Clinical Development

Topirimate®

MIGR002

Anonymisation Data Derivation Specification Document

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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
Description	Short description
Unique Identifier	Unique key

Part II: Variables within dataset

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

1.1.   Data Domains

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.
- Age at trial start date will be calculated and grouped in intervals of ten years to protect PII as per HIPAA rules. A deidentified age variable will be created in which a new age is randomly selected within the original interval.
- Height will be converted to inches and grouped in intervals of 4 inches to protect PII as per HIPAA rules. A deidentified height variable will be created in which a new height is randomly selected within the original interval. Heights less than 60 inches will be assigned 59 in. Heights greater than or equal to 72 inches will be assigned 72 inches.
- Weight will be converted to pounds and grouped to protect PII as per HIPAA rules. A deidentified weight variable will be created in which a new weight is randomly selected within the original interval. Weights less than 90 lbs will be

assigned 89 lbs. Weights greater than or equal to 290 lbs will be assigned 290 lbs.

- Patient identification numbers will be assigned in a random manner so they are not matching the patient identification numbers that were used in the actual trial.
- Free text verbatim terms will not be provided.
- Free text summary terms will not be provided.
- "Other" free text terms will not be provided.
- 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 Sample Identifier will not be provided.
- Central Lab Batch Identifier 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.
- A reference date (REF.DATE) will be randomly created for every individual in the dataset and used to calculate relative time (in days) in place of dates.
- All original dates relating to individuals subject will be removed. Instead a relative study day will be provided which is the number of days from a randomly sampled reference date (REF.DATE) to the original date.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- The preg and pregtest datasets will not be provided because these datasets contain variables related to child-bearing potential information.

1.3.   Data Files

The MIGR002 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.3.1. DEMOGRAPHICS – DEMOG

Dataset	DEMOG
Description	DEMOGRAPHICS
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
EVENT_ID	integer	Visit identifier	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATE	logical	Event date, "ddmonyyyy" date	Suppressed all records to protect PII
BIRTHDT	logical	Birth date, "ddmmmyyyy" format	Suppressed all records to protect PII
SEX	integer	Subject's gender	Collected at CRF.
RACE	logical	Subject's Race	Suppressed all records to protect PII
RACESPEC	logical	Race specification for 'other'	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII

EVDATEN	logical	SAS NUMERICAL DATE9.FORMAT FOR EVDATE	Suppressed all records to protect PII
BIRTHDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR BIRTHDT	Suppressed all records to protect PII
SEXF	character	DECODE FOR VARIABLE SEX	Collected at CRF.
RACEF	logical	DECODE FOR VARIABLE RACE	Suppressed all records to protect PII
DAGEGP	character	De-identified subject's age group	Subject's age at trial start date, 10 year age groupings to protect PII
DAGE	integer	De-identified subject's age at trial start date in years	Subject's age at trial start date in years, randomly sampled within 10 year age grouping to protect PII. Ages greater than 89 years were assigned 90.
DRACE	integer	De-identified subject's race	Subject's race, group elements to protect PII
DRACEF	character	Decode for variable DRACE	Decode for variable DRACE, group elements to protect PII
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DCOUNTRY	character	De-identified protocol in which country	Country, group elements to continent protect PII

1.3.2. ADVEDTL – ADVEDTL

Dataset	ADVEDTL
Description	ADVEDTL
Unique identifier	DPATNO

Variable	Type	Label	Comments
PATNO	logical	Patient number	Suppressed all records to protect PII
PATNOCHR	logical	PATNOCHR	Suppressed all records to protect PII
CNO	integer	CNO	Collected at CRF.
REC_ID	double	UNIQUE NUMERIC IDENTIFIER	Collected at CRF.
F_STATUS	character	STATUS OF RECORD	Collected at CRF.
DRUG	character	DRUG CODE FOR THE DRUG PROGRAM	Collected at CRF.
TAREA	character	DEFINING THE DRUG PROGRAM	Collected at CRF.
PNO	character	PROTOCOL NUMBER	Collected at CRF.
SCTRY	logical	PROTOCOL IN WHICH COUNTRY	Suppressed all records to protect PII
EVENT_ID	integer	EVENT(VISIT) NAME	Collected at CRF.
PAG_NAME	character	PAGE NAME	Collected at CRF.
ACTION	integer	ACTION TAKEN	Collected at CRF.
ADVCODE	logical	DICTIONARY CODE ASSIGNED TO AE	Suppressed all records to protect PII
ADVCODE2	logical	WHOART DICTIONARY CODE AT TIME FINAL DB	Collected at CRF.
ADVDESC	logical	WHOART DICTIONARY DESCRIPTION	Suppressed all records to protect PII
ADVDESC2	logical	WHOART DICTIONARY DESCRIPTION FINAL DB	Collected at CRF.
CONCOM	integer	WERE CONCOMITANT MEDICATIONS GIVEN?	Collected at CRF.
DRUGREL	integer	WAS AE RELATED TO DRUG?	Collected at CRF.
ENTRYNO	integer	ENTRY NUMBER	Collected at CRF.
ONSETDT	logical	DATE OF ONSET, 'DDMMMYYYY'FORMAT	Suppressed all records to protect PII

ONSETDTN	logical	SAS DATE, ONSETDT	Suppressed all records to protect PII
OUTCOME	integer	AE OUTCOME	Collected at CRF.
PHASE	integer	PHASE OF STUDY	Collected at CRF.
SERIOUS	integer	WAS AE SERIOUS?	Collected at CRF.
SEVERITY	integer	SEVERITY OF AE	Collected at CRF.
STOPDT	logical	STOP DATE, FORMAT 'DDMONYYYY'	Suppressed all records to protect PII
STOPDTN	logical	SAS DATE, STOPDT	Suppressed all records to protect PII
STOPTIM	logical	STOP TIME, AS ENTERED ON DCI	Collected at CRF.
STOPTIME	logical	STOP TIME, 24 HOUR CLOCK, 'HH:MM'	Collected at CRF.
TONSE	logical	TIME OF ONSET AS ENTERED ON DCI	Collected at CRF.
TONSET	logical	TIME OF ONSET, FORMAT 24 HR CLOCK	Collected at CRF.
VERBATIM	logical	DESCRIPTION OF AE	Suppressed all records to protect PII
VISITNO	integer	VISIT NUMBER	Collected at CRF.
ACTIONF	character	DECODING, ACTION TAKEN	Collected at CRF.
CONCOMF	character	DECODING, WERE CONCOMITANT MEDICATIONS G	Collected at CRF.
DRUGRELF	character	DECODING, WAS AE RELATED TO DRUG?	Collected at CRF.
OUTCOMEF	character	DECODING, AE OUTCOME	Collected at CRF.
SERIOUSF	character	DECODING, WAS AE SERIOUS?	Collected at CRF.
SEVERITF	character	DECODING, SEVERITY OF AE	Collected at CRF.
PHASEF	character	DECODE, PHASE	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DONSETDTN	integer	Relative day of onset	Relative day of onset from randomly assigned reference date (ONSETDTN-REF.DA
DSTOPDTN	integer	Relative stop day	Relative stop day from randomly assigned reference date (STOPDTN-REF.DATE)
DADVCODE	double	De-identified WHOART DICTIONARY DESCRIPTION	DICTIONARY CODE ASSIGNED TO AE, some records masked to protect PII
DADVDESC	character	De-identified DICTIONARY CODE ASSIGNED TO AE	WHOART DICTIONARY DESCRIPTION, some records masked to protect PII

1.3.3. ADVEHDR – ADVEHDR

Dataset	ADVEHDR
Description	ADVEHDR
Unique identifier	DPATNO

Variable	Type	Label	Comments
EVDATE	logical	Event date, "ddmonyyyy" format	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
PAG_NAME	character	Page name	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
ADVEXP	integer	Were there any treatment emergent AEs?	Collected at CRF.
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVDATEN	logical	SAS NUMERICAL DATE9.FORMAT FOR EVDATE	Suppressed all records to protect PII
ADVEXPF	character	DECODE FOR VARIABLE ADVEXP	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.4. ADVETHR – ADVETHR

Dataset	ADVETHR
Description	ADVETHR
Unique identifier	DPATNO

Variable	Type	Label	Comments
PATNO	logical	Patient number	Suppressed all records to protect PII
PATNOCHR	logical	PATNOCHR	Suppressed all records to protect PII
CNO	integer	CNO	Collected at CRF.
REC_ID	double	UNIQUE NUMERIC IDENTIFIER	Collected at CRF.
F_STATUS	character	STATUS OF RECORD	Collected at CRF.
DRUG	character	DRUG CODE FOR THE DRUG PROGRAM	Collected at CRF.
TAREA	character	DEFINING THE DRUG PROGRAM	Collected at CRF.
PNO	character	PROTOCOL NUMBER	Collected at CRF.
SCTRY	logical	PROTOCOL IN WHICH COUNTRY	Suppressed all records to protect PII
EVENT_ID	integer	EVENT(VISIT) NAME	Collected at CRF.
PAG_NAME	character	PAGE NAME	Collected at CRF.
ATC_CD	character	ATC CODE	Collected at CRF.
ATC_TEXT	character	ATC TEXT	Collected at CRF.
DRUGCOD2	logical	WHODRUG DICTIONARY CODE AT TIME FINAL DB	Collected at CRF.
DRUGCODE	character	CURRENT WHODRUG DICTIONARY CODE USED	Collected at CRF.
DRUGDES2	logical	WHODRUG DICTIONARY DECRIPTION FINAL DB	Collected at CRF.
DRUGDESC	character	CURRENT WHODRUG DICTIONARY DESCRIPTION	Collected at CRF.

ENTRYNO	integer	ENTRY NUMBER OF AE	Collected at CRF.
PHASE	integer	PHASE OF STUDY	Collected at CRF.
THRPYNO	integer	THERAPY NUMBER	Collected at CRF.
VERBATIM	logical	DESCRIPTION OF THERAPY GIVEN FOR AE	Suppressed all records to protect PII
VISITNO	integer	VISIT NUMBER	Collected at CRF.
PHASEF	character	PHASEF	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.5. COMMENT – COMMENT

Dataset	COMMENT
Description	COMMENT
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
TYPE	character	Type of comment I=Item, F=Form	Collected at CRF.
ENTRYNO	integer	Entry Number	Collected at CRF.
EVDATE	logical	Event date, "ddmonyyyy" date	Suppressed all records to protect PII
MODNAME	character	Module to which the comment relates	Collected at CRF.
TYPEC	character	DECODE FOR VARIABLE TYPE	Collected at CRF.
COMMENTS	logical	Text of the comment	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
MODNAMEF	character	DECODE FOR VARIABLE MODNAME	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASEF	Collected at CRF.

EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)

1.3.6. COMPDTL – COMPDTL

Dataset	COMPDTL
Description	COMPDTL
Unique identifier	DPATNO

Variable	Type	Label	Comments
PATNO	logical	Patient number	Suppressed all records to protect PII
PATNOCHR	logical	PATNOCHR	Suppressed all records to protect PII
CNO	integer	CNO	Collected at CRF.
REC_ID	double	UNIQUE NUMERIC IDENTIFIER	Collected at CRF.
F_STATUS	character	STATUS OF RECORD	Collected at CRF.
DRUG	character	DRUG CODE FOR THE DRUG PROGRAM	Collected at CRF.
TAREA	character	DEFINING THE DRUG PROGRAM	Collected at CRF.
PNO	character	PROTOCOL NUMBER	Collected at CRF.
SCTRY	logical	PROTOCOL IN WHICH COUNTRY	Suppressed all records to protect PII
EVENT_ID	integer	EVENT(VISIT) NAME	Collected at CRF.
PAG_NAME	character	PAGE NAME	Collected at CRF.
ADVCODE	logical	DICTIONARY CODE ASSIGNED TO AE	Suppressed all records to protect PII
ADVCODE2	logical	WHOART DICTIONARY CODE AT TIME FINAL DB	Collected at CRF.
ADVDESC	logical	WHOART DICTIONARY DESCRIPTION	Suppressed all records to protect PII
ADVDESC2	logical	WHOART DICTIONARY DESCRIPTION FINAL DB	Collected at CRF.

ENTRYNO	integer	ENTRY NUMBER	Collected at CRF.
EVDATE	logical	EVENT DATE, 'DDMONYYYY' FORMAT	Suppressed all records to protect PII
EVDATEN	logical	SAS DATE, EVDATE	Suppressed all records to protect PII
PHASE	integer	PHASE OF STUDY	Collected at CRF.
VERBATIM	logical	AE SPECIFICATION	Suppressed all records to protect PII
VISITNO	integer	VISIT NUMBER	Collected at CRF.
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DADVCODE	double	De-identified WHOART DICTIONARY DESCRIPTION	DICTIONARY CODE ASSIGNED TO AE, some records masked to protect PII
DADVDESC	character	De-identified DICTIONARY CODE ASSIGNED TO AE	WHOART DICTIONARY DESCRIPTION, some records masked to protect PII

1.3.7. COMPHDR – COMPHDR

Dataset	COMPHDR
Description	COMPHDR
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
LASTDT	logical	Date of last dose of trial therapy	Suppressed all records to protect PII
REASONF	character	DECODE FOR VARIABLE REASON	Suppressed all records to protect PII

EVDATE	logical	Event date, "ddmonyyyy" date	Suppressed all records to protect PII
VISNUM	logical	Number of last visit	Collected at CRF.
STATUS	integer	Completion status	Collected at CRF.
ENTERNXT	integer	Will subject enter the next phase?	Collected at CRF.
TAPER	integer	Will subject taper from study medication	Collected at CRF.
TAPERDT	logical	Date study medication taper began	Suppressed all records to protect PII
STATUSDT	logical	Date of Completion, Withdrawal, etc.	Suppressed all records to protect PII
REASON	integer	Reason for withdrawal	Suppressed all records to protect PII
OTHRSPEC	logical	Other specification	Suppressed all records to protect PII
DEATH	integer	Did subject die?	Collected at CRF.
DEATHDT	logical	Date of death, "ddmonyyyy" format	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
STATUSF	character	DECODE FOR VARIABLE STATUS	Collected at CRF.
ENTERNXF	character	DECODE FOR VARIABLE ENTERNXT	Collected at CRF.
TAPERF	character	DECODE FOR VARIABLE TAPER	Collected at CRF.
DEATHF	character	DECODE FOR VARIABLE DEATH	Collected at CRF.

PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
TAPERDTN	logical	SAS NUMERICAL DATE9.FORMAT FOR TAPERDT	Suppressed all records to protect PII
STATUSDN	logical	SAS NUMERICAL DATE9. FORMAT FOR STATUSDT	Suppressed all records to protect PII
DEATHDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR DEATH	Suppressed all records to protect PII
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DSTATUSDN	integer	Relative day of completion, withdrawal, etc.	Relative day of completion, withdrawal, etc., from randomly assigned reference date (STATUSDN-REF.DATE)
DTAPERDTN	integer	Relative study day taper medication began	Relative study day taper medication began from randomly assigned reference date (TAPERDTN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.8. CURMDTL – CURMDTL

Dataset	CURMDTL
Description	CURMDTL
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
PRNF	character	DECODE FOR VARIABLE PRN	Collected at CRF.
STARTIME	character	Time of concurrent medication, format "h	Collected at CRF.
ENTRYNO	integer	Entry Number	Collected at CRF.
STARTDT	logical	Start date of concurrent medication	Suppressed all records to protect PII
STOPDT	logical	Stop date, format "ddmonyyyy"	Suppressed all records to protect PII
CONT	integer	Is the drug continuing?	Collected at CRF.
AEDATE	logical	Date of serious adverse event	Suppressed all records to protect PII
ROUTE	character	Route of Administration	Collected at CRF.
OTRRT	character	Other route of Administration	Suppressed all records to protect PII
TOTDOSE	character	Total daily dose	Collected at CRF.
PRN	integer	If drug taken as needed PRN	Collected at CRF.
INDICT	logical	Indication	Suppressed all records to protect PII

FORTAE	integer	For treatment emergent adverse event	Collected at CRF.
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
PATNOCHR	logical	PATNOCHR	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
CNO	integer	CNO	Collected at CRF.
CONTF	character	DECODE FOR VARIABLE CONT	Collected at CRF.
FORTAEF	logical	DECODE FOR VARIABLE FORTAE	Collected at CRF.
STARTDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR STARTDT	Suppressed all records to protect PII
STOPDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR STOPDT	Suppressed all records to protect PII
AEDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR AEDATE	Suppressed all records to protect PII
VERBATIM	logical	INVESTIGATOR VERBATIM	Suppressed all records to protect PII
ATC_CD	character	ATC CODE	Collected at CRF.
ATC_TEXT	character	ATC TEXT	Collected at CRF.
DRUGCOD2	logical	WHODRUG DICTIONARY CODE AT TIME FINAL DB	Collected at CRF.
DRUGCODE	character	CURRENT WHODRUG DICTIONARY CODE USED	Collected at CRF.
DRUGDES2	logical	WHODRUG DICTIONARY DESCRIPTION FINAL DB	Collected at CRF.
DRUGDESC	character	CURRENT WHODRUG DICTIONARY DESCRIPTION	Collected at CRF.

DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DSTARTDTN	integer	Relative start day	Relative start day from randomly assigned reference date (STARTDTN-REF.DATE)
DSTOPDTN	integer	Relative stop day	Relative stop day from randomly assigned reference date (STOPDTN-REF.DATE)
DAEDATEN	integer	Relative day of serious adverse event	Relative day of serious adverse event from randomly assigned reference date (AEDATEN-REF.DATE)

1.3.9. CURMHDR – CURMHDR

Dataset	CURMHDR
Description	CURMHDR
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATE	logical	Event date, "ddmonyyyy" format	Suppressed all records to protect PII
CONMED	integer	Did patient receive concurrent medicatio	Collected at CRF.
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.

PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
CONMEDF	character	DECODE FOR VARIABLE CONMED	Collected at CRF.
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.10.   HEADACHE – HEADACHE

Dataset	HEADACHE
Description	HEADACHE
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
HEADTYPF	character	DECODE FOR VARIABLE HEADTYPE	Collected at CRF.
PAIDWORF	character	DECODE FOR VARIABLE PAIDWORK	Collected at CRF.
NONMGOTR	logical	Non-migraine headache other specified	Suppressed all records to protect PII
ENTRYNO	integer	Entry Number	Collected at CRF.

EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
HEADTYPE	integer	Type of Headache	Collected at CRF.
NONMIGRT	logical	Non-Migraine Headache type	Suppressed all records to protect PII
AURASDT	logical	Aura start date	Suppressed all records to protect PII
AURASTM	character	Aura start time	Collected at CRF.
PAINSDT	logical	Pain start date	Suppressed all records to protect PII
PAINSTM	character	Pain start time	Collected at CRF.
PAINSPDT	logical	Pain stop date	Suppressed all records to protect PII
PAINSPT	character	Pain stop time	Collected at CRF.
PSEVER	integer	Pain severity	Collected at CRF.
ONESIDE	integer	Pain one-sided during attack?	Collected at CRF.
THROB	integer	Was pain throbbing?	Collected at CRF.
PAINPHY	integer	Pain increase with physical activity?	Collected at CRF.
VOMIT	integer	Did Subject Vomit?	Collected at CRF.
NAUSEA	integer	Severity of Nausea symptoms	Collected at CRF.
PHOTOP	integer	Photophobia, Sensitivity to Light	Collected at CRF.
PHONOP	integer	Phonophobia, Sensitivity to Sound	Collected at CRF.
PLANHR	double	Hours subject planned to work?	Collected at CRF.
ABSHR	double	Hours subject absent from work?	Collected at CRF.
MIGRHR	double	Hours subject worked during migraine?	Collected at CRF.
OALEFF	integer	Rate overall effectiveness during migrai	Collected at CRF.
PAIDWORK	integer	Rate affect on activities outside pd wk	Collected at CRF.
PHASE	integer	Phase of Study	Collected at CRF.

DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
NONMIGRF	logical	DECODE FOR VARIABLE NONMIGRT	Suppressed all records to protect PII
PSEVERF	character	DECODE FOR VARIABLE PSEVER	Collected at CRF.
ONESIDEF	character	DECODE FOR VARIABLE ONESIDE	Collected at CRF.
THROBF	character	DECODE FOR VARIABLE THROB	Collected at CRF.
PAINPHYF	character	DECODE FOR VARIABLE PAINPHY	Collected at CRF.
VOMITF	character	DECODE FOR VARIABLE VOMIT	Collected at CRF.
NAUSEAF	character	DECODE FOR VARIABLE NAUSEA	Collected at CRF.
PHOTOPF	character	DECODE FOR VARIABLE PHOTOP	Collected at CRF.
PHONOPF	character	DECODE FOR VARIABLE PHONOP	Collected at CRF.
OALEFFF	character	DECODE FOR VARIABLE OALEFF	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
AURASDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR AURASDT	Suppressed all records to protect PII

PAINSDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR PAINSDT	Suppressed all records to protect PII
PAINSPDN	logical	SAS NUMERICAL DATE9. FORMAT FOR PAINSPDT	Suppressed all records to protect PII
DNONMIGRT	integer	De-identified non-Migraine headache type	Non-Migraine headache type, group elements to protect PII
DNONMIGRF	character	Decode for variable DNONMIGRT	Decode for variable DNONMIGRT, group elements to protect PII
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DAURASDTN	integer	Relative Aura start day	Relative Aura start day from randomly assigned reference date (AURASDTN-REF.DATE)
DPAINSDTN	integer	Relative pain start day	Relative pain start day from randomly assigned reference date (PAINSDTN-REF.DATE)
DPAINSPDN	integer	Relative pain stop day	Relative pain stop day from randomly assigned reference date (PAINSPDN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.11.   HEADHDR – HEADHDR

Dataset	HEADHDR
Description	HEADHDR
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
ANYHEAD	integer	Subject have any aura or headaches?	Collected at CRF.
EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
VISITDT	logical	Visit Date Vitals Taken	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
ANYHEADF	character	DECODE FOR VARIABLE ANYHEAD	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
VISITDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR VISITDT	Suppressed all records to protect PII
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.

DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DVISITDTN	integer	Relative visit day	Relative visit day from randomly assigned reference date (VISITDTN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.12.   LABS – LABS

Dataset	LABS
Description	LABS
Unique identifier	REC_ID

Variable	Type	Label	Comments
REC_ID	integer	UNIQUE NUMERIC IDENTIFIER	Collected at CRF.
F_STATUS	character	STATUS OF RECORD	Collected at CRF.
DRUG	character	DRUG CODE FOR THE DRUG PROGRAM	Collected at CRF.
TAREA	character	DEFINING THE DRUG PROGRAM	Collected at CRF.
PNO	character	PROTOCOL NUMBER	Collected at CRF.
SCTRY	logical	PROTOCOL IN WHICH COUNTRY	Suppressed all records to protect PII
EVENT_ID	integer	EVENT(VISIT) NAME	Collected at CRF.
PAG_NAME	character	PAGE NAME	Collected at CRF.

ACCNO	logical	CENTRAL LAB SAMPLE IDENTIFIER	Suppressed all records to protect PII
BATCHID	logical	CENTRAL LAB BATCH IDENTIFIER	Suppressed all records to protect PII
COLLECT	logical	PRE-DETERMINED COLLECTION TIMES	Collected at CRF.
CRESULT	character	CHARACTER LAB RESULT	Collected at CRF.
FLAG	character	HIGH/LOW LAB VALUE FLAG	Collected at CRF.
HIRANGE	double	HIGH RANGE NORMAL VALUE	Collected at CRF.
LABCODE	character	LABORATORY TEST CODE	Collected at CRF.
LABLOC	integer	LOCATION OF LAB DOING ANALYSIS	Collected at CRF.
LABNAME	logical	NAME OF LABORATORY DOING ANALYSIS	Collected at CRF.
LABSPEC	logical	DESCRIPTION FOR OTHER LAB TESTS	Collected at CRF.
LORANGE	double	LOW RANGE NORMAL VALUE	Collected at CRF.
PHASE	integer	PHASE OF STUDY	Collected at CRF.
RESULT	double	NUMERIC LAB RESULT	Collected at CRF.
SAMPD	logical	DATE TEST, AS ENTERED ON DCI	Collected at CRF.
SAMPDT	logical	DATE TEST PERFORMED	Suppressed all records to protect PII
SAMPTIM	logical	TIME TEST PERFORMED AS ON DCI	Collected at CRF.
SAMPTIME	character	TIME TEST PERFORMED	Collected at CRF.
TUPID	integer	RSM UNIQUE RECORD ID WITHIN PROTOCOL	Collected at CRF.
UNITCODE	integer	LABORATORY UNIT CODE	Collected at CRF.
VISITYPE	integer	TYPE OF VISIT	Collected at CRF.

PATNO	logical	PATIENT NUMBER	Suppressed all records to protect PII
VISITNO	integer	VISIT NUMBER	Collected at CRF.
FLAGF	character	DECODING, HIGH/LOW LAB VALUE FLAG	Collected at CRF.
PHASEF	character	DECODING, PHASE OF STUDY	Collected at CRF.
VISITYPF	character	DECODING, TYPE OF VISIT	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DSAMPDT	integer	Relative day test performed	Relative day test performed from randomly assigned reference date (SAMPDT-REF.DATE)

1.3.13.   MEDCAREQ – MEDCAREQ

Dataset	MEDCAREQ
Description	MEDCAREQ
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
PVNECYN	integer	Physician visit necessary?	Collected at CRF.
MEDDOCT	integer	Seen any medical doctors since last visi	Collected at CRF.

PVTP	integer	Trial Physican number of visits	Collected at CRF.
PVOPSP1	logical	Other Physician 1, speciality	Suppressed all records to protect PII
PVOP1	integer	Number of visits to other physician 1	Collected at CRF.
PVOPSP2	logical	Other Physician 2, speciality	Suppressed all records to protect PII
PVOP2	integer	Number of visits to other physician 2	Collected at CRF.
PVOPSP3	logical	Other Physician 3, speciality	Suppressed all records to protect PII
PVOP3	integer	Number of visits to other physican 3	Collected at CRF.
URGCRYN	integer	Unscheduled visits for ER/urgent care	Collected at CRF.
ERUC	logical	Number of urgent care/ER visits	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
PVNECYNF	character	DECODE FOR VARIABLE PVNECYN	Collected at CRF.
MEDDOCTF	character	DECODE FOR VARIABLE MEDDOCT	Collected at CRF.
URGCRYNF	character	DECODE FOR VARIABLE URGCRYN	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII

DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DERUC	character	De-identified number of urgent care/ER visits	Number of urgent care/ER visits, group elements to protect PII

1.3.14.   MEDMONIT – MEDMONIT

Dataset	MEDMONIT
Description	MEDMONIT
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
EVENT_ID	integer	Visit identifier	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
ELIGMEET	integer	Did the subject meet all eligibility cri	Collected at CRF.
INCLVIOL	logical	Inclusion criteria violated	Suppressed all records to protect PII
EXCLVIOL	logical	Exclusion criteria violated	Suppressed all records to protect PII
APPDATE	logical	Date approved by Med Monitor	Suppressed all records to protect PII
SUMMARY	logical	Summary	Suppressed all records to protect PII

PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
APPDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR APPDATE	Suppressed all records to protect PII
ELIGMEEF	character	DECODE FOR VARIABLE ELIGMEET	Collected at CRF.
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DAPPDATEN	integer	Relative day approved by Med Monitor	Relative day approved by Med Monitor from randomly assigned reference date (APPDATEN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.15.   MHIST – MHIST

Dataset	MHIST
Description	MHIST
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
EVENT_ID	integer	Visit identifier	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
SYSTEMF	character	DECODE FOR VARIABLE SYSTEM	Collected at CRF.
ABNCODE	logical	Abnormality code	Collected at CRF.
NORMABF	character	DECODE FOR VARIABLE NORMAB	Collected at CRF.
ENTRYNO	integer	Entry Number	Collected at CRF.
EVDATE	logical	Event date, "ddmonyyyy" date	Suppressed all records to protect PII
SYSTEM	integer	System for which history is taken	Collected at CRF.
NORMAB	integer	Status	Collected at CRF.
VERBATIM	logical	Description	Suppressed all records to protect PII
MIGRAINE	integer	Migraine Present/Occur?	Collected at CRF.
CHANGE	integer	Changes since Baseline Visit 1	Collected at CRF.
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.

SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
MIGRAINF	character	DECODE FOR VARIABLE MIGRAINE	Collected at CRF.
CHANGEF	character	DECODE FOR VARIABLE CHANGE	Collected at CRF.
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.16.   MSQ – MSQ

Dataset	MSQ
Description	MSQ
Unique identifier	DPATNO

Variable	Type	Label	Comments
REC_ID	integer	UNIQUE NUMERIC IDENTIFIER	Collected at CRF.
F_STATUS	character	STATUS OF RECORD	Collected at CRF.
DRUG	character	DRUG CODE FOR THE DRUG PROGRAM	Collected at CRF.
TAREA	character	DEFINING THE DRUG PROGRAM	Collected at CRF.
PNO	character	PROTOCOL NUMBER	Collected at CRF.

SCTRY	logical	PROTOCOL IN WHICH COUNTRY	Suppressed all records to protect PII
EVENT_ID	integer	EVENT(VISIT) NAME	Collected at CRF.
PAG_NAME	character	PAGE NAME	Collected at CRF.
EVDATE	logical	EVENT DATE, 'DDMMMYYYY' DATE	Suppressed all records to protect PII
MSQ1	integer	INTERFERED WITH HOW WELL DEALT W/ FAMILY	Collected at CRF.
MSQ10	integer	HAVE TO STOP WORK OR DAILY ACTIVITIES	Collected at CRF.
MSQ11	integer	NOT ABLE TO GO TO SOCIAL ACTIVITIES	Collected at CRF.
MSQ12	integer	FELT FED UP OR FRUSTRATED	Collected at CRF.
MSQ13	integer	FELT YOU WERE BURDEN ON OTHERS	Collected at CRF.
MSQ14	integer	AFRAID OF LETTING OTHERS DOWN	Collected at CRF.
MSQ2	integer	INTERFERED WITH LEISURE TIME ACTIVITIES	Collected at CRF.
MSQ3	integer	DIFFICULTY PERFORMING WORK/DAILY ACTIVIT	Collected at CRF.
MSQ4	integer	KEEP YOU FROM GETTING AS MUCH DONE	Collected at CRF.
MSQ5	integer	LIMIT ABILITY TO CONCENTRATE ON WORK	Collected at CRF.
MSQ6	integer	LEFT YOU TOO TIRED TO DO WORK	Collected at CRF.
MSQ7	integer	LIMITED NUMBER OF DAYS FELT ENERGETIC	Collected at CRF.
MSQ8	integer	HAD TO CANCEL WORK OR DAILY ACTIVITIES	Collected at CRF.
MSQ9	integer	NEED HELP HANDLING ROUTINE TASKS	Collected at CRF.

PATNO	logical	PATIENT NUMBER	Suppressed all records to protect PII
VISITNO	integer	VISIT NUMBER	Collected at CRF.
MSQ1F	character	DECODING, INTERFERED WITH HOW WELL DEALT	Collected at CRF.
MSQ10F	character	DECODING, HAVE TO STOP WORK OR DAILY ACT	Collected at CRF.
MSQ11F	character	DECODING, NOT ABLE TO GO TO SOCIAL ACTIV	Collected at CRF.
MSQ12F	character	DECODING, FELT FED UP OR FRUSTRATED	Collected at CRF.
MSQ13F	character	DECODING, FELT YOU WERE BURDEN ON OTHERS	Collected at CRF.
MSQ14F	character	DECODING, AFRAID OF LETTING OTHERS DOWN	Collected at CRF.
MSQ2F	character	DECODING, INTERFERED WITH LEISURE TIME A	Collected at CRF.
MSQ3F	character	DECODING, DIFFICULTY PERFORMING WORK/DAI	Collected at CRF.
MSQ4F	character	DECODING, KEEP YOU FROM GETTING AS MUCH	Collected at CRF.
MSQ5F	character	DECODING, LIMIT ABILITY TO CONCENTRATE O	Collected at CRF.
MSQ6F	character	DECODING, LEFT YOU TOO TIRED TO DO WORK	Collected at CRF.
MSQ7F	character	DECODING, LIMITED NUMBER OF DAYS FELT EN	Collected at CRF.
MSQ8F	character	DECODING, HAD TO CANCEL WORK OR DAILY AC	Collected at CRF.
MSQ9F	character	DECODING, NEED HELP HANDLING ROUTINE TAS	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

			Relative event day from randomly assigned
DEVDATE	integer	Relative event day	reference date (EVDATE-REF.DATE)

1.3.17.   MSQSF36 – MSQSF36

Dataset	MSQSF36
Description	MSQSF36
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
COMPQ	logical	Did Subject Complete the MSQ & SF-36 ?	Suppressed all records to protect PII
QOLBKNO	logical	Quality of Life Book Number	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII

Variable	Type	Label	Comments
COMPQF	logical	DECODE FOR VARIABLE COMPQ	Suppressed all records to protect PII
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)

1.3.18.   NEUREXAM – NEUREXAM

Dataset	NEUREXAM
Description	NEUREXAM
Unique identifier	NEUREXAM

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
EVENT_ID	integer	Visit identifier	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
ENTRYNO	integer	Entry Number	Collected at CRF.
EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
NTEST	integer	Neurological test	Collected at CRF.
NSYSTEM	integer	Neurological system	Collected at CRF.

NARESULT	integer	Normal or Abnormal test result	Collected at CRF.
ABDESC	logical	Abnormality, described from test result	Suppressed all records to protect PII
MUSCRSLT	logical	Muscle strength result	Suppressed all records to protect PII
REFLRSLT	logical	Reflexes result	Suppressed all records to protect PII
NOTHER	logical	Neurological Exam other specified	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
NSYSTEMF	character	DECODE FOR VARIABLE NSYSTEM	Collected at CRF.
NTESTF	character	DECODE FOR VARIABLE NTEST	Collected at CRF.
ARESULTF	character	DECODE FOR VARIABLE NARESULT	Collected at CRF.
MUSCRSLF	logical	DECODE FOR VARIABLE MUSCRSLT	Suppressed all records to protect PII
REFLRSLF	logical	DECODE FOR VARIABLE REFLRSLT	Suppressed all records to protect PII
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT OF EVDATE	Suppressed all records to protect PII
DREFLRSLT	integer	De-identified reflexes result	Reflexes result, group elements to protect PII
DREFLRSLF	character	DECODE FOR VARIABLE DREFLRSLT	Decode for variable DREFLRSLT, group elements to protect PII
DMUSCRSLT	integer	De-identified muscle strength result	Muscle strength result, group elements to protect PII

DMUSCRSLF	character	DECODE FOR VARIABLE DMUSCRSLT	Decode for variable DMUSCRSLT, group elements to protect PII
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.19.   PLASMA – PLASMA

Dataset	PLASMA
Description	PLASMA
Unique identifier	DPATNO

Variable	Type	Label	Comments
PAG_NAME	character	Page name	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATE	logical	Event date, "ddmmmyyyy" date	Suppressed all records to protect PII
PLSAMPDT	logical	Date Plasma sample taken	Suppressed all records to protect PII
PLSAMPTM	character	Time Plasma sample taken	Collected at CRF.
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII

PATNO	logical	Patient number	Suppressed all records to protect PII
EVENT_ID	integer	Visit identifier	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
PLSMPDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR PLSAMPDT	Suppressed all records to protect PII
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DPLSMPDTN	integer	Relative day plasma sample taken	Relative day plasma sample taken from randomly assigned reference date (PLSMPDTN-REF.DATE)

1.3.20.   SF36 – SF36

Dataset	SF36
Description	SF36
Unique identifier	DPATNO

Variable	Type	Label	Comments
REC_ID	integer	UNIQUE NUMERIC IDENTIFIER	Collected at CRF.
F_STATUS	character	STATUS OF RECORD	Collected at CRF.
DRUG	character	DRUG CODE FOR THE DRUG PROGRAM	Collected at CRF.
TAREA	character	DEFINING THE DRUG PROGRAM	Collected at CRF.
PNO	character	PROTOCOL NUMBER	Collected at CRF.
SCTRY	logical	PROTOCOL IN WHICH COUNTRY	Suppressed all records to protect PII
EVENT_ID	integer	EVENT(VISIT) NAME	Collected at CRF.

PAG_NAME	character	PAGE NAME	Collected at CRF.
BP1	integer	HOW MUCH BODILY PAIN DURING PAST 4 WKS	Collected at CRF.
BP2	integer	HOW MUCH DID PAIN INTERFER NORMAL WORK	Collected at CRF.
EVDATE	logical	EVENT DATE, 'DDMMMYYYY' DATE	Suppressed all records to protect PII
GH1	integer	IN GENERAL, WOULD YOU SAY YOUR HEALTH IS	Collected at CRF.
GH2	integer	I SEEM TO GET SICK A LITTLE EASIER THAN	Collected at CRF.
GH3	integer	I AM AS HEALTHY AS ANYBODY I KNOW	Collected at CRF.
GH4	integer	I EXPECT MY HEALTH TO GET WORSE	Collected at CRF.
GH5	integer	MY HEALTH IS EXCELLENT	Collected at CRF.
HT	integer	COMPARED TO A YEAR AGO, RATE YOUR HEALTH	Collected at CRF.
MH1	integer	HAVE YOU BEEN A VERY NERVOUS PERSON?	Collected at CRF.
MH2	integer	HAVE YOU FELT SO DOWN NOTHING CHEERED ?	Collected at CRF.
MH3	integer	HAVE YOU FELT CALM AND PEACEFUL?	Collected at CRF.
MH4	integer	HAVE YOU FELT DOWNHEARTED AND BLUE?	Collected at CRF.
MH5	integer	HAVE YOU BEEN A HAPPY PERSON?	Collected at CRF.
PF01	integer	HEALTH LIMIT VIGOROUS ACTIVITIES	Collected at CRF.
PF02	integer	HEALTH LIMIT MODERATE ACTIVITIES	Collected at CRF.

PF03	integer	HEALTH LIMIT LIFTING/CARRYING GROCERIES	Collected at CRF.
PF04	integer	HEALTH LIMIT CLIMBING SEVERAL FLIGHTS OF	Collected at CRF.
PF05	integer	HEALTH LIMIT CLIMBING 1 FLIGHT OF STAIRS	Collected at CRF.
PF06	integer	HEALTH LIMIT BENDING, KNEELING, STOOPING	Collected at CRF.
PF07	integer	HEALTH LIMIT WALKING MORE THAN A MILE	Collected at CRF.
PF08	integer	HEALTH LIMIT WALKING SEVERAL BLOCKS	Collected at CRF.
PF09	integer	HEALTH LIMIT WALKING ONE BLOCK	Collected at CRF.
PF10	integer	HEALTH LIMIT BATHING OR DRESSING YRSELF	Collected at CRF.
RE1	integer	EP/CUT DOWN AMOUNT TIME SPENT ON WORK	Collected at CRF.
RE2	integer	EP/ACCOMPLISHED LESS THAN YOU WOULD LIKE	Collected at CRF.
RE3	integer	EP/DIDN'T DO WORK/ACTIVITIES AS CAREFULL	Collected at CRF.
RP1	integer	PH/CUT DOWN AMOUNT OF TIME SPENT ON WORK	Collected at CRF.
RP2	integer	PH/ACCOMPLISHED LESS THAN YOU WOULD LIKE	Collected at CRF.
RP3	integer	PH/LIMITED IN KIND OF WORK OR ACTIVITIES	Collected at CRF.
RP4	integer	PH/DIFFICULTY PERFORMING WORK OR ACTIVIT	Collected at CRF.
SF1	integer	PH OR EP INTERFERED W/ SOCIAL ACTIVITIES	Collected at CRF.
SF2	integer	HOW MUCH TIME HAS PE/EP INTERFERD SOCIAL	Collected at CRF.

VT1	integer	FEEL FULL OF PEP?	Collected at CRF.
VT2	integer	DID YOU HAVE A LOT OF ENERGY?	Collected at CRF.
VT3	integer	DID YOU FEEL WORN OUT?	Collected at CRF.
VT4	integer	DID YOU FEEL TIRED?	Collected at CRF.
PATNO	logical	PATIENT NUMBER	Suppressed all records to protect PII
VISITNO	integer	VISIT NUMBER	Collected at CRF.
BP1F	character	DECODING, HOW MUCH BODILY PAIN DURING PA	Collected at CRF.
BP2F	character	DECODING, HOW MUCH DID PAIN INTERFER NOR	Collected at CRF.
GH1F	character	DECODING, IN GENERAL, WOULD YOU SAY YOUR	Collected at CRF.
GH2F	character	DECODING, I SEEM TO GET SICK A LITTLE EA	Collected at CRF.
GH3F	character	DECODING, I AM AS HEALTHY AS ANYBODY I K	Collected at CRF.
GH4F	character	DECODING, I EXPECT MY HEALTH TO GET WORS	Collected at CRF.
GH5F	character	DECODING, MY HEALTH IS EXCELLENT	Collected at CRF.
HTF	character	DECODING, COMPARED TO A YEAR AGO, RATE Y	Collected at CRF.
MH1F	character	DECODING, HAVE YOU BEEN A VERY NERVOUS P	Collected at CRF.
MH2F	character	DECODING, HAVE YOU FELT SO DOWN NOTHING	Collected at CRF.
MH3F	character	DECODING, HAVE YOU FELT CALM AND PEACEFU	Collected at CRF.
MH4F	character	DECODING, HAVE YOU FELT DOWNHEARTED AND	Collected at CRF.
MH5F	character	DECODING, HAVE YOU BEEN A HAPPY PERSON?	Collected at CRF.

PF01F	character	DECODING, HEALTH LIMIT VIGOROUS ACTIVITI	Collected at CRF.
PF02F	character	DECODING, HEALTH LIMIT MODERATE ACTIVITI	Collected at CRF.
PF03F	character	DECODING, HEALTH LIMIT LIFTING/CARRYING	Collected at CRF.
PF04F	character	DECODING, HEALTH LIMIT CLIMBING SEVERAL	Collected at CRF.
PF05F	character	DECODING, HEALTH LIMIT CLIMBING 1 FLIGHT	Collected at CRF.
PF06F	character	DECODING, HEALTH LIMIT BENDING, KNEELING	Collected at CRF.
PF07F	character	DECODING, HEALTH LIMIT WALKING MORE THAN	Collected at CRF.
PF08F	character	DECODING, HEALTH LIMIT WALKING SEVERAL B	Collected at CRF.
PF09F	character	DECODING, HEALTH LIMIT WALKING ONE BLOCK	Collected at CRF.
PF10F	character	DECODING, HEALTH LIMIT BATHING OR DRESSI	Collected at CRF.
RE1F	character	DECODING, EP/CUT DOWN AMOUNT TIME SPENT	Collected at CRF.
RE2F	character	DECODING, EP/ACCOMPLISHED LESS THAN YOU	Collected at CRF.
RE3F	character	DECODING, EP/DIDN'T DO WORK/ACTIVITIES A	Collected at CRF.
RP1F	character	DECODING, PH/CUT DOWN AMOUNT OF TIME SPE	Collected at CRF.
RP2F	character	DECODING, PH/ACCOMPLISHED LESS THAN YOU	Collected at CRF.
RP3F	character	DECODING, PH/LIMITED IN KIND OF WORK OR	Collected at CRF.
RP4F	character	DECODING, PH/DIFFICULTY PERFORMING WORK	Collected at CRF.

SF1F	character	DECODING, PH OR EP INTERFERED W/ SOCIAL	Collected at CRF.
SF2F	character	DECODING, HOW MUCH TIME HAS PE/EP INTERF	Collected at CRF.
VT1F	character	DECODING, FEEL FULL OF PEP?	Collected at CRF.
VT2F	character	DECODING, DID YOU HAVE A LOT OF ENERGY?	Collected at CRF.
VT3F	character	DECODING, DID YOU FEEL WORN OUT?	Collected at CRF.
VT4F	character	DECODING, DID YOU FEEL TIRED?	Collected at CRF.
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DEVDATE	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATE-REF.DATE)

1.3.21.   SMED – SMED

Dataset	SMED
Description	SMED
Unique identifier	DPATNO

Variable	Type	Label	Comments
EVENT_ID	logical	Visit identifier	Collected at CRF.
PHASEF	logical	DECODE FOR VARIABLE PHASE	Collected at CRF.

MEDSTPTM	logical	Time medication stopped, "hh:mm" format	Collected at CRF.
MEDSTRTM	logical	Time medication started, "hh:mm" format	Collected at CRF.
ENTRYNO	integer	Entry Number	Collected at CRF.
CARDNO	character	Blister Card ID	Collected at CRF.
MEDSTRDT	logical	Date medication started, "ddmonyyyy"	Suppressed all records to protect PII
MEDSTRT	logical	Time medication started as on DCI	Collected at CRF.
MEDSTPDT	logical	Date medication stopped, "ddmonyyyy"	Suppressed all records to protect PII
MEDSTPT	logical	Time medication stopped, as entered DCI	Collected at CRF.
TABSAMA	integer	Tabs taken AM - A	Collected at CRF.
TABSAMB	integer	Tabs taken AM - B	Collected at CRF.
TABSAMC	integer	Tabs taken AM - C	Collected at CRF.
TABSAMD	integer	Tabs taken AM - D	Collected at CRF.
TABSPME	integer	Tabs taken PM - E	Collected at CRF.
TABSPMF	integer	Tabs taken PM - F	Collected at CRF.
TABSPMG	integer	Tabs taken PM - G	Collected at CRF.
TABSPMH	integer	Tabs taken PM - H	Collected at CRF.
NOMEDS	integer	No Meds Taken	Collected at CRF.
TOTDDOS	character	Total Daily Dose	Collected at CRF.
PERIOD	logical	Period designation	Collected at CRF.
PHASE	logical	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII

PAG_NAME	character	Page name	Collected at CRF.
TABSAMAF	character	DECODE FOR VARIABLE TABSAMA	Collected at CRF.
TABSAMBF	character	DECODE FOR VARIABLE TABSAMB	Collected at CRF.
TABSAMCF	character	DECODE FOR VARIABLE TABSAMC	Collected at CRF.
TABSAMDF	character	DECODE FOR VARIABLE TABSAMD	Collected at CRF.
TABSPMEF	character	DECODE FOR VARIABLE TABSPME	Collected at CRF.
TABSPMFF	character	DECODE FOR VARIABLE TABSPMF	Collected at CRF.
TABSPMGF	character	DECODE FOR VARIABLE TABSPMG	Collected at CRF.
TABSPMHF	character	DECODE FOR VARIABLE TABSPMH	Collected at CRF.
NOMEDSF	character	DECODE FOR VARIABLE NOMEDS	Collected at CRF.
MEDSTRDN	logical	SAS NUMERICAL DATE9. FORMAT FOR MEDSTRDT	Suppressed all records to protect PII
MEDSTPDN	logical	SAS NUMERICAL DATE9. FORMAT FOR MEDSTPDT	Suppressed all records to protect PII
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification
DMEDSTPDN	integer	Relative day medication stopped	Relative day medication stopped from randomly assigned reference date (MEDSTPDN-REF.DATE)
DMEDSTRDN	integer	Relative day medication started	Relative day medication started from randomly assigned reference date (MEDSTRDN-REF.DATE)

1.3.22.   SUBJID – SUBJID

Dataset	SUBJID
Description	SUBJID
Unique identifier	DPATNO

Variable	Type	Label	Comments
EVENT_ID	integer	Visit identifier	Collected at CRF.
PAG_NAME	character	Page name	Collected at CRF.
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
INO	logical	Investigator Number	Suppressed all records to protect PII
MEDKITNO	logical	Medication Kit Number	Suppressed all records to protect PII
SUBJINIT	logical	Subject Initials	Suppressed all records to protect PII
SUBJNO	logical	Subject Number	Suppressed all records to protect PII
IFORENAM	logical	Investigator Forename	Suppressed all records to protect PII
ISURNAME	logical	Investigator Surname	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.
SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification

1.3.23.   VITALS – VITALS

Dataset	VITALS
Description	VITALS
Unique identifier	DPATNO

Variable	Type	Label	Comments
EVENT_ID	integer	Visit identifier	Collected at CRF.
PAG_NAME	character	Page name	Collected at CRF.
HGTUNITF	logical	DECODE FOR VARIABLE HGTUNIT	Suppressed all records to protect PII
VISITYPF	character	DECODE FOR VARIABLE VISITYPE	Collected at CRF.
WGTUNITF	logical	DECODE FOR VARIABLE WGTUNIT	Suppressed all records to protect PII
ENTRYNO	logical	Entry Number	Collected at CRF.
EVDATE	logical	Event date, "ddmonyyyy" date	Suppressed all records to protect PII
VISITDT	logical	Visit Date Vitals Taken	Suppressed all records to protect PII
VISITYPE	integer	Type of visit	Collected at CRF.
SYST	integer	Systolic blood pressure	Collected at CRF.
DIAS	integer	Diastolic blood pressure	Collected at CRF.
PULS	integer	Pulse rate, per minute	Collected at CRF.
WGT	logical	Weight	Suppressed all records to protect PII
WGTUNIT	logical	Weight unit	Suppressed all records to protect PII
HGT	logical	Height	Suppressed all records to protect PII
HGTUNIT	logical	Height unit	Suppressed all records to protect PII
PHASE	integer	Phase of Study	Collected at CRF.
DRUG	character	Drug code	Collected at CRF.
TAREA	character	Indication	Collected at CRF.
PNO	character	Protocol number	Collected at CRF.

SCTRY	logical	Study country	Suppressed all records to protect PII
PATNO	logical	Patient number	Suppressed all records to protect PII
PHASEF	character	DECODE FOR VARIABLE PHASE	Collected at CRF.
EVDATEN	logical	SAS NUMERICAL DATE9. FORMAT FOR EVDATE	Suppressed all records to protect PII
VISITDTN	logical	SAS NUMERICAL DATE9. FORMAT FOR VISITDT	Suppressed all records to protect PII
DHEIGHTINGP	character	De-identified subject's height group	Subject's height, 4 inch groupings to protect PII
DHEIGHTIN	integer	De-identified subject's height in inches	Subject's height in inches, randomly sampled within 4 inch height grouping to pr
DWEIGHTLBGP	character	De-identified subject's weight group	Subject's weight in pounds, group elements to protect PII
DWEIGHTLB	integer	De-identified subject's weight in pounds	Subject's weight in pounds, randomly sampled within weight grouping to protect
DEVDATEN	integer	Relative event day	Relative event day from randomly assigned reference date (EVDATEN-REF.DATE)
DVISITDTN	integer	Relative visit day	Relative visit day from randomly assigned reference date (VISITDTN-REF.DATE)
DPATNO	integer	Patient number assigned for de-identification	Randomly assigned patient number for de-identification