Clinical Development

JNJ-7472179

EPO_INT2

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided due to sensitivity of the data.
- 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+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Catalog number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Datasets with zero observations will not be submitted (ex. KEYADVE, KEYDOSE, PROFILE, REASON).
- JOURNAL dataset will not be submitted because It seems to be investigators diary information.
- Comment dataset (CMNT) will be submitted with zero observation.
- DEMO.VDATE (Visit Date) will be used as Reference Date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files

The EPO_INT2 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domain

1.4.1. Demographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE,BIRTH, BIRTHF,OTHER Below listed variable is not a part of raw dataset. It has been added to retain the age related information in the De-identified dataset: AGE (Source: PAT Dataset) DCOUNTRY (Source: PAT Dataset)

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.

Variable	Type	Label	Codes	Comments
DSITE	char	SITE ASSIGNED FOR DE-IDENTITY		Randomly assigned site for De-Identity.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
SEX	num	SEX		Collected at CRF.
RACE	num	RACE		Collected at CRF.
AGE	char	AGE IN YEARS		Element will be grouped to protect subject PII as per HIPPA rules: If age is greater than 89 then "90+".
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.

1.4.2. Study Drug Administration S.C.– ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Study Drug Administration S.C.
Unique identifier	STUDY,DPAT,GROUP,VDAY,DOSENO,EVNT_ID
Sorted by	STUDY,DPAT,GROUP,VDAY,DOSENO,EVNT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
DOSENO	num	DOSE NO.		Collected at CRF.
VDATEF	num	DATE FLAG		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
DOSE	num	DOSE (U/KG)		Collected at CRF.
DISP	num	DISPENSED (MLS)		Collected at CRF.
VDY	num	RELATIVE DAY		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.3. Clinical Adverse Events – ADVE

Dataset	ADVE
Creating program	adve.sas
Description	Clinical Adverse Events
Unique identifier	STUDY,DPAT,GROUP,WHOCODE ,EVNT_ID,CDAY,SDAY,ONSETDY
Sorted by	STUDY,DPAT,GROUP, WHOCODE,EVNT_ID,CDAY,SDAY,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,CDATE,DONSET,SDATE,ADVCOM,ADVCOM1,_USER_,_DATE_, ADVSPE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
CDATEF	num	DATE COMPLETED FLAG		Collected at CRF.
ADVEXP	num	CHECK IF NO TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
WHOCODE	char	WHOCODE		Collected at CRF.
BY_WHOCO	char	CODE DEFINITION SAS		Collected at CRF.
ADVNOV	char	NOVACODE NOT ENTERED		Collected at CRF.
DONSETF	num	ONSET DATE FLAG		Collected at CRF.
ADVSEV	num	SEVERITY		Collected at CRF.
ADVREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
ADVCON	num	CONTROL MEASURE		Collected at CRF.
RESULT	num	RESULTS		Collected at CRF.
SDATEF	num	STOP DATE FLAG		Collected at CRF.
DEATH	num	DEATH		Collected at CRF.
LIFE	num	LIFE THREATENING		Collected at CRF.
DISABIL	num	PERMANENT DISABILITY		Collected at CRF.
HOSP	num	HOSPITALIZATION		Collected at CRF.
CANCER	num	CANCER		Collected at CRF.
CONGEN	num	CONGENITAL ANOMALY		Collected at CRF.
OVERDOSE	num	OVERDOSE		Collected at CRF.
ORIG_TXT	char	ORIGINAL TEXT SAS		Collected at CRF.
CDY	num	RELATIVE DAY COMPLETED		If CDATE and REF. DATE not missing then perform below logic to calculate CDY, If CDATE less than REF. DATE then (CDATE - REF.DATE). Else if CDATE is greater than equal to REF. DATE then (CDATE-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ONSETDY	num	RELATIVE ONSET DAY		If DONSET and REF. DATE not missing then perform below logic to calculate ONSETDY, If DONSET less than REF. DATE then (DONSET - REF.DATE). Else if DONSET is greater than equal to REF. DATE then (DONSET- REF.DATE) +1.
SDY	num	RELATIVE STOP DAY		If SDATE and REF. DATE not missing then perform below logic to calculate SDY, If SDATE less than REF. DATE then (SDATE - REF.DATE). Else if SDATE is greater than equal to REF. DATE then (SDATE- REF.DATE) +1.
_TM	num	CODE TIME SAS		If _DATE_ contains time part then timepart(_DATE_) else _TM equal to NULL.
_DY	num	RELATIVE CODE DAY SAS		If _DATE_ and REF. DATE not missing then perform below logic to calculate _DY, If _DATE_ less than REF. DATE then (_DATE_ - REF.DATE). Else if _DATE_ is greater than equal to REF. DATE then (_DATE_- REF.DATE) +1.

1.4.4. Clinical Adverse Events 2 – ADVE2

Dataset	ADVE2
Creating program	adve2.sas
Description	Clinical Adverse Events 2
Unique identifier	STUDY,DPAT,GROUP, EVNT_ID,CDAY,SDAY,ONSETDY
Sorted by	STUDY,DPAT,GROUP, EVNT_ID,CDAY,SDAY,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,CDATE,DONSET,SDATE,ADVCOM,ADVCOM1

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
CDATEF	num	DATE COMPLETED FLAG		Collected at CRF.
ADVEXP	num	CHECK IF NO TREATMENT		Collected at CRF.
ADVNOV	char	NOVACODE NOT ENTERED		Collected at CRF.
DONSETF	num	ONSET DATE FLAG		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVSEV	num	SEVERITY		Collected at CRF.
ADVREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
ADVCON	num	CONTROL MEASURE		Collected at CRF.
RESULT	num	RESULTS		Collected at CRF.
SDATEF	num	STOP DATE FLAG		Collected at CRF.
DEATH	num	DEATH		Collected at CRF.
LIFE	num	LIFE THREATENING		Collected at CRF.
DISABIL	num	PERMANENT DISABILITY		Collected at CRF.
HOSP	num	HOSPITALIZATION		Collected at CRF.
CANCER	num	CANCER		Collected at CRF.
CONGEN	num	CONGENITAL ANOMALY		Collected at CRF.
OVERDOSE	num	OVERDOSE		Collected at CRF.
CDY	num	RELATIVE DAY COMPLETED		If CDATE and REF. DATE not missing then perform below logic to calculate CDY, If CDATE less than REF. DATE then (CDATE - REF.DATE). Else if CDATE is greater than equal to REF. DATE then (CDATE-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ONSETDY	num	RELATIVE ONSET DAY		If DONSET and REF. DATE not missing then perform below logic to calculate DY, If DONSET less than REF. DATE then (DONSET - REF.DATE). Else if DONSET is greater than equal to REF. DATE then (DONSET- REF.DATE) +1.
SDY	num	RELATIVE STOP DAY		If SDATE and REF. DATE not missing then perform below logic to calculate SDY, If SDATE less than REF. DATE then (SDATE - REF.DATE). Else if SDATE is greater than equal to REF. DATE then (SDATE-REF.DATE) +1.

1.4.5.Auxi – AUXI

Dataset	AUXI
Creating program	auxi.sas
Description	Auxi
Unique identifier	STUDY,DPAT,EVNT_ID,IN_OUT,AUXIT
Sorted by	STUDY,DPAT,EVNT_ID,IN_OUT,AUXIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,AUXI1,AUXI_T1,AUXI2,AUXI_T2,AUXI3,AUXI_T3

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
OUTVNO	num	OUTVNO		Collected at CRF.
AUXI4	num	AUXI4		Collected at CRF.
AUXI_T4	num	AUXI_T4		Collected at CRF.
AUXI_OT	num	AUXI_OT		Collected at CRF.
AUXI_T5	num	AUXI_T5		Collected at CRF.
AUXI_SP	char	AUXI_SP		Collected at CRF.
AUXIT	num	AUXIT		Collected at CRF.

1.4.6.Check – CHECK

Dataset	CHECK
Creating program	check.sas
Description	Check
Unique identifier	STUDY,DPAT,GROUP,VDAY
Sorted by	STUDY,DPAT,GROUP,VDAY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
Q1	num	COMPLETED DOUBLE-BLIND PHASE ?		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q2	num	THERMINATION OF DB PHASE < 7 DAYS		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.7.Chem – CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Chem
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDAY,IDAY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDAY,IDAY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE,IDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE BLOOD CHEMISTRY FLAG		Collected at CRF.
C208	num	CALCIUM		Collected at CRF.
C201	num	SODIUM		Collected at CRF.
C202	num	POTASSIUM		Collected at CRF.
C203	num	CHLORIDE		Collected at CRF.
C206	num	BUN		Collected at CRF.
C215	num	TOTAL BILIRUBIN		Collected at CRF.
C210	num	TOTAL PROTEIN		Collected at CRF.
C213	num	ALBUMIN		Collected at CRF.
C207	num	URIC ACID		Collected at CRF.
C214	num	ALK.PHOSPHATASE		Collected at CRF.
C217	num	SGOT		Collected at CRF.
C225	num	SGPT		Collected at CRF.
C218	num	LDH		Collected at CRF.
C205	num	CREATININE		Collected at CRF.
IDATEF	num	VISIT DATE FLAG IRON PROFILE		Collected at CRF.
C216	num	SERUM IRON		Collected at CRF.

Variable	Type	Label	Codes	Comments
C285	num	SERUM FERRITIN		Collected at CRF.
C289	num	TIBC		Collected at CRF.
C287	num	TRANSFERRIN		Collected at CRF.
C283	num	SERUM FOLATE		Collected at CRF.
C284	num	SERUM B 12		Collected at CRF.
OBS	num	OBS		Collected at CRF.
VDY	num	RELATIVE VISIT DAY BLOOD CHEMISTRY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.
IDY	num	RELATIVE VISIT DAY IRON PROFILE		If IDATE and REF. DATE not missing then perform below logic to calculate IDY, If IDATE less than REF. DATE then (IDATE - REF.DATE). Else if IDATE is greater than equal to REF. DATE then (IDATE-REF.DATE) +1.

1.4.8.Chemotherapy – CHEMO

Dataset	CHEMO
Creating program	chemo.sas
Description	Chemotherapy
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,DRUG,STARTDY,STOPDY,STRENG
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,DRUG,STARTDY,STOPDY,STRENG
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,CODE,START,STOP

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
CYCLES	num	HOW MANY CYCLES OF CHEMOTHERAPY		Collected at CRF.
CHEMO	num	CHEMOTHERAPY YES/NO		Collected at CRF.
DRUG	char	DRUG/TREATMENT		Collected at CRF.
STARTF	num	START DATE FLAG		Collected at CRF.

Variable	Type	Label	Codes	Comments
STOPF	num	STOP DATE FLAG		Collected at CRF.
ROUTE	char	ROUTE		Collected at CRF.
STRENG	char	STRENGTH		Collected at CRF.
REGI	char	REGIMEN		Collected at CRF.
STARTDY	num	RELATIVE START DAY		If START and REF. DATE not missing then perform below logic to calculate STARTDY, If START less than REF. DATE then (START - REF.DATE). Else if START is greater than equal to REF. DATE then (START- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOP and REF. DATE not missing then perform below logic to calculate STOPDY, If STOP less than REF. DATE then (STOP - REF.DATE). Else if STOP is greater than equal to REF. DATE then (STOP- REF.DATE) +1.

1.4.9.Comment – CMNT

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

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Empty data will be submitted.
STUDY	char	STUDY NUMBER		Empty data will be submitted.
GROUP	num	RANDOMIZATION GROUP		Empty data will be submitted.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Empty data will be submitted.
EVNT_ID	num	WEEK		Empty data will be submitted.
QU	num	QUESTION NUMBER		Empty data will be submitted.
OBS	num	OBS		Empty data will be submitted.

1.4.10. Current Medications – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Current Medications
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,CDAY,DRUG,STARTDY,STOPDY,INDICAT
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,CDAY,DRUG,STARTDY,STOPDY,INDICAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,CDATE,CODE,START,STOP,INDICAT

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
CDATEF	num	DATE FORM COMPLETED FLAG		Collected at CRF.
EVNT_ID	num	WEEK		Collected at CRF.
CONMED	num	CONCURRENT THERAPY/CHANGE		Collected at CRF.
NO	num	NUMBER		Collected at CRF.
DRUG	char	DRUG/TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTF	num	START DATE FLAG		Collected at CRF.
CONT	num	CONTINUED		Collected at CRF.
STOPF	num	STOP DATE FLAG		Collected at CRF.
RTE	char	ROUTE		Collected at CRF.
TDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
EMERG	num	TREATMENT FOR AE		Collected at CRF.
CDY	num	RELATIVE DAY FORM COMPLETED		If CDATE and REF. DATE not missing then perform below logic to calculate CDY, If CDATE less than REF. DATE then (CDATE - REF.DATE). Else if CDATE is greater than equal to REF. DATE then (CDATE-REF.DATE) +1.
STARTDY	num	RELATIVE START DAY		If START and REF. DATE not missing then perform below logic to calculate STARTDY, If START less than REF. DATE then (START - REF.DATE). Else if START is greater than equal to REF. DATE then (START- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOP and REF. DATE not missing then perform below logic to calculate STOPDY, If STOP less than REF. DATE then (STOP - REF.DATE). Else if STOP is greater than equal to REF. DATE then (STOP-REF.DATE) +1.

1.4.11. Current Medications – CONMEDCC

Dataset	CONMEDCC
Creating program	conmedcc.sas
Description	Current Medications
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,CDAY,DRUG,STARTDY,STOPDY.
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,CDAY,DRUG,STARTDY,STOPDY.
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,CDATE,START,STOP,INDICAT

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
CDATEF	num	DATE FORM COMPLETED FLAG		Collected at CRF.
EVNT_ID	num	WEEK		Collected at CRF.
CONMED	num	CONCURRENT THERAPY/CHANGE		Collected at CRF.
NO	num	NUMBER		Collected at CRF.
DRUG	char	DRUG/TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
STARTF	num	START DATE FLAG		Collected at CRF.
CONT	num	CONTINUED		Collected at CRF.
STOPF	num	STOP DATE FLAG		Collected at CRF.
RTE	char	ROUTE		Collected at CRF.
TDOSE	char	TOTAL DAILY DOSE		Collected at CRF.
EMERG	num	TREATMENT FOR AE		Collected at CRF.
CODE	char	WHO*DRUG*CODE		Collected at CRF.
DRUG_NEW	char	DRUG_NEW		Collected at CRF.
CDY	num	RELATIVE DAY FORM COMPLETED		If CDATE and REF. DATE not missing then perform below logic to calculate CDY, If CDATE less than REF. DATE then (CDATE - REF.DATE). Else if CDATE is greater than equal to REF. DATE then (CDATE-REF.DATE) +1.
STARTDY	num	RELATIVE START DAY		If START and REF. DATE not missing then perform below logic to calculate STARTDY, If START less than REF. DATE then (START - REF.DATE). Else if START is greater than equal to REF. DATE then (START- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOP and REF. DATE not missing then perform below logic to calculate STOPDY, If STOP less than REF. DATE then (STOP - REF.DATE). Else if STOP is greater than equal to REF. DATE then (STOP-REF.DATE) +1.

1.4.12. Cost – COST

Dataset	COST
Creating program	cost.sas
Description	Cost
Unique identifier	STUDY,DPAT
Sorted by	STUDY,DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,COUNTRY, CENTER

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.

1.4.13. Dchem – DCHEM

Dataset	DCHEM
Creating program	dchem.sas
Description	Dchem
Unique identifier	STUDY,DPAT,EVNT_ID,VISIT
Sorted by	STUDY,DPAT,EVNT_ID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
CHEM	num	CHEM		Collected at CRF.
C208	num	C208		Collected at CRF.
C201	num	C201		Collected at CRF.
C202	num	C202		Collected at CRF.

Variable	Type	Label	Codes	Comments
C203	num	C203		Collected at CRF.
C206	num	C206		Collected at CRF.
C215	num	C215		Collected at CRF.
C210	num	C210		Collected at CRF.
C213	num	C213		Collected at CRF.
C207	num	C207		Collected at CRF.
C214	num	C214		Collected at CRF.
C217	num	C217		Collected at CRF.
C225	num	C225		Collected at CRF.
C218	num	C218		Collected at CRF.
C205	num	C205		Collected at CRF.
IRON	num	IRON		Collected at CRF.
C216	num	C216		Collected at CRF.
C285	num	C285		Collected at CRF.
C289	num	C289		Collected at CRF.
C287	num	C287		Collected at CRF.
C283	num	C283		Collected at CRF.
C284	num	C284		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.14. Dhem – DHEM

Dataset	DHEM
Creating program	dhem.sas
Description	Dhem
Unique identifier	STUDY,DPAT,EVNT_ID,VISIT
Sorted by	STUDY,DPAT,EVNT_ID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
HEM	num	HEM		Collected at CRF.
H103	num	H103		Collected at CRF.
H104	num	H104		Collected at CRF.
H102	num	H102		Collected at CRF.

Variable	Type	Label	Codes	Comments
H131	num	H131		Collected at CRF.
H101	num	H101		Collected at CRF.
DIFF	num	DIFF		Collected at CRF.
H108	num	H108		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.15. Doubled – DOUBLED

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

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
VDATEF	num	DATE FLAG		Collected at CRF.

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

1.4.16. Duri – DURI

Dataset	DURI
Creating program	duri.sas
Description	Duri
Unique identifier	STUDY,DPAT,EVNT_ID,VISIT
Sorted by	STUDY,DPAT,EVNT_ID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.

Variable	Type	Label	Codes	Comments
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
DURI	num	DURI		Collected at CRF.
DURI1	num	DURI1		Collected at CRF.
DURI2	num	DURI2		Collected at CRF.
DURI3	num	DURI3		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.17. Serum Electrophoresis – ELECTR

Dataset	ELECTR
Creating program	electr.sas
Description	Serum Electrophoresis
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,ELDY,ELECTR,LEVEL,TYPE
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,ELDY,ELECTR,LEVEL,TYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,ELDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
ELDATEF	num	DATE SAMPLE TAKEN FLAG		Collected at CRF.
ELECTR	char	DESCRIPTION OF ELECTROPHORESIS		Collected at CRF.
TYPE	char	TYPE		Collected at CRF.
LEVEL	char	LEVEL		Collected at CRF.
ELDY	num	RELATIVE DAY SAMPLE TAKEN		If ELDATE and REF. DATE not missing then perform below logic to calculate ELDY, If ELDATE less than REF. DATE then (ELDATE - REF.DATE). Else if ELDATE is greater than equal to REF. DATE then (ELDATE- REF.DATE) +1.

1.4.18. Hematology – HEM

Dataset	HEM
Creating program	hem.sas
Description	Hematology
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
H103	num	HEMOGLOBIN		Collected at CRF.
H104	num	HEMATOCRIT		Collected at CRF.
H102	num	ERYTHROCYTE COUNT		Collected at CRF.

Variable	Type	Label	Codes	Comments
H131	num	RETICULOCYTE COUNT		Collected at CRF.
H101	num	LEUKOCYTE COUNT		Collected at CRF.
H117	num	NEUTROPHILS		Collected at CRF.
H110	num	BANDS		Collected at CRF.
H111	num	LYMPHOCYTES		Collected at CRF.
H112	num	MONOCYTES		Collected at CRF.
H113	num	EOSINOPHILS		Collected at CRF.
H114	num	BASOPHILS		Collected at CRF.
CH116	char	OTHER SPECIFY		Collected at CRF.
H116	num	OTHER		Collected at CRF.
H108	num	PLATELET COUNT		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.19. Hospitalization – HOSP

Dataset	HOSP
Creating program	hosp.sas
Description	Hospitalization
Unique identifier	STUDY,DPAT,EVNT_ID,HOSP,HOSP1,HOSP2,HOSP3
Sorted by	STUDY,DPAT,EVNT_ID,HOSP,HOSP1,HOSP2,HOSP3
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,HOSP_SP1,HOSP_SP2

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
HOSP	num	HOSPITALIZATION		Collected at CRF.
HOSP1	num	HOSP1		Collected at CRF.
HOSP2	num	HOSP2		Collected at CRF.
HOSP3	num	HOSP3		Collected at CRF.
HOSP4	num	HOSP4		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOSP5	num	HOSP5		Collected at CRF.
HOSP6	num	HOSP6		Collected at CRF.
HOSP7	num	HOSP7		Collected at CRF.
HOSP8	num	HOSP8		Collected at CRF.
HOSP_OT1	num	HOSP_OT1		Collected at CRF.
HOSP_OT2	num	HOSP_OT2		Collected at CRF.

1.4.20. Keyadold – KEYADOLD

Dataset	KEYADOLD
Creating program	keyadold.sas
Description	Keyadold
Unique identifier	DPATNO,ONSETDY,EVENT_ID,PREF_TRM,STOPDY
Sorted by	DPATNO,ONSETDY,EVENT_ID,PREF_TRM,STOPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DONSET,ONSETDT,STOPDT,VERBATIM,TONSET,STOPTIME, ADVDESC

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
ADVEXP	num	CHECK IF NO TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
ADVCODE	char	ADVCODE		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
SERIOUS	num	SERIOUS		Collected at CRF.
DRUGREL	num	DRUGREL		Collected at CRF.
ACTION	num	ACTION		Collected at CRF.
CONCOM	num	CONCOM		Collected at CRF.
OUTCOME	num	OUTCOME		Collected at CRF.
PHASE	num	PHASE		Collected at CRF.
BODYSYS	char	BODYSYS		Collected at CRF.
SEXAE	char	BODY SYSTEM SEX		Collected at CRF.
PREF_TRM	char	PREF_TRM		Collected at CRF.
PERIOD	num	PERIOD		Collected at CRF.
ADVEXPF	char	ADVEXPF		Collected at CRF.
SEVERITF	char	SEVERITF		Collected at CRF.
SERIOUSF	char	SERIOUSF		Collected at CRF.
DRUGRELF	char	DRUGRELF		Collected at CRF.
ACTIONF	char	ACTIONF		Collected at CRF.
CONCOMF	char	CONCOMF		Collected at CRF.
OUTCOMEF	char	OUTCOMEF		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYDAY	num	STUDYDAY		Collected at CRF.
REGDAY	num	REGDAY		Collected at CRF.
DURDAY	num	DURDAY		Collected at CRF.
ONSETDY	num	RELATIVE ONSET DAY		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.21. Keyadve2 – KEYADVE2

Dataset	KEYADVE2
Creating program	keyadve2.sas
Description	Keyadve2
Unique identifier	DPATNO,ONSETDY,EVENT_ID,PREF_TRM,STOPDY
Sorted by	DPATNO,ONSETDY,EVENT_ID,PREF_TRM,STOPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DONSET,ONSETDT,STOPDT,VERBATIM,TONSET,STOPTIME,ADVDESC

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
ADVEXP	num	CHECK IF NO TREATMENT		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
ADVCODE	char	ADVCODE		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
SERIOUS	num	SERIOUS		Collected at CRF.
DRUGREL	num	DRUGREL		Collected at CRF.
ACTION	num	ACTION		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONCOM	num	CONCOM		Collected at CRF.
OUTCOME	num	OUTCOME		Collected at CRF.
PHASE	num	PHASE		Collected at CRF.
BODYSYS	char	BODYSYS		Collected at CRF.
SEXAE	char	BODY SYSTEM SEX		Collected at CRF.
PREF_TRM	char	PREF_TRM		Collected at CRF.
PERIOD	num	PERIOD		Collected at CRF.
ADVEXPF	char	ADVEXPF		Collected at CRF.
SEVERITF	char	SEVERITF		Collected at CRF.
SERIOUSF	char	SERIOUSF		Collected at CRF.
DRUGRELF	char	DRUGRELF		Collected at CRF.
ACTIONF	char	ACTIONF		Collected at CRF.
CONCOMF	char	CONCOMF		Collected at CRF.
OUTCOMEF	char	OUTCOMEF		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
REGDAY	num	REGDAY		Collected at CRF.
DURDAY	num	DURDAY		Collected at CRF.
AF_DOUB	num	1= STUDY DAY AFTER DOSE DOUBLING		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONSETDY	num	RELATIVE ONSET DAY		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.22. Keycomp – KEYCOMP

Dataset	KEYCOMP
Creating program	keycomp.sas
Description	Keycomp
Unique identifier	DPATNO,EVENT_ID,ADVCODE
Sorted by	DPATNO,EVENT_ID,ADVCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STATUSDT,DEATHDT,STATUS,REASON,VERBATIM,SEVERITY,SERIOUS, DRUGREL,BODYSYS,ADVDESC,PREF_TRM,PERIOD,SEVERITF,SERIOUSF,DRUGRELF,STUDYDAY,REGDAY,DURDAY

Variable	Type	Label	Codes	Comments
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
ADVCODE	char	ADVCODE		Collected at CRF.

1.4.23. Quality Of Life – LIVE1

Dataset	LIVE1
Creating program	live1.sas
Description	Quality Of Life
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
Q1	num	HOW WOULD YOU RATE YOUR ENERGY LEVEL …		Collected at CRF.
Q2	num	HOW WOULD YOU RATE YOUR ABILITY TO DO ..		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q3	num	HOW WOULD YOU RATE YOUR OVERALL QOL		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.24. Quality Of Life – LIVE2

Dataset	LIVE2
Creating program	live2.sas
Description	Quality Of Life
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
EN1	num	I'M TIRED ALL THE TIME		Collected at CRF.
P1	num	I HAVE PAIN AT NIGHT		Collected at CRF.
EM1	num	THINGS ARE GETTING ME DOWN		Collected at CRF.
P2	num	I HAVE UNBEARABLE PAIN		Collected at CRF.
SL1	num	I TAKE TABLETS TO HELP ME SLEEP		Collected at CRF.
EM2	num	I'VE FORGOTTEN WHAT IT'S LIKE TO ENJOY..		Collected at CRF.
EM3	num	I'M FEELING ON EDGE		Collected at CRF.
P3	num	I FIND IT PAINFUL TO CHANGE POSITION		Collected at CRF.
SO1	num	I FEEL LONELY		Collected at CRF.
PM1	num	I CAN ONLY WALK ABOUT INDOORS		Collected at CRF.
PM2	num	I FIND IT HARD TO BEND		Collected at CRF.

Variable	Type	Label	Codes	Comments
EN2	num	EVERYTHING IS AN EFFORT		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.25. Quality Of Life – LIVE3

Dataset	LIVE3
Creating program	live3.sas
Description	Quality Of Life
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
SL2	num	I'M WAKING UP IN THE EARLY HOURS OF ...		Collected at CRF.
PM3	num	I'M UNABLE TO WALK AT ALL		Collected at CRF.
SO2	num	I'M FINDING IT HARD TO MAKE CONTACT ...		Collected at CRF.
EM4	num	THE DAYS SEEM TO DRAG		Collected at CRF.
PM4	num	I HAVE TROUBLE GETTING UP AND DOWN ...		Collected at CRF.
PM5	num	I FIND IT HARD TO REACH FOR THINGS		Collected at CRF.
P4	num	I'M IN PAIN WHEN I WALK		Collected at CRF.
EM5	num	I LOSE MY TEMPER EASILY THESE DAYS		Collected at CRF.
SO3	num	I FEEL THERE IS NOBODY I AM CLOSE TO		Collected at CRF.
SL3	num	I LIE AWAKE FOR MOST OF THE NIGHT		Collected at CRF.
EM6	num	I FEEL AS IF I'M LOSING CONTROL		Collected at CRF.

Variable	Type	Label	Codes	Comments
P5	num	I'M IN PAIN WHEN I'M STANDING		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.26. Quality Of Life – LIVE4

Dataset	LIVE4
Creating program	live4.sas
Description	Quality Of Life
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
PM6	num	I FIND IF HARD TO DRESS MYSELF		Collected at CRF.
EN3	num	I SOON RUN OUT OF ENERGY		Collected at CRF.
PM7	num	I FIND IT HARD TO STAND FOR LONG		Collected at CRF.
P6	num	I'M IN CONSTANT PAIN		Collected at CRF.
SL4	num	IT TAKEN ME A LONG TIME TO GET TO SLEEP		Collected at CRF.
SO4	num	I FEEL I AM BURDEN TO PEOPLE		Collected at CRF.
EM7	num	WORRY IS KEEPING ME AWAKE AT NIGHT		Collected at CRF.
EM8	num	I FEEL THAT LIFE IS NOT WORTH LIVING		Collected at CRF.
SL5	num	I SLEEP BADLY AT NIGHT		Collected at CRF.
SO5	num	I'M FINDING IT HARD TO GET ON WITH PE...		Collected at CRF.
PM8	num	I NEED HELP TO WALK ABOUT OUTSIDE		Collected at CRF.
P7	num	I'M IN PAIN WHEN GOING UP AND DOWN STA..		Collected at CRF.

Variable	Type	Label	Codes	Comments
EM9	num	I WAKE UP FEELING DEPRESSED		Collected at CRF.
P8	num	I'M IN PAIN WHEN I'M SITTING		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.27. Location – LOCA

Dataset	LOCA
Creating program	loca.sas
Description	Location
Unique identifier	STUDY,DPAT,EVNT_ID,VDY
Sorted by	STUDY,DPAT,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,VDATE,LOCA2,LOCA3,LOCA_SP

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
OUTVNO	num	OUTVNO		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
LOCA1	num	LOCA1		Collected at CRF.
LOCA4	num	LOCA4		Collected at CRF.
LOCA_OT	num	LOCA_OT		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.28. Bone Marrow – MARROW

Dataset	MARROW
Creating program	marrow.sas
Description	Bone Marrow
Unique identifier	STUDY,DPAT,EVNT_ID,MDY
Sorted by	STUDY,DPAT,EVNT_ID,MDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,MDATE,XDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
MDATEF	num	BONE MARROW DATE FLAG		Collected at CRF.
MRESULT	num	BONE MARROW RESULT		Collected at CRF.
CELL	num	PLASMA CELLS		Collected at CRF.
XDATEF	num	DATE OF X-RAY FLAG		Collected at CRF.

Variable	Type	Label	Codes	Comments
XRESULT	num	X-RAY RESULT		Collected at CRF.
MDY	num	RELATIVE BONE MARROW DAY		If MDATE and REF. DATE not missing then perform below logic to calculate MDY, If MDATE less than REF. DATE then (MDATE - REF.DATE). Else if MDATE is greater than equal to REF. DATE then (MDATE- REF.DATE) +1.
XDY	num	RELATIVE DAY OF X-RAY		If XDATE and REF. DATE not missing then perform below logic to calculate XDY, If XDATE less than REF. DATE then (XDATE - REF.DATE). Else if XDATE is greater than equal to REF. DATE then (XDATE- REF.DATE) +1.

1.4.29. Medical History – MEDHIS

Dataset	MEDHIS
Creating program	medhis.sas
Description	Medical History
Unique identifier	STUDY,DPAT,GROUP,VDY
Sorted by	STUDY,DPAT,GROUP,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
EYES	num	EYES, EARS, NOSE & THROAT		Collected at CRF.
RESP	num	RESPIRATORY		Collected at CRF.
CARD	num	CARDIOVASCULAR		Collected at CRF.
GAST	num	GASTROINTESTINAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
GENI	num	GENITO-URINARY		Collected at CRF.
MUSC	num	MUSCULOSKELETAL		Collected at CRF.
NEUR	num	NEUROLOGICAL		Collected at CRF.
ENDO	num	ENDOCRINE & METABOLIC		Collected at CRF.
HEMA	num	HEMATOPOIETIC/LYMPHATIC		Collected at CRF.
DERM	num	DERMATOLOGICAL		Collected at CRF.
PSYCH	num	PSYCHOLOGICAL		Collected at CRF.
SURG	num	SURGERY HISTORY		Collected at CRF.
ALLERG	num	ALLERGIES		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.30. Miscellaneous – MISC

Dataset	MISC
Creating program	misc.sas
Description	Miscellaneous
Unique identifier	STUDY,DPAT,EVNT_ID,VISIT
Sorted by	STUDY, DPAT,EVNT_ID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
MISC	num	MISC		Collected at CRF.
MISC1	num	MISC1		Collected at CRF.
MISC2	num	MISC2		Collected at CRF.
MISC3	num	MISC3		Collected at CRF.

Variable	Type	Label	Codes	Comments
MISC4	num	MISC4		Collected at CRF.
MISC5	num	MISC5		Collected at CRF.
MISC6	num	MISC6		Collected at CRF.
MISC7	num	MISC7		Collected at CRF.
MISC8	num	MISC8		Collected at CRF.
MISC9	num	MISC9		Collected at CRF.
MISC10	num	MISC10		Collected at CRF.
MISC11	num	MISC11		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.31. Myeloma – MYELOMA

Dataset	MYELOMA
Creating program	myeloma.sas
Description	Myeloma
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,MDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,MDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,MDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
MDATEF	num	DATE OF DIAGNOSIS FLAG		Collected at CRF.
STAG	num	STAGING		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUB	num	SUBCLASSIFICATION		Collected at CRF.
MDY	num	RELATIVE DAY OF DIAGNOSIS		If MDATE and REF. DATE not missing then perform below logic to calculate MDY, If MDATE less than REF. DATE then (MDATE - REF.DATE). Else if MDATE is greater than equal to REF. DATE then (MDATE- REF.DATE) +1.

1.4.32. Nmc – NMC

Dataset	NMC
Creating program	nmc.sas
Description	Nmc
Unique identifier	STUDY,DPAT,EVNT_ID,VDY,NMC1,NMC2,NMC3,NMC4
Sorted by	STUDY,DPAT,EVNT_ID,VDY,NMC1,NMC2,NMC3,NMC4
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
NMC_NO	num	NMC_NO		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
NMC1	num	NMC1		Collected at CRF.
NMC2	num	NMC2		Collected at CRF.
NMC3	num	NMC3		Collected at CRF.
NMC4	num	NMC4		Collected at CRF.
NMC5	num	NMC5		Collected at CRF.
NMC6	num	NMC6		Collected at CRF.
NMC_OT1	num	NMC_OT1		Collected at CRF.
MNC_SP1	char	MNC_SP1		Collected at CRF.
NMC_OT2	num	NMC_OT2		Collected at CRF.
NMC_SP2	char	NMC_SP2		Collected at CRF.
NMC7	num	NMC7		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.33. Normal – NORMAL

Dataset	NORMAL
Creating program	normal.sas
Description	Normal
Unique identifier	OBSNO,SEX,VARNAM,LR,UR,UNIT
Sorted by	OBSNO,SEX,VARNAM,LR,UR,UNIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INV

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
SEX	num	SEX		Collected at CRF.
VARNAM	char	VARNAM		Collected at CRF.
LR	num	LR		Collected at CRF.
UR	num	UR		Collected at CRF.
UNIT	char	UNIT		Collected at CRF.

1.4.34. Nurc – NURC

Dataset	NURC
Creating program	nurc.sas
Description	Nurc
Unique identifier	STUDY,DPAT,EVNT_ID,IN_OUT,OUTVNO,NURC1,NURS_T
Sorted by	STUDY,DPAT,EVNT_ID,IN_OUT,OUTVNO,NURC1,NURS_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,NURC1,NURC_T1,NURC2,NURC_T2,NURC3,NURC_T3,NURC_OT, NURC_T5,NURC_SP

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
OUTVNO	num	OUTVNO		Collected at CRF.
NURC4	num	NURC4		Collected at CRF.
NURC_T4	num	NURC_T4		Collected at CRF.
NURS_T	num	NURS_T		Collected at CRF.

1.4.35. Otes – OTES

Dataset	OTES
Creating program	otes.sas
Description	Otes
Unique identifier	STUDY,DPAT,EVNT_ID,VISIT
Sorted by	STUDY,DPAT,EVNT_ID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
OTES	num	OTES		Collected at CRF.
OTES_SP	char	OTES_SP		Collected at CRF.
OTES_NO	num	OTES_NO		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.36. Patient Number – PAT

Dataset	PAT
Creating program	pat.sas
Description	Patient Number
Unique identifier	DPAT
Sorted by	DPAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INV,SHORTNAM,EXACTAGE,AGE,CORR_DT,RESP_DT,MAX_DT,LAST_DT, INVCNTRY,SEX

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
BASEHGT	num	HEIGHT[CM]		Collected at CRF.
BASEWGT	num	WEIGHT [KG]		Collected at CRF.
BASE_HB	num	HB [G/DL]		Collected at CRF.
BASE_HCT	num	HEMATOCRIT [%]		Collected at CRF.
BASE_RC	num	RETICULOCYTE COUNT [%]		Collected at CRF.
BASE_NE	num	NEUTROPHIL COUNT [%]		Collected at CRF.
BASE_PS	num	PERFORMANCE SCORE[0-4]		Collected at CRF.
BLINDED	num	RANDOMIZATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDSTRT	num	DAY 1		Collected at CRF.
STUDEND1	num	END OF DB-PHASE		Collected at CRF.
CUMTX0	num	TX-RATE		Collected at CRF.
PRETX	num	BL TRANSFUSION DEPENDENCE		Collected at CRF.
CUMTX1	num	TX-RATE DB PHASE		Collected at CRF.
CUMTX1WO	num	TX-RATE DB PHASE AFTER 1ST MONTH		Collected at CRF.
STAG0	num	MALIGNANCY STAGING [I,II,III]		Collected at CRF.
SUB0	num	SUBCLASSIFICATION [A,B]		Collected at CRF.
MON_DIAG	num	MONTHS SINCE DIAGNOSIS		Collected at CRF.
LASTWK1	num	LASTWK1		Collected at CRF.
TX2OR3	num	TRANSFUSED DURING MONTHS 2 OR 3		Collected at CRF.
DEADISC1	num	DIED OR DISC DUE ADE (1=NO, 2=YES)		Collected at CRF.
TRE	num	RANDOMIZATION		Collected at CRF.
CORR_HB	num	FIRST HB >=12 G/DL		Collected at CRF.
RESP_HB	num	HB [G/DL] AT RESPONSE		Collected at CRF.
MAX_HB	num	MAXIMAL HB [G/DL]		Collected at CRF.
LAST_HB	num	LAST HB [G/DL]		Collected at CRF.
ORDNER	num	ORDNER		Collected at CRF.
SUBGROUP	num	SUBGROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVAL	num	EVALUABLE		Collected at CRF.
EPOLEVEL	num	SERUM ERYTHROPOIETIN LEVEL [MU/ML]		Collected at CRF.
BASE_NEA	num	NEUTROPHIL COUNT [10/L]		Collected at CRF.
CORR_DY	num	RELATIVE FIRST DAY OF HB >=12 G/DL		If CORR_DT and REF. DATE not missing then perform below logic to calculate CORR_DY, If CORR_DT less than REF. DATE then (CORR_DT - REF.DATE). Else if CORR_DT is greater than equal to REF. DATE then (CORR_DT- REF.DATE) +1.
RESP_DY	num	RELATIVE DAY OF RESPONSE		If RESP_DT and REF. DATE not missing then perform below logic to calculate RESP_DY, If RESP_DT less than REF. DATE then (RESP_DT - REF.DATE). Else if RESP_DT is greater than equal to REF. DATE then (RESP_DT- REF.DATE) +1.
MAX_DY	num	RELATIVE DAY OF MAXIMAL HB		If MAX_DT and REF. DATE not missing then perform below logic to calculate MAX_DY, If MAX_DT less than REF. DATE then (MAX_DT - REF.DATE). Else if MAX_DT is greater than equal to REF. DATE then (MAX_DT- REF.DATE) +1.
LAST_DY	num	RELATIVE DAY OF LAST HB		If LAST_DT and REF. DATE not missing then perform below logic to calculate LAST_DY, If LAST_DT less than REF. DATE then (LAST_DT - REF.DATE). Else if LAST_DT is greater than equal to REF. DATE then (LAST_DT- REF.DATE) +1.

1.4.37. Pat_1– PAT_1

Dataset	PAT_1
Creating program	pat_1.sas
Description	Pat_1
Unique identifier	DPAT
Sorted by	DPAT
Notes	

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
TRE	num	RANDOMIZATION		Collected at CRF.
EVAL	num	EVALUABLE		Collected at CRF.

1.4.38. Performance Score – PERFOR

Dataset	PERFOR
Creating program	perfor.sas
Description	Performance Score
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,CDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,CDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE,CDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
PERFOR	num	PERFORMANCE SCORE		Collected at CRF.
PHYSI	num	PHYSICIAN'S GLOBAL ASSESSMENT		Collected at CRF.
CDATEF	num	DATE OF LAST CHEMOTHERAPY FLAG		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHEMO	num	RESPONSE TO CHEMOTHERAPY		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.
CDY	num	RELATIVE DAY OF LAST CHEMOTHERAPY		If CDATE and REF. DATE not missing then perform below logic to calculate CDY, If CDATE less than REF. DATE then (CDATE - REF.DATE). Else if CDATE is greater than equal to REF. DATE then (CDATE-REF.DATE) +1.

1.4.39. Physical Examination – PHYSEX

Dataset	PHYSEX
Creating program	physex.sas
Description	Physical Examination
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
HEAD	num	HEAD, NECK AND THYROID		Collected at CRF.
EARS	num	EARS, NOSE AND THROAT		Collected at CRF.
EYES	num	EYES		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHEST	num	CHEST		Collected at CRF.
LUNGS	num	LUNGS		Collected at CRF.
HEART	num	HEART		Collected at CRF.
LYMPH	num	LYMPH NODES		Collected at CRF.
ABDO	num	ABDOMEN		Collected at CRF.
ANOR	num	ANORECTAL		Collected at CRF.
GENI	num	GENITALIA		Collected at CRF.
SKIN	num	SKIN		Collected at CRF.
MUSC	num	MUSCULOSKELETAL		Collected at CRF.
NEURO	num	NEUROLOGICAL		Collected at CRF.
OTHER	num	OTHER		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.40. Vital Signs, Height and Weight – PPVI

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

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
SBP	num	BLOOD PRESSURE SYSTOLIC		Collected at CRF.
DBP	num	BLOOD PRESSURE DIASTOLIC		Collected at CRF.
PULSE	num	PULSE RATE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEMP	num	TEMPERATURE		Collected at CRF.
RESP	num	RESPIRATION RATE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.41. Protocol – PROTOCOL

Dataset	PROTOCOL
Creating program	protocol.sas
Description	Protocol
Unique identifier	PROTOCOL
Sorted by	PROTOCOL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TAREA,TITLE1,TITLE2,FIRSTDB.

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

Variable	Type	Label	Codes	Comments
RSM	char	RSM		Collected at CRF.
FINALDB	num	FINAL DB DATE		Collected at CRF.
AVAILABL	char	AVAILABL		Collected at CRF.
SHRTPROT	char	SHRTPROT		Collected at CRF.
DMODIFY	num	MODIFY DATE		Collected at CRF.
DSTAMP	num	STAMP DATE		Collected at CRF.

1.4.42. Platelet Transfusion Information – PTRANS

Dataset	PTRANS
Creating program	ptrans.sas
Description	Platelet Transfusion Information
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,CODE,VDATE,GIVEN

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
TRANS	num	PLATELET TRANSFUSION REQUIRED ?		Collected at CRF.
TYPE	char	TYPE OF BLOOD PRODUCT		Collected at CRF.
VDATEF	num	DATE GIVEN FLAG		Collected at CRF.
H108	num	PLATELET COUNT		Collected at CRF.
UNITS	num	NUMBER OF UNITS		Collected at CRF.
VDY	num	RELATIVE DAY GIVEN		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.43. Reason – REAS

Dataset	REAS
Creating program	reas.sas
Description	Reason
Unique identifier	STUDY,DPAT,EVNT_ID,VDY,REAS1,REAS2,REAS4
Sorted by	STUDY,DPAT,EVNT_ID,VDY,REAS1,REAS2,REAS4
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
OUTVNO	num	OUTVNO		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
REAS1	num	REAS1		Collected at CRF.
REAS2	num	REAS2		Collected at CRF.

Variable	Type	Label	Codes	Comments
REAS3	num	REAS3		Collected at CRF.
REAS4	num	REAS4		Collected at CRF.
REAS5	num	REAS5		Collected at CRF.
REAS6	num	REAS6		Collected at CRF.
REAS7	num	REAS7		Collected at CRF.
REAS_OT	num	REAS_OT		Collected at CRF.
REAS_SP	char	REAS_SP		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.44. Serum Sample – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	Serum Sample
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,SDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,SDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,SDATE,EDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
SDATEF	num	DATE SERUM SAMPLE FLAG		Collected at CRF.
EDATEF	num	DATE EPO SERUM LEVEL FLAG		Collected at CRF.

Variable	Type	Label	Codes	Comments
SDY	num	RELATIVE DAY SERUM SAMPLE		If SDATE and REF. DATE not missing then perform below logic to calculate SDY, If SDATE less than REF. DATE then (SDATE - REF.DATE). Else if SDATE is greater than equal to REF. DATE then (SDATE-REF.DATE) +1.
EDY	num	RELATIVE DAY EPO SERUM LEVEL		If EDATE and REF. DATE not missing then perform below logic to calculate EDY, If EDATE less than REF. DATE then (EDATE - REF.DATE). Else if EDATE is greater than equal to REF. DATE then (EDATE-REF.DATE) +1.

1.4.45. Discontinuation/Completion Information – TERM

Dataset	TERM
Creating program	term.sas
Description	Discontinuation/Completion Information
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,LDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,LDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,LDATE,DDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
LDATEF	num	DATE OF LAST EPO DOSE FLAG		Collected at CRF.
COMPLETE	num	DID PAT COMPLETE THE STUDY ?		Collected at CRF.
REASON	num	REASON		Collected at CRF.
DIE	num	DID PATIENT DIE ?		Collected at CRF.

Variable	Type	Label	Codes	Comments
DDATEF	num	DEATH DATE FLAG		Collected at CRF.
AUTO	num	AUTOPSY PERFORMED ?		Collected at CRF.
LDY	num	RELATIVE DAY OF LAST EPO DOSE		If LDATE and REF. DATE not missing then perform below logic to calculate LDY, If LDATE less than REF. DATE then (LDATE - REF.DATE). Else if LDATE is greater than equal to REF. DATE then (LDATE-REF.DATE) +1.
DDY	num	RELATIVE DEATH DAY		If DDATE and REF. DATE not missing then perform below logic to calculate DDY, If DDATE less than REF. DATE then (DDATE - REF.DATE). Else if DDATE is greater than equal to REF. DATE then (DDATE-REF.DATE) +1.

1.4.46. Transfusion Information – TRANS

Dataset	TRANS
Creating program	trans.sas
Description	Transfusion Information
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,CODE,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
TRANS	num	HAS PAT. REQUIRED ANY CELL TRANSFUSIONS		Collected at CRF.
TYPE	char	TYPE OF BLOOD		Collected at CRF.
VDATEF	num	DATE GIVEN FLAG		Collected at CRF.
H103	num	HEMOGLOBIN		Collected at CRF.

Variable	Type	Label	Codes	Comments
UNITS	num	AMOUNT GIVEN (UNITS)		Collected at CRF.
GIVEN	char	AMOUNT GIVEN SPECIFY		Collected at CRF.
OBS	num	OBS		Collected at CRF.
VDY	num	RELATIVE DAY GIVEN		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.47. Treatment – TREAT

Dataset	TREAT
Creating program	treat.sas
Description	Treatment
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,VDATE,ADMIN

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.48. Urinalysis – URIN

Dataset	URIN
Creating program	urin.sas
Description	Urinalysis
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
U303	num	PH		Collected at CRF.
U304	num	SPECIFIC GRAVITY		Collected at CRF.
U307	char	KETONES		Collected at CRF.

Variable	Type	Label	Codes	Comments
U348	char	PROTEIN		Collected at CRF.
U306	char	GLUCOSE		Collected at CRF.
U309	char	BLOOD		Collected at CRF.
U316	char	RBC		Collected at CRF.
U315	char	WBC		Collected at CRF.
U320	char	CASTS		Collected at CRF.
U314	char	BACTERIA		Collected at CRF.
CU319	char	OTHER SPECIFY		Collected at CRF.
U319	char	OTHER		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.49. Visit – VISI

Dataset	VISI
Creating program	visi.sas
Description	Visit
Unique identifier	STUDY,DPAT,EVNT_ID,ADY,VDY,OUTVNO
Sorted by	STUDY,DPAT,EVNT_ID,ADY,VDY,OUTVNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,ADATE,DDATE,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
IN_OUT	num	IN_OUT		Collected at CRF.
HOSP	num	HOSPITALIZATION		Collected at CRF.
ADATEF	num	RANDOMIZATION GROUP FLAG		Collected at CRF.
DDATEF	num	DEATH DATE FLAG		Collected at CRF.
OUTVNO	num	OUTVNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
OUT	num	OUT		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
OUT1	char	OUT1		Collected at CRF.
ADY	num	RELATIVE RANDOMIZATION GROUP DAY		If ADATE and REF. DATE not missing then perform below logic to calculate ADY, If ADATE less than REF. DATE then (ADATE - REF.DATE). Else if ADATE is greater than equal to REF. DATE then (ADATE-REF.DATE) +1.
DDY	num	RELATIVE DEATH DAY		If DDATE and REF.DATE not missing then perform below logic to calculate DDY, If DDATE less than REF.DATE then (DDATE - REF.DATE). Else if DDATE is greater than equal to REF.DATE then (DDATE-REF.DATE) +1.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.50. Xchem – XCHEM

Dataset	XCHEM
Creating program	xchem.sas
Description	Xchem
Unique identifier	STUDY,DPAT,EVNT_ID,VDY,IDY
Sorted by	STUDY,DPAT,EVNT_ID,VDY,IDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE,IDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE BLOOD CHEMISTRY FLAG		Collected at CRF.
C208	num	CALCIUM		Collected at CRF.
C201	num	SODIUM		Collected at CRF.
C202	num	POTASSIUM		Collected at CRF.

Variable	Type	Label	Codes	Comments
C203	num	CHLORIDE		Collected at CRF.
C206	num	BUN		Collected at CRF.
C215	num	TOTAL BILIRUBIN		Collected at CRF.
C210	num	TOTAL PROTEIN		Collected at CRF.
C213	num	ALBUMIN		Collected at CRF.
C207	num	URIC ACID		Collected at CRF.
C214	num	ALK.PHOSPHATASE		Collected at CRF.
C217	num	SGOT		Collected at CRF.
C225	num	SGPT		Collected at CRF.
C218	num	LDH		Collected at CRF.
C205	num	CREATININE		Collected at CRF.
IDATEF	num	VISIT DATE FLAG IRON PROFILE		Collected at CRF.
C216	num	SERUM IRON		Collected at CRF.
C285	num	SERUM FERRITIN		Collected at CRF.
C289	num	TIBC		Collected at CRF.
C287	num	TRANSFERRIN		Collected at CRF.
C283	num	SERUM FOLATE		Collected at CRF.
C284	num	SERUM B 12		Collected at CRF.
OBS	num	OBS		Collected at CRF.

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

1.4.51. Xhem – XHEM

Dataset	XHEM
Creating program	xhem.sas
Description	Xhem
Unique identifier	STUDY,DPAT,EVNT_ID,VDY
Sorted by	STUDY,DPAT,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT,INV,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
VDATEF	num	VISIT DATE FLAG		Collected at CRF.
H103	num	HEMOGLOBIN		Collected at CRF.
H104	num	HEMATOCRIT		Collected at CRF.
H102	num	ERYTHROCYTE COUNT		Collected at CRF.
H131	num	RETICULOCYTE COUNT		Collected at CRF.
H101	num	LEUKOCYTE COUNT		Collected at CRF.
H117	num	NEUTROPHILS		Collected at CRF.
H110	num	BANDS		Collected at CRF.
H111	num	LYMPHOCYTES		Collected at CRF.
H112	num	MONOCYTES		Collected at CRF.
H113	num	EOSINOPHILS		Collected at CRF.
H114	num	BASOPHILS		Collected at CRF.
CH116	char	OTHER SPECIFY		Collected at CRF.
H116	num	OTHER		Collected at CRF.

Variable	Type	Label	Codes	Comments
H108	num	PLATELET COUNT		Collected at CRF.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.

1.4.52. Xtrans – XTRANS

Dataset	XTRANS
Creating program	xtrans.sas
Description	Xtrans
Unique identifier	STUDY,DPAT,GROUP,EVNT_ID,VDY
Sorted by	STUDY,DPAT,GROUP,EVNT_ID,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INIT,INV,CODE,VDATE

Variable	Type	Label	Codes	Comments
OBSNO	num	SAS NO.		Collected at CRF.
STUDY	char	STUDY NUMBER		Collected at CRF.
GROUP	num	RANDOMIZATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPAT	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for de-identity.
EVNT_ID	num	WEEK		Collected at CRF.
TRANS	num	HAS PAT. REQUIRED ANY CELL TRANSFUSIONS		Collected at CRF.
TYPE	char	TYPE OF BLOOD		Collected at CRF.
VDATEF	num	DATE GIVEN FLAG		Collected at CRF.
H103	num	HEMOGLOBIN		Collected at CRF.
UNITS	num	AMOUNT GIVEN (UNITS)		Collected at CRF.
GIVEN	char	AMOUNT GIVEN SPECIFY		Collected at CRF.
OBS	num	OBS		Collected at CRF.
VDY	num	RELATIVE DAY GIVEN		If VDATE and REF. DATE not missing then perform below logic to calculate VDY, If VDATE less than REF. DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF. DATE then (VDATE-REF.DATE) +1.