

Clinical Development

Topirimate[®]

MIGR001

Anonymisation Data Derivation Specification Document

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Table of contents

Clinical Development	1
1. Datasets	4
1.1. Specifications Introduction	4
1.2. Guidelines for Preparing Data.....	4
1.3. Data Files.....	5
1.4. Data Domains.....	6
1.4.1. DEMOGRAPHICS – DEMOG.....	6
1.4.2. ADVEDTL – ADVEDTL.....	8
1.4.3. ADVEHDR – ADVEHDR.....	10
1.4.4. ADVETHR – ADVETHR.....	12
1.4.5. COMMENTS – COMMENT.....	13
1.4.6. COMPDTL – COMPDTL.....	15
1.4.7. COMPHDR – COMPHDR.....	16
1.4.8. CURMDTL – CURMDTL.....	19
1.4.9. CURMHDR – CURMHDR.....	21
1.4.10. HEADACHE – HEADACHE.....	23
1.4.11. HEADHDR – HEADHDR.....	26
1.4.12. LABNORM – LABNORM.....	28
1.4.13. MEDCAREQ – MEDCAREQ.....	30
1.4.14. MEDMONIT – MEDMONIT.....	32
1.4.15. SUBJID – SUBJID.....	34

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty COMMENT (comments) data will be submitted due to sensitivity of data.
- LABS, MHIST, MSQSF36, NEUREXAM, PLASMA, PREG, PREGTEST, SMED and VITALS datasets contains zero observations at source. Hence these datasets will not be submitted.
- DEMOG. EVDATEN (Event Date) will be used as reference date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The MIGR001 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	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EVDATE,BIRTHDT,RACESPEC,EVDATEN,BIRTHDTN</p> <p>Below listed variable is not a part of the Raw dataset. This have been added to retain the Site information in the de-identified dataset: DSITEID (Source: SUBJID dataset)</p>

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
EVENT_ID	char	Visit Identifier		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
SEX	num	Subject's Gender		Collected at CRF.
RACE	num	Subject's Race		Collected at CRF.
AGE	char	Age in Years		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned Study Site Id for De-identity
SEXF	char	Decode for Variable Sex		Collected at CRF.
RACEF	char	Decode for Variable Race		Collected at CRF.

1.4.2. ADVEDTL – ADVEDTL

Dataset	ADVEDTL
Creating program	advedtl.sas
Description	ADVEDTL
Unique identifier	DPATNO,ADVDESC,PHASE,ONSETDY,ENTRYNO
Sorted by	DPATNO,ADVDESC,PHASE,ONSETDY,ENTRYNO
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: STOPTIME,TONSET,VERBATIM,ONSETDT,STOPDT,SCTRY,ONSETDTN,STOPDTN

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Visit Identifier		Collected at CRF.
PAG_NAME	char	Page Name		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
ACTIONF	char	Decode for Variable Action		Collected at CRF.
DRUGRELF	char	Decode for Variable Drugrel		Collected at CRF.
OUTCOME F	char	Decode for Variable Outcome		Collected at CRF.
SEVERITF	char	Decode for Variable Severity		Collected at CRF.
ENTRYNO	num	Entry Number		Collected at CRF.
ADV CODE	char	Dictionary Code Assigned to AE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVDESC	char	Whoart Dictionary Description		Collected at CRF.
SEVERITY	num	Severity of AE		Collected at CRF.
SERIOUS	num	Was AE Serious?		Collected at CRF.
DRUGREL	num	Was AE Related to Drug?		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
CONCOM	num	Were Concomitant Medications Given?		Collected at CRF.
OUTCOME	num	AE Outcome		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
SERIOUSF	char	Decode for Variable AE Serious		Collected at CRF.
CONCOMF	char	Decode for Variable Concomf		Collected at CRF.

Variable	Type	Label	Codes	Comments
ONSETDY	num	Relative Day of Onset		If ONSETDTN and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDTN less than REF.DATE then (ONSETDTN - REF.DATE). Else if ONSETDTN is greater than equal to REF.DATE then (ONSETDTN- REF.DATE) +1.
STOPDY	num	Relative Stop Day		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.

1.4.3. ADVEHDR – ADVEHDR

Dataset	ADVEHDR
Creating program	advehdr.sas
Description	ADVEHDR
Unique identifier	DPATNO,PHASE,ADVEXPF,EVENT_ID
Sorted by	DPATNO,PHASE,ADVEXPF,EVENT_ID
Notes	Below listed variables will be dropped from dataset due to repetition of the information or due to missing values: EVDATE,SCTRY,EVDATEN

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Visit Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
ADVEXP	num	Were There Any Treatment Emergent AEs?		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
ADVEXPF	char	Decode for Variable Advexp		Collected at CRF.

1.4.4. ADVETHR – ADVETHR

Dataset	ADVETHR
Creating program	advethr.sas
Description	ADVETHR
Unique identifier	DPATNO,DRUGDESC,PHASE,ENTRYNO,THRPYNO
Sorted by	DPATNO,DRUGDESC,PHASE,ENTRYNO,THRPYNO
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: VERBATIM,SCTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Visit Identifier		Collected at CRF.
PAG_NAME	char	Page Name		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
ENTRYNO	num	Entry Number		Collected at CRF.
THRPYNO	num	Therapy Number		Collected at CRF.
DRUGCODE	char	Current Whodrug Dictionary Code Used		Collected at CRF.
DRUGDESC	char	Current Whodrug Dictionary Description		Collected at CRF.
ATC_CD	char	ATC Code		Collected at CRF.
ATC_TEXT	char	ATC Text		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity

1.4.5. COMMENTS – COMMENT

Dataset	COMMENT
Creating program	comment.sas
Description	COMMENTS
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Empty data will be submitted.
TYPE	char	Type of Comment I=Item, F=Form		Empty data will be submitted.
ENTRYNO	num	Entry Number		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
MODNAME	char	Module to Which the Comment Relates		Empty data will be submitted.
TYPEC	char	Decode for Variable Type		Empty data will be submitted.
PHASE	num	Phase of Study		Empty data will be submitted.
DRUG	char	Drug Code		Empty data will be submitted.
TAREA	char	Indication		Empty data will be submitted.
PNO	char	Protocol Number		Empty data will be submitted.
DPATNO	char	Patient Number Assigned for De-identity		Empty data will be submitted.
EVENT_ID	char	Visit Identifier		Empty data will be submitted.
MODNAMEF	char	Decode for Variable Modname		Empty data will be submitted.
PHASEF	char	Decode for Variable Phase		Empty data will be submitted.
EVDY	num	Relative Event Day		Empty data will be submitted.

1.4.6. COMPDTL – COMPDTL

Dataset	COMPDTL
Creating program	compdtl.sas
Description	COMPDTL
Unique identifier	DPATNO,ADVDESC
Sorted by	DPATNO,ADVDESC
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: EVDATE,VERBATIM,SCTRY,EVDATEN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
ADVCODE	char	Dictionary Code Assigned to AE		Collected at CRF.
ADVDESC	char	Whoart Dictionary Description		Collected at CRF.
ENTRYNO	num	Entry Number		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Visit Identifier		Collected at CRF.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.

1.4.7. COMPHDR – COMPHDR

Dataset	COMPHDR
Creating program	comphdr.sas
Description	COMPHDR
Unique identifier	DPATNO,PHASE
Sorted by	DPATNO,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 or due to missing values: LASTDT,EVDATE,VISNUM,TAPERDT,STATUSDT,OTHRSPEC,DEATHDT,SCTRY, TAPERDTN,STATUSDN,DEATHDTN,EVDATEN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
REASONF	char	Decode for Variable Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
STATUS	num	Completion Status		Collected at CRF.
ENTERNXT	num	Will Subject Enter the Next Phase?		Collected at CRF.
TAPER	num	Will Subject Taper From Study Medication		Collected at CRF.
REASON	num	Reason for Withdrawal		Collected at CRF.
DEATH	num	Did Subject Die?		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Visit Identifier		Collected at CRF.
STATUSF	char	Decode for Variable Status		Collected at CRF.
ENTERNXF	char	Decode for Variable Enternxt		Collected at CRF.
TAPERF	char	Decode for Variable Taper		Collected at CRF.
DEATHF	char	Decode for Variable Death		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
TAPERDY	num	Relative Day of Medication Taper Began		If TAPERDTN and REF.DATE not missing then perform below logic to calculate TAPERDY, If TAPERDTN less than REF.DATE then (TAPERDTN - REF.DATE). Else if TAPERDTN is greater than equal to REF.DATE then (TAPERDTN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STATUSDY	num	Relative Day of Completion, Withdrawal		If STATUSDN and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDN less than REF.DATE then (STATUSDN - REF.DATE). Else if STATUSDN is greater than equal to REF.DATE then (STATUSDN- REF.DATE) +1.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.

1.4.8. CURMDTL – CURMDTL

Dataset	CURMDTL
Creating program	curmdtl.sas
Description	CURMDTL
Unique identifier	DPATNO,DRUGDESC,PRNF,ATC_TEXT,TOTDOSE,STARTDY,STOPDY,STARTIME,ENTRYNO
Sorted by	DPATNO,DRUGDESC,PRNF,ATC_TEXT,TOTDOSE,STARTDY,STOPDY,STARTIME,ENTRYNO
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: VERBATIM,STARTDT,STOPDT,AEDATE,INDICT,FORTAE,SCTRY,FORTAEF,STARTDTN,STOPDTN,AEDATEN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
PRNF	char	Decode for Variable PRN		Collected at CRF.
STARTIME	char	Time of Concurrent Medication		Collected at CRF.
ENTRYNO	num	Entry Number		Collected at CRF.
DRUGCODE	char	Current Whodrug Dictionary Code Used		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGDESC	char	Current Whodrug Dictionary Description		Collected at CRF.
ATC_CD	char	ATC Code		Collected at CRF.
ATC_TEXT	char	ATC Text		Collected at CRF.
CONT	num	Is the Drug Continuing?		Collected at CRF.
ROUTE	char	Route of Administration		Collected at CRF.
OTRRT	char	Other Route of Administration		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.
PRN	char	If Drug Taken as Needed PRN		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Visit Identifier		Collected at CRF.
CONTF	char	Decode for Variable Cont		Collected at CRF.
STARTDY	num	Relative Start Day of Concurrent Med		If STARTDTN and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDTN less than REF.DATE then (STARTDTN - REF.DATE). Else if STARTDTN is greater than equal to REF.DATE then (STARTDTN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STOPDY	num	Relative Stop Day		If STOPDTN and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDTN less than REF.DATE then (STOPDTN - REF.DATE). Else if STOPDTN is greater than equal to REF.DATE then (STOPDTN- REF.DATE) +1.
AEDY	num	Relative Day of Serious Adverse Event		If AEDATEN and REF.DATE not missing then perform below logic to calculate AEDY, If AEDATEN less than REF.DATE then (AEDATEN - REF.DATE). Else if AEDATEN is greater than equal to REF.DATE then (AEDATEN- REF.DATE) +1.

1.4.9. CURMHDR – CURMHDR

Dataset	CURMHDR
Creating program	curmhdr.sas
Description	CURMHDR
Unique identifier	DPATNO,PHASE,CONMED,EVENT_ID,PAG_NAME,EVDY
Sorted by	DPATNO,PHASE,CONMED,EVENT_ID,PAG_NAME,EVDY
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: EVDATE,SCTRY,EVDATEN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASEF	char	Decode for Variable Phase		Collected at CRF.
CONMED	num	Did Patient Receive Concurrent Medicatio		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Visit Identifier		Collected at CRF.
CONMEDF	char	Decode for Variable Conmed		Collected at CRF.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.

1.4.10. HEADACHE – HEADACHE

Dataset	HEADACHE
Creating program	headache.sas
Description	HEADACHE
Unique identifier	DPATNO,HEADTYPF,PAIDWORF,NONMIGRT,PHASE,ENTRYNO,EVDY, PAINSPDY
Sorted by	DPATNO,HEADTYPF,PAIDWORF,NONMIGRT,PHASE,ENTRYNO,EVDY, PAINSPDY
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: NONMGOTR,EVDATE,AURASDT,PAINSDT,PAINSPDT,SCTRY,EVDATEN, AURASDTN,PAINSDTN,PAINSPDN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
HEADTYPF	char	Decode for Variable Headtype		Collected at CRF.
PAIDWORF	char	Decode for Variable Paidwork		Collected at CRF.
ENTRYNO	num	Entry Number		Collected at CRF.
HEADTYPE	num	Type of Headache		Collected at CRF.
NONMIGRT	num	Non-Migraine Headache Type		Collected at CRF.
AURASTM	char	Aura Start Time		Collected at CRF.
PAINSTM	char	Pain Start Time		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAINSPT	char	Pain Stop Time		Collected at CRF.
PSEVER	num	Pain Severity		Collected at CRF.
ONESIDE	num	Pain One-Sided During Attack?		Collected at CRF.
THROB	num	Was Pain Throbbing?		Collected at CRF.
PAINPHY	num	Pain Increase With Physical Activity?		Collected at CRF.
VOMIT	num	Did Subject Vomit?		Collected at CRF.
NAUSEA	num	Severity of Nausea Symptoms		Collected at CRF.
PHOTOP	num	Photophobia, Sensitivity to Light		Collected at CRF.
PHONOP	num	Phonophobia, Sensitivity to Sound		Collected at CRF.
PLANHR	num	Hours Subject Planned to Work?		Collected at CRF.
ABSHR	num	Hours Subject Absent From Work?		Collected at CRF.
MIGRHR	num	Hours Subject Worked During Migraine?		Collected at CRF.
OALEFF	num	Rate Overall Effectiveness During Migrai		Collected at CRF.
PAIDWORK	num	Rate Affect on Activities Outside Pd Wk		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Visit Identifier		Collected at CRF.
NONMIGRF	char	Decode for Variable Nonmigrt		Collected at CRF.
PSEVERF	char	Decode for Variable Psever		Collected at CRF.
ONESIDEF	char	Decode for Variable Oneside		Collected at CRF.
THROBF	char	Decode for Variable Throb		Collected at CRF.
PAINPHYF	char	Decode for Variable Painphy		Collected at CRF.
VOMITF	char	Decode for Variable Vomit		Collected at CRF.
NAUSEAF	char	Decode for Variable Nausea		Collected at CRF.
PHOTOPF	char	Decode for Variable Photop		Collected at CRF.
PHONOPF	char	Decode for Variable Phonop		Collected at CRF.
OALEFF	char	Decode for Variable Oaleff		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.
AURASDY	num	Relative Aura Start Day		If AURASDTN and REF.DATE not missing then perform below logic to calculate AURASDY, If AURASDTN less than REF.DATE then (AURASDTN - REF.DATE). Else if AURASDTN is greater than equal to REF.DATE then (AURASDTN- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
PAINSDY	num	Relative Pain Start Day		If PAINSDTN and REF.DATE not missing then perform below logic to calculate PAINSDY, If PAINSDTN less than REF.DATE then (PAINSDTN - REF.DATE). Else if PAINSDTN is greater than equal to REF.DATE then (PAINSDTN- REF.DATE) +1.
PAINSPDY	num	Relative Pain Stop Day		If PAINSPDN and REF.DATE not missing then perform below logic to calculate PAINSPDY, If PAINSPDN less than REF.DATE then (PAINSPDN - REF.DATE). Else if PAINSPDN is greater than equal to REF.DATE then (PAINSPDN- REF.DATE) +1.

1.4.11. HEADHDR – HEADHDR

Dataset	HEADHDR
Creating program	headhdr.sas
Description	HEADHDR
Unique identifier	DPATNO,ANYHEADF,PHASE,EVDY
Sorted by	DPATNO,ANYHEADF,PHASE,EVDY
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: EVDATE,VISITDT,SCTRY,EVDATEN,VISITDTN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
ANYHEAD	num	Subject Have Any Aura or Headaches?		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Visit Identifier		Collected at CRF.
ANYHEADF	char	Decode for Variable Anyhead		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.
VISITDY	num	Relative Visit Day Vitals Taken		If VISITDTN and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDTN less than REF.DATE then (VISITDTN - REF.DATE). Else if VISITDTN is greater than equal to REF.DATE then (VISITDTN- REF.DATE) +1.

1.4.12. LABNORM – LABNORM

Dataset	LABNORM
Creating program	labnorm.sas
Description	LABNORM
Unique identifier	LABCODE,ENTNO
Sorted by	LABCODE,ENTNO
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,LABLOC,MODIFYDT,STOPDT,UNITCODE,PATNO

Variable	Type	Label	Codes	Comments
F_STATUS	char	Status of Record		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
EVENT_ID	char	Visit Identifier		Collected at CRF.
PAG_NAME	char	Page Name		Collected at CRF.
AGEUNIT	char	Age Unit		Collected at CRF.
ENTNO	num	Entry Number		Collected at CRF.
ENTRYDT	char	Entry Date		Collected at CRF.

Variable	Type	Label	Codes	Comments
HIAGE	num	Hi Age for Lab Normal Range		Collected at CRF.
HIRANGE	num	High Range Normal Value		Collected at CRF.
LABCODE	char	Laboratory Test Code		Collected at CRF.
LOAGE	num	Lo Age		Collected at CRF.
LORANGE	num	Low Range Normal Value		Collected at CRF.
SEX	num	Sex		Collected at CRF.
STARTDT	char	Start Date From Which Ranges Effective		Collected at CRF.
VISITNO	num	Visit Number		Collected at CRF.
SEXF	char	Decoding, Sex		Collected at CRF.

1.4.13. MEDCAREQ – MEDCAREQ

Dataset	MEDCAREQ
Creating program	medcareq.sas
Description	MEDCAREQ
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 repetition of the information or due to missing values: EVDATE,PVOPSP1,PVOPSP3,SCTRY,EVDATEN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
PVNECYN	num	Physician Visit Necessary?		Collected at CRF.
MEDDOCT	num	Seen Any Medical Doctors Since Last Visi		Collected at CRF.
PVTP	num	Trial Physican Number of Visits		Collected at CRF.
PVOP1	num	Number of Visits to Other Physician 1		Collected at CRF.
PVOPSP2	char	Other Physician 2, Speciality		Collected at CRF.
PVOP2	num	Number of Visits to Other Physician 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
PVOP3	num	Number of Visits to Other Physican 3		Collected at CRF.
URGCRYN	num	Unscheduled Visits for ER/Urgent Care		Collected at CRF.
ERUC	num	Number of Urgent Care/ER Visits		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De- identity		Randomly assigned Patient Number for De-identity
EVENT_ID	char	Visit Identifier		Collected at CRF.
PVNECYNF	char	Decode for Variable Pvnecyn		Collected at CRF.
MEDDOCTF	char	Decode for Variable Meddoct		Collected at CRF.
URGCRYNF	char	Decode for Variable Urgcryn		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.

1.4.14. MEDMONIT – MEDMONIT

Dataset	MEDMONIT
Creating program	medmonit.sas
Description	MEDMONIT
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: EVDATE,APPDATE,SUMMARY,SCTRY,EVDATEN,APPDATEN

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page Name		Collected at CRF.
EVENT_ID	char	Visit Identifier		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
ELIGMEET	num	Did the Subject Meet All Eligibility Cri		Collected at CRF.
INCLVIOL	char	Inclusion Criteria Violated		Collected at CRF.
EXCLVIOL	char	Exclusion Criteria Violated		Collected at CRF.
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
ELIGMEEF	char	Decode for Variable Eligmeet		Collected at CRF.
EVDY	num	Relative Event Day		If EVDATEN and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATEN less than REF.DATE then (EVDATEN - REF.DATE). Else if EVDATEN is greater than equal to REF.DATE then (EVDATEN- REF.DATE) +1.
APPDY	num	Relative Day Approved by Med Monitor		If APPDATEN and REF.DATE not missing then perform below logic to calculate APPDY, If APPDATEN less than REF.DATE then (APPDATEN - REF.DATE). Else if APPDATEN is greater than equal to REF.DATE then (APPDATEN- REF.DATE) +1.

1.4.15. SUBJID – SUBJID

Dataset	SUBJID
Creating program	subjid.sas
Description	SUBJID
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: MEDKITNO,SUBJINIT,SUBJNO,IFORENAM,ISURNAME,SCTRY

Variable	Type	Label	Codes	Comments
EVENT_ID	char	Visit Identifier		Collected at CRF.
PAG_NAME	char	Page Name		Collected at CRF.
PHASEF	char	Decode for Variable Phase		Collected at CRF.
DSITEID	char	Study Site Id Assigned for De-identity		Randomly assigned Study Site Id for De-identity
PHASE	num	Phase of Study		Collected at CRF.
DRUG	char	Drug Code		Collected at CRF.
TAREA	char	Indication		Collected at CRF.
PNO	char	Protocol Number		Collected at CRF.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity