Clinical Development

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EPO_INT10

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.
- Due to sensitive information INVN dataset will be removed.
- STUDSTRT from PAT dataset will be used as Reference Date to derive relative days (referred as Ref. Date in the document).
- Dataset with zero observation will not be submitted (ex. KEYCOMP).

1.3. Data Files

The EPO_INT10 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics Data – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics Data
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CENTER, INV, INIT, VDATE, BIRTH, SPECIFY Below listed variables were not part of the Raw dataset. These have been added to retain the Demographic related information in the de-identified datasets: AGE (Source: PROFILE dataset) AGEUNIT (Source: PROFILE dataset) SEXF (Source: PROFILE dataset) RACEF (Source: PROFILE dataset) SITEID (Source: NKEYDOSE dataset)

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
VDATEF	num	Vdate Flag		Collected at CRF.

Variable	Type	Label	Codes	Comments
BIRTHF	num	Birth Flag		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
AGE	char	Age in Years		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.

1.4.2. Adverse Events Data – ADE

Dataset	ADE
Creating program	ade.sas
Description	Adverse Events Data
Unique identifier	DPAT,SECTION,ONSETDY,ADVCOD,OBSNO
Sorted by	DPAT,SECTION,ONSETDY,ADVCOD,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,CDATE,DONSET,SDATE,ADVSPE,INIT Below variable was not part of the Raw dataset. These have been added to retain the Adverse Events related information in the de-identified datasets: PREF_TRM (Source: KEYADVE dataset)

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
CDATEF	num	Cdate Flag		Collected at CRF.
ADVEXP	num	AE Experienced		Collected at CRF.
DONSETF	num	Donset Flag		Collected at CRF.
ADVSEV	num	Severity		Collected at CRF.
SERAE	num	Serious		Collected at CRF.
ADVREL	num	Drug Relation		Collected at CRF.
ACTION	num	Action		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONGIV	num	Concom Given		Collected at CRF.
RESULT	num	Outcome		Collected at CRF.
SDATEF	num	Sdate Flag		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
ADVCOD	char	Advcod		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.
VISITDY	num	Relative Visit Day		If CDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.
ONSETDY	num	Relative Onset Day		If DONSET and REF.DATE not missing then perform below logic to calculate ONSETDY, If DONSET less than REF.DATE then (DONSET - REF.DATE). Else if DONSET is greater than equal to REF.DATE then (DONSET- REF.DATE) +1.

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

1.4.3.Study Drug Administration Data – ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Study Drug Administration Data
Unique identifier	DPAT,SECTION,ADMINDY
Sorted by	DPAT,SECTION,ADMINDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,DATE,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
DATEF	num	Date Flag		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
ML1	num	Disp Ml1		Collected at CRF.
ML2	num	Disp Ml2		Collected at CRF.

Variable	Type	Label	Codes	Comments
PATHOME	num	Pat Home		Collected at CRF.
MEDFAC	num	Med Facility		Collected at CRF.
DOSENO	num	Dose Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
WEEKC	num	Weekc		Collected at CRF.
OBSNO	num	Observation Number		Collected at CRF.
MEAS1	num	Unit Measure1		Collected at CRF.
MEAS2	num	Unit Measure2		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
ADMINDY	num	Relative Day		If DATE and REF.DATE not missing then perform below logic to calculate ADMINDY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE- REF.DATE) +1.

1.4.4.Cchemo – CCHEMO

Dataset	CCHEMO
Creating program	cchemo.sas
Description	Cchemo
Unique identifier	DPAT,SECTION,CHEMCAT,CSTARDY,OBSNO
Sorted by	DPAT,SECTION,CHEMCAT,CSTARDY,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,CSTART,CSTOP,DRUG,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
TOTDOSE	char	Total Dose		Collected at CRF.
HOSP	num	Hospital		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
TOTNUM	char	Total Number Ct Cycles Prestudy		Collected at CRF.
WHODRUG	char	Drug Code		Collected at CRF.
CHEMCAT	num	New Code for Drug(Only Db)		Collected at CRF.
CHEMCATF	char	New Drug Description(Only Db)		Collected at CRF.
CSTARTDY	num	Relative Start Day		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, 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.
CSTOPDY	num	Relative Stop Day		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, 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.

1.4.5.Chemcurm – CHEMCURM

Dataset	CHEMCURM
Creating program	chemcurm.sas
Description	Chemcurm
Unique identifier	DPAT,TOTDOSE,DRUGDESC,CSTARDY,EVENT_ID
Sorted by	DPAT,TOTDOSE,DRUGDESC,CSTARDY,EVENT_ID
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: CONTF,CSTART,CSTARTDT,CSTOP,CSTOPDT,DATE,DBENDDT,FORE,FORTAE, FORTAEF,INO,INVNAME,MEDSTRDT,STARDATE,STARTDT,SURN,VERBATIM

Variable	Type	Label	Codes	Comments
VISITNO	char	Visit Number		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
ROUTE	char	Rt of Adm		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.
HOSP	num	Hospital		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PNO	char	Protocol Number		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
TOTNUM	char	Total Number Ct Cycles Prestudy		Collected at CRF.
DRUGCODE	char	Who Art Code		Collected at CRF.
INDICT	char	Indication		Collected at CRF.
EVENT_ID	char	Event Id		Collected at CRF.
CONT	num	Con Med Continued		Collected at CRF.
GENDESC	char	Generic Description		Collected at CRF.
ATC_CD	char	Atc Code		Collected at CRF.
ATC_TEXT	char	Atc Text		Collected at CRF.
DRUGDESC	char	Who Art Description		Collected at CRF.
THERCLAS	char	Therapeutic*Class		Collected at CRF.
PHRMCLAS	char	Pharmacologic*Class		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
CONMEDF	char	Con Med Given? (char)		Collected at CRF.
STUDYDAY	num	Days on Study		Collected at CRF.
DURATION	num	Duration of Conmed		Collected at CRF.
REGDAY	num	Days on Regimen		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	Study Phase		Collected at CRF.
CSTARTDY	num	Relative Con Med Start Day		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 Con Med 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.
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.
DBENDDY	num	Relative Last Day of Double-Blind Phase		If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT- REF.DATE) +1.

1.4.6.Chemhema – CHEMHEMA

Dataset	CHEMHEMA
Creating program	chemhema.sas
Description	Chemhema
Unique identifier	DPAT,SECTION,_FROM,_LABTEST,SMPLDY,WEEK,VISITDY
Sorted by	DPAT,SECTION,_FROM,_LABTEST,SMPLDY,WEEK,VISITDY
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: CENTER,SEX,VISITD,SDATE,HDATE,IDATE,SMPLD,CDATE

Variable	Type	Label	Codes	Comments
LN_CODE	num	Lab Normal Code (Key=Center Ln_Code Sex)		Collected at CRF.
SECTION	char	Section		Collected at CRF.
CENTLAB	num	Central Lab or Not		Collected at CRF.
SDATEF	num	Lab1Date Flag		Collected at CRF.
HDATEF	num	Lab2Date Flag		Collected at CRF.
IDATEF	num	Lab3Date Flag		Collected at CRF.
_LABTEST	char	Laboratory Test		Collected at CRF.
_FROM	char	Specification Lab Type		Collected at CRF.
_VALUES	num	Original Values		Collected at CRF.

Variable	Type	Label	Codes	Comments
_UNIT	num	Original Unit		Collected at CRF.
_LNUNIT	num	Lab Normal Unit		Collected at CRF.
_LOW	num	Lab Normal Range - Low		Collected at CRF.
_HIGH	num	Lab Normal Range - High		Collected at CRF.
_SIGN	num	Sign (>,<,...)		Collected at CRF.
_OTHER	char	Others (Differential)		Collected at CRF.
SMPLDF	num	Sample Date Flag		Collected at CRF.
REPEAT	char	Repeat		Collected at CRF.
CDATEF	num	Cdate Flag		Collected at CRF.
NEWUNIT	num	New Unit		Collected at CRF.
NEWVALUE	num	Newvalue		Collected at CRF.
FACTOR	num	Conversion Factor (9999 - Not Converted)		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDY	char	Name of Study		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
UNSCHED	num	Unsched Visits from The Central Lab		Collected at CRF.
WEEK	num	Week		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative Day of Visit		If VISITD and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITD less than REF.DATE then (VISITD - REF.DATE). Else if VISITD is greater than equal to REF.DATE then (VISITD-REF.DATE) +1.
HEMASTDY	num	Relative Day (Hema) Start of The Cycle		If SDATE and REF.DATE not missing then perform below logic to calculate HEMASTDY, If SDATE less than REF.DATE then (SDATE - REF.DATE). Else if SDATE is greater than equal to REF.DATE then (SDATE- REF.DATE) +1.
SMPLDY	num	Relative Sample Day for Hema And Chem		If SMPLD and REF.DATE not missing then perform below logic to calculate SMPLDY, If SMPLD less than REF.DATE then (SMPLD - REF.DATE). Else if SMPLD is greater than equal to REF.DATE then (SMPLD- REF.DATE) +1.

1.4.7. Chemotherapy Data – CHEMO

Dataset	CHEMO
Creating program	chemo.sas
Description	Chemotherapy Data
Unique identifier	DPAT,SECTION,ROUTE,TOTDOSE,CSTARDY,OBSNO
Sorted by	DPAT,SECTION,ROUTE,TOTDOSE,CSTARDY,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,CSTART,CSTOP,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
TOTDOSE	char	Total Dose		Collected at CRF.
HOSP	num	Hospital		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
TOTNUM	char	Total Number Ct Cycles Prestudy		Collected at CRF.
WHODRUG	char	Drug Code		Collected at CRF.
CSTARTDY	num	Relative Start Day		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, 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.
CSTOPDY	num	Relative Stop Day		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, 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.

1.4.8.Chemster – CHEMSTER

Dataset	CHEMSTER
Creating program	chemster.sas
Description	Chemster
Unique identifier	DPAT,SECTION,ROUTE,CSTARDY
Sorted by	DPAT,SECTION,ROUTE,CSTARDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,CSTART,CSTOP,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
TOTDOSE	char	Total Dose		Collected at CRF.
HOSP	num	Hospital		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
TOTNUM	char	Total Number Ct Cycles Prestudy		Collected at CRF.
WHODRUG	char	Drug Code		Collected at CRF.
CSTARTDY	num	Relative Start Day		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, 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.
CSTOPDY	num	Relative Stop Day		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, 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.

1.4.9.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
SECTION	char	Section		Empty dataset will be submitted.
VDATEF	num	Vdate Flag		Empty dataset will be submitted.
MODNAME	char	Pag Name		Empty dataset will be submitted.
STUDY	char	Name of Study		Empty dataset will be submitted.
DPAT	char	Subject Number Assigned for De-identity		Empty dataset will be submitted.
CYCLE	num	Cycle Number		Empty dataset will be submitted.
WEEK	num	Week		Empty dataset will be submitted.
OBSNO	num	Observation Number		Empty dataset will be submitted.
VISITDY	num	Relative Visit Day		Empty dataset will be submitted.

1.4.10. Concomitant Medication Data – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Medication Data
Unique identifier	DPAT,SECTION,ROUTE,DDOSE,CSTARDY,OBSNO
Sorted by	DPAT,SECTION,ROUTE,DDOSE,CSTARDY,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,INDICAT,INDICAT1,CSTART,CSTOP,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
CONT	num	Continued		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
DDOSE	char	Daily Dose		Collected at CRF.
PRN	num	Prn		Collected at CRF.
PRESC	num	For AE		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
WHODRUG	char	Drug Code		Collected at CRF.
CSTARTDY	num	Relative Con Med Start Day		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, 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.
CSTOPDY	num	Relative Stop Day		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, 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.

1.4.11. Death Data – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death Data
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,DDATE, DAE1,DAE2,DAE3,DAE4

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DDATEF	num	Death Date Flag		Collected at CRF.
DEATHDY	num	Relative Death Day		If DDATE and REF.DATE not missing then perform below logic to calculate DEATHDY, If DDATE less than REF.DATE then (DDATE - REF.DATE). Else if DDATE is greater than equal to REF.DATE then (DDATE- REF.DATE) +1.

1.4.12. Doubled – DOUBLED

Dataset	DOUBLED
Creating program	doubled.sas
Description	Doubled
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DATE

Variable	Type	Label	Codes	Comments
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DATEF	num	Date Flag		Collected at CRF.
DOUBLED	num	Doubled		Collected at CRF.
DOUBLEDY	num	Relative Day		If DATE and REF.DATE not missing then perform below logic to calculate DOUBLEDY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE- REF.DATE) +1.

1.4.13. Ecog Performance Score Data – ECOG

Dataset	ECOG
Creating program	ecog.sas
Description	Ecog Performance Score Data
Unique identifier	DPAT,SECTION
Sorted by	DPAT,SECTION
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,DECOG,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
DECOGF	num	Decog Flag		Collected at CRF.
PERFOS	num	Performance Score		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.

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

1.4.14. Eligibility Data – ELIGI

Dataset	ELIGI
Creating program	eligi.sas
Description	Eligibility Data
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,INIT,WHATC,WHATC1,NAMEC,NAMEC1,DCONT

Variable	Type	Label	Codes	Comments
SATIS	num	Pat Satisfies		Collected at CRF.
DCONTF	num	Dcont Flag		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
CONTDY	num	Relative Contact Day		If DCONT and REF.DATE not missing then perform below logic to calculate CONTDY, If DCONT less than REF.DATE then (DCONT - REF.DATE). Else if DCONT is greater than equal to REF.DATE then (DCONT- REF.DATE) +1.

1.4.15. Entrance Checklist-Inclusion/Exclusion Criteria Data – ENTR

Dataset	ENTR
Creating program	entr.sas
Description	Entrance Checklist-Inclusion/Exclusion Criteria Data
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,INIT

Variable	Type	Label	Codes	Comments
INCL1	num	Incl1		Collected at CRF.
INCL2	num	Incl2		Collected at CRF.
INCL3	num	Incl3		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCL4	num	Incl4		Collected at CRF.
INCL5	num	Incl5		Collected at CRF.
INCL6	num	Incl6		Collected at CRF.
INCL7	num	Incl7		Collected at CRF.
INCL8	num	Incl8		Collected at CRF.
INCL9	num	Incl9		Collected at CRF.
INCL10	num	Incl10		Collected at CRF.
INCL11	num	Incl11		Collected at CRF.
EXCL1	num	Excl1		Collected at CRF.
EXCL2	num	Excl2		Collected at CRF.
EXCL3	num	Excl3		Collected at CRF.
EXCL4	num	Excl4		Collected at CRF.
EXCL5	num	Excl5		Collected at CRF.
EXCL6	num	Excl6		Collected at CRF.
EXCL7	num	Excl7		Collected at CRF.
EXCL8	num	Excl8		Collected at CRF.
ENTR9	num	Entr9		Collected at CRF.
ENTR10	num	Entr10		Collected at CRF.
ENTR11	num	Entr11		Collected at CRF.
ENTR12	num	Entr12		Collected at CRF.
ENTR13	num	Entr13		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTR14	num	Entr14		Collected at CRF.
ENTR15	num	Entr15		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.

1.4.16. Epolevel – EPOLEVEL

Dataset	EPOLEVEL
Creating program	epolevel.sas
Description	Epolevel
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVESTIG,PAT_INIT,PRE_STUD,WEEK_2_S

Variable	Type	Label	Codes	Comments
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
REQUEST	char	Request Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
ERYTHROP	char	Erythropoietin Mu/Ml		Collected at CRF.
REQUEST1	char	Request Code_1		Collected at CRF.
ERYTHRO1	char	Erythropoietin Mu/Ml_1		Collected at CRF.
PRESTUDY	num	Relative Pre Study Sample Day		If PRE_STUD and REF.DATE not missing then perform below logic to calculate PRESTUDY, If PRE_STUD less than REF.DATE then (PRE_STUD - REF.DATE). Else if PRE_STUD is greater than equal to REF.DATE then (PRE_STUD- REF.DATE) +1.
WEEK2SDY	num	Relative Week 2 Sample Day		If WEEK_2_S and REF.DATE not missing then perform below logic to calculate WEEK2SDY, If WEEK_2_S less than REF.DATE then (WEEK_2_S - REF.DATE). Else if WEEK_2_S is greater than equal to REF.DATE then (WEEK_2_S- REF.DATE) +1.

1.4.17. Generic – GENERIC

Dataset	GENERIC
Creating program	generic.sas
Description	Generic
Unique identifier	OBSNO,VARNAM
Sorted by	OBSNO,VARNAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
SEX	num	Sex (1=Male, 2=Female)		Collected at CRF.
VARNAM	char	Varnam		Collected at CRF.
AGE_L	num	Age_L		Collected at CRF.
AGE_U	num	Age_U		Collected at CRF.
LR	num	Lr		Collected at CRF.
UR	num	Ur		Collected at CRF.
UNIT	char	Unit		Collected at CRF.

1.4.18. History – HISTORY

Dataset	HISTORY
Creating program	history.sas
Description	History
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,OTHSPE,OTHSPE1,DIAGNOS,SYMP,SYMP1,SYMP2,SYMP3, VDATE,DIAG,INIT

Variable	Type	Label	Codes	Comments
DIAGF	num	Diag Flag		Collected at CRF.
HEMMAL	num	Hema Malig		Collected at CRF.
SOLTUM	num	Solid Tumors		Collected at CRF.
METAST	char	Metastatic Sites		Collected at CRF.
PRIMAR	num	Primary Involve		Collected at CRF.
METMAR	num	Metastatic Involve		Collected at CRF.
OTHERM	num	Otherm		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	Name of Study		Collected at CRF.
VDATEF	num	Vdate Flag		Collected at CRF.
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.
DIAGDY	num	Relative Diag Day		If DIAG and REF.DATE not missing then perform below logic to calculate DIAGDY, If DIAG less than REF.DATE then (DIAG - REF.DATE). Else if DIAG is greater than equal to REF.DATE then (DIAG-REF.DATE) +1.

1.4.19. Hormone Therapy Data – HORMON

Dataset	HORMON
Creating program	hormon.sas
Description	Hormone Therapy Data
Unique identifier	DPAT,TYPE,HSTARDY
Sorted by	DPAT,TYPE,HSTARDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,HSTART,HSTOP,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
HORGIV	num	Hormone Given		Collected at CRF.
HSTARTF	num	Hstart Flag		Collected at CRF.
HSTOPF	num	Hstop Flag		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
TOTDOSE	char	Total Dose		Collected at CRF.
TYPE	char	Type		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	Name of Study		Collected at CRF.
HSTARTDY	num	Relative Start Day		If HSTART and REF.DATE not missing then perform below logic to calculate HSTARTDY, If HSTART less than REF.DATE then (HSTART - REF.DATE). Else if HSTART is greater than equal to REF.DATE then (HSTART- REF.DATE) +1.
HSTOPDY	num	Relative Stop Day		If HSTOP and REF.DATE not missing then perform below logic to calculate HSTOPDY, If HSTOP less than REF.DATE then (HSTOP - REF.DATE). Else if HSTOP is greater than equal to REF.DATE then (HSTOP- REF.DATE) +1.

1.4.20. Ineval – INEVAL

Dataset	INEVAL
Creating program	ineval.sas
Description	Ineval
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset due to missing values: SUBGROUP

Variable	Type	Label	Codes	Comments
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
REASON	char	Reason		Collected at CRF.
EVAL	num	Eva- Lua- Ble		Collected at CRF.

1.4.21. Key Adverse Events Data – KEYADVE

Dataset	KEYADVE
Creating program	keyadve.sas
Description	Key Adverse Events Data
Unique identifier	DPAT,SECTION,PREF_TRM,ADVCODE,ONSETDY
Sorted by	DPAT,SECTION,PREF_TRM,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: EVENT_ID,ADVDESC,ONSETDT,VERBATIM,TONSET,STOPDT,STOPTIME, REGDAY

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PERIOD	num	Medication Period		Collected at CRF.
SECTION	char	Section		Collected at CRF.
ADVEXP	num	AE Experienced		Collected at CRF.
ADVCODE	char	Who Included Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGREL	num	Drug Relation		Collected at CRF.
ACTION	num	Action		Collected at CRF.
CONCOM	num	Concom Given		Collected at CRF.
OUTCOME	num	Outcome		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.
BODYSYS	char	Who Body System Description		Collected at CRF.
SEXAE	char	Sexae		Collected at CRF.
ADVEXPF	char	AE Experienced (char)		Collected at CRF.
SEVERITF	char	Severity (char)		Collected at CRF.
SERIOUSF	char	Serious (char)		Collected at CRF.
DRUGRELF	char	Drug Relation (char)		Collected at CRF.
ACTIONF	char	Action (char)		Collected at CRF.
CONCOMF	char	Concom Given (char)		Collected at CRF.
OUTCOMEF	char	Outcome (char)		Collected at CRF.
STUDYDAY	num	Days On Study		Collected at CRF.
DURDAY	num	Durday		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONSETDY	num	Relative Onset Day		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		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.

1.4.22. Key Adverse Events 2 – KEYADVE2

Dataset	KEYADVE2
Creating program	keyadve2.sas
Description	Key Adverse Events 2
Unique identifier	DPAT,SECTION,PREF_TRM,ADVCODE,ONSETDY
Sorted by	DPAT,SECTION,PREF_TRM,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: EVENT_ID,ADVDESC,ONSETDT,VERBATIM,TONSET,STOPDT,STOPTIME, REGDAY

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PERIOD	num	Medication Period		Collected at CRF.
SECTION	char	Section		Collected at CRF.
ADVEXP	num	AE Experienced		Collected at CRF.
ADVCODE	char	Who Included Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGREL	num	Drug Relation		Collected at CRF.
ACTION	num	Action		Collected at CRF.
CONCOM	num	Concom Given		Collected at CRF.
OUTCOME	num	Outcome		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.
BODYSYS	char	Who Body System Description		Collected at CRF.
SEXAE	char	Sexae		Collected at CRF.
ADVEXPF	char	AE Experienced (char)		Collected at CRF.
SEVERITF	char	Severity (char)		Collected at CRF.
SERIOUSF	char	Serious (char)		Collected at CRF.
DRUGRELF	char	Drug Relation (char)		Collected at CRF.
ACTIONF	char	Action (char)		Collected at CRF.
CONCOMF	char	Concom Given (char)		Collected at CRF.
OUTCOMEF	char	Outcome (char)		Collected at CRF.
STUDYDAY	num	Days On Study		Collected at CRF.
DURDAY	num	Durday		Collected at CRF.
AF_DOUB	num	1= Study Day After Dose Doubling		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONSETDY	num	Relative Onset Day		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		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.

1.4.23. Keycurm – KEYCURM

Dataset	KEYCURM
Creating program	keycurm.sas
Description	Keycurm
Unique identifier	DPAT,ROUTE,TOTDOSE,DRUGDESC,CSTARDY,EVENT_ID
Sorted by	DPAT,ROUTE,TOTDOSE,DRUGDESC,CSTARDY,EVENT_ID
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: CSTART,CSTARTDT,CSTOP,CSTOPDT,DATE,FORE,FORTAE,FORTAEF,INDICAT, INDICAT1,INDICT,INO,INVNAME,MEDSTRDT,SURN,VERBATIM

Variable	Type	Label	Codes	Comments
VISITNO	char	Visit Number		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
CONT	num	Con Med Continued		Collected at CRF.
ROUTE	char	Rt of Adm		Collected at CRF.
DDOSE	char	Daily Dose		Collected at CRF.
PRN	num	Prn		Collected at CRF.
PRESC	num	For AE		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PNO	char	Protocol Number		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
DRUGCODE	char	Who Art Code		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.
EVENT_ID	char	Event Id		Collected at CRF.
GENDESC	char	Generic Description		Collected at CRF.
ATC_CD	char	Atc Code		Collected at CRF.
ATC_TEXT	char	Atc Text		Collected at CRF.
DRUGDESC	char	Who Art Description		Collected at CRF.
THERCLAS	char	Therapeutic*Class		Collected at CRF.
PHRMCLAS	char	Pharmacologic*Class		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
CONTF	char	Con Med Continued (char)		Collected at CRF.
CONMEDF	char	Con Med Given? (char)		Collected at CRF.
STUDYDAY	num	Days On Study		Collected at CRF.
DURATION	num	Duration of Conmed		Collected at CRF.
REGDAY	num	Days On Regimen		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
CSTARTDY	num	Relative Con Med Start Day		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, 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.
CSTOPDY	num	Relative Con Med Stop Day		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, 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.
MEDSTRDY	num	Relative First Med 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.

1.4.24. Key Dose – KEYDOSE

Dataset	KEYDOSE
Creating program	keydose.sas
Description	Key Dose
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STARTDT,MEDSTRTM,STOPDT,MEDSTPTM,REGIMEN,RTITLE1,RTITLE2, RTITLE3

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PERIOD	num	Medication Period		Collected at CRF.
SEQUENCE	num	Sequence		Collected at CRF.
XORDER	num	Xorder		Collected at CRF.

Variable	Type	Label	Codes	Comments
THRPYDAY	num	Total Days On Therapy		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.

1.4.25. Key Laboratory Data (Listing) – KEYLAB1

Dataset	KEYLAB1
Creating program	keylab1.sas
Description	Key Laboratory Data (Listing)
Unique identifier	DPAT,LABORDER,SECTION,LABTST,SAMPDY,VISITDY
Sorted by	DPAT,LABORDER,SECTION,LABTST,SAMPDY,VISITDY
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: SEX,LABLOC,SAMPDT,CENTLAB,INIT,EVDATE,EVDATEN,SAMPDTN,INVNAME, AGEUNIT,CNTRYF,STD_STRT,STDCSTRT,RACE,RACEF,AGE,CNTRY,FORE,SURN, SEXF

Variable	Type	Label	Codes	Comments
LABORDER	num	Order of Lab to Appear in Report		Collected at CRF.
CHGBASE	num	Change From Baseline		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOBASE	char	No Baseline Established Flag		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
USUNIT	char	Us Unit		Collected at CRF.
SIUNIT	char	Si Unit		Collected at CRF.
LABDESC	char	Full Lab Description		Collected at CRF.
LABTST	char	Abbreviated Lab Description		Collected at CRF.
USVAL	num	Us Value		Collected at CRF.
SIVAL	num	Si Value		Collected at CRF.
USCODE	num	Us Unit Code		Collected at CRF.
USFACTOR	num	Us Conversion Factor		Collected at CRF.
PAG_NAM	char	Page Name		Collected at CRF.
EVENT_ID	char	Visit Number		Collected at CRF.
VISITYPE	num	Visit Type		Collected at CRF.
RESULT	num	Raw Numeric Lab Result		Collected at CRF.
UNITCODE	num	Raw Unit Code		Collected at CRF.
EUVAL	num	European Value		Collected at CRF.
LABCODE	char	Lab Test Code		Collected at CRF.
LABSPEC	char	Other Lab Test Description		Collected at CRF.
EUCODE	num	European Unit Code		Collected at CRF.
COLORD	num	Collection Period Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
COLORDF	char	Decode, Colord		Collected at CRF.
HIRANGE	num	Upper Bound Reference Range		Collected at CRF.
LORANGE	num	Lower Bound Reference Range		Collected at CRF.
TUPID	num	Lab Sequence Number		Collected at CRF.
VISITYPF	char	Decode, Visitype		Collected at CRF.
CENTLAB	num	Central Lab?		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
SAMPDTF	num	Sample Date Flag		Collected at CRF.
CRESULT	char	Raw Character Lab Result		Collected at CRF.
EUFACTOR	num	European Conversion Factor		Collected at CRF.
LABCLASS	char	Type of Lab Test		Collected at CRF.
SIGN	num	Sign Code		Collected at CRF.
SIGNF	char	Decode, Sign		Collected at CRF.
COLLECT	char	Collection Time		Collected at CRF.
SECTION	char	Section		Collected at CRF.
VISITNO	num	Visit Number		Collected at CRF.
LNCODE	num	Lab Normal Unit Code		Collected at CRF.
WEEK	num	Week		Collected at CRF.
REPEAT	char	Repeat Flag		Collected at CRF.
OBSNO	num	Obs Within Section By Patient		Collected at CRF.
EUUNIT	char	European Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
REUCODE	num	Raritan Eu Unit Code		Collected at CRF.
REUUNIT	char	Raritan Eu Unit		Collected at CRF.
SICODE	num	Sicode		Collected at CRF.
SIFACTOR	num	Sifactor		Collected at CRF.
BASELINE	num	Baseline Value		Collected at CRF.
BASEFLAG	char	Baseline Flag		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.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
EVALF	char	Decode, Eval		Collected at CRF.
HB_STRAF	char	Decode, Hb_Strat		Collected at CRF.
HB_STRAT	num	Hemoglobin Stratum		Collected at CRF.
EVAL	num	Evaluable?		Collected at CRF.
REGDESC	char	Decode, Regorder		Collected at CRF.
REGORDER	num	Treatment Group Order		Collected at CRF.
TRE_HB	num	Trt Group + Hb Stratum		Collected at CRF.
TRE_HBF	char	Decode, Tre_Hb		Collected at CRF.
TRE_TU	num	Trt Group + Tumor Stratum		Collected at CRF.
TRE_TUF	char	Decode, Tre_Tu		Collected at CRF.
TU_STRAT	num	Tumor Type Stratum		Collected at CRF.

Variable	Type	Label	Codes	Comments
TU_STRAF	char	Decode, Tu_Strat		Collected at CRF.
SAF	num	Safety Population?		Collected at CRF.
SAFF	char	Decode, Saf		Collected at CRF.
ITT	num	Intent to Treat Population?		Collected at CRF.
ITTF	char	Decode, Itt		Collected at CRF.
PHASE	num	Study Phase		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.
VISITDY	num	Relative Visit Day		If EVDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.
STDSTRDY	num	Relative Study Start Day		If STDCSTRT and REF.DATE not missing then perform below logic to calculate STDSTRDY, If STDCSTRT less than REF.DATE then (STDCSTRT - REF.DATE). Else if STDCSTRT is greater than equal to REF.DATE then (STDCSTRT- REF.DATE) +1.

1.4.26. Kpro10 – KPRO10

Dataset	KPRO10
Creating program	kpro10.sas
Description	Kpro10
Unique identifier	DPAT
Sorted by	DPAT
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: SEX,AGE,AGEUNIT,DEATHDT,STATUSDT,OTHRSPEC,INO,SURN,FORE,RACE, RACESPEC,RACEF,INVNAME,CNTRY,COUNTRYF,DATE,STARTDT,DTERM, DBENDDT,SEXF

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DEATH	num	Did Patient Die?		Collected at CRF.
STATUS	num	Study Completed		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
REASONF	char	Decode for Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASEWGT	num	Baseline Weight		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
STATUSF	char	Completion Status		Collected at CRF.
COMPDAYS	num	Number of Days to Study Completion		Collected at CRF.
OL	num	Was Patient in Open-Label Study		Collected at CRF.
OLF	char	Decode for Ol		Collected at CRF.
CHEMOTYP	num	Type Chemotherapy (2=Non-Platinum)		Collected at CRF.
CHEMOTYF	char	Decode for Chemotyp		Collected at CRF.
TUMOR	num	Diagnosis of Malignancy		Collected at CRF.
TIMEDIAG	num	Months Since Diagnosis		Collected at CRF.
PERFPRE	num	Performance Score Prestudy		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
BHGB	num	Baseline Hb (G/Dl)		Collected at CRF.
BABSNEUT	num	Baseline Neutrophils (10^9/L)		Collected at CRF.
BRCT	num	Baseline Rc (%)		Collected at CRF.
BHCT	num	Baseline Hct (%)		Collected at CRF.
PRETRND	num	Baseline Transfusion Dependent		Collected at CRF.
PRETRNDF	char	Decode for Pretrnd		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUMORTYP	num	Tumor Type		Collected at CRF.
SAF	num	Safety Population?		Collected at CRF.
DEATHDY	num	Relative Day of Death		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.
STATUSDY	num	Relative Completion 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.
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.
COMPDY	num	Relative Completion Status Day		If DTERM and REF.DATE not missing then perform below logic to calculate COMPDY, If DTERM less than REF.DATE then (DTERM - REF.DATE). Else if DTERM is greater than equal to REF.DATE then (DTERM- REF.DATE) +1.
DBENDDY	num	Relative Last Day of Double-Blind Phase		If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT- REF.DATE) +1.

1.4.27. Kyadved – KYADVED

Dataset	KYADVED
Creating program	kyadved.sas
Description	Kyadved
Unique identifier	DPAT,SECTION,ADVCODE,PREF_TRM,ONSETDY
Sorted by	DPAT,SECTION,ADVCODE,PREF_TRM,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: EVENT_ID,ADVDESC,ONSETDT,VERBATIM,TONSET,STOPDT,STOPTIME, REGDAY,AEDT,DOUBLEDT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PERIOD	num	Medication Period		Collected at CRF.
SECTION	char	Section		Collected at CRF.
ADVEXP	num	AE Experienced		Collected at CRF.
ADVCODE	char	Who Included Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGREL	num	Drug Relation		Collected at CRF.
ACTION	num	Action		Collected at CRF.
CONCOM	num	Concom Given		Collected at CRF.
OUTCOME	num	Outcome		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.
BODYSYS	char	Who Body System Description		Collected at CRF.
SEXAE	char	Sexae		Collected at CRF.
ADVEXPF	char	AE Experienced (char)		Collected at CRF.
SEVERITF	char	Severity (char)		Collected at CRF.
SERIOUSF	char	Serious (char)		Collected at CRF.
DRUGRELF	char	Drug Relation (char)		Collected at CRF.
ACTIONF	char	Action (char)		Collected at CRF.
CONCOMF	char	Concom Given (char)		Collected at CRF.
OUTCOMEF	char	Outcome (char)		Collected at CRF.
STUDYDAY	num	Days On Study		Collected at CRF.
DURDAY	num	Durday		Collected at CRF.
AF_DOUB	num	1= Study Day After Dose Doubling		Collected at CRF.
DOUBLED	num	Doubled		Collected at CRF.
VDATEC	char	Vdatec		Collected at CRF.
GE_DOUB	num	Ge_Doub		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONSETDY	num	Relative Onset Day		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		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.

1.4.28. Laboratory Normal Ranges – LABNORM

Dataset	LABNORM
Creating program	labnorm.sas
Description	Laboratory Normal Ranges
Unique identifier	LN_CODE,STARTCDY
Sorted by	LN_CODE,STARTCDY
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: CENTER,AGE,STOPCD,STOPHD

Variable	Type	Label	Codes	Comments
STUDY	char	Name of Study		Collected at CRF.
LN_CODE	num	Lab Normal Code (Key:Center Ln_Code Sex)		Collected at CRF.
SEX	num	Sex (1=Male, 2=Female)		Collected at CRF.
AGE	char	Age Border		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
STARTCD	num	Start Date of Validity (Chem)		Collected at CRF.
STARTHD	num	Start Date of Validity (Hema)		Collected at CRF.
LC208	num	Calcium Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
HC208	num	Calcium High		Collected at CRF.
C208_U	num	Calcium Unit		Collected at CRF.
LC201	num	Sodium Low		Collected at CRF.
HC201	num	Sodium High		Collected at CRF.
C201_U	num	Sodium Unit		Collected at CRF.
LC202	num	Potassium Low		Collected at CRF.
HC202	num	Potassium High		Collected at CRF.
C202_U	num	Potassium Unit		Collected at CRF.
LC203	num	Chloride Low		Collected at CRF.
HC203	num	Chloride High		Collected at CRF.
C203_U	num	Chloride Unit		Collected at CRF.
LC304	num	Glucose Low		Collected at CRF.
HC304	num	Glucose High		Collected at CRF.
C304_U	num	Glucose Unit		Collected at CRF.
LC209	num	Phosphorus Low		Collected at CRF.
HC209	num	Phosphorus High		Collected at CRF.
C209_U	num	Phosphorus Unit		Collected at CRF.
LC230	num	Bicarbonate Low		Collected at CRF.
HC230	num	Bicarbonate High		Collected at CRF.
C230_U	num	Bicarbonate Unit		Collected at CRF.
LC205	num	Creatinine Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
HC205	num	Creatinine High		Collected at CRF.
C205_U	num	Creatinine Unit		Collected at CRF.
LC207	num	Uricacid Low		Collected at CRF.
HC207	num	Uricacid High		Collected at CRF.
C207_U	num	Uricacid Unit		Collected at CRF.
LC206	num	Bun Low		Collected at CRF.
HC206	num	Bun High		Collected at CRF.
C206_U	num	Bun Unit		Collected at CRF.
LC218	num	Ldh Low		Collected at CRF.
HC218	num	Ldh High		Collected at CRF.
C218_U	num	Ldh Unit		Collected at CRF.
LC214	num	Alkphos Low		Collected at CRF.
HC214	num	Alkphos High		Collected at CRF.
C214_U	num	Alkphos Unit		Collected at CRF.
LC210	num	Protein Low		Collected at CRF.
HC210	num	Protein High		Collected at CRF.
C210_U	num	Protein Unit		Collected at CRF.
LC215	num	Bilirubin Low		Collected at CRF.
HC215	num	Bilirubin High		Collected at CRF.
C215_U	num	Bilirubin Unit		Collected at CRF.
LC221	num	Cholesterol Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
HC221	num	Cholesterol High		Collected at CRF.
C221_U	num	Cholesterol Unit		Collected at CRF.
LC222	num	Triglyceride Low		Collected at CRF.
HC222	num	Triglyceride High		Collected at CRF.
C222_U	num	Triglyceride Unit		Collected at CRF.
LC217	num	Sgot Low		Collected at CRF.
HC217	num	Sgot High		Collected at CRF.
C217_U	num	Sgot Unit		Collected at CRF.
LC225	num	Sgpt Low		Collected at CRF.
HC225	num	Sgpt High		Collected at CRF.
C225_U	num	Sgpt Unit		Collected at CRF.
LC275	num	Ggt Low		Collected at CRF.
HC275	num	Ggt High		Collected at CRF.
C275_U	num	Ggt Unit		Collected at CRF.
LC226	num	Creact Low		Collected at CRF.
HC226	num	Creact High		Collected at CRF.
C226_U	num	Creact Unit		Collected at CRF.
LH141	num	Fibrinogen Low		Collected at CRF.
HH141	num	Fibrinogen High		Collected at CRF.
H141_U	num	Fibrinogen Unit		Collected at CRF.
LHBVAL	num	Hb Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
HHBVAL	num	Hb High		Collected at CRF.
HB_U	num	Hb Unit		Collected at CRF.
LH103	num	Hemoglobin Low		Collected at CRF.
HH103	num	Hemoglobin High		Collected at CRF.
H103_U	num	Hemoglobin Unit		Collected at CRF.
LH104	num	Hematocrit Low		Collected at CRF.
HH104	num	Hematocrit High		Collected at CRF.
H104_U	num	Hematocrit Unit		Collected at CRF.
LH102	num	Rbc Low		Collected at CRF.
HH102	num	Rbc High		Collected at CRF.
H102_U	num	Rbc Unit		Collected at CRF.
LH131	num	Reticu Low		Collected at CRF.
HH131	num	Reticulo High		Collected at CRF.
H131_U	num	Reticu Unit		Collected at CRF.
LH101	num	Wbc Low		Collected at CRF.
HH101	num	Wbc High		Collected at CRF.
H101_U	num	Wbc Unit		Collected at CRF.
LH117	num	Neutro Low		Collected at CRF.
HH117	num	Neutro High		Collected at CRF.
H117_U	num	Neutro Unit		Collected at CRF.
LH110	num	Band Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
HH110	num	Band High		Collected at CRF.
H110_U	num	Band Unit		Collected at CRF.
LH111	num	Lympho Low		Collected at CRF.
HH111	num	Lympho High		Collected at CRF.
H111_U	num	Lympho Unit		Collected at CRF.
LH112	num	Mono Low		Collected at CRF.
HH112	num	Mono High		Collected at CRF.
H112_U	num	Mono Unit		Collected at CRF.
LH113	num	Eosino Low		Collected at CRF.
HH113	num	Eosino High		Collected at CRF.
H113_U	num	Eosino Unit		Collected at CRF.
LH114	num	Baso Low		Collected at CRF.
HH114	num	Baso High		Collected at CRF.
H114_U	num	Baso Unit		Collected at CRF.
LH116	num	Other Low		Collected at CRF.
HH116	num	Other High		Collected at CRF.
H116_U	num	Other Unit		Collected at CRF.
CH116	char	Other Spec		Collected at CRF.
LH1161	num	Other Low1		Collected at CRF.
HH1161	num	Other High1		Collected at CRF.
H1161_U	num	Other Unit1		Collected at CRF.

Variable	Type	Label	Codes	Comments
CH1161	char	Other Spec1		Collected at CRF.
LH108	num	Platelet Low		Collected at CRF.
HH108	num	Platelet High		Collected at CRF.
H108_U	num	Platelet Unit		Collected at CRF.
LC216	num	Iron Low		Collected at CRF.
HC216	num	Iron High		Collected at CRF.
C216_U	num	Iron Unit		Collected at CRF.
LC285	num	Ferritin Low		Collected at CRF.
HC285	num	Ferritin High		Collected at CRF.
C285_U	num	Ferritin Unit		Collected at CRF.
LC287	num	Transferrin Low		Collected at CRF.
HC287	num	Transferrin High		Collected at CRF.
C287_U	num	Transferrin Unit		Collected at CRF.

1.4.29. Malignancy Data – MALIGN

Dataset	MALIGN
Creating program	malign.sas
Description	Malignancy Data
Unique identifier	DPAT,SECTION
Sorted by	DPAT,SECTION
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INV,OTHERSC,OTHERSC1,DMALI,DSTAG,DHEMAT,CYCLE,WEEK,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
DMALIF	num	Dmali Flag		Collected at CRF.
DSTAGF	num	Dstag Flag		Collected at CRF.
STAGI	char	Staging		Collected at CRF.
PRTUMO	char	Primary Tumor		Collected at CRF.
NODAL	char	Nodal Involve		Collected at CRF.
DISTAN	char	Distant Meta		Collected at CRF.
DHEMATF	num	Dhemat Flag		Collected at CRF.
OTHERS	num	Others		Collected at CRF.
STAGE	char	Stage		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
MALIVSDY	num	Relative Visit Day		If DMALI and REF.DATE not missing then perform below logic to calculate MALIVSDY, If DMALI less than REF.DATE then (DMALI - REF.DATE). Else if DMALI is greater than equal to REF.DATE then (DMALI- REF.DATE) +1.
STAGDY	num	Relative Staging Day		If DSTAG and REF.DATE not missing then perform below logic to calculate STAGDY, If DSTAG less than REF.DATE then (DSTAG - REF.DATE). Else if DSTAG is greater than equal to REF.DATE then (DSTAG- REF.DATE) +1.
HEMATDY	num	Relative Staging Day		If DHEMAT and REF.DATE not missing then perform below logic to calculate HEMATDY, If DHEMAT less than REF.DATE then (DHEMAT - REF.DATE). Else if DHEMAT is greater than equal to REF.DATE then (DHEMAT- REF.DATE) +1.

1.4.30. Medical History Data – MEDHIS

Dataset	MEDHIS
Creating program	medhis.sas
Description	Medical History Data
Unique identifier	DPAT,VISITDY,SYSTEM,OBSNO
Sorted by	DPAT,VISITDY,SYSTEM,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INV,VERBATIM,VDATE,CYCLE,WEEK,INIT

Variable	Type	Label	Codes	Comments
VDATEF	num	Vdate Flag		Collected at CRF.
NORMAB	num	Normab		Collected at CRF.
SYSTEM	num	Body System		Collected at CRF.
SECTION	char	Section		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.

1.4.31. Newtve – NEWTVE

Dataset	NEWTVE
Creating program	newtve.sas
Description	Newtve
Unique identifier	ADVCODE,PREF_TRM
Sorted by	ADVCODE,PREF_TRM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TVENO,ADVDESC

Variable	Type	Label	Codes	Comments
ADVCODE	char	Who Included Code		Collected at CRF.
SEXAE	char	Sexae		Collected at CRF.
BODYSYS	char	Who Body System Description		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.

1.4.32. Key Exposure Data – NKEYDOSE

Dataset	NKEYDOSE
Creating program	nkeydose.sas
Description	Key Exposure Data
Unique identifier	DPAT
Sorted by	DPAT
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: SEX,RTITLE1,STARTDT,STOPDT,MEDSTART,MEDSTOP,,INVNAME,AGEUNIT, CNTRYF,STD_STRT,STDCSTRT,RACE,RACEF,AGE,CNTRY,FORE,SURN,SEXF

Variable	Type	Label	Codes	Comments
THRPYDAY	num	Total Days on Therapy		Collected at CRF.
RTITLE2	char	2Nd Line of Column Header		Collected at CRF.
RTITLE3	char	3Rd Line of Column Header		Collected at CRF.
REGORDER	num	Treatment Group Order		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
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
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
EVALF	char	Decode, Eval		Collected at CRF.
HB_STRAF	char	Decode, Hb_Strat		Collected at CRF.
HB_STRAT	num	Hemoglobin Stratum		Collected at CRF.
EVAL	num	Evaluable?		Collected at CRF.
REGDESC	char	Decode, Regorder		Collected at CRF.
TRE_HB	num	Trt Group + Hb Stratum		Collected at CRF.
TRE_HBF	char	Decode, Tre_Hb		Collected at CRF.
TRE_TU	num	Trt Group + Tumor Stratum		Collected at CRF.
TRE_TUF	char	Decode, Tre_Tu		Collected at CRF.
TU_STRAT	num	Tumor Type Stratum		Collected at CRF.
TU_STRAF	char	Decode, Tu_Strat		Collected at CRF.
SAF	num	Safety Population?		Collected at CRF.
SAFF	char	Decode, Saf		Collected at CRF.
ITT	num	Intent to Treat Population?		Collected at CRF.
ITTF	char	Decode, Itt		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTDY	num	Relative Study 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 Study 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.

1.4.33. Patient – PAT

Dataset	PAT
Creating program	pat.sas
Description	Patient
Unique identifier	DPAT
Sorted by	DPAT
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: SEX,INV,SHORTNAM,COUNTRY,EXACTAGE,AGE,STUDSTRT,STUDEND, CORR_DT,RESP_DT,MAX_DT,LAST_DT

Variable	Type	Label	Codes	Comments
EVAL	num	Eva- Lua- Ble		Collected at CRF.
SUBGROUP	num	1=Itt, 1.5=Saf, 2=Eff		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
HEIGHT	num	Height (Cm)		Collected at CRF.
WEIGHT	num	Weight (Kg)		Collected at CRF.
TRE	num	Randomization		Collected at CRF.
TU_STRAT	num	Tumor Type		Collected at CRF.
PRECHEMO	num	Chemotherapy Within 3 Months Prestudy		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOTNUM	char	Total Number Ct Cycles Prestudy		Collected at CRF.
HB_STRAT	num	Hemoglobin		Collected at CRF.
PRETRND	num	Baseline Transfusion Dependent		Collected at CRF.
CUMTX0	num	Baseline Transfusion Rate		Collected at CRF.
TXAF28	num	Transfused After Day 28		Collected at CRF.
TXAF28HB	num	Transfused or Hb <8 G/Dl After Day 28		Collected at CRF.
CUMTX1WO	num	Cum. Transfusion Rate After First Month		Collected at CRF.
BASE_HB	num	Baseline Hb (G/Dl)		Collected at CRF.
BASE_HC	num	Baseline Hct (%)		Collected at CRF.
BASE_RC	num	Baseline Rc (%)		Collected at CRF.
BASE_NE	num	Baseline Neutrophils (%)		Collected at CRF.
DOSEGIVN	num	Any Dose Given		Collected at CRF.
DEATH	num	Did Patient Die?		Collected at CRF.
DISCAE	num	Discontinued Due to AE		Collected at CRF.
SER_AE	num	Had Any Serious AE		Collected at CRF.
CENLABPT	num	Lab Data All from Central Lab		Collected at CRF.
CORR_HB	num	First Hb >=12 G/Dl		Collected at CRF.
RESP_HB	num	Hb [G/Dl] at Response		Collected at CRF.
MAX_HB	num	Maximal Hb [G/Dl]		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAST_HB	num	Last Hb [G/Dl] (Transfusion Independent)		Collected at CRF.
FINLRESP	num	Final Response		Collected at CRF.
LAST_HBA	num	Last Hb [G/Dl] (of All Hbs)		Collected at CRF.
STUDENDY	num	Relative Day off-Study		If STUDEND and REF.DATE not missing then perform below logic to calculate STUDENDY, If STUDEND less than REF.DATE then (STUDEND - REF.DATE). Else if STUDEND is greater than equal to REF.DATE then (STUDEND- REF.DATE) +1.
CORR_DY	num	Relative First Day of Hb >=12 G/Dl		If CORR_DT and REF.DATE not missing then perform below logic to calculate CORR_DY, If CORR_DT less than REF.DATE then (CORR_DT - REF.DATE). Else if CORR_DT is greater than equal to REF.DATE then (CORR_DT- REF.DATE) +1.
RESP_DY	num	Relative Day of Response		If RESP_DT and REF.DATE not missing then perform below logic to calculate RESP_DY, If RESP_DT less than REF.DATE then (RESP_DT - REF.DATE). Else if RESP_DT is greater than equal to REF.DATE then (RESP_DT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MAX_DY	num	Relative Day of Maximal Hb		If MAX_DT and REF.DATE not missing then perform below logic to calculate MAX_DY, If MAX_DT less than REF.DATE then (MAX_DT - REF.DATE). Else if MAX_DT is greater than equal to REF.DATE then (MAX_DT- REF.DATE) +1.
LAST_DY	num	Relative Day of Last Hb		If LAST_DT and REF.DATE not missing then perform below logic to calculate LAST_DY, If LAST_DT less than REF.DATE then (LAST_DT - REF.DATE). Else if LAST_DT is greater than equal to REF.DATE then (LAST_DT- REF.DATE) +1.

1.4.34. Physical Examination Data – PHYSEX

Dataset	PHYSEX
Creating program	physex.sas
Description	Physical Examination Data
Unique identifier	DPAT,SECTION,SYSTEM,OBSNO
Sorted by	DPAT,SECTION,SYSTEM,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INV,VERBATIM,VDATE,CYCLE,WEEK,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.

Variable	Type	Label	Codes	Comments
VDATEF	num	Vdate Flag		Collected at CRF.
OTHRSPEC	char	Other Reason Specified		Collected at CRF.
SYSTEM	num	Body System		Collected at CRF.
NORMAB	num	Result		Collected at CRF.
CHANGE	num	Change From Previous Visit		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.

1.4.35. Vital Signs Data – PPVI

Dataset	PPVI
Creating program	ppvi.sas
Description	Vital Signs Data
Unique identifier	DPAT,SECTION,VISITDY
Sorted by	DPAT,SECTION,VISITDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,VDATE,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
VDATEF	num	Vdate Flag		Collected at CRF.
PULSE	num	Pulse		Collected at CRF.
SBP	num	Bp Systolic		Collected at CRF.
DBP	num	Bp Diastolic		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
WEIGHT	num	Weight (Kg)		Collected at CRF.
HEIGHT	num	Height (Cm)		Collected at CRF.
TEMP	num	Temperature		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEMPUNIT	num	Unit Temperature		Collected at CRF.
WGTUNIT	num	Unit Weight		Collected at CRF.
HGTUNIT	num	Unit Height		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.

1.4.36. Precurm – PRECURM

Dataset	PRECURM
Creating program	precurm.sas
Description	Precurm
Unique identifier	DPAT,ROUTE,TOTDOSE,DRUGDESC,CSTARDY
Sorted by	DPAT,ROUTE,TOTDOSE,DRUGDESC,CSTARDY
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: CSTART,CSTARTDT,CSTOP,CSTOPDT,CYCLE,DATE,FORE,FORTAE,FORTAEF, INDICAT,INDICAT1,INDICT,INO,INVNAME,MEDSTRDT,PRESC,REGDAY,SURN, VERBATIM,WEEK

Variable	Type	Label	Codes	Comments
VISITNO	char	Visit Number		Collected at CRF.
CSTARTF	num	Cstart Flag		Collected at CRF.
CSTOPF	num	Cstop Flag		Collected at CRF.
CONT	num	Con Med Continued		Collected at CRF.
ROUTE	char	Rt of Adm		Collected at CRF.
DDOSE	char	Daily Dose		Collected at CRF.
PRN	num	Prn		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
PNO	char	Protocol Number		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
DRUGCODE	char	Who Art Code		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.
EVENT_ID	char	Event Id		Collected at CRF.
GENDESC	char	Generic Description		Collected at CRF.
ATC_CD	char	Atc Code		Collected at CRF.
ATC_TEXT	char	Atc Text		Collected at CRF.
DRUGDESC	char	Who Art Description		Collected at CRF.
THERCLAS	char	Therapeutic*Class		Collected at CRF.
PHRMCLAS	char	Pharmacologic*Class		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
CONTF	char	Con Med Continued (char)		Collected at CRF.
CONMEDF	char	Con Med Given? (char)		Collected at CRF.
STUDYDAY	num	Days On Study		Collected at CRF.
DURATION	num	Duration of Conmed		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
CSTARTDY	num	Relative Con Med Start Day		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, 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.
CSTOPDY	num	Relative Con Med Stop Day		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, 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.
MEDSTRDY	num	Relative First Med 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.

1.4.37. Profi10 – PROFI10

Dataset	PROFI10
Creating program	profi10.sas
Description	Profi10
Unique identifier	DPAT
Sorted by	DPAT
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: SEX,AGE,AGEUNIT,DEATHDT,STATUSDT,OTHRSPEC,INO,SURN,FORE,RACE, RACESPEC,RACEF,INVNAME,BIRTHDT,COUNTRY,CNTRY,COUNTRYF,VDATE, DATE,STARTDT,EPO,LEPODT,DTERM,DBENDDT,DIAGDT,LCHEMDT,PHYSDB, PHYSOL,PHYSDBF,PHYSOLF,SEXF

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DEATH	num	Did Patient Die?		Collected at CRF.
STATUS	num	Study Completed		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
REASONF	char	Decode for Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASEWGT	num	Baseline Weight		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
TRTMEN10	num	Treatment Code		Collected at CRF.
TRTMENTF	char	Decode for Treatment		Collected at CRF.
STATUSF	char	Completion Status		Collected at CRF.
COMPDAYS	num	Number of Days to Study Completion		Collected at CRF.
OL	num	Was Patient in Open-Label Study		Collected at CRF.
OLF	char	Decode for Ol		Collected at CRF.
CRESP10	num	Response to Chemotherapy		Collected at CRF.
CRESPF	char	Decode for Cresp10		Collected at CRF.
CHEMOTYP	num	Type Chemotherapy (2=Non-Platinum)		Collected at CRF.
CHEMOTYF	char	Decode for Chemotyp		Collected at CRF.
DIAGF	num	Flag for Diagdt		Collected at CRF.
DIAGDTF	char	Flag for Missing Parts of Dates		Collected at CRF.
MDIAGN10	num	Diagnosis of Malignancy		Collected at CRF.
MDIAGNOF	char	Decode for Mdiagnos		Collected at CRF.
TIMEDIAG	num	Months Since Diagnosis		Collected at CRF.
PERFPRE	num	Performance Score Prestudy		Collected at CRF.
PERFTERM	num	Performance Score at Termination		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERFCHG	num	Chge in Perform from Pre to Term		Collected at CRF.
CHEMOYN	num	Did Pat Receive Chemo Dur Past 6 Mon		Collected at CRF.
CHEMOYNF	char	Decode for Chemoyn (1=No, 2=Yes)		Collected at CRF.
PRECHEMO	num	Did Pat Have Chemo in Past 3 Mon		Collected at CRF.
PRECHEMF	char	Decode for Prechemo (1=No, 2=Yes)		Collected at CRF.
CYCLES	num	# of Chemo Cycles Prestudy		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
BASE_HB	num	Baseline Hb (G/Dl)		Collected at CRF.
BASE_NE	num	Baseline Neutrophils (10^9/L)		Collected at CRF.
BASE_RC	num	Baseline Rc (%)		Collected at CRF.
BASE_HC	num	Baseline Hct (%)		Collected at CRF.
PRETRND	num	Baseline Transfusion Dependent		Collected at CRF.
PRETRNDF	char	Decode for Pretrnd		Collected at CRF.
TUSTRAT	num	Tumor Type		Collected at CRF.
TUSTRATF	char	Decode for Tustrat		Collected at CRF.
DEATHDY	num	Relative Day of Death		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
STATUSDY	num	Relative Completion 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.
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.
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.
LEPODY	num	Relative Day of Last Study Dose		If LEPODT and REF.DATE not missing then perform below logic to calculate LEPODY, If LEPODT less than REF.DATE then (LEPODT - REF.DATE). Else if LEPODT is greater than equal to REF.DATE then (LEPODT- REF.DATE) +1.
DBENDDY	num	Relative Last Day of Double-Blind Phase		If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DIAGDY	num	Relative Day of Diagnosis of Malignancy		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.
LCHEMDY	num	Relative Day of Last Chemotherapy		If LCHEMDT and REF.DATE not missing then perform below logic to calculate LCHEMDY, If LCHEMDT less than REF.DATE then (LCHEMDT - REF.DATE). Else if LCHEMDT is greater than equal to REF.DATE then (LCHEMDT- REF.DATE) +1.

1.4.38. Profile – PROFILE

Dataset	PROFILE
Creating program	profile.sas
Description	Profile
Unique identifier	DPAT
Sorted by	DPAT
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: SEX,AGE,AGEUNIT,DEATHDT,STATUSDT,OTHRSPEC,INO,SURN,FORE,RACE, RACESPEC,RACEF,CNTRY,INVNAME,SEXF

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DEATH	num	Did Patient Die?		Collected at CRF.
STATUS	num	Study Completed		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
REASONF	char	Decode for Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.
BASEWGT	num	Baseline Weight		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGORDER	num	Randomization		Collected at CRF.
TRTMENT	num	Randomization-Trtment		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
STATUSF	char	Completion Status		Collected at CRF.
COMPDAYS	num	Number of Days to Study Completion		Collected at CRF.
_I	num	_I		Collected at CRF.
DEATHDY	num	Relative Day of Death		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.
STATUSDY	num	Relative Completion 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.

1.4.39. Protocol – PROTOCOL

Dataset	PROTOCOL
Creating program	protocol.sas
Description	Protocol
Unique identifier	DRUG
Sorted by	DRUG
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: AGEUNIT,FIRSTDB

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	Unit for Age		Collected at CRF.

Variable	Type	Label	Codes	Comments
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	Date of Modify		Collected at CRF.
DSTAMP	num	Stamp Date		Collected at CRF.

1.4.40. Ptransf – PTRANSF

Dataset	PTRANSF
Creating program	ptransf.sas
Description	Ptransf
Unique identifier	DPAT,SECTION,OBSNO
Sorted by	DPAT,SECTION,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,DATE,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
TRANS	num	Any Platelets		Collected at CRF.
DATEF	num	Date Flag		Collected at CRF.
H108	num	Platelet Count - Original Value		Collected at CRF.
UNIT	num	Unit Field		Collected at CRF.
PLATTEXT	char	Plat Text		Collected at CRF.
NEWUNIT	num	Platelet Count - Si Unit		Collected at CRF.
H108_U	num	Platelet Count - Original Unit		Collected at CRF.
FACTOR	num	Conversion Factor		Collected at CRF.

Variable	Type	Label	Codes	Comments
NEWH108	num	Platelet Count - Converted Value		Collected at CRF.
TYPE	char	Type		Collected at CRF.
UNITMLS	num	Unitmls		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
VISITDY	num	Relative Visit Day		If DATE and REF.DATE not missing then perform below logic to calculate VISITDY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE-REF.DATE) +1.

1.4.41. Questionnaire Data – QOL

Dataset	QOL
Creating program	qol.sas
Description	Questionnaire Data
Unique identifier	DPAT,SECTION,VISITDY
Sorted by	DPAT,SECTION,VISITDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,DQOL,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
QL1_1	num	Ql1 1		Collected at CRF.
QL1_2	num	Ql1 2		Collected at CRF.
QL1_3A	num	Ql1 3A		Collected at CRF.
QL1_3B	num	Ql1 3B		Collected at CRF.
QL1_3C	num	Ql1 3C		Collected at CRF.
QL1_3D	num	Ql1 3D		Collected at CRF.
QL1_3E	num	Ql1 3E		Collected at CRF.
QL1_3F	num	Ql1 3F		Collected at CRF.

Variable	Type	Label	Codes	Comments
QL1_3G	num	Ql1 3G		Collected at CRF.
QL1_3H	num	Ql1 3H		Collected at CRF.
QL1_3I	num	Ql1 3I		Collected at CRF.
QL1_3J	num	Ql1 3J		Collected at CRF.
QL1_4A	num	Ql1 4A		Collected at CRF.
QL1_4B	num	Ql1 4B		Collected at CRF.
QL1_4C	num	Ql1 4C		Collected at CRF.
QL1_4D	num	Ql1 4D		Collected at CRF.
QL1_5A	num	Ql1 5A		Collected at CRF.
QL1_5B	num	Ql1 5B		Collected at CRF.
QL1_5C	num	Ql1 5C		Collected at CRF.
QL1_6	num	Ql1 6		Collected at CRF.
QL1_7	num	Ql1 7		Collected at CRF.
QL1_8	num	Ql1 8		Collected at CRF.
QL1_9A	num	Ql1 9A		Collected at CRF.
QL1_9B	num	Ql1 9B		Collected at CRF.
QL1_9C	num	Ql1 9C		Collected at CRF.
QL1_9D	num	Ql1 9D		Collected at CRF.
QL1_9E	num	Ql1 9E		Collected at CRF.
QL1_9F	num	Ql1 9F		Collected at CRF.
QL1_9G	num	Ql1 9G		Collected at CRF.

Variable	Type	Label	Codes	Comments
QL1_9H	num	Ql1 9H		Collected at CRF.
QL1_9I	num	Ql1 9I		Collected at CRF.
QL1_10	num	Ql1 10		Collected at CRF.
QL1_11A	num	Ql1 11A		Collected at CRF.
QL1_11B	num	Al1 11B		Collected at CRF.
QL1_11C	num	Ql1 11C		Collected at CRF.
QL1_11D	num	Ql1 11D		Collected at CRF.
QL2_1	num	Ql2 1		Collected at CRF.
QL2_2	num	Ql2 2		Collected at CRF.
QL2_3	num	Ql2 3		Collected at CRF.
QL2_4	num	Ql2 4		Collected at CRF.
QL2_5	num	Ql2 5		Collected at CRF.
QL2_6	num	Ql2 6		Collected at CRF.
QL2_7	num	Ql2 7		Collected at CRF.
QL2_8	num	Ql2 8		Collected at CRF.
QL2_9	num	Ql2 9		Collected at CRF.
QL2_10	num	Ql2 10		Collected at CRF.
QL2_11	num	Ql2 11		Collected at CRF.
QL2_12	num	Ql2 12		Collected at CRF.
QL2_13	num	Ql2 13		Collected at CRF.
QL2_14	num	Ql2 14		Collected at CRF.

Variable	Type	Label	Codes	Comments
QL2_15A	num	Ql2 15A		Collected at CRF.
QL2_15	num	Ql2 15		Collected at CRF.
QL2_16	num	Ql2 16		Collected at CRF.
QL2_17	num	Ql2 17		Collected at CRF.
QL2_18	num	Ql2 18		Collected at CRF.
QL2_19	num	Ql2 19		Collected at CRF.
QL2_20	num	Ql2 20		Collected at CRF.
QL2_21	num	Ql2 21		Collected at CRF.
QL2_22	num	Ql2 22		Collected at CRF.
QL2_23	num	Ql2 23		Collected at CRF.
QL2_24	num	Ql2 24		Collected at CRF.
QL2_25	num	Ql2 25		Collected at CRF.
QL2_26	num	Ql2 26		Collected at CRF.
QL2_27	num	Ql2 27		Collected at CRF.
QL2_28	num	Ql2 28		Collected at CRF.
QL2_29	num	Ql2 29		Collected at CRF.
QL2_30	num	Ql2 30		Collected at CRF.
QL2_31	num	Ql2 31		Collected at CRF.
QL2_32	num	Ql2 32		Collected at CRF.
QL2_33	num	Ql2 33		Collected at CRF.
QL2_34	num	Ql2 34		Collected at CRF.

Variable	Type	Label	Codes	Comments
QL2_35	num	Ql2 35		Collected at CRF.
QL2_36	num	Ql2 36		Collected at CRF.
QL2_37	num	Ql2 37		Collected at CRF.
QL2_38	num	Ql2 38		Collected at CRF.
QL2_39	num	Ql2 39		Collected at CRF.
QL2_40	num	Ql2 40		Collected at CRF.
QL2_41	num	Ql2 41		Collected at CRF.
QL2_42	num	Ql2 42		Collected at CRF.
QL2_43	num	Ql2 43		Collected at CRF.
QL2_44	num	Ql2 44		Collected at CRF.
QL2_45	num	Ql2 45		Collected at CRF.
QL2_46	num	Ql2 46		Collected at CRF.
QL2_47	num	Ql2 47		Collected at CRF.
QL2_48	num	Ql2 48		Collected at CRF.
QL2_49	num	Ql2 49		Collected at CRF.
QL2_50	num	Ql2 50		Collected at CRF.
QL2_51	num	Ql2 51		Collected at CRF.
QL2_52	num	Ql2 52		Collected at CRF.
QL2_53	num	Ql2 53		Collected at CRF.
QL2_54	num	Ql2 54		Collected at CRF.
QL2_55	num	Ql2 55		Collected at CRF.

Variable	Type	Label	Codes	Comments
DQOLF	num	Dqolf		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
VISITDY	num	Relative Visit Day		If DQOL and REF.DATE not missing then perform below logic to calculate VISITDY, If DQOL less than REF.DATE then (DQOL - REF.DATE). Else if DQOL is greater than equal to REF.DATE then (DQOL-REF.DATE) +1.

1.4.42. Quality of Life – QUALLIFE

Dataset	QUALLIFE
Creating program	quallife.sas
Description	Quality of Life
Unique identifier	DPAT,SECT
Sorted by	DPAT,SECT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
SECT	num	Sect		Collected at CRF.
VDATEF	num	Vdate Flag		Collected at CRF.
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
Q1	num	Q1		Collected at CRF.
Q2	num	Q2		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q3	num	Q3		Collected at CRF.
VISITDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VISITDY, 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.

1.4.43. Radiation Therapy Data – RADIO

Dataset	RADIO
Creating program	radio.sas
Description	Radiation Therapy Data
Unique identifier	DPAT,SECTION,TOTDOSE,RSTARDY
Sorted by	DPAT,SECTION,TOTDOSE,RSTARDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,RSTART,RSTOP,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
RADGIV	num	Radiation Therapy		Collected at CRF.
TOTDOSE	char	Total Dose		Collected at CRF.
RSTARTF	num	Rstartf		Collected at CRF.

Variable	Type	Label	Codes	Comments
RSTOPF	num	Rstopf		Collected at CRF.
TYPE	char	Type		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
RSTARTDY	num	Relative Start Day		If RSTART and REF.DATE not missing then perform below logic to calculate RSTARTDY, If RSTART less than REF.DATE then (RSTART - REF.DATE). Else if RSTART is greater than equal to REF.DATE then (RSTART- REF.DATE) +1.
RSTOPDY	num	Relative Stop Day		If RSTOP and REF.DATE not missing then perform below logic to calculate RSTOPDY, If RSTOP less than REF.DATE then (RSTOP - REF.DATE). Else if RSTOP is greater than equal to REF.DATE then (RSTOP- REF.DATE) +1.

1.4.44. Sample – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	Sample
Unique identifier	DPAT,SECTION,SAMPLEDY
Sorted by	DPAT,SECTION,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,EPO,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
EPOF	num	Epo Flag		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.

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

1.4.45. Patient Status Data – STATUS98

Dataset	STATUS98
Creating program	status98.sas
Description	Patient Status Data
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,DDATE,ADATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STATUS	char	Study Completed		Collected at CRF.

Variable	Type	Label	Codes	Comments
DDATEF	num	Death Date Flag		Collected at CRF.
CAUSE	num	Cause		Collected at CRF.
AFLAG	num	Aflag		Collected at CRF.
DEATHDY	num	Relative Death Day		If DDATE and REF.DATE not missing then perform below logic to calculate DEATHDY, If DDATE less than REF.DATE then (DDATE - REF.DATE). Else if DDATE is greater than equal to REF.DATE then (DDATE- REF.DATE) +1.
ADY	num	Relative Analysis Day		If ADATE and REF.DATE not missing then perform below logic to calculate ADY, If ADATE less than REF.DATE then (ADATE - REF.DATE). Else if ADATE is greater than equal to REF.DATE then (ADATE- REF.DATE) +1.

1.4.46. Strat – STRAT

Dataset	STRAT
Creating program	strat.sas
Description	Strat
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,INIT

Variable	Type	Label	Codes	Comments
SOLID	num	Solid Tumor		Collected at CRF.
HEMAL	num	Hema Malignancy		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.

1.4.47. Surgery Data – SURGERY

Dataset	SURGERY
Creating program	surgery.sas
Description	Surgery Data
Unique identifier	DPAT,VISITDY,OBSNO
Sorted by	DPAT,VISITDY,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INV,SITE,SITE1,PROC,PROC1,DATE,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
PERFOR	num	Any Surgery		Collected at CRF.
DATEF	num	Date Flag		Collected at CRF.
RESDIS	num	Residual Disease		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.

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

1.4.48. Term – TERM

Dataset	TERM
Creating program	term.sas
Description	Term
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,INIT,COMM,COMM1,COMM2,COMM3,DATE,EPO,WIDATE

Variable	Type	Label	Codes	Comments
DATEF	num	Finaldate Flag		Collected at CRF.
RESPO	num	Response		Collected at CRF.
TERM	num	Study Completed		Collected at CRF.
WIDATEF	num	Widate Flag		Collected at CRF.
REASON	num	Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPOF	num	Last Dose Flag		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
VISITDY	num	Relative Visit Day		If DATE and REF.DATE not missing then perform below logic to calculate VISITDY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE-REF.DATE) +1.
LSTDOSDY	num	Relative Last Dose Day		If EPO and REF.DATE not missing then perform below logic to calculate LSTDOSDY, If EPO less than REF.DATE then (EPO - REF.DATE). Else if EPO is greater than equal to REF.DATE then (EPO-REF.DATE) +1.
WITHDRDY	num	Relative Withdrawal Day		If WIDATE and REF.DATE not missing then perform below logic to calculate WITHDRDY, If WIDATE less than REF.DATE then (WIDATE - REF.DATE). Else if WIDATE is greater than equal to REF.DATE then (WIDATE- REF.DATE) +1.

1.4.49. Transfusion Information Data – TRANSF

Dataset	TRANSF
Creating program	transf.sas
Description	Transfusion Information Data
Unique identifier	DPAT,SECTION,TYPE,VISITDY,OBSNO
Sorted by	DPAT,SECTION,TYPE,VISITDY,OBSNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV,DATE,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
TRANS	num	Any Trans		Collected at CRF.
DATEF	num	Date Flag		Collected at CRF.
H103	num	Hemoglobin - Original Value		Collected at CRF.
UNIT	num	Unit Field		Collected at CRF.
HB_TEXT	char	Hb Text		Collected at CRF.
NEWUNIT	num	Hemoglobin - Si Unit		Collected at CRF.
H103_U	num	Hemoglobin - Original Unit		Collected at CRF.
NEWH103	num	Hemoglobin - Converted Value		Collected at CRF.
FACTOR	num	Conversion Factor		Collected at CRF.

Variable	Type	Label	Codes	Comments
TYPE	char	Type		Collected at CRF.
UNITMLS	num	Unitmls		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
CYCLE	num	Cycle Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
VISITDY	num	Relative Visit Day		If DATE and REF.DATE not missing then perform below logic to calculate VISITDY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE-REF.DATE) +1.

1.4.50. Tve – TVE

Dataset	TVE
Creating program	tve.sas
Description	Tve
Unique identifier	PREF_TRM,ADVCODE
Sorted by	PREF_TRM,ADVCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ADVDESC

Variable	Type	Label	Codes	Comments
TVENO	num	Tveno		Collected at CRF.
ADVCODE	char	Who Included Code		Collected at CRF.
SEXAE	char	Sexae		Collected at CRF.
BODYSYS	char	Who Body System Description		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.

1.4.51. Tve9709 – TVE9709

Dataset	TVE9709
Creating program	tve9709.sas
Description	Tve9709
Unique identifier	PREF_TRM,ADVCODE
Sorted by	PREF_TRM,ADVCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ADVDESC

Variable	Type	Label	Codes	Comments
TVENO	num	Tveno		Collected at CRF.
ADVCODE	char	Who Included Code		Collected at CRF.
SEXAE	char	Sexae		Collected at CRF.
BODYSYS	char	Who Body System Description		Collected at CRF.
PREF_TRM	char	Who Preferred Term Description		Collected at CRF.

1.4.52. Uniqhorm – UNIQHORM

Dataset	UNIQHORM
Creating program	uniqhorm.sas
Description	Uniqhorm
Unique identifier	TYPE
Sorted by	TYPE
Notes	

Variable	Type	Label	Codes	Comments
TYPE	char	Type		Collected at CRF.

1.4.53. Urine Analysis Results – URIN

Dataset	URIN
Creating program	urin.sas
Description	Urine Analysis Results
Unique identifier	DPAT,SAMPDY
Sorted by	DPAT,SAMPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INV,CU3192,U3192,UDATE,WEEK,CYCLE,INIT

Variable	Type	Label	Codes	Comments
SECTION	char	Section		Collected at CRF.
UDATEF	num	Udate Flag		Collected at CRF.
U303	char	Ph Result		Collected at CRF.
U306	char	Glucose Result		Collected at CRF.
U307	char	Ketones Result		Collected at CRF.
U348	char	Protein Result		Collected at CRF.
U329	char	Nitrite Result		Collected at CRF.
U309	char	Blood Result		Collected at CRF.
U315	char	Wbc Result		Collected at CRF.
U315B	char	Wbc2 Result		Collected at CRF.

Variable	Type	Label	Codes	Comments
U316	char	Rbc Result		Collected at CRF.
U320	char	Casts Result		Collected at CRF.
U318	char	Crystals Result		Collected at CRF.
U314	char	Bacteria Result		Collected at CRF.
CU319	char	Other Specify		Collected at CRF.
U319	char	Other Result		Collected at CRF.
CU3191	char	Other Specify1		Collected at CRF.
U3191	char	Other Result1		Collected at CRF.
DPAT	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
OBSNO	num	Observation Number		Collected at CRF.
STUDY	char	Name of Study		Collected at CRF.
SAMPDY	num	Relative Sample Day		If UDATE and REF.DATE not missing then perform below logic to calculate SAMPDY, If UDATE less than REF.DATE then (UDATE - REF.DATE). Else if UDATE is greater than equal to REF.DATE then (UDATE- REF.DATE) +1.