Clinical Development

CONSTATRE®

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's Relative day cannot be calculated.
- Remove Child-bearing potential information.
- Remove ethnic information.
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg.MOM_QCRF).
- Empty dataset will not be submitted(eg.MOM_FUEMER).
- IC Signed date(MOM_CRF.IC_SUBJECT_D) will be used as Reference Date to derive relative days.

1.3. Data Files

The RIS-SCH-3001 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographic Data – MOM_CRF

Dataset	MOM_CRF
Creating program	mom_crf.sas
Description	Demographic Data
Unique identifier	DCRFID
Sorted by	DCRFID
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: INIT, CLIN_ID, CLIN_D, RANDOM_NR, IC_SUBJECT_D, IC_Relative_D, BIRTH_D, RACE_SP, FAM_1, ILL_1, FAM_2, ILL_2, SCHIZOP_D, SCHIZOP_M, SCHIZOP_Y, SCHIZOA_D, SCHIZOA_M, SCHIZOA_Y, MEDCHANGE_SIDEEFFECTS_SP,MEDCHANGE_OTHER_SP,SF_REASON

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
DCENTRE	char	Center Number Assigned For De-identity		Randomly assigned Center Number For De-identity.
DCOUNTRY	char	De-identify Country		Element will be grouped to protect PII.
SEX	char	Gender		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
HEIGHT	num	Height		Collected at CRF.
HEIGHT_ND	char	Height Not Done		Collected at CRF.
SYMP_YEAR	num	Year Symptoms Started		Collected at CRF.
SYMP_YEAR_NK	char	Unknown Year Symptoms Started		Collected at CRF.
TREATMENT_YEAR	num	Year Treatment Started		Collected at CRF.
TREATMENT_YEAR_NK	char	Unknown Year Treatment Started		Collected at CRF.
HOSP	char	Ever Been Hospitalised		Collected at CRF.
HOSP_YEAR	num	Year 1St Psychiatric Hospitalisation		Collected at CRF.
HOSP_YEAR_NK	char	Unknown Year 1St Psychiatric Hospitalisation		Collected at CRF.
HOSP_NR	num	Number Previous Psychiatric Hospitalisations		Collected at CRF.
HOSP_NR_NK	char	Unknown Number Previous Psychiatric Hospitalisations		Collected at CRF.
HOSP_NR_6MON	num	Number Previous Psychiatric Hospitalisations Past 6 Months		Collected at CRF.
HOSP_NR_6MON_NK	char	Unknown Number Previous Psychiatric Hospitalisations Past 6		Collected at CRF.

Variable	Type	Label	Codes	Comments
FAM_PSYCHHIS	char	Family History		Collected at CRF.
SIMILAR_ILL	char	Family With Similar Illness		Collected at CRF.
FIRST_DEGREE	char	First Degree Relative		Collected at CRF.
SECOND_DEGREE	char	Second Degree Relative		Collected at CRF.
AXIS_1	char	Dsm-Iv Diagnosis		Collected at CRF.
SCHIZOP_TYPE	char	Type Schizophrenia		Collected at CRF.
SCHIZOP_NK	char	Unknown Date Diagnosis Schizophrenia		Collected at CRF.
SCHIZOA_NK	char	Unknown Date Diagnosis Schizoaffective		Collected at CRF.
MEDCHANGE_NEG	char	Insufficient Efficacy on Negative Symptoms		Collected at CRF.
MEDCHANGE_POS	char	Insufficient Efficacy on Positive Symptoms		Collected at CRF.
MEDCHANGE_GEN	char	Insufficient Efficacy on General Symptoms		Collected at CRF.
MEDCHANGE_SIDEEFFECTS	char	Side Effects		Collected at CRF.
MEDCHANGE_REQUEST	char	Patients Request		Collected at CRF.
MEDCHANGE_COMPLIANCE	char	Patients Compliance		Collected at CRF.

Variable	Type	Label	Codes	Comments
MEDCHANGE_ OTHER	char	Other		Collected at CRF.
CT_NONE	num	CT None		Collected at CRF.
AE_NONE	num	AE None		Collected at CRF.
SF	char	Screen Failure		Collected at CRF.
TM	char	Trial Medication		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= int((IC_SUBJECT_D – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
CLIN_DY	num	Relative Randomisation Day		If CLIN_D and IC_SUBJECT_D not missing then perform below logic to calculate CLIN_DY, If CLIN_D less than IC_SUBJECT_D then (CLIN_D - IC_SUBJECT_D).Else if CLIN_D is greater than equal to IC_SUBJECT_D then (CLIN_D- IC_SUBJECT_D) +1.
ICFUPDY	num	Relative Day IC Follow-Up Signed		If IC_Relative_D and IC_SUBJECT_D not missing then perform below logic to calculate ICFUPDY, If IC_Relative_D less than IC_SUBJECT_D then (IC_Relative_D - IC_SUBJECT_D).Else if IC_Relative_D is greater than equal to IC_SUBJECT_D then (IC_Relative_D- IC_SUBJECT_D) +1.

Variable	Type	Label	Codes	Comments
SCHZPDY	num	Relative Day Diagnosis Schizophrenia		If SCHIZOP_D and IC_SUBJECT_D not missing then perform below logic to calculate SCHZPDY, If SCHIZOP_D less than IC_SUBJECT_D then (SCHIZOP_D - IC_SUBJECT_D).Else if SCHIZOP_D is greater than equal to IC_SUBJECT_D then (SCHIZOP_D- IC_SUBJECT_D) +1.
SCHZADY	num	Relative Day Diagnosis Schizoaffective		If SCHIZOA_D and IC_SUBJECT_D not missing then perform below logic to calculate SCHZADY, If SCHIZOA_D less than IC_SUBJECT_D then (SCHIZOA_D - IC_SUBJECT_D).Else if SCHIZOA_D is greater than equal to IC_SUBJECT_D then (SCHIZOA_D- IC_SUBJECT_D) +1.

1.4.2. Adverse Events – MOM_AE

Dataset	MOM_AE
Creating program	mom_ae.sas
Description	Adverse Events
Unique identifier	DCRFID,LLT_CODE,AE_SEV,START_DY
Sorted by	DCRFID,LLT_CODE,AE_SEV,START_DY
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: AE_V, AE_START_M, AE_START_Y, AE_END_M, AE_END_Y, AE_BRM, START_D,END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
LLT_CODE	char	AE_Meddra		Collected at CRF.
AE_SEV	char	Severity		Collected at CRF.
AE_ACT	char	Action Taken		Collected at CRF.
AE_COTH	char	Concomitant Medication Started		Collected at CRF.
AE_REL	char	Relation to Trial Medication		Collected at CRF.
AE_OUT	char	Subject Outcome		Collected at CRF.

Variable	Type	Label	Codes	Comments
AE_SER	char	Reported as Serious		Collected at CRF.
FIELD1_LLTCODE	char	Field1_Lltcode		Collected at CRF.
FIELD2_LLTTEXT	char	Field2_Lltext		Collected at CRF.
FIELD1_PTCODE	char	Field1_Ptcode		Collected at CRF.
FIELD2_PTTEXT	char	Field2_Pttext		Collected at CRF.
FIELD1_SOCCODE	char	Field1_Soccode		Collected at CRF.
FIELD2_SOCTEXT	char	Field2_Soctext		Collected at CRF.
START_DY	num	Relative AE Start Day		If START_D and IC_SUBJECT_D not missing then perform below logic to calculate START_DY, If START_D less than IC_SUBJECT_D then (START_D - IC_SUBJECT_D).Else if START_D is greater than equal to IC_SUBJECT_D then (START_D- IC_SUBJECT_D) +1.
END_DY	num	Relative AE End Day		If END_D and IC_SUBJECT_D not missing then perform below logic to calculate END_DY, If END_D less than IC_SUBJECT_D then (END_D - IC_SUBJECT_D).Else if END_D is greater than equal to IC_SUBJECT_D then (END_D- IC_SUBJECT_D) +1.

1.4.3. Clinical Global Impression - MOM_CGI

Dataset	MOM_CGI
Creating program	mom_cgi.sas
Description	Clinical Global Impression
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
Q1	char	Cgi-Severity		Collected at CRF.
Q2	char	Cgi-Change		Collected at CRF.

1.4.4. Concomitant Therapy – MOM_CONMED

Dataset	MOM_CONMED
Creating program	mom_conmed.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,CT_WHONO,CT_VALUE,CT_FREQ_ID,START_DY,END_DY,RECORDID
Sorted by	DCRFID,CT_WHONO,CT_VALUE,CT_FREQ_ID,START_DY,END_DY,RECORDID
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 missing values: CT_V, CT_INDICATION, CT_START_M, CT_START_Y, CT_END_M, CT_END_Y, AE_NO5, START_D, END_D, DRUG_KEY,DRUG, CT_UNIT_SP, CT_FREQ_SP, CT_ROUTE_SP

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
CT_WHONO	char	WHO Number		Collected at CRF.
CT_VALUE	num	Value		Collected at CRF.
CT_UNIT_ID	char	Unit		Collected at CRF.
CT_RANGEMIN	num	Range Min		Collected at CRF.

Variable	Type	Label	Codes	Comments
CT_RANGEMAX	num	Range Max		Collected at CRF.
CT_FREQ_ID	char	Frequency		Collected at CRF.
CT_ROUTE_ID	num	Route of Administration		Collected at CRF.
AE_NO1	num	AE No 1		Collected at CRF.
AE_NO2	num	AE No 2		Collected at CRF.
CT_PRETRIAL	char	Pretrial		Collected at CRF.
CT_ONGO	char	Ongoing		Collected at CRF.
AE_NO3	num	AE No 3		Collected at CRF.
AE_NO4	num	AE No 4		Collected at CRF.
GENERIC	char	Generic		Collected at CRF.
ATC_CDE0	char	Atc_Cde0		Collected at CRF.
ATC_TXT0	char	Atc_Txt0		Collected at CRF.

Variable	Type	Label	Codes	Comments
START_DY	num	Relative Start Day of Therapy		If START_D and IC_SUBJECT_D not missing then perform below logic to calculate START_DY, If START_D less than IC_SUBJECT_D then (START_D - IC_SUBJECT_D).Else if START_D is greater than equal to IC_SUBJECT_D then (START_D- IC_SUBJECT_D) +1.
END_DY	num	Relative End Day of Therapy		If END_D and IC_SUBJECT_D not missing then perform below logic to calculate END_DY, If END_D less than IC_SUBJECT_D then (END_D - IC_SUBJECT_D).Else if END_D is greater than equal to IC_SUBJECT_D then (END_D- IC_SUBJECT_D) +1.

1.4.5. Risperdal Consta – MOM_CONSTA

Dataset	MOM_CONSTA
Creating program	mom_consta.sas
Description	Risperdal Consta
Unique identifier	DCRFID,DOSE_ID,ADMIN_DY
Sorted by	DCRFID,DOSE_ID,ADMIN_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ADMIN_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
DOSE_ID	char	Dose Id		Collected at CRF.
REASON_CHANGE	char	Reason Change		Collected at CRF.
ADMIN_DY	num	Relative Administration Day		If ADMIN_D and IC_SUBJECT_D not missing then perform below logic to calculate ADMIN_DY, If ADMIN_D less than IC_SUBJECT_D then (ADMIN_D - IC_SUBJECT_D).Else if ADMIN_D is greater than equal to IC_SUBJECT_D then (ADMIN_D-IC_SUBJECT_D) +1.

1.4.6. Extrapyramidal Symptom Rating Scale – MOM_ESRS

Dataset	MOM_ESRS
Creating program	mom_esrs.sas
Description	Extrapyramidal Symptom Rating Scale
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
I1	num	Impression Slowness Code		Collected at CRF.
I1_C	char	Impression Slowness		Collected at CRF.
I2	num	Difficulty Walking Code		Collected at CRF.
I2_C	char	Difficulty Walking		Collected at CRF.
I3	num	Difficulty Swallowing Code		Collected at CRF.
I3_C	char	Difficulty Swallowing		Collected at CRF.
I4	num	Stiffness, Stiff Post. Code		Collected at CRF.
I4_C	char	Stiffness, Stiff Post.		Collected at CRF.
I5	num	Cramps/Pains Limbs. Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
I5_C	char	Cramps/Pains Limbs.		Collected at CRF.
I6	char	Restless/Nervous Code		Collected at CRF.
I6_C	num	Restless/Nervous		Collected at CRF.
I7	num	Tremors/Shaking Code		Collected at CRF.
I7_C	char	Tremors/Shaking		Collected at CRF.
I8	num	Oculogyric Crisis Code		Collected at CRF.
I8_C	char	Oculogyric Crisis		Collected at CRF.
I9	num	Increased Salivation Code		Collected at CRF.
I9_C	char	Increased Salivation		Collected at CRF.
I10	num	Dyskinesia Extrem. Code		Collected at CRF.
I10_C	char	Dyskinesia Extrem.		Collected at CRF.
I11	num	Dyskinesia Tongue/Jaw. Code		Collected at CRF.
I11_C	char	Dyskinesia Tongue/Jaw.		Collected at CRF.
I12	num	Dizziness Code		Collected at CRF.
I12_C	char	Dizziness		Collected at CRF.
A1	num	Expressive Autom.Mov. Code		Collected at CRF.
A1_C	char	Expressive Autom.Mov.		Collected at CRF.
A2	num	Bradykinesia Code		Collected at CRF.
A2_C	char	Bradykinesia		Collected at CRF.
A3	num	Rigidity R.U.L. Code		Collected at CRF.
A3_C	char	Rigidity R.U.L.		Collected at CRF.

Variable	Type	Label	Codes	Comments
A4	num	Rigidity L.U.L. Code		Collected at CRF.
A4_C	char	Rigidity L.U.L.		Collected at CRF.
A5	num	Rigidity R.L.L. Code		Collected at CRF.
A5_C	char	Rigidity R.L.L.		Collected at CRF.
A6	num	Rigidity L.L.L. Code		Collected at CRF.
A6_C	char	Rigidity L.L.L.		Collected at CRF.
A7	num	Gait/Posture Code		Collected at CRF.
A7_C	char	Gait/Posture		Collected at CRF.
A8	num	Tremor R.U.L.		Collected at CRF.
A9	num	Tremor L.U.L.		Collected at CRF.
A10	num	Tremor R.L.L.		Collected at CRF.
A11	num	Tremor L.L.L.		Collected at CRF.
A12	num	Tremor Head		Collected at CRF.
A13	num	Tremor Jaw/Chin		Collected at CRF.
A14	num	Tremor Tongue		Collected at CRF.
A15	num	Tremor Lips		Collected at CRF.
A16	num	Akathisia Code		Collected at CRF.
A16_C	char	Akathisia		Collected at CRF.
A17	num	Sialorrhea Code		Collected at CRF.
A17_C	char	Sialorrhea		Collected at CRF.
A18	num	Postural Stab. Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
A18_C	char	Postural Stab.		Collected at CRF.
D1	num	Acute R.U.L. Code		Collected at CRF.
D1_C	char	Acute R.U.L.		Collected at CRF.
D2	num	Acute L.U.L. Code		Collected at CRF.
D2_C	char	Acute L.U.L.		Collected at CRF.
D3	num	Acute R.L.L. Code		Collected at CRF.
D3_C	char	Acute R.L.L.		Collected at CRF.
D4	num	Acute L.L.L. Code		Collected at CRF.
D4_C	char	Acute L.L.L.		Collected at CRF.
D5	num	Acute Head Code		Collected at CRF.
D5_C	char	Acute Head		Collected at CRF.
D6	num	Acute Jaw Code		Collected at CRF.
D6_C	char	Acute Jaw		Collected at CRF.
D7	num	Acute Tongue Code		Collected at CRF.
D7_c	char	Acute Tongue		Collected at CRF.
D8	num	Acute Lips Code		Collected at CRF.
D8_C	char	Acute Lips		Collected at CRF.
D9	num	Acute Eyes Code		Collected at CRF.
D9_C	char	Acute Eyes		Collected at CRF.

Variable	Type	Label	Codes	Comments
D10	num	Acute Trunk Code		Collected at CRF.
D10_C	char	Acute Trunk		Collected at CRF.
D11	num	Non-Ac. R.U.L. Code		Collected at CRF.
D11_C	char	Non-Ac. R.U.L.		Collected at CRF.
D12	num	Non-Ac. L.U.L. Code		Collected at CRF.
D12_C	char	Non-Ac. L.U.L.		Collected at CRF.
D13	num	Non-Ac. R.L.L. Code		Collected at CRF.
D13_C	char	Non-Ac. R.L.L.		Collected at CRF.
D14	num	Non-Ac. L.L.L. Code		Collected at CRF.
D14_C	char	Non-Ac. L.L.L.		Collected at CRF.
D15	num	Non-Ac. Head Code		Collected at CRF.
D15_C	char	Non-Ac. Head		Collected at CRF.
D16	num	Non-Ac. Jaw Code		Collected at CRF.
D16_C	char	Non-Ac. Jaw		Collected at CRF.
D17	num	Non-Ac. Tongue Code		Collected at CRF.
D17_C	char	Non-Ac. Tongue		Collected at CRF.
D18	num	Non-Ac. Lips Code		Collected at CRF.
D18_C	char	Non-Ac. Lips		Collected at CRF.
D19	num	Non-Ac. Face Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
D19_C	char	Non-Ac. Face		Collected at CRF.
D20	num	Non-Ac. Trunk Code		Collected at CRF.
D20_C	char	Non-Ac. Trunk		Collected at CRF.
M1	num	Lingual Mov.		Collected at CRF.
M2	num	Jaw Mov.		Collected at CRF.
M3	num	Bucco-Lab Mov.		Collected at CRF.
M4	num	Truncal Mov.		Collected at CRF.
M5	num	Upper Extrem.		Collected at CRF.
M6	num	Lower Extrem.		Collected at CRF.
M7	num	Other Unvol.Mov.		Collected at CRF.
CGIDYSKINESIA	num	Cgi Dyskinesia Code		Collected at CRF.
CGIDYSKINESIA_C	char	Cgi Dyskinesia		Collected at CRF.
CGIPARK	num	Cgi Parkinsonism Code		Collected at CRF.
CGIPARK_C	char	Cgi Parkinsonism		Collected at CRF.
CGIDYSTONIA	num	Cgi Dystonia Code		Collected at CRF.
CGIDYSTONIA_C	char	Cgi Dystonia		Collected at CRF.
STAGEPARK	num	Stage Park Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
STAGEPARK_C	char	Stage Park		Collected at CRF.

1.4.7. Follow-up Clinical Global Impression – MOM_FUCGI

Dataset	MOM_FUCGI
Creating program	mom_fucgi.sas
Description	Follow-up Clinical Global Impression
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
Q1	char	Fucgi-Severity		Collected at CRF.
Q2	char	Fucgi-Change		Collected at CRF.

1.4.8. Follow-up Demographic Data – MOM_FUCRF

Dataset	MOM_FUCRF
Creating program	mom_fucrf.sas
Description	Follow-up Demographic Data
Unique identifier	DCRFID
Sorted by	DCRFID
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: INIT, RANDOM_NR,COUNTRY

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
HOSP	char	Hospitalisation		Collected at CRF.
EMER	char	Emergency		Collected at CRF.
DAY_NIGHT	char	Day_Night		Collected at CRF.
OUTPATIENT	char	Outpatient		Collected at CRF.
OCCU	char	Occu		Collected at CRF.

1.4.9. Follow-up Days Lost – MOM_FUDAYSLOST

Dataset	MOM_FUDAYSLOST
Creating program	mom_fudayslost.sas
Description	Follow-up Days Lost
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset due to missing values: RU_SCHOOLDAYSLOST_SP

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RU_WORKDAYSLOST	char	Work Days Lost		Collected at CRF.
RU_WORKDAYSLOST_SP	num	Work Days Lost_Sp		Collected at CRF.
RU_SCHOOLDAYSLOST	char	Schooldays Lost		Collected at CRF.

1.4.10. Follow-up Daily Living – MOM_FUDL

Dataset	MOM_FUDL
Creating program	mom_fudl.sas
Description	Follow-up Daily Living
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
DL_1	char	Living Situation - At Home, Alone		Collected at CRF.
DL_1_P	num	At Home, Alone Percentage		Collected at CRF.
DL_2	char	Living Situation - At Home, With Family		Collected at CRF.
DL_2_P	num	At Home, With Family Percentage		Collected at CRF.
DL_3	char	Living Situation - Homeless		Collected at CRF.
DL_3_P	num	Homeless Percentage		Collected at CRF.
DL_4	char	Living Situation-Psychtc Institution		Collected at CRF.
DL_4_P	num	Psychiatric Institution Percentage		Collected at CRF.
DL_5	char	Living Situation - Sheltered Living		Collected at CRF.

Variable	Type	Label	Codes	Comments
DL_5_P	num	Sheltered Living Percentage		Collected at CRF.
DL_6	char	Living Situation - Prison		Collected at CRF.
DL_6_P	num	Prison Percentage		Collected at CRF.
DL_7	char	Living Situation - Other		Collected at CRF.
DL_7_P	num	Other Percentage		Collected at CRF.

1.4.11. Follow-up Hospitalization – MOM_FUHOSP

Dataset	MOM_FUHOSP
Creating program	mom_fuhosp.sas
Description	Follow-up Hospitalization
Unique identifier	DCRFID,HOSPSDY,VISIT_DY
Sorted by	DCRFID, HOSPSDY,VISIT_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IRUBHOSP_START_D, IRUBHOSP_END_D,VISIT_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
IRUB_HOSPTYPE	char	Hospital Type		Collected at CRF.
IRUB_WARD	char	Ward		Collected at CRF.
IRUB_REASON	char	Reason		Collected at CRF.
IRUB_ONGO_START	char	Ongoing Start		Collected at CRF.
IRUB_ONGO_END	char	Ongoing End		Collected at CRF.
IRUB_REASON_ONGO	char	Reason Ongoing		Collected at CRF.
HOSPSDTY	num	Relative IRUB Hosp Start Day		If IRUBHOSP_START_D and IC_SUBJECT_D not missing then perform below logic to calculate HOSPSDTY, If IRUBHOSP_START_D less than IC_SUBJECT_D then (IRUBHOSP_START_D - IC_SUBJECT_D).Else if IRUBHOSP_START_D is greater than equal to IC_SUBJECT_D then (IRUBHOSP_START_D- IC_SUBJECT_D) +1.
HOSPEDY	num	Relative IRUB Hosp End Day		If IRUBHOSP_END_D and IC_SUBJECT_D not missing then perform below logic to calculate HOSPEDY, If IRUBHOSP_END_D less than IC_SUBJECT_D then (IRUBHOSP_END_D - IC_SUBJECT_D).Else if IRUBHOSP_END_D is greater than equal to IC_SUBJECT_D then (IRUBHOSP_END_D- IC_SUBJECT_D) +1.

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

1.4.12. Follow-up Outpatient Treatment – MOM_FUOUTPAT

Dataset	MOM_FUOUTPAT
Creating program	mom_fuoutpat.sas
Description	Follow-up Outpatient Treatment
Unique identifier	DCRFID,RU_FREQ,RU_SERVICEPROV,OUTPSDY
Sorted by	DCRFID,RU_FREQ,RU_SERVICEPROV, OUTPSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RU_START_M, RU_START_Y, RU_END_M, RU_END_Y, OUT_START_D, OUT_END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.

Variable	Type	Label	Codes	Comments
RECORDID	num	Record Id		Collected at CRF.
RU_SERVICEPROV	char	Service Provider		Collected at CRF.
RU_MAINREASON	char	Main Reason		Collected at CRF.
RU_SECREASON	char	Secreason		Collected at CRF.
RU_FREQ	num	Freq		Collected at CRF.
OUTPSDY	num	Relative Outpatient Start Day		If OUT_START_D and IC_SUBJECT_D not missing then perform below logic to calculate OUTPSDY, If OUT_START_D less than IC_SUBJECT_D then (OUT_START_D - IC_SUBJECT_D).Else if OUT_START_D is greater than equal to IC_SUBJECT_D then (OUT_START_D- IC_SUBJECT_D) +1.
OUTPEDY	num	Relative Outpatient End Day		If OUT_END_D and IC_SUBJECT_D not missing then perform below logic to calculate OUTPEDY, If OUT_END_D less than IC_SUBJECT_D then (OUT_END_D - IC_SUBJECT_D).Else if OUT_END_D is greater than equal to IC_SUBJECT_D then (OUT_END_D- IC_SUBJECT_D) +1.

1.4.13. Follow-up Partial Hospitalization – MOM_FUPART

Dataset	MOM_FUPART
Creating program	mom_fupart.sas
Description	Follow-up Partial Hospitalization
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RU_START_M, RU_START_Y, RU_END_M, RU_END_Y, PART_START_D,PART_END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_OUTREACH	char	Out Reach		Collected at CRF.
RU_DAYNIGHT	char	Day_Night		Collected at CRF.
RU_HOSPTYPE	char	Hospital Type		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
RU_DAYS	num	Days		Collected at CRF.
PARTHSDY	num	Relative Partial Hosp Start Day		If PART_START_D and IC_SUBJECT_D not missing then perform below logic to calculate PARTHSDY, If PART_START_D less than IC_SUBJECT_D then (PART_START_D - IC_SUBJECT_D).Else if PART_START_D is greater than equal to IC_SUBJECT_D then (PART_START_D- IC_SUBJECT_D) +1.
PARTHEDY	num	Relative Partial Hosp End Day		If PART_END_D and IC_SUBJECT_D not missing then perform below logic to calculate PARTHEDY, If PART_END_D less than IC_SUBJECT_D then (PART_END_D - IC_SUBJECT_D).Else if PART_END_D is greater than equal to IC_SUBJECT_D then (PART_END_D- IC_SUBJECT_D) +1.

1.4.14. Follow-up Productivity of Subject – MOM_FUPROD

Dataset	MOM_FUPROD
Creating program	mom_fuprod.sas
Description	Follow-up Productivity of Subject
Unique identifier	DCRFID,RU_REASON,RU_STATUS
Sorted by	DCRFID,RU_REASON,RU_STATUS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RU_START_M, RU_START_Y,PROD_START_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_STATUS	char	Status		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
PRODSDY	num	Relative Productivity Start Day		If PROD_START_D and IC_SUBJECT_D not missing then perform below logic to calculate PRODSDY, If PROD_START_D less than IC_SUBJECT_D then (PROD_START_D - IC_SUBJECT_D).Else if PROD_START_D is greater than equal to IC_SUBJECT_D then (PROD_START_D-IC_SUBJECT_D) +1.

1.4.15. Follow-up Resourse Use Battery – MOM_FURESUSE

Dataset	MOM_FURESUSE
Creating program	mom_furesuse.sas
Description	Follow-up Resourse Use Battery
Unique identifier	DCRFID,RU_WEEK,RU_DY
Sorted by	DCRFID,RU_WEEK,RU_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RU_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_WEEK	num	Week Number		Collected at CRF.
RU_STATUS	char	Patient Status		Collected at CRF.
RU_UPDATED	char	Relevant Pages Updated		Collected at CRF.
RU_DY	num	Relative Day Follow Up Visit		If RU_D and IC_SUBJECT_D not missing then perform below logic to calculate RU_DY, If RU_D less than IC_SUBJECT_D then (RU_D - IC_SUBJECT_D).Else if RU_D is greater than equal to IC_SUBJECT_D then (RU_D- IC_SUBJECT_D) +1.

1.4.16. Mom_Gcrf – MOM_GCRF

Dataset	MOM_GCRF
Creating program	mom_gcrf.sas
Description	Mom_Gcrf
Unique identifier	DCRFID
Sorted by	DCRFID
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 missing values: INIT, CLIN_ID, CLIN_D, CENTRE,COUNTRY

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
PM_NONE	char	PM None		Collected at CRF.
QUEARI	char	Queari		Collected at CRF.
CT_NONE	char	CT None		Collected at CRF.
AE_NONE	char	AE None		Collected at CRF.
HOSP	char	Hospitalization		Collected at CRF.
EMER	char	Emergency		Collected at CRF.
DAY_NIGHT	char	Day_Night		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACCO	char	Acco		Collected at CRF.
OCCU	char	Occu		Collected at CRF.

1.4.17. Inclusion/Exclusion Criteria – MOM_INEX

Dataset	MOM_INEX
Creating program	mom_inex.sas
Description	Inclusion/Exclusion Criteria
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
INCL1	char	Inclusion 1		Collected at CRF.
INCL2	char	Inclusion 2		Collected at CRF.
INCL3	char	Inclusion 3		Collected at CRF.
INCL4	char	Inclusion 4		Collected at CRF.
INCL5	char	Inclusion 5		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCL6	char	Inclusion 6		Collected at CRF.
INCL7	char	Inclusion 7		Collected at CRF.
INCL8	char	Inclusion 8		Collected at CRF.
EXCL1	char	Exclusion 1		Collected at CRF.
EXCL2	char	Exclusion 2		Collected at CRF.
EXCL3	char	Exclusion 3		Collected at CRF.
EXCL4	char	Exclusion 4		Collected at CRF.
EXCL5	char	Exclusion 5		Collected at CRF.
EXCL6	char	Exclusion 6		Collected at CRF.
EXCL7	char	Exclusion 7		Collected at CRF.
EXCL8	char	Exclusion 8		Collected at CRF.
EXCL9	char	Exclusion 9		Collected at CRF.
EXCL10	char	Exclusion 10		Collected at CRF.
EXCL11	char	Exclusion 11		Collected at CRF.
EXCL12	char	Exclusion 12		Collected at CRF.
EXCL13	char	Exclusion 13		Collected at CRF.
EXCL14	char	Exclusion 14		Collected at CRF.
EXCL15	char	Exclusion 15		Collected at CRF.
EXCL16	char	Exclusion 16		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCL17	char	Exclusion 17		Collected at CRF.
EXCL18	char	Exclusion 18		Collected at CRF.

1.4.18. Laboratory Sample – MOM_LABSAMPLE

Dataset	MOM_LABSAMPLE
Creating program	mom_labsample.sas
Description	Laboratory Sample
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: REPORT_D,SIGN_DATE

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
TEST_OUTSIDENR	char	Result Outside Normal Range?		Collected at CRF.
SIGN_YN	char	Labreport Signed		Collected at CRF.

Variable	Type	Label	Codes	Comments
DIFFDATE	num	Diffdate		Collected at CRF.
ABSDIFFDATE	num	Absdiffdate		Collected at CRF.
PREV_DIFFDATE	num	Prev_Diffdate		Collected at CRF.
REPORTDY	num	Relative Lab Assessment Day		If REPORT_D and IC_SUBJECT_D not missing then perform below logic to calculate REPORTDY, If REPORT_D less than IC_SUBJECT_D then (REPORT_D - IC_SUBJECT_D).Else if REPORT_D is greater than equal to IC_SUBJECT_D then (REPORT_D- IC_SUBJECT_D) +1.
SIGNDY	num	Relative Signature Day		If SIGN_DATE and IC_SUBJECT_D not missing then perform below logic to calculate SIGNDY, If SIGN_DATE less than IC_SUBJECT_D then (SIGN_DATE - IC_SUBJECT_D).Else if SIGN_DATE is greater than equal to IC_SUBJECT_D then (SIGN_DATE- IC_SUBJECT_D) +1.

1.4.19. Laboratory Test – MOM_LABTEST

Dataset	MOM_LABTEST
Creating program	mom_labtest.sas
Description	Laboratory Test
Unique identifier	DCRFID,VISITID,TEST
Sorted by	DCRFID,VISITID,TEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant element: REPORT_D, FIRSTVISIT_D, LASTVISIT_D, VISIT2_D,CONFIRMATION_D, CONFRELAPSE_D, FIRSTMED_D, LASTMED_D, FIRSTIRUB_D,LASTIRUB_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
RECORDID	num	Record Id		Collected at CRF.
TESTID	char	Labtest		Collected at CRF.
CLINSIG	char	Clinical Significant		Collected at CRF.
TESTID0	num	Test Id		Collected at CRF.
TESTGROUP	char	Test Group		Collected at CRF.
TEST	char	Test		Collected at CRF.

Variable	Type	Label	Codes	Comments
LASTVISITID	num	Last Visit Id		Collected at CRF.
LASTVISID	num	Lastvisid		Collected at CRF.
CONFRELAPSE01	num	Confrelapse01		Collected at CRF.
CONFRELAPSEVISIT	num	Confrelapsevisit		Collected at CRF.
FVISTDY	num	Relative First Visit Day		If FIRSTVISIT_D and IC_SUBJECT_D not missing then perform below logic to calculate FVISTDY, If FIRSTVISIT_D less than IC_SUBJECT_D then (FIRSTVISIT_D - IC_SUBJECT_D).Else if FIRSTVISIT_D is greater than equal to IC_SUBJECT_D then (FIRSTVISIT_D- IC_SUBJECT_D) +1.
LVISTDY	num	Relative Last Visit Day		If LASTVISIT_D and IC_SUBJECT_D not missing then perform below logic to calculate LVISTDY, If LASTVISIT_D less than IC_SUBJECT_D then (LASTVISIT_D - IC_SUBJECT_D).Else if LASTVISIT_D is greater than equal to IC_SUBJECT_D then (LASTVISIT_D- IC_SUBJECT_D) +1.
VIST2DY	num	Relative Visit2 Day		If VISIT2_D and IC_SUBJECT_D not missing then perform below logic to calculate VIST2DY, If VISIT2_D less than IC_SUBJECT_D then (VISIT2_D - IC_SUBJECT_D).Else if VISIT2_D is greater than equal to IC_SUBJECT_D then (VISIT2_D- IC_SUBJECT_D) +1.

Variable	Type	Label	Codes	Comments
CONFDY	num	Relative Day Relapse Confirmation		If CONFIRMATION_D and IC_SUBJECT_D not missing then perform below logic to calculate CONFDY, If CONFIRMATION_D less than IC_SUBJECT_D then (CONFIRMATION_D - IC_SUBJECT_D).Else if CONFIRMATION_D is greater than equal to IC_SUBJECT_D then (CONFIRMATION_D- IC_SUBJECT_D) +1.
CONFREDY	num	Relative Confrelapse_D		If CONFRELAPSE_D and IC_SUBJECT_D not missing then perform below logic to calculate CONFREDY, If CONFRELAPSE_D less than IC_SUBJECT_D then (CONFRELAPSE_D - IC_SUBJECT_D).Else if CONFRELAPSE_D is greater than equal to IC_SUBJECT_D then (CONFRELAPSE_D- IC_SUBJECT_D) +1.
FMEDDY	num	Relative Firstmed Day		If FIRSTMED_D and IC_SUBJECT_D not missing then perform below logic to calculate FMEDDY, If FIRSTMED_D less than IC_SUBJECT_D then (FIRSTMED_D - IC_SUBJECT_D).Else if FIRSTMED_D is greater than equal to IC_SUBJECT_D then (FIRSTMED_D- IC_SUBJECT_D) +1.
LMEDDY	num	Relative Lastmed Day		If LASTMED_D and IC_SUBJECT_D not missing then perform below logic to calculate LMEDDY, If LASTMED_D less than IC_SUBJECT_D then (LASTMED_D - IC_SUBJECT_D).Else if LASTMED_D is greater than equal to IC_SUBJECT_D then (LASTMED_D- IC_SUBJECT_D) +1.

Variable	Type	Label	Codes	Comments
FIRUBDY	num	Relative Firstirub Day		If FIRSTIRUB_D and IC_SUBJECT_D not missing then perform below logic to calculate FIRUBDY, If FIRSTIRUB_D less than IC_SUBJECT_D then (FIRSTIRUB_D - IC_SUBJECT_D).Else if FIRSTIRUB_D is greater than equal to IC_SUBJECT_D then (FIRSTIRUB_D- IC_SUBJECT_D) +1.
LIRUBDY	num	Relative Lastirub Day		If LASTIRUB_D and IC_SUBJECT_D not missing then perform below logic to calculate LIRUBDY, If LASTIRUB_D less than IC_SUBJECT_D then (LASTIRUB_D - IC_SUBJECT_D).Else if LASTIRUB_D is greater than equal to IC_SUBJECT_D then (LASTIRUB_D- IC_SUBJECT_D) +1.

1.4.20. Laboratory Test - BARC – MOM_LABTESTBARC

Dataset	MOM_LABTESTBARC
Creating program	mom_labtestbarc.sas
Description	Laboratory Test - BARC
Unique identifier	DCRFID,VISITID,TEST
Sorted by	DCRFID,VISITID,TEST
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: SEX,SAMPLE_DATE

Variable	Type	Label	Codes	Comments
VISITID	char	Visit Id		Collected at CRF.
CLASS	char	Class		Collected at CRF.
FLAG	char	Flag		Collected at CRF.
SIUNIT	char	SI Unit		Collected at CRF.
LABVALUE	char	Lab Value		Collected at CRF.
LABVAL_NUM	num	Lab Value Number		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
TEST	char	Test		Collected at CRF.
DIFFDATE	num	Diffdate		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABSDIFFDATE	num	Absdiffdate		Collected at CRF.
PREV_DIFFDATE	num	Prev_Diffdate		Collected at CRF.
SAMPLDY	num	Relative Sample Day		If SAMPLE_DATE and IC_SUBJECT_D not missing then perform below logic to calculate SAMPLDY, If SAMPLE_DATE less than IC_SUBJECT_D then (SAMPLE_DATE - IC_SUBJECT_D).Else if SAMPLE_DATE is greater than equal to IC_SUBJECT_D then (SAMPLE_DATE-IC_SUBJECT_D) +1.

1.4.21. Montgomery - Asberg Depression Rating Scale – MOM_MADRS

Dataset	MOM_MADRS
Creating program	mom_madrs.sas
Description	Montgomery - Asberg Depression Rating Scale
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visitid		Collected at CRF.
Q1	num	Apparent Sadness Code		Collected at CRF.
Q1_C	char	Apparent Sadness		Collected at CRF.
Q2	num	Reported Sadness Code		Collected at CRF.
Q2_C	char	Reported Sadness		Collected at CRF.
Q3	num	Inner Tension Code		Collected at CRF.
Q3_C	char	Inner Tension		Collected at CRF.
Q4	num	Reduced Sleep Code		Collected at CRF.
Q4_C	char	Reduced Sleep		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q5	num	Reduced Appetite Code		Collected at CRF.
Q5_C	char	Reduced Appetite		Collected at CRF.
Q6	num	Concentration Difficulty Code		Collected at CRF.
Q6_C	char	Concentration Difficulty		Collected at CRF.
Q7	num	Lassitude Code		Collected at CRF.
Q7_C	char	Lassitude		Collected at CRF.
Q8	num	Inability to Feel Code		Collected at CRF.
Q8_C	char	Inability to Feel		Collected at CRF.
Q9	num	Pessimistic Thought Code		Collected at CRF.
Q9_C	char	Pessimistic Thought		Collected at CRF.
Q10	num	Suicidal Thoughts Code		Collected at CRF.
Q10_C	char	Suicidal Thoughts		Collected at CRF.

1.4.22. Medical and Surgical History – MOM_MH

Dataset	MOM_MH
Creating program	mom_mh.sas
Description	Medical and Surgical History
Unique identifier	DCRFID,MH_SYSTEM
Sorted by	DCRFID,MH_SYSTEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MH_HIS_SP,MH_CUR_SP

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
MH_SYSTEM	char	System		Collected at CRF.
MH_NONE	char	None		Collected at CRF.
MH_HIS	char	History, Not Active		Collected at CRF.
MH_CUR	char	Currently Active		Collected at CRF.

1.4.23. Nurse Contact – MOM_NURSECONTACT

Dataset	MOM_NURSECONTACT
Creating program	mom_nursecontact.sas
Description	Nurse Contact
Unique identifier	DCRFID,WEEK,RECORDID
Sorted by	DCRFID,WEEK,RECORDID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: UNSCHEDULED_SP, CONTACTS_D,UNSCHED_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
WEEK	num	Week		Collected at CRF.
PATIENT_FEEL	char	Patient Feel		Collected at CRF.
IMPRESSION	char	Impression		Collected at CRF.
UNSCHEDULED	char	Unscheduled		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONTDY	num	Relative Contact Day		If CONTACTS_D and IC_SUBJECT_D not missing then perform below logic to calculate CONTDY, If CONTACTS_D less than IC_SUBJECT_D then (CONTACTS_D - IC_SUBJECT_D).Else if CONTACTS_D is greater than equal to IC_SUBJECT_D then (CONTACTS_D- IC_SUBJECT_D) +1.
UNSCHDY	num	Relative Unscheduled Day		If UNSCHED_D and IC_SUBJECT_D not missing then perform below logic to calculate UNSCHDY, If UNSCHED_D less than IC_SUBJECT_D then (UNSCHED_D - IC_SUBJECT_D).Else if UNSCHED_D is greater than equal to IC_SUBJECT_D then (UNSCHED_D- IC_SUBJECT_D) +1.

1.4.24. Risperidone Oro – MOM_ORO

Dataset	MOM_ORO
Creating program	mom_oro.sas
Description	Risperidone Oro
Unique identifier	DCRFID,DOSE,START_DY
Sorted by	DCRFID,DOSE,START_DY
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 missing values: MED_START_M, MED_START_Y, MED_END_M, MED_END_Y, START_D,END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
REASON_CHANGE	char	Reason Change		Collected at CRF.

Variable	Type	Label	Codes	Comments
START_DY	num	Relative Start Day		If START_D and IC_SUBJECT_D not missing then perform below logic to calculate START_DY, If START_D less than IC_SUBJECT_D then (START_D - IC_SUBJECT_D).Else if START_D is greater than equal to IC_SUBJECT_D then (START_D- IC_SUBJECT_D) +1.
END_DY	num	Relative End Day		If END_D and IC_SUBJECT_D not missing then perform below logic to calculate END_DY, If END_D less than IC_SUBJECT_D then (END_D - IC_SUBJECT_D).Else if END_D is greater than equal to IC_SUBJECT_D then (END_D- IC_SUBJECT_D) +1.

1.4.25. Positive And Negative Syndrome Scale for Schizophrenia – MOM_PANSS

Dataset	MOM_PANSS
Creating program	mom_panss.sas
Description	Positive And Negative Syndrome Scale for Schizophrenia
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
P1	num	Delusions Code		Collected at CRF.
P1_C	char	Delusions		Collected at CRF.
P2	num	Conceptual Disorganisation Code		Collected at CRF.
P2_C	char	Conceptual Disorganisation		Collected at CRF.
P3	num	Hallucinatory Behaviour Code		Collected at CRF.
P3_C	char	Hallucinatory Behaviour		Collected at CRF.
P4	num	Excitement Code		Collected at CRF.
P4_C	char	Excitement		Collected at CRF.

Variable	Type	Label	Codes	Comments
P5	num	Grandiosity Code		Collected at CRF.
P5_C	char	Grandiosity		Collected at CRF.
P6	num	Suspiciousness Code		Collected at CRF.
P6_C	char	Suspiciousness		Collected at CRF.
P7	num	Hostility Code		Collected at CRF.
P7_C	char	Hostility		Collected at CRF.
N1	num	Blunted Affect Code		Collected at CRF.
N1_C	char	Blunted Affect		Collected at CRF.
N2	num	Emotional Withdrawal Code		Collected at CRF.
N2_C	char	Emotional Withdrawal		Collected at CRF.
N3	num	Poor Rapport Code		Collected at CRF.
N3_C	char	Poor Rapport		Collected at CRF.
N4	num	Passive/Apathic Code		Collected at CRF.
N4_C	char	Passive/Apathic		Collected at CRF.
N5	num	Difficulty Abstract Thinking Code		Collected at CRF.
N5_C	char	Difficulty Abstract Thinking		Collected at CRF.
N6	num	Lack of Spontaneity Code		Collected at CRF.
N6_C	char	Lack of Spontaneity		Collected at CRF.
N7	num	Stereotyped Thinking Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
N7_C	char	Stereotyped Thinking		Collected at CRF.
G1	num	Somatic Concern Code		Collected at CRF.
G1_C	char	Somatic Concern		Collected at CRF.
G2	num	Anxiety Code		Collected at CRF.
G2_C	char	Anxiety		Collected at CRF.
G3	num	Guilt Feeling Code		Collected at CRF.
G3_C	char	Guilt Feeling		Collected at CRF.
G4	num	Tension Code		Collected at CRF.
G4_C	char	Tension		Collected at CRF.
G5	num	Mannerisms / Posturing Code		Collected at CRF.
G5_C	char	Mannerisms / Posturing		Collected at CRF.
G6	num	Depression Code		Collected at CRF.
G6_C	char	Depression		Collected at CRF.
G7	num	Motor Retardation Code		Collected at CRF.
G7_C	char	Motor Retardation		Collected at CRF.
G8	num	Uncooperativeness Code		Collected at CRF.
G8_C	char	Uncooperativeness		Collected at CRF.
G9	num	Unusual Thought Content Code		Collected at CRF.
G9_C	char	Unusual Thought Content		Collected at CRF.

Variable	Type	Label	Codes	Comments
G10	num	Disorientation Code		Collected at CRF.
G10_C	char	Disorientation		Collected at CRF.
G11	num	Poor Attention Code		Collected at CRF.
G11_C	char	Poor Attention		Collected at CRF.
G12	num	Lack of Judgement / Insight Code		Collected at CRF.
G12_C	char	Lack of Judgement / Insight		Collected at CRF.
G13	num	Disturbance Volition Code		Collected at CRF.
G13_C	char	Disturbance Volition		Collected at CRF.
G14	num	Poor Impulse Control Code		Collected at CRF.
G14_C	char	Poor Impulse Control		Collected at CRF.
G15	num	Preoccupation Code		Collected at CRF.
G15_C	char	Preoccupation		Collected at CRF.
G16	num	Active Social Avoidance Code		Collected at CRF.
G16_C	char	Active Social Avoidance		Collected at CRF.
TOTPOS	num	Positive Subscale Score		Collected at CRF.
TOTNEG	num	Negative Subscale Score		Collected at CRF.
TOTGENERAL	num	General Subscale Score		Collected at CRF.
TOTPANSS	num	Total PANSS Score		Collected at CRF.

1.4.26. Physical Examination – MOM_PE

Dataset	MOM_PE
Creating program	mom_pe.sas
Description	Physical Examination
Unique identifier	DCRFID,SYSTEM
Sorted by	DCRFID,SYSTEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ABNORMAL_SP

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
SYSTEM	char	System		Collected at CRF.
PE_NONE	char	None		Collected at CRF.
PE_NORMAL	char	Normal		Collected at CRF.
PE_ABNORMAL	char	Abnormal		Collected at CRF.

1.4.27. Pervious Medication – MOM_PREVMED

Dataset	MOM_PREVMED
Creating program	mom_prevmed.sas
Description	Pervious Medication
Unique identifier	DCRFID,PM_WHONO,PM_FREQ,PM_TOTALDOSE,START_DY,END_DY, RECORDID
Sorted by	DCRFID,PM_WHONO,PM_FREQ,PM_TOTALDOSE,START_DY,END_DY, RECORDID
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 missing values: PM_V, PM_ROUTE_SP, PM_UNIT2_SP, PM_START_M, PM_START_Y, PM_END_M, PM_END_Y, START_D, END_D, DRUG_KEY, DRUG,PM_UNIT_SP,PM_FREQ_SP,IC_SUBJECT_D,DAT1

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
PM_WHONO	char	WHO Number		Collected at CRF.
PM_VALUE	num	Value		Collected at CRF.
PM_UNIT	char	Unit		Collected at CRF.
PM_FREQ	char	Freq		Collected at CRF.

Variable	Type	Label	Codes	Comments
PM_ROUTE	char	Route		Collected at CRF.
PM_TOTALDOSE	num	Total Dose		Collected at CRF.
PM_UNIT2	char	Unit2		Collected at CRF.
GENERIC	char	Generic		Collected at CRF.
ATC_CDE0	char	Atc_Cde0		Collected at CRF.
ATC_TXT0	char	Atc_Txt0		Collected at CRF.
START_DY	num	Relative PM Start Day		If START_D and IC_SUBJECT_D not missing then perform below logic to calculate START_DY, If START_D less than IC_SUBJECT_D then (START_D - IC_SUBJECT_D).Else if START_D is greater than equal to IC_SUBJECT_D then (START_D- IC_SUBJECT_D) +1.
END_DY	num	Relative PM End Day		If END_D and IC_SUBJECT_D not missing then perform below logic to calculate END_DY, If END_D less than IC_SUBJECT_D then (END_D - IC_SUBJECT_D).Else if END_D is greater than equal to IC_SUBJECT_D then (END_D- IC_SUBJECT_D) +1.
DAT1DY	num	Relative Date1		If DAT1 and IC_SUBJECT_D not missing then perform below logic to calculate DAT1DY , If DAT1 less than IC_SUBJECT_D then (DAT1 - IC_SUBJECT_D).Else if DAT1 is greater than equal to IC_SUBJECT_D then (DAT1- IC_SUBJECT_D) +1.

1.4.28. Quetiapine/Aripiprazole – MOM_QUEARI

Dataset	MOM_QUEARI
Creating program	mom_queari.sas
Description	Quetiapine/Aripiprazole
Unique identifier	DCRFID,DOSE,REASON_CHANGE,START_DY
Sorted by	DCRFID,DOSE,REASON_CHANGE,START_DY
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: MED_START_M, MED_START_Y, MED_END_M, MED_END_Y, START_D,END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
REASON_CHANGE	char	Reason Change		Collected at CRF.

Variable	Type	Label	Codes	Comments
START_DY	num	Relative Start Day		If START_D and IC_SUBJECT_D not missing then perform below logic to calculate START_DY, If START_D less than IC_SUBJECT_D then (START_D - IC_SUBJECT_D).Else if START_D is greater than equal to IC_SUBJECT_D then (START_D- IC_SUBJECT_D) +1.
END_DY	num	Relative End Day		If END_D and IC_SUBJECT_D not missing then perform below logic to calculate END_DY, If END_D less than IC_SUBJECT_D then (END_D - IC_SUBJECT_D).Else if END_D is greater than equal to IC_SUBJECT_D then (END_D- IC_SUBJECT_D) +1.

1.4.29. SQLS - R4– MOM_R4

Dataset	MOM_R4
Creating program	mom_r4.sas
Description	SQLS - R4
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
Q1	num	Lacked Energy to Do Things Code		Collected at CRF.
Q1_C	char	Lacked Energy to Do Things		Collected at CRF.
Q2	num	Couldn’t Be Bothered to Do Things Code		Collected at CRF.
Q2_C	char	Couldn’t Be Bothered to Do Things		Collected at CRF.
Q3	num	Was Worried About Future Code		Collected at CRF.
Q3_C	char	Was Worried About Future		Collected at CRF.
Q4	num	Felt Lonely Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q4_C	char	Felt Lonely		Collected at CRF.
Q5	num	Felt Hopeless Code		Collected at CRF.
Q5_C	char	Felt Hopeless		Collected at CRF.
Q6	num	Felt Panicky Code		Collected at CRF.
Q6_C	char	Felt Panicky		Collected at CRF.
Q7	num	Able to Carry Out Day-to-Day Actvty Code		Collected at CRF.
Q7_C	char	Able to Carry Out Day-to-Day Activity		Collected at CRF.
Q8	num	Took Thngs People Said The Wrng Way Code		Collected at CRF.
Q8_C	char	Took Things People Said The Wrong Way		Collected at CRF.
Q9	num	Found It Hard to Concentrate Code		Collected at CRF.
Q9_C	char	Found It Hard to Concentrate		Collected at CRF.
Q10	num	Found It Dificlt to Mix With People Code		Collected at CRF.
Q10_C	char	Found It Difficult to Mix With People		Collected at CRF.
Q11	num	Felt Down Code		Collected at CRF.
Q11_C	char	Felt Down		Collected at CRF.
Q12	num	Felt That I Could Cope Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q12_C	char	Felt That I Could Cope		Collected at CRF.
Q13	num	Felt Mixed Up And Unsure of Myself Code		Collected at CRF.
Q13_C	char	Felt Very Mixed Up And Unsure of Myself		Collected at CRF.
Q14	num	Slept Well Code		Collected at CRF.
Q14_C	char	Slept Well		Collected at CRF.
Q15	num	Feelings Swung From High to Low Code		Collected at CRF.
Q15_C	char	Feelings Swung From High to Low		Collected at CRF.
Q16	num	Felt Concend That, Wudn't Get Bettr Code		Collected at CRF.
Q16_C	char	Felt Concerned That, Wouldn't Get Better		Collected at CRF.
Q17	num	Worried About Things Code		Collected at CRF.
Q17_C	char	Worried About Things		Collected at CRF.
Q18	num	Felt That People Tended to Avoid Me Code		Collected at CRF.
Q18_C	char	Felt That People Tended to Avoid Me		Collected at CRF.
Q19	num	Got Upset Thinking About The Past Code		Collected at CRF.
Q19_C	char	Got Upset Thinking About The Past		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q20	num	Had Trouble Remembering Things Code		Collected at CRF.
Q20_C	char	Had Trouble Remembering Things		Collected at CRF.
Q21	num	Felt Cut Off From The World Code		Collected at CRF.
Q21_C	char	Felt Cut Off From The World		Collected at CRF.
Q22	num	Felt Uncomfortable With People Code		Collected at CRF.
Q22_C	char	Felt Uncomfortable With People		Collected at CRF.
Q23	num	Had Trouble Thinking Clearly Code		Collected at CRF.
Q23_C	char	Had Trouble Thinking Clearly		Collected at CRF.
Q24	num	Had Upsetting Thoughts Code		Collected at CRF.
Q24_C	char	Had Upsetting Thoughts		Collected at CRF.
Q25	num	Had Suicidal Thoughts Code		Collected at CRF.
Q25_C	char	Had Suicidal Thoughts		Collected at CRF.
Q26	num	Felt Happy Code		Collected at CRF.
Q26_C	char	Felt Happy		Collected at CRF.
Q27	num	Felt Depressed Code		Collected at CRF.
Q27_C	char	Felt Depressed		Collected at CRF.
Q28	num	Felt Drowsy Code		Collected at CRF.
Q28_C	char	Felt Drowsy		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q29	num	Felt Restless Code		Collected at CRF.
Q29_C	char	Felt Restless		Collected at CRF.
Q30	num	Was Concerned About Social Life Code		Collected at CRF.
Q30_C	char	Was Concerned About Social Life		Collected at CRF.
Q31	num	Felt Tired Code		Collected at CRF.
Q31_C	char	Felt Tired		Collected at CRF.
Q32	num	Felt Physically Weak Code		Collected at CRF.
Q32_C	char	Felt Physically Weak		Collected at CRF.
Q33	num	Felt I Wasn't Leading A Normal Life Code		Collected at CRF.
Q33_C	char	Felt I Wasn't Leading A Normal Life		Collected at CRF.

1.4.30. Relapse – MOM_RELAPSE

Dataset	MOM_RELAPSE
Creating program	mom_relapse.sas
Description	Relapse
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RELAPSE_D, REASSESSMENT_D, CONFIRMATION_D,SUMMARY

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
CRITERIA	char	Fulfil Relapse Criteria		Collected at CRF.
PSYCHHOS	char	Psychiatric Hospitalisation		Collected at CRF.
INCREASECARE	char	Increase Care PANSS Increase 25%		Collected at CRF.
SELFINJURY	char	Deliberate Self-Injury		Collected at CRF.
DANGER	char	Emergence Suicidal-Homicidal Ideation		Collected at CRF.
VIOLENT	char	Violent Behaviour		Collected at CRF.

Variable	Type	Label	Codes	Comments
CLINDETERIORATION	char	Clinical Deterioration		Collected at CRF.
EXCEEDDOSE	char	Exceeding Registered Dose		Collected at CRF.
FOLLOWUP	char	IRUB Done		Collected at CRF.
CRITERIUM_VALID	char	Relapse Criterium Still Valid		Collected at CRF.
RELAPDY	num	Relative Day of Relapse		If RELAPSE_D and IC_SUBJECT_D not missing then perform below logic to calculate RELAPDY, If RELAPSE_D less than IC_SUBJECT_D then (RELAPSE_D - IC_SUBJECT_D).Else if RELAPSE_D is greater than equal to IC_SUBJECT_D then (RELAPSE_D- IC_SUBJECT_D) +1.
REASSMDY	num	Relative Day Reassessment Scheduled		If REASSESSMENT_D and IC_SUBJECT_D not missing then perform below logic to calculate REASSMDY, If REASSESSMENT_D less than IC_SUBJECT_D then (REASSESSMENT_D - IC_SUBJECT_D).Else if REASSESSMENT_D is greater than equal to IC_SUBJECT_D then (REASSESSMENT_D- IC_SUBJECT_D) +1.
CONFDY	num	Relative Day Relapse Confirmation		If CONFIRMATION_D and IC_SUBJECT_D not missing then perform below logic to calculate CONFDY, If CONFIRMATION_D less than IC_SUBJECT_D then (CONFIRMATION_D - IC_SUBJECT_D).Else if CONFIRMATION_D is greater than equal to IC_SUBJECT_D then (CONFIRMATION_D- IC_SUBJECT_D) +1.

1.4.31. Resource Use Battery – MOM_RU

Dataset	MOM_RU
Creating program	mom_ru.sas
Description	Resource Use Battery
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: OTHER_SP1, OTHER_SP2, OTHERCONS3, OTHER_SP3,I,VISIT_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
HOSPITALISATION	char	Admitted to Hospital		Collected at CRF.
EMERGENCY	char	Admitted to Emergency Room		Collected at CRF.
DAYNIGHTCLINIC	char	Require Day/Night Clinic		Collected at CRF.
OUTPATIENT	char	Outpatient Consultation		Collected at CRF.
DAILYLIVING_CHANGE	char	Daily Living Changed		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRODUCTIVITY_CHANGE	char	Productivity Changed		Collected at CRF.
PSYCHIATRIST	char	Pychiatrist/Neurologist		Collected at CRF.
PSYCHIATRISTCONS	num	Cons Pychiatrist/Neurologist		Collected at CRF.
PSYCHOLOGIST	char	Psychologist		Collected at CRF.
PSYCHOLOGISTCONS	num	Cons Psychologist		Collected at CRF.
PSYNURSE	char	Psychiatric Nurse		Collected at CRF.
PSYNURSECONS	num	Cons Psychiatric Nurse		Collected at CRF.
GP	char	General Practitioner		Collected at CRF.
GPCONS	num	Cons General Practitioner		Collected at CRF.
SW	char	Social Worker		Collected at CRF.
SWCONS	num	Cons Social Worker		Collected at CRF.
THERAPIST	char	Therapist		Collected at CRF.
THERAPISTCONS	num	Cons Therapist		Collected at CRF.
OTHER	char	Other		Collected at CRF.
OTHERCONS1	num	Cons Other 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
OTHERCONS 2	num	Cons Other 2		Collected at CRF.
LOSTWORKI NG	char	Working Days Lost		Collected at CRF.
LOSTWORKI NGDAYS	num	Lost Working Days		Collected at CRF.
LOSTSCHOOL	char	School Days Lost		Collected at CRF.
LOSTSCHOOL DAYS	num	Lost School Days		Collected at CRF.
VISIT_DY	num	Relative Visit Day		If VISIT_D and IC_SUBJECT_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than IC_SUBJECT_D then (VISIT_D - IC_SUBJECT_D).Else if VISIT_D is greater than equal to IC_SUBJECT_D then (VISIT_D- IC_SUBJECT_D) +1.

1.4.32. Resource Use Battery Daily Living – MOM_RUDL

Dataset	MOM_RUDL
Creating program	mom_rudl.sas
Description	Resource Use Battery Daily Living
Unique identifier	DCRFID,RU_STATUS,DLSTDY,RECORDID
Sorted by	DCRFID,RU_STATUS,DLSTDY,RECORDID
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 missing values: RU_START_M, RU_START_Y, DL_START_D,START_AT_EXIT

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_STATUS	char	Status		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
DLSTDY	num	Relative DL Start Day		If DL_START_D and IC_SUBJECT_D not missing then perform below logic to calculate DLSTDY, If DL_START_D less than IC_SUBJECT_D then (DL_START_D - IC_SUBJECT_D).Else if DL_START_D is greater than equal to IC_SUBJECT_D then (DL_START_D- IC_SUBJECT_D) +1.

1.4.33. Resource Use Battery Emergency – MOM_RUEMER

Dataset	MOM_RUEMER
Creating program	mom_ruemer.sas
Description	Resource Use Battery Emergency
Unique identifier	DCRFID,RU_REASON,EMRSTDY
Sorted by	DCRFID,RU_REASON,EMRSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RU_START_M, RU_START_Y,EMER_START_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
RU_REASON	char	Reason For Change Code		Collected at CRF.
EMRSTDY	num	Relative RU Start Day		If EMER_START_D and IC_SUBJECT_D not missing then perform below logic to calculate EMRSTDY, If EMER_START_D less than IC_SUBJECT_D then (EMER_START_D - IC_SUBJECT_D).Else if EMER_START_D is greater than equal to IC_SUBJECT_D then (EMER_START_D-IC_SUBJECT_D) +1.

1.4.34. Resource Use Battery Hospitalization – MOM_RUHOSP

Dataset	MOM_RUHOSP
Creating program	mom_ruhosp.sas
Description	Resource Use Battery Hospitalization
Unique identifier	DCRFID,RU_HOSPTYPE,RU_WARD,RU_REASON,RUHOSTDY,RECORDID
Sorted by	DCRFID,RU_HOSPTYPE,RU_WARD,RU_REASON, RUHOSTDY,RECORDID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RU_REASON_ONGO, RUHOSP_START_D,RUHOSP_END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_HOSPTYPE	char	Hospital Type		Collected at CRF.
RU_WARD	char	Ward		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
RU_ONGO_START	char	Ongoing Start		Collected at CRF.
RU_ONGO_END	char	Ongoing End		Collected at CRF.
RUHOSTDY	num	Relative Hosp Start Day		If RUHOSP_START_D and IC_SUBJECT_D not missing then perform below logic to calculate RUHOSTDY, If RUHOSP_START_D less than IC_SUBJECT_D then (RUHOSP_START_D - IC_SUBJECT_D).Else if RUHOSP_START_D is greater than equal to IC_SUBJECT_D then (RUHOSP_START_D- IC_SUBJECT_D) +1.
RUHOENDY	num	Relative Hosp End Day		If RUHOSP_END_D and IC_SUBJECT_D not missing then perform below logic to calculate RUHOENDY, If RUHOSP_END_D less than IC_SUBJECT_D then (RUHOSP_END_D - IC_SUBJECT_D).Else if RUHOSP_END_D is greater than equal to IC_SUBJECT_D then (RUHOSP_END_D- IC_SUBJECT_D) +1.

1.4.35. Resource Use Battery Partial Hospitalization – MOM_RUPART

Dataset	MOM_RUPART
Creating program	mom_rupart.sas
Description	Resource Use Battery Partial Hospitalization
Unique identifier	DCRFID,PARTHSDY
Sorted by	DCRFID,PARTHSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RU_START_M, RU_START_Y, RU_END_M, RU_END_Y, PART_START_D, PART_END_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_HOSPTYPE	char	Hospital Type		Collected at CRF.
RU_DAYNIGHT	char	Day_Night		Collected at CRF.
RU_FREQ	num	Freq		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
RU_ONGO_START	char	Ongoing Start		Collected at CRF.
RU_ONGO_END	char	Ongoing End		Collected at CRF.
HOSPTYPE	char	Hospital Type		Collected at CRF.
PARTHSDY	num	Relative Partial Hospitalisation Start Day		If PART_START_D and IC_SUBJECT_D not missing then perform below logic to calculate PARTHSDY, If PART_START_D less than IC_SUBJECT_D then (PART_START_D - IC_SUBJECT_D).Else if PART_START_D is greater than equal to IC_SUBJECT_D then (PART_START_D- IC_SUBJECT_D) +1.
PARTHEDY	num	Relative Partial Hospitalisation End Day		If PART_END_D and IC_SUBJECT_D not missing then perform below logic to calculate PARTHEDY, If PART_END_D less than IC_SUBJECT_D then (PART_END_D - IC_SUBJECT_D).Else if PART_END_D is greater than equal to IC_SUBJECT_D then (PART_END_D- IC_SUBJECT_D) +1.

1.4.36. Resource Use Battery Productivity of Subject – MOM_RUPROD

Dataset	MOM_RUPROD
Creating program	mom_ruprod.sas
Description	Resource Use Battery Productivity of Subject
Unique identifier	DCRFID,RU_STATUS,RU_REASON,PRODSTDY,RECORDID
Sorted by	DCRFID,RU_STATUS,RU_REASON,PRODSTDY,RECORDID
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: RU_START_M, RU_START_Y,PROD_START_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
RECORDID	num	Record Id		Collected at CRF.
RU_STATUS	char	Status		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
PRODSTDY	num	Relative Productivity Start Day		If PROD_START_D and IC_SUBJECT_D not missing then perform below logic to calculate PRODSTDY, If PROD_START_D less than IC_SUBJECT_D then (PROD_START_D - IC_SUBJECT_D).Else if PROD_START_D is greater than equal to IC_SUBJECT_D then (PROD_START_D-IC_SUBJECT_D) +1.

1.4.37. SF-12 Health Survey - MOM_SF12

Dataset	MOM_SF12
Creating program	mom_sf12.sas
Description	SF-12 Health Survey
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: QVISIT_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
Q1	num	In General, Your Health Is: Code		Collected at CRF.
Q1_C	char	In General, Your Health Is:		Collected at CRF.
Q2	num	Moderate Activities Code		Collected at CRF.
Q2_C	char	Moderate Activities		Collected at CRF.
Q3	num	Climbing Several Flights of Stairs Code		Collected at CRF.
Q3_C	char	Climbing Several Flights of Stairs		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q4	num	Accomplshed Less Than You Wuld Like Code		Collected at CRF.
Q4_C	char	Accomplished Less Than You Would Like		Collected at CRF.
Q5	num	Limted in The Kind of Work Or Other Code		Collected at CRF.
Q5_C	char	Limited in The Kind of Work Or Other		Collected at CRF.
Q6	num	Accomplshed Less Than You Wuld Like Code		Collected at CRF.
Q6_C	char	Accomplished Less Than You Would Like.		Collected at CRF.
Q7	num	Din't Do Work Other Actvty Carefuly Code		Collected at CRF.
Q7_C	char	Didn't Do Work, Other Activity Carefully		Collected at CRF.
Q8	num	How Much Pain With Your Normal Work Code		Collected at CRF.
Q8_C	char	How Much Pain With Your Normal Work		Collected at CRF.
Q9	num	Have You Felt Calm And Peaceful Code		Collected at CRF.
Q9_C	char	Have You Felt Calm And Peaceful		Collected at CRF.
Q10	num	Did You Have A Lot Of Energy Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q10_C	char	Did You Have A Lot Of Energy		Collected at CRF.
Q11	num	Have You Felt Downhearted And Blue Code		Collected at CRF.
Q11_C	char	Have You Felt Downhearted And Blue		Collected at CRF.
Q12	num	Physicl Health Affctd Social Actvty Code		Collected at CRF.
Q12_C	char	Physical Health Affected Social Activity		Collected at CRF.
QVISDY	num	Relative Visit Day Questionnaire		If QVISIT_D and IC_SUBJECT_D not missing then perform below logic to calculate QVISDY, If QVISIT_D less than IC_SUBJECT_D then (QVISIT_D - IC_SUBJECT_D).Else if QVISIT_D is greater than equal to IC_SUBJECT_D then (QVISIT_D-IC_SUBJECT_D) +1.

1.4.38. Social and Occupational Functioning Assessment Scale – MOM_SOFAS

Dataset	MOM_SOFAS
Creating program	mom_sofas.sas
Description	Social and Occupational Functioning Assessment Scale
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visit Id		Collected at CRF.
SCORE	num	Sofas Score		Collected at CRF.

1.4.39. Trial Termination - MOM_TERM

Dataset	MOM_TERM
Creating program	mom_term.sas
Description	Trial Termination
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LASTCONTACT_D, DEATH_D, REASON_OTHER_SP, INVEST_NAME, SIGN_D, IRUBNOTCOMPL,DROPOUT_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
COMPL_ACCORD_PROT	char	Completed Entire Course of Trial		Collected at CRF.
REASON	char	Main Reason Discontinuation		Collected at CRF.
AE_NO1	num	AE No 1		Collected at CRF.
AE_NO2	num	AE No 2		Collected at CRF.
AE_NO3	num	AE No 3		Collected at CRF.
SIGN_YN	char	Investigators Signature		Collected at CRF.

Variable	Type	Label	Codes	Comments
LCONTDY	num	Relative Day Last Contact With Subject		If LASTCONTACT_D and IC_SUBJECT_D not missing then perform below logic to calculate LCONTDY, If LASTCONTACT_D less than IC_SUBJECT_D then (LASTCONTACT_D - IC_SUBJECT_D).Else if LASTCONTACT_D is greater than equal to IC_SUBJECT_D then (LASTCONTACT_D- IC_SUBJECT_D) +1.
DEATH_DY	num	Relative Day of Death		If DEATH_D and IC_SUBJECT_D not missing then perform below logic to calculate DEATH_DY, If DEATH_D less than IC_SUBJECT_D then (DEATH_D - IC_SUBJECT_D).Else if DEATH_D is greater than equal to IC_SUBJECT_D then (DEATH_D- IC_SUBJECT_D) +1.
SIGN_DY	num	Relative Signature Day		If SIGN_D and IC_SUBJECT_D not missing then perform below logic to calculate SIGN_DY, If SIGN_D less than IC_SUBJECT_D then (SIGN_D - IC_SUBJECT_D).Else if SIGN_D is greater than equal to IC_SUBJECT_D then (SIGN_D- IC_SUBJECT_D) +1.
DROPDY	num	Relative Drop Out Day		If DROPOUT_D and IC_SUBJECT_D not missing then perform below logic to calculate DROPDY, If DROPOUT_D less than IC_SUBJECT_D then (DROPOUT_D - IC_SUBJECT_D).Else if DROPOUT_D is greater than equal to IC_SUBJECT_D then (DROPOUT_D- IC_SUBJECT_D) +1.

1.4.40. Visit - MOM_VIS

Dataset	MOM_VIS
Creating program	mom_vis.sas
Description	Visit
Unique identifier	DCRFID,VISITID
Sorted by	DCRFID,VISITID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VISIT_D,OCCU_CODE

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Collected at CRF.
DCRFID	num	Crfid Assigned For De-identity		Randomly assigned Crfid For De-identity.
VISITID	char	Visitid		Collected at CRF.
WEIGHT	num	Weight		Collected at CRF.
WEIGHT_ND	char	Weight Not Done		Collected at CRF.
HR	num	Pulse		Collected at CRF.
HR_ND	char	Pulse Not Done		Collected at CRF.
SBP	num	Systolic Bloodpressure		Collected at CRF.
SBP_ND	char	Systolic Bloodpressure Not Done		Collected at CRF.
DBP	num	Diastolic Bloodpressure		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBP_ND	char	Diastolic Bloodpressure Not Done		Collected at CRF.
EDU_COMP	char	Educational Degree Achieved		Collected at CRF.
EDU_BUSY	char	Completing Education		Collected at CRF.
EDU_CURRENT	char	Current Education		Collected at CRF.
LAB_ASS	char	Blood Sample		Collected at CRF.
URINALYSIS	char	Urine Sample		Collected at CRF.
PREGTEST	char	Pregnancy Test		Collected at CRF.
PREVIOUS_THERAPY	char	Previous Antipsychotic Therapy		Collected at CRF.
CT_NONE	char	Concomitant Therapy (Change)		Collected at CRF.
AE_NONE	char	Adverse Event (New)		Collected at CRF.
SF_12	char	SF-12 Questionnaire		Collected at CRF.
SQLS_R4	char	Sqls-R4 Questionnaire		Collected at CRF.
WAIST	num	Waist Circumference		Collected at CRF.
WAIST_ND	char	Waist Circumference Not Done		Collected at CRF.
HIP	num	Hip Circumference		Collected at CRF.

Variable	Type	Label	Codes	Comments
HIP_ND	char	Hip Circumference Not Done		Collected at CRF.
VISIT_DY	num	Relative Visit Day		If VISIT_D and IC_SUBJECT_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than IC_SUBJECT_D then (VISIT_D - IC_SUBJECT_D).Else if VISIT_D is greater than equal to IC_SUBJECT_D then (VISIT_D-IC_SUBJECT_D) +1.