

Clinical Development

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PR98-15-014

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

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's Relative day cannot be calculated.
- Reference number will not be provided.
- Reference Start Date (RFSTDT) will be used as Reference Date to derive relative days.

1.3. Data Files

The PR98-15-014 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. EPO 2 Derived Demographics (DM) – KDEMOG

Dataset	KDEMOG
Creating program	kdemog.sas
Description	EPO 2 Derived Demographics (DM)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
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:</p> <p>RFENDT, RFSTDT, APACHEDT, BIRTHDT, DMACTDT, DMINFDT, DMSCRDT, ADACTDT, DMINFTM, MALYEAR, TVESPEC, EXCLOTH, CONSOTH, EXCLCODE, COUNTRYC, MALTYPE, MALDESC, CONSRSN, SUBJINIT, IVNAME, SITENAME, IVID</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
AGEUNIT	char	Age Unit		Collected at CRF.
HEIGHTCM	num	Baseline Height (Centimeters)		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAFETY	char	Evaluable for Safety		Collected at CRF.
WEIGHTKG	num	Baseline Weight (Kilograms)		Collected at CRF.
PROSPC	num	Prospective Code		Collected at CRF.
RETROC	num	Retrospective Code		Collected at CRF.
PROSP	char	Data Collected Prospectively		Collected at CRF.
RETRO	char	Data Collected Retrospectively		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
APACHE	num	Total APACHE II Scores		Collected at CRF.
DIAGNOSC	num	Type of Admission Code		Collected at CRF.
SEXC	num	Sex Code		Collected at CRF.
RACEC	num	Race Code		Collected at CRF.
ETHNICC	num	Hispanic Ethnicity Code		Collected at CRF.
TVEHISTC	num	History of TVE Code		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
DIAG1	num	Post Operative		Collected at CRF.
DIAG2	num	Trauma		Collected at CRF.
DIAG3	num	Neurological		Collected at CRF.
DIAG4	num	Cardiovascular		Collected at CRF.
DIAG5	num	Other Respiratory		Collected at CRF.
DIAG6	num	Pneumonia		Collected at CRF.
DIAG7	num	ARDS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DIAG8	num	SIRS		Collected at CRF.
DIAG9	num	Sepsis		Collected at CRF.
DIAG10	num	Primary Hematologic Disease		Collected at CRF.
DIAG11	num	Other Non-surgical		Collected at CRF.
DVTC	num	Deep Vein Thrombosis - code		Collected at CRF.
PEC	num	Pulmonary Embolus - code		Collected at CRF.
CVIC	num	Cerebral Vascular Incident - code		Collected at CRF.
OTHTVEC	num	Other TVE code		Collected at CRF.
ANYEXLC	num	Any Section B Diagnostic excl? code		Collected at CRF.
ANYEXL2C	num	Any Section C Other excl? code		Collected at CRF.
ANYEXL3C	num	Any Section G Checklist yes? code		Collected at CRF.
CONSENTC	num	consent signed - code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DRUGID	char	Compound Name		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
CONSR SNC	char	Other Reason Consent Not Obtained - code		Collected at CRF.
HCGDRAW	char	HCG Drawn		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGEGRP	char	Age Group (Years)		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
ANYEXL	char	Any Section B Diagnostic excl? - decode		Collected at CRF.
ANYEXL2	char	Any Section C Other excl? - decode		Collected at CRF.
ANYEXL3	char	Any Section G Checklist yes? - decode		Collected at CRF.
CONSENT	char	Was Informed Consent Obtained?		Collected at CRF.
DIAGNOS	char	Type of Admission		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
ETHNIC	char	Hispanic Ethnicity		Collected at CRF.
RACESPEC	char	Race Other		Collected at CRF.
DVT	char	Deep Vein Thrombosis - decode		Collected at CRF.
PE	char	Pulmonary Embolus - decode		Collected at CRF.
CVI	char	Cerebral Vascular Incident - decode		Collected at CRF.
OTHTVE	char	Other TVE - decode		Collected at CRF.

Variable	Type	Label	Codes	Comments
TVEHIST	char	History of TVE		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
APAPS	num	APACHE II APS Subtotal		Collected at CRF.
APAGE	num	APACHE II Age Pts Subtotal		Collected at CRF.
APCHS	num	APACHE II Chronic Health Points		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
MEDHIST1	num	Cardiac Disease		Collected at CRF.
MEDHIST2	num	Chronic Pulmonary Disease		Collected at CRF.
MEDHIST3	num	Diabetes Mellitus		Collected at CRF.
MEDHIST4	num	Hypertension		Collected at CRF.
MEDHIST5	num	Malignancy		Collected at CRF.
MEDHIST6	num	Peripheral Vascular Disease		Collected at CRF.
MEDHIST7	num	Primary Hematologic Disease		Collected at CRF.
MEDHIST8	num	Thromboembolic Disease		Collected at CRF.
HGBASE	num	Baseline Hemoglobin		Collected at CRF.
HCTBASE	num	Baseline Hematocrit		Collected at CRF.
MVDAY1C	num	Mechanical Ventilation on Day 1 Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
MVDAY1	char	Mechanical Ventilation on Day 1		Collected at CRF.
COMPND	char	study drug name		Collected at CRF.
COMPNDC	char	study drug name code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
AGE	char	Age (Years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RFENDY	num	Relative Reference End Day		If RFENDT and RFSTDT not missing then perform below logic to calculate RFENDY, If RFENDT less than RFSTDT then (RFENDT - RFSTDT).Else if RFENDT is greater than equal to RFSTDT then (RFENDT- RFSTDT) +1.
APACHEDY	num	Relative Apache II Assessment Day		If APACHEDT and RFSTDT not missing then perform below logic to calculate APACHEDY, If APACHEDT less than RFSTDT then (APACHEDT - RFSTDT).Else if APACHEDT is greater than equal to RFSTDT then (APACHEDT- RFSTDT) +1.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and RFSTDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than RFSTDT then (DMACTDT - RFSTDT).Else if DMACTDT is greater than equal to RFSTDT then (DMACTDT- RFSTDT) +1.

Variable	Type	Label	Codes	Comments
DMINFDY	num	Relative Day of Sign. On Inf. Consent		If DMINFDT and RFSTDT not missing then perform below logic to calculate DMINFDY, If DMINFDT less than RFSTDT then (DMINFDT - RFSTDT).Else if DMINFDT is greater than equal to RFSTDT then (DMINFDT- RFSTDT) +1.
DMSCRDY	num	Relative Day of First Trial Rel. Proc.		If DMSCRDT and RFSTDT not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than RFSTDT then (DMSCRDT - RFSTDT).Else if DMSCRDT is greater than equal to RFSTDT then (DMSCRDT- RFSTDT) +1.
ADACTDY	num	Relative Hospital admission day		If ADACTDT and RFSTDT not missing then perform below logic to calculate ADACTDY, If ADACTDT less than RFSTDT then (ADACTDT - RFSTDT).Else if ADACTDT is greater than equal to RFSTDT then (ADACTDT- RFSTDT) +1.

1.4.2.EPO 2 Adverse Events Data – KAE

Dataset	KAE
Creating program	kae.sas
Description	EPO 2 Adverse Events Data
Unique identifier	DUSUBJID, AEDECOD, VISIT, AESEQ
Sorted by	DUSUBJID, AEDECOD, VISIT, AESEQ
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: AETERM, AESTDT, AEENDT, AESTDTC, AEENDTC, IVNAME, SITENAME, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE

Variable	Type	Label	Codes	Comments
AESEQ	num	AE Sequence Number		Collected at CRF.
AEDYONDS	char	Days on Onset Dose		Collected at CRF.
AEACTDOS	char	Onset Dose		Collected at CRF.
AEACTSDY	num	Actual Day of Start of Event		Collected at CRF.
AEDUR	num	Duration		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTTRT	char	Actual Treatment		Collected at CRF.
AEDOSUNT	char	Onset Dose Unit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
AEBODSYS	char	Body System		Collected at CRF.
AEDECOD1	char	Included Term		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		Collected at CRF.
AEACTTRC	num	Action Taken With Treatment Code		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AEREPRT	char	Were Any Aes Reported ?		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AEDECOD	char	Preferred Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
TVEC	num	TVE Event Code		Collected at CRF.
TVE	char	TVE Event		Collected at CRF.
AEREPTC	num	Were Any Aes Reported Code		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
PROSPC	num	Prospective Code		Collected at CRF.
RETROC	num	Retrospective Code		Collected at CRF.
PROSP	char	Data Collected Prospectively		Collected at CRF.
RETRO	char	Data Collected Retrospectively		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AERELDY	num	Relative Day		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and RFSTDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than RFSTDT then (AESTDTC - RFSTDT).Else if AESTDTC is greater than equal to RFSTDT then (AESTDTC- RFSTDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and RFSTDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than RFSTDT then (AEENDTC - RFSTDT).Else if AEENDTC is greater than equal to RFSTDT then (AEENDTC- RFSTDT) +1.

1.4.3. Patient Disposition – KDISPO

Dataset	KDISPO
Creating program	kdispo.sas
Description	Patient Disposition
Unique identifier	DUSUBJID, DSREAS
Sorted by	DUSUBJID, DSREAS
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: RFENDT, RFSTDT, DSACTDT, DEATHDT, DSPRTDEV, DRSOTH, IVNAME, SITENAME, AUTOPDT, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE, MEDSTDT, MEDENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DEATHDY	num	Relative Actual Day of Death		If DEATHDT and RFSTDT not missing then perform below logic to calculate DEATHDY, If DEATHDT less than RFSTDT then (DEATHDT - RFSTDT).Else if DEATHDT is greater than equal to RFSTDT then (DEATHDT - RFSTDT) +1.

Variable	Type	Label	Codes	Comments
DSACTDY	num	Relative Actual Day Trial Compl/Withdl		If DSACTDT and RFSTDT not missing then perform below logic to calculate DSACTDY, If DSACTDT less than RFSTDT then (DSACTDT - RFSTDT).Else if DSACTDT is greater than equal to RFSTDT then (DSACTDT - RFSTDT) +1.
DSDEATH	char	Subject Died During Study		Collected at CRF.
DSRELDY	num	Relative Day		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Term		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Term Code		Collected at CRF.
DSSTAT	char	Subj Compl Trtment/Trial		Collected at CRF.
DSSTATC	num	Subj Compl Trtment/Trial Code		Collected at CRF.
AUTOPSYC	num	Autopsy Done Code		Collected at CRF.
AUTOPSY	char	Autopsy Done		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSSTA42C	num	Was Pt Followed Through D 42 Code		Collected at CRF.
DSSTAT42	char	Was Pt Followed Through D 42		Collected at CRF.
AE28DC	num	Any AEs Since Last Scheduled Dose Code		Collected at CRF.
AE28D	char	Any AEs Since Last Scheduled Dose		Collected at CRF.
TRF28DC	num	Any Transf Since Last Sched Dose Code		Collected at CRF.
TRF28D	char	Any Transfusions Since Last Sched Dose		Collected at CRF.
AE42DC	num	Any AEs Not Previously Reported Code		Collected at CRF.
AE42D	char	Any AEs Not Previously Reported		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
RFENDY	num	Relative Reference End Day		If RFENDT and RFSTDT not missing then perform below logic to calculate RFENDY, If RFENDT less than RFSTDT then (RFENDT - RFSTDT).Else if RFENDT is greater than equal to RFSTDT then (RFENDT- RFSTDT) +1.
AUTOPDY	num	Relative Day of Autopsy		If AUTOPDT and RFSTDT not missing then perform below logic to calculate AUTOPDY, If AUTOPDT less than RFSTDT then (AUTOPDT - RFSTDT).Else if AUTOPDT is greater than equal to RFSTDT then (AUTOPDT- RFSTDT) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and RFSTDT not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than RFSTDT then (MEDSTDT - RFSTDT).Else if MEDSTDT is greater than equal to RFSTDT then (MEDSTDT- RFSTDT) +1.
MEDENDY	num	Relative End Medication Day		If MEDENDT and RFSTDT not missing then perform below logic to calculate MEDENDY, If MEDENDT less than RFSTDT then (MEDENDT - RFSTDT).Else if MEDENDT is greater than equal to RFSTDT then (MEDENDT- RFSTDT) +1.

1.4.4.EPO 2 Efficacy Data – KEFF

Dataset	KEFF
Creating program	keff.sas
Description	EPO 2 Efficacy Data
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SEX, RACE, COUNTRY, RACE, SEX, IVNAME, SITENAME, AGE, ICUDT, ICUADM, DMACTDT, RE42DATE, RE42DEST

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DIAGNOSC	num	Type of Admission Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity

Variable	Type	Label	Codes	Comments
DIAGNOS	char	Type of Admission		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
MVDAY1C	num	Mechanical Ventilation on Day 1 Code		Collected at CRF.
MVDAY1	char	Mechanical Ventilation on Day 1		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
REICU42C	num	Readmission to ICU Through Day 42 Code		Collected at CRF.
REICU42	char	Readmission to ICU Through Day 42		Collected at CRF.
ICUL42C	num	Initial ICU Dischar Through Day 42 Code		Collected at CRF.
ICUL42	char	Initial ICU Discharge Through Day 42		Collected at CRF.
ICUATM	num	Initial Admission to ICU Time		Collected at CRF.
TICUL140	num	Init. ICU Length of Stay through D140		Collected at CRF.

Variable	Type	Label	Codes	Comments
ICUDDAY	num	Study Day of Initial ICU Discharge		Collected at CRF.
RBC29	char	RBC transfusion D1-D29		Collected at CRF.
RBC29C	num	RBC transfusion D1-D29 Code		Collected at CRF.
RBACTDY	num	First Medication Date		Collected at CRF.
RBCCUM29	num	Tot Vol of Transf Through Study Day 29		Collected at CRF.
NRBCUM29	num	Total Non-RBC Units Transfused On Study		Collected at CRF.
NCCCUM29	num	Total Non-RBC Vol(CC) Transf On Study		Collected at CRF.
DEATHDY	num	Day of Death		Collected at CRF.
DSACTDY	num	Actual Day of Disposition		Collected at CRF.
TFRBC29	num	Time to 1st RBC Transfusion through D29		Collected at CRF.
MORT29C	num	Died On or Before Day 29 Code		Collected at CRF.
MORT29	char	Died On or Before Day 29		Collected at CRF.
MORT42C	num	Died On or Before Day 42 Code		Collected at CRF.
MORT42	char	Died On or Before Day 42		Collected at CRF.
MORT140C	num	Died On or Before Day 140 Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
MORT140	char	Died On or Before Day 140		Collected at CRF.
THSPL42	num	Hospital Length through Study Day 42		Collected at CRF.
HSPL42C	num	Hosp. Length through Study Day 42 Code		Collected at CRF.
THSPL140	num	Hospital Length through Study Day 140		Collected at CRF.
HSPL140C	num	Hosp. Length through Study Day 140 Code		Collected at CRF.
REHOS42C	num	Hosp. Readm. Prior to Study Day 42 Code		Collected at CRF.
HSPL42	char	Hosp. Length through D42		Collected at CRF.
HSPL140	char	Hosp. Length through D140		Collected at CRF.
REHOSP42	char	Hosp. Readm. Prior to Study Day 42		Collected at CRF.
NDOSE	num	Number of Doses Received		Collected at CRF.
ICUDY	num	Relative Day of Initial Dischg from ICU		If ICUDT and RFSTDT not missing then perform below logic to calculate ICUDY, if ICUDT less than RFSTDT then (ICUDT - RFSTDT).Else if ICUDT is greater than equal to RFSTDT then (ICUDT - RFSTDT) +1.

Variable	Type	Label	Codes	Comments
ICUADM DY	num	Relative Day of Initial Admn to ICU		If ICUADM and RFSTDT not missing then perform below logic to calculate ICUADM DY, if ICUADM less than RFSTDT then (ICUADM - RFSTDT).Else if ICUADM is greater than equal to RFSTDT then (ICUADM- RFSTDT) +1.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and RFSTDT not missing then perform below logic to calculate DMACTDY, if DMACTDT less than RFSTDT then (DMACTDT - RFSTDT).Else if DMACTDT is greater than equal to RFSTDT then (DMACTDT- RFSTDT) +1.
RE42DY	num	Relative Day of HospReadm Prior to D42		If RE42DATE and RFSTDT not missing then perform below logic to calculate RE42DY, if RE42DATE less than RFSTDT then (RE42DATE - RFSTDT).Else if RE42DATE is greater than equal to RFSTDT then (RE42DATE- RFSTDT) +1.

1.4.5.EPO 2 Enrollment Data – KENROLL

Dataset	KENROLL
Creating program	kenroll.sas
Description	EPO 2 Enrollment Data
Unique identifier	DUSUBJID, ENTEXT
Sorted by	DUSUBJID, ENTEXT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SEX, RACE, COUNTRY, RACE, SEX, IVNAME, SITENAME

Variable	Type	Label	Codes	Comments
ENCRIT	char	Inclusion or Exclusion Criterion		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
ENTEXT	char	Criterion Text		Collected at CRF.
ENCRESC	num	Criterion Result Code		Collected at CRF.
ENCRES	char	Criterion Result		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DRUGIDC	char	Compound Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.

1.4.6. Study Drug Exposure – KEXPO

Dataset	KEXPO
Creating program	kexpo.sas
Description	Study Drug Exposure
Unique identifier	DUSUBJID, EXSEQ
Sorted by	DUSUBJID, EXSEQ
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: EXSTDT, MEDENDT, MEDSTDT, EXENDT, EXPRTDEV, EXOTH, SUBJECT, IVNAME, SITENAME, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
TRTGRP	char	Treatment Group		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
DOSETOT	num	Total Daily Dose		Collected at CRF.
EXACTEDY	num	Actual Day of End of Dose		Collected at CRF.
EXACTSDY	num	Actual Day of Start of Dose		Collected at CRF.
EXDUR	num	Duration		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity

Variable	Type	Label	Codes	Comments
ANYAE	char	Any AEs Since Last Dose		Collected at CRF.
ANYTRF	char	Any Transfusions Since Last Dose		Collected at CRF.
DOSERECD	char	Was 2nd/3rd/4th Dose Given?		Collected at CRF.
DOSENUM	num	Dose Number		Collected at CRF.
DOSE	num	Dose per Administration		Collected at CRF.
EXPTM	num	Planned Admin Time Code		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXSTTM	num	Start Time of Exposure		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PRDOSHR	num	Time in ICU Prior to First Dose (Hours)		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
ICUTIMEC	num	Time in ICU Prior to First Dose Code		Collected at CRF.
EXREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
ANYAEC	num	Any AEs Since Last Dose Code		Collected at CRF.
ANYTRFC	num	Any Transfusions Since Last Dose Code		Collected at CRF.
DOSERECC	num	Was 2nd/3rd/4th Dose Given Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSEUNIT	char	Dose Unit		Collected at CRF.
EXREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
EXTMLBL	char	Planned Admin Time		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ICUTIME	char	Time in ICU Prior to First Dose (Hours)		Collected at CRF.
DSITEID	num	Site ID Assigned for De- identity		Randomly assigned Site ID for De-identity
TRTGRPC	num	Treatment Group Code		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
DOSEFREQ	char	Frequency of Dosing		Collected at CRF.
STRENGTH	num	Drug Strength		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXSTDY	num	Relative Start Day of Exposure		If EXSTDY and RFSTDY not missing then perform below logic to calculate EXSTDY, If EXSTDY less than RFSTDY then (EXSTDY - RFSTDY).Else if EXSTDY is greater than equal to RFSTDY then (EXSTDY- RFSTDY) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDY and RFSTDY not missing then perform below logic to calculate MEDENDY, If MEDENDY less than RFSTDY then (MEDENDY - RFSTDY).Else if MEDENDY is greater than equal to RFSTDY then (MEDENDY- RFSTDY) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDY and RFSTDY not missing then perform below logic to calculate MEDSTDY, If MEDSTDY less than RFSTDY then (MEDSTDY - RFSTDY).Else if MEDSTDY is greater than equal to RFSTDY then (MEDSTDY- RFSTDY) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDY and RFSTDY not missing then perform below logic to calculate EXENDY, If EXENDY less than RFSTDY then (EXENDY - RFSTDY).Else if EXENDY is greater than equal to RFSTDY then (EXENDY- RFSTDY) +1.

1.4.7.EPO 2 Lab Data – KHEMA

Dataset	KHEMA
Creating program	khema.sas
Description	EPO 2 Lab Data
Unique identifier	DUSUBJID, LBTEST, VISIT
Sorted by	DUSUBJID, LBTEST, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SEX, RACE, COUNTRY, COUNTRYC, RACE, SEX, IVNAME, SITENAME, AGE, RFENDT, RFSTDT, MEDSTDT, MEDENDT, LBACTDT

Variable	Type	Label	Codes	Comments
BASE	num	Value at Baseline		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
DBASE	char	Value Description at Baseline		Collected at CRF.
DVALUE	char	Value Description		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and RFSTDT not missing then perform below logic to calculate LBACTDY, If LBACTDT less than RFSTDT then (LBACTDT - RFSTDT).Else if LBACTDT is greater than equal to RFSTDT then (LBACTDT - RFSTDT) +1.
LBTESTC	num	Lab Test Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORGUNIT	char	Original Unit		Collected at CRF.
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DRUGIDC	char	Compound Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
CLASS	char	Class		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
VALUE	num	Value		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
RFENDY	num	Relative Reference End Day		If RFENDT and RFSTDT not missing then perform below logic to calculate RFENDY, If RFENDT less than RFSTDT then (RFENDT - RFSTDT).Else if RFENDT is greater than equal to RFSTDT then (RFENDT- RFSTDT) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and RFSTDT not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than RFSTDT then (MEDSTDT - RFSTDT).Else if MEDSTDT is greater than equal to RFSTDT then (MEDSTDT- RFSTDT) +1.
MEDENDY	num	Relative End Medication Day		If MEDENDT and RFSTDT not missing then perform below logic to calculate MEDENDY, If MEDENDT less than RFSTDT then (MEDENDT - RFSTDT).Else if MEDENDT is greater than equal to RFSTDT then (MEDENDT- RFSTDT) +1.

1.4.8.EPO 2 Hospital Discharge Data – KHOSPDIS

Dataset	KHOSPDIS
Creating program	khospdis.sas
Description	EPO 2 Hospital Discharge Data
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: HDDISDT, HDDISDTC, HDESTOTH, IVNAME, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE

Variable	Type	Label	Codes	Comments
HDDESTC	num	Hospital Discharge Destination Code		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
HDDEST	char	Hospital Discharge Destination		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
HDDISDY	num	Relative Day of Hospital Discharge		If HDDISDTC and RFSTDT not missing then perform below logic to calculate HDDISDY, If HDDISDTC less than RFSTDT then (HDDISDTC - RFSTDT).Else if HDDISDTC is greater than equal to RFSTDT then (HDDISDTC- RFSTDT) +1.

1.4.9.EPO 2 Hospital Transfer Data – KHOSPXFR

Dataset	KHOSPXFR
Creating program	khospxfr.sas
Description	EPO 2 Hospital Transfer Data
Unique identifier	DUSUBJID, HOSEQ
Sorted by	DUSUBJID, HOSEQ
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: HOACTDT, IVNAME, HOACTDG, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE

Variable	Type	Label	Codes	Comments
HOSEQ	num	Transfer Sequence Number		Collected at CRF.
HOLOCAT	char	Subject's Location		Collected at CRF.
HOLOCATC	num	Subject's Location Code		Collected at CRF.
PHASEC	num	Study phase code		Collected at CRF.
PHASE	char	Study phase		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
HOACTDY	num	Relative Day of Admission for location		If HOACTDT and RFSTDT not missing then perform below logic to calculate HOACTDY, If HOACTDT less than RFSTDT then (HOACTDT - RFSTDT).Else if HOACTDT is greater than equal to RFSTDT then (HOACTDT- RFSTDT) +1.
HODGLDY	num	Relative Day of Discharge for location		If HOACTDG and RFSTDT not missing then perform below logic to calculate HODGLDY , If HOACTDG less than RFSTDT then (HOACTDG - RFSTDT).Else if HOACTDG is greater than equal to RFSTDT then (HOACTDG- RFSTDT) +1.

1.4.10. EPO 2 Mechanical Ventilation Data – KMCHVENT

Dataset	KMCHVENT
Creating program	kmchvent.sas
Description	EPO 2 Mechanical Ventilation Data
Unique identifier	DUSUBJID, MVCONT, VISIT
Sorted by	DUSUBJID, MVCONT, VISIT
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: MVSTDT, MVENDT, MVSTDT, MVENDT, IVNAME, SITENAME, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
MVDUR	num	Mech. Ventilation Duration		Collected at CRF.
MVCONT	char	Ventilation Continuing		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity

Variable	Type	Label	Codes	Comments
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEG	char	Age Group (Years)		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
MVREPRTC	num	Subject Required Mech. Vent. Code		Collected at CRF.
MVREPRT	char	Subject Required Mech. Ventilation		Collected at CRF.
MVCONTC	num	Ventilation Continuing Code		Collected at CRF.
MVSEQ	num	MV Sequence		Collected at CRF.
MVTOTDUR	num	Total Time on MV		Collected at CRF.
REVENTC	num	Re-Ventilation Code		Collected at CRF.
REVENT	char	Re-Ventilation		Collected at CRF.

Variable	Type	Label	Codes	Comments
MVSTDY	num	Relative Start Day of Ventilation		If MVSTDTC and RFSTDT not missing then perform below logic to calculate MVSTDY, if MVSTDTC less than RFSTDT then (MVSTDTC - RFSTDT).Else if MVSTDTC is greater than equal to RFSTDT then (MVSTDTC- RFSTDT) +1.
MVENDY	num	Relative End Day of Ventilation.		If MVENDTC and RFSTDT not missing then perform below logic to calculate MVENDY, if MVENDTC less than RFSTDT then (MVENDTC - RFSTDT).Else if MVENDTC is greater than equal to RFSTDT then (MVENDTC- RFSTDT) +1.

1.4.11. EPO 2 RBC and Non-RBC Transfusion Data – KTRANSFU

Dataset	KTRANSFU
Creating program	ktransfu.sas
Description	EPO 2 RBC and Non-RBC Transfusion Data
Unique identifier	DUSUBJID, TFTYPE, RBACTDY, RBACTTM, NRBCUNIT
Sorted by	DUSUBJID, TFTYPE, RBACTDY, RBACTTM, NRBCUNIT
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:</p> <p>RINDOTH, NROTH, RCOMPOTH, RCOMP1DT, RCOMP2DT, RCOMP2TM, RCOMP3DT, NCOMPOTH, NCOMP1DT, NCOMP2DT, NCOMP2TM, NCOMP3DT, SUBJECT, RBACTDT, RBACTDTM, TFOTH, RECENTDT, POSTDT, IVNAME, SITENAME, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, AGE</p>

Variable	Type	Label	Codes	Comments
RBC29	char	RBC transfusion D1-D29		Collected at CRF.
RBC29C	num	RBC transfusion D1-D29 Code		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
RBACTDY	num	Relative Transfusion Day		If RBACTDT and RFSTDT not missing then perform below logic to calculate RBACTDY, If RBACTDT less than RFSTDT then (RBACTDT - RFSTDT).Else if RBACTDT is greater than equal to RFSTDT then (RBACTDT- RFSTDT) +1.
RBCC	num	RBC Transfusion Code		Collected at CRF.
NRBCC	num	Non-RBC Tranfusion Code		Collected at CRF.
RBC	char	RBC Transfusion		Collected at CRF.
NRBC	char	Non-RBC Transfusion		Collected at CRF.
TFTYPE	char	Type of Transfusion		Collected at CRF.
TFTYPEC	num	Type of Transfusion Code		Collected at CRF.
NRBCUNIT	num	Non-RBC Units Transfused		Collected at CRF.
NRBCCC	num	Non-RBC Volume Transfused (CC)		Collected at CRF.
RBCUNIT	num	RBC Units Transfused		Collected at CRF.
RINDIC	char	RBC Transfusion Indication		Collected at CRF.
RINDICC	num	RBC Tranfusion Indication Code		Collected at CRF.
NRIND1C	num	Non-RBC Indication:Thrombocytopenia Code		Collected at CRF.
NRIND1	char	Non-RBC Indication: Thrombocytopenia		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND2C	num	Non-RBC Indication: Leukopenia Code		Collected at CRF.
NRIND2	char	Non-RBC Indication: Leukopenia		Collected at CRF.
NRIND3C	num	Non-RBC Indication: Von Willebrands Code		Collected at CRF.
NRIND3	char	Non-RBC Indication: Von Willebrands		Collected at CRF.
NRIND4C	num	Non-RBC Indication: Coagulopathy Code		Collected at CRF.
NRIND4	char	Non-RBC Indication: Coagulopathy		Collected at CRF.
NRIND5C	num	Non-RBC Indication:Volume Expansion Code		Collected at CRF.
NRIND5	char	Non-RBC Indication: Volume Expansion		Collected at CRF.
NRIND6C	num	Non-RBC Indication: Other Code		Collected at CRF.
NRIND6	char	Non-RBC Indication: Other		Collected at CRF.
RCOMP1C	num	RBC Complication - Fever Code		Collected at CRF.
RCOMP1	char	RBC Complication - Fever		Collected at CRF.
RCOMP2C	num	RBC Complication - Rash Code		Collected at CRF.
RCOMP2	char	RBC Complication - Rash		Collected at CRF.

Variable	Type	Label	Codes	Comments
RCOMP3C	num	RBC Complication - Other Code		Collected at CRF.
RCOMP3	char	RBC Complication - Other		Collected at CRF.
RCOMP1TM	num	RBC Complication - Fever - Time		Collected at CRF.
RCOMP3TM	num	RBC Complication - Other - Time		Collected at CRF.
NRCOMP1C	num	Non-RBC Complication - Fever Code		Collected at CRF.
NRCOMP1	char	Non-RBC Complication - Fever		Collected at CRF.
NRCOMP2C	num	Non-RBC Complication - Rash Code		Collected at CRF.
NRCOMP2	char	Non-RBC Complication - Rash		Collected at CRF.
NRCOMP3C	num	Non-RBC Complication - Other Code		Collected at CRF.
NRCOMP3	char	Non-RBC Complication - Other		Collected at CRF.
NCOMP1TM	num	Non-RBC Complication - Fever - Time		Collected at CRF.
NCOMP3TM	num	Non-RBC Complication - Other - Time		Collected at CRF.
POSTHG	num	Post Transfusion Hemoglobin (g/dL)		Collected at CRF.
RECENTHG	num	Most Recent Hemoglobin (g/dL)		Collected at CRF.

Variable	Type	Label	Codes	Comments
POSTHCT	num	Post Transfusion Hematocrit (%)		Collected at CRF.
RECENHCT	num	Most Recent Hematocrit (%)		Collected at CRF.
RINDOTHC	num	RBC Indication Other Specify Category		Collected at CRF.
RBACTTM	num	Transfusion Time		Collected at CRF.
RECENTTM	num	Most Recent HGB Time		Collected at CRF.
POSTTM	num	Post Transfusion HGB Time		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPC	num	Treatment Group Code		Collected at CRF.
RBCCUM29	num	Tot Vol of Transf Through Study Day 29		Collected at CRF.
NRBCUM29	num	Total Non-RBC Units Transfused On Study		Collected at CRF.
NCCCUM29	num	Total Non-RBC Vol(CC) Transf On Study		Collected at CRF.
RCOMP1DY	num	Relative RBC Complication Fever Day		If RCOMP1DT and RFSTDT not missing then perform below logic to calculate RCOMP1DY, If RCOMP1DT less than RFSTDT then (RCOMP1DT - RFSTDT).Else if RCOMP1DT is greater than equal to RFSTDT then (RCOMP1DT- RFSTDT) +1.
RCOMP3DY	num	Relative RBC Complication Other Day		If RCOMP3DT and RFSTDT not missing then perform below logic to calculate RCOMP3DY, If RCOMP3DT less than RFSTDT then (RCOMP3DT - RFSTDT).Else if RCOMP3DT is greater than equal to RFSTDT then (RCOMP3DT- RFSTDT) +1.
NCOMP1DY	num	Relative Non-RBC Complication Fever Day		If NCOMP1DT and RFSTDT not missing then perform below logic to calculate NCOMP1DY, If NCOMP1DT less than RFSTDT then (NCOMP1DT - RFSTDT).Else if NCOMP1DT is greater than equal to RFSTDT then (NCOMP1DT- RFSTDT) +1.
NCOMP3DY	num	Relative Non-RBC Complication Other Day		If NCOMP3DT and RFSTDT not missing then perform below logic to calculate NCOMP3DY, If NCOMP3DT less than RFSTDT then (NCOMP3DT - RFSTDT).Else if NCOMP3DT is greater than equal to RFSTDT then (NCOMP3DT- RFSTDT) +1.

Variable	Type	Label	Codes	Comments
RECENTDY	num	Relative Most Recent HGB Day		If RECENTDT and RFSTDT not missing then perform below logic to calculate RECENTDY, If RECENTDT less than RFSTDT then (RECENTDT - RFSTDT).Else if RECENTDT is greater than equal to RFSTDT then (RECENTDT- RFSTDT) +1.
POSTDY	num	Relative Post Transfusion HGB Day		If POSTDT and RFSTDT not missing then perform below logic to calculate POSTDY, If POSTDT less than RFSTDT then (POSTDT - RFSTDT).Else if POSTDT is greater than equal to RFSTDT then (POSTDT- RFSTDT) +1.

1.4.12. EPO 2 Vital Signs Data – KVITAL

Dataset	KVITAL
Creating program	kvital.sas
Description	EPO 2 Vital Signs Data
Unique identifier	DUSUBJID, PARAM
Sorted by	DUSUBJID, PARAM
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: VSACTDT, SEXC, RACEC, COUNTRY, COUNTRYC, RACE, SEX, IVNAME, SITENAME, AGE

Variable	Type	Label	Codes	Comments
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned Unique Subject Id for De-Identity
VSSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
VSSTUNIT	char	Vital Signs Standard Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSTEST	char	Vital Signs Test Name		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
AGEGRP	char	Age Group (Years)		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned Subject Number for De-Identity
DRUGIDC	char	Compound Number		Collected at CRF.
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and RFSTDT not missing then perform below logic to calculate VSACTDY, If VSACTDT less than RFSTDT then (VSACTDT - RFSTDT).Else if VSACTDT is greater than equal to RFSTDT then (VSACTDT- RFSTDT) +1.