

Clinical Development

JNJ-410397

RIS-BIM-301

Anonymisation Data Derivation Specification Document

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

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

- Subject initials will not be provided.
- Investigator Name will not be provided.
- Date of birth will not be provided, only age in years.
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Subjects with 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.
- Vial and Bottle number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Remove ethnic information.
- Empty comments (REMARK) data will be submitted.
- Empty comments (DEATH) data will be submitted.
- Empty comments (ECGABN) data will be submitted.
- Empty comments (NODATA) data will be submitted.
- Empty comments (PKOUTL) data will be submitted.
- Empty comments (PKRES) data will be submitted.
- Remove DNA, DNRSLT, DISEASES and PPSURG dataset (its sensitive information). It may reveal subject personal identification information.
- Remove INVEST dataset; it's not a subject level data.
- Remove LABNOR dataset, it's not a subject level data.
- Remove TRLDISC, TRLLIST, TRLRAND, and TRLREGM datasets, these are not subject level datasets.
- If no observations reported in source data; will be submitted as is (i.e. empty dataset).
- Country information will be grouped to protect PII.

1.3. Data Files

The RIS-BIM-301 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. ADMINISTRATION OF TRIAL MEDICATION (AM) – ADMMED

| | |
|--------------------------|---|
| Dataset | ADMMED |
| Creating program | admmed.sas |
| Description | ADMINISTRATION OF TRIAL MEDICATION (AM) |
| Unique identifier | DCRFID, AMFROMDY |
| Sorted by | DCRFID, AMFROMDY |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AMFROM_D, AMTO_D, NUMFORM, BOX |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| PHASE | char | TRIAL PHASE | | Collected at CRF |
| SEGMENT | num | SEGMENT | | Collected at CRF |
| AMDAY | num | ADMIN. DAY | | Collected at CRF |
| CARD | char | ADMIN. CARD | | Collected at CRF |
| NUMFORM1 | num | UNITS PER ADMIN. (ROW1) | | Collected at CRF |
| NUMFORM2 | num | UNITS PER ADMIN. (ROW2) | | Collected at CRF |
| NUMFORM3 | num | UNITS PER ADMIN. (ROW3) | | Collected at CRF |
| NUMFORM4 | num | UNITS PER ADMIN. (ROW4) | | Collected at CRF |
| NUMFORM5 | num | UNITS PER ADMIN. (ROW5) | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------------|-------|---|
| NUMFORM6 | num | UNITS PER ADMIN. (ROW6) | | Collected at CRF |
| AMFREQ | char | ADMIN. FREQ. | | Collected at CRF |
| AMREAS | char | REGIMEN CHANGE REASON | | Collected at CRF |
| ZAMREAS | char | REGIMEN CHANGE REASON | | Collected at CRF |
| AMDOSE | num | DOSE | | Collected at CRF |
| AMDOSE_U | char | DOSE UNIT | | Collected at CRF |
| AMNONE | char | NO TABLETS TAKEN | | Collected at CRF |
| AMFROMDY | num | Relative ADMIN. FROM Day | | If AMFROM_D and RAND_D not missing then perform below logic to calculate relative day. If AMFROM_D less than RAND_D then (AMFROM_D - RAND_D). Else if AMFROM_D is greater than equal to RAND_D then (AMFROM_D - RAND_D) +1. |
| AMTO_DY | num | Relative ADMIN. TO Day | | If AMTO_D and RAND_D not missing then perform below logic to calculate relative day. If AMTO_D less than RAND_D then (AMTO_D - RAND_D). Else if AMTO_D is greater than equal to RAND_D then (AMTO_D - RAND_D) +1. |

1.4.2. ADVERSE EVENTS (AE) – AE

| | |
|--------------------------|---|
| Dataset | AE |
| Creating program | ae.sas |
| Description | ADVERSE EVENTS (AE) |
| Unique identifier | DCRFID, AESEQNO, AEPREF |
| Sorted by | DCRFID, AESEQNO, AEPREF |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AE_V, AEFROM_D, AETO_D, SAEREFNO |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| AESEQNO | num | AE SEQ. | | Collected at CRF |
| AEINCL | char | AE INCLUDED TERM | | Collected at CRF |
| PHASE | char | TRIAL PHASE | | Collected at CRF |
| AEFROM_C | char | AE FROM CODE | | Collected at CRF |
| AETO_C | char | AE TO CODE | | Collected at CRF |
| AESEV | char | AE SEVERITY | | Collected at CRF |
| ZAESV | num | AE SEVERITY | | Collected at CRF |
| AEACT | char | AE ACTION TAKEN | | Collected at CRF |
| ZAEACT | num | AE ACTION TAKEN | | Collected at CRF |
| AECONRX | char | AE CO-RX START | | Collected at CRF |
| ZAECONRX | num | AE CO-RX START | | Collected at CRF |
| AERELAT | char | AE DRUG RELATION | | Collected at CRF |
| ZAERELAT | num | AE DRUG RELATION | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|------------------------------|-------|---|
| AEOUT | char | AE OUTCOME | | Collected at CRF |
| ZAEOUT | num | AE OUTCOME | | Collected at CRF |
| AESER | char | AE SERIOUSNESS | | Collected at CRF |
| ZAESER | num | AE SERIOUSNESS | | Collected at CRF |
| AESOC | char | AE SYSTEM ORGAN CLASS | | Collected at CRF |
| AEWHONUM | char | AE WHO CODE | | Collected at CRF |
| AEPREF | char | ADVERSE EVENT PREFERRED TERM | | Collected at CRF |
| AESOC1 | char | AE SYSTEM ORGAN CLASS 1 | | Collected at CRF |
| AESOC2 | char | AE SYSTEM ORGAN CLASS 2 | | Collected at CRF |
| AESOC3 | char | AE SYSTEM ORGAN CLASS 3 | | Collected at CRF |
| AEFROMDY | num | Relative AE FROM Day | | If AEFROM_D and RAND_D not missing then perform below logic to calculate relative day. If AEFROM_D less than RAND_D then (AEFROM_D - RAND_D). Else if AEFROM_D is greater than equal to RAND_D then (AEFROM_D - RAND_D) +1. |
| AETO_DY | num | Relative AE TO Day | | If AETO_D and RAND_D not missing then perform below logic to calculate relative day. If AETO_D less than RAND_D then (AETO_D - RAND_D). Else if AETO_D is greater than equal to RAND_D then (AETO_D - RAND_D) +1. |

1.4.3. ABNORMAL INVOLUNTARY MOVEMENT SCALE (AI) – AIMS

| | |
|--------------------------|--|
| Dataset | AIMS |
| Creating program | aims.sas |
| Description | ABNORMAL INVOLUNTARY MOVEMENT SCALE (AI) |
| Unique identifier | DCRFID, VISIT, AIITEM |
| Sorted by | DCRFID, VISIT, AIITEM |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| AIGROUP | char | GROUP | | Collected at CRF |
| AIITEM | char | AIMS ITEM | | Collected at CRF |
| AISCORE | char | AIMS SCORE | | Collected at CRF |
| ZAISCORE | num | AIMS SCORE | | Collected at CRF |

1.4.4. DRUG ADMINISTRATION BEFORE SAMPLING (BA) – BANADM

| | |
|--------------------------|---|
| Dataset | BANADM |
| Creating program | banadm.sas |
| Description | DRUG ADMINISTRATION BEFORE SAMPLING (BA) |
| Unique identifier | DCRFID, SPECIMEN, SAMTYPE, BAADM_DY, BAADM_T, BAADMSEQ, VISIT |
| Sorted by | DCRFID, SPECIMEN, SAMTYPE, BAADM_DY, BAADM_T, BAADMSEQ, VISIT |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMREFNO, BAADM_D, LABINTNO, TREAT |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| SAMTYPE | char | PURPOSE OF SAMPLE | | Collected at CRF |
| BAADM_T | num | DRUG ADMIN. TIME | | Collected at CRF |
| BAADMSEQ | char | DRUG ADMIN. SEQ. | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| BAADM_DY | num | Relative DRUG ADMIN. Day | | If BAADM_D and RAND_D not missing then perform below logic to calculate relative day. If BAADM_D less than RAND_D then (BAADM_D - RAND_D). Else if BAADM_D is greater than equal to RAND_D then (BAADM_D - RAND_D) +1. |

1.4.5. BIOANALYSIS RESULTS (BR) – BANRES

| | |
|--------------------------|--|
| Dataset | BANRES |
| Creating program | banres.sas |
| Description | BIOANALYSIS RESULTS (BR) |
| Unique identifier | DCRFID, SPECIMEN, SAMTYPE, SAMPLEDY, SAMPLE_T, BRVAL, BRVAL_V, BRVAL_U, BRQUANT, VISIT, SAMTM_S, EVENT |
| Sorted by | DCRFID, SPECIMEN, SAMTYPE, SAMPLEDY, SAMPLE_T, BRVAL, BRVAL_V, BRVAL_U, BRQUANT, VISIT, SAMTM_S, EVENT |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, SAMREFNO, LABINTNO, BRINTNO, PERIOD |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| SAMTYPE | char | PURPOSE OF SAMPLE | | Collected at CRF |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF |
| SUBST | char | SUBSTANCE | | Collected at CRF |
| BRVAL | num | BAN MEASUREMENT | | Collected at CRF |
| BRVAL_V | char | BAN MEASUREMENT (VERB.) | | Collected at CRF |
| BRVAL_U | char | UNIT | | Collected at CRF |
| BRQUANT | num | LIMIT OF QUANTIFICATION | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| SAMTM_S | char | SCHEDULED TIME | | Collected at CRF |
| EVENT | char | SCHEDULED VISIT OR DAY | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|---|
| SAMPLEDY | num | Relative SAMPLING Day | | If SAMPLE_D and RAND_D not missing then perform below logic to calculate relative day. If SAMPLE_D less than RAND_D then (SAMPLE_D - RAND_D). Else if SAMPLE_D is greater than equal to RAND_D then (SAMPLE_D - RAND_D) +1. |

1.4.6. BARNES AKATHISIA RATING SCLAE (BA) – BARS

| | |
|--------------------------|------------------------------------|
| Dataset | BARS |
| Creating program | bars.sas |
| Description | BARNES AKATHISIA RATING SCLAE (BA) |
| Unique identifier | DCRFID, VISIT, BAGROUP, BAITEM |
| Sorted by | DCRFID, VISIT, BAGROUP, BAITEM |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| BAGROUP | char | BARS GROUP | | Collected at CRF |
| BAITEM | char | BARS ITEM | | Collected at CRF |
| BASCORE | char | BARS SCORE | | Collected at CRF |
| ZBASCORE | num | BARS SCORE | | Collected at CRF |

1.4.7. BRIEF PSYCHIATRIC RATING SCALE (BP) – BPRS

| | |
|--------------------------|-------------------------------------|
| Dataset | BPRS |
| Creating program | bprs.sas |
| Description | BRIEF PSYCHIATRIC RATING SCALE (BP) |
| Unique identifier | DCRFID, VISIT, BPITEM |
| Sorted by | DCRFID, VISIT, BPITEM |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| BPITEM | char | BPRS ITEM | | Collected at CRF |
| BPSCORE | char | BPRS SCORE | | Collected at CRF |
| ZBPSCORE | num | BPRS SCORE | | Collected at CRF |

1.4.8. CLINICAL GLOBAL IMPRESSION (CG) – CGI

| | |
|--------------------------|---------------------------------|
| Dataset | CGI |
| Creating program | cgi.sas |
| Description | CLINICAL GLOBAL IMPRESSION (CG) |
| Unique identifier | DCRFID, VISIT, CGITEM |
| Sorted by | DCRFID, VISIT, CGITEM |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| CGGROUP | char | CGI GROUP | | Collected at CRF |
| CGITEM | char | CGI ITEM | | Collected at CRF |
| CGSCORE | char | CG SCORE | | Collected at CRF |
| ZCGSCORE | num | CG SCORE | | Collected at CRF |

1.4.9. COTHER AE RELATED TABLE (AC) – CONAE

| | |
|--------------------------|--|
| Dataset | CONAE |
| Creating program | conae.sas |
| Description | COTHER AE RELATED TABLE (AC) |
| Unique identifier | DCRFID, AESEQNO, CTTYPE, CTSEQNO |
| Sorted by | DCRFID, AESEQNO, CTTYPE, CTSEQNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CONRX_V |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| AESEQNO | num | AE SEQ. | | Collected at CRF |
| CTTYPE | char | CO-RX TYPE | | Collected at CRF |
| CTSEQNO | num | CO-RX SEQ. | | Collected at CRF |

1.4.10. CONCOMITANT THERAPY (CT) – COTHER

| | |
|--------------------------|--|
| Dataset | COTHER |
| Creating program | cother.sas |
| Description | CONCOMITANT THERAPY (CT) |
| Unique identifier | DCRFID, CTSEQNO, CTTYPE |
| Sorted by | DCRFID, CTSEQNO, CTTYPE |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CONRX_V, CTIND_V, CTIND, CTFROM_D, CTTO_D |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| CTSEQNO | num | CO-RX SEQ. | | Collected at CRF |
| CTTYPE | char | CO-RX TYPE | | Collected at CRF |
| CONRX | char | CO-RX | | Collected at CRF |
| CTSCHED | char | CO-RX DAILY SCHEDULE | | Collected at CRF |
| CTPRIOR | char | CO-RX PRE-TRIAL | | Collected at CRF |
| CTFROM_C | char | CO-RX START CODE | | Collected at CRF |
| CTONGO | char | CO-RX ONGOING | | Collected at CRF |
| CTTO_C | char | CO-RX END CODE | | Collected at CRF |
| CTPREF | char | INDICATION PREFERRED TERM | | Collected at CRF |
| RXWHONUM | char | WHO DRUG CODE | | Collected at CRF |
| ATCCODE0 | char | ATC CODE 0 | | Collected at CRF |
| ATCCODE1 | char | ATC CODE 1 | | Collected at CRF |
| ATCCODE2 | char | ATC CODE 2 | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------------|-------|---|
| ATCCODE3 | char | ATC CODE 3 | | Collected at CRF |
| ATCCODE4 | char | ATC CODE 4 | | Collected at CRF |
| ATCCODE5 | char | ATC CODE 5 | | Collected at CRF |
| ATCCODE6 | char | ATC CODE 6 | | Collected at CRF |
| ATCCODE7 | char | ATC CODE 7 | | Collected at CRF |
| ATCCODE8 | char | ATC CODE 8 | | Collected at CRF |
| ATCCODE9 | char | ATC CODE 9 | | Collected at CRF |
| ATCTEXT0 | char | ATC TEXT 0 | | Collected at CRF |
| ATCTEXT1 | char | ATC TEXT 1 | | Collected at CRF |
| ATCTEXT2 | char | ATC TEXT 2 | | Collected at CRF |
| ATCTEXT3 | char | ATC TEXT 3 | | Collected at CRF |
| ATCTEXT4 | char | ATC TEXT 4 | | Collected at CRF |
| ATCTEXT5 | char | ATC TEXT 5 | | Collected at CRF |
| ATCTEXT6 | char | ATC TEXT 6 | | Collected at CRF |
| ATCTEXT7 | char | ATC TEXT 7 | | Collected at CRF |
| ATCTEXT8 | char | ATC TEXT 8 | | Collected at CRF |
| ATCTEXT9 | char | ATC TEXT 9 | | Collected at CRF |
| RXPREF | char | PREFERRED NAME | | Collected at CRF |
| CTFROMDY | num | Relative CO-RX START Day | | If CTFROM_D and RAND_D not missing then perform below logic to calculate relative day. If CTFROM_D less than RAND_D then (CTFROM_D - RAND_D). Else if CTFROM_D is greater than equal to RAND_D then (CTFROM_D - RAND_D) +1. |
| CTTO_DY | num | Relative CO-RX END Day | | If CTTO_D and RAND_D not missing then perform below logic to calculate relative day. If CTTO_D less than RAND_D then (CTTO_D - RAND_D). Else if CTTO_D is greater than equal to RAND_D then (CTTO_D - RAND_D) +1. |

1.4.11. DEATH REPORT (DT) – DEATH

| | |
|--------------------------|--|
| Dataset | DEATH |
| Creating program | death.sas |
| Description | DEATH REPORT (DT) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>DCRFID, DEATH_D, DTREAS_V</p> <p>Note: No death cases reported in this study, empty dataset will be submitted.</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| DEATH_DY | num | Relative Death Day | | Date will be dropped after deriving relative day. |
| DTREAS | char | DEATH CAUSE | | Collected at CRF |

1.4.12. DEVIATION (DV) – DEVIATN

| | |
|--------------------------|---|
| Dataset | DEVIATN |
| Creating program | deviatn.sas |
| Description | DEVIATION (DV) |
| Unique identifier | DCRFID, ZDEVIAT |
| Sorted by | DCRFID, ZDEVIAT |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DVTYPE, DEVIAT_V |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| DEVIAT | char | DEVIATION | | Collected at CRF |
| ZDEVIAT | char | DEVIATION | | Collected at CRF |

1.4.13. ELECTROCARDIOGRAM (EG) – ECG

| | |
|--------------------------|---|
| Dataset | ECG |
| Creating program | ecg.sas |
| Description | ELECTROCARDIOGRAM (EG) |
| Unique identifier | DCRFID, ECG_DY, ECG_T |
| Sorted by | DCRFID, ECG_DY, ECG_T |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE, EGLIMITS, EGRELCHA, LEADQT, ECGINTNO, ECGREFNO |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| ECG_T | num | ECG TIME | | Collected at CRF |
| EGRESULT | char | ECG RESULT | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| ECG_DY | num | Relative ECG Day | | If ECG_D and RAND_D not missing then perform below logic to calculate relative day. If ECG_D less than RAND_D then (ECG_D - RAND_D). Else if ECG_D is greater than equal to RAND_D then (ECG_D - RAND_D) +1. |

1.4.14. ECG OTHER ABNORMALITIES (EA) – ECGABN

| | |
|--------------------------|---|
| Dataset | ECGABN |
| Creating program | ecgabn.sas |
| Description | ECG OTHER ABNORMALITIES (EA) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>CRFID, ECG_D, ECGSRCE, ECGOTH_V, ECGINTNO</p> <p>Note: No data reported, empty dataset will be submitted.</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| ECG_DY | num | Relative ECG Day | | Date will be dropped after deriving relative day. |
| ECG_T | num | ECG TIME | | Collected at CRF |
| EASEQNO | num | SEQUENCE NUMBER | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |

1.4.15. ELECTROCARDIOGRAM EVALUATION (EE) – ECGEVAL

| | |
|--------------------------|---|
| Dataset | ECGEVAL |
| Creating program | ecgeval.sas |
| Description | ELECTROCARDIOGRAM EVALUATION (EE) |
| Unique identifier | DCRFID, ECG_DY, ECG_T, EEEVAL |
| Sorted by | DCRFID, ECG_DY, ECG_T, EEEVAL |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE, ECGINTNO |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| ECG_T | num | ECG TIME | | Collected at CRF |
| EEASPECT | char | ECG ASPECT | | Collected at CRF |
| EEEVAL | char | ECG EVALUATION | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| ECG_DY | num | Relative ECG Day | | If ECG_D and RAND_D not missing then perform below logic to calculate relative day. If ECG_D less than RAND_D then (ECG_D - RAND_D). Else if ECG_D is greater than equal to RAND_D then (ECG_D - RAND_D) +1. |

1.4.16. ELECTROCARDIOGRAM MEASUREMENTS (EP) – ECGPAR

| | |
|--------------------------|---|
| Dataset | ECGPAR |
| Creating program | ecgpar.sas |
| Description | ELECTROCARDIOGRAM MEASUREMENTS (EP) |
| Unique identifier | DCRFID, ECG_DY, ECG_T, ECGPAR, EPSEQNO |
| Sorted by | DCRFID, ECG_DY, ECG_T, ECGPAR, EPSEQNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE, ECGINTNO |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| ECG_T | num | ECG TIME | | Collected at CRF |
| ECGPAR | char | ECG PARAMETER | | Collected at CRF |
| EPSEQNO | num | SEQUENCE NUMBER | | Collected at CRF |
| ECGVAL | num | ECG MEASUREMENT | | Collected at CRF |
| ECGPAR_U | char | ECG MEASUREMENT UNIT | | Collected at CRF |
| ECGVAL_V | char | ECG MEASUREMENT (VERB.) | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| ECG_DY | num | Relative ECG Day | | If ECG_D and RAND_D not missing then perform below logic to calculate relative day. If ECG_D less than RAND_D then (ECG_D - RAND_D). Else if ECG_D is greater than equal to RAND_D then (ECG_D - RAND_D) +1. |

1.4.17. ELECTROCARDIOGRAM (ER) – ECGREF

| | |
|--------------------------|---|
| Dataset | ECGREF |
| Creating program | ecgref.sas |
| Description | ELECTROCARDIOGRAM (ER) |
| Unique identifier | DCRFID, ECG_DY, VISIT |
| Sorted by | DCRFID, ECG_DY, VISIT |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGSRCE |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| EGRELCHA | char | CLIN. SIGNIFICANT CHANGES | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| ECG_DY | num | Relative ECG Day | | If ECG_D and RAND_D not missing then perform below logic to calculate relative day. If ECG_D less than RAND_D then (ECG_D - RAND_D). Else if ECG_D is greater than equal to RAND_D then (ECG_D - RAND_D) +1. |

1.4.18. HOSPITAL RELATED AES (HA) – HOSAE

| | |
|--------------------------|----------------------|
| Dataset | HOSAE |
| Creating program | hosae.sas |
| Description | HOSPITAL STATUS (HO) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| HOSEQNO | num | HOSPITAL SEQUENCE NUMBER | | Collected at CRF |
| AESEQNO | num | AE SEQ. | | Collected at CRF |

1.4.19. HOSPITAL STATUS (HO) – HOSPITAL

| | |
|--------------------------|---|
| Dataset | HOSPITAL |
| Creating program | hospital.sas |
| Description | HOSPITAL STATUS (HO) |
| Unique identifier | DCRFID, HOSEQNO |
| Sorted by | DCRFID, HOSEQNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HOFROM_D, HOTO_D |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| HOSEQNO | num | HOSPITAL SEQUENCE NUMBER | | Collected at CRF |
| HOONGO | char | ADMISSION ONGOING? | | Collected at CRF |
| HOFROMDY | num | Relative ADMISSION Day | | If HOFROM_D and RAND_D not missing then perform below logic to calculate relative day. If HOFROM_D less than RAND_D then (HOFROM_D - RAND_D). Else if HOFROM_D is greater than equal to RAND_D then (HOFROM_D - RAND_D) +1. |
| HOTO_DY | num | Relative DISCHARGE Day | | If HOTO_D and RAND_D not missing then perform below logic to calculate relative day. If HOTO_D less than RAND_D then (HOTO_D - RAND_D). Else if HOTO_D is greater than equal to RAND_D then (HOTO_D - RAND_D) +1. |

1.4.20. INCLUSION-EXCLUSION CRITERIA (IE) – INEX

| | |
|--------------------------|---|
| Dataset | INEX |
| Creating program | inex.sas |
| Description | INCLUSION-EXCLUSION CRITERIA (IE) |
| Unique identifier | DCRFID, IETYPE, ZIECRIT |
| Sorted by | DCRFID, IETYPE, ZIECRIT |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IECRIT |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| IETYPE | char | TYPE OF INCLUSION CRITERIA | | Collected at CRF |
| IECRIT | char | SELECTION CRITERIA | | Collected at CRF |
| ZIECRIT | num | SELECTION CRITERIA | | Collected at CRF |
| IEYN | char | NON-ELIGIBILITY EXPR. | | Collected at CRF |

1.4.21. LABORATORY RESULTS (LR) – LABRES

| | |
|--------------------------|---|
| Dataset | LABRES |
| Creating program | labres.sas |
| Description | LABORATORY RESULTS (LR) |
| Unique identifier | DCRFID, LABTEST, VISIT |
| Sorted by | DCRFID, LABTEST, VISIT |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>SAMPLE_D, LABID, ZLABID, LABVAL_V, SAMREFNO, LABINTNO</p> <p>Note: Protocol unplanned tests will be removed; it may reveal participant information.</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| SAMTYPE | char | PURPOSE OF SAMPLE | | Collected at CRF |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF |
| LABTEST | char | LAB. TEST | | Collected at CRF |
| ZLABTEST | char | LAB. TEST | | Collected at CRF |
| LABVAL | num | LAB. TEST VALUE | | Collected at CRF |
| LABLOW | num | LOWER NORMAL LIMIT | | Collected at CRF |
| LABUPP | num | UPPER NORMAL LIMIT | | Collected at CRF |
| LABTST_U | char | LAB. TEST UNIT | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------------|-------|---|
| LOWPATHO | num | LOWER PATHOLOGICAL LIMIT | | Collected at CRF |
| UPPPATHO | num | UPPER PATHOLOGICAL LIMIT | | Collected at CRF |
| CFACTOR | num | CONVERSION FACTOR | | Collected at CRF |
| SIUNIT | char | STANDARD INTERNATIONAL UNIT | | Collected at CRF |
| LABTSTNO | num | LAB. TEST NUMBER | | Collected at CRF |
| LABCLASS | char | LAB CLASS | | Collected at CRF |
| ENZYME | char | ENZYME | | Collected at CRF |
| SAMPLEDY | num | Relative SAMPLING Day | | If SAMPLE_D and RAND_D not missing then perform below logic to calculate relative day. If SAMPLE_D less than RAND_D then (SAMPLE_D - RAND_D). Else if SAMPLE_D is greater than equal to RAND_D then (SAMPLE_D - RAND_D) +1. |

1.4.22. LABORATORY URINE RESULTS (LU) – LABURI

| | |
|--------------------------|--|
| Dataset | LABURI |
| Creating program | laburi.sas |
| Description | LABORATORY URINE RESULTS (LU) |
| Unique identifier | DCRFID, LABTEST, VISIT |
| Sorted by | DCRFID, LABTEST, VISIT |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>SAMPLE_D, LABID, ZLABID, SAMREFNO, LABINTNO, LUVAL_V</p> <p>Note: Protocol unplanned tests will be removed; it may reveal participant information.</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| SAMTYPE | char | PURPOSE OF SAMPLE | | Collected at CRF |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF |
| LABTEST | char | LAB. TEST | | Collected at CRF |
| ZLABTEST | char | LAB. TEST | | Collected at CRF |
| LUVAL | char | URINE VALUE | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| LABTSTNO | num | LAB. TEST NUMBER | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|---|
| LABCLASS | char | LAB CLASS | | Collected at CRF |
| SAMPLEDY | num | Relative SAMPLING Day | | If SAMPLE_D and RAND_D not missing then perform below logic to calculate relative day. If SAMPLE_D less than RAND_D then (SAMPLE_D - RAND_D). Else if SAMPLE_D is greater than equal to RAND_D then (SAMPLE_D - RAND_D) +1. |

1.4.23. NO DATA ON VISITS/PAGES (ND) – NODATA

| | |
|--------------------------|------------------------------|
| Dataset | NODATA |
| Creating program | nodata.sas |
| Description | NO DATA ON VISITS/PAGES (ND) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| NDSEQNO | num | SEQUENCE NUMBER | | Collected at CRF |
| NDFROM | num | NO DATA START | | Collected at CRF |
| NDTO | num | NO DATA END | | Collected at CRF |

1.4.24. NON-PHARMACOLOGIC THERAPY (NP) – NPHATHER

| | |
|--------------------------|--------------------------------|
| Dataset | NPHATHER |
| Creating program | nphather.sas |
| Description | NON-PHARMACOLOGIC THERAPY (NP) |
| Unique identifier | DCRFID, VISIT, NPOTHER |
| Sorted by | DCRFID, VISIT, NPOTHER |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| NPOTHER | char | NON-PHARMACOLOGIC THERAPY | | Collected at CRF |
| NPYESNO | char | NON-PHARMACOLOGIC THERAPY, YESNO | | Collected at CRF |
| NPTPWK | char | NON-PHARMACOLOGIC THERAPY TIME | | Collected at CRF |

1.4.25. PHYSICAL EXAMINATION (PE) – PHYSEXAM

| | |
|--------------------------|---|
| Dataset | PHYSEXAM |
| Creating program | PHYSEXAM.sas |
| Description | PHYSICAL EXAMINATION (PE) |
| Unique identifier | DCRFID, VISIT, PESEQNO |
| Sorted by | DCRFID, VISIT, PESEQNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXAM_V, EXAM |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| PESEQNO | num | SEQUENCE NUMBER | | Collected at CRF |
| PESYSTEM | char | PHYS. EXAM. BODY SYSTEM | | Collected at CRF |
| PERESULT | char | PHYS. EXAM. RESULT | | Collected at CRF |

1.4.26. PHARMACOKINETIC OUTLIERS (PO) – PKOUTL

| | |
|--------------------------|--|
| Dataset | PKOUTL |
| Creating program | PKOUTL.sas |
| Description | PHARMACOKINETIC OUTLIERS (PO) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>DCRFID, SAMTYPE, SAMPLE_D, BRINTNO, PKOUTL_V, SAMREFNO, LABINTNO</p> <p>Note: No data reported, empty dataset will be submitted.</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| SAMPLEDY | num | RELATIVE SAMPLING DAY | | Date will be dropped after deriving relative day. |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF |
| SUBST | char | SUBSTANCE | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |

1.4.27. PHARMACOKINETIC RESULTS (PK) – PKRES

| | |
|--------------------------|---|
| Dataset | PKRES |
| Creating program | PKRES.sas |
| Description | PHARMACOKINETIC RESULTS (PK) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | <p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines:</p> <p>CRFID, SAMTYPE, PKVAL_V, PKOUTL_V</p> <p>Note: No data reported, empty dataset will be submitted.</p> |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| PKPARAM | char | PK PARAMETER | | Collected at CRF |
| PKVAL | num | PK MEASUREMENT | | Collected at CRF |
| SUBST | char | SUBSTANCE | | Collected at CRF |
| PKVAL_U | char | UNIT | | Collected at CRF |

1.4.28. PREVIOUS THERAPY (PT) – PRETHER

| | |
|--------------------------|--|
| Dataset | PRETHER |
| Creating program | PRETHER.sas |
| Description | PREVIOUS THERAPY (PT) |
| Unique identifier | DCRFID, PTSEQNO |
| Sorted by | DCRFID, PTSEQNO |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PRVRX_V, PTSCHED, PTIND_V, PTIND, PTFROM_D, PTADM_D, PTTO_D, PTAE_V |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| PTSEQNO | num | PREV. RX SEQ. | | Collected at CRF |
| PRVRX | char | PREV. RX | | Collected at CRF |
| PTFROM_C | char | PREV. RX START DATE CODE | | Collected at CRF |
| PTADM_C | char | PREV. RX LAST ADMIN. DATE CODE | | Collected at CRF |
| RXWHONUM | char | WHO DRUG CODE | | Collected at CRF |
| ATCCODE0 | char | ATC CODE 0 | | Collected at CRF |
| ATCCODE1 | char | ATC CODE 1 | | Collected at CRF |
| ATCCODE2 | char | ATC CODE 2 | | Collected at CRF |
| ATCCODE3 | char | ATC CODE 3 | | Collected at CRF |
| ATCCODE4 | char | ATC CODE 4 | | Collected at CRF |
| ATCCODE5 | char | ATC CODE 5 | | Collected at CRF |
| ATCCODE6 | char | ATC CODE 6 | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------------------|-------|---|
| ATCCODE7 | char | ATC CODE 7 | | Collected at CRF |
| ATCCODE8 | char | ATC CODE 8 | | Collected at CRF |
| ATCCODE9 | char | ATC CODE 9 | | Collected at CRF |
| ATCTEXT0 | char | ATC TEXT 0 | | Collected at CRF |
| ATCTEXT1 | char | ATC TEXT 1 | | Collected at CRF |
| ATCTEXT2 | char | ATC TEXT 2 | | Collected at CRF |
| ATCTEXT3 | char | ATC TEXT 3 | | Collected at CRF |
| ATCTEXT4 | char | ATC TEXT 4 | | Collected at CRF |
| ATCTEXT5 | char | ATC TEXT 5 | | Collected at CRF |
| ATCTEXT6 | char | ATC TEXT 6 | | Collected at CRF |
| ATCTEXT7 | char | ATC TEXT 7 | | Collected at CRF |
| ATCTEXT8 | char | ATC TEXT 8 | | Collected at CRF |
| ATCTEXT9 | char | ATC TEXT 9 | | Collected at CRF |
| RXPREF | char | PREFERRED NAME | | Collected at CRF |
| PTFROMDY | char | Relative PREV. RX START Day | | If PTFROM_D and RAND_D not missing then perform below logic to calculate relative day. If PTFROM_D less than RAND_D then (PTFROM_D - RAND_D). Else if PTFROM_D is greater than equal to RAND_D then (PTFROM_D - RAND_D) +1. |
| PTADM_DY | char | Relative PREV. RX LAST ADMIN. Day | | If PTADM_D and RAND_D not missing then perform below logic to calculate relative day. If PTADM_D less than RAND_D then (PTADM_D - RAND_D). Else if PTADM_D is greater than equal to RAND_D then (PTADM_D - RAND_D) +1. |

1.4.29. RELATED AES FOR TERMINATION OR DEATH(RA) – RELAE

| | |
|--------------------------|--|
| Dataset | RELAE |
| Creating program | RELAE.sas |
| Description | RELATED AES FOR TERMINATION OR DEATH(RA) |
| Unique identifier | DCRFID, AESEQNO |
| Sorted by | DCRFID, AESEQNO |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| RATYPE | char | AE CONSEQUENCE | | Collected at CRF |
| AESEQNO | num | AE SEQ. | | Collected at CRF |

1.4.30. REMARKS AND COMMENTS (RM) – REMARK

| | |
|--------------------------|---|
| Dataset | REMARK |
| Creating program | REMARK.sas |
| Description | REMARKS AND COMMENTS (RM) |
| Unique identifier | Not Applicable |
| Sorted by | Not Applicable |
| Notes | Remark data is sensitive data, contains free text information. Will be submitted as an empty dataset. |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|---|
| TRIAL | char | TRIAL ID. | | Its comment data will not be submitted. |
| DCRFID | char | CRF ID Assigned for De-identity | | Its comment data will not be submitted. |
| RMSEQNO | num | SEQUENCE NUMBER | | Its comment data will not be submitted. |
| RMTYPE | char | REMARK TYPE | | Its comment data will not be submitted. |

1.4.31. SAMPLES (SA) – SAMPLE

| | |
|--------------------------|--|
| Dataset | SAMPLE |
| Creating program | SAMPLE.sas |
| Description | SAMPLES (SA) |
| Unique identifier | DCRFID, SPECIMEN, VISIT, SAMTM_S |
| Sorted by | DCRFID, SPECIMEN, VISIT, SAMTM_S |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, SAMREFNO, LABINTNO |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SPECIMEN | char | SPECIMEN | | Collected at CRF |
| SAMTYPE | char | PURPOSE OF SAMPLE | | Collected at CRF |
| SAMPLE_T | num | SAMPLING TIME | | Collected at CRF |
| HAEMOLYS | char | SAMPLE HAEMOLYSED | | Collected at CRF |
| FASTED | char | SUBJECT FASTED | | Collected at CRF |
| SASAME | char | SAME NORMAL RANGES | | Collected at CRF |
| SARELCHA | char | CLIN. SIGNIFICANT CHANGES | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| SAMTM_S | char | SCHEDULED TIME | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|---|
| SAMPLEDY | num | Relative SAMPLING Day | | If SAMPLE_D and RAND_D not missing then perform below logic to calculate relative day. If SAMPLE_D less than RAND_D then (SAMPLE_D - RAND_D). Else if SAMPLE_D is greater than equal to RAND_D then (SAMPLE_D - RAND_D) +1. |

1.4.32. SAMPLE REQUISITION NUMBERS (SR) – SAMREF

| | |
|--------------------------|---|
| Dataset | SAMREF |
| Creating program | SAMREF.sas |
| Description | SAMPLE REQUISITION NUMBERS (SR) |
| Unique identifier | DCRFID, SASEQ, SARELCHA, VISIT, SAMTM_S, SAMPLEDY |
| Sorted by | DCRFID, SASEQ, SARELCHA, VISIT, SAMTM_S, SAMPLEDY |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMREFNO, SAMTYPE, LABID, ZLABID, SAMPLE_D |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SASEQ | num | SAMPLE SEQ | | Collected at CRF |
| SARELCHA | char | CLIN. SIGNIFICANT CHANGES | | Collected at CRF |
| VISIT | num | VISIT | | Collected at CRF |
| SAMTM_S | char | SCHEDULED TIME | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------|-------|---|
| SAMPLEDY | num | Relative SAMPLING Day | | If SAMPLE_D and RAND_D not missing then perform below logic to calculate relative day. If SAMPLE_D less than RAND_D then (SAMPLE_D - RAND_D). Else if SAMPLE_D is greater than equal to RAND_D then (SAMPLE_D - RAND_D) +1. |

1.4.33. SIMPSON AND ANGUS RATING SCALE (SR) – SARS

| | |
|--------------------------|-------------------------------------|
| Dataset | SARS |
| Creating program | SARS.sas |
| Description | SIMPSON AND ANGUS RATING SCALE (SR) |
| Unique identifier | DCRFID, VISIT, SAITEM |
| Sorted by | DCRFID, VISIT, SAITEM |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| SAITEM | char | SIMPSON AND ANGUS ITEM | | Collected at CRF |
| SASCORE | char | SIMPSON AND ANGUS SCORE | | Collected at CRF |
| ZSASCORE | num | SIMPSON AND ANGUS SCORE | | Collected at CRF |

1.4.34. SUBJECT CHARACTERISTICS (SC) – SUBJCHAR

| | |
|--------------------------|--|
| Dataset | SUBJCHAR |
| Creating program | SUBJCHAR.sas |
| Description | SUBJECT CHARACTERISTICS (SC) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDNO, INVEST, ZINVEST, INITIALS, BIRTH_D, BREAK_D, BREAK_V, DRYRUN, RAND_D, COINV, ZCOINV, BATCHNO, ETHNIC |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| SEX | char | SEX | | Collected at CRF |
| RACE | char | RACE | | Collected at CRF |
| DEATHNA | char | EVENT OF DEATH | | Collected at CRF |
| BREAK | char | CODE BROKEN ? | | Collected at CRF |
| ENTRYCOM | char | ENTRY COMPLETED | | Collected at CRF |
| DCOUNTRY | char | CONTINENT | | Grouping element to protect subject PII. |
| DZCONTRY | char | CONTINENT | | Grouping element to protect subject PII. |
| DSITEID | num | SITE NO. Assigned for De-identity | | Randomly assigned Unique Site No for De-identity |
| HISBIP1 | char | HISTORY BIPOLAR I DISORDER | | Collected at CRF |
| MANICEP | char | MANIC EPISODE | | Collected at CRF |
| MIXEDEP | char | MIXED EPISODE | | Collected at CRF |
| CONDIS | char | CONDUCT DISORDER | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|--|-------|---|
| ADHDIS | char | ATT. DEFICIT HYPERACTIVITY DISORDER | | Collected at CRF |
| DISBEDIS | char | DISRUPTIVE BEHAVIORAL DISORDER | | Collected at CRF |
| OPPEDIS | char | OPPOSITIONAL DEFIANT DISORDER | | Collected at CRF |
| ONAGE | num | ONSET AGE FOR BIPOLAR DISORDER | | Grouping element to protect subject PII. |
| TIMEAGE | char | AGE OF FIRST PSYCHIATRIC HOSPITALIZATION | | Grouping element to protect subject PII. |
| DRUGAGE | char | AGE OF FIRST PHARMALOGIC TREATMENT | | Grouping element to protect subject PII. |
| HOSPNO | num | NUMBER PREVIOUS PSYCH HOSPITALIZATIONS | | Collected at CRF |
| DISCVIS | num | D/C VISIT | | Collected at CRF |
| HOSPND | char | NOT HOSPITALIZED | | Collected at CRF |
| HOSCRNA | char | HOSPITALIZATION AT SCREENING | | Collected at CRF |
| AMNA | char | ADMMED ADDTL. FLEX TARGET NOT APPLICABLE | | Collected at CRF |
| RACENEW | char | RACE (NEW) | | Collected at CRF |
| RANDGRP | char | RANDOMISATION GROUP | | Assigned per randomization schedule. |
| AGE | num | Age in Years | | If BIRTH_D and VISIT_D (Visit 1) not missing then perform below logic to derive age. INT(VISIT_D - BIRTH_D)/365.25 |
| RAND_DY | num | Relative RANDOMISATION Day | | If RAND_D and RAND_D not missing then perform below logic to calculate relative day. If RAND_D less than RAND_D then (RAND_D - RAND_D). Else if RAND_D is greater than equal to RAND_D then (RAND_D - RAND_D) +1. |

1.4.35. TREATMENT / TRIAL TERMINATION (TR) – TRTTERM

| | |
|--------------------------|---|
| Dataset | TRTTERM |
| Creating program | TRTTERM.sas |
| Description | TREATMENT / TRIAL TERMINATION (TR) |
| Unique identifier | DCRFID |
| Sorted by | DCRFID |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TRREAS_V, TRFROM_D |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|---|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| TRTYPE | char | TYPE OF TERMINATION | | Collected at CRF |
| TRSTATE | char | STATE OF TERMINATION | | Collected at CRF |
| TRREAS | char | TERM. REASON | | Collected at CRF |
| TRFROMDY | num | Relative LAST CONTACT Day | | If TRFROM_D and RAND_D not missing then perform below logic to calculate relative day. If TRFROM_D less than RAND_D then (TRFROM_D - RAND_D). Else if TRFROM_D is greater than equal to RAND_D then (TRFROM_D - RAND_D) +1. |

1.4.36. VISITS (VI) – VISIT

| | |
|--------------------------|--|
| Dataset | VSIT |
| Creating program | VISIT.sas |
| Description | VISITS (VI) |
| Unique identifier | DCRFID, VISIT |
| Sorted by | DCRFID, VISIT |
| Notes | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| HOADMIS | char | SUBJ. ADMITTED TO THE HOSPITAL | | Collected at CRF |
| PREVMED | char | LORAZEPAM WITHIN 8 HOURS | | Collected at CRF |
| TANNER1 | num | TANNER STAGE 1 | | Collected at CRF |
| TANNER2 | num | TANNER STAGE 2 | | Collected at CRF |
| ECGND | char | ECG DATA NOT DONE | | Collected at CRF |
| VSND | char | VITAL SIGN NOT DONE | | Collected at CRF |
| LABND | char | LAB DATA NOT DONE | | Collected at CRF |
| SARSND | char | SARS NOT DONE | | Collected at CRF |
| BARSND | char | BARS NOT DONE | | Collected at CRF |
| AIMSND | char | AIMS NOT DONE | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|--------------------|-------|--|
| VISIT_DY | num | Relative VISIT Day | | If VISIT_D and RAND_D not missing then perform below logic to calculate relative day. If VISIT_D less than RAND_D then (VISIT_D - RAND_D). Else if VISIT_D is greater than equal to RAND_D then (VISIT_D - RAND_D) +1. |

1.4.37. VITAL SIGNS (VS) – VITSIGN

| | |
|--------------------------|-------------------------|
| Dataset | VITSIGN |
| Creating program | VITSIGN.sas |
| Description | VITAL SIGNS (VS) |
| Unique identifier | DCRFID, VISIT, POSITION |
| Sorted by | DCRFID, VISIT, POSITION |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| POSITION | char | POSITION | | Collected at CRF |
| PULSE | num | PULSE, beats/min | | Collected at CRF |
| WEIGHT_U | char | WEIGHT UNIT | | All data converted into KGs. |
| WEIGHT | num | WEIGHT | | Convert data to standardized "kg" unit values. Grouped weight to protect PII. |

| Variable | Type | Label | Codes | Comments |
|----------|------|-------------------------------|-------|--|
| HEIGHT | num | HEIGHT | | Convert data to standardized "cm" unit values. Grouped weight to protect PII. |
| HEIGHT_U | char | HEIGHT UNIT | | All data converted into CMs. |
| SBP | num | SYSTOLIC BP, mmHg | | Collected at CRF |
| DBP | num | DIASTOLIC BP, mmHg | | Collected at CRF |
| RESPRATE | num | RESPIRATION RATE, breaths/min | | Collected at CRF |
| TEMP | num | BODY TEMP. | | Collected at CRF |
| TEMP_U | char | BODY TEMP. UNIT | | Collected at CRF |

1.4.38. YOUNG MANIA RATING SCALE (YM) – YMRS

| | |
|--------------------------|-------------------------------|
| Dataset | YMRS |
| Creating program | YMRS.sas |
| Description | YOUNG MANIA RATING SCALE (YM) |
| Unique identifier | DCRFID, VISIT, YMITEM |
| Sorted by | DCRFID, VISIT, YMITEM |
| Notes | |

| Variable | Type | Label | Codes | Comments |
|----------|------|---------------------------------|-------|--|
| TRIAL | char | TRIAL ID. | | Collected at CRF |
| DCRFID | char | CRF ID Assigned for De-identity | | Randomly assigned CRF ID for De-identity |
| VISIT | num | VISIT | | Collected at CRF |
| YMITEM | char | YMRS ITEM | | Collected at CRF |
| YMCHSC | char | YMRS CHILD/ADOLESCENT SCORE | | Collected at CRF |

| Variable | Type | Label | Codes | Comments |
|----------|------|-----------------------------|-------|------------------|
| ZYMCHSC | num | YMRS CHILD/ADOLESCENT SCORE | | Collected at CRF |
| YMPASC | char | YMRS PARENT SCORE | | Collected at CRF |
| ZYMPASC | num | YMRS PARENT SCORE | | Collected at CRF |
| YMCFSC | char | YMRS CONSENSUS FINAL SCORE | | Collected at CRF |
| ZYMCFSC | num | YMRS CONSENSUS FINAL SCORE | | Collected at CRF |