

Clinical Development

## DOXIL

NCT00653952\_3049

Anonymisation Data Derivation Specification Document

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

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

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

#### Part II: Variables within dataset

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

### 1.2. Guidelines for Preparing Data

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

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

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated.
- SS\_SURV dataset is a derived dataset. Hence will not be submitted.
- Consent Date will be used as Reference Date (REF.DATE) to derive relative days in general. Randomization Date or First Dose Date, whichever available first, will be used instead, if Consent Date is not available.

### 1.3. Data Files

The NCT00653952\_3049 CSR Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics – DEMO

<b>Dataset</b>	DEMO
<b>Creating program</b>	demo.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, SUBJINIT, RACESPEC, INVID, INVNAME, DMDD, DMMM, DMY, DMDT, DMDTC, BIRDD, BIRMM, BIRYY, BIRTHDT, BIRTHDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity

Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
RANDOM	char	Was Subject Randomized		Collected at CRF.
TREATED	char	Was Subject Treated		Collected at CRF.
AGE	char	Age in Years		Date of birth is collected but can not be submitted as per HIPAA rules. Hence deriving AGE element. Derivation follows below rule: $AGE = \text{int}((REF.DATE - BIRTHDT)/365.25)$ For Partial dates, only Year part of the date is considered for AGE calculation. If age greater than 89+ years then will be grouped as per HIPAA rules.
SEX	char	Sex		Collected at CRF.
SEXN	num	Sex (Num)		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACEN	num	Race (Num)		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
WEIGHT	num	Weight in Kilograms		Collected at CRF.
HEIGHT	num	Height in Centimeters		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DMDY	num	Relative Visit Day		If DMDTC and REF.DATE not missing then perform below logic to calculate DMDY, If DMDTC less than REF.DATE then (DMDTC - REF.DATE).Else if DMDTC is greater than equal to REF.DATE then (DMDTC-REF.DATE) +1.
HT	num	Height in Original Units		Collected at CRF.
HTUNIT	char	Original Height Unit		Collected at CRF.
WT	num	Weight in Original Units		Collected at CRF.
WTUNIT	char	Original Weight Unit		Collected at CRF.
ELIGVIOL	char	Any eligibility violations?		Collected at CRF.
NUMDOSES	num	Total number of doses		Collected at CRF.
DFI	num	Drug Free Interval		Collected at CRF.
NLESIONS	num	Number of Lesions		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.2. Adverse Events – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DUSUBJID,AEDECOD,AEBODSYS,AESEV,AEREL,AESEQ
<b>Sorted by</b>	DUSUBJID,AEDECOD,AEBODSYS,AESEV,AEREL,AESEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBJIDN, DOSE1DT, DOSE99DT, HADAE, AETERM, AESTDD, AESTMM, AESTYY, AESTDT, AESTDTC, AEENDD, AEENMM, AEENYY, AEENDT, AEENDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
AENONE	char	No Adverse Event Check Box per CRF		Collected at CRF.
NOAE	char	No Adverse Event		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEBODSYS	char	Body System		Collected at CRF.
AESTDY	num	Relative Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE).Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
AEENDY	num	Relative End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE).Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.
AESEV	char	Severity of Event (Grade)		Collected at CRF.
AESEVC	char	Severity of Event		Collected at CRF.
AESEVN	num	Severity of Event (Num)		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
SAELIFE	char	Is Life-threatening		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEINFRXN	char	Infusion Reaction		Collected at CRF.
AEREL	char	Causality (Relationship to Treatment)		Collected at CRF.
AERELN	num	Causality (Num)		Collected at CRF.
AEACTRTC	char	Action Taken with Study Treatment		Collected at CRF.
AEACTTRT	num	Action Taken with Study Treatment (Num)		Collected at CRF.
AEACTNON	char	No Action Taken		Collected at CRF.
AEACTRED	char	Dose Reduced		Collected at CRF.
AEACTDEL	char	Drug Delayed		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECTINT	char	Infusion Interrupted		Collected at CRF.
AECTDIS	char	Drug Discontinued		Collected at CRF.
AESTTRT	char	Treatment at Start of Event		Collected at CRF.
AEENTRT	char	Treatment at End of Event		Collected at CRF.
AETRTEM	char	Treatment Emergent		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.3. Assessment of Evaluable/Non-Evaluable Disease – AOED

<b>Dataset</b>	AOED
<b>Creating program</b>	aoed.sas
<b>Description</b>	Assessment of Evaluable/Non-Evaluable Disease
<b>Unique identifier</b>	DUSUBJID, AOEDNM, AOEDSTAT, LSNNUM, AOEDSEQ
<b>Sorted by</b>	DUSUBJID, AOEDNM, AOEDSTAT, LSNNUM, AOEDSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, AOEDDD, AOEDMM, AOEDYY, AOEDDT, AOEDDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
AOEDDY	num	Relative Diagnostic Procedure Day		If AOEDDTC and REF.DATE not missing then perform below logic to calculate AOEDDY, If AOEDDTC less than REF.DATE then (AOEDDTC - REF.DATE).Else if AOEDDTC is greater than equal to REF.DATE then (AOEDDTC- REF.DATE) +1.
AOEDANY	char	Any Evaluable Disease?		Collected at CRF.
AOEDNON	char	Any Non-evaluable Disease?		Collected at CRF.
AOEDNEW	char	Any New Evaluable Lesions?		Collected at CRF.
AOEDNM	char	Diagnostic Procedure		Collected at CRF.
AOEDNMN	num	Diagnostic Procedure (Num)		Collected at CRF.
AOEDTYPE	char	Type of Disease		Collected at CRF.

Variable	Type	Label	Codes	Comments
AOEDTYPN	num	Type of Disease (Num)		Collected at CRF.
AOEDSTAT	char	Disease Status		Collected at CRF.
AOEDSTAN	num	Disease Status (Num)		Collected at CRF.
AOEDND	char	No Assessment of Evaluable Disease		Collected at CRF.
AOEDDONE	char	Assessment of Evaluable Disease		Collected at CRF.
LSNSITE	char	Lesion Site		Collected at CRF.
LSNNUM	num	Lesion Number		Collected at CRF.
AOEDSEQ	num	Sequence Number		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

## 1.4.4. Assessment of Measurable Disease – AOMD

<b>Dataset</b>	AOMD
<b>Creating program</b>	aomd.sas
<b>Description</b>	Assessment of Measurable Disease
<b>Unique identifier</b>	DUSUBJID,AOMDNM,LSNNUM,AOMDND,AOMDSEQ
<b>Sorted by</b>	DUSUBJID,AOMDNM,LSNNUM,AOMDND,AOMDSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, AOMDDD, AOMDMM, AOMDYY, AOMDDT, AOMDDTC, LSNM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
AOMDDY	num	Relative Diagnostic Procedure Day		If AOMDDTC and REF.DATE not missing then perform below logic to calculate AOMDDY, If AOMDDTC less than REF.DATE then (AOMDDTC - REF.DATE).Else if AOMDDTC is greater than equal to REF.DATE then (AOMDDTC- REF.DATE) +1.
AOMDANY	char	Any Measurable Lesions?		Collected at CRF.
AOMDNEW	char	Any New Measurable Lesions?		Collected at CRF.
AOMDNM	char	Diagnostic Procedure		Collected at CRF.
AOMDNMN	num	Diagnostic Procedure (Num)		Collected at CRF.
LSNSZ1	char	Lesion Measurement 1 (cm)		Collected at CRF.
LSNSZ2	char	Lesion Measurement 2 (cm)		Collected at CRF.

Variable	Type	Label	Codes	Comments
LSNAREA	char	Lesion Area (sq. cm)		Collected at CRF.
LSNSZ1N	num	Lesion Measurement 1 (cm)		Collected at CRF.
LSNSZ2N	num	Lesion Measurement 2 (cm)		Collected at CRF.
LSNAREAN	num	Lesion Area (sq. cm)		Collected at CRF.
AOMDND	char	No Assessment of Measurable Disease		Collected at CRF.
AOMDDONE	char	Assessment of Measurable Disease?		Collected at CRF.
LSNSITE	char	Lesion Site		Collected at CRF.
LSNNUM	num	Lesion Number		Collected at CRF.
AOMDSEQ	num	Sequence Number		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

## 1.4.5. Concomitant Medications – CONMEDS

<b>Dataset</b>	CONMEDS
<b>Creating program</b>	conmeds.sas
<b>Description</b>	Concomitant Medications
<b>Unique identifier</b>	DUSUBJID,CMDECOD,CMONGO,CMPRIOR,CMROUTE,CMFREQ
<b>Sorted by</b>	DUSUBJID,CMDECOD,CMONGO,CMPRIOR,CMROUTE,CMFREQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, CMTERM, CMREAS, CMSTDD, CMSTMM, CMSTYY, CMSTDT, CMSTDTC, CMENDD, CMENMM, CMENYY, CMENDT, CMENDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
CMSEQ	num	Sequence Number		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.
CMSTDY	num	Relative Start Day of Medication		If CMSTDT and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDT less than REF.DATE then (CMSTDT - REF.DATE).Else if CMSTDT is greater than equal to REF.DATE then (CMSTDT- REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDT and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDT less than REF.DATE then (CMENDT - REF.DATE).Else if CMENDT is greater than equal to REF.DATE then (CMENDT- REF.DATE) +1.
CMONGO	char	Ongoing Medication		Collected at CRF.
CMPRIOR	char	Taken Prior to Study		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCONT	char	Continuing as per CRF		Collected at CRF.
CMDOSE	char	Medication dose		Collected at CRF.
CMUNIT	char	Dose unit		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.
CMFREQ	char	Frequency		Collected at CRF.
CMNONE	char	No Con Meds as per CRF		Collected at CRF.
NOCM	char	No Concomitant Medications		Collected at CRF.
CMCAT1	char	Medication Category 1		Collected at CRF.
CMCATCD1	char	Medication Category 1 Code		Collected at CRF.
CMCAT2	char	Medication Category 2		Collected at CRF.
CMCATCD2	char	Medication Category 2 Code		Collected at CRF.
CMCAT3	char	Medication Category 3		Collected at CRF.
CMCATCD3	char	Medication Category 3 Code		Collected at CRF.
CMCAT4	char	Medication Category 4		Collected at CRF.
CMCATCD4	char	Medication Category 4 Code		Collected at CRF.
CMCAT5	char	Medication Category 5		Collected at CRF.
CMCATCD5	char	Medication Category 5 Code		Collected at CRF.
CMSRCE	char	Medication Category Source		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

## 1.4.6. Concurrent Radiotherapy – CONRAD

<b>Dataset</b>	CONRAD
<b>Creating program</b>	conrad.sas
<b>Description</b>	Concurrent Radiotherapy
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, CRBDD, CRBMM, CRBY, CRBDT, CRBDTC, CREDD, CREMM, CREYY, CREDT, CREDTC, CRFIELD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
CRNONE	char	No Concurrent Radiotherapy		Collected at CRF.
CRYN	char	Was there Concurrent Radiotherapy?		Collected at CRF.
CRRESPO	char	Response to Concurrent Radio (ORIG)		Collected at CRF.
CRRESPN	num	Response to Concurrent Radio (Num)		Collected at CRF.
CRRESPC	char	Response to Concurrent Radiotherapy		Collected at CRF.
CRBDY	num	Relative Radiotherapy Start Day		If CRBDTC and REF.DATE not missing then perform below logic to calculate CRBDY, If CRBDTC less than REF.DATE then (CRBDTC - REF.DATE).Else if CRBDTC is greater than equal to REF.DATE then (CRBDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CREDY	num	Relative Radiotherapy Stop Day		If CREDTC and REF.DATE not missing then perform below logic to calculate CREDY, If CREDTC less than REF.DATE then (CREDTC - REF.DATE).Else if CREDTC is greater than equal to REF.DATE then (CREDTC- REF.DATE) +1.
CRDOSEC	char	Dose		Collected at CRF.
CRDOSEN	num	Dose (Num)		Collected at CRF.
CRUNIT	char	Dose Unit		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
DHAUTYN	char	Was an Autopsy Performed?		Collected at CRF.
DHAUTN	num	Was an Autopsy Performed? (Num)		Collected at CRF.
DHREAS	char	Primary Cause of Death		Collected at CRF.
DHREASN	num	Primary Cause of Death (Num)		Collected at CRF.
DHREL	char	Relationship to Study Drug		Collected at CRF.
DHRELN	num	Relationship to Study Drug (Num)		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.
DHDY	num	Relative Day of Death		If DHDTTC and REF.DATE not missing then perform below logic to calculate DHDY, If DHDTTC less than REF.DATE then (DHDTTC - REF.DATE).Else if DHDTTC is greater than equal to REF.DATE then (DHDTTC- REF.DATE) +1.

## 1.4.8. Disposition – DISPOSIT

<b>Dataset</b>	DISPOSIT
<b>Creating program</b>	disposit.sas
<b>Description</b>	Disposition
<b>Unique identifier</b>	DUSUBJID,DSSTAT
<b>Sorted by</b>	DUSUBJID,DSSTAT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, DSDD, DSMM, DSY, DSDT, DSDTC, DRSOTH

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity-Randomized		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
DSDY	num	Relative Day of Disposition Status		If DSDTC and REF.DATE not missing then perform below logic to calculate DSDY, If DSDTC less than REF.DATE then (DSDTC - REF.DATE).Else if DSDTC is greater than equal to REF.DATE then (DSDTC- REF.DATE) +1.
DSRSORG	char	Reason for Non-Completion (Original)		Collected at CRF.
DSREASN	num	Reason for Non-Completion (Num)		Collected at CRF.
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSSTAT	char	Disposition Status		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.9.Diagnostics Procedures – DP

<b>Dataset</b>	DP
<b>Creating program</b>	dp.sas
<b>Description</b>	Diagnostics Procedures
<b>Unique identifier</b>	DUSUBJID,DPPROC,DPSITE,DPSEQ
<b>Sorted by</b>	DUSUBJID,DPPROC,DPSITE,DPSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, DPDD, DPMM, DPYY, DPDT, DPDTC, DPABFIND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
DPDY	num	Relative Diagnostic Procedure Day		If DPDTC and REF.DATE not missing then perform below logic to calculate DPDY, If DPDTC less than REF.DATE then (DPDTC - REF.DATE).Else if DPDTC is greater than equal to REF.DATE then (DPDTC- REF.DATE) +1.
DPPROC	char	Diagnostic Procedure		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPNONE	char	No Diagnostic Procedures		Collected at CRF.
DPDONE	char	Diagnostic Procedure Done		Collected at CRF.
DPRESULT	char	Result of Diagnostic Procedure		Collected at CRF.
DPRESULN	num	Result of Diagnostic Procedure (Num)		Collected at CRF.
DPSITE	char	Procedural Site		Collected at CRF.
DPSEQ	num	Sequence Number		Collected at CRF.
DPEJPER	char	Ejection Fraction (Percent)		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.10. Dxhist – DXHIST

<b>Dataset</b>	DXHIST
<b>Creating program</b>	dxhist.sas
<b>Description</b>	Dxhist
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, DXDD, DXMM, DXYY, DXDT, DXDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity-Randomized		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
DXFIGO	char	FIGO Stage at Diagnosis		Collected at CRF.
DXTUMTYP	char	Histologic Tumor Type		Collected at CRF.
HISTCAT	num	Histologic Tumor Category		Collected at CRF.
HISTGRD	num	Histologic Tumor Grade		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DXDY	num	Relative Day of Ovarian Cancer Diagnosis		If DXDTC and REF.DATE not missing then perform below logic to calculate DXDY, If DXDTC less than REF.DATE then (DXDTC - REF.DATE).Else if DXDTC is greater than equal to REF.DATE then (DXDTC- REF.DATE) +1.

### 1.4.11. Patient Eligibility – ENTRY

<b>Dataset</b>	ENTRY
<b>Creating program</b>	entry.sas
<b>Description</b>	Patient Eligibility
<b>Unique identifier</b>	DUSUBJID,QNUM, QTYPE
<b>Sorted by</b>	DUSUBJID,QNUM, QTYPE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, CNSNTDD, CNSNTMM, CNSNTYY, CNSNTDT, CNSNTDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
QNUM	num	Question Number		Collected at CRF.
QTYPE	char	Criteria Type		Collected at CRF.
QYN	char	Yes or No		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

#### 1.4.12. Exposure – EXPOSURE

<b>Dataset</b>	EXPOSURE
<b>Creating program</b>	exposure.sas
<b>Description</b>	Exposure
<b>Unique identifier</b>	DUSUBJID,EXSEQ
<b>Sorted by</b>	DUSUBJID,EXSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBJIDN, DOSE1DT, DOSE99DT, EXSTDD, EXSTMM, EXSTYY, EXSTDY, EXENDT, EXSTDTC, EXENDTC, EXSTMN, EXSTHR, EXENMN, EXENHR, EXLOT, EXDELRO, EXINTRO, EXREDRO, EXENHR1, EXENMN1, EXSTHR1, EXSTMN1, EXENHR2, EXENMN2, EXSTHR2, EXSTMN2, EXSTDY2

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXSTDY	num	Relative Start Day of Dose		If EXSTDTC and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDTC less than REF.DATE then (EXSTDTC - REF.DATE).Else if EXSTDTC is greater than equal to REF.DATE then (EXSTDTC- REF.DATE) +1.
EXENDY	num	Relative End Day of Dose		If EXENDTC and REF.DATE not missing then perform below logic to calculate EXENDY, If EXENDTC less than REF.DATE then (EXENDTC - REF.DATE).Else if EXENDTC is greater than equal to REF.DATE then (EXENDTC- REF.DATE) +1.
EXSTTM	num	Start Time of Dose, 24 hr Clock		Collected at CRF.
EXENTM	num	End Time of Dose, 24 hr Clock		Collected at CRF.
EXDSDAY	char	Dose Day within each Cycle		Collected at CRF.
EXDSDAYN	num	Dose Day within each Cycle (Num)		Collected at CRF.
EXSEQ	num	Sequence Number		Collected at CRF.
BSA	num	Body Surface Area		Collected at CRF.
ROUTE	char	Route of Administration		Collected at CRF.
DOSE	num	Dose per Administration		Collected at CRF.
DOSEUNIT	char	Dose Units		Collected at CRF.
EXDEL	char	Dose Delayed		Collected at CRF.
EXINT	char	Dose Interrupted		Collected at CRF.
EXRED	char	Dose Reduced		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXDELRC	char	Dose Delayed Reason		Collected at CRF.
EXINTRC	char	Dose Interrupted Reason		Collected at CRF.
EXREDRC	char	Dose Reduced Reason		Collected at CRF.
EXDELRN	num	Dose Delayed Reason (Num)		Collected at CRF.
EXINTRN	num	Dose Interrupted Reason (Num)		Collected at CRF.
EXREDRN	num	Dose Reduced Reason (Num)		Collected at CRF.
EXENDT1	num	First Interruption Time		Collected at CRF.
EXSTDT1	num	First Restart Time		Collected at CRF.
EXENDT2	num	Second Interruption Time		Collected at CRF.
TOTALCYC	num	Total Number Cycles Dosed		Collected at CRF.
TOTALDS	num	Total Number Doses		Collected at CRF.
CYCGAP	num	Days Between Cycles		Collected at CRF.
CYCDSL	num	Dose Level Per Cycle (Mg/M2)		Collected at CRF.
DSLMAX	num	Maximum Dose Level (Mg/M2)		Collected at CRF.
DSLMEAN	num	Mean Dose Level (Mg/M2)		Collected at CRF.
CUMDSMG	num	Cumulative Dose (Mg)		Collected at CRF.
CUMDSL	num	Cumulative Dose (Mg/M2)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

## 1.4.13. Family History of Malignancy – FAMLYHX

<b>Dataset</b>	FAMLYHX
<b>Creating program</b>	familyhx.sas
<b>Description</b>	Family History of Malignancy
<b>Unique identifier</b>	DUSUBJID,RELATIVE,MALNONE,OVARIAN
<b>Sorted by</b>	DUSUBJID,RELATIVE,MALNONE,OVARIAN
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, OTHMALSP

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity-Randomized		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
RELATIVE	char	Relative		Collected at CRF.
MALNONE	char	No Family History of Malignancy		Collected at CRF.
OVARIAN	char	Ovarian Malignancy		Collected at CRF.
BREAST	char	Breast Malignancy		Collected at CRF.
COLON	char	Colon Malignancy		Collected at CRF.
OTHERMAL	char	Other Malignancy (Specify)		Collected at CRF.
RELAGE	char	Age at Diagnosis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

#### 1.4.14. Follow-Up – FOLLOWUP

<b>Dataset</b>	FOLLOWUP
<b>Creating program</b>	followup.sas
<b>Description</b>	Follow-Up
<b>Unique identifier</b>	DUSUBJID,VISIT,FUSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,FUSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, FUDD, FUMM, FUY, FUDT, FUDTC, PROGDD, PROGMM, PROGY, PROGDT, PROGDT, CHEMODD, CHEMOMM, CHEMOY, CHEMODT, CHEMODTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
FUND	char	Follow-Up not done		Collected at CRF.
FUYN	char	Was Follow-Up done		Collected at CRF.
FUTRTMN	num	Number of Months since End of TRT Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
FUDY	num	Relative Follow-Up Visit Day		If FUDTC and REF.DATE not missing then perform below logic to calculate FUDY, If FUDTC less than REF.DATE then (FUDTC - REF.DATE).Else if FUDTC is greater than equal to REF.DATE then (FUDTC- REF.DATE) +1.
FUPROG	char	Has Patients's Disease Progressed?		Collected at CRF.
FUPROGN	num	Has Patients's Disease Progressed? (Num)		Collected at CRF.
PROGDY	num	Relative Day of Progression		If PROGDTC and REF.DATE not missing then perform below logic to calculate PROGDY, If PROGDTC less than REF.DATE then (PROGDTC - REF.DATE).Else if PROGDTC is greater than equal to REF.DATE then (PROGDTC- REF.DATE) +1.
FUCHEMO	char	Received Additional Chemotherapy?		Collected at CRF.
FUCHEMON	num	Received Additional Chemotherapy? (Num)		Collected at CRF.
CHEMODY	num	Relative Start Day of Chemotherapy		If CHEMODTC and REF.DATE not missing then perform below logic to calculate CHEMODY, If CHEMODTC less than REF.DATE then (CHEMODTC - REF.DATE).Else if CHEMODTC is greater than equal to REF.DATE then (CHEMODTC- REF.DATE) +1.
FUALIVE	char	Is Patient Alive?		Collected at CRF.
FUALIVEN	num	Is Patient Alive? (Num)		Collected at CRF.

Variable	Type	Label	Codes	Comments
FUDTHRPT	char	If not Alive was Death Rpt Completed?		Collected at CRF.
FUSEQ	num	Sequence Number		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.15. Laboratory Data – LABS

<b>Dataset</b>	LABS
<b>Creating program</b>	labs.sas
<b>Description</b>	Laboratory Data
<b>Unique identifier</b>	DUSUBJID, LBTEST, LBORRES, VISITNUM, LBSEQ
<b>Sorted by</b>	DUSUBJID, LBTEST, LBORRES, VISITNUM, LBSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, LBDD, LBMM, LBYY, LBDT, LBDTC, LB1572, LABID

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REF.DATE not missing then perform below logic to calculate LBDY, If LBDTC less than REF.DATE then (LBDTC - REF.DATE).Else if LBDTC is greater than equal to REF.DATE then (LBDTC- REF.DATE) +1.
LBTEST	char	Lab Test Name		Collected at CRF.
LBSEQ	num	Sequence Number		Collected at CRF.
LBORRES	num	Result in Original Units		Collected at CRF.
LBORRESC	char	Result in Original Units		Collected at CRF.
LBORUNIT	char	Original Units		Collected at CRF.
LBORNRL0	num	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBGRP	char	Lab Group Name		Collected at CRF.
LBND	char	Not Done		Collected at CRF.
LBSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
MHDY	num	Relative Day of History Collection		If MHDTC and REF.DATE not missing then perform below logic to calculate MHDY, If MHDTC less than REF.DATE then (MHDTC - REF.DATE).Else if MHDTC is greater than equal to REF.DATE then (MHDTC- REF.DATE) +1.
MHBODSYS	char	Body System		Collected at CRF.
MHSTAT	char	Medical History or Condition Status		Collected at CRF.
MHSEQ	num	Sequence Number		Collected at CRF.
MHNONE	char	No Medical History Check Box per CRF		Collected at CRF.
MHIND	char	No Medical History Check Box per CRF		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.17. Physical Examination – PE

<b>Dataset</b>	PE
<b>Creating program</b>	pe.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	DUSUBJID,VISITNUM,PEBODSYS,PESEQ
<b>Sorted by</b>	DUSUBJID,VISITNUM,PEBODSYS,PESEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, PEDD, PEMM, PEYY, PEDT, PEDTC, PECM, PEFIND, PEREAS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
PEDY	num	Relative Day of Physical Exam		If PEDTC and REF.DATE not missing then perform below logic to calculate PEDY, If PEDTC less than REF.DATE then (PEDTC - REF.DATE).Else if PEDTC is greater than equal to REF.DATE then (PEDTC- REF.DATE) +1.
PEND	char	PE not done Check Box per CRF		Collected at CRF.
PEDONE	char	Physical Exam was Performed		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESEQ	num	Sequence Number		Collected at CRF.
PENORM	char	PE Normal as per Crf		Collected at CRF.
PENORMAL	char	Findings were Normal		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

### 1.4.18. Quality of Life Questionnaire – QOL

<b>Dataset</b>	QOL
<b>Creating program</b>	qol.sas
<b>Description</b>	Quality of Life Questionnaire
<b>Unique identifier</b>	DUSUBJID,QNUM,QDESC,QRESP
<b>Sorted by</b>	DUSUBJID,QNUM,QDESC,QRESP
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:                  SUBJIDN, DOSE1DT, DOSE99DT, VISDD, VISMM, VISYY, VISDT, VISDTC, QLNDOTH</p> <p><b>NOTE:</b> <i>It's noted that some records in the QOL data, where the QDESC variable had the description collected in non-English text. We leave the data as is without translation to ensure the data integrity from original source, however we'd assume for the same QNUM, QDESC stands for the same meaning regardless of language.</i></p> <p><i>In addition, as indicated in the CSR that there were changes made on the questions after the study has begun. With that, the QDESC reflected mixed description for questions 36-54, including old description matched with CRF, and new description matched with CSR Appendix per Amendment. We leave the data as is to reflect what's been collected to avoid confusion. Assume QOL response has been collected accordingly based on the question.</i></p>

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISDY	num	Relative Visit Day		If VISDTC and REF.DATE not missing then perform below logic to calculate VISDY, If VISDTC less than REF.DATE then (VISDTC - REF.DATE).Else if VISDTC is greater than equal to REF.DATE then (VISDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
QLND	char	Quality of Life not Done		Collected at CRF.
QLNDRSN	char	Reason Questionnaire was not Completed		Collected at CRF.
QNUM	char	Quality of Life Question Number		Collected at CRF.
QNUMN	num	Quality of Life Question Number (Num)		Collected at CRF.
QDESC	char	Quality of Life, Description		Collected at CRF.
QRESP	num	Quality of Life, Response		Collected at CRF.
QRESPC	char	Quality of Life, Response		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

## 1.4.19. Evaluation of Response – RESP

<b>Dataset</b>	RESP
<b>Creating program</b>	resp.sas
<b>Description</b>	Evaluation of Response
<b>Unique identifier</b>	DUSUBJID,VISITNUM
<b>Sorted by</b>	DUSUBJID,VISITNUM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, RSDD, RSMM, RSY, RSDT, RSDTC, ANALDT, CONF1DT, ENDCONDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
RSDY	num	Relative Evaluation Day		If RSDTC and REF.DATE not missing then perform below logic to calculate RSDY, If RSDTC less than REF.DATE then (RSDTC - REF.DATE).Else if RSDTC is greater than equal to REF.DATE then (RSDTC- REF.DATE) +1.
RSND	char	Evaluation of Response Not Done		Collected at CRF.
RSDONE	char	Evaluation of Response Was Done		Collected at CRF.
RSPONSEO	char	Response to Treatment (Orig)		Collected at CRF.
RSPONSEN	num	Response to Treatment (Num)		Collected at CRF.
RSPONSEC	char	Response to Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
RSSEQ	num	Sequence Number		Collected at CRF.
ANDTSRC	char	Source of Analysis Date		Collected at CRF.
BESTRESP	char	Best Response		Collected at CRF.
TM2DAYS	num	Time to Confirmed Response (Days)		Collected at CRF.
TM2CEN	num	Censor Value: Time to Response Code		Collected at CRF. (0= N (Not Censored), 1=Y ( Censored))
PDDAYS	num	Time to Progression (Days)		Collected at CRF.
PDCEN	num	Censor Value: Time to Progression Code		Collected at CRF. (0= N (Not Censored), 1=Y ( Censored))
DURDAYS	num	Duration of Confirmed Response (Days)		Collected at CRF.
DURCEN	num	Censor Value: Duration of Response Code		Collected at CRF. (0= N (Not Censored), 1= Y ( Censored))
PFSDAYS	num	Progression Free Survival (Days)		Collected at CRF.
PFSCEN	num	Censor: Progression Free Surv. Days Code		Collected at CRF. (0= N (Not Censored), 1= Y (Censored))
DAYSURV	num	Total No. Days Survived(wrt 1st dose dt)		Collected at CRF.
SRVCEN	num	Surv. Censor Flag Code		Collected at CRF. (0= N (Died), 1= Y (Did Not Die))

Variable	Type	Label	Codes	Comments
SRVCEN_C	char	Surv. Censor Flag		Collected at CRF. (Y= Did Not Die/ Censored, N= Died/ Not Censored)
TM2CEN_C	char	Censor Value: Time to Response		Collected at CRF. (Y= Censored, N= Not Censored)
PDCEN_C	char	Censor Value: Time to Progression		Collected at CRF. (Y= Censored, N= Not Censored)
DURCEN_C	char	Censor Value: Duration of Response		Collected at CRF. (Y= Censored, N= Not Censored)
PFSCEN_C	char	Censor: Progression Free Surv. Days		Collected at CRF. (Y= Censored, N= Not Censored)
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.
ANALDY	num	Relative Ending Day to Be Used In Resp. Analysis		If ANALDT and REF.DATE not missing then perform below logic to calculate ANALDY, If ANALDT less than REF.DATE then (ANALDT - REF.DATE).Else if ANALDT is greater than equal to REF.DATE then (ANALDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CONF1DY	num	Relative Day of First Confirmed Cr/Pr		If CONF1DT and REF.DATE not missing then perform below logic to calculate CONF1DY, If CONF1DT less than REF.DATE then (CONF1DT - REF.DATE).Else if CONF1DT is greater than equal to REF.DATE then (CONF1DT- REF.DATE) +1.
ENDCONDY	num	Relative End Day of Confirmed Response		If ENDCONDT and REF.DATE not missing then perform below logic to calculate ENDCONDY, If ENDCONDT less than REF.DATE then (ENDCONDT - REF.DATE).Else if ENDCONDT is greater than equal to REF.DATE then (ENDCONDT- REF.DATE) +1.

## 1.4.20. Transfusion Record – TRNFUSE

<b>Dataset</b>	TRNFUSE
<b>Creating program</b>	trnfuse.sas
<b>Description</b>	Transfusion Record
<b>Unique identifier</b>	DUSUBJID,TNFTYPE,TNFDONE
<b>Sorted by</b>	DUSUBJID,TNFTYPE,TNFDONE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, TNFDD, TNFMM, TNFY, TNFDT, TNFDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity-Randomized		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
TNFDONE	char	Transfusion Not Done		Collected at CRF.
TNFDONE	char	Transfusion Was Done		Collected at CRF.
TNFDY	num	Relative Transfusion Day		If TNFDTC and REF.DATE not missing then perform below logic to calculate TNFDY, If TNFDTC less than REF.DATE then (TNFDTC - REF.DATE).Else if TNFDTC is greater than equal to REF.DATE then (TNFDTC- REF.DATE) +1.
TNFTYPE	char	Blood Component		Collected at CRF.
TNFTYPEN	num	Blood Component (Num)		Collected at CRF.
TNFUNIT	char	Number of Units		Collected at CRF.
TNFUNITN	num	Number of Units (Num)		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.

#### 1.4.21. Chemotherapy – TUMCHEMO

<b>Dataset</b>	TUMCHEMO
<b>Creating program</b>	tumchemo.sas
<b>Description</b>	Chemotherapy
<b>Unique identifier</b>	DUSUBJID,MDNM,MDCYCN
<b>Sorted by</b>	DUSUBJID,MDNM,MDCYCN
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBJIDN, DOSE1DT, DOSE99DT, MDNONE, RECURDD, RECURMM, RECURYY, RECURDT, RECURDTC, MDBDD, MDBMM, MDBYY, MDBDT, MDBDTC, MDEDD, MDEMM, MDEYY, MDEDT, MDEDTC, MDCAT3, MDCATCD3, MDCAT4, MDCATCD4, MDCAT5, MDCATCD5

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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
MDRESPO	char	Best Response		Collected at CRF.
MDRESPC	char	Best Response		Collected at CRF.
MDRESPN	num	Best Response (Num)		Collected at CRF.
MDASSRSP	char	Method of Assessing Response		Collected at CRF.
MDASSRSN	num	Method of Assessing Response (Num)		Collected at CRF.

Variable	Type	Label	Codes	Comments
MDASSREL	char	Method of Assessing Relapse/Progression		Collected at CRF.
MDASSREN	num	Method of Assessing Relapse/Prog (Num)		Collected at CRF.
MDSTPRSC	char	Reason for Stopping Treatment		Collected at CRF.
MDSTPRSN	num	Reason for Stopping Treatment (Num)		Collected at CRF.
MDNM	char	Medication		Collected at CRF.
MDGEN	char	Medication Name (Generic)		Collected at CRF.
MDDS	char	Medication Dose		Collected at CRF.
MDUN	char	Medication Dose Units		Collected at CRF.
MDCYCN	char	Number of Cycles		Collected at CRF.
MDCAT1	char	Medication Category 1		Collected at CRF.
MDCATCD1	char	Medication Category 1 Code		Collected at CRF.
MDCAT2	char	Medication Category 2		Collected at CRF.
MDCATCD2	char	Medication Category 2 Code		Collected at CRF.
MDSRCE	char	Medication Category Source		Collected at CRF.
CARBO	char	Carboplatin Medication Given?		Collected at CRF.
CIS	char	Cisplatin Medication Given?		Collected at CRF.
ANTHRA	char	Anthracycline Medication Given?		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAXANE	char	Taxane Medication Given?		Collected at CRF.
PLATTAX	num	Prior Platinum and Taxane Therapy		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.
RECURDY	num	Relative Relapse/Progression Day		If RECURDTC and REF.DATE not missing then perform below logic to calculate RECURDY, If RECURDTC less than REF.DATE then (RECURDTC - REF.DATE).Else if RECURDTC is greater than equal to REF.DATE then (RECURDTC- REF.DATE) +1.
MDBDY	num	Relative Medication Start Day		If MDBDTC and REF.DATE not missing then perform below logic to calculate MDBDY, If MDBDTC less than REF.DATE then (MDBDTC - REF.DATE).Else if MDBDTC is greater than equal to REF.DATE then (MDBDTC- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MDEDY	num	Relative Medication Stop Day		If MDEDTC and REF.DATE not missing then perform below logic to calculate MDEDY, If MDEDTC less than REF.DATE then (MDEDTC - REF.DATE).Else if MDEDTC is greater than equal to REF.DATE then (MDEDTC- REF.DATE) +1.

#### 1.4.22. Radiotherapy – TUMRADIO

<b>Dataset</b>	TUMRADIO
<b>Creating program</b>	tumradio.sas
<b>Description</b>	Radiotherapy
<b>Unique identifier</b>	DUSUBJID,RADRESPO
<b>Sorted by</b>	DUSUBJID,RADRESPO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, RADBDD, RADBMM, RADBY, RADBDT, RADBDTC, RADEDD, RADEMM, RADEYY, RADEDT, RADEDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
RADNONE	char	No Radiotherapy Performed		Collected at CRF.
RADSITE	char	Specify Field		Collected at CRF.
RADRESPO	char	Response to Radiotherapy (Original)		Collected at CRF.
RADRESPC	char	Response to Radiotherapy		Collected at CRF.
RADRESPN	num	Response to Radiotherapy (Num)		Collected at CRF.
RADOS	char	Total Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
RADOSUN	char	Dose Units		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.
RADBDY	num	Relative Radiotherapy Start Day		If RADBDTC and REF.DATE not missing then perform below logic to calculate RADBDY, If RADBDTC less than REF.DATE then (RADBDTC - REF.DATE).Else if RADBDTC is greater than equal to REF.DATE then (RADBDTC- REF.DATE) +1.
RADEDY	num	Relative Radiotherapy Stop Day		If RADEDTC and REF.DATE not missing then perform below logic to calculate RADEDY, If RADEDTC less than REF.DATE then (RADEDTC - REF.DATE).Else if RADEDTC is greater than equal to REF.DATE then (RADEDTC- REF.DATE) +1.

## 1.4.23. Biopsy and Surgery – TUMSURG

<b>Dataset</b>	TUMSURG
<b>Creating program</b>	tumsurg.sas
<b>Description</b>	Biopsy and Surgery
<b>Unique identifier</b>	DUSUBJID,SURGNONE,SURGDMAX
<b>Sorted by</b>	DUSUBJID,SURGNONE,SURGDMAX
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, SURGDESC, SURGDD, SURGMM, SURGY, SURGDT, SURGDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSRAND	char	Platinum Sensitivity- Randomized		Collected at CRF.
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
SURGNONE	char	No Biopsy nor Surgery		Collected at CRF.
SURGDMAX	char	Surgical Debulking Maximal		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.
SURGDY	num	Relative Procedure Day		If SURGDTC and REF.DATE not missing then perform below logic to calculate SURGDY, If SURGDTC less than REF.DATE then (SURGDTC - REF.DATE).Else if SURGDTC is greater than equal to REF.DATE then (SURGDTC- REF.DATE) +1.

## 1.4.24. Vital Signs – VITALS

<b>Dataset</b>	VITALS
<b>Creating program</b>	vitals.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID,VISITNUM,SYSBP,DIABP,HEART, PULSE
<b>Sorted by</b>	DUSUBJID,VISITNUM,SYSBP,DIABP,HEART, PULSE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBJIDN, DOSE1DT, DOSE99DT, VSDD, VSMM, VSY, VSDT, VSDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-Identity		Randomly assigned Site ID for De-Identity
DUSUBJID	char	Unique Subject ID Assign for De-Identity		Randomly assigned Unique Subject ID for De-Identity
DSUBJID	char	Subject ID Assigned for De-Identity		Randomly assigned Subject ID for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTCD	num	Treatment Code		Collected at CRF.
PSRAND	char	Platinum Sensitivity-Randomized		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSSPON	char	Platinum Sensitivity- Sponsor		Collected at CRF.
PS	char	Platinum Sensitivity- Modified		Collected at CRF.
BDRAND	char	Bulky Disease- Randomized		Collected at CRF.
BD	char	Bulky Disease- Modified		Collected at CRF.
ITT	char	Intent-to-Treat Population?		Collected at CRF.
EVALUABL	char	Patient Evaluable?		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
DCYCLE	num	Actual Dose Cycle		Collected at CRF.
VSDY	num	Relative Day of Collection		If VSDTC and REF.DATE not missing then perform below logic to calculate VSDY, If VSDTC less than REF.DATE then (VSDTC - REF.DATE).Else if VSDTC is greater than equal to REF.DATE then (VSDTC- REF.DATE) +1.
SYSBP	num	Systolic Blood Pressure in mm Hg		Collected at CRF.
DIABP	num	Diastolic Blood Pressure in mm Hg		Collected at CRF.
HEART	num	Heart Rate in BPM		Collected at CRF.
PULSE	num	Pulse Rate in BPM		Collected at CRF.
TMP	num	Temperature in original unit		Collected at CRF.
TMPUNIT	char	Original unit for temperature		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEMP	num	Temperature in Degrees Centigrade		Collected at CRF.
KS	num	Karnofsky Score		Collected at CRF.
HT	num	Height in Original Units		Collected at CRF.
HTUNIT	char	Original Height Unit		Collected at CRF.
WT	num	Weight in Original Units		Collected at CRF.
WTUNIT	char	Original Weight Unit		Collected at CRF.
WEIGHT	num	Weight in Kilograms		Collected at CRF.
HEIGHT	num	Height in Centimeters		Collected at CRF.
PRE	char	Pre-Treatment Check Box per CRF		Collected at CRF.
EOSF	char	Eosf		Collected at CRF.
VSND	char	Vitals Not Done Check Box per CRF		Collected at CRF.
VSIND	char	Were Vitals Done?		Collected at CRF.
DOSE1DY	num	Relative First Dose Day		If DOSE1DT and REF.DATE not missing then perform below logic to calculate DOSE1DY, If DOSE1DT less than REF.DATE then (DOSE1DT - REF.DATE).Else if DOSE1DT is greater than equal to REF.DATE then (DOSE1DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DOSE99DY	num	Relative Last Dose Day		If DOSE99DT and REF.DATE not missing then perform below logic to calculate DOSE99DY, If DOSE99DT less than REF.DATE then (DOSE99DT - REF.DATE).Else if DOSE99DT is greater than equal to REF.DATE then (DOSE99DT- REF.DATE) +1.