

Clinical Development

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RIS-INT-84

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.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- REMARK dataset will be submitted with 0 observations due to sensitivity of data.
- INVEST dataset contains Investigator information, which is sensitive. Hence, this dataset will not be submitted.
- DEATH,RANDGRP,TRLLIST dataset contain zero observation hence these dataset will not be submitted.
- Datasets containing insignificant information will not be submitted (ex. MAP).
- For Randomized subjects, VISIT .VISIT_D (visit date) when VISIT =1 will be used as a reference date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files

The RIS-INT-84 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. SUBJECT CHARACTERISTICS (SC) – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	SUBJECT CHARACTERISTICS (SC)
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: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,BREAK, BREAK_D,BREAK_V, DRYRUN,ELIGIBLE,ENTRYCOM,ZCOUNTRY,COINV,ZCOINV,BATCHNO

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
PRVTRIAL	char	PREV. TRIAL		Collected at CRF.
DPRCRFID	char	PREVIOUS CRFID ASSIGN FOR DE-IDENTITY		Randomly assigned previous crf Id for De-identity
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned site no. for De-identity
DNAYN	char	DNA SAMPLE TAKEN?		Collected at CRF.
DNACONST	char	DNA CONSENT		Collected at CRF.
DNAANAL	char	DNA ANALYSIS OBTAINED		Collected at CRF.
DNASTOR	char	DNA SAMPLE OBTAINED FOR STORAGE		Collected at CRF.
DISCVIS	char	D/C VISIT		Collected at CRF.
PREGRES	char	RESULT OF PREGNANCY TEST		Collected at CRF.
AGE	char	AGE IN YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.

1.4.2.ADMINISTRATION OF TRIAL MEDICATION (AM) – ADMMED

Dataset	ADMED
Creating program	admmed.sas
Description	ADMINISTRATION OF TRIAL MEDICATION (AM)
Unique identifier	DCRFID,AMFROMDY
Sorted by	DCRFID,AMFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BOX,AMFROM_D,AMTO_D,AMDOSE,AMDOSE_U

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.
AMREAS1	char	REGIMEN CHANGE REASON (AM)		Collected at CRF.
ZAMREAS1	char	REGIMEN CHANGE REASON (AM) CODE		Collected at CRF.
AMREAS2	char	REGIMEN CHANGE REASON (PM)		Collected at CRF.
ZAMREAS2	char	REGIMEN CHANGE REASON (PM) CODE		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
NUMFORM1	num	UNITS PER ADMIN (AM)		Collected at CRF.

Variable	Type	Label	Codes	Comments
NUMFORM2	num	UNITS PER ADMIN (PM)		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 EVENTS (AE) – AE

Dataset	AE
Creating program	ae.sas
Description	ADVERSE EVENTS (AE)
Unique identifier	DCRFID, AEPREF, AEFROMDY, AESEQNO
Sorted by	DCRFID, AEPREF, AEFROMDY, 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, AETO_D, 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.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AERONRX	char	AE CO-RX START		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAECNRX	num	AE CO-RX START CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME CODE		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS CODE		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.DICTIONARY VERSION CONTROL – CODE

Dataset	CODE
Creating program	code.sas
Description	DICTIONARY VERSION CONTROL
Unique identifier	CODELIST
Sorted by	CODELIST
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
CODELIST	char	CODELIST		Collected at CRF.
VALID_D	num	VALID DATE		Collected at CRF.

1.4.5.RELATED AES FOR CONCOMITANT THERAPY (AC) – CONAE

Dataset	CONAE
Creating program	conae.sas
Description	RELATED AES FOR CONCOMITANT THERAPY (AC)
Unique identifier	DCRFID,CTSEQNO,AESEQNO
Sorted by	DCRFID,CTSEQNO,AESEQNO
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

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
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.6. CONCOMITANT THERAPY (CT) – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	CONCOMITANT THERAPY (CT)
Unique identifier	DCRFID,CTSEQNO
Sorted by	DCRFID,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 ,CTIND,CTFROM_D,CTTO_D,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
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTIND_V	char	INDICATION (VERB.)		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTTO_C	char	CO-RX END CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
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.
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.

1.4.7.DEVIATION (DV) – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	DEVIATION (DV)
Unique identifier	DCRFID,DEVIAT,ZDEVIAT,DVTYPE
Sorted by	DCRFID,DEVIAT,ZDEVIAT,DVTYPE
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

Variable	Type	Label	Codes	Comments
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION CODE		Collected at CRF.
DVTYPE	char	TYPE OF DEVIATION		Collected at CRF.

1.4.8. ELECTROCARDIOGRAM (EG) – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ELECTROCARDIOGRAM (EG)
Unique identifier	DCRFID,ECG_DY
Sorted by	DCRFID,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D,EGLIMITS,LEADQT,EGRESULT,ECGREFNO,ECGINTNO

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
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.9.ECG OTHER ABNORMALITIES (EA) – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG OTHER ABNORMALITIES (EA)
Unique identifier	DCRFID,ECG_DY
Sorted by	DCRFID,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D ,ECGINTNO

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
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EASEQNO	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGOTH_V	char	ECG OTHER ABN. (VERB.)		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.10. ELECTROCARDIOGRAM MEASUREMENTS (EP) – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ELECTROCARDIOGRAM MEASUREMENTS (EP)
Unique identifier	DCRFID ,ECGPAR ,ECGVAL,ECG_DY
Sorted by	DCRFID ,ECGPAR ,ECGVAL,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D,ECGVAL_V,ECGINTNO

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
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EPSEQNO	num	SEQUENCE NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ECGPAR_U	char	ECG MEASUREMENT UNIT		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.11. INCLUSION-EXCLUSION CRITERIA (IE) – INEX

Dataset	INEX
Creating program	inex.sas
Description	INCLUSION-EXCLUSION CRITERIA (IE)
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.

Variable	Type	Label	Codes	Comments
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	num	SELECTION CRITERIA CODE		Collected at CRF.
IEYN	char	ELIGIBILITY EXPR.		Collected at CRF.

1.4.12. LABORATORY RESULTS (LR) – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	LABORATORY RESULTS (LR)
Unique identifier	DCRFID,LABTEST,VISIT
Sorted by	DCRFID,LABTEST,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID,SAMREFNO,LABINTNO

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
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
VISIT	num	VISIT		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.
ENZYME	char	ENZYME		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.

1.4.13. LABORATORY URINE RESULTS (LU) – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	LABORATORY URINE RESULTS (LU)
Unique identifier	DCRFID,LABTEST,VISIT
Sorted by	DCRFID,LABTEST,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D,LABID,ZLABID,LUVAL_V,SAMREFNO,LABINTNO

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
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LUVAL	char	URINE VALUE		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.14. NISONGER CHILD BEHAVIOUR RATING (NI) – NISONG

Dataset	NISONG
Creating program	nisong.sas
Description	NISONGER CHILD BEHAVIOUR RATING (NI)
Unique identifier	DCRFID, NIGROUP, NIITEM, NISCORE, VISIT
Sorted by	DCRFID, NIGROUP, NIITEM, NISCORE, VISIT
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
VISIT	num	VISIT		Collected at CRF.
NIGROUP	char	NISONGER GROUP		Collected at CRF.
NIITEM	char	NISONGER ITEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
NISCORE	char	NISINGER SCORE		Collected at CRF.
ZNISCORE	num	NISINGER SCORE CODE		Collected at CRF.

1.4.15. NO DATA ON VISITS/PAGES (ND) – NODATA

Dataset	NODATA
Creating program	nodata.sas
Description	NO DATA ON VISITS/PAGES (ND)
Unique identifier	DCRFID,NDSEQNO
Sorted by	DCRFID,NDSEQNO
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
NDSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
NDFROM	char	NO DATA START		Collected at CRF.
NDTO	char	NO DATA END		Collected at CRF.

1.4.16. PHYSICAL EXAMINATION (PE) – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	PHYSICAL EXAMINATION (PE)
Unique identifier	DCRFID, VISIT, PESEQNO
Sorted by	DCRFID, VISIT, PESEQNO
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.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-identity
VISIT	num	VISIT		Collected at CRF.
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.

1.4.17. RELATED AES FOR TERMINATION OR DEATH(RA) – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	RELATED AES FOR TERMINATION OR DEATH(RA)
Unique identifier	DCRFID,AESEQNO
Sorted by	DCRFID,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.

1.4.18. REMARKS AND COMMENTS (RM) – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	REMARKS AND COMMENTS (RM)
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
DRCRFD	char	CRF ID ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
RMSEQNO	num	SEQUENCE NUMBER		Empty dataset will be submitted
RMTYPE	char	REMARK TYPE		Empty dataset will be submitted

1.4.19. SAMPLES (SA) – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	SAMPLES (SA)
Unique identifier	DCRFID, SPECIMEN, SAMPLEDY
Sorted by	DCRFID, SPECIMEN, SAMPLEDY
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, SAMREFNO, SASAME, SARELCHA, LABINTNO

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
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
FASTED	char	SUBJECT FASTED		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		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. SAMPLE REQUISITION NUMBERS (SR) – SAMREF

Dataset	SAMREF
Creating program	samref.sas
Description	SAMPLE REQUISITION NUMBERS (SR)
Unique identifier	DCRFID,SPECIMEN,SARELCHA,VISIT
Sorted by	DCRFID,SPECIMEN,SARELCHA,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMREFNO,SFADDSAM

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
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SARELCHA	char	CLIN. SIGNIFICANT CHANGES		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

1.4.21. TRIAL DESCRIPTION (TD) – TRLDDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	TRIAL DESCRIPTION (TD)
Unique identifier	COMPOND
Sorted by	COMPOND
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME CODE		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.

Variable	Type	Label	Codes	Comments
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.22. RANDOMISATION GROUPS (TN) – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	RANDOMISATION GROUPS (TN)
Unique identifier	RANDGRP
Sorted by	RANDGRP
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.

1.4.23. TRIAL MEDICATION REGIMENS (TM) – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	TRIAL MEDICATION REGIMENS (TM)
Unique identifier	RANDGRP
Sorted by	RANDGRP
Notes	

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	SEGMENT		Collected at CRF.
BOX	char	BOX		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 CODE		Collected at CRF.
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.24. TREATMENT / TRIAL TERMINATION (TR) – TRTERM

Dataset	TRTERM
Creating program	trterm.sas
Description	TREATMENT / TRIAL TERMINATION (TR)
Unique identifier	DCRFID,TRFROMDY
Sorted by	DCRFID,TRFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TRREAS_V,TRFROM_D

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
TRTYPE	char	TYPE OF TERMINATION		Collected at CRF.
TRSTATE	char	STATE OF TERMINATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRREAS	char	TERM. REASON		Collected at CRF.
TRFROMDY	num	RELATIVE LAST CONTACT DAY		If TRFROM_D and REF.DATE not missing then perform below logic to calculate TRFROMDY, If TRFROM_D less than REF.DATE then (TRFROM_D - REF.DATE). Else if TRFROM_D is greater than equal to REF.DATE then (TRFROM_D- REF.DATE) +1.

1.4.25. VISITS (VI) – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	VISITS (VI)
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 or due to missing values: VISIT_D,INICGI,VASSYM_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
VISIT	num	VISIT		Collected at CRF.
VITYPE	char	VISIT TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TANNER	num	TANNER SEXUAL MATURITY RATING STAGE		Collected at CRF.
VICGAS	num	CGAS		Collected at CRF.
CGIS	char	CGIS		Collected at CRF.
VAS	num	VAS		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.

1.4.26. VITAL SIGNS (VS) – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	VITAL SIGNS (VS)
Unique identifier	DCRFID,VISIT
Sorted by	DCRFID,VISIT
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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT 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.