

Clinical Development

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EPO_INT3

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 due to sensitivity of the data.
- 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.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Datasets with zero observations will not be submitted (ex. EPDEMO, NORMAL, SMEDBI3X)
- Comment datasets (CMNT, EPCMNT) will be submitted with zero observation.
- AGE is not present in DEMO dataset. So it will be added in DEMO from PROFILE dataset.
- PPROFILE dataset is meant for data reconciliation purpose. This datasets will be removed.
- Due to sensitive information INVN and JOURNAL datasets will be removed.
- REF.DATE (Visit Date) will be used as Reference Date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files

The EPO_INT3 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics - DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	<p>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: INIT, INO, VDATE, BIRTH, BIRTHF, VISITNO, EVENT_ID, SPECIFY</p> <p>Below listed variable is not a part of raw dataset. It has been added to retain the age related information in the De-identified dataset: AGE (Source: PROFILE Dataset) AGEUNIT (Source: PROFILE Dataset)</p>

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for De-Identity

Variable	Type	Label	Codes	Comments
DCENTER	num	Center Assigned for De-Identity		Randomly assigned Center for De-Identity
DCOUNTRY	num	De-Identify Country		Group element to protect PII.
VDATEF	num	Vdatef		Collected at CRF.
SEX	num	Sex		Collected at CRF.
RACE	num	Race		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.

1.4.2. Study Drug Administrator - ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Study Drug Administrator
Unique identifier	DPATNO,DY,EVENT_ID,VISITNO,WEEK,DOSENO
Sorted by	DPATNO,DY,EVENT_ID,VISITNO,WEEK,DOSENO
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: INIT,INO,DATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
DOSENO	num	Dose Number Within Week (1,2,3)		Collected at CRF.
DATEF	num	Datef		Collected at CRF.
WEIGHT	num	Weight (Kg)		Collected at CRF.
DOSE	num	Dose Given (U/Kg)		Collected at CRF.
MEASU	num	Measu		Collected at CRF.
ML	num	MI		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
DY	num	Relative Medication Start Day		If DATE and REF.DATE not missing then perform below logic to calculate DY, 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.

1.4.3. Adverse Events - ADVE

Dataset	ADVE
Creating program	adve.sas
Description	Adverse Events
Unique identifier	DPATNO,ONSETDT,WHOCODE,EVENT_ID
Sorted by	DPATNO,ONSETDT,WHOCODE,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 non significant elements: INIT,INO,ADVSPE,DONSET,STOPD,ORIG_TXT,_USER_,_DATE_

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
WHOCODE	char	Who Included Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
BY_WHOCO	char	By_Whoco		Collected at CRF.
ADVNOV	char	Advnov		Collected at CRF.
DONSETF	num	Donsetf		Collected at CRF.
ADVSEV	num	Advsev		Collected at CRF.
ADVSER	num	Advser		Collected at CRF.
ADVREL	num	Advrel		Collected at CRF.
ADVOTHER	num	Advther		Collected at CRF.
ADVCON	num	Advcon		Collected at CRF.
OUTCOME	num	Outcome		Collected at CRF.
STOPDF	num	Stopdf		Collected at CRF.
OBS	num	Obs		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
ONSETDY	num	Relative Onset Day of AE		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.
STOPDY	num	Relative Stop day		If STOPD and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPD less than REF.DATE then (STOPD - REF.DATE). Else if STOPD is greater than equal to REF.DATE then (STOPD- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADVE_TM	num	Time		Collected at CRF.
ADVE_DY	num	Relative Day		If _DATE_ and REF.DATE not missing then perform below logic to calculate ADVE_DY, 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. Bone marrow - BONEMARR

Dataset	BONEMARR
Creating program	bonemarr.sas
Description	Bonemarr
Unique identifier	DPATNO,MMETAF
Sorted by	DPATNO,MMETAF
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
MMETAF	char	Mmetaf		Collected at CRF.
MMETA	num	Mmeta		Collected at CRF.

1.4.5. Chemotherapy - CHEMO

Dataset	CHEMO
Creating program	chemo.sas
Description	Chemotherapy
Unique identifier	DPATNO,VISITNO,CYCLES,DRUG,CSTARTDY,OBSNO
Sorted by	DPATNO,VISITNO,CYCLES,DRUG,CSTARTDY,OBSNO
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 non significant elements: INIT,INO,CSTART,CSTOP,ORIG_TXT,_USER_,_DATE_

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
CHEMO	num	Chemo		Collected at CRF.
CYCLES	num	Cycles		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
WHODRUG	char	Who*Drug*Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
BY_WHODR	char	By_Whodr		Collected at CRF.
CSTARTF	num	Cstartf		Collected at CRF.
CSTOPF	num	Cstopf		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
TDOSE	char	Tdose		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
CSTARTDY	num	Relative Cstart 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 Cstart 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.
CHEMO_TM	num	Time		Collected at CRF.
CHEMO_DY	num	Relative Day		If _DATE_ and REF.DATE not missing then perform below logic to calculate CHEMO_DY, 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.

1.4.6. Serum Chemistry - CHEM_SI

Dataset	CHEM_SI
Creating program	chem_si.sas
Description	Serum Chemistry
Unique identifier	DPATNO,VISITNO,VDY,IDY
Sorted by	DPATNO,VISITNO,VDY,IDY
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: INIT,INO,VDATE,IDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
IDATEF	num	Idatef		Collected at CRF.
C201	num	C201		Collected at CRF.
C202	num	C202		Collected at CRF.

Variable	Type	Label	Codes	Comments
C203	num	C203		Collected at CRF.
C205	num	C205		Collected at CRF.
C208	num	C208		Collected at CRF.
C213	num	C213		Collected at CRF.
C215	num	C215		Collected at CRF.
C216	num	C216		Collected at CRF.
C217	num	C217		Collected at CRF.
C225	num	C225		Collected at CRF.
C283	num	C283		Collected at CRF.
C284	num	C284		Collected at CRF.
C285	num	C285		Collected at CRF.
C287	num	C287		Collected at CRF.
C344	num	C344		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.

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

1.4.7. Comment - CMNT

Dataset	CMNT
Creating program	cmnt.sas
Description	Comment
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
STUDY	char	Study		Empty data will be submitted.
DPATNO	num	Patient Number Assigned for De-Identity		Empty data will be submitted.
CMTCODE	char	Cmtcode		Empty data will be submitted.
VISITNO	num	Visit Number		Empty data will be submitted.
WEEK	num	Study Week		Empty data will be submitted.
QU	num	Qu		Empty data will be submitted.
EVENT_ID	char	Event_Id		Empty data will be submitted.

1.4.8. Compdtl - COMPDTL

Dataset	COMPDTL
Creating program	compdtl.sas
Description	Compdtl
Unique identifier	DPATNO,VDY,ADVCODE
Sorted by	DPATNO,VDY,ADVCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: INIT,INO,VDATE,VISITNO,EVENT_ID,EVDATE,VERBATIM,ADVDESC

Variable	Type	Label	Codes	Comments
ENTRYNO	num	Entryno		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VDATEF	num	Vdatef		Collected at CRF.
TERM	num	Term		Collected at CRF.
REASON	num	Reason		Collected at CRF.
DIED	num	Died		Collected at CRF.
PHASE	num	Phase		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
VDY	num	Relative Visit day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.9. Concomitant Therapy - CURM

Dataset	CURM
Creating program	curm.sas
Description	Concomitant Therapy
Unique identifier	DPATNO,VISITNO,DRUG,TDOSE,CSTARTDY,CSTOPDY,OBSNO
Sorted by	DPATNO,VISITNO,DRUG,TDOSE,CSTARTDY,CSTOPDY,OBSNO
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 non significant elements: INIT,INO,CSTART,CSTOP,INDICAT,ORIG_TXT,_USER_,_DATE_

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
CONMED	num	Conmed		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
WHODRUG	char	Who*Drug*Code		Collected at CRF.
BY_WHODR	char	By_Whodr		Collected at CRF.

Variable	Type	Label	Codes	Comments
CSTARTF	num	Cstartf		Collected at CRF.
CONT	num	Cont		Collected at CRF.
CSTOPF	num	Cstopf		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
TDOSE	char	Tdose		Collected at CRF.
PRN	num	Prn		Collected at CRF.
AE	num	AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
CSTARTDY	num	Relative Cstart 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 Cstop 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.
CURM_TM	num	Time		Collected at CRF.
CURM_DY	num	Relative Day		If _DATE_ and REF.DATE not missing then perform below logic to calculate CURM_DY, 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.

1.4.10. Doseeval - DOSEEVAL

Dataset	DOSEEVAL
Creating program	doseeval.sas
Description	Doseeval
Unique identifier	DPATNO,STARTDY,STOPDY
Sorted by	DPATNO,STARTDY,STOPDY
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 non significant elements or due to missing values: INO,INVNAME,EPO,DATE,STARTDT,STOPDT,MEDSTRTM,MEDSTPTM,RTITLE1,RTITLE2,RTITLE3,REGIMEN

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
EFFC	num	Is Patient Evaluable For Efficacy Analys		Collected at CRF.
ITT	num	Is Patient Evaluable Fot Itt Analysis		Collected at CRF.
TUMORTYP	num	Tumor Type		Collected at CRF.
TUMORTYF	char	Decode For Ttype		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAF	num	Is Patient Evaluable For Safety Analysis		Collected at CRF.
EFF	num	Is Patient Evaluable For Efficacy Analys		Collected at CRF.
EFFF	char	Decode For Eff (1=No, 2=Yes)		Collected at CRF.
EFFCF	char	Decode For Eff (1=No, 2=Yes)		Collected at CRF.
ITTF	char	Decode For Itt (1=No, 2=Yes)		Collected at CRF.
SAFF	char	Decode For Saf (1=No, 2=Yes)		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
PERIOD	num	Period For Initiation of Study Med		Collected at CRF.
SEQUENCE	num	Treatment Sequence		Collected at CRF.
XORDER	num	Cross-Over Order		Collected at CRF.
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.
STOPDY	num	Relative Medication Stop Day		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.11. Doseex - DOSEEX

Dataset	DOSEEX
Creating program	doseex.sas
Description	Doseex
Unique identifier	DPATNO,STARTDY,STOPDY
Sorted by	DPATNO,STARTDY,STOPDY
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: RTITLE2,EPO,DATE,STARTDT,STOPDT,MEDSTRTM,MEDSTPTM,RTITLE1, RTITLE3,REGIMEN

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Order of Regimens		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
PERIOD	num	Period For Initiation of Study Med		Collected at CRF.
SEQUENCE	num	Treatment Sequence		Collected at CRF.
XORDER	num	Cross-Over Order		Collected at CRF.
THRPYDAY	num	Total Days On Therapy		Collected at CRF.

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

1.4.12. Effpval - EFPVAL

Dataset	EFPVAL
Creating program	effpval.sas
Description	Effpval
Unique identifier	PVAL
Sorted by	PVAL
Notes	

Variable	Type	Label	Codes	Comments
PVAL	num	Pr>Chi		Collected at CRF.

1.4.13. EPO Comment - EPCMNT

Dataset	EPCMNT
Creating program	epcmnt.sas
Description	EPO Comment
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Empty data will be submitted.
STUDY	char	Study		Empty data will be submitted.
DPATNO	num	Patient Number Assigned for De-Identity		Empty data will be submitted.
CMTCODE	char	Cmtcode		Empty data will be submitted.
SAMDY	num	Relative Sample Day		Empty data will be submitted.
SAMDF	num	Samdf		Empty data will be submitted.
VISITNO	num	Visit Number		Empty data will be submitted.
EVENT_ID	char	Event_Id		Empty data will be submitted.

1.4.14. Epepo - EPEPO

Dataset	EPEPO
Creating program	epepo.sas
Description	Epepo
Unique identifier	DPATNO,EPODY,EPOVAL,OBSNO
Sorted by	DPATNO,EPODY,EPOVAL,OBSNO
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: INIT,EPOD

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
FORCEN	num	Forcen		Collected at CRF.
EPODF	num	Epodf		Collected at CRF.
EPOVAL	num	Epoval		Collected at CRF.
VISITNO	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event_Id		Collected at CRF.
EPODY	num	Relative Epod Day		If EPOD and REF.DATE not missing then perform below logic to calculate EPODY, If EPOD less than REF.DATE then (EPOD - REF.DATE). Else if EPOD is greater than equal to REF.DATE then (EPOD - REF.DATE) +1.

1.4.15. EPO Serum Levels - EPO

Dataset	EPO
Creating program	epo.sas
Description	EPO Serum Levels
Unique identifier	DPATNO,VISITNO,EPODY,OBSNO
Sorted by	DPATNO,VISITNO,EPODY,OBSNO
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: INIT,INO,EPO

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
EPOF	num	Epof		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
EPODY	num	Relative Epo Day		If EPO and REF.DATE not missing then perform below logic to calculate EPODY, 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.

1.4.16. Eposerum - EPOSERUM

Dataset	EPOSERUM
Creating program	eposerum.sas
Description	Eposerum
Unique identifier	DPATNO,VISITNO,EPODY,STARTDY,EPOVAL
Sorted by	DPATNO,VISITNO,EPODY,STARTDY,EPOVAL
Notes	Below listed variables will be dropped from dataset due to repetition of the information: EPO,EPOD,STARTDT

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
EPOF	num	Date Flag		Collected at CRF.
EPODF	num	Date Flag		Collected at CRF.
EPOVAL	num	Epo Serum Level Result		Collected at CRF.
EPO_DY	num	Relative Day Recorded When Sample Taken		If EPO and REF.DATE not missing then perform below logic to calculate EPO_DY, 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.

Variable	Type	Label	Codes	Comments
EPODY	num	Relative Day Recorded With Sample Results		If EPOD and REF.DATE not missing then perform below logic to calculate EPODY, If EPOD less than REF.DATE then (EPOD - REF.DATE). Else if EPOD is greater than equal to REF.DATE then (EPOD - REF.DATE) +1.
STARTDY	num	Relative Medication Start Day		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.

1.4.17. Evali3 - EVALI3

Dataset	EVALI3
Creating program	evali3.sas
Description	Evali3
Unique identifier	DPATNO,REGDESC
Sorted by	DPATNO,REGDESC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INO,INVNAME

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
EFFC	num	Is Patient Evaluable For Efficacy Analys		Collected at CRF.
ITT	num	Is Patient Evaluable Fot Itt Analysis		Collected at CRF.
TUMORTYP	num	Tumor Type		Collected at CRF.
TUMORTYF	char	Decode For Ttype		Collected at CRF.
SAF	num	Is Patient Evaluable For Safety Analysis		Collected at CRF.

Variable	Type	Label	Codes	Comments
EFF	num	Is Patient Evaluable For Efficacy Analys		Collected at CRF.
EFFF	char	Decode For Eff (1=No, 2=Yes)		Collected at CRF.
EFFCF	char	Decode For Eff (1=No, 2=Yes)		Collected at CRF.
ITTF	char	Decode For Itt (1=No, 2=Yes)		Collected at CRF.
SAFF	char	Decode For Saf (1=No, 2=Yes)		Collected at CRF.

1.4.18. HemaI3 - HEMA3

Dataset	HEMA3
Creating program	hemai3.sas
Description	Hemai3
Unique identifier	DPATNO,VISITNO,STARTDY,LABDY,CRFWEEK
Sorted by	DPATNO,VISITNO,STARTDY,LABDY,CRFWEEK
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: DATE,STARTDT,DBENDDT,INVNAME,LABDATE,SAMPDT

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Order of Regimens		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGDESC	char	Treatment		Collected at CRF.
VISITNO	num	Visit Number		Collected at CRF.
CRFWEEK	num	Study Week From Data		Collected at CRF.
HGB	num	Hemoglobin Value		Collected at CRF.
NEUTR	num	Neutrophil Value (%)		Collected at CRF.
RCT	num	Reticulocyte		Collected at CRF.
ABSNEUT	num	Absolute Neutrophil Value		Collected at CRF.
TRANRL14	num	Are Labs Rela To Trans <= 14 Days		Collected at CRF.
TRANRL28	num	Are Labs Rela To Trans <= 28 Days		Collected at CRF.
TRNRL14F	char	Decode For Tranrl14 (1=No, 2=Yes)		Collected at CRF.
TRNRL28F	char	Decode For Tranrl28 (1=No, 2=Yes)		Collected at CRF.
WEEK	num	Derived Week		Collected at CRF.
STARTDY	num	Relative Medication Start Day		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.

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

1.4.19. Hemi3 - HEMBI3

Dataset	HEMBI3
Creating program	hemi3.sas
Description	Hemi3
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CORRDT,RESPDT,MAXHBDT,INVNAME

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
BHGB	num	Baseline Hemoglobin Value		Collected at CRF.
FHGB	num	Last Hemoglobin Value		Collected at CRF.
CHHGB	num	Change of Hgb From Base To Last Value		Collected at CRF.
BRCT	num	Baseline Reticulocyte Value		Collected at CRF.
FRCT	num	Last Reticulocyte Value		Collected at CRF.
CHRCT	num	Change of Rct From Base To Last Value		Collected at CRF.
CORRHB	num	Hgb Value At Corrdays		Collected at CRF.

Variable	Type	Label	Codes	Comments
CORRECT	num	Was Patient A Corrector		Collected at CRF.
RESPHB	num	Hgb Value At Respday		Collected at CRF.
RESPOND	num	Did Patient Respond To Therapy		Collected at CRF.
MAXHB	num	Max. Hgb Value During Db Phase		Collected at CRF.
BEPO	num	Baseline Epo Serum Value		Collected at CRF.
BNEUTR	num	Baseline Neutrophil Value (%)		Collected at CRF.
BABSNEUT	num	Absolute Baseline Neutrophil Value		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
CORRECTF	char	Decode For Correct (1=No, 2=Yes)		Collected at CRF.
RESPONDF	char	Decode For Respond (1=No, 2=Yes)		Collected at CRF.
CORRDAY	num	Day of Correction		Collected at CRF.
RESPDAY	num	Day of Response		Collected at CRF.
MAXHBDAY	num	Day of Maximum Hgb Value		Collected at CRF.
FHGBDAY	num	Day of Last Hemoglobin		Collected at CRF.
CORRDY	num	Relative Day of Correction		If CORRDY and REF.DATE not missing then perform below logic to calculate CORRDY, If CORRDY less than REF.DATE then (CORRDY - REF.DATE). Else if CORRDY is greater than equal to REF.DATE then (CORRDY-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RESPDY	num	Relative Day of Response		If RESPDT and REF.DATE not missing then perform below logic to calculate RESPDY, If RESPDT less than REF.DATE then (RESPDT - REF.DATE). Else if RESPDT is greater than equal to REF.DATE then (RESPDT- REF.DATE) +1.
MAXHBDY	num	Relative Day of Maximum Hgb Value		If MAXHBDT and REF.DATE not missing then perform below logic to calculate MAXHBDY, If MAXHBDT less than REF.DATE then (MAXHBDT - REF.DATE). Else if MAXHBDT is greater than equal to REF.DATE then (MAXHBDT- REF.DATE) +1.

1.4.20. Hematology - HEM_SI

Dataset	HEM_SI
Creating program	hem_si.sas
Description	Hematology
Unique identifier	DPATNO,VISITNO,VDY,OBSNO
Sorted by	DPATNO,VISITNO,VDY,OBSNO
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: INIT,INO,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
CH116	char	Ch116		Collected at CRF.
H132	num	H132		Collected at CRF.
H108	num	H108		Collected at CRF.

Variable	Type	Label	Codes	Comments
H111	num	H111		Collected at CRF.
H103	num	H103		Collected at CRF.
H114	num	H114		Collected at CRF.
H117	num	H117		Collected at CRF.
H112	num	H112		Collected at CRF.
H116	num	H116		Collected at CRF.
H113	num	H113		Collected at CRF.
H101	num	H101		Collected at CRF.
H102	num	H102		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
VDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.21. History and Extent of Malignancy - HISTORY

Dataset	HISTORY
Creating program	history.sas
Description	History and Extent of Malignancy
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INIT,INO,VDATE,DIAG,DIAGNOS,RECENT,VISITNO,EVENT_ID

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VDATEF	num	Vdatef		Collected at CRF.
DIAGF	num	Diagf		Collected at CRF.
MALIGN	num	Malign		Collected at CRF.
SITE	char	Site		Collected at CRF.
TNM	char	Tnm		Collected at CRF.
C_TUMOR	char	C_Tumor		Collected at CRF.

Variable	Type	Label	Codes	Comments
METAST	char	Metast		Collected at CRF.
VDY	num	Relative Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.
DIAG_DY	num	Relative Diagnosis Day		If DIAG and REF.DATE not missing then perform below logic to calculate DIAG_DY, 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.

1.4.22. Hormone Therapy, Immunotherapy - HORRA

Dataset	HORRA
Creating program	horra.sas
Description	Hormone Therapy, Immunotherapy
Unique identifier	DPATNO,LDY,DRUG,THERAPY,TYPE
Sorted by	DPATNO,LDY,DRUG,THERAPY,TYPE
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 non significant elements or due to missing values: INIT,INO,WHODRUG,INDICAT,LDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
TYPE	num	Type		Collected at CRF.
THERAPY	num	Therapy		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
LDATEF	num	Ldatef		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONT	num	Cont		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
LDY	num	L Day		If LDATE and REF.DATE not missing then perform below logic to calculate LDY, If LDATE less than REF.DATE then (LDATE - REF.DATE). Else if LDATE is greater than equal to REF.DATE then (LDATE-REF.DATE) +1.

1.4.23. Iron Supplementation - IRON

Dataset	IRON
Creating program	iron.sas
Description	Iron Supplementation
Unique identifier	DPATNO,VISITNO,WEEK
Sorted by	DPATNO,VISITNO,WEEK
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INO,NAME

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
ADM	char	Administration		Collected at CRF.
TDOSE	char	Total Weekly Dose		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.

1.4.24. Ittpval - ITTPVAL

Dataset	ITTPVAL
Creating program	ittpval.sas
Description	Ittpval
Unique identifier	PVAL
Sorted by	PVAL
Notes	

Variable	Type	Label	Codes	Comments
PVAL	num	Pr>Chi		Collected at CRF.

1.4.25. Keyadve - KEYADVE

Dataset	KEYADVE
Creating program	keyadve.sas
Description	Keyadve
Unique identifier	DPATNO,VISITNO,ONSETDY,STARTDY,DBENDDY,BODYSYS
Sorted by	DPATNO,VISITNO,ONSETDY,STARTDY,DBENDDY,BODYSYS
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 non significant elements or due to missing values: VERBATIM,DONSET,STOPD,STOPDT,ONSETDT,ADVDESC,INO,DATE,STARTDT, DBENDDT,INVNAME,SURN,FORE,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONCOM	num	Com Med Given		Collected at CRF.
OUTCOME	num	Outcome of AE		Collected at CRF.
STOPDF	num	Stop Date of AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMNT	num	Treatment Code		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
OUTCOMEF	char	Outcome of AE		Collected at CRF.
CONCOMF	char	Com Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPF	char	AE Occured		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
ONSETDY	num	Relative Onset Day of AE		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.
STOPDY	num	Relative Stop Day of AE		If STOPD and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPD less than REF.DATE then (STOPD - REF.DATE). Else if STOPD is greater than equal to REF.DATE then (STOPD- 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.

1.4.26. Keyadve1- KEYADVE1

Dataset	KEYADVE1
Creating program	keyadve1.sas
Description	Keyadve1
Unique identifier	DPATNO,VISITNO,ONSETDY,STARTDY,DBENDDY,BODYSYS
Sorted by	DPATNO,VISITNO,ONSETDY,STARTDY,DBENDDY,BODYSYS
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 non significant elements or due to missing values: VERBATIM,DONSET,STOPD,STOPDT,ONSETDT,ADVDESC,INO,DATE,STARTDT, DBENDDT,INVNAME,SURN,FORE,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONCOM	num	Com Med Given		Collected at CRF.
OUTCOME	num	Outcome of AE		Collected at CRF.
STOPDF	num	Stop Date of AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMNT	num	Treatment Code		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
OUTCOMEF	char	Outcome of AE		Collected at CRF.
CONCOMF	char	Com Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPF	char	Ae Occured		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
ONSETDY	num	Relative Onset Day of AE		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.
STOPDY	num	Relative Stop Day of AE		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
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.

1.4.27. Keyadve2 - KEYADVE2

Dataset	KEYADVE2
Creating program	keyadve2.sas
Description	Keyadve2
Unique identifier	DPATNO,VISITNO,ONSETDY,STARTDY,DBENDDY,BODYSYS
Sorted by	DPATNO,VISITNO,ONSETDY,STARTDY,DBENDDY,BODYSYS
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 non significant elements or due to missing values: VERBATIM,DONSET,STOPD,STOPDT,ONSETDT,ADVDESC,INO,DATE,STARTDT, DBENDDT,INVNAME,SURN,FORE,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONCOM	num	Com Med Given		Collected at CRF.
OUTCOME	num	Outcome of AE		Collected at CRF.
STOPDF	num	Stop Date of AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMNT	num	Treatment Code		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
OUTCOMEF	char	Outcome of AE		Collected at CRF.
CONCOMF	char	Com Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPF	char	AE Occured		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
ONSETDY	num	Relative Onset Day of AE		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.
STOPDY	num	Relative Stop Day of AE		If STOPD and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPD less than REF.DATE then (STOPD - REF.DATE). Else if STOPD is greater than equal to REF.DATE then (STOPD- 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.

1.4.28. Keyaeex - KEYAEEX

Dataset	KEYAEEX
Creating program	keyaeex.sas
Description	Keyaeex
Unique identifier	DPATNO,VISITNO,ONSETDY,STOPDY,BODYSYS,SEVERITY
Sorted by	DPATNO,VISITNO,ONSETDY,STOPDY,BODYSYS,SEVERITY
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 non significant elements or due to missing values: VERBATIM,DONSET,STOPD,STOPDT,ONSETDT,ADVDESC,INO,DATE,STARTDT, DBENDDT,INVNAME,SURN,FORE,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Week		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONCOM	num	Com Med Given		Collected at CRF.
OUTCOME	num	Outcome of AE		Collected at CRF.
STOPDF	num	Stop Date of AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMNT	num	Treatment Code		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
OUTCOMEF	char	Outcome of AE		Collected at CRF.
CONCOMF	char	Com Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPF	char	AE Occured		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
ONSETDY	num	Relative Onset Day of AE		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.
STOPDY	num	Relative Stop Day of AE		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
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.

1.4.29. Keycomp - KEYCOMP

Dataset	KEYCOMP
Creating program	keycomp.sas
Description	Keycomp
Unique identifier	DPATNO,STATUSDY,BODYSYS
Sorted by	DPATNO,STATUSDY,BODYSYS
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 non significant elements or due to missing values: INO,STATUSDT,DEATHDT,INVNAME,SURN,FORE,VERBATIM,ADVDESC,REGDAY

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
STATUS	num	Completion Status		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
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.

1.4.30. Keycomp1 - KEYCOMP1

Dataset	KEYCOMP1
Creating program	keycomp1.sas
Description	Keycomp1
Unique identifier	DPATNO,STATUSDY, BODYSYS
Sorted by	DPATNO,STATUSDY, BODYSYS
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 non significant elements or due to missing values: INO,STATUSDT,DEATHDT,INVNAME,SURN,FORE,VERBATIM,ADVDESC,REGDAY

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
STATUS	num	Completion Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
REASON	num	Discontinuation Reason		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.

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.
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.

1.4.31. Keycomp2 - KEYCOMP2

Dataset	KEYCOMP2
Creating program	keycomp2.sas
Description	Keycomp2
Unique identifier	DPATNO,STATUSDY,BODYSYS
Sorted by	DPATNO,STATUSDY,BODYSYS
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 non significant elements or due to missing values: INO,STATUSDT,DEATHDT,INVNAME,SURN,FORE,VERBATIM,ADVDESC,REGDAY

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
STATUS	num	Completion Status		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
COMP_DAYS	num	Number of Days To Study Completion		Collected at CRF.
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.

SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
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.

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.
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1.4.32. Keycurm - KEYCURM

Dataset	KEYCURM
Creating program	keycurm.sas
Description	Keycurm
Unique identifier	DPATNO,VISITNO,CSTARTDY,CSTOPDY,DRUGCODE,TOTDOSE
Sorted by	DPATNO,VISITNO,CSTARTDY,CSTOPDY,DRUGCODE,TOTDOSE
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 non significant elements: VERBATIM,CSTART,CSTOP,INDICAT,ORIG_TXT,_USER_,_DATE_,INDICT, CSTARTDT,CSTOPDT,GENDESC,ATC_CD,ATC_TEXT,INO,DATE,INVNAME,SURN, FORE,MEDSTRDT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEEK	num	Study Week		Collected at CRF.
CONMED	num	Con Med Given?		Collected at CRF.
DRUGCODE	char	Who Art Code		Collected at CRF.
BY_WHODR	char	By_Whodr		Collected at CRF.
CSTARTF	num	Cstartf		Collected at CRF.
CONT	num	Con Med Continued		Collected at CRF.
CSTOPF	num	Cstopf		Collected at CRF.
ROUTE	char	Rt of Adm		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.
PRN	num	Prn		Collected at CRF.
FORTAE	num	For Trt Emerg AE		Collected at CRF.
EVENT_ID	char	Event_Id		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		Collected at CRF.
CONMEDF	char	Con Med Given?		Collected at CRF.
FORTAEF	char	For Trt Emerg AE		Collected at CRF.
STUDYDAY	num	Days On Study		Collected at CRF.
DURATION	num	Duration of Conmed		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGDAY	num	Days On Regimen		Collected at CRF.
PHASE	num	Study Phase		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 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.
KYCRM_TM	num	Time		Collected at CRF.
KYCRM_DY	num	Relative Day		If _DATE_ and REF.DATE not missing then perform below logic to calculate KYCRM_DY, 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.

Variable	Type	Label	Codes	Comments
DY	num	Relative Medication Start Day		If DATE and REF.DATE not missing then perform below logic to calculate DY, 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.
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.

1.4.33. Keydose - KEYDOSE

Dataset	KEYDOSE
Creating program	keydose.sas
Description	Keydose
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: EPO,DATE,STARTDT,STOPDT,MEDSTRTM,MEDSTPTM,RTITLE1,RTITLE2,RTITLE3,REGIMEN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
PERIOD	num	Period For Initiation of Study Med		Collected at CRF.
SEQUENCE	num	Treatment Sequence		Collected at CRF.
XORDER	num	Cross-Over Order		Collected at CRF.
THRPYDAY	num	Total Days On Therapy		Collected at CRF.

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

1.4.34. Keylab1 - KEYLAB1

Dataset	KEYLAB1
Creating program	keylab1.sas
Description	Keylab1
Unique identifier	DPATNO,VISITNO,WEEK,LABDY,STOPDY,LABCODE
Sorted by	DPATNO,VISITNO,WEEK,LABDY,STOPDY,LABCODE
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: LABDATE, LABDT,SAMPDT,COLLECT,COLLECTF,FLAGF,LABLOC,ENDPT,DATE, STARTDT,REC_ID,COLORDCOLORDF,ORIGFLAG,BIRTHDT,SEX,AGE,SASDATE, STOPDT,START,STOP

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
LABDATEF	num	Code For Missing Dates		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
LABCODE	char	Lab Code		Collected at CRF.
RESULT	num	Lab Value		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRESULT	char	Character Result Value		Collected at CRF.
PAG_NAME	char	Page Name of Crf		Collected at CRF.
PHASE	num	Phase		Collected at CRF.
VISITYPE	num	Visit Type		Collected at CRF.
VISITYPF	char	Formatted Visit Type		Collected at CRF.
UNITCODE	num	Code For Collected Lab Unit		Collected at CRF.
UNIT	char	Unit For Lab		Collected at CRF.
LABCLASS	char	H, C, Or U		Collected at CRF.
SIVAL	num	Si Value		Collected at CRF.
SIUNIT	char	Si Unit Format		Collected at CRF.
SICODE	num	Code For Si Unit		Collected at CRF.
BASELINE	num	Baseline Value		Collected at CRF.
CHGBASE	num	Change From Baseline		Collected at CRF.
PCTCHG	num	% Change From Baseline		Collected at CRF.
BASEFLAG	char	Baseline Flag		Collected at CRF.
LABORDER	num	Sort Order		Collected at CRF.
SIFMT	char	Sifmt		Collected at CRF.
LABDESC	char	Full Lab Description		Collected at CRF.
LABTST	char	Abbreviated Lab Description		Collected at CRF.
STUDYDAY	num	Day of Treatment		Collected at CRF.
CENTRAL	char	Central		Collected at CRF.

Variable	Type	Label	Codes	Comments
NEWVIS	num	Newvis		Collected at CRF.
LOAGE	num	Loage		Collected at CRF.
HIAGE	num	Hiage		Collected at CRF.
LORANGE	num	Lorange		Collected at CRF.
HIRANGE	num	Hirange		Collected at CRF.
I	num	I		Collected at CRF.
FLAG	char	Flag		Collected at CRF.
LABDY	num	Relative Lab Day		If LABDT and REF.DATE not missing then perform below logic to calculate LABDY, If LABDT less than REF.DATE then (LABDT - REF.DATE). Else if LABDT is greater than equal to REF.DATE then (LABDT- REF.DATE) +1.
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.
STARTDY	num	Relative Medication Start Day		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SASDY	num	SAS Day		If SASDATE and REF.DATE not missing then perform below logic to calculate SASDY, If SASDATE less than REF.DATE then (SASDATE - REF.DATE). Else if SASDATE is greater than equal to REF.DATE then (SASDATE- REF.DATE) +1.
STOPDY	num	Relative Stop Day of AE		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
STARTDY	num	Relative Start Day		If START and REF.DATE not missing then perform below logic to calculate STARTDY, If START less than REF.DATE then (START - REF.DATE). Else if START is greater than equal to REF.DATE then (START- REF.DATE) +1.

1.4.35. Keysae - KEYSAE

Dataset	KEYSAE
Creating program	keysae.sas
Description	Keysae
Unique identifier	DPATNO,ONSETDY,STOPDY,BODYSYS,EVENT_ID
Sorted by	DPATNO,ONSETDY,STOPDY,BODYSYS,EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: VERBATIM,STOPDT,ONSETDT,ADVDESC,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Whoart Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
CONCOM	num	Con Med Given		Collected at CRF.
OUTCOME	num	AE Outcome		Collected at CRF.
EVENT_ID	char	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Drug Delationship		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.
PERIOD	num	Treatment Period		Collected at CRF.
OUTCOMEF	char	AE Outcome		Collected at CRF.
CONCOMF	char	Con Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Drug Delationship		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPF	char	Ae Occured		Collected at CRF.
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
STOPDY	num	Relative AE 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.
ONSETDY	num	Relative AE 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.

1.4.36. Keysae1 - KEYSAE1

Dataset	KEYSAE1
Creating program	keysae1.sas
Description	Keysae1
Unique identifier	DPATNO,ONSETDY,STOPDY,BODYSYS,EVENT_ID
Sorted by	DPATNO,ONSETDY,STOPDY,BODYSYS,EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: VERBATIM,STOPDT,ONSETDT,ADVDESC,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
CONCOM	num	Com Med Given		Collected at CRF.
OUTCOME	num	Outcome of AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
OUTCOMEF	char	Outcome of AE		Collected at CRF.
CONCOMF	char	Com Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPF	char	AE Occured		Collected at CRF.
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.

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

1.4.37. Keysae2 - KAYSAE2

Dataset	KEYSAE2
Creating program	keysae2.sas
Description	Keysae2
Unique identifier	DPATNO,ONSETDY,STOPDY,ADVDESC,EVENT_ID
Sorted by	DPATNO,ONSETDY,STOPDY,ADVDESC,EVENT_ID
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: VERBATIM,STOPDT,ONSETDT,ADVDESC,REGDAY,STOPTIME,TONSET

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
ADVEXP	num	AE Occured		Collected at CRF.
ADVCODE	char	Who Art Code		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious AE		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
CONCOM	num	Com Med Given		Collected at CRF.
OUTCOME	num	Outcome of AE		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGREL	num	Relationship To Study Drug		Collected at CRF.
SEXAE	char	Sex Specific AE		Collected at CRF.
BODYSYS	char	Body System		Collected at CRF.
PREF_TRM	char	Perferred Term		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.
PERIOD	num	Medication Period		Collected at CRF.
OUTCOMEF	char	Outcome of AE		Collected at CRF.
CONCOMF	char	Com Med Given		Collected at CRF.
ACTIONF	char	Action Taken		Collected at CRF.
DRUGRELF	char	Relationship To Study Drug		Collected at CRF.
SEVERITF	char	Severity		Collected at CRF.
SERIOUSF	char	Serious AE		Collected at CRF.
ADVEXPf	char	AE Occured		Collected at CRF.
DURDAY	num	Duration of AE		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
PHASE	num	Study Phase		Collected at CRF.

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

1.4.38. Keyvit1 - KEYVIT1

Dataset	KEYVIT1
Creating program	keyvit1.sas
Description	Keyvit1
Unique identifier	DPATNO,VISITNO,EVDY,VORDER
Sorted by	DPATNO,VISITNO,EVDY,VORDER
Notes	Below listed variables will be dropped from dataset due to repetition of the information: VDATE,EVDATE,DATE,FRSTMED

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Week of Visit		Collected at CRF.
VDATEF	num	Visit Date Flag		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
VISITYPE	num	Visit Type		Collected at CRF.
PHASE	num	Phase		Collected at CRF.
PERIOD	num	Period		Collected at CRF.
VITAL	char	Vital Sign		Collected at CRF.

Variable	Type	Label	Codes	Comments
VALUE	num	Value		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
VORDER	num	Order For Output		Collected at CRF.
BASEFLAG	char	Baseline Flag		Collected at CRF.
ENDPT	char	End Point		Collected at CRF.
COLORDF	char	Format For Sort		Collected at CRF.
CHGBASE	num	Change From Baseline		Collected at CRF.
PCTCHG	num	Percent Change		Collected at CRF.
COLORD	num	Sort Order		Collected at CRF.
STUDYDAY	num	Study Day		Collected at CRF.
REGDAY	num	Day Within Treatment		Collected at CRF.
EVDY	num	Relative Visit Day		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
FRSTMEDY	num	Relative Medication Start Day		If FRSTMED and REF.DATE not missing then perform below logic to calculate FRSTMEDY, If FRSTMED less than REF.DATE then (FRSTMED - REF.DATE). Else if FRSTMED is greater than equal to REF.DATE then (FRSTMED- REF.DATE) +1.

1.4.39. Keyfile_2 - KFILE_2

Dataset	KFILE_2
Creating program	kfile_2.sas
Description	Keyfile_2
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset due to repetition of the information or due to missing values: SEX,SEXF,FER2,FE2,CFER2,CFE2,EFFF,EFF,METAF,META

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
TRTMENT	num	Trtment		Collected at CRF.
TRTMENTF	char	Trtmentf		Collected at CRF.
REGORDER	num	Regorder		Collected at CRF.
TIMEDIAG	num	Time To Diagnosis In Months		Collected at CRF.
PRETRND	num	At Prestudy Was Pat Trans Dependent?		Collected at CRF.
PRETRNDF	char	Decode For Pretrnd (1=No, 2=Yes)		Collected at CRF.
MDIAGNOS	num	Diagnosis of Malignancy		Collected at CRF.
MDIAGNOF	char	Decode For Mdiagnos		Collected at CRF.

Variable	Type	Label	Codes	Comments
EPO2	num	Epo Level At Week=2		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
BEPO	num	Baseline Epo		Collected at CRF.
BWBC	num	Baseline Wbc		Collected at CRF.
BHGB	num	Baseline Hgb		Collected at CRF.
BHCT	num	Baseline Hct		Collected at CRF.
BRCT	num	Baseline Rct		Collected at CRF.
BFER	num	Baseline Ferritin		Collected at CRF.
BFE	num	Baseline Transferrin Sat.		Collected at CRF.
WBC2	num	Wbc At Week 2		Collected at CRF.
HGB2	num	Hgb At Week 2		Collected at CRF.
HCT2	num	Hct At Week 2		Collected at CRF.
RCT2	num	Rct At Week 2		Collected at CRF.
WBC4	num	Wbc At Week 4		Collected at CRF.
HGB4	num	Hgb At Week 4		Collected at CRF.
HCT4	num	Hct At Week 4		Collected at CRF.
RCT4	num	Rct At Week 4		Collected at CRF.
FER4	num	Fer At Week 4		Collected at CRF.
FE4	num	Transferrin Sat. At Week 4		Collected at CRF.
CWBC2	num	Change From Base To Week 2		Collected at CRF.
CHGB2	num	Change From Base To Week 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHCT2	num	Change From Base To Week 2		Collected at CRF.
CRCT2	num	Change From Base To Week 2		Collected at CRF.
CWBC4	num	Change From Base To Week 4		Collected at CRF.
CHGB4	num	Change From Base To Week 4		Collected at CRF.
CHCT4	num	Change From Base To Week 4		Collected at CRF.
CRCT4	num	Change From Base To Week 4		Collected at CRF.
CFER4	num	Change From Base To Week 4		Collected at CRF.
CFE4	num	Change From Base To Week 4		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
BEPOCAT	num	Baseline Epo Category		Collected at CRF.
BEPOCATF	char	Decoding For Bepocat		Collected at CRF.
STUDY	char	Study		Collected at CRF.

1.4.40. Labnorm - LABNORM

Dataset	LABNORM
Creating program	labnorm.sas
Description	Labnorm
Unique identifier	LABCODE,SEX
Sorted by	LABCODE,SEX
Notes	Below listed variables will be dropped from dataset due to repetition of the information or due to missing values: STOPDT

Variable	Type	Label	Codes	Comments
LABCODE	char	Labcode		Collected at CRF.
LOAGE	num	Loage		Collected at CRF.
HIAGE	num	Hiage		Collected at CRF.
LORANGE	num	Lorange		Collected at CRF.
HIRANGE	num	Hirange		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
STARTDT	char	Start Date		Collected at CRF.
LABLOC	num	Labloc		Collected at CRF.
AGEUNIT	char	Ageunit		Collected at CRF.
SEX	char	Sex		Collected at CRF.

1.4.41. Labs - LABS

Dataset	LABS
Creating program	labs.sas
Description	Labs
Unique identifier	DPATNO,LABCODE,LABDY,EVENT_ID
Sorted by	DPATNO,LABCODE,LABDY,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 non significant elements or due to missing values: LABDATE,LABSPEC,COL2,LABDT,SAMPDT,COLLECT,COLLECTF,SAMPTIME,FLAG,FLAGF,LABLOC,UNITCODE,REC_ID

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
LABDATEF	num	Labdatef		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
LABCODE	char	Name of Former Variable		Collected at CRF.
RESULT	num	Result		Collected at CRF.
CRESULT	char	Cresult		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Pag_Name		Collected at CRF.
PHASE	num	Phase		Collected at CRF.
VISITYPE	num	Visit Type		Collected at CRF.
VISITYPF	char	Formatted Visit Type		Collected at CRF.
LABDY	num	Relative Lab Day		If LABDT and REF.DATE not missing then perform below logic to calculate LABDY, If LABDT less than REF.DATE then (LABDT - REF.DATE). Else if LABDT is greater than equal to REF.DATE then (LABDT - REF.DATE) +1.

1.4.42. Labs1 - LABS1

Dataset	LABS1
Creating program	labs1.sas
Description	Labs1
Unique identifier	DPATNO,LABCODE,LABDY,EVENT_ID
Sorted by	DPATNO,LABCODE,LABDY,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: LABDATE,LABDT,SAMPDT,COLLECT,COLLECTF,FLAG,FLAGF,LABLOC,ENDPT,DATE,STARTDT,REC_ID,COLORD,COLORDF

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
LABDATEF	num	Code For Missing Dates		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
LABCODE	char	Lab Code		Collected at CRF.
RESULT	num	Lab Value		Collected at CRF.
CRESULT	char	Character Result Value		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name of Crf		Collected at CRF.
PHASE	num	Phase		Collected at CRF.
VISITYPE	num	Visit Type		Collected at CRF.
VISITYPF	char	Formatted Visit Type		Collected at CRF.
UNITCODE	num	Code For Collected Lab Unit		Collected at CRF.
UNIT	char	Unit For Lab		Collected at CRF.
LABCLASS	char	H, C, Or U		Collected at CRF.
SIVAL	num	Si Value		Collected at CRF.
SIUNIT	char	Si Unit Format		Collected at CRF.
SICODE	num	Code For Si Unit		Collected at CRF.
BASELINE	num	Baseline Value		Collected at CRF.
CHGBASE	num	Change From Baseline		Collected at CRF.
PCTCHG	num	% Change From Baseline		Collected at CRF.
BASEFLAG	char	Baseline Flag		Collected at CRF.
LABORDER	num	Sort Order		Collected at CRF.
SIFMT	char	Sifmt		Collected at CRF.
LABDESC	char	Full Lab Description		Collected at CRF.
LABTST	char	Abbreviated Lab Description		Collected at CRF.
STUDYDAY	num	Day of Treatment		Collected at CRF.

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

1.4.43. Medical History - MEDHIS

Dataset	MEDHIS
Creating program	medhis.sas
Description	Medical History
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INIT,INO,VDATE,VISITNO,EVENT_ID

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VDATEF	num	Vdatef		Collected at CRF.
EYES	num	Eyes		Collected at CRF.
RESP	num	Respiratory		Collected at CRF.
CARD	num	Cardiovascular		Collected at CRF.
GAST	num	Gastrointestinal		Collected at CRF.
GENI	num	Genito-Urinary		Collected at CRF.

Variable	Type	Label	Codes	Comments
MUSC	num	Musculoskeleton		Collected at CRF.
NEUR	num	Neurologic		Collected at CRF.
ENDO	num	Endocrine & Metabolic		Collected at CRF.
HEMA	num	Hematopoietic/Lymphatic		Collected at CRF.
DERM	num	Dermatologic		Collected at CRF.
PSYCH	num	Psychological		Collected at CRF.
VDY	num	Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE - REF.DATE) + 1.

1.4.44. Normalsi - NORMALSI

Dataset	NORMALSI
Creating program	normalsi.sas
Description	Normalsi
Unique identifier	SEX,VARNAM,OBSNO,LR
Sorted by	SEX,VARNAM,OBSNO,LR
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: INO,AGE_L,VISITNO,EVENT_ID

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
SEX	num	Sex		Collected at CRF.
VARNAM	char	Varnam		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.

1.4.45. Otherlab - OTHERLAB

Dataset	OTHERLAB
Creating program	otherlab.sas
Description	Otherlab
Unique identifier	DPATNO,VISITNO,LABDY,LABCODE
Sorted by	DPATNO,VISITNO,LABDY,LABCODE
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: LABDATE,LABSPEC,CRESULT,LABDT,SAMPDT,COLLECT,COLLECTF,SAMPTIME,FLAG,FLAGF,UNITCODE,REC_ID

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
LABDATEF	num	Labdatef		Collected at CRF.
RESULT	num	Result		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
LABCODE	char	Labcode		Collected at CRF.
U319	char	U319		Collected at CRF.

Variable	Type	Label	Codes	Comments
U303	num	U303		Collected at CRF.
U304	num	U304		Collected at CRF.
LABDESC	char	Labdesc		Collected at CRF.
PAG_NAME	char	Pag_Name		Collected at CRF.
PHASE	num	Phase		Collected at CRF.
VISITYPE	num	Visit Type		Collected at CRF.
VISITYPF	char	Formatted Visit Type		Collected at CRF.
LABLOC	num	Labloc		Collected at CRF.
LABDY	num	Relative Lab Day		If LABDT and REF.DATE not missing then perform below logic to calculate LABDY, If LABDT less than REF.DATE then (LABDT - REF.DATE). Else if LABDT is greater than equal to REF.DATE then (LABDT-REF.DATE) +1.
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.

1.4.46. Performance Score - PERFOR

Dataset	PERFOR
Creating program	perfor.sas
Description	Performance Score
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT,INO,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
PERFOR	num	Perfor		Collected at CRF.
PHYSI	char	Physi		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event_Id		Collected at CRF.
VDY	num	Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.47. Initial Physical Examination - PHYSEX

Dataset	PHYSEX
Creating program	physex.sas
Description	Initial Physical Examination
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT,INO,VDATE,OTHERC

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity

Variable	Type	Label	Codes	Comments
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
HEAD	num	Head		Collected at CRF.
EARS	num	Ears		Collected at CRF.
EYES	num	Eyes		Collected at CRF.
CHEST	num	Chest		Collected at CRF.
LUNGS	num	Lungs		Collected at CRF.
HEART	num	Heart		Collected at CRF.
LYMPH	num	Lymph		Collected at CRF.
ABDOMEN	num	Abdomen		Collected at CRF.
ANORE	num	Anore		Collected at CRF.
GENIT	num	Genit		Collected at CRF.
SKIN	num	Skin		Collected at CRF.
MUSC	num	Musc		Collected at CRF.
NEURO	num	Neuro		Collected at CRF.
OTHER	num	Other		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Event_Id		Collected at CRF.
VDY	num	Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.48. Initial Blood Pressure, Ht., Wt. - PPVI

Dataset	PPVI
Creating program	ppvi.sas
Description	Initial Blood Pressure, Ht., Wt.
Unique identifier	DPATNO,VISITNO,WEEK,VDY,OBSNO
Sorted by	DPATNO,VISITNO,WEEK,VDY,OBSNO
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: INIT,INO,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity

Variable	Type	Label	Codes	Comments
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
SBP	num	Sbp		Collected at CRF.
DBP	num	Dbp		Collected at CRF.
HEIGHT	num	Height		Collected at CRF.
WEIGHT	num	Weight		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
VDY	num	Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.49. Profdose - PROFDOSE

Dataset	PROFDOSE
Creating program	profdose.sas
Description	Profdose
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: EPO,DATE,STARTDT,STOPDT,MEDSTRTM,MEDSTPTM,RTITLE2,RTITLE3,REGIMEN,INO,COUNTRY,VDATE,BIRTHDT,SEX,RACE,RACESPEC,DTERM,STATUSDT,DEATHDT,LEPODT,DBENDDT,DIAGDT,LCHEMDT,SEXF,COUNTRYF,CNTRY,RACEF,AGE,INVNAME,SURN,FORE,OTHRSPEC,AGEUNIT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
PERIOD	num	Period For Initiation of Study Med		Collected at CRF.
SEQUENCE	num	Treatment Sequence		Collected at CRF.
XORDER	num	Cross-Over Order		Collected at CRF.
RTITLE1	char	First Regimen Title		Collected at CRF.
THRPYDAY	num	Total Days On Therapy		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRESP	num	Patient's Response To Chemotherapy		Collected at CRF.
STATUS	num	Completion Status		Collected at CRF.
DEATH	num	Death		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.
BASEWGT	num	Baseline Weight		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
CHEMOTYP	num	Type of Chemotherapy		Collected at CRF.
CHEMOTYF	char	Decode For Chemotyp		Collected at CRF.
DIAGF	num	Flag For Diagdt		Collected at CRF.
MDIAGNOS	num	Diagnosis of Malignancy		Collected at CRF.
PERFPRE	num	Performance Score At Prestudy		Collected at CRF.
PERFTERM	num	Performance Score At Termination		Collected at CRF.
PHYSDB	char	Physician'S Global Assess. At Wk 12		Collected at CRF.
PHYSOL	char	Physician'S Global Assess. At Wk 24		Collected at CRF.
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.
PRECHEMO	num	Did Pat Have Chemo In Past 3 Mon		Collected at CRF.
CYCLES	num	# of Chemo Cycles In Past 6 Mon		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
REASONF	char	Discontinuation Reason		Collected at CRF.
PHYSDBF	char	Decode For Physdb		Collected at CRF.
PHYSOLF	char	Decode For Physol		Collected at CRF.
STATUSF	char	Completion Status		Collected at CRF.
CRESPF	char	Decode For Cresp		Collected at CRF.
MDIAGNOF	char	Decode For Mdiagnos		Collected at CRF.
OLF	char	Decode For Ol		Collected at CRF.
CHEMOYNF	char	Decode For Chemoy (1=No, 2=Yes)		Collected at CRF.
PRECHEMF	char	Decode For Prechemo (1=No, 2=Yes)		Collected at CRF.
DIAGDTF	char	Flag For Missing Parts of Dates		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
TIMEDIAG	num	Time To Diagnosis In Months		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTDY	num	Relative Medication Start Day		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	Relative Medication Stop Day		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
VDY	num	Relative Visit Day In Demo Dataset		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.
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.
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
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.
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.

1.4.50. Profeval - PROFEVAL

Dataset	PROFEVAL
Creating program	profeval.sas
Description	Profeval
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INO, INVNAME, COUNTRY, VDATE, BIRTHDT, SEX, RACE, RACESPEC, EPO, DTERM, STATUSDT, DEATHDT, LEPODT, DATE, STARTDT, DBENDDT, DIAGDT, LCHEMDT, SEXF, COUNTRYF, CNTRY, RACEF, AGE, SURN, FORE, OTHRSPEC, AGEUNIT

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
EFFC	num	Is Patient Evaluable For Efficacy Analys		Collected at CRF.
ITT	num	Is Patient Evaluable Fot Itt Analysis		Collected at CRF.
TUMORTYP	num	Tumor Type		Collected at CRF.
TUMORTYF	char	Decode For Ttype		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAF	num	Is Patient Evaluable For Safety Analysis		Collected at CRF.
EFF	num	Is Patient Evaluable For Efficacy Analys		Collected at CRF.
EFFF	char	Decode For Eff (1=No, 2=Yes)		Collected at CRF.
EFFCF	char	Decode For Eff (1=No, 2=Yes)		Collected at CRF.
ITTF	char	Decode For Itt (1=No, 2=Yes)		Collected at CRF.
SAFF	char	Decode For Saf (1=No, 2=Yes)		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
CRISP	num	Patient's Response To Chemotherapy		Collected at CRF.
STATUS	num	Completion Status		Collected at CRF.
DEATH	num	Death		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.
BASEWGT	num	Baseline Weight		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
CHEMOTYP	num	Type of Chemotherapy		Collected at CRF.
CHEMOTYF	char	Decode For Chemotyp		Collected at CRF.
DIAGF	num	Flag For Diagdt		Collected at CRF.
MDIAGNOS	num	Diagnosis of Malignancy		Collected at CRF.
PERFPRE	num	Performance Score At Prestudy		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERFTERM	num	Performance Score At Termination		Collected at CRF.
PHYSDB	char	Physician'S Global Assess. At Wk 12		Collected at CRF.
PHYSOL	char	Physician'S Global Assess. At Wk 24		Collected at CRF.
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.
PRECHEMO	num	Did Pat Have Chemo In Past 3 Mon		Collected at CRF.
CYCLES	num	# of Chemo Cycles In Past 6 Mon		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
REASONF	char	Discontinuation Reason		Collected at CRF.
PHYSDBF	char	Decode For Physdb		Collected at CRF.
PHYSOLF	char	Decode For Physol		Collected at CRF.
STATUSF	char	Completion Status		Collected at CRF.
CRESPF	char	Decode For Cresp		Collected at CRF.
MDIAGNOF	char	Decode For Mdiagnos		Collected at CRF.
OLF	char	Decode For Ol		Collected at CRF.
CHEMOYNF	char	Decode For Chemoyrn (1=No, 2=Yes)		Collected at CRF.
PRECHEMF	char	Decode For Prechemo (1=No, 2=Yes)		Collected at CRF.
DIAGDTF	char	Flag For Missing Parts of Dates		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
TIMEDIAG	num	Time To Diagnosis In Months		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.
VDY	num	Relative Visit Day In Demo Dataset		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.
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.
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.
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.

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

1.4.51. Profex - PROFEX

Dataset	PROFEX
Creating program	profex.sas
Description	Profex
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INO,COUNTRY,VDATE,BIRTHDT,SEX,RACE,RACESPEC,EPO,DTERM,STATUSDT,DEATHDT,LEPODT,DATE,STARTDT,DBENDDT,DIAGDT,LCHEMDT,SEXF,COUNTRYF,CNTRY,RACEF,AGE,INVNAME,SURN,FORE,OTHRSPEC,AGEUNIT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
CRESP	num	Patient's Response To Chemotherapy		Collected at CRF.
STATUS	num	Completion Status		Collected at CRF.
DEATH	num	Death		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASEWGT	num	Baseline Weight		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
CHEMOTYP	num	Type of Chemotherapy		Collected at CRF.
CHEMOTYF	char	Decode For Chemotyp		Collected at CRF.
DIAGF	num	Flag For Diagdt		Collected at CRF.
MDIAGNOS	num	Diagnosis of Malignancy		Collected at CRF.
PERFPRE	num	Performance Score At Prestudy		Collected at CRF.
PERFTERM	num	Performance Score At Termination		Collected at CRF.
PHYSDB	char	Physician'S Global Assess. At Wk 12		Collected at CRF.
PHYSOL	char	Physician'S Global Assess. At Wk 24		Collected at CRF.
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.
PRECHEMO	num	Did Pat Have Chemo In Past 3 Mon		Collected at CRF.
CYCLES	num	# of Chemo Cycles In Past 6 Mon		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
REASONF	char	Discontinuation Reason		Collected at CRF.
PHYSDBF	char	Decode For Physdb		Collected at CRF.
PHYSOLF	char	Decode For Physol		Collected at CRF.

Variable	Type	Label	Codes	Comments
STATUSF	char	Completion Status		Collected at CRF.
CRESPF	char	Decode For Cresp		Collected at CRF.
MDIAGNOF	char	Decode For Mdiagnos		Collected at CRF.
OLF	char	Decode For Ol		Collected at CRF.
CHEMOYNF	char	Decode For Chemoy (1=No, 2=Yes)		Collected at CRF.
PRECHEMF	char	Decode For Prechemo (1=No, 2=Yes)		Collected at CRF.
DIAGDTF	char	Flag For Missing Parts of Dates		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
TIMEDIAG	num	Time To Diagnosis In Months		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.
VDY	num	Relative Visit Day In Demo Dataset		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.
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.

Variable	Type	Label	Codes	Comments
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.
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.
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.

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.

1.4.52. Profile - PROFILE

Dataset	PROFILE
Creating program	profile.sas
Description	Profile
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INO,COUNTRY,VDATE,BIRTHDT,SEX,RACE,RACESPEC,EPO,DTERM,STATUSDT,DEATHDT,LEPODT,DATE,STARTDT,DBENDDT,DIAGDT,LCHEMDT,SEXF,COUNTRYF,INVNAME,SURN,FORE,OTHRSPEC

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
CRESP	num	Patient's Response To Chemotherapy		Collected at CRF.
STATUS	num	Completion Status		Collected at CRF.
DEATH	num	Death		Collected at CRF.
REASON	num	Discontinuation Reason		Collected at CRF.
BASEHGT	num	Baseline Height		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASEWGT	num	Baseline Weight		Collected at CRF.
OL	num	Was Patient In Open-Label Study		Collected at CRF.
CHEMOTYP	num	Type of Chemotherapy		Collected at CRF.
CHEMOTYF	char	Decode For Chemotyp		Collected at CRF.
DIAGF	num	Flag For Diagdt		Collected at CRF.
MDIAGNOS	num	Diagnosis of Malignancy		Collected at CRF.
PERFPRE	num	Performance Score At Prestudy		Collected at CRF.
PERFTERM	num	Performance Score At Termination		Collected at CRF.
PHYSDB	char	Physician'S Global Assess. At Wk 12		Collected at CRF.
PHYSOL	char	Physician'S Global Assess. At Wk 24		Collected at CRF.
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.
PRECHEMO	num	Did Pat Have Chemo In Past 3 Mon		Collected at CRF.
CYCLES	num	# of Chemo Cycles In Past 6 Mon		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
TRTMENTF	char	Treatment		Collected at CRF.
REASONF	char	Discontinuation Reason		Collected at CRF.
PHYSDBF	char	Decode For Physdb		Collected at CRF.
PHYSOLF	char	Decode For Physol		Collected at CRF.

Variable	Type	Label	Codes	Comments
STATUSF	char	Completion Status		Collected at CRF.
CRESPF	char	Decode For Cresp		Collected at CRF.
MDIAGNOF	char	Decode For Mdiagnos		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
RACEF	char	Race		Collected at CRF.
OLF	char	Decode For Ol		Collected at CRF.
CHEMOYNF	char	Decode For Chemoy (1=No, 2=Yes)		Collected at CRF.
PRECHEMF	char	Decode For Prechemo (1=No, 2=Yes)		Collected at CRF.
DIAGDTF	char	Flag For Missing Parts of Dates		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		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.
TIMEDIAG	num	Time To Diagnosis In Months		Collected at CRF.
AGEUNIT	char	Unit For Age		Collected at CRF.
TRTMENT	num	Treatment Code		Collected at CRF.
VDY	num	Relative Visit Day In Demo Dataset		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

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.
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.
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.
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.

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.

1.4.53. Protocol - PROTOCOL

Dataset	PROTOCOL
Creating program	protocol.sas
Description	Protocol
Unique identifier	PROTOCOL
Sorted by	PROTOCOL
Notes	Below listed variables will be dropped from dataset due to non significant elements: TITLE1,TITLE2

Variable	Type	Label	Codes	Comments
AGEUNIT	char	Unit For Age		Collected at CRF.

Variable	Type	Label	Codes	Comments
BLINDED	char	Blinded		Collected at CRF.
CROSOVER	char	Crossover		Collected at CRF.
PROTOCOL	char	Protocol		Collected at CRF.
STDYTYPE	char	Stdytype		Collected at CRF.
FINALDB	num	Finaldb		Collected at CRF.
FIRSTDB	num	Firstdb		Collected at CRF.
TOTREGI	num	Totregi		Collected at CRF.
EVENTUNT	char	Eventunt		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
PROJECT	num	Project		Collected at CRF.
AVAILABL	char	Availabl		Collected at CRF.

1.4.54. Pvalue - PVALUE

Dataset	PVALUE
Creating program	pvalue.sas
Description	Pvalue
Unique identifier	PVAL
Sorted by	PVAL
Notes	

Variable	Type	Label	Codes	Comments
PVAL	num	Pr>Chi		Collected at CRF.

1.4.55. EORTC QLQ-C30 - QLQC30

Dataset	QLQC30
Creating program	qlqc30.sas
Description	EORTCQLQ-C30
Unique identifier	DPATNO,VISITNO,VDY,OBSNO
Sorted by	DPATNO,VISITNO,VDY,OBSNO
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: INIT,INO,BIRTH,BIRTHF,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
Q1	num	Q1		Collected at CRF.
Q2	num	Q2		Collected at CRF.
Q3	num	Q3		Collected at CRF.
Q4	num	Q4		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q5	num	Q5		Collected at CRF.
Q6	num	Q6		Collected at CRF.
Q7	num	Q7		Collected at CRF.
Q8	num	Q8		Collected at CRF.
Q9	num	Q9		Collected at CRF.
Q10	num	Q10		Collected at CRF.
Q11	num	Q11		Collected at CRF.
Q12	num	Q12		Collected at CRF.
Q13	num	Q13		Collected at CRF.
Q14	num	Q14		Collected at CRF.
Q15	num	Q15		Collected at CRF.
Q16	num	Q16		Collected at CRF.
Q17	num	Q17		Collected at CRF.
Q18	num	Q18		Collected at CRF.
Q19	num	Q19		Collected at CRF.
Q20	num	Q20		Collected at CRF.
Q21	num	Q21		Collected at CRF.
Q22	num	Q22		Collected at CRF.
Q23	num	Q23		Collected at CRF.
Q24	num	Q24		Collected at CRF.
Q25	num	Q25		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q26	num	Q26		Collected at CRF.
Q27	num	Q27		Collected at CRF.
Q28	num	Q28		Collected at CRF.
Q29	num	Q29		Collected at CRF.
Q30	num	Q30		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
VDY	num	Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE - REF.DATE) +1.

1.4.56. Regi - REGI

Dataset	REGI
Creating program	regi.sas
Description	Regi
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Regorder		Collected at CRF.
REGDESC	char	Regdesc		Collected at CRF.
TRTMENTF	char	Trtmentf		Collected at CRF.

1.4.57. Smedai3 - SMEDAI3

Dataset	SMEDAI3
Creating program	smedai3.sas
Description	Smedai3
Unique identifier	DPATNO,VISITNO,WEEK,DBENDDY,SMEDDY,DOSENO
Sorted by	DPATNO,VISITNO,WEEK,DBENDDY,SMEDDY,DOSENO
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: SDATE,DBENDDT,INVNAME,SMEDDT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
DOSENO	num	Dose Number Within Week (1,2,3)		Collected at CRF.
WEIGHT	num	Weight (Kg)		Collected at CRF.
DOSE	num	Dose Given (U/Kg)		Collected at CRF.
UNIT	num	Unit Measure		Collected at CRF.
ML	num	Mls Dispensed		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
DDOSE	num	Derived Dose (U/Kg)		Collected at CRF.
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.
SMEDDY	num	Relative Day of Med Administration		If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT- REF.DATE) +1.

1.4.58. Smedbi3 - SMEDBI3

Dataset	SMEDBI3
Creating program	smedbi3.sas
Description	Smedbi3
Unique identifier	DPATNO,WEEK
Sorted by	DPATNO,WEEK
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVNAME

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
WEEK	num	Study Week		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
DOUBLE	num	Was Patient's Dose Doubled		Collected at CRF.
WITHHELD	num	Was Patient's Dose Withheld		Collected at CRF.
CHANGE	num	Was There A Change In Dosing		Collected at CRF.
TOTDOSE	num	Total Weely Dose		Collected at CRF.
DOUBLEF	char	Decode of Double (1=No, 2=Yes)		Collected at CRF.

Variable	Type	Label	Codes	Comments
WITHHLDF	char	Decode of Withheld (1=No, 2=Yes)		Collected at CRF.
CHANGEF	char	Decode of Change (1=No, 2=Yes)		Collected at CRF.

1.4.59. Smedci3 - SMEDCI3

Dataset	SMEDCI3
Creating program	smedci3.sas
Description	Smedci3
Unique identifier	DPATNO,WEEK
Sorted by	DPATNO,WEEK
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: INVNAME,STARTDT

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
WEEK	num	Study Week		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
WEEKDOUB	num	Weekdoub		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSENODB	num	Dosenodb		Collected at CRF.
DTDOUB	num	Dtdoub		Collected at CRF.
DOSENOHD	num	Dosenohd		Collected at CRF.
WEEKHELD	num	Weekheld		Collected at CRF.
DOUBLE	num	Was Patient's Dose Doubled		Collected at CRF.
WITHHELD	num	Was Patient's Dose Withheld		Collected at CRF.
DAYDOUB	num	Daydoub		Collected at CRF.
CHANGE	num	Was There A Change In Dosing		Collected at CRF.
TOTDOSE	num	Total Weely Dose		Collected at CRF.
DOUBLEF	char	Decode of Double (1=No, 2=Yes)		Collected at CRF.
WITHHLDF	char	Decode of Withheld (1=No, 2=Yes)		Collected at CRF.
CHANGEF	char	Decode of Change (1=No, 2=Yes)		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.

1.4.60. Smedci3b - SMEDCI3B

Dataset	SMEDCI3B
Creating program	smedci3b.sas
Description	Smedci3b
Unique identifier	DPATNO,WEEK
Sorted by	DPATNO,WEEK
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: INVNAME,DOSENOHD,STARTDT

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
WEEK	num	Study Week		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
WEEKDOUB	num	Weekdoub		Collected at CRF.
DOSENODB	num	Dosenodb		Collected at CRF.
DTDOUB	num	Dtdoub		Collected at CRF.
WEEKHELD	num	Weekheld		Collected at CRF.
DOUBLE	num	Was Patient's Dose Doubled		Collected at CRF.

Variable	Type	Label	Codes	Comments
WITHHELD	num	Was Patient's Dose Withheld		Collected at CRF.
CHANGE	num	Was There A Change In Dosing		Collected at CRF.
TOTDOSE	num	Total Weely Dose		Collected at CRF.
DOUBLEF	char	Decode of Double (1=No, 2=Yes)		Collected at CRF.
WITHHLDF	char	Decode of Withheld (1=No, 2=Yes)		Collected at CRF.
CHANGEF	char	Decode of Change (1=No, 2=Yes)		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.

1.4.61. Surgery - SURGERY

Dataset	SURGERY
Creating program	surgery.sas
Description	Surgery
Unique identifier	DPATNO,DY,PROCE
Sorted by	DPATNO,DY,PROCE
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: INIT,INO,DATE,VISITNO,EVENT_ID

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
SURG	num	Surg		Collected at CRF.
DATEF	num	Datef		Collected at CRF.
PROCE	char	Proce		Collected at CRF.
FINDINGS	char	Findings		Collected at CRF.

Variable	Type	Label	Codes	Comments
DISEASE	char	Disease		Collected at CRF.
DY	num	Relative Medication Start Day		If DATE and REF.DATE not missing then perform below logic to calculate DY, 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.

1.4.62. Respose to Chemotherapy - TERM

Dataset	TERM
Creating program	term.sas
Description	Respose to Chemotherapy
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INIT,INO,CHEMO,VDATE,EPO,DTERM,DDATE,VISITNO,EVENT_ID

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
CHEMOF	num	Chemof		Collected at CRF.
RESPO	num	Respo		Collected at CRF.
VDATEF	num	Vdatef		Collected at CRF.
EPOF	num	Epof		Collected at CRF.
TERM	num	Term		Collected at CRF.
DTERMF	num	Dtermf		Collected at CRF.
REASON	num	Reason		Collected at CRF.
DIED	num	Died		Collected at CRF.
DDATEF	num	Ddatef		Collected at CRF.
AUTOPSY	num	Autopsy		Collected at CRF.
CHEMODY	num	Relative Chemo Day		If CHEMO and REF.DATE not missing then perform below logic to calculate CHEMODY, If CHEMO less than REF.DATE then (CHEMO - REF.DATE). Else if CHEMO is greater than equal to REF.DATE then (CHEMO- REF.DATE) +1.
VDY	num	Visit Day		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
EPODY	num	Epo Day		If EPO and REF.DATE not missing then perform below logic to calculate EPODY, 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.
TERMDY	num	Term Day		If DTERM and REF.DATE not missing then perform below logic to calculate TERMDY, 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.
DDY	num	D Date		If DDATE and REF.DATE not missing then perform below logic to calculate DDY, 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.

1.4.63. Tranai3 - TRANAI3

Dataset	TRANAI3
Creating program	tranai3.sas
Description	Tranai3
Unique identifier	DPATNO,VISITNO,BTYPE,HGB
Sorted by	DPATNO,VISITNO,BTYPE,HGB
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: BCODE,BBDATE,BDATE,DATE,STARTDT,DBENDDT,INVNAME

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
REQUIRE	num	Has Patient Required Any Transfusions		Collected at CRF.
BTYPE	char	Type of Blood Product Transfused		Collected at CRF.
UNIT	num	Units Given		Collected at CRF.
ML	num	Mls Given		Collected at CRF.
HGB	num	Hemoglobin Value		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRANREL	num	Are Hgbs Related To Trans. Within 14 Day		Collected at CRF.
HBTRIG	num	Hgb Recorded Immed.Prior Transfusion		Collected at CRF.
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
REQUIREF	char	Decode For Require (1=No, 2=Yes)		Collected at CRF.
TRANRELF	char	Decode For Tranrel (1=No, 2=Yes)		Collected at CRF.
BDY	num	Relative Blood Transfusion Day		If BDATE and REF.DATE not missing then perform below logic to calculate BDY, If BDATE less than REF.DATE then (BDATE - REF.DATE). Else if BDATE is greater than equal to REF.DATE then (BDATE-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.

1.4.64. Tranbi3 - TRANBI3

Dataset	TRANBI3
Creating program	tranbi3.sas
Description	Tranbi3
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
TRANSOL	num	Was Pat Trans During Open-Label		Collected at CRF.
PRETRND	num	Was Pat Trans Dependent At Prestudy		Collected at CRF.
UNITSM0	num	Sum of Units Transfused Prestudy		Collected at CRF.
TRANSM1	num	Was Pat Trans During Month 1		Collected at CRF.
UNITSM1	num	Sum of Units Trans During Month 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRANSM2	num	Was Pat Trans During Month 2 Or 3		Collected at CRF.
UNITSM2	num	Sum of Units Trans During Mon 2 And 3		Collected at CRF.
UNITSOL	num	Sum of Units Trans During Open-Label		Collected at CRF.
TRANSDB	num	Was Pat Trans During Db Phase		Collected at CRF.
DAYSM1	num	# of Days On Study During Month 1		Collected at CRF.
DAYSM2	num	# of Days On Study During Month 2 And 3		Collected at CRF.
CUMTRNM2	num	Cumul. Trans. Rate During Mon 2 And 3		Collected at CRF.
HBTRIG0	num	Pre-Study Pre-Transusion Hgb		Collected at CRF.
HBTRIG1	num	During Db Pre-Transusion Hgb		Collected at CRF.
TRANSDBF	char	Decode For Transdb (1=No, 2=Yes)		Collected at CRF.
PRETRNDF	char	Decode For Pretrnd (1=No, 2=Yes)		Collected at CRF.
TRANSOLF	char	Decode For Transol (1=No, 2=Yes)		Collected at CRF.
TRANSM1F	char	Decode For Transm1 (1=No, 2=Yes)		Collected at CRF.
TRANSM2F	char	Decode For Transm2 (1=No, 2=Yes)		Collected at CRF.
TRANM2P	num	Transm2=Yes Or Study Days <=28		Collected at CRF.
TRANM2PF	char	Decode For Transm2P (1=No, 2=Yes)		Collected at CRF.

1.4.65. Tranci3 - TRANCI3

Dataset	TRANCI3
Creating program	tranci3.sas
Description	Tranci3
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset due to repetition of the information: DATE56,DATE28

Variable	Type	Label	Codes	Comments
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for De-Identity
REGORDER	num	Order of Regimens		Collected at CRF.
REGDESC	char	Treatment		Collected at CRF.
COMPDAYS	num	Number of Days To Study Completion		Collected at CRF.
TRANSOL	num	Was Pat Trans During Open-Label		Collected at CRF.
PRETRND	num	Was Pat Trans Dependent At Prestudy		Collected at CRF.
UNITSMO	num	Sum of Units Transfused Prestudy		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRANSM1	num	Was Pat Trans During Month 1		Collected at CRF.
UNITSM1	num	Sum of Units Trans During Month 1		Collected at CRF.
TRANSM2	num	Was Pat Trans During Month 2 Or 3		Collected at CRF.
UNITSM2	num	Sum of Units Trans During Mon 2 And 3		Collected at CRF.
TRANSM3	num	Was Pat Trans During Month 3		Collected at CRF.
UNITSM3	num	Unitsm3		Collected at CRF.
UNITSQL	num	Sum of Units Trans During Open-Label		Collected at CRF.
TRANSDB	num	Was Pat Trans During Db Phase		Collected at CRF.
DAYSM1	num	# of Days On Study During Month 1		Collected at CRF.
DAYSM2	num	# of Days On Study During Month 2 And 3		Collected at CRF.
CUMTRNM2	num	Cumul. Trans. Rate During Mon 2 And 3		Collected at CRF.
HBTRIG0	num	Pre-Study Pre-Transusion Hgb		Collected at CRF.
HBTRIG1	num	During Db Pre-Transusion Hgb		Collected at CRF.
TRANSDBF	char	Decode For Transdb (1=No, 2=Yes)		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRETRNDF	char	Decode For Pretrnd (1=No, 2=Yes)		Collected at CRF.
TRANSOLF	char	Decode For Transol (1=No, 2=Yes)		Collected at CRF.
TRANSM1F	char	Decode For Transm1 (1=No, 2=Yes)		Collected at CRF.
TRANSM2F	char	Decode For Transm2 (1=No, 2=Yes)		Collected at CRF.
TRANSM3F	char	Decode For Transm3 (1=No, 2=Yes)		Collected at CRF.
TRANM2P	num	Transm2=Yes Or Study Days <=28		Collected at CRF.
TRANM2PF	char	Decode For Transm2P (1=No, 2=Yes)		Collected at CRF.
_56DY	num	Relative Day of 2 Months After Stdy Day		If DATE56 and REF.DATE not missing then perform below logic to calculate _56DY, If DATE56 less than REF.DATE then (DATE56 - REF.DATE). Else if DATE56 is greater than equal to REF.DATE then (DATE56-REF.DATE) +1.
_28DY	num	Relative Day of 1 Month After Study Day		If DATE28 and REF.DATE not missing then perform below logic to calculate _28DY, If DATE28 less than REF.DATE then (DATE28 - REF.DATE). Else if DATE28 is greater than equal to REF.DATE then (DATE28-REF.DATE) +1.

1.4.66. Transfusion Information - TRANS_SI

Dataset	TRANS_SI
Creating program	trans_si.sas
Description	Transfusion Information
Unique identifier	DPATNO,VISITNO,OBSNO
Sorted by	DPATNO,VISITNO,OBSNO
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: INIT,INO,CODE,DATE

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
TRANS	num	Trans		Collected at CRF.
TYPE	char	Type		Collected at CRF.
DATEF	num	Datef		Collected at CRF.
UNIT	num	Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
MLS	num	Mls		Collected at CRF.
H103	num	H103		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.
DY	num	Relative Medication Start Day		If DATE and REF.DATE not missing then perform below logic to calculate DY, 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.

1.4.67. Tve - TVE

Dataset	TVE
Creating program	tve.sas
Description	Tve
Unique identifier	BODYSYS,PREF_TRM,TVENO,ADVCODE
Sorted by	BODYSYS,PREF_TRM,TVENO,ADVCODE
Notes	Below listed variables will be dropped from dataset due to non significant elements: ADVDESC

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

1.4.68. Urinalysis (Test Tape) - URIN_SI

Dataset	URIN_SI
Creating program	urin_si.sas
Description	Urinalysis (Test Tape)
Unique identifier	DPATNO,VISITNO
Sorted by	DPATNO,VISITNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INO

Variable	Type	Label	Codes	Comments
OBSNO	num	Obsno		Collected at CRF.
STUDY	char	Study		Collected at CRF.
DPATNO	num	Patient Number Assigned for De-Identity		Randomly assigned Patient Number for de-identity
VISITNO	num	Visit Number		Collected at CRF.
WEEK	num	Study Week		Collected at CRF.
URIN	num	Urin		Collected at CRF.
URINF	num	Urinf		Collected at CRF.
U307	char	U307		Collected at CRF.
U348	char	U348		Collected at CRF.

Variable	Type	Label	Codes	Comments
U306	char	U306		Collected at CRF.
U309	char	U309		Collected at CRF.
U316	char	U316		Collected at CRF.
U315	char	U315		Collected at CRF.
U320	char	U320		Collected at CRF.
U314	char	U314		Collected at CRF.
CU319	char	Cu319		Collected at CRF.
U319	char	U319		Collected at CRF.
U303	num	U303		Collected at CRF.
U304	num	U304		Collected at CRF.
EVENT_ID	char	Event_Id		Collected at CRF.