

Clinical Development

**JNJ-16232411**

R076477SCH3015

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 Name will not be provided.
- Date of birth will not be provided, only age in years.
- 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.
- Subjects with age grouped to protect PII.
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Remove ethnic information.
- Empty comments data will be submitted.
- ECGDATE and LABASS datasets were meant for data reconciliation purpose will be removed.
- Remove DNRSLT dataset (its sensitive information). It may reveal subject personal identification information.
- Due to sensitive information SUBST, MEDHIST, UDS and TU datasets will be removed.
- Country will be grouped as regions to protect PII.
- Subjects with OUTCOME as "DEATH" will be removed from all domains; it's a sensitive information and may reveal subject identifier information.

### 1.3. Data Files

The R076477SCH3015 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics – DEMOG

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | DEMOG   |
| <b>Creating program</b>  | demog.sas   |
| <b>Description</b>       | Demographics  |
| <b>Unique identifier</b> | DUSUBJID  |
| <b>Sorted by</b>         | DUSUBJID  |
| <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:<br><br>PHASE, PHASENUM, SUBJINIT, BIRTHDT, BIRTHDTC, CBPOT, CBPOTC, DMACTDT, EDUSTAT, EMPSTAT, LIVSTAT, DMACTDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |

| Variable | Type | Label        | Codes | Comments  |
|----------|------|--------------|-------|---|
| SEX      | char | Sex          |       | Collected at CRF  |
| SEXC     | char | Sex Code     |       | Collected at CRF  |
| RACE     | char | Race         |       | Collected at CRF  |
| RACEC    | char | Race Code    |       | Collected at CRF  |
| AGE      | num  | Age in Years |       | If BIRTHDTC and DMACTDTC not missing then perform below logic to derive age.<br>$\text{INT}(\text{DMACTDTC} - \text{BIRTHDTC}) / 365.25$<br>Grouped element to protect PII. |



### 1.4.2. Adverse Events – AE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | AE   |
| <b>Creating program</b>  | ae.sas   |
| <b>Description</b>       | Adverse Events   |
| <b>Unique identifier</b> | DUSUBJID, AESEQ  |
| <b>Sorted by</b>         | DUSUBJID, AESEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing:<br><br>PHASE, PHASENUM, VISIT, AETERM, AESTDT, AEENDT, AESTDTC, AEENDTC, AESERREF, AECONG, AECONGC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| AEREPRT  | char | Were any AEs reported                    |       | Collected at CRF                                    |
| AEREPRTC | char | Were any AEs reported code               |       | Collected at CRF                                    |
| AESEQ    | num  | AE Sequence Number                       |       | Collected at CRF                                    |

| Variable | Type | Label                                 | Codes | Comments         |
|----------|------|---------------------------------------|-------|------------------|
| AECTTRTC | num  | Action Taken with Treatment Code      |       | Collected at CRF |
| AECTTRT  | char | Action Taken with Treatment           |       | Collected at CRF |
| AEOUTC   | num  | Outcome of Event Code                 |       | Collected at CRF |
| AEOU     | char | Outcome of Event                      |       | Collected at CRF |
| AEREL    | char | Relationship to Treatment             |       | Collected at CRF |
| AERELC   | num  | Relationship to Treatment Code        |       | Collected at CRF |
| AESEV    | char | Severity of Event                     |       | Collected at CRF |
| AESEVC   | num  | Severity of Event Code                |       | Collected at CRF |
| AECONTR  | char | Concomitant/Additional Treatment      |       | Collected at CRF |
| AECONRC  | num  | Concomitant/Additional Treatment Code |       | Collected at CRF |
| AEDEATH  | char | Death                                 |       | Collected at CRF |
| AEDEATH  | char | Death Code                            |       | Collected at CRF |
| AEHOSP   | char | Hospitalization Required              |       | Collected at CRF |
| AEHOSPC  | char | Hospitalization Required Code         |       | Collected at CRF |
| AEIMED   | char | Important Medical Event               |       | Collected at CRF |
| AEIMEDC  | char | Important Medical Event Code          |       | Collected at CRF |
| AELIFET  | char | Life Threatening                      |       | Collected at CRF |
| AELIFETC | char | Life Threatening Code                 |       | Collected at CRF |

| Variable | Type | Label                                   | Codes | Comments         |
|----------|------|---|-------|------------------|
| AEPSDIS  | char | Persistent/Significant Disability       |       | Collected at CRF |
| AEPSDISC | char | Persistent/Significant Disability Code  |       | Collected at CRF |
| AEPHOSP  | char | Prolonged Hospitalization Required      |       | Collected at CRF |
| AEPHOSPC | char | Prolonged Hospitalization Required Code |       | Collected at CRF |
| PT_NAME  | char | MedDra Preferred Term                   |       | Collected at CRF |
| PT_NAMEC | char | MedDra Preferred Term Code              |       | Collected at CRF |
| SOC_NAME | char | MedDra System Organ Class Term          |       | Collected at CRF |
| SOCNAMEC | char | MedDra System Organ Class Term Code     |       | Collected at CRF |
| LLTNAMEC | char | MedDra Low Level Term Code              |       | Collected at CRF |
| LLT_NAME | char | MedDra Low Level Term                   |       | Collected at CRF |
| HLTNAMEC | char | MedDra High Level Term Code             |       | Collected at CRF |
| HLT_NAME | char | MedDra High Level Term                  |       | Collected at CRF |
| HGTNAMEC | char | MedDra High Level Group Term Code       |       | Collected at CRF |
| HGT_NAME | char | MedDra High Level Group Term            |       | Collected at CRF |
| AEDICTDM | char | MedDra Dictionary Version               |       | Collected at CRF |

| Variable | Type | Label                              | Codes | Comments   |
|----------|------|------------------------------------|-------|--|
| AESTDY   | num  | Relative Actual Start Day of Event |       | <p>If AESTDTC and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If AESTDTC less than DMACTDTC then (AESTDTC - DMACTDTC). Else if AESTDTC is greater than equal to DMACTDTC then (AESTDTC - DMACTDTC) +1.</p> |
| AEENDY   | num  | Relative Actual End Day of Event   |       | <p>If AEENDTC and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If AEENDTC less than DMACTDTC then (AEENDTC - DMACTDTC). Else if AEENDTC is greater than equal to DMACTDTC then (AEENDTC - DMACTDTC) +1.</p> |

### 1.4.3. Abnormal Involuntary Movement Scale - AIMS

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | AIMS   |
| <b>Creating program</b>  | aims.sas   |
| <b>Description</b>       | Abnormal Involuntary Movement Scale  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, AISEQ  |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, AISEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing:<br><br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| AISEQ    | num  | AIMS sequence number                     |       | Collected at CRF                                    |
| AIGROUP  | char | AIMS Group                               |       | Collected at CRF                                    |
| AIITEM   | char | AIMS Item                                |       | Collected at CRF                                    |

| Variable | Type | Label       | Codes | Comments         |
|----------|------|-------------|-------|------------------|
| AISCORE  | char | Score       |       | Collected at CRF |
| AISCOREC | num  | Coded Score |       | Collected at CRF |

#### 1.4.4. Barnes Akathisia Scale - BARS

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | BARS   |
| <b>Creating program</b>  | bars.sas   |
| <b>Description</b>       | Barnes Akathisia Scale   |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, BASEQ  |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, BASEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing:<br><br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |

| Variable | Type | Label                | Codes | Comments         |
|----------|------|----------------------|-------|------------------|
| VISIT    | char | Visit                |       | Collected at CRF |
| BASEQ    | num  | BARS sequence number |       | Collected at CRF |
| BAGROUP  | char | BARS Group           |       | Collected at CRF |
| BAITEM   | char | BARS Item            |       | Collected at CRF |
| BASCORE  | char | Score                |       | Collected at CRF |
| BASCOREC | num  | Coded Score          |       | Collected at CRF |

#### 1.4.5. Clinical Global Impression - CGI

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | CGI   |
| <b>Creating program</b>  | cgi.sas   |
| <b>Description</b>       | Clinical Global Impression  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, CGCAT   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, CGCAT   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>PHASE, PHASENUM |

| Variable | Type | Label     | Codes | Comments         |
|----------|------|-----------|-------|------------------|
| TRIAL    | char | TRIAL ID. |       | Collected at CRF |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| CGCAT    | char | CGI Category                             |       | Collected at CRF                                    |
| CGSEVC   | num  | CGI Severity Code                        |       | Collected at CRF                                    |
| CGSEV    | char | CGI Severity                             |       | Collected at CRF                                    |
| CHCHGC   | num  | CGI Change Code                          |       | Collected at CRF                                    |
| CHCHG    | char | CGI Change                               |       | Collected at CRF                                    |



## 1.4.6. Comments - COMMENTS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | COMMENTS  |
| <b>Creating program</b>  | comments.sas  |
| <b>Description</b>       | Comments  |
| <b>Unique identifier</b> | Not applicable  |
| <b>Sorted by</b>         | Not applicable  |
| <b>Notes</b>             | Comments data is sensitive data, contains free text information. Will be submitted empty dataset. |

| Variable | Type | Label                 | Codes | Comments                      |
|----------|------|-----------------------|-------|-------------------------------|
| TRIAL    | char | TRIAL ID.             |       | Empty data will be submitted. |
| SITE     | char | Site                  |       | Empty data will be submitted. |
| SUBJECT  | char | Subject ID            |       | Empty data will be submitted. |
| DOMAIN   | char | Domain of Origin      |       | Empty data will be submitted. |
| DOMAINC  | char | Domain of Origin Code |       | Empty data will be submitted. |
| VISIT    | char | Visit                 |       | Empty data will be submitted. |
| VISITC   | char | Visit Code            |       | Empty data will be submitted. |

## 1.4.7. Concomitant Meds - CONMED

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | CONMED   |
| <b>Creating program</b>  | conmed.sas   |
| <b>Description</b>       | Concomitant Meds   |
| <b>Unique identifier</b> | DUSUBJID, CMSEQ  |
| <b>Sorted by</b>         | DUSUBJID, CMSEQ  |
| <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:<br><br>PHASE, PHASENUM, CMTERM, CMREAS, CMSTDT, CMENDT, CMREGIM, CMREGUNT, CMSTDTC, CMENDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| CMTYPEC  | num  | Medication type Code                     |       | Collected at CRF                                    |
| CMTYPE   | char | Medication type                          |       | Collected at CRF                                    |

| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| CSTATC   | num  | No Concomitant Medication Code          |       | Collected at CRF   |
| CSTAT    | char | No Concomitant Medication               |       | Collected at CRF   |
| CMSEQ    | num  | Conmed Sequence Number                  |       | Collected at CRF   |
| CMROUTE  | char | Route of Administration                 |       | Collected at CRF   |
| CMROUTEC | num  | Route of Administration Code            |       | Collected at CRF   |
| CMREPRT  | char | Were Any Meds Administered              |       | Collected at CRF   |
| CMREPRTC | num  | Were Any Meds Administered Code         |       | Collected at CRF   |
| CMCONT   | char | Medication Continuing                   |       | Collected at CRF   |
| CMCONTC  | char | Medication Continuing Code              |       | Collected at CRF   |
| CMDECOD  | char | Medication Generic Term                 |       | Collected at CRF   |
| CMCODE   | char | Medication Disctionary Code             |       | Collected at CRF   |
| CMPN     | char | Preferred Medication Name               |       | Collected at CRF   |
| ATCCODE  | char | ATC Code                                |       | Collected at CRF   |
| ATCTEXT  | char | ATC Text                                |       | Collected at CRF   |
| CMSTDY   | num  | Relative Actual Start Day of Medication |       | <p>If CMSTDTC and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If CMSTDTC less than DMACTDTC then (CMSTDTC - DMACTDTC). Else if CMSTDTC is greater than equal to DMACTDTC then (CMSTDTC - DMACTDTC) +1.</p> |

| Variable | Type | Label                                 | Codes | Comments  |
|----------|------|---------------------------------------|-------|---|
| CMENDY   | num  | Relative Actual End Day of Medication |       | If CMENDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If CMENDTC less than DMACTDTC then (CMENDTC - DMACTDTC). Else if CMENDTC is greater than equal to DMACTDTC then (CMENDTC - DMACTDTC) +1. |

#### 1.4.8. Disposition - DISPOSIT

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | DISPOSIT   |
| <b>Creating program</b>  | disposit.sas   |
| <b>Description</b>       | Disposition  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, DSTYPE   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, DSTYPE   |
| <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:<br><br>PHASE, PHASENUM, DSACTDT, DRSOTH, DSACTDTC |

| Variable | Type | Label                         | Codes | Comments                                  |
|----------|------|-------------------------------|-------|---|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF                          |
| DSITE    | char | Site Assigned for De-identity |       | Randomly assigned Site ID for De-identity |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| DSTYPE   | char | End of Treatment or Trial                |       | Collected at CRF                                    |
| DSTYPEC  | char | End of Treatment or Trial Code           |       | Collected at CRF                                    |
| DSSTAT   | char | Subject Completed Treatment/Trial        |       | Collected at CRF                                    |
| DSSTATC  | char | Subject Completed Treatment/Trial Code   |       | Collected at CRF                                    |
| DSREAS   | char | Reason for Withdrawal/Termination        |       | Collected at CRF                                    |
| DSREASC  | num  | Reason for Withdrawal/Termination Code   |       | Collected at CRF                                    |
| DSCONT   | char | Subject continued day 42                 |       | Collected at CRF                                    |
| DSCONTC  | char | Subject continued day 42 Code            |       | Collected at CRF                                    |

| Variable | Type | Label                                   | Codes | Comments  |
|----------|------|---|-------|---|
| DSACTDY  | num  | Relative Actual Day Trial Comp./Witdra. |       | <p>If DSACTDTC and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If DSACTDTC less than DMACTDTC then (DSACTDTC - DMACTDTC). Else if DSACTDTC is greater than equal to DMACTDTC then (DSACTDTC - DMACTDTC) +1.</p> |

### 1.4.9. Electrocardiogram - ECG

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | ECG  |
| <b>Creating program</b>  | ecg.sas  |
| <b>Description</b>       | Electrocardiogram  |
| <b>Unique identifier</b> | DUSUBJCT, VISIT, EGDY, EGACTTM, EGTESTC  |
| <b>Sorted by</b>         | DUSUBJCT, VISIT, EGDY, EGACTTM, EGTESTC  |
| <b>Notes</b>             | <p>Below listed variables will be dropped from De-identify dataset to protect PII as per HIPAA and EMA guidelines.</p> <p>RECDT, EGDT, DIAGC8, DIAGC9, DIAGC10, DIAGT8, DIAGT9, DIAGT10, EGDRCOM, EGDRCOM2, RECDTC, EGDT</p> |

| Variable | Type | Label                         | Codes | Comments                                  |
|----------|------|-------------------------------|-------|---|
| TRIAL    | char | Protocol Name                 |       | Collected at CRF                          |
| DSITE    | char | Site Assigned for De-identity |       | Randomly assigned Site ID for De-identity |

| Variable | Type | Label                                   | Codes | Comments                                     |
|----------|------|---|-------|--|
| DSUBJECT | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject ID for De-identity |
| VISIT    | char | Visit Number                            |       | Collected at CRF                             |
| EGACTTM  | num  | Time of ECG                             |       | Collected at CRF                             |
| EGTESTC  | char | ECG Test code                           |       | Collected at CRF                             |
| EGTEST   | char | ECG Test name                           |       | Collected at CRF                             |
| EGRESN   | num  | ECG Test numeric                        |       | Collected at CRF                             |
| EGRESC   | char | ECG Test character                      |       | Collected at CRF                             |
| RATE     | char | Heart Rate                              |       | Collected at CRF                             |
| EGINTPC  | char | ECG Assessment Code                     |       | Collected at CRF                             |
| EGINTP   | char | ECG Assessment Text                     |       | Collected at CRF                             |
| EGCHGC   | char | Comparison Code                         |       | Collected at CRF                             |
| EGCHG    | char | Comparison Text                         |       | Collected at CRF                             |
| DIAGC1   | char | Diagnostic Code 1                       |       | Collected at CRF                             |
| DIAGC2   | char | Diagnostic Code 2                       |       | Collected at CRF                             |
| DIAGC3   | char | Diagnostic Code 3                       |       | Collected at CRF                             |
| DIAGC4   | char | Diagnostic Code 4                       |       | Collected at CRF                             |
| DIAGC5   | char | Diagnostic Code 5                       |       | Collected at CRF                             |
| DIAGC6   | char | Diagnostic Code 6                       |       | Collected at CRF                             |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DIAGC7   | char | Diagnostic Code 7                        |       | Collected at CRF   |
| DIAGT1   | char | Diagnostic Text 1                        |       | Collected at CRF   |
| DIAGT2   | char | Diagnostic Text 2                        |       | Collected at CRF   |
| DIAGT3   | char | Diagnostic Text 3                        |       | Collected at CRF   |
| DIAGT4   | char | Diagnostic Text 4                        |       | Collected at CRF   |
| DIAGT5   | char | Diagnostic Text 5                        |       | Collected at CRF   |
| DIAGT6   | char | Diagnostic Text 6                        |       | Collected at CRF   |
| DIAGT7   | char | Diagnostic Text 7                        |       | Collected at CRF   |
| EGLDPQC  | char | Lead PQRST Code                          |       | Collected at CRF   |
| EGLDPQ   | char | Lead PQRST Text                          |       | Collected at CRF   |
| EGLDRRC  | char | Lead RR Code                             |       | Collected at CRF   |
| EGLDRR   | char | Lead RR Text                             |       | Collected at CRF   |
| DUSUBJCT | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity  |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF   |
| RECDY    | char | Relative Received Day                    |       | If RECDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If RECDTC less than DMACTDTC then (RECDTC - DMACTDTC). Else if RECDTC is greater than equal to DMACTDTC then (RECDTC - DMACTDTC) +1. |



| Variable | Type | Label               | Codes | Comments   |
|----------|------|---------------------|-------|--|
| EGDY     | char | Relative Day of ECG |       | <p>If EGDTC and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If EGDTC less than DMACTDTC then (EGDTC - DMACTDTC). Else if EGDTC is greater than equal to DMACTDTC then (EGDTC - DMACTDTC) +1.</p> |

#### 1.4.10. Hospital Admission and Discharge Summary - HOSPADM

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | HOSPADM   |
| <b>Creating program</b>  | hospadm.sas   |
| <b>Description</b>       | Hospital Admission and Discharge Summary  |
| <b>Unique identifier</b> | DUSUBJID, HOSEQ   |
| <b>Sorted by</b>         | DUSUBJID, HOSEQ   |
| <b>Notes</b>             | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:</p> <p>PHASE, PHASENUM, HOSTDT, HOENDT, HOSPEC, HOSTDTC, HOENDTC, HOREHOC</p> |

| Variable | Type | Label                         | Codes | Comments                                  |
|----------|------|-------------------------------|-------|---|
| TRIAL    | char | TRIAL ID.                     |       | Collected at CRF                          |
| DSITE    | char | Site Assigned for De-identity |       | Randomly assigned Site ID for De-identity |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity  |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity   |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF  |
| VISIT    | char | Visit                                    |       | Collected at CRF  |
| HOSEQ    | num  | Hospital Admission sequence number       |       | Collected at CRF  |
| HODISTOC | char | Subject discharged to code               |       | Collected at CRF  |
| HODISTO  | char | Subject discharged to                    |       | Collected at CRF  |
| HOREHO   | char | Subject re-hospitalized?                 |       | Collected at CRF  |
| HOREAS   | char | Reason for hospitalization               |       | Collected at CRF  |
| HOREAS   | num  | Reason code                              |       | Collected at CRF  |
| HOSTDY   | num  | Relative Day of Hospital Admission       |       | If HOSTDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If HOSTDTC less than DMACTDTC then (HOSTDTC - DMACTDTC). Else if HOSTDTC is greater than equal to DMACTDTC then (HOSTDTC - DMACTDTC) +1. |
| HOENDY   | num  | Relative Day of Hospital Discharge       |       | If HOENDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If HOENDTC less than DMACTDTC then (HOENDTC - DMACTDTC). Else if HOENDTC is greater than equal to DMACTDTC then (HOENDTC - DMACTDTC) +1. |

## 1.4.11. Inclusion/Exclusion Exceptions - IE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | IE  |
| <b>Creating program</b>  | ie.sas  |
| <b>Description</b>       | Inclusion/Exclusion Exceptions  |
| <b>Unique identifier</b> | DUSUBJID, IESEQ   |
| <b>Sorted by</b>         | DUSUBJID, IESEQ   |
| <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:<br><br>PHASE, PHASENUM, IETEST |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| IECAT    | char | Inclusion/Exclusion Category             |       | Collected at CRF                                    |
| IESEQ    | num  | Inclusion/Exclusion sequence number      |       | Collected at CRF                                    |

| Variable | Type | Label                                    | Codes | Comments         |
|----------|------|--|-------|------------------|
| IETESTCD | char | Inclusion/Exclusion Criterion Short Name |       | Collected at CRF |
| IEORRES  | char | IE Criterion Original Result             |       | Collected at CRF |
| IEORRESC | char | IE Criterion Original Result Code        |       | Collected at CRF |

### 1.4.12. Laboratory - LAB

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | LAB   |
| <b>Creating program</b>  | lab.sas   |
| <b>Description</b>       | Laboratory  |
| <b>Unique identifier</b> | DUSUBJECT, VISITNUM, LBTYPE, LBTESTC, LBACTDY, LBACTTM  |
| <b>Sorted by</b>         | DUSUBJECT, VISITNUM, LBTYPE, LBTESTC, LBACTDY, LBACTTM  |
| <b>Notes</b>             | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>LBREF LBACTDT LBRECDT</p> <p>Note: Protocol unplanned tests will be removed; it may reveal participant information.</p> |

| Variable | Type | Label                                   | Codes | Comments                                     |
|----------|------|---|-------|--|
| TRIAL    | char | Study ID                                |       | Collected at CRF                             |
| DSITE    | char | Site Assigned for De-identity           |       | Randomly assigned Site ID for De-identity    |
| DSUBJECT | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject ID for De-identity |
| VISIT    | char | Visit                                   |       | Collected at CRF                             |
| LBACTTM  | num  | Actual Time of Lab Sample               |       | Collected at CRF                             |
| LBTYPE   | char | Laboratory type                         |       | Collected at CRF                             |

| Variable  | Type | Label                                    | Codes | Comments  |
|-----------|------|--|-------|---|
| LBTESTC   | char | Lab Test Code                            |       | Collected at CRF                                    |
| LBTEST    | char | Lab Test Name                            |       | Collected at CRF                                    |
| ORGRES    | char | Character lab result                     |       | Collected at CRF                                    |
| ORGRESN   | num  | Numeric lab result                       |       | Collected at CRF                                    |
| ORGUNIT   | char | Original Units                           |       | Collected at CRF                                    |
| STDRESN   | num  | S.I. Numeric Results                     |       | Collected at CRF                                    |
| STDUNIT   | char | S.I. Units                               |       | Collected at CRF                                    |
| ORGRRC    | char | Reference range textual                  |       | Collected at CRF                                    |
| ORGNRLO   | num  | Lower limit for the lab normal range     |       | Collected at CRF                                    |
| ORGNRHI   | num  | Upper limit for the lab normal range     |       | Collected at CRF                                    |
| STDNRLO   | num  | S.I. lower limit                         |       | Collected at CRF                                    |
| STDNRHI   | num  | S.I. upper limit                         |       | Collected at CRF                                    |
| NRIND     | char | High/Low Lab Value Flag                  |       | Collected at CRF                                    |
| DUSUBJECT | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM  | num  | Visit Number                             |       | Collected at CRF                                    |

| Variable | Type | Label                         | Codes | Comments  |
|----------|------|-------------------------------|-------|---|
| LBACTDY  | num  | Relative Actual Day of Sample |       | If LBACTDT and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If LBACTDT less than DMACTDTC then (LBACTDT - DMACTDTC). Else if LBACTDT is greater than equal to DMACTDTC then (LBACTDT - DMACTDTC) +1. |
| LBRECDY  | num  | Relative Received Day         |       | If LBRECDT and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If LBRECDT less than DMACTDTC then (LBRECDT - DMACTDTC). Else if LBRECDT is greater than equal to DMACTDTC then (LBRECDT - DMACTDTC) +1. |

### 1.4.13. Medication Kit - MEDKIT

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | MEDKIT  |
| <b>Creating program</b>  | medkit.sas  |
| <b>Description</b>       | Medication Kit  |
| <b>Unique identifier</b> | DUSUBJID, DISPDY, DISNUM, RETDY, RETNUM, TAKNUM   |
| <b>Sorted by</b>         | DUSUBJID, DISPDY, DISNUM, RETDY, RETNUM, TAKNUM   |
| <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:<br><br>PHASE, PHASENUM, KITNUM, DISPDT, RETDT, DISPDTC, RETDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| DISNUM   | num  | Number Dispensed                         |       | Collected at CRF                                    |
| RETNUM   | num  | Number Returned                          |       | Collected at CRF                                    |



| Variable | Type | Label                             | Codes | Comments   |
|----------|------|-----------------------------------|-------|--|
| TAKNUM   | num  | Number Taken                      |       | Collected at CRF   |
| DISPDY   | char | Relative Actual Day Kit Dispensed |       | If DISPDC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If DISPDC less than DMACTDTC then (DISPDC - DMACTDTC). Else if DISPDC is greater than equal to DMACTDTC then (DISPDC - DMACTDTC) +1. |
| RETDY    | char | Relative Actual Day Kit Returned  |       | If RETDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If RETDTC less than DMACTDTC then (RETDTC - DMACTDTC). Else if RETDTC is greater than equal to DMACTDTC then (RETDTC - DMACTDTC) +1. |

## 1.4.14. Positive And Negative Syndrome Scale - PANSS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PANSS   |
| <b>Creating program</b>  | panss.sas   |
| <b>Description</b>       | Positive And Negative Syndrome Scale  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, PASEQ   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, PASEQ   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| PASEQ    | num  | PANSS sequence                           |       | Collected at CRF                                    |
| PAGROUP  | char | PANSS Group                              |       | Collected at CRF                                    |
| PAITEM   | char | PANNS Item                               |       | Collected at CRF                                    |

| Variable  | Type | Label             | Codes | Comments         |
|-----------|------|-------------------|-------|------------------|
| PASSCORE  | char | PANSS Score       |       | Collected at CRF |
| PASSCOREC | num  | PANSS Coded Score |       | Collected at CRF |

#### 1.4.15. Physical Exam - PE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PE  |
| <b>Creating program</b>  | pe.sas  |
| <b>Description</b>       | Physical Exam   |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, PESEQ   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, PESEQ   |
| <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:<br><br>PHASE, PHASENUM, PEFIND |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |

| Variable | Type | Label                | Codes | Comments         |
|----------|------|----------------------|-------|------------------|
| VISITNUM | num  | Visit Number         |       | Collected at CRF |
| VISIT    | char | Visit                |       | Collected at CRF |
| PEBODSYS | char | Body System          |       | Collected at CRF |
| PESEQ    | num  | Phys Sequence Number |       | Collected at CRF |
| PESTAT   | char | Exam Result          |       | Collected at CRF |

#### 1.4.16. Urine Pregnancy Screen - PREGNCY

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PREGNCY   |
| <b>Creating program</b>  | pregncy.sas   |
| <b>Description</b>       | Urine Pregnancy Screen  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM  |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM  |
| <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:<br><br>PHASE, PHASENUM, PGACTDT, PGACTDT C |

| Variable | Type | Label     | Codes | Comments         |
|----------|------|-----------|-------|------------------|
| TRIAL    | char | TRIAL ID. |       | Collected at CRF |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity   |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity  |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity   |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF  |
| VISIT    | char | Visit                                    |       | Collected at CRF  |
| PGSTAT   | char | Pregnancy Test status                    |       | Collected at CRF  |
| PGSTATC  | char | Pregnancy Test status code               |       | Collected at CRF  |
| PGNA     | char | Pregnancy Test not applicable            |       | Collected at CRF  |
| PGRES    | char | Pregnancy Test Result                    |       | Collected at CRF  |
| PGRESC   | char | Pregnancy Test Result Code               |       | Collected at CRF  |
| PGACTDY  | num  | Relative Actual Day of Pregnancy Test    |       | <p>If PGACTDTC and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If PGACTDTC less than DMACTDTC then (PGACTDTC - DMACTDTC). Else if PGACTDTC is greater than equal to DMACTDTC then (PGACTDTC - DMACTDTC) +1.</p> |

### 1.4.17. Protocol Deviations - PROTDEV

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PROTDEV   |
| <b>Creating program</b>  | protdev.sas   |
| <b>Description</b>       | Protocol Deviations   |
| <b>Unique identifier</b> | DSUBJID, DEVIAT   |
| <b>Sorted by</b>         | DSUBJID, DEVIAT   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:<br><br>DEVIAT_V |

| Variable | Type | Label                                   | Codes | Comments                                     |
|----------|------|---|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject ID for De-identity |
| DEVIAT   | char | Deviation Category                      |       | Collected at CRF                             |
| ZDEVIAT  | char | Deviation Class                         |       | Collected at CRF                             |
| DVTYPE   | char | Deviation Type                          |       | Collected at CRF                             |

## 1.4.18. Psychiatric History - PSYHIST

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PSYHIST   |
| <b>Creating program</b>  | psyhist.sas   |
| <b>Description</b>       | Psychiatric History   |
| <b>Unique identifier</b> | DUSUBJID  |
| <b>Sorted by</b>         | DUSUBJID  |
| <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:<br><br>PHASE, PHASENUM, PYCUDT, PYCUDT C, PYSUDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| PYDIAG   | char | Diagnosis                                |       | Collected at CRF                                    |
| PYDIAGC  | char | Diagnosis coded                          |       | Collected at CRF                                    |
| PYSYMP   | num  | Schizophrenia symptoms age               |       | Grouped weight to protect PII.                      |

| Variable | Type | Label                                   | Codes | Comments  |
|----------|------|---|-------|---|
| PYSYUNK  | num  | Schizophrenia symptoms age unknown      |       | Collected at CRF  |
| PYSCHZ   | num  | Schizophrenia diagnosis age             |       | Grouped weight to protect PII.  |
| PYSCUNK  | num  | Schizophrenia diagnosis age unknown     |       | Collected at CRF  |
| PYHOAGE  | num  | Psychiatric hospitalization age         |       | Grouped weight to protect PII.  |
| PYHOUNK  | num  | Psychiatric hospitalization age unknown |       | Collected at CRF  |
| PYHOSP1  | num  | Hospitalizations within 12 months       |       | Collected at CRF  |
| PYHOSP2  | num  | Hospitalizations between 12-24          |       | Collected at CRF  |
| PYHOSP3  | num  | Hospitalizations greater than 25        |       | Collected at CRF  |
| PYHOSP4  | num  | Hospitalizations > 25 unknown           |       | Collected at CRF  |
| PYLSTHO  | char | Last psychiatric hospitalization        |       | Collected at CRF  |
| PYSUIC   | char | Suicide attempt?                        |       | Collected at CRF  |
| PYSUICC  | char | Suicide attempt? Code                   |       | Collected at CRF  |
| PYSUNUM  | char | Suicide attempt number                  |       | Collected at CRF  |
| PYCUDY   | num  | Relative Day of Current Hospitalization |       | If PYCUDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br>If PYCUDTC less than DMACTDTC then (PYCUDTC - DMACTDTC). Else if PYCUDTC is greater than equal to DMACTDTC then (PYCUDTC - DMACTDTC) +1. |



| Variable | Type | Label                        | Codes | Comments  |
|----------|------|------------------------------|-------|---|
| PYSUDY   | num  | Relative Suicide attempt day |       | <p>If PYSUDT and DMACTDTC not missing then perform below logic to calculate relative day.</p> <p>If PYSUDT less than DMACTDTC then (PYSUDT - DMACTDTC). Else if PYSUDT is greater than equal to DMACTDTC then (PYSUDT - DMACTDTC) +1.</p> |

1.4.19. Additional Psychotropic Medications – PSYCHMED

|                          |                                     |
|--------------------------|-------------------------------------|
| <b>Dataset</b>           | PSYCHMED                            |
| <b>Creating program</b>  | psychmed.sas                        |
| <b>Description</b>       | Additional Psychotropic Medications |
| <b>Unique identifier</b> | CMTYPE, CMTERM , CLASS              |
| <b>Sorted by</b>         | CMTYPE, CMTERM , CLASS              |
| <b>Notes</b>             |                                     |

| Variable | Type | Label                                    | Codes | Comments                                       |
|----------|------|--|-------|--|
| CMTYPE   |      | Medication Type                          |       | Not Subject level data, not required to submit |
| CMTERM   |      | Reported Name of Drug/Medication/Therapy |       | Not Subject level data, not required to submit |

| Variable | Type | Label                                   | Codes | Comments                                       |
|----------|------|---|-------|--|
| CLASS    |      | Psychotropic Medication Classification  |       | Not Subject level data, not required to submit |
| ADD_F    |      | Additional Psychotropic Medication Flag |       | Not Subject level data, not required to submit |

### 1.4.20. Randomization - RANDOM

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | RANDOM   |
| <b>Creating program</b>  | random.sas   |
| <b>Description</b>       | Randomization  |
| <b>Unique identifier</b> | DUSUBJID   |
| <b>Sorted by</b>         | DUSUBJID   |
| <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:<br><br>PHASE, PHASENUM, RAACTDT, RANDNUM, RANREAS, RAACTDTC |

| Variable | Type | Label                               | Codes | Comments                                     |
|----------|------|-------------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                           |       | Collected at CRF                             |
| DSITE    | char | Site Assigned for De-identity       |       | Randomly assigned Site ID for De-identity    |
| DSUBJECT | char | Subject ID Assigned for De-identity |       | Randomly assigned Subject ID for De-identity |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity  |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF   |
| VISIT    | char | Visit                                    |       | Collected at CRF   |
| RANSTAT  | char | Randomization status                     |       | Collected at CRF   |
| RANSTATC | char | Randomization status                     |       | Collected at CRF   |
| RAACTDY  | num  | Relative Actual Day of Randomization     |       | If RAACTDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br>If RAACTDTC less than DMACTDTC then (RAACTDTC - DMACTDTC). Else if RAACTDTC is greater than equal to DMACTDTC then (RAACTDTC - DMACTDTC) +1. |

## 1.4.21. Readiness to Discharge Questionnaire - RDQ

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | RDQ   |
| <b>Creating program</b>  | rdq.sas   |
| <b>Description</b>       | Readiness to Discharge Questionnaire  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, RQSEQ   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, RQSEQ   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| RQSEQ    | num  | RDQ sequence number                      |       | Collected at CRF                                    |
| RQITEM   | char | RDQ item                                 |       | Collected at CRF                                    |
| RQRESPC  | char | RDQ response code                        |       | Collected at CRF                                    |

| Variable | Type | Label        | Codes | Comments         |
|----------|------|--------------|-------|------------------|
| RQRESP   | char | RDQ response |       | Collected at CRF |

### 1.4.22. Rescue Medications – RESCUMED

|                          |                                |
|--------------------------|--------------------------------|
| <b>Dataset</b>           | RESCUMED                       |
| <b>Creating program</b>  | rescumed.sas                   |
| <b>Description</b>       | Rescue Medications             |
| <b>Unique identifier</b> | ATCTEXT, CMPN, CMROUTE, CMREAS |
| <b>Sorted by</b>         | ATCTEXT ,CMPN ,CMROUTE ,CMREAS |
| <b>Notes</b>             |                                |

| Variable | Type | Label                            | Codes | Comments                                       |
|----------|------|----------------------------------|-------|--|
| ATCTEXT  | char | ATC Text                         |       | Not Subject level data, not required to submit |
| CMPN     | char | Preferred Medication Name        |       | Not Subject level data, not required to submit |
| CMROUTE  | char | Route of Administration          |       | Not Subject level data, not required to submit |
| CMREAS   | char | Reason for Medication            |       | Not Subject level data, not required to submit |
| RESCCLAS | num  | Rescue Medication Classification |       | Not Subject level data, not required to submit |
| RESCUE_F | num  | Rescue Medication Flag           |       | Not Subject level data, not required to submit |

## 1.4.23. Simpson Angus Scale – SAS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SAS   |
| <b>Creating program</b>  | sas.sas   |
| <b>Description</b>       | Simpson Angus Scale   |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM, SASEQ   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM, SASEQ   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |
| SASEQ    | num  | SAS sequence number                      |       | Collected at CRF                                    |
| SASCAC   | num  | SAS scale code                           |       | Collected at CRF                                    |
| SASCA    | char | SAS scale                                |       | Collected at CRF                                    |

| Variable | Type | Label    | Codes | Comments         |
|----------|------|----------|-------|------------------|
| SAITEM   | char | SAS Item |       | Collected at CRF |

#### 1.4.24. Study Medication satisfaction - SMSQ

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SMSQ  |
| <b>Creating program</b>  | smsq.sas  |
| <b>Description</b>       | Study Medication satisfaction   |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM  |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br><br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |

| Variable | Type | Label              | Codes | Comments         |
|----------|------|--------------------|-------|------------------|
| SMRESPC  | num  | SMSQ response code |       | Collected at CRF |
| SMRESP   | char | SMSQ response      |       | Collected at CRF |

### 1.4.25. Sleepiness/Sedation - SSS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | SSS   |
| <b>Creating program</b>  | sss.sas   |
| <b>Description</b>       | Sleepiness/Sedation   |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM  |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br><br>PHASE, PHASENUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |



| Variable | Type | Label                     | Codes | Comments         |
|----------|------|---------------------------|-------|------------------|
| SSSCDC   | num  | Sleep/Sedation Scale code |       | Collected at CRF |
| SSSCA    | char | Sleep/Sedation Scale      |       | Collected at CRF |

1.4.26. Unblinded Subject Randomization File – Unblind

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | UNBLIND   |
| <b>Creating program</b>  | unblind.sas   |
| <b>Description</b>       | Unblinded Subject Randomization File  |
| <b>Unique identifier</b> | DSUBJID   |
| <b>Sorted by</b>         | DSUBJID   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br>STUDYID ,SITEID ,KITNUM1, KITDOSE1, KITNUM2 ,KITDOSE2 ,RANDNUM,<br>BIRTHDT, DISPDT ,RAACTDT |

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| SUBJID   | char | Subject Number                |       | Randomly assigned Subject ID for De-identity       |
| DCONTRYC | char | De-identify Country Code      |       | Country information will be groped to protect PII. |
| RANDGRP  | char | Randomization Treatment group |       | Collected at CRF                                   |

## 1.4.27. Visit - VISIT

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | VISIT  |
| <b>Creating program</b>  | visit.sas  |
| <b>Description</b>       | Visit  |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM   |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM   |
| <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:<br><br>PHASE, PHASENUM, VISITDT, VISITDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| TRIAL    | char | TRIAL ID.                                |       | Collected at CRF                                    |
| DSITE    | char | Site Assigned for De-identity            |       | Randomly assigned Site ID for De-identity           |
| DSUBJECT | char | Subject ID Assigned for De-identity      |       | Randomly assigned Subject ID for De-identity        |
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF                                    |
| VISIT    | char | Visit                                    |       | Collected at CRF                                    |

| Variable | Type | Label              | Codes | Comments   |
|----------|------|--------------------|-------|--|
| VISITDY  | char | Relative Visit Day |       | If VISITDTC and DMACTDTC not missing then perform below logic to calculate relative day.<br><br>If VISITDTC less than DMACTDTC then (VISITDTC - DMACTDTC). Else if VISITDTC is greater than equal to DMACTDTC then (VISITDTC - DMACTDTC) +1. |

#### 1.4.28. Vital Signs - VITAL

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | VITAL   |
| <b>Creating program</b>  | vital.sas   |
| <b>Description</b>       | Vital Signs   |
| <b>Unique identifier</b> | DUSUBJID, VISITNUM  |
| <b>Sorted by</b>         | DUSUBJID, VISITNUM  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to missing values:<br><br>PHASE, PHASENUM |

| Variable | Type | Label                               | Codes | Comments                                     |
|----------|------|-------------------------------------|-------|--|
| TRIAL    | char | TRIAL ID.                           |       | Collected at CRF                             |
| DSITE    | char | Site Assigned for De-identity       |       | Randomly assigned Site ID for De-identity    |
| DSUBJECT | char | Subject ID Assigned for De-identity |       | Randomly assigned Subject ID for De-identity |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DUSUBJID | char | Unique Subject ID Assign for De-identity |       | Randomly assigned Unique Subject ID for De-identity                              |
| VISITNUM | num  | Visit Number                             |       | Collected at CRF   |
| VISIT    | char | Visit                                    |       | Collected at CRF   |
| WEIGHT   | char | Weight                                   |       | Convert data to standardized "kg" unit values.<br>Grouped Weight to protect PII. |
| WTUNIT   | char | Weight unit                              |       | All data converted into KGs.   |
| HEIGHT   | char | Height                                   |       | Convert data to standardized "cm" unit values.<br>Grouped Height to protect PII. |
| HTUNIT   | char | Height unit                              |       | All data converted into CMs.   |
| PULSE    | num  | Pulse Rate (bpm)                         |       | Collected at CRF   |
| TEMP     | num  | Temperature                              |       | Collected at CRF   |
| TEMPUNIT | char | Temperature Unit                         |       | Collected at CRF   |
| SYSBP    | num  | Systolic Blood Pressure (mmHg)           |       | Collected at CRF   |
| DIABP    | num  | Diastolic Blood Pressure (mmHg)          |       | Collected at CRF   |
| RESP     | num  | Respiration Rate (/min)                  |       | Collected at CRF   |