

Clinical Development

**JNJ-410397<sup>®</sup>**

**RIS-PSY-301**

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

# 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.
- Lab Identifier information 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.
- Partial date's Relative day cannot be calculated.
- Datasets containing zero observations will not be submitted. (eg. RESUSE\_DLCHANGTOT, RESUSE\_NIGHTCLINICTOT)
- Informed Consent Date is used as Reference Date to calculate Relative Day.

### 1.3 Data Files

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

## 1.4 Data Domains

### 1.4.1 Demographic Data – ACRFTOT

<b>Dataset</b>	ACRFTOT
<b>Creating program</b>	acrftot.sas
<b>Description</b>	Demographic Data
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INITIALS, CONSENT_D, BIRTH_D, RACE_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
DCOUNTRY	char	De-identify Country		Element will be grouped to protect PII.
DCENTRE_NO	char	centre_no Assigned for De-identity		Randomly assigned centre_no for De-identity
GENDER	char	Gender		Collected at CRF.
RACE	char	Race		Collected at CRF.
CT_NONE	char	ct_None		Collected at CRF.

Variable	Type	Label	Codes	Comments
AE_NONE	char	ae_None		Collected at CRF.
PREVMED_NONE	char	prevMed_None		Collected at CRF.
AGE	char	Age in Years		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:  <math>AGE = \text{floor}((CONSENT\_D - DOB)/365.25)</math></p> <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>



## 1.4.2 Adverse Events – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	AE_SEV,DCRFID,FIELD2_PTTEXT,FIELD2_SOCTEXT, AE_START_DY
<b>Sorted by</b>	AE_SEV,DCRFID,FIELD2_PTTEXT,FIELD2_SOCTEXT, AE_START_DY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V, AE_START_D, AE_START_M, AE_START_Y, AE_END_D, AE_END_M, AE_END_Y, AE_DSS

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_CO TH	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_OUTCOME	char	Subject Outcome		Collected at CRF.
AE_SER	char	Reported as Serious		Collected at CRF.
FIELD1_LLTCODE	num	Lower Level Term Code		Collected at CRF.
FIELD2_LLTEXT	char	Lower 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 CDS for Schizophrenia – CDSSTOT

<b>Dataset</b>	CDSSTOT
<b>Creating program</b>	cdsstot.sas
<b>Description</b>	CDS for Schizophrenia
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	

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	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 of Reference Code		Collected at CRF.
Q4_c	char	Guilty Feelings of Reference		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

## 1.4.4 Clinical Global Impression – CGITOT

<b>Dataset</b>	CGITOT
<b>Creating program</b>	cgitot.sas
<b>Description</b>	Clinical Global Impression
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	

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.

## 1.4.5 Concomitant Therapy – CT

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

Variable	Type	Label	Codes	Comments
CT_WHONAME	char	WHO Dictionary Name		Collected at CRF.
GENERIC	char	GENERIC		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
RECORDID	num	Record Identifier		Collected at CRF.
CT_WHONO	char	WHO Dictionary Number		Collected at CRF.
CT_VALUE	num	Dose		Collected at CRF.
CT_FREQ	char	Frequency		Collected at CRF.
CT_UNIT	char	Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
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_INT	num	ct_int		Collected at CRF.
CT_PRN	num	ct_prn		Collected at CRF.
AE_NO3	num	AE line no 3		Collected at CRF.
AE_NO4	num	AE line no 4		Collected at CRF.
CT_MAX_VALUE	num	Maximum Value		Collected at CRF.
AE_NO5	num	AE line no 5		Collected at CRF.
DRUG	char	DRUG		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.



## 1.4.6 Drug Attitude Inventory – DAI

<b>Dataset</b>	DAI
<b>Creating program</b>	dai.sas
<b>Description</b>	Drug Attitude Inventory
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: COMMENTS

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.
NO_ANSWER1	char	Patient Too Psychotic to Answer Code		Collected at CRF.
NO_ANSWER2	char	Patient Did Not Take Any Med Code		Collected at CRF.
Q1	num	Good Things About Med Outweigh Bad Code		Collected at CRF.
Q1_c	char	Good Things About Med Outweigh Bad		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q2	num	I Feel Weird Like a Zombie On Medication Code		Collected at CRF.
Q2_c	char	I Feel Weird Like a Zombie On Medication		Collected at CRF.
Q3	num	I Take Medication of My Own Free Choice Code		Collected at CRF.
Q3_c	char	I Take Medication of My Own Free Choice		Collected at CRF.
Q4	num	Medications Make Me Feel More Relaxed Code		Collected at CRF.
Q4_c	char	Medications Make Me Feel More Relaxed		Collected at CRF.
Q5	num	Meds Make Me Feel Tired And Sluggish Code		Collected at CRF.
Q5_c	char	Meds Make Me Feel Tired And Sluggish		Collected at CRF.
Q6	num	I Take Medication Only When I Feel Unwell Code		Collected at CRF.
Q6_c	char	I Take Medication Only When I Feel Unwell		Collected at CRF.
Q7	num	I Feel More Normal On Medication Code		Collected at CRF.
Q7_c	char	I Feel More Normal On Medication		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q8	num	It is Unnatural To Be Controlled By Meds Code		Collected at CRF.
Q8_c	char	It is Unnatural To Be Controlled By Meds		Collected at CRF.
Q9	num	When Taking Med My Thoughts Are Clearer Code		Collected at CRF.
Q9_c	char	When Taking Med My Thoughts Are Clearer		Collected at CRF.
Q10	num	By staying on Med I Avoid Feeling Unwell Code		Collected at CRF.
Q10_c	char	By staying on Med I Avoid Feeling Unwell		Collected at CRF.
ASSISTANCE	char	Was Assistance Provided To Subject Code		Collected at CRF.

## 1.4.7 Electrocardiogram – ECGTOT

<b>Dataset</b>	ECGTOT
<b>Creating program</b>	ecgtot.sas
<b>Description</b>	Electrocardiogram
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	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	char	Visit Identifier		Collected at CRF.
RR	num	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.
TACHY	char	Sinus Tachycardia (>=100 bpm)		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 Performed		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.

#### 1.4.8 Extrapyramidal Symptom Rating Scale – ESRSTOT

<b>Dataset</b>	ESRSTOT
<b>Creating program</b>	esrstot.sas
<b>Description</b>	Extrapyramidal Symptom Rating Scale
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	

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

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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.



Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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 Extremities		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.

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

#### 1.4.9 Inclusion Exclusion Criteria – INEX

<b>Dataset</b>	INEX
<b>Creating program</b>	inex.sas
<b>Description</b>	Inclusion Exclusion Criteria
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	

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
INCL1	char	Inclusion Criteria 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCL2	char	Inclusion Criteria 2		Collected at CRF.
INCL3	char	Inclusion Criteria 3		Collected at CRF.
INCL4	char	Inclusion Criteria 4		Collected at CRF.
INCL5	char	Inclusion Criteria 5		Collected at CRF.
INCL6	char	Inclusion Criteria 6		Collected at CRF.
INCL7	char	Inclusion Criteria 7		Collected at CRF.
EXCL1	char	Exclusion Criteria 1		Collected at CRF.
EXCL2	char	Exclusion Criteria 2		Collected at CRF.
EXCL3	char	Exclusion Criteria 3		Collected at CRF.
EXCL4	char	Exclusion Criteria 4		Collected at CRF.
EXCL5	char	Exclusion Criteria 5		Collected at CRF.
EXCL6	char	Exclusion Criteria 6		Collected at CRF.
EXCL7	char	Exclusion Criteria 7		Collected at CRF.
EXCL8	char	Exclusion Criteria 8		Collected at CRF.
EXCL9	char	Exclusion Criteria 9		Collected at CRF.
EXCL10	char	Exclusion Criteria 10		Collected at CRF.
EXCL11	char	Exclusion Criteria 11		Collected at CRF.
EXCL12	char	Exclusion Criteria 12		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCL13	char	Exclusion Criteria 13		Collected at CRF.
EXCL14	char	Exclusion Criteria 14		Collected at CRF.

#### 1.4.10 Medical Surgical History Conmed Diseases – MEDHIS

<b>Dataset</b>	MEDHIS
<b>Creating program</b>	medhis.sas
<b>Description</b>	Medical,Surgical History Conmed diseases
<b>Unique identifier</b>	DCRFID, SYSTEM
<b>Sorted by</b>	DCRFID, SYSTEM
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HIS_SP, CUR_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
RECORDID	num	Record Identifier		Collected at CRF.
SYSTEM	char	System		Collected at CRF.
MH_NONE	char	None		Collected at CRF.



Variable	Type	Label	Codes	Comments
MH_HIS	char	History and Not Active		Collected at CRF.
MH_CUR	char	Currently Active		Collected at CRF.

#### 1.4.11 PANS for Schizophrenia – PANSSTOT

<b>Dataset</b>	PANSSTOT
<b>Creating program</b>	pansstot.sas
<b>Description</b>	PANS for Schizophrenia
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	

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.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
G6	num	General Psychopathology Subscale 6 Code		Collected at CRF.
G6_c	char	General Psychopathology Subscale 6		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
G12	num	General Psychopathology Subscale 12 Code		Collected at CRF.
G12_c	char	General Psychopathology Subscale 12		Collected at CRF.
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.

## 1.4.12 Patient Global Impression – PGI

<b>Dataset</b>	PGI
<b>Creating program</b>	pgi.sas
<b>Description</b>	Patient Global Impression
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	

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.

## 1.4.13 Physical Examination – PHYSEXAMTOT

<b>Dataset</b>	PHYSEXAMTOT
<b>Creating program</b>	physexamtot.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	DCRFID,SYSTEM, VISITID
<b>Sorted by</b>	DCRFID,SYSTEM, VISITID
<b>Notes</b>	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
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.
VISITID	char	Visit Identifier		Collected at CRF.

## 1.4.14 Previous Antipsychotic Medication – PREVIOUSMED

<b>Dataset</b>	PREVIOUSMED
<b>Creating program</b>	previousmed.sas
<b>Description</b>	Previous Antipsychotic medication
<b>Unique identifier</b>	CT_ROUTE,CT_START_DY,DCRFID, RECORDID
<b>Sorted by</b>	CT_ROUTE,CT_START_DY,DCRFID, RECORDID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CT_V ,CT_UNIT_SP, CT_ROUTE_SP, CT_START_D, CT_START_M, CT_START_Y, CT_END_D, CT_END_M, CT_END_Y

Variable	Type	Label	Codes	Comments
CT_WHONAME	char	WHO Dictionary Name		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
RECORDID	num	Record Identifier		Collected at CRF.
CT_WHONO	char	WHO Dictionary Number		Collected at CRF.
CT_VALUE	num	Dose		Collected at CRF.
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.



Variable	Type	Label	Codes	Comments
CT_FREQ	char	Frequency		Collected at CRF.
CT_ROUTE	char	Route of administration		Collected at CRF.
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.

## 1.4.15 Psychiatric History – PSYHIS

<b>Dataset</b>	PSYHIS
<b>Creating program</b>	psyhis.sas
<b>Description</b>	Psychiatric History
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SCHIZOPHRENIFORM_D, SCHIZOPHRENIFORM_M, SCHIZOPHRENIFORM_Y, SCHIZOPHRENIA_D, SCHIZOPHRENIA_M, SCHIZOPHRENIA_Y, SCHIZOAFFECTIVE_D, SCHIZOAFFECTIVE_M, SCHIZOAFFECTIVE_Y, OTHER_SP, PRODRO_D, PRODRO_M, PRODRO_Y, SYMPTOMS_D, SYMPTOMS_M, SYMPTOMS_Y, HOSP_D, MEMBER1, MEMBER2, MEMBER3, DIAG3, EDUCATION, EDUCATION_COMP_Y, EDUCATION_COR

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
SCHIZOPHRENIFORM	char	Schizophreniform Disorder		Collected at CRF.
SCHIZOPHRENIA	char	Schizophrenia		Collected at CRF.
TYPE	char	Schizophrenia Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
SCHIZOAFFECTIVE	char	Schizoaffective Disorder		Collected at CRF.
OTHER	char	Other		Collected at CRF.
PRODRO_NK	char	Date of onset of pronomes to Psychosis Not known		Collected at CRF.
SYMPTOMS_NK	char	Date of onset of First Psychotic symptoms Not known		Collected at CRF.
EPISODES	num	Number of Psychotic episodes		Collected at CRF.
NOT_HOSP	v	Not Hospitalized		Collected at CRF.
NOT_TREATED	num	Not Treated With AntiPsychotics		Collected at CRF.
FAMHIS	num	Family history		Collected at CRF.
DIAG1	char	Diagnosis of First Family member		Collected at CRF.
DIAG2	char	Diagnosis of Second Family member		Collected at CRF.
NOT_FAM_SIMILAR	char	No Family Members With Similar Disease		Collected at CRF.
DEGREE	char	Family Relative Degree		Collected at CRF.
EDUCATION_COMP	char	Is Patient Still Completing Education		Collected at CRF.
REGULAR_CLASSES	char	Is Patient Attending Regular Classes		Collected at CRF.

Variable	Type	Label	Codes	Comments
SCHIZOPHRENIFORM_DY	num	Relative Day of Diagnosis of Schizophreniform Disorder		If SCHIZOPHRENIFORM_D and CONSENT_D not missing then perform below logic to calculate SCHIZOPHRENIFORM_DY, If SCHIZOPHRENIFORM_D less than CONSENT_D then (SCHIZOPHRENIFORM_D - CONSENT_D).Else if SCHIZOPHRENIFORM_D is greater than equal to CONSENT_D then (SCHIZOPHRENIFORM_D- CONSENT_D) +1.
SCHIZOPHRENIA_DY	num	Relative Day of Diagnosis of Schizophrenia		If SCHIZOPHRENIA_D and CONSENT_D not missing then perform below logic to calculate SCHIZOPHRENIA_DY, If SCHIZOPHRENIA_D less than CONSENT_D then (SCHIZOPHRENIA_D - CONSENT_D).Else if SCHIZOPHRENIA_D is greater than equal to CONSENT_D then (SCHIZOPHRENIA_D- CONSENT_D) +1.
PRODRO_DY	num	Relative Day of Onset of prodromes to Psychosis		If PRODRO_D and CONSENT_D not missing then perform below logic to calculate PRODRO_DY, If PRODRO_D less than CONSENT_D then (PRODRO_D - CONSENT_D).Else if PRODRO_D is greater than equal to CONSENT_D then (PRODRO_D- CONSENT_D) +1.

Variable	Type	Label	Codes	Comments
SYMPTOMS_DY	num	Relative Day of Onset of 1st Psychotic Symptoms		If SYMPTOMS_D and CONSENT_D not missing then perform below logic to calculate SYMPTOMS_DY, If SYMPTOMS_D less than CONSENT_D then (SYMPTOMS_D - CONSENT_D).Else if SYMPTOMS_D is greater than equal to CONSENT_D then (SYMPTOMS_D- CONSENT_D) +1.
HOSP_DY	num	Relative Day of Hospitalization		If HOSP_D and CONSENT_D not missing then perform below logic to calculate HOSP_DY, If HOSP_D less than CONSENT_D then (HOSP_D - CONSENT_D).Else if HOSP_D is greater than equal to CONSENT_D then (HOSP_D- CONSENT_D) +1.

## 1.4.16 Relapse – RELAPSETOT

<b>Dataset</b>	RELAPSETOT
<b>Creating program</b>	relapsetot.sas
<b>Description</b>	Relapse
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	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
VISITID	char	Visit Identifier		Collected at CRF.
RELAPSE	char	Relapse		Collected at CRF.
HOSP	char	Psychiatric Hospitalisation		Collected at CRF.
JUDGEMENT	char	Judgement by Treating Psychiatrist		Collected at CRF.
SELF_INJURY	char	Deliberate Self Injury		Collected at CRF.
SUICIDAL	char	Suicidal Ideation		Collected at CRF.
VIOLENT	char	Violent Behaviour		Collected at CRF.

Variable	Type	Label	Codes	Comments
DETORINATION	char	Significant Clinical Deterioration		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.

## 1.4.17 Resource Use Questionnaire – RESOURCEUSETOT

<b>Dataset</b>	RESOURCEUSETOT
<b>Creating program</b>	resourceusetot.sas
<b>Description</b>	Resource Use Questionnaire
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SWCONS, THERAPISTCONS, OTHER_SP1, OTHERCONS2, OTHER_SP2, OTHERCONS3, OTHER_SP3

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.
EMERGENGY	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	num	Psychiatrist – no. of Consultations		Collected at CRF.
PSYCHOLOGIST	char	Psychologist – Outpatient Treatment		Collected at CRF.
PSYCHOLOGISTCONS	num	Psychologist – no. of Consultations		Collected at CRF.
PSYNURSE	char	Psychiatric Nurse – Outpatient Treatment		Collected at CRF.
PSYNURSECONS	num	Psychiatric Nurse – no. of Consultations		Collected at CRF.
GP	char	General Practitioner – Outpatient Treatment		Collected at CRF.
GPCONS	num	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	num	Other – no of Consultations		Collected at CRF.
DAILYLIVING	char	DailyLiving accommodation Code		Collected at CRF.
EMPLOYED	char	employed		Collected at CRF.
OCCUPATSTATUS	char	Occupational Status Code		Collected at CRF.
OCCUPATREASON	char	Occupational Code Reason for Change		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.
LOSTSCHOOL	char	If in School, Lost School Days?		Collected at CRF.
LOSTSCHOOLDAYS	char	No of Lost School Days		Collected at CRF.

## 1.4.18 Resource Use Day clinic Questionnaire – RESUSE\_DAYCLINICTOT

<b>Dataset</b>	RESUSE_DAYCLINICTOT
<b>Creating program</b>	resuse_dayclinctot.sas
<b>Description</b>	Resource Use Day clinic Questionnaire
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: 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_FREQ	num	Frequency Per Week		Collected at CRF.
RU_REASON	char	Reason		Collected at CRF.
RU_ONGO_START	char	ru_ongo_start		Collected at CRF.
RU_ONGO_END	char	ru_ongo_end		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

### 1.4.19 Resource Emergency Room Visits without Hosp Questionnaire – RESUSE\_EMERGENCYTOT

<b>Dataset</b>	RESUSE_EMERGENCYTOT
<b>Creating program</b>	resuse_emergencytot.sas
<b>Description</b>	Resource Emergency Room Visits without Hosp Questionnaire
<b>Unique identifier</b>	DCRFID,VISITID, RU_START_DY
<b>Sorted by</b>	DCRFID,VISITID, RU_START_DY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: 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.
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 Resource Hospitalisation Questionnaire – RESUSE\_HOSPTOT

<b>Dataset</b>	RESUSE_HOSPTOT
<b>Creating program</b>	resuse_hosptot.sas
<b>Description</b>	Resource Hospitalisation Questionnaire
<b>Unique identifier</b>	DCRFID,VISITID, RECORDID
<b>Sorted by</b>	DCRFID,VISITID, RECORDID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.
RU_ONGO_END	char	ru_ongo_end		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

## 1.4.21 Resource Prod of Subject Questionnaire – RESUSE\_PRODCHANGETOT

<b>Dataset</b>	RESUSE_PRODCHANGETOT
<b>Creating program</b>	resuse_prodchangetot.sas
<b>Description</b>	Resource Prod of Subject Questionnaire
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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.



## 1.4.22 Risperidone Long Acting Injectable – RISINJECT

<b>Dataset</b>	RISINJECT
<b>Creating program</b>	risinject.sas
<b>Description</b>	Risperidone Long Acting Injectable
<b>Unique identifier</b>	DCRFID, TM_START_DY
<b>Sorted by</b>	DCRFID, TM_START_DY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: 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.

## 1.4.23 Risperidone Orodispersable Tablets – RISTABL

<b>Dataset</b>	RISTABL
<b>Creating program</b>	ristabl.sas
<b>Description</b>	Risperidone Orodispersable Tablets
<b>Unique identifier</b>	DCRFID, TM_START_DY
<b>Sorted by</b>	DCRFID, TM_START_DY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: 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.

## 1.4.24 SF-12 health survey – SF12

<b>Dataset</b>	SF12
<b>Creating program</b>	sf12.sas
<b>Description</b>	SF-12 health survey
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	

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.
Q4	num	Accomplished Less in Regular Activities Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
Q12	num	Social Activities Code		Collected at CRF.
Q12_c	char	Social Activities		Collected at CRF.
NO_ANSWER	char	no_answer		Collected at CRF.

## 1.4.25 Trial Termination – TERM

<b>Dataset</b>	TERM
<b>Creating program</b>	term.sas
<b>Description</b>	Trial Termination
<b>Unique identifier</b>	DCRFID
<b>Sorted by</b>	DCRFID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LASTCONTACT_D, AE_NO1, AE_NO2, AE_NO3, REASON_INSUFRES_SP, REASON_LOSTFUP_SP, REASON_NONCOMPL_SP, REASON_INELIGIBLE_SP, REASON_ADM_SP, REASON_OTHER_SP, DATE_LAST, NODATA2_START, NODATA2_END, NODATA3_START, NODATA3_END, INVEST_NAME, SIGN_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.
REASON	char	Reason For Discontinuation		Collected at CRF.
VISIT_LAST	num	visit_last		Collected at CRF.
NODATA1_START	num	nodata1_start		Collected at CRF.
NODATA1_END	num	nodata1_end		Collected at CRF.

Variable	Type	Label	Codes	Comments
INVEST_SIGN	char	Signature of Investigator		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_DATE	num	Relative Day of Discontinuation		If DATE_LAST and CONSENT_D not missing then perform below logic to calculate LAST_DATE, 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.

## 1.4.26 Vital Signs – VISITTOT

<b>Dataset</b>	VISITTOT
<b>Creating program</b>	visittot.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DCRFID, VISITID
<b>Sorted by</b>	DCRFID, VISITID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial		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.
TEMPERATURE	num	Temperature (C)		Collected at CRF.
TEMPERATURE_ND	char	Temperature Not Done		Collected at CRF.
PULSE	num	Pulse (bpm)		Collected at CRF.
PULSE_ND	char	Pulse Not Done		Collected at CRF.
SYSTOLIC	num	Systolic Blood Pressure (mmHG)		Collected at CRF.
DIASTOLIC	num	Diastolic Blood Pressure (mmHG)		Collected at CRF.



Variable	Type	Label	Codes	Comments
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_PGI	char	check_PGI		Collected at CRF.
CHECK_ANTIPSYMED	char	check_antiPsymed		Collected at CRF.
CHECK_CT	char	check_CT		Collected at CRF.
CHECK_DAI	char	check_DAI		Collected at CRF.
CHECK_SF12	char	check_SF12		Collected at CRF.
CHECK_TRIALMED	char	check_TrialMed		Collected at CRF.
CHECK_AE	char	check_AE		Collected at CRF.
CHECK_TOLE	char	check_tole		Collected at CRF.
SOFAS	num	Social and Occupational Functioning Assessment Scale		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.

Variable	Type	Label	Codes	Comments
HIP	num	Hip Circumference (cm)		Collected at CRF.
HIP_ND	char	Hip Not Done		Collected at CRF.
VISIT_DY	num	Relative Day of Visit		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.