

Clinical Development

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I88036

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.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- CMNTI036 dataset will be submitted with 0 observations due to sensitivity of data.
- LOTTI036 and SRCEI036 datasets contains sensitive information. Hence, these datasets will not be submitted.
- DEMOI036.VDATE will be used as a reference date(referred as REF. DATE in the document) to derive relative days.

1.3. Data Files

The I88036 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHIC AND BASELINE CHARACTERISTIC – DEMOI036

Dataset	DEMOI036
Creating program	demoi036.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 or due to repetition of the information: SUBINI,INVNUM,VDATE ,BIRTH

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum for de-identity
DSITE	char	SITE ASSIGNED FOR DE-IDENTITY		Randomly assigned 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.
SEX	num	GENDER (1=M, 2=F)		Collected at CRF.
RACE	num	RACE		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
REDGESC	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 – ADVEI036

Dataset	ADVEI036
Creating program	advei036.sas
Description	ADVERSE EVENTS
Unique identifier	DSUBNUM,PERIOD,PHASE,ADVSpe,NUMABN,ADVNOV,ONSETDY
Sorted by	DSUBNUM,PERIOD,PHASE,ADVSpe,NUMABN,ADVNOV,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,DONSET,ADV DUR,ADVCOM

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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.
ADVSP	char	ADVERSE EVENT DIAGNOSIS		Collected at CRF.
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 – AGESI036

Dataset	AGESI036
Creating program	agesi036.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 missing values: BIRTH,SUBINI,MEDSTART,TIMESTAR,LASTMED,TIMESTOP,INVNUM, LASTNAME,INVNAME,AGE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.

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 MEDSDY, 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.
MEDLDY	num	RELATIVE DAY OF LAST DOSE OF STUDY MED		If LASTMED and REF.DATE not missing then perform below logic to calculate MEDLDY, 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)		Element will be grouped to protect subject PII as per HIPPA rules: If age is greater than 89 then "90+".

1.4.4. ALLERGY INFORMATION – ALLEI036

Dataset	ALLEI036
Creating program	alleI036.sas
Description	ALLERGY INFORMATION
Unique identifier	ALLERGY
Sorted by	ALLERGY
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.CADMI036 – CADMI036

Dataset	CADMI036
Creating program	cadmi036.sas
Description	CADMI036
Unique identifier	DSUBNUM,PERIOD,PHASE,DAYNUM,TYPE,CDY
Sorted by	DSUBNUM,PERIOD,PHASE,DAYNUM,TYPE,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – CHEMI036

Dataset	CHEMI036
Creating program	chemi036.sas
Description	CHEMOTHERAPY INFORMATION
Unique identifier	DSUBNUM,THERAPY,LASTDY
Sorted by	DSUBNUM,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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 – CHISI036

Dataset	CHISI036
Creating program	chisi036.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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – CMNTI036

Dataset	CMNTI036
Creating program	cmnti036.sas
Description	COMMENTS RECORDE ON CRF
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	CMNTI036 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	num	SUBNUM 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
SYCODE	num	SYSTEM CODE		Empty dataset will be submitted

1.4.9. CONCOMITANT MEDICATIONS – CURMI036

Dataset	CURMI036
Creating program	curmi036.sas
Description	CONCOMITANT MEDICATIONS
Unique identifier	DSUBNUM,PERIOD,COURSE,NUMABN,DRUG,STARTDY,STOPDY
Sorted by	DSUBNUM,PERIOD,COURSE,NUMABN,DRUG,STARTDY,STOPDY
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
CONT	num	THERAPY CONTINUED?(1=NO,2=YES,-9=UNK)		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 REF.DATE is greater than equal to VDATE then (VDATE - REF.DATE) +1.
CSTARTDY	num	RELATIVE DAY CHEMOTHERAPY STARTED		If CSTART and REF.DATE not missing then perform below logic to calculate STARTDY, 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 STOPDY, 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.

1.4.10. DISCONTIATION DUE TO AE INFO – DCADI036

Dataset	DCADI036
Creating program	dcadi036.sas
Description	DISCONTIATION 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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.

1.4.11. STUDY DISCONTINUATION INFORMATION – DCHEI036

Dataset	DCHEI036
Creating program	dchei036.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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
MEDLDT	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 LVISDY, 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 MEDSDY, 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.
MEDLDY	num	RELATIVE DAY OF LAST DOSE OF STUDY MED		If LASTMED and REF.DATE not missing then perform below logic to calculate MEDLDY, 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.

1.4.12. DISCONTINUATION REASON – DCREI036

Dataset	DCREI036
Creating program	dcrei036.sas
Description	DISCONTINUATION REASON
Unique identifier	DSUBNUM,PERIOD,PHASE,REA
Sorted by	DSUBNUM,PERIOD,PHASE,REA
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.

1.4.13. STUDY MEDICATION DOSING INFORMATION – DOSEI036

Dataset	DOSEI036
Creating program	dosei036.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.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
WGT	num	WEIGHT		Collected at CRF.

1.4.14. STUDY DRUG REGIMEN – DRGNI036

Dataset	DRGNI036
Creating program	drgni036.sas
Description	STUDY DRUG REGIMEN
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset due to missing values: SCHEME,QUAL

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum for de-identity
PERIOD	num	STUDY PERIOD		Collected at CRF.
FULLGLOB	char	FULL GLOBAL REGIMEN DESCRIPTION		Collected at CRF.
GLOBALDE	char	DECODED RANDOMIZATION		Collected at CRF.

1.4.15. POLI036 – EPOLI036

Dataset	EPOLI036
Creating program	epoli036.sas
Description	EPOLI036
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum for de-identity
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 – FMEDI036

Dataset	FMEDI036
Creating program	fmedi036.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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum for de-identity
MEDSTDY	num	RELATIVE DAY OF FIRST DOSE OF STUDY MED		If MEDSTART and REF.DATE not missing then perform below logic to calculate MEDSDY, 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.
MEDLDY	num	RELATIVE DAY OF LAST DOSE OF STUDY MED		If LASTMED and REF.DATE not missing then perform below logic to calculate MEDLDY, 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 – HISTI036

Dataset	HISTI036
Creating program	histi036.sas
Description	HISTORY OF DISEASE
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,VDATE ,DDATE,HISTOLGY,CURDATE,THERAPY,HISTORY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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.

Variable	Type	Label	Codes	Comments
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.
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 – HMALI036

Dataset	HMALI036
Creating program	hmali036.sas
Description	HISTORY OF MALIGNANCY
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – LCMNI036

Dataset	LCMNI036
Creating program	lcmni036.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.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – LIFEI036

Dataset	LIFEI036
Creating program	lifei036.sas
Description	QUALITY OF LIFE
Unique identifier	DSUBNUM,PERIOD,VDY
Sorted by	DSUBNUM,PERIOD,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – MHABI036

Dataset	MHABI036
Creating program	mhabi036.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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
MABNO	char	MEDICAL HISTORY ABNORMALITY NUMBER		Collected at CRF.
MSYCOD	num	MEDICAL HISTORY BODY SYSTEM CODE		Collected at CRF.

1.4.22. MEDICAL HISTORY – MHSYI036

Dataset	MHSYI036
Creating program	mhsyi036.sas
Description	MEDICAL HISTORY
Unique identifier	DSUBNUM,SYDESC
Sorted by	DSUBNUM,SYDESC
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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 – NLABI036

Dataset	NLABI036
Creating program	nlabi036.sas
Description	LABORATORY NORMAL RANGES
Unique identifier	DSUBNUM,UNQID
Sorted by	DSUBNUM,UNQID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVNUM,STOPDATE,SUBNUM

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.

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

1.4.24. OTHER LABORATORY VALUES – OLABI036

Dataset	OLABI036
Creating program	olabi036.sas
Description	OTHER LABORATORY VALUES
Unique identifier	DSUBNUM,PHASE,PERIOD,LABTST,RPT,LABVAL,HTIME,VDY
Sorted by	DSUBNUM,PHASE,PERIOD,LABTST,RPT,LABVAL,HTIME,VDY
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
LABTST	char	LABORATORY TEST CODE		Collected at CRF.
LABVAL	num	TEST RESULT		Collected at CRF.
LABVERB	char	LABORATORY TEST VERBATIM		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 – OTVII036

Dataset	OTVII036
Creating program	otvii036.sas
Description	ON-THERAPY VITAL SIGNS
Unique identifier	DSUBNUM,PHASE,PERIOD,VDY
Sorted by	DSUBNUM,PHASE,PERIOD,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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 – PEABI036

Dataset	PEABI036
Creating program	peabi036.sas
Description	PHYSICAL EXAMINATION ABNORMALITIES
Unique identifier	DSUBNUM,PERIOD,PHASE,PSYCOD,PABNO
Sorted by	DSUBNUM,PERIOD,PHASE,PSYCOD,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – PERFI036

Dataset	PERFI036
Creating program	perfi036.sas
Description	PERFORMANCE SCORES
Unique identifier	DSUBNUM,PERIOD,VDY
Sorted by	DSUBNUM,PERIOD,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – PESYI036

Dataset	PESYI036
Creating program	pesyi036.sas
Description	PHYSICAL EXAMINATION
Unique identifier	DSUBNUM,PERIOD,PHASE,SYDESC
Sorted by	DSUBNUM,PERIOD,PHASE,SYDESC
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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 – PPVII036

Dataset	PPVII036
Creating program	ppvii036.sas
Description	PRE/POST VITAL SIGNS
Unique identifier	DSUBNUM,PERIOD,PHASE,RPT
Sorted by	DSUBNUM,PERIOD,PHASE,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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
BPSYS	num	SYSTOLIC BP		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 – PRTHI036

Dataset	PRTHI036
Creating program	prthi036.sas
Description	PRIOR THERAPY
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,DIAGDT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum for de-identity

Variable	Type	Label	Codes	Comments
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 – REGII036

Dataset	REGII036
Creating program	regii036.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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – SLABI036

Dataset	SLABI036
Creating program	slabi036.sas
Description	LABORATORY VALUES
Unique identifier	DSUBNUM,PHASE,PERIOD,LABTST,RPT,LABVAL,HTIME,VDY
Sorted by	DSUBNUM,PHASE,PERIOD,LABTST,RPT,LABVAL,HTIME,VDY
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 ,CONDIT

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
LABVAL	num	TEST RESULT		Collected at CRF.
LABVERB	char	LABORATORY TEST VERBATIM		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.33. STUDY MEDICATION – SMEDI036

Dataset	SMEDI036
Creating program	smedi036.sas
Description	STUDY MEDICATION
Unique identifier	DSUBNUM,PERIOD,PHASE,DOSENUM,SDY
Sorted by	DSUBNUM,PERIOD,PHASE,DOSENUM,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.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum for de-identity
PHASE	num	STUDY PHASE		Collected at CRF.
COURSE	num	COURSE OF TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 – SPTLI036

Dataset	SPTLI036
Creating program	sptli036.sas
Description	SPECIAL TESTS
Unique identifier	DSUBNUM,PERIOD,PHASE,RPT
Sorted by	DSUBNUM,PERIOD,PHASE,RPT
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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 – SURGI036

Dataset	SURGI036
Creating program	surgi036.sas
Description	SURGERY INFORMATION
Unique identifier	DSUBNUM,NUMABN,FINDINGS,VDY,SDY
Sorted by	DSUBNUM,NUMABN,FINDINGS,VDY,SDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE ,SDATE,SSITE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL NUMBER		Collected at CRF.
DSUBNUM	char	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
NUMABN	num	ABNORMALITY NUMBER		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 – SURVI036

Dataset	SURVI036
Creating program	survi036.sas
Description	SURVIVAL/AUTOPSY INFORMATION
Unique identifier	DSUBNUM,PHASE,VDY,DDY
Sorted by	DSUBNUM,PHASE,VDY,DDY
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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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_I88036 – S_I88036

Dataset	S_I88036
Creating program	s_i88036.sas
Description	S_I88036
Unique identifier	DSUBJID,AESEQ,AESTDY
Sorted by	DSUBJID AESEQ AESTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PATNO,AETERM,AESTDTC,AEENDTC,AEOUTC,AEOUT,AEACTTRC,AEACTTRT, AECONTRC,AECONTRT

Variable	Type	Label	Codes	Comments
AESEQ	num	C_AESEQ		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESERC	num	C_AESERC		Collected at CRF.
AESER	char	C_AESER		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.
DSUBJID	char	SUBJID ASSIGNED FOR DE-IDENTITY		Randomly assigned subjid 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 – TRANI036

Dataset	TRANI036
Creating program	trani036.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	SUBNUM ASSIGNED FOR DE-IDENTITY		Randomly assigned subnum 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.
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.

Variable	Type	Label	Codes	Comments
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.