Clinical Development

JNJ-7472179

J89040

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	22 Feb 2017

Table of contents

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.
- AGES, ASSIGN, KEYCOMP, VITALSSVW, INVNAM datasets has zero observations. Hence these datasets will not be submitted.
- DEMOJ040.MEDSTART will be used as a Reference Date to derive relative days (referred as REF.DATE in the document).

1.3. Data Files

The J89040 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHICS – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	DEMOGRAPHICS
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REC_ID,EVDAT,EVDATE,BIRTHD,BIRTHDT,RACESPEC Below listed variables were not part of the Raw dataset. These have been added to retain the Demographic related information in the de-identified datasets: AGE (Source: PROFILE1 dataset) AGEUNIT (Source: PROFILE1 dataset) DSITEID (Source: PROFILE1 dataset)

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DSCTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
VISITNO	num	VISIT NUMBER		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.
AGEUNIT	char	AGEUNIT		Collected at CRF.
RACE	char	RACE		Collected at CRF.
SEX	char	SEX		Collected at CRF.
DSITEID	char	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned Site id for De-identity

1.4.2.ADVEDTL – ADVEDTL

Dataset	ADVEDTL
Creating program	advedtl.sas
Description	ADVEDTL
Unique identifier	DPATNO,EVENT_ID,ADVDESC,ADVNOV,ADVDUR,ONSETDY,
Sorted by	DPATNO,EVENT_ID,ADVDESC,ADVNOV,ADVDUR,ONSETDY,
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 non significant elements or due to missing values: REC_ID,SCTRY,VERBATIM,ADVSPE,ONSETD,ONSETDT,TONSE,TONSET, SERIOUS,ACTION,CONCOM,OUTCOME,ADVCOM,ACTIONF,CONCOMF, OUTCOMEF, SERIOUSF

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ENTRYNO	num	ENTRY NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVNOV	char	ADVERSE NOVA CODE		Collected at CRF.
ADVCODE	char	WHO ART CODE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
ADVDUR	char	ADVERSE DURATION		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
VISITNO	num	VISIT NUMBER		Collected at CRF.
DRUGRELF	char	DECODING, WAS AE RELATED TO DRUG?		Collected at CRF.
SEVERITF	char	DECODING,SEVERITY		Collected at CRF.
ONSETDY	num	RELATIVE ONSET DAY OF AE		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.

1.4.3.ADVEHDR – ADVEHDR

Dataset	ADVEHDR
Creating program	advehdr.sas
Description	ADVEHDR
Unique identifier	DPATNO,EVENT_ID
Sorted by	DPATNO,EVENT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE

Variable	Type	Label	Codes	Comments
F_STATUS	char	STATUS OF RECORD		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
TAREA	char	DEFINING THE DRUG PROGRAM		Collected at CRF.
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
PAG_NAME	char	PAGE NAME		Collected at CRF.
ADVEXP	num	AE OCCURED		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity

Variable	Type	Label	Codes	Comments
VISITNO	num	VISIT NUMBER		Collected at CRF.
ADVEXPF	char	DECODING,AE OCCURED		Collected at CRF.

1.4.4.ADVERSE EXPERIENCES – ADVEJ040

Dataset	ADVEJ040
Creating program	advej040.sas
Description	Adverse Experiences
Unique identifier	DSUBNUM,PERIOD,ADVNOV, ADVDUR, ONSETDY
Sorted by	DSUBNUM,PERIOD,ADVNOV,ADVDUR,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,ADVSPE,VERBATIM,DONSET,ADVCOM,DSTAMP,DMODIFY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
ADVEXP	num	AE OCCURED		Collected at CRF.
NUMABN	num	NUMABN		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVNOV	char	ADVERSE NOVA CODE		Collected at CRF.
TONSET	char	TIME OF ONSET, FORMAT 24 HR CLOCK		Collected at CRF.
ADVSEV	num	ADVSEV		Collected at CRF.
ADVDUR	char	ADVERSE DURATION		Collected at CRF.
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 ONSET and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSET less than REF.DATE then (ONSET - REF.DATE). Else if ONSET is greater than equal to REF.DATE then (ONSET- 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.
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.

1.4.5.AGESJ040 – AGESJ040

Dataset	AGESJ040
Creating program	agesj040.sas
Description	AGESJ040
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	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
SOURCE	char	SOURCE		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

1.4.6.BCVRJ040 – BCVRJ040

Dataset	BCVRJ040
Creating program	bcvrj040.sas
Description	BCVRJ040
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: LASTNAME, LASTMED, MEDSTART

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
TOS	num	TIME ON STUDY		Collected at CRF.
BAS_ANC	num	BASELINE ABSOLUTE NEUTROPHIL COUNT		Collected at CRF.
BAS_WBC	num	BASELINE WBC		Collected at CRF.
BAS_HGB	num	BASELINE HEMOGLOBIN		Collected at CRF.
BAS_HCT	num	BASELINE HEMATOCRIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
BAS_PLAT	num	BASELINE PLATELET COUNT		Collected at CRF.
BAS_LYMP	num	BASELINE LYMPHOCYTES		Collected at CRF.
BAS_NEUT	num	BASELINE NEUTROPHIL COUNT		Collected at CRF.
BAS_RET	num	BASELINE RETICULOCYTE COUNT		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

1.4.7.CHEMJ040 – CHEMJ040

Dataset	CHEMJ040
Creating program	chemj040.sas
Description	CHEMJ040
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: LASTNAME,LASTMED,MEDSTART

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

Variable	Type	Label	Codes	Comments
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
TOS	num	TIME ON STUDY		Collected at CRF.
PRE_CHEM	num	PRESTUDY CHEMOTHERAPY USAGE INDICATOR		Collected at CRF.
PRE_FLUD	num	PRESTUDY FLUDARABINE COURSES		Collected at CRF.
DB_CHEM	num	ON STUDY CHEMOTHERAPY USAGE INDICATOR		Collected at CRF.
DB_FLUD	num	DOUBLE-BLIND FLUDARABINE COURSES		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

1.4.8.CHEMO – CHEMO

Dataset	CHEMO
Creating program	chemo.sas
Description	CHEMO
Unique identifier	DSUBNUM,TUPID
Sorted by	DSUBNUM,TUPID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,VERBATIM,CSTART,CSTOP,DSTAMP,DMODIFY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
RECHEM	num	RECHEM		Collected at CRF.
TYPE	char	TYPE		Collected at CRF.
CONT	num	CONT		Collected at CRF.
SUNIT	char	SUNIT		Collected at CRF.
STR	num	STR		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGI	char	REGI		Collected at CRF.
DOSE	num	DOSE		Collected at CRF.
DUNIT	char	DUNIT		Collected at CRF.
BATCHID	num	BATCHID		Collected at CRF.
INTERIM	num	INTERIM		Collected at CRF.
TUPID	num	TUPID		Collected at CRF.
STARTDY	num	RELATIVE START DAY		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.
STOPDY	num	RELATIVE STOP DAY		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.
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.
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.

1.4.9.DBPROF40 – DBPROF40

Dataset	DBPROF40
Creating program	dbprof40.sas
Description	DBPROF40
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,MEDSTART,TIMESTAR,LASTMED,TIMESTOP,INVNUM,LASTNAME, INVNAME,SEX,AGE,RACE,VDATE,SVDATE,SDDATE,MONTH

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
OL	num	OL		Collected at CRF.
EPOEXPOS	num	EPOEXPOS		Collected at CRF.

Variable	Type	Label	Codes	Comments
WGT	num	WEIGHT		Collected at CRF.
HGT	num	HEIGHT		Collected at CRF.
SPLEN	num	SPLEN		Collected at CRF.
FLUDAR	num	FLUDAR		Collected at CRF.
CYTOTOX	num	CYTOTOX		Collected at CRF.
CHEMO	num	CHEMO		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
LABTST	char	LABTST		Collected at CRF.
LABVAL	num	LABVAL		Collected at CRF.
STAGE	num	STAGE		Collected at CRF.
DSTAGE	num	DSTAGE		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.
VDY	num	RELATIVE VDAY		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
SVDY	num	RELATIVE SV DAY		If SVDATE and REF.DATE not missing then perform below logic to calculate SVDY, If SVDATE less than REF.DATE then (SVDATE - REF.DATE). Else if SVDATE is greater than equal to REF.DATE then (SVDATE- REF.DATE) +1.
SDDY	num	RELATIVE SD DAY		If SDDATE and REF.DATE not missing then perform below logic to calculate SDDY, If SDDATE less than REF.DATE then (SDDATE - REF.DATE). Else if SDDATE is greater than equal to REF.DATE then (SDDATE- REF.DATE) +1.

1.4.10. DCADJ040 – DCADJ040

Dataset	DCADJ040
Creating program	dcadj040.sas
Description	DCADJ040
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,ADVESPE,VERBATIM,DSTAMP,DMODIFY

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

Variable	Type	Label	Codes	Comments
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
ADVNOV	char	ADVERSE NOVA CODE		Collected at CRF.
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.
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.

1.4.11. DOUBLE BLIND PHASE COMPLETION INFO – DCHEJ040

Dataset	DCHEJ040
Creating program	dchej040.sas
Description	Double Blind Phase Completion 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 or due to repetition of the information: SUBINI,LASTVIS,MEDSTART,LASTMED,DSTAMP,DMODIFY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PHASE	num	PHASE OF STUDY		Collected at CRF.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
COMPLETE	num	COMPLETE		Collected at CRF.
CONT	num	CONT		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
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.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.
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.
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.

1.4.12. DCREJ040 – DCREJ040

Dataset	DCREJ040
Creating program	dcrej040.sas
Description	DCREJ040
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: SUBINI,REASSPEC,DSTAMP,DMODIFY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
REA	num	REA		Collected at CRF.
REASON	char	DISCONTINUATION REASON		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
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.
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.

1.4.13. PATIENT BACKGROUND – DEMOJ040

Dataset	DEMOJ040
Creating program	demoj040.sas
Description	Patient Background
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: LASTNAME,MEDSTART,LASTMED,PRDESC,SEX,RACE,RACESPEC,AGE

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

Variable	Type	Label	Codes	Comments
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
TOS	num	TIME ON STUDY		Collected at CRF.
STAGE_B	num	STAGE OF DISEASE AT BASELINE		Collected at CRF.
COMPLET	num	PATIENT DISPOSITION		Collected at CRF.
PRIMREA	num	PRIMARY REASON FOR DISCONTINUATION		Collected at CRF.
SPLENOMG	num	BASELINE SPLENOMEGALY		Collected at CRF.
STAGE_D	num	STAGE OF DISEASE AT DIAGNOSIS		Collected at CRF.
EPO	num	EPO LEVEL		Collected at CRF.
WGT	num	WEIGHT		Collected at CRF.
HGT	num	HEIGHT		Collected at CRF.
TIMEDIAG	num	TIME FROM DIAGNOSIS TO STUDY START		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

1.4.14. DRGNJ040 – DRGNJ040

Dataset	DRGNJ040
Creating program	drgnj040.sas
Description	DRGNJ040
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		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
FULLGLOB	char	FULLGLOBAL		Collected at CRF.
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.

1.4.15. KEYADVE1 – KEYADVE1

Dataset	KEYADVE1
Creating program	keyadve1.sas
Description	KEYADVE1
Unique identifier	DPATNO,DRUGRELF,ADVDUR,ADVDESC,ONSETDY
Sorted by	DPATNO,DRUGRELF,ADVDUR,ADVDESC,ONSETDY
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 non significant elements or due to missing values: VERBATIM,ADVSPE,ONSETDT,TONSET,SERIOUS,ACTION,CONCOM,OUTCOME, ADVCOM,ACTIONF,CONCOMF,OUTCOMEF,SERIOUSF,STOPDT,STOPTIME, MEDSTRDT,MEDSTPDT,DURDAY,REGDAY

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
ADVNOV	char	ADVERSE NOVA CODE		Collected at CRF.
ADVCODE	char	WHO ART CODE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVDUR	char	ADVERSE DURATION		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
DRUGRELF	char	DECODING, WAS AE RELATED TO DRUG?		Collected at CRF.
SEVERITF	char	DECODING,SEVERITY		Collected at CRF.
ADVEXP	num	AE OCCURED		Collected at CRF.
ADVEXPF	char	DECODING,AE OCCURED		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
BODYSYS	char	WHO BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	WHO PREFERRED TERM DESCRIPTION		Collected at CRF.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
ONSETDY	num	RELATIVE ONSET DAY OF AE		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.

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

1.4.16. KEYADVE2 – KEYADVE2

Dataset	KEYADVE2
Creating program	keyadve2.sas
Description	KEYADVE2
Unique identifier	DPATNO,DRUGRELF,ADVDESC,ONSETDY
Sorted by	DPATNO,DRUGRELF,ADVDESC,ONSETDY
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 non significant elements or due to missing values: VERBATIM,ADVSPE,ONSETDT,TONSET,SERIOUS,ACTION,CONCOM,OUTCOME, ACTIONF,CONCOMF,OUTCOMEF,SERIOUSF,STOPDT,STOPTIME,MEDSTRDT, MEDSTPDT,DURDAY,REGDAY

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVNOV	char	ADVERSE NOVA CODE		Collected at CRF.
ADVCODE	char	WHO ART CODE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.
ADVDUR	char	ADVERSE DURATION		Collected at CRF.
ADVCOM	char	ADVERSE COMMENTS		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
DRUGRELF	char	DECODING, WAS AE RELATED TO DRUG?		Collected at CRF.
SEVERITF	char	DECODING,SEVERITY		Collected at CRF.
ADVEXP	num	AE OCCURED		Collected at CRF.
ADVEXPF	char	DECODING,AE OCCURED		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
BODYSYS	char	WHO BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	WHO PREFERRED TERM DESCRIPTION		Collected at CRF.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.

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

1.4.17. KEYADVE3 – KEYADVE3

Dataset	KEYADVE3
Creating program	keyadve3.sas
Description	KEYADVE3
Unique identifier	DPATNO,ADVDESC,ADVDUR,PHASE,ONSETDY
Sorted by	DPATNO,ADVDESC,ADVDUR,PHASE,ONSETDY
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 non significant elements or due to missing values: VERBATIM,ADVSPE,ONSETDT,TONSET,SERIOUS,ACTION,CONCOM,OUTCOME, ADVCOM,ACTIONF,CONCOMF,OUTCOMEF,SERIOUSF,STOPDT, MEDSTRDT, MEDSTPDT,DURDAY,REGDAY

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
EVENT_ID	char	EVENT(VISIT) NAME		Collected at CRF.
ADVNOV	char	ADVERSE NOVA CODE		Collected at CRF.
ADVCODE	char	WHO ART CODE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.
DRUGREL	num	RELATIONSHIP TO STUDY DRUG		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVDUR	char	ADVERSE DURATION		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
DRUGRELF	char	DECODING, WAS AE RELATED TO DRUG?		Collected at CRF.
SEVERITF	char	DECODING,SEVERITY		Collected at CRF.
STOPTIME	char	STOP TIME OF AE		Collected at CRF.
ADVEXP	num	AE OCCURED		Collected at CRF.
ADVEXPF	char	DECODING,AE OCCURED		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
BODYSYS	char	WHO BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	WHO PREFERRED TERM DESCRIPTION		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
ONSETDY	num	RELATIVE ONSET DAY OF AE		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.

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

1.4.18. KEYDOSE1 – KEYDOSE1

Dataset	KEYDOSE1
Creating program	keydose1.sas
Description	KEYDOSE1
Unique identifier	DPATNO
Sorted by	DPATNO
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 non significant elements or due to missing values: STARTDT,STOPDT,RTITLE3,MEDSTART,LASTMED,MEDSTRTM,MEDSTPTM

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.

Variable	Type	Label	Codes	Comments
RTITLE1	char	FIRST REGIMEN TITLE		Collected at CRF.
RTITLE2	char	SECOND REGIMEN TITLE		Collected at CRF.
XORDER	num	CROSS-OVER ORDER		Collected at CRF.
SEQUENCE	num	TREATMENT SEQUENCE		Collected at CRF.
REGIMEN	num	REGIMEN ID		Collected at CRF.
THRPYDAY	num	TOTAL DAYS ON THERAPY		Collected at CRF.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

1.4.19. KEYDOSE2 – KEYDOSE2

Dataset	KEYDOSE2
Creating program	keydose2.sas
Description	KEYDOSE2
Unique identifier	DPATNO
Sorted by	DPATNO
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 non significant elements or due to missing values: STARTDT,STOPDT,RTITLE3,MEDSTART,LASTMED,MEDSTRTM,MEDSTPTM

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
RTITLE1	char	FIRST REGIMEN TITLE		Collected at CRF.
RTITLE2	char	SECOND REGIMEN TITLE		Collected at CRF.
XORDER	num	CROSS-OVER ORDER		Collected at CRF.
SEQUENCE	num	TREATMENT SEQUENCE		Collected at CRF.
REGIMEN	num	REGIMEN ID		Collected at CRF.
THRPYDAY	num	TOTAL DAYS ON THERAPY		Collected at CRF.

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

1.4.20. KEYDOSE3 – KEYDOSE3

Dataset	KEYDOSE3
Creating program	keydose3.sas
Description	KEYDOSE3
Unique identifier	DPATNO
Sorted by	DPATNO
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 non significant elements or due to missing values: STARTDT,STOPDT,RTITLE3,MEDSTART,LASTMED,MEDSTRTM,MEDSTPTM

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
RTITLE1	char	FIRST REGIMEN TITLE		Collected at CRF.
RTITLE2	char	SECOND REGIMEN TITLE		Collected at CRF.
XORDER	num	CROSS-OVER ORDER		Collected at CRF.
SEQUENCE	num	TREATMENT SEQUENCE		Collected at CRF.
REGIMEN	num	REGIMEN ID		Collected at CRF.
THRPYDAY	num	TOTAL DAYS ON THERAPY		Collected at CRF.

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

1.4.21. QUALITY OF LIFE- PATIENT ASSESSMENT – LIFEJ040

Dataset	LIFEJ040
Creating program	lifej040.sas
Description	Quality Of Life- Patient Assessment
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: LASTNAME,MEDSTART,LASTMED,SASMED

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

Variable	Type	Label	Codes	Comments
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
TOS	num	TIME ON STUDY		Collected at CRF.
BENERGY	num	PRESTUDY ENERGY LEVEL		Collected at CRF.
BWORK	num	PRESTUDY DAILY ACTIVITY		Collected at CRF.
BQUAL	num	PRESTUDY OVERALL QUALITY		Collected at CRF.
LENERGY	num	POST-STUDY ENERGY LEVEL		Collected at CRF.
LWORK	num	POST-STUDY DAILY ACTIVITY		Collected at CRF.
LQUAL	num	POST-STUDY OVERALL QUALITY		Collected at CRF.
BPSCORE	num	PRESTUDY PERFORMANCE SCORE		Collected at CRF.
LPSCORE	num	POST-STUDY PERFORMANCE SCROE		Collected at CRF.
LEVAL	num	POST-STUDY GLOBAL EVALUATION		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

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

1.4.22. OLPROF40 – OLPROF40

Dataset	OLPROF40
Creating program	olprof40.sas
Description	OLPROF40
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,MEDSTART,TIMESTAR,LASTMED,TIMESTOP,INVNUM,LASTNAME, INVNAME,SEX,AGE,RACE,VDATE,SVDATE,SDDATE,MONTH

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity

Variable	Type	Label	Codes	Comments
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
OL	num	OL		Collected at CRF.
EPOEXPOS	num	EPOEXPOS		Collected at CRF.
WGT	num	WEIGHT		Collected at CRF.
HGT	num	HEIGHT		Collected at CRF.
SPLEN	num	SPLEN		Collected at CRF.
FLUDAR	num	FLUDAR		Collected at CRF.
CYTOTOX	num	CYTOTOX		Collected at CRF.
CHEMO	num	CHEMO		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
LABTST	char	LABTST		Collected at CRF.
LABVAL	num	LABVAL		Collected at CRF.
STAGE	num	STAGE		Collected at CRF.
DSTAGE	num	DSTAGE		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

Variable	Type	Label	Codes	Comments
VDY	num	RELATIVE V 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.
SVDY	num	RELATIVE SV DAY		If SVDATE and REF.DATE not missing then perform below logic to calculate SVDY, If SVDATE less than REF.DATE then (SVDATE - REF.DATE). Else if SVDATE is greater than equal to REF.DATE then (SVDATE- REF.DATE) +1.
SDDY	num	RELATIVE SD DAY		If SDDATE and REF.DATE not missing then perform below logic to calculate SDDY, If SDDATE less than REF.DATE then (SDDATE - REF.DATE). Else if SDDATE is greater than equal to REF.DATE then (SDDATE- REF.DATE) +1.

1.4.23. OPROFILE – OPROFILE

Dataset	OPROFILE
Creating program	oprofile.sas
Description	OPROFILE
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,MEDSTART,TIMESTAR,LASTMED,TIMESTOP,INVNUM,LASTNAME, INVNAME,SEX,AGE,RACE,VDATE,SVDATE,SDDATE,MONTH

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
OL	num	OL		Collected at CRF.
EPOEXPOS	num	EPOEXPOS		Collected at CRF.

Variable	Type	Label	Codes	Comments
WGT	num	WEIGHT		Collected at CRF.
HGT	num	HEIGHT		Collected at CRF.
SPLEN	num	SPLEN		Collected at CRF.
FLUDAR	num	FLUDAR		Collected at CRF.
CYTOTOX	num	CYTOTOX		Collected at CRF.
CHEMO	num	CHEMO		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.
LABTST	char	LABTST		Collected at CRF.
LABVAL	num	LABVAL		Collected at CRF.
STAGE	num	STAGE		Collected at CRF.
DSTAGE	num	DSTAGE		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

Variable	Type	Label	Codes	Comments
VDY	num	RELATIVE V 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.
SVDY	num	RELATIVE SV DAY		If SVDATE and REF.DATE not missing then perform below logic to calculate SVDY, If SVDATE less than REF.DATE then (SVDATE - REF.DATE). Else if SVDATE is greater than equal to REF.DATE then (SVDATE- REF.DATE) +1.
SDDY	num	RELATIVE SD DAY		If SDDATE and REF.DATE not missing then perform below logic to calculate SDDY, If SDDATE less than REF.DATE then (SDDATE - REF.DATE). Else if SDDATE is greater than equal to REF.DATE then (SDDATE- REF.DATE) +1.

1.4.24. PROFILE1 – PROFILE1

Dataset	PROFILE1
Creating program	profile1.sas
Description	PROFILE1
Unique identifier	DPATNO
Sorted by	DPATNO
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: INO,SURN,INVNAME,SEX,AGE,RACE,VDATE,AGEUNIT,DEATH,DEATHDT,FORE, CNTRY,BIRTHDT,STARTDT,STOPDT,RACEF,SEXF,STATUSDT

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
OL	num	OL		Collected at CRF.
BASEWGT	num	BASEWGT		Collected at CRF.
BASEHGT	num	BASEHGT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Collected at CRF.
TRTMENT	num	TREATMENT CODE		Collected at CRF.
TRTMENTF	char	DECODING,TREATMENT		Collected at CRF.
STATUS	num	COMPLETION STATUS		Collected at CRF.
STATUSF	char	DECODING,COMPLETION STATUS		Collected at CRF.
REASONF	char	DECODING,DISCONTINUATION REASON		Collected at CRF.
REASON	num	DISCONTINUATION REASON		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS TO STUDY COMPLETION		Collected at CRF.
VDY	num	RELATIVE V 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.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY OF WITHDRAWAL		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

1.4.25. PROFILE2 – PROFILE2

Dataset	PROFILE2
Creating program	profile2.sas
Description	PROFILE2
Unique identifier	DPATNO
Sorted by	DPATNO
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: INO,SURN,INVNAME,SEX,AGE,AGEUNIT,RACE,VDATE,DEATH,DEATHDT,FORE, CNTRY, BIRTHDT,STARTDT,STOPDT,RACEF,SEXF,STATUSDT

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
OL	num	OL		Collected at CRF.
BASEWGT	num	BASEWGT		Collected at CRF.
BASEHGT	num	BASEHGT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE OF STUDY		Collected at CRF.
TRTMENT	num	TREATMENT CODE		Collected at CRF.
TRTMENTF	char	DECODING,TREATMENT		Collected at CRF.
STATUS	num	COMPLETION STATUS		Collected at CRF.
STATUSF	char	DECODING,COMPLETION STATUS		Collected at CRF.
REASONF	char	DECODING,DISCONTINUATION REASON		Collected at CRF.
REASON	num	DISCONTINUATION REASON		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS TO STUDY COMPLETION		Collected at CRF.
VDY	num	RELATIVE V 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.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY OF WITHDRAWAL		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

1.4.26. PROFILE3 – PROFILE3

Dataset	PROFILE3
Creating program	profile3.sas
Description	PROFILE3
Unique identifier	DPATNO
Sorted by	DPATNO
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: INO,SURN,INVNAME,SEX,AGE,RACE,VDATE,AGEUNIT,DEATH,DEATHDT,FORE, CNTRY, BIRTHDT,STARTDT,STOPDT,RACEF,SEXF,STATUSDT

Variable	Type	Label	Codes	Comments
PNO	char	PROTOCOL NUMBER		Collected at CRF.
DPATNO	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
REGORDER	num	ORDER OF REGIMENS		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
BASEWGT	num	BASEWGT		Collected at CRF.
BASEHGT	num	BASEHGT		Collected at CRF.
PHASE	num	PHASE OF STUDY		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTMENT	num	TREATMENT CODE		Collected at CRF.
TRTMENTF	char	DECODING,TREATMENT		Collected at CRF.
STATUS	num	COMPLETION STATUS		Collected at CRF.
STATUSF	char	DECODING,COMPLETION STATUS		Collected at CRF.
REASONF	char	DECODING,DISCONTINUATION REASON		Collected at CRF.
REASON	num	DISCONTINUATION REASON		Collected at CRF.
SPHASE	num	PHASE		Collected at CRF.
COMPDAYS	num	NUMBER OF DAYS TO STUDY COMPLETION		Collected at CRF.
VDY	num	RELATIVE V 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.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
STATUSDY	num	RELATIVE DAY OF WITHDRAWAL		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

1.4.27. PROTOCOL – PROTOCOL

Dataset	PROTOCOL
Creating program	protocol.sas
Description	PROTOCOL
Unique identifier	PROTOCOL
Sorted by	PROTOCOL
Notes	

Variable	Type	Label	Codes	Comments
AGEUNIT	char	BLINDED		Collected at CRF.
BLINDED	char	BLINDED		Collected at CRF.
CROSOVER	char	CROSOVER		Collected at CRF.
PROTOCOL	char	PROTOCOL		Collected at CRF.
STDYTYPE	char	STDYTYPE		Collected at CRF.
TITLE1	char	TITLE1		Collected at CRF.
TITLE2	char	TITLE2		Collected at CRF.
FINALDB	num	FINALDB		Collected at CRF.
FIRSTDB	num	FIRSTDB		Collected at CRF.
TOTREGI	num	TOTREGI		Collected at CRF.
EVENTUNT	char	EVENTUNT		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
PROJECT	num	PROJECT		Collected at CRF.
AVAILABL	char	AVAILABL		Collected at CRF.

1.4.28. REGIJ040 – REGIJ040

Dataset	REGIJ040
Creating program	regij040.sas
Description	REGIJ040
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	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PERIOD	num	MEDICATION PERIOD		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGCODE	num	REGCODE		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.

1.4.29. REGIMEN – REGIMEN

Dataset	REGIMEN
Creating program	regimen.sas
Description	REGIMEN
Unique identifier	DRUG,FORMULAT,ROUTE,DOSE,FREQUENC,DURATION,TITLE1,TITLE2,TITLE3, APPROVAL
Sorted by	DRUG,FORMULAT,ROUTE,DOSE,FREQUENC,DURATION,TITLE1,TITLE2,TITLE3, APPROVAL
Notes	

Variable	Type	Label	Codes	Comments
CODE	char	CODE		Collected at CRF.
DRUG	char	DRUG CODE FOR THE DRUG PROGRAM		Collected at CRF.
FORMULAT	char	FORMULAT		Collected at CRF.
STRENGTH	char	STRENGTH		Collected at CRF.
ROUTE	char	ROUTE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE	char	DOSE		Collected at CRF.
FREQUENC	char	FREQUENC		Collected at CRF.
DURATION	char	DURATION		Collected at CRF.
INSTRUCT	char	INSTRUCT		Collected at CRF.
TITLE1	char	TITLE1		Collected at CRF.
TITLE2	char	TITLE2		Collected at CRF.
TITLE3	char	TITLE3		Collected at CRF.
SUB_SEQU	char	SUB_SEQU		Collected at CRF.
APPROVAL	char	APPROVAL		Collected at CRF.

1.4.30. STUDY MEDICATION ADMINISTRATION – SMEDJ040

Dataset	SMEDJ040
Creating program	smedj040.sas
Description	Study Medication Administration
Unique identifier	DSUBNUM,TUPID
Sorted by	DSUBNUM,TUPID
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,SDATE,DSTAMP,DMODIFY

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
PHASE	num	PHASE OF STUDY		Collected at CRF.
PERIOD	num	MEDICATION PERIOD		Collected at CRF.
WGT	num	WEIGHT		Collected at CRF.
DOSE	num	DOSE		Collected at CRF.
UNITS	num	UNITS		Collected at CRF.
DISP	num	DISP		Collected at CRF.
DOSENUM	num	DOSENUM		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.
SDY	num	RELATIVE S 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.
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.
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.

1.4.31. TRNAJ040 – TRNAJ040

Dataset	TRNAJ040
Creating program	trnaj040.sas
Description	TRNAJ040
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: LASTNAME, LASTMED, MEDSTART

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
REGLOBAL	char	TREATMENT GROUP DESCRIPTION		Collected at CRF.
DSUBNUM	num	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient Number for De-identity
GLOBALDE	char	TREATMENT GROUP		Collected at CRF.
TOS	num	TIME ON STUDY		Collected at CRF.
BAS_TRAN	num	BASELINE TRANSFUSION RATE		Collected at CRF.
BASTRNST	num	BASELINE TRANSFUSION STATUS		Collected at CRF.
PM_HEMTR	num	PATIENTS, DB, MEAN HEMATOCRIT TRIGGER		Collected at CRF.
CUM_TRAN	num	CUMULATIVE TRANSFUSION RATE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBTRNST	num	DOUBLE-BLIND TRANSFUSION STATUS		Collected at CRF.
TRP23	num	IND FOR TRANSFUSED PATIENT IN MON 2 OR 3		Collected at CRF.
EFF_TIND	num	IND FOR EFFCY POPU TRANSFUSION INDEP PTS		Collected at CRF.
ITT_TIND	num	IND FOR TRANSFUSION INDEP ITT PTS		Collected at CRF.
ITTTIND2	num	IND FOR TRANSFUSION INDEP ITT PTS		Collected at CRF.
LSTMEDDY	num	RELATIVE DAY OF LAST MEDICATION		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.

1.4.32. TVE – TVE

Dataset	TVE
Creating program	tve.sas
Description	TVE
Unique identifier	TVENO,ADVCODE
Sorted by	TVENO,ADVCODE
Notes	

Variable	Type	Label	Codes	Comments
TVENO	num	TVENO		Collected at CRF.
ADVCODE	char	WHO ART CODE		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
BODYSYS	char	WHO BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	WHO PREFERRED TERM DESCRIPTION		Collected at CRF.

1.4.33. TVE40 – TVE40

Dataset	TVE40
Creating program	tve40.sas
Description	TVE40
Unique identifier	TVENO,ADVCODE
Sorted by	TVENO,ADVCODE
Notes	

Variable	Type	Label	Codes	Comments
TVENO	num	TVENO		Collected at CRF.
ADVCODE	char	WHO ART CODE		Collected at CRF.
SEXAE	char	SEX SPECIFIC AE		Collected at CRF.
ADVDESC	char	WHOART DICTIONARY DESCRIPTION		Collected at CRF.
BODYSYS	char	WHO BODY SYSTEM DESCRIPTION		Collected at CRF.
PREF_TRM	char	WHO PREFERRED TERM DESCRIPTION		Collected at CRF.