

Clinical Development

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I88037

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- CMNTI037 dataset will be submitted with zero observation due to sensitivity of data.
- LOTTI037 and SRCEI037 datasets contains sensitive information. Hence, these datasets will not be submitted.
- DEMOI037. VDATE will be used as reference date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The I88037 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHIC AND BASELINE CHARACTERISTIC – DEMOI037

Dataset	DEMOI037
Creating program	demoi037.sas
Description	DEMOGRAPHIC AND BASELINE CHARACTERISTIC
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNUM,VDATE,BIRTH

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
DSITE	char	INVESTIGATOR SITE ASSIGN FOR DE-IDENTITY		Randomly assigned investigator site for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	num	GENDER (1=M, 2=F)		Collected at CRF.
RACE	num	RACE		Collected at CRF.
RACE_C	char	RACE (CHAR)		Collected at CRF.
AGE	char	AGE IN YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
REGDESC	char	TREATMENT REGIMEN		Collected at CRF.
TRTGRPF	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.

1.4.2. ADVERSE EVENTS – ADVEI037

Dataset	ADVEI037
Creating program	advei037.sas
Description	ADVERSE EVENTS
Unique identifier	DSUBNUM,PERIOD,PHASE,ADVSPE,ONSETDY
Sorted by	DSUBNUM,PERIOD,PHASE,ADVSPE,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,DONSET,ADVDUR,ADVCOM

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
ADVEXP	num	AE?(1=NO,2=YES)		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
ADVNOV	char	NOVA CODE FOR AE		Collected at CRF.
ADVSPE	char	ADVERSE EVENT DIAGNOSIS		Collected at CRF.

Variable	Type	Label	Codes	Comments
TONSET	char	TIME OF ONSET, FORMAT 24 HR CLOCK		Collected at CRF.
ADVSEV	num	SEVERITY OF AE		Collected at CRF.
ADVREL	num	RELATION OF AE		Collected at CRF.
ONSETDY	num	RELATIVE DAY AE STARTED		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.

1.4.3. DERIVED AGE – AGESI037

Dataset	AGESI037
Creating program	agesi037.sas
Description	DERIVED AGE
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
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: BIRTH, SUBINI, MEDSTART, TIMESTAR, LASTMED, TIMESTOP, INVNUM, LASTNAME, INVNAME, AGE_C

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
SEX_C	char	SEX (CHARACTER)		Collected at CRF.
SEX	num	GENDER (1=M, 2=F)		Collected at CRF.
SOURCE	char	STUDY DRUG SOURCE		Collected at CRF.
MEDSTDY	num	RELATIVE DAY OF FIRST DOSE OF STUDY MED		If MEDSTART and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTART less than REF.DATE then (MEDSTART - REF.DATE). Else if MEDSTART is greater than equal to REF.DATE then (MEDSTART- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
LASTMEDY	num	RELATIVE DAY OF LAST DOSE OF STUDY MED		If LASTMED and REF.DATE not missing then perform below logic to calculate LASTMEDY, If LASTMED less than REF.DATE then (LASTMED - REF.DATE). Else if LASTMED is greater than equal to REF.DATE then (LASTMED- REF.DATE) +1.
AGE	char	AGE (YR)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.

1.4.4. ALLERGY INFORMATION – ALLEI037

Dataset	ALLEI037
Creating program	alleI037.sas
Description	ALLERGY INFORMATION
Unique identifier	DSUBNUM,ALLERGY,REACTION
Sorted by	DSUBNUM,ALLERGY,REACTION
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
ALLER	num	ANY ALLERGIES		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
ALLERGY	char	ALLERGY		Collected at CRF.
REACTION	char	REACTION		Collected at CRF.

1.4.5. CADMI037 – CADMI037

Dataset	CADMI037
Creating program	cadmi037.sas
Description	CADMI037
Unique identifier	DSUBNUM,PERIOD,TYPE,DOSE,CDY
Sorted by	DSUBNUM,PERIOD,TYPE,DOSE,CDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,CDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
DAYNUM	num	DAY NUMBER		Collected at CRF.
TYPE	char	NOVA CODE FOR THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE	num	DOSE TO BE GIVEN		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.

1.4.6. CHEMOTHERAPY INFORMATION – CHEMI037

Dataset	CHEMI037
Creating program	chemi037.sas
Description	CHEMOTHERAPY INFORMATION
Unique identifier	DSUBNUM,TYPETHER,THERAPY,LASTDY
Sorted by	DSUBNUM,TYPETHER,THERAPY,LASTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DURATION,LASTDAY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
TYPETHER	num	THERAPY TYPE		Collected at CRF.
THERAPY	char	THERAPY GIVEN?		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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.
LASTDY	num	RELATIVE LAST DAY OF CHEMOTHERAPY		If LASTDAY and REF.DATE not missing then perform below logic to calculate LASTDY, If LASTDAY less than REF.DATE then (LASTDAY - REF.DATE). Else if LASTDAY is greater than equal to REF.DATE then (LASTDAY- REF.DATE) +1.

1.4.7. CANCER TREATMENT HISTORY – CHISI037

Dataset	CHISI037
Creating program	chisi037.sas
Description	CANCER TREATMENT HISTORY
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PHASE	num	STUDY PHASE		Collected at CRF.
PERIOD	num	STUDY PERIOD		Collected at CRF.
SURGERY	num	PREVIOUS SURGER?		Collected at CRF.
PRCHCODE	num	PRIOR CHEMOTHERAPY GIVEN (1=NO, 2=YES)		Collected at CRF.
PRCHNUM	num	NUMBER OF DOSES OF PRIOR CHEMOTHERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRRDCODE	num	PRIOR RADIOTHERAPY (1=NO, 2=YES)		Collected at CRF.
PRRDNUM	num	NUMBER OF DOSES OF PRIOR RADIOTHERAPY		Collected at CRF.

1.4.8. COMMENTS RECORDE ON CRF – CMNTI037

Dataset	CMNTI037
Creating program	cmnti037.sas
Description	COMMENTS RECORDE ON CRF
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	CMNTI037 dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Empty dataset will be submitted
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
PERIOD	num	STUDY PERIOD		Empty dataset will be submitted
PHASE	num	STUDY PHASE		Empty dataset will be submitted
COURSE	num	COURSE OF TREATMENT		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
CMTCODE	char	COMMENT CODE		Empty dataset will be submitted
SYCODE	num	SYSTEM CODE		Empty dataset will be submitted

1.4.9. CRSEI037 – CRSEI037

Dataset	CRSEI037
Creating program	crsei037.sas
Description	CRSEI037
Unique identifier	DSUBNUM,PERIOD,STARTDY
Sorted by	DSUBNUM,PERIOD,STARTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,START,STOP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
AOLCRS	char	AOLCRS		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGE	char	PAGE		Collected at CRF.
STARTDY	num	RELATIVE CHEMOTHERAPY START SAS DAY,NUM		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 CHEMOTHERAPY STOP SAS DAY,NUM		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.

1.4.10. CONCOMITANT MEDICATIONS – CURMI037

Dataset	CURMI037
Creating program	curmi037.sas
Description	CONCOMITANT MEDICATIONS
Unique identifier	DSUBNUM,PERIOD,DRUG,CSTARTDY
Sorted by	DSUBNUM,PERIOD,DRUG,CSTARTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,CSTART,CSTOP,INDIC

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
CONMED	num	HAVE A CONCOMITANT MED?		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
DRUG	char	NOVA CODE FOR THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONT	num	THERAPY CONTINUED?(1=NO,2=YES,-9=UNK)		Collected at CRF.
RT	char	ROUTE		Collected at CRF.
STR	char	STRENGTH		Collected at CRF.
REGI	char	REGIMEN: # (D)AY,(W)EEK,(M)ONTH		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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.
CSTARTDY	num	RELATIVE DAY CHEMOTHERAPY STARTED		If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTART less than REF.DATE then (CSTART - REF.DATE). Else if CSTART is greater than equal to REF.DATE then (CSTART- REF.DATE) +1.
CSTOPDY	num	RELATIVE DAY CHEMOTHERAPY STOPPED		If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOP less than REF.DATE then (CSTOP - REF.DATE). Else if CSTOP is greater than equal to REF.DATE then (CSTOP- REF.DATE) +1.

1.4.11. DISCONTINUATION DUE TO AE INFO – DCADI037

Dataset	DCADI037
Creating program	dcadi037.sas
Description	DISCONTINUATION DUE TO AE INFO
Unique identifier	DSUBNUM,ADVNOV
Sorted by	DSUBNUM,ADVNOV
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
ADVNOV	char	NOVA CODE FOR AE		Collected at CRF.

1.4.12. STUDY DISCONTINUATION INFORMATION – DCHEI037

Dataset	DCHEI037
Creating program	dchei037.sas
Description	STUDY DISCONTINUATION INFORMATION
Unique identifier	DSUBNUM,PERIOD,PHASE
Sorted by	DSUBNUM,PERIOD,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI, LASTVIS, MEDSTART, LASTMED

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
COMPLETE	num	COMPLETE CHEMOTHERAPY?		Collected at CRF.
LSTVISDY	num	RELATIVE LAST VISIT DAY		If LASTVIS and REF.DATE not missing then perform below logic to calculate LSTVISDY, If LASTVIS less than REF.DATE then (LASTVIS - REF.DATE). Else if LASTVIS is greater than equal to REF.DATE then (LASTVIS- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MEDSTDY	num	RELATIVE DAY OF FIRST DOSE OF STUDY MED		If MEDSTART and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTART less than REF.DATE then (MEDSTART - REF.DATE). Else if MEDSTART is greater than equal to REF.DATE then (MEDSTART- REF.DATE) +1.
LASTMEDY	num	RELATIVE DAY OF LAST DOSE OF STUDY MED		If LASTMED and REF.DATE not missing then perform below logic to calculate LASTMEDY, If LASTMED less than REF.DATE then (LASTMED - REF.DATE). Else if LASTMED is greater than equal to REF.DATE then (LASTMED- REF.DATE) +1.

1.4.13. DISCONTINUATION REASON – DCREI037

Dataset	DCREI037
Creating program	dcrei037.sas
Description	DISCONTINUATION REASON
Unique identifier	DSUBNUM,PHASE,REASON
Sorted by	DSUBNUM,PHASE,REASON
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,REASSPEC

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
REA	num	REASON FOR DISCONTINUATION		Collected at CRF.
REASON	char	REASON FOR DISCONTINUATION		Collected at CRF.

1.4.14. STUDY MEDICATION DOSING INFORMATION – DOSEI037

Dataset	DOSEI037
Creating program	dosei037.sas
Description	STUDY MEDICATION DOSING INFORMATION
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
WGT	num	WEIGHT		Collected at CRF.

1.4.15. EPOLI037 – EPOLI037

Dataset	EPOLI037
Creating program	epoli037.sas
Description	EPOLI037
Unique identifier	DSUBNUM,PERIOD,PHASE,EPCODE,VDY
Sorted by	DSUBNUM,PERIOD,PHASE,EPCODE,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity

Variable	Type	Label	Codes	Comments
PHASE	num	STUDY PHASE		Collected at CRF.
PERIOD	num	STUDY PERIOD		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
EPCODE	num	EPCODE		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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. STUDY MEDICATION START AND STOP DATES – FMEDI037

Dataset	FMEDI037
Creating program	fmedi037.sas
Description	STUDY MEDICATION START AND STOP DATES
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MEDSTART, LASTMED, TIMESTAR, TIMESTOP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
MEDSTDY	num	RELATIVE DAY OF FIRST DOSE OF STUDY MED		If MEDSTART and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTART less than REF.DATE then (MEDSTART - REF.DATE). Else if MEDSTART is greater than equal to REF.DATE then (MEDSTART- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
LASTMEDY	num	RELATIVE DAY OF LAST DOSE OF STUDY MED		If LASTMED and REF.DATE not missing then perform below logic to calculate LASTMEDY, If LASTMED less than REF.DATE then (LASTMED - REF.DATE). Else if LASTMED is greater than equal to REF.DATE then (LASTMED- REF.DATE) +1.

1.4.17. HISTORY OF DISEASE – HISTI037

Dataset	HISTI037
Creating program	histi037.sas
Description	HISTORY OF DISEASE
Unique identifier	DSUBNUM,ORIGTNM
Sorted by	DSUBNUM,ORIGTNM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DDATE,HISTOLGY,CURDATE,THERAPY,HISTORY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
PRIMSITE	char	PRIMARY MALIGNANCY SITE		Collected at CRF.
ICDOCODE	char	ICD DICTIONARY CODE		Collected at CRF.
ORIGTNM	char	ORIGINAL TNM		Collected at CRF.
TNM	char	TNM STAGING		Collected at CRF.
SITE1	char	CURRENT METASTATIC DISEASE SITE 1		Collected at CRF.
SITE2	char	CURRENT METASTATIC DISEASE SITE 2		Collected at CRF.
SITE3	char	CURRENT METASTATIC DISEASE SITE 3		Collected at CRF.
SITE4	char	CURRENT METASTATIC DISEASE SITE 4		Collected at CRF.
SITE5	char	CURRENT METASTATIC DISEASE SITE 5		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DDY	num	RELATIVE DAY OF DIAGNOSIS		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.
CURDY	num	RELATIVE DIAGNOSIS DAY		If CURDATE and REF.DATE not missing then perform below logic to calculate CURDY, If CURDATE less than REF.DATE then (CURDATE - REF.DATE). Else if CURDATE is greater than equal to REF.DATE then (CURDATE- REF.DATE) +1.

1.4.18. HISTORY OF MALIGNANCY – HMALI037

Dataset	HMALI037
Creating program	hmali037.sas
Description	HISTORY OF MALIGNANCY
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset due to missing values: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
CTYPE	num	CANCER TYPE		Collected at CRF.
BMINV	num	BONE MARROW INVOLVED?		Collected at CRF.

1.4.19. LABORATORY COMMENTS – LCMNI037

Dataset	LCMNI037
Creating program	lcmni037.sas
Description	LABORATORY COMMENTS
Unique identifier	DSUBNUM,PERIOD,PHASE,LABTST,VDY
Sorted by	DSUBNUM,PERIOD,PHASE,LABTST,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI, VDATE, LABCMNT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
LABTST	char	LABORATORY TEST CODE		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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.

1.4.20. QUALITY OF LIFE – LIFEI037

Dataset	LIFEI037
Creating program	lifei037.sas
Description	QUALITY OF LIFE
Unique identifier	DSUBNUM,PERIOD,PHASE
Sorted by	DSUBNUM,PERIOD,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
ENERGY	num	ENERGY LEVEL(1-100,-9=MISSING)		Collected at CRF.
WORK	num	WORK ABILITY		Collected at CRF.
QUALITY	num	QUALITY OF LIFE(1-100,-9=MISSING)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVAL	num	1=POOR,2=FAIR,3=GD,4-VGD,5=EXCEL,-9=UNK		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.

1.4.21. MEDICAL HISTORY ABNORMALITIES – MHABI037

Dataset	MHABI037
Creating program	mhabi037.sas
Description	MEDICAL HISTORY ABNORMALITIES
Unique identifier	DSUBNUM,MSYCOD,MABNO
Sorted by	DSUBNUM,MSYCOD,MABNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity

Variable	Type	Label	Codes	Comments
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
MABNO	char	MEDICAL HISTORY ABNORMALITY NUMBER		Collected at CRF.
MSYCOD	num	MEDICAL HISTORY BODY SYSTEM CODE		Collected at CRF.

1.4.22. MEDICAL HISTORY – MHSYI037

Dataset	MHSYI037
Creating program	mhsyi037.sas
Description	MEDICAL HISTORY
Unique identifier	DSUBNUM,MSYCOD
Sorted by	DSUBNUM,MSYCOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
SYDESC	char	SYSTEM DESCRIPTION		Collected at CRF.
NORMAB	num	NORMAL/ABNORMAL		Collected at CRF.
MSYCOD	num	MEDICAL HISTORY BODY SYSTEM CODE		Collected at CRF.

1.4.23. LABORATORY NORMAL RANGES – NLABI037

Dataset	NLABI037
Creating program	nlabi037.sas
Description	LABORATORY NORMAL RANGES
Unique identifier	LABTST,UNQID
Sorted by	LABTST,UNQID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: INVNUM,SUBNUM,STOPDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
LABCODE	num	LABORATORY TEST CODE		Collected at CRF.
EFDATE	char	EFFECTIVE DATE		Collected at CRF.
UNQID	num	UNIQUE ID		Collected at CRF.
LABTST	char	LABORATORY TEST CODE		Collected at CRF.
LABDESC	char	FULL LAB DESCRIPTION		Collected at CRF.
SEX	num	GENDER (1=M, 2=F)		Collected at CRF.
AGELOW	num	LOWER LIMIT OF AGE RANGE		Collected at CRF.
AGEHIGH	num	UPPER LIMIT OF AGE RANGE		Collected at CRF.
NORML	num	LOWER LIMIT OF NORMAL RANGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORMH	num	UPPER LIMIF OF NORMAL RANGE		Collected at CRF.
UNIT	char	UNIT FOR DOENUM		Collected at CRF.

1.4.24. OTHER LABORATORY VALUES – OLABI037

Dataset	OLABI037
Creating program	olabi037.sas
Description	OTHER LABORATORY VALUES
Unique identifier	DSUBNUM,LABTST,PERIOD,PHASE,VDY,HTIME
Sorted by	DSUBNUM,LABTST,PERIOD,PHASE,VDY,HTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI, VDATE, FLAG, CONDIT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
RPT	num	REPEATED LAB TEST?		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTST	char	LABORATORY TEST CODE		Collected at CRF.
LABVAL	num	TEST RESULT		Collected at CRF.
LABVERB	char	LABORATORY TEST VERBATIM		Collected at CRF.
HTIME	char	TIME OF TEST		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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. ON-THERAPY VITAL SIGNS – OTVII037

Dataset	OTVII037
Creating program	otvii037.sas
Description	ON-THERAPY VITAL SIGNS
Unique identifier	DSUBNUM,PERIOD,PHASE,VDY,RPT
Sorted by	DSUBNUM,PERIOD,PHASE,VDY,RPT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
RPT	num	REPEATED LAB TEST?		Collected at CRF.
READING	num	READING		Collected at CRF.
BPSYS	num	SYSTOLIC BP		Collected at CRF.
BPDIAS	num	DIASTOLIC BP		Collected at CRF.
PULSE	num	PULSE		Collected at CRF.
RESP	num	RESPIRATION RATE		Collected at CRF.
TEMP	num	ORAL TEMPERATURE		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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. PHYSICAL EXAMINATION ABNORMALITIES – PEABI037

Dataset	PEABI037
Creating program	peabi037.sas
Description	PHYSICAL EXAMINATION ABNORMALITIES
Unique identifier	DSUBNUM,PSYCOD,PERIOD,PHASE,PABNO
Sorted by	DSUBNUM,PSYCOD,PERIOD,PHASE,PABNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
PABNO	char	PHYSICAL EXAMINATION ABNORMALITY NUMBER		Collected at CRF.
PSYCOD	num	PHYSICAL EXAMINATION BODY SYSTEM		Collected at CRF.

1.4.27. PERFORMANCE SCORES – PERFI037

Dataset	PERFI037
Creating program	perfi037.sas
Description	PERFORMANCE SCORES
Unique identifier	DSUBNUM,PERIOD,PHASE,VDY
Sorted by	DSUBNUM,PERIOD,PHASE,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI, VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PSCORE	num	1(NO RESTRICT),2,3,4,5(DISABLED),-9=UNK)		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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. PHYSICAL EXAMINATION – PESYI037

Dataset	PESYI037
Creating program	pesyi037.sas
Description	PHYSICAL EXAMINATION
Unique identifier	DSUBNUM,PSYCOD,PERIOD,PHASE
Sorted by	DSUBNUM,PSYCOD,PERIOD,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
RPT	num	REPEATED LAB TEST?		Collected at CRF.
SYDESC	char	SYSTEM DESCRIPTION		Collected at CRF.
NORMAB	num	NORMAL/ABNORMAL		Collected at CRF.
PSYCOD	num	PHYSICAL EXAMINATION BODY SYSTEM		Collected at CRF.

1.4.29. PRE/POST VITAL SIGNS – PPVII037

Dataset	PPVII037
Creating program	ppvii037.sas
Description	PRE/POST VITAL SIGNS
Unique identifier	DSUBNUM,PERIOD,PHASE
Sorted by	DSUBNUM,PERIOD,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
RPT	num	REPEATED LAB TEST?		Collected at CRF.
TEMP	num	ORAL TEMPERATURE		Collected at CRF.
RESP	num	RESPIRATION RATE		Collected at CRF.
PULSE	num	PULSE		Collected at CRF.

Variable	Type	Label	Codes	Comments
BPSYS	num	SYSTOLIC BP		Collected at CRF.
BPDIAS	num	DIASTOLIC BP		Collected at CRF.
HGT	num	HEIGHT		Collected at CRF.
WGT	num	WEIGHT		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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. PRIOR THERAPY – PRTHI037

Dataset	PRTHI037
Creating program	prthi037.sas
Description	PRIOR THERAPY
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,DIAGDT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PHASE	num	STUDY PHASE		Collected at CRF.
PERIOD	num	STUDY PERIOD		Collected at CRF.
ILLDUR	num	ILLNESS DURATION		Collected at CRF.
PCOURSE	num	COURSE OF PREVIOUS THERAPY		Collected at CRF.
NCYCLE	num	NUMBER OF CYCLES OF THERAPY		Collected at CRF.
PCYCLE	num	PREVIOUS CYCLE		Collected at CRF.
DIAGDY	num	RELATIVE DIAGNOSIS DAY		If DIAGDT and REF.DATE not missing then perform below logic to calculate DIAGDY, If DIAGDT less than REF.DATE then (DIAGDT - REF.DATE). Else if DIAGDT is greater than equal to REF.DATE then (DIAGDT- REF.DATE) +1.

1.4.31. STUDY DRUG REGIMEN – REGII037

Dataset	REGII037
Creating program	regii037.sas
Description	STUDY DRUG REGIMEN
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset due to missing values: QUAL

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
REGCODE	num	REGIMEN CODE		Collected at CRF.
REGLOBAL	char	CODED RANDOMIZATION		Collected at CRF.

1.4.32. LABORATORY VALUES – SLABI037

Dataset	SLABI037
Creating program	slabi037.sas
Description	LABORATORY VALUES
Unique identifier	DSUBNUM,LABTST,PERIOD,PHASE,VDY,HTIME,RPT
Sorted by	DSUBNUM,LABTST,PERIOD,PHASE,VDY,HTIME,RPT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI, VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
RPT	num	REPEATED LAB TEST?		Collected at CRF.
FLAG	char	HIGH/LOW LAB VALUE FLAG		Collected at CRF.
UNQID	num	UNIQUE ID		Collected at CRF.
LABTST	char	LABORATORY TEST CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABVAL	num	TEST RESULT		Collected at CRF.
LABVERB	char	LABORATORY TEST VERBATIM		Collected at CRF.
HTIME	char	TIME OF TEST		Collected at CRF.
CONDIT	char	CONDITION OF SAMPLE		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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. STUDY MEDICATION – SMEDI037

Dataset	SMEDI037
Creating program	smedi037.sas
Description	STUDY MEDICATION
Unique identifier	DSUBNUM,PHASE,CHEM,SDY
Sorted by	DSUBNUM,PHASE,CHEM,SDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,SDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
PERIOD	num	STUDY PERIOD		Collected at CRF.
SOURCE	num	STUDY DRUG SOURCE		Collected at CRF.
DOSENUM	num	DOSE NUMBER		Collected at CRF.
DOSE	num	DOSE TO BE GIVEN		Collected at CRF.
CHEM	num	CHEMOTHERAPY GIVEN		Collected at CRF.
CRSNO	char	STUDY MEDICATION COURSE NUMBER		Collected at CRF.
SDY	num	RELATIVE STUDY DRUG ADMINISTRATION 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.

1.4.34. SPECIAL TESTS – SPTLI037

Dataset	SPTLI037
Creating program	sptli037.sas
Description	SPECIAL TESTS
Unique identifier	DSUBNUM,PERIOD,PHASE
Sorted by	DSUBNUM,PERIOD,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNUM,VDATE,SPCMT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
RPT	num	REPEATED LAB TEST?		Collected at CRF.
SPCODE	char	SPECIAL TEST CODE		Collected at CRF.
NORMAB	num	NORMAL/ABNORMAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHG	num	CHANGE FROM PREVIOUS VISIT		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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.

1.4.35. SURGERY INFORMATION – SURGI037

Dataset	SURGI037
Creating program	surgi037.sas
Description	SURGERY INFORMATION
Unique identifier	DSUBNUM,FINDINGS,VDY
Sorted by	DSUBNUM,FINDINGS,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,SDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
SSITE	char	SURGERY SITE		Collected at CRF.
FINDINGS	char	FINDINGS		Collected at CRF.
RESIDUAL	char	EXTENT OF RESIDUAL DISEASE		Collected at CRF.
VDY	num	RELATIVE DAY OF ASSESSMENT		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.
SDY	num	RELATIVE STUDY DRUG ADMINISTRATION 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.

1.4.36. SURVIVAL/AUTOPSY INFORMATION – SURVI037

Dataset	SURVI037
Creating program	survi037.sas
Description	SURVIVAL/AUTOPSY INFORMATION
Unique identifier	DSUBNUM,PHASE
Sorted by	DSUBNUM,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVNUM,SUBINI,VDATE,DDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity
STATUS	num	COMPLETION WITHDRAWAL STATUS		Collected at CRF.

Variable	Type	Label	Codes	Comments
VDY	num	RELATIVE DAY OF ASSESSMENT		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.
DDY	num	RELATIVE DAY OF DIAGNOSIS		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.

1.4.37. S_I88037 – S_I88037

Dataset	S_I88037
Creating program	s_i88037.sas
Description	S_I88037
Unique identifier	DSUBJID,AETERM
Sorted by	DSUBJID,AETERM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PATNO,AESTDTC,AEENDTC,AEOUTC,AEOUT,AEACTTRC,AEACTTRT,AECONTRC,AECONTRT

Variable	Type	Label	Codes	Comments
AESEQ	num	C_AESEQ		Collected at CRF.
AESERC	num	C_AESERC		Collected at CRF.
AESER	char	C_AESER		Collected at CRF.
AETERM	char	C_AETERM		Collected at CRF.
AESEVC	num	C_AESEVC		Collected at CRF.
AESEV	char	C_AESEV		Collected at CRF.
AERELC	num	C_AERELC		Collected at CRF.
AEREL	char	C_AEREL		Collected at CRF.
STUDYID	char	STUDY IDENTIFIER		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	SUBJID ASSIGNED FOR DE-IDENTITY		Randomly assigned SUBJID ASSIGNED FOR DE-IDENTITY
AESTDY	num	RELATIVE AE START DAY		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.

1.4.38. TRANSFUSION INFORMATION – TRANI037

Dataset	TRANI037
Creating program	trani037.sas
Description	TRANSFUSION INFORMATION
Unique identifier	DSUBNUM,PERIOD,PHASE,BDY
Sorted by	DSUBNUM,PERIOD,PHASE,BDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,BDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBJECT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned subject number for De-identity

Variable	Type	Label	Codes	Comments
PERIOD	num	STUDY PERIOD		Collected at CRF.
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.
REQUIRE	num	BLOOD REQUIRED?		Collected at CRF.
NUMABN	num	ABNORMALITY NUMBER		Collected at CRF.
TBLOOD	char	NOVA CODE FOR TYPE OF BLOOD		Collected at CRF.
HGBL	num	HGB LEVEL		Collected at CRF.
AMT	num	AMOUNT GIVEN (UNITS)		Collected at CRF.
BDY	num	RELATIVE DAY OF TRANSFUSION		If BDATE and REF.DATE not missing then perform below logic to calculate BDY, If BDATE less than REF.DATE then (BDATE - REF.DATE). Else if BDATE is greater than equal to REF.DATE then (BDATE-REF.DATE) +1.