Clinical Development

JNJ-7472179

I88009

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.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- DRGNI009 dataset contains zero observations. Hence will not be submitted.
- DEMOI009. 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 I88009 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHICS – DEMOI009

Dataset	DEMOI009
Creating program	demoi009.sas
Description	DEMOGRAPHICS
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,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
DSITE	num	site assigned for de-identity		Randomly assigned site for de-identity
PHASE	num	phase		Collected at CRF.
RACE	num	race		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	sex		Collected at CRF.
AGE	char	age		Collected at CRF.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.2. ADVERSE EVENTS – ADVEI009

Dataset	ADVEI009
Creating program	advei009.sas
Description	ADVERSE EVENTS
Unique identifier	DSUBNUM,PERIOD,PHASE,ADVSPE,NUMABN,ADVNOV,STAMPDY,ONSETDY
Sorted by	DSUBNUM,PERIOD,PHASE,ADVSPE,NUMABN,ADVNOV,STAMPDY,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,DONSET,ADVDUR,ADVCOM,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
ADVEXP	num	advexp		Collected at CRF.
NUMABN	num	numabn		Collected at CRF.
ADVNOV	char	advnov		Collected at CRF.
ADVSPE	char	advspe		Collected at CRF.
TONSET	char	tonset		Collected at CRF.
ADVSEV	num	advsev		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVREL	num	advrel		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.3. AGE – AGESI009

Dataset	AGESI009
Creating program	agesi009.sas
Description	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,SEX_C,SEX,AGE_C,AGE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
SOURCE	char	source		Collected at CRF.
MEDSTRDY	num	Relative medstart day		If MEDSTART and REF.DATE not missing then perform below logic to calculate MEDSTRDY, 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
LSTMEDDY	num	Relative lastmed day		If LASTMED and REF.DATE not missing then perform below logic to calculate LSTMEDDY, 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.

1.4.4. ALLERGY – ALLEI009

Dataset	ALLEI009
Creating program	allei009.sas
Description	ALLERGY
Unique identifier	DSUBNUM,REACTION,STAMPDY,MODIFYDY
Sorted by	DSUBNUM,REACTION,STAMPDY,MODIFYDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PHASE	num	phase		Collected at CRF.
ALLER	num	aller		Collected at CRF.
NUMABN	num	numabn		Collected at CRF.

Variable	Type	Label	Codes	Comments
ALLERGY	char	allergy		Collected at CRF.
REACTION	char	reaction		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.5. BLABI009 – BLABI009

Dataset	BLABI009
Creating program	blabi009.sas
Description	BLABI009
Unique identifier	DSUBNUM,PERIOD,LABTST,STAMPDY,HTIME
Sorted by	DSUBNUM,PERIOD,LABTST,STAMPDY,HTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,ACCNO,VDATE,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
HTIME	char	htime		Collected at CRF.
PHASE	num	phase		Collected at CRF.
PERIOD	num	period		Collected at CRF.
RPT	num	rpt		Collected at CRF.
FLAG	char	flag		Collected at CRF.
XFLAG	char	xflag		Collected at CRF.
DELTA	char	delta		Collected at CRF.
UNQID	num	unqid		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTST	char	labtst		Collected at CRF.
LABVAL	num	labval		Collected at CRF.
LABVERB	char	labverb		Collected at CRF.
CONDIT	char	condit		Collected at CRF.
TERM	char	term		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.6. COMMENT – CMNTI009

Dataset	CMNTI009
Creating program	cmnti009.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
PROTOCOL	char	protocol		Empty data will be submitted.
DSUBNUM	num	subnum assigned for de-identity		Empty data will be submitted.
PERIOD	num	period		Empty data will be submitted.
PHASE	num	phase		Empty data will be submitted.
CMTCODE	char	cmtcode		Empty data will be submitted.
SYCODE	num	sycode		Empty data will be submitted.
BATCHID	num	batchid		Empty data will be submitted.
INTERIM	num	interim		Empty data will be submitted.
TUPID	num	tupid		Empty data will be submitted.
MODIFYDY	num	Relative modify Day		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
STAMPDY	num	Relative stamp Day		Empty data will be submitted.

1.4.7. CURMI009 – CURMI009

Dataset	CURMI009
Creating program	curmi009.sas
Description	CURMI009
Unique identifier	DSUBNUM,PERIOD,DRUG,REGI,RT,STR,STAMPDY,CSTARTDY,CSTOPDY
Sorted by	DSUBNUM,PERIOD,DRUG,REGI,RT,STR,STAMPDY,CSTARTDY,CSTOPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,CSTART,CSTOP,INDIC,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
CONMED	num	conmed		Collected at CRF.
NUMABN	num	numabn		Collected at CRF.
DRUG	char	drug		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONT	num	cont		Collected at CRF.
RT	char	rt		Collected at CRF.
STR	char	str		Collected at CRF.
REGI	char	regi		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
CSTARTDY	num	Relative cstart Day		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 cstop Day		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.

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

1.4.8. DCADI009 – DCADI009

Dataset	DCADI009
Creating program	dcadi009.sas
Description	DCADI009
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 or due to missing values: SUBINI,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
ADVNOV	char	advnov		Collected at CRF.

Variable	Type	Label	Codes	Comments
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.9. DCHEI009 – DCHEI009

Dataset	DCHEI009
Creating program	dchei009.sas
Description	DCHEI009
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,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity

Variable	Type	Label	Codes	Comments
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
COMPLETE	num	complete		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
LSTVISDY	num	Relative lastvis 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.
MEDSTRDY	num	Relative medstart Day		If MEDSTART and REF.DATE not missing then perform below logic to calculate MEDSTRDY, 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.
LSTMEDDY	num	Relative lastmed Day		If LASTMED and REF.DATE not missing then perform below logic to calculate LSTMEDDY, 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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.

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

1.4.10. DCREI009 – DCREI009

Dataset	DCREI009
Creating program	dcrei009.sas
Description	DCREI009
Unique identifier	DSUBNUM,REA
Sorted by	DSUBNUM,REA
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,REASSPEC,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
REA	num	rea		Collected at CRF.

Variable	Type	Label	Codes	Comments
REASON	char	reason		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.11. EPOCI009 – EPOCI009

Dataset	EPOCI009
Creating program	epoci009.sas
Description	EPOCI009
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: AMGSTRT,AMGSTOP,OBIBSTRT,OBIBSTOP,OBIFSTRT,OBIFSTOP,DMODIFY, DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
AMGSTRDY	num	Relative amgstrt Day		If AMGSTRT and REF.DATE not missing then perform below logic to calculate AMGSTRDY, If AMGSTRT less than REF.DATE then (AMGSTRT - REF.DATE). Else if AMGSTRT is greater than equal to REF.DATE then (AMGSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OBBSTRDY	num	Relative obibstrt Day		If OBIBSTRT and REF.DATE not missing then perform below logic to calculate OBBSTRDY, If OBIBSTRT less than REF.DATE then (OBIBSTRT - REF.DATE). Else if OBIBSTRT is greater than equal to REF.DATE then (OBIBSTRT- REF.DATE) +1.
OBSTOPDY	num	Relative obibstop Day		If OBIBSTOP and REF.DATE not missing then perform below logic to calculate OBSTOPDY, If OBIBSTOP less than REF.DATE then (OBIBSTOP - REF.DATE). Else if OBIBSTOP is greater than equal to REF.DATE then (OBIBSTOP- REF.DATE) +1.
OBFSTRDY	num	Relative obifstrt Day		If OBIFSTRT and REF.DATE not missing then perform below logic to calculate OBFSTRDY, If OBIFSTRT less than REF.DATE then (OBIFSTRT - REF.DATE). Else if OBIFSTRT is greater than equal to REF.DATE then (OBIFSTRT- REF.DATE) +1.
OFSTOPDY	num	Relative obifstop Day		If OBIFSTOP and REF.DATE not missing then perform below logic to calculate OFSTOPDY, If OBIFSTOP less than REF.DATE then (OBIFSTOP - REF.DATE). Else if OBIFSTOP is greater than equal to REF.DATE then (OBIFSTOP- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.12. LCMNI009 – LCMNI009

Dataset	LCMNI009
Creating program	lcmni009.sas
Description	LCMNI009
Unique identifier	DSUBNUM,PERIOD,PHASE,LABTST,STAMPDY
Sorted by	DSUBNUM,PERIOD,PHASE,LABTST,STAMPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,ACCNO,VDATE,LABCMNT,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
LABTST	char	labtst		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.13. LIFE – LIFEI009

Dataset	LIFEI009
Creating program	lifei009.sas
Description	LIFE
Unique identifier	DSUBNUM,PERIOD
Sorted by	DSUBNUM,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
ENERGY	num	energy		Collected at CRF.
WORK	num	work		Collected at CRF.
QUALITY	num	quality		Collected at CRF.
EVAL	num	eval		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.14. MHABI009 – MHABI009

Dataset	MHABI009
Creating program	mhabi009.sas
Description	MHABI009
Unique identifier	DSUBNUM,MSYCOD,MABNO,STAMPDY,MODIFYDY
Sorted by	DSUBNUM,MSYCOD,MABNO,STAMPDY,MODIFYDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PHASE	num	phase		Collected at CRF.
NUMABN	num	numabn		Collected at CRF.
MABNO	char	mabno		Collected at CRF.
MSYCOD	num	msycod		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.

Variable	Type	Label	Codes	Comments
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.15. MHSYI009 – MHSYI009

Dataset	MHSYI009
Creating program	mhsyi009.sas
Description	MHSYI009
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,DMODIFY,DSTAMP

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

Variable	Type	Label	Codes	Comments
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PHASE	num	phase		Collected at CRF.
SYDESC	char	sydesc		Collected at CRF.
NORMAB	num	normab		Collected at CRF.
MSYCOD	num	msycod		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.16. NLABI009 – NLABI009

Dataset	NLABI009
Creating program	nlabi009.sas
Description	NLABI009
Unique identifier	LABTST,NORML,AGELOW
Sorted by	LABTST,NORML,AGELOW
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

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
LABCODE	num	labcode		Collected at CRF.
EFDATE	char	ef date		Collected at CRF.
UNQID	num	unqid		Collected at CRF.
STOPDATE	char	stop date		Collected at CRF.
LABTST	char	labtst		Collected at CRF.
LABDESC	char	labdesc		Collected at CRF.
SEX	num	sex		Collected at CRF.
AGELOW	num	agelow		Collected at CRF.
AGEHIGH	num	agehigh		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORML	num	norml		Collected at CRF.
NORMH	num	normh		Collected at CRF.
UNIT	char	unit		Collected at CRF.
DMODIFY	num	modify date		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
DSTAMP	num	stamp date		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.

1.4.17. OLABI009 – OLABI009

Dataset	OLABI009
Creating program	olabi009.sas
Description	OLABI009
Unique identifier	DSUBNUM,PHASE,PERIOD,LABTST,RPT,FLAG,LABVAL,STAMPDY,MODIFYDY,HTIME
Sorted by	DSUBNUM,PHASE,PERIOD,LABTST,RPT,FLAG,LABVAL,STAMPDY,MODIFYDY,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,ACCNO,VDATE,XFLAG,LABVERB,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
HTIME	char	htime		Collected at CRF.
PHASE	num	phase		Collected at CRF.
PERIOD	num	period		Collected at CRF.
RPT	num	rpt		Collected at CRF.
FLAG	char	flag		Collected at CRF.
DELTA	char	delta		Collected at CRF.
UNQID	num	unqid		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTST	char	labtst		Collected at CRF.
LABVAL	num	labval		Collected at CRF.
CONDIT	char	condit		Collected at CRF.
TERM	char	term		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.18. OTBPI009 – OTBPI009

Dataset	OTBPI009
Creating program	otbpi009.sas
Description	OTBPI009
Unique identifier	DSUBNUM,PERIOD,PHASE,DOSENUM,RPT,BPSYS,STAMPDY
Sorted by	DSUBNUM,PERIOD,PHASE,DOSENUM,RPT,BPSYS,STAMPDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
RPT	num	rpt		Collected at CRF.
DOSENUM	num	dosenum		Collected at CRF.
BPSYS	num	bpsys		Collected at CRF.
BPDIAS	num	bpdias		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.19. PEABI009 – PEABI009

Dataset	PEABI009
Creating program	peabi009.sas
Description	PEABI009
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,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
NUMABN	num	numabn		Collected at CRF.
PABNO	char	pabno		Collected at CRF.
PSYCOD	num	psycod		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.

Variable	Type	Label	Codes	Comments
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.20. PERFI009 – PERFI009

Dataset	PERFI009
Creating program	perfi009.sas
Description	PERFI009
Unique identifier	DSUBNUM,PERIOD,MODIFYDY
Sorted by	DSUBNUM,PERIOD,MODIFYDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DMODIFY,DSTAMP

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

Variable	Type	Label	Codes	Comments
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
PSCORE	num	pscore		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.21. PESYI009– PESYI009

Dataset	PESYI009
Creating program	pesyi009.sas
Description	PESYI009
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,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
RPT	num	rpt		Collected at CRF.
SYDESC	char	sydesc		Collected at CRF.
NORMAB	num	normab		Collected at CRF.
PSYCOD	num	psycod		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUPID	num	tupid		Collected at CRF.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.22. PPVII009 – PPVII009

Dataset	PPVII009
Creating program	ppvii009.sas
Description	PPVII009
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,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
RPT	num	rpt		Collected at CRF.
TEMP	num	temp		Collected at CRF.
RESP	num	resp		Collected at CRF.
PULSE	num	pulse		Collected at CRF.
BPSYS	num	bpsys		Collected at CRF.
BPDIAS	num	bpdias		Collected at CRF.

Variable	Type	Label	Codes	Comments
HGT	num	hgt		Collected at CRF.
WGT	num	wgt		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.23. REGIMEN – REGII009

Dataset	REGII009
Creating program	regii009.sas
Description	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		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for De-Identity
PERIOD	num	period		Collected at CRF.
REGCODE	num	regcode		Collected at CRF.
REGLOBAL	char	reglobal		Collected at CRF.

1.4.24. SLABI009 – SLABI009

Dataset	SLABI009
Creating program	slabi009.sas
Description	SLABI009
Unique identifier	DSUBNUM,PHASE,PERIOD,LABTST,RPT,LABVAL,STAMPDY,MODIFYDY,HTIME
Sorted by	DSUBNUM,PHASE,PERIOD,LABTST,RPT,LABVAL,STAMPDY,MODIFYDY,HTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,ACCNO,VDATE,LABVERB,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
HTIME	char	htime		Collected at CRF.
PHASE	num	phase		Collected at CRF.
PERIOD	num	period		Collected at CRF.
RPT	num	rpt		Collected at CRF.
FLAG	char	flag		Collected at CRF.
XFLAG	char	xflag		Collected at CRF.
DELTA	char	delta		Collected at CRF.
UNQID	num	unqid		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTST	char	labtst		Collected at CRF.
LABVAL	num	labval		Collected at CRF.
CONDIT	char	condit		Collected at CRF.
TERM	char	term		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.25. SMEDI009 – SMEDI009

Dataset	SMEDI009
Creating program	smedi009.sas
Description	SMEDI009
Unique identifier	DSUBNUM,PERIOD,PHASE,DOSENUM,VTIME
Sorted by	DSUBNUM,PERIOD,PHASE,DOSENUM,VTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
DOSENUM	num	dosenum		Collected at CRF.
VTIME	char	vtime		Collected at CRF.
WGT	num	wgt		Collected at CRF.
DOSE	num	dose		Collected at CRF.
UNITS	num	units		Collected at CRF.
DISP	num	disp		Collected at CRF.

Variable	Type	Label	Codes	Comments
SRT	num	srt		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.
SOURCE	num	source		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.26. SPTLI009 – SPTLI009

Dataset	SPTLI009
Creating program	sptli009.sas
Description	SPTLI009
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,SPCMT,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
RPT	num	rpt		Collected at CRF.
SPCODE	char	spcode		Collected at CRF.
NORMAB	num	normab		Collected at CRF.
CHG	num	chg		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUPID	num	tupid		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.27. TAZTI009 – TAZTI009

Dataset	TAZTI009
Creating program	tazti009.sas
Description	TAZTI009
Unique identifier	DSUBNUM,PERIOD,PHASE,TAZT
Sorted by	DSUBNUM,PERIOD,PHASE,TAZT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VDATE,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
TAZT	num	tazt		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.
TUPID	num	tupid		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.

1.4.28. TRANI009 – TRANI009

Dataset	TRANI009
Creating program	trani009.sas
Description	TRANI009
Unique identifier	DSUBNUM,PERIOD,PHASE,STAMPDY,BDY
Sorted by	DSUBNUM,PERIOD,PHASE,STAMPDY,BDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,BDATE,DMODIFY,DSTAMP

Variable	Type	Label	Codes	Comments
PROTOCOL	char	protocol		Collected at CRF.
DSUBNUM	num	subnum assigned for de-identity		Randomly assigned subnum for de-identity
PERIOD	num	period		Collected at CRF.
PHASE	num	phase		Collected at CRF.
REQUIRE	num	require		Collected at CRF.
NUMABN	num	numabn		Collected at CRF.
TBLOOD	char	tblood		Collected at CRF.
AMT	num	amt		Collected at CRF.
BATCHID	num	batchid		Collected at CRF.
INTERIM	num	interim		Collected at CRF.

Variable	Type	Label	Codes	Comments
TUPID	num	tupid		Collected at CRF.
BDY	num	Relative b Day		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.
MODIFYDY	num	Relative modify Day		If DMODIFY and REF.DATE not missing then perform below logic to calculate MODIFYDY, If DMODIFY less than REF.DATE then (DMODIFY - REF.DATE). Else if DMODIFY is greater than equal to REF.DATE then (DMODIFY- REF.DATE) +1.
STAMPDY	num	Relative stamp Day		If DSTAMP and REF.DATE not missing then perform below logic to calculate STAMPDY, If DSTAMP less than REF.DATE then (DSTAMP - REF.DATE). Else if DSTAMP is greater than equal to REF.DATE then (DSTAMP- REF.DATE) +1.