

Clinical Development

Trabectedin

ET743-STS-201

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	02 July 2019

Property of Janssen

Confidential

May not be used, divulged, published or otherwise disclosed
without the consent of Janssen

Table of contents

Clinical Development.....	1
1. Datasets.....	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Domains	7
1.3.1. DEMOGRAPHICS - DEMOG	7
1.3.2. ADJUDICATION – ADJICTN.....	9
1.3.2 ADVERSE EVENT – AE.....	10
1.3.3 BIOANALYSIS RESULTS - BANRES	12
1.3.4 RESULTS OF LAB TESTS - CHEM	13
1.3.5 CONCOMITANT MEDICATIONS – CONMED	16
1.3.6.CROSSOVER - CROSSOVR.....	19
1.3.7.DEATH – DEATH.....	20
1.3.8.DIAGNOSIS – DIAGNOS	21
1.3.9. DISPOSITION ADVERSE AVENTS – DISPAE.....	24
1.3.10. DISPOSITION - DISPOSIT	25
1.3.11 DNA TAKEN – DNA.....	27
1.3.12. COVANCE DNA SAMPLE – DNACENT.....	28
1.3.13. ELECTROCARDIOGRAM – ECG	29
1.3.14. ECOG PERFORMANCE STATUS – ECOG.....	31
1.3.15. EXPOSURE DETAILS RELATED AE – EDAE	33

1.3.16. ENROLLMENT – ENROLL.....	34
1.3.17. EVALUATION OF RESPONSE – EVALRES.....	35
1.3.18. EXPOSURE AE – EXAE.....	37
1.3.19. EXPOSURE – EXPOSURE.....	38
1.3.20. SUBSEQUENT TREATMENT – FUTRT.....	40
1.3.21. LABORATORY TEST RESULTS – HEMAT.....	41
1.3.22. HISTOLOGY REVIEW – HISTREV.....	43
1.3.23. LABORATORY NORMAL RANGES – LABNORM.....	45
1.3.24. RESULTS OF AE RELATED TESTS – LABSAE.....	46
1.3.25. MEDICAL HISTORY – MEDHIST.....	48
1.3.26. MEDICATION KIT – MEDKIT.....	49
1.3.27. NON-TARGET LESION – NTLESIONS.....	50
1.3.28. NEW LESION – NWLESION.....	52
1.3.29. ONCOLOGY ASSESSMENT – ONCOASMT.....	53
1.3.30. OVERALL TUMOR ASSESSMENT – OVTASMNT.....	55
1.3.31. PHYSICAL EXAM - PE.....	57
1.3.32. RADIOTHERAPY – PRERADIA.....	58
1.3.33. PREVIOUS CANCER SURGERY – PRESURG.....	60
1.3.34. PREVIOUS THERAPY – PRETHER.....	61
1.3.35. PROTOCOL DESCRIPTION – PROTDESC.....	64
1.3.36. PROTOCOL DEVIATION – PROTDEV.....	65
1.3.37. SURVIVAL STATUS SURVEY – PTSUSTAT.....	66
1.3.38. COVANCE SAMPLE – SAMPCENT.....	67
1.3.39. SAMPLES – SAMPLE.....	68

1.3.40. SURGERY – SURGERY	70
1.3.41. SURVIVAL STATISTICS – SURVSTAT	71
1.3.42. TARGET LESIONS – TLESION	73
1.3.43. TREATMENT CYCLE DELAY AE REFERENCE – TRTCYCAE.....	75
1.3.44. TREATMENT CYCLE – TRTCYCLE.....	76
1.3.45. TREATMENT REGIMEN SWITCH – TTGSWTCH	77
1.3.46. TUMOR LESIONS – TUMMEAS.....	78
1.3.47. VITAL SIGNS – VITAL	80

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 De-identified 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, INVEST, IVRS, RANDOM

1.3. Data Domains

1.3.1. DEMOGRAPHICS - DEMOG

Dataset	DEMOG
Description	DEMOGRAPHICS
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SUBJINIT	character	Subject Initials	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
SITEID	character	Site	Suppressed all records to protect PII.
IVID	double	Investigator ID	Suppressed all records to protect PII.

IVNAME	character	Investigator Name	Suppressed all records to protect PII.
SEXC	double	Sex Code	Collected at CRF.
SEX	character	Sex	Collected at CRF.
RACESPEC	character	Race Other	Suppressed all records to protect PII.
DMARMC	double	Treatment Arm Code	Collected at CRF.
DMARM	character	Treatment Arm	Collected at CRF.
CIVNAME	character	Co-Investigator Name	Suppressed all records to protect PII
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DRACE	character	Race	Suppressed low frequency race groups to protect PII.
DRACEC	character	Race Code	Suppressed low frequency race groups to protect PII.
DAGEGROUP	double	De-identified Age Group	Grouped by age to protect PII
DAGE	double	De-identified Age	Randomly sampled within age group to protect PII.
DDMCONSDT	double	De-identified Actual Date of Informed Consent	Relative day of signature on informed consent from randomly assigned reference date (DMCONSDT-REF.DATE)
DDMACTDT	double	De-identified Actual Date of Demography	Relative day of demography from randomly assigned reference date (DMACTDT-REF.DATE)

1.3.2. ADJUDICATION – ADJDICTN

Dataset	ADJDICTN
Description	ADJUDICATION
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
SITEID2	character	Site ID (As Provided by Perceptive)	Suppressed all records to protect PII.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
VISIT	character	Visit	Collected at CRF.
BIRTHDT	double	Date of Birth	Suppressed all records to protect PII.
READTYP	character	Read Type	Collected at CRF.
ADJID	double	Adjudicator	Collected at CRF.
REVID	double	Reviewer Agreed With	Collected at CRF.
REVASMT	character	Reviewer Assessment	Collected at CRF.
SELSNC1	character	Reason for Selection Comments 1	Suppressed all records to protect PII.
SELSNC2	character	Reason for Selection Comments 2	Suppressed all records to protect PII.
SELSNC3	character	Reason for Selection Comments 3	Suppressed all records to protect PII.
SELSNC4	character	Reason for Selection Comments 4	Suppressed all records to protect PII.
SELSNC5	character	Reason for Selection Comments 5	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification

DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DREVDT	double	De-identified Date of Review	Relative day of review from randomly assigned reference date (REVDT-REF.DATE)

1.3.2 ADVERSE EVENT – AE

Dataset	AE
Description	ADVERSE EVENT
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
AEREPRTC	double	Were any AEs Reported Code	Collected at CRF.
AEREPRT	character	Were any AEs Reported	Collected at CRF.
AESEQ	double	AE Sequence Number	Collected at CRF.

PAGNUM	double	Page Number	Collected at CRF.
AETERM	character	Reported Term	Suppressed all records to protect PII.
AEACTTRC	double	Action Taken with Treatment Code	Collected at CRF.
AEACTTRT	character	Action Taken with Treatment	Collected at CRF.
AEOUTC	double	Outcome of Event Code	Collected at CRF.
AEOUT	character	Outcome of Event	Collected at CRF.
AERELC	double	Relationship to Treatment Code	Collected at CRF.
AEREL	character	Relationship to Treatment	Collected at CRF.
AESERC	double	Seriousness Criteria Code	Collected at CRF.
AESER	character	Seriousness Criteria	Collected at CRF.
AESERREF	character	Serious AE Reference Number	Suppressed all records to protect PII.
AESEVC	double	Severity of Event Code	Collected at CRF.
AESEV	character	Severity of Event	Collected at CRF.
AECONTRC	double	Concomitant/Additional Treatment Code	Collected at CRF.
AECONTRT	character	Concomitant/Additional Treatment	Collected at CRF.
AETOXC	double	AE Toxicity Grade Code	Collected at CRF.
AETOX	character	AE Toxicity Grade	Collected at CRF.
AEDICTDM	character	Adverse Events Dictionary	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DAESTDT	double	De-identified Actual Start Date of Event	Relative start day of event from randomly assigned reference date (AESTDT-REF.DATE). Masked outlying durations.
DAEENDT	double	De-identified Actual End Date of Event	Relative end day of event from randomly assigned reference date (AEENDT-REF.DATE). Masked outlying durations.
DAEDECOD	character	De-identified Dictionary-Derived Term	Suppressed sensitive terms to protect PII.

DAEDECOD1	character	De-identified Dictionary-Derived Lower Level Term	Suppressed sensitive terms to protect PII.
DAECODE	character	De-identified AE Dictionary Code	Suppressed sensitive terms to protect PII.
DAEDECODW	character	De-identified WHO Preferred Term	Suppressed sensitive terms to protect PII.
DAEDECOD1W	character	De-identified WHO Included Term	Suppressed sensitive terms to protect PII.
DAECODEW	character	De-identified WHO AE Dictionary Code	Suppressed sensitive terms to protect PII.
DAEBODSYC	character	De-identified Body System or Organ Class Code	Suppressed sensitive terms to protect PII.
DAEBODSYS	character	De-identified Body System or Organ Class Code	Suppressed sensitive terms to protect PII.
DAEBODSCW	character	De-identified WHO Body System Code	Suppressed sensitive terms to protect PII.
DAEBODSYW	character	De-identified WHO Body System	Suppressed sensitive terms to protect PII.
DSOC1W	character	De-identified AE System Organ Class 1	Suppressed sensitive terms to protect PII.
DSOC2W	character	De-identified AE System Organ Class 2	Suppressed sensitive terms to protect PII.
DSOC3W	character	De-identified AE System Organ Class 3	Suppressed sensitive terms to protect PII.

1.3.3 BIOANALYSIS RESULTS - BANRES

Dataset	BANRES
Description	Bioanalysis Results
Unique identifier	DSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site	Suppressed all records to protect PII.
SPECIMEN	character	Specimen	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
SAMTYPE	character	Purpose of Sample	Collected at CRF.
SAMPLE_D	Date	Sampling Date	Original is <NA> for all values.
SAMPLE_T	double	Sampling Time	Collected at CRF.
SAMTM_S	character	Scheduled Sampling Time	Collected at CRF.
SUBST	character	Substance	Collected at CRF.
SAMREFNO	character	Sample Ref. No.	Suppressed all records to protect PII.
BRVAL	double	BAN Measurement	Collected at CRF.
BRVAL_V	character	BAN Measurement (Verb.)	Collected at CRF.
BRVAL_U	character	Unit	Collected at CRF.
BRQUANT	double	Limit of Quantification	Collected at CRF.
LABINTNO	character	Laboratory Internal No.	Suppressed all records to protect PII.
BRINTNO	character	Bioanalysis Internal No.	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Retained blanked to match original

1.3.4 RESULTS OF LAB TESTS - CHEM

Dataset	CHEM
Description	Results of Lab Tests
Unique identifier	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	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day In Cycle	Collected at CRF.
LBABBR	character	Lab Test Abbreviation	Collected at CRF.
LBDESCR	character	Full Test Description	Collected at CRF.
LBPRVID	character	Laboratory ID	Suppressed all records to protect PII.
LBPRVIDC	double	Laboratory ID Code	Suppressed all records to protect PII.
LBREF	character	Lab Reference #	Collected at CRF.
LBSEQ	double	Lab Sample Sequence Number	Collected at CRF.
LBSIFACT	double	Std. Intl. Conversion Factor	Collected at CRF.
LBTEST	character	Lab Test Name	Collected at CRF.
LBTESTC	double	Lab Test Code	Collected at CRF.
LBTYPE	character	Lab Type	Collected at CRF.
NRIND	character	Normal Range Indicator	Collected at CRF.
ORGNRHI	double	Normal Range Upper Limit in Orig. Units	Suppressed all records to protect PII.
ORGNRLO	double	Normal Range Lower Limit in Orig. Units	Suppressed all records to protect PII.
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.
ORGUNIT	character	Original Unit	Suppressed all records to protect PII.

PAGNUM	double	Page Number	Collected at CRF.
STDNRC	character	Normal Range in Char Result in Std Units	Collected at CRF.
STDNRHI	double	Normal Range Upper Limit in Std Units	Collected at CRF.
STDNRLO	double	Normal Range Lower Limit in Std Units	Collected at CRF.
STDRESC	character	Analysis Character Result in Std. Unit	Collected at CRF.
STDRESN	double	Analysis Num Result in Std. Unit	Collected at CRF.
STDUNIT	character	Standard Unit	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
LBDESC	character	Lab Test Description From CRF	Collected at CRF.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DLBACTDT	double	De-identified Actual Date of Sample	Relative day of sample from randomly assigned reference date (DLBACTDT-REF.DATE). Suppress values for outliers.

1.3.5 CONCOMITANT MEDICATIONS – CONMED

Dataset	CONMED
Description	Concomitant Medications
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
CMREPRTC	double	Were Any Meds Reported Administered Code	Collected at CRF.
CMREPRT	character	Were Any Meds Reported Administered	Collected at CRF.
CMSEQ	double	Conmed Sequence Number	Collected at CRF.
CMTYPEC	double	Prior/Concomitant Medication Code	Collected at CRF.
CMTYPE	character	Prior/Concomitant Medication	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
CMDECOD	character	Medication Generic Term	Suppressed all records to protect PII.
CMDECOD1	character	Medication Specified Term	Suppressed all records to protect PII.

CMTERM	character	Reported Name of Drug/Medication/Therapy	Suppressed all records to protect PII.
CMREAS	character	Reason for Medication	Suppressed all records to protect PII.
CMROUTE	character	Route	Collected at CRF.
CMCONTC	double	Medication Continuing Code	Collected at CRF.
CMCONT	character	Medication Continuing	Collected at CRF.
CMPRIORC	double	Med Started Prior to Trial Code?	Collected at CRF.
CMPRIOR	character	Med Started Prior to Trial ?	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
CMCLAS0	character	ATC Text 0	Suppressed all records to protect PII.
CMCLAS	character	ATC Text	Suppressed all records to protect PII.
CMCLASC	character	ATC Code	Suppressed all records to protect PII.
CMCLASC0	character	ATC Code 0	Suppressed all records to protect PII.
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.
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.
CMCODE	character	Medication Dictionary Code	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DCMSTDT	character	De-identified Actual Start Date of Medication	Relative day of start of medication from randomly assigned reference date (CMSTDT-REF.DATE)
DCMENDT	character	De-identified Actual End Date of Medication	Relative day of end of medication from randomly assigned reference date (CMSTDT-REF.DATE)
DCMREGIM	character	De-identified Regimen (Dose and Frequency)	Suppressed some records to protect PII.

1.3.6.CROSSOVER - CROSSOVR

Dataset	CROSSOVR
Description	Crossover
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
CONARMC	double	New Arm Post-Crossover Code	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	DayNumber	Collected at CRF.
DAY	character	Day	Collected at CRF.
CONARM	character	New Arm Post-Crossover	Collected at CRF.
COCYNARM	double	Cycle of crossover to new Arm	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification.

DCOACTDT	double	De-identified Date of treatment crossover	Relative day of treatment crossover from randomly assigned reference date (DCOACTDT-REF.DATE)
----------	--------	---	---

1.3.7.DEATH – DEATH

Dataset	DEATH
Description	Death
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DTCAUSEC	double	Cause of Death	Collected at CRF.
DTCAUSE	character	Cause of Death	Collected at CRF.
DTOTH	character	Other Reason, Specify	Suppressed all records to protect PII.
AESERREF	character	Serious AE Reference Number	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.

DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification.
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification.
DDTACTDT	double	De-identified Date of Death	Relative end day of death from randomly assigned reference date (DTACTDT-REF.DATE). Capped at 90 the percentile.

1.3.8.DIAGNOSIS – DIAGNOS

Dataset	DIAGNOS
Description	Diagnosis
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DIAGNOSC	double	Diagnosis Code	Collected at CRF.
DIAGNOS	character	Diagnosis	Collected at CRF.
DGHSTC	double	Histology Code	Collected at CRF.

DGHST	character	Histology	Collected at CRF.
DGHSTOTH	character	Histology Other	Suppressed all records to protect PII.
DGDPSPEC	character	Reason Subject Considered to Have PD	Suppressed all records to protect PII.
DGPTSPEC	character	Primary Tumor Site Specify	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
DGFMREAS	character	Reason of unobtainable 1st metastatic	Suppressed all records to protect PII.
DGGRADE	character	Grade	Collected at CRF.
DGCMTERM	character	Comments	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DDGACTDT	double	De-identified Actual Date of Diagnosis	Relative actual day of diagnosis from randomly assigned reference date (DGACTION-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DDGDPADT	double	De-identified Date of Dis. Prog. After Anthracycline	Relative day of disease progression after Anthracycline from randomly assigned reference date (DGDPACTION-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DDGDPIDT	double	De-identified Date of Dis. Prog. After Ifosfamide	Relative day of disease progression after Ifosfamide from randomly assigned reference date (DDGDPIDT-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DDGDPSDT	double	De-identified Date of Dis. Prog. After Rec. Sys. Ther.	Relative day of disease progression after Rec. Sys. Ther. from randomly assigned reference date (DDGDPSDT-REF.DATE). Values outside the 10 th and

			90 th percentiles were substituted with the respective percentiles.
DDGFMSDT	double	De-identified Date of first metastatic event	Relative day of first metastatic event from randomly assigned reference date (DGFMSDT-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DDGPTS	character	De-identified Primary Tumor Site at Initial Diagnosis	Suppressed certain specific records to protect PII
DDGPTSC	double	De-identified Primary Tumor Site at Initial Diagnosis Code	Suppressed certain specific records to protect PII
DDGHST	character	De-identified Histology	Suppressed small cell counts.
DDGHSTC	double	De-identified Histology Code	Suppressed small cell counts.
DDGPTS	character	De-identified Primary Tumor Site At Initial Diagnosis	Substituted small cell counts with 'other'
DDGPTSC	double	De-identified Primary Tumor Site At Initial Diagnosis	Substituted small cell counts with the code corresponding to other.

1.3.9. DISPOSITION ADVERSE AVENTS – DISP AE

Dataset	DISP AE
Description	Disposition Adverse Avents
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
AESEQ	double	Adverse Event Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DATYPEC	double	Disposition Type Code	Collected at CRF.
DATYPE	character	Disposition Type	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.10. DISPOSITION - DISPOSIT

Dataset	DISPOSIT
Description	Disposition
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
DSTYPEC	double	End of Treatment or Trial Code	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
DSTYPE	character	End of Treatment or Trial	Collected at CRF.
DSREASC	double	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.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSRABKDT	double	Actual Date Randomization Code Broken	Original values all blank.
PREGDUDT	double	Pregnancy Due Date	Original values all blank.
DEATHDT	double	Actual Date of Death	Original values all blank.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DDSACTDT	double	De-identified Actual Date Trial Completion/Withdrawal	Relative day of actual date trial completion/withdrawal from randomly assigned reference date (DDSACTDT-REF.DATE).
DDSPROGDT	double	De-identified Date of Progressive Disease	Relative day of progressive disease from randomly assigned reference date (DDSPROGDT-REF.DATE).

1.3.11 DNA TAKEN – DNA

Dataset	DNA
Description	DNA taken
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
DNICNOC	double	Informed Consent (IC) Not Obtained Code	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
DNICNO	character	Informed Consent (IC) Not Obtained	Collected at CRF.
DNICAC	double	IC Obtained for Current Analysis Code	Collected at CRF.
DNICCA	character	IC Obtained for Current Analysis	Collected at CRF.
DNICFAC	double	IC Obtained for Future Analysis Code	Collected at CRF.
DNICFA	character	IC Obtained for Future Analysis	Collected at CRF.

DNYNC	double	DNA Taken Yes/No Code	Collected at CRF.
DNYN	character	DNA Taken Yes/No	Collected at CRF.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.12. COVANCE DNA SAMPLE – DNACENT

Dataset	DNACENT
Description	Covance DNA Sample
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SUBJINIT	character	Subject Initials	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day In Cycle	Collected at CRF.
SADAY	character	Sampling Day	Collected at CRF.
SAMPLE_T	double	Sampling Time	Collected at CRF.

BIRTHDT	double	Date of Birth	Suppressed all records to protect PII.
SEXC	double	Sex Code	Collected at CRF.
SEX	character	Sex	Collected at CRF.
RACEC	double	Race Code	Original values NA
RACE	character	Race	Original values blank.
ACCNO	character	Accession Number	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification.
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification.
DSAMPLE_D	double	De-identified Sampling Date	Relative day of sample from randomly assigned reference date (SAMPLE_D-REF.DATE).

1.3.13. ELECTROCARDIOGRAM – ECG

Dataset	ECG
Description	Electrocardiogram
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
EGTESTCD	character	ECG Test Short Name	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
EGREF	character	ECG Reference Number	Collected at CRF.
EGABNC	double	Clinical Significant Abnormalities Y/N	Collected at CRF.
EGABN	character	Clinical Significant Abnormalities Y/N	Collected at CRF.
EGPTMNUM	double	Label of Planned Elapsed Time	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
EGPTM	character	Planned Elapsed Time of ECG	Collected at CRF.
EGACTTM	double	Actual Time of ECG	Collected at CRF.
EGPOS	character	Position	Collected at CRF.
EGQUAL	character	Qualifier	Collected at CRF.
EGTEST	character	ECG Test	Collected at CRF.
EGSTRESN	double	Result Numeric in Standard Units	Collected at CRF.
EGSTUNIT	character	Standard Unit	Collected at CRF.
EGSTRESC	character	Result Character	Collected at CRF.
EGPRVIDC	double	ECG Provider ID Code	Collected at CRF.
EGPRVID	character	ECG Provider ID	Collected at CRF.
EGORRESN	double	Result Numeric in Original Units	Suppressed all records to protect PII.
EGORUNIT	character	Original Units	Suppressed all records to protect PII.
EGINTPC	double	Interpretation Code	Collected at CRF.
EGINTP	character	Interpretation	Collected at CRF.
EGLEAD	character	Lead Used for Measurement	Collected at CRF.
EGND	character	ECG Not Done	Collected at CRF.
EGSEQ	double	ECG Sequence Number	Collected at CRF.
EGREAD	character	ECG Reader	Collected at CRF.

EGVTYPEC	double	ECG Visit Type Code	Collected at CRF.
EGVTYPE	character	ECG Visit Type	Collected at CRF.
EGCHGC	double	Sig. Change from Prev. ECG Code	Collected at CRF.
EGCHG	character	Sig. Change from Prev. ECG	Collected at CRF.
BATCHID	double	Central ECG batch identifier	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DEGDT	double	De-identified Actual Date of ECG	Relative day of ECG from randomly assigned reference date (EGDT-REF.DATE).

1.3.14. ECOG PERFORMANCE STATUS – ECOG

Dataset	ECOG
Description	ECOG Performance Status
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
ECECOGC	double	ECOG Performance Status	Collected at CRF.
ECECOG	character	ECOG Performance Status	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DEACTDT	double	De-identified ECOG Actual Date	Relative day of ECOG from randomly assigned reference date (EACTDT-REF.DATE). Values outside the 90 th percentiles were substituted with the 90 th percentile.

1.3.15. EXPOSURE DETAILS RELATED AE – EDAE

Dataset	EDAE
Description	Exposure Details Related AE
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
EDSEQ	double	Exposure Details Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
AESEQ	double	AE Sequence Number	Collected at CRF.
ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
ACTTRT	character	Drug/Therapy	Collected at CRF.
EXSEQ	double	Exposure Sequence Number	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.

DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.16. ENROLLMENT – ENROLL

Dataset	ENROLL
Description	Enrollment
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
ENCRIT	character	Inclusion or Exclusion Criterion	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
ENSEQ	double	Criterion Sequence Number	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
ENTEXT	character	Criterion Text	Collected at CRF.

HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DENACTDT	double	De-identified Actual Date of Enrollment	Relative day of ECOG from randomly assigned reference date (EACTDT-REF.DATE).
ENCRESC	double	Criterion Result Code	Suppressed for criteria with small counts.
ENCRESC	character	Criterion Result	Suppressed for criteria with small counts.

1.3.17. EVALUATION OF RESPONSE – EVALRES

Dataset	EVALRES
Description	Evaluation of Response
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
ERNDC	double	Not Done Code	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.

CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
ERND	character	Not Done	Collected at CRF.
ERTARGC	double	Eval. Of Resp., Target Lesions	Collected at CRF.
ERTARG	character	Eval. Of Resp., Target Lesions	Collected at CRF.
ERTSPEC	character	Eval. Of Resp., Target Lesions, Spec.	Suppressed all records to protect PII.
ERNTARGC	double	Eval. Of Resp., Non-target Lesions	Collected at CRF.
ERNTARG	character	Eval. Of Resp., Non-target Lesions	Collected at CRF.
ERNTSPEC	character	Eval. Of Resp., Non-target Lesions, Spec.	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DERDT	double	De-identified Date of Evaluation	Relative day of evaluation from randomly assigned reference date (ERDT-REF.DATE). Capped at 90 the percentile.

1.3.18. EXPOSURE AE – EXAE

Dataset	EXAE
Description	Exposure AE
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
AESEQ	double	AE Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	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.
EXSEQ	double	Exposure Sequence Number	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.19. EXPOSURE – EXPOSURE

Dataset	EXPOSURE
Description	Exposure
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
EXSEQ	double	Exposure Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
EXREASC	double	Reason for Change Code	Collected at CRF.
EXREAS	character	Reason for Change	Collected at CRF.
ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
ACTTRT	character	Drug/Therapy	Collected at CRF.
ROUTE	character	Route of Administration	Collected at CRF.
DOSE	double	Dose per Administration	Collected at CRF.
DOSEUNIT	character	Dose Unit	Collected at CRF.

EXTMLBL	character	Label of Planned Administration Time	Collected at CRF.
EXPTM	double	Planned Time of Administration	Collected at CRF.
EXDOSPRE	double	Prescribed Dose	Collected at CRF.
EXPRUNIT	character	Prescribed Dose Unit	Collected at CRF.
EXDOSCAL	double	Calculated Dose	Collected at CRF.
EXCHGC	double	Actual-Dose Mod. Necessary Code	Collected at CRF.
EXCHG	character	Actual-Dose Mod. Necessary	Collected at CRF.
EXRSNOTH	character	Other Reason, Specify	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
EDENDTM	double	End Time	Collected at CRF.
EDSEQ	double	Interruption Sequence Number	Collected at CRF.
EDSTTM	double	Start Time	Collected at CRF.
EDRSNOTH	character	Other Reason For Interruption	Suppressed all records to protect PII.
BSA	double	Body Surface Area	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Collected at CRF.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DEXSTDT	double	De-identified Start Date of Exposure	Relative start day of exposure from randomly assigned reference date (EXSTDT-REF.DATE).
DEXENDT	double	De-identified End Date of Exposure	Relative end day of exposure from randomly assigned reference date (EXENDT-REF.DATE).
DEDENDT	double	De-identified End Date of Exposure Segment	Relative start day of exposure segment from randomly assigned reference date (EDENDT-REF.DATE).
DEDSTDT	double	De-identified Start Date of Exposure Segment	Relative end day of exposure segment from randomly assigned reference date (EDSTDT-REF.DATE).

1.3.20. SUBSEQUENT TREATMENT – FUTRT

Dataset	FUTRT
Description	Subsequent Treatment
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
FUPDC	double	Progressive Disease Code	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
FUPD	character	Progressive Disease	Collected at CRF.
FUSTC	double	Was New Anti-Cancer Therapy Started Code	Collected at CRF.
FUST	character	Was New Anti-Cancer Therapy Started	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification

DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DFUPROGDT	double	De-identified Date of Progressive Disease	Relative day of progressive disease from randomly assigned reference date (FUPROGDT-REF.DATE)
DFUSTDT	double	De-identified Date Therapy Started	Relative day of therapy start from randomly assigned reference date (FUSTDT-REF.DATE)

1.3.21. LABORATORY TEST RESULTS – HEMAT

Dataset	HEMAT
Description	Laboratory Test Results
Unique identifier	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 Number	Collected at CRF.
VISIT	character	Visit	Collected at CRF.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day In Cycle	Collected at CRF.
LBABBR	character	Lab Test Abbreviation	Collected at CRF.
LBDESCR	character	Full Test Description	Collected at CRF.

LBPRVID	character	Laboratory ID	Suppressed all records to protect PII.
LBPRVIDC	double	Laboratory ID Code	Suppressed all records to protect PII.
LBREF	character	Lab Reference #	Collected at CRF.
LBSEQ	double	Lab Sample Sequence Number	Collected at CRF.
LBSIFACT	double	Std. Intl. Conversion Factor	Collected at CRF.
LBTEST	character	Lab Test Name	Collected at CRF.
LBTESTC	double	Lab Test Code	Collected at CRF.
LBTYPE	character	Lab Type	Collected at CRF.
NRIND	character	Normal Range Indicator	Collected at CRF.
ORGNRHI	double	Normal Range Upper Limit in Orig. Units	Suppressed all records to protect PII.
ORGNRLO	double	Normal Range Lower Limit in Orig. Units	Suppressed all records to protect PII.
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.
ORGUNIT	character	Original Unit	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
STDNRC	character	Normal Range in Char Result in Std Units	Collected at CRF.
STDNRHI	double	Normal Range Upper Limit in Std Units	Collected at CRF.
STDNRLO	double	Normal Range Lower Limit in Std Units	Collected at CRF.
STDRESC	character	Analysis Character Result in Std. Unit	Collected at CRF.
STDRESN	double	Analysis Num Result in Std. Unit	Collected at CRF.
STDUNIT	character	Standard Unit	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
LBDESC	character	Lab Test Description From CRF	Collected at CRF.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DLBACTDT	double	De-identified Actual Date of Sample	Relative day of sample from randomly assigned reference date (LBACTDT-REF.DATE)

1.3.22. HISTOLOGY REVIEW – HISTREV

Dataset	HISTREV
Description	Histology Review
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
HRSUBJID	character	Subject ID	Suppressed all records to protect PII. See DSUBJID
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
HRSUBINI	character	Subject Initials	Suppressed all records to protect PII.
HRHSTDGC	double	Histology Diagnosis Code	Collected at CRF.
HRHSTDG	character	Histology Diagnosis	Collected at CRF.
HRDIFSTC	double	Differentiation Status Code	Collected at CRF.
HRDIFST	character	Differentiation Status	Collected at CRF.
HRHSTGRD	character	Grade	Collected at CRF.
HRHSSPEC	character	Histology Diagnosis Other Specify	Suppressed all records to protect PII.
HRCMTERM	character	Comments	Suppressed all records to protect PII.

HRPATHNM	character	Name of Pathologist	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DHRREVDT	double	De-identified Date of Histology Review	Relative day of histology review from randomly assigned reference date (HRREVDT-REF.DATE)

1.3.23. LABORATORY NORMAL RANGES – LABNORM

Dataset	LABNORM
Description	Laboratory Normal Ranges
Unique identifier	LBSEQ, LBPRVIDC

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
LBSEQ	double	Lab Sequence Number	Collected at CRF.
LBPRVIDC	double	Laboratory ID Code	Suppressed all records to protect PII.
LNSTDT	double	Lab Normal Range Start Date	Suppressed all records to protect PII.
LNENDT	double	Lab Normal Range End Date	Suppressed all records to protect PII.
LBTESTC	double	Lab Test Code	Collected at CRF.
LBTEST	character	Lab Test	Collected at CRF.
SEXC	double	Sex Code	Collected at CRF.
SEX	character	Sex	Collected at CRF.
LNHIAGE	double	High Age	Collected at CRF.
LNLOAGE	double	Low Age	Collected at CRF.
LNAGUNIT	character	Age Unit	Collected at CRF.
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.
ORGUNIT	character	Original Units	Suppressed all records to protect PII.

1.3.24. RESULTS OF AE RELATED TESTS – LABSAE

Dataset	LABSAE
Description	Results of AE Related Tests
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
LBSEQ	double	Sample Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
LBPRVIDC	double	Laboratory ID Code	Suppressed all records to protect PII.
LBPRVID	character	Laboratory ID	Suppressed all records to protect PII.
LBTTERM	character	Description for Other Lab Tests	Collected at CRF.
ORGRESN	double	Numeric Result in Original Units	Suppressed all records to protect PII.
ORGRES	character	Character Result in 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.
ORGUNIT	character	Original Unit	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
LBREF	character	Lab Reference #	Collected at CRF.
LBSIFACT	double	Std. Intl. Conversion Factor	Suppressed all records to protect PII.
LBTYPEC	double	Lab Type Code	Collected at CRF.
NRIND	character	Normal Range Indicator	Collected at CRF.
STDNRC	character	Normal Range in Char Result in Std Units	Collected at CRF.
STDRESC	character	Analysis Character Result in Std. Unit	Collected at CRF.
STDRESN	double	Analysis Num Result in Std. Unit	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DLBACTDT	double	De-identified Actual Date of Sample	Relative day of sample from randomly assigned reference date (LBACTDT-REF.DATE)
DLBTDECOD	character	De-identified Laboratory Test Description	Masked values corresponding to tests for sensitive data.
DLBABBR	character	De-identified Lab Test Abbreviation	Masked values corresponding to tests for sensitive data.
DLBDESCR	character	De-identified Full Test Description	Masked values corresponding to tests for sensitive data.
DLBTEST	character	De-identified Lab Test Name	Masked values corresponding to tests for sensitive data.
DLBTESTC	double	De-identified Lab Test Code	Masked values corresponding to tests for sensitive data.
DLBTYPE	character	De-identified Lab Type	Masked values corresponding to tests for sensitive data.

DSTDNRHI	double	De-identified Normal Range Upper Limit in Std Units	Masked values corresponding to tests for sensitive data.
DSTDNRLO	double	De-identified Normal Range Lower Limit in Std Units	Masked values corresponding to tests for sensitive data.
DSTDUNIT	character	De-identified Standard Unit	Masked values corresponding to tests for sensitive data.

1.3.25. MEDICAL HISTORY – MEDHIST

Dataset	MEDHIST
Description	Medical History
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
MHSEQ	double	MH Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
MHBODSYC	double	Body System Code	Collected at CRF.

PAGNUM	double	Page Number	Collected at CRF.
MHBODSYS	character	Body System	Collected at CRF.
MHTERM	character	Reported Term for Condition	Suppressed all records to protect PII.
MHSTATC	double	Condition Code	Collected at CRF.
MHSTAT	character	Condition	Collected at CRF.
MHCONDNC	double	Status Code	Collected at CRF.
MHCOND	character	Status	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DMHACTDT	double	De-identified Actual Date of Collection	Relative day of collection from randomly assigned reference date (MHACTDT-REF.DATE)

1.3.26. MEDICATION KIT – MEDKIT

Dataset	MEDKIT
Description	Medication Kit
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
MKSEQ	double	Medication Kit Sequence Number	Collected at CRF.

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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
KITNUM	double	Medication Kit Number	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.27. NON-TARGET LESION – NTLESIONS

Dataset	NTLESIONS
Description	Non-Target Lesion
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.

SITEID2	character	Site ID (As Provided by Perceptive)	Suppressed all records to protect PII.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
VISIT	character	Visit	Collected at CRF.
SCANMOD	character	Modality of Scan	Collected at CRF.
READTYP	character	Read Type	Collected at CRF.
REVID	double	Reviewer ID	Collected at CRF.
LESID	character	Lesion ID	Collected at CRF.
LESSLOC	character	Lesion Sub-Location	Suppressed all records to protect PII.
LABIOR	character	Lesion Assessment By Individ. Organ/Region	Collected at CRF.
LESLOCC1	character	Lesion Location - Comments 1	Suppressed all records to protect PII.
LESLOCC2	character	Lesion Location - Comments 2	Suppressed all records to protect PII.
LESLOCC3	character	Lesion Location - Comments 3	Suppressed all records to protect PII.
LESLOCC4	character	Lesion Location - Comments 4	Suppressed all records to protect PII.
LESLOCC5	character	Lesion Location - Comments 5	Suppressed all records to protect PII.
LABOC1	character	Lesion Assessment By Organ - Comment 1	Suppressed all records to protect PII.
LABOC2	character	Lesion Assessment By Organ - Comment 2	Suppressed all records to protect PII.
LABOC3	character	Lesion Assessment By Organ - Comment 3	Suppressed all records to protect PII.
LABOC4	character	Lesion Assessment By Organ - Comment 4	Suppressed all records to protect PII.
LABOC5	character	Lesion Assessment By Organ - Comment 5	Suppressed all records to protect PII.
LAC1	character	Lesion Assessment - Comments 1	Suppressed all records to protect PII.
LAC2	character	Lesion Assessment - Comments 2	Suppressed all records to protect PII.
LAC3	character	Lesion Assessment - Comments 3	Suppressed all records to protect PII.
LAC4	character	Lesion Assessment - Comments 4	Suppressed all records to protect PII.

LAC5	character	Lesion Assessment - Comments 5	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DSCANDT	double	De-identified Date of Scan	Relative day of scan from randomly assigned reference date (SCANDT -REF.DATE).
DREVDT	double	De-identified Date of Review	Relative day of review from randomly assigned reference date (REVDT -REF.DATE).
DLESLOC	character	De-identified Lesion Location	Substituted locations with small counts with 'other'.

1.3.28. NEW LESION – NWLESION

Dataset	NWLESION
Description	New Lesion
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
SITEID2	character	Site ID (As Provided by Perceptive)	Suppressed all records to protect PII.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
VISIT	character	Visit	Collected at CRF.
SCANMOD	character	Modality of the Scan	Collected at CRF.
READTYP	character	Read Type	Collected at CRF.

REVID	double	Reviewer ID	Collected at CRF.
LESID	character	Lesion ID	Collected at CRF.
LESSLOC	character	Lesion Sub-Location	Suppressed all records to protect PII.
LC1	character	Lesion Comments 1	Suppressed all records to protect PII.
LC2	character	Lesion Comments 2	Suppressed all records to protect PII.
LC3	character	Lesion Comments 3	Suppressed all records to protect PII.
LC4	character	Lesion Comments 4	Suppressed all records to protect PII.
LC5	character	Lesion Comments 5	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DSCANDT	double	De-identified Date of Scan	Relative day of scan from randomly assigned reference date (SCANDT -REF.DATE).
DREVDT	double	De-identified Date of Review	Relative day of review from randomly assigned reference date (REVDT -REF.DATE).
DLESLOC	character	De-identified Lesion Location	Substituted locations with small counts with 'other'.

1.3.29. ONCOLOGY ASSESSMENT – ONCOASMT

Dataset	ONCOASMT
Description	Oncology Assessment
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.

SITEID2	character	Site ID (As Provided by Perceptive)	Suppressed all records to protect PII.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
REVID	double	Reviewer ID	Collected at CRF.
ASMTSEQ	double	Assessment Sequence Number	Collected at CRF.
IDQACPT	character	Image & Clinical Data Quality	Collected at CRF.
IDQC	character	Image & Clin. Data Quality Comments	Suppressed all records to protect PII.
DIASMT	character	Clinical Data Impact Assessment	Collected at CRF.
DIASMTC	character	Clin. Data Impact Assess. Comments	Suppressed all records to protect PII.
BSTOVRES	character	Best Overall Response	Collected at CRF.
ANTSITE	character	Anatomical Site	Collected at CRF.
MTHD	character	Method	Collected at CRF.
PROGDTC	character	Date of Progression Comments	Suppressed all records to protect PII.
CONRSPDT	double	Date of Confirmed Response	Suppressed all records to protect PII.
CONRSPTY	character	Type of Confirmed Response	Collected at CRF.
OVONCOC1	character	Overall Oncology Comments 1	Suppressed all records to protect PII.
OVONCOC2	character	Overall Oncology Comments 2	Suppressed all records to protect PII.
OVONCOC3	character	Overall Oncology Comments 3	Suppressed all records to protect PII.
OVONCOC4	character	Overall Oncology Comments 4	Suppressed all records to protect PII.
OVONCOC5	character	Overall Oncology Comments 5	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DCENSORDT	double	De-identified Date of Censoring	Relative day of censoring from randomly assigned reference date (CENSORDT-REF.DATE)
DREVDT	double	De-identified Date of Review	Relative day of review from randomly assigned reference date (REVDT-REF.DATE)
DPROGDT	character	De-identified Date of Progression	Relative day of progression from randomly assigned reference date (PROGDT-REF.DATE)

DCONRSPDT	double	De-identified Date of Confirmed Response	Relative day of end of confirmed response from randomly assigned reference date (CONRSPDT-REF.DATE)
-----------	--------	--	---

1.3.30. OVERALL TUMOR ASSESSMENT – OVTASMNT

Dataset	OVTASMNT
Description	Overall Tumor Assessment
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
SITEID2	character	Site ID (As Provided by Perceptive)	Suppressed all records to protect PII.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
VISIT	character	Visit	Collected at CRF.
READTYP	character	Read Type	Collected at CRF.
REVID	double	Reviewer ID	Suppressed all records to protect PII.
OVTASMNT	character	Overall Tumor Assessment	Collected at CRF.
SUMLD	double	Sum of Longest Diameter (All T. Lesions)	Collected at CRF.
ASMTTL	character	Target Lesion Assessment	Collected at CRF.
CHGB	double	Change From Baseline	Collected at CRF.
CHGBPCT	double	Change From Baseline (Percent)	Collected at CRF.

CHGN	double	Change From Nadir	Collected at CRF.
CHGNPCT	double	Change From Nadir (Percent)	Collected at CRF.
MTLS	double	Minimum Target Lesion Size	Collected at CRF.
PREVIR	character	Previously Irradiated	Collected at CRF.
PRRES	character	Prior Resection	Collected at CRF.
ONRES	character	On-Study Resection	Collected at CRF.
ONRESTXT	character	On-Study Resection Text	Suppressed all records to protect PII.
ASMTNLT	character	Non-Target Lesion Assessment	Collected at CRF.
NLPRESNT	character	New Lesion Present	Collected at CRF.
OAC1	character	Overall Assessment - Comments 1	Suppressed all records to protect PII.
OAC2	character	Overall Assessment - Comments 2	Suppressed all records to protect PII.
OAC3	character	Overall Assessment - Comments 3	Suppressed all records to protect PII.
OAC4	character	Overall Assessment - Comments 4	Suppressed all records to protect PII.
OAC5	character	Overall Assessment - Comments 5	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DSCANDT	double	De-identified Date of Scan	Relative day of scan from randomly assigned reference date (SCANDT-REF.DATE)
DREVDT	double	De-identified Date of Review	Relative day of review from randomly assigned reference date (REVDT-REF.DATE)

1.3.31. PHYSICAL EXAM - PE

Dataset	PE
Description	Physical Exam
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
PESEQ	double	Phys Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PEBODSYC	double	Body System Code	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
PEBODSYS	character	Body System	Collected at CRF.
PESYSOTH	character	Body System Other	Suppressed all records to protect PII.
PESTATC	double	Exam Result Code	Collected at CRF.
PESTAT	character	Exam Result	Collected at CRF.
PEFIND	character	Description of Exam Findings	Suppressed all records to protect PII.
HRECID	double	RECID	Suppressed all records to protect PII.

RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DPEACTDT	double	De-identified Actual date of Phys Exam	Relative day of physical exam from randomly assigned reference date (PEACTDT-REF.DATE)
DPEBODSYS	character	De-identified Body System	Substituted cells with small counts with 'Other'
DPEBODSYSC	double	De-identified Body System Code	Substituted cells with small counts with 99

1.3.32. RADIOTHERAPY – PRERADIA

Dataset	PRERADIA
Description	Radiotherapy
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.

DAY	character	Day	Collected at CRF.
PRNONEC	double	None Code	Collected at CRF.
PRNONE	character	None	Collected at CRF.
PRSEQ	double	Radiotherapy Site Sequence Number	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
PRTERM	character	Radiotherapy Site Term	Suppressed all records to protect PII.
PRDOSE	double	Total Dose	Collected at CRF.
PRUNIT	character	Dose Unit	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DPRENDT	double	De-identified End Date of Radiotherapy	Relative day of end of radiotherapy from randomly assigned reference date (PRENDT-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DPRDECOD	character	De-identified Radiotherapy Site	Substituted small counts with 'Other'

1.3.33. PREVIOUS CANCER SURGERY – PRESURG

Dataset	PRESURG
Description	Previous Cancer Surgery
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PSNONEC	double	None	Collected at CRF.
PSNONE	character	None	Collected at CRF.
PSSEQ	double	Surgery/Procedure Sequence Number	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
PSTERM	character	Surgery/Procedure Term	Collected at CRF.
PSACTDTC	character	Actual Date of Surgery	Suppressed all records to protect PII.
PSACTDT	double	Actual Date of Surgery	Suppressed all records to protect PII.
HRECID	double	RECID	Suppressed all records to protect PII.

RECID	double	RECID	Suppressed all records to protect PII.
DSITEID	double	De-identified Site ID	Randomly assigned Site ID for de-identification
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DPSACTDT	double	Actual Date of Surgery	Relative day of surgery from randomly assigned reference date (PSACTDT-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DPSDECOD	character	De-identified Surgery/Procedure	Substituted small counts with 'Other'.

1.3.34. PREVIOUS THERAPY – PRETHER

Dataset	PRETHER
Description	Previous Therapy
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.

CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
PTSEQ	double	Sequence Number	Collected at CRF.
PTTERM	character	Reported Name of Previous Therapy	Suppressed all records to protect PII.
PTDECOD1	character	Previous Therapy Specified Term	Suppressed all records to protect PII.
PTTHPHC	double	Therapeutic Phase Code	Collected at CRF.
PTTHPH	character	Therapeutic Phase	Collected at CRF.
PTBRESPC	double	Best Response	Suppressed all records to protect PII.
PTBRESP	character	Best Response	Suppressed all records to protect PII.
PTCLASC	character	ATC Code	Suppressed all records to protect PII.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
PTCLAS	character	ATC Text	Suppressed all records to protect PII.
PTCLASC0	character	ATC Code 0	Suppressed all records to protect PII.
PTCLASC1	character	ATC Code 1	Suppressed all records to protect PII.
PTCLASC2	character	ATC Code 2	Suppressed all records to protect PII.
PTCLASC3	character	ATC Code 3	Suppressed all records to protect PII.
PTCLASC4	character	ATC Code 4	Suppressed all records to protect PII.
PTCLASC5	character	ATC Code 5	Suppressed all records to protect PII.
PTCLASC6	character	ATC Code 6	Suppressed all records to protect PII.
PTCLASC7	character	ATC Code 7	Suppressed all records to protect PII.
PTCLASC8	character	ATC Code 8	Suppressed all records to protect PII.
PTCLASC9	character	ATC Code 9	Suppressed all records to protect PII.
PTCLAS0	character	ATC Text 0	Suppressed all records to protect PII.
PTCLAS1	character	ATC Text 1	Suppressed all records to protect PII.
PTCLAS2	character	ATC Text 2	Suppressed all records to protect PII.
PTCLAS3	character	ATC Text 3	Suppressed all records to protect PII.
PTCLAS4	character	ATC Text 4	Suppressed all records to protect PII.

PTCLAS5	character	ATC Text 5	Suppressed all records to protect PII.
PTCLAS6	character	ATC Text 6	Suppressed all records to protect PII.
PTCLAS7	character	ATC Text 7	Suppressed all records to protect PII.
PTCLAS8	character	ATC Text 8	Suppressed all records to protect PII.
PTCLAS9	character	ATC Text 9	Suppressed all records to protect PII.
PTCODE	character	Previous Therapy Dictionary Code	Suppressed all records to protect PII.
PTDECOD	character	Previous Therapy Generic Term	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DPTSTDT	double	De-identified Previous Therapy Start Date	Relative day of start of previous therapy from randomly assigned reference date (PTSTDT-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.
DPTENDT	double	De-identified Previous Therapy End Date	Relative day of end of previous therapy from randomly assigned reference date (PTENDT-REF.DATE). Values outside the 10 th and 90 th percentiles were substituted with the respective percentiles.

1.3.35. PROTOCOL DESCRIPTION – PROTDESC

Dataset	PROTDESC
Description	Protocol Description
Unique identifier	STUDYID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
COMPND	character	Compound Number	Collected at CRF.
COMPND	character	Compound Number	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	Proceeding Study Id	Collected at CRF.
STUDPHAS	character	Phase of Study	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.

1.3.36. PROTOCOL DEVIATION – PROTDEV

Dataset	PROTDEV
Description	Protocol Deviation
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
PVSEQ	double	Protocol Deviation Seq Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PVTERM	character	Protocol Deviation Term	Suppressed all records to protect PII.
PVDECOD	character	Protocol Deviation Coded Term	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	Character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	Character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.37. SURVIVAL STATUS SURVEY – PTSUSTAT

Dataset	PTSUSTAT
Description	Survival Status Survey
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	Character	Study ID	Collected at CRF.
SITEID	Character	Site ID	Suppressed all records to protect PII.
SUBJINIT	Character	Subject Initials	Suppressed all records to protect PII.
SSSUSTAC	Double	Survival Status Code	Collected at CRF.
SSSUSTA	Character	Survival Status	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DSSALVDT	double	De-identified Date Last Known To Be Alive	Relative day of last known to be alive from randomly assigned reference date (SSALVDT-REF.DATE). Values outside the 90 th percentile were substituted with the 90 th percentile.
DSSDTHDT	double	De-identified Date of Death	Relative day of death from randomly assigned reference date (SSDTHDT-REF.DATE). Values outside the 90 th percentile were substituted with the 90 th percentile.

1.3.38. COVANCE SAMPLE – SAMPCENT

Dataset	SAMPCENT
Description	Covance Sample
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study Id	Collected at CRF.
SUBJINIT	character	Subject Initials	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day In Cycle	Collected at CRF.
SADAY	character	Sampling Day	Collected at CRF.
SAMTM_S	character	Scheduled Sampling Time	Collected at CRF.
SAMPLE_T	double	Sampling Time	Collected at CRF.
SEXC	double	Sex Code	Collected at CRF.
SEX	character	Sex	Collected at CRF.
RACEC	double	Race Code	Original data is blank.
RACE	character	Race	Original data is blank.
ACCNO	character	Accession Number	Suppressed all records to protect PII.

DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DSAMPLE_D	double	De-identified Sampling Date	Relative day of sampling from randomly assigned reference date (SAMPLE_D-REF.DATE)

1.3.39. SAMPLES – SAMPLE

Dataset	SAMPLE
Description	Samples
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
SPECIMEN	character	Specimen	Collected at CRF.

SASTRGYC	double	Sampling Strategy Code	Collected at CRF.
SASTRGY	character	Sampling Strategy	Collected at CRF.
SAMTYPE	character	Purpose of Sample	Collected at CRF.
SANOPK	character	No PK Sampling Being Done In This Cycle	Collected at CRF.
SADAY	double	Sampling Day	Collected at CRF.
SAMTM_S	character	Scheduled Sampling Time	Collected at CRF.
SAMPLE_D	double	Sampling Date	Collected at CRF.
SAMPLE_T	double	Sampling Time	Collected at CRF.
LABIDC	double	Lab Id.	Suppressed all records to protect PII.
LABID	character	Lab Id.	Suppressed all records to protect PII.
HAEMOLYS	character	Sample Haemolysed	Collected at CRF.
FASTED	character	Subject Fasted	Collected at CRF.
SAMREFNO	character	Sample Ref. No.	Collected at CRF.
SASAME	character	Same Normal Ranges	Collected at CRF.
SARELCHA	character	Clin. Significant Changes	Collected at CRF.
LABINTNO	character	Laboratory Internal No.	Collected at CRF.
SATAKENC	double	Sample Taken Code	Collected at CRF.
SATAKEN	character	Sample Taken	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.40.SURGERY – SURGERY

Dataset	SURGERY
Description	Surgery
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
SGSEQ	double	Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
SGNONEC	double	None Code	Collected at CRF.
SGNONE	character	None	Collected at CRF.
SGBODSYC	double	Surgery Body System Code	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
SGBODSYS	character	Surgery Body System	Suppressed all records to protect PII.
SGPROC	character	Surgery/Procedure	Suppressed all records to protect PII.
SGINDIC	character	Indication for Surgery/Procedure	Suppressed all records to protect PII.

SGPLNDT	date	Date of Planned Surgery/Procedure	Suppressed all records to protect PII. Majority were already NA.
SGPLNDTC	character	Date of Planned Surgery/Procedure	Suppressed all records to protect PII. Majority were already NA.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.41. SURVIVAL STATISTICS – SURVSTAT

Dataset	SURVSTAT
Description	Survival Statistics
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.

CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
SUSTATC	double	Survival Status Code	Collected at CRF.
SUSTAT	character	Survival Status	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DSUFUDT	double	De-identified Survival Follow Up Date	Relative day of survival follow-up from randomly assigned reference date (SUFUDT-REF.DATE). Values outside the 90 th percentile were substituted with the 90 th percentile from the PTSUSTAT dataset.
DSUALIVDT	double	De-identified Date Subject Last Known to be Alive	Relative day of subject last known to be alive from randomly assigned reference date (SUALIVDT-REF.DATE). Values outside the 90 th percentile were substituted with the 90 th percentile from the PTSUSTAT dataset

1.3.42. TARGET LESIONS – TLESION

Dataset	TLESION
Description	Target Lesions
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
SITEID2	character	Site ID (As Provided by Perceptive)	Suppressed all records to protect PII.
COUNTRYC	character	Country Code	Suppressed all records to protect PII.
COUNTRY	character	Country	Suppressed all records to protect PII.
VISIT	character	Visit	Collected at CRF.
SCANMOD	character	Modality of the Scan	Collected at CRF.
READTYP	character	Read Type	Collected at CRF.
REVID	double	Reviewer ID	Suppressed all records to protect PII.
IQACCPT	character	Image Quality Acceptable?	Collected at CRF.
IQC1	character	Image Quality Comments 1	Suppressed all records to protect PII.
IQC2	character	Image Quality Comments 2	Suppressed all records to protect PII.
IQC3	character	Image Quality Comments 3	Suppressed all records to protect PII.
IQC4	character	Image Quality Comments 4	Suppressed all records to protect PII.
IQC5	character	Image Quality Comments 5	Suppressed all records to protect PII.
INTERVAL	double	Distance Between Slice Locations of Imag	Collected at CRF.
LESID	character	Lesion ID	Collected at CRF.
LESLOC	character	Lesion Location	Collected at CRF.

LESSLOC	character	Lesion Sub-Location	Suppressed all records to protect PII.
LESLOCC1	character	Lesion Location - Comments 1	Suppressed all records to protect PII.
LESLOCC2	character	Lesion Location - Comments 2	Suppressed all records to protect PII.
LESLOCC3	character	Lesion Location - Comments 3	Suppressed all records to protect PII.
LESLOCC4	character	Lesion Location - Comments 4	Suppressed all records to protect PII.
LESLOCC5	character	Lesion Location - Comments 5	Suppressed all records to protect PII.
LESSIZE	double	Lesion Size	Collected at CRF.
SIZUNKC1	character	Lesion Size Unknown - Comments 1	Suppressed all records to protect PII.
SIZUNKC2	character	Lesion Size Unknown - Comments 2	Suppressed all records to protect PII.
SIZUNKC3	character	Lesion Size Unknown - Comments 3	Suppressed all records to protect PII.
SIZUNKC4	character	Lesion Size Unknown - Comments 4	Suppressed all records to protect PII.
SIZUNKC5	character	Lesion Size Unknown - Comments 5	Suppressed all records to protect PII.
SIZUNKRS	character	Lesion Size Unknown - Reason	Collected at CRF.
LAC1	character	Lesion Assessment - Comments 1	Suppressed all records to protect PII.
LAC2	character	Lesion Assessment - Comments 2	Suppressed all records to protect PII.
LAC3	character	Lesion Assessment - Comments 3	Suppressed all records to protect PII.
LAC4	character	Lesion Assessment - Comments 4	Suppressed all records to protect PII.
LAC5	character	Lesion Assessment - Comments 5	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DLESLOC	character	De-identified Lesion Location	Substituted locations with small counts with 'other'
DSCANDT	double	De-identified Date of Scan	Relative day of scan from randomly assigned reference date (SCANDT-REF.DATE)
DREVDT	double	De-identified Date of Review	Relative day of review from randomly assigned reference date (REVDT-REF.DATE)

1.3.43. TREATMENT CYCLE DELAY AE REFERENCE – TRTCYCAE

Dataset	TRTCYCAE
Description	Treatment Cycle Delay AE Reference
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
AESEQ	double	AE Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

1.3.44. TREATMENT CYCLE – TRTCYCLE

Dataset	TRTCYCLE
Description	Treatment Cycle
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
TCDEL	double	Treatment Cycle Delay Code	Collected at CRF.
TCDEL	character	Treatment Cycle Delay	Collected at CRF.
TCSRNC	double	Treatment Cycle Delay Reason Code	Collected at CRF.
TCSRNC	character	Treatment Cycle Delay Reason	Collected at CRF.
TCSRNOTH	character	Treatment Cycle Delay Other Reason	Suppressed all records to protect PII.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification

DTCACTDT	double	De-identified Treatment Cycle Actual Date	Relative day of treatment cycle from randomly assigned reference date (TCACTDT-REF.DATE)
----------	--------	---	--

1.3.45. TREATMENT REGIMEN SWITCH – TTGSWTCH

Dataset	TTGSWTCH
Description	Treatment Regimen Switch
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
TSCYCNUM	double	Cycle of crossover to new Arm	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
TSARM	character	New Arm	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.

DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DTSACTDT	double	De-identified Date of regimen switch	Relative day of end of regimen switch from randomly assigned reference date (TSACTDT-REF.DATE)

1.3.46. TUMOR LESIONS – TUMMEAS

Dataset	TUMMEAS
Description	Tumor Lesions
Unique identifier	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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
TMSEQ	double	Tumor Measurement Sequence Number	Collected at CRF.
TMTERM	character	Anatomic Site Term	Suppressed all records to protect PII.

TMDECOD1	character	Lower-Level Anatomic Site	Suppressed all records to protect PII.
TMDECOD	character	Higher-Level Anatomic Site	Collected at CRF.
TMTARGC	double	Target (Yes/ No) Code	Collected at CRF.
TMTARG	character	Target (Yes/ No)	Collected at CRF.
TMSTATC	double	Tumor Status Code	Collected at CRF.
TMSTAT	character	Tumor Status	Collected at CRF.
TMMEAS	double	Longest Diameter (mm)	Collected at CRF.
TMMETHC	double	Method Code	Collected at CRF.
TMMETH	character	Method	Collected at CRF.
HRECID	double	RECID	Suppressed all records to protect PII.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DTMTSTD	double	De-identified Date of Test	Relative day of test from randomly assigned reference date (TMTSTD-REF.DATE)

1.3.47. VITAL SIGNS – VITAL

Dataset	VITAL
Description	Vital Signs
Unique identifier	DUSUBJID

Variable	Type	Label	Comments
STUDYID	character	Study ID	Collected at CRF.
SITEID	character	Site ID	Suppressed all records to protect PII.
VSSEQ	double	Vital Sequence Number	Collected at CRF.
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.
CYCLENUM	double	Cycle Number	Collected at CRF.
CYCLE	character	Cycle	Collected at CRF.
DAYNUM	double	Day Number	Collected at CRF.
DAY	character	Day	Collected at CRF.
PULSE	double	Pulse Rate (bpm)	Collected at CRF.
SYSBP	double	Systolic Blood Pressure (mm/Hg)	Collected at CRF.
DIABP	double	Diastolic Blood Pressure (mm/Hg)	Collected at CRF.
VSHEIGHT	double	Height	Suppressed all records to protect PII.
VSWEIGHT	double	Weight	Suppressed all records to protect PII.
VSWTUNIT	character	Weight Unit	Collected at CRF.
VSHTUNIT	character	Height Unit	Collected at CRF.
VSVTYPEC	double	Vital Signs Visit Type Code	Collected at CRF.

VSVTYPE	character	Vital Signs Visit Type	Collected at CRF.
PAGNUM	double	Page Number	Collected at CRF.
RECID	double	RECID	Suppressed all records to protect PII.
DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
DVSACTDT	double	De-identified Actual Date of Vital Sign	Relative day of vital sign from randomly assigned reference date (VSACTDT-REF.DATE)
DBSAGP	double	Body Surface Area Group	Grouped from actual bsa.
DBSA	double	De-identified Body Surface Area (m2)	Randomly sampled withing Group.
DTEMP	double	Temperature	Converted original values in Farenheit to Celsius
DTEMPUNIT	character	Temperature Unit	Changed respective values to 'C'