

Clinical Development

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EPO-ICU-002

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.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.
- Complete missing value variables will be removed.

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's Relative day cannot be calculated.
- Comments dataset will be submitted with zero observation.
- Lab Name and Lab Identifier information will not be provided.
- Patient's Initial will not be provided as it is sensitive.
- Dataset containing information related to Medication Kit numbers will not be submitted (e.g. KMEDKIT)
- Dataset containing Investigator information will not be submitted. (eg. KINVEST)
- KSURGERY and KSRGHIST dataset will not be submitted due to sensitivity of information.
- Reference Start Date (RFSTDT) will be used as Reference Date(referred as REF.DATE in this document) to derive relative days.

1.3. Data Files

The EPO-ICU-002 CSR Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Derived Demographics Data – KDEMOG

Dataset	KDEMOG
Creating program	kdemog.sas
Description	Derived Demographics 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: SUBJINIT, DMACTDT, IVID, BIRTHDT, DMINFDT, RACESPEC, COUNTRYC, IVNAME, VSACTDT, IVFINIT, DMSCRDT, RFENDT, RFSTDT

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SEXC	num	Sex Code		Collected at CRF.
RACE	char	Race		Collected at CRF.
RACEC	num	Race Code		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
ETHNIC	char	Ethnicity		Collected at CRF.
ETHNICC	num	Ethnicity Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
AGEUNIT	char	Age Unit		Collected at CRF.
AGE	char	Age in Years		Date of birth is collected but can not be submitted as per HIPAA rules. Hence deriving AGE element. Derivation follows below rule: $AGE = \text{int}((REF.DATE - BIRTHDT)/365.25)$ If age greater than 89+ years then will be grouped as per HIPAA rules.

Variable	Type	Label	Codes	Comments
WEIGHTKG	num	Baseline Weight in Kilograms		Collected at CRF.
HEIGHTCM	num	Baseline Height in Centimeters		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and REF.DATE not missing then perform below logic to calculate DMACTDY, If DMACTDT less than REF.DATE then (DMACTDT - REF.DATE).Else if DMACTDT is greater than equal to REF.DATE then (DMACTDT- REF.DATE) +1.
DMINFDY	num	Relative Day of Sign. on Informed Consent		If DMINFDT and REF.DATE not missing then perform below logic to calculate DMINFDY, If DMINFDT less than REF.DATE then (DMINFDT - REF.DATE).Else if DMINFDT is greater than equal to REF.DATE then (DMINFDT- REF.DATE) +1.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and REF.DATE not missing then perform below logic to calculate VSACTDY, If VSACTDT less than REF.DATE then (VSACTDT - REF.DATE).Else if VSACTDT is greater than equal to REF.DATE then (VSACTDT- REF.DATE) +1.
DMSCRDY	num	Relative Day of First Trial Related Procedure		If DMSCRDT and REF.DATE not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than REF.DATE then (DMSCRDT - REF.DATE).Else if DMSCRDT is greater than equal to REF.DATE then (DMSCRDT- REF.DATE) +1.

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

1.4.2. Derived Admission Information Data – KADMIT

Dataset	KADMIT
Creating program	kadmit.sas
Description	Derived Admission Information Data
Unique identifier	DUSUBJID,VISITNUM, ADICUDG
Sorted by	DUSUBJID,VISITNUM, ADICUDG
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: ADACTDT, ADICUDT, ADTMOTH, ADOTHDT, ADDGOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ADICUTM	char	ICU Admission Time		Collected at CRF.
ADHSTYP	char	Hospital From Type		Collected at CRF.
ADHSTYPC	num	Hospital From Type Code		Collected at CRF.
ADRMTYP	char	Room From Type		Collected at CRF.
ADRMTYPC	num	Room From Type Code		Collected at CRF.
ADICUTP	char	ICU Admission Type		Collected at CRF.
ADICUTPC	num	ICU Admission Type Code		Collected at CRF.
ADICUSEQ	num	ICU Admission Sequence Number		Collected at CRF.
ADICUDG	char	ICU Admission Diagnostic Category Code		Collected at CRF.
ADICUYN	char	ICU Admission Diagnostic Category YN		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADICUYNC	num	ICU Admission Diagnostic Category YN Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
ADACTDY	num	Relative Actual Day of Admission		If ADACTDT and REF.DATE not missing then perform below logic to calculate ADACTDY, If ADACTDT less than REF.DATE then (ADACTDT - REF.DATE).Else if ADACTDT is greater than equal to REF.DATE then (ADACTDT- REF.DATE) +1.
ADICUDY	num	Relative ICU Admission Day		If ADICUDT and REF.DATE not missing then perform below logic to calculate ADICUDY, If ADICUDT less than REF.DATE then (ADICUDT - REF.DATE).Else if ADICUDT is greater than equal to REF.DATE then (ADICUDT- REF.DATE) +1.
ADOTHDY	num	Relative Admission day at other hospital		If ADOTHDT and REF.DATE not missing then perform below logic to calculate ADOTHDY, If ADOTHDT less than REF.DATE then (ADOTHDT - REF.DATE).Else if ADOTHDT is greater than equal to REF.DATE then (ADOTHDT- REF.DATE) +1.

1.4.3. Derived Adverse Events Data – KAE

Dataset	KAE
Creating program	kae.sas
Description	Derived Adverse Events Data
Unique identifier	DUSUBJID, VISITNUM, AEDECOD1, AESTDY, AESEQ
Sorted by	DUSUBJID, VISITNUM, AEDECOD1, AESTDY, 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 or due to missing values: AETERM, AESTDT, AEENDT, AESTDTC, AEENDTC, AEIRPDT, AEIRPDT, AEFRPDT, AEFRPDT, AEACTTM, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study ID		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AEBODSYS	char	Body System		Collected at CRF.
AEDECOD1	char	Included Term		Collected at CRF.
AEACTTRC	num	Action Taken with Treatment Code		Collected at CRF.
SOC1	char	AE System Organ Class 1		Collected at CRF.
SOC2	char	AE System Organ Class 2		Collected at CRF.
SOC3	char	AE System Organ Class 3		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		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.
AESERC	num	Seriousness Criteria Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESER	char	Seriousness Criteria		Collected at CRF.
AESERREF	char	Serious AE Reference Number		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment Given		Collected at CRF.
AETVEC	num	Is AE Reported as TVE Code		Collected at CRF.
AETVE	char	Is AE Reported as TVE		Collected at CRF.
AEDECOD	char	Preferred Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
AESHOSP	char	Requires or Prolongs Hospitalization		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
AEDUR	num	Duration		Collected at CRF.
AERELDY	num	Relative Day		Collected at CRF.
AEACTDOS	char	Onset Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEDYONDS	char	Days on Onset Dose		Collected at CRF.
AEACTSDY	num	Actual Day of Start of Event		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE).Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE).Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.
AEIRPDY	num	Relative Initial SAE Report Day		If AEIRPDTC and REF.DATE not missing then perform below logic to calculate AEIRPDY, If AEIRPDTC less than REF.DATE then (AEIRPDTC - REF.DATE).Else if AEIRPDTC is greater than equal to REF.DATE then (AEIRPDTC- REF.DATE) +1.
AEFRPDY	num	Relative Follow-up SAE Report Day		If AEFRPDTC and REF.DATE not missing then perform below logic to calculate AEFRPDY, If AEFRPDTC less than REF.DATE then (AEFRPDTC - REF.DATE).Else if AEFRPDTC is greater than equal to REF.DATE then (AEFRPDTC- REF.DATE) +1.

1.4.4. Derived History of Anti-Cancer Agents Data – KANTICAN

Dataset	KANTICAN
Creating program	kantican.sas
Description	Derived History of Anti-Cancer Agents Data
Unique identifier	DUSUBJID, VISITNUM, ACAGENTC
Sorted by	DUSUBJID, VISITNUM, ACAGENTC
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: ACAGOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
ACAGENT	char	Anti-Cancer Agent		Collected at CRF.
ACAGENTC	num	Anti-Cancer Agent Code		Collected at CRF.
ACRES	char	Anti-Cancer Result		Collected at CRF.
ACRESC	num	Anti-Cancer Result Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.5. Derived History of Anti-Thrombotic Agent Data – KANTITHR

Dataset	KANTITHR
Creating program	kantithr.sas
Description	Derived History of Anti-Thrombotic Agent Data
Unique identifier	DUSUBJID, VISITNUM, ATAGENT
Sorted by	DUSUBJID, VISITNUM, ATAGENT
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: ATAGOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
ATSEQ	num	AT Sequence Number		Collected at CRF.
ATAGENT	char	Anti-thrombolic Agent		Collected at CRF.
ATAGYN	char	Anti-thrombolic Agent YN		Collected at CRF.
ATAGYNC	num	Anti-thrombolic Agent YN Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.6. Derived APACHEI Data – KAPACHEI

Dataset	KAPACHEI
Creating program	kapachei.sas
Description	Derived APACHEI Data
Unique identifier	DUSUBJID, VISITNUM, APDIAG
Sorted by	DUSUBJID, VISITNUM, APDIAG
Notes	Below listed variables will be dropped from dataset due to repetition of the information: SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
APS	num	APACHE II Subtotal		Collected at CRF.
APCHP	num	APACHE II Chronic Health Points		Collected at CRF.
APDIAG	char	APACHE II Diagnostic Category		Collected at CRF.
APDIAGC	num	APACHE II Diagnostic Category Code		Collected at CRF.
APICUDG	char	ICU Diagnostic Category		Collected at CRF.
APICUDGC	num	ICU Diagnostic Category Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
AGEPT	num	Age Points		Collected at CRF.
APACHEII	num	Total APACHE II Scores		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.7. Derived BRM Data – KBRM

Dataset	KBRM
Creating program	kbrm.sas
Description	Derived BRM Data
Unique identifier	DUSUBJID, BAEOUT, BAESTDY
Sorted by	DUSUBJID, BAEOUT, BAESTDY
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: AEVTERM, BAESTDT, BAEENDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
PREFTERM	char	Preferred Term		Collected at CRF.
BAEOUT	char	Outcome		Collected at CRF.
BAERNO	char	AER Number		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DEATHFLG	char	Death Flag		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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity

Variable	Type	Label	Codes	Comments
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
BAESTDY	num	Relative AE Onset Day		If BAESTDT and REF.DATE not missing then perform below logic to calculate BAESTDY, If BAESTDT less than REF.DATE then (BAESTDT - REF.DATE).Else if BAESTDT is greater than equal to REF.DATE then (BAESTDT- REF.DATE) +1.
BAEENDY	num	Relative AE End Day		If BAEENDT and REF.DATE not missing then perform below logic to calculate BAEENDY, If BAEENDT less than REF.DATE then (BAEENDT - REF.DATE).Else if BAEENDT is greater than equal to REF.DATE then (BAEENDT- REF.DATE) +1.

1.4.8. Derived Chemistry Results 01 Data– KCHEM01

Dataset	KCHEM01
Creating program	kchem01.sas
Description	Derived Chemistry Results 01 Data
Unique identifier	DUSUBJID, VISITNUM, LBTYPEC, LBTESTC, LBACTDY
Sorted by	DUSUBJID, VISITNUM, LBTYPEC, LBTESTC, LBACTDY
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: LBPRVID, LBPRVIDC, LBACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, 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
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPESPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPECPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTERM	char	Lab Test Term		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGNRHI	num	Upper Normal Range in Orig Unit		Collected at CRF.
ORGNRLO	num	Lower Normal Range in Orig Unit		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
ORGRESN	num	Numeric Result in Orig Unit		Collected at CRF.
ORGUNIT	char	Original Unit		Collected at CRF.
LBSIFACT	num	Conversion Factor to Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
STDNRLO	num	Lower Normal Range in Std Unit		Collected at CRF.
STDNRC	char	N Range for Std Char Result		Collected at CRF.
STDNRHI	num	Upper Normal Range in Std Unit		Collected at CRF.
STDUNIT	char	Standard Unit		Collected at CRF.
STDRESN	num	Numeric Result in Std Unit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
VALUE	num	Value		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.9. Derived Chemistry Results 02 Data – KCHEM02

Dataset	KCHEM02
Creating program	kchem02.sas
Description	Derived Chemistry Results 02 Data
Unique identifier	DUSUBJID, VISITNUM, LBTYPEC, LBTESTC, LBACTDY
Sorted by	DUSUBJID, VISITNUM, LBTYPEC, LBTESTC, LBACTDY
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: LBPRVID, LBPRVIDC, LBACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDY, MEDENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPESPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPECPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTERMIN	char	Lab Test Term		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGNRHI	num	Upper Normal Range in Orig Unit		Collected at CRF.
ORGNRLO	num	Lower Normal Range in Orig Unit		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
ORGRESN	num	Numeric Result in Orig Unit		Collected at CRF.
ORGUNIT	char	Original Unit		Collected at CRF.
LBSIFACT	num	Conversion Factor to Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
STDNRLO	num	Lower Normal Range in Std Unit		Collected at CRF.
STDNRC	char	N Range for Std Char Result		Collected at CRF.
STDNRHI	num	Upper Normal Range in Std Unit		Collected at CRF.
STDUNIT	char	Standard Unit		Collected at CRF.
STDRESN	num	Numeric Result in Std Unit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
VALUE	num	Value		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.10. Derived Chemistry Results 03 Data– KCHEM03

Dataset	KCHEM03
Creating program	kchem03.sas
Description	Derived Chemistry Results 03 Data
Unique identifier	DUSUBJID, VISITNUM, LBTYPEC, LBTESTC, LBACTDY
Sorted by	DUSUBJID, VISITNUM, LBTYPEC, LBTESTC, LBACTDY
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: LBPRVID, LBPRVIDC, LBACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDY, MEDENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPESPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPECPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTERMIN	char	Lab Test Term		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGNRHI	num	Upper Normal Range in Orig Unit		Collected at CRF.
ORGNRLO	num	Lower Normal Range in Orig Unit		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
ORGRESN	num	Numeric Result in Orig Unit		Collected at CRF.
ORGUNIT	char	Original Unit		Collected at CRF.
LBSIFACT	num	Conversion Factor to Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
STDNRLO	num	Lower Normal Range in Std Unit		Collected at CRF.
STDNRC	char	N Range for Std Char Result		Collected at CRF.
STDNRHI	num	Upper Normal Range in Std Unit		Collected at CRF.
STDUNIT	char	Standard Unit		Collected at CRF.
STDRESN	num	Numeric Result in Std Unit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result (Verbatim)		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
VALUE	num	Value		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.11. Derived Chronic Co-Existing Conditions Data – KCHRCON

Dataset	KCHRCON
Creating program	kchrncon.sas
Description	Derived Chronic Co-Existing Conditions Data
Unique identifier	DUSUBJID, VISITNUM, CCDIS, CCSEQ
Sorted by	DUSUBJID, VISITNUM, CCDIS, CCSEQ
Notes	Below listed variables will be dropped from dataset due to repetition of the information: SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
CCSEQ	num	CC Sequence Number		Collected at CRF.
CCDIS	char	Chronic Co-Existing Condition Code		Collected at CRF.
CCEXIST	char	Is Condition Existing		Collected at CRF.
CCEXISTC	num	Is Condition Existing Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.12. Derived Concomitant Med/Therapy Data – KCMED

Dataset	KCMED
Creating program	kcmed.sas
Description	Derived Concomitant Med/Therapy Data
Unique identifier	DUSUBJID, VISITNUM, CMDECOD1, CMTYPEC, CMSEQ
Sorted by	DUSUBJID, VISITNUM, CMDECOD1, CMTYPEC, CMSEQ
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: CMSTDT, CMTERM, CMREAS, CMENDT, CMSTDTC, CMENDTC, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDT, MEDENDT

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMREPRT	char	Administered/Changed		Collected at CRF.
CMREPRTC	num	Administered/Changed		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.
CMCONT	char	Is Medication Continuing?		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
CMCAUS	char	Cause of Concom/Drug/Therapy		Collected at CRF.
CMCAUSC	num	Cause of Concom/Drug/Therapy Code		Collected at CRF.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
CMDUR	num	Duration of Medication in Days		Collected at CRF.
CMRELDY	num	Relative Day		Collected at CRF.
CMACTSDY	num	Actual Day of Start of Medication		Collected at CRF.
CMCLAS	char	ATC Text		Collected at CRF.
CMCLASC	char	ATC Code		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE).Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE).Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.

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

1.4.13. Derived Comments Data – KCOMMENT

Dataset	KCOMMENT
Creating program	kcomment.sas
Description	Derived Comments Data
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Empty dataset will be submitted.
DSUBJID	char	Subject Number Assigned for De-identity		Empty dataset will be submitted.
DSITEID	char	Site Assigned for De-identity		Empty dataset will be submitted.
PHASENUM	num	Phase Number		Empty dataset will be submitted.
PHASE	char	Phase		Empty dataset will be submitted.
PRDNUM	num	Period Number		Empty dataset will be submitted.
PERIOD	char	Period		Empty dataset will be submitted.
VISITNUM	num	Visit ID		Empty dataset will be submitted.
VISIT	char	Visit		Empty dataset will be submitted.
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted.
DOMAIN	char	Domain of Origin		Empty dataset will be submitted.
DRUGID	char	Compound Name		Empty dataset will be submitted.
DRUGIDC	char	Compound Number		Empty dataset will be submitted.
TRTGRPC	num	Treatment Group Code		Empty dataset will be submitted.
TRTGRP	char	Treatment Group		Empty dataset will be submitted.
ITT	char	Evaluable for Intent-to-Treat		Empty dataset will be submitted.
SAFETY	char	Evaluable for Safety		Empty dataset will be submitted.
CTACTDY	num	Relative Actual Day of Comment		Empty dataset will be submitted.

1.4.14. Derived History of Corticosteroid Data – KCORTSTE

Dataset	KCORTSTE
Creating program	kcortste.sas
Description	Derived History of Corticosteroid Data
Unique identifier	DUSUBJID, CSAGENT, CSSEQ
Sorted by	DUSUBJID, CSAGENT, CSSEQ
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: CSAGOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
CSSEQ	num	CS Sequence Number		Collected at CRF.
CSAGENT	char	Corticosteroid Agent		Collected at CRF.
CSYN	char	Corticosteroid Agent YN		Collected at CRF.
CSYNC	num	Corticosteroid Agent YN Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.15. Derived Death Data – KDEATH

Dataset	KDEATH
Creating program	kdeath.sas
Description	Derived Death Data
Unique identifier	DUSUBJID, VISITNUM, DTACTION, DTSEQ
Sorted by	DUSUBJID, VISITNUM, DTACTION, DTSEQ
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: DTACTDT, DTACTION, DTOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DTINTRL	char	Subject Died During the Trial		Collected at CRF.
DTINTRLC	num	Subject Died During the Trial Code		Collected at CRF.
DTSPOFF	char	Was Support Withdrawn		Collected at CRF.
DTSPOFFC	num	Was Support Withdrawn Code		Collected at CRF.
AESEQ	num	SAE Sequence for Primary Cause of Death		Collected at CRF.
DTSEQ	num	Sequence Number for Causes of Death		Collected at CRF.
DTCAUSE	char	Causes of Death		Collected at CRF.
DTCSRES	char	Result for Cause of Death		Collected at CRF.
DTCSRESC	num	Result for Cause of Death Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		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.
DTACTDY	num	Relative Actual Day of Death		If DTACTDTC and REF.DATE not missing then perform below logic to calculate DTACTDY, If DTACTDTC less than REF.DATE then (DTACTDTC - REF.DATE).Else if DTACTDTC is greater than equal to REF.DATE then (DTACTDTC- REF.DATE) +1.

1.4.16. Derived Disposition/Termination Data – KDISPO

Dataset	KDISPO
Creating program	kdispo.sas
Description	Derived Disposition/Termination Data
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 or due to missing values: DSACTDT, DRSOTH, DSRABKDT, PREGDUDT, DSRABKRS, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDT, MEDENDT, DEATHDT, AESEQ

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
BRMDEATH	char	Subject Death Identified Via CIOMS Form		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
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DSTYPE	char	End of Treatment or End of Trial		Collected at CRF.
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial?		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DEATHDY	num	Day of Death		Collected at CRF.
DSRELDY	num	Relative Day		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSACTDY	num	Relative Actual Day Trial Completion/Withdrawal		If DSACTDT and REF.DATE not missing then perform below logic to calculate DSACTDY, If DSACTDT less than REF.DATE then (DSACTDT - REF.DATE).Else if DSACTDT is greater than equal to REF.DATE then (DSACTDT- REF.DATE) +1.
DSDEATH	char	Subject Died During the Trial		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
PREGDUDY	num	Relative Pregnancy Due Day		If PREGDUDT and REF.DATE not missing then perform below logic to calculate PREGDUDY, If PREGDUDT less than REF.DATE then (PREGDUDT - REF.DATE).Else if PREGDUDT is greater than equal to REF.DATE then (PREGDUDT- REF.DATE) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDY and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDY less than REF.DATE then (MEDSTDY - REF.DATE).Else if MEDSTDY is greater than equal to REF.DATE then (MEDSTDY- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.17. Derived Efficacy Data – KEFF

Dataset	KEFF
Creating program	keff.sas
Description	Derived Efficacy Data
Unique identifier	DUSUBJID, ICUDY
Sorted by	DUSUBJID, ICUDY
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: ICUDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
RBCCUM29	num	Total Transfusion Units through D29		Collected at CRF.
RBCCUM42	num	Total Transfusion Units through D42		Collected at CRF.
HE29	num	D29 hemoglobin value		Collected at CRF.
HECHG29	num	D29 hemoglobin change from baseline		Collected at CRF.
HE42	num	D42 hemoglobin value		Collected at CRF.

Variable	Type	Label	Codes	Comments
HECHG42	num	D42 hemoglobin change from baseline		Collected at CRF.
HE140	num	D140 hemoglobin value		Collected at CRF.
HECHG140	num	D140 hemoglobin change from baseline		Collected at CRF.
NDOSE	num	Number of Doses Received		Collected at CRF.
MVDAY1	char	Require Mech. Vent. on D1		Collected at CRF.
MVDAY1C	num	Require Mech. Vent. on D1 Code		Collected at CRF.
MVDAY42	char	Init. Mech. Vent. off before D42		Collected at CRF.
MVDAY42C	num	Init. Mech. Vent. off before D42 Code		Collected at CRF.
MVDAY140	char	Init. Mech. Vent. off before D140		Collected at CRF.
MVDY140C	num	Init. Mech. Vent. off before D140 Code		Collected at CRF.
MVDUR42	num	Init. Mech. Vent. Duration through D42		Collected at CRF.
MVDUR140	num	Init. Mech. Vent. Duration through D140		Collected at CRF.
REMV42	char	Re-MV from D1 through D42		Collected at CRF.
REMV42C	num	Re-MV from D1 through D42 Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
REMV140	char	Re-MV from D1 through D140		Collected at CRF.
REMV140C	num	Re-MV from D1 through D140 Code		Collected at CRF.
NMV42	char	New MV from D1 through D42		Collected at CRF.
NMV42C	num	New MV from D1 through D42 Code		Collected at CRF.
NMV140	char	New MV from D1 through D140		Collected at CRF.
NMV140C	num	New MV from D1 through D140 Code		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
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MPD1	char	Commercial EPO use on or before D29		Collected at CRF.
MPD2	char	Expect Die/Discharge within 48 hrs		Collected at CRF.

Variable	Type	Label	Codes	Comments
MPD3	char	Acute Ischemic Cardiac Disease		Collected at CRF.
MPD4	char	History of TVE		Collected at CRF.
MPD5	char	New Seizures/not Controlled by Med.		Collected at CRF.
MPD6	char	At least 1 Dose Not Given due to PD		Collected at CRF.
MPD7	char	Dose Given when Hb \geq 12 g/dL		Collected at CRF.
MPD1C	num	Commercial EPO use on or before D29 Code		Collected at CRF.
MPD2C	num	Expect Die/Discharge within 48 hrs Code		Collected at CRF.
MPD3C	num	Acute Ischemic Cardiac Disease Code		Collected at CRF.
MPD4C	num	History of TVE Code		Collected at CRF.
MPD5C	num	New Seizures/not Controlled by Med. Code		Collected at CRF.
MPD6C	num	At least 1 Dose Not Given due to PD Code		Collected at CRF.
MPD7C	num	Dose Given when Hb \geq 12 g/dL Code		Collected at CRF.
RBC29	char	RBC transfusion D1-D29		Collected at CRF.
RBC29C	num	RBC transfusion D1-D29 Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
RBC42	char	RBC transfusion D1-D42		Collected at CRF.
RBC42C	num	RBC transfusion D1-D42 Code		Collected at CRF.
MORT29	char	Died on or before D29		Collected at CRF.
MORT29C	num	Died on or before D29 Code		Collected at CRF.
MORT140	char	Died on or before D140		Collected at CRF.
MORT140C	num	Died on or before D140 Code		Collected at CRF.
TMORT140	num	Time to Death through D140		Collected at CRF.
TFRBC29	num	Time to 1st RBC Transfusion through D29		Collected at CRF.
NSDOSE	num	Number of Sequential Doses Received		Collected at CRF.
ICUDDAY	num	Study Day of Initial ICU Discharge Date		Collected at CRF.
ICUL42	char	Init. ICU Discharge through D42		Collected at CRF.
ICUL42C	num	Init. ICU Discharge through D42 Code		Collected at CRF.
TICUL42	num	Init. ICU Length of Stay through D42		Collected at CRF.
ICUL140	char	Init. ICU Discharge through D140		Collected at CRF.
ICUL140C	num	Init. ICU Discharge through D140 Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
TICUL140	num	Init. ICU Length of Stay through D140		Collected at CRF.
REICU42	char	ICU readmissions through D42		Collected at CRF.
REICU42C	num	ICU readmissions through DCode		Collected at CRF.
HSPL42	char	Hosp. Length through D42		Collected at CRF.
HSPL42C	num	Hosp. Length through D42 Code		Collected at CRF.
THSPL42	num	Hosp. Length through D42		Collected at CRF.
HSPL140	char	Hosp. Length through D140		Collected at CRF.
HSPL140C	num	Hosp. Length through D140 Code		Collected at CRF.
THSPL140	num	Hosp. Length through D140		Collected at CRF.
ICUDY	num	Relative Day of Initial Discharge from ICU		If ICUDT and REF.DATE not missing then perform below logic to calculate ICUDY, If ICUDT less than REF.DATE then (ICUDT - REF.DATE).Else if ICUDT is greater than equal to REF.DATE then (ICUDT-REF.DATE) +1.

1.4.18. Derived Enrollment Data – KENROLL

Dataset	KENROLL
Creating program	kenroll.sas
Description	Derived Enrollment Data
Unique identifier	DUSUBJID, VISITNUM, ENCRESC, ENSEQ
Sorted by	DUSUBJID, VISITNUM, ENCRESC, ENSEQ
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: ENACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
STUDYID	char	Study ID		Collected at CRF.
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
ENCRIT	char	Inclusion or Exclusion Criterion		Collected at CRF.
ENSEQ	num	Criterion Sequence Number		Collected at CRF.
ENCRES	char	Criterion Result		Collected at CRF.
ENCRESC	num	Criterion Result Code		Collected at CRF.
ENTEXT	char	Criterion Text		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
ENACTDY	num	Relative Actual Day of Enrollment		If ENACTDT and REF.DATE not missing then perform below logic to calculate ENACTDY, If ENACTDT less than REF.DATE then (ENACTDT - REF.DATE).Else if ENACTDT is greater than equal to REF.DATE then (ENACTDT- REF.DATE) +1.

1.4.19. Derived Exposure Data – KEXPO

Dataset	KEXPO
Creating program	kexpo.sas
Description	Derived Exposure Data
Unique identifier	DUSUBJID, ACTTRT, EXSTDY
Sorted by	DUSUBJID, ACTTRT, EXSTDY
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: EXSTDY, MEDSTDY, MEDENDY, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXPTM	num	Planned Time of Administration		Collected at CRF.
EXTMLBL	char	Label of Planned Administration Time		Collected at CRF.
DOSENUM	num	Dose Number		Collected at CRF.
EXSTTM	num	Start Time of Exposure		Collected at CRF.
DOSE	num	Dose per Administration		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
EXRSND	char	Reason for Not Administering Drug		Collected at CRF.
EXRSNDC	num	Reason for Not Administering Drug Code		Collected at CRF.
EXPRTDEV	char	Protocol Violation		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
PRDOSHR	num	Time in ICU Prior to First Dose (Hour)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ICUTIME	char	Time in ICU Prior to First Dose		Collected at CRF.
ICUTIMEC	num	Time in ICU Prior to First Dose Code		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
EXACTSDY	num	Actual Day of Start of Dose		Collected at CRF.
EXACTEDY	num	Actual Day of End of Dose		Collected at CRF.
EXDUR	num	Duration		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDT less than REF.DATE then (EXSTDT - REF.DATE).Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.20. Derived Hematology Results 01 Data – KHEMA01

Dataset	KHEMA01
Creating program	khema01.sas
Description	Derived Hematology Results 01 Data
Unique identifier	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
Sorted by	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
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: LBPRVID, LBPRVIDC, LBACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDY, MEDENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPESPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPECPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTERMIN	char	Lab Test Term		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGNRHI	num	Upper Normal Range in Orig Unit		Collected at CRF.
ORGNRLO	num	Lower Normal Range in Orig Unit		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
ORGRESN	num	Numeric Result in Orig Unit		Collected at CRF.
ORGUNIT	char	Original Unit		Collected at CRF.
LBSIFACT	num	Conversion Factor to Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
STDNRLO	num	Lower Normal Range in Std Unit		Collected at CRF.
STDNRC	char	N Range for Std Char Result		Collected at CRF.
STDNRHI	num	Upper Normal Range in Std Unit		Collected at CRF.
STDUNIT	char	Standard Unit		Collected at CRF.
STDRESN	num	Numeric Result in Std Unit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
VALUE	num	Value		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.21. Derived Hematology Results 02 Data – KHEMA02

Dataset	KHEMA02
Creating program	khema02.sas
Description	Derived Hematology Results 02 Data
Unique identifier	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
Sorted by	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
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: LBPRVID, LBPRVIDC, LBACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDY, MEDENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
STUDYID	char	Study ID		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPESPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPECPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTERMIN	char	Lab Test Term		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGNRHI	num	Upper Normal Range in Orig Unit		Collected at CRF.
ORGNRLO	num	Lower Normal Range in Orig Unit		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
ORGRESN	num	Numeric Result in Orig Unit		Collected at CRF.
ORGUNIT	char	Original Unit		Collected at CRF.
LBSIFACT	num	Conversion Factor to Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
STDNRLO	num	Lower Normal Range in Std Unit		Collected at CRF.
STDNRC	char	N Range for Std Char Result		Collected at CRF.
STDNRHI	num	Upper Normal Range in Std Unit		Collected at CRF.
STDUNIT	char	Standard Unit		Collected at CRF.
STDRESN	num	Numeric Result in Std Unit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result (Verbatim)		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
VALUE	num	Value		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.22. Derived Hospital Discharge Data – KHOSPDIS

Dataset	KHOSPDIS
Creating program	khospdis.sas
Description	Derived Hospital Discharge Data
Unique identifier	DUSUBJID, VISITNUM, HDDEST
Sorted by	DUSUBJID, VISITNUM, HDDEST
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, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
HDNA	char	Hospital Discharge N/A		Collected at CRF.
HDNAC	num	Hospital Discharge N/A Code		Collected at CRF.
HDDEST	char	Hospital Discharge Destination		Collected at CRF.
HDDESTC	num	Hospital Discharge Destination Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
HDDISDY	num	Relative Day of hospital discharge		If HDDISDTC and REF.DATE not missing then perform below logic to calculate HDDISDY, If HDDISDTC less than REF.DATE then (HDDISDTC - REF.DATE).Else if HDDISDTC is greater than equal to REF.DATE then (HDDISDTC- REF.DATE) +1.

1.4.23. Derived All Transfers Within Hospital Data – KHOSPXFR

Dataset	KHOSPXFR
Creating program	khospxfr.sas
Description	Derived All Transfers Within Hospital Data
Unique identifier	DUSUBJID, VISITNUM, HOSEQ
Sorted by	DUSUBJID, VISITNUM, 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: HOACTDTC, HOACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
HOLOCAT	char	Subject's Location		Collected at CRF.
HOLOCATC	num	Subject's Location Code		Collected at CRF.
HOPAGNA	char	Not Applicable		Collected at CRF.
HOPAGNAC	num	Not Applicable Code		Collected at CRF.
HOSEQ	num	Transfer Sequence Number		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
HOACTDY	num	Relative Day of Admission for location		If HOACTDTC and REF.DATE not missing then perform below logic to calculate HOACTDY, If HOACTDTC less than REF.DATE then (HOACTDTC - REF.DATE).Else if HOACTDTC is greater than equal to REF.DATE then (HOACTDTC- REF.DATE) +1.

1.4.24. Derived Immunology Data – KIMMU

Dataset	KIMMU
Creating program	kimmu.sas
Description	Derived Immunology Data
Unique identifier	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
Sorted by	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
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: LBPRVID, LBPRVIDC, LBACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPESPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPECPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
LBTERM	char	Lab Test Term		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.25. Derived Surgical/Invasive Procedure Data – KINVASIV

Dataset	KINVASIV
Creating program	kinvasiv.sas
Description	Derived Surgical/Invasive Procedure Data
Unique identifier	DUSUBJID, VISITNUM, INDECOD1, INSEQ
Sorted by	DUSUBJID, VISITNUM, INDECOD1, INSEQ
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: INACTDT, INPROC, INRSN, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
INREPR	char	Were Any InvesProc. Reported		Collected at CRF.
INREPRC	num	Were Any InvesProc. Reported Code		Collected at CRF.
INSEQ	num	Invasive Procedure Sequence Number		Collected at CRF.
INAESEQ	num	AE/SAE Sequence Number		Collected at CRF.
INDECOD1	char	Procedure Specified Term		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
INACTDY	num	Relative Actual Day of Invasive Procedure		If INACTDT and REF.DATE not missing then perform below logic to calculate INACTDY, If INACTDT less than REF.DATE then (INACTDT - REF.DATE).Else if INACTDT is greater than equal to REF.DATE then (INACTDT- REF.DATE) +1.

1.4.26. Derived Mechanical Ventilation Data – KMCHVENT

Dataset	KMCHVENT
Creating program	kmchvent.sas
Description	Derived Mechanical Ventilation Data
Unique identifier	DUSUBJID, VISITNUM, MVSTDY, MVSEQ
Sorted by	DUSUBJID, VISITNUM, MVSTDY, MVSEQ
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: MVSTDTC, MVSTDY, MVENDTC, MVENDY, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MVREPR	char	Subject Required Mechanical Vent		Collected at CRF.
MVREPRC	num	Subject Required Mechanical Vent Code		Collected at CRF.
MVSEQ	num	Sequence Number		Collected at CRF.
MVCONT	char	Ventilation Continuing		Collected at CRF.
MVCONTC	num	Ventilation Continuing Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MVSTDY	num	Relative Start Day of Ventilation		If MVSTDTC and REF.DATE not missing then perform below logic to calculate MVSTDY, If MVSTDTC less than REF.DATE then (MVSTDTC - REF.DATE).Else if MVSTDTC is greater than equal to REF.DATE then (MVSTDTC- REF.DATE) +1.

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

1.4.27. Derived Medical History Data – KMEDHIST

Dataset	KMEDHIST
Creating program	kmedhist.sas
Description	Derived Medical History Data
Unique identifier	DUSUBJID, VISITNUM, MHBODSYS, MHSEQ
Sorted by	DUSUBJID, VISITNUM, MHBODSYS, MHSEQ
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: MHTERM, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.
MHBODSYC	num	Body System Code		Collected at CRF.
MHBODSYS	char	Body System		Collected at CRF.
MHSTAT	char	Condition		Collected at CRF.
MHSTATC	num	Condition Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.28. Derived Primary Malignancy Data – KMLIGNCY

Dataset	KMLIGNCY
Creating program	kmligncy.sas
Description	Derived Primary Malignancy Data
Unique identifier	DUSUBJID, VISITNUM, MGSEQ
Sorted by	DUSUBJID, VISITNUM, MGSEQ
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: MGSPEC, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
MGACCEL	char	Evidence of Disease Progression		Collected at CRF.
MGACCELC	num	Evidence of Disease Progression		Collected at CRF.
MGBIOLO	char	Anti-cancer Treatment - BIOLOGIC THERAPY		Collected at CRF.
MGBIOLOC	num	Anti-cancer Treatment - BIOLOGIC THERAPY		Collected at CRF.
MGCHEMO	char	Anti-cancer Treatment - CHEMOTHERAPY		Collected at CRF.
MGCHEMOC	num	Anti-cancer Treatment - CHEMOTHERAPY		Collected at CRF.
MGDGYR	num	Year Malignancy Diagnosed		Collected at CRF.
MGHEMAT	char	Primary Malignancy - Hematologic		Collected at CRF.
MGHEMATC	num	Primary Malignancy - Hematologic		Collected at CRF.
MGHOSP	char	Hospitalization Related to Malignancy		Collected at CRF.
MGHOSPC	num	Hospitalization Related to Malignancy		Collected at CRF.
MGHRMON	char	Anti-cancer Treatment - HORMONAL THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
MGHRMONC	num	Anti-cancer Treatment - HORMONAL THERAPY		Collected at CRF.
MGMTAST	char	Subject has Known Metastatic Disease		Collected at CRF.
MGMTASTC	num	Subject has Known Metastatic Disease		Collected at CRF.
MGNONE	char	Anti-cancer Treatment - NONE		Collected at CRF.
MGNONEC	num	Anti-cancer Treatment - NONE		Collected at CRF.
MGRADIA	char	Anti-cancer Treatment - RADIATION		Collected at CRF.
MGRADIAC	num	Anti-cancer Treatment - RADIATION		Collected at CRF.
MGREPRT	char	History of Malignancy		Collected at CRF.
MGREPRTC	num	History of Malignancy		Collected at CRF.
MGSEQ	num	MG Sequence Number		Collected at CRF.
MGSOLID	char	Primary Malignancy - Solid Tumor		Collected at CRF.
MGSOLIDC	num	Primary Malignancy - Solid Tumor		Collected at CRF.
MGSURGI	char	Anti-cancer Treatment - SURGICAL		Collected at CRF.
MGSURGIC	num	Anti-cancer Treatment - SURGICAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
MGYRUNK	char	Malignancy Diagnosis Year Unknown		Collected at CRF.
MGYRUNKC	num	Malignancy Diagnosis Year Unknown		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.29. Derived History of Myocardial Ischemia/Infarction Data – KMYISCIN

Dataset	KMYISCIN
Creating program	kmyiscin.sas
Description	Derived History of Myocardial Ischemia/Infarction Data
Unique identifier	DUSUBJID, VISITNUM, MYEVENTC
Sorted by	DUSUBJID, VISITNUM, MYEVENTC
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, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
MYEVENT	char	Type of Event		Collected at CRF.
MYEVENTC	num	Type of Event Code		Collected at CRF.
MYOCCUR	char	Did the Event Occur?		Collected at CRF.
MYOCCURC	num	Did the Event Occur?		Collected at CRF.
MYWHEN	char	When did the Event Occur?		Collected at CRF.
MYWHENC	num	When did the Event Occur?		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.30. Derived Non-Red Blood Cell Transfusions Data– KNRTFRFS

Dataset	KNRTFRFS
Creating program	knrtfrfs.sas
Description	Derived Non-Red Blood Cell Transfusions Data
Unique identifier	DUSUBJID, VISITNUM, NRPRODC, NRACTDY, NRSEQ
Sorted by	DUSUBJID, VISITNUM, NRPRODC, NRACTDY, NRSEQ
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: NRACTDTC, NRACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
NRREPRT	char	Any Non-Red Blood Cell Transfusions		Collected at CRF.
NRREPRTC	num	Any Non-Red Blood Cell Transfusions Code		Collected at CRF.
NRSEQ	num	Sequence Number		Collected at CRF.
NRTRFSN	num	Total Number of Units Transfused		Collected at CRF.
NRTRFUNT	char	Label for Total Number of Units		Collected at CRF.
NRVOLUME	num	Total Volume of Transfusion		Collected at CRF.
NRVOLUNT	char	Label for Unit of Volume		Collected at CRF.
NRPROD	char	Product Transfusion		Collected at CRF.
NRPRODC	num	Product Transfusion Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		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.
NRACTDY	num	Relative Day of Transfusion		If NRACTDTC and REF.DATE not missing then perform below logic to calculate NRACTDY, If NRACTDTC less than REF.DATE then (NRACTDTC - REF.DATE).Else if NRACTDTC is greater than equal to REF.DATE then (NRACTDTC- REF.DATE) +1.

1.4.31. Derived Predose Blood Samples Data – KPCCNC

Dataset	KPCCNC
Creating program	kpcnc.sas
Description	Derived Predose Blood Samples Data
Unique identifier	DUSUBJID, VISITNUM, PCTEST, PCSEQ
Sorted by	DUSUBJID, VISITNUM, PCTEST, PCSEQ
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: PCSTDT, PCPRVIDC, TPT, TPTNUM, PCSPEC, ACQREF, SPPRVIDC, SAMREF, PCORRES, PCORUNIT, PCORRESN, PCSTRESC, PCSTUNIT, PCSTRESN, PCSPCOM, PCLOQ, PCPRMTYP, PCVTYPE, PCVTYPEC, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PCSTTM	num	Start Time of Collection (24hr clock)		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
PCTEST	char	Test Name		Collected at CRF.
PCTESTC	num	Test Name Code		Collected at CRF.
PCNAC	num	Page Not Applicable Code		Collected at CRF.
PCNA	char	Page Not Applicable		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

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

1.4.32. Derived Physical Examination Data – KPE

Dataset	KPE
Creating program	kpe.sas
Description	Derived Physical Examination Data
Unique identifier	DUSUBJID, VISITNUM, PEBODSYS, PEACTION, PESEQ
Sorted by	DUSUBJID, VISITNUM, PEBODSYS, PEACTION, PESEQ
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: PEACTDT, PESYSOTH, PEFIND, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.
PEBODSYC	num	Body System Code		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESTAT	char	Exam Result		Collected at CRF.
PESTATC	num	Exam Result Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
PERELDY	num	Relative Day		Collected at CRF.
PEACTDY	num	Actual Day of Phys Exam		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.

1.4.33. Derived Phone Call Log Data – KPHONELO

Dataset	KPHONELO
Creating program	kphoneho.sas
Description	Derived Phone Call Log Data
Unique identifier	DUSUBJID, VISITNUM, PLACTDY, PLSEQ
Sorted by	DUSUBJID, VISITNUM, PLACTDY, PLSEQ
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: PLACTDTC, PLACTDT, PLPEROTH, PLLOCOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PLPAGNA	char	Not Applicable		Collected at CRF.
PLPAGNAC	num	Not Applicable Code		Collected at CRF.
PLSEQ	num	Sequence Number		Collected at CRF.
PLPERSN	char	Person Who Was Contacted		Collected at CRF.
PLPERSNC	num	Person Who Was Contacted Code		Collected at CRF.
PLOCATE	char	Subject Location		Collected at CRF.
PLOCATEC	num	Subject Location Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		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.
PLACTDY	num	Relative Day of Phone Call		If PLACTDTC and REF.DATE not missing then perform below logic to calculate PLACTDY, If PLACTDTC less than REF.DATE then (PLACTDTC - REF.DATE).Else if PLACTDTC is greater than equal to REF.DATE then (PLACTDTC- REF.DATE) +1.

1.4.34. Derived Phlebotomy Data – KPLEBOTM

Dataset	KPLEBOTM
Creating program	kplebotm.sas
Description	Derived Phlebotomy Data
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
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: FLPRHGDT, FLACTDT, FLPSHGDT, FLPRHGRS, FLPRHGUC, FLPRHGU, FLVOL, FLPSHGRS, FLPSHGUC, FLPSHGU, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

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

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
FLREPRTC	num	Were any phlebotomies reported code		Collected at CRF.
FLREPRT	char	Were any phlebotomies reported?		Collected at CRF.
FLSEQ	num	Phlebotomy Information		Collected at CRF.
FLVOLUC	num	Original Units of Volume Code (308)		Collected at CRF.
FLVOLU	char	Original Units of Volume (ml)		Collected at CRF.
FLHGTSC	num	Hemoglobin Test Code (1075)		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.35. Derived Pneumatic Compression Data – KPNECOMP

Dataset	KPNECOMP
Creating program	kpnecomp.sas
Description	Derived Pneumatic Compression Data
Unique identifier	DUSUBJID, VISITNUM, NCSTDY, NCSEQ
Sorted by	DUSUBJID, VISITNUM, NCSTDY, NCSEQ
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: NCSTDTC, NCSTDY, NCENDTC, NCENDY, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
NCREPRT	char	Were Any NCs Reported		Collected at CRF.
NCREPRTC	num	Were Any NCs Reported Code		Collected at CRF.
NCSEQ	num	NC Sequence Number		Collected at CRF.
NCCONT	char	NC Continuing		Collected at CRF.
NCCONTC	num	NC Continuing Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

Variable	Type	Label	Codes	Comments
NCSTDY	num	Relative Actual Start Day of Event		If NCSTDTC and REF.DATE not missing then perform below logic to calculate NCSTDY, If NCSTDTC less than REF.DATE then (NCSTDTC - REF.DATE).Else if NCSTDTC is greater than equal to REF.DATE then (NCSTDTC- REF.DATE) +1.
NCENDY	num	Relative Actual End Day of Event		If NCENDTC and REF.DATE not missing then perform below logic to calculate NCENDY, If NCENDTC less than REF.DATE then (NCENDTC - REF.DATE).Else if NCENDTC is greater than equal to REF.DATE then (NCENDTC- REF.DATE) +1.

1.4.36. Derived Serum Pregnancy Test Data – KPREGNCY

Dataset	KPREGNCY
Creating program	kpregncy.sas
Description	Derived Serum Pregnancy Test Data
Unique identifier	DUSUBJID, VISITNUM, PGTYPE, PGACTDY
Sorted by	DUSUBJID, VISITNUM, PGTYPE, PGACTDY
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: PGACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
PREGRES	char	Pregnancy Test Result		Collected at CRF.
PREGRESC	num	Pregnancy Test Result Code		Collected at CRF.
PGNA	char	Pregnancy N/A		Collected at CRF.
PGNAC	num	Pregnancy N/A Code		Collected at CRF.
PGTYPE	char	Type of Pregnancy Test Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
PGACTDY	num	Relative Actual Day of Pregnancy Test		If PGACTDT and REF.DATE not missing then perform below logic to calculate PGACTDY, If PGACTDT less than REF.DATE then (PGACTDT - REF.DATE).Else if PGACTDT is greater than equal to REF.DATE then (PGACTDT- REF.DATE) +1.

1.4.37. Derived Protocol Description Data – KPROTDES

Dataset	KPROTDES
Creating program	kprotdes.sas
Description	Derived Protocol Description Data
Unique identifier	STUDYID
Sorted by	STUDYID
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
COMPND	char	Compound Name		Collected at CRF.
COMPNDC	char	Compound Number		Collected at CRF.
BLINDING	char	Blinding Level		Collected at CRF.
ACTCONTR	char	Active Control		Collected at CRF.
PLACONTR	char	Placebo Control		Collected at CRF.
DESIGN	char	Trial Design		Collected at CRF.
MULTCENT	char	Multi Center		Collected at CRF.
INDICAT	char	Indication		Collected at CRF.
DEVPROID	char	Development Program Id		Collected at CRF.
AGEGRP	char	Age Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
SPECPOP	char	Special Population		Collected at CRF.
SUBJTYPE	char	Subject Type		Collected at CRF.
PROCSTUD	char	Proceeding Study Id		Collected at CRF.
STUDPHAS	char	Phase of Study		Collected at CRF.

1.4.38. Derived Protocol Deviation Data – KPROTDEV

Dataset	KPROTDEV
Creating program	kprotdev.sas
Description	Derived Protocol Deviation Data
Unique identifier	DUSUBJID, PVDECOD, PVSEQ
Sorted by	DUSUBJID, PVDECOD, PVSEQ
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: PVTERM, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.39. Derived Randomization Data – KRANDOM

Dataset	KRANDOM
Creating program	krandom.sas
Description	Derived Randomization Data
Unique identifier	DUSUBJID, TRTGRP
Sorted by	DUSUBJID, TRTGRP
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: RAACTDT, RANDNUM, KITNUM1, KITNUM2, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DOSE	char	Dose		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
DURATION	char	Duration		Collected at CRF.
FORMULAT	char	Formulation		Collected at CRF.
FREQ	char	Frequency		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
STRENGTH	char	Strength		Collected at CRF.
INSTRUCT	char	Instructions		Collected at CRF.
RASEQ	num	Randomization Sequence Number		Collected at CRF.
STRATUM1	char	Stratum 1		Collected at CRF.
REGIMEN	char	Regimen		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		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.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and REF.DATE not missing then perform below logic to calculate RAACTDY, If RAACTDT less than REF.DATE then (RAACTDT - REF.DATE).Else if RAACTDT is greater than equal to REF.DATE then (RAACTDT- REF.DATE) +1.

1.4.40. Derived Red Blood Cell Transfusions Data – KRBCTRFS

Dataset	KRBCTRFS
Creating program	krbctrfs.sas
Description	Derived Red Blood Cell Transfusions Data
Unique identifier	DUSUBJID, VISITNUM, RBACTDY, RBSEQ
Sorted by	DUSUBJID, VISITNUM, RBACTDY, RBSEQ
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: RBACTDTC, RBACTDT, RBRSNOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		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
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
RBREPRT	char	Did subject require RBC transfusion?		Collected at CRF.
RBREPRTC	num	Did subject require RBC transfusion Code		Collected at CRF.
RBSEQ	num	Sequence Number		Collected at CRF.
RBPRHG	num	Pre-Transfusion Hemoglobin		Collected at CRF.
RBPRHGUC	num	Pre-Transfusion Hemoglobin Unit Code		Collected at CRF.
RBPRHGU	char	Pre-Transfusion Hemoglobin Unit		Collected at CRF.
RBUNUM	num	Total Number of Daily Units Trans.		Collected at CRF.
RBLKDP	char	Leukocyte Depleted		Collected at CRF.
RBNLKDP	char	Non-Leukocyte Depleted		Collected at CRF.

Variable	Type	Label	Codes	Comments
RBLKUNK	char	Leukocyte Types Unknown		Collected at CRF.
RBRHMG	char	Reason Maint. Hemoglobin between 7-9g/dL		Collected at CRF.
RBRBLD	char	Reason Acute Bleeding		Collected at CRF.
RBRISCH	char	Reason Ischemia (Cardiac or Vascular)		Collected at CRF.
RBRUNK	char	Unknown Reason for Transfusion		Collected at CRF.
RBROTH	char	Other Reason for Transfusion		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
RBACTDY	num	Relative Day of Transfusion		If RBACTDTC and REF.DATE not missing then perform below logic to calculate RBACTDY, If RBACTDTC less than REF.DATE then (RBACTDTC - REF.DATE).Else if RBACTDTC is greater than equal to REF.DATE then (RBACTDTC- REF.DATE) +1.

1.4.41. Derived Smoking History Data– KSMOKING

Dataset	KSMOKING
Creating program	ksmoking.sas
Description	Derived Smoking History Data
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
Notes	Below listed variables will be dropped from dataset due to repetition of the information: SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
SMWHEN	char	History of Smoking		Collected at CRF.
SMWHENC	num	History of Smoking Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.

1.4.42. Derived SOFA Scores Data – KSOFA

Dataset	KSOFA
Creating program	ksofa.sas
Description	Derived SOFA Scores Data
Unique identifier	DUSUBJID, VISITNUM, SFACTDY, SFSEQ
Sorted by	DUSUBJID, VISITNUM, SFACTDY, SFSEQ
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: SFACTDTC, SFACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SFSEQ	num	SOFA Sequence Number		Collected at CRF.
SFRSP	num	SOFA Respiration		Collected at CRF.
SFRCPND	char	SOFA Respiration Not Done		Collected at CRF.
SFRCPNDC	num	SOFA Respiration Not Done Code		Collected at CRF.
SFPC	num	SOFA Coagulation		Collected at CRF.
SFPCND	char	SOFA Coagulation Not Done		Collected at CRF.
SFPCNDC	num	SOFA Coagulation Not Done Code		Collected at CRF.
SFLIV	num	SOFA Liver		Collected at CRF.
SFLIVNDC	num	SOFA Liver Not Done Code		Collected at CRF.
SFLIVND	char	SOFA Liver Not Done		Collected at CRF.
SFCV	num	SOFA Cardiovascular		Collected at CRF.
SFCNS	num	SOFA CNS		Collected at CRF.
SFREN	num	SOFA Renal		Collected at CRF.
SFRENDC	num	SOFA Renal Not Done Code		Collected at CRF.
SFRENND	char	SOFA Renal Not Done		Collected at CRF.
SFDAY	char	SOFA DAY		Collected at CRF.
SFDAYNA	char	SOFA Day Not Applicable		Collected at CRF.

Variable	Type	Label	Codes	Comments
SFDAYNAC	num	SOFA Day Not Applicable Code		Collected at CRF.
TSCORE	num	Total SOFA Score		Collected at CRF.
TSCORBAS	num	Total SOFA Score at Baseline		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TSCORCHG	num	Total SOFA Score Change from Baseline		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
SFACTDY	num	Relative Actual day of SOFA		If SFACTDTC and REF.DATE not missing then perform below logic to calculate SFACTDY, If SFACTDTC less than REF.DATE then (SFACTDTC - REF.DATE).Else if SFACTDTC is greater than equal to REF.DATE then (SFACTDTC- REF.DATE) +1.

1.4.43. Derived Trauma Assessment Data – KTRAUMA

Dataset	KTRAUMA
Creating program	ktrauma.sas
Description	Derived Trauma Assessment Data
Unique identifier	DUSUBJID, VISITNUM, TRINJURC, TRSEQ
Sorted by	DUSUBJID, VISITNUM, TRINJURC, TRSEQ
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: TRACTDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
TRPAGNU	char	Is Page Not Used		Collected at CRF.
TRPAGNUC	num	Is Page Not Used Code		Collected at CRF.
TRSEQ	num	Trauma Sequence Number		Collected at CRF.
TRSITE	char	Site of Injury		Collected at CRF.
TRRESN	num	Abbreviated Injury Score		Collected at CRF.
TRINJUR	char	Injury Type		Collected at CRF.
TRINJURC	num	Injury Type Code		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
TRACTDY	num	Relative Actual Recorded Day of Trauma		If TRACTDT and REF.DATE not missing then perform below logic to calculate TRACTDY, If TRACTDT less than REF.DATE then (TRACTDT - REF.DATE).Else if TRACTDT is greater than equal to REF.DATE then (TRACTDT- REF.DATE) +1.

1.4.44. Derived Thrombo-Vascular Event Data – KTVEVENT

Dataset	KTVEVENT
Creating program	ktvevent.sas
Description	Derived Thrombo-Vascular Event Data
Unique identifier	DUSUBJID, VISITNUM, TVEVENTC, TVACTDY, TVSEQ
Sorted by	DUSUBJID, VISITNUM, TVEVENTC, TVACTDY, TVSEQ
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: TVACTDTC, TVACTDT, TVARTOTH , TVDVTOTH, TVVENOTH, TVCNFOTH, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
TVSEQ	num	TVE Sequence Number		Collected at CRF.
AESEQ	num	AE/SAE Sequence Number from AE/SAE Page		Collected at CRF.
TVEVENTC	num	Type of TVE Code		Collected at CRF.
TVEVENT	char	Type of TVE		Collected at CRF.
TVSBSTRC	num	Type of Stroke Code		Collected at CRF.
TVSBSTR	char	Type of Stroke		Collected at CRF.
TVSBDVTC	num	Type of DVT Code		Collected at CRF.
TVSBDVT	char	Type of DVT		Collected at CRF.
TVCATHC	num	Is TVE Catheter Related Code		Collected at CRF.
TVCATH	char	Is TVE Catheter Related		Collected at CRF.
TVCNFRMC	num	Is TVE Confirmed Code		Collected at CRF.
TVCNFRM	char	Is TVE Confirmed		Collected at CRF.
TVCNFSEQ	num	TVE Sequence Number, Confirming Methods		Collected at CRF.
TVCNMET	char	Confirming Methods for TVE		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
TVACTDY	num	Relative Actual Day of TV Event		If TVACTDTC and REF.DATE not missing then perform below logic to calculate TVACTDY, If TVACTDTC less than REF.DATE then (TVACTDTC - REF.DATE).Else if TVACTDTC is greater than equal to REF.DATE then (TVACTDTC- REF.DATE) +1.

1.4.45. Derived Urinalysis Data – KURIN

Dataset	KURIN
Creating program	kurin.sas
Description	Derived Urinalysis Data
Unique identifier	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
Sorted by	DUSUBJID, VISITNUM, LBTESTC, LBACTDY, LBSEQ
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: LBPRVID, LBPRVIDC, LBACTDT, LBTERM, STDUNIT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE, MEDSTDY, MEDENDT

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBTSPEC	char	Specified/Unspecified Test		Collected at CRF.
LBTSPEC	num	Specified/Unspecified Test Code		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBDESCR	char	Full Lab Test Description		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
ORGRES	char	Char Result in Orig Unit		Collected at CRF.
ORGRESN	num	Numeric Result in Orig Unit		Collected at CRF.
ORGUNIT	char	Original Unit		Collected at CRF.
ORGNRHI	num	Upper Normal Range in Orig Unit		Collected at CRF.
ORGNRLO	num	Lower Normal Range in Orig Unit		Collected at CRF.
LBSIFACT	num	Conversion Factor to Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
NRIND	char	Normal Range Indicator		Collected at CRF.
STDRESC	char	Character Result in Std Unit		Collected at CRF.
STDNRLO	num	Lower Normal Range in Std Unit		Collected at CRF.
STDNRC	char	N Range for Std Char Result		Collected at CRF.
STDNRHI	num	Upper Normal Range in Std Unit		Collected at CRF.
STDRESN	num	Numeric Result in Std Unit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
LBTERM	char	Lab Result		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
LBACTDY	num	Actual Day of Sample		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.
PCHANGE	num	Percent Change from Baseline		Collected at CRF.

Variable	Type	Label	Codes	Comments
VALUE	num	Value		Collected at CRF.
LBACTTM	num	Actual Time of Sample		Collected at CRF.
LBSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE).Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- REF.DATE) +1.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE).Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.

1.4.46. Derived Visit Data – KVISIT

Dataset	KVISIT
Creating program	kvisit.sas
Description	Derived Visit Data
Unique identifier	DUSUBJID, VISITNUM
Sorted by	DUSUBJID, VISITNUM
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: VISITDT, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
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
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE).Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

1.4.47. Derived Vital Signs Data – KVITAL

Dataset	KVITAL
Creating program	kvital.sas
Description	Derived Vital Signs Data
Unique identifier	DUSUBJID, VISITNUM, VSTESTCD, VSACTDY, VSSEQ
Sorted by	DUSUBJID, VISITNUM, VSTESTCD, VSACTDY, VSSEQ
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, SEX, SEXC, RACE, RACEC, COUNTRY, COUNTRYC, IVNAME, AGE

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISITNUM	num	Visit ID		Collected at CRF.
VSORUNIT	char	Original Units		Collected at CRF.
VSSTUNIT	char	Standard Unit		Collected at CRF.
VSORRESN	num	Numeric Result in Original Units		Collected at CRF.
BASE	num	Value at Baseline		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISIT	char	Visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
VSORRES	char	Result in Original Units		Collected at CRF.
VSSTRESC	char	Character Result in Standard Units		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
CHANGE	num	Change from Baseline		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSRELDY	num	Relative Day		Collected at CRF.
PCHANGE	num	Percent Change from Baseline		Collected at CRF.
ITT	char	Evaluable for Intent-to-Treat		Collected at CRF.
SAFETY	char	Evaluable for Safety		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and REF.DATE not missing then perform below logic to calculate VSACTDY, If VSACTDT less than REF.DATE then (VSACTDT - REF.DATE).Else if VSACTDT is greater than equal to REF.DATE then (VSACTDT- REF.DATE) +1.