Clinical Development

JNJ-7472179

EPO_INT76

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

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.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- 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 and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- 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.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty comments data will be submitted due to sensitivity of data.
- Comments (COMMENT) dataset will be submitted with zero observation due to sensitivity of data.
- COMMENT2, MIXEDMOD datasets have zero observation, hence will not be submitted.
- ACT1, ACT2, ACT3, ACT4, ENER1, ENER2, ENER3, ENER4, FACTG1, FACTG2, FACTG3, FACTG4, FATS1, FATS2, FATS3, FATS4, NFATS1, NFATS2, NFATS3, NFATS4, OVER1, OVER2, OVER3, OVER4 datasets will not be submitted as it contains zero variable and zero observation.
- In CARDEV dataset after removing the sensitive information, no significant information is available. Hence, dataset will not be submitted.
- COUNTRY dataset does not contain any patient level information apart from country. Hence the COUNTRY dataset will not be submitted.
- Dataset containing sensitive information about medication kit will not be submitted. (eg. KITLOT)
- Due to sensitive information CDL_DAT2, COMOTHER, COMPDTH, COMPDTH2, COMPDTH3 datasets will not be submitted.
- DEMOG.EVDATE will be used as a Reference Date to derive relative days (referred as REF.DATE in the document).

1.3. Data Files

The EPO_INT76 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHICS – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	DEMOGRAPHICS
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REC_ID,SCTRY,BIRTHD,BIRTHDT,EVDAT,EVDATE,RACESPEC Below listed variables were not parts of the Raw dataset. These have been added to retain the Demographic related information in the de-identified datasets: CNTRY(Source: PROFILE dataset) SITESZ(Source: ALL_QOL dataset) AGE (Source: PROFILE dataset) AGEUNIT (Source: PROFILE dataset)

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
RACE	char	SUBJECT'S RACE		Collected at CRF.
SEX	char	SUBJECT'S GENDER		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
DCNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITESZ	num	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned site ID for De-Identity.
AGE	char	AGE(Y)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEUNIT	char	UNIT FOR AGE		Collected at CRF.

1.4.2.ALL_QOL – ALL_QOL

Dataset	ALL_QOL
Creating program	all_qol.sas
Description	ALL_QOL
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REGIONF,RANDDN,DIAGDT,DIAGIVDT,DIAGDN,DIAGIVDN,FCHEMODN, FCHEMEND,COUNTRY,INVNAME,RACE,RACEF,BIRTHDN,IVRSDT,INIT, OTHRSPEC,STATUSDN,FSMEDDN,LSMEDDN,PRECTST,PRECTSP,PREHTST, PREHTSP,PREITST,PREITSP,PRERTST,PRERTSP,ADJCTST,ADJCTSP,ADJHTST, ADJHTSP,ADJITST,ADJITSP,ADJRTST,ADJRTSP,METCTST,METCTSP,METHTST, METHTSP,METITST,METITSP,METRTST,METRTSP,ONCTST,ONCTSP,ONHTST, ONHTSP,ONRTST,ONRTSP,SITESZ,ADJTHST,ADJTHSP,AGE,DEATHDN,ALIVEDN, DATE1,DATE2,DATE3,PROGDT,ONSETDN

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
BLHB	num	BLHB		Collected at CRF.
BIRON	num	BIRON		Collected at CRF.
BLDH	num	BLDH		Collected at CRF.
BASEHGT	num	BASELINE HEIGHT (CM)		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASEWGT	num	BASELINE WEIGHT (KG)		Collected at CRF.
STRATI	num	CORRECT STRATIFICATION		Collected at CRF.
STRATIF	char	DECODING,STRATI BO/OTHER		Collected at CRF.
STRAT	num	STRAT		Collected at CRF.
STRATF	char	DECODE, STRAT		Collected at CRF.
MDSTRATF	char	MDSTRATF		Collected at CRF.
MDSTRAT	num	MDSTRAT		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CSTRATF	char	DECODE, CSTRAT		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
STATUS	num	COMPLETION STATUS		Collected at CRF.
REASONF	char	DECODING, REASON FOR WITHDRAWAL		Collected at CRF.
STATUSF	char	DECODING, COMPLETION STATUS		Collected at CRF.
PRECHEMO	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PREHORMO	num	PREHORMO		Collected at CRF.
PREIMMUN	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PRERADTH	num	PRERADTH		Collected at CRF.

Variable	Type	Label	Codes	Comments
METCHEMO	num	METCHEMO		Collected at CRF.
METHORMO	num	METHORMO		Collected at CRF.
METIMMUN	num	METIMMUN		Collected at CRF.
METRADTH	num	METRADTH		Collected at CRF.
ADJCHEMO	num	ADJCHEMO		Collected at CRF.
ADJHORMO	num	ADJHORMO		Collected at CRF.
ADJIMMUN	num	ADJIMMUN		Collected at CRF.
ADJRADTH	num	ADJRADTH		Collected at CRF.
ONCHEMO	num	ONCHEMO		Collected at CRF.
ONHORMO	num	ONHORMO		Collected at CRF.
ONRADTH	num	ONRADTH		Collected at CRF.
METHOTRX	num	METHOTRX		Collected at CRF.
TAMOXIFN	num	TAMOXIFN		Collected at CRF.
ADJTRT	num	ADJTRT		Collected at CRF.
PRETRT	num	PRETRT		Collected at CRF.
ADJCRAD	num	ADJCRAD		Collected at CRF.
TAMOCHEM	num	TAMOCHEM		Collected at CRF.
ASCITES	num	ASCITES		Collected at CRF.
PLEUEFF	num	PLEURAL EFFUSION		Collected at CRF.
ECOGSTAT	num	ECOG STATUS		Collected at CRF.
ERRESULT	num	ESTROGEN RECEPTOR RESULT		Collected at CRF.

Variable	Type	Label	Codes	Comments
METBONE	char	BONE METASTASIS		Collected at CRF.
POSTMENO	char	POSTMENOPAUSAL		Collected at CRF.
STAGDIAG	num	STAGE AT DIAGNOSIS		Collected at CRF.
BONE	num	BONE		Collected at CRF.
RBREAST	num	RBREAST		Collected at CRF.
LIVER	num	LIVER		Collected at CRF.
LBREAST	num	LBREAST		Collected at CRF.
LUNG	num	LUNG LESION YES/NO		Collected at CRF.
SKIN	num	SKIN		Collected at CRF.
NLESION	num	NUMBER OF LESIONS		Collected at CRF.
OTHRLES	num	OTHRLES		Collected at CRF.
NLESITE	num	NLESITE		Collected at CRF.
ACTIVITY	num	ACTIVITY		Collected at CRF.
ANS	num	FACT-AN: TOTAL ANEMIN SUBSCALE SCORE		Collected at CRF.
ENERGY	num	CLAS: ENERGY		Collected at CRF.
EWB	num	FACT-AN: EMOTIONAL WELL-BEING		Collected at CRF.
FACTG	num	FACT-AN: FACT-G TOTAL SCORE		Collected at CRF.
FATS	num	FACT-AN: FATIGUE SUBSCALE SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
FWB	num	FACT-AN: FUNCTIONAL WELL-BEING		Collected at CRF.
NFATS	num	FACT-AN: NON-FATIGUE SUBSCALE SCORE		Collected at CRF.
OVERALL	num	CLAS: OVERALL QUALITY-OF-LIFE		Collected at CRF.
PWB	num	FACT-AN: PHYSICAL WELL-BEING		Collected at CRF.
SFWB	num	FACT-AN: SOCIAL/FAMILY WELL-BEING		Collected at CRF.
TOI	num	FACT-AN: TOI SCORE		Collected at CRF.
TOTAL	num	FACT-AN: FACT-ANEMIA TOTAL SCORE		Collected at CRF.
TOTFAT	num	FACT-AN: FACT-FATIGUE TOTAL SCORE		Collected at CRF.
CLASMIS	num	CLASMIS		Collected at CRF.
FACTMIS	num	FACTMIS		Collected at CRF.
QOLMIS	num	QOLMIS		Collected at CRF.
BSA	num	BASELINE BODY SURFACE AREA		Collected at CRF.
BMI	num	BODY MASS INDEX		Collected at CRF.
TDIAGIV	num	TDIAGIV		Collected at CRF.
TDIAG	num	TDIAG		Collected at CRF.
IVIDIAG	num	IVIDIAG		Collected at CRF.
IVADJSP	num	IVADJSP		Collected at CRF.

Variable	Type	Label	Codes	Comments
IVMHTSP	num	IVMHTSP		Collected at CRF.
NWINST	num	NWINST		Collected at CRF.
STRAT1	num	STRAT1		Collected at CRF.
STRAT2	num	STRAT2		Collected at CRF.
STRAT3	num	STRAT3		Collected at CRF.
ENROLDAY	num	ENROLDAY		Collected at CRF.
MEDRAND	num	MEDRAND		Collected at CRF.
QRAND1	num	QRAND1		Collected at CRF.
QRAND2	num	QRAND2		Collected at CRF.
QRAND3	num	QRAND3		Collected at CRF.
QRAND4	num	QRAND4		Collected at CRF.
QRAND	num	QRAND		Collected at CRF.
MEDAGE	char	MEDAGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
QAGE1	char	QAGE1		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
QAGE2	char	QAGE2		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.

Variable	Type	Label	Codes	Comments
QAGE3	char	QAGE3		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
QAGE4	char	QAGE4		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
QAGE	char	QAGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
QBHB1	num	QBHB1		Collected at CRF.
QBHB2	num	QBHB2		Collected at CRF.
QBHB3	num	QBHB3		Collected at CRF.
QBHB4	num	QBHB4		Collected at CRF.
QBHB	num	QBHB		Collected at CRF.
MEDBIRON	num	MEDBIRON		Collected at CRF.
QBIRON1	num	QBIRON1		Collected at CRF.
QBIRON2	num	QBIRON2		Collected at CRF.
QBIRON3	num	QBIRON3		Collected at CRF.
QBIRON4	num	QBIRON4		Collected at CRF.
QBIRON	num	QBIRON		Collected at CRF.
MEDBLDH	num	MEDBLDH		Collected at CRF.
QBLDH1	num	QBLDH1		Collected at CRF.
QBLDH2	num	QBLDH2		Collected at CRF.

Variable	Type	Label	Codes	Comments
QBLDH3	num	QBLDH3		Collected at CRF.
QBLDH4	num	QBLDH4		Collected at CRF.
QBLDH	num	QBLDH		Collected at CRF.
MEDWGT	num	MEDWGT		Collected at CRF.
QBWGT1	num	QBWGT1		Collected at CRF.
QBWGT2	num	QBWGT2		Collected at CRF.
QBWGT3	num	QBWGT3		Collected at CRF.
QBWGT4	num	QBWGT4		Collected at CRF.
QBWGT	num	QBWGT		Collected at CRF.
MEDBSA	num	MEDBSA		Collected at CRF.
QBSA1	num	QBSA1		Collected at CRF.
QBSA2	num	QBSA2		Collected at CRF.
QBSA3	num	QBSA3		Collected at CRF.
QBSA4	num	QBSA4		Collected at CRF.
QBSA	num	QBSA		Collected at CRF.
MEDBMI	num	MEDBMI		Collected at CRF.
QBMI1	num	QBMI1		Collected at CRF.
QBMI2	num	QBMI2		Collected at CRF.
QBMI3	num	QBMI3		Collected at CRF.
QBMI4	num	QBMI4		Collected at CRF.
QBMI	num	QBMI		Collected at CRF.

Variable	Type	Label	Codes	Comments
BMICAT	num	BMICAT		Collected at CRF.
UNDERWGT	num	UNDER WEIGHT		Collected at CRF.
NORMALWT	num	NORMAL WEIGHT		Collected at CRF.
OVERWGT1	num	OVER WEIGHT1		Collected at CRF.
OVERWGT2	num	OVER WEIGHT2		Collected at CRF.
OBESE	num	OBESE		Collected at CRF.
ECOG0	num	ECOG0		Collected at CRF.
ECOG1	num	ECOG1		Collected at CRF.
ECOG2	num	ECOG2		Collected at CRF.
ERNEG	num	ERNEG		Collected at CRF.
ERPOS	num	ERPOS		Collected at CRF.
ERMIS	num	ERMIS		Collected at CRF.
BMYES	num	BMYES		Collected at CRF.
BMNO	num	BMNO		Collected at CRF.
LIVLUNG	num	LIVLUNG		Collected at CRF.
VISCE	num	VISCE		Collected at CRF.
MEDBHB	num	MEDBHB		Collected at CRF.
PMYES	num	PMYES		Collected at CRF.
PMNO	num	PMNO		Collected at CRF.
WHITE	num	WHITE		Collected at CRF.
ISTAGE1	num	ISTAGE1		Collected at CRF.

Variable	Type	Label	Codes	Comments
ISTAGE2	num	ISTAGE2		Collected at CRF.
ISTAGE3	num	ISTAGE3		Collected at CRF.
ISTAGE4	num	ISTAGE4		Collected at CRF.
SMEDYN	num	SMEDYN		Collected at CRF.
MEDTDIAG	num	MEDTDIAG		Collected at CRF.
QTDIAG1	num	QTDIAG1		Collected at CRF.
QTDIAG2	num	QTDIAG2		Collected at CRF.
QTDIAG3	num	QTDIAG3		Collected at CRF.
QTDIAG4	num	QTDIAG4		Collected at CRF.
QTDIAG	num	QTDIAG		Collected at CRF.
MEDTDIV	num	MEDTDIV		Collected at CRF.
QTDIV1	num	QTDIV1		Collected at CRF.
QTDIV2	num	QTDIV2		Collected at CRF.
QTDIV3	num	QTDIV3		Collected at CRF.
QTDIV4	num	QTDIV4		Collected at CRF.
QTDIV	num	QTDIV		Collected at CRF.
MEDTDIVI	num	MEDTDIVI		Collected at CRF.
QTDIVI1	num	QTDIVI1		Collected at CRF.
QTDIVI2	num	QTDIVI2		Collected at CRF.
QTDIVI3	num	QTDIVI3		Collected at CRF.
QTDIVI4	num	QTDIVI4		Collected at CRF.

Variable	Type	Label	Codes	Comments
QTDIVI	num	QTDIVI		Collected at CRF.
QIVADJ1	num	QIVADJ1		Collected at CRF.
QIVADJ2	num	QIVADJ2		Collected at CRF.
QIVADJ3	num	QIVADJ3		Collected at CRF.
QIVADJ4	num	QIVADJ4		Collected at CRF.
MEDIVADJ	num	MEDIVADJ		Collected at CRF.
QIVADJ	num	QIVADJ		Collected at CRF.
CIVADJ	num	CIVADJ		Collected at CRF.
CIVADJ0	num	CIVADJ0		Collected at CRF.
CIVADJ1	num	CIVADJ1		Collected at CRF.
CIVADJ2	num	CIVADJ2		Collected at CRF.
CIVADJ9	num	CIVADJ9		Collected at CRF.
QIVMHT1	num	QIVMHT1		Collected at CRF.
QIVMHT2	num	QIVMHT2		Collected at CRF.
QIVMHT3	num	QIVMHT3		Collected at CRF.
QIVMHT4	num	QIVMHT4		Collected at CRF.
QIVMHT9	num	QIVMHT9		Collected at CRF.
MEDIVMHT	num	MEDIVMHT		Collected at CRF.
QIVMHT	num	QIVMHT		Collected at CRF.
MEDSITE	num	MEDSITE		Collected at CRF.
QSTSZ1	num	QSTSZ1		Collected at CRF.

Variable	Type	Label	Codes	Comments
QSTSZ2	num	QSTSZ2		Collected at CRF.
QSTSZ3	num	QSTSZ3		Collected at CRF.
QSTSZ4	num	QSTSZ4		Collected at CRF.
QSTSZ	num	QSTSZ		Collected at CRF.
TRT	num	TRT		Collected at CRF.
CAUDEATH	num	CAUSE OF DEATH		Collected at CRF.
DEATH	num	DID SUBJECT DIE?		Collected at CRF.
MDCAUSEF	char	DECODE, MDCAUSE		Collected at CRF.
MDCAUSE	num	CAUSE OF DEATH		Collected at CRF.
T_DEATH	num	TIME IN DAYS TO DEATH		Collected at CRF.
DBDEATH	num	DEATH AT DB 0=NO 1=YES		Collected at CRF.
T_DBDEA	num	TIME IN DAYS TO DEATH AT DB		Collected at CRF.
EARLY4	num	EARLY4		Collected at CRF.
EARLY6	num	EARLY6		Collected at CRF.
T_EARLY4	num	T_EARLY4		Collected at CRF.
T_EARLY6	num	T_EARLY6		Collected at CRF.
TDIESMED	num	TDIESMED		Collected at CRF.
RESP1	num	RESP1		Collected at CRF.
RESP2	num	RESP2		Collected at CRF.
RESP3	num	RESP3		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_PROG	num	CENSORING STATUS TUMOR RESPONCE		Collected at CRF.
C_PROG2	num	CENCORING PROGRESSION-FREE TUMOR RESP		Collected at CRF.
T_PROG	num	TIME TO DISEASE PROGRESSION		Collected at CRF.
OPRESP	num	OPTIMAL TUMOR RESPONSE		Collected at CRF.
PREFTERM	char	PREFTERM		Collected at CRF.
TVE	num	TVE		Collected at CRF.
TFTVE	num	TFTVE		Collected at CRF.
SUMUNIT	num	SUMUNIT		Collected at CRF.
TRAN	num	TRAN		Collected at CRF.
NUMMON	num	NUMMON		Collected at CRF.
LOGMON	num	LOGMON		Collected at CRF.
URATE	num	URATE		Collected at CRF.
TRUEWD	num	TRUEWD		Collected at CRF.
TIMEWD	num	TIMEWD		Collected at CRF.
REGION	num	REGION		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.
BLANEM	num	BLANEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGECAT	num	AGECAT		Collected at CRF.
AGECATF	char	AGECATF		Collected at CRF.
RANDDY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RANDDN and REF.DATE not missing then perform below logic to calculate RAND_DY, If RANDDN less than REF.DATE then (RANDDN - REF.DATE). Else if RANDDN is greater than equal to REF.DATE then (RANDDN- REF.DATE) +1.
DIAGDY	num	RELATIVE DAY OF INITIAL DIAGNOSIS		If DIAGDN and REF.DATE not missing then perform below logic to calculate DIAGDY, If DIAGDN less than REF.DATE then (DIAGDN - REF.DATE). Else if DIAGDN is greater than equal to REF.DATE then (DIAGDN- REF.DATE) +1.
DIAGIVDY	num	RELATIVE DAY OF META DIAGNOSIS		If DIAGIVDN and REF.DATE not missing then perform below logic to calculate DIAGV_DY, If DIAGIVDN less than REF.DATE then (DIAGIVDN - REF.DATE). Else if DIAGIVDN is greater than equal to REF.DATE then (DIAGIVDN- REF.DATE) +1.
FCHEMODY	num	RELATIVE FCHEMO DAY		If FCHEMODN and REF.DATE not missing then perform below logic to calculate FCHEMODY, If FCHEMODN less than REF.DATE then (FCHEMODN - REF.DATE). Else if FCHEMODN is greater than equal to REF.DATE then (FCHEMODN- REF.DATE) +1.
FCHEMNDY	num	RELATIVE END OF FIRST LINE CHEMO DAY		If FCHEMEND and REF.DATE not missing then perform below logic to calculate FCHEMNDY, If FCHEMEND less than REF.DATE then (FCHEMEND - REF.DATE). Else if FCHEMEND is greater than equal to REF.DATE then (FCHEMEND- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
IVRSDY	num	RELATIVE RANDOMIZATION DAY FROM IVRS		If IVRSDT and REF.DATE not missing then perform below logic to calculate IVRSDY, If IVRSDT less than REF.DATE then (IVRSDT - REF.DATE). Else if IVRSDT is greater than equal to REF.DATE then (IVRSDT-REF.DATE) +1.
STATUSDY	num	RELATIVE COMPLETION/WITHDRAWAL DAY		If STATUSDN and REF.DATE not missing then perform below logic to calculate STATSNDY, If STATUSDN less than REF.DATE then (STATUSDN - REF.DATE). Else if STATUSDN is greater than equal to REF.DATE then (STATUSDN- REF.DATE) +1.
FSMEDDY	num	RELATIVE FSMED DAY		If FSMEDDN and REF.DATE not missing then perform below logic to calculate FSMEDDY, If FSMEDDN less than REF.DATE then (FSMEDDN - REF.DATE). Else if FSMEDDN is greater than equal to REF.DATE then (FSMEDDN- REF.DATE) +1.
LSMEDDY	num	RELATIVE LSMED DAY		If LSMEDDN and REF.DATE not missing then perform below logic to calculate LSMEDDY, If LSMEDDN less than REF.DATE then (LSMEDDN - REF.DATE). Else if LSMEDDN is greater than equal to REF.DATE then (LSMEDDN- REF.DATE) +1.
PRECTSDY	num	RELATIVE SMALLEST DAY-PRECTST		If PRECTST and REF.DATE not missing then perform below logic to calculate PRECTSDY, If PRECTST less than REF.DATE then (PRECTST - REF.DATE). Else if PRECTST is greater than equal to REF.DATE then (PRECTST- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
PRECSPDY	num	RELATIVE LARGEST DAY-PRECTSP		If PRECTSP and REF.DATE not missing then perform below logic to calculate PRECSPDY, If PRECTSP less than REF.DATE then (PRECTSP - REF.DATE). Else if PRECTSP is greater than equal to REF.DATE then (PRECTSP- REF.DATE) +1.
PREHDY	num	RELATIVE SMALLEST DAY-PREHTST		If PREHTST and REF.DATE not missing then perform below logic to calculate PREHDY, If PREHTST less than REF.DATE then (PREHTST - REF.DATE). Else if PREHTST is greater than equal to REF.DATE then (PREHTST- REF.DATE) +1.
PREHSPDY	num	RELATIVE LARGEST DAY-PREHTSP		If PREHTSP and REF.DATE not missing then perform below logic to calculate PREHSPDY, If PREHTSP less than REF.DATE then (PREHTSP - REF.DATE). Else if PREHTSP is greater than equal to REF.DATE then (PREHTSP- REF.DATE) +1.
PRITSTDY	num	RELATIVE SMALLEST DAY-PREITST		If PREITST and REF.DATE not missing then perform below logic to calculate PRITSTDY, If PREITST less than REF.DATE then (PREITST - REF.DATE). Else if PREITST is greater than equal to REF.DATE then (PREITST- REF.DATE) +1.
PRITSPDY	num	RELATIVE LARGEST DAY-PREITSP		If PREITSP and REF.DATE not missing then perform below logic to calculate PRITSPDY, If PREITSP less than REF.DATE then (PREITSP - REF.DATE). Else if PREITSP is greater than equal to REF.DATE then (PREITSP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
PRRTSTDY	num	RELATIVE SMALLEST DAY-PRERTST		If PRERTST and REF.DATE not missing then perform below logic to calculate PRRTSTDY, If PRERTST less than REF.DATE then (PRERTST - REF.DATE). Else if PRERTST is greater than equal to REF.DATE then (PRERTST- REF.DATE) +1.
PRRTSPDY	num	RELATIVE LARGEST DAY-PRERTSP		If PRERTSP and REF.DATE not missing then perform below logic to calculate PRRTSPDY, If PRERTSP less than REF.DATE then (PRERTSP - REF.DATE). Else if PRERTSP is greater than equal to REF.DATE then (PRERTSP- REF.DATE) +1.
ADJCSTDY	num	RELATIVE SMALLEST DAY-ADJCTST		If ADJCTST and REF.DATE not missing then perform below logic to calculate ADJCSTDY, If ADJCTST less than REF.DATE then (ADJCTST - REF.DATE). Else if ADJCTST is greater than equal to REF.DATE then (ADJCTST- REF.DATE) +1.
ADJCSPDY	num	RELATIVE LARGEST DAY-ADJCTSP		If ADJCTSP and REF.DATE not missing then perform below logic to calculate ADJCSPDY, If ADJCTSP less than REF.DATE then (ADJCTSP - REF.DATE). Else if ADJCTSP is greater than equal to REF.DATE then (ADJCTSP- REF.DATE) +1.
ADHTSTDY	num	RELATIVE SMALLEST DAY-ADJHTST		If ADJHTST and REF.DATE not missing then perform below logic to calculate ADHTSTDY, If ADJHTST less than REF.DATE then (ADJHTST - REF.DATE). Else if ADJHTST is greater than equal to REF.DATE then (ADJHTST- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADHTSPDY	num	RELATIVE LARGEST DAY-ADJHTSP		If ADJHTSP and REF.DATE not missing then perform below logic to calculate ADHTSPDY, If ADJHTSP less than REF.DATE then (ADJHTSP - REF.DATE). Else if ADJHTSP is greater than equal to REF.DATE then (ADJHTSP- REF.DATE) +1.
ADJTSTDY	num	RELATIVE SMALLEST DAY-ADJITST		If ADJITST and REF.DATE not missing then perform below logic to calculate ADJTSTDY, If ADJITST less than REF.DATE then (ADJITST - REF.DATE). Else if ADJITST is greater than equal to REF.DATE then (ADJITST- REF.DATE) +1.
ADJIT_DY	num	RELATIVE LARGEST DAY-ADJITSP		If ADJITSP and REF.DATE not missing then perform below logic to calculate ADJTSTDY, If ADJITSP less than REF.DATE then (ADJITSP - REF.DATE). Else if ADJITSP is greater than equal to REF.DATE then (ADJITSP- REF.DATE) +1.
ADRTSTDY	num	RELATIVE SMALLEST DAY-ADJRTST		If ADJRTST and REF.DATE not missing then perform below logic to calculate ADRTSTDY, If ADJRTST less than REF.DATE then (ADJRTST - REF.DATE). Else if ADJRTST is greater than equal to REF.DATE then (ADJRTST- REF.DATE) +1.
ADRTSPDY	num	RELATIVE LARGEST DAY-ADJRTSP		If ADJRTSP and REF.DATE not missing then perform below logic to calculate ADRTSPDY, If ADJRTSP less than REF.DATE then (ADJRTSP - REF.DATE). Else if ADJRTSP is greater than equal to REF.DATE then (ADJRTSP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
METCTSDY	num	RELATIVE SMALLEST DAY-METCTST		If METCTST and REF.DATE not missing then perform below logic to calculate METCTSDY, If METCTST less than REF.DATE then (METCTST - REF.DATE). Else if METCTST is greater than equal to REF.DATE then (METCTST- REF.DATE) +1.
METCT_DY	num	RELATIVE LARGEST DAY-METCTSP		If METCTSP and REF.DATE not missing then perform below logic to calculate METCTSDY, If METCTSP less than REF.DATE then (METCTSP - REF.DATE). Else if METCTSP is greater than equal to REF.DATE then (METCTSP- REF.DATE) +1.
METHTSDY	num	RELATIVE SMALLEST DAY-METHTST		If METHTST and REF.DATE not missing then perform below logic to calculate METHTSDY, If METHTST less than REF.DATE then (METHTST - REF.DATE). Else if METHTST is greater than equal to REF.DATE then (METHTST- REF.DATE) +1.
METHSPDY	num	RELATIVE LARGEST DAY-METHTSP		If METHTSP and REF.DATE not missing then perform below logic to calculate METHSPDY, If METHTSP less than REF.DATE then (METHTSP - REF.DATE). Else if METHTSP is greater than equal to REF.DATE then (METHTSP- REF.DATE) +1.
MTITSTDY	num	RELATIVE SMALLEST DAY-METITST		If METITST and REF.DATE not missing then perform below logic to calculate MTITSTDY, If METITST less than REF.DATE then (METITST - REF.DATE). Else if METITST is greater than equal to REF.DATE then (METITST- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MTITSPDY	num	RELATIVE LARGEST DAY-METITSP		If METITSP and REF.DATE not missing then perform below logic to calculate MTITSPDY, If METITSP less than REF.DATE then (METITSP - REF.DATE). Else if METITSP is greater than equal to REF.DATE then (METITSP- REF.DATE) +1.
METRTSDY	num	RELATIVE SMALLEST DAY-METRTST		If METRTST and REF.DATE not missing then perform below logic to calculate METRTSDY, If METRTST less than REF.DATE then (METRTST - REF.DATE). Else if METRTST is greater than equal to REF.DATE then (METRTST- REF.DATE) +1.
METRSPDY	num	RELATIVE LARGEST DAY-METRTSP		If METRTSP and REF.DATE not missing then perform below logic to calculate METRSPDY, If METRTSP less than REF.DATE then (METRTSP - REF.DATE). Else if METRTSP is greater than equal to REF.DATE then (METRTSP- REF.DATE) +1.
ONCTSTDY	num	RELATIVE SMALLEST DAY-ONCTST		If ONCTST and REF.DATE not missing then perform below logic to calculate ONCTSTDY, If ONCTST less than REF.DATE then (ONCTST - REF.DATE). Else if ONCTST is greater than equal to REF.DATE then (ONCTST- REF.DATE) +1.
ONCTSPDY	num	RELATIVE LARGEST DAY-ONCTSP		If ONCTSP and REF.DATE not missing then perform below logic to calculate ONCTSPDY, If ONCTSP less than REF.DATE then (ONCTSP - REF.DATE). Else if ONCTSP is greater than equal to REF.DATE then (ONCTSP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ONHTSDY	num	RELATIVE SMALLEST DAY-ONHTST		If ONHTST and REF.DATE not missing then perform below logic to calculate ONHTSDY, If ONHTST less than REF.DATE then (ONHTST - REF.DATE). Else if ONHTST is greater than equal to REF.DATE then (ONHTST- REF.DATE) +1.
ONHTSPDY	num	RELATIVE LARGEST DAY-ONHTSP		If ONHTSP and REF.DATE not missing then perform below logic to calculate ONHTSPDY, If ONHTSP less than REF.DATE then (ONHTSP - REF.DATE). Else if ONHTSP is greater than equal to REF.DATE then (ONHTSP- REF.DATE) +1.
ONRTSTDY	num	RELATIVE SMALLEST DAY-ONRTST		If ONRTST and REF.DATE not missing then perform below logic to calculate ONRTSTDY, If ONRTST less than REF.DATE then (ONRTST - REF.DATE). Else if ONRTST is greater than equal to REF.DATE then (ONRTST- REF.DATE) +1.
ONRTSDY	num	RELATIVE LARGEST DAY-ONRTSP		If ONRTSP and REF.DATE not missing then perform below logic to calculate ONRTSDY, If ONRTSP less than REF.DATE then (ONRTSP - REF.DATE). Else if ONRTSP is greater than equal to REF.DATE then (ONRTSP- REF.DATE) +1.
ADTHSTDY	num	RELATIVE ADJTHST DAY		If ADJTHST and REF.DATE not missing then perform below logic to calculate ADTHSTDY, If ADJTHST less than REF.DATE then (ADJTHST - REF.DATE). Else if ADJTHST is greater than equal to REF.DATE then (ADJTHST- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADTHSPDY	num	RELATIVE ADJTHSP DAY		If ADJTHSP and REF.DATE not missing then perform below logic to calculate ADTHSPDY, If ADJTHSP less than REF.DATE then (ADJTHSP - REF.DATE). Else if ADJTHSP is greater than equal to REF.DATE then (ADJTHSP- REF.DATE) +1.
DEATHDY	num	RELATIVE DAY OF DEATH		If DEATHDN and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDN less than REF.DATE then (DEATHDN - REF.DATE). Else if DEATHDN is greater than equal to REF.DATE then (DEATHDN- REF.DATE) +1.
ALIVEDY	num	RELATIVE DAY PATIANT WAS ALIVE		If ALIVEDN and REF.DATE not missing then perform below logic to calculate ALIVEDY, If ALIVEDN less than REF.DATE then (ALIVEDN - REF.DATE). Else if ALIVEDN is greater than equal to REF.DATE then (ALIVEDN- REF.DATE) +1.
DATE1DY	num	RELATIVE 1ST DAY		If DATE1 and REF.DATE not missing then perform below logic to calculate DATE1DY, If DATE1 less than REF.DATE then (DATE1 - REF.DATE). Else if DATE1 is greater than equal to REF.DATE then (DATE1- REF.DATE) +1.
DATE2DY	num	RELATIVE 2ND DAY		If DATE2 and REF.DATE not missing then perform below logic to calculate DATE2DY, If DATE2 less than REF.DATE then (DATE2 - REF.DATE). Else if DATE2 is greater than equal to REF.DATE then (DATE2- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DATE3DY	num	RELATIVE 3RD DAY		If DATE3 and REF.DATE not missing then perform below logic to calculate DATE3DY, If DATE3 less than REF.DATE then (DATE3 - REF.DATE). Else if DATE3 is greater than equal to REF.DATE then (DATE3- REF.DATE) +1.
PROGDY	num	RELATIVE DAY OF DISEASE PROFRESSION		If PROGDT and REF.DATE not missing then perform below logic to calculate PROGDY, If PROGDT less than REF.DATE then (PROGDT - REF.DATE). Else if PROGDT is greater than equal to REF.DATE then (PROGDT- REF.DATE) +1.
ONSETDY	num	RELATIVE ONSETDN DAY		If ONSETDN and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDN less than REF.DATE then (ONSETDN - REF.DATE). Else if ONSETDN is greater than equal to REF.DATE then (ONSETDN- REF.DATE) +1.

1.4.3.CE – CE

Dataset	CE
Creating program	ce.sas
Description	CE
Unique identifier	ADVCODE
Sorted by	ADVCODE
Notes	

Variable	Type	Label	Codes	Comments
SEXAE	char	SEX TO WHICH AE IS APPLICABLE (M/F/B)		Collected at CRF.
ADVDESC	char	INCLUDED TERM DESCRIPTION		Collected at CRF.
ADVCODE	char	INCLUDED TERM CODE		Collected at CRF.
BODYSYS	char	BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	PREFERRED TERM DESCRIPTION		Collected at CRF.
CENO	num	CENO		Collected at CRF.

1.4.4.CHEMREG – CHEMREG

Dataset	CHEMREG
Creating program	chemreg.sas
Description	CHEMREG
Unique identifier	REGIMEN
Sorted by	REGIMEN
Notes	

Variable	Type	Label	Codes	Comments
REGIMEN	char	REGIMEN CODE		Collected at CRF.
CLASSF	char	DECODE, CLASS		Collected at CRF.
LCLASSF	char	LONG NAME FOR CHEMO REGIMEN CLASS		Collected at CRF.
SUBCLASF	char	DECODE, SUBCLASS		Collected at CRF.
CLASS	num	CLASS		Collected at CRF.
SUBCLASS	char	SUBCLASS		Collected at CRF.

1.4.5.CLAS – CLAS

Dataset	CLAS
Creating program	clas.sas
Description	CLASS
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EVDATE

Variable	Type	Label	Codes	Comments
ENERGY	num	CLAS: ENERGY		Collected at CRF.
ACTIVITY	num	CLAS: DAILY ACTIVITIES		Collected at CRF.
OVERALL	num	CLAS: OVERALL QUALITY-OF-LIFE		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.

1.4.6.COMMENT – COMMENT

Dataset	COMMENT
Creating program	comment.sas
Description	COMMENT
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Empty dataset will be submitted
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Empty dataset will be submitted
TAREA	char	DEFINING THE DRUG PROGRAM		Empty dataset will be submitted
PNO	char	PROTOCOL NUMBER		Empty dataset will be submitted
EVENT_ID	char	EVENT(VISIT) NAME		Empty dataset will be submitted
PAG_NAME	char	PAGE NAME		Empty dataset will be submitted
COMMENT	char	TEXT OF THE COMMENT		Empty dataset will be submitted
ENTRYNO	num	ENTRY NUMBER		Empty dataset will be submitted
MODNAME	char	MODULE TO WHICH THE COMMENT RELATES		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Empty dataset will be submitted
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
VISITNO	num	VISIT NUMBER		Empty dataset will be submitted
MODNAMEF	char	DECODING, MODULE TO WHICH THE COMMENT RE		Empty dataset will be submitted
EVDY	num	RELATIVE EVENT DAY		Empty dataset will be submitted

1.4.7.COMPAES – COMPAES

Dataset	COMPAES
Creating program	compaes.sas
Description	COMPAES
Unique identifier	ADVDESC
Sorted by	ADVDESC
Notes	

Variable	Type	Label	Codes	Comments
ADVDESC	char	ADVDESC		Collected at CRF.
CAT_AES	num	CAT_AES		Collected at CRF.
CAT_AESF	char	CAT_AESF		Collected at CRF.

1.4.8.EVN_DEFN – EVN_DEFN

Dataset	EVN_DEFN
Creating program	evn_defn.sas
Description	EVN_DEFN
Unique identifier	EVENT_ID,DSCR
Sorted by	EVENT_ID,DSCR
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SCTRY,PRV_EVEN

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
SEQ_NO	num	SEQ_NO		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
DSCR	char	DSCR		Collected at CRF.
ABS_DAYS	num	ABS_DAYS		Collected at CRF.
REL_DAYS	num	REL_DAYS		Collected at CRF.
VAR_DAYS	num	VAR_DAYS		Collected at CRF.

1.4.9.FACT – FACT

Dataset	FACT
Creating program	fact.sas
Description	FACT
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EVDATE

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
PWB	num	FACT-AN: PHYSICAL WELL-BEING		Collected at CRF.
SFWB	num	FACT-AN: SOCIAL/FAMILY WELL-BEING		Collected at CRF.
EWB	num	FACT-AN: EMOTIONAL WELL-BEING		Collected at CRF.
FWB	num	FACT-AN: FUNCTIONAL WELL-BEING		Collected at CRF.
FACTG	num	FACT-AN: FACT-G TOTAL SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
FATS	num	FACT-AN: FATIGUE SUBSCALE SCORE		Collected at CRF.
NFATS	num	FACT-AN: NON-FATIGUE SUBSCALE SCORE		Collected at CRF.
ANS	num	FACT-AN: TOTAL ANEMIN SUBSCALE SCORE		Collected at CRF.
TOTAL	num	FACT-AN: FACT-ANEMIA TOTAL SCORE		Collected at CRF.
TOTFAT	num	FACT-AN: FACT-FATIGUE TOTAL SCORE		Collected at CRF.
TOI	num	FACT-AN: TOI SCORE		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.

1.4.10. FUDEATH – FUDEATH

Dataset	FUDEATH
Creating program	fudeath.sas
Description	FUDEATH
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EVDATE,COMMENTS

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
SURVIVED	char	SURVIVED		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.

1.4.11. KEY FILE FOR ADVERSE EVENTS – KEYADVE

Dataset	KEYADVE
Creating program	keyadve.sas
Description	KEY FILE FOR ADVERSE EVENTS
Unique identifier	DUSUBJID,EVENT_ID,ADVCODE,ONSETDY
Sorted by	DUSUBJID,EVENT_ID,ADVCODE,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: ONSETDT,STOPDT,STOPTIME,TONSET,VERBATIM,MEDSTRDT,MEDSPDT, RACE,SEX,RACEF,SEXF,RAND_DT,RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY, CNTRYF,STDYEND,ONSETDTN,ONSET,ONSETN,STOPDTN,STOPTIMN,TONSETN

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
ADVEXP	num	DID AE OCCUR (Y/N?)		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
ADVEXPF	char	DECODE, ADVEXP		Collected at CRF.
ACTION	num	ACTION TAKEN		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVCODE	char	WHOART CODE		Collected at CRF.
ADVDESC	char	WHOART DESCRIPTION		Collected at CRF.
CONCOM	num	WAS CONCOMITANT THERAPY GIVEN (Y/N?)		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
OUTCOME	num	AE OUTCOME		Collected at CRF.
SERIOUS	num	IS AE SERIOUS (Y/N?)		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
ACTIONF	char	DECODE, ACTION		Collected at CRF.
CONCOMF	char	DECODE, CONCOM		Collected at CRF.
DRUGRELF	char	DECODE, DRUGREL		Collected at CRF.
OUTCOMEF	char	DECODE, OUTCOME		Collected at CRF.
SERIOUSF	char	DECODE, SERIOUS		Collected at CRF.
SEVERITF	char	DECODE, SEVERITY		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
BODYSYS	char	WHOART BODY SYSTEM		Collected at CRF.
PREF_TRM	char	WHOART PREFERRED TERM		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGIMEN	char	REGIMEN CODE		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DURDAY	num	DURATION OF AE		Collected at CRF.
PERIOD	num	PERIOD OF STUDY - NA		Collected at CRF.
REGDAY	num	REGIMEN DAY - NA		Collected at CRF.
AFMEDSTF	char	AR AFTER MED START DATE DECODING		Collected at CRF.
AFMEDSPF	char	AFTER MED STOP DATE +14,DECODING		Collected at CRF.
AFMEDST	num	AE AFTER MED START DATE YES/NO		Collected at CRF.
AFMEDSP	num	AF MEDSTOP DATE+14 OR >13MAY2002, YES/NO		Collected at CRF.
ONSETDY	num	RELATIVE ONSET AE DAY WT FILLED IN DAYS		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STOPDY	num	RELATIVE STOP DAY OF AE		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT-REF.DATE) +1.
MEDSTRDY	num	RELATIVE MEDICATION START DAY		If MEDSTRDT and REF.DATE not missing then perform below logic to calculate MEDSTRDY, If MEDSTRDT less than REF.DATE then (MEDSTRDT - REF.DATE). Else if MEDSTRDT is greater than equal to REF.DATE then (MEDSTRDT- REF.DATE) +1.
MEDSPDY	num	RELATIVE MEDICATION STOP DAY		If MEDSPDT and REF.DATE not missing then perform below logic to calculate MEDSPDY, If MEDSPDT less than REF.DATE then (MEDSPDT - REF.DATE). Else if MEDSPDT is greater than equal to REF.DATE then (MEDSPDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
STDYENDY	num	RELATIVE INDIVIDUAL STUDY END DAY		If STDYEND and REF.DATE not missing then perform below logic to calculate STDYENDY, If STDYEND less than REF.DATE then (STDYEND - REF.DATE). Else if STDYEND is greater than equal to REF.DATE then (STDYEND- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ONSETNDY	num	RELATIVE ONSET AE DAY WT FILLED IN DAYS		If ONSETDTN and REF.DATE not missing then perform below logic to calculate ONSETNDY, If ONSETDTN less than REF.DATE then (ONSETDTN - REF.DATE). Else if ONSETDTN is greater than equal to REF.DATE then (ONSETDTN- REF.DATE) +1.
ONST_DY	num	RELATIVE ORIGINAL ONSET DAY OF AE		If ONSET and REF.DATE not missing then perform below logic to calculate ONST_DY, If ONSET less than REF.DATE then (ONSET - REF.DATE). Else if ONSET is greater than equal to REF.DATE then (ONSET- REF.DATE) +1.
ONSET_DY	num	RELATIVE ORIGINAL ONSET DAY OF AE		If ONSETN and REF.DATE not missing then perform below logic to calculate ONSET_DY, If ONSETN less than REF.DATE then (ONSETN - REF.DATE). Else if ONSETN is greater than equal to REF.DATE then (ONSETN- REF.DATE) +1.
STOP_DY	num	RELATIVE STOP DAY OF AE		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOP_DY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.

1.4.12. KEYCANS – KEYCANS

Dataset	KEYCANS
Creating program	keycans.sas
Description	KEYCANS
Unique identifier	DUSUBJID,ENTRYNO
Sorted by	DUSUBJID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,CANSURDT,RACE,SEX,RACEF,SEXF,FORE,SURN,RAND_DT, RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY,CANSURD,DAY,MONTH,YEAR, MONTH_

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
CANCPROC	char	CANCER PROCEDURE		Collected at CRF.
CANCSITE	char	CANCER SITE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY		Collected at CRF.
VISITF	char	DECODE, VISITNO		Collected at CRF.
CANSURDY	num	RELATIVE CANCER SURGERY DAY		If CANSURDT and REF.DATE not missing then perform below logic to calculate CANSURDY, If CANSURDT less than REF.DATE then (CANSURDT - REF.DATE). Else if CANSURDT is greater than equal to REF.DATE then (CANSURDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

1.4.13. KEY CHEMO INTENSITY 1 – KEYCHEM1

Dataset	KEYCHEM1
Creating program	keychem1.sas
Description	KEY CHEMO INTENSITY 1
Unique identifier	DPATNO,EVENT_ID,TOTDOSE,DRUGDESC,START_DY
Sorted by	DPATNO,EVENT_ID,TOTDOSE,DRUGDESC,START_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: VERBATIM,CSTARTDT,CSTOPDT,ENDCHEM,RAND_DT,CNTRY,ENDCHEMN, STARTDD,STOPDD,STARTDN,STOPDN,START,STOP,LN1STPDT,STDYEND

Variable	Type	Label	Codes	Comments
DOSENUM	num	NUMERIC CHEMO DOSE		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
ROUTE	char	RT OF ADM		Collected at CRF.
TOTDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYDAY	num	DAYS ON STUDY		Collected at CRF.
DRUGDESC	char	COLLAPSED DRUG DESCRIPTION		Collected at CRF.
GENDESC	char	COLLAPSED GENERIC DESCRIPTION RUN		Collected at CRF.
BASEWGT	num	BASELINE WEIGHT (KG)		Collected at CRF.
BSA	num	BASELINE BODY SURFACE AREA		Collected at CRF.
DURATION	num	ACTUAL OR IMPUTED DURATION		Collected at CRF.
UNIT	char	UNIT FOR DOSENUM		Collected at CRF.
CFACTOR	num	UNIT CONVERSION FACTOR		Collected at CRF.
CUNIT	char	UNIT FOR CDOSENUM		Collected at CRF.
FFACTOR	num	FREQUENCY CONVERSION FACTOR		Collected at CRF.
OFACTOR	char	OFACTOR		Collected at CRF.
CDOSENUM	num	CONVERTED NUMERIC CHEMO DOSE		Collected at CRF.
CSTARTDY	num	RELATIVE STRT DAY OF CONCURNT MEDCATION		If CSTARTDT and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTARTDT less than REF.DATE then (CSTARTDT - REF.DATE). Else if CSTARTDT is greater than equal to REF.DATE then (CSTARTDT- REF.DATE) +1.
CSTOPDY	num	RELATIVE STOP DAY		If CSTOPDT and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOPDT less than REF.DATE then (CSTOPDT - REF.DATE). Else if CSTOPDT is greater than equal to REF.DATE then (CSTOPDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ENDCHMDY	num	RELATIVE END OF FIRST LINE CHEMO DAY		If ENDCHEM and REF.DATE not missing then perform below logic to calculate ENDCHMDY, If ENDCHEM less than REF.DATE then (ENDCHEM - REF.DATE). Else if ENDCHEM is greater than equal to REF.DATE then (ENDCHEM- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
STARTDDY	num	RELATIVE FILLES DAY IN CSTART		If STARTDD and REF.DATE not missing then perform below logic to calculate TADY, If STARTDD less than REF.DATE then (STARTDD - REF.DATE). Else if STARTDD is greater than equal to REF.DATE then (STARTDD- REF.DATE) +1.
STOPDDY	num	RELATIVE FILLED DAY IN CSTOP		If STOPDD and REF.DATE not missing then perform below logic to calculate STOPDDY, If STOPDD less than REF.DATE then (STOPDD - REF.DATE). Else if STOPDD is greater than equal to REF.DATE then (STOPDD- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
LN1STPDY	num	RELATIVE DAY OF END OF FIRST LINE CHEMO		If LN1STPDT and REF.DATE not missing then perform below logic to calculate LN1STPDY, If LN1STPDT less than REF.DATE then (LN1STPDT - REF.DATE). Else if LN1STPDT is greater than equal to REF.DATE then (LN1STPDT- REF.DATE) +1.
STDYENDY	num	RELATIVE INDIVIDUAL STUDY END DAY		If STDYEND and REF.DATE not missing then perform below logic to calculate STDYENDY, If STDYEND less than REF.DATE then (STDYEND - REF.DATE). Else if STDYEND is greater than equal to REF.DATE then (STDYEND- REF.DATE) +1.

1.4.14. KEY FILE FOR COMPLITION/WITHDRAWAL – KEYCOMP

Dataset	KEYCOMP
Creating program	keycomp.sas
Description	KEY FILE FOR COMPLITION/WITHDRAWAL
Unique identifier	DUSUBJID,REGDESC,STATUSDY,STARTDY,SMEDDY
Sorted by	DUSUBJID,REGDESC,STATUSDY,STARTDY,SMEDDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DEATHDT,DEATHDTN,RACE,SEX,RACEF,SEXF,DEATHODT,RAND_DD,AGE, CNTRY,CNTRYF,EVDATE,RAND_DT,SMEDDT,STARTDT,STATUSDT,STOPDT, SMEDD,DEATHODN,OCAUSE

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
THERDAYS	num	DAYS ON THERAPY		Collected at CRF.
THERWKS	num	WEEKS ON THERAPY		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
CAUDEATH	num	CAUSE OF DEATH		Collected at CRF.
CAUSPEC	char	CAUSE OF DEATH SPECIFY		Collected at CRF.
DEATH	num	DID SUBJECT DIE?		Collected at CRF.
OTHRSPEC	char	OTHER SPECIFICATION		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
STATUS	num	STATUS		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
CAUDEATF	char	DECODE, CAUDEATH		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
STATUSF_	char	STATUS AS COMPLETED/WITHDREW		Collected at CRF.
VOLUME	num	LAST DOSE OF STUDY DRUG		Collected at CRF.
OREASONF	char	REASON TO WITHDRAW		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DEATHDAY	num	STUDY DAY FOR DEATH		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATHDTN and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATHDTN less than REF.DATE then (DEATHDTN - REF.DATE). Else if DEATHDTN is greater than equal to REF.DATE then (DEATHDTN- REF.DATE) +1.
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DEATHODY	num	RELATIVE ORIGINAL DAY OF DEATH		If DEATHODT and REF.DATE not missing then perform below logic to calculate DEATHODY, If DEATHODT less than REF.DATE then (DEATHODT - REF.DATE). Else if DEATHODT is greater than equal to REF.DATE then (DEATHODT- REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE - REF.DATE) +1.
STATUSDY	num	RELATIVE STATUS DAY		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
SMEDDY	num	RELATIVE LAST DAY FOR STUDY DRUG DOSE		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.

1.4.15. KEYCOMP1 – KEYCOMP1

Dataset	KEYCOMP1
Creating program	keycomp1.sas
Description	KEYCOMP1
Unique identifier	DUSUBJID, BODYSYS, ADVCODE, REGDESC, STATUSDY, SMEDDY
Sorted by	DUSUBJID, BODYSYS, ADVCODE, REGDESC, STATUSDY, SMEDDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDT, STOPDT, RACE, SEX, RACEF, SEXF, RAND_DT, AGE, DEATHDTN, DEATHDT, DEATHODT, EVDATE, STATUSDT, VERBATIM, ONSETDT, SMEDDT, DEATHODN, OCAUSE

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
THERDAYS	num	DAYS ON THERAPY		Collected at CRF.
THERWKS	num	WEEKS ON THERAPY		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
CAUDEATH	num	CAUSE OF DEATH		Collected at CRF.
CAUSPEC	char	CAUSE OF DEATH SPECIFY		Collected at CRF.
DEATH	num	DID SUBJECT DIE?		Collected at CRF.
OTHRSPEC	char	OTHER SPECIFICATION		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
STATUS	num	STATUS		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
CAUDEATF	char	DECODE, CAUDEATH		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
STATUSF_	char	STATUS AS COMPLETED/WITHDREW		Collected at CRF.
ADVCODE	char	DICTIONARY CODE ASSIGNED TO AE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEXAE	char	SEX TO WHICH AE IS APPLICABLE (M/F/B)		Collected at CRF.
BODYSYS	char	BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	PREFERRED TERM DESCRIPTION		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
OUTCOME	num	AE OUTCOME		Collected at CRF.
DURDAY	num	DURATION OF AE		Collected at CRF.
VOLUME	num	LAST DOSE OF STUDY DRUG		Collected at CRF.
SMEDDAY	num	STUDY DAY FOR STUDY MEDICATION		Collected at CRF.
OREASONF	char	REASON TO WITHDRAW		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DEATHDAY	num	STUDY DAY FOR DEATH		Collected at CRF.
CAT_OTH	num	CATEGORIES FOR DISC REASON=OTHER		Collected at CRF.
CAT_OTHF	char	DECODE, CAT_OTH		Collected at CRF.
CAT_AES	num	CATEGORIES FOR DISC REASON=AES		Collected at CRF.
CAT_AESF	char	DECODE, CAT_AES		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.
DEATHODY	num	RELATIVE ORIGINAL DAY OF DEATH		If DEATHODT and REF.DATE not missing then perform below logic to calculate DEATHODY, If DEATHODT less than REF.DATE then (DEATHODT - REF.DATE). Else if DEATHODT is greater than equal to REF.DATE then (DEATHODT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
ONSETDY	num	RELATIVE ONSET AE DAY WT		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
SMEDDY	num	RELATIVE LAST DAY FOR STUDY DRUG DOSE		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.

1.4.16. KEYCOMP2 – KEYCOMP2

Dataset	KEYCOMP2
Creating program	keycomp2.sas
Description	KEYCOMP2
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: OTHRSPEC,STATUSDT,STARTDT,STOPDT,RACE,SEX,RACEF,SEXF,RAND_DT, RAND_DD,AGE,CNTRY,CNTRYF,DEATHDTN,DEATHDT,STATUSDN,DETHDT, SMEDDT,OCAUSE

Variable	Type	Label	Codes	Comments
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
STATUS	num	COMPLITION/WITHDRAWAL STATUS		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REASONF	char	DECODE, REASON		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
STATUSF_	char	DECODE, STATUS AS COMPLETED/WITHDREW		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMPLTR	num	COMPLITERS, ALSO IF WITHDR AND DIED		Collected at CRF.
COMPLTRF	char	DECODE, COMPLTR		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DETH_STF	char	DECODE, DETH_ST		Collected at CRF.
DEATH	num	DEATH AT ALL YES/NO		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.
CAUSP	char	CAUSE OF DEATH AT ALL/SPECIFY		Collected at CRF.
CAUDETHF	char	DECODE, CAUDETH		Collected at CRF.
CAUDETH	num	CAUSE OF DEATH AT ALL		Collected at CRF.
DETH_ST	num	WHEN PAT DIED: DB OR FU		Collected at CRF.
VOLUME	num	LAST DOSE OF STUDY DRUG		Collected at CRF.
SMEDDAY	num	STUDY DAY FOR STUDY MEDICATION		Collected at CRF.
OREASONF	char	REASON TO WITHDRAW		Collected at CRF.
STUDYDAY	num	STUDY DAY FOR COMP/W STATUS		Collected at CRF.
THERAPY	num	TOTAL DAYS ON THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEATHDAY	num	STUDY DAY FOR DEATH		Collected at CRF.
DBDEATHF	char	DECODE, DBDEATH		Collected at CRF.
DBDEATH	num	DEATH AT DOUBLE BLIND (Y/N)		Collected at CRF.
CAT_DTHF	char	DECODE, CAT_DTH		Collected at CRF.
CAT_DTH	num	CATEGORIES FOR DEATHS		Collected at CRF.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.
DETHDY	num	RELATIVE DAY OF DEATH AT ALL		If DETHDT and REF.DATE not missing then perform below logic to calculate DETHDY, If DETHDT less than REF.DATE then (DETHDT - REF.DATE). Else if DETHDT is greater than equal to REF.DATE then (DETHDT- REF.DATE) +1.
SMEDDY	num	RELATIVE LAST DAY FOR STUDY DRUG DOSE		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.

1.4.17. CHEMOTHERAPY WITH REGIMENS – KEYCREG1

Dataset	KEYCREG1
Creating program	keycreg1.sas
Description	CHEMOTHERAPY WITH REGIMENS
Unique identifier	DUSUBJID,ENTRYNO,EVENT_ID,CSTARTDY
Sorted by	DUSUBJID,ENTRYNO,EVENT_ID,CSTARTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: FORTAEF,REC_ID,SCTRY,DRUGCOD2,DRUGDES2,THRPYNO,VERBATIM, ONSETDT,FORTAE,REGI,STARTD,CSTARTDT,STOPD,CSTOPDT,STR,EVDATE, RACE,SEX,RACEF,SEXF,FORE,SURN,DIAGIVDT,ENDCHEM,RAND_DT,RAND_DD, AGE,INVNAME,CNTRY,ENDCHEMN,STARTDD,STOPDD,DIAGIVDD,DIAGIVN, STARTDN,STOPDN,CSTART,CSTOP,CSTOPDT_,CPMONTH_,CYEAR_,CPYEAR_, CDAY_,CPDAY_,CMONTH_

Variable	Type	Label	Codes	Comments
DRUGCODE	char	COLLAPSED DRUG CODE		Collected at CRF.
CONMEDF	char	DECODE, CONMED		Collected at CRF.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ATC_CD	char	ATC CODE		Collected at CRF.
ATC_TEXT	char	ATC TEXT		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER OF AE		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
INDICT	char	INDICATION		Collected at CRF.
CONMED	num	CON MED GIVEN (Y/N)		Collected at CRF.
CONT	num	MEDICATION CONTINUEING? (Y/N)		Collected at CRF.
PRN	char	IF DRUG TAKEN AS NEEDED PRN		Collected at CRF.
ROUTE	char	ROUTE OF ADMINISTRATION		Collected at CRF.
TOTDOSE	char	TOTAL DAYLY DOSE		Collected at CRF.
CONTF	char	DECODE, CONT		Collected at CRF.
PRNF	char	DECODING, IF DRUG TAKEN AS NEEDED PRN		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHRMCLAS	char	PHARMACOLOGICAL CLASS		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PRE_LSTF	char	PRE-STUDY FOR LISTING/DECODING		Collected at CRF.
ON_LSTF	char	ON-STUDY FOR LISTING/DECODING		Collected at CRF.
PRE_LST	num	PRE-STUDY FOR LISTING		Collected at CRF.
ON_LST	num	ON-STUDY FOR LISTING		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DURATION	num	DURATION OF CONMED		Collected at CRF.
REGDAY	num	DAYS ON REGIMEN		Collected at CRF.
WEEK	num	WEEK=INT(STUDYDAY/7)		Collected at CRF.
NEWVIS	num	VISIT NUMBER WHERE VN20 IN PROPER PLACE		Collected at CRF.

Variable	Type	Label	Codes	Comments
FLI_SUMF	char	FIRST LINE CHEMO/DECODING/SUMMARIES		Collected at CRF.
FLI_SUM	num	FIRST LINE CHEMO/SUMMARIES		Collected at CRF.
AFL_SUMF	char	AFTER FIRST LINE/DECODING/SUMMARIES		Collected at CRF.
AFL_SUM	num	AFTER FIRST LINE/SUMMARIES		Collected at CRF.
PRE_SUMF	char	PRESTUDY THERAPY,ADJUV. DECODE		Collected at CRF.
PRE_SUM	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PRE_MSF	char	PRESTUDY THERPY, METAST SET DECODING		Collected at CRF.
PRE_MS	num	PRESTUDY THERPAY, METASTAT SETTING		Collected at CRF.
OLDGEN	char	ORIGINAL GENERIC DESCRIPTION		Collected at CRF.
OLDDESC	char	ORIGINAL DRUG DESCRIPTION		Collected at CRF.
OLDCODE	char	ORIGINAL WHO DRUG CODE FROM DATABASE		Collected at CRF.
DRUGDESC	char	COLLAPSED DRUG DESCRIPTION		Collected at CRF.
GENDESC	char	COLLAPSED GENERIC DESCRIPTION RUN		Collected at CRF.
REGIMEN	char	CHEMO REGIMEN		Collected at CRF.
AGENT8	char	AGENT 8 FOR CHEMO REGIMEN		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGENT9	char	AGENT 9 FOR CHEMO REGIMEN		Collected at CRF.
AGENT10	char	AGENT 10 FOR CHEMO REGIMEN		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CLASSF	char	DECODE, CLASS		Collected at CRF.
LCLASSF	char	LONG NAME FOR CHEMO REGIMEN CLASS		Collected at CRF.
SUBCLASF	char	DECODE, SUBCLASS		Collected at CRF.
CLASS	num	CLASS OF CHEMO REGIMEN		Collected at CRF.
SUBCLASS	char	SUB CLASS FOR CHEMO REGIMEN		Collected at CRF.
CSTARTDY	num	RELATIVE STRT DAY OF CONCURNT MEDCATION		If CSTARTDT and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTARTDT less than REF.DATE then (CSTARTDT - REF.DATE). Else if CSTARTDT is greater than equal to REF.DATE then (CSTARTDT- REF.DATE) +1.
CSTOPDY	num	RELATIVE STOP DAY		If CSTOPDT and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOPDT less than REF.DATE then (CSTOPDT - REF.DATE). Else if CSTOPDT is greater than equal to REF.DATE then (CSTOPDT- REF.DATE) +1.
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ENDCHMDY	num	RELATIVE END OF FIRST LINE CHEMO DAY		If ENDCHEM and REF.DATE not missing then perform below logic to calculate ENDCHMDY, If ENDCHEM less than REF.DATE then (ENDCHEM - REF.DATE). Else if ENDCHEM is greater than equal to REF.DATE then (ENDCHEM- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
STARTDDY	num	RELATIVE FILLES DAY IN CSTART		If STARTDD and REF.DATE not missing then perform below logic to calculate START_DY, If STARTDD less than REF.DATE then (STARTDD - REF.DATE). Else if STARTDD is greater than equal to REF.DATE then (STARTDD- REF.DATE) +1.
STOPDDY	num	RELATIVE FILLED DAY IN CSTOP		If STOPDD and REF.DATE not missing then perform below logic to calculate STOPDDY, If STOPDD less than REF.DATE then (STOPDD - REF.DATE). Else if STOPDD is greater than equal to REF.DATE then (STOPDD- REF.DATE) +1.
DIAGIVDDY	num	RELATIVE FILLED DAY IN DIAGIV		If DIAGIVDD and REF.DATE not missing then perform below logic to calculate DIAGVDY, If DIAGIVDD less than REF.DATE then (DIAGIVDD - REF.DATE). Else if DIAGIVDD is greater than equal to REF.DATE then (DIAGIVDD- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CSTRTDY	num	RELATIVE CON MED START DAY		If CSTART and REF.DATE not missing then perform below logic to calculate CSTRTDY, If CSTART less than REF.DATE then (CSTART - REF.DATE). Else if CSTART is greater than equal to REF.DATE then (CSTART-REF.DATE) +1.
C_STOPDY	num	RELATIVE CON MED STOP DAY		If CSTOP and REF.DATE not missing then perform below logic to calculate C_STOPDY, If CSTOP less than REF.DATE then (CSTOP - REF.DATE). Else if CSTOP is greater than equal to REF.DATE then (CSTOP- REF.DATE) +1.
CSTOP_DY	num	RELATIVE MED STOP OR CONTINUEING DAY		If CSTOPDT_ and REF.DATE not missing then perform below logic to calculate CSTOP_DY, If CSTOPDT_ less than REF.DATE then (CSTOPDT_ - REF.DATE). Else if CSTOPDT_ is greater than equal to REF.DATE then (CSTOPDT_- REF.DATE) +1.

1.4.18. CHEMO REGIMENS FOR SUMMARIES – KEYCREG2

Dataset	KEYCREG2
Creating program	keycreg2.sas
Description	CHEMO REGIMENS FOR SUMMARIES
Unique identifier	DPATNO,REGIMEN
Sorted by	DPATNO,REGIMEN
Notes	

Variable	Type	Label	Codes	Comments
REGIMEN	char	CHEMO REGIMEN		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
AGENT8	char	AGENT 8 FOR CHEMO REGIMEN		Collected at CRF.
AGENT9	char	AGENT 9 FOR CHEMO REGIMEN		Collected at CRF.
AGENT10	char	AGENT 10 FOR CHEMO REGIMEN		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CLASSF	char	DECODE, CLASS		Collected at CRF.
LCLASSF	char	LONG NAME FOR CHEMO REGIMEN CLASS		Collected at CRF.
SUBCLASF	char	DECODE, SUBCLASS		Collected at CRF.

Variable	Type	Label	Codes	Comments
CLASS	num	CLASS OF CHEMO REGIMEN		Collected at CRF.
SUBCLASS	char	SUB CLASS FOR CHEMO REGIMEN		Collected at CRF.

1.4.19. PRE CHEMOTHERAPY WITH REGIMENS – KEYCREG3

Dataset	KEYCREG3
Creating program	keycreg3.sas
Description	PRE CHEMOTHERAPY WITH REGIMENS
Unique identifier	DPATNO,REGIMEN
Sorted by	DPATNO,REGIMEN
Notes	

Variable	Type	Label	Codes	Comments
REGIMEN	char	CHEMO REGIMEN		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CLASSF	char	DECODE, CLASS		Collected at CRF.
LCLASSF	char	LONG NAME FOR CHEMO REGIMEN CLASS		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBCLASF	char	DECODE, SUBCLASS		Collected at CRF.
CLASS	num	CLASS OF CHEMO REGIMEN		Collected at CRF.
SUBCLASS	char	SUB CLASS FOR CHEMO REGIMEN		Collected at CRF.

1.4.20. FIRST LINE CHEMOTHERAPY – KEYCREG4

Dataset	KEYCREG4
Creating program	keycreg4.sas
Description	FIRST LINE CHEMOTHERAPY
Unique identifier	DPATNO,REGIMEN
Sorted by	DPATNO,REGIMEN
Notes	

Variable	Type	Label	Codes	Comments
REGIMEN	char	CHEMO REGIMEN		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CLASSF	char	DECODE, CLASS		Collected at CRF.

Variable	Type	Label	Codes	Comments
LCLASSF	char	LONG NAME FOR CHEMO REGIMEN CLASS		Collected at CRF.
SUBCLASF	char	DECODE, SUBCLASS		Collected at CRF.
CLASS	num	CLASS OF CHEMO REGIMEN		Collected at CRF.
SUBCLASS	char	SUB CLASS FOR CHEMO REGIMEN		Collected at CRF.

1.4.21. KEYCURM – KEYCURM

Dataset	KEYCURM
Creating program	keycurm.sas
Description	KEYCURM
Unique identifier	DUSUBJID,VISITNO,REGDESC,ENTRYNO,ONSETDY,ATC_CD,THRPYNO
Sorted by	DUSUBJID,VISITNO,REGDESC,ENTRYNO,ONSETDY,ATC_CD,THRPYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,DRUGCOD2,DRUGDES2,VERBATIM,ONSETDT, INDICT,REGI,STARTD,CSTARTDT,STOPD,CSTOPDT,STR,EVDATE,RACE,SEX, RACEF,SEXF,FORE,SURN,DIAGIVDT,ENDCHEM,RAND_DT,RAND_DD,AGE, INVNAME,CNTRY,ENDCHEMN,STARTDD,STOPDD,DIAGIVDD,DIAGIVN, STARTDN,STOPDN,CSTART,CSTOP,CSTOPDT_,CPMONTH_,CYEAR_,CPYEAR_, CDAY_,CPDAY_,CMONTH_

Variable	Type	Label	Codes	Comments
CONMEDF	char	DECODE, CONMED		Collected at CRF.
FORTAEF	char	DECODE, FORTAE		Collected at CRF.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ATC_CD	char	ATC CODE		Collected at CRF.
ATC_TEXT	char	ATC TEXT		Collected at CRF.
DRUGCODE	char	WHO ART CODE		Collected at CRF.
DRUGDESC	char	WHO ART DESCRIPTION		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER OF AE		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
THRPYNO	num	THERAPY NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
CONMED	num	CON MED GIVEN(Y/N)		Collected at CRF.
FORTAE	num	FOT TRT EMERGENT AE		Collected at CRF.
CONT	num	CON MED CONTINUED		Collected at CRF.
PRN	char	IF DRUG TAKEN AS NEEDED PRN		Collected at CRF.
ROUTE	char	ROUTE OF ADMINISTRATION		Collected at CRF.
TOTDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
CONTF	char	DECODE, CONT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRNF	char	DECODING, IF DRUG TAKEN AS NEEDED PRN		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGICAL CLASS		Collected at CRF.
GENDESC	char	GENERIC DESCRIPTION		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PRE_LSTF	char	PRE-STUDY FOR LISTING/DECODING		Collected at CRF.
ON_LSTF	char	ON-STUDY FOR LISTING/DECODING		Collected at CRF.
PRE_LST	num	PRE-STUDY FOR LISTING		Collected at CRF.
ON_LST	num	ON-STUDY FOR LISTING		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DURATION	num	DURATION OF CONMED		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGDAY	num	DAYS ON REGIMEN		Collected at CRF.
WEEK	num	WEEK=INT(STUDYDAY/7)		Collected at CRF.
NEWVIS	num	CORRECTED VISIT# (VIS20 IN PROPER PLACE)		Collected at CRF.
FLI_SUMF	char	FIRST LINE CHEMO/DECODING/SUMMARIES		Collected at CRF.
FLI_SUM	num	FIRST LINE CHEMO/SUMMARIES		Collected at CRF.
AFL_SUMF	char	AFTER FIRST LINE/DECODING/SUMMARIES		Collected at CRF.
AFL_SUM	num	AFTER FIRST LINE/SUMMARIES		Collected at CRF.
PRE_SUMF	char	PRESTUDY THERAPY,ADJUV. DECODE		Collected at CRF.
PRE_SUM	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PRE_MSF	char	PRESTUDY THERPY, METAST SET DECODING		Collected at CRF.
PRE_MS	num	PRESTUDY THERPAY, METASTAT SETTING		Collected at CRF.
ONSETDY	num	RELATIVE DAY OF ONSET		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CSTARTDY	num	RELATIVE STRT DAY OF CONCURNT MEDCATION		If CSTARTDT and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTARTDT less than REF.DATE then (CSTARTDT - REF.DATE). Else if CSTARTDT is greater than equal to REF.DATE then (CSTARTDT- REF.DATE) +1.
CSTOPDY	num	RELATIVE STOP DAY		If CSTOPDT and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOPDT less than REF.DATE then (CSTOPDT - REF.DATE). Else if CSTOPDT is greater than equal to REF.DATE then (CSTOPDT- REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.
ENDCHMDY	num	RELATIVE END OF FIRST LINE CHEMO DAY		If ENDCHEM and REF.DATE not missing then perform below logic to calculate ENDCHMDY, If ENDCHEM less than REF.DATE then (ENDCHEM - REF.DATE). Else if ENDCHEM is greater than equal to REF.DATE then (ENDCHEM- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
STARTDDY	num	RELATIVE FILLES DAY IN CSTART		If STARTDD and REF.DATE not missing then perform below logic to calculate STARTDDY, If STARTDD less than REF.DATE then (STARTDD - REF.DATE). Else if STARTDD is greater than equal to REF.DATE then (STARTDD- REF.DATE) +1.
STOPDDY	num	RELATIVE FILLED DAY IN CSTOP		If STOPDD and REF.DATE not missing then perform below logic to calculate STOPDDY, If STOPDD less than REF.DATE then (STOPDD - REF.DATE). Else if STOPDD is greater than equal to REF.DATE then (STOPDD- REF.DATE) +1.
DIAGIVDDY	num	RELATIVE FILLED DAY IN DIAGIV		If DIAGIVDD and REF.DATE not missing then perform below logic to calculate DIAGIVDDY, If DIAGIVDD less than REF.DATE then (DIAGIVDD - REF.DATE). Else if DIAGIVDD is greater than equal to REF.DATE then (DIAGIVDD- REF.DATE) +1.
CSTOP_DY	num	RELATIVE MED STOP OR CONTINUEING DAY		If CSTOPDT_ and REF.DATE not missing then perform below logic to calculate CSTOP_DY, If CSTOPDT_ less than REF.DATE then (CSTOPDT_ - REF.DATE). Else if CSTOPDT_ is greater than equal to REF.DATE then (CSTOPDT_- REF.DATE) +1.

1.4.22. KEY CONCOMITANT THERAPIES (SUM) – KEYCURM2

Dataset	KEYCURM2
Creating program	keycurm2.sas
Description	KEY CONCOMITANT THERAPIES (SUM)
Unique identifier	DUSUBJID, VISITNO, REGDESC, ENTRYNO, ONSETDY, ATC_CD, THRPYNO
Sorted by	DUSUBJID, VISITNO, REGDESC, ENTRYNO, ONSETDY, ATC_CD, THRPYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID, SCTRY, DRUGCOD2, DRUGDES2, VERBATIM, ONSETDT, INDICT, REGI, STARTD, CSTARTDT, STOPD, CSTOPDT, STR, EVDATE, RACE, SEX, RACEF, SEXF, FORE, SURN, DIAGIVDT, RAND_DT, RAND_DD, AGE, INVNAME, CNTRY, ENDCHEMN, STARTDD, STOPDD, DIAGIVDD, DIAGIVN, STARTDN, STOPDN, CSTART, CSTOP, CSTOPDT_, CPMONTH_, CYEAR_, CPYEAR_, CDAY_, CPDAY_, CMONTH_

Variable	Type	Label	Codes	Comments
DRUGCODE	char	COLLAPSED DRUG CODE		Collected at CRF.
CONMEDF	char	DECODE, CONMED		Collected at CRF.
FORTAEF	char	DECODE, FORTAE		Collected at CRF.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ATC_CD	char	ATC CODE		Collected at CRF.
ATC_TEXT	char	ATC TEXT		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER OF AE		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
THRPYNO	num	THERAPY NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
CONMED	num	CON MED GIVEN(Y/N)		Collected at CRF.
FORTAE	num	FOT TRT EMERGENT AE		Collected at CRF.
CONT	num	CON MED CONTINUED		Collected at CRF.
PRN	char	IF DRUG TAKEN AS NEEDED PRN		Collected at CRF.
ROUTE	char	ROUTE OF ADMINISTRATION		Collected at CRF.
TOTDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
CONTF	char	DECODE, CONT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRNF	char	DECODING, IF DRUG TAKEN AS NEEDED PRN		Collected at CRF.
THERCLAS	char	THERAPEUTIC CLASS		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGICAL CLASS		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
ENDCHEM	char	END OF FIRST LINE CHEMO		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PRE_LSTF	char	PRE-STUDY FOR LISTING/DECODING		Collected at CRF.
ON_LSTF	char	ON-STUDY FOR LISTING/DECODING		Collected at CRF.
PRE_LST	num	PRE-STUDY FOR LISTING		Collected at CRF.
ON_LST	num	ON-STUDY FOR LISTING		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DURATION	num	DURATION OF CONMED		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGDAY	num	DAYS ON REGIMEN		Collected at CRF.
WEEK	num	WEEK=INT(STUDYDAY/7)		Collected at CRF.
NEWVIS	num	CORRECTED VISIT# (VIS20 IN PROPER PLACE)		Collected at CRF.
FLI_SUMF	char	FIRST LINE CHEMO/DECODING/SUMMARIES		Collected at CRF.
FLI_SUM	num	FIRST LINE CHEMO/SUMMARIES		Collected at CRF.
AFL_SUMF	char	AFTER FIRST LINE/DECODING/SUMMARIES		Collected at CRF.
AFL_SUM	num	AFTER FIRST LINE/SUMMARIES		Collected at CRF.
PRE_SUMF	char	PRESTUDY THERAPY,ADJUV. DECODE		Collected at CRF.
PRE_SUM	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PRE_MSF	char	PRESTUDY THERPY, METAST SET DECODING		Collected at CRF.
PRE_MS	num	PRESTUDY THERPAY, METASTAT SETTING		Collected at CRF.
OLDGEN	char	ORIGINAL GENERIC DESCRIPTION		Collected at CRF.
OLDDESC	char	ORIGINAL DRUG DESCRIPTION		Collected at CRF.
OLDCODE	char	ORIGINAL WHO DRUG CODE FROM DATABASE		Collected at CRF.
DRUGDESC	char	COLLAPSED DRUG DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
GENDESC	char	COLLAPSED GENERIC DESCRIPTION RUN		Collected at CRF.
ONSETDY	num	RELATIVE DAY OF ONSET		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
CSTARTDY	num	RELATIVE STRT DAY OF CONCURNT MEDCATION		If CSTARTDT and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTARTDT less than REF.DATE then (CSTARTDT - REF.DATE). Else if CSTARTDT is greater than equal to REF.DATE then (CSTARTDT- REF.DATE) +1.
CSTOPDY	num	RELATIVE STOP DAY		If CSTOPDT and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOPDT less than REF.DATE then (CSTOPDT - REF.DATE). Else if CSTOPDT is greater than equal to REF.DATE then (CSTOPDT- REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
STARTDDY	num	RELATIVE FILLES DAY IN CSTART		If STARTDD and REF.DATE not missing then perform below logic to calculate STARTDDY, If STARTDD less than REF.DATE then (STARTDD - REF.DATE). Else if STARTDD is greater than equal to REF.DATE then (STARTDD- REF.DATE) +1.
STOPDDY	num	RELATIVE FILLED DAY IN CSTOP		If STOPDD and REF.DATE not missing then perform below logic to calculate STOPDDY, If STOPDD less than REF.DATE then (STOPDD - REF.DATE). Else if STOPDD is greater than equal to REF.DATE then (STOPDD- REF.DATE) +1.
DIAGIVDDY	num	RELATIVE FILLED DAY IN DIAGIV		If DIAGIVDD and REF.DATE not missing then perform below logic to calculate DIAGIVDDY, If DIAGIVDD less than REF.DATE then (DIAGIVDD - REF.DATE). Else if DIAGIVDD is greater than equal to REF.DATE then (DIAGIVDD- REF.DATE) +1.
STARTDY	num	RELATIVE FILLES DAY IN CSTART		If STARTDN and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDN less than REF.DATE then (STARTDN - REF.DATE). Else if STARTDN is greater than equal to REF.DATE then (STARTDN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STOPDY	num	RELATIVE FILLED DAY IN CSTOP		If STOPDN and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDN less than REF.DATE then (STOPDN - REF.DATE). Else if STOPDN is greater than equal to REF.DATE then (STOPDN-REF.DATE) +1.
CSTOP_DY	num	RELATIVE MED STOP OR CONTINUEING DAY		If CSTOPDT_ and REF.DATE not missing then perform below logic to calculate CSTOP_DY, If CSTOPDT_ less than REF.DATE then (CSTOPDT_ - REF.DATE). Else if CSTOPDT_ is greater than equal to REF.DATE then (CSTOPDT_- REF.DATE) +1.

1.4.23. KEY DOSING DATA – KEYDOSE

Dataset	KEYDOSE
Creating program	keydose.sas
Description	KEY DOSING DATA
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: STARTDT,STOPDT,RACEF,SEXF,FORE,SURN,AGE,AGEUNIT,INVNAME,CNTRY, RTITLE1,RTITLE2

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGIMEN	char	REGIMEN ID		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
RTITLE3	char	THIRD REGIMEN TITLE		Collected at CRF.
THRPYDAY	num	TOTAL DAYS ON THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	num	PERIOD FOR INITIATION OF STUDY MED		Collected at CRF.
XORDER	num	CROSS-OVER ORDER		Collected at CRF.
STARTDY	num	RELATIVE STUDY THERAPY START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE STUDY THERAPY STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.24. ECOG PERFORMANCE STATUS RECORD – KEYECOGS

Dataset	KEYECOGS
Creating program	keyecogs.sas
Description	ECOG PERFORMANCE STATUS RECORD
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: RACE,SEX,RACEF,SEXF,FORE,SURN,RAND_DT,RAND_DD,AGE,AGEUNIT, INVNAME,CNTRY,ECOGDT

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
PNO	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECOGSTAT	num	ECOG STATUS		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
ECOGSTAF	char	DECODE, ECOGSTAT		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
ECOGDY	num	RELATIVE ECOG DAY		If ECOGDT and REF.DATE not missing then perform below logic to calculate ECOGDY, If ECOGDT less than REF.DATE then (ECOGDT - REF.DATE). Else if ECOGDT is greater than equal to REF.DATE then (ECOGDT- REF.DATE) +1.

1.4.25. KEY EFFICACY ANALYSES FILE – KEYEFF

Dataset	KEYEFF
Creating program	keyeff.sas
Description	KEY EFFICACY ANALYSES FILE
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,TOPDT,TCOMPDT,TFLDT,STARTDT,STOPDT,BIRTHDT,RACE,SEX, RACEF,SEXF,STATUSDT,DIAGDT,DIAGIVDT,ENDCHEM,RAND_DT,RAND_DD, AGE,AGEUNIT,CNTRY,CNTRYF,DEATHDT,ENDCHEMN,STATUSDN,DEATHDN, ALIVEDN,ENDDT,PROGDT,FRSTCHEM,FRSTCHDT

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID (VISIT)		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUMOROP	num	OPTIMAL TUMOR RESPONSE		Collected at CRF.
TUMOROPF	char	DECODE, TUMOROP		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
TUMCOMP	num	TUMOR RESPONSE AT COMPLITION		Collected at CRF.
TUMCOMPF	char	DECODE, TUMCOMP		Collected at CRF.
TUMORFL	num	1-ST LINE CHEMO TUMOR RESPONSE		Collected at CRF.
TUMORFLF	char	DECODE, TUMORFL		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
STATUS	num	COMPLETION/WITHDRAWAL STATUS		Collected at CRF.
BASEHGT	num	BASELINE HEIGHT (CM)		Collected at CRF.
BASEWGT	num	BASELINE WEIGHT (KG)		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
ERRESULT	num	ESTROGEN RECEPTOR RESULT		Collected at CRF.
STAGDIAG	num	STAGE AT DIAGNOSIS		Collected at CRF.
STAGDIAF	char	DECODE, STAGDIAG		Collected at CRF.
METBONE	num	ONLY BONE METASTASIS (Y/N)		Collected at CRF.
POSTMENO	num	POST-MENOPAUSAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
ASCITES	num	ASCITES		Collected at CRF.
PLEUEFF	num	PLEURAL EFFUSION		Collected at CRF.
ASCITESF	char	DECODE, ASCITES		Collected at CRF.
PLEUEFFF	char	DECODE, PLEUEFF		Collected at CRF.
STRATIF	char	DECODE, STRATI BO/OTHER		Collected at CRF.
STRATI	num	STRATIFICATION BY MDS BO/MES/NMES		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CSTRATF	char	DECODE, CSTRAT		Collected at CRF.
ECOGSTAT	num	ECOG STATUS		Collected at CRF.
ECOGSTAF	char	DECODE, ECOGSTAT		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
DIAGMNTH	num	MONTHS INITIAL DIAGNOSIS		Collected at CRF.
DIAGIVMN	num	MONTHS METASTATIC DIAGNOSIS		Collected at CRF.
DETH_ST	num	WHEN PAT DIED: DB OR FU		Collected at CRF.
DETH_STF	char	DECODE, DETH_ST		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity
BSA	num	BASELINE BODY SURFACE AREA		Collected at CRF.
BMI	num	BODY MASS INDEX		Collected at CRF.
STUDYDAY	num	DAY OF DEATH		Collected at CRF.
CAUSP	char	CAUSE OF DEATH AT ALL/SPECIFY		Collected at CRF.
CAUDETHF	char	DECODE, CAUDETH		Collected at CRF.
CAUDETH	num	CAUSE OF DEATH AT ALL		Collected at CRF.
CENTSIZE	num	CENTER SIZE		Collected at CRF.
BC216	num	BASELINE SERUM IRON/ C216		Collected at CRF.
BC285	num	BASELINE FERRITIN / C285		Collected at CRF.
BC289	num	BASELINE TIBC / C289		Collected at CRF.
BH103	num	BASELINE HEMOGLOBIN		Collected at CRF.
BC344	num	BASELINE TRASFERRIN SATURATIN/ C344		Collected at CRF.
CH103	num	CHANGE LAST VALUE TO BL HEMOGLOBIN		Collected at CRF.
ONTRAN	num	ON-STUDY TRANSFUSION		Collected at CRF.
SUMUNON	num	SUM UNITS OF TRANS FOR ON-STUDY		Collected at CRF.
SUMUN28	num	UNITS TRANSFUSED ON STUDY / 28DAYS		Collected at CRF.

Variable	Type	Label	Codes	Comments
CAUDEATH	num	CAUSE OF DEATH		Collected at CRF.
DEATH	num	DID SUBJECT DIE?		Collected at CRF.
MDCAUSEF	char	DECODE, MDCAUSE		Collected at CRF.
MDCAUSE	num	CAUSE OF DEATH		Collected at CRF.
T_DEATH	num	TIME IN DAYS TO DEATH		Collected at CRF.
DBDEATH	num	DEATH AT DB 0=NO 1=YES		Collected at CRF.
T_DBDEA	num	TIME IN DAYS TO DEATH AT DB		Collected at CRF.
C_PROG	num	CENSORING STATUS TUMOR RESPONCE		Collected at CRF.
C_PROG2	num	CENCORING PROGRESSION-FREE TUMOR RESP		Collected at CRF.
T_PROG	num	TIME TO DISEASE PROGRESSION		Collected at CRF.
T_PROG2	num	T_PROG2		Collected at CRF.
OPRESP	num	OPTIMAL TUMOR RESPONSE		Collected at CRF.
T_PROG1	num	T_DEATH AS (ANYDETH-RAND_DT + 1)		Collected at CRF.
C_PROG1	num	STATUS FOR PROG FROM ANY DEATH		Collected at CRF.
LIVERF	char	DECODE, LIVER		Collected at CRF.
LUNGF	char	DECODE, LUNG		Collected at CRF.
LIV_LUNF	char	DECODE, LIVER OF LUNG		Collected at CRF.
VISCERAF	char	DECODE, VISCERA		Collected at CRF.

Variable	Type	Label	Codes	Comments
LIVER	num	LIVER LESION YES/NO		Collected at CRF.
LUNG	num	LUNG LESION YES/NO		Collected at CRF.
LIV_LUN	num	LIVER OR LUNG LESION		Collected at CRF.
VISCERA	num	VISCERAL LESION PRESENT		Collected at CRF.
PRERAD	num	PRE-ST BF METAST RADTHERAPY YES/NO		Collected at CRF.
PRERADF	char	DECODE, PRERAD		Collected at CRF.
PRE_RAD	num	PRE-ST BF RANDOMIZATION RAD THERAPY		Collected at CRF.
PRE_RADF	char	DECODE, PRE_RAD		Collected at CRF.
PRE_MS	num	PRE-ST META SETTING, MAX(ST,SP)<DIAGIV		Collected at CRF.
PRE_MSF	char	DECODE, PRE_MS		Collected at CRF.
PRECHEMF	char	PRESTUDY THERAPY,ADJUV. DECODE		Collected at CRF.
PRECHEMO	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PREIMMUF	char	PRESTUDY THERAPY,ADJUV. DECODE		Collected at CRF.
PREIMMUN	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PREHORMF	char	PRESTUDY THERAPY,ADJUV. DECODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PREHORM	num	PRESTUDY THERAPY,ADJUV. SETTING		Collected at CRF.
PREH_RDF	char	PRE-STUDY FOR LISTING/DECODING		Collected at CRF.
PREH_RD	num	PRE-STUDY FOR LISTING		Collected at CRF.
PREH_MSF	char	PRESTUDY THERPY, METAST SET DECODING		Collected at CRF.
PREH_MS	num	PRESTUDY THERPAY, METASTAT SETTING		Collected at CRF.
NLESIONS	num	NUMBER OF LESIONS		Collected at CRF.
NLESIONF	char	DECODE, NLESIONS		Collected at CRF.
NSITES	num	NUMBER OF SITES		Collected at CRF.
NSITESF	char	DECODE, NSITES		Collected at CRF.
PRECRTH	num	BOTH PRE-CHEMO&RAD THERAPY		Collected at CRF.
PRECRTHF	char	DECODE, PRECRTH		Collected at CRF.
CHEMDAYS	num	FIRST LINE CHEMO THERAPY IN DAYS		Collected at CRF.
CHEMWKS	num	FIRST LINE CHEMO IN WEEKS		Collected at CRF.
MTXF	char	DECODE, MTX		Collected at CRF.
TAMOF	char	DECODE, TAMO		Collected at CRF.
MTX	num	RECEIVED METHOTREXATE ONSTUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAMO	num	RECEIVED TAMOXIFEN & CHEMO ONSTUDY		Collected at CRF.
TOPDY	num	RELATIVE DAY OF OPTIMAL TUMOR RESPONSE		If TOPDT and REF.DATE not missing then perform below logic to calculate TOPDY, If TOPDT less than REF.DATE then (TOPDT - REF.DATE). Else if TOPDT is greater than equal to REF.DATE then (TOPDT-REF.DATE) +1.
TCOMPDY	num	RELATIVE DAY OF COMPLITION TUMOR RSPNSE		If TCOMPDT and REF.DATE not missing then perform below logic to calculate TCOMPDY, If TCOMPDT less than REF.DATE then (TCOMPDT - REF.DATE). Else if TCOMPDT is greater than equal to REF.DATE then (TCOMPDT- REF.DATE) +1.
TFLDY	num	RELATIVE DAY 1-ST LINE CHEM TUMR RSPNCE		If TFLDT and REF.DATE not missing then perform below logic to calculate TFLDY, If TFLDT less than REF.DATE then (TFLDT - REF.DATE). Else if TFLDT is greater than equal to REF.DATE then (TFLDT-REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
DIAGDY	num	RELATIVE INITIAL DIAGNOSIS DAY		If DIAGDT and REF.DATE not missing then perform below logic to calculate DIAGDY, If DIAGDT less than REF.DATE then (DIAGDT - REF.DATE). Else if DIAGDT is greater than equal to REF.DATE then (DIAGDT- REF.DATE) +1.
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.
ENDCHMDY	num	RELATIVE END OF FIRST LINE CHEMO DAY		If ENDCHEM and REF.DATE not missing then perform below logic to calculate ENDCHMDY, If ENDCHEM less than REF.DATE then (ENDCHEM - REF.DATE). Else if ENDCHEM is greater than equal to REF.DATE then (ENDCHEM- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.
ALIVEDY	num	RELATIVE DAY PATIANT WAS ALIVE		If ALIVEDN and REF.DATE not missing then perform below logic to calculate ALIVEDY, If ALIVEDN less than REF.DATE then (ALIVEDN - REF.DATE). Else if ALIVEDN is greater than equal to REF.DATE then (ALIVEDN- REF.DATE) +1.
ENDDY	num	RELATIVE END DAY OF STUDY/STATUS/LHGB		If ENDDT and REF.DATE not missing then perform below logic to calculate ENDDY, If ENDDT less than REF.DATE then (ENDDT - REF.DATE). Else if ENDDT is greater than equal to REF.DATE then (ENDDT- REF.DATE) +1.
PROGDY	num	RELATIVE DAY OF DISEASE PROFRESSION		If PROGDT and REF.DATE not missing then perform below logic to calculate PROGDY, If PROGDT less than REF.DATE then (PROGDT - REF.DATE). Else if PROGDT is greater than equal to REF.DATE then (PROGDT- REF.DATE) +1.
FRSTCHDY	num	RELATIVE START DAY OF 1ST LINE CHEMO		If FRSTCHDT and REF.DATE not missing then perform below logic to calculate FRSTCHDY, If FRSTCHDT less than REF.DATE then (FRSTCHDT - REF.DATE). Else if FRSTCHDT is greater than equal to REF.DATE then (FRSTCHDT- REF.DATE) +1.

1.4.26. ELIGIBILITY CRITERIA – KEYELIG

Dataset	KEYELIG
Creating program	keyelig.sas
Description	ELIGIBILITY CRITERIA
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: RACE,SEX,RACEF,SEXF,FORE,SURN,AGE,AGEUNIT,INVNAME,CNTRY,CONTDT, EVDATE,NAME1,NAME2,NAME

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
PNO	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRIT1	char	CRITERIA 1		Collected at CRF.
CRIT2	char	CRITERIA 2		Collected at CRF.
INCEXC	num	INCLUSION/EXCLUSION CRITERIA		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
INCEXCF	char	DECODE, INCEXC		Collected at CRF.
CRIT	char	CRITERIA 1 AND CRITERIA 2		Collected at CRF.
CONTDY	num	RELATIVE CONTACT DAY		If CONTDT and REF.DATE not missing then perform below logic to calculate CONTDY, If CONTDT less than REF.DATE then (CONTDT - REF.DATE). Else if CONTDT is greater than equal to REF.DATE then (CONTDT-REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.

1.4.27. KEYLAB1 – KEYLAB1

Dataset	KEYLAB1
Creating program	keylab1.sas
Description	KEYLAB1
Unique identifier	DUSUBJID,EVENT_ID,SAMPDY,VISITNO,LABDESC,RESULT
Sorted by	DUSUBJID,EVENT_ID,SAMPDY,VISITNO,LABDESC,RESULT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABLOC,SAMPDT,NUMDT,STARTDT,STATUSDT,RAND_DT

Variable	Type	Label	Codes	Comments
USUNIT	char	US UNIT FORMAT		Collected at CRF.
SIUNIT	char	SI UNIT FORMAT		Collected at CRF.
UNIT	char	UNIT		Collected at CRF.
USFMT	char	US VALUE FORMAT		Collected at CRF.
LABCODE	char	LABORATORY TEST CODE		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
BASELINE	num	BASELINE VALUE		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	PAGE NAME		Collected at CRF.
COLLECT	char	PRE-DETERMINED COLLECTION TIMES		Collected at CRF.
CRESULT	char	CHARACTER LAB RESULT		Collected at CRF.
FLAG	char	HI/LOW FLAG		Collected at CRF.
LABSPEC	char	DESCRIPTION FOR OTHER LAB TESTS		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
RESULT	num	LAB VALUE		Collected at CRF.
UNITCODE	num	LABORATORY UNIT CODE		Collected at CRF.
VISITYPE	num	VISIT TYPE		Collected at CRF.
VISITNO	num	VISIT		Collected at CRF.
VISITYPF	char	FORMATTED VISIT TYPE		Collected at CRF.
USCODE	num	US STD UNIT CODE		Collected at CRF.
SICODE	num	SI STD UNIT CODE		Collected at CRF.
SIFMT	char	SIFMT		Collected at CRF.
UNITFMT	char	UNITFMT		Collected at CRF.
LOAGE	num	LOAGE		Collected at CRF.
HIAGE	num	HIAGE		Collected at CRF.
LORANGE	num	LORANGE		Collected at CRF.
HIRANGE	num	HIRANGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
USVAL	num	US VALUE		Collected at CRF.
SIVAL	num	SI VALUE		Collected at CRF.
PERIOD	num	PERIOD		Collected at CRF.
BASEFLAG	char	BASELINE FLAG		Collected at CRF.
ENDPT	char	END POINT		Collected at CRF.
CHGBASE	num	CHANGE FROM BASELINE		Collected at CRF.
PCTCHG	num	% CHANGE FROM BASELINE		Collected at CRF.
LABORDER	num	SORT ORDER		Collected at CRF.
LABDESC	char	FULL LAB DESCRIPTION		Collected at CRF.
LABTST	char	ABBREVIATED LAB DESCRIPTION		Collected at CRF.
LABCLASS	char	LABCLASS		Collected at CRF.
STATUS	num	SIFMT		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	DAY AFTER RANDOMIZATION		Collected at CRF.
COLORD	num	COLUMN ORDER		Collected at CRF.
COLORDF	char	COLUMN ORDER, FORMATED		Collected at CRF.
WEEK	num	WEEK = INT((STUDYDAY-5)/7)+1		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPDY	num	RELATIVE SAMPLE DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
NUMDY	num	RELATIVE SAMPLE DAY		If NUMDT and REF.DATE not missing then perform below logic to calculate NUMDY, If NUMDT less than REF.DATE then (NUMDT - REF.DATE). Else if NUMDT is greater than equal to REF.DATE then (NUMDT- REF.DATE) +1.
STARTDY	num	RELATIVE UNIT DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY OF LAB CLASS		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

1.4.28. KEYLAB2 – KEYLAB2

Dataset	KEYLAB2
Creating program	keylab2.sas
Description	KEYLAB2
Unique identifier	DUSUBJID,COLORDF,EVENT_ID,SAMPDY,VISITNO,LABDESC,RESULT
Sorted by	DUSUBJID,COLORDF,EVENT_ID,SAMPDY,VISITNO,LABDESC,RESULT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABLOC,LABSPEC,SAMPDT,NUMDT,STARTDT,STATUSDT,RAND_DT

Variable	Type	Label	Codes	Comments
COLORDF	char	WEEK DESCRIPTION - WINDOWED		Collected at CRF.
USUNIT	char	US UNIT FORMAT		Collected at CRF.
SIUNIT	char	SI UNIT FORMAT		Collected at CRF.
UNIT	char	UNIT		Collected at CRF.
USFMT	char	SIFMT		Collected at CRF.
LABCODE	char	LABCLASS		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
BASELINE	num	BASELINE		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
COLLECT	char	COLLECT		Collected at CRF.
CRESULT	char	CRESULT		Collected at CRF.
FLAG	char	FLAG		Collected at CRF.
PHASE	num	PHASE		Collected at CRF.
RESULT	num	LAB VALUE		Collected at CRF.
UNITCODE	num	LABORATORY UNIT CODE		Collected at CRF.
VISITYPE	num	VISIT TYPE		Collected at CRF.
VISITNO	num	VISIT		Collected at CRF.
VISITYPF	char	FORMATTED VISIT TYPE		Collected at CRF.
USCODE	num	US STD UNIT CODE		Collected at CRF.
SICODE	num	SI STD UNIT CODE		Collected at CRF.
SIFMT	char	SIFMT		Collected at CRF.
UNITFMT	char	UNITFMT		Collected at CRF.
LOAGE	num	LOAGE		Collected at CRF.
HIAGE	num	HIAGE		Collected at CRF.
LORANGE	num	LORANGE		Collected at CRF.
HIRANGE	num	HIRANGE		Collected at CRF.
USVAL	num	US VALUE		Collected at CRF.
SIVAL	num	SI VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	num	PERIOD		Collected at CRF.
BASEFLAG	char	BASELINE FLAG		Collected at CRF.
ENDPT	char	END POINT		Collected at CRF.
CHGBASE	num	CHANGE FROM BASELINE		Collected at CRF.
PCTCHG	num	% CHANGE FROM BASELINE		Collected at CRF.
LABORDER	num	SORT ORDER		Collected at CRF.
LABDESC	char	FULL LAB DESCRIPTION		Collected at CRF.
LABTST	char	ABBREVIATED LAB DESCRIPTION		Collected at CRF.
LABCLASS	char	LABCLASS		Collected at CRF.
STATUS	num	COMPLETION/WITHDRAWAL STATUS		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	DAY AFTER RANDOMIZATION		Collected at CRF.
COLORD	num	WEEK ORDER - WINDOWED		Collected at CRF.
WEEK	num	WEEK ON STUDY - WINDOWED		Collected at CRF.
USVAL_	num	THE MEAN, USVAL		Collected at CRF.
WKACT	num	WEEK ON STUDY - ACTUAL		Collected at CRF.
WEEKF	char	WEEKF		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPDY	num	RELATIVE SAMPLE DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
NUMDY	num	RELATIVE SAMPLE DAY		If NUMDT and REF.DATE not missing then perform below logic to calculate NUMDY, If NUMDT less than REF.DATE then (NUMDT - REF.DATE). Else if NUMDT is greater than equal to REF.DATE then (NUMDT- REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

1.4.29. KEYMHIST – KEYMHIST

Dataset	KEYMHIST
Creating program	keymhist.sas
Description	KEYMHIST
Unique identifier	DUSUBJID,DUSUBJID,ENTRYNO
Sorted by	DUSUBJID,DUSUBJID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: RACE,SEX,RACEF,SEXF,FORE,SURN,AGE,AGEUNIT,INVNAME,CNTRY,REC_ID, SCTRY,ABNCODE,EVDAT,EVDATE,VERBATIM

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity..
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
NORMAB	num	STATUS		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
SYSTEM	num	SYSTEM FOR WHICH HISTORY IS TAKEN		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
NORMABF	char	DECODING, STATUS		Collected at CRF.
SYSTEMF	char	DECODE, SYSTEM		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.

1.4.30. KEYMLHIS – KEYMLHIS

Dataset	KEYMLHIS
Creating program	keymlhis.sas
Description	KEYMLHIS
Unique identifier	DUSUBJID,DUSUBJID,EVENT_ID,VISITNO,ENTRYNO
Sorted by	DUSUBJID,DUSUBJID,EVENT_ID,VISITNO,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID, SCTRY,EVDATE,RACE,SEX,RACEF,SEXF,FORE,SURN, RAND_DT,RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
LESION	num	LESION NUMBER		Collected at CRF.
LSIZE	char	SIZE OF LESION		Collected at CRF.

Variable	Type	Label	Codes	Comments
OTHRSPEC	char	OTHER SPECIFICATION		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
SITES	num	SITE CODES		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
SITESF	char	DECODING, SITE CODES		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
VISITF	char	DECODE, VISITNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

1.4.31. QOL KEYFILE – KEYQOL

Dataset	KEYQOL
Creating program	keyqol.sas
Description	QOL KEYFILE
Unique identifier	DPATNO,VISITNO,STARTDY,EVDAY,VALUE,QOL
Sorted by	DPATNO,VISITNO,STARTDY,EVDAY,VALUE,QOL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EVDATE,STARTDT,SEX,STARTDTN,RAND_DD,AGE,CNTRY,EVDATEN

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
STUDYDAY	num	STUDY DAY		Collected at CRF.
QOL	char	QOL		Collected at CRF.
BASEFLAG	char	BASELINE FLAG		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
VALUE	num	QOL VALUE		Collected at CRF.
BASELINE	num	BASELINE VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.

1.4.32. RADIATION THERAPY – KEYRAD

Dataset	KEYRAD
Creating program	keyrad.sas
Description	RADIATION THERAPY
Unique identifier	DUSUBJID,EVENT_ID,ENTRYNO
Sorted by	DUSUBJID,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,RSTARTDT,RSTOPDT,STARTDT,RACE,SEX,RACEF,SEXF, DIAGIVDT,ENDCHEM,RAND_DT,RAND_DD,AGE,INVNAME,CNTRY,RAWSTART, RAWSTOP,RSTARTD,RSTOPD,STARTDD,RSTARTN,STOPDD,RSTOPN,CDATE, CPDATE

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Collected at CRF.
RADFRAC	char	RADIATION THERAPY FRACTIONATION		Collected at CRF.
RADLOC	char	RADIATION LOCATION		Collected at CRF.
RADOSE	char	RADIATION DOSE (CGY)		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
PRERADF	char	DECODE, PRERAD		Collected at CRF.
PRERAD	num	PRE-ST BF METAST RADTHERAPY YES/NO		Collected at CRF.
PRE_RAD	num	PRE-ST BF RANDOMIZATION RAD THERAPY		Collected at CRF.
PRE_RADF	char	DECODE, PRE_RAD		Collected at CRF.
PRE_MS	num	PRE-ST META SETTING, MAX(ST,SP)<DIAGIV		Collected at CRF.
PRE_MSF	char	DECODE, PRE-MS		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYDAY	num	STUDY DAY		Collected at CRF.
NEWVIS	num	VISIT NUM WHERE VIS20 IN PROPER PLACE		Collected at CRF.
RSTARTDY	num	RELATIVE RADIATION THERAPY START DAY		If RSTARTDT and REF.DATE not missing then perform below logic to calculate RSTARTDY, If RSTARTDT less than REF.DATE then (RSTARTDT - REF.DATE). Else if RSTARTDT is greater than equal to REF.DATE then (RSTARTDT- REF.DATE) +1.
RSTOPDY	num	RELATIVE RADIATION THERAPY STOP DAY		If RSTOPDT and REF.DATE not missing then perform below logic to calculate RSTOPDY, If RSTOPDT less than REF.DATE then (RSTOPDT - REF.DATE). Else if RSTOPDT is greater than equal to REF.DATE then (RSTOPDT- REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ENDCHMDY	num	RELATIVE END OF FIRST LINE CHEMO DAY		If ENDCHEM and REF.DATE not missing then perform below logic to calculate ENDCHMDY, If ENDCHEM less than REF.DATE then (ENDCHEM - REF.DATE). Else if ENDCHEM is greater than equal to REF.DATE then (ENDCHEM- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
RSATRTDY	num	RELATIVE START DAY FROM CRF		If RAWSTART and REF.DATE not missing then perform below logic to calculate RSATRTDY, If RAWSTART less than REF.DATE then (RAWSTART - REF.DATE). Else if RAWSTART is greater than equal to REF.DATE then (RAWSTART- REF.DATE) +1.
RWSTOPDY	num	RELATIVE STOP DAY FROM CRF		If RAWSTOP and REF.DATE not missing then perform below logic to calculate RWSTOPDY, If RAWSTOP less than REF.DATE then (RAWSTOP - REF.DATE). Else if RAWSTOP is greater than equal to REF.DATE then (RAWSTOP- REF.DATE) +1.
STARTDDY	num	RELATIVE STRT DAY OF RAD FILLED MISSING		If STARTDD and REF.DATE not missing then perform below logic to calculate STARTDDY, If STARTDD less than REF.DATE then (STARTDD - REF.DATE). Else if STARTDD is greater than equal to REF.DATE then (STARTDD- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RSTRT_DY	num	RELATIVE START DAY OF RAD FILLED MISS		If RSTARTN and REF.DATE not missing then perform below logic to calculate RSTRT_DY, If RSTARTN less than REF.DATE then (RSTARTN - REF.DATE). Else if RSTARTN is greater than equal to REF.DATE then (RSTARTN- REF.DATE) +1.
STOPDDY	num	RELATIVE STOP DAY OF RAD FILLED MISSING		If STOPDD and REF.DATE not missing then perform below logic to calculate STOPDDY, If STOPDD less than REF.DATE then (STOPDD - REF.DATE). Else if STOPDD is greater than equal to REF.DATE then (STOPDD- REF.DATE) +1.
RSTOP_DY	num	RELATIVE STOP DAY OF RAD FILLED MISS		If RSTOPN and REF.DATE not missing then perform below logic to calculate RSTOP_DY, If RSTOPN less than REF.DATE then (RSTOPN - REF.DATE). Else if RSTOPN is greater than equal to REF.DATE then (RSTOPN- REF.DATE) +1.
CDAY	num	RELATIVE C DAY		If CDATE and REF.DATE not missing then perform below logic to calculate CDAY, If CDATE less than REF.DATE then (CDATE - REF.DATE). Else if CDATE is greater than equal to REF.DATE then (CDATE - REF.DATE) +1.
CPDAY	num	RELATIVE CP DAY		If CPDATE and REF.DATE not missing then perform below logic to calculate CPDAY, If CPDATE less than REF.DATE then (CPDAY_ - REF.DATE). Else if CPDATE is greater than equal to REF.DATE then (CPDATE - REF.DATE) +1.

1.4.33. STUDY MEDICATION – KEYSMED

Dataset	KEYSMED
Creating program	keysmed.sas
Description	STUDY MEDICATION
Unique identifier	DUSUBJID,EVENT_ID,RAND_DY,ENTRYNO
Sorted by	DUSUBJID,EVENT_ID,RAND_DY,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,ROUTE,SMEDDT,RACE,SEX,RACEF,SEXF,FORE,SURN,STATUSDT, RAND_DT,RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY,CNTRYF,DEATHDTN, DEATHDT,SMEDD

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Collected at CRF.
VOLUME	num	VOLUME ADMINISTERED		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY FOR STUDY MEDICATION		Collected at CRF.
WEEK	num	WEEK OF STUDY		Collected at CRF.
DOSE	num	DOSE OF MEDICATION VOL*40,000		Collected at CRF.

Variable	Type	Label	Codes	Comments
SMEDDY	num	RELATIVE DOSE DAY		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT-REF.DATE) +1.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.

1.4.34. STUDY MEDICATION FOR SUMMARIES – KEYSMED2

Dataset	KEYSMED2
Creating program	keysmed2.sas
Description	STUDY MEDICATION FOR SUMMARIES
Unique identifier	DUSUBJID,EVENT_ID,RAND_DY,ENTRYNO
Sorted by	DUSUBJID,EVENT_ID,RAND_DY,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: RACE,SEX,RACEF,SEXF,FORE,SURN,STATUSDT,RAND_DT, RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY,REC_ID,SCTRY,CNTRYF, DEATHDTN,DEATHDT

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
WEEK	num	WEEK OF STUDY		Collected at CRF.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY FOR STUDY MEDICATION		Collected at CRF.
VOL	num	CUMMULATIVE VOLUMES BY WEEK		Collected at CRF.
DOSE	num	CUMMULATIVE DOSE OF STUDY MED BY WEEK		Collected at CRF.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.

1.4.35. DEATH INFORMATION – KEYSURV

Dataset	KEYSURV
Creating program	keysurv.sas
Description	DEATH INFORMATION
Unique identifier	DUSUBJID,VISITNO,BODYSYS,PREF_TRM,RAND_DY,STATUSDY
Sorted by	DUSUBJID,VISITNO,BODYSYS,PREF_TRM,RAND_DY,STATUSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDT,STOPDT,RACE,SEX,RACEF,SEXF,RAND_DT,RAND_DD,AGE,ONSETDT, DEATHDT,EVDATE,OTHRSPEC,STATUSDT,VERBATIM,SMEDDT,OCAUSE

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
ADVCODE	char	WHOART CODE		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
OUTCOME	num	AE OUTCOME		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURDAY	num	DURATION OF AE		Collected at CRF.
CAUDEATH	num	CAUSE OF DEATH		Collected at CRF.
CAUSPEC	char	CAUSE OF DEATH SPECIFY		Collected at CRF.
DEATH	num	DID SUBJECT DIE?		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
STATUS	num	STATUS		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
CAUDEATF	char	DECODE, CAUDEATH		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
STATUSF_	char	STATUS AS COMPLETED/WITHDREW		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
SEXAE	char	SEX TO WHICH AE IS APPLICABLE (M/F/B)		Collected at CRF.
BODYSYS	char	BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	PREFERRED TERM DESCRIPTION		Collected at CRF.
VOLUME	num	LAST DOSE OF STUDY DRUG		Collected at CRF.

Variable	Type	Label	Codes	Comments
SMEDDAY	num	STUDY DAY FOR STUDY MEDICATION		Collected at CRF.
OREASONF	char	REASON TO WITHDRAW		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DEATHDAY	num	STUDY DAY FOR DEATH		Collected at CRF.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
ONSETDY	num	RELATIVE ONSET AE DAY WT FILLED IN DAYS		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
SMEDDY	num	RELATIVE LAST DAY FOR STUDY DRUG DOSE		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.
SMEDDY	num	RELATIVE LAST DAY FOR STUDY DRUG DOSE		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.

1.4.36. KEY ANALYSES FILE FOR THERAPIES – KEYTHER

Dataset	KEYTHER
Creating program	keyther.sas
Description	KEY ANALYSES FILE FOR THERAPIES
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DIAGDT,DIAGIVDT,STATUSDN,DEATHDN,IVRSDT,DIAGIVDN,DIAGDN,ONCTST, ONCTSP,ADJCTST,ADJCTSP,METCTST,METCTSP,PRECTST,PRECTSP,ONRTST, ONRTSP,ADJRTST,ADJRTSP,METRTST,METRTSP,PRERTST,PRERTSP,ONHTST, ONHTSP,ADJHTST,ADJHTSP,METHTST,METHTSP,PREHTST,PREHTSP,ADJCHTSP

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
FCHEMEND	num	END OF FIRST LINE CHEMO		Collected at CRF.
T_ADJCHT	num	TIME ADJ END TO META SIAG IN MONTHS		Collected at CRF.
C_TACHT	num	4 CATEGORIES END OF CHEMO/HOR TO META DI		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_TACHTF	char	4 CATEGORIES END OF CHEMO/HOR TO META DI		Collected at CRF.
TONCHEM	num	TIME ON STUDY CHEMO IN WEEKS		Collected at CRF.
DIAGDY	num	RELATIVE INITIAL DIAGNOSIS DAY		If DIAGDT and REF.DATE not missing then perform below logic to calculate DIAGDY, If DIAGDT less than REF.DATE then (DIAGDT - REF.DATE). Else if DIAGDT is greater than equal to REF.DATE then (DIAGDT-REF.DATE) +1.
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.
STATUSDY	num	RELATIVE COMPLETION/WITHDRAWAL DAY		If STATUSDN and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDN less than REF.DATE then (STATUSDN - REF.DATE). Else if STATUSDN is greater than equal to REF.DATE then (STATUSDN- REF.DATE) +1.
DEATHDY	num	RELATIVE DAY OF DEATH		If DEATHDN and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDN less than REF.DATE then (DEATHDN - REF.DATE). Else if DEATHDN is greater than equal to REF.DATE then (DEATHDN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
IVRSDY	num	RELATIVE RANDOMIZATION DAY FROM IVRS		If IVRSDT and REF.DATE not missing then perform below logic to calculate IVRSDY, If IVRSDT less than REF.DATE then (IVRSDT - REF.DATE). Else if IVRSDT is greater than equal to REF.DATE then (IVRSDT- REF.DATE) +1.
ONCTSTDY	num	RELATIVE STRT DAY ONSTUDY CHEMO THERAPY		If ONCTST and REF.DATE not missing then perform below logic to calculate ONCTSTDY, If ONCTST less than REF.DATE then (ONCTST - REF.DATE). Else if ONCTST is greater than equal to REF.DATE then (ONCTST- REF.DATE) +1.
ONCTSPDY	num	RELATIVE STOP DAY ONSTUDY CHEMO THERAPY		If ONCTSP and REF.DATE not missing then perform below logic to calculate ONCTSPDY, If ONCTSP less than REF.DATE then (ONCTSP - REF.DATE). Else if ONCTSP is greater than equal to REF.DATE then (ONCTSP- REF.DATE) +1.
ADJCSTDY	num	RELATIVE STRT DAY ADJUVANT CHEMO THRPY		If ADJCTST and REF.DATE not missing then perform below logic to calculate ADJCSTDY, If ADJCTST less than REF.DATE then (ADJCTST - REF.DATE). Else if ADJCTST is greater than equal to REF.DATE then (ADJCTST- REF.DATE) +1.
ADJCSPDY	num	RELATIVE STP DAY OF ADJUVANT CHEM THRPY		If ADJCTSP and REF.DATE not missing then perform below logic to calculate ADJCSPDY, If ADJCTSP less than REF.DATE then (ADJCTSP - REF.DATE). Else if ADJCTSP is greater than equal to REF.DATE then (ADJCTSP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
METCTSDY	num	RELATIVE STRT DAY OF METAST CHEMO THRPY		If METCTST and REF.DATE not missing then perform below logic to calculate METCTSDY, If METCTST less than REF.DATE then (METCTST - REF.DATE). Else if METCTST is greater than equal to REF.DATE then (METCTST- REF.DATE) +1.
METCT_DY	num	RELATIVE STP DAY OF METART CHEMO THRAPY		If METCTSP and REF.DATE not missing then perform below logic to calculate METCT_DY, If METCTSP less than REF.DATE then (METCTSP - REF.DATE). Else if METCTSP is greater than equal to REF.DATE then (METCTSP- REF.DATE) +1.
PRECTSDY	num	RELATIVE STRT DAY PRESTUDY CHEMO THRPY		If PRECTST and REF.DATE not missing then perform below logic to calculate PRECTSDY, If PRECTST less than REF.DATE then (PRECTST - REF.DATE). Else if PRECTST is greater than equal to REF.DATE then (PRECTST- REF.DATE) +1.
PRECSPDY	num	RELATIVE STP DAY OF PRESTUDY CHEM THRPY		If PRECTSP and REF.DATE not missing then perform below logic to calculate PRECSPDY, If PRECTSP less than REF.DATE then (PRECTSP - REF.DATE). Else if PRECTSP is greater than equal to REF.DATE then (PRECTSP- REF.DATE) +1.
ONRTSTDY	num	RELATIVE START DAY ONSTUDY RAD THERAPY		If ONRTST and REF.DATE not missing then perform below logic to calculate ONRTSTDY, If ONRTST less than REF.DATE then (ONRTST - REF.DATE). Else if ONRTST is greater than equal to REF.DATE then (ONRTST- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ONRTSDY	num	RELATIVE STOP DAY ONSTUDY RAD THERAPY		If ONRTSP and REF.DATE not missing then perform below logic to calculate ONRTSDY, If ONRTSP less than REF.DATE then (ONRTSP - REF.DATE). Else if ONRTSP is greater than equal to REF.DATE then (ONRTSP- REF.DATE) +1.
ADRTSTDY	num	RELATIVE STRT DAY OF ADJUVANT RAD THRPY		If ADJRTST and REF.DATE not missing then perform below logic to calculate ADRTSTDY, If ADJRTST less than REF.DATE then (ADJRTST - REF.DATE). Else if ADJRTST is greater than equal to REF.DATE then (ADJRTST- REF.DATE) +1.
ADRTSPDY	num	RELATIVE STP DAY OF ADJUVANT RAD THRAPY		If ADJRTSP and REF.DATE not missing then perform below logic to calculate ADRTSPDY, If ADJRTSP less than REF.DATE then (ADJRTSP - REF.DATE). Else if ADJRTSP is greater than equal to REF.DATE then (ADJRTSP- REF.DATE) +1.
METRTSDY	num	RELATIVE STRT DAY OF METAST RAD THERAPY		If METRTST and REF.DATE not missing then perform below logic to calculate METRTSDY, If METRTST less than REF.DATE then (METRTST - REF.DATE). Else if METRTST is greater than equal to REF.DATE then (METRTST- REF.DATE) +1.
METRSPDY	num	RELATIVE STOP DAY OF METART RAD THERAPY		If METRTSP and REF.DATE not missing then perform below logic to calculate METRSPDY, If METRTSP less than REF.DATE then (METRTSP - REF.DATE). Else if METRTSP is greater than equal to REF.DATE then (METRTSP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
PRRTSTDY	num	RELATIVE STRT DAY OF PRESTUDY RAD THRPY		If PRERTST and REF.DATE not missing then perform below logic to calculate PRRTSTDY, If PRERTST less than REF.DATE then (PRERTST - REF.DATE). Else if PRERTST is greater than equal to REF.DATE then (PRERTST- REF.DATE) +1.
PRRTSPDY	num	RELATIVE STP DAY OF PRESTDY RAD THERAPY		If PRERTSP and REF.DATE not missing then perform below logic to calculate PRRTSPDY, If PRERTSP less than REF.DATE then (PRERTSP - REF.DATE). Else if PRERTSP is greater than equal to REF.DATE then (PRERTSP- REF.DATE) +1.
ONHTSDY	num	RELATIVE STRT DAY ONSTUDY HORMO THERAPY		If ONHTST and REF.DATE not missing then perform below logic to calculate ONHTSDY, If ONHTST less than REF.DATE then (ONHTST - REF.DATE). Else if ONHTST is greater than equal to REF.DATE then (ONHTST- REF.DATE) +1.
ONHTSPDY	num	RELATIVE STOP DAY ONSTUDY HORMO THERAPY		If ONHTSP and REF.DATE not missing then perform below logic to calculate ONHTSPDY, If ONHTSP less than REF.DATE then (ONHTSP - REF.DATE). Else if ONHTSP is greater than equal to REF.DATE then (ONHTSP- REF.DATE) +1.
ADHTSTDY	num	RELATIVE STRT DAY ADJUVANT HORMO THRPY		If ADJHTST and REF.DATE not missing then perform below logic to calculate ADHTSTDY, If ADJHTST less than REF.DATE then (ADJHTST - REF.DATE). Else if ADJHTST is greater than equal to REF.DATE then (ADJHTST- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADHTSPDY	num	RELATIVE STOP DAY ADJUVANT HORMO THRPY		If ADJHTSP and REF.DATE not missing then perform below logic to calculate ADHTSPDY, If ADJHTSP less than REF.DATE then (ADJHTSP - REF.DATE). Else if ADJHTSP is greater than equal to REF.DATE then (ADJHTSP- REF.DATE) +1.
METHTSDY	num	RELATIVE STRT DAY OF METAST HORMO THRPY		If METHTST and REF.DATE not missing then perform below logic to calculate METHTSDY, If METHTST less than REF.DATE then (METHTST - REF.DATE). Else if METHTST is greater than equal to REF.DATE then (METHTST- REF.DATE) +1.
METHSPDY	num	RELATIVE STP DAY OF METART HORMO THRAPY		If METHTSP and REF.DATE not missing then perform below logic to calculate METHSPDY, If METHTSP less than REF.DATE then (METHTSP - REF.DATE). Else if METHTSP is greater than equal to REF.DATE then (METHTSP- REF.DATE) +1.
PREHDY	num	RELATIVE STRT DAY PRESTUDY HORMO THRPY		If PREHTST and REF.DATE not missing then perform below logic to calculate PREHDY, If PREHTST less than REF.DATE then (PREHTST - REF.DATE). Else if PREHTST is greater than equal to REF.DATE then (PREHTST- REF.DATE) +1.
PREHSPDY	num	RELATIVE STOP DAY PRESTUDY HORMO THRPY		If PREHTSP and REF.DATE not missing then perform below logic to calculate PREHSPDY, If PREHTSP less than REF.DATE then (PREHTSP - REF.DATE). Else if PREHTSP is greater than equal to REF.DATE then (PREHTSP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADJCHTDY	num	RELATIVE END DAY ADJVNT CHEMO/HOR THRPY		If ADJCHTSP and REF.DATE not missing then perform below logic to calculate ADJCHTDY, If ADJCHTSP less than REF.DATE then (ADJCHTSP - REF.DATE). Else if ADJCHTSP is greater than equal to REF.DATE then (ADJCHTSP- REF.DATE) +1.

1.4.37. TRANSFUSIONS – KEYTRAN1

Dataset	KEYTRAN1
Creating program	keytran1.sas
Description	TRANSFUSIONS
Unique identifier	DUSUBJID,EVENT_ID,ENTRYNO
Sorted by	DUSUBJID,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,TDATE,STARTDT,RACE,SEX,RACEF,SEXF,RAND_DT,AGE,INVNAME,CNTRY

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
NUMUNIT	num	NUMBER OF UNITS		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
POSTHGB	num	POST TRANSFUSION HEMOGLOBIN		Collected at CRF.
PTHGB	num	HEMOGLOBIN PRETRANSFUSION		Collected at CRF.
TRANTYPE	num	TRANSFUSION TYPE		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
TRANTYPF	char	DECODING, TRANSFUSION TYPE		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY		Collected at CRF.
PRETRANF	char	DECODE, PRETRAN		Collected at CRF.
ONTRANF	char	DECODE, ONTRAN		Collected at CRF.
PRETRAN	num	PRE-STUDY TRANSFUSION		Collected at CRF.
ONTRAN	num	ON-STUDY TRANSFUSION		Collected at CRF.
TDY	num	RELATIVE TRANSFUSION DAY		If TDATE and REF.DATE not missing then perform below logic to calculate TDY, If TDATE less than REF.DATE then (TDATE - REF.DATE). Else if TDATE is greater than equal to REF.DATE then (TDATE-REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

1.4.38. TRANSFUSIONS FOR SUMMARIES – KEYTRAN2

Dataset	KEYTRAN2
Creating program	keytran2.sas
Description	TRANSFUSIONS FOR SUMMARIES
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDT,RACE,SEX,RACEF,SEXF,AGE,INVNAME,CNTRY,CNTRYF

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	`	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.

Variable	Type	Label	Codes	Comments
ONTRANF	char	DECODE, ONTRAN		Collected at CRF.
ONTRAN	num	ON-STUDY TRANSFUSION		Collected at CRF.
NP_	num	NUMBER OF NONMISSING VALUES, PTHGB		Collected at CRF.
MEANP_	num	THE MEAN, PTHGB		Collected at CRF.
STDP_	num	THE STANDARD DEVIATION, PTHGB		Collected at CRF.
MAXP_	num	THE LARGEST VALUE, PTHGB		Collected at CRF.
MEDIANP_	num	THE MEDIAN, PTHGB		Collected at CRF.
MINP_	num	THE SMALLEST VALUE, PTHGB		Collected at CRF.
SUMUNON	num	SUM UNITS OF TRANS FOR ON-STUDY		Collected at CRF.
SUMUNPRE	num	SUM UNITS OF TRANS FOR PRE-STUDY		Collected at CRF.
PRETRANF	char	DECODE, PRETRAN		Collected at CRF.
PRETRAN	num	PRE-STUDY TRANSFUSION		Collected at CRF.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.

1.4.39. TUMOR RESPONSE/EFFICACY – KEYTRESP

Dataset	KEYTRESP
Creating program	keytresp.sas
Description	TUMOR RESPONSE/EFFICACY
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,TOPDT,TCOMPDT,TFLDT,RACE,SEX,RACEF,SEXF,ALLDTHDT, STATUSDT,RAND_DT,AGE,INVNAME,CNTRY,CNTRYF,DEATHDT,ENDDT, PROGDT

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
LNEWOP	num	NEW LESIONS AT OPTIMAL TUMOR RESPONCE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Collected at CRF.
TUMOROP	num	OPTIMAL TUMOR RESPONCE		Collected at CRF.
LNEWOPF	char	DECODE, LNEWOPF		Collected at CRF.
TUMOROPF	char	DECODE, TUMOROP		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
LNEWCOM	num	NEW LESIONS AT COMPLITION TUMOR RESPONCE		Collected at CRF.
TUMCOMP	num	TUMOR RESPONCE AT COMPLITION		Collected at CRF.
LNEWCOMF	char	DECODE, LNEWCOM		Collected at CRF.
TUMCOMPF	char	DECIDE, TUMCOMP		Collected at CRF.
LNEWFL	num	NEW LESIONS AT 1-ST LINE TUMOR RESPONCE		Collected at CRF.
TUMORFL	num	1-ST LINE CHEMO TUMOR RESPONCE		Collected at CRF.
LNEWFLF	char	DECODE, LNEWFLF		Collected at CRF.
TUMORFLF	char	DECODE, TUMORFL		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.

Variable	Type	Label	Codes	Comments
TOPDY	num	RELATIVE DAY OF OPTIMAL TUMOR RSPONCE		If TOPDT and REF.DATE not missing then perform below logic to calculate TOPDY, If TOPDT less than REF.DATE then (TOPDT - REF.DATE). Else if TOPDT is greater than equal to REF.DATE then (TOPDT-REF.DATE) +1.
TCOMPDY	num	RELATIVE DAY COMPLITION TUMOR RSPONCE		If TCOMPDT and REF.DATE not missing then perform below logic to calculate TCOMPDY, If TCOMPDT less than REF.DATE then (TCOMPDT - REF.DATE). Else if TCOMPDT is greater than equal to REF.DATE then (TCOMPDT- REF.DATE) +1.
TFLDY	num	RELATIVE DAY 1-ST LINE CHEM TUMR RSPNCE		If TFLDT and REF.DATE not missing then perform below logic to calculate TFLDY, If TFLDT less than REF.DATE then (TFLDT - REF.DATE). Else if TFLDT is greater than equal to REF.DATE then (TFLDT-REF.DATE) +1.
ALLDTHDY	num	RELATIVE DAY OF DEATH IN ALL PHASES		If ALLDTHDT and REF.DATE not missing then perform below logic to calculate ALLDTHDY, If ALLDTHDT less than REF.DATE then (ALLDTHDT - REF.DATE). Else if ALLDTHDT is greater than equal to REF.DATE then (ALLDTHDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.
ENDDY	num	RELATIVE END DAY OF STUDY/STATUS/LHGB		If ENDDT and REF.DATE not missing then perform below logic to calculate ENDDY, If ENDDT less than REF.DATE then (ENDDT - REF.DATE). Else if ENDDT is greater than equal to REF.DATE then (ENDDT- REF.DATE) +1.
PROGDY	num	RELATIVE DAY OF DISEASE PROFRESSION		If PROGDT and REF.DATE not missing then perform below logic to calculate PROGDY, If PROGDT less than REF.DATE then (PROGDT - REF.DATE). Else if PROGDT is greater than equal to REF.DATE then (PROGDT- REF.DATE) +1.

1.4.40. TUMOR RESPONSE – KEYTUMOR

Dataset	KEYTUMOR
Creating program	keytumor.sas
Description	TUMOR RESPONSE
Unique identifier	DUSUBJID,EVENT_ID,TIMEPT
Sorted by	DUSUBJID,EVENT_ID,TIMEPT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,TUMRESDT,RACE,SEX,RACEF,SEXF,RAND_DT,RAND_DD,AGE, INVNAME,CNTRY

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
LESIONEW	num	NEW LESIONS		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
TUMOR	num	TUMOR RESPONSE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
LESIONEF	char	DECODING, NEW LESIONS		Collected at CRF.
TUMORF	char	DECODE, TUMOR		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
TIMEPTF	char	DECODE, TIMEPT		Collected at CRF.
TIMEPT	num	TIME POINT FOR RESPONSE		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY		Collected at CRF.
TUMRESDY	num	RELATIVE TUMOR RESPONSE DAY		If TUMRESDT and REF.DATE not missing then perform below logic to calculate TUMRESDY, If TUMRESDT less than REF.DATE then (TUMRESDT - REF.DATE). Else if TUMRESDT is greater than equal to REF.DATE then (TUMRESDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

1.4.41. THROMBOTIC/VASCULAR EVENTS – KEYTVE

Dataset	KEYTVE
Creating program	keytve.sas
Description	THROMBOTIC/VASCULAR EVENTS
Unique identifier	DUSUBJID,VISITNO,ONSETDY,ADVCODE
Sorted by	DUSUBJID,VISITNO,ONSETDY,ADVCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: ONSETDT,STOPDT,STOPTIME,TONSET,VERBATIM,MEDSTRDT,MEDSPDT,RACE, SEX,RACEF,SEXF,RAND_DT,RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY, CNTRYF,STDYEND,ONSETDTN,ONSET,ONSETN,STOPDTN,STOPTIMN,TONSETN

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
EVENT_ID	char	EVENT (VISIT) NUMVER, CHAR		Collected at CRF.
ADVEXP	num	DID AE OCCUR (Y/N?)		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVEXPF	char	DECODE, ADVEXP		Collected at CRF.
ACTION	num	ACTION TAKEN		Collected at CRF.
ADVCODE	char	WHOART CODE		Collected at CRF.
ADVDESC	char	WHOART DESCRIPTION		Collected at CRF.
CONCOM	num	WAS CONCOMITANT THERAPY GIVEN (Y/N?)		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
OUTCOME	num	AE OUTCOME		Collected at CRF.
SERIOUS	num	IS AE SERIOUS (Y/N?)		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
ACTIONF	char	DECODE, ACTION		Collected at CRF.
CONCOMF	char	DECODE, CONCOM		Collected at CRF.
DRUGRELF	char	DECODE, DRUGREL		Collected at CRF.
OUTCOMEF	char	DECODE, OUTCOME		Collected at CRF.
SERIOUSF	char	DECODE, SERIOUS		Collected at CRF.
SEVERITF	char	DECODE, SEVERITY		Collected at CRF.
DELREC	num	DELREC		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
BODYSYS	char	WHOART BODY SYSTEM		Collected at CRF.
PREF_TRM	char	WHOART PREFERRED TERM		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGIMEN	char	REGIMEN CODE		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
STUDYDAY	num	STUDY DAY		Collected at CRF.
DURDAY	num	DURATION OF AE		Collected at CRF.
PERIOD	num	PERIOD OF STUDY - NA		Collected at CRF.
REGDAY	num	REGIMEN DAY - NA		Collected at CRF.
AFMEDSTF	char	AR AFTER MED START DATE DECODING		Collected at CRF.
AFMEDSPF	char	AFTER MED STOP DATE +14,DECODING		Collected at CRF.
AFMEDST	num	AE AFTER MED START DATE YES/NO		Collected at CRF.
AFMEDSP	num	AF MEDSTOP DATE+14 OR >13MAY2002, YES/NO		Collected at CRF.
TVENO	num	NUMBER OF TVE FROM TVE DICTIONARY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONSETDY	num	RELATIVE ONSET AE DAY WT FILLED IN DAYS		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY OF AE		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
MEDSTRDY	num	RELATIVE MEDICATION START DAY		If MEDSTRDT and REF.DATE not missing then perform below logic to calculate MEDSTRDY, If MEDSTRDT less than REF.DATE then (MEDSTRDT - REF.DATE). Else if MEDSTRDT is greater than equal to REF.DATE then (MEDSTRDT- REF.DATE) +1.
MEDSPDY	num	RELATIVE MEDICATION STOP DAY		If MEDSPDT and REF.DATE not missing then perform below logic to calculate MEDSPDY, If MEDSPDT less than REF.DATE then (MEDSPDT - REF.DATE). Else if MEDSPDT is greater than equal to REF.DATE then (MEDSPDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STDYENDY	num	RELATIVE INDIVIDUAL STUDY END DAY		If STDYEND and REF.DATE not missing then perform below logic to calculate STDYENDY, If STDYEND less than REF.DATE then (STDYEND - REF.DATE). Else if STDYEND is greater than equal to REF.DATE then (STDYEND- REF.DATE) +1.
ONST_DY	num	RELATIVE ORIGINAL ONSET DAY OF AE		If ONSET and REF.DATE not missing then perform below logic to calculate ONST_DY, If ONSET less than REF.DATE then (ONSET - REF.DATE). Else if ONSET is greater than equal to REF.DATE then (ONSET- REF.DATE) +1.
STOP_DY	num	RELATIVE STOP DAY OF AE		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOP_DY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.

1.4.42. VITAL SIGNS – KEYVIT1

Dataset	KEYVIT1
Creating program	keyvit1.sas
Description	VITAL SIGNS
Unique identifier	DUSUBJID, VISITNO, RAND_DY, BASEFLAG, VITALF
Sorted by	DUSUBJID, VISITNO, RAND_DY, BASEFLAG, VITALF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDT, RACE, SEX, RACEF, SEXF, FORE, SURN, RAND_DT, AGE, AGEUNIT, INVNAME, CNTRY, EVDATE

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
BASELINE	num	BASELINE VALUE		Collected at CRF.
VITAL	char	VITAL SIGN		Collected at CRF.
VITALF	char	DECODE, VITAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT NUMBER (CHARACTER)		Collected at CRF.
VALUE	num	VITAL SIGN VALUE		Collected at CRF.
VISITYPE	num	VISIT TYPE		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
REGDAY	num	REGIMEN DAY		Collected at CRF.
BASEFLAG	char	BASELINE IDENTIFIER (Y)		Collected at CRF.
ENDPT	char	END POINT (Y)		Collected at CRF.
COLORD	num	SORT ORDER		Collected at CRF.
VORDER	num	ORDER OF VITALS FOR OUTPUT		Collected at CRF.
CHGBASE	num	CHANGE FROM BASELINE		Collected at CRF.
PCTCHG	num	PERCENT CHANGE		Collected at CRF.
COLORDF	char	VISIT DISCRIPTION		Collected at CRF.
WEEKF	char	DECODE, WEEK		Collected at CRF.
WEEK	num	WEEK ON STUDY - ACTUAL		Collected at CRF.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.43. VITAL SIGNS FOR SUMMARIES – KEYVIT2

Dataset	KEYVIT2
Creating program	keyvit2.sas
Description	VITAL SIGNS FOR SUMMARIES
Unique identifier	DUSUBJID,COLORDF,VISITNO,RAND_DY,BASEFLAG,VITALF
Sorted by	DUSUBJID,COLORDF,VISITNO,RAND_DY,BASEFLAG,VITALF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDT,RACE,SEX,RACEF,SEXF,FORE,SURN,RAND_DT,AGE,AGEUNIT, INVNAME,CNTRY,EVDATE

Variable	Type	Label	Codes	Comments
COLORDF	char	WEEK DESCRIPTION - WINDOWED		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
BASELINE	num	BASELINE VALUE		Collected at CRF.
VITAL	char	VITAL SIGN		Collected at CRF.

Variable	Type	Label	Codes	Comments
VITALF	char	DECODE, VITAL		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT NUMBER (CHARACTER)		Collected at CRF.
VALUE	num	VITAL SIGN VALUE		Collected at CRF.
VISITYPE	num	VISIT TYPE		Collected at CRF.
VISITNO	num	VISIT NUMBER		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
REGDAY	num	REGIMEN DAY		Collected at CRF.
BASEFLAG	char	BASELINE IDENTIFIER (Y)		Collected at CRF.
ENDPT	char	END POINT (Y)		Collected at CRF.
COLORD	num	WEEK ORDER - WINDOWED		Collected at CRF.
VORDER	num	ORDER OF VITALS FOR OUTPUT		Collected at CRF.
CHGBASE	num	CHANGE FROM BASELINE		Collected at CRF.
PCTCHG	num	PERCENT CHANGE		Collected at CRF.
WEEKF	char	DECODE, WEEK		Collected at CRF.
WEEK	num	WEEK ON STUDY - WINDOWED		Collected at CRF.
WKACT	num	WEEK ON STUDY - ACTUAL		Collected at CRF.
MAXIMUM	num	MAXIMUM VALUE		Collected at CRF.
CHGMAX	num	CHANGES FROM MAXIMUM VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.44. DERIVED: OL STUDY MEDICATION – KSMED_OL

Dataset	KSMED_OL
Creating program	ksmed_ol.sas
Description	DERIVED: OL STUDY MEDICATION
Unique identifier	DUSUBJID,RAND_DY,SMEDDY
Sorted by	DUSUBJID,RAND_DY,SMEDDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: ROUTE,SMEDDT,RACE,SEX,RACEF,SEXF,FORE,SURN,STATUSDT,RAND_DT, RAND_DD,AGE,AGEUNIT,INVNAME,CNTRY,DEATHDTN,DEATHDT,SMEDD

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
VOLUME	num	DOSE OF MEDICATION (IU)		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
COMPWKS	num	COMPLETE WEEKS ON STUDY		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
WEEK	num	WEEK ON STUDY - DERIVED		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
SMEDDY	num	RELATIVE DOSE DAY		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATHDY	num	RELATIVE DEATH DAY		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.

1.4.45. LABS1 – LABS1

Dataset	LABS1
Creating program	labs1.sas
Description	LABS1
Unique identifier	DPATNO,EVENT_ID,SAMPDY,VISITNO,LABDESC,RESULT
Sorted by	DPATNO,EVENT_ID,SAMPDY,VISITNO,LABDESC,RESULT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,ACCNO,BATCHID,LABLOC,LABNAME,LABSPEC,REC_NUM, SAMPD,SAMPDT,SAMPTIM,SAMPTIME,EVDATE,SASDATE,BIRTHDT,SEX,AGE, STARTDT,STOPDT,AGEUNIT,ENTRYDT,MODIFYDT,START,STOP

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
COLLECT	char	PRE-DETERMINED COLLECTION TIMES		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRESULT	char	CHARACTER LAB RESULT		Collected at CRF.
FLAG	char	HIGH/LOW LAB VALUE FLAG		Collected at CRF.
LABCODE	char	LABORATORY TEST CODE		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
RESULT	num	NUMERIC LAB RESULT		Collected at CRF.
TUPID	num	RSM UNIQUE RECORD ID WITHIN PROTOCOL		Collected at CRF.
UNITCODE	num	LABORATORY UNIT CODE		Collected at CRF.
VISITYPE	num	TYPE OF VISIT		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
VISITYPF	char	DECODING, TYPE OF VISIT		Collected at CRF.
CENTRAL	char	CENTRAL LABORATORY (Y/N) * DROP START S		Collected at CRF.
NEWVIS	num	NEWVIS		Collected at CRF.
USCODE	num	USCODE		Collected at CRF.
USFACTOR	num	USFACTOR		Collected at CRF.
SICODE	num	SICODE		Collected at CRF.
SIFACTOR	num	SIFACTOR		Collected at CRF.
USFMT	char	USFMT		Collected at CRF.
SIFMT	char	SIFMT		Collected at CRF.

Variable	Type	Label	Codes	Comments
UNITFMT	char	UNITFMT		Collected at CRF.
LOAGE	num	LOAGE		Collected at CRF.
HIAGE	num	HIAGE		Collected at CRF.
LORANGE	num	LORANGE		Collected at CRF.
HIRANGE	num	HIRANGE		Collected at CRF.
I	num	I		Collected at CRF.
USVAL	num	USVAL		Collected at CRF.
SIVAL	num	SIVAL		Collected at CRF.
LABCLASS	char	TYPE OF LAB		Collected at CRF.
LABDESC	char	FULL LAB DESCRIPTION		Collected at CRF.
LABTST	char	ABBREVIATED LAB DESCRIPTION		Collected at CRF.
PERIOD	num	PERIOD		Collected at CRF.
UNIT	char	UNIT		Collected at CRF.
USUNIT	char	USUNIT		Collected at CRF.
SIUNIT	char	SIUNIT		Collected at CRF.
SAMPDY	num	RELATIVE DAY TEST PERFORMED		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE EVENT DAY		If EDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.
SASDY	num	RELATIVE DAY		If SASDATE and REF.DATE not missing then perform below logic to calculate SASDY, If SASDATE less than REF.DATE then (SASDATE - REF.DATE). Else if SASDATE is greater than equal to REF.DATE then (SASDATE- REF.DATE) +1.
STARTDY	num	RELATIVE START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ENTRYDY	num	RELATIVE ENTRY DAY		If ENTRYDT and REF.DATE not missing then perform below logic to calculate ENTRYDY, If ENTRYDT less than REF.DATE then (ENTRYDT - REF.DATE). Else if ENTRYDT is greater than equal to REF.DATE then (ENTRYDT- REF.DATE) +1.
MODIFYDY	num	RELATIVE MODIFY DAY		If MODIFYDT and REF.DATE not missing then perform below logic to calculate MODIFYDY, If MODIFYDT less than REF.DATE then (MODIFYDT - REF.DATE). Else if MODIFYDT is greater than equal to REF.DATE then (MODIFYDT- REF.DATE) +1.

1.4.46. MDCAUSE – MDCAUSE

Dataset	MDCAUSE
Creating program	mdcause.sas
Description	MDCAUSE
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
MDCAUSEF	char	DECODE, MDCAUSE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
MDCAUSE	num	CAUSE OF DEATH		Collected at CRF.

1.4.47. MDSTRAT – MDSTRAT

Dataset	MDSTRAT
Creating program	mdstrat.sas
Description	MDSTRAT
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
MDSTRATF	char	MDSTRATF		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
MDSTRAT	num	MDSTRAT		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CSTRATF	char	DECODE, CSTRAT		Collected at CRF.

1.4.48. MIXEDQOL – MIXEDQOL

Dataset	MIXEDQOL
Creating program	mixedqol.sas
Description	MIXEDQOL
Unique identifier	PARM,SCORE
Sorted by	PARM,SCORE
Notes	

Variable	Type	Label	Codes	Comments
PARM	char	PARAMETER		Collected at CRF.
EST	num	ESTIMATE		Collected at CRF.
SE	num	STD ERROR		Collected at CRF.
DF	num	DF		Collected at CRF.
T	num	T		Collected at CRF.
P_T	num	PR > |T|		Collected at CRF.
CCOL1	char	CCOL1		Collected at CRF.
SCORE	char	SCORE		Collected at CRF.
N_SS	num	N_SS		Collected at CRF.
TXGROUP	num	TXGROUP		Collected at CRF.
N	num	FREQUENCY COUNT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERCENT	num	PERCENT OF TOTAL FREQUENCY		Collected at CRF.
N_BASE	num	FREQUENCY COUNT		Collected at CRF.

1.4.49. MIXQOLCF – MIXQOLCF

Dataset	MIXQOLCF
Creating program	mixqolcf.sas
Description	MIXQOLCF
Unique identifier	PARM,SCORE
Sorted by	PARM,SCORE
Notes	

Variable	Type	Label	Codes	Comments
PARM	char	PARAMETER		Collected at CRF.
EST	num	ESTIMATE		Collected at CRF.
SE	num	STD ERROR		Collected at CRF.
DF	num	DF		Collected at CRF.
T	num	T		Collected at CRF.
P_T	num	PR > |T|		Collected at CRF.
CCOL1	char	CCOL1		Collected at CRF.

Variable	Type	Label	Codes	Comments
SCORE	char	SCORE		Collected at CRF.
N_SS	num	N_SS		Collected at CRF.
TXGROUP	num	TXGROUP		Collected at CRF.
N	num	FREQUENCY COUNT		Collected at CRF.
PERCENT	num	PERCENT OF TOTAL FREQUENCY		Collected at CRF.
N_BASE	num	FREQUENCY COUNT		Collected at CRF.

1.4.50. STUDY DRUG ADMINISTRATION – OLSMED

Dataset	OLSMED
Creating program	olsmed.sas
Description	STUDY DRUG ADMINISTRATION
Unique identifier	DPATNO,VISITNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,VISITNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REC_ID,SCTRY,ROUTE,SMEDDT

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
VOLUME	num	VOLUME ADMINISTERED		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
SMEDDY	num	RELATIVE DOSE DAY		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.

1.4.51. PATEINT RECORD – PATIENT

Dataset	PATIENT
Creating program	patient.sas
Description	PATEINT RECORD
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDTN,STOPDTN,FRSTCHEM,ENDCHEMN,RAND_DD,DBSTRTN,STATUSDN, DEATHDTN

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
CHEMDAYS	num	FIRST LINE CHEMO THERAPY IN DAYS		Collected at CRF.
DBDUR	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
STATUS	num	COMPLETION/WITHDRAWAL STATUS		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.

Variable	Type	Label	Codes	Comments
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
DEATH	num	DID SUBJECT DIE (Y/N)		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.
L_DAY_CL	num	LAST DAY EVAL CLAS		Collected at CRF.
L_VIS_CL	num	LAST VISIT WITH CLAS		Collected at CRF.
QDROPC4	num	ON DB LT 4 WEEKS		Collected at CRF.
QDROPC16	num	ON DB 4 TO 15 WEEKS		Collected at CRF.
QDROPC24	num	ON DB 16 TO 23 WEEKS		Collected at CRF.
QDROPC32	num	ON DB 24 TO 31 WEEKS		Collected at CRF.
DROPCGP	num	TIME OF DROPOUT 5 LEVELS		Collected at CRF.
L_DAY_FA	num	LAST DAY EVAL FACT		Collected at CRF.
L_VIS_FA	num	LAST VISIT WITH FACT		Collected at CRF.
QDROPF4	num	ON DB LT 4 WEEKS		Collected at CRF.
QDROPF16	num	ON DB 4 TO 15 WEEKS		Collected at CRF.
QDROPF24	num	ON DB 16 TO 23 WEEKS		Collected at CRF.
QDROPF32	num	ON DB 24 TO 31 WEEKS		Collected at CRF.
DROPFGP	num	TIME OF DROPOUT 5 LEVELS		Collected at CRF.
L_DBDUR	num	L_DBDUR		Collected at CRF.
C_DBDUR	num	C_DBDUR		Collected at CRF.
L_DAY	num	LAST DAY WITH CLAS OR FACT		Collected at CRF.

Variable	Type	Label	Codes	Comments
L_QOL	num	LOG(LAST DAY WITH QOL)		Collected at CRF.
C_QOL	num	C_QOL		Collected at CRF.
STARTNDY	num	RELATIVE MEDICATION START DAY		If STARTDTN and REF.DATE not missing then perform below logic to calculate STARTNDY, If STARTDTN less than REF.DATE then (STARTDTN - REF.DATE). Else if STARTDTN is greater than equal to REF.DATE then (STARTDTN- REF.DATE) +1.
STOP_DY	num	RELATIVE MEDICATION STOP DAY		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOP_DY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.
FRSTCHDY	num	RELATIVE START DAY OF 1ST LINE CHEMO		If FRSTCHEM and REF.DATE not missing then perform below logic to calculate FRSTCHDY, If FRSTCHEM less than REF.DATE then (FRSTCHEM - REF.DATE). Else if FRSTCHEM is greater than equal to REF.DATE then (FRSTCHEM- REF.DATE) +1.
ENDCHMDY	num	RELATIVE FILLED IN END,1-ST LINE CHEM DAY		If ENDCHEMN and REF.DATE not missing then perform below logic to calculate ENDCHMDY, If ENDCHEMN less than REF.DATE then (ENDCHEMN - REF.DATE). Else if ENDCHEMN is greater than equal to REF.DATE then (ENDCHEMN- REF.DATE) +1.
DBSTR_DY	num	RELATIVE RANDOMIZATION IVRS DAY		If DBSTRTN and REF.DATE not missing then perform below logic to calculate DBSTR_DY, If DBSTRTN less than REF.DATE then (DBSTRTN - REF.DATE). Else if DBSTRTN is greater than equal to REF.DATE then (DBSTRTN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STATUSDY	num	RELATIVE COMPLETION/WITHDRAWAL DAY		If STATUSDN and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDN less than REF.DATE then (STATUSDN - REF.DATE). Else if STATUSDN is greater than equal to REF.DATE then (STATUSDN- REF.DATE) +1.
DEATH_DY	num	RELATIVE ALLDTHDT WT FILL IN DAY OF DTH		If DEATHDTN and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATHDTN less than REF.DATE then (DEATHDTN - REF.DATE). Else if DEATHDTN is greater than equal to REF.DATE then (DEATHDTN- REF.DATE) +1.

1.4.52. PLATLETS – PLATLETS

Dataset	PLATLETS
Creating program	platlets.sas
Description	PLATLETS
Unique identifier	DPATNO,SAMPDY,LABDESC,USVAL
Sorted by	DPATNO,SAMPDY,LABDESC,USVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPDT,NUMDT

Variable	Type	Label	Codes	Comments
USUNIT	char	US UNIT FORMAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABCODE	char	LABORATORY TEST CODE		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
USVAL	num	US VALUE		Collected at CRF.
LABDESC	char	FULL LAB DESCRIPTION		Collected at CRF.
WEEK	num	WEEK ON STUDY - WINDOWED		Collected at CRF.
SAMPDY	num	RELATIVE SAMPLE DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
NUMDY	num	RELATIVE SAMPLE DAY		If NUMDT and REF.DATE not missing then perform below logic to calculate NUMDY, If NUMDT less than REF.DATE then (NUMDT - REF.DATE). Else if NUMDT is greater than equal to REF.DATE then (NUMDT- REF.DATE) +1.

1.4.53. PROFILE – PROFILE

Dataset	PROFILE
Creating program	profile.sas
Description	PROFILE
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: STARTDT,STOPDT,BIRTHDT,RACE,RACESPEC,SEX,RACEF,SEXF,BIRTHDTN, FORE,SURN,INIT,ALLDTHDT,OTHRSPEC,STATUSDT,STARTDTN,STOPDTN, LABDTN,TITLE1,TITLE2,DIAGDT,DIAGIVDT,DIAGIVDN,DIAGDTN,RAND_DT, RAND_DD,AGE,AGEUNIT,INVNAME,COUNTRY,CNTRY,CNTRYF,DEATHDTN, DEATHDT,DBDETHDT,ENDCHEMN,STATUSDN,STDYEND,REGIONF

Variable	Type	Label	Codes	Comments
ITTF	char	DECODE, ITT		Collected at CRF.
EFFF	char	DECODE, EFF		Collected at CRF.
SAFF	char	DECODE, SAF		Collected at CRF.
MSAFF	char	DECODE, MSAF		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.

Variable	Type	Label	Codes	Comments
DCNO	num	CENTER NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned center number for De-Identity.
STATUS	num	COMPLETION/WITHDRAWAL STATUS		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
THERDAYS	num	DAYS ON THERAPY		Collected at CRF.
THERWKS	num	WEEKS ON THERAPY		Collected at CRF.
BASEHGT	num	BASELINE HEIGHT (CM)		Collected at CRF.
BASEWGT	num	BASELINE WEIGHT (KG)		Collected at CRF.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
REGIMEN	char	REGIMEN CODE		Collected at CRF.
TITLE3	char	THIRD REGIMEN TITLE		Collected at CRF.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.
SAF	num	SAFETY POPULATION		Collected at CRF.
ERRESULT	num	ESTROGEN RECEPTOR RESULT		Collected at CRF.
STAGDIAG	num	STAGE AT DIAGNOSIS		Collected at CRF.
ERRESULF	char	DECODE, ERRESULT		Collected at CRF.
METBONEF	char	DECODE, METBONE		Collected at CRF.

Variable	Type	Label	Codes	Comments
POSTMENF	char	DECODE, POSTMENO		Collected at CRF.
STAGDIAF	char	DECODE, STAGDIAG		Collected at CRF.
METBONE	num	ONLY BONE METASTASIS (Y/N)		Collected at CRF.
POSTMENO	num	POST-MENOPAUSAL		Collected at CRF.
ASCITES	num	ASCITES		Collected at CRF.
PLEUEFF	num	PLEURAL EFFUSION		Collected at CRF.
ASCITESF	char	DECODE, ASCITES		Collected at CRF.
PLEUEFFF	char	DECODE, PLEUEFF		Collected at CRF.
ENDCHEM	char	END OF FIRST LINE CHEMO		Collected at CRF.
STRATIF	char	DECODE, STRATI BO/OTHER		Collected at CRF.
STRATI	num	STRATIFICATION BY MDS BO/MES/NMES		Collected at CRF.
CSTRAT	num	STRATIFICATION 1=BONE 2=OTHER		Collected at CRF.
CSTRATF	char	DECODE, CSTRAT		Collected at CRF.
ECOGSTAT	num	ECOG STATUS		Collected at CRF.
ECOGSTAF	char	DECODE, ECOGSTAT		Collected at CRF.
QOLF	char	DECODE, QOL		Collected at CRF.
QOL	num	QUALITY OF LIFE POPULATION		Collected at CRF.
NUMDOSES	num	NUMBER OF DOSES(>0) PER PATIENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGEDIAG	char	AGE AT INITIAL DIAGNOSIS (Y)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
STATUSF	char	DECODE, STATUS		Collected at CRF.
DIAGMNTH	num	MONTHS INITIAL DIAGNOSIS		Collected at CRF.
DIAGIVMN	num	MONTHS METASTATIC DIAGNOSIS		Collected at CRF.
DIAGSMN	num	MONTHS FROM INITIAL TO META DIAGNOSIS		Collected at CRF.
DETH_ST	num	WHEN PAT DIED: DB OR FU		Collected at CRF.
DETH_STF	char	DECODE, DETH_ST		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
COMPWKS	num	WEEKS ON STUDY=FLOOR((COMPDAYS - 4)/7)+1		Collected at CRF.
ITT	num	INTENT-TO-TREAT POPULATION		Collected at CRF.
EFF	num	EFFICACY POPULATION		Collected at CRF.
MSAF	num	MODIFIED SAFETY POPULATION		Collected at CRF.
STUDY	char	UNIQUE STUDY NAME		Collected at CRF.
DUSUBJID	char	UNIQUE SUBJECT ID ASSIGN FOR DE-IDENTITY		Randomly assigned unique subject ID for De-Identity.
DEATHF	char	DECODE, DEATH		Collected at CRF.
DEATH	num	DID SUBJECT DIE (Y/N)		Collected at CRF.
REGION	num	REGION		Collected at CRF.

Variable	Type	Label	Codes	Comments
RAN_SMED	num	TIME FROM RANDOMIZATION TO SMED START		Collected at CRF.
BSA	num	BASELINE BODY SURFACE AREA		Collected at CRF.
BMI	num	BODY MASS INDEX		Collected at CRF.
AGE_CAT	num	AGE CATEGORIES		Collected at CRF.
AGE_CATF	char	DECODE, AGE_CAT		Collected at CRF.
AGI_CAT	num	AGE AT INITIAL DIAG CATEGORIES		Collected at CRF.
AGI_CATF	char	DECODE, AGI_CAT		Collected at CRF.
BMI_CAT	num	BMI CATEGORIES		Collected at CRF.
BMI_CATF	char	DECODE, BMI_CAT		Collected at CRF.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
ALLDTHDY	num	RELATIVE DAY OF DEATH IN ALL PHASES		If ALLDTHDT and REF.DATE not missing then perform below logic to calculate ALLDTHDY, If ALLDTHDT less than REF.DATE then (ALLDTHDT - REF.DATE). Else if ALLDTHDT is greater than equal to REF.DATE then (ALLDTHDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STATUSDY	num	RELATIVE DAY COMPLTION, WITHDRWAL, ETC		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
STARTNDY	num	RELATIVE MEDICATION START DAY		If STARTDTN and REF.DATE not missing then perform below logic to calculate STARTNDY, If STARTDTN less than REF.DATE then (STARTDTN - REF.DATE). Else if STARTDTN is greater than equal to REF.DATE then (STARTDTN- REF.DATE) +1.
STOP_DY	num	RELATIVE MEDICATION STOP DAY		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOP_DY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.
LABDY	num	RELATIVE LAST DAY OF HGB SAMPLE		If LABDTN and REF.DATE not missing then perform below logic to calculate LABDY, If LABDTN less than REF.DATE then (LABDTN - REF.DATE). Else if LABDTN is greater than equal to REF.DATE then (LABDTN- REF.DATE) +1.
DIAGDY	num	RELATIVE INITIAL DIAGNOSIS DAY		If DIAGDT and REF.DATE not missing then perform below logic to calculate DIAGDY, If DIAGDT less than REF.DATE then (DIAGDT - REF.DATE). Else if DIAGDT is greater than equal to REF.DATE then (DIAGDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DIAGIVDY	num	RELATIVE DIAGNOSIS DAY OF STAGE IV		If DIAGIVDT and REF.DATE not missing then perform below logic to calculate DIAGIVDY, If DIAGIVDT less than REF.DATE then (DIAGIVDT - REF.DATE). Else if DIAGIVDT is greater than equal to REF.DATE then (DIAGIVDT- REF.DATE) +1.
RAND_DY	num	RELATIVE RANDMZ DAY FROM THE IVRS TABLE		If RAND_DT and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_DT less than REF.DATE then (RAND_DT - REF.DATE). Else if RAND_DT is greater than equal to REF.DATE then (RAND_DT- REF.DATE) +1.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATHDTN and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATHDTN less than REF.DATE then (DEATHDTN - REF.DATE). Else if DEATHDTN is greater than equal to REF.DATE then (DEATHDTN- REF.DATE) +1.
DBDETHDY	num	RELATIVE DAY OF DEATH IN DOUBLE BLND		If DBDETHDT and REF.DATE not missing then perform below logic to calculate DBDETHDY, If DBDETHDT less than REF.DATE then (DBDETHDT - REF.DATE). Else if DBDETHDT is greater than equal to REF.DATE then (DBDETHDT- REF.DATE) +1.
STDYENDY	num	RELATIVE INDIVIDUAL STUDY END DAY		If STDYEND and REF.DATE not missing then perform below logic to calculate STDYENDY, If STDYEND less than REF.DATE then (STDYEND - REF.DATE). Else if STDYEND is greater than equal to REF.DATE then (STDYEND- REF.DATE) +1.

1.4.54. PROTOCOL – PROTOCOL

Dataset	PROTOCOL
Creating program	protocol.sas
Description	PROTOCOL
Unique identifier	DRUG
Sorted by	DRUG
Notes	

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PROJECT	char	PROJECT		Collected at CRF.
PROTOCOL	char	PROTOCOL		Collected at CRF.
TITLE1	char	TITLE1		Collected at CRF.
TITLE2	char	TITLE2		Collected at CRF.
BLINDED	char	BLINDED		Collected at CRF.
CROSOVER	char	CROSOVER		Collected at CRF.
STDYTYPE	char	STDYTYPE		Collected at CRF.
AGEUNIT	char	AGEUNIT		Collected at CRF.
EVENTUNT	char	EVENTUNT		Collected at CRF.
TOTREGI	num	TOTREGI		Collected at CRF.

Variable	Type	Label	Codes	Comments
ELABTRAN	char	ELABTRAN		Collected at CRF.
RSM	char	RSM		Collected at CRF.
FIRSTDB	num	FIRSTDB		Collected at CRF.
FINALDB	num	FINALDB DATE		Collected at CRF.
AVAILABL	char	AVAILABL		Collected at CRF.
SHRTPROT	char	SHRTPROT		Collected at CRF.
DMODIFY	num	DMODIFY		Collected at CRF.
DSTAMP	num	DSTAMP DATE		Collected at CRF.

1.4.55. PROT_ – PROT_

Dataset	PROT_
Creating program	prot_.sas
Description	PROT_
Unique identifier	DRUG
Sorted by	DRUG
Notes	

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.

Variable	Type	Label	Codes	Comments
PROJECT	char	PROJECT		Collected at CRF.
PROTOCOL	char	PROTOCOL		Collected at CRF.
TITLE1	char	TITLE1		Collected at CRF.
TITLE2	char	TITLE2		Collected at CRF.
BLINDED	char	BLINDED		Collected at CRF.
CROSOVER	char	CROSOVER		Collected at CRF.
STDYTYPE	char	STDYTYPE		Collected at CRF.
AGEUNIT	char	AGEUNIT		Collected at CRF.
EVENTUNT	char	EVENTUNT		Collected at CRF.
TOTREGI	num	TOTREGI		Collected at CRF.
ELABTRAN	char	ELABTRAN		Collected at CRF.
RSM	char	RSM		Collected at CRF.
FIRSTDB	num	FIRSTDB		Collected at CRF.
FINALDB	num	FINALDB DATE		Collected at CRF.
AVAILABL	char	AVAILABL		Collected at CRF.
SHRTPROT	char	SHRTPROT		Collected at CRF.
DMODIFY	num	DMODIFY		Collected at CRF.
DSTAMP	num	DSTAMP DATE		Collected at CRF.

1.4.56. PS_QOL – PS_QOL

Dataset	PS_QOL
Creating program	ps_qol.sas
Description	PS_QOL
Unique identifier	ECOGSTAT,QOLMIS
Sorted by	ECOGSTAT,QOLMIS
Notes	

Variable	Type	Label	Codes	Comments
QOLMIS	num	QOLMIS		Collected at CRF.
ECOGSTAT	num	ECOG STATUS		Collected at CRF.
PLACEBO	num	PLACEBO		Collected at CRF.
EPOETIN	num	EPOETIN		Collected at CRF.
TOTAL	num	TOTAL		Collected at CRF.
PCT_PLA	num	PCT_PLA		Collected at CRF.
PCT_EPO	num	PCT_EPO		Collected at CRF.
PCT_TOT	num	PCT_TOT		Collected at CRF.

1.4.57. QOL_C – QOL_C

Dataset	QOL_C
Creating program	qol_c.sas
Description	QOL_C
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EVDATE,STARTDTN,STOPDTN,FRSTCHEM,ENDCHEMN,RAND_DD,DBSTRTN, STATUSDN,DEATHDTN,VDATE

Variable	Type	Label	Codes	Comments
ENERGY	num	CLAS: ENERGY		Collected at CRF.
ACTIVITY	num	CLAS: DAILY ACTIVITIES		Collected at CRF.
OVERALL	num	CLAS: OVERALL QUALITY-OF-LIFE		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
CHEMDAYS	num	FIRST LINE CHEMO THERAPY IN DAYS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBDUR	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
STATUS	num	COMPLETION/WITHDRAWAL STATUS		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
DEATH	num	DID SUBJECT DIE (Y/N)		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.
TXGROUP	num	EPO		Collected at CRF.
DAYS	num	DAYS TO QOL		Collected at CRF.
WEEK	num	WEEKS TO QOL		Collected at CRF.
WEEK04	num	CHANGE IN SLOPE WK4		Collected at CRF.
WEEK16	num	CHANGE IN SLOPE WK16		Collected at CRF.
WEEK24	num	CHANGE IN SLOPE WK24		Collected at CRF.
WEEK32	num	CHANGE IN SLOPE WK32		Collected at CRF.
N_QOL	num	ITEMS COMPLETED		Collected at CRF.
LAGVISIT	num	LAGGED VISITNO		Collected at CRF.
VISITSEQ	num	VISITNO (SEQUENTIAL)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.
STATUSDY	num	RELATIVE COMPLETION/WITHDRAWAL DAY		If STATUSDN and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDN less than REF.DATE then (STATUSDN - REF.DATE). Else if STATUSDN is greater than equal to REF.DATE then (STATUSDN - REF.DATE) +1.
STARTNDY	num	RELATIVE MEDICATION START DAY		If STARTDTN and REF.DATE not missing then perform below logic to calculate STARTNDY, If STARTDTN less than REF.DATE then (STARTDTN - REF.DATE). Else if STARTDTN is greater than equal to REF.DATE then (STARTDTN- REF.DATE) +1.
STOP_DY	num	RELATIVE MEDICATION STOP DAY		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOP_DY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.
FRSTCHDY	num	RELATIVE START DAY OF 1ST LINE CHEMO		If FRSTCHEM and REF.DATE not missing then perform below logic to calculate FRSTCHDY, If FRSTCHEM less than REF.DATE then (FRSTCHEM - REF.DATE). Else if FRSTCHEM is greater than equal to REF.DATE then (FRSTCHEM- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBSTR_DY	num	RELATIVE RANDOMIZATION IVRS DAY		If DBSTRTN and REF.DATE not missing then perform below logic to calculate DBSTR_DY, If DBSTRTN less than REF.DATE then (DBSTRTN - REF.DATE). Else if DBSTRTN is greater than equal to REF.DATE then (DBSTRTN- REF.DATE) +1.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATHDTN and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATHDTN less than REF.DATE then (DEATHDTN - REF.DATE). Else if DEATHDTN is greater than equal to REF.DATE then (DEATHDTN- REF.DATE) +1.
VDY	num	RELATIVE DAY QOL EVALUATION		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.

1.4.58. QOL_F – QOL_F

Dataset	QOL_F
Creating program	qol_f.sas
Description	QOL_F
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EVDATE,STARTDTN,STOPDTN,FRSTCHEM,ENDCHEMN,RAND_DD,DBSTRTN, STATUSDN,DEATHDTN,VDATE

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
PWB	num	FACT-AN: PHYSICAL WELL-BEING		Collected at CRF.
SFWB	num	FACT-AN: SOCIAL/FAMILY WELL-BEING		Collected at CRF.
EWB	num	FACT-AN: EMOTIONAL WELL-BEING		Collected at CRF.
FWB	num	FACT-AN: FUNCTIONAL WELL-BEING		Collected at CRF.
FACTG	num	FACT-AN: FACT-G TOTAL SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
FATS	num	FACT-AN: FATIGUE SUBSCALE SCORE		Collected at CRF.
NFATS	num	FACT-AN: NON-FATIGUE SUBSCALE SCORE		Collected at CRF.
ANS	num	FACT-AN: TOTAL ANEMIN SUBSCALE SCORE		Collected at CRF.
TOTAL	num	FACT-AN: FACT-ANEMIA TOTAL SCORE		Collected at CRF.
TOTFAT	num	FACT-AN: FACT-FATIGUE TOTAL SCORE		Collected at CRF.
TOI	num	FACT-AN: TOI SCORE		Collected at CRF.
TRTMENT	num	TREATMENT GROUP NUMBER		Collected at CRF.
TRTMENTF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
CHEMDAYS	num	FIRST LINE CHEMO THERAPY IN DAYS		Collected at CRF.
DBDUR	num	NUMBER OF DAYS ON STUDY		Collected at CRF.
STATUS	num	COMPLETION/WITHDRAWAL STATUS		Collected at CRF.
STATUSF	char	DECODE, STATUS		Collected at CRF.
REASON	num	REASON FOR WITHDRAWAL		Collected at CRF.
REASONF	char	DECODE, REASON		Collected at CRF.
DEATH	num	DID SUBJECT DIE (Y/N)		Collected at CRF.
DEATHF	char	DECODE, DEATH		Collected at CRF.

Variable	Type	Label	Codes	Comments
TXGROUP	num	EPO		Collected at CRF.
DAYS	num	DAYS TO QOL		Collected at CRF.
WEEK	num	WEEKS TO QOL		Collected at CRF.
WEEK04	num	CHANGE IN SLOPE WK4		Collected at CRF.
WEEK16	num	CHANGE IN SLOPE WK16		Collected at CRF.
WEEK24	num	CHANGE IN SLOPE WK24		Collected at CRF.
WEEK32	num	CHANGE IN SLOPE WK32		Collected at CRF.
N_QOL	num	ITEMS COMPLETED		Collected at CRF.
LAGVISIT	num	LAGGED VISITNO		Collected at CRF.
VISITSEQ	num	VISITNO (SEQUENTIAL)		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.
STARTNDY	num	RELATIVE MEDICATION START DAY		If STARTDTN and REF.DATE not missing then perform below logic to calculate STARTNDY, If STARTDTN less than REF.DATE then (STARTDTN - REF.DATE). Else if STARTDTN is greater than equal to REF.DATE then (STARTDTN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STOP_DY	num	RELATIVE MEDICATION STOP DAY		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOP_DY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.
FRSTCHDY	num	RELATIVE START DAY OF 1ST LINE CHEMO		If FRSTCHEM and REF.DATE not missing then perform below logic to calculate FRSTCHDY, If FRSTCHEM less than REF.DATE then (FRSTCHEM - REF.DATE). Else if FRSTCHEM is greater than equal to REF.DATE then (FRSTCHEM- REF.DATE) +1.
DBSTR_DY	num	RELATIVE RANDOMIZATION IVRS DAY		If DBSTRTN and REF.DATE not missing then perform below logic to calculate DBSTR_DY, If DBSTRTN less than REF.DATE then (DBSTRTN - REF.DATE). Else if DBSTRTN is greater than equal to REF.DATE then (DBSTRTN- REF.DATE) +1.
STATUSDY	num	RELATIVE COMPLETION/WITHDRAWAL DAY		If STATUSDN and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDN less than REF.DATE then (STATUSDN - REF.DATE). Else if STATUSDN is greater than equal to REF.DATE then (STATUSDN- REF.DATE) +1.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATHDTN and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATHDTN less than REF.DATE then (DEATHDTN - REF.DATE). Else if DEATHDTN is greater than equal to REF.DATE then (DEATHDTN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
VDY	num	RELATIVE DAY QOL EVALUATION		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.59. QOL_PS – QOL_PS

Dataset	QOL_PS
Creating program	qol_ps.sas
Description	QOL_PS
Unique identifier	VARIABLE,ECOGSTAT,STAT
Sorted by	VARIABLE,ECOGSTAT,STAT
Notes	

Variable	Type	Label	Codes	Comments
VARIABLE	char	VARIABLE		Collected at CRF.
ECOGSTAT	num	ECOG STATUS		Collected at CRF.
STAT	char	STAT		Collected at CRF.
PLACEBO	num	PLACEBO		Collected at CRF.
EPOETIN	num	EPOETIN		Collected at CRF.
TOTAL	num	TOTAL		Collected at CRF.

1.4.60. RANDOM – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	RANDOM
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
REGDESC	char	REGIMEN DESCRIPTION		Collected at CRF.
REGORDER	num	SORT ORDER FOR REGIMENS		Collected at CRF.

1.4.61. RAPRAS – RAPRAS

Dataset	RAPRAS
Creating program	rapras.sas
Description	RAPRAS
Unique identifier	DPATNO,SAMPDY,USVAL,RAPRAS
Sorted by	DPATNO,SAMPDY,USVAL,RAPRAS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: NUMDT,SAMPDT,TDATE,TDATEN,NUMDT1

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
USVAL	num	US VALUE		Collected at CRF.
USVAL1	num	US VALUE		Collected at CRF.
RAPRASF	char	RAPRASF		Collected at CRF.
RAPRAS	num	RAPRAS		Collected at CRF.
DIFF	num	DIFF		Collected at CRF.
SAMPDY	num	RELATIVE SAMPLE DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TDY	num	RELATIVE TRANSFUSION DAY		If TDATE and REF.DATE not missing then perform below logic to calculate TDY, If TDATE less than REF.DATE then (TDATE - REF.DATE). Else if TDATE is greater than equal to REF.DATE then (TDATE-REF.DATE) +1.
NUM1_DY	num	RELATIVE SAMPLE DAY		If NUMDT1 and REF.DATE not missing then perform below logic to calculate NUM1_DY, If NUMDT1 less than REF.DATE then (NUMDT1 - REF.DATE). Else if NUMDT1 is greater than equal to REF.DATE then (NUMDT1- REF.DATE) +1.

1.4.62. SUBQOL – SUBQOL

Dataset	SUBQOL
Creating program	subqol.sas
Description	SUBQOL
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SCTRY,EVDATE

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
ENERGY	num	CLAS: ENERGY		Collected at CRF.
ACTIVITY	num	CLAS: DAILY ACTIVITIES		Collected at CRF.
OVERALL	num	CLAS: OVERALL QUALITY-OF-LIFE		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
VISITNO	num	VISIT NUMBER		Collected at CRF.
PWB	num	FACT-AN: PHYSICAL WELL-BEING		Collected at CRF.

Variable	Type	Label	Codes	Comments
SFWB	num	FACT-AN: SOCIAL/FAMILY WELL-BEING		Collected at CRF.
EWB	num	FACT-AN: EMOTIONAL WELL-BEING		Collected at CRF.
FWB	num	FACT-AN: FUNCTIONAL WELL-BEING		Collected at CRF.
FACTG	num	FACT-AN: FACT-G TOTAL SCORE		Collected at CRF.
FATS	num	FACT-AN: FATIGUE SUBSCALE SCORE		Collected at CRF.
NFATS	num	FACT-AN: NON-FATIGUE SUBSCALE SCORE		Collected at CRF.
ANS	num	FACT-AN: TOTAL ANEMIN SUBSCALE SCORE		Collected at CRF.
TOTAL	num	FACT-AN: FACT-ANEMIA TOTAL SCORE		Collected at CRF.
TOTFAT	num	FACT-AN: FACT-FATIGUE TOTAL SCORE		Collected at CRF.
TOI	num	FACT-AN: TOI SCORE		Collected at CRF.
EVDY	num	RELATIVE EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE-REF.DATE) +1.

1.4.63. DERIVED: TRT CROSSOVER DATASET – TCROSS

Dataset	TCROSS
Creating program	tcross.sas
Description	DERIVED: TRT CROSSOVER DATASET
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PSEPOST,PSEPOSP

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity.
POSTEPO	num	EPO TRT AF DB PHASE 0=NO,1=YES		Collected at CRF.
COMEPO	num	COMMERCIAL EPO AFT DB 0=NO,1=YES		Collected at CRF.
OLEPO	num	OL EPO AFTER DB PHASE 0=NO,1=YES		Collected at CRF.
DEATHNEW	num	DEATH W/TRT CROSSOVER 0=NO,1=YES		Collected at CRF.
TCRDEATH	num	TIEM TO DEATH(DAYS) W/TRT CROSSO		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBDEANEW	num	DB DEATH W/TRT CROSSO 0=NO,1=YES		Collected at CRF.
TCRDBDEA	num	TIME DB DEATH(DAYS) W/TRT CROSSO		Collected at CRF.
PSPOSTDY	num	RELATIVE START DAY EPO TRT AF DB PHASE		If PSEPOST and REF.DATE not missing then perform below logic to calculate PSPOSTDY, If PSEPOST less than REF.DATE then (PSEPOST - REF.DATE). Else if PSEPOST is greater than equal to REF.DATE then (PSEPOST- REF.DATE) +1.
PSPOSPDY	num	RELATIVE STOP DAY EPO TRT AF DB PHASE		If PSEPOSP and REF.DATE not missing then perform below logic to calculate PSPOSPDY, If PSEPOSP less than REF.DATE then (PSEPOSP - REF.DATE). Else if PSEPOSP is greater than equal to REF.DATE then (PSEPOSP- REF.DATE) +1.

1.4.64. TVE – TVE

Dataset	TVE
Creating program	tve.sas
Description	TVE
Unique identifier	BODYSYS,ADVCODE
Sorted by	BODYSYS,ADVCODE
Notes	

Variable	Type	Label	Codes	Comments
SEXAE	char	SEX TO WHICH AE IS APPLICABLE (M/F/B)		Collected at CRF.
ADVDESC	char	INCLUDED TERM DESCRIPTION		Collected at CRF.
ADVCODE	char	INCLUDED TERM CODE		Collected at CRF.
BODYSYS	char	BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	PREFERRED TERM DESCRIPTION		Collected at CRF.
TVENO	num	TVENO		Collected at CRF.