

Clinical Development

Trabectedin

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Anonymisation Data Derivation Specification Document

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1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Description	Short description
Unique Identifier	Unique key

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will be masked.
- Investigator Information will be masked.
- Date of birth will not be provided to protect PII as per HIPAA rules.
- Age at subject start date will be calculated and grouped in intervals to protect PII as per HIPAA rules. A deidentified age variable will be created in which a new age is randomly selected within the original interval.

- Patient identification numbers will be assigned in a random manner so they are not matching the patient identification numbers that were used in the actual trial. Site and location information will not be preserved.
- Site number will be masked to reduce re-identification risk.
- Country will be masked to reduce re-identification risk.
- Race will be masked to reduce re-identification risk.
- Free text verbatim terms will be masked.
- Free text summary terms will be masked.
- “Other” free text terms will be masked.
- Drug Record Number will be masked.
- Drug Sequence Number will be masked.
- Accession Number will be masked.
- Vial and Bottle number will be masked.
- Central Lab Sample Identifier will be masked.
- Central Lab Batch Identifier will be masked.
- Vendor Panel Comments will be masked.
- Vendor Test Specific Comments will be masked.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a relative study day will be provided which is the number of days from a randomly sampled reference date (REF.DATE) to the original date.
- Completely missing variables those are not annotated in CRF will not be included in the de-identified datasets.
- Partial date’s relative day cannot be calculated.
- The following dataset will not be provided: COMMENTS, INVEST

1.3. Data Domains

1.3.1. DEMOGRAPHICS - DEMOG

Dataset	DEMOG
Description	DEMOGRAPHICS
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
DEMOG	STUDYID	character	Study Id	Collected at CRF.
DEMOG	PHASENUM	double	Phase Number	Collected at CRF.
DEMOG	PHASE	character	Phase	Collected at CRF.
DEMOG	VISITNUM	double	Visit Number	Collected at CRF.
DEMOG	VISIT	character	Visit	Collected at CRF.
DEMOG	CYCLENUM	character	Cycle Number	Collected at CRF.
DEMOG	CYCLE	character	Cycle	Collected at CRF.
DEMOG	DAYNUM	character	Day Number	Collected at CRF.
DEMOG	DAY	character	Day	Collected at CRF.
DEMOG	PAGNUM	double	Page Number	Collected at CRF.
DEMOG	SUBJINIT	character	Subject Initials	Suppressed all records to protect PII.
DEMOG	SITEID	character	Site	Suppressed all records to protect PII.
DEMOG	IVNAME	character	Investigator Name	Suppressed all records to protect PII.
DEMOG	IVID	character	Investigator ID	Suppressed all records to protect PII.
DEMOG	SEXC	character	Sex Code	Collected at CRF.
DEMOG	SEX	character	Sex	Collected at CRF.
DEMOG	RACEC	character	Race Code	Suppressed all records to protect PII.

DEMOG	RACE	character	Race	Suppressed all records to protect PII.
DEMOG	RACESPEC	character	Race Other	Suppressed all records to protect PII.
DEMOG	COUNTRYC	character	Country Code	Suppressed all records to protect PII.
DEMOG	COUNTRY	character	Country	Suppressed all records to protect PII.
DEMOG	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DEMOG	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DEMOG	DAGEGROUP	character	Age Group	Generalized to 2 groups using median as cutpoint
DEMOG	DAGE	double	De-identified Age	Randomly sampled within age group to protect PII.
DEMOG	DDMACTDT	character	De-identified Actual Date of Demography	Relative day of actual date of demography from randomly assigned reference date (DMACTDT-REF.DATE)
DEMOG	DDMSCRDT	character	De-identified Date of First Trial Related Procedure	Relative day of first trial related procedure from randomly assigned reference date (DMSCRDT-REF.DATE)
DEMOG	DDMINFDT	character	De-identified Date of Sign. on Informed Consent	Relative day of signature on informed consent from randomly assigned reference date (DMINFDT-REF.DATE)

1.3.2. ADVERSE EVENT – AE

Dataset	AE
Description	ADVERSE EVENT
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
AE	STUDYID	character	Study Id	Collected at CRF.
AE	SITEID	character	Site	Suppressed all records to protect PII.
AE	PHASENUM	double	Phase Number	Collected at CRF.
AE	PHASE	character	Phase	Collected at CRF.
AE	VISITNUM	double	Visit Number	Collected at CRF.
AE	VISIT	character	Visit	Collected at CRF.
AE	CYCLENUM	character	Cycle Number	Collected at CRF.
AE	CYCLE	character	Cycle	Collected at CRF.
AE	DAYNUM	character	Day Number	Collected at CRF.
AE	DAY	character	Day	Collected at CRF.
AE	PAGNUM	double	Page Number	Collected at CRF.
AE	AEREPRTC	double	Were any AEs Reported Code	Collected at CRF.
AE	AEREPRT	character	Were any AEs Reported	Collected at CRF.
AE	AESQ	character	AE Sequence Number	Collected at CRF.
AE	AETERM	character	Reported Term	Suppressed all records to protect PII.
AE	AEDICTDM	character	Adverse Events Dictionary	Collected at CRF.
AE	AEACTTRC	character	Action Taken with Treat. YONDELIS Code	Collected at CRF.
AE	AEACTTRT	character	Action Taken with Treat. YONDELIS	Collected at CRF.
AE	AEOUTC	character	Outcome of Event Code	Collected at CRF.

AE	AEOUT	character	Outcome of Event	Collected at CRF.
AE	AERELC	character	Relationship to Treatment Code	Collected at CRF.
AE	AEREL	character	Relationship to Treatment	Collected at CRF.
AE	AESERC	character	Seriousness Criteria Code	Collected at CRF.
AE	AESER	character	Seriousness Criteria	Collected at CRF.
AE	AESERREF	character	Serious AE Reference Number	Suppressed all records to protect PII.
AE	AESEVC	character	Severity of Event Code	Collected at CRF.
AE	AESEV	character	Severity of Event	Collected at CRF.
AE	AECONTRC	character	Concomitant/Additional Treatment Code	Collected at CRF.
AE	AECONTRT	character	Concomitant/Additional Treatment	Collected at CRF.
AE	AETOXC	character	AE Toxicity Grade Code	Collected at CRF.
AE	AETOX	character	AE Toxicity Grade	Collected at CRF.
AE	AEDECOD1	character	Dictionary-Derived Lower Level Term	Suppressed all records to protect PII.
AE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
AE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
AE	DAEBODSY1	character	De-identified Body System or Organ Class Code	Suppressed records for which outcome of AE was death and the frequency count was low. Suppressed records containing sensitive data.
AE	DAEBODSYS	character	De-identified Body System or Organ Class	Suppressed records for which outcome of AE was death and the frequency count was low. Suppressed records containing sensitive data.
AE	DAECODE	character	De-identified AE Dictionary Code	Suppressed records for which outcome of AE was death. Suppressed records containing sensitive data.
AE	DAEDECOD	character	De-identified Dictionary-Derived Term	Suppressed records for which outcome of AE was death. Suppressed records containing sensitive data.
AE	DAESTDT	character	De-identified Actual Start Date of AE	Relative day of actual start date of AE from randomly assigned reference date (AESTDT-REF.DATE). Suppressed relative days resulting in duration of adverse event > 15 days.
AE	DAEENDT	character	De-identified Actual End Date of AE	Relative day of actual end date of AE from randomly assigned reference date (AEENDT-REF.DATE). Suppressed relative days resulting in duration of adverse event > 15 days.

1.3.3. BEST OVERALL RESPONSE - BESTRES

Dataset	BESTRES
Description	Best Overall Response
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
BESTRES	STUDYID	character	Study Id	Collected at CRF.
BESTRES	SITEID	character	Site	Suppressed all records to protect PII.
BESTRES	PHASENUM	double	Phase Number	Collected at CRF.
BESTRES	PHASE	character	Phase	Collected at CRF.
BESTRES	VISITNUM	double	Visit Number	Collected at CRF.
BESTRES	VISIT	character	Visit	Collected at CRF.
BESTRES	CYCLENUM	character	Cycle Number	Collected at CRF.
BESTRES	CYCLE	character	Cycle	Collected at CRF.
BESTRES	DAYNUM	character	Day Number	Collected at CRF.
BESTRES	DAY	character	Day	Collected at CRF.
BESTRES	PAGNUM	double	Page Number	Collected at CRF.
BESTRES	BRRESP	character	Best Response	Collected at CRF.
BESTRES	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
BESTRES	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.4. CONMED RELATED AE - CMAE

Dataset	CMAE
Description	Conmed Related AE
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
CMAE	STUDYID	character	Study Id	Collected at CRF.
CMAE	SITEID	character	Site	Suppressed all records to protect PII.
CMAE	PHASENUM	double	Phase Number	Collected at CRF.
CMAE	PHASE	character	Phase	Collected at CRF.
CMAE	VISITNUM	double	Visit Number	Collected at CRF.
CMAE	VISIT	character	Visit	Collected at CRF.
CMAE	CYCLENUM	character	Cycle Number	Collected at CRF.
CMAE	CYCLE	character	Cycle	Collected at CRF.
CMAE	DAYNUM	character	Day Number	Collected at CRF.
CMAE	DAY	character	Day	Collected at CRF.
CMAE	AESEQ	double	AE Sequence Number for conmed	Collected at CRF.
CMAE	CMSEQ	double	Conmed Sequence Number	Collected at CRF.
CMAE	PAGNUM	double	Page Number	Collected at CRF.
CMAE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
CMAE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.5. CONCOMITANT MEDICATIONS – CONMED

Dataset	CONMED
Description	Concomitant Medications
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
CONMED	STUDYID	character	Study Id	Collected at CRF.
CONMED	SITEID	character	Site	Suppressed all records to protect PII.
CONMED	PHASENUM	double	Phase Number	Collected at CRF.
CONMED	PHASE	character	Phase	Collected at CRF.
CONMED	VISITNUM	character	Visit Number	Collected at CRF.
CONMED	VISIT	character	Visit	Collected at CRF.
CONMED	CYCLENUM	character	Cycle Number	Collected at CRF.
CONMED	CYCLE	character	Cycle	Collected at CRF.
CONMED	DAYNUM	character	Day Number	Collected at CRF.
CONMED	DAY	character	Day	Collected at CRF.
CONMED	PAGNUM	character	Page Number	Collected at CRF.
CONMED	CMTYPEC	character	Prior/Concomitant Medication Code	Collected at CRF.
CONMED	CMTYPE	character	Prior/Concomitant Medication	Collected at CRF.
CONMED	CMREPTC	character	Were Any Meds Administered Code	Collected at CRF.
CONMED	CMREPT	character	Were Any Meds Administered	Collected at CRF.
CONMED	CMSEQ	character	Conmed Sequence Number	Collected at CRF.
CONMED	CMDECOD1	character	Medication Specified Term	Collected at CRF.
CONMED	CMTERM	character	Reported Name of Drug/Medication/Therapy	Suppressed all records to protect PII.
CONMED	CMREAS	character	Reason for Medication	Suppressed all records to protect PII.

CONMED	CMREGIM	character	Regimen (Dose + Frequency)	Collected at CRF.
CONMED	CMROUTE	character	Route	Collected at CRF.
CONMED	CMCONTC	character	Medication Continuing Code	Collected at CRF.
CONMED	CMCONT	character	Medication Continuing	Collected at CRF.
CONMED	CMPRIORC	character	Med Started Prior to Trial Code	Collected at CRF.
CONMED	CMPRIOR	character	Med Started Prior to Trial	Collected at CRF.
CONMED	AESEQ	character	AE Sequence Number	Collected at CRF.
CONMED	CMCAUSC	character	Given for AE Code	Collected at CRF.
CONMED	CMCAUS	character	Given for AE	Collected at CRF.
CONMED	CMCLASC	character	ATC Code	Collected at CRF.
CONMED	CMCLASC0	character	ATC Code 0	Collected at CRF.
CONMED	CMCLASC1	character	ATC Code 1	Collected at CRF.
CONMED	CMCLASC2	character	ATC Code 2	Collected at CRF.
CONMED	CMCLASC3	character	ATC Code 3	Collected at CRF.
CONMED	CMCLASC4	character	ATC Code 4	Collected at CRF.
CONMED	CMCLASC5	character	ATC Code 5	Collected at CRF.
CONMED	CMCLASC6	character	ATC Code 6	Collected at CRF.
CONMED	CMCLASC7	character	ATC Code 7	Collected at CRF.
CONMED	CMCLASC8	character	ATC Code 8	Collected at CRF.
CONMED	CMCLASC9	character	ATC Code 9	Collected at CRF.
CONMED	CMCLAS0	character	ATC Text 0	Collected at CRF.
CONMED	CMCLAS1	character	ATC Text 1	Collected at CRF.
CONMED	CMCLAS2	character	ATC Text 2	Collected at CRF.
CONMED	CMCLAS3	character	ATC Text 3	Collected at CRF.
CONMED	CMCLAS4	character	ATC Text 4	Collected at CRF.
CONMED	CMCLAS5	character	ATC Text 5	Collected at CRF.
CONMED	CMCLAS6	character	ATC Text 6	Collected at CRF.
CONMED	CMCLAS7	character	ATC Text 7	Collected at CRF.
CONMED	CMCLAS8	character	ATC Text 8	Collected at CRF.
CONMED	CMCLAS9	character	ATC Text 9	Collected at CRF.

CONMED	CMCODE	character	Medication Dictionary Code	Collected at CRF.
CONMED	CMDECOD	character	Medication Generic Term	Collected at CRF.
CONMED	CMCLAS	character	ATC Text	Collected at CRF.
CONMED	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
CONMED	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
CONMED	DCMSTDT	character	De-identified Actual Start Date of Medication	Relative day of actual start date of medication from randomly assigned reference date (CMSTDT-REF.DATE)
CONMED	DCMENDT	character	De-identified Actual End Date of Medication	Relative day of actual end date of medication from randomly assigned reference date (CMSENDT-REF.DATE)

1.3.7. DEATH - DEATH

Dataset	DEATH
Description	Death
Unique identifier	DUSUBJID

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

DEATH	VISIT	character	Visit	Collected at CRF.
DEATH	CYCLENUM	character	Cycle Number	Collected at CRF.
DEATH	CYCLE	character	Cycle	Collected at CRF.
DEATH	DAYNUM	character	Day Number	Collected at CRF.
DEATH	DAY	character	Day	Collected at CRF.
DEATH	AESEQ	character	AE for Death	Collected at CRF.
DEATH	DTCAUSEC	character	Cause of Death Code	Collected at CRF.
DEATH	DTCAUSE	character	Cause of Death	Collected at CRF.
DEATH	DTOTH	character	Other Reason, Specify	Suppressed all records to protect PII.
DEATH	DTPROGC	character	Evidence of Prog.Dise. at Death Code	Collected at CRF.
DEATH	DTPROG	character	Evidence of Prog.Dise. at Death	Collected at CRF.
DEATH	DTEPDC	character	Evidence of Prog.Dise, Specify Code	Collected at CRF.
DEATH	DTEPD	character	Evidence of Prog.Dise, Specify	Collected at CRF.
DEATH	DTEPDOTH	character	Evidence of Prog.Dise Other, Specify	Collected at CRF.
DEATH	PAGNUM	double	Page Number	Collected at CRF.
DEATH	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DEATH	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DEATH	DDTACTDT	character	De-identified Date of Death	Relative day of death from randomly assigned reference date (DTACTDT-REF.DATE)
DEATH	DDTPROGDT	character	De-identified Date of Disease Progression	Relative day of disease progression from randomly assigned reference date (DTPROGDT-REF.DATE)

1.3.8. DIAGNOSIS – DIAGNOS

Dataset	DIAGNOS
Description	Diagnosis
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
DIAGNOS	STUDYID	character	Study Id	Collected at CRF.
DIAGNOS	SITEID	character	Site	Suppressed all records to protect PII.
DIAGNOS	PHASENUM	double	Phase Number	Collected at CRF.
DIAGNOS	PHASE	character	Phase	Collected at CRF.
DIAGNOS	VISITNUM	double	Visit Number	Collected at CRF.
DIAGNOS	VISIT	character	Visit	Collected at CRF.
DIAGNOS	CYCLENUM	character	Cycle Number	Collected at CRF.
DIAGNOS	CYCLE	character	Cycle	Collected at CRF.
DIAGNOS	DAYNUM	character	Day Number	Collected at CRF.
DIAGNOS	DAY	character	Day	Collected at CRF.
DIAGNOS	PAGNUM	double	Page Number	Collected at CRF.
DIAGNOS	DGHSTC	character	Histology Code	Collected at CRF.
DIAGNOS	DGHST	character	Histology	Collected at CRF.
DIAGNOS	DGHSTOTH	character	Histology Other	Suppressed all records to protect PII.
DIAGNOS	DGTUMGR	character	Tumor Grade	Collected at CRF.
DIAGNOS	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DIAGNOS	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DIAGNOS	DDGACTDT	character	De-identified Actual Date of Diagnosis	Relative day of actual date of diagnosis from randomly assigned reference date (DGACTDT-REF.DATE)
DIAGNOS	DDGHACTDT	character	De-identified Actual Date of History Info Recorded	Relative day of actual date of history info recorded from randomly assigned reference date (DGHACTDT-REF.DATE)

1.3.9. DISPOSITION ADVERSE EVENTS - DISP AE

Dataset	DISPAE
Description	Disposition Adverse Events
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
DISPAE	STUDYID	character	Study Id	Collected at CRF.
DISPAE	SITEID	character	Site	Suppressed all records to protect PII.
DISPAE	PHASENUM	double	Phase Number	Collected at CRF.
DISPAE	PHASE	character	Phase	Collected at CRF.
DISPAE	VISITNUM	double	Visit Number	Collected at CRF.
DISPAE	VISIT	character	Visit	Collected at CRF.
DISPAE	CYCLENUM	character	Cycle Number	Collected at CRF.
DISPAE	CYCLE	character	Cycle	Collected at CRF.
DISPAE	DAYNUM	character	Day Number	Collected at CRF.
DISPAE	DAY	character	Day	Collected at CRF.
DISPAE	PAGNUM	double	Page Number	Collected at CRF.
DISPAE	DATYPEC	double	Disposition Type Code	Collected at CRF.
DISPAE	DATYPE	character	Disposition Type	Collected at CRF.
DISPAE	AESQ	double	Adverse Event Sequence Number	Collected at CRF.
DISPAE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DISPAE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.10. DISPOSITION - DISPOSIT

Dataset	DISPOSIT
Description	Disposition
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
DISPOSIT	STUDYID	character	Study Id	Collected at CRF.
DISPOSIT	SITEID	character	Site	Suppressed all records to protect PII.
DISPOSIT	PHASENUM	double	Phase Number	Collected at CRF.
DISPOSIT	PHASE	character	Phase	Collected at CRF.
DISPOSIT	VISITNUM	double	Visit Number	Collected at CRF.
DISPOSIT	VISIT	character	Visit	Collected at CRF.
DISPOSIT	CYCLENUM	character	Cycle Number	Collected at CRF.
DISPOSIT	CYCLE	character	Cycle	Collected at CRF.
DISPOSIT	DAYNUM	character	Day Number	Collected at CRF.
DISPOSIT	DAY	character	Day	Collected at CRF.
DISPOSIT	PAGNUM	double	Page Number	Collected at CRF.
DISPOSIT	DSTYPEC	double	End of Treatment or Trial Code	Collected at CRF.
DISPOSIT	DSTYPE	character	End of Treatment or Trial	Collected at CRF.
DISPOSIT	DSREASC	character	Reason for Withdrawal/Termination Code	Collected at CRF.
DISPOSIT	DSREAS	character	Reason for Withdrawal/Termination	Collected at CRF.
DISPOSIT	DSSCRNC	character	Reason for Screen Failure Code	Collected at CRF.
DISPOSIT	DSSCRN	character	Reason for Screen Failure	Collected at CRF.
DISPOSIT	DSASEQ	character	Screen Adverse Event Sequence Number	Collected at CRF.
DISPOSIT	DSSTATC	double	Subject Completed Treatment/Trial Code	Collected at CRF.

DISPOSIT	DSSTAT	character	Subject Completed Treatment/Trial	Collected at CRF.
DISPOSIT	DSSCSPEC	character	Subject Choice - Specify	Suppressed all records to protect PII.
DISPOSIT	DSRSOTH	character	Other Reason - Specify	Suppressed all records to protect PII.
DISPOSIT	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
DISPOSIT	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
DISPOSIT	DDSACTDT	character	De-identified Actual Date Trial Completion/Withdrawal	Relative day of actual date trial completion/withdrawal from randomly assigned reference date (DSACTDT-REF.DATE)
DISPOSIT	DDSPROGDT	character	De-identified Actual Date of Disease Progression	Relative day of actual date of disease progression from randomly assigned reference date (DSPROGDT-REF.DATE)

1.3.11. ELECTROCARDIOGRAM - ECG

Dataset	ECG
Description	Electrocardiogram
Unique identifier	DUSUBJID

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

ECG	VISIT	character	Visit	Collected at CRF.
ECG	CYCLENUM	character	Cycle Number	Collected at CRF.
ECG	CYCLE	character	Cycle	Collected at CRF.
ECG	DAYNUM	character	Day Number	Collected at CRF.
ECG	DAY	character	Day	Collected at CRF.
ECG	EGTESTCD	character	ECG Test Short Name	Collected at CRF.
ECG	EGREF	character	ECG Reference Number	Collected at CRF.
ECG	EGACTTM	character	Actual Time of ECG	Collected at CRF.
ECG	EGPOS	character	Position	Collected at CRF.
ECG	EGQUAL	character	Qualifier	Collected at CRF.
ECG	EGTEST	character	ECG Test	Collected at CRF.
ECG	EGSTRESN	character	Numeric Result in Standard Units	Collected at CRF.
ECG	EGSTUNIT	character	Standard Units	Collected at CRF.
ECG	EGSTRESC	character	Character Result in Standard Units	Collected at CRF.
ECG	EGPRVIDC	character	ECG Provider Name Code	Collected at CRF.
ECG	EGPRVID	character	ECG Provider Name	Collected at CRF.
ECG	EGORRESN	character	Numeric Result in Original Units	Collected at CRF.
ECG	EGORUNIT	character	Original Units	Collected at CRF.
ECG	EGINTPC	character	Interpretation Code	Collected at CRF.
ECG	EGINTP	character	Interpretation	Collected at CRF.
ECG	EGLEAD	character	Lead Used for Measurement	Collected at CRF.
ECG	EGSEQ	character	ECG Sequence Number	Collected at CRF.
ECG	EGREADC	character	ECG Reader Code	Collected at CRF.
ECG	EGREAD	character	ECG Reader	Collected at CRF.
ECG	EGCHGC	character	Sig Change from Prev/Baseline ECG Code	Collected at CRF.
ECG	EGCHG	character	Sig Change from Prev/Baseline ECG	Collected at CRF.
ECG	EGINTOTH	character	ECG Intrepretation, Specify	Suppressed all records to protect PII.
ECG	EGCHGOTH	character	Change, Specify	Collected at CRF.
ECG	PAGNUM	double	Page Number	Collected at CRF.

ECG	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
ECG	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
ECG	DEGDT	character	De-identified Actual Date of ECG	Relative day of actual date of ECG from randomly assigned reference date (EGDT-REF.DATE)

1.3.12. ECOG PERFORMANCE STATUS – ECOG

Dataset	ECOG
Description	ECOG Performance Status
Unique identifier	DUSUBJID

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

ECOG	PAGNUM	double	Page Number	Collected at CRF.
ECOG	ECECOGC	character	ECOG Performance Status	Collected at CRF.
ECOG	ECECOG	character	ECOG Performance Status	Collected at CRF.
ECOG	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
ECOG	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
ECOG	DECACTDT	character	De-identified ECOG Actual Date	Relative day of actual date of ECOG from randomly assigned reference date (EGDT-REF.DATE)

1.3.13. EXPOSURE DETAILS RELATED AE - EDAE

Dataset	EDAE
Description	Exposure Details Related AE
Unique identifier	DUSUBJID

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

EDAE	DAY	character	Day	Collected at CRF.
EDAE	ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
EDAE	ACTTRT	character	Drug/Therapy	Collected at CRF.
EDAE	AESEQ	double	AE Sequence Number	Collected at CRF.
EDAE	EDSEQ	double	Exposure Details Sequence Number	Collected at CRF.
EDAE	EXSEQ	double	Exposure Sequence Number	Collected at CRF.
EDAE	PAGNUM	double	Page Number	Collected at CRF.
EDAE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
EDAE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.14. ENROLLMENT - ENROLL

Dataset	ENROLL
Description	Enrollment
Unique identifier	DUSUBJID

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

ENROLL	CYCLE	character	Cycle	Collected at CRF.
ENROLL	DAYNUM	character	Day Number	Collected at CRF.
ENROLL	DAY	character	Day	Collected at CRF.
ENROLL	PAGNUM	double	Page Number	Collected at CRF.
ENROLL	ENCRIT	character	Inclusion or Exclusion Criterion	Collected at CRF.
ENROLL	ENSEQ	double	Criterion Sequence Number	Collected at CRF.
ENROLL	ENTEXT	character	Criterion Text	Collected at CRF.
ENROLL	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
ENROLL	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
ENROLL	DENCRES	character	De-identified Criterion Result	Masked results containing PII or sensitive information.
ENROLL	DENCRESC	character	De-identified Criterion Result Code	Masked results containing PII or sensitive information.
ENROLL	DENACTDT	character	De-identified Actual Date of Enrollment	Relative day of actual date of enrollment from randomly assigned reference date (EGDT-REF.DATE)

1.3.15. EXPOSURE AE - EXAE

Dataset	EXAE
Description	Exposure AE
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
EXAE	STUDYID	character	Study Id	Collected at CRF.
EXAE	SITEID	character	Site	Suppressed all records to protect PII.
EXAE	PHASENUM	double	Phase Number	Collected at CRF.
EXAE	PHASE	character	Phase	Collected at CRF.
EXAE	VISITNUM	double	Visit Number	Collected at CRF.
EXAE	VISIT	character	Visit	Collected at CRF.
EXAE	CYCLENUM	double	Cycle Number	Collected at CRF.
EXAE	CYCLE	character	Cycle	Collected at CRF.
EXAE	DAYNUM	double	Day Number	Collected at CRF.
EXAE	DAY	character	Day	Collected at CRF.
EXAE	AESEQ	double	AE Sequence Number	Collected at CRF.
EXAE	ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
EXAE	ACTTRT	character	Drug/Therapy	Collected at CRF.
EXAE	EXSEQ	double	Exposure Sequence Number	Collected at CRF.
EXAE	PAGNUM	double	Page Number	Collected at CRF.
EXAE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
EXAE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.16. EXPOSURE – EXPOSURE

Dataset	EXPOSURE
Description	Exposure
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
EXPOSURE	STUDYID	character	Study Id	Collected at CRF.
EXPOSURE	SITEID	character	Site	Suppressed all records to protect PII.
EXPOSURE	PHASENUM	double	Phase Number	Collected at CRF.
EXPOSURE	PHASE	character	Phase	Collected at CRF.
EXPOSURE	VISITNUM	double	Visit Number	Collected at CRF.
EXPOSURE	VISIT	character	Visit	Collected at CRF.
EXPOSURE	CYCLENUM	double	Cycle Number	Collected at CRF.
EXPOSURE	CYCLE	character	Cycle	Collected at CRF.
EXPOSURE	DAYNUM	double	Day Number	Collected at CRF.
EXPOSURE	DAY	character	Day	Collected at CRF.
EXPOSURE	EXSEQ	double	Exposure Sequence Number	Collected at CRF.
EXPOSURE	EXSTATC	character	Exposure Status Code	Collected at CRF.
EXPOSURE	EXSTAT	character	Exposure Status	Collected at CRF.
EXPOSURE	EXREASC	character	Reason for Dose Change Code	Collected at CRF.
EXPOSURE	EXREAS	character	Reason for Dose Change	Collected at CRF.
EXPOSURE	EXRSNOTH	character	Dose Chang Other Reason, Specify	Suppressed all records to protect PII.
EXPOSURE	ACTTRTC	double	Drug/Therapy Code	Collected at CRF.
EXPOSURE	ACTTRT	character	Drug/Therapy	Collected at CRF.
EXPOSURE	ROUTE	character	Route of Administration	Collected at CRF.

EXPOSURE	DOSE	character	Dose per Administration	Collected at CRF.
EXPOSURE	DOSEUNIT	character	Dose Unit	Collected at CRF.
EXPOSURE	EXTMLBL	character	Label of Planned Administration Time	Collected at CRF.
EXPOSURE	EXDOSPRE	character	Prescribed Dose	Collected at CRF.
EXPOSURE	EXPRUNIT	character	Prescribed Dose Unit	Collected at CRF.
EXPOSURE	EXDOSCAL	character	Calculated Dose	Collected at CRF.
EXPOSURE	EXCHGC	character	Actual-Dose Mod. Necessary Code	Collected at CRF.
EXPOSURE	EXCHG	character	Actual-Dose Mod. Necessary	Collected at CRF.
EXPOSURE	EDSEQ	character	Interruption Sequence Number	Collected at CRF.
EXPOSURE	EDSTTM	character	Start Time	Collected at CRF.
EXPOSURE	EDENDTM	character	End Time	Collected at CRF.
EXPOSURE	EDRSNOTH	character	Temp. Interrupted Other Reason, Specify	Suppressed all records to protect PII.
EXPOSURE	PAGNUM	double	Page Number	Collected at CRF.
EXPOSURE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
EXPOSURE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
EXPOSURE	DEXSTDT	character	De-identified Start Date of Exposure	Relative day of start date of exposure from randomly assigned reference date (EXSTDT-REF.DATE)

1.3.17. FIRST LINE OF TREATMENT REGIMEN - FLTRTREG

Dataset	FLTRTREG
Description	First Line of Treatment Regimen
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
FLTRTREG	STUDYID	character	Study Id	Collected at CRF.
FLTRTREG	SITEID	character	Site	Suppressed all records to protect PII.
FLTRTREG	PHASENUM	double	Phase Number	Collected at CRF.
FLTRTREG	PHASE	character	Phase	Collected at CRF.
FLTRTREG	VISITNUM	double	Visit Number	Collected at CRF.
FLTRTREG	VISIT	character	Visit	Collected at CRF.
FLTRTREG	CYCLENUM	character	Cycle Number	Collected at CRF.
FLTRTREG	CYCLE	character	Cycle	Collected at CRF.
FLTRTREG	DAYNUM	character	Day Number	Collected at CRF.
FLTRTREG	DAY	character	Day	Collected at CRF.
FLTRTREG	PAGNUM	double	Page Number	Collected at CRF.
FLTRTREG	FTSEQ	double	Treatment Regimen Sequence Number	Collected at CRF.
FLTRTREG	FTTERM	character	Treatment Regimen Term	Suppressed all records to protect PII.
FLTRTREG	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
FLTRTREG	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.18. HISTORY OF RECUR/METASTATIC DISEASE - HXRMDIS

Dataset	HXRMDIS
Description	History of Recur/Metastatic Disease
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
HXRMDIS	STUDYID	character	Study Id	Collected at CRF.
HXRMDIS	SITEID	character	Site	Suppressed all records to protect PII.
HXRMDIS	PHASENUM	double	Phase Number	Collected at CRF.
HXRMDIS	PHASE	character	Phase	Collected at CRF.
HXRMDIS	VISITNUM	double	Visit Number	Collected at CRF.
HXRMDIS	VISIT	character	Visit	Collected at CRF.
HXRMDIS	CYCLENUM	character	Cycle Number	Collected at CRF.
HXRMDIS	CYCLE	character	Cycle	Collected at CRF.
HXRMDIS	DAYNUM	character	Day Number	Collected at CRF.
HXRMDIS	DAY	character	Day	Collected at CRF.
HXRMDIS	PAGNUM	double	Page Number	Collected at CRF.
HXRMDIS	HDSEQ	double	Disease Sequence Number	Collected at CRF.
HXRMDIS	HDTERM	character	HDTERM	Suppressed all records to protect PII.
HXRMDIS	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
HXRMDIS	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
HXRMDIS	DHDACTDT	character	De-identified Actual Date of Disease	Relative day of actual date of disease from randomly assigned reference date (HDACTDT-REF.DATE)

1.3.19. INCLUSION/EXCLUSION EXCEPTIONS – IE

Dataset	IE
Description	Inclusion/Exclusion Exceptions
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
IE	STUDYID	character	Study Id	Collected at CRF.
IE	SITEID	character	Site	Suppressed all records to protect PII.
IE	PAGNUM	double	Page Number	Collected at CRF.
IE	IEMETC	double	Overall Criteria Met Code	Collected at CRF.
IE	IEMET	character	Overall Criteria Met	Collected at CRF.
IE	IECATC	double	Inclusion/Exclusion Category Code	Collected at CRF.
IE	IECAT	character	Inclusion/Exclusion Category	Collected at CRF.
IE	IETESTCD	character	Inclusion/Exclusion Criterion Short Name	Collected at CRF.
IE	IETEST	character	Inclusion/Exclusion Criterion	Collected at CRF.
IE	IESPID	character	Sponsor-defined Identifier	Suppressed all records to protect PII.
IE	IEORRES	character	Exception Criterion Original Result	Suppressed all records to protect PII.
IE	IESTRESC	character	Exception Criterion Result in Std Format	Collected at CRF.
IE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
IE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
IE	DIEDT	character	De-identified Date of Collection	Relative day of collection from randomly assigned reference date (IEDT-REF.DATE)

1.3.20. RESULTS OF AE RELATED TESTS – LABSAE

Dataset	LABSAE
Description	Results of AE Related Tests
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
LABSAE	STUDYID	character	Study Id	Collected at CRF.
LABSAE	SITEID	character	Site	Suppressed all records to protect PII.
LABSAE	PHASENUM	double	Phase Number	Collected at CRF.
LABSAE	PHASE	character	Phase	Collected at CRF.
LABSAE	VISITNUM	double	Visit Number	Collected at CRF.
LABSAE	VISIT	character	Visit	Collected at CRF.
LABSAE	CYCLENUM	character	Cycle Number	Collected at CRF.
LABSAE	CYCLE	character	Cycle	Collected at CRF.
LABSAE	DAYNUM	character	Day Number	Collected at CRF.
LABSAE	DAY	character	Day	Collected at CRF.
LABSAE	LBSEQ	character	Sample Sequence Number	Collected at CRF.
LABSAE	LBSIFACT	character	Std. Intl. Conversion Factor	Suppressed all records to protect PII.
LABSAE	LBPRVIDC	character	Laboratory ID Code	Suppressed all records to protect PII.
LABSAE	LBPRVID	character	Laboratory ID	Suppressed all records to protect PII.
LABSAE	LBREF	character	Lab Reference #	Collected at CRF.
LABSAE	LBVTYPEC	double	Lab Visit Type Code	Collected at CRF.
LABSAE	LBVTYPE	character	Lab Visit Type	Collected at CRF.

LABSAE	LBTERM	character	Description for Other Lab Tests	Suppressed all records to protect PII.
LABSAE	ORGRES	character	Character Result in Original Units	Suppressed all records to protect PII.
LABSAE	LBTESTC	character	Lab Test Code	Collected at CRF.
LABSAE	LBTEST	character	Lab Test Name	Collected at CRF.
LABSAE	LBABBR	character	Lab Test Abbreviation	Collected at CRF.
LABSAE	LBDESCR	character	Full Test Description	Collected at CRF.
LABSAE	LBTYPE	character	Lab Type	Collected at CRF.
LABSAE	LBTYPEC	character	Lab Type Code	Collected at CRF.
LABSAE	NRIND	character	Normal Range Indicator	Collected at CRF.
LABSAE	ORGRESN	character	Numeric Result in Original Units	Suppressed all records to protect PII.
LABSAE	ORGNRLO	character	Normal Range Lower Limit in Orig. Units	Suppressed all records to protect PII.
LABSAE	ORGNRHI	character	Normal Range Upper Limit in Orig. Units	Suppressed all records to protect PII.
LABSAE	ORGUNIT	character	Original Unit	Suppressed all records to protect PII.
LABSAE	REPUNIT	character	Reported Unit	Suppressed all records to protect PII.
LABSAE	STDNRC	character	Normal Range in Char Result in Std Units	Collected at CRF.
LABSAE	STDNRHI	character	Normal Range Upper Limit in Std Units	Collected at CRF.
LABSAE	STDNRLO	character	Normal Range Lower Limit in Std Units	Collected at CRF.
LABSAE	STDRESC	character	Character Result in Standard Units	Collected at CRF.
LABSAE	STDRESN	character	Numeric Result in Standard Units	Collected at CRF.
LABSAE	STDUNIT	character	Standard Unit	Collected at CRF.
LABSAE	LBTDECOD	character	Laboratory Test Description	Collected at CRF.
LABSAE	PAGNUM	double	Page Number	Collected at CRF.
LABSAE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
LABSAE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
LABSAE	DLBACTDT	character	De-identified Actual Date of Sample	Relative day of actual date of sample from randomly assigned reference date (LBACTDT-REF.DATE)

1.3.21. MEDICAL HISTORY - MEDHIST

Dataset	MEDHIST
Description	Medical History
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
MEDHIST	STUDYID	character	Study Id	Collected at CRF.
MEDHIST	SITEID	character	Site	Suppressed all records to protect PII.
MEDHIST	PHASENUM	double	Phase Number	Collected at CRF.
MEDHIST	PHASE	character	Phase	Collected at CRF.
MEDHIST	VISITNUM	double	Visit Number	Collected at CRF.
MEDHIST	VISIT	character	Visit	Collected at CRF.
MEDHIST	CYCLENUM	character	CYCLENUM	Collected at CRF.
MEDHIST	CYCLE	character	CYCLE	Collected at CRF.
MEDHIST	DAYNUM	character	DAYNUM	Collected at CRF.
MEDHIST	DAY	character	Day	Collected at CRF.
MEDHIST	PAGNUM	double	Page Number	Collected at CRF.
MEDHIST	MHSEQ	double	MH Sequence Number	Collected at CRF.
MEDHIST	MHBODSYC	double	Body System Code	Collected at CRF.
MEDHIST	MHBODSYS	character	Body System	Collected at CRF.
MEDHIST	MHTERM	character	Reported Term for Condition	Suppressed all records to protect PII.
MEDHIST	MHSTATC	character	Condition Code	Collected at CRF.
MEDHIST	MHSTAT	character	Condition	Collected at CRF.

MEDHIST	MHCONDC	double	Status Code	Collected at CRF.
MEDHIST	MHCOND	character	Status	Collected at CRF.
MEDHIST	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
MEDHIST	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
MEDHIST	DMHACTDT	character	De-identified Actual Date of Collection	Relative day of actual date of collection from randomly assigned reference date (MHACTDT-REF.DATE)

1.3.22. MEDICATION VIAL NUMBERS - MEDVIAL

Dataset	MEDVIAL
Description	Medication Vial Numbers
Unique identifier	DUSUBJID

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

MEDVIAL	MVMEDC	double	Medication Name Code	Collected at CRF.
MEDVIAL	MVMED	character	Medication Name	Collected at CRF.
MEDVIAL	MVNUM	double	Medication Vial Number	Suppressed all records to protect PII.
MEDVIAL	PAGNUM	double	Page Number	Collected at CRF.
MEDVIAL	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
MEDVIAL	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.23. PROTOCOL DESCRIPTION – PROTDESC

Dataset	PROTDESC
Description	Protocol Description
Unique identifier	NA

Domain	Variable	Type	Label	Comments
PROTDESC	STUDYID	character	Study Id	Collected at CRF.
PROTDESC	COMPND	character	Compound Name	Collected at CRF.
PROTDESC	COMPNDC	character	Compound Number	Collected at CRF.
PROTDESC	BLINDING	character	Blinding Level	Collected at CRF.
PROTDESC	ACTCONTR	character	Active Control	Collected at CRF.
PROTDESC	PLACONTR	character	Placebo Control	Collected at CRF.
PROTDESC	DESIGN	character	Trial Design	Collected at CRF.
PROTDESC	MULTCENT	character	Multi Center	Collected at CRF.
PROTDESC	INDICAT	character	Indication	Collected at CRF.

PROTDESC	DEVPROID	character	Development Program Id	Suppressed all records to protect PII.
PROTDESC	AGEGRP	character	Age Group	Collected at CRF.
PROTDESC	SPECPOP	character	Special Population	Collected at CRF.
PROTDESC	SUBJTYPE	character	Subject Type	Collected at CRF.
PROTDESC	PROCSTUD	character	Preceding Study Id	Collected at CRF.
PROTDESC	STUDPHAS	character	Phase of Study	Collected at CRF.

1.3.24. PROTOCOL DEVIATION – PROTDEV

Dataset	PROTDEV
Description	Protocol Deviation
Unique identifier	DUSUBJID

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

PROTDEV	DAY	character	Day	Collected at CRF.
PROTDEV	PVSEQ	double	Protocol Deviation Seq Number	Collected at CRF.
PROTDEV	PVTERM	character	Protocol Deviation Term	Collected at CRF.
PROTDEV	PVDECOD	character	Protocol Deviation Coded Term	Collected at CRF.
PROTDEV	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
PROTDEV	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.25. SURGERY – SURGERY

Dataset	SURGERY
Description	Surgery
Unique identifier	DUSUBJID

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

SURGERY	DAY	character	Day	Collected at CRF.
SURGERY	PAGNUM	double	Page Number	Collected at CRF.
SURGERY	SGREPRTC	double	Are any Surg/Proc. Planned Code	Collected at CRF.
SURGERY	SGREPRT	character	Are any Surg/Proc. Planned	Collected at CRF.
SURGERY	SGSEQ	character	Sequence Number	Collected at CRF.
SURGERY	SGPROC	character	Surgery/Procedure	Suppressed all records to protect PII.
SURGERY	SGINDIC	character	Indication for Surgery/Procedure	Suppressed all records to protect PII.
SURGERY	DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
SURGERY	DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
SURGERY	DSGPLNDT	character	De-identified Date of Planned Surgery/Procedure	Relative day of actual date of planned surgery/procedure from randomly assigned reference date (SGPLNDT-REF.DATE)
SURGERY	DSGBODSYC	character	De-identified Surgery Body System Code	Generalized small frequency cells to 99
SURGERY	DSGBODSYS	character	De-identified Surgery Body System	Generalized small frequency cells to 'Other'

1.3.26. SURVIVAL STATISTICS – SURVSTAT

Dataset	SURVSTAT
Description	Survival Statistics
Unique identifier	DUSUBJID

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

SURVSTAT	PHASENUM	double	Phase Number	Collected at CRF.
SURVSTAT	PHASE	character	Phase	Collected at CRF.
SURVSTAT	VISITNUM	double	Visit Number	Collected at CRF.
SURVSTAT	VISIT	character	Visit	Collected at CRF.
SURVSTAT	CYCLENUM	character	Cycle Number	Collected at CRF.
SURVSTAT	CYCLE	character	Cycle	Collected at CRF.
SURVSTAT	DAYNUM	character	Day Number	Collected at CRF.
SURVSTAT	DAY	character	Day	Collected at CRF.
SURVSTAT	PAGNUM	double	Page Number	Collected at CRF.
SURVSTAT	SUSTATC	character	Survival Status Code	Collected at CRF.
SURVSTAT	SUSTAT	character	Survival Status	Collected at CRF.
SURVSTAT	SUREPRTC	character	Consent to Overall Survival FU? (Code)	Collected at CRF.
SURVSTAT	SUREPRT	character	Consent to Overall Survival FU? ()	Collected at CRF.
SURVSTAT	DUSUBJID	character	De-identified Short subject ID	Randomly assigned patient number for de-identification
SURVSTAT	DSUBJID	character	De-identified Long subject ID	Randomly assigned patient number for de-identification
SURVSTAT	DSUFUDT	character	De-identified Survival Follow Up Date	Relative day of survival follow up date from randomly assigned reference date (SUFUDT-REF.DATE)
SURVSTAT	DSUALVDT	character	De-identified Date Subject Last Known be Alive	Relative day subject last known to be alive from randomly assigned reference date (SUALVDT-REF.DATE)

1.3.27. TREATMENT CYCLE DELAY AE REFERENCE - TRTCYCAE

Dataset	TRTCYCAE
Description	Treatment Cycle Delay AE Reference
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
TRTCYCAE	STUDYID	character	Study Id	Collected at CRF.
TRTCYCAE	SITEID	character	Site	Suppressed all records to protect PII.
TRTCYCAE	PHASENUM	double	Phase Number	Collected at CRF.
TRTCYCAE	PHASE	character	Phase	Collected at CRF.
TRTCYCAE	VISITNUM	double	Visit Number	Collected at CRF.
TRTCYCAE	VISIT	character	Visit	Collected at CRF.
TRTCYCAE	CYCLENUM	double	Cycle Number	Collected at CRF.
TRTCYCAE	CYCLE	character	Cycle	Collected at CRF.
TRTCYCAE	DAYNUM	double	Day Number	Collected at CRF.
TRTCYCAE	DAY	character	Day	Collected at CRF.
TRTCYCAE	AESEQ	double	AE Sequence Number	Collected at CRF.
TRTCYCAE	PAGNUM	double	Page Number	Collected at CRF.
TRTCYCAE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification
TRTCYCAE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification

1.3.28. TREATMENT CYCLE - TRTCYCLE

Dataset	TRTCYCLE
Description	Treatment Cycle
Unique identifier	DUSUBJID

Domain	Variable	Type	Label	Comments
TRTCYCLE	STUDYID	character	Study Id	Collected at CRF.
TRTCYCLE	SITEID	character	Site	Suppressed all records to protect PII.
TRTCYCLE	PHASENUM	double	Phase Number	Collected at CRF.
TRTCYCLE	PHASE	character	Phase	Collected at CRF.
TRTCYCLE	VISITNUM	double	Visit Number	Collected at CRF.
TRTCYCLE	VISIT	character	Visit	Collected at CRF.
TRTCYCLE	CYCLENUM	double	Cycle Number	Collected at CRF.
TRTCYCLE	CYCLE	character	Cycle	Collected at CRF.
TRTCYCLE	DAYNUM	double	Day Number	Collected at CRF.
TRTCYCLE	DAY	character	Day	Collected at CRF.
TRTCYCLE	TCDELC	double	Treatment Cycle Delay Code	Collected at CRF.
TRTCYCLE	TCDEL	character	Treatment Cycle Delay	Collected at CRF.
TRTCYCLE	TCRSNC	character	Treatment Cycle Delay Reason Code	Collected at CRF.
TRTCYCLE	TCRSN	character	Treatment Cycle Delay Reason	Collected at CRF.
TRTCYCLE	TCRSNOTH	character	Treatment Cycle Delay Other Reason, Spec	Suppressed all records to protect PII.
TRTCYCLE	PAGNUM	double	Page Number	Collected at CRF.
TRTCYCLE	DUSUBJID	character	De-identified Unique Subject Id	Randomly assigned patient number for de-identification

TRTCYCLE	DSUBJID	character	De-identified Subject Number	Randomly assigned patient number for de-identification
TRTCYCLE	DTCACTDT	character	De-identified Treatment Cycle Actual Date	Relative day of treatment cycle actual date from randomly assigned reference date (TCACTDT-REF.DATE)

1.3.29. VISIT – VISIT

Dataset	VISIT
Description	Visit
Unique identifier	DUSUBJID

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