Clinical Development

# Paliperidone Palmitate®

## R092670-PSY3005

## Anonymisation Data Derivation Specification Document

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| Status and Version | Release Date | Summary of Key Changes |
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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.
- Lab Identifier information will not be provided.

- 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.
- Lab Name information will not be provided
- Comments Dataset will be submitted with zero observations.
- Specimen ID will not be submitted due to sensitivity of data. (eg. LBREFID)
- Completely missing variables will not be included in the De-Identified datasets.
- SURGERY dataset will not be submitted due to sensitivity of data.
- Pharmacogenetics Dataset will not be submitted due to sensitivity of information. (eg. DNRSLT).
- Dataset contains sensitive information related to "Kit Number" which after removed, no significant information is available for further analysis. Hence, dataset will not be submitted.(eg. MEDKIT).
- Dataset does not have any significant information left, after removing sensitive information, for further analysis. Hence, will not be submitted in De-identified datasets (eg. RELATED).
- Dataset does not have any subject level information will not be submitted. (eg. PROTDESC).
- Datasets containing insignificant information will not be submitted. (eg. CODELIST)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg. INVEST)
- Variables with completely missing values will not be submitted.
- Informed Consent Date will be used as Reference Date to derive relative days.

## 1.3. Data Files

The R092670-PSY3005 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4.     Data Domains

### 1.4.1. Demographics – DEMOG

| | |
|---|---|
| **Dataset** | DEMOG |
| **Creating program** | demog.sas |
| **Description** | Demographics |
| **Unique identifier** | DUSUBJID |
| **Sorted by** | DUSUBJID |
| **Notes** | 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, SUBJINIT, DMACTDT, DMSCRDT, IVNAME, IVID, BIRTHDT, DMINFDT, RACESPEC, COUNTRYC, ETHNSPEC |

| 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 Number | | 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 | | Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= floor((DMINFDT – BIRTHDT)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DMACTDY | num | Relative Actual Day of 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. |
| DMSCRDY | num | Relative Day of 1st Trial Related Procedure | | 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. |

## 1.4.2. Adverse Events – AE

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

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| AEREPRTC | num | Were Any AEs Reported Code | | Collected at CRF. |
| AEREPRT | char | Were Any AEs Reported | | Collected at CRF. |
| AESEQ | num | AE Sequence Number | | Collected at CRF. |
| AEACTTRC | num | Action Taken with Treatment Code | | Collected at CRF. |
| AEACTTRT | 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. |
| AESERREF | char | Serious AE Reference Number | | 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. |
| AECODE | char | AE Dictionary Code | | Collected at CRF. |
| AEDICTDM | char | Adverse Events Dictionary | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| AEDECOD1 | char | Dictionary-Derived Lower Level Term | | Collected at CRF. |
| AEDECOD | char | Dictionary-Derived Term | | Collected at CRF. |
| AEBODSYC | char | Body System or Organ Class Code | | Collected at CRF. |
| AEBODSYS | char | Body System or Organ Class | | 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

| | |
|---|---|
| **Dataset** | AIMS |
| **Creating program** | aims.sas |
| **Description** | Abnormal Involuntary Movement Scale |
| **Unique identifier** | DUSUBJID,AIITEM |
| **Sorted by** | DUSUBJID,AIITEM |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| AIVTYPEC | num | AIMS Visit Type Code | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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 | AIMS 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

| Dataset | BARS |
|---|---|
| Creating program | bars.sas |
| Description | Barnes Akathisia Rating Scale |
| Unique identifier | DUSUBJID,BAITEM,VISITNUM |
| Sorted by | DUSUBJID,BAITEM,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| BAVTYPEC | num | BARS Visit Type Code | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| 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 | BARS 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

| | |
|---|---|
| **Dataset** | CGI |
| **Creating program** | cgi.sas |
| **Description** | Clinical Global Impression |
| **Unique identifier** | DUSUBJID,CGSEV,VISITNUM |
| **Sorted by** | DUSUBJID,CGSEV,VISITNUM |
| **Notes** | 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,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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| CGSEVC | num | CGI Severity Code | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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. Laboratory Result – CHEM

| Dataset | CHEM |
|---|---|
| Creating program | chem.sas |
| Description | Laboratory Result |
| Unique identifier | DUSUBJID,LBTEST,LBABBR, VISITNUM |
| Sorted by | DUSUBJID,LBTEST,LBABBR, VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGNUM,LBTMLBL,LBPRVIDC,LBPRVID,LBREF,LBACTDT,STDRESC,STDNRC |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| LBPTM | num | Planned Collection Time | | Collected at CRF. |
| LBSEQ | num | Lab Sequence Number | | Collected at CRF. |
| LBVTYPEC | num | Lab Visit Type Code | | Collected at CRF. |
| LBVTYPE | char | Lab Visit Type | | Collected at CRF. |
| LBACTTM | num | Actual Time of Lab Sample | | Collected at CRF. |
| LBTESTC | num | Lab Test Code | | Collected at CRF. |
| LBTEST | char | Lab Test Name | | Collected at CRF. |
| LBABBR | char | Lab Test Abbreviation | | Collected at CRF. |
| LBDESCR | char | Full Test Description | | Collected at CRF. |
| ORGRESN | num | Numeric Result in Original Units | | Collected at CRF. |
| REPUNIT | char | Reported Unit | | Collected at CRF. |
| ORGUNIT | char | Original Units | | Collected at CRF. |
| ORGRES | char | Character Result in Original Units | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| ORGNRLO | num | Normal Range Lower Limit in Orig Units | | Collected at CRF. |
| ORGNRHI | num | Normal Range Upper Limit in Orig Units | | Collected at CRF. |
| NRIND | char | Normal Range Indicator | | Collected at CRF. |
| STDRESN | num | Numeric Result in Standard Units | | Collected at CRF. |
| STDUNIT | char | Standard Units | | Collected at CRF. |
| STDNRLO | num | Normal Range Lower Limit in Std Units | | Collected at CRF. |
| STDNRHI | num | Normal Range Upper Limit in Std Units | | Collected at CRF. |
| LBFASTC | num | Fasted Code | | Collected at CRF. |
| LBFAST | char | Fasted | | Collected at CRF. |
| LAGE | char | Age at 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 | | Collected at CRF. |
| LBTYPEC | num | Lab Type Code | | Collected at CRF. |
| LBTYPE | char | Lab Type | | Collected at CRF. |
| LBSIFACT | num | Std. Intl. Conversion Factor | | 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

| Dataset | COMMENTS |
|---------|----------|
| Creating program | comments.sas |
| Description | Comments |
| Unique identifier | Not applicable |
| Sorted by | Not applicable |
| Notes | Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| STUDYID | char | Study Id | | Empty dataset will be submitted |
| DUSUBJID | char | Unique Subject ID Assign for De-identity | | Empty dataset will be submitted |
| DSUBJID | char | Subject Number Assigned for De-identity | | Empty dataset will be submitted |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| DSITEID | char | Site Assigned for De-identity | | Empty dataset will be submitted |
| PHASENUM | num | Phase Number | | Empty dataset will be submitted |
| PHASE | char | Phase | | Empty dataset will be submitted |
| VISITNUM | num | Visit Number | | Empty dataset will be submitted |
| VISIT | char | Visit | | Empty dataset will be submitted |
| CTSEQ | num | Comment Sequence Number | | Empty dataset will be submitted |
| CTPAGE | num | CRF Page Number | | Empty dataset will be submitted |
| DOMAIN | char | Domain of Origin | | Empty dataset will be submitted |

### 1.4.8. Concomitant Drug/Therapy – CONMED

| Dataset | CONMED |
|---|---|
| Creating program | conmed.sas |
| Description | Concomitant Drug/Therapy |
| Unique identifier | DUSUBJID,CMDECOD1,CMGROUP,VISITNUM,CMSEQ |
| Sorted by | DUSUBJID,CMDECOD1,CMGROUP,VISITNUM,CMSEQ |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:<br>PAGNUM,CMTERM,CMSTDTC,CMSTDT,CMENDTC,CMENDT,CMCLASC,<br>CMCLASC8,CMCLASC9,CMCLAS8,CMCLAS9,CMCLAS,CMREAS,CMREGIM |

| 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 Number | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| VISIT | char | Visit | | Collected at CRF. |
| CMTYPEC | num | Prior/Concomitant Medication Code | | Collected at CRF. |
| CMTYPE | char | Prior/Concomitant Medication | | Collected at CRF. |
| CMGROUP | char | Medication Grouping | | Collected at CRF. |
| CMREPRTC | num | Were Any Meds Administered Code | | Collected at CRF. |
| CMREPRT | char | Were Any Meds Administered | | Collected at CRF. |
| CMSEQ | num | Conmed Sequence Number | | Collected at CRF. |
| CMDECOD1 | char | Medication Specified Term | | Collected at CRF. |
| CMDOSE | num | Dosage | | Collected at CRF. |
| CMUNIT | char | Dose Unit | | Collected at CRF. |
| CMROUTE | char | Route of Administration | | Collected at CRF. |
| CMCAUSC | num | Given for AE Code | | Collected at CRF. |
| CMCAUS | char | Given for AE | | Collected at CRF. |
| AESEQ | num | AE Sequence Number | | Collected at CRF. |
| AESEQ1 | num | AE Sequence Number 1 | | Collected at CRF. |
| AESEQ2 | num | AE Sequence Number 2 | | Collected at CRF. |
| CMPRIORC | num | Med Started Prior to Trial Code | | Collected at CRF. |
| CMPRIOR | char | Med Started Prior to Trial | | Collected at CRF. |
| CMCONTC | num | Medication Continuing Code | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| CMCONT | char | Medication Continuing | | 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. |
| 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. |
| CMCODE | char | Medication Dictionary Code | | Collected at CRF. |
| CMDECOD | char | Medication Generic Term | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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

| | |
|---|---|
| **Dataset** | DIAGNOS |
| **Creating program** | diagnos.sas |
| **Description** | Schizophrenia Diagnosis |
| **Unique identifier** | DUSUBJID |
| **Sorted by** | DUSUBJID |
| **Notes** | 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,DGDT,DGACTDTC,DGACTDT |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| DIAGNOSC | num | Diagnosis Code | | Collected at CRF. |
| DIAGNOS | char | Diagnosis | | Collected at CRF. |
| DGTYPEC | num | Schizophrenia Type Code | | Collected at CRF. |
| DGTYPE | char | Schizophrenia Type | | Collected at CRF. |
| DGAGE | char | Age At First 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. |
| DGDY | num | Relative Day of Collection | | If DGDT and DMINFDT not missing then perform below logic to calculate DGDY, If DGDT less than DMINFDT then (DGDT - DMINFDT).Else if DGDT is greater than equal to DMINFDT then (DGDT-DMINFDT) +1. |

## 1.4.10. End Of Trial Information – DISPOSIT

| Dataset | DISPOSIT |
|---|---|
| Creating program | disposit.sas |
| Description | End Of Trial Information |
| Unique identifier | DUSUBJID |
| Sorted by | DUSUBJID |
| Notes | 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,DSACTDT,PREGDUDT,DEATHDT,DSRSOTH,DSRABKDT,DSRABKTM, DSRABKRS |

| 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 Number | | Collected at CRF. |

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

## 1.4.11. Electrocardiogram – ECG

| Dataset | ECG |
|---|---|
| Creating program | ecg.sas |
| Description | Electro Cardio Gram |
| Unique identifier | DUSUBJID,EGSTRESC,EGVTYPE,VISITNUM, EGTESTCD |
| Sorted by | DUSUBJID,EGSTRESC,EGVTYPE,VISITNUM, EGTESTCD |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values:<br>EGREF,EGDT,EGPTM,EGPOS,EGPRVIDC,EGPRVID,EGND,EGCHGC,EGCHG, BATCHID,EGINTOTH,EGCHGOTH |

| 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 Number | | 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 | Planned Time Point Number | | 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 | Numeric Result in Standard Units | | Collected at CRF. |
| EGSTUNIT | char | Standard Units | | Collected at CRF. |
| EGSTRESC | char | Character Result in Standard Units | | Collected at CRF. |
| EGORRESN | num | Numeric Result 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. |

## 1.4.12.    Enroll – ENROLL

| Dataset | ENROLL |
|---------|--------|
| Creating program | enroll.sas |
| Description | Enroll |
| Unique identifier | DUSUBJID,ENTEXT,VISITNUM |
| Sorted by | DUSUBJID,ENTEXT,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or 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 Number | | 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. |

## 1.4.13. Administration Of Trial Medication – EXPOSURE

| Dataset | EXPOSURE |
|---|---|
| Creating program | exposure.sas |
| Description | Administration Of Trial Medication |
| Unique identifier | DUSUBJID,VISITNUM |
| Sorted by | DUSUBJID,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,EXRATERI,EXSTDT |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| EXSTTM | num | Start Time of Exposure | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| EXSITEC | num | Injection Site Code | | Collected at CRF. |
| EXSITE | char | Injection Site | | Collected at CRF. |
| EXPOSC | num | Position of Injection Code | | Collected at CRF. |
| EXPOS | char | Position of Injection | | Collected at CRF. |
| EXSTDY | num | Relative Start Day of Exposure | | If EXSTDT and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDT less than DMINFDT then (EXSTDT - DMINFDT).Else if EXSTDT is greater than equal to DMINFDT then (EXSTDT-DMINFDT) +1. |

## 1.4.14.    Smoking History – HABIT

| Dataset | HABIT |
|---|---|
| Creating program | habit.sas |
| Description | Smoking History |
| Unique identifier | DUSUBJID,VISITNUM |
| Sorted by | DUSUBJID,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or 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 Number | | 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 Smoking Habit | | 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. |

## 1.4.15. Laboratory Result – HEMAT

| Dataset | HEMAT |
|---|---|
| Creating program | hemat.sas |
| Description | Laboratory Result |
| Unique identifier | DUSUBJID,LBTEST,VISITNUM |
| Sorted by | DUSUBJID,LBTEST,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGNUM,LBTMLBL,LBPRVIDC,LBPRVID,LBREF,LBACTDT,ORGRES,STDRESC, STDNRC |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| LBPTM | num | Planned Collection Time | | Collected at CRF. |
| LBSEQ | num | Lab Sequence Number | | Collected at CRF. |
| LBVTYPEC | num | Lab Visit Type Code | | Collected at CRF. |
| LBVTYPE | char | Lab Visit Type | | Collected at CRF. |
| LBACTTM | num | Actual Time of Lab Sample | | Collected at CRF. |
| LBTESTC | num | Lab Test Code | | Collected at CRF. |
| LBTEST | char | Lab Test Name | | Collected at CRF. |
| LBABBR | char | Lab Test Abbreviation | | Collected at CRF. |
| LBDESCR | char | Full Test Description | | Collected at CRF. |
| ORGRESN | num | Numeric Result in Original Units | | Collected at CRF. |
| REPUNIT | char | Reported Unit | | Collected at CRF. |
| ORGUNIT | char | Original Units | | Collected at CRF. |
| ORGNRLO | num | Normal Range Lower Limit in Orig Units | | Collected at CRF. |
| ORGNRHI | num | Normal Range Upper Limit in Orig Units | | Collected at CRF. |
| NRIND | char | Normal Range Indicator | | Collected at CRF. |
| STDRESN | num | Numeric Result in Standard Units | | Collected at CRF. |
| STDUNIT | char | Standard Units | | Collected at CRF. |
| STDNRLO | num | Normal Range Lower Limit in Std Units | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| STDNRHI | num | Normal Range Upper Limit in Std Units | | Collected at CRF. |
| LBFASTC | num | Fasted Code | | Collected at CRF. |
| LBFAST | char | Fasted | | Collected at CRF. |
| LAGE | char | Age at 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 | | Collected at CRF. |
| LBTYPEC | num | Lab Type Code | | Collected at CRF. |
| LBTYPE | char | Lab Type | | Collected at CRF. |
| LBSIFACT | num | Std. Intl. Conversion Factor | | 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. |

## 1.4.16.     Investigator Evaluation Of Injection Site – IVEVINJ

| Dataset | IVEVINJ |
|---|---|
| Creating program | ivevinj.sas |
| Description | Investigator Evaluation Of Injection Site |
| Unique identifier | DUSUBJID,IERELAT,IEITEM,VISITNUM |
| Sorted by | DUSUBJID,IERELAT,IEITEM,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM, IERATERI,IEACTDT |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| IERELAT | char | Related to Injection | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| IEITEM | char | Evaluation Item | | Collected at CRF. |
| IESCOREC | num | Evaluation Score Code | | Collected at CRF. |
| IESCORE | char | Evaluation Score | | Collected at CRF. |
| IEACTTM | num | Actual Time of Inve. Eval. of Inj. Site | | Collected at CRF. |
| IEACTDY | num | Relative Act Day of Inv Eval of Inj Site | | If IEACTDT and DMINFDT not missing then perform below logic to calculate IEACTDY, If IEACTDT less than DMINFDT then (IEACTDT - DMINFDT).Else if IEACTDT is greater than equal to DMINFDT then (IEACTDT- DMINFDT) +1. |

### 1.4.17. Medical History – MEDHIST

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

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| MHSEQ | num | MH Sequence Number | | Collected at CRF. |

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

### 1.4.18.    Medication Preference Questionnaire For Patients – MPQ

| Dataset | MPQ |
|---|---|
| Creating program | mpq.sas |
| Description | Medication Preference Questionnaire For Patients |
| Unique identifier | DUSUBJID,MQCHOI,MQITEM,VISITNUM |
| Sorted by | DUSUBJID, MQCHOI,MQITEM,VISITNUM |
| Notes | 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, MQACTDT,MQRSOTH |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| MQGROUP | char | MPQ Group | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| MQCHOIC | num | MPQ Choice Code | | Collected at CRF. |
| MQCHOI | char | MPQ Choice | | Collected at CRF. |
| MQITEMC | char | MPQ Item Code | | Collected at CRF. |
| MQITEM | char | MPQ Item | | Collected at CRF. |
| MQSCOREC | num | MPQ Score Code | | Collected at CRF. |
| MQSCORE | char | MPQ Score | | Collected at CRF. |
| MQACTDY | num | Relative Actual Day of MPQ | | If MQACTDT and DMINFDT not missing then perform below logic to calculate MQACTDY, If MQACTDT less than DMINFDT then (MQACTDT - DMINFDT).Else if MQACTDT is greater than equal to DMINFDT then (MQACTDT- DMINFDT) +1. |

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

| Dataset | PANSS |
|---|---|
| Creating program | panss.sas |
| Description | Positive And Negative Syndrome Scale For Schizophrenia |
| Unique identifier | DUSUBJID, PAITEM,VISITNUM |
| Sorted by | DUSUBJID, PAITEM,VISITNUM |
| Notes | 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| PAVTYPEC | num | PANSS Visit Type Code | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PAVTYPE | char | PANSS Visit Type | | Collected at CRF. |
| 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. |

### 1.4.20. Blood Sampling For Pharmacokinetics – PCCNC

| | |
|---|---|
| **Dataset** | PCCNC |
| **Creating program** | pccnc.sas |
| **Description** | Blood Sampling For Pharmacokinetics |
| **Unique identifier** | DUSUBJID,VISITNUM |
| **Sorted by** | DUSUBJID,VISITNUM |
| **Notes** | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,SPPRVIDC,SPPRVID,PCPRVIDC,PCPRVID,ACQREF,SAMREF,PCSTDT, PCENDT,PCSPCOM |

| 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 |
| DSITEID | char | Site Assigned for De-identity | | Randomly assigned Site 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. |
| VISITNUM | num | Visit Number | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| VISIT | char | Visit | | Collected at CRF. |
| TPTNUM | num | Planned Time Point Number | | Collected at CRF. |
| TPT | char | Planned Time Point Name | | Collected at CRF. |
| PCVTYPEC | num | PK/PD Sample Visit Type Code | | Collected at CRF. |
| PCVTYPE | char | PK/PD Sample Visit Type | | Collected at CRF. |
| PCPRMTYP | char | Parameter Type | | Collected at CRF. |
| PCCAT | char | Category for Test or Examination | | Collected at CRF. |
| SAMMAT | char | Sample Material | | Collected at CRF. |
| PCSPEC | char | Specimen Material | | Collected at CRF. |
| PCSEQ | num | Sample Sequence Number | | Collected at CRF. |
| PCSTTM | num | Start Time of Specimen Collection | | Collected at CRF. |
| PCENTM | num | End Time of Specimen Collection | | Collected at CRF. |
| PCTEST | char | Test Name | | Collected at CRF. |
| PCORRESN | num | Numeric Result in Original Units | | Collected at CRF. |
| PCORUNIT | char | Original Units | | Collected at CRF. |
| PCNRLO | num | Normal Range Lower Limit in Orig Units | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| PCNRHI | num | Normal Range Upper Limit in Orig Units | | Collected at CRF. |
| PCORRES | char | Result in Original Units | | Collected at CRF. |
| PCSTRESN | num | Numeric Result in Standard Units | | Collected at CRF. |
| PCSTUNIT | char | Standard Units | | Collected at CRF. |
| PCSTRESC | char | Character Result in Standard Units | | Collected at CRF. |
| PCSTATC | num | Sample Collection Status Code | | Collected at CRF. |
| PCSTAT | char | Sample Collection Status | | 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. |
| PCENDY | num | Relative End Day of Specimen Collection | | If PCENDT and DMINFDT not missing then perform below logic to calculate PCENDY, If PCENDT less than DMINFDT then (PCENDT - DMINFDT). Else if PCENDT is greater than equal to DMINFDT then (PCENDT- DMINFDT) +1. |

### 1.4.21.     Blood Sampling For Pharmacokinetics (ONC)  –  PCCONC

| Dataset | PCCONC |
|---|---|
| Creating program | pcconc.sas |
| Description | Blood Sampling For Pharmacokinetics (ONC) |
| Unique identifier | DUSUBJID,VISITNUM |
| Sorted by | DUSUBJID,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,PCPRVIDC,PCPRVID,SAMREF |

| 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 |
| DSITEID | char | Site Assigned for De-identity | | Randomly assigned Site 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. |
| VISITNUM | num | Visit Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| TPTNUM | num | Planned Time Point Number | | Collected at CRF. |
| TPT | char | Planned Time Point Name | | Collected at CRF. |
| PCPRMTYP | char | Parameter Type | | Collected at CRF. |
| PCCAT | char | Category for Test or Examination | | Collected at CRF. |
| SAMMAT | char | Sample Material | | Collected at CRF. |
| PCSPEC | char | Specimen Material | | Collected at CRF. |
| PCSEQ | num | Sample Sequence Number | | Collected at CRF. |
| PCTEST | char | Test Name | | Collected at CRF. |
| PCORRESN | num | Numeric Result in Original Units | | Collected at CRF. |
| PCORUNIT | char | Original Units | | Collected at CRF. |
| PCNRLO | num | Normal Range Lower Limit in Orig Units | | Collected at CRF. |
| PCNRHI | num | Normal Range Upper Limit in Orig Units | | Collected at CRF. |
| PCORRES | char | Result in Original Units | | Collected at CRF. |
| PCSTRESN | num | Numeric Result in Standard Units | | Collected at CRF. |
| PCSTUNIT | char | Standard Units | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| PCSTRESC | char | Character Result in Standard Units | | Collected at CRF. |

## 1.4.22.    Pharmacokinetics Sample – PCSAMP

| Dataset | PCSAMP |
|---------|--------|
| Creating program | pcsamp.sas |
| Description | Pharmacokinetics Sample |
| Unique identifier | DUSUBJID,VISITNUM,SPSTDY |
| Sorted by | DUSUBJID,VISITNUM,SPSTDY |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,SPPRVIDC,SPPRVID,SPSTDT,SPENDT,ACQREF,SAMREF,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 |
| 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 |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| PHASENUM | num | Phase Number | | Collected at CRF. |
| PHASE | char | Phase | | Collected at CRF. |
| VISITNUM | num | Visit Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| TPTNUM | num | Planned Time Point Number | | Collected at CRF. |
| TPT | char | Planned Time Point Name | | Collected at CRF. |
| SPVTYPEC | num | PK/PD Sample Visit Type Code | | Collected at CRF. |
| SPVTYPE | char | PK/PD Sample Visit Type | | Collected at CRF. |
| PCPRMTYP | char | Parameter Type | | Collected at CRF. |
| SPCAT | char | Category for Test or Examination | | Collected at CRF. |
| SAMMAT | char | Sample Material | | Collected at CRF. |
| SAMSEQ | num | Sample Sequence Number | | Collected at CRF. |
| SPSTTM | num | Start Time of Specimen Collection | | Collected at CRF. |
| SPENTM | num | End Time of Specimen Collection | | Collected at CRF. |
| SPSTATC | num | Sample Status Code | | Collected at CRF. |
| SPSTAT | char | Sample Status | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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. |
| SPENDY | num | Relative End Day of Specimen Collection | | If SPENDT and DMINFDT not missing then perform below logic to calculate SPENDY, If SPENDT less than DMINFDT then (SPENDT - DMINFDT). Else if SPENDT is greater than equal to DMINFDT then (SPENDT-DMINFDT) +1. |

## 1.4.23.      Physical Examination – PE

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

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| PESEQ | num | Phys Sequence Number | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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 PEACTDT and DMINFDT not missing then perform below logic to calculate PEACTDY, If PEACTDT less than DMINFDT then (PEACTDT - DMINFDT).Else if PEACTDT is greater than equal to DMINFDT then (PEACTDT- DMINFDT) +1. |

## 1.4.24.      Protocol Deviation – PROTDEV

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

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

## 1.4.25.     Psychiatric History – PSYHIST

| Dataset | PSYHIST |
|---|---|
| Creating program | psyhist.sas |
| Description | Psychiatric History |
| Unique identifier | DUSUBJID,PYHOSP,PESEQ,PYSTDY,PYENDY,VISITNUM |
| Sorted by | DUSUBJID,PYHOSP,PESEQ,PYSTDY,PYENDY,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: PAGNUM,PYDIAG,PYSTDTC,PYSTDT,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 |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| PYHOSPC | num | Hospitalizations for Psychosis Code | | Collected at CRF. |
| PYHOSP | char | Hospitalizations for Psychosis | | Collected at CRF. |
| PYSEQ | num | Psychiatric History Sequence Number | | Collected at CRF. |
| PYSTDY | num | Relative Act. Strt Day of Psychosis Trt. | | 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 Act. End Day of Psychosis Trt. | | 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. |

## 1.4.26. Randomization – RANDOM

| Dataset | RANDOM |
|---|---|
| Creating program | random.sas |
| Description | Randomization |
| Unique identifier | DUSUBJID |
| Sorted by | DUSUBJID |
| Notes | 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,RAACTDT,RANDNUM,SUB |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| RASEQ | num | Randomization Sequence Number | | Collected at CRF. |
| TRTGRPC | num | Treatment Group Code | | Collected at CRF. |
| TRTGRP | char | Treatment Group | | Collected at CRF. |
| REGIMEN | char | Regimen Code | | Collected at CRF. |
| RADOSE | 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. |
| ROUTE | char | Route | | Collected at CRF. |
| STRENGTH | char | Strength | | Collected at CRF. |
| INSTRUCT | char | Instructions | | 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. |

## 1.4.27.     Simpson – Angus Scale – SARS

| Dataset | SARS |
|---|---|
| Creating program | sars.sas |
| Description | Simpson - Angus Scale |
| Unique identifier | DUSUBJID,SRITEM,VISITNUM |
| Sorted by | DUSUBJID,SRITEM,VISITNUM |
| Notes | 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| SRVTYPEC | num | SARS Visit Type Code | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| 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 | SARS 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. |

## 1.4.28.    Subject Evaluation Of Injection Site – SUEVINJ

| Dataset | SUEVINJ |
|---|---|
| Creating program | suevinj.sas |
| Description | Subject Evaluation Of Injection Site |
| Unique identifier | DUSUBJID,SEITEM,VISITNUM |
| Sorted by | DUSUBJID,SEITEM,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,SEACTDT |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| SEITEM | char | Evaluation Item | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| SESCORE | num | Evaluation Score | | Collected at CRF. |
| SEACTTM | num | Actual Time of Subj. Eval. of Inj. Site | | Collected at CRF. |
| SEUNIT | char | Unit of Score from VAS Scale | | Collected at CRF. |
| SEACTDY | num | Relative Actual Day of Subj Eval Inj site | | If SEACTDT and DMINFDT not missing then perform below logic to calculate SEACTDY, If SEACTDT less than DMINFDT then (SEACTDT - DMINFDT).Else if SEACTDT is greater than equal to DMINFDT then (SEACTDT- DMINFDT) +1. |

## 1.4.29. Tolerability Testing – TOLTEST

| Dataset | TOLTEST |
|---|---|
| Creating program | toltest.sas |
| Description | Tolerability Testing |
| Unique identifier | DUSUBJID,TPT,VISITNUM |
| Sorted by | DUSUBJID,TPT,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAGNUM,TTSTDT |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| TTNAC | num | Tolerability Testing Not Applicable Code | | Collected at CRF. |
| TTNA | char | Tolerability Testing Not Applicable | | Collected at CRF. |
| TPTNUM | num | Planned Time Point Number | | Collected at CRF. |
| TPT | char | Planned Time Point Name | | Collected at CRF. |
| TTTAKEN | num | Number of Pills Taken | | Collected at CRF. |
| TTSTDY | num | Relative Start Day of Tolerability Expos | | If TTSTDT and DMINFDT not missing then perform below logic to calculate TTSTDY, If TTSTDT less than DMINFDT then (TTSTDT - DMINFDT).Else if TTSTDT is greater than equal to DMINFDT then (TTSTDT-DMINFDT) +1. |

## 1.4.30.    Laboratory Result – URINE

| Dataset | URINE |
|---|---|
| Creating program | urine.sas |
| Description | Laboratory Result |
| Unique identifier | DUSUBJID,LBTEST,VISITNUM |
| Sorted by | DUSUBJID,LBTEST,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PAGNUM,LBTMLBL,LBPRVIDC,LBPRVID,LBREF,LBACTDT,STDRESC, STDNRC,LBSIGLO,LBSIGHI |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------|-------|----------|
| LBPTM | num | Planned Collection Time | | Collected at CRF. |
| LBSEQ | num | Lab Sequence Number | | Collected at CRF. |
| LBVTYPEC | num | Lab Visit Type Code | | Collected at CRF. |
| LBVTYPE | char | Lab Visit Type | | Collected at CRF. |
| LBACTTM | num | Actual Time of Lab Sample | | Collected at CRF. |
| LBTESTC | num | Lab Test Code | | Collected at CRF. |
| LBTEST | char | Lab Test Name | | Collected at CRF. |
| LBABBR | char | Lab Test Abbreviation | | Collected at CRF. |
| LBDESCR | char | Full Test Description | | Collected at CRF. |
| ORGRESN | num | Numeric Result in Original Units | | Collected at CRF. |
| REPUNIT | char | Reported Unit | | Collected at CRF. |
| ORGUNIT | char | Original Units | | Collected at CRF. |
| ORGRES | char | Character Result in Original Units | | Collected at CRF. |
| ORGNRLO | num | Normal Range Lower Limit in Orig Units | | Collected at CRF. |
| ORGNRHI | num | Normal Range Upper Limit in Orig Units | | Collected at CRF. |
| NRIND | char | Normal Range Indicator | | Collected at CRF. |
| STDRESN | num | Numeric Result in Standard Units | | Collected at CRF. |
| STDUNIT | char | Standard Units | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| STDNRLO | num | Normal Range Lower Limit in Std Units | | Collected at CRF. |
| STDNRHI | num | Normal Range Upper Limit in Std Units | | Collected at CRF. |
| LBFASTC | num | Fasted Code | | Collected at CRF. |
| LBFAST | char | Fasted | | Collected at CRF. |
| LAGE | char | Age at 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 | | Collected at CRF. |
| LBTYPEC | num | Lab Type Code | | Collected at CRF. |
| LBTYPE | char | Lab Type | | Collected at CRF. |
| LBSIFACT | num | Std. Intl. Conversion Factor | | 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. |

## 1.4.31.     Visit – VISIT

| Dataset | VISIT |
|---|---|
| Creating program | visit.sas |
| Description | Visit |
| Unique identifier | DUSUBJID,VISITNUM |
| Sorted by | DUSUBJID,VISITNUM |
| Notes | 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,VISITDT |

| 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 Number | | Collected at CRF. |

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

## 1.4.32.     Vital Signs – VITAL

| Dataset | VITAL |
|---|---|
| Creating program | vital.sas |
| Description | Vital Signs |
| Unique identifier | DUSUBJID,VSVTYPE,VSSEQ,VSPOS,VISITNUM |
| Sorted by | DUSUBJID,VSVTYPE,VSSEQ,VSPOS,VISITNUM |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or 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 |

| 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 Number | | Collected at CRF. |
| VISIT | char | Visit | | Collected at CRF. |
| VSVTYPEC | num | Vital Signs Visit Type Code | | Collected at CRF. |
| VSVTYPE | char | Vital Signs Visit Type | | Collected at CRF. |
| VSSEQ | num | Vital Signs Sequence Number | | 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. |
| PULSE | num | Pulse Rate (bpm) | | Collected at CRF. |
| SYSBP | num | Systolic Blood Pressure (mmHg) | | Collected at CRF. |
| DIABP | num | Diastolic Blood Pressure (mmHg) | | Collected at CRF. |
| TEMP | num | Temperature | | Collected at CRF. |
| TEMPUNIT | char | Temperature Unit | | Collected at CRF. |

| Variable | Type | Label | Codes | Comments |
|---|---|---|---|---|
| VSWAIST | num | Waist | | Collected at CRF. |
| VSWSUNIT | char | Waist 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. |