

Clinical Development

**Topiramate<sup>®</sup>**

CAPSS276

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 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.
- Due to sensitive information INVESTIG(Investigator information) and PV(Protocol Violations) datasets will be removed.
- For Randomized subjects, VISITDT.VISITDT (Visit Date when VISITNO=1) will be used as Reference Date (referred as REF.DATE in the document) to derive relative days. For Screen Failure subjects, ADVE.ONSETDT will be used as a Reference date (referred as REF.DATE in the document) to derive relative days.

### 1.3. Data Files

The CAPSS276 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographic Information – DEMO

<b>Dataset</b>	DEMO
<b>Creating program</b>	demo.sas
<b>Description</b>	Demographic Information
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE,BIRTHDT,BIRTH_D,BIRTH_M,BIRTH_Y,RACESPEC

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
GENDER	num	Subject's Gender		Collected at CRF.
GENDERC	char	Subject's Gender		Collected at CRF.
AGE_ENTR	char	Age at Entry		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGE	char	Subject Age(yrs) at Study Start		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
RACE	num	Subject's Race		Collected at CRF.
RACEC	char	Subject's Race		Collected at CRF.



## 1.4.2. Hx Acute and Prophylactic Migraine Med – ACUTEHIS

<b>Dataset</b>	ACUTEHIS
<b>Creating program</b>	acutehis.sas
<b>Description</b>	Hx Acute and Prophylactic Migraine Med
<b>Unique identifier</b>	DPATNO,VERBATIM,STARTDY,STOPDY,MONTH
<b>Sorted by</b>	DPATNO,VERBATIM,STARTDY,STOPDY,MONTH
<b>Notes</b>	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,INVNAME,STARTDT,START_M,START_D,START_Y,STOPDT,STOP_M,STOP_D,STOP_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
VERBATIM	char	Drug Name		Collected at CRF.
AVGDOSE	char	Average Daily Dose		Collected at CRF.
MONTH	num	>6 Months		Collected at CRF.
CONT	num	Continues		Collected at CRF.
REASON	num	Reason for Migraine Therapy		Collected at CRF.
SEQNO1	char	WHODRL Sequence Number		Collected at CRF.
SEQNO2	char	WHODRL Sequence Number		Collected at CRF.
DRUGCD	char	WHODRL Record Number		Collected at CRF.
STARTDY	num	Relative Start Day Migraine Therapy		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	Relative Stop Day Migraine Therapy		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.

## 1.4.3. Adverse Experiences – ADVE

<b>Dataset</b>	ADVE
<b>Creating program</b>	adve.sas
<b>Description</b>	Adverse Experiences
<b>Unique identifier</b>	DPATNO,BODYSYS,PREF_TRM,CONCOM,ADVCODE,ONSETDY,STOPDY,PAGEID
<b>Sorted by</b>	DPATNO,BODYSYS,PREF_TRM,CONCOM,ADVCODE,ONSETDY,STOPDY,PAGEID
<b>Notes</b>	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: SUBINI,INVNAME,VERBATIM,ONSETDT,ONSET_M,ONSET_D,ONSET_Y, STOPDT,STOP_D,STOP_M,STOP_Y,INCL_TRM,FULLWHO

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
PERSISTE	num	Persisted		Collected at CRF.
OUTCOME	num	Outcome Unknown		Collected at CRF.
SEVERITY	num	Severity		Collected at CRF.
SERIOUS	num	Serious Adverse Event		Collected at CRF.
RELATION	num	Relation to Study Drug		Collected at CRF.
ACTION	num	Action Taken		Collected at CRF.
CONCOM	num	Therapy Given		Collected at CRF.
ADVCODE	char	WHOART Code		Collected at CRF.
BODYSYS	char	WHOART System Organ Class Term		Collected at CRF.
PREF_TRM	char	WHOART Preferred Term		Collected at CRF.
ONSETDY	num	Relative Onset Day		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.
STOPDY	num	Relative 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.

## 1.4.4. Adverse Events Check – ADVE\_TOP

<b>Dataset</b>	ADVE_TOP
<b>Creating program</b>	adve_top.sas
<b>Description</b>	Adverse Events Check
<b>Unique identifier</b>	DPATNO,PAGEID,PAGE
<b>Sorted by</b>	DPATNO,PAGEID,PAGE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNAME

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
ADVEXP	num	No Treatmnt-Emergent AE Occurred		Collected at CRF.

#### 1.4.5. AEs/Concom Medications – AECNMED

<b>Dataset</b>	AECNMED
<b>Creating program</b>	aecnmed.sas
<b>Description</b>	AEs/Concom Medications
<b>Unique identifier</b>	DPATNO,VISITNO
<b>Sorted by</b>	DPATNO,VISITNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity

Variable	Type	Label	Codes	Comments
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
NA	num	N/A		Collected at CRF.
AES	num	Adverse Events Reported?		Collected at CRF.
CONMEDS	num	Concomitant Medication Reported?		Collected at CRF.

#### 1.4.6. Clinical Significance – CLINSIG

<b>Dataset</b>	CLINSIG
<b>Creating program</b>	clinsig.sas
<b>Description</b>	Clinical Significance
<b>Unique identifier</b>	DPATNO,PN_TESTC,VISITNO,COLDY
<b>Sorted by</b>	DPATNO,PN_TESTC,VISITNO,COLDY
<b>Notes</b>	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,INVNAME,CSCOM,COLDT,COLDTD,COLDTY,COLDTM,ACCNO

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
CLINSIG	num	Clinically Significant?		Collected at CRF.
SIGYN	num	Signature Present?		Collected at CRF.
SIGDTYN	num	Signature Date Present?		Collected at CRF.
PN_TESTC	char	PN Lab Test Code		Collected at CRF.
DPNCLSIT	char	CL Site ID Assigned for De-identity		Randomly assigned CL Site ID for De-identity
COLDY	num	Relative Sample Collection Day - Derived		If COLDT and REF.DATE not missing then perform below logic to calculate COLDY, If COLDT less than REF.DATE then (COLDT - REF.DATE). Else if COLDT is greater than equal to REF.DATE then (COLDT - REF.DATE) +1.



## 1.4.7. Completion/Discontinuation Summary – COMP

<b>Dataset</b>	COMP
<b>Creating program</b>	comp.sas
<b>Description</b>	Completion/Discontinuation Summary
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	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: SUBINI,INVNAME,RPTPAGE,STOPDT,STOP_M,STOP_D,STOP_Y,REASPEC, REASPEC1,REASPEC2,REASPEC3,LASTDT,LAST_M,LAST_D,LAST_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
RAND	num	Subject Randomized to Study Drug		Collected at CRF.
COMPDB	num	Subj Comp Double-Blind(DB) Phase		Collected at CRF.
PRIMREAS	num	Reason for Discontinuation		Collected at CRF.
ENTOL	num	Subj Enter Open Label Extension		Collected at CRF.
STOPDY	num	Relative 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.
LASTDY	num	Relative Last Day		If LASTDT and REF.DATE not missing then perform below logic to calculate LASTDY, If LASTDT less than REF.DATE then (LASTDT - REF.DATE). Else if LASTDT is greater than equal to REF.DATE then (LASTDT- REF.DATE) +1.

## 1.4.8. Recent/Concomitant Therapy – CURM

<b>Dataset</b>	CURM
<b>Creating program</b>	curm.sas
<b>Description</b>	Recent/Concomitant Therapy
<b>Unique identifier</b>	DPATNO,VERBATIM,STARTDY,STOPDY
<b>Sorted by</b>	DPATNO,VERBATIM,STARTDY,STOPDY
<b>Notes</b>	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,INVNAME,STARTDT,START_M,START_D,START_Y,STOPDT,STOP_M,STOP_D,STOP_Y,CURMREAS

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
VERBATIM	char	Medication Name		Collected at CRF.
ROUTE	char	Route of Admin.		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.
CONT	num	Ongoing		Collected at CRF.
SEQNO1	char	WHODRL Sequence Number		Collected at CRF.
SEQNO2	char	WHODRL Sequence Number		Collected at CRF.
DRUGCD	char	WHODRL Record Number		Collected at CRF.
STARTDY	num	Relative Start Day		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	Relative 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.

## 1.4.9. Recent/Concomitant Therapy Check – CURM\_TOP

<b>Dataset</b>	CURM_TOP
<b>Creating program</b>	curm_top.sas
<b>Description</b>	Recent/Concomitant Therapy Check
<b>Unique identifier</b>	DPATNO,PAGEID,PAGE
<b>Sorted by</b>	DPATNO,PAGEID,PAGE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNAME

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
CURMEXP	num	No Concomitant Therapy		Collected at CRF.

#### 1.4.10. Study Medication Dosage – DOSE

<b>Dataset</b>	DOSE
<b>Creating program</b>	dose.sas
<b>Description</b>	Study Medication Dosage
<b>Unique identifier</b>	DPATNO,VISITNO
<b>Sorted by</b>	DPATNO,VISITNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
TOTDOSE	char	Total Daily Dose		Collected at CRF.

#### 1.4.11. Study Medication Compliance – DRUGDISP

<b>Dataset</b>	DRUGDISP
<b>Creating program</b>	drugdisp.sas
<b>Description</b>	Study Medication Compliance
<b>Unique identifier</b>	DPATNO,DISPDY,RETDY,RDISPDY,RRETDY,NUMDISP,NUMRET
<b>Sorted by</b>	DPATNO,DISPDY,RETDY,RDISPDY,RRETDY,NUMDISP,NUMRET
<b>Notes</b>	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: SUBINI,INVNAME,RPTPAGE,BOTTLE,DISPDT,DISP_M,DISP_D,DISP_Y,RETDT,RET_M,RET_D,RET_Y,RDISPDT,RDISP_M,RDISP_D,RDISP_Y,RRETDY,RRET_M,RRET_D,RRET_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity

Variable	Type	Label	Codes	Comments
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
NUMDISP	num	# Tablets Dispensed		Collected at CRF.
NUMRET	num	# Tablets Returned		Collected at CRF.
NUMRRET	num	# Tablets Re-returned		Collected at CRF.
DISPDY	num	Relative Day Dispensed		If DISPDT and REF.DATE not missing then perform below logic to calculate DISPDY, If DISPDT less than REF.DATE then (DISPDT - REF.DATE). Else if DISPDT is greater than equal to REF.DATE then (DISPDT - REF.DATE) +1.
RETDY	num	Relative Returned Day		If RETDT and REF.DATE not missing then perform below logic to calculate RETDY, If RETDT less than REF.DATE then (RETDY - REF.DATE). Else if RETDT is greater than equal to REF.DATE then (RETDY - REF.DATE) +1.



Variable	Type	Label	Codes	Comments
RDISPDY	num	Relative Re-dispensed Day		If RDISPDT and REF.DATE not missing then perform below logic to calculate RDISPDY, If RDISPDT less than REF.DATE then (RDISPDT - REF.DATE). Else if RDISPDT is greater than equal to REF.DATE then (RDISPDT- REF.DATE) +1.
RRETDY	num	Relative Re-returned Day		If RRETDT and REF.DATE not missing then perform below logic to calculate RRETDY, If RRETDT less than REF.DATE then (RRETDT - REF.DATE). Else if RRETDT is greater than equal to REF.DATE then (RRETDT- REF.DATE) +1.

#### 1.4.12. Headache History – HDHIS

<b>Dataset</b>	HDHIS
<b>Creating program</b>	hdhis.sas
<b>Description</b>	Headache History
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
ONSETAGE	char	Age(yrs) at Migraine Onset		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DURY	num	Duration of Headache - Years		Collected at CRF.
DURM	num	Duration of Headache - Months		Collected at CRF.

## 1.4.13. Headache Record Log – HDLOG

<b>Dataset</b>	HDLOG
<b>Creating program</b>	hdlog.sas
<b>Description</b>	Headache Record Log
<b>Unique identifier</b>	DPATNO,VISITNO,HDEXP,FIRSTDY,HDDY
<b>Sorted by</b>	DPATNO,VISITNO,HDEXP,FIRSTDY,HDDY
<b>Notes</b>	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,INVNAME,FIRSTDT,FIRST_M,FIRST_D,FIRST_Y,HDDT,HD_M,HD_D,HD_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
DAY	num	Day		Collected at CRF.
HDEXP	num	Subject Experience Headache?		Collected at CRF.
FIRSTDY	num	Relative First Dose Day		If FIRSTDT and REF.DATE not missing then perform below logic to calculate FIRSTDY, If FIRSTDT less than REF.DATE then (FIRSTDT - REF.DATE). Else if FIRSTDT is greater than equal to REF.DATE then (FIRSTDT- REF.DATE) +1.
HDDY	num	Relative Headache Day		If HDDT and REF.DATE not missing then perform below logic to calculate HDDY, If HDDT less than REF.DATE then (HDDT - REF.DATE). Else if HDDT is greater than equal to REF.DATE then (HDDT- REF.DATE) +1.

## 1.4.14. Headache Medication – HDMED

<b>Dataset</b>	HDMED
<b>Creating program</b>	hdmed.sas
<b>Description</b>	Headache Medication
<b>Unique identifier</b>	DPATNO,MEDTYPE,VERBATIM,VISITNO,NUMDOSE,PAGEID,PAGE
<b>Sorted by</b>	DPATNO,MEDTYPE,VERBATIM,VISITNO,NUMDOSE,PAGEID,PAGE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNAME

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
ANYMED	num	Medication Taken?		Collected at CRF.
VERBATIM	char	Medication Name		Collected at CRF.
NUMDOSE	num	Number of Doses		Collected at CRF.
MEDTYPE	num	Type of Medication		Collected at CRF.
DRUGCD	char	WHODRL Record Number		Collected at CRF.
SEQNO1	char	WHODRL Sequence Number		Collected at CRF.
SEQNO2	char	WHODRL Sequence Number		Collected at CRF.

#### 1.4.15. Headache Record - Condition – HDREC

<b>Dataset</b>	HDREC
<b>Creating program</b>	hdrec.sas
<b>Description</b>	Headache Record - Condition
<b>Unique identifier</b>	DPATNO,VISITNO,HD_HR,HD_MN,PAGEID,PAGE
<b>Sorted by</b>	DPATNO,VISITNO,HD_HR,HD_MN,PAGEID,PAGE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNAME

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
HEADACHE	num	Have Headache Yesterday?		Collected at CRF.
HD_HR	num	Headache Duration-Hours		Collected at CRF.
HD_MN	num	Headache Duration-Minutes		Collected at CRF.
AURA	num	Did You Have an Aura?		Collected at CRF.
AVGPAIN	num	Average Pain		Collected at CRF.
WRSTPAIN	num	Worst Pain		Collected at CRF.
NAUSEA	num	Nausea		Collected at CRF.
PHOTOP	num	Sensitive To Light		Collected at CRF.
PHONOP	num	Sensitive To Sound		Collected at CRF.
VOMIT	num	Vomiting		Collected at CRF.
ONESIDE	num	Is Pain One Sided?		Collected at CRF.

Variable	Type	Label	Codes	Comments
THROB	num	Pain Throbbing?		Collected at CRF.
PHYSINC	num	Pain Increase with Activity?		Collected at CRF.

#### 1.4.16. Inclusion/Exclusion Criteria – INEXCRIT

<b>Dataset</b>	INEXCRIT
<b>Creating program</b>	inexcrit.sas
<b>Description</b>	Inclusion/Exclusion Criteria
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	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: SUBINI,INVNAME,RPTPAGE,EXEMPTDT,EXEMPT_M,EXEMPT_D,EXEMPT_Y, COMMENT1,COMMENT2,COMMENT3

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity



Variable	Type	Label	Codes	Comments
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
ELIGIBLE	num	Did Subject Meet all Criteria?		Collected at CRF.
EXEMPT	num	Was Entrance Authorized by OMP?		Collected at CRF.
INCNO1	num	Incl Criterion Exception Granted		Collected at CRF.
INCNO2	num	Incl Criterion Exception Granted		Collected at CRF.
INCNO3	num	Incl Criterion Exception Granted		Collected at CRF.
INCNO4	num	Incl Criterion Exception Granted		Collected at CRF.
INCNO5	num	Incl Criterion Exception Granted		Collected at CRF.
EXCNO1	num	Excl Criterion Exception Granted		Collected at CRF.
EXCNO2	num	Excl Criterion Exception Granted		Collected at CRF.
EXCNO3	num	Excl Criterion Exception Granted		Collected at CRF.
EXCNO4	num	Excl Criterion Exception Granted		Collected at CRF.
EXCNO5	num	Excl Criterion Exception Granted		Collected at CRF.
INCNOA1	num	Inclusion Criterion Not Met		Collected at CRF.
INCNOA2	num	Inclusion Criterion Not Met		Collected at CRF.
INCNOA3	num	Inclusion Criterion Not Met		Collected at CRF.
INCNOA4	num	Inclusion Criterion Not Met		Collected at CRF.
INCNOA5	num	Inclusion Criterion Not Met		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCNOA1	num	Exclusion Criterion Not Met		Collected at CRF.
EXCNOA2	num	Exclusion Criterion Not Met		Collected at CRF.
EXCNOA3	num	Exclusion Criterion Not Met		Collected at CRF.
EXCNOA4	num	Exclusion Criterion Not Met		Collected at CRF.
EXCNOA5	num	Exclusion Criterion Not Met		Collected at CRF.
EXEMPTDY	num	Relative Exempt Day		If EXEMPTDT and REF.DATE not missing then perform below logic to calculate EXEMPTDY, If EXEMPTDT less than REF.DATE then (EXEMPTDT - REF.DATE). Else if EXEMPTDT is greater than equal to REF.DATE then (EXEMPTDT- REF.DATE) +1.

## 1.4.17. Clinical Laboratory Tests – LAB

<b>Dataset</b>	LAB
<b>Creating program</b>	lab.sas
<b>Description</b>	Clinical Laboratory Tests
<b>Unique identifier</b>	DPATNO,TEST,VISITNO,COLDY,PAGE
<b>Sorted by</b>	DPATNO,TEST,VISITNO,COLDY,PAGE
<b>Notes</b>	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,INVNAME,COLDT,SAMPL_M,SAMPL_D,SAMPL_Y,ACCNO

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEST	num	Laboratory Test		Collected at CRF.
ND	num	Not Done		Collected at CRF.
COLDY	num	Relative Sample Day		If COLDT and REF.DATE not missing then perform below logic to calculate COLDY, If COLDT less than REF.DATE then (COLDT - REF.DATE). Else if COLDT is greater than equal to REF.DATE then (COLDT - REF.DATE) +1.

## 1.4.18. Lab Results – LAB\_RESU

<b>Dataset</b>	LAB_RESU
<b>Creating program</b>	lab_resu.sas
<b>Description</b>	Lab Results
<b>Unique identifier</b>	DPATNO,CL_TESTC,CL_RESUL,CL2CP_VI,COLDY
<b>Sorted by</b>	DPATNO,CL_TESTC,CL_RESUL,CL2CP_VI,COLDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,PAGE,RPTPAGE,VISIDESC,CL_GRPDC,CL_DELTA,CL_ACCNO, CL_COMME,CL_BIRDT,CL_BIRTX,CL_FILED,CL_COLDT,CL_INITI,COLDT, COLDTD,COLDTM,COLDTY,CSCOM,CLINSIG,COLLECTH,COLLECTM,CL_UNITC, CL_SCRNO,CL_RECDDT,ACCTNUM

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
PROTOCOL	char	PNET Protocol		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
CL_TESTC	char	CL Test Code		Collected at CRF.
CL_VISCD	num	CL Visit Code		Collected at CRF.
CL_RESUL	char	CL Test Result		Collected at CRF.
CL_NORMH	char	High Lab Reference Range		Collected at CRF.
CL_NORML	char	Low Lab Reference Range		Collected at CRF.
CL_ALERT	char	Lab Alert Flag		Collected at CRF.
CL_CSLIN	num	Clin. Signif. Trigger Line Pres.		Collected at CRF.
NORMHI	num	Derived Reference Range High		Collected at CRF.
NORMFLAG	char	Derived Normal Range Flag		Collected at CRF.
CL2CP_VI	char	Converted CP Visit Code		Collected at CRF.
CL_COLTM	char	Collection Time		Collected at CRF.
LAB_RESU	num	Numeric Lab Result		Collected at CRF.
CL_SEXCD	char	CL Sex Code		Collected at CRF.
LAB_AGE	char	Age - Using CL_BIRTHDT		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAB_SEX	char	Patient Sex (Demographic)		Collected at CRF.
PN_TESTC	char	PN Lab Test Code		Collected at CRF.
PN_UNITC	num	PN Unit Code Map		Collected at CRF.
DPNCLSIT	char	CL Site ID Assigned for De-identity		Randomly assigned CL Site ID for De-identity
NORMLO	num	Derived Reference Range Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
COLLECTT	char	Collection Time (HH24:MI)		Collected at CRF.
TERM	num	Termination Visit Type		Collected at CRF.
REPEAT	num	Unscheduled Visit Type		Collected at CRF.
LABCODE	char	OMP Lab Code		Collected at CRF.
UNITCODE	num	OMP Unit Code		Collected at CRF.
CL_TOXGR	char	Lab Toxicity Grade		Collected at CRF.
CL_TESTD	char	CL Test Description		Collected at CRF.
BLINDED	num	Blinded?		Collected at CRF.
CL_UNSCH	num	Unscheduled Visit?		Collected at CRF.
CLFILEDY	num	Relative Day Lab Sent File		If CL_FILED and REF.DATE not missing then perform below logic to calculate CLFILEDY, If CL_FILED less than REF.DATE then (CL_FILED - REF.DATE). Else if CL_FILED is greater than equal to REF.DATE then (CL_FILED- REF.DATE) +1.
COLDY	num	Relative Sample Collection Day - Derived		If COLDT and REF.DATE not missing then perform below logic to calculate COLDY, If COLDT less than REF.DATE then (COLDT - REF.DATE). Else if COLDT is greater than equal to REF.DATE then (COLDT- REF.DATE) +1.
CL_REC DY	num	Relative Day Lab Rec'd Sample		If CL_REC DT and REF.DATE not missing then perform below logic to calculate CL_REC DY, If CL_REC DT less than REF.DATE then (CL_REC DT - REF.DATE). Else if CL_REC DT is greater than equal to REF.DATE then (CL_REC DT- REF.DATE) +1.

## 1.4.19. Medication Code Number – MEDCODE

<b>Dataset</b>	MEDCODE
<b>Creating program</b>	medcode.sas
<b>Description</b>	Medication Code Number
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE,MEDCODE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.



## 1.4.20. Medical History – MHIST

<b>Dataset</b>	MHIST
<b>Creating program</b>	mhist.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DPATNO,SYSTEM
<b>Sorted by</b>	DPATNO,SYSTEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE,VERBATIM

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
SYSTEM	num	Body System		Collected at CRF.
HX	num	History/No History		Collected at CRF.

#### 1.4.21. Midas Questionnaire – MIDAS

<b>Dataset</b>	MIDAS
<b>Creating program</b>	midas.sas
<b>Description</b>	Midas Questionnaire
<b>Unique identifier</b>	DPATNO,VISITNO
<b>Sorted by</b>	DPATNO,VISITNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINI,INVNAME,RPTPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
QUEST1	num	Response(days) to Midas Quest 1		Collected at CRF.
QUEST2	num	Response(days) to Midas Quest 2		Collected at CRF.
QUEST3	num	Response(days) to Midas Quest 3		Collected at CRF.
QUEST4	num	Response(days) to Midas Quest 4		Collected at CRF.
QUEST5	num	Response(days) to Midas Quest 5		Collected at CRF.
RATING	num	Midas Rating		Collected at CRF.
QUESTA	num	Response(days) to Midas Quest A		Collected at CRF.
QUESTB	num	Response to Midas Quest B		Collected at CRF.

## 1.4.22. Migraine Spec Quality of Life Quest – MSQLQ

<b>Dataset</b>	MSQLQ
<b>Creating program</b>	msqlq.sas
<b>Description</b>	Migraine Spec Quality of Life Quest
<b>Unique identifier</b>	DPATNO,VISITNO
<b>Sorted by</b>	DPATNO,VISITNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
NA	num	N/A		Collected at CRF.

Variable	Type	Label	Codes	Comments
QUEST1	num	Interfered With Family/Others		Collected at CRF.
QUEST2	num	Interfered Leisure Activities		Collected at CRF.
QUEST3	num	Difficulty in Performing Work		Collected at CRF.
QUEST4	num	Reduced Work/Home Activities		Collected at CRF.
QUEST5	num	Limited Ability To Concentrate		Collected at CRF.
QUEST6	num	Too Tired To Work		Collected at CRF.
QUEST7	num	Limited No. Days Felt Energetic		Collected at CRF.
QUEST8	num	Cancelled Work/Daily Activities		Collected at CRF.
QUEST9	num	Need Help Handling Routine Tasks		Collected at CRF.
QUEST10	num	Stopped Work/Daily Activities		Collected at CRF.
QUEST11	num	Limited Social Activities		Collected at CRF.
QUEST12	num	Felt Fed Up Or Frustrated		Collected at CRF.
QUEST13	num	Felt Like You Were A Burden		Collected at CRF.
QUEST14	num	Afraid Of Letting Others Down		Collected at CRF.

## 1.4.23. Not Applicable – NA

<b>Dataset</b>	NA
<b>Creating program</b>	na.sas
<b>Description</b>	Not Applicable
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RTPPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
NA	num	N/A		Collected at CRF.

## 1.4.24. Brief Neurological Examination – NEURO

<b>Dataset</b>	NEURO
<b>Creating program</b>	neuro.sas
<b>Description</b>	Brief Neurological Examination
<b>Unique identifier</b>	DPATNO,TEST
<b>Sorted by</b>	DPATNO,TEST
<b>Notes</b>	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: SUBINI,INVNAME,RPTPAGE,ASSESSDT,ASSESS_M,ASSESS_D,ASSESS_Y, VERBATIM

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIDESC	char	Visit Description		Collected at CRF.
TEST	num	Neurological Test		Collected at CRF.
RSLT	num	Neurological Test Results		Collected at CRF.
ASSESSDY	num	Relative Assessment Day		If ASSESSDT and REF.DATE not missing then perform below logic to calculate ASSESSDY, If ASSESSDT less than REF.DATE then (ASSESSDT - REF.DATE). Else if ASSESSDT is greater than equal to REF.DATE then (ASSESSDT- REF.DATE) +1.

#### 1.4.25. Lab Reference Ranges – NORMAL\_R

<b>Dataset</b>	NORMAL_R
<b>Creating program</b>	normal_r.sas
<b>Description</b>	Lab Reference Ranges
<b>Unique identifier</b>	PN_TESTC,NR_SEX,NR_AGELO,NR_LO,NR_HI
<b>Sorted by</b>	PN_TESTC,NR_SEX,NR_AGELO,NR_LO,NR_HI
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: NRSRTDTD,NRSRTDTM,NRSRTDTY

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
NR_SEX	char	Patient Gender		Collected at CRF.



Variable	Type	Label	Codes	Comments
NR_AGELO	num	Age Low		Collected at CRF.
NR_AGEHI	num	Age High		Collected at CRF.
NR_LO	num	NR Low Value		Collected at CRF.
NR_HI	num	NR High Value		Collected at CRF.
NORMTXT	char	NR Text Value		Collected at CRF.
NR_PEDYN	num	Pediatric Study?		Collected at CRF.
PN_UNITC	num	PN Unit Code Map		Collected at CRF.
PN_TESTC	char	PN Test Code Map		Collected at CRF.
NRSRTDT	num	NR Start Date		Collected at CRF.
DPNCLSIT	char	CL Site ID Assigned for De-identity		Randomly assigned CL Site ID for De-identity
PN_DISEA	char	Using for a spec. disease?		Collected at CRF.
PN_CTPRO	char	PN Clintrial Protocol		Collected at CRF.
NO_NORMA	num	Flag for test no normal ranges		Collected at CRF.

## 1.4.26. Phys Global Impression of Change – PGIC

<b>Dataset</b>	PGIC
<b>Creating program</b>	pgic.sas
<b>Description</b>	Phys Global Impression of Change
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RTPPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
PGIC	num	Phys Global Impression of Change		Collected at CRF.

## 1.4.27. Phone Contact – PHONE

<b>Dataset</b>	PHONE
<b>Creating program</b>	phone.sas
<b>Description</b>	Phone Contact
<b>Unique identifier</b>	DPATNO,MEDTAKE,CNTCTDY
<b>Sorted by</b>	DPATNO,MEDTAKE,CNTCTDY
<b>Notes</b>	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: SUBINI,INVNAME,RPTPAGE,CNTCTDT,CNTCT_M,CNTCT_D,CNTCT_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
ANYAE	num	Experienced Adverse Events?		Collected at CRF.
MEDTAKE	num	Medication Taken Each Day		Collected at CRF.
DOSEINC	num	Will Dosage Increase?		Collected at CRF.
RECCOMP	num	Completed Record?		Collected at CRF.
NOTCOMP	num	Days Record Not Completed?		Collected at CRF.
CNTCTDY	num	Relative Day of Contact		If CNTCTDT and REF.DATE not missing then perform below logic to calculate CNTCTDY, If CNTCTDT less than REF.DATE then (CNTCTDT - REF.DATE). Else if CNTCTDT is greater than equal to REF.DATE then (CNTCTDT- REF.DATE) +1.

## 1.4.28. Physical Examination – PHYS

<b>Dataset</b>	PHYS
<b>Creating program</b>	phys.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	DPATNO,SYSTEM,VISITNO
<b>Sorted by</b>	DPATNO,SYSTEM,VISITNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE,VERBATIM

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
SYSTEM	num	Body System		Collected at CRF.

Variable	Type	Label	Codes	Comments
RSLTAB	num	Result		Collected at CRF.
RSLTNC	num	Result		Collected at CRF.

#### 1.4.29. Pregnancy Test – PREGTEST

<b>Dataset</b>	PREGTEST
<b>Creating program</b>	pregtest.sas
<b>Description</b>	Pregnancy Test
<b>Unique identifier</b>	DPATNO,VISITNO,RESULT,SAMPLDY,PAGEID,PAGE
<b>Sorted by</b>	DPATNO,VISITNO,RESULT,SAMPLDY,PAGEID,PAGE
<b>Notes</b>	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,INVNAME,SAMPLDT,SAMPL_M,SAMPL_D,SAMPL_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
NA	num	N/A		Collected at CRF.
RESULT	num	Pregnant Test Result		Collected at CRF.
SAMPLDY	num	Relative Sample Day		If SAMPLDT and REF.DATE not missing then perform below logic to calculate SAMPLDY, If SAMPLDT less than REF.DATE then (SAMPLDT - REF.DATE). Else if SAMPLDT is greater than equal to REF.DATE then (SAMPLDT- REF.DATE) +1.

## 1.4.30. Screen failure subjects – SCRNFALL

<b>Dataset</b>	SCRNFALL
<b>Creating program</b>	scrnfail.sas
<b>Description</b>	Screen failure subjects
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity



## 1.4.31. Subj Global Impression of Change – SGIC

<b>Dataset</b>	SGIC
<b>Creating program</b>	sgic.sas
<b>Description</b>	Subj Global Impression of Change
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RTPPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
SGIC	num	Subj Global Impression of Change		Collected at CRF.

## 1.4.32. Investigator's signature – SIGNATUR

<b>Dataset</b>	SIGNATUR
<b>Creating program</b>	signatur.sas
<b>Description</b>	Investigator's signature
<b>Unique identifier</b>	DPATNO
<b>Sorted by</b>	DPATNO
<b>Notes</b>	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: SUBINI,INVNAME,RPTPAGE,SIGDT,SIG_M,SIG_D,SIG_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.

Variable	Type	Label	Codes	Comments
SIG	num	Investigator Signature		Collected at CRF.
SIGDY	num	Relative Signature Day		If SIGDT and REF.DATE not missing then perform below logic to calculate SIGDY, If SIGDT less than REF.DATE then (SIGDT - REF.DATE). Else if SIGDT is greater than equal to REF.DATE then (SIGDT - REF.DATE) +1.

### 1.4.33. Headache Record - Time – TIMEPT

<b>Dataset</b>	TIMEPT
<b>Creating program</b>	timept.sas
<b>Description</b>	Headache Record - Time
<b>Unique identifier</b>	DPATNO,VISITNO,EVALDY
<b>Sorted by</b>	DPATNO,VISITNO,EVALDY
<b>Notes</b>	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,INVNAME,EVALDT,EVAL_M,EVAL_D,EVAL_Y,WAKETM,WAKE_H, WAKE_MN,WAKEAMP, SLEEPTM,SLEEP_H,SLEEP_MN,SLPAMP

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity

Variable	Type	Label	Codes	Comments
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
WAKETMC	char	Wake Up Time-Char		Collected at CRF.
SLEEPTMC	char	Bed Time-Char		Collected at CRF.
EVALDY	num	Relative Evaluation Day		If EVALDT and REF.DATE not missing then perform below logic to calculate EVALDY, If EVALDT less than REF.DATE then (EVALDT - REF.DATE). Else if EVALDT is greater than equal to REF.DATE then (EVALDT- REF.DATE) +1.

## 1.4.34. Visit date – VISITDT

<b>Dataset</b>	VISITDT
<b>Creating program</b>	visitdt.sas
<b>Description</b>	Visit date
<b>Unique identifier</b>	DPATNO,VISITNO,VISITDY,PAGEID,PAGE
<b>Sorted by</b>	DPATNO,VISITNO,VISITDY,PAGEID,PAGE
<b>Notes</b>	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,INVNAME,VISITDT,VISIT_M,VISIT_D,VISIT_Y

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
RPTPAGE	num	Repeat Page Key		Collected at CRF.

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

#### 1.4.35. Vital Signs – VITAL

<b>Dataset</b>	VITAL
<b>Creating program</b>	vital.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DPATNO,VISITNO
<b>Sorted by</b>	DPATNO,VISITNO
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SUBINI,INVNAME,RPTPAGE

Variable	Type	Label	Codes	Comments
PNO	char	Client Protocol Number		Collected at CRF.
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity
DPID	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity

Variable	Type	Label	Codes	Comments
DPATNO	char	Unique Subject No Assign for De-identity		Randomly assigned Unique Subject No for De-identity
VISITNO	num	Visit Number		Collected at CRF.
PAGEID	num	Page Number		Collected at CRF.
PAGE	char	CRF Page Number		Collected at CRF.
VISIDESC	char	Visit Description		Collected at CRF.
NA	num	N/A		Collected at CRF.
BPSYS	num	Systolic BP(mmHg)		Collected at CRF.
BPDIAS	num	Diastolic BP(mmHg)		Collected at CRF.
PULSE	num	Pulse Rate(beats/min)		Collected at CRF.
WEIGHT	num	Weight		Collected at CRF.
WGTUNIT	char	Weight Unit		Collected at CRF.
HEIGHT	num	Height		Collected at CRF.
HGTUNIT	char	Height Unit		Collected at CRF.