

Clinical Development

**Paliperidone<sup>®</sup>**

R076477-SCH305

Anonymisation Data Derivation Specification Document

|                  |                    |
|------------------|--------------------|
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## Table of contents

|  |    |
|--|----|
| Clinical Development .....   | 1  |
| 1. Datasets .....  | 5  |
| 1.1. Specifications Introduction .....                                       | 5  |
| 1.2. Guidelines for Preparing Data .....                                     | 5  |
| 1.3. Data Files .....  | 6  |
| 1.4. Data Domains .....  | 7  |
| 1.4.1. Demographics – DEMOG .....  | 7  |
| 1.4.2. Adverse Events – AE .....   | 10 |
| 1.4.3. Abnormal Involuntary Movement Scale – AIMS .....                      | 13 |
| 1.4.4. Barnes Akathisia Rating Scale – BARS .....                            | 15 |
| 1.4.5. Clinical Global Impression – CGI .....                                | 17 |
| 1.4.6. Chemistry – CHEM .....  | 18 |
| 1.4.7. Comments – COMMENTS .....   | 21 |
| 1.4.8. Concomitant Drug/Therapy – CONMED .....                               | 23 |
| 1.4.9. Schizophrenia Diagnosis – DIAGNOS .....                               | 27 |
| 1.4.10. Diabetes-Related History – DIAHIST .....                             | 28 |
| 1.4.11. End Of Trial Information – DISPOSIT .....                            | 30 |
| 1.4.12. Electrocardiogram – ECG .....  | 32 |
| 1.4.13. Enrollment – ENROLL .....  | 34 |
| 1.4.14. Exposure – EXPOSURE .....  | 36 |
| 1.4.15. Family History – FAMHIST .....                                       | 38 |
| 1.4.16. Habit – HABIT .....  | 40 |
| 1.4.17. Hematology – HEMAT .....   | 42 |
| 1.4.18. Hospitalisation – HOSPITAL .....                                     | 45 |
| 1.4.19. Drug Intake – INTAKE .....   | 47 |
| 1.4.20. Medical History – MEDHIST .....                                      | 48 |
| 1.4.21. Positive And Negative Syndrome Scale For Schizophrenia – PANSS ..... | 50 |
| 1.4.22. Blood Sampling For Pharmacokinetics – PCCNC .....                    | 52 |
| 1.4.23. Blood Sampling For Pharmacokinetics – PCCONC .....                   | 54 |

|         |   |    |
|---------|---|----|
| 1.4.24. | Pharmacokinetics Sample– PCSAMP .....             | 56 |
| 1.4.25. | Physical Examination – PE.....                    | 58 |
| 1.4.26. | Protdev – PROTDEV .....                           | 60 |
| 1.4.27. | Personal And Social Performance Scale – PSP ..... | 61 |
| 1.4.28. | Psychotic History – PSYHIST .....                 | 63 |
| 1.4.29. | Randomisation – RANDOM.....                       | 65 |
| 1.4.30. | Simpson - Angus Scale – SARS.....                 | 67 |
| 1.4.31. | SQLS-R4 – SQLSR4 .....                            | 69 |
| 1.4.32. | Urine – URINE.....                                | 71 |
| 1.4.33. | Sleep Vas Scale Scores – VAS .....                | 74 |
| 1.4.34. | Visit – VISIT.....                                | 75 |
| 1.4.35. | Vital Signs – VITAL.....                          | 77 |

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|---------------------------|---------------------|-------------------------------|
|                           |                     |                               |
|                           |                     |                               |

## 1. Datasets

### 1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

#### Part I: Dataset description

|                   |                                      |
|-------------------|--------------------------------------|
| Dataset           | Name of dataset                      |
| 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
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- 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.
- Central Lab Specimen Label Number will not be provided.
- Complete missing value variables will be removed.

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's Relative day cannot be calculated.
- Reference number will not be provided.
- COMMENTS dataset will be submitted with zero observations..
- Dataset INVEST containing investigator information will not be submitted.
- Dataset MEDKIT containing information regarding Medical-Kit number will not be submitted.
- SURGERY dataset contains sensitive information regarding surgery. Hence, will not be submitted.
- Labname information will not be submitted (e.g. LBPRVID, LBPRVID, ITPRVID, LBPRVID).
- Dataset does not have any subject level information will not be submitted. (eg. PROTDESC).
- Dataset containing Pharmacogenetic information will not be submitted due to sensitivity of information. (eg. DNRSLT)
- Informed Consent Date will be used as Reference Date to derive relative days.

### 1.3. Data Files

The R076477-SCH305 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 repetition of the information or due to non significant elements:<br>DMSCRDT, SUBJINIT, DMACTDT, IVID, IVNAME, BIRTHDT, DMINFDT, RACESPEC, PAGNUM, COUNTRYC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| VISITNUM | num  | Visit Id                      |       | Collected at CRF.  |
| VISIT    | char | Visit                         |       | Collected at CRF.  |
| DSITEID  | char | Site Assigned for De-identity |       | Randomly assigned Site for De-identity   |
| SEXC     | num  | Sex Code                      |       | Collected at CRF.  |
| SEX      | char | Sex                           |       | Collected at CRF.  |
| RACEC    | num  | Race Code                     |       | Collected at CRF.  |
| RACE     | char | Race                          |       | Collected at CRF.  |
| DCOUNTRY | char | De-identify Country           |       | Element will be grouped to protect PII.  |
| ETHNICC  | num  | Ethnicity Code                |       | Collected at CRF.  |
| ETHNIC   | char | Ethnicity                     |       | Collected at CRF.  |
| AGE      | char | Age in Years                  |       | <p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{floor}((\text{DMINFDT} - \text{DOB})/365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p> |



| Variable | Type | Label                                       | Codes | Comments   |
|----------|------|---|-------|--|
| DMSCRDY  | num  | Relative Day of First Trial<br>Related Proc |       | If DMSCRDT and DMINFDT not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than DMINFDT then (DMSCRDT - DMINFDT).Else if DMSCRDT is greater than equal to DMINFDT then (DMSCRDT- DMINFDT) +1. |
| DMACTDY  | num  | Relative Actual Day of<br>Demography        |       | If DMACTDT and DMINFDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT).Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT- DMINFDT) +1. |

## 1.4.2. Adverse Events – AE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | AE   |
| <b>Creating program</b>  | ae.sas   |
| <b>Description</b>       | Adverse Event  |
| <b>Unique identifier</b> | DUSUBJID, AEBODSCW, AESEQ  |
| <b>Sorted by</b>         | DUSUBJID, AEBODSCW, AESEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:<br>PAGNUM, AETERM, AESTDT, AEENDT, AESTDTC, AEENDTC, AESERREF |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                 | Codes | Comments          |
|----------|------|---------------------------------------|-------|-------------------|
| AEREPRTC | num  | Were Any AEs Reported Code            |       | Collected at CRF. |
| AEREPR   | char | Were Any AEs Reported                 |       | Collected at CRF. |
| AESEQ    | num  | AE Sequence Number                    |       | Collected at CRF. |
| AECTTRC  | 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. |
| AEOUT    | char | Outcome of Event                      |       | Collected at CRF. |
| AERELC   | num  | Relationship to Treatment Code        |       | Collected at CRF. |
| AEREL    | char | Relationship to Treatment             |       | Collected at CRF. |
| AESERC   | num  | Seriousness Criteria Code             |       | Collected at CRF. |
| AESER    | char | Seriousness Criteria                  |       | Collected at CRF. |
| AESEVC   | num  | Severity of Event Code                |       | Collected at CRF. |
| AESEV    | char | Severity of Event                     |       | Collected at CRF. |
| AECONTRC | num  | Concomitant/Additional Treatment Code |       | Collected at CRF. |
| AECONTRT | char | Concomitant/Additional Treatment      |       | Collected at CRF. |
| AEDCOD1W | char | WHO Included Term                     |       | Collected at CRF. |
| AEBODSCW | char | Body System Code                      |       | Collected at CRF. |
| AEBODSYW | char | Body System                           |       | Collected at CRF. |

| Variable | Type | Label                              | Codes | Comments  |
|----------|------|------------------------------------|-------|---|
| AEDICTDM | char | Adverse Events Dictionary          |       | Collected at CRF.   |
| AECODEW  | char | AE Dictionary Code                 |       | Collected at CRF.   |
| AEDECODW | char | WHO Preferred Term                 |       | Collected at CRF.   |
| AECODE   | char | AE Dictionary Code                 |       | Collected at CRF.   |
| SOC1W    | char | AE System Organ Class 1            |       | Collected at CRF.   |
| SOC2W    | char | AE System Organ Class 2            |       | Collected at CRF.   |
| SOC3W    | char | AE System Organ Class 3            |       | Collected at CRF.   |
| AESTDY   | num  | Relative Actual Start Day of Event |       | If AESTDTC and DMINFDT not missing then perform below logic to calculate AESTDY, If AESTDTC less than DMINFDT then (AESTDTC - DMINFDT).Else if AESTDTC is greater than equal to DMINFDT then (AESTDTC- DMINFDT) +1. |
| AEENDY   | num  | Relative Actual End Day of Event   |       | If AEENDTC and DMINFDT not missing then perform below logic to calculate AEENDY, If AEENDTC less than DMINFDT then (AEENDTC - DMINFDT).Else if AEENDTC is greater than equal to DMINFDT then (AEENDTC- DMINFDT) +1. |

## 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,VISIT, AIITEM  |
| <b>Sorted by</b>         | DUSUBJID,VISIT, AIITEM  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements:<br>PAGNUM, AIRATERI, AIACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                       | Codes | Comments   |
|----------|------|-----------------------------|-------|--|
| AIVTYPEC | num  | AIMS Visit Type Code        |       | Collected at CRF.  |
| AIVTYPE  | char | AIMS Visit Type             |       | Collected at CRF.  |
| AIGROUP  | char | AIMS Group                  |       | Collected at CRF.  |
| AIITEM   | char | AIMS Item                   |       | Collected at CRF.  |
| AISCOREC | num  | AIMS Score Code             |       | Collected at CRF.  |
| AISCORE  | char | Score                       |       | Collected at CRF.  |
| AIACTDY  | num  | Relative Actual Day of AIMS |       | If AIACTDT and DMINFDT not missing then perform below logic to calculate AIACTDY, If AIACTDT less than DMINFDT then (AIACTDT - DMINFDT).Else if AIACTDT is greater than equal to DMINFDT then (AIACTDT- DMINFDT) +1. |

## 1.4.4. Barnes Akathisia Rating Scale – BARS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | BARS  |
| <b>Creating program</b>  | bars.sas  |
| <b>Description</b>       | Barnes Akathisia Rating Scale   |
| <b>Unique identifier</b> | DUSUBJID,VISIT,BAGROUP, BAITEM  |
| <b>Sorted by</b>         | DUSUBJID,VISIT,BAGROUP, BAITEM  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements:<br>PAGNUM, BARATERI, BAACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                       | Codes | Comments   |
|----------|------|-----------------------------|-------|--|
| BAVTYPEC | num  | BARS Visit Type Code        |       | Collected at CRF.  |
| BAVTYPE  | char | BARS Visit Type             |       | Collected at CRF.  |
| BAGROUP  | char | BARS Group                  |       | Collected at CRF.  |
| BAITEM   | char | BARS Item                   |       | Collected at CRF.  |
| BASCOREC | num  | BARS Score Code             |       | Collected at CRF.  |
| BASCORE  | char | Score                       |       | Collected at CRF.  |
| BAACTDY  | num  | Relative Actual Day of BARS |       | If BAACTDT and DMINFDT not missing then perform below logic to calculate BAACTDY, If BAACTDT less than DMINFDT then (BAACTDT - DMINFDT).Else if BAACTDT is greater than equal to DMINFDT then (BAACTDT- DMINFDT) +1. |



## 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, VISIT  |
| <b>Sorted by</b>         | DUSUBJID, VISIT  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, CGRATERI, CGACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |

| Variable | Type | Label                      | Codes | Comments   |
|----------|------|----------------------------|-------|--|
| VISIT    | char | Visit                      |       | Collected at CRF.  |
| CGSEVC   | num  | CGI Severity Code          |       | Collected at CRF.  |
| CGSEV    | char | CGI Severity               |       | Collected at CRF.  |
| CGACTDY  | num  | Relative Actual Day of CGI |       | If CGACTDT and DMINFDT not missing then perform below logic to calculate CGACTDY, If CGACTDT less than DMINFDT then (CGACTDT - DMINFDT).Else if CGACTDT is greater than equal to DMINFDT then (CGACTDT- DMINFDT) +1. |

#### 1.4.6. Chemistry – CHEM

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | CHEM  |
| <b>Creating program</b>  | chem.sas  |
| <b>Description</b>       | Chemistry   |
| <b>Unique identifier</b> | DUSUBJID,VISIT,LBVTYP, LBTEST, LBACTDY  |
| <b>Sorted by</b>         | DUSUBJID,VISIT,LBVTYP, LBTEST, LBACTDY  |
| <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: LBPTM, LBFASTC, LBFAST, LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID |

| Variable | Type | Label    | Codes | Comments          |
|----------|------|----------|-------|-------------------|
| STUDYID  | char | Study Id |       | Collected at CRF. |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| STDUNIT  | char | Standard Units                           |       | Collected at CRF.                                   |
| LBVTYPE  | char | Lab Visit Type                           |       | Collected at CRF.                                   |
| LBTYPES  | num  | Lab Type Code                            |       | Collected at CRF.                                   |
| LBCVRES  | num  | Result in Conventional Units             |       | Collected at CRF.                                   |
| LBCVUNIT | char | Conventional Units                       |       | Collected at CRF.                                   |
| LBACTTM  | num  | Actual Time of Lab Sample                |       | Collected at CRF.                                   |
| ORGUNIT  | char | Original Units                           |       | Collected at CRF.                                   |
| LBTESTC  | num  | Lab Test Code                            |       | Collected at CRF.                                   |
| LBVTYPEC | num  | Lab Visit Type Code                      |       | Collected at CRF.                                   |
| LBTMLBL  | char | Pre-determined collection times          |       | Collected at CRF.                                   |
| ORGRESN  | num  | Numeric lab result                       |       | Collected at CRF.                                   |
| ORGRES   | char | Character lab result                     |       | Collected at CRF.                                   |

| Variable | Type | Label                                | Codes | Comments  |
|----------|------|--------------------------------------|-------|---|
| NRIND    | char | High/Low Lab Value Flag              |       | Collected at CRF.   |
| ORGNRHI  | num  | Upper limit for the lab normal range |       | Collected at CRF.   |
| ORGNRLO  | num  | Lower limit for the lab normal range |       | Collected at CRF.   |
| STDNRLO  | num  | S.I. lower limit                     |       | Collected at CRF.   |
| STDRESN  | num  | S.I. numeric result                  |       | Collected at CRF.   |
| STDNRHI  | num  | S.I. upper limit                     |       | Collected at CRF.   |
| LAGE     | char | Age: time of visit                   |       | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules. |
| LAGEUNIT | char | Age Unit (M or Y)                    |       | Collected at CRF.   |
| LBSEQ    | num  | RSM unique record id within protocol |       | Collected at CRF.   |
| LBSIFACT | num  | Std. Intl. Conversion Factor         |       | Collected at CRF.   |
| LBTEST   | char | Lab Test Name                        |       | Collected at CRF.   |
| LBDESCR  | char | Full Test Description                |       | Collected at CRF.   |
| LBTYPE   | char | Lab Type                             |       | Collected at CRF.   |
| LBABBR   | char | Lab Abbreviation                     |       | Collected at CRF.   |
| LBSIGLO  | num  | Significant Range Low                |       | Collected at CRF.   |

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| LBSIGHI  | num  | Significant Range High        |       | Collected at CRF.  |
| LBACTDY  | num  | Relative Actual Day of Sample |       | If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, if LBACTDT less than DMINFDT then (LBACTDT - DMINFDT).Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1. |

#### 1.4.7. 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. Empty dataset will be submitted. |

| Variable | Type | Label                                    | Codes | Comments                      |
|----------|------|--|-------|-------------------------------|
| STUDYID  | char | Study Id                                 |       | Empty data will be submitted. |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Empty data will be submitted. |

| Variable | Type | Label                                   | Codes | Comments                      |
|----------|------|---|-------|-------------------------------|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Empty data will be submitted. |
| DSITEID  | char | Site Assigned for De-identity           |       | Empty data will be submitted. |
| PHASENUM | num  | Phase Number                            |       | Empty data will be submitted. |
| PHASE    | char | Phase                                   |       | Empty data will be submitted. |
| VISITNUM | num  | Visit Id                                |       | Empty data will be submitted. |
| VISIT    | char | Visit                                   |       | Empty data will be submitted. |
| CTSEQ    | num  | Comment Sequence Number                 |       | Empty data will be submitted. |
| DOMAIN   | char | Domain of Origin                        |       | Empty data will be submitted. |

## 1.4.8. Concomitant Drug/Therapy – CONMED

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | CONMED   |
| <b>Creating program</b>  | conmed.sas   |
| <b>Description</b>       | Concomitant Drug/Therapy   |
| <b>Unique identifier</b> | DUSUBJID,VISIT,CMGROUP,CMCLASCO,CMSTDY, CMSEQ  |
| <b>Sorted by</b>         | DUSUBJID,VISIT,CMGROUP,CMCLASCO,CMSTDY, CMSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values:<br>PAGNUM, CMCLASC, AESEQ, CMSTDY, CMTERM, CMREAS, CMENDT, CMREGIM, CMSTDTC, CMENDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable  | Type | Label                                   | Codes | Comments          |
|-----------|------|---|-------|-------------------|
| CMREPRTC  | num  | Were Any Meds Administered/Changed Code |       | Collected at CRF. |
| CMGROU PC | num  | Medication Grouping Code                |       | Collected at CRF. |
| CMTYPEC   | num  | Prior/Concomitant Medication Code       |       | Collected at CRF. |
| CMREPR T  | char | Were Any Meds Administered/Changed      |       | Collected at CRF. |
| CMGROUP   | char | Medication Grouping                     |       | Collected at CRF. |
| CMTYPE    | char | Prior/Concomitant Medication            |       | Collected at CRF. |
| CMSEQ     | num  | Conmed Sequence Number                  |       | Collected at CRF. |
| CMDECOD1  | char | Medication Specified Term               |       | Collected at CRF. |
| CMROUTE   | char | Route                                   |       | Collected at CRF. |
| CMCONT C  | num  | Medication Continuing Code              |       | Collected at CRF. |
| CMCONT    | char | Medication Continuing                   |       | Collected at CRF. |
| CMPRIOR C | num  | Med Started Prior to Trial Code         |       | Collected at CRF. |
| CMPRIOR   | char | Med Started Prior to Trial              |       | Collected at CRF. |
| CMCAUS C  | num  | Cause of Concom/Drug/Therapy Code       |       | Collected at CRF. |
| CMCAUS    | char | Cause of Concom/Drug/Therapy            |       | Collected at CRF. |
| CMDOSE    | num  | Dosage                                  |       | Collected at CRF. |



| Variable | Type | Label      | Codes | Comments          |
|----------|------|------------|-------|-------------------|
| CMUNIT   | char | Dose Unit  |       | Collected at CRF. |
| CMCLASC0 | char | ATC Code 0 |       | Collected at CRF. |
| CMCLASC1 | char | ATC Code 1 |       | Collected at CRF. |
| CMCLASC2 | char | ATC Code 2 |       | Collected at CRF. |
| CMCLASC3 | char | ATC Code 3 |       | Collected at CRF. |
| CMCLASC4 | char | ATC Code 4 |       | Collected at CRF. |
| CMCLASC5 | char | ATC Code 5 |       | Collected at CRF. |
| CMCLASC6 | char | ATC Code 6 |       | Collected at CRF. |
| CMCLASC7 | char | ATC Code 7 |       | Collected at CRF. |
| CMCLASC8 | char | ATC Code 8 |       | Collected at CRF. |
| CMCLASC9 | char | ATC Code 9 |       | Collected at CRF. |
| CMCLAS0  | char | ATC Text 0 |       | Collected at CRF. |
| CMCLAS1  | char | ATC Text 1 |       | Collected at CRF. |
| CMCLAS2  | char | ATC Text 2 |       | Collected at CRF. |
| CMCLAS3  | char | ATC Text 3 |       | Collected at CRF. |
| CMCLAS4  | char | ATC Text 4 |       | Collected at CRF. |
| CMCLAS5  | char | ATC Text 5 |       | Collected at CRF. |
| CMCLAS6  | char | ATC Text 6 |       | Collected at CRF. |
| CMCLAS7  | char | ATC Text 7 |       | Collected at CRF. |
| CMCLAS8  | char | ATC Text 8 |       | Collected at CRF. |
| CMCLAS9  | char | ATC Text 9 |       | Collected at CRF. |

| Variable | Type | Label                                   | Codes | Comments  |
|----------|------|---|-------|---|
| CMCODE   | char | Medication Dictionary Code              |       | Collected at CRF.   |
| CMDECOD  | char | Medication Generic Term                 |       | Collected at CRF.   |
| CMCLAS   | char | ATC Text                                |       | Collected at CRF.   |
| CMSTDY   | num  | Relative Actual Start Day of Medication |       | If CMSTDTC and DMINFDT not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than DMINFDT then (CMSTDTC - DMINFDT).Else if CMSTDTC is greater than equal to DMINFDT then (CMSTDTC- DMINFDT) +1. |
| CMENDY   | num  | Relative Actual End Day of Medication   |       | If CMENDTC and DMINFDT not missing then perform below logic to calculate CMENDY, If CMENDTC less than DMINFDT then (CMENDTC - DMINFDT).Else if CMENDTC is greater than equal to DMINFDT then (CMENDTC- DMINFDT) +1. |

## 1.4.9. Schizophrenia Diagnosis – DIAGNOS

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | DIAGNOS   |
| <b>Creating program</b>  | diagnos.sas   |
| <b>Description</b>       | Diagnosis   |
| <b>Unique identifier</b> | DUSUBJID  |
| <b>Sorted by</b>         | DUSUBJID  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| DGTYPEC  | num  | Schizophrenia Type Code                  |       | Collected at CRF.                                   |

| Variable | Type | Label                             | Codes | Comments  |
|----------|------|-----------------------------------|-------|---|
| DGTYPE   | char | Schizophrenia Type                |       | Collected at CRF.   |
| DIAGNOSC | num  | Diagnosis Code                    |       | Collected at CRF.   |
| DIAGNOS  | char | Diagnosis                         |       | Collected at CRF.   |
| DGAGE    | char | Age at Diagnosis of Schizophrenia |       | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules. |

#### 1.4.10. Diabetes-Related History – DIAHIST

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | DIAHIST  |
| <b>Creating program</b>  | diahist.sas  |
| <b>Description</b>       | Diagnosis History  |
| <b>Unique identifier</b> | DUSUBJID, DHDIAG   |
| <b>Sorted by</b>         | DUSUBJID, DHDIAG   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, DHACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity   |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity   |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.  |
| PHASE    | char | Phase                                    |       | Collected at CRF.  |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.  |
| VISIT    | char | Visit                                    |       | Collected at CRF.  |
| DHCHILD  | num  | Number of Children Born Weight >10 lbs   |       | Collected at CRF.  |
| DHDIAG   | char | Diagnosis                                |       | Collected at CRF.  |
| DHHISTC  | num  | Diabetes History Code                    |       | Collected at CRF.  |
| DHHIST   | char | Diabetes History                         |       | Collected at CRF.  |
| DHAGE    | char | Age at Diagnosis                         |       | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.  |
| DHACTDY  | num  | Relative Actual Day of Diabetes Rel Hist |       | If DHACTDT and DMINFDT not missing then perform below logic to calculate DHACTDY, If DHACTDT less than DMINFDT then (DHACTDT - DMINFDT).Else if DHACTDT is greater than equal to DMINFDT then (DHACTDT- DMINFDT) +1. |

## 1.4.11. End Of Trial Information – DISPOSIT

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | DISPOSIT   |
| <b>Creating program</b>  | disposit.sas   |
| <b>Description</b>       | Disposition  |
| <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 non significant elements or due to missing values: PAGNUM, DEATHDT, PREGDUDT, DSACTDT, DSRSOOTH, DSRABKDT, DSRABKRS, DSRABKTM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DSTYPEC  | num  | End of Treatment or Trial Code           |       | Collected at CRF.  |
| DSTYPE   | char | End of Treatment or Trial                |       | Collected at CRF.  |
| DSREASC  | num  | Reason for Withdrawal/Termination Code   |       | Collected at CRF.  |
| DSREAS   | char | Reason for Withdrawal/Termination        |       | Collected at CRF.  |
| DSSTATC  | num  | Subject Completed Treatment/Trial Code   |       | Collected at CRF.  |
| DSSTAT   | char | Subject Completed Treatment/Trial        |       | Collected at CRF.  |
| DSOLC    | num  | Continue into Open Label Code            |       | Collected at CRF.  |
| DSOL     | char | Continue into Open Label                 |       | Collected at CRF.  |
| DSSCRNC  | num  | Screen Failure Code                      |       | Collected at CRF.  |
| DSSCRN   | char | Screen Failure                           |       | Collected at CRF.  |
| AESEQ    | num  | AE Sequence Number                       |       | Collected at CRF.  |
| DSACTDY  | num  | Relative Actual Day Trial Compl/Withdraw |       | If DSACTDT and DMINFDT not missing then perform below logic to calculate DSACTDY, If DSACTDT less than DMINFDT then (DSACTDT - DMINFDT).Else if DSACTDT is greater than equal to DMINFDT then (DSACTDT- DMINFDT) +1. |

## 1.4.12. Electrocardiogram – ECG

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | ECG  |
| <b>Creating program</b>  | ecg.sas  |
| <b>Description</b>       | Electrocardiogram  |
| <b>Unique identifier</b> | DUSUBJID,VISIT,EGTESTCD,EGDY, EGSEQ  |
| <b>Sorted by</b>         | DUSUBJID,VISIT,EGTESTCD,EGDY, EGSEQ  |
| <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: EGPOS, EGND, EGCHGC, EGCHG, EGINTOTH, EGCHGOTH, EGREF, EGDT, EGPRVIDC, EGPRVID, BATCHID |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |



| Variable | Type | Label                            | Codes | Comments          |
|----------|------|----------------------------------|-------|-------------------|
| EGTESTCD | char | ECG Test Short Name              |       | Collected at CRF. |
| EGPTMNUM | num  | Label of Planned Elapsed Time    |       | Collected at CRF. |
| EGPTM    | char | Planned Elapsed Time of ECG      |       | Collected at CRF. |
| EGACTTM  | num  | Actual Time of ECG               |       | Collected at CRF. |
| EGQUAL   | char | Qualifier                        |       | Collected at CRF. |
| EGTEST   | char | ECG Test                         |       | Collected at CRF. |
| EGSTRESN | num  | Result Numeric in Standard Units |       | Collected at CRF. |
| EGSTUNIT | char | Standard Units                   |       | Collected at CRF. |
| EGSTRESC | char | Result Character                 |       | Collected at CRF. |
| EGORRESN | num  | Result Numeric in Original Units |       | Collected at CRF. |
| EGORUNIT | char | Original Units                   |       | Collected at CRF. |
| EGINTPC  | num  | Interpretation Code              |       | Collected at CRF. |
| EGINTP   | char | Interpretation                   |       | Collected at CRF. |
| EGLEAD   | char | Lead Used for Measurement        |       | Collected at CRF. |
| EGSEQ    | num  | ECG Sequence Number              |       | Collected at CRF. |
| EGREADC  | num  | ECG Reader Code                  |       | Collected at CRF. |
| EGREAD   | char | ECG Reader                       |       | Collected at CRF. |
| EGVTYPEC | num  | ECG Visit Type Code              |       | Collected at CRF. |
| EGVTYPE  | char | ECG Visit Type                   |       | Collected at CRF. |

| Variable | Type | Label                      | Codes | Comments  |
|----------|------|----------------------------|-------|---|
| MDS_CODE | char | MDS CODE                   |       | Collected at CRF.   |
| EGDY     | num  | Relative Actual Day of ECG |       | If EGDT and DMINFDT not missing then perform below logic to calculate EGDY, If EGDT less than DMINFDT then (EGDT - DMINFDT).Else if EGDT is greater than equal to DMINFDT then (EGDT - DMINFDT) +1. |

#### 1.4.13. Enrollment – ENROLL

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | ENROLL   |
| <b>Creating program</b>  | enroll.sas   |
| <b>Description</b>       | Enrollment   |
| <b>Unique identifier</b> | DUSUBJID, ENTEXT   |
| <b>Sorted by</b>         | DUSUBJID, ENTEXT   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, ENACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject Number for De-identity   |
| DSITEID  | char | Site Assigned for De-identity           |       | Randomly assigned Site for De-identity   |
| PHASENUM | num  | Phase Number                            |       | Collected at CRF.  |
| PHASE    | char | Phase                                   |       | Collected at CRF.  |
| VISITNUM | num  | Visit Id                                |       | Collected at CRF.  |
| VISIT    | char | Visit                                   |       | Collected at CRF.  |
| ENCRIT   | char | Inclusion or Exclusion Criterion        |       | Collected at CRF.  |
| ENSEQ    | num  | Criterion Sequence Number               |       | Collected at CRF.  |
| ENCRESC  | num  | Criterion Result Code                   |       | Collected at CRF.  |
| ENCRES   | char | Criterion Result                        |       | Collected at CRF.  |
| ENTEXT   | char | Criterion Text                          |       | Collected at CRF.  |
| ENACTDY  | num  | Relative Actual Day of Enrollment       |       | If ENACTDT and DMINFDT not missing then perform below logic to calculate ENACTDY, If ENACTDT less than DMINFDT then (ENACTDT - DMINFDT).Else if ENACTDT is greater than equal to DMINFDT then (ENACTDT- DMINFDT) +1. |

## 1.4.14. Exposure – EXPOSURE

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | EXPOSURE  |
| <b>Creating program</b>  | exposure.sas  |
| <b>Description</b>       | Exposure  |
| <b>Unique identifier</b> | DUSUBJID, EXSTDY  |
| <b>Sorted by</b>         | DUSUBJID, EXSTDY  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, EXSTRDT, EXENDDT, EXSTDT, EXENDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| EXSEQ    | num  | Exposure Sequence Number                 |       | Collected at CRF.                                   |

| Variable | Type | Label   | Codes | Comments   |
|----------|------|---|-------|--|
| EXGIVENA | num  | Number of A Capsules Taken                      |       | Collected at CRF.  |
| EXGIVENB | num  | Number of B Capsules Taken                      |       | Collected at CRF.  |
| EXGIVENC | num  | Number of C Capsules Taken                      |       | Collected at CRF.  |
| EXSTRDY  | num  | Relative Start Day of Med. Taken from W1 Medkit |       | If EXSTRDT and DMINFDT not missing then perform below logic to calculate EXSTRDY, If EXSTRDT less than DMINFDT then (EXSTRDT - DMINFDT).Else if EXSTRDT is greater than equal to DMINFDT then (EXSTRDT- DMINFDT) +1. |
| EXENDDY  | num  | Relative End Day of Med. Taken from W1 Medkit   |       | If EXENDDT and DMINFDT not missing then perform below logic to calculate EXENDDY, If EXENDDT less than DMINFDT then (EXENDDT - DMINFDT).Else if EXENDDT is greater than equal to DMINFDT then (EXENDDT- DMINFDT) +1. |
| EXSTDY   | num  | Relative Start Day of Exposure                  |       | If EXSTDY and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDY less than DMINFDT then (EXSTDY - DMINFDT).Else if EXSTDY is greater than equal to DMINFDT then (EXSTDY- DMINFDT) +1.       |
| EXENDY   | num  | Relative End Day of Exposure                    |       | If EXENDY and DMINFDT not missing then perform below logic to calculate EXENDY, If EXENDY less than DMINFDT then (EXENDY - DMINFDT).Else if EXENDY is greater than equal to DMINFDT then (EXENDY- DMINFDT) +1.       |

## 1.4.15. Family History – FAMHIST

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | FAMHIST  |
| <b>Creating program</b>  | famhist.sas  |
| <b>Description</b>       | Family History   |
| <b>Unique identifier</b> | DUSUBJID, FHMEM  |
| <b>Sorted by</b>         | DUSUBJID, FHMEM  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, FFACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                              | Codes | Comments   |
|----------|------|------------------------------------|-------|--|
| FHHISTC  | num  | Relatives History of Diabetes Code |       | Collected at CRF.  |
| FHHIST   | char | Relatives History of Diabetes      |       | Collected at CRF.  |
| FHMEM    | char | Family Member                      |       | Collected at CRF.  |
| FHDTYPE  | char | Diabetes Types                     |       | Collected at CRF.  |
| FHACTDY  | num  | Relative Actual Day of Collection  |       | If FHACTDT and DMINFDT not missing then perform below logic to calculate FHACTDY, If FHACTDT less than DMINFDT then (FHACTDT - DMINFDT).Else if FHACTDT is greater than equal to DMINFDT then (FHACTDT- DMINFDT) +1. |

## 1.4.16. Habit – HABIT

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | HABIT   |
| <b>Creating program</b>  | habit.sas   |
| <b>Description</b>       | Habit   |
| <b>Unique identifier</b> | DUSUBJID  |
| <b>Sorted by</b>         | DUSUBJID  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, HAACTDT, HAENDTC |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |



| Variable | Type | Label                               | Codes | Comments   |
|----------|------|-------------------------------------|-------|--|
| HASMOCUC | num  | Does Subject Currently Smoke Code   |       | Collected at CRF.  |
| HASMOCU  | char | Does Subject Currently Smoke        |       | Collected at CRF.  |
| HACGTNUM | num  | Number of Cigarettes                |       | Collected at CRF.  |
| HACGRNUM | num  | Number of Cigars                    |       | Collected at CRF.  |
| HAPIPNUM | num  | Number of Pipes                     |       | Collected at CRF.  |
| HASMOPSC | num  | Has Subject Smoked in the Past Code |       | Collected at CRF.  |
| HASMOPS  | char | Has Subject Smoked in the Past      |       | Collected at CRF.  |
| HAYEAR   | num  | Number of Years Subject Has Smoked  |       | Collected at CRF.  |
| HAACTDY  | num  | Relative Actual Day of Collection   |       | If HAACTDT and DMINFDT not missing then perform below logic to calculate HAACTDY, If HAACTDT less than DMINFDT then (HAACTDT - DMINFDT).Else if HAACTDT is greater than equal to DMINFDT then (HAACTDT- DMINFDT) +1. |

## 1.4.17. Hematology – HEMAT

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | HEMAT  |
| <b>Creating program</b>  | hemat.sas  |
| <b>Description</b>       | Hematology   |
| <b>Unique identifier</b> | DUSUBJID,VISIT,LBVTYPE, LBTEST   |
| <b>Sorted by</b>         | DUSUBJID,VISIT,LBVTYPE, LBTEST   |
| <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: LBPTM, LBFASTC, LBFAST, LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID, LBSEQ |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                | Codes | Comments          |
|----------|------|--------------------------------------|-------|-------------------|
| STDUNIT  | char | Standard Units                       |       | Collected at CRF. |
| LBVTYPE  | char | Lab Visit Type                       |       | Collected at CRF. |
| LBTYPEC  | num  | Lab Type Code                        |       | Collected at CRF. |
| LBCVRES  | num  | Result in Conventional Units         |       | Collected at CRF. |
| LBCVUNIT | char | Conventional Units                   |       | Collected at CRF. |
| LBACTTM  | num  | Actual Time of Lab Sample            |       | Collected at CRF. |
| ORGUNIT  | char | Original Units                       |       | Collected at CRF. |
| LBTESTC  | num  | Lab Test Code                        |       | Collected at CRF. |
| LBVTYPEC | num  | Lab Visit Type Code                  |       | Collected at CRF. |
| LBTMLBL  | char | Pre-determined collection times      |       | Collected at CRF. |
| ORGRESN  | num  | Numeric lab result                   |       | Collected at CRF. |
| ORGRES   | char | Character lab result                 |       | Collected at CRF. |
| NRIND    | char | High/Low Lab Value Flag              |       | Collected at CRF. |
| ORGNRHI  | num  | Upper limit for the lab normal range |       | Collected at CRF. |
| ORGNRLO  | num  | Lower limit for the lab normal range |       | Collected at CRF. |
| STDNRLO  | num  | S.I. lower limit                     |       | Collected at CRF. |
| STDRESN  | num  | S.I. numeric result                  |       | Collected at CRF. |
| STDNRHI  | num  | S.I. upper limit                     |       | Collected at CRF. |

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| LAGE     | char | Age: time of visit            |       | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.  |
| LAGEUNIT | char | Age Unit (M or Y)             |       | Collected at CRF.  |
| LBSIFACT | num  | Std. Intl. Conversion Factor  |       | Collected at CRF.  |
| LBTEST   | char | Lab Test Name                 |       | Collected at CRF.  |
| LBDESCR  | char | Full Test Description         |       | Collected at CRF.  |
| LBTYPE   | char | Lab Type                      |       | Collected at CRF.  |
| LBABBR   | char | Lab Abbreviation              |       | Collected at CRF.  |
| LBSIGLO  | num  | Significant Range Low         |       | Collected at CRF.  |
| LBSIGHI  | num  | Significant Range High        |       | Collected at CRF.  |
| LBACTDY  | num  | Relative Actual Day of Sample |       | If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT).Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1. |

## 1.4.18. Hospitalisation – HOSPITAL

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | HOSPITAL  |
| <b>Creating program</b>  | hospital.sas  |
| <b>Description</b>       | Hospitalisation   |
| <b>Unique identifier</b> | DUSUBJID  |
| <b>Sorted by</b>         | DUSUBJID  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, HOSTDT, HOENDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                     | Codes | Comments   |
|----------|------|---|-------|--|
| HODISCHC | num  | Was the Subject Discharged Code           |       | Collected at CRF.  |
| HODISCH  | char | Was the Subject Discharged                |       | Collected at CRF.  |
| HOSTDY   | num  | Relative Admission Day of Hospitalization |       | If HOSTDT and DMINFDT not missing then perform below logic to calculate HOSTDY, If HOSTDT less than DMINFDT then (HOSTDT - DMINFDT).Else if HOSTDT is greater than equal to DMINFDT then (HOSTDT- DMINFDT) +1. |
| HOENDY   | num  | Relative Discharge Day                    |       | If HOENDT and DMINFDT not missing then perform below logic to calculate HOENDY, If HOENDT less than DMINFDT then (HOENDT - DMINFDT).Else if HOENDT is greater than equal to DMINFDT then (HOENDT- DMINFDT) +1. |

## 1.4.19. Drug Intake – INTAKE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | INTAKE   |
| <b>Creating program</b>  | intake.sas   |
| <b>Description</b>       | Drug Intake  |
| <b>Unique identifier</b> | DUSUBJID,VISIT,ITTYPE, ITACTDY   |
| <b>Sorted by</b>         | DUSUBJID,VISIT,ITTYPE, ITACTDY   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ACQREF, ITACTDT, ITPRVIDC, ITPRVID |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| ITTYPE   | char | Intake Type                              |       | Collected at CRF.                                   |

| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| ITACTTM  | num  | Actual Time of Intake         |       | Collected at CRF.  |
| ITACTDY  | num  | Relative Actual Day of Intake |       | If ITACTDT and DMINFDT not missing then perform below logic to calculate ITACTDY, If ITACTDT less than DMINFDT then (ITACTDT - DMINFDT).Else if ITACTDT is greater than equal to DMINFDT then (ITACTDT- DMINFDT) +1. |

#### 1.4.20. Medical History – MEDHIST

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | MEDHIST  |
| <b>Creating program</b>  | medhist.sas  |
| <b>Description</b>       | Medical History  |
| <b>Unique identifier</b> | DUSUBJID,MHBODSYS, MHSEQ   |
| <b>Sorted by</b>         | DUSUBJID,MHBODSYS, MHSEQ   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, MHTERM, MHACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |



| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject Number for De-identity   |
| DSITEID  | char | Site Assigned for De-identity           |       | Randomly assigned Site for De-identity   |
| PHASENUM | num  | Phase Number                            |       | Collected at CRF.  |
| PHASE    | char | Phase                                   |       | Collected at CRF.  |
| VISITNUM | num  | Visit Id                                |       | Collected at CRF.  |
| VISIT    | char | Visit                                   |       | Collected at CRF.  |
| MHSEQ    | num  | MH Sequence Number                      |       | Collected at CRF.  |
| MHBODSYC | num  | Body System Code                        |       | Collected at CRF.  |
| MHBODSYS | char | Body System                             |       | Collected at CRF.  |
| MHSTATC  | num  | Condition Code                          |       | Collected at CRF.  |
| MHSTAT   | char | Condition                               |       | Collected at CRF.  |
| MHACTDY  | num  | Relative Actual Day of Collection       |       | If MHACTDT and DMINFDT not missing then perform below logic to calculate MHACTDY, If MHACTDT less than DMINFDT then (MHACTDT - DMINFDT).Else if MHACTDT is greater than equal to DMINFDT then (MHACTDT- DMINFDT) +1. |

## 1.4.21. Positive And Negative Syndrome Scale For Schizophrenia – PANSS

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | PANSS  |
| <b>Creating program</b>  | panss.sas  |
| <b>Description</b>       | Positive And Negative Syndrome Scale For Schizophrenia   |
| <b>Unique identifier</b> | DUSUBJID,VISIT, PAITEM   |
| <b>Sorted by</b>         | DUSUBJID,VISIT, PAITEM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, PARATERI, PAACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                        | Codes | Comments   |
|----------|------|------------------------------|-------|--|
| PAGROUP  | char | PANSS Group                  |       | Collected at CRF.  |
| PAITEM   | char | PANSS Item                   |       | Collected at CRF.  |
| PASCOREC | num  | PANSS Score Code             |       | Collected at CRF.  |
| PASCORE  | char | PANSS Score                  |       | Collected at CRF.  |
| PAACTDY  | num  | Relative Actual Day of PANSS |       | If PAACTDT and DMINFDT not missing then perform below logic to calculate PAACTDY, If PAACTDT less than DMINFDT then (PAACTDT - DMINFDT).Else if PAACTDT is greater than equal to DMINFDT then (PAACTDT- DMINFDT) +1. |

## 1.4.22. Blood Sampling For Pharmacokinetics – PCCNC

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | PCCNC  |
| <b>Creating program</b>  | pccnc.sas  |
| <b>Description</b>       | Blood Sampling For Pharmacokinetics  |
| <b>Unique identifier</b> | DUSUBJID, VISIT  |
| <b>Sorted by</b>         | DUSUBJID, VISIT  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values:<br>PAGNUM, PCSTRESC, PCSTUNIT, PCSTRESN, PCENDT, PCNRLO, PCNRHI, PCENTM, PCREAS, PCRSOTH, PCSTDT, PCPRVIDC, PCPRVID, ACQREF, SAMREF, PCLBREF, PCSCOM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                    | Codes | Comments          |
|----------|------|--|-------|-------------------|
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF. |
| VISIT    | char | Visit                                    |       | Collected at CRF. |
| TPT      | char | Planned Timepoint Name                   |       | Collected at CRF. |
| TPTNUM   | num  | Planned Timepoint                        |       | Collected at CRF. |
| PCSTTM   | num  | Start Time of Collection (24hr clock)    |       | Collected at CRF. |
| PCSPEC   | char | Specimen Material                        |       | Collected at CRF. |
| SAMMAT   | char | Sample Material                          |       | Collected at CRF. |
| SPPRVIDC | num  | Sample Provider ID Code                  |       | Collected at CRF. |
| SPPRVID  | char | Sample Provider ID                       |       | Collected at CRF. |
| PCSEQ    | num  | Sample Sequence Number                   |       | Collected at CRF. |
| PCTEST   | char | Test Name                                |       | Collected at CRF. |
| PCORRES  | char | Result in Original Units                 |       | Collected at CRF. |
| PCORUNIT | char | Original Unit                            |       | Collected at CRF. |
| PCORRESN | num  | Analysis numeric Result in Original Unit |       | Collected at CRF. |
| PCLOQ    | char | Limit of Quantification                  |       | Collected at CRF. |
| PCPRMTYP | char | Parameter Type                           |       | Collected at CRF. |
| PCVTYPEC | num  | PK/PD Sample Visit Type Code             |       | Collected at CRF. |
| PCVTYPE  | char | PK/PD Sample Visit Type                  |       | Collected at CRF. |
| PCCAT    | char | Category for Test or Examination         |       | Collected at CRF. |

| Variable | Type | Label                                     | Codes | Comments   |
|----------|------|---|-------|--|
| PCTAKENC | num  | Was Sample Taken Code                     |       | Collected at CRF.  |
| PCTAKEN  | char | Was Sample Taken                          |       | Collected at CRF.  |
| PCSTDY   | num  | Relative Start Day of Specimen Collection |       | If PCSTDT and DMINFDT not missing then perform below logic to calculate PCSTDY, If PCSTDT less than DMINFDT then (PCSTDT - DMINFDT).Else if PCSTDT is greater than equal to DMINFDT then (PCSTDT- DMINFDT) +1. |

#### 1.4.23. Blood Sampling For Pharmacokinetics– PCCONC

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PCCONC  |
| <b>Creating program</b>  | pcconc.sas  |
| <b>Description</b>       | Blood Sampling For Pharmacokinetics   |
| <b>Unique identifier</b> | DUSUBJID, VISIT   |
| <b>Sorted by</b>         | DUSUBJID, VISIT   |
| <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: PCSTRESC, PCSTUNIT, PCSTRESN, PCNRLO, PCNRHI, PCPRVIDC, PCPRVID, SAMREF, PCLBREF |

| Variable | Type | Label    | Codes | Comments          |
|----------|------|----------|-------|-------------------|
| STUDYID  | char | Study Id |       | Collected at CRF. |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| PCSEQ    | num  | Sample Sequence Number                   |       | Collected at CRF.                                   |
| TPTNUM   | num  | Planned Timepoint Number                 |       | Collected at CRF.                                   |
| TPT      | char | Planned Timepoint Name                   |       | Collected at CRF.                                   |
| PCPRMTYP | char | Parameter Type                           |       | Collected at CRF.                                   |
| SAMMAT   | char | Sample Material                          |       | Collected at CRF.                                   |
| PCSPEC   | char | Specimen Material                        |       | Collected at CRF.                                   |
| PCTEST   | char | Test Name                                |       | Collected at CRF.                                   |
| PCORRES  | char | Result in Original Units                 |       | Collected at CRF.                                   |
| PCORUNIT | char | Original Unit                            |       | Collected at CRF.                                   |
| PCORRESN | num  | Analysis numeric Result in Original Unit |       | Collected at CRF.                                   |

| Variable | Type | Label                            | Codes | Comments          |
|----------|------|----------------------------------|-------|-------------------|
| PCLOQ    | char | Limit of Quantification          |       | Collected at CRF. |
| PCCAT    | char | Category for Test or Examination |       | Collected at CRF. |

#### 1.4.24. Pharmacokinetics Sample– PCSAMP

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | PCSAMP  |
| <b>Creating program</b>  | pcsamp.sas  |
| <b>Description</b>       | Pharmacokinetics Sample   |
| <b>Unique identifier</b> | DUSUBJID, VISIT   |
| <b>Sorted by</b>         | DUSUBJID, VISIT   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAGNUM, SPENDT, SPENTM, SPREAS, SPRSOTH, SPSTDT, SPPRVIDC, SPPRVID, SAMREF, ACQREF, SPCOM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |



| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject Number for De-identity |
| DSITEID  | char | Site Assigned for De-identity           |       | Randomly assigned Site for De-identity           |
| PHASENUM | num  | Phase Number                            |       | Collected at CRF.                                |
| PHASE    | char | Phase                                   |       | Collected at CRF.                                |
| VISITNUM | num  | Visit Id                                |       | Collected at CRF.                                |
| VISIT    | char | Visit                                   |       | Collected at CRF.                                |
| SAMSEQ   | num  | Sample Sequence Number                  |       | Collected at CRF.                                |
| SPTAKENC | num  | Was Sample Taken Code?                  |       | Collected at CRF.                                |
| SPTAKEN  | char | Was Sample Taken ?                      |       | Collected at CRF.                                |
| TPTNUM   | num  | Planned Timepoint Number                |       | Collected at CRF.                                |
| TPT      | char | Planned Time Point Name                 |       | Collected at CRF.                                |
| SAMMAT   | char | Sample Material                         |       | Collected at CRF.                                |
| SPSTTM   | num  | Start Time of Collection (24 hr clock)  |       | Collected at CRF.                                |
| SPVTYPEC | num  | PK/PD Sample Visit Type Code            |       | Collected at CRF.                                |
| SPVTYPE  | char | PK/PD Sample Visit Type                 |       | Collected at CRF.                                |

| Variable | Type | Label                                     | Codes | Comments   |
|----------|------|---|-------|--|
| SPCAT    | char | Category for Test or Examination          |       | Collected at CRF.  |
| SPSTDY   | num  | Relative Start Day of Specimen Collection |       | If SPSTDT and DMINFDT not missing then perform below logic to calculate SPSTDY, If SPSTDT less than DMINFDT then (SPSTDT - DMINFDT).Else if SPSTDT is greater than equal to DMINFDT then (SPSTDT- DMINFDT) +1. |

#### 1.4.25. Physical Examination – PE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | PE   |
| <b>Creating program</b>  | pe.sas   |
| <b>Description</b>       | Physical Examination   |
| <b>Unique identifier</b> | DUSUBJID,VISIT,PEBODSYS, PESEQ   |
| <b>Sorted by</b>         | DUSUBJID,VISIT,PEBODSYS, PESEQ   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, PEFIND, PEACTDT |

| Variable | Type | Label    | Codes | Comments          |
|----------|------|----------|-------|-------------------|
| STUDYID  | char | Study Id |       | Collected at CRF. |

| Variable | Type | Label                                    | Codes | Comments   |
|----------|------|--|-------|--|
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity  |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity   |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity   |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.  |
| PHASE    | char | Phase                                    |       | Collected at CRF.  |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.  |
| VISIT    | char | Visit                                    |       | Collected at CRF.  |
| PESEQ    | num  | Phys Sequence Number                     |       | Collected at CRF.  |
| PEBODSYC | num  | Body System Code                         |       | Collected at CRF.  |
| PEBODSYS | char | Body System                              |       | Collected at CRF.  |
| PESTATC  | num  | Exam Result Code                         |       | Collected at CRF.  |
| PESTAT   | char | Exam Result                              |       | Collected at CRF.  |
| PEACTDY  | num  | Relative Actual Day of Phys Exam         |       | If PEACTION and DMINFDT not missing then perform below logic to calculate PEACTIONDY, If PEACTIONDT less than DMINFDT then (PEACTIONDT - DMINFDT).Else if PEACTIONDT is greater than equal to DMINFDT then (PEACTIONDT- DMINFDT) +1. |

## 1.4.26. Protdev – PROTDEV

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | PROTDEV  |
| <b>Creating program</b>  | protdev.sas  |
| <b>Description</b>       | Protdev  |
| <b>Unique identifier</b> | DUSUBJID,PVDECOD, PVSEQ  |
| <b>Sorted by</b>         | DUSUBJID,PVDECOD, PVSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PVTERM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                         | Codes | Comments          |
|----------|------|-------------------------------|-------|-------------------|
| PVSEQ    | num  | Protocol Deviation Seq Number |       | Collected at CRF. |
| PVDECOD  | char | Protocol Deviation Coded Term |       | Collected at CRF. |

#### 1.4.27. Personal And Social Performance Scale – PSP

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | PSP  |
| <b>Creating program</b>  | psp.sas  |
| <b>Description</b>       | Personal And Social Performance Scale  |
| <b>Unique identifier</b> | DUSUBJID,VISIT, PASACTDY   |
| <b>Sorted by</b>         | DUSUBJID,VISIT, PASACTDY   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, PSRATERI, PSACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject Number for De-identity   |
| DSITEID  | char | Site Assigned for De-identity           |       | Randomly assigned Site for De-identity   |
| PHASENUM | num  | Phase Number                            |       | Collected at CRF.  |
| PHASE    | char | Phase                                   |       | Collected at CRF.  |
| VISITNUM | num  | Visit Id                                |       | Collected at CRF.  |
| VISIT    | char | Visit                                   |       | Collected at CRF.  |
| PSSCORE  | num  | PSP Score                               |       | Collected at CRF.  |
| PSACTDY  | num  | Relative Actual Day of PSP              |       | If PSACTDT and DMINFDT not missing then perform below logic to calculate PSACTDY, If PSACTDT less than DMINFDT then (PSACTDT - DMINFDT).Else if PSACTDT is greater than equal to DMINFDT then (PSACTDT- DMINFDT) +1. |

## 1.4.28. Psychotic History – PSYHIST

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | PSYHIST  |
| <b>Creating program</b>  | psyhist.sas  |
| <b>Description</b>       | Psychotic History  |
| <b>Unique identifier</b> | DUSUBJID,PYSTDY, PYSEQ   |
| <b>Sorted by</b>         | DUSUBJID,PYSTDY, PYSEQ   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: PAGNUM, PYEPIDTC, PYEPIDT, PYDIAG, PYSTDT, PYSTDTC, PYENDTC, PYENDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| PYSEQ    | num  | Psychiatric History Sequence Number      |       | Collected at CRF.   |
| PYEPIDY  | num  | Relative Day of Lst Acute Psychotic Symp |       | If PYEPIDTC and DMINFDT not missing then perform below logic to calculate PYEPIDY, If PYEPIDTC less than DMINFDT then (PYEPIDTC - DMINFDT).Else if PYEPIDTC is greater than equal to DMINFDT then (PYEPIDTC- DMINFDT) +1. |
| PYSTDY   | num  | Relative Start Day of Psychosis Trtmt    |       | If PYSTDTC and DMINFDT not missing then perform below logic to calculate PYSTDY, If PYSTDTC less than DMINFDT then (PYSTDTC - DMINFDT).Else if PYSTDTC is greater than equal to DMINFDT then (PYSTDTC- DMINFDT) +1.       |
| PYENDY   | num  | Relative End Day of Psychosis Treatment  |       | If PYENDTC and DMINFDT not missing then perform below logic to calculate PYENDY, If PYENDTC less than DMINFDT then (PYENDTC - DMINFDT).Else if PYENDTC is greater than equal to DMINFDT then (PYENDTC- DMINFDT) +1.       |



## 1.4.29. Randomisation – RANDOM

|                          |   |
|--------------------------|---|
| <b>Dataset</b>           | RANDOM  |
| <b>Creating program</b>  | random.sas  |
| <b>Description</b>       | Randomisation   |
| <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 non significant elements or due to missing values: PAGNUM, SUB, RAACTDT, RANDNUM |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                | Codes | Comments   |
|----------|------|--------------------------------------|-------|--|
| RASEQ    | num  | Randomization Sequence Number        |       | Collected at CRF.  |
| REGIMEN  | char | Regimen                              |       | Collected at CRF.  |
| TRTGRPC  | num  | Treatment Group Code                 |       | Collected at CRF.  |
| TRTGRP   | char | Treatment Group                      |       | Collected at CRF.  |
| DOSE     | char | Dose                                 |       | Collected at CRF.  |
| DRUG     | char | Drug                                 |       | Collected at CRF.  |
| DURATION | char | Duration                             |       | Collected at CRF.  |
| FORMULAT | char | Formulation                          |       | Collected at CRF.  |
| FREQ     | char | Frequency                            |       | Collected at CRF.  |
| INSTRUCT | char | Instructions                         |       | Collected at CRF.  |
| ROUTE    | char | Route                                |       | Collected at CRF.  |
| STRENGTH | char | Strength                             |       | Collected at CRF.  |
| RAACTDY  | num  | Relative Actual Day of Randomization |       | If RAACTDT and DMINFDT not missing then perform below logic to calculate RAACTDY, If RAACTDT less than DMINFDT then (RAACTDT - DMINFDT).Else if RAACTDT is greater than equal to DMINFDT then (RAACTDT- DMINFDT) +1. |

## 1.4.30. Simpson - Angus Scale – SARS

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | SARS   |
| <b>Creating program</b>  | sars.sas   |
| <b>Description</b>       | Simpson - Angus Scale  |
| <b>Unique identifier</b> | DUSUBJID,VISIT,SRITEM, SRACTDY   |
| <b>Sorted by</b>         | DUSUBJID,VISIT,SRITEM, SRACTDY   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, SRRATERI, SRACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                       | Codes | Comments   |
|----------|------|-----------------------------|-------|--|
| SRVTYPEC | num  | SARS Visit Type Code        |       | Collected at CRF.  |
| SRVTYPE  | char | SARS Visit Type             |       | Collected at CRF.  |
| SRITEM   | char | SARS Item                   |       | Collected at CRF.  |
| SRSCOREC | num  | SARS Score Code             |       | Collected at CRF.  |
| SRSCORE  | char | Score                       |       | Collected at CRF.  |
| SRACTDY  | num  | Relative Actual Day of SARS |       | If SRACTDT and DMINFDT not missing then perform below logic to calculate SRACTDY, If SRACTDT less than DMINFDT then (SRACTDT - DMINFDT).Else if SRACTDT is greater than equal to DMINFDT then (SRACTDT- DMINFDT) +1. |

## 1.4.31. SQLS-R4 – SQLSR4

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | SQLSR4   |
| <b>Creating program</b>  | sqlsr4.sas   |
| <b>Description</b>       | SQLS-R4  |
| <b>Unique identifier</b> | DUSUBJID,VISIT, SQITEM   |
| <b>Sorted by</b>         | DUSUBJID,VISIT, SQITEM   |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, SQACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| SQSEQ    | num  | SQLSR4 Sequence Number                   |       | Collected at CRF.                                   |

| Variable | Type | Label                          | Codes | Comments   |
|----------|------|--------------------------------|-------|--|
| SQITEM   | char | SQLSR4 Item                    |       | Collected at CRF.  |
| SQSCOREC | num  | Score Code                     |       | Collected at CRF.  |
| SQSCORE  | char | Score                          |       | Collected at CRF.  |
| SQACTDY  | num  | Relative Actual Day of SQLS-R4 |       | If SQACTDT and DMINFDT not missing then perform below logic to calculate SQACTDY, If SQACTDT less than DMINFDT then (SQACTDT - DMINFDT).Else if SQACTDT is greater than equal to DMINFDT then (SQACTDT- DMINFDT) +1. |

## 1.4.32. Urine – URINE

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | URINE  |
| <b>Creating program</b>  | urine.sas  |
| <b>Description</b>       | Urine  |
| <b>Unique identifier</b> | DUSUBJID,VISIT,LBVTYP, LBTEST  |
| <b>Sorted by</b>         | DUSUBJID,VISIT,LBVTYP, LBTEST  |
| <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: LBPTM, LBFASTC, LBFAST, LBSIGLO, LBSIGHI, LBACTDT, LBPRVIDC, LBPRVID, LBREF, BATCHID, LBSEQ |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |

| Variable | Type | Label                                | Codes | Comments          |
|----------|------|--------------------------------------|-------|-------------------|
| STDUNIT  | char | Standard Units                       |       | Collected at CRF. |
| LBVTYPE  | char | Lab Visit Type                       |       | Collected at CRF. |
| LBTYPEC  | num  | Lab Type Code                        |       | Collected at CRF. |
| LBCVRES  | num  | Result in Conventional Units         |       | Collected at CRF. |
| LBCVUNIT | char | Conventional Units                   |       | Collected at CRF. |
| LBACTTM  | num  | Actual Time of Lab Sample            |       | Collected at CRF. |
| ORGUNIT  | char | Original Units                       |       | Collected at CRF. |
| LBTESTC  | num  | Lab Test Code                        |       | Collected at CRF. |
| LBVTYPEC | num  | Lab Visit Type Code                  |       | Collected at CRF. |
| LBTMLBL  | char | Pre-determined collection times      |       | Collected at CRF. |
| ORGRESN  | num  | Numeric lab result                   |       | Collected at CRF. |
| ORGRES   | char | Character lab result                 |       | Collected at CRF. |
| NRIND    | char | High/Low Lab Value Flag              |       | Collected at CRF. |
| ORGNRHI  | num  | Upper limit for the lab normal range |       | Collected at CRF. |
| ORGNRLO  | num  | Lower limit for the lab normal range |       | Collected at CRF. |
| STDNRLO  | num  | S.I. lower limit                     |       | Collected at CRF. |
| STDRESN  | num  | S.I. numeric result                  |       | Collected at CRF. |
| STDNRHI  | num  | S.I. upper limit                     |       | Collected at CRF. |



| Variable | Type | Label                         | Codes | Comments   |
|----------|------|-------------------------------|-------|--|
| LAGE     | char | Age: time of visit            |       | If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.  |
| LAGEUNIT | char | Age Unit (M or Y)             |       | Collected at CRF.  |
| LBSIFACT | num  | Std. Intl. Conversion Factor  |       | Collected at CRF.  |
| LBTEST   | char | Lab Test Name                 |       | Collected at CRF.  |
| LBDESCR  | char | Full Test Description         |       | Collected at CRF.  |
| LBTYPE   | char | Lab Type                      |       | Collected at CRF.  |
| LBABBR   | char | Lab Abbreviation              |       | Collected at CRF.  |
| LBACTDY  | num  | Relative Actual Day of Sample |       | If LBACTDT and DMINFDT not missing then perform below logic to calculate LBACTDY, If LBACTDT less than DMINFDT then (LBACTDT - DMINFDT).Else if LBACTDT is greater than equal to DMINFDT then (LBACTDT- DMINFDT) +1. |

## 1.4.33. Sleep Vas Scale Scores – VAS

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | VAS  |
| <b>Creating program</b>  | vas.sas  |
| <b>Description</b>       | Sleep Vas Scale Scores   |
| <b>Unique identifier</b> | DUSUBJID, VISIT  |
| <b>Sorted by</b>         | DUSUBJID, VISIT  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, VAACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| VASCORE  | num  | VAS Score (mm)                           |       | Collected at CRF.                                   |

| Variable | Type | Label                      | Codes | Comments   |
|----------|------|----------------------------|-------|--|
| VASCALE  | char | VAS Scale                  |       | Collected at CRF.  |
| VAACTDY  | num  | Relative Actual Day of VAS |       | If VAACTDT and DMINFDT not missing then perform below logic to calculate VAACTDY, If VAACTDT less than DMINFDT then (VAACTDT - DMINFDT).Else if VAACTDT is greater than equal to DMINFDT then (VAACTDT- DMINFDT) +1. |

#### 1.4.34. Visit – VISIT

|                          |                         |
|--------------------------|-------------------------|
| <b>Dataset</b>           | VISIT                   |
| <b>Creating program</b>  | visit.sas               |
| <b>Description</b>       | Visit                   |
| <b>Unique identifier</b> | DUSUBJID,VISIT, VISITDY |
| <b>Sorted by</b>         | DUSUBJID,VISIT, VISITDY |
| <b>Notes</b>             |                         |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |

| Variable | Type | Label                                   | Codes | Comments   |
|----------|------|---|-------|--|
| DSUBJID  | char | Subject Number Assigned for De-identity |       | Randomly assigned Subject Number for De-identity   |
| DSITEID  | char | Site Assigned for De-identity           |       | Randomly assigned Site for De-identity   |
| PHASENUM | num  | Phase Number                            |       | Collected at CRF.  |
| PHASE    | char | Phase                                   |       | Collected at CRF.  |
| VISITNUM | num  | Visit Id                                |       | Collected at CRF.  |
| VISIT    | char | Visit                                   |       | Collected at CRF.  |
| VISITDY  | num  | Relative Visit Day                      |       | If VISITDT and DMINFDT not missing then perform below logic to calculate VISITDY, If VISITDT less than DMINFDT then (VISITDT - DMINFDT).Else if VISITDT is greater than equal to DMINFDT then (VISITDT- DMINFDT) +1. |

## 1.4.35. Vital Signs – VITAL

|                          |  |
|--------------------------|--|
| <b>Dataset</b>           | VITAL  |
| <b>Creating program</b>  | vital.sas  |
| <b>Description</b>       | Vital Signs  |
| <b>Unique identifier</b> | DUSUBJID,VISIT,VSACTDY, VSSEQ  |
| <b>Sorted by</b>         | DUSUBJID,VISIT,VSACTDY, VSSEQ  |
| <b>Notes</b>             | Below listed variables will be dropped from dataset due to non significant elements: PAGNUM, VSACTDT |

| Variable | Type | Label                                    | Codes | Comments  |
|----------|------|--|-------|---|
| STUDYID  | char | Study Id                                 |       | Collected at CRF.                                   |
| DUSUBJID | char | Unique Subject Id Assign for De-identity |       | Randomly assigned Unique Subject Id for De-identity |
| DSUBJID  | char | Subject Number Assigned for De-identity  |       | Randomly assigned Subject Number for De-identity    |
| DSITEID  | char | Site Assigned for De-identity            |       | Randomly assigned Site for De-identity              |
| PHASENUM | num  | Phase Number                             |       | Collected at CRF.                                   |
| PHASE    | char | Phase                                    |       | Collected at CRF.                                   |
| VISITNUM | num  | Visit Id                                 |       | Collected at CRF.                                   |
| VISIT    | char | Visit                                    |       | Collected at CRF.                                   |
| VSSEQ    | num  | Vital Signs Sequence Number              |       | Collected at CRF.                                   |

| Variable | Type | Label                              | Codes | Comments   |
|----------|------|------------------------------------|-------|--|
| 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.  |
| VSVTYPEC | num  | Vital Signs Visit Type Code        |       | Collected at CRF.  |
| VSVTYPE  | char | Vital Signs Visit Type             |       | Collected at CRF.  |
| VSPOS    | char | Position                           |       | Collected at CRF.  |
| VSWEIGHT | num  | Weight                             |       | Collected at CRF.  |
| VSWTUNIT | char | Weight Unit                        |       | Collected at CRF.  |
| VSHEIGHT | num  | Height                             |       | Collected at CRF.  |
| VSHTUNIT | char | Height Unit                        |       | Collected at CRF.  |
| VSACTDY  | num  | Relative Actual Day of Vital Signs |       | If VSACTDT and DMINFDT not missing then perform below logic to calculate VSACTDY, If VSACTDT less than DMINFDT then (VSACTDT - DMINFDT).Else if VSACTDT is greater than equal to DMINFDT then (VSACTDT- DMINFDT) +1. |