

Clinical Development

Risperidone[®]

RIS-INT-3

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.
- Vial, Bottle, lot, kit 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.
- Regimen Start Date will be used as Reference Date to derive relative days.

1.3. Data Files

The RIS-INT-3 CSR Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demography – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demography
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: BDATE,ENTDATE,INV,SCRNNO,PAT,INITIALS,WCOMM,EVALUBLE

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
AGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DURYR	num	PSYCHOTIC SYM(YRS)		Collected at CRF.
HOSPMON	num	DURATION (MONTHS)		Collected at CRF.
HOSPWK	num	DURATION (WEEKS)		Collected at CRF.
HOSPYR	num	DURATION (YEARS)		Collected at CRF.

Variable	Type	Label	Codes	Comments
WDAYS	num	WASHOUT DAYS		Collected at CRF.
TG	char	TREATMENT GROUP		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
HOSPDUR	num	HOSPITALIZATN (YRS)		Collected at CRF.
PREVHOSP	num	PREVIOUS HOSPIALIZATION		Collected at CRF.
DIAG	char	DIAGNOSIS		Collected at CRF.
FAMILLYN	char	FAMILY HX ILLNESS?		Collected at CRF.
MEMBER1	char	FAMILY MEMBER #1		Collected at CRF.
ILLNESS1	char	ILLNESS DESCR #1		Collected at CRF.
MEMBER2	char	FAMILY MEMBER #2		Collected at CRF.
ILLNESS2	char	ILLNESS DESCR #2		Collected at CRF.
MEMBER3	char	FAMILY MEMBER #3		Collected at CRF.
ILLNESS3	char	ILLNESS DESCR #3		Collected at CRF.
MEMBER4	char	FAMILY MEMBER #4		Collected at CRF.
ILLNESS4	char	ILLNESS DESCR #4		Collected at CRF.
HT	num	HEIGHT (CM)		Collected at CRF.
CRITERIA	char	CRITERIA PASSED ?		Collected at CRF.
WASHOUT	char	WASHOUT PERIOD ?		Collected at CRF.
RBATCH	char	RBATCH		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTDY	num	RELATIVE STUDY ENTRY DAY		If ENTDATE and XAMFROM not missing then perform below logic to calculate ENTDY, If ENTDATE less than XAMFROM then (ENTDATE - XAMFROM).Else if ENTDATE is greater than equal to XAMFROM then (ENTDATE- XAMFROM) +1.

1.4.2. Analysis Dataset for Demography – XDEMOG

Dataset	XDEMOG
Creating program	xdemog.sas
Description	Analysis Dataset for Demography
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: MEDNO, BIRTH_D, WEIGHT, WEIGHT_U, HEIGHT, HEIGHT_U, INITIALS, XDIAGDAT,INVEST

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
SEX	char	SEX		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	RACE		Collected at CRF.
XAGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XWEIGHT	num	WEIGHT, KG		Collected at CRF.
XHEIGHT	num	HEIGHT, CM		Collected at CRF.
XDIAGN	char	DIAGNOSIS		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
DSITEID	char	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned SITE ID for de-identity.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
AGEFHOSP	char	AGE FIRST HOSPITALIZATION (YEARS)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DURASYMP	num	DURATION OF SYMPTONS (YEARS)		Collected at CRF.
BMI	num	BODY MASS INDEX		Collected at CRF.

1.4.3. Physical Examination – INT3EXAM

Dataset	INT3EXAM
Creating program	int3exam.sas
Description	Physical Examination
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISIT_D, VISIT_T, EXAM_V, EXAM, SORT_NO, COUNTRY, INVEST, PERPROT, SEX, RACE, AGE

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.

Variable	Type	Label	Codes	Comments
VALUE	num	VALUE		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
DBASE	char	VALUE DESCRIPTION AT BASELINE		Collected at CRF.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and XAMFROM not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than XAMFROM then (VISIT_D - XAMFROM).Else if VISIT_D is greater than equal to XAMFROM then (VISIT_D- XAMFROM) +1.

1.4.4. Study Drug Administration – XADMMED

Dataset	XADMMED
Creating program	xadmmmed.sas
Description	Study Drug Administration
Unique identifier	DCRFID,PHASE,SEGMENT, AMFROMDY
Sorted by	DCRFID,PHASE,SEGMENT, AMFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AMFROM_D,AMFROM_T,AMTO_D,AMTO_T,COUNTRY,INVEST,PERPROT,SEX, RACE,XAMFROM,XAMTO,XAMREAS

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
XDUR	num	DURATION		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
XSTR_U	char	STRENGTH UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
XTDD	char	TOTAL DAILY DOSE		Collected at CRF.
AMFROMDY	num	RELATIVE ADMIN. FROM DAY		If AMFROM_D and XAMFROM not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than XAMFROM then (AMFROM_D - XAMFROM).Else if AMFROM_D is greater than equal to XAMFROM then (AMFROM_D- XAMFROM) +1.
AMTO_DY	num	RELATIVE ADMIN. TO DAY		If AMTO_D and XAMFROM not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than XAMFROM then (AMTO_D - XAMFROM).Else if AMTO_D is greater than equal to XAMFROM then (AMTO_D- XAMFROM) +1.

1.4.5. Adverse Events – XAE

Dataset	XAE
Creating program	xae.sas
Description	Adverse Events
Unique identifier	DCRFID, AEPREF, PPHASE, ZAEOUT, AESEQNO
Sorted by	DCRFID, AEPREF, PPHASE, ZAEOUT, AESEQNO
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values:</p> <p>AE_V, COUNTRY, INVEST, PERPROT, SEX, RACE, PHASE, AEFROM_D, AEFROM_C, AETO_D, AETO_C, AEFREQ, ZAEFREQ, AETYPE, AESER, ZAESER, AECONRX, ZAECONRX, SAEREFNO, AEWHONUM, XTE, XDYSONDS, XREACH, XINREACH, XSTR_U, SEGMENT</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID assigned for de-identity
AESEQNO	num	AE SEQ.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
AEINCL	char	AE INCLUDED TERM		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESV	num	AE SEVERITY		Collected at CRF.

Variable	Type	Label	Codes	Comments
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME		Collected at CRF.
AEPREF	char	AE PREFERRED TERM		Collected at CRF.
AESOC	char	ADVERSE EVENT SYSTEM ORGAN CLASS		Collected at CRF.
PPHASE	char	TRIAL PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XONSETDS	char	ONSET DOSE		Collected at CRF.
XONSETDY	num	DAYS TO ONSET		Collected at CRF.
XAEDUR	num	DURATION IN PHASE		Collected at CRF.
XTAEDUR	char	TOTAL DURATION		Collected at CRF.
AEFROMDY	num	RELATIVE AE FROM DAY		If AEFROM_D and XAMFROM not missing then perform below logic to calculate AEFROMDY, If AEFROM_D less than XAMFROM then (AEFROM_D - XAMFROM).Else if AEFROM_D is greater than equal to XAMFROM then (AEFROM_D- XAMFROM) +1.
AETO_DY	num	RELATIVE AE TO DAY		If AETO_D and XAMFROM not missing then perform below logic to calculate AETO_DY, If AETO_D less than XAMFROM then (AETO_D - XAMFROM).Else if AETO_D is greater than equal to XAMFROM then (AETO_D- XAMFROM) +1.

1.4.6. Clinical Global Impression – XCGI

Dataset	XCGI
Creating program	xcgi.sas
Description	Clinical Global Impression
Unique identifier	DCRFID,XTIME,VISIT, DVALUE
Sorted by	DCRFID,XTIME,VISIT, DVALUE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISIT_D, COUNTRY, INVEST, PERPROT, SEX, RACE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
XTIME	char	TIME INTERVAL		Collected at CRF.
VISIT	num	VISIT NO		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM TREATMENT BASELINE		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
DBASE	char	VALUE DESC. AT BASELINE		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
ZPARAM	char	PARAMETER CODE		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and XAMFROM not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than XAMFROM then (VISIT_D - XAMFROM).Else if VISIT_D is greater than equal to XAMFROM then (VISIT_D- XAMFROM) +1.

1.4.7. Concomitant Medication – XCOTHER

Dataset	XCOTHER
Creating program	xcother.sas
Description	Concomitant Medication
Unique identifier	DCRFID,CONRX,XGENERIC,RXWHONUM,CTFROMDY,CTTO_DY, CTPRIOR, CTONGO
Sorted by	DCRFID,CONRX,XGENERIC,RXWHONUM,CTFROMDY,CTTO_DY, CTPRIOR, CTONGO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: CTTYPE, CTSEQNO, CONRX_V, COUNTRY, INVEST, PERPROT, SEX, RACE, XATC, ATCCODE, CTFROM_D, CTTO_D, CTSCHED, CTIND_V, CTIND

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
CONRX	char	WHO DRUG TERM		Collected at CRF.
XGENERIC	char	WHO GENERIC TERM		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
CTFROMDY	num	RELATIVE CO_RX START DAY		If CTFROM_D and XAMFROM not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than XAMFROM then (CTFROM_D - XAMFROM).Else if CTFROM_D is greater than equal to XAMFROM then (CTFROM_D- XAMFROM) +1.
CTTO_DY	num	RELATIVE CO_RX END DAY		If CTTO_D and XAMFROM not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than XAMFROM then (CTTO_D - XAMFROM).Else if CTTO_D is greater than equal to XAMFROM then (CTTO_D- XAMFROM) +1.

1.4.8. Medical History – XDISEASE

Dataset	XDISEASE
Creating program	xdisease.sas
Description	Medical History
Unique identifier	DCRFID, DSSEQNO
Sorted by	DCRFID, DSSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: DISEASE, DISEAS_V, DSCLIN, NBR_DIS, COUNTRY, INVEST, PERPROT, SEX, RACE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

1.4.9. Electrocardiogram – XECG

Dataset	XECG
Creating program	xecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID,PARAM, XTIME
Sorted by	DCRFID,PARAM, XTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: COUNTRY, INVEST, PERPROT, SEX, RACE, DVALUE, DBASE, ZCHANGE, ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
VISIT	num	VISIT NO		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
PARAM	char	PARAMETER		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM TREATMENT BASELINE		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
ECG_DY	num	RELATIVE VISIT DAY		If ECG_D and XAMFROM not missing then perform below logic to calculate ECG_DY, If ECG_D less than XAMFROM then (ECG_D - XAMFROM).Else if ECG_D is greater than equal to XAMFROM then (ECG_D- XAMFROM) +1.

1.4.10. Extrapyramidal Symptom Rating Scale – XESRS

Dataset	XESRS
Creating program	xesrs.sas
Description	Extrapyramidal Symptom Rating Scale
Unique identifier	DCRFID,VISIT,XTIME,XTREAT,VALUE, PARAM
Sorted by	DCRFID,VISIT,XTIME,XTREAT,VALUE, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISIT_D, COUNTRY, INVEST, PERPROT, SEX, RACE, ZESGROUP, ESGROUP

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
VISIT	num	VISIT NO		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
RELDAY	num	DAYS IN PHASE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM TREATMENT BASELINE		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
ZPARAM	char	CODE ESRS-PARAMETER		Collected at CRF.
PARAM	char	ESRS-PARAMETER		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and XAMFROM not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than XAMFROM then (VISIT_D - XAMFROM).Else if VISIT_D is greater than equal to XAMFROM then (VISIT_D- XAMFROM) +1.

1.4.11. Laboratory Results – XLABRES

Dataset	XLABRES
Creating program	xlabres.sas
Description	Laboratory Results
Unique identifier	DCRFID,SAMPLEDY,ZLABTEST,LABVAL, XTIME
Sorted by	DCRFID,SAMPLEDY,ZLABTEST,LABVAL, XTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SAMPLE_D, SAMPLE_T, ZLABID, COUNTRY, INVEST, PERPROT, SEX, RACE, LABID, SIVALUE, SIUNIT, CFACTOR, ABNCODE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
ZLABTEST	char	LAB.TEST		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
LABTEST	char	LAB.TEST		Collected at CRF.
LABTSTNO	num	LAB.TEST NUMBER		Collected at CRF.
LABCLASS	char	LABCLASS		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENZYME	char	ENZYME		Collected at CRF.
LABVAL	num	LAB.TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB.TEST VALUE (VERB)		Collected at CRF.
LABTST_U	char	TEST UNIT		Collected at CRF.
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
LOWPATHO	num	LOWER PATHOLOGICAL LIMIT		Collected at CRF.
UPPPATHO	num	UPPER PATHOLOGICAL LIMIT		Collected at CRF.
REGION	char	REGION OF THE VALUE		Collected at CRF.
SHIFTBAS	char	SHIFT VERSUS BASELINE		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
SEQUSE	num	PRIORITY		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
RELDAY2	num	RELDAY2		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and XAMFROM not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than XAMFROM then (SAMPLE_D - XAMFROM).Else if SAMPLE_D is greater than equal to XAMFROM then (SAMPLE_D- XAMFROM) +1.

1.4.12. Laboratory Urinalysis – XLABURI

Dataset	XLABURI
Creating program	xlaburi.sas
Description	Laboratory Urinalysis
Unique identifier	DCRFID,SAMPLEDY,ZLABTEST,LABVAL, XTIME
Sorted by	DCRFID,SAMPLEDY,ZLABTEST,LABVAL, XTIME
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values:</p> <p>SAMPLE_D, SAMPLE_T, ZLABID, COUNTRY, INVEST, PERPROT, SEX, RACE, LABID, ENZYME,LABTST_U, SIVALUE, SIUNIT, CFACTOR, LOWPATHO, UPPPATHO, ABNCODE</p>

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
ZLABTEST	char	LAB.TEST		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
LABTEST	char	LAB.TEST		Collected at CRF.
LABTSTNO	num	LAB.TEST NUMBER		Collected at CRF.
LABCLASS	char	LABCLASS		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABVAL	num	LAB.TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB.TEST VALUE (VERB)		Collected at CRF.
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
REGION	char	REGION OF THE VALUE		Collected at CRF.
SHIFTBAS	char	SHIFT VERSUS BASELINE		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
SEQUE	num	PRIORITY		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
RELDAY2	num	RELDAY2		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and XAMFROM not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than XAMFROM then (SAMPLE_D - XAMFROM).Else if SAMPLE_D is greater than equal to XAMFROM then (SAMPLE_D- XAMFROM) +1.

1.4.13. Positive and Negative Syndrome Scale for Schizophrenia – XPANSS

Dataset	XPANSS
Creating program	xpanss.sas
Description	Positive and Negative Syndrome Scale for Schizophrenia
Unique identifier	DCRFID,VISIT,VISIT_DY,XTIME,RELDAY,ZPAGROUP, ZPARAM
Sorted by	DCRFID,VISIT,VISIT_DY,XTIME,RELDAY,ZPAGROUP, ZPARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISIT_D, COUNTRY, INVEST, PERPROT, SEX, RACE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
VISIT	num	VISIT NO		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
SEQUSE	num	TIME PRIORITY		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
RELDAY	num	DAYS IN PHASE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM TREATMENT BASELINE		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
DBASE	char	VALUE DESC. AT BASELINE		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
ZPAGROUP	char	CODE PANSS-GROUP		Collected at CRF.
ZPARAM	char	CODE PANSS-PARAMETER		Collected at CRF.
PAGROUP	char	PANSS-GROUP		Collected at CRF.
PARAM	char	PANSS-PARAMETER		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and XAMFROM not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than XAMFROM then (VISIT_D - XAMFROM).Else if VISIT_D is greater than equal to XAMFROM then (VISIT_D- XAMFROM) +1.

1.4.14. Subject Background and Demographics – XSUB

Dataset	XSUB
Creating program	xsub.sas
Description	Subject Background and Demographics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: COUNTRY, INVEST, PERPROT, SEX, RACE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

1.4.15. Phase/Termination Data – XTRLTERM

Dataset	XTRLTERM
Creating program	xtrlterm.sas
Description	Phase/Termination Data
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: COUNTRY,INVEST,PERPROT,SEX,RACE,TTFROM_D,TTFROM_T,TTREAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
TTTYPE	char	TERM. TYPE		Collected at CRF.
TTRELDAY	num	DAYS IN PHASE		Collected at CRF.
TTREAS	char	TERM. REASON		Collected at CRF.

Variable	Type	Label	Codes	Comments
TTFROMDY	num	RELATIVE LAST CONTACT DAY		If TTFROM_D and XAMFROM not missing then perform below logic to calculate TTFROMDY, If TTFROM_D less than XAMFROM then (TTFROM_D - XAMFROM).Else if TTFROM_D is greater than equal to XAMFROM then (TTFROM_D- XAMFROM) +1.

1.4.16. The UKU Side Effect Rating Scale – XUKU

Dataset	XUKU
Creating program	xuku.sas
Description	The UKU Side Effect Rating Scale
Unique identifier	DCRFID,VISIT, PARAM
Sorted by	DCRFID,VISIT, PARAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISIT_D, COUNTRY, INVEST, PERPROT, SEX, RACE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id assigned for de-identity
VISIT	num	VISIT NO		Collected at CRF.

Variable	Type	Label	Codes	Comments
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
PARAM	char	SYMPTOM OF UKU		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
DVALUE	char	VALUE DESCRIPTION		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
DBASE	char	VALUE DESC. AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
RELDAY	num	DAYS IN PHASE		Collected at CRF.
DRELAT	char	CASUAL RELATIONSHIP		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and XAMFROM not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than XAMFROM then (VISIT_D - XAMFROM).Else if VISIT_D is greater than equal to XAMFROM then (VISIT_D- XAMFROM) +1.

1.4.17. Vital Signs – XVITSIGN

Dataset	XVITSIGN
Creating program	xvitsign.sas
Description	Vital Signs
Unique identifier	DCRFID,PARAM,VISIT,XTIME, VSPOS
Sorted by	DCRFID,PARAM,VISIT,XTIME, VSPOS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VISIT_D, VISIT_T, XCENTER, COUNTRY, INVEST, PERPROT, SEX, RACE, DVALUE, DBASE, ZCHANGE, XIMPUTE, CENSOR

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned CRFID for de-identity.
PARAM	char	PARAMETER		Collected at CRF.
VISIT	num	VISIT NO		Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
XPHASE	char	ANALYSIS PHASE		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
ITT	char	INTENT-TO-TREAT		Collected at CRF.

Variable	Type	Label	Codes	Comments
RELDAY	num	DAYS IN PHASE		Collected at CRF.
XTREAT	char	TREATMENT		Collected at CRF.
VALUE	num	VALUE		Collected at CRF.
BASE	num	VALUE AT BASELINE		Collected at CRF.
CHANGE	num	CHANGE FROM BASELINE		Collected at CRF.
PCHANGE	num	PCT CHANGE FROM TREATMENT BASELINE		Collected at CRF.
VSPOS	char	VITAL SIGNS POSITION		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and XAMFROM not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than XAMFROM then (VISIT_D - XAMFROM).Else if VISIT_D is greater than equal to XAMFROM then (VISIT_D- XAMFROM) +1.