

Clinical Development

Topiramate[®]

CAPSS-381

Anonymisation Data Derivation Specification Document

| | |
|------------------|--------------------|
| Document Type | Reference document |
| Document Version | Final |
| Date | 22 NOV 2017 |

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| Status and Version | Release Date | Summary of Key Changes |
|---------------------------|---------------------|-------------------------------|
| | | |
| | | |

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- 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 PD(Protocol Deviation) dataset will be removed.
- VISITDT.VISITDT (Visit Date when OVISITNO=1) will be used as Reference Date (referred as REF.DATE in the document) to derive relative days

1.3. Data Files

The CAPSS-381 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHIC DATA – DEMO

| | |
|--------------------------|--|
| Dataset | DEMO |
| Creating program | demo.sas |
| Description | DEMOGRAPHIC DATA |
| Unique identifier | DSASPAT_ |
| Sorted by | DSASPAT_ |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,RACESPEC,BIRTHDT,BIRTH_M,BIRTH_D,BIRTH_Y</p> <p>Below listed variables were not part of the Raw dataset. These have been added to retain the Demographic related information in the de-identified datasets: CNTRY (Source: PROFILE2 dataset) TRTMENTF (Source: PROFILE2 dataset)</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|---|
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| GENDER | num | GENDER | | Collected at CRF. |
| GENDER_C | char | GENDER (CHAR) | | Collected at CRF. |
| RACE | num | RACE | | Collected at CRF. |
| RACE_C | char | RACE (CHAR) | | Collected at CRF. |
| AGE | char | AGE | | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules. |
| DCOUNTRY | char | DE-IDENTIFY COUNTRY | | Group element to protect PII. |
| TRTMENF | char | DECODE, TRTMENT | | Collected at CRF. |

1.4.2. HISTORY OF ACUTE/PROPHYLACTIC HEADACHE M – ACUTEHIS

| | |
|--------------------------|--|
| Dataset | ACUTEHIS |
| Creating program | acutehis.sas |
| Description | HISTORY OF ACUTE/PROPHYLACTIC HEADACHE M |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,STARTDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,STARTDY |
| 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: PAT_NUM,VERBATIM,STARTDT,START_M,START_D,START_Y,STOPDT, STOP_M,STOP_D,STOP_Y,DRUGNAME |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|-------------------|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| NONE | num | NONE | | Collected at CRF. |
| ROUTE | char | ROUTE OF ADMIN | | Collected at CRF. |
| TOTDOSE | char | TOTAL DAILY DOSE | | Collected at CRF. |
| MONTH | num | GREATER 6 MONTHS AGO | | Collected at CRF. |
| ONGOING | num | ONGOING | | Collected at CRF. |
| REASN | num | REASON FOR MIGRAINE THERAPY | | Collected at CRF. |
| RECNO | char | RECORD NUMBER+SEQUENCE NO 1+ SEQUENCE NO | | Collected at CRF. |
| PTRECNO | char | PREFERRED TERM RECORD NUMBER | | Collected at CRF. |
| PT | char | PREFERRED TERM | | Collected at CRF. |
| ATCC | char | ATC CODE | | Collected at CRF. |
| ATC | char | ATC TEXT | | Collected at CRF. |
| ATCT1 | char | ATC LEVEL 1 TEXT | | Collected at CRF. |
| ATCT2 | char | ATC LEVEL 2 TEXT | | Collected at CRF. |
| ATCT3 | char | ATC LEVEL 3 TEXT | | Collected at CRF. |
| PREF_ATC | char | PREFERRED ATC CODE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------------------|-------|--|
| 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 DAY STOPPED | | 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 EVENTS – ADVE

| | |
|--------------------------|--|
| Dataset | ADVE |
| Creating program | adve.sas |
| Description | ADVERSE EVENTS |
| Unique identifier | DSASPAT_,VISIDESC,VISITREP,SEQNO |
| Sorted by | DSASPAT_,VISIDESC,VISITREP,SEQNO |
| 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: PAT_NUM,VERBATIM,ONSETDT,ONSET_M,ONSET_D,ONSET_Y,STOPDT, STOP_M,STOP_D,STOP_Y, ENGLISH |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------------|-------|-------------------|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| ADVEXP | num | NONE | | Collected at CRF. |
| ONGOING | num | ONGOING | | 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 | RELATIONSHIP TO STUDY DRUG | | Collected at CRF. |
| ACTN | num | ACTION TAKEN | | Collected at CRF. |
| CONCOM | num | CONCOMITANT MEDICATION GIVEN | | Collected at CRF. |
| PREFTERM | char | PREFERRED TERM | | Collected at CRF. |
| DSCR | char | DESCRIPTION | | Collected at CRF. |
| RECNO | char | RECORD NUMBER | | Collected at CRF. |
| SEQNO | char | SEQUENCE NUMBER | | Collected at CRF. |
| BODY_SY1 | char | BODY SYSTEM 1 | | Collected at CRF. |
| BODY_SY2 | char | BODY SYSTEM 2 | | Collected at CRF. |
| BODY_SYS | char | BODY SYSTEM | | Collected at CRF. |
| FULLWHO | char | WHO NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|--|
| ONSETDY | num | RELATIVE AE START 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 AE 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. BACKGROUND QUESTIONNAIRE – BGQUES

| | |
|--------------------------|--|
| Dataset | BGQUES |
| Creating program | bgques.sas |
| Description | BACKGROUND QUESTIONNAIRE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,QUES1 |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,QUES1 |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,Q2SPC,Q7SPC8,Q7SPC9,Q9HSPC,Q12ESPC,Q5CSPC |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|-------------------|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| QUES1 | num | QUESTION 1 | | Collected at CRF. |
| QUES2 | num | QUESTION 2 | | Collected at CRF. |
| QUES3 | num | QUESTION 3 | | Collected at CRF. |
| QUES4 | num | QUESTION 4 MAIN | | Collected at CRF. |
| QUES4A | num | QUESTION 4A MOTHER | | Collected at CRF. |
| QUES4B | num | QUESTION 4B FATHER | | Collected at CRF. |
| QUES4C | num | QUESTION 4C SISTER | | Collected at CRF. |
| QUES4D | num | QUESTION 4D BROTHER | | Collected at CRF. |
| QUES4E | num | QUESTION 4E GRANDMOTHER | | Collected at CRF. |
| QUES4F | num | QUESTION 4F GRANDFATHER | | Collected at CRF. |
| QUES4G | num | QUESTION 4G AUNT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|-------------------|
| QUES4H | num | QUESTION 4H UNCLE | | Collected at CRF. |
| QUES4I | num | QUESTION 4I COUSIN | | Collected at CRF. |
| QUES4J | num | QUESTION 4J DAUGHTER | | Collected at CRF. |
| QUES4K | num | QUESTION 4K SON | | Collected at CRF. |
| QUES4L | num | QUESTION 4L GRANDDAUGHTER | | Collected at CRF. |
| QUES4M | num | QUESTION 4M GRANDSON | | Collected at CRF. |
| QUES4N | num | QUESTION 4N NIECE | | Collected at CRF. |
| QUES4O | num | QUESTION 4O NEPHEW | | Collected at CRF. |
| QUES5 | num | QUESTION 5 MAIN | | Collected at CRF. |
| QUES5A | num | QUESTION 5 HYPOTHYROIDISM | | Collected at CRF. |
| QUES5B | num | QUESTION 5 HYPERTHYROIDISM | | Collected at CRF. |
| QUES5C | num | QUESTION 5 OTHER THYROID CONDITION | | Collected at CRF. |
| QUES5D | num | QUESTION 5 DONT KNOW | | Collected at CRF. |
| QUES6 | num | QUESTION 6 | | Collected at CRF. |
| QUES7 | num | QUESTION 7 | | Collected at CRF. |
| QUES8 | num | QUESTION 8 | | Collected at CRF. |
| QUES9 | num | QUESTION 9 - MAIN | | Collected at CRF. |
| QUES9A | num | QUESTION 9A - VIOLENT PERSONAL ASSAULT | | Collected at CRF. |
| QUES9B | num | QUESTION 9B - SERIOUS ACCIDENT | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|-----------|------|--|-------|-------------------|
| QUES9C | num | QUESTION 9C - DEATH OF A FAMILY MEMBER/F | | Collected at CRF. |
| QUES9D | num | QUESTION 9D - DIAGNOSIS OF LIFE THREATEN | | Collected at CRF. |
| QUES9E | num | QUESTION 9E - DIVORCE OR SEPARATION | | Collected at CRF. |
| QUES9F | num | QUESTION 9F - EMOTIONAL ABUSE | | Collected at CRF. |
| QUES9G | num | QUESTION 9G - MILITARY COMBAT-RELATED ST | | Collected at CRF. |
| QUES9H | num | QUESTION 9H - OTHER SPECIFY | | Collected at CRF. |
| QUES10 | num | QUESTION 10 | | Collected at CRF. |
| QUES11 | num | QUESTION 11 | | Collected at CRF. |
| QUES12 | num | QUESTION 12 - MAIN | | Collected at CRF. |
| QUES12A | num | QUESTION 12A - CAFFEINATED COFFEE | | Collected at CRF. |
| COFFEEPDP | num | QUESTION 12A- COFFEE NUMBER OF SERVINGS | | Collected at CRF. |
| QUES12B | num | QUESTION 12B - CAFFEINATED TEA | | Collected at CRF. |
| TEAPDP | num | QUESTION 12B - TEA NUMBER OF SERVINGS | | Collected at CRF. |
| QUES12C | num | QUESTION 12C - CAFFEINATED SODA | | Collected at CRF. |
| SODAPDP | num | QUESTION 12C - SODA NUMBER OF SERVINGS | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|-------------------|
| QUES12D | num | QUESTION 12D - CAFFEINATED ENERGY DRINK | | Collected at CRF. |
| ENERGYPD | num | QUESTION 12D - ENERGY DRINK NUMBER OF SE | | Collected at CRF. |
| QUES12E | num | QUESTION 12E - OTHER SPECIFY | | Collected at CRF. |
| OTHERPD | num | QUESTION 12E - OTHER NUMBER OF SERVINGS | | Collected at CRF. |
| QUES13 | num | QUESTION 13 | | Collected at CRF. |
| QUES14 | num | QUESTION 14 | | Collected at CRF. |
| QUES15 | num | QUESTION 15 | | Collected at CRF. |
| QUES16A | num | QUESTION 16 - PERTAINING TO MIGRAINE | | Collected at CRF. |
| Q16ADK | num | QUESTION 16 - PERTAINING TO MIGRAINE DO | | Collected at CRF. |
| QUES16B | num | QUESTION 16 - ALL OTHER MEDICAL/HEALTH-R | | Collected at CRF. |
| Q16BDK | num | QUESTION 16 - ALL OTHER MED/HEALTH COND | | Collected at CRF. |

1.4.5.COMPLETION/DISCONTINUATION SUMMARY – COMP

| | |
|--------------------------|---|
| Dataset | COMP |
| Creating program | comp.sas |
| Description | COMPLETION/DISCONTINUATION SUMMARY |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,TAPERDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,TAPERDY |
| 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: PAT_NUM,RANDSPEC,FIRST_M,FIRST_D,FIRST_Y,FIRSTDT,TAPER_M, TAPER_D,TAPER_Y,TAPERDT,LAST_M,LAST_D,LAST_Y,LASTDT,REASPEC |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------------------|-------|--|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| RAND | num | RANDOMIZED | | Collected at CRF. |
| TAPER | num | TAPER MEDICATION | | Collected at CRF. |
| COMP_ST | num | STUDY COMPLETED | | Collected at CRF. |
| PRIMREAS | num | PRIMARY REASON NOT COMPLETED | | Collected at CRF. |
| REASPEC1 | char | STUDY COMPLETED - DETAILS | | Collected at CRF. |
| FIRSTDY | num | RELATIVE FIRST DOSE STUDY MED 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. |
| TAPERDY | num | RELATIVE TAPER DOSE STUDY MED DAY | | If TAPERDT and REF.DATE not missing then perform below logic to calculate TAPERDY, If TAPERDT less than REF.DATE then (TAPERDT - REF.DATE). Else if TAPERDT is greater than equal to REF.DATE then (TAPERDT- REF.DATE) +1. |
| LASTDY | num | RELATIVE LAST DOSE STUDY MED 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. |

1.4.6. RECENT/CONCOMITANT MEDICATION – CURM

| | |
|--------------------------|---|
| Dataset | CURM |
| Creating program | curm.sas |
| Description | RECENT/CONCOMITANT MEDICATION |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,STARTDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,STARTDY |
| 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: PAT_NUM,VERBATIM,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. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|-------------------|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| CURMEX | num | NONE | | Collected at CRF. |
| ROUTE | char | ROUTE OF ADMIN | | Collected at CRF. |
| TOTDOSE | char | TOTAL DAILY DOSE | | Collected at CRF. |
| MONTH | num | >6 MONTHS | | Collected at CRF. |
| ONGOING | num | ONGOING | | Collected at CRF. |
| CURMREAS | char | REASON FOR THERAPY | | Collected at CRF. |
| RECNO | char | RECORD NUMBER+SEQUENCE NO 1+ SEQUENCE NO | | Collected at CRF. |
| DRUGNAME | char | DRUG NAME | | Collected at CRF. |
| PTRECNO | char | PREFERRED TERM RECORD NUMBER | | Collected at CRF. |
| PT | char | PREFERRED TERM | | Collected at CRF. |
| ATCC | char | ATC CODE | | Collected at CRF. |
| ATC | char | ATC TEXT | | Collected at CRF. |
| ATCT1 | char | ATC LEVEL 1 TEXT | | Collected at CRF. |
| ATCT2 | char | ATC LEVEL 2 TEXT | | Collected at CRF. |
| ATCT3 | char | ATC LEVEL 3 TEXT | | Collected at CRF. |
| PREF_ATC | char | PREFERRED ATC CODE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------------------|-------|--|
| STARTDY | num | RELATIVE DAY STARTED | | 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 DAY STOPPED | | 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. |

1.4.7. DNA INFORMATION – DNA

| | |
|--------------------------|--|
| Dataset | DNA |
| Creating program | dna.sas |
| Description | DNA INFORMATION |
| Unique identifier | DSASPAT_,CONSENT,SERA1,SERA2 |
| Sorted by | DSASPAT_,CONSENT,SERA1,SERA2 |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: COMMENT |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|-------------------|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| CONSENT | char | SIGNED CONSENT FORM FOR DNA TEST(Y/N) | | Collected at CRF. |
| SERA1 | char | 1ST SERA SAMPLE OBTAINED (Y/N) | | Collected at CRF. |
| SERA2 | char | 2ND SERA SAMPLE OBTAINED (Y/N) | | Collected at CRF. |

1.4.8. STUDY MEDICATION MAINTENANCE DOSE – DOSE

| | |
|--------------------------|--|
| Dataset | DOSE |
| Creating program | dose.sas |
| Description | STUDY MEDICATION MAINTENANCE DOSE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,DOSE |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,DOSE |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|-------------------|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| DOSE | num | MAINTENANCE DOSE | | Collected at CRF. |

1.4.9.OPTIONAL ECG – EKG

| | |
|--------------------------|---|
| Dataset | EKG |
| Creating program | ekg.sas |
| Description | OPTIONAL ECG |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,EKG |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,EKG |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,COMMENT1 |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------|-------|-------------------|
| EKGND | num | NOT DONE | | Collected at CRF. |
| EKG | num | EKG | | Collected at CRF. |

1.4.10. HEADACHE HISTORY – HDHIST

| | |
|--------------------------|--|
| Dataset | HDHIST |
| Creating program | hdhist.sas |
| Description | HEADACHE HISTORY |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,ONSETAGE |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,ONSETAGE |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|---|
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| ONSETAGE | char | AGE 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. |
| HD | num | NUMBER OF MIGRAINES OVER LAST 28 DAYS | | Collected at CRF. |
| AURA | num | MIGRAINE WITH AURA | | Collected at CRF. |
| NOAURN | num | MIGRAINE WITHOUT AURA | | Collected at CRF. |
| SEV | num | USUAL MIGRAINE INTENSITY | | Collected at CRF. |
| DUR_H | num | USUAL MIGRAINE DURATION - HOURS | | Collected at CRF. |
| DUR_M | num | USUAL MIGRAINE DURATION - MINUTES | | Collected at CRF. |
| VOMIT | num | USUAL SEVERITY OF SYMPTOM - VOMITING | | Collected at CRF. |
| NAUSEA | num | USUAL SEVERITY OF SYMPTOM - NAUSEA | | Collected at CRF. |
| PHOTOP | num | USUAL SEVERITY OF SYMPTOM - PHOTOPHOBIA | | Collected at CRF. |
| PHONOP | num | USUAL SEVERITY OF SYMPTOM - PHONOPHOBIA | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|-------------------|
| HDEXP | num | ANY NON-MIGRAINE HEADACHES | | Collected at CRF. |
| HDDAY | num | NUMBER OF HEADACHE DAYS OVER LAST 28 DAY | | Collected at CRF. |

1.4.11. HEADACHE RECORD (MEDICATIONS) – HDMED

| | |
|--------------------------|---|
| Dataset | HDMED |
| Creating program | hdmed.sas |
| Description | HEADACHE RECORD (MEDICATIONS) |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,MEDTKNDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,MEDTKNDY |
| 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: PAT_NUM,MEDTKNDT,MEDTKN_M,MEDTKN_D,MEDTKN_Y,MED_H, MED_MN |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| VERBATIM | char | MEDICATION NAME | | Collected at CRF. |
| MEDTYPE | num | ROUTE OF ADMIN | | Collected at CRF. |
| NUMDOSE | num | NUMBER OF DOSES TAKEN | | Collected at CRF. |
| MEDAMPM | num | TIME MEDICATION TAKEN - AM/PM | | Collected at CRF. |
| MEDTM | char | TIME MEDICATION TAKEN (DERIVED) | | Collected at CRF. |
| MEDTMC | char | TIME MEDICATION TAKEN (DERIVED 24 Hr Clo | | Collected at CRF. |
| DSUNIT | char | DSUNIT | | Collected at CRF. |
| MEDTKNDY | num | RELATIVE DAY MEDICATION TAKEN | | If MEDTKNDT and REF.DATE not missing then perform below logic to calculate MEDTKNDY, If MEDTKNDT less than REF.DATE then (MEDTKNDT - REF.DATE). Else if MEDTKNDT is greater than equal to REF.DATE then (MEDTKNDT- REF.DATE) +1. |

1.4.12. HEADACHE RECORD – HDREC

| | |
|--------------------------|---|
| Dataset | HDREC |
| Creating program | hdrec.sas |
| Description | HEADACHE RECORD |
| Unique identifier | DSASPAT_,HDTYPE,MODNAME,VISIDESC,VISITREP,OVISITNO,ASTRTDY |
| Sorted by | DSASPAT_,HDTYPE,MODNAME,VISIDESC,VISITREP,OVISITNO,ASTRTDY |
| 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: PAT_NUM,ASTRT_M,ASTRT_D,ASTRT_Y,ASTRTDT,START_M,START_D, START_Y,STARTDT,STRTTM_H,STRTTM_M,STOP_M,STOP_D,STOP_Y, STPTM_H,STPTM_MN,STOPDT |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|-------------------|
| VISIDESC | char | CRF VISIT DISCRPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| HDTYPE | num | TYPE OF HEADACHE | | Collected at CRF. |
| ANYMEDA | num | ANY MEDS TAKEN FOR AURA | | Collected at CRF. |
| PAINSTR | num | HEADACHE PAIN WITH AURA | | Collected at CRF. |
| STRAMPM | num | HEADACHE PAIN START TIME - AM/PM | | Collected at CRF. |
| STRTTM | char | HEADACHE PAIN START TIME (DERIVED) | | Collected at CRF. |
| STRTTMC | char | HEADACHE PAIN START TIME (DERIVED 24 Hr | | Collected at CRF. |
| STPAMPM | num | HEADACHE PAIN STOP TIME - AM/PM | | Collected at CRF. |
| STPTM | char | HEADACHE PAIN STOP TIME (DERIVED) | | Collected at CRF. |
| STPTMC | char | HEADACHE PAIN STOP TIME (DERIVED 24 Hr C | | Collected at CRF. |
| ANYMEDHP | num | ANY MEDS TAKEN FOR PAIN | | Collected at CRF. |
| SEV | num | INTENSITY OF HEADACHE PAIN | | Collected at CRF. |
| ONESIDE | num | PAIN ONE-SIDED | | Collected at CRF. |
| THROB | num | PAIN THROBBING | | Collected at CRF. |
| PHYSIC | num | PAIN INCREASE WITH PHYSICAL ACTIVITY | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------------------------------|-------|--|
| VOMIT | num | VOMIT | | Collected at CRF. |
| NAUSEA | num | RATE NAUSEA | | Collected at CRF. |
| PHOTOP | num | RATE SENSITIVITY (LIGHT) | | Collected at CRF. |
| PHONOP | num | RATE SENSITIVITY (SOUND) | | Collected at CRF. |
| ASTRTDY | num | RELATIVE AURA DAY | | If ASTRTDT and REF.DATE not missing then perform below logic to calculate ASTRTDY, If ASTRTDT less than REF.DATE then (ASTRTDT - REF.DATE). Else if ASTRTDT is greater than equal to REF.DATE then (ASTRTDT- REF.DATE) +1. |
| STARTDY | num | RELATIVE HEADACHE PAIN 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. |

1.4.13. ENTRANCE CRITERIA – INEXCRIT

| | |
|--------------------------|--|
| Dataset | INEXCRIT |
| Creating program | inexcrit.sas |
| Description | ENTRANCE CRITERIA |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| 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: PAT_NUM,EXEMPTDT,EXEMPT_M,EXEMPT_D,EXEMPT_Y,COMMENT1,COMMENT2 |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------------------------|-------|-------------------|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| ELIGIBLE | num | ELIGIBLE | | Collected at CRF. |
| EXEMPT | num | EXEMPT | | Collected at CRF. |
| INCNO1 | num | INCLUSION #1 (EXCEPTION GRANTED) | | Collected at CRF. |
| INCNO2 | num | INCLUSION #2 (EXCEPTION GRANTED) | | Collected at CRF. |
| INCNO3 | num | INCLUSION #3 (EXCEPTION GRANTED) | | Collected at CRF. |
| EXCNO1 | num | EXCLUSION #1 (EXCEPTION GRANTED) | | Collected at CRF. |
| EXCNO2 | num | EXCLUSION #2 (EXCEPTION GRANTED) | | Collected at CRF. |
| EXCNO3 | num | EXCLUSION #3 (EXCEPTION GRANTED) | | Collected at CRF. |
| INCNOA1 | num | INCLUSION #1 (EXCEPTION NOT GRANTED) | | Collected at CRF. |
| INCNOA2 | num | INCLUSION #2 (EXCEPTION NOT GRANTED) | | Collected at CRF. |
| INCNOA3 | num | INCLUSION #3 (EXCEPTION NOT GRANTED) | | Collected at CRF. |
| EXCNOA1 | num | EXCLUSION #1 (EXCEPTION NOT GRANTED) | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------------------------|-------|---|
| EXCNOA2 | num | EXCLUSION #2 (EXCEPTION NOT GRANTED) | | Collected at CRF. |
| EXCNOA3 | num | EXCLUSION #3 (EXCEPTION NOT GRANTED) | | Collected at CRF. |
| EXEMPTDY | num | RELATIVE EXCEPTION 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. |

1.4.14. CLINICAL LABORATORY TESTS – LAB

| | |
|--------------------------|---|
| Dataset | LAB |
| Creating program | lab.sas |
| Description | CLINICAL LABORATORY TESTS |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,ACCNUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|-------------------|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

1.4.15. CLINICAL SIGNIFICANCE – LABCLIN

| | |
|--------------------------|--|
| Dataset | LABCLIN |
| Creating program | labclin.sas |
| Description | CLINICAL SIGNIFICANCE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,PERFDDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,PERFDDY |
| 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: PAT_NUM,ACCESNUM,LABID,CSCOMM,PERFDD,PERFDD_D,PERFDD_M,PERFDD_Y |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| PN_TESTC | char | STANDARD TEST CODE | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------------------------|-------|---|
| CLINSIG | num | CLINICAL SIGNIFICANCE | | Collected at CRF. |
| SIGYN | num | SIGYN | | Collected at CRF. |
| SIGDTYN | num | SIGDTYN | | Collected at CRF. |
| PERFDDY | num | RELATIVE COLLECTION DAY | | If PERFDD and REF.DATE not missing then perform below logic to calculate PERFDDY, If PERFDD less than REF.DATE then (PERFDD - REF.DATE). Else if PERFDD is greater than equal to REF.DATE then (PERFDD- REF.DATE) +1. |

1.4.16. LAB HEADER – LABHEAD

| | |
|--------------------------|--|
| Dataset | LABHEAD |
| Creating program | labhead.sas |
| Description | LAB HEADER |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| 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: PAT_NUM,ACCESNUM,LABID,CSCOMM,PERFDD,PERFDD_D,PERFDD_M,PERFDD_Y |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|-------------------|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

1.4.17. LAB RESULTS – LABRES

| | |
|--------------------------|--|
| Dataset | LABRES |
| Creating program | labres.sas |
| Description | LAB RESULTS |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,LSDRVY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,LSDRVY |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAT_NUM,ACCTNUM,CL_ACCNO,CL_INVSI,CL_SUBNO,CL_INITI,CL_BIRTH,CL_RACE,CL_COLDT,CL_COMME,LABNAME,PNLABID,BIRTHDT,COLLECTD, COLLECT1,COLLECT2,COLLECT3,CL_DELTA,CLINSIG,CL_RCPTD,CL_FILED, CL_ALIEN,CSCOMM,LSDRVDT,CL_SCRNO |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------------------|-------|-------------------|
| PROTID | num | WEBSYS UNIQUE PROTOCOL IDENTIFIER | | Collected at CRF. |
| CL_PROT | char | LAB PROTOCOL NAME | | Collected at CRF. |
| CL_SEXCD | char | CENTRAL LAB SEX CODE | | Collected at CRF. |
| CL_COLTM | char | COLLECTION TIME | | Collected at CRF. |
| CL_VISCD | char | CENTRAL LAB VISIT NAME | | Collected at CRF. |
| CL_VISTY | num | CENTRAL LAB VISIT TYPE | | Collected at CRF. |
| CL_TERMV | num | TERMINATION VISIT | | Collected at CRF. |
| CL_TESTC | char | CENTRAL LAB TEST CODE | | Collected at CRF. |
| CL_UNITC | char | CENTRAL LAB UNIT CODE | | Collected at CRF. |
| CL_TESTD | char | LAB TEST CODE DESCRIPTION | | Collected at CRF. |
| RESULTTX | char | LAB RESULT IN TEXT FORMAT | | Collected at CRF. |
| NORMFLAG | char | NORMAL RANGE FLAG | | Collected at CRF. |
| PN_TESTC | char | STANDARD TEST CODE | | Collected at CRF. |
| PN_UNITC | char | STANDARD UNIT CODE | | Collected at CRF. |
| CL_NORMH | num | LAB NORMAL RANGE HIGH | | Collected at CRF. |
| CL_NORML | num | LAB NORMAL RANGE LOW | | Collected at CRF. |
| CL_CSLIN | num | CLINICAL SIGNIFICANCE TRIGGER | | Collected at CRF. |
| NORMHI | num | NORMAL RANGE HIGH | | Collected at CRF. |
| NORMLO | num | NORMAL RANGE LOW | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|-----------|------|---|-------|--|
| LAB_AGE | char | PATIENT AGE AT THE TIME OF COLLECTION | | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules. |
| RESULTN | num | NUMERIC LAB RESULT | | Collected at CRF. |
| LAB_SEX | char | PATIENT GENDER | | Collected at CRF. |
| PNVISIT | char | NAME OF VISIT WHERE SAMPLE WAS TAKEN | | Collected at CRF. |
| CL_GRPDCD | char | GROUP CODE | | Collected at CRF. |
| CL_ALERT | char | ALERT FLAG | | Collected at CRF. |
| CL_TOXGR | char | TOXICITY GRADE | | Collected at CRF. |
| LABCODE | char | OMP LAB CODE | | Collected at CRF. |
| UNITCODE | num | OMP UNIT CODE | | Collected at CRF. |
| LSDRVVER | num | VERSION OF RECORD WHEN DERIVATIONS WERE | | Collected at CRF. |
| CL_COLDY | num | RELATIVE COLLECTION DAY IN TEXT FORMAT | | If CL_COLDT and REF.DATE not missing then perform below logic to calculate CL_COLDY, If CL_COLDT less than REF.DATE then (CL_COLDT - REF.DATE). Else if CL_COLDT is greater than equal to REF.DATE then (CL_COLDT- REF.DATE) +1. |
| COLECTDY | num | RELATIVE SAMPLE COLLECTION DAY | | If COLLECTD and REF.DATE not missing then perform below logic to calculate COLLETDY, If COLLECTD less than REF.DATE then (COLLECTD - REF.DATE). Else if COLLECTD is greater than equal to REF.DATE then (COLLECTD- REF.DATE) +1. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| CLRCPTDY | num | RELATIVE LAB RECEIPT DAY | | If CL_RCPTD and REF.DATE not missing then perform below logic to calculate CLRCPTDY, If CL_RCPTD less than REF.DATE then (CL_RCPTD - REF.DATE). Else if CL_RCPTD is greater than equal to REF.DATE then (CL_RCPTD- REF.DATE) +1. |
| CLFILEDY | num | RELATIVE FILE CREATION DAY | | 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. |
| LSDRVDY | num | RELATIVE DAY DERIVATIONS WERE LAST RUN | | If LSDRVDT and REF.DATE not missing then perform below logic to calculate LSDRVDY, If LSDRVDT less than REF.DATE then (LSDRVDT - REF.DATE). Else if LSDRVDT is greater than equal to REF.DATE then (LSDRVDT- REF.DATE) +1. |

1.4.18. MEDICATION CODE NUMBER – MEDCODE

| | |
|--------------------------|--|
| Dataset | MEDCODE |
| Creating program | medcode.sas |
| Description | MEDICATION CODE NUMBER |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,MEDCODE |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

1.4.19. STUDY MEDICATION COMPLIANCE – MEDCOMP

| | |
|--------------------------|--|
| Dataset | MEDCOMP |
| Creating program | medcomp.sas |
| Description | STUDY MEDICATION COMPLIANCE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,DISPDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,DISPDY |
| 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: PAT_NUM,DISP_M,DISP_D,DISP_Y,DISPDT,RET1_M,RET1_D,RET1_Y,RET1DT, REDISP_M,REDISP_D,REDISP_Y,REDISPDT,RET2_M,RET2_D,RET2_Y,RET2DT |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------------|-------|--|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| BOTTLE | num | BOTTLE # | | Collected at CRF. |
| TABDISP | num | # TABLETS DISPENSED | | Collected at CRF. |
| TABRET1 | num | # TABLETS RETURNED | | Collected at CRF. |
| TABRET2 | num | # TABLETS REReturned | | 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. |
| RET1DY | num | RELATIVE DAY RETURNED | | If RET1DT and REF.DATE not missing then perform below logic to calculate RET1DY, If RET1DT less than REF.DATE then (RET1DT - REF.DATE). Else if RET1DT is greater than equal to REF.DATE then (RET1DT- REF.DATE) +1. |
| REDISPDY | num | RELATIVE DAY REDISPENSED | | If REDISPDT and REF.DATE not missing then perform below logic to calculate REDISPDY, If REDISPDT less than REF.DATE then (REDISPDY - REF.DATE). Else if REDISPDT is greater than equal to REF.DATE then (REDISPDY- REF.DATE) +1. |
| RET2DY | num | RELATIVE DAY REReturned | | If RET2DT and REF.DATE not missing then perform below logic to calculate RET2DY, If RET2DT less than REF.DATE then (RET2DT - REF.DATE). Else if RET2DT is greater than equal to REF.DATE then (RET2DT- REF.DATE) +1. |

1.4.20. SIGNIFICANT MEDICAL HISTORY – MHIST

| | |
|--------------------------|---|
| Dataset | MHIST |
| Creating program | mhist.sas |
| Description | SIGNIFICANT MEDICAL HISTORY |
| Unique identifier | DSASPAT_,SYSTEM,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,SYSTEM,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,VERBATIM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------|-------|-------------------|
| SYSTEM | num | SYSTEM | | Collected at CRF. |
| HX | num | HISTORY | | Collected at CRF. |

1.4.21. MIDAS QUESTIONNAIRE – MIDAS

| | |
|--------------------------|--|
| Dataset | MIDAS |
| Creating program | midas.sas |
| Description | MIDAS QUESTIONNAIRE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|-------------------|
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| QUEST1 | num | QUESTION 1 | | Collected at CRF. |
| QUEST2 | num | QUESTION 2 | | Collected at CRF. |
| QUEST3 | num | QUESTION 3 | | Collected at CRF. |
| QUEST4 | num | QUESTION 4 | | Collected at CRF. |
| QUEST5 | num | QUESTION 5 | | Collected at CRF. |
| QUESTA | num | QUESTION A | | Collected at CRF. |
| QUESTB | num | QUESTION B | | Collected at CRF. |

1.4.22. MIGRAINE SPECIFIC QUALITY-OF-LIFE QUESTI – MSQLQ

| | |
|--------------------------|--|
| Dataset | MSQLQ |
| Creating program | msqlq.sas |
| Description | MIGRAINE SPECIFIC QUALITY-OF-LIFE QUESTI |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,QUEST1 |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,QUEST1 |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------------|-------|-------------------|
| QUEST1 | num | QUESTION 1 | | Collected at CRF. |
| QUEST2 | num | QUESTION 2 | | Collected at CRF. |
| QUEST3 | num | QUESTION 3 | | Collected at CRF. |
| QUEST4 | num | QUESTION 4 | | Collected at CRF. |
| QUEST5 | num | QUESTION 5 | | Collected at CRF. |
| QUEST6 | num | QUESTION 6 | | Collected at CRF. |
| QUEST7 | num | QUESTION 7 | | Collected at CRF. |
| QUEST8 | num | QUESTION 8 | | Collected at CRF. |
| QUEST9 | num | QUESTION 9 | | Collected at CRF. |
| QUEST10 | num | QUESTION 10 | | Collected at CRF. |
| QUEST11 | num | QUESTION 11 | | Collected at CRF. |
| QUEST12 | num | QUESTION 12 | | Collected at CRF. |
| QUEST13 | num | QUESTION 13 | | Collected at CRF. |
| QUEST14 | num | QUESTION 14 | | Collected at CRF. |

1.4.23. NOT APPLICABLE – NA

| | |
|--------------------------|--|
| Dataset | NA |
| Creating program | na.sas |
| Description | NOT APPLICABLE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------|-------|-------------------|
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| NA | num | NOT APPLICABLE | | Collected at CRF. |

1.4.24. BRIEF NEUROLOGICAL EXAM – NEURO

| | |
|--------------------------|---|
| Dataset | NEURO |
| Creating program | neuro.sas |
| Description | BRIEF NEUROLOGICAL EXAM |
| Unique identifier | DSASPAT_,TEST,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,TEST,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,VERBATIM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|-------------------|
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| TEST | num | TEST | | Collected at CRF. |
| RSLT | num | RESULT | | Collected at CRF. |
| RSLTAP | num | RESULT | | Collected at CRF. |

1.4.25. LAB REFERENCE RANGES – NORMAL_R

| | |
|--------------------------|---|
| Dataset | NORMAL_R |
| Creating program | normal_r.sas |
| Description | LAB REFERENCE RANGES |
| Unique identifier | NR_SEX,NR_AGELO,LABTESTD |
| Sorted by | NR_SEX,NR_AGELO,LABTESTD |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NRID,LAB_ID,LABNAME,STRDTD |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|-------------------|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------|-------|-------------------|
| LABTESTC | char | CENTRAL LAB TEST CODE | | Collected at CRF. |
| LABTESTD | char | LAB TEST CODE DESCRIPTION | | Collected at CRF. |
| LABUNITC | char | LAB UNIT | | Collected at CRF. |
| STRTDT | num | NR START DATE | | Collected at CRF. |
| NR_AGELO | num | AGE LOW | | Collected at CRF. |
| NR_AGEHI | num | AGE HIGH | | Collected at CRF. |
| NR_SEX | char | NR GENDER | | 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. |

1.4.26. BRIEF PHYSICAL EXAM – PHYS

| | |
|--------------------------|---|
| Dataset | PHYS |
| Creating program | phys.sas |
| Description | BRIEF PHYSICAL EXAM |
| Unique identifier | DSASPAT_,SYSTEM,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,SYSTEM,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM,VERBATIM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------|-------|-------------------|
| SYSTEM | num | SYSTEM | | Collected at CRF. |
| RSLTAB | num | RESULT | | Collected at CRF. |
| RSLTNC | num | RESULT | | Collected at CRF. |
| RSLTNY | num | RSLTNY | | Collected at CRF. |

1.4.27. URINE PREGNANCY TEST – PREGTEST

| | |
|--------------------------|--|
| Dataset | PREGTEST |
| Creating program | pregtest.sas |
| Description | URINE PREGNANCY TEST |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|-------------------|
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |
| RESULT | num | RESULT | | Collected at CRF. |
| RRSLT | num | RESULT (RETEST) | | Collected at CRF. |

1.4.28. PRODUCTIVITY QUESTIONNAIRE – PRODQUES

| | |
|--------------------------|---|
| Dataset | PRODQUES |
| Creating program | prodques.sas |
| Description | PRODUCTIVITY QUESTIONNAIRE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,STRAMP |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,STRAMP |
| 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: PAT_NUM,STARTDT,START_M,START_D,START_Y,START_H,START_MN |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|--|
| NAAURA | num | HEADACHE AURA - N/A | | Collected at CRF. |
| STRAMPM | num | HEADACHE/AURA START TIME - AM/PM | | Collected at CRF. |
| STARTTM | char | HEADACH/AURA START TIME (DERIVED) | | Collected at CRF. |
| STARTTMC | char | HEADACH/AURA START TIME (DERIVED 24 Hr C | | Collected at CRF. |
| SCHWORK | num | QUESTION 1 | | Collected at CRF. |
| ABSENT | num | QUESTION 2 | | Collected at CRF. |
| WORK | num | QUESTION 3 | | Collected at CRF. |
| EFFECTIV | num | QUESTION 4 | | Collected at CRF. |
| AFFECT | num | QUESTION 5 | | Collected at CRF. |
| STARTDY | num | RELATIVE HEADACHE/AURA 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. |

1.4.29. SIGNATURE – SIGNATUR

| | |
|--------------------------|--|
| Dataset | SIGNATURE |
| Creating program | signatur.sas |
| Description | VISIT DATE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,SIGDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,SIGDY |
| 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: PAT_NUM,SIG_M,SIG_D,SIG_Y,SIGDT |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------|-------|---|
| SIG | num | 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. |

1.4.30. VISIT DATE – VISITDT

| | |
|--------------------------|--|
| Dataset | VISITDT |
| Creating program | visitdt.sas |
| Description | VISIT DATE |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,VISITDY |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,VISITDY |
| 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: PAT_NUM,VISITDT,VISIT_M,VISIT_D,VISIT_Y |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------------------------|-------|---|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | 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. |

1.4.31. VITAL – VITALS

| | |
|--------------------------|--|
| Dataset | VITAL |
| Creating program | vital.sas |
| Description | VITALS |
| Unique identifier | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,BPSYS |
| Sorted by | DSASPAT_,MODNAME,VISIDESC,VISITREP,OVISITNO,BPSYS |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PAT_NUM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---|-------|--|
| PNO | char | CLIENT PROTOCOL NUMBER | | Collected at CRF. |
| DSASSITE | char | SITE NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Site Number for De-identity |
| DSASPAT_ | char | PATIENT NUMBER ASSIGNED FOR DE-IDENTITY | | Randomly assigned Patient Number for De-identity |
| OVISITNO | num | CRF VISIT NUMBER | | Collected at CRF. |
| VISITREP | num | VISIT REPEAT FLAG | | Collected at CRF. |
| PAGE | num | PAGE NUMBER | | Collected at CRF. |
| PAGEREP | num | PAGE REPEAT NUMBER | | Collected at CRF. |
| VISIDESC | char | CRF VISIT DISCRIPTION | | Collected at CRF. |
| MODNAME | char | PAGE IDENTIFIER | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|----------------------------|-------|-------------------|
| BPSYS | num | BLOOD PRESSURE (SYSTOLIC) | | Collected at CRF. |
| BPDIA | num | BLOOD PRESSURE (DIASTOLIC) | | Collected at CRF. |
| PULSE | num | PULSE | | 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. |