Clinical Development

JNJ-410397

RISSCH3024 Relapse

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

- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Partial date's relative day cannot be calculated.
- Reference number will not be provided.
- Empty dataset will not be submitted i.e.(RESUSE_DAYCLINIC and RESUSE_NIGHTCLINIC).
- RISSCH3024 Relapse data does not contain informed consent information hence using RISSCH3024 discontinuation study collected consent date as reference date to derive relative days.

1.3 Data Files

The RISSCH3024 Relapse Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4 Data Domains

1.4.1 Demographic Data – ACRF

Dataset	ACRF
Creating program	acrf.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: INITIALS

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
DPREV_CRFID	char	prev_crfID Assigned for De-identity		Randomly assigned prev_crfID for De-identity
DCOUNTRY	char	De-identify Country		Element will be grouped to protect PII.
DCENTRE	char	centre Assigned for De-identity		Randomly assigned centre for De-identity
PROTDEV_YN	char	protdev_yn		Collected at CRF.

Variable	Type	Label	Codes	Comments
CT_NONE	char	CT_none		Collected at CRF.
AE_NONE	char	AE_none		Collected at CRF.
AGE	char	Age in Years		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= floor((CONSENT_D – DOB)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.

1.4.2 Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,FIELD2_PTTEXT, RECORDID
Sorted by	DCRFID,FIELD2_PTTEXT, RECORDID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V, AE_START_D, AE_START_M, AE_START_Y, AE_END_D, AE_END_M, AE_END_Y, AE_ACT1

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
AE_MEDDRA	num	MedDra Dictionary Code		Collected at CRF.
AE_SEV	char	Severity		Collected at CRF.
AE_ACT	char	Action Taken Regarding Trial Medication		Collected at CRF.
AE_COTH	char	Concomitant Therapy Due To AE		Collected at CRF.
AE_REL	char	Relation to Trial Medication		Collected at CRF.

Variable	Type	Label	Codes	Comments
AE_OUT	char	Subject Outcome		Collected at CRF.
FIELD1_LLTCODE	num	Lower Level Term Code		Collected at CRF.
FIELD2_LLTTEXT	char	Lover Level Term		Collected at CRF.
FIELD1_PTCODE	num	Preferred Term Code		Collected at CRF.
FIELD2_PTTEXT	char	Preferred Term		Collected at CRF.
FIELD1_SOCCODE	num	System Organ Class Code		Collected at CRF.
FIELD2_SOCTEXT	char	System Organ Class		Collected at CRF.
AE_START_DY	num	Relative AE Start Day		If AE_START_D and CONSENT_D not missing then perform below logic to calculate AE_START_DY, If AE_START_D less than CONSENT_D then (AE_START_D - CONSENT_D).Else if AE_START_D is greater than equal to CONSENT_D then (AE_START_D- CONSENT_D) +1.
AE_END_DY	num	Relative AE End Day		If AE_END_D and CONSENT_D not missing then perform below logic to calculate AE_END_DY, If AE_END_D less than CONSENT_D then (AE_END_D - CONSENT_D).Else if AE_END_D is greater than equal to CONSENT_D then (AE_END_D-CONSENT_D) +1.

1.4.3 All Labdata – ALL_LABDATA

Dataset	ALL_LABDATA
Creating program	all_labdata.sas
Description	All_Labdata
Unique identifier	DCRFID,TESTNAME,TESTGROUP,VISITID, RESULT
Sorted by	DCRFID,TESTNAME,TESTGROUP,VISITID, RESULT
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: EXTRALABTESTDATE, TESTID0, SIGN_DATE, LABRECNO, DOCOL, LABNAME, LABNO, SPECNO, INVESTIGATOR, INITIALS, TRIALNO, DOB, DORES, COMMENT

Variable	Type	Label	Codes	Comments
TESTNAME	char	Name of Test		Collected at CRF.
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
TESTID	num	Test Identifier		Collected at CRF.
CLINSIG	char	Clinically relevant		Collected at CRF.
TESTGROUP	char	Test Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEST	char	Test		Collected at CRF.
SIGN_YN	char	Sign_YN		Collected at CRF.
PROTOCOL	char	Protocol num Code num for the protocol		Collected at CRF.
ACCESSNO	char	Visit Identifier (if supplied)		Collected at CRF.
SEX	char	Patients Sex		Collected at CRF.
RESULT	char	Test Results		Collected at CRF.
UNITS	char	Test Units		Collected at CRF.
LONRNG	num	Low normal ranges		Collected at CRF.
HINRNG	num	High normal ranges		Collected at CRF.
FLAG	char	Out of normal range		Collected at CRF.
EXTRALABTESTDY	num	Relative Extra Lab Test Day		If EXTRALABTESTDATE and CONSENT_D not missing then perform below logic to calculate EXTRALABTESTDY, If EXTRALABTESTDATE less than CONSENT_D then (EXTRALABTESTDATE - CONSENT_D).Else if EXTRALABTESTDATE is greater than equal to CONSENT_D then (EXTRALABTESTDATE- CONSENT_D) +1.
SIGN_DY	num	Relative Day of Signature		If SIGN_DATE and CONSENT_D not missing then perform below logic to calculate SIGN_DY, If SIGN_DATE less than CONSENT_D then (SIGN_DATE - CONSENT_D).Else if SIGN_DATE is greater than equal to CONSENT_D then (SIGN_DATE- CONSENT_D) +1.

Variable	Type	Label	Codes	Comments
DOCOLDY	num	Relative Specimen Collection Day		If DOCOL and CONSENT_D not missing then perform below logic to calculate DOCOLDY, If DOCOL less than CONSENT_D then (DOCOL - CONSENT_D).Else if DOCOL is greater than equal to CONSENT_D then (DOCOL- CONSENT_D) +1.
DORESDY	num	Relative Day of Result Verification		If DORES and CONSENT_D not missing then perform below logic to calculate DORESDY, If DORES less than CONSENT_D then (DORES - CONSENT_D).Else if DORES is greater than equal to CONSENT_D then (DORES- CONSENT_D) +1.

1.4.4 All_Labtest – ALL_LABTEST

Dataset	ALL_LABTEST
Creating program	all_labtest.sas
Description	All_Labtest
Unique identifier	DCRFID,TESTNAME,VISITID, RECORDID
Sorted by	DCRFID,TESTNAME,VISITID, 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: EXTRALABTESTDATE, TESTID0, SIGN_DATE, LABRECNO, DOCOL

Variable	Type	Label	Codes	Comments
TESTNAME	char	Name of Test		Collected at CRF.
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
TESTID	num	Test Identifier		Collected at CRF.
CLINSIG	char	Clinically relevant		Collected at CRF.
EXTRALABTEST	char	Repeated test		Collected at CRF.
TESTGROUP	char	Test Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEST	char	Test		Collected at CRF.
TEST_OUTSIDENR	char	Abnormalities reported		Collected at CRF.
SIGN_YN	char	Sign_YN		Collected at CRF.
EXTRALABTESTDY	num	Relative Extra Lab Test Day		If EXTRALABTESTDATE and CONSENT_D not missing then perform below logic to calculate EXTRALABTESTDY, If EXTRALABTESTDATE less than CONSENT_D then (EXTRALABTESTDATE - CONSENT_D).Else if EXTRALABTESTDATE is greater than equal to CONSENT_D then (EXTRALABTESTDATE- CONSENT_D) +1.
SIGN_DY	num	Relative Day of Signature		If SIGN_DATE and CONSENT_D not missing then perform below logic to calculate SIGN_DATE, If SIGN_DATE less than CONSENT_D then (SIGN_DATE - CONSENT_D).Else if SIGN_DATE is greater than equal to CONSENT_D then (SIGN_DATE- CONSENT_D) +1.
DOCOLDY	num	Relative Specimen Collection Day		If DOCOL and CONSENT_D not missing then perform below logic to calculate DOCOLDY, If DOCOL less than CONSENT_D then (DOCOL - CONSENT_D).Else if DOCOL is greater than equal to CONSENT_D then (DOCOL- CONSENT_D) +1.

1.4.5 CDS for Schizophrenia – CDSS

Dataset	CDSS
Creating program	cdss.sas
Description	CDSfor Schizophrenia
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
Q1	num	Depression Code		Collected at CRF.
Q1_C	char	Depression		Collected at CRF.
Q2	num	Hopelessness Code		Collected at CRF.
Q2_C	char	Hopelessness		Collected at CRF.
Q3	num	Self Depreciation Code		Collected at CRF.
Q3_C	char	Self Depreciation		Collected at CRF.
Q4	num	Guilty Feelings Ideas of Reference Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q4_C	char	Guilty Feelings Ideas of Reference		Collected at CRF.
Q5	num	Pathological Guilt Code		Collected at CRF.
Q5_C	char	Pathological Guilt		Collected at CRF.
Q6	num	Morning Depression Code		Collected at CRF.
Q6_C	char	Morning Depression		Collected at CRF.
Q7	num	Early Wakening Code		Collected at CRF.
Q7_C	char	Early Wakening		Collected at CRF.
Q8	num	Suicide Code		Collected at CRF.
Q8_C	char	Suicide		Collected at CRF.
Q9	num	Observed Depression Code		Collected at CRF.
Q9_C	char	Observed Depression		Collected at CRF.

1.4.6 Clinical Global Expression – CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Expression
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
Q1	num	CGI Severity Code		Collected at CRF.
Q1_C	char	CGI Severity		Collected at CRF.
Q2	num	CGI Change Code		Collected at CRF.
Q2_C	char	CGI Change		Collected at CRF.

1.4.7 Concomitant Therapy – CT

Dataset	CT
Creating program	ct.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,CT_WHONO, RECORDID
Sorted by	DCRFID,CT_WHONO, RECORDID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CT_ROUTE_SP, CT_INDICATION, AE_NO3, AE_NO4, AE_NO5, AE_NO6, CT_START_D, CT_START_M, CT_START_Y, CT_END_D, CT_END_M, CT_END_Y, CT_FREQ_SP, CT_UNIT_SP, CT_V

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
CT_WHONO	char	WHO Dictionary Number		Collected at CRF.
CT_WHONAME	char	WHO Dictionary Name		Collected at CRF.
CT_VALUE	num	Dose		Collected at CRF.
CT_FREQ	char	Frequency		Collected at CRF.

Variable	Type	Label	Codes	Comments
CT_UNIT	char	Unit		Collected at CRF.
CT_RANGE_ MIN	num	Minimum Range		Collected at CRF.
CT_RANGE_ MAX	num	Maximum Range		Collected at CRF.
CT_ROUTE	char	Route of Administration		Collected at CRF.
AE_NO1	num	AE line no 1		Collected at CRF.
AE_NO2	num	AE line no 2		Collected at CRF.
CT_PRETRIAL	char	Started pretrial		Collected at CRF.
CT_ONGO	char	Ongoing post-trial		Collected at CRF.
CT_PRN	num	ct_prn		Collected at CRF.
DRUG_KEY	char	Drug Key		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
GENERIC	char	Generic		Collected at CRF.
CT_START_T	num	CT Start Time		Collected at CRF.
CT_END_T	num	CT End Time		Collected at CRF.
CT_START_X	num	Ct_Start_X		Collected at CRF.
CT_END_X	num	Ct_End_X		Collected at CRF.

Variable	Type	Label	Codes	Comments
CT_START_DY	num	Relative Start Day of Therapy		If CT_START_D and CONSENT_D not missing then perform below logic to calculate CT_START_DY, If CT_START_D less than CONSENT_D then (CT_START_D - CONSENT_D).Else if CT_START_D is greater than equal to CONSENT_D then (CT_START_D- CONSENT_D) +1.
CT_END_DY	num	Relative End Day of Therapy		If CT_END_D and CONSENT_D not missing then perform below logic to calculate CT_END_DY, If CT_END_D less than CONSENT_D then (CT_END_D - CONSENT_D).Else if CT_END_D is greater than equal to CONSENT_D then (CT_END_D- CONSENT_D) +1.

1.4.8 Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
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: ECG_D, AB_OTHER_SP

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
RR	char	RR Interval		Collected at CRF.
PR	num	PR Interval		Collected at CRF.
QRS	num	QRS Width		Collected at CRF.
QT	num	QT Interval		Collected at CRF.
QTC	num	QT Conduction Interval		Collected at CRF.
BRADY	char	Sinus Bradycardia (<50 bpm)		Collected at CRF.

Variable	Type	Label	Codes	Comments
TACHY	char	Sinus Tachycardia (>=100 bpm)		Collected at CRF.
SUPRA	char	Supraventricular Premature Beat(s)		Collected at CRF.
VENTRI	char	Ventricular Premature Beat(s)		Collected at CRF.
AF	char	Atrial Fibrillation		Collected at CRF.
LVH	char	Left Ventricular Hypertrophy		Collected at CRF.
MI_ACUTE	char	MI Acute		Collected at CRF.
MI_SUB	char	MI Sub Acute		Collected at CRF.
MI_OLD	char	MI Old		Collected at CRF.
AV_FD	char	AV Block First Degree		Collected at CRF.
AV_SD	char	AV Block Second Degree		Collected at CRF.
AV_TD	char	AV Block Third Degree		Collected at CRF.
LBB_I	char	LBB Block Incomplete		Collected at CRF.
LBB_C	char	LBB Block Complete		Collected at CRF.
RBB_I	char	RBB Block Incomplete		Collected at CRF.
RBB_C	char	RBB Block Complete		Collected at CRF.
ISCHEMIA	char	Myocardial Ischemia		Collected at CRF.
REPOL	char	Atypical Repolarisation Disturbance(s)		Collected at CRF.
ECG_NORMAL	char	ECG Normal		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECG_CHANGES	char	ECG Changes		Collected at CRF.
ECG_DY	num	Relative Day of ECG Collection		If ECG_D and CONSENT_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than CONSENT_D then (ECG_D - CONSENT_D).Else if ECG_D is greater than equal to CONSENT_D then (ECG_D- CONSENT_D) +1.

1.4.9 Elabdata – ELABDATA

Dataset	ELABDATA
Creating program	elabdata.sas
Description	Elabdata
Unique identifier	DCRFID,TESTNAME, VISITID
Sorted by	DCRFID,TESTNAME, VISITID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABNAME, LABNO, SPECNO, INVESTIGATOR, INITIALS, TRIALNO, DOB, DOCOL, DORES, COMMENT, LABRECNO

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Protocol num Code num for the protocol		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACCESSNO	char	Visit Identifier (if supplied)		Collected at CRF.
SEX	char	Patients Sex		Collected at CRF.
TESTNAME	char	Name of Test		Collected at CRF.
RESULT	char	Test Results		Collected at CRF.
UNITS	char	Test Units		Collected at CRF.
LONRNG	num	Low normal ranges		Collected at CRF.
HINRNG	num	High normal ranges		Collected at CRF.
FLAG	char	Out of normal range		Collected at CRF.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
DOCOLDY	num	Relative Specimen Collection Day		If DOCOL and CONSENT_D not missing then perform below logic to calculate DOCOLDY, If DOCOL less than CONSENT_D then (DOCOL - CONSENT_D).Else if DOCOL is greater than equal to CONSENT_D then (DOCOL- CONSENT_D) +1.
DORESDY	num	Relative Day of Result verification		If DORES and CONSENT_D not missing then perform below logic to calculate DORESDY, If DORES less than CONSENT_D then (DORES - CONSENT_D).Else if DORES is greater than equal to CONSENT_D then (DORES- CONSENT_D) +1.

1.4.10 Extrapyramidal Symptom Rating Scale – ESRS

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

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
I1	num	Impression of Slowness or Weakness Code		Collected at CRF.
I1_C	char	Impression of Slowness or Weakness		Collected at CRF.
I2	num	Difficulty Walking or With Balance Code		Collected at CRF.
I2_C	char	Difficulty Walking or With Balance		Collected at CRF.
I3	num	Difficulty Swallowing or Talking Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
I3_C	char	Difficulty Swallowing or Talking		Collected at CRF.
I4	num	Stiffness, Stiff Posture Code		Collected at CRF.
I4_C	char	Stiffness, Stiff Posture		Collected at CRF.
I5	num	Cramps or Pains in Limbs, Back or Neck Code		Collected at CRF.
I5_C	char	Cramps or Pains in Limbs, Back or Neck		Collected at CRF.
I6	num	Restless, Nervous, Unable to Keep Still Code		Collected at CRF.
I6_C	char	Restless, Nervous, Unable to Keep Still		Collected at CRF.
I7	num	Tremors, Shaking Code		Collected at CRF.
I7_C	char	Tremors, Shaking		Collected at CRF.
I8	num	Oculogyric Crisis, Abnormal Posture Code		Collected at CRF.
I8_C	char	Oculogyric Crisis, Abnormal Posture		Collected at CRF.
I9	num	Increased Salivation Code		Collected at CRF.
I9_C	char	Increased Salivation		Collected at CRF.
I10	num	Dyskinesia of Extremities or Trunk Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
I10_C	char	Dyskinesia of Extremities or Trunk		Collected at CRF.
I11	num	Dyskinesia of Tongue, Jaw, Lips or Face Code		Collected at CRF.
I11_C	char	Dyskinesia of Tongue, Jaw, Lips or Face		Collected at CRF.
I12	num	Dizziness When Standing Up, Esp Morning Code		Collected at CRF.
I12_C	char	Dizziness When Standing Up, Esp Morning		Collected at CRF.
A1	num	Excessive Automatic Movements Code		Collected at CRF.
A1_C	char	Excessive Automatic Movements		Collected at CRF.
A2	num	Bradykinesia Code		Collected at CRF.
A2_C	char	Bradykinesia		Collected at CRF.
A3	num	Rigidity, Right Upper Limb Code		Collected at CRF.
A3_C	char	Rigidity, Right Upper Limb		Collected at CRF.
A4	num	Rigidity, Left Upper Limb Code		Collected at CRF.
A4_C	char	Rigidity, Left Upper Limb		Collected at CRF.
A5	num	Rigidity, Right Lower Limb Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
A5_C	char	Rigidity, Right Lower Limb		Collected at CRF.
A6	num	Rigidity, Left Lower Limb Code		Collected at CRF.
A6_C	char	Rigidity, Left Lower Limb		Collected at CRF.
A7	num	Gait And Posture Code		Collected at CRF.
A7_C	char	Gait And Posture		Collected at CRF.
A8	num	Right Upper Limb		Collected at CRF.
A9	num	Left Upper Limb		Collected at CRF.
A10	num	Right Lower Limb		Collected at CRF.
A11	num	Left Lower Limb		Collected at CRF.
A12	num	Head		Collected at CRF.
A13	num	Jaw/Chin		Collected at CRF.
A14	num	Tongue		Collected at CRF.
A15	num	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 Stability Code		Collected at CRF.
A18_C	char	Postural Stability		Collected at CRF.
D1	num	Acute Torsion Dystonia, Right Upper Limb Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
D1_C	char	Acute Torsion Dystonia, Right Upper Limb		Collected at CRF.
D2	num	Acute Torsion Dystonia, Left Upper Limb Code		Collected at CRF.
D2_C	char	Acute Torsion Dystonia, Left Upper Limb		Collected at CRF.
D3	num	Acute Torsion Dystonia, Right Lower Limb Code		Collected at CRF.
D3_C	char	Acute Torsion Dystonia, Right Lower Limb		Collected at CRF.
D4	num	Acute Torsion Dystonia, Left Lower Limb Code		Collected at CRF.
D4_C	char	Acute Torsion Dystonia, Left Lower Limb		Collected at CRF.
D5	num	Acute Torsion Dystonia, head Code		Collected at CRF.
D5_C	char	Acute Torsion Dystonia, head		Collected at CRF.
D6	num	Acute Torsion Dystonia, Jaw Code		Collected at CRF.
D6_C	char	Acute Torsion Dystonia, Jaw		Collected at CRF.
D7	num	Acute Torsion Dystonia, Tongue Code		Collected at CRF.
D7_C	char	Acute Torsion Dystonia, Tongue		Collected at CRF.

Variable	Type	Label	Codes	Comments
D8	num	Acute Torsion Dystonia, Lips Code		Collected at CRF.
D8_C	char	Acute Torsion Dystonia, Lips		Collected at CRF.
D9	num	Acute Torsion Dystonia, Eyes Code		Collected at CRF.
D9_C	char	Acute Torsion Dystonia, Eyes		Collected at CRF.
D10	num	Acute Torsion Dystonia, Trunk Code		Collected at CRF.
D10_C	char	Acute Torsion Dystonia, Trunk		Collected at CRF.
D11	num	Non-acute Dystonia, Right Upper Limb Code		Collected at CRF.
D11_C	char	Non-acute Dystonia, Right Upper Limb		Collected at CRF.
D12	num	Non-acute Torsion Dystonia, Left Upper Limb Code		Collected at CRF.
D12_C	char	Non-acute Torsion Dystonia, Left Upper Limb		Collected at CRF.
D13	num	Non-acute Torsion Dystonia, Right Lower Limb Code		Collected at CRF.
D13_C	char	Non-acute Torsion Dystonia, Right Lower Limb		Collected at CRF.
D14	num	Non-acute Torsion Dystonia, Left Lower Limb Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
D14_C	char	Non-acute Torsion Dystonia, Left Lower Limb		Collected at CRF.
D15	num	Non-acute Torsion Dystonia, head Code		Collected at CRF.
D15_C	char	Non-acute Torsion Dystonia, head		Collected at CRF.
D16	num	Non-acute Torsion Dystonia, Jaw Code		Collected at CRF.
D16_C	char	Non-acute Torsion Dystonia, Jaw		Collected at CRF.
D17	num	Non-acute Torsion Dystonia, Tongue Code		Collected at CRF.
D17_C	char	Non-acute Torsion Dystonia, Tongue		Collected at CRF.
D18	num	Non-acute Torsion Dystonia, Lips Code		Collected at CRF.
D18_C	char	Non-acute Torsion Dystonia, Lips		Collected at CRF.
D19	num	Non-acute Torsion Dystonia, Eyes Code		Collected at CRF.
D19_C	char	Non-acute Torsion Dystonia, Eyes		Collected at CRF.
D20	num	Non-acute Torsion Dystonia, Trunk Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
D20_C	char	Non-acute Torsion Dystonia, Trunk		Collected at CRF.
M1	num	Lingual Movements		Collected at CRF.
M2	num	Jaw Movements		Collected at CRF.
M3	num	Bucco-Labial Movements		Collected at CRF.
M4	num	Truncal Movements		Collected at CRF.
M5	num	Upper Extemities		Collected at CRF.
M6	num	Lower Extremities		Collected at CRF.
M7	num	Other involuntary Movements		Collected at CRF.
CGIDYSKINESIA	num	Clinical Global Impression of Severity of Dyskinesia Code		Collected at CRF.
CGIDYSKINESIA_C	char	Clinical Global Impression of Severity of Dyskinesia		Collected at CRF.
CGIPARK	num	Clinical Global Impression of Severity of Parkinsonism Code		Collected at CRF.
CGIPARK_C	char	Clinical Global Impression of Severity of Parkinsonism		Collected at CRF.
CGIDYSTONIA	num	Clinical Global Impression of Severity of Dystonia Code		Collected at CRF.
CGIDYSTONIA_C	char	Clinical Global Impression of Severity of Dystonia		Collected at CRF.

Variable	Type	Label	Codes	Comments
STAGEPARK	num	Stage of Parkinsonism Code		Collected at CRF.
STAGEPARK_C	char	Stage of Parkinsonism		Collected at CRF.

1.4.11 Labdone – LABDONE

Dataset	LABDONE
Creating program	labdone.sas
Description	Labdone
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: SIGN_DATE, LABRECNO, DOCOL

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
TEST_OUTSIDENR	char	Abnormalities Reported		Collected at CRF.

Variable	Type	Label	Codes	Comments
SIGN_YN	char	Sign_YN		Collected at CRF.
SIGN_DY	num	Relative Day of Signature		If SIGN_DATE and CONSENT_D not missing then perform below logic to calculate SIGN_DY, If SIGN_DATE less than CONSENT_D then (SIGN_DATE - CONSENT_D).Else if SIGN_DATE is greater than equal to CONSENT_D then (SIGN_DATE- CONSENT_D) +1.
DOCOLDY	num	Relative Specimen Collection Day		If DOCOL and CONSENT_D not missing then perform below logic to calculate DOCOLDY, If DOCOL less than CONSENT_D then (DOCOL - CONSENT_D).Else if DOCOL is greater than equal to CONSENT_D then (DOCOL- CONSENT_D) +1.

1.4.12 Laboratory Tests – LABTEST

Dataset	LABTEST
Creating program	labtest.sas
Description	Laboratory Tests
Unique identifier	DCRFID,TESTID,VISITID, RECORDID
Sorted by	DCRFID,TESTID,VISITID, RECORDID
Notes	Below listed variables will be dropped from dataset due to repetition of the information: EXTRALABTESTDATE, TESTID0, DOCOL

Variable	Type	Label	Codes	Comments
TESTNAME	char	Name of Test		Collected at CRF.
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	num	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
TESTID	num	Test Identifier		Collected at CRF.
CLINSIG	char	Clinically relevant		Collected at CRF.
EXTRALABTEST	char	Repeated test		Collected at CRF.
TESTGROUP	char	Test Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
TEST	char	Test		Collected at CRF.
EXTRALABTESTDY	num	Relative Extra Lab Test Day		If EXTRALABTESTDATE and CONSENT_D not missing then perform below logic to calculate EXTRALABTESTDY, If EXTRALABTESTDATE less than CONSENT_D then (EXTRALABTESTDATE - CONSENT_D).Else if EXTRALABTESTDATE is greater than equal to CONSENT_D then (EXTRALABTESTDATE- CONSENT_D) +1.
DOCOLDY	num	Relative Specimen Collection Day		If DOCOL and CONSENT_D not missing then perform below logic to calculate DOCOLDY, If DOCOL less than CONSENT_D then (DOCOL - CONSENT_D).Else if DOCOL is greater than equal to CONSENT_D then (DOCOL- CONSENT_D) +1.

1.4.13 PANS for Schizophrenia – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	PANS for Schizophrenia
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
P1	num	Positive Subscale 1 Code		Collected at CRF.
P1_C	char	Positive Subscale 1		Collected at CRF.
P2	num	Positive Subscale 2 Code		Collected at CRF.
P2_C	char	Positive Subscale 2		Collected at CRF.
P3	num	Positive Subscale 3 Code		Collected at CRF.
P3_C	char	Positive Subscale 3		Collected at CRF.
P4	num	Positive Subscale 4 Code		Collected at CRF.
P4_C	char	Positive Subscale 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
P5	num	Positive Subscale 5 Code		Collected at CRF.
P5_C	char	Positive Subscale 5		Collected at CRF.
P6	num	Positive Subscale 6 Code		Collected at CRF.
P6_C	char	Positive Subscale 6		Collected at CRF.
P7	num	Positive Subscale 7 Code		Collected at CRF.
P7_C	char	Positive Subscale 7		Collected at CRF.
N1	num	Negative Subscale 1 Code		Collected at CRF.
N1_C	char	Negative Subscale 1		Collected at CRF.
N2	num	Negative Subscale 2 Code		Collected at CRF.
N2_C	char	Negative Subscale 2		Collected at CRF.
N3	num	Negative Subscale 3 Code		Collected at CRF.
N3_C	char	Negative Subscale 3		Collected at CRF.
N4	num	Negative Subscale 4 Code		Collected at CRF.
N4_C	char	Negative Subscale 4		Collected at CRF.
N5	num	Negative Subscale 5 Code		Collected at CRF.
N5_C	char	Negative Subscale 5		Collected at CRF.
N6	num	Negative Subscale 6 Code		Collected at CRF.
N6_C	char	Negative Subscale 6		Collected at CRF.
N7	num	Negative Subscale 7 Code		Collected at CRF.
N7_C	char	Negative Subscale 7		Collected at CRF.

Variable	Type	Label	Codes	Comments
G1	num	General Psychopathology Subscale 1 Code		Collected at CRF.
G1_C	char	General Psychopathology Subscale 1		Collected at CRF.
G2	num	General Psychopathology Subscale 2 Code		Collected at CRF.
G2_C	char	General Psychopathology Subscale 2		Collected at CRF.
G3	num	General Psychopathology Subscale 3 Code		Collected at CRF.
G3_C	char	General Psychopathology Subscale 3		Collected at CRF.
G4	num	General Psychopathology Subscale 4 Code		Collected at CRF.
G4_C	char	General Psychopathology Subscale 4		Collected at CRF.
G5	num	General Psychopathology Subscale 5 Code		Collected at CRF.
G5_C	char	General Psychopathology Subscale 5		Collected at CRF.
G6	num	General Psychopathology Subscale 6 Code		Collected at CRF.
G6_C	char	General Psychopathology Subscale 6		Collected at CRF.

Variable	Type	Label	Codes	Comments
G7	num	General Psychopathology Subscale 7 Code		Collected at CRF.
G7_C	char	General Psychopathology Subscale 7		Collected at CRF.
G8	num	General Psychopathology Subscale 8 Code		Collected at CRF.
G8_C	char	General Psychopathology Subscale 8		Collected at CRF.
G9	num	General Psychopathology Subscale 9 Code		Collected at CRF.
G9_C	char	General Psychopathology Subscale 9		Collected at CRF.
G10	num	General Psychopathology Subscale 10 Code		Collected at CRF.
G10_C	char	General Psychopathology Subscale 10		Collected at CRF.
G11	num	General Psychopathology Subscale 11 Code		Collected at CRF.
G11_C	char	General Psychopathology Subscale 11		Collected at CRF.
G12	num	General Psychopathology Subscale 12 Code		Collected at CRF.
G12_C	char	General Psychopathology Subscale 12		Collected at CRF.

Variable	Type	Label	Codes	Comments
G13	num	General Psychopathology Subscale 13 Code		Collected at CRF.
G13_C	char	General Psychopathology Subscale 13		Collected at CRF.
G14	num	General Psychopathology Subscale 14 Code		Collected at CRF.
G14_C	char	General Psychopathology Subscale 14		Collected at CRF.
G15	num	General Psychopathology Subscale 15 Code		Collected at CRF.
G15_C	char	General Psychopathology Subscale 15		Collected at CRF.
G16	num	General Psychopathology Subscale 16 Code		Collected at CRF.
G16_C	char	General Psychopathology Subscale 16		Collected at CRF.
SOM1	num	Positive Subscale		Collected at CRF.
SOM2	num	Negative Subscale		Collected at CRF.
SOM3	num	General Psychopathology Subscale		Collected at CRF.
SOM4	num	Total PANSS		Collected at CRF.

1.4.14 Patient Global Impression – PGI

Dataset	PGI
Creating program	pgi.sas
Description	Patient Global Impression
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: INVEST_COMMENT

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
Q1	num	PGI Severity Code		Collected at CRF.
Q1_C	char	PGI Severity		Collected at CRF.
Q2	num	PGI Change Code		Collected at CRF.
Q2_C	char	PGI Change		Collected at CRF.

1.4.15 Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID,VISITID, SYSTEM
Sorted by	DCRFID,VISITID, 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		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
SYSTEM	char	System		Collected at CRF.
PE_NONE	char	Not Dome		Collected at CRF.
PE_NORMAL	char	Normal		Collected at CRF.
PE_ABNORMAL	char	Abnormal		Collected at CRF.

1.4.16 Protocol Deviation – PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviation
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: PROTDEV_SP, PROTDEV_ID0

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
PROTDEV_ID	num	Protocol Deviation ID		Collected at CRF.
PROTDEV_CAT	char	Protocol Deviation Category ID		Collected at CRF.

1.4.17 Relapse – RELAPSE

Dataset	RELAPSE
Creating program	relapse.sas
Description	Relapse
Unique identifier	DCRFID, RECORDID
Sorted by	DCRFID, RECORDID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RELAPSE_D, RELAPSE_SUM

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
PANSS	char	Panss		Collected at CRF.
CGIC	char	Cgi-C		Collected at CRF.
HOSP	char	Psychiatric Hospitalisation		Collected at CRF.
SELF_INJURY	char	Deliberate Self Injury		Collected at CRF.
SUICIDAL	char	Suicidal Ideation		Collected at CRF.

Variable	Type	Label	Codes	Comments
VIOLENT	char	Violent Behavior		Collected at CRF.
RELAPSE_DY	num	Relative Day of Relapse		If RELAPSE_D and CONSENT_D not missing then perform below logic to calculate RELAPSE_DY, If RELAPSE_D less than CONSENT_D then (RELAPSE_D - CONSENT_D).Else if RELAPSE_D is greater than equal to CONSENT_D then (RELAPSE_D- CONSENT_D) +1.

1.4.18 Resource Use Questionnaire – RESOURCEUSE

Dataset	RESOURCEUSE
Creating program	resourceuse.sas
Description	Resource Use Questionnaire
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: PSYCHOLOGISTCONS, SWCONS, THERAPISTCONS, OTHER_SP1, OTHERCONS2, OTHER_SP2, OTHERCONS3, OTHER_SP3, DAILYLIVING, EMPLOYED, OCCUPATSTATUS, OCCUPATREASON, LOSTSCHOOL, LOSTSCHOOLDAYS

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
HOSPITALISATION	char	Hospitalisation		Collected at CRF.
EMERGENCY	char	Emergency Room Visit Without Hospitalisation		Collected at CRF.
DAYCLINIC	char	Required Day Clinic (under 24 hr stay)		Collected at CRF.

Variable	Type	Label	Codes	Comments
NIGHTCLINIC	char	Required Night Clinic (under 24 hr stay)		Collected at CRF.
OUTPATIENT	char	Outpatient Treatment		Collected at CRF.
DAILYLIVING_CHANGE	char	Has Accommodation Status Changed Since Last Month		Collected at CRF.
PRODUCTIVITY_CHANGE	char	Has Occupational Status Changed Since Last Month		Collected at CRF.
PSYCHIATRIST	char	Psychiatrist – Outpatient Treatment		Collected at CRF.
PSYCHIATRISTCONS	char	Psychiatrist – no. of Consultations		Collected at CRF.
PSYCHOLOGIST	char	Psychologist – Outpatient Treatment		Collected at CRF.
PSYNURSE	char	Psychiatric Nurse – Outpatient Treatment		Collected at CRF.
PSYNURSECONS	char	Psychiatric Nurse – no. of Consultations		Collected at CRF.
GP	char	General Practitioner – Outpatient Treatment		Collected at CRF.
GPCONS	char	General Practitioner – no. of Consultations		Collected at CRF.
SW	char	Social Worker – Outpatient Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
THERAPIST	char	Therapist – Outpatient Treatment		Collected at CRF.
OTHER	char	Other – Outpatient Treatment		Collected at CRF.
OTHERCONS1	char	Other – no of Consultations		Collected at CRF.
LOSTWORKING	char	If Employed, lost Working Days		Collected at CRF.
LOSTWORKINGDAYS	char	No Working Days Lost Since Last Month		Collected at CRF.

1.4.19 Resource Daily Living – RESUSE_DLCHANGE

Dataset	RESUSE_DLCHANGE
Creating program	resuse_dlchange.sas
Description	Resource Daily Living
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	Below listed variables will be dropped from dataset due to missing values: RU_START_D, RU_START_M, RU_START_Y

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
RU_STATUS	char	Status		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
RU_START_DY	num	Relative Day of Beginning		If RU_START_D and CONSENT_D not missing then perform below logic to calculate RU_START_DY, If RU_START_D less than CONSENT_D then (RU_START_D - CONSENT_D).Else if RU_START_D is greater than equal to CONSENT_D then (RU_START_D- CONSENT_D) +1.

1.4.20 ResourceEmerg without Hosp Questionnaire – RESUSE_EMERGENCY

Dataset	RESUSE_EMERGENCY
Creating program	resuse_emergency.sas
Description	Resource Emergency Room Visits without Hosp Questionnaire
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	Below listed variables will be dropped from dataset due to missing values: RU_START_D, RU_START_M, RU_START_Y

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.

1.4.21 Resource Hospitalisation Questionnaire – RESUSE_HOSP

Dataset	RESUSE_HOSP
Creating program	resuse_hosp.sas
Description	Resource Hospitalisation Questionnaire
Unique identifier	DCRFID,VISITID, RECORDID
Sorted by	DCRFID,VISITID, RECORDID
Notes	Below listed variables will be dropped from dataset due to missing values: RU_START_D, RU_START_M, RU_START_Y, RU_END_D, RU_END_M, RU_END_Y

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
RU_HOSPTYPE	char	Type of Hospital		Collected at CRF.
RU_WARD	char	Ward		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
RU_ONGO_START	char	ru_ongo_start		Collected at CRF.

Variable	Type	Label	Codes	Comments
RU_ONGO_END	char	ru_ongo_end		Collected at CRF.
RU_START_DY	num	Relative Day of Beginning		If RU_START_D and CONSENT_D not missing then perform below logic to calculate RU_START_DY, If RU_START_D less than CONSENT_D then (RU_START_D - CONSENT_D).Else if RU_START_D is greater than equal to CONSENT_D then (RU_START_D- CONSENT_D) +1.
RU_END_DY	num	Relative Day of End		If RU_END_D and CONSENT_D not missing then perform below logic to calculate RU_END_DY, If RU_END_D less than CONSENT_D then (RU_END_D - CONSENT_D).Else if RU_END_D is greater than equal to CONSENT_D then (RU_END_D- CONSENT_D) +1.

1.4.22 Resource Prod of Subject Questionnaire – RESUSE_PRODCHANGE

Dataset	RESUSE_PRODCHANGE
Creating program	resuse_prodchange.sas
Description	Resource Prod of Subject Questionnaire
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	Below listed variables will be dropped from dataset due to missing values: RU_START_D, RU_START_M, RU_START_Y

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
RECORDID	num	Record Identifier		Collected at CRF.
RU_STATUS	char	Status		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
RU_START_DY	num	Relative Day of Beginning		If RU_START_D and CONSENT_D not missing then perform below logic to calculate RU_START_DY, If RU_START_D less than CONSENT_D then (RU_START_D - CONSENT_D).Else if RU_START_D is greater than equal to CONSENT_D then (RU_START_D- CONSENT_D) +1.

1.4.23 Risperidone Long Acting Injectable – RISINJECT

Dataset	RISINJECT
Creating program	risinject.sas
Description	Risperidone Long Acting Injectable
Unique identifier	DCRFID, RECORDID
Sorted by	DCRFID, RECORDID
Notes	Below listed variables will be dropped from dataset due to missing values: TM_RANGE_MIN, TM_RANGE_MAX, TM_START_D, TM_START_M, TM_START_Y, TM_END_D, TM_END_M, TM_END_Y

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
TM_VALUE	char	Dose(mg)		Collected at CRF.
REASON	char	Reason for dose change		Collected at CRF.
TM_START_DY	num	Relative Dose Start Day		If TM_START_D and CONSENT_D not missing then perform below logic to calculate TM_START_DY, If TM_START_D less than CONSENT_D then (TM_START_D - CONSENT_D).Else if TM_START_D is greater than equal to CONSENT_D then (TM_START_D- CONSENT_D) +1.

1.4.24 Risperidone Orodispersable Tablets – RISTABL

Dataset	RISTABL
Creating program	ristabl.sas
Description	Risperidone Orodispersable Tablets
Unique identifier	DCRFID, RECORDID
Sorted by	DCRFID, RECORDID
Notes	Below listed variables will be dropped from dataset due to missing values: TM_RANGE_MIN, TM_RANGE_MAX, TM_START_D, TM_START_M, TM_START_Y, TM_END_D, TM_END_M, TM_END_Y

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
TM_VALUE	num	Dose (total no tablets/day)		Collected at CRF.
REASON	char	Reason for Dose Change		Collected at CRF.

Variable	Type	Label	Codes	Comments
TM_START_DY	num	Relative Dose Start Day		If TM_START_D and CONSENT_D not missing then perform below logic to calculate TM_START_DY, If TM_START_D less than CONSENT_D then (TM_START_D - CONSENT_D).Else if TM_START_D is greater than equal to CONSENT_D then (TM_START_D- CONSENT_D) +1.
TM_END_DY	num	Relative Dose end day		If TM_END_D and CONSENT_D not missing then perform below logic to calculate TM_END_DY, If TM_END_D less than CONSENT_D then (TM_END_D - CONSENT_D).Else if TM_END_D is greater than equal to CONSENT_D then (TM_END_D- CONSENT_D) +1.

1.4.25 Serous Adverse Events – SAE

Dataset	SAE
Creating program	sae.sas
Description	Serous Adverse Events
Unique identifier	DCRFID,FIELD1_PTCODE,DRUG_KEY, RECORDID
Sorted by	DCRFID,FIELD1_PTCODE,DRUG_KEY, RECORDID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V, AE_START_D, AE_START_M, AE_START_Y, AE_RELOTH_SP, AE_END_D, AE_END_M, AE_END_Y, DEATH_D, SAE_BRM, REFNUMBER, AGENT_V, AGENT_START_D, AGENT_START_M, AGENT_START_Y, AGENT_END_D, AGENT_END_M, AGENT_END_Y, UNIT_SP, ROUTE_SP, AGENT_V1, AGENT_START_D1, AGENT_START_M1, AGENT_START_Y1, AGENT_END_D1, AGENT_END_M1, AGENT_END_Y1, UNIT_SP1, ROUTE_SP1, AGENT_V_OTH, AGENT_WHO_OTH, AGENT_START_D_OTH, AGENT_START_M_OTH, AGENT_START_Y_OTH, AGENT_END_D_OTH, AGENT_END_M_OTH, AGENT_END_Y_OTH, DOSE_OTH, UNIT_OTH, UNIT_SP_OTH, ROUTE_OTH, ROUTE_SP_OTH, AE_ACT_OTH, DRUG_KEY1, DRUG1, GENERIC1

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
RECORDID	num	Record Identifier		Collected at CRF.
AE_MEDDRA	num	MedDra Dictionary Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AE_SEV	char	Severity		Collected at CRF.
AE_REL	char	Relation to Trial Medication		Collected at CRF.
AE_REL1	char	Relation to Trial Medication1		Collected at CRF.
AE_RELOTH	char	Related to other drug in therapy		Collected at CRF.
AE_RELTP	char	Related to Trial procedure		Collected at CRF.
AE_OUT	char	Subject Outcome		Collected at CRF.
AESDTH	char	Death		Collected at CRF.
AESHOSPR	char	Hospitalisation Required		Collected at CRF.
AESHOSPP	char	Prolonged Hospitalisation		Collected at CRF.
AESLIFE	char	Life Threatning		Collected at CRF.
AESDISAB	char	Persisting/significant disability		Collected at CRF.
AESCONG	char	Congenital anomaly/birth defect		Collected at CRF.
AESMIE	char	Other medically important condition		Collected at CRF.
AGENT_NONE	char	Subject did not receive any study agent		Collected at CRF.
AE_COTH	char	ConMed taken for AE		Collected at CRF.
AGENT_WHO	char	WHO Drug Name for Study Agent		Collected at CRF.
DOSE	num	Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
UNIT	char	Unit		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
AE_ACT	char	Action Taken Regarding Trial Medication		Collected at CRF.
AGENT_WHO1	char	WHO Drug Name for Study Agent 1		Collected at CRF.
DOSE1	num	Dose1		Collected at CRF.
UNIT1	char	Unit1		Collected at CRF.
ROUTE1	char	Route1		Collected at CRF.
AE_ACT1	char	Action Taken Regarding Trial Medication1		Collected at CRF.
DRUG_KEY	char	Drug Key		Collected at CRF.
DRUG	char	Drug		Collected at CRF.
GENERIC	char	Generic		Collected at CRF.
DRUG_KEY0	char	Drug Key0		Collected at CRF.
DRUG0	char	Drug0		Collected at CRF.
GENERIC0	char	Generic0		Collected at CRF.
FIELD1_LLTCODE	num	Lower Level Term Code		Collected at CRF.
FIELD2_LLTTEXT	char	Lover Level Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
FIELD1_PTCODE	num	Preferred Term Code		Collected at CRF.
FIELD2_PTTEXT	char	Preferred Term		Collected at CRF.
FIELD1_SOCCODE	num	System Organ Class Code		Collected at CRF.
FIELD2_SOCTEXT	char	System Organ Class		Collected at CRF.
AE_START_DY	num	Relative AE Start Day		If AE_START_D and CONSENT_D not missing then perform below logic to calculate AE_START_DY, If AE_START_D less than CONSENT_D then (AE_START_D - CONSENT_D).Else if AE_START_D is greater than equal to CONSENT_D then (AE_START_D- CONSENT_D) +1.
AE_END_DY	num	Relative AE End Day		If AE_END_D and CONSENT_D not missing then perform below logic to calculate AE_END_DY, If AE_END_D less than CONSENT_D then (AE_END_D - CONSENT_D).Else if AE_END_D is greater than equal to CONSENT_D then (AE_END_D- CONSENT_D) +1.
AGENT_START_DY	num	Relative Day of Start of Study Agent Dosing		If AGENT_START_D and CONSENT_D not missing then perform below logic to calculate AGENT_START_DY, If AGENT_START_D less than CONSENT_D then (AGENT_START_D - CONSENT_D).Else if AGENT_START_D is greater than equal to CONSENT_D then (AGENT_START_D- CONSENT_D) +1.

Variable	Type	Label	Codes	Comments
AGENT_END_DY	num	Relative Day of End of Study Agent Dosing		If AGENT_END_D and CONSENT_D not missing then perform below logic to calculate AGENT_END_DY, If AGENT_END_D less than CONSENT_D then (AGENT_END_D - CONSENT_D).Else if AGENT_END_D is greater than equal to CONSENT_D then (AGENT_END_D- CONSENT_D) +1.
AGENT_START_1DY	num	Relative Day of Start of Study Agent Dosing 1		If AGENT_START_D1 and CONSENT_D not missing then perform below logic to calculate AGENT_START_1DY, If AGENT_START_D1 less than CONSENT_D then (AGENT_START_D1 - CONSENT_D).Else if AGENT_START_D1 is greater than equal to CONSENT_D then (AGENT_START_D1- CONSENT_D) +1.
AGENT_END_1DY	num	Relative Day of End of Study Agent Dosing 1		If AGENT_END_D1 and CONSENT_D not missing then perform below logic to calculate AGENT_END_1DY, If AGENT_END_D1 less than CONSENT_D then (AGENT_END_D1 - CONSENT_D).Else if AGENT_END_D1 is greater than equal to CONSENT_D then (AGENT_END_D1- CONSENT_D) +1.

1.4.26 SF-12 health survey – SF12

Dataset	SF12
Creating program	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: INVEST_COMMENT

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
Q1	num	Health in General Code		Collected at CRF.
Q1_C	char	Health in General		Collected at CRF.
Q2	num	Moderate Activities Code		Collected at CRF.
Q2_C	char	Moderate Activities		Collected at CRF.
Q3	num	Climbing Stairs Code		Collected at CRF.
Q3_C	char	Climbing Stairs		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q4	num	Accomplished Less in Regular Activities Code		Collected at CRF.
Q4_C	char	Accomplished Less in Regular Activities		Collected at CRF.
Q5	num	Limited in Kind of Work Code		Collected at CRF.
Q5_C	char	Limited in Kind of Work		Collected at CRF.
Q6	num	Accomplished Less Than Expected Code		Collected at CRF.
Q6_C	char	Accomplished Less Than Expected		Collected at CRF.
Q7	num	Carefulness in Work Code		Collected at CRF.
Q7_C	char	Carefulness in Work		Collected at CRF.
Q8	num	Pain Interference With Work Code		Collected at CRF.
Q8_C	char	Pain Interference With Work		Collected at CRF.
Q9	num	Feel - Calm and Peaceful Code		Collected at CRF.
Q9_C	char	Feel - Calm and Peaceful		Collected at CRF.
Q10	num	Feel - Energy Code		Collected at CRF.
Q10_C	char	Feel - Energy		Collected at CRF.
Q11	num	Feel - Downhearted Code		Collected at CRF.
Q11_C	char	Feel - Downhearted		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q12	num	Social Activities Code		Collected at CRF.
Q12_C	char	Social Activities		Collected at CRF.

1.4.27 Social & Occ. Functional Ass. Scale – SOFAS

Dataset	SOFAS
Creating program	sofas.sas
Description	Social & Occ. Functional Ass. Scale
Unique identifier	DCRFID, VISITID
Sorted by	DCRFID, VISITID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
SOFAS	char	Social and Occupational Functioning Assessment Scale		Collected at CRF.

1.4.28 Trial Termination – TERM

Dataset	TERM
Creating program	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 or due to missing values: LASTCONTACT_D, OTH_SP, DATE_LAST, NODATA2_START, NODATA2_END, NODATA3_START, NODATA3_END, SIGN_D, DEATH_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
COMPL_ACCORD_PROT	char	Subject completed trial per protocol		Collected at CRF.
AE_NO1	num	AE line no 1		Collected at CRF.
AE_NO2	num	AE line no 2		Collected at CRF.
AE_NO3	num	AE line no 3		Collected at CRF.
AE_NO4	num	AE line no 4		Collected at CRF.
VISIT_LAST	num	visit_last		Collected at CRF.

Variable	Type	Label	Codes	Comments
NODATA1_START	num	nodata1_start		Collected at CRF.
NODATA1_END	num	nodata1_end		Collected at CRF.
INVEST_SIGN	char	Signature of Investigator		Collected at CRF.
REASON1	char	Reason-Death		Collected at CRF.
REASON2	char	Reason-Adverse Event(s)		Collected at CRF.
REASON3	char	Reason-Pregnancy		Collected at CRF.
REASON4	char	Reason-Relapse		Collected at CRF.
REASON5	char	Reason-Subject Withdrew Consent		Collected at CRF.
REASON6	char	Reason-Subject Refuses Injection		Collected at CRF.
REASON7	char	Reason-Subject Feels No More Need to Continue Medical Treatm		Collected at CRF.
REASON8	char	Reason-Insufficient Response		Collected at CRF.
REASON9	char	Reason-Subject Lost to Follow-Up		Collected at CRF.
REASON10	char	Reason-Subject Non-Compliant		Collected at CRF.
REASON11	char	Reason-Ineligble		Collected at CRF.
REASON12	char	Reason-Administrative		Collected at CRF.

Variable	Type	Label	Codes	Comments
REASON13	char	Reason-Other		Collected at CRF.
LASTCONTACT_DY	num	Relative Day of Last Contact		If LASTCONTACT_D and CONSENT_D not missing then perform below logic to calculate LASTCONTACT_DY, If LASTCONTACT_D less than CONSENT_D then (LASTCONTACT_D - CONSENT_D).Else if LASTCONTACT_D is greater than equal to CONSENT_D then (LASTCONTACT_D- CONSENT_D) +1.
LAST_DY	num	Relative Day of Discontinuation		If DATE_LAST and CONSENT_D not missing then perform below logic to calculate LAST_DY, If DATE_LAST less than CONSENT_D then (DATE_LAST - CONSENT_D).Else if DATE_LAST is greater than equal to CONSENT_D then (DATE_LAST- CONSENT_D) +1.
SIGN_DY	num	Relative Day of Signature		If SIGN_D and CONSENT_D not missing then perform below logic to calculate SIGN_DY, If SIGN_D less than CONSENT_D then (SIGN_D - CONSENT_D).Else if SIGN_D is greater than equal to CONSENT_D then (SIGN_D- CONSENT_D) +1.

1.4.29 Vital Signs – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Vital Signs
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: VISIT_D, LAB1, LAB2

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		Element will be grouped to protect PII.
DCRFID	char	crfID Assigned for De-identity		Randomly assigned crfID for De-identity
VISITID	char	Visit Identifier		Collected at CRF.
PULSE	num	Pulse (bpm)		Collected at CRF.
PULSE_ND	char	Pulse Not Done		Collected at CRF.
TEMPERATURE	num	Temperature (C)		Collected at CRF.
TEMPERATURE_ND	char	Temperature Not Done		Collected at CRF.
SYSTOLIC	num	Systolic blood pressure (mmHG)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DIASTOLIC	num	Diastolic blood pressure (mmHG)		Collected at CRF.
BP_ND	char	Blood Pressure Not Done		Collected at CRF.
RESP	num	Respiration rate (bpm)		Collected at CRF.
RESP_ND	char	Resp Not Done		Collected at CRF.
PREGNANCY	char	Pregnancy		Collected at CRF.
CHECK_SF12	char	check_SF12		Collected at CRF.
CHECK_PGI	char	check_PGI		Collected at CRF.
CHECK_TRIALMED	char	check_TrialMed		Collected at CRF.
CHECK_CT	char	check_CT		Collected at CRF.
CHECK_AE	char	check_AE		Collected at CRF.
WEIGHT	num	Weight(kg)		Collected at CRF.
WEIGHT_ND	char	Weight Not Done		Collected at CRF.
HEIGHT	num	Height (cm)		Collected at CRF.
HEIGHT_ND	char	Height Not Done		Collected at CRF.
WAIST	num	Waist Circumference (cm)		Collected at CRF.
WAIST_ND	char	Waist Not Done		Collected at CRF.
HIP	num	Hip Circumference (cm)		Collected at CRF.
HIP_ND	char	Hip Not Done		Collected at CRF.
RETHEIGHT	num	Retheight		Collected at CRF.

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