected at CRF.
IECAT	character	Inclusion/Exclusion Category	Collected at CRF.
IETEST	character	Inclusion/Exclusion Criterion	Collected at CRF.
IETESTCD	character	Inclusion/Exclusion Criterion Short Name	Collected at CRF.
IELN	double	Line Number	Collected at CRF.

### 1.3.37. VISIT – VISIT

<b>Dataset</b>	VISIT
<b>Description</b>	Visit
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
CYCLENUM	character	Cycle Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DVISITDT	numeric	De-identified Visit Date	Relative day of visit from randomly assigned reference date (VISITDT-REF.DATE)

### 1.3.38.VITAL SIGNS – VITAL

<b>Dataset</b>	VITAL
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID

Variable	Type	Label	Comments
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SUBJID	character	Subject Number	Suppressed all records to protect PII.
STUDYID	character	Study Id	Collected at CRF.
DUSUBJID	character	Unique Subject Id	Suppressed all records to protect PII.
SITEID	character	Site	Suppressed all records to protect PII.
PHASENUM	double	Phase Number	Collected at CRF.
PHASE	character	Phase	Collected at CRF.
VISITNUM	double	Visit Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
VSSEQ	double	Vital Signs Sequence Number	Collected at CRF.
CYCLENUM	character	Study Cycle Number	Collected at CRF.
CYCLE	character	Study Cycle	Collected at CRF.
DAYNUM	character	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
VSPPOS	character	Position	Collected at CRF.
VSWTUNIT	character	Weight Unit	Suppressed all records to protect PII.
VSHTUNIT	character	Height Unit	Suppressed all records to protect PII.
TEMP	character	Temperature	Collected at CRF.
TEMPUNIT	character	Temperature Unit	Collected at CRF.
PULSE	character	Pulse Rate (bpm)	Collected at CRF.
SYSBP	character	Systolic Blood Pressure (mm/Hg)	Collected at CRF.
DIABP	character	Diastolic Blood Pressure (mm/Hg)	Collected at CRF.
RESP	character	Respiration Rate (/min)	Collected at CRF.
VSVTYPEC	character	Vital Signs Visit Type Code	Collected at CRF.
VSVTYPE	character	Vital Signs Visit Type	Collected at CRF.
DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DVSACTDT	numeric	De-identified Actual Date of Vital Signs	Relative day of vital signs from randomly assigned reference date (VSACTDT-REF.DATE)
DVSHEIGHTGP	character	De-identified Height Group	Generalized height (first visit only)
DVSHEIGHT	character	De-identified Height	Randomly sampled within height group.

DVSWEIGHTGP	character	De-identified Weight Group	Generalized weight (first visit only)
DVSWEIGHT	character	De-identified Weight	Randomly sampled within weight group.
DBSAGP	character	De-identified Body Surface Area (m2) Group	Generalized body surface area (first visit only)
DBSA	character	De-identified Body Surface Area (m2)	Randomly sampled within body surface are group.