Clinical Development

RISPERIDONE®

RIS-AUS-5

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Remove ethnic information.
- Remark dataset will be submitted with zero observations.
- Datasets containing insignificant information will not be submitted. (e.g. MAP ,TRLLIST)
- Dataset containing investigator information is sensitive and hence will not be submitted. (e.g. INVEST).
- Visit Date(VISIT_D) when Visit=1 will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

1.3. Data Files

The RIS-AUS-5 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
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,COINV,ZCOINV,INVEST,INITIALS,BIRTH_D,ENTRYCOM,BREAK_V, ONSDEM_M,ONSDEM_Y,ONSBEH_M,ONSBEH_Y,DATHOS_M,DATHOS_Y, DATCUR_M,DATCUR_Y,RANDOM_V Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment related information and Country information in the de-identified datasets: RANDGRP (Source: TRLRAND dataset) DCOUNTRY (Source: INVEST dataset)

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
DSITEID	num	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned site ID for De-Identity

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
DEMALZH	char	DEMENTIA ALZHEIMER'S TYPE		Collected at CRF.
DEMVAS	char	VASCULAR DEMENTIA		Collected at CRF.
HOSP_PRE	num	NUMBER OF PREV. HOSP.		Collected at CRF.
SCHISILL	char	FAM. HISTORY NEUROL./PSYCH. ILLNESS		Collected at CRF.
RANDOMIZ	char	QUALIFY FOR RANDOMIZATION		Collected at CRF.
EDUCAT	char	EDUCATION LEVEL		Collected at CRF.
DIAG_PER	char	DIAGNOSIS PERIOD ONSET		Collected at CRF.
RESCARE	char	RESIDENT CARE REQUIREMENT		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Element will be grouped to protect PII.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((REF.DATE – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and REF.DATE not missing then perform below logic to calculate BREAK_DY, If BREAK_D less than REF.DATE then (BREAK_D - REF.DATE). Else if BREAK_D is greater than equal to REF.DATE then (BREAK_D- REF.DATE) +1.

1.4.2. Administration of Trial Medication – ADMMED

Dataset	ADMMED
Creating program	admmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID,PHASE,AMREAS,NUMFORM,AMFROMDY,AMSEQNO
Sorted by	DCRFID,PHASE,AMREAS,NUMFORM,AMFROMDY,AMSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AMFROM_D,AMTO_D,AMDOSE

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
AMSEQNO	num	ADMIN. SEQ. NO.		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.

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

1.4.3. Adverse Event - AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event
Unique identifier	DCRFID,AEPREF,AEWHONUM,AESEQNO
Sorted by	DCRFID,AEPREF,AEWHONUM,AESEQNO
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,PHASE,AEFROM_D,AEFROM_C,AETO_D,AETO_C,SAEREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
AESEQNO	num	AE SEQ.		Collected at CRF.
AEINCL	char	AE INCLUDED TERM		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESEV	num	AE SEVERITY		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN		Collected at CRF.
AECONRX	char	AE CO-RX START		Collected at CRF.
ZAECONRX	num	AE CO-RX START		Collected at CRF.

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

1.4.4. Behavioral Pathology - BEHAVE

Dataset	BEHAVE
Creating program	behave.sas
Description	Behavioral Pathology
Unique identifier	DCRFID, BEGROUP, BEITEM, BESCORE, VISIT
Sorted by	DCRFID, BEGROUP, BEITEM, BESCORE, VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
BEGROUP	char	BEHAVE SUBGROUP		Collected at CRF.
BEITEM	char	BEHAVE ITEM		Collected at CRF.
BESCORE	char	BEHAVE SCORE		Collected at CRF.
ZBESCORE	num	BEHAVE SCORE		Collected at CRF.

1.4.5. Caregiver Time – CARETIME

Dataset	CARETIME
Creating program	caretime.sas
Description	Caregiver Time
Unique identifier	DCRFID, CRNOTDNE, CRACTIV, CRTMHR, CRTMMIN, VISIT
Sorted by	DCRFID, CRNOTDNE, CRACTIV, CRTMHR, CRTMMIN, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CRACT_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
CRACTIV	char	ACTIVITIES		Collected at CRF.
CRSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
CRNOTDNE	char	DONE		Collected at CRF.
CRTMHR	num	DAILY HOURS SPENT ON ACTIVITY		Collected at CRF.
CRTMMIN	num	DAILY MINUTES SPENT ON ACTIVITY		Collected at CRF.

1.4.6.Cohen- Mansfield – CMAI

Dataset	CMAI
Creating program	cmai.sas
Description	Cohen- Mansfield
Unique identifier	DCRFID,CMITEM,CMFREQ,CMDISR,VISIT
Sorted by	DCRFID,CMITEM,CMFREQ,CMDISR,VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: CMITEM_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
CMITEM	char	CMAI ITEM		Collected at CRF.
CMFREQ	char	CMAI FREQUENCY		Collected at CRF.
ZCMFREQ	num	CMAI FREQUENCY		Collected at CRF.
CMDISR	char	CMAI DISRUPTIVENESS		Collected at CRF.
ZCMDISR	num	CMAI DISRUPTIVENESS		Collected at CRF.

1.4.7. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,CTTYPE,CONRX,CTSEQNO
Sorted by	DCRFID,CTTYPE,CONRX,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CONRX_V,CONRX,CTIND_V,CTIND,CTFROM_D,CTFROM_C, CTTO_D,CTTO_C,ATCCODE8,ATCCODE9,ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
ATCTEXT3	char	ATC TEXT 3		Collected at CRF.
ATCTEXT4	char	ATC TEXT 4		Collected at CRF.
ATCTEXT5	char	ATC TEXT 5		Collected at CRF.
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D- REF.DATE) +1.

1.4.8. Death Report – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death Report
Unique identifier	DCRFID, DTREAS, DEATH_DY
Sorted by	DCRFID, DTREAS, DEATH_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEATH_D, DTREAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
DTREAS	char	DEATH CAUSE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEATH_DY	num	RELATIVE DEATH DAY		If DEATH_D and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATH_D less than REF.DATE then (DEATH_D - REF.DATE). Else if DEATH_D is greater than equal to REF.DATE then (DEATH_D- REF.DATE) +1.

1.4.9.Dependence Scale – DEPENDS

Dataset	DEPENDS
Creating program	depends.sas
Description	Dependence Scale
Unique identifier	DCRFID,DEPEND,DEPRESP,VISIT
Sorted by	DCRFID,DEPEND,DEPRESP,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
DEPEND	char	SYMPTOM		Collected at CRF.
DEPRESP	char	RESPONSE		Collected at CRF.

1.4.10. Protocol Deviation – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Protocol Deviation
Unique identifier	DCRFID,DEVIAT,ZDEVIAT
Sorted by	DCRFID,DEVIAT,ZDEVIAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEVIAT_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION		Collected at CRF.

1.4.11. Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
Unique identifier	DCRFID, DIAGN
Sorted by	DCRFID, DIAGN
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
DIAGN	char	DIAGNOSIS		Collected at CRF.
ZDIAGN	char	DIAGNOSIS		Collected at CRF.

1.4.12. Medical History – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Medical History
Unique identifier	DCRFID, DSSYSTEM, DSCOND, DSSEQNO
Sorted by	DCRFID, DSSYSTEM, DSCOND, DSSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISEAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
DSSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.
DISEASE	char	DISEASE		Collected at CRF.

1.4.13. Esrs – ESRS

Dataset	ESRS
Creating program	esrs.sas
Description	Esrs
Unique identifier	DCRFID,ESGROUP,ESITEM,ESSCORE,ESSTAT,VISIT
Sorted by	DCRFID,ESGROUP,ESITEM,ESSCORE,ESSTAT,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
ESGROUP	char	ESRS SUBGROUP		Collected at CRF.
ESITEM	char	ESRS ITEM		Collected at CRF.
ESSCORE	char	ESRS SCORE		Collected at CRF.
ZESSCORE	num	ESRS SCORE		Collected at CRF.
ESSTAT	char	ESRS STATUS		Collected at CRF.

1.4.14. Psychiatric – FAMHIS

Dataset	FAMHIS
Creating program	famhis.sas
Description	Psychiatric
Unique identifier	DCRFID,FHMEM,FHSEQNO
Sorted by	DCRFID,FHMEM,FHSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FHDIS

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
FHMEM	char	FAMILY MEMBERS		Collected at CRF.
FHSEQNO	num	FAMILY HISTORY SEQUENCE NUMBER		Collected at CRF.

1.4.15. Fast – FAST

Dataset	FAST
Creating program	fast.sas
Description	Fast
Unique identifier	DCRFID,FAITEM,FASCORE,VISIT
Sorted by	DCRFID,FAITEM,FASCORE,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
FAITEM	char	FAST ITEM		Collected at CRF.
FASCORE	char	FAST SCORE		Collected at CRF.

1.4.16. Inclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion Criteria
Unique identifier	DCRFID,IECRIT
Sorted by	DCRFID,IECRIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
IETYPE	char	TYPE OF SELECTION CRITERIA		Collected at CRF.
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA		Collected at CRF.
IEYN	char	ELIGIBILITY EXPR.		Collected at CRF.

1.4.17. Institute – INSTITUT

Dataset	INSTITUT
Creating program	institut.sas
Description	Institute
Unique identifier	DCRFID,INSTTYP,WARDTYP,INREAS,INSEQNO,VISIT
Sorted by	DCRFID,INSTTYP,WARDTYP,INREAS,INSEQNO,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INFROM_D,INTO_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
INSTTYP	char	TYPE OF INSTITUTION		Collected at CRF.
ZINSTTYP	num	TYPE OF INSTITUTION		Collected at CRF.
WARDTYP	char	TYPE OF WARD		Collected at CRF.
ZWARDTYP	char	TYPE OF WARD		Collected at CRF.
INREAS	char	INSTITUTION REASON		Collected at CRF.
ZINREAS	num	INSTITUTION REASON		Collected at CRF.
INSEQNO	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
INPRIOR	char	ONGOING FROM		Collected at CRF.
INONGO	char	ONGOING TO		Collected at CRF.
INFROMDY	num	RELATIVE FROM DAY		If INFROM_D and REF.DATE not missing then perform below logic to calculate INFROMDY, If INFROM_D less than REF.DATE then (INFROM_D - REF.DATE). Else if INFROM_D is greater than equal to REF.DATE then (INFROM_D- REF.DATE) +1.
INTO_DY	num	RELATIVE TO DAY		If INTO_D and REF.DATE not missing then perform below logic to calculate INTO_DY, If INTO_D less than REF.DATE then (INTO_D - REF.DATE). Else if INTO_D is greater than equal to REF.DATE then (INTO_D- REF.DATE) +1.

1.4.18. Labnor – LABNOR

Dataset	LABNOR
Creating program	labnor.sas
Description	Labnor
Unique identifier	LABTEST,LNFROM_D,LNTO_D,LNSEQNO,LABTST_U,LABLOW,LABUPP,SEX
Sorted by	LABTEST,LNFROM_D,LNTO_D,LNSEQNO,LABTST_U,LABLOW,LABUPP,SEX
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABID,ZLABID, AGEFROM,AGETO,AGE_U,WGHTFROM,WGHTTO,WGHT_U

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST		Collected at CRF.
LNFROM_D	num	RANGE APPLICABLE FROM		Collected at CRF.
LNTO_D	num	RANGE APPLICABLE TO		Collected at CRF.
LNSEQNO	num	LAB. NORMAL SEQ.		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
SEX	char	SEX		Collected at CRF.

1.4.19. Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results
Unique identifier	DCRFID,LABTEST,SAMPLEDY,LABVAL
Sorted by	DCRFID,LABTEST,SAMPLEDY,LABVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,ENZYME

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
LRRELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
LABLH	char	LAB. RESULTS LOW OR HIGH		Collected at CRF.
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.

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

1.4.20. Laboratory Sample Info – LABSAM

Dataset	LABSAM
Creating program	labsam.sas
Description	Laboratory Sample Info
Unique identifier	DCRFID,SAMPLEDY,FASTED
Sorted by	DCRFID,SAMPLEDY,FASTED
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,HAEMOLYS,LABREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
FASTED	char	SUBJECT FASTED		Collected at CRF.
LSSAME	char	SAME NORMAL RANGES		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D- REF.DATE) +1.

1.4.21. Mini-Mental State Examination – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	Mini-Mental State Examination
Unique identifier	DCRFID,MMITEM,MMSCORE,VISIT
Sorted by	DCRFID,MMITEM,MMSCORE,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
MMITEM	char	MMSE ITEM		Collected at CRF.
MMSCORE	num	MMSE SCORE		Collected at CRF.

1.4.22. Ncas – NCAS

Dataset	NCAS
Creating program	ncas.sas
Description	Ncas
Unique identifier	DCRFID,NCASITEM,NCASAGR,NCASDIF,VISIT
Sorted by	DCRFID,NCASITEM,NCASAGR,NCASDIF,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
NCASITEM	char	ITEM		Collected at CRF.
NCASAGR	num	NCAS AGREE OR DISAGREE		Collected at CRF.
NCASDIF	num	NCAS DIFFICULT TO COPE WITH THIS		Collected at CRF.

1.4.23. Resource Use – OUTPAT

Dataset	OUTPAT
Creating program	outpat.sas
Description	Resource Use
Unique identifier	DCRFID,SERVICE,SERVUSED,SERVNO,VISIT
Sorted by	DCRFID,SERVICE,SERVUSED,SERVNO,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
SERVICE	char	OUTPATIENT SERVICE		Collected at CRF.
SERVUSED	char	SERVICE USED?		Collected at CRF.
SERVNO	num	SERVICE NUMBER		Collected at CRF.

1.4.24. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID,PESYSTEM,VISIT
Sorted by	DCRFID,PESYSTEM,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EXAM_V,EXAM

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.

1.4.25. Current Medication – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	Current Medication
Unique identifier	DCRFID,PTTYPE,PRVRX,PTSCHED,PTSEQNO
Sorted by	DCRFID,PTTYPE,PRVRX,PTSCHED,PTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PRVRX_V,PTFROM_D,PTTO_D,PTAE_V,ATCCODE1,ATCCODE2,ATCCODE3, ATCCODE4,ATCCODE5,ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9, ATCTEXT1,ATCTEXT2,ATCTEXT3,ATCTEXT4,ATCTEXT5,ATCTEXT6,ATCTEXT7, ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
PTTYPE	char	PREV. RX TYPE		Collected at CRF.
PTSEQNO	num	PREV. RX SEQ.		Collected at CRF.
PRVRX	char	PREV. RX		Collected at CRF.
PTSCHED	char	PREV. RX DAILY SCHEDULE		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.
PTFROMDY	num	RELATIVE PREV. RX START DAY		If PTFROM_D and REF.DATE not missing then perform below logic to calculate PTFROMDY, If PTFROM_D less than REF.DATE then (PTFROM_D - REF.DATE). Else if PTFROM_D is greater than equal to REF.DATE then (PTFROM_D- REF.DATE) +1.
PTTO_DY	num	RELATIVE PREV. RX END DAY		If PTTO_D and REF.DATE not missing then perform below logic to calculate PTTO_DY, If PTTO_D less than REF.DATE then (PTTO_D - REF.DATE). Else if PTTO_D is greater than equal to REF.DATE then (PTTO_D- REF.DATE) +1.

1.4.26. Related AEs for Trial Termination or Death – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	Related AEs for Trial Termination or Death
Unique identifier	DCRFID,RATYPE,AESEQNO
Sorted by	DCRFID,RATYPE,AESEQNO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.27. Remarks – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remarks
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Remark dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Empty dataset will be submitted
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
RCSEQNO	num	REMARK LINE NO.		Empty dataset will be submitted
REMARKDY	num	RELATIVE REMARK DAY		Empty dataset will be submitted

1.4.28. Sci – SCI

Dataset	SCI
Creating program	sci.sas
Description	Sci
Unique identifier	DCRFID,SCIGROUP,SCIITEM,SCISCORE,VISIT
Sorted by	DCRFID,SCIGROUP,SCIITEM,SCISCORE,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
SCIGROUP	char	SCI GROUP		Collected at CRF.
SCIITEM	char	SCI ITEM		Collected at CRF.
SCISCORE	char	SCI SCORE		Collected at CRF.

1.4.29. Scinf – SCIINF

Dataset	SCIINF
Creating program	sciinf.sas
Description	Scinf
Unique identifier	DCRFID,SCIINFTY,SCIINFIT,SCIINFSC,VISIT
Sorted by	DCRFID,SCIINFTY,SCIINFIT,SCIINFSC,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
SCIINFTY	char	TYPE (CARE PROGRAMMES/MEDICAL PROBLEMS)		Collected at CRF.
SCIINFIT	char	SCI INFORMATION ITEM		Collected at CRF.
SCIINFSC	num	SCI INFORMATION SCORE		Collected at CRF.

1.4.30. Resource Use – TESTREQ

Dataset	TESTREQ
Creating program	testreq.sas
Description	Resource Use
Unique identifier	DCRFID,TESTREQ,TRSEQNO,PATH_D,VISIT
Sorted by	DCRFID,TESTREQ,TRSEQNO,PATH_D,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PATH_D,TESTR_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
TESTREQ	char	TEST REQUESTED		Collected at CRF.
TRSEQNO	num	TEST REQUEST SEQUENCE NUMBER		Collected at CRF.
PATH_DY	num	RELATIVE USE PATHOLOGY SERVICES DAY		If PATH_D and REF.DATE not missing then perform below logic to calculate PATH_DY, If PATH_D less than REF.DATE then (PATH_D - REF.DATE). Else if PATH_D is greater than equal to REF.DATE then (PATH_D- REF.DATE) +1.

1.4.31. Trial Description – TRLDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	Trial Description
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.
MULTCENT	char	MULTICENTRE		Collected at CRF.
BLKSIZE	num	BLOCK SIZE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.32. Trial Randomization – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Trial Randomization
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.

1.4.33. Trial Regimen – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Regimen
Unique identifier	RANDGRP,TREAT,SEGMENT
Sorted by	RANDGRP,TREAT,SEGMENT
Notes	Below listed variables will be dropped from dataset due to missing values: BOX

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZTMROUTE	char	ADMIN. ROUTE		Collected at CRF.
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.34. Trial Termination – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.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: TTFROM_D,TTREAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
TTTYPE	char	TERM. TYPE		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 REF.DATE not missing then perform below logic to calculate TTFROMDY, If TTFROM_D less than REF.DATE then (TTFROM_D - REF.DATE). Else if TTFROM_D is greater than equal to REF.DATE then (TTFROM_D- REF.DATE) +1.

1.4.35. Visit General Info – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit General Info
Unique identifier	DCRFID, VISIT
Sorted by	DCRFID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
CGI_I	char	CLIN. GL. IMPRESSION - INVESTIG.		Collected at CRF.

Variable	Type	Label	Codes	Comments
CGI_C	char	CLIN. GL. IMPRESSION - CAREGIVER		Collected at CRF.
ESRSQUES	char	ESRS QUESTIONNAIRE COMPLETION		Collected at CRF.
SYMPVIT	char	SUBJECT SYMPTOMATIC OR VITALS REQUIRED		Collected at CRF.
SCIEPTY	char	DIAGNOSIS PERIOD ONSET		Collected at CRF.
OUTPATNT	char	OUTPATIENT SERVICE USED		Collected at CRF.
INSTITUT	char	INSTITUTION STAY		Collected at CRF.
ANTICHOL	char	ANTICHOLINERGICS		Collected at CRF.
CGI_CH_I	char	CGI CONDITION CHANGE - INVESTIG.		Collected at CRF.
CGI_CH_C	char	CGI CONDITION CHANGE - CAREGIVER		Collected at CRF.
TH_EFF_I	char	THERAPEUTIC EFFECT - INVESTIG.		Collected at CRF.
TH_EFF_C	char	THERAPEUTIC EFFECT - CAREGIVER		Collected at CRF.
SE_I	char	SIDE EFFECT - INVESTIG.		Collected at CRF.
SE_C	char	SIDE EFFECT - CAREGIVER		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and REF.DATE not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than REF.DATE then (VISIT_D - REF.DATE). Else if VISIT_D is greater than equal to REF.DATE then (VISIT_D- REF.DATE) +1.

1.4.36. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	DCRFID, VISIT
Sorted by	DCRFID, VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf ID for De-Identity
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, beats/min		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.