

Clinical Development

JNJ410397

RISCAN23

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.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Empty COMMENTS (Comments) data will be submitted due to sensitivity of data.
- Due to sensitive information ECGABN dataset will be removed.
- SUBJCHAR.VISITD1 ("SAS Visit Date") will be used as a Reference date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The RISCAN23 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 repetition of the information: VISITD1,VISITD2,BIRTHD1,BIRTHD2,RACESP,INIT6,RANDD1,MEDCODE, RREFNO,DOMSP

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
AGE	char	Age of Subject		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SEX	num	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	num	Race		Collected at CRF.
DOM1	num	Lives with Parents?		Collected at CRF.
DOM2	num	Lives with Others?		Collected at CRF.
DFPL6	num	Plate 6		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.2. Aberrant Behaviour Checklist (ABC) – ABC

Dataset	ABC
Creating program	abc.sas
Description	Aberrant Behaviour Checklist (ABC)
Unique identifier	DCRFID,RANDDY,DFSEQ
Sorted by	DCRFID,RANDDY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT41,INIT42,INIT43,INIT44,RANDD1,MEDCODE,RREFNO,COMPSP

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
COMPBY	num	ABC Completed By		Collected at CRF.
ABC1	num	Item 1		Collected at CRF.
ABC2	num	Item 2		Collected at CRF.
ABC3	num	Item 3		Collected at CRF.
ABC4	num	Item 4		Collected at CRF.
ABC5	num	Item 5		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABC6	num	Item 6		Collected at CRF.
ABC7	num	Item 7		Collected at CRF.
ABC8	num	Item 8		Collected at CRF.
ABC9	num	Item 9		Collected at CRF.
ABC10	num	Item 10		Collected at CRF.
ABC11	num	Item 11		Collected at CRF.
ABC12	num	Item 12		Collected at CRF.
ABC13	num	Item 13		Collected at CRF.
ABC14	num	Item 14		Collected at CRF.
ABC15	num	Item 15		Collected at CRF.
ABC16	num	Item 16		Collected at CRF.
ABC17	num	Item 17		Collected at CRF.
ABC18	num	Item 18		Collected at CRF.
ABC19	num	Item 19		Collected at CRF.
ABC20	num	Item 20		Collected at CRF.
ABC21	num	Item 21		Collected at CRF.
ABC22	num	Item 22		Collected at CRF.
ABC23	num	Item 23		Collected at CRF.
ABC24	num	Item 24		Collected at CRF.
ABC25	num	Item 25		Collected at CRF.
ABC26	num	Item 26		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABC27	num	Item 27		Collected at CRF.
ABC28	num	Item 28		Collected at CRF.
ABC29	num	Item 29		Collected at CRF.
ABC30	num	Item 30		Collected at CRF.
ABC31	num	Item 31		Collected at CRF.
ABC32	num	Item 32		Collected at CRF.
ABC33	num	Item 33		Collected at CRF.
ABC34	num	Item 34		Collected at CRF.
ABC35	num	Item 35		Collected at CRF.
ABC36	num	Item 36		Collected at CRF.
ABC37	num	Item 37		Collected at CRF.
ABC38	num	Item 38		Collected at CRF.
ABC39	num	Item 39		Collected at CRF.
ABC40	num	Item 40		Collected at CRF.
ABC41	num	Item 41		Collected at CRF.
ABC42	num	Item 42		Collected at CRF.
ABC43	num	Item 43		Collected at CRF.
ABC44	num	Item 44		Collected at CRF.
ABC45	num	Item 45		Collected at CRF.
ABC46	num	Item 46		Collected at CRF.
ABC47	num	Item 47		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABC48	num	Item 48		Collected at CRF.
ABC49	num	Item 49		Collected at CRF.
ABC50	num	Item 50		Collected at CRF.
ABC51	num	Item 51		Collected at CRF.
ABC52	num	Item 52		Collected at CRF.
ABC53	num	Item 53		Collected at CRF.
ABC54	num	Item 54		Collected at CRF.
ABC55	num	Item 55		Collected at CRF.
ABC56	num	Item 56		Collected at CRF.
ABC57	num	Item 57		Collected at CRF.
ABC58	num	Item 58		Collected at CRF.
DFPL41	num	Plate 41		Collected at CRF.
DFPL42	num	Plate 42		Collected at CRF.
DFPL43	num	Plate 43		Collected at CRF.
DFPL44	num	Plate 44		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse events
Unique identifier	DCRFID, AEPREF, RANDDY, DFSEQ
Sorted by	DCRFID, AEPREF, RANDDY, DFSEQ
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: INIT80, AESEQV, AE_V, AEFROMD1, AEFROMD2, AETOD1, AETOD2, RANDD1, MEDCODE, RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DFSEQ	num	AE Pg No.		Collected at CRF.
AE	num	Adverse Events?		Collected at CRF.
AESEQNO	num	AE Number Calculated		Collected at CRF.
AEJOI	char	Data Entry Coding Term		Collected at CRF.
ZAESV	num	Severity		Collected at CRF.
ZAESER	num	Serious?		Collected at CRF.
ZAERELAT	num	Relation To Study Drug		Collected at CRF.
ZAEACT1	num	Action Taken 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAECNRX	num	Concom Therapy Required?		Collected at CRF.
ZAEOU	num	Outcome		Collected at CRF.
DFPL80	num	Plate 80		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
AEINCL	char	AE Included Term		Collected at CRF.
AEPREF	char	Adverse Event Preferred Term		Collected at CRF.
AEWHONUM	char	AE Who Code		Collected at CRF.
AESOC	char	AE System Organ Class		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.
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
AEFROMDY	num	Relative SAS Start Day		If AEFROMD1 and REF.DATE not missing then perform below logic to calculate AEFROMDY, If AEFROMD1 less than REF.DATE then (AEFROMD1 - REF.DATE). Else if AEFROMD1 is greater than equal to REF.DATE then (AEFROMD1- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
AETODY	num	Relative SAS Stop Day		If AETOD1 and REF.DATE not missing then perform below logic to calculate AETODY, If AETOD1 less than REF.DATE then (AETOD1 - REF.DATE). Else if AETOD1 is greater than equal to REF.DATE then (AETOD1- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.4. Childhood Autism Rating Scale (CARS) – CARS

Dataset	CARS
Creating program	cars.sas
Description	Childhood Autism Rating Scale (CARS)
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT40,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CARS1	num	Cars I - Relating To People		Collected at CRF.
CARS2	num	Cars II - Imitation		Collected at CRF.
CARS3	num	Cars III - Emotional Response		Collected at CRF.
CARS4	num	Cars IV - Body Use		Collected at CRF.
CARS5	num	Cars V - Object Use		Collected at CRF.
CARS6	num	Cars VI - Adaptaion To Change		Collected at CRF.

Variable	Type	Label	Codes	Comments
CARS7	num	Cars VII - Visual Response		Collected at CRF.
CARS8	num	Cars VIII - Listening Response		Collected at CRF.
CARS9	num	Cars IX - Taste, Smell, And Touch Respon		Collected at CRF.
CARS10	num	Cars X - Fear Or Nervousness		Collected at CRF.
CARS11	num	Cars XI - Verbal Communication		Collected at CRF.
CARS12	num	Cars XII - Non-Verbal Communication		Collected at CRF.
CARS13	num	Cars XIII - Activity Level		Collected at CRF.
CARS14	num	Cars XIV - Level And Consistency of Inte		Collected at CRF.
CARS15	num	Cars XV - General Impressions		Collected at CRF.
SCORE	num	Total Cars Score Verbatim		Collected at CRF.
CALCSCOR	num	Calculated Total Cars Score		Collected at CRF.
DFPL40	num	Plate 40		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.5.Code Breaking – CBREAK

Dataset	CBREAK
Creating program	cbreak.sas
Description	Code Breaking
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: CBREAKD1,CBREAKD2,BYWHOM,INIT92,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CBROKEN	num	Code Broken?		Collected at CRF.
HR	num	Code Break Hour		Collected at CRF.
MIN	num	Code Breaking Min		Collected at CRF.
CBREAKT	num	SAS Calculated Time		Collected at CRF.
REASON	char	Reason Code Broken?		Collected at CRF.
DFPL92	num	Plate 92		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
CBREAKDY	num	Relative SAS Code Break Day		If CBREAKD1 and REF.DATE not missing then perform below logic to calculate CBREAKDY, If CBREAKD1 less than REF.DATE then (CBREAKD1 - REF.DATE). Else if CBREAKD1 is greater than equal to REF.DATE then (CBREAKD1- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.6.Clinical Global Impression (CGI) – CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impression (CGI)
Unique identifier	DCRFID,DFSEQ
Sorted by	DCRFID,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT57,INIT157,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
CGIPPD	num	CGI of Subject's PPD?		Collected at CRF.
CGICHG	num	Change from Baseline		Collected at CRF.
DFPL57	num	Plate 57		Collected at CRF.
DFPL157	num	Plate 157		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.7. 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.

1.4.8.Cognitive Tests – COGTESTS

Dataset	COGTESTS
Creating program	cogtests.sas
Description	Cognitive Tests
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT30,INIT31,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
COGTEST	num	Cognitive Test Performed		Collected at CRF.
SCORE	num	Test Score		Collected at CRF.
VSCORE	num	Vineland Score		Collected at CRF.
PDDTYPE	num	PDD Type		Collected at CRF.
DFPL30	num	Plate 30		Collected at CRF.
DFPL31	num	Plate 31		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.9. Comments – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Empty data will be submitted.
DCRFID	char	Crf Id Assigned for De-Identity		Empty data will be submitted.
DFSEQ	num	Visit Number		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
DFPLATE	num	Plate Number		Empty data will be submitted.
RANDGRP	num	Randomization Group		Empty data will be submitted.
RANDDY	num	Relative SAS Randomization Day		Empty data will be submitted.

1.4.10. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
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: CONRX_V,CFROMD1,CFROMD2,CTOD1,CTOD2,INIT70,RANDD1,MEDCODE, RREFNO,CTIND_V,ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9,ATCTEXT6,AT CTEXT7,ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DFSEQ	num	Conmed Page Number		Collected at CRF.
CONMED	num	Any Conmeds?		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTSEQNO	num	Calculated Sequence Number		Collected at CRF.
CTSEQV	num	Verbatim Sequence Number		Collected at CRF.
CONRX	char	Who Name Of Conmed		Collected at CRF.
CTDOSE	char	Dose		Collected at CRF.
CTUNIT	char	Unit		Collected at CRF.
CTFREQ	char	Frequency Of Dose		Collected at CRF.
CTROUTE	char	Route Of Administration		Collected at CRF.
CTPRIOR	num	Pretrial?		Collected at CRF.
CTONGO	num	Therapy Ongoing Trial?		Collected at CRF.
DFPL70	num	Plate 70		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
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.
ATCTEXT0	char	ATC Text 0		Collected at CRF.
ATCTEXT1	char	ATC Text 1		Collected at CRF.
ATCTEXT2	char	ATC Text 2		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCTEXT3	char	ATC Text 3		Collected at CRF.
ATCTEXT4	char	ATC Text 4		Collected at CRF.
ATCTEXT5	char	ATC Text 5		Collected at CRF.
RXPREF	char	Preferred Name		Collected at CRF.
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
CFROMDY	num	Relative SAS Therapy Start Day		If CFROMD1 and REF.DATE not missing then perform below logic to calculate CFROMDY, If CFROMD1 less than REF.DATE then (CFROMD1 - REF.DATE). Else if CFROMD1 is greater than equal to REF.DATE then (CFROMD1- REF.DATE) +1.
CTODY	num	Relative SAS Therapy Stop Day		If CTOD1 and REF.DATE not missing then perform below logic to calculate CTODY, If CTOD1 less than REF.DATE then (CTOD1 - REF.DATE). Else if CTOD1 is greater than equal to REF.DATE then (CTOD1- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.11. Decode – DECODE

Dataset	DECODE
Creating program	decode.sas
Description	Decode
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
RANDGRP	num	Randomization Group		Collected at CRF.

1.4.12. Medical and Surgical History, Concomitant Diseases – DISEASE

Dataset	DISEASE
Creating program	disease.sas
Description	Medical and Surgical History, Concomitant Diseases
Unique identifier	DCRFID,DSSYSTEM,RANDDY,DFSEQ
Sorted by	DCRFID,DSSYSTEM,RANDDY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NOTSP,ACTSP,INIT8,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
DSSYSTEM	char	Body System		Collected at CRF.
HISTORY	num	History Status		Collected at CRF.
NOTACT	num	None or Not Active		Collected at CRF.
ACTIVE	num	Active/Not Active		Collected at CRF.
DFPL8	num	Plate 8		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1-REF.DATE)+1.

1.4.13. Electrocardiogram (12-lead ECG) – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram (12-lead ECG)
Unique identifier	DCRFID,ECGDY
Sorted by	DCRFID,ECGDY
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: ECGD1,ECGD2,ECGABNSP,INIT32,INIT132,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORMAL	num	ECG Normal?		Collected at CRF.
RELCHG	num	Any Relevant Changes from V1?		Collected at CRF.
DFPL32	num	Plate 32		Collected at CRF.
DFPL132	num	Plate 132		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
ECGDY	num	Relative SAS ECG Day Performed		If ECGD1 and REF.DATE not missing then perform below logic to calculate ECGDY, If ECGD1 less than REF.DATE then (ECGD1 - REF.DATE). Else if ECGD1 is greater than equal to REF.DATE then (ECGD1 - REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1 - REF.DATE) +1.

1.4.14. ECG EVAL from Expert – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ECG EVAL from Expert
Unique identifier	DCRFID,EEASPECT,EEEVAL,VISIT,ECG_DY
Sorted by	DCRFID,EEASPECT,EEEVAL,VISIT,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
ECGSRCE	char	Source ECG Reading		Collected at CRF.
TRIAL	char	Trial Id.		Collected at CRF.
EEASPECT	char	ECG Aspect		Collected at CRF.
EEEVAL	char	ECG Evaluation		Collected at CRF.
VISIT	num	Visit		Collected at CRF.
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
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.

1.4.15. ECG PARAMS from Expert – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG PARAMS from Expert
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: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial Id.		Collected at CRF.
ECGSRCE	char	Source ECG Reading		Collected at CRF.
ECGPAR	char	ECG Parameter		Collected at CRF.
ECGPAR_U	char	ECG Measurement Unit		Collected at CRF.
EPSEQNO	num	Sequence Number		Collected at CRF.
ECGVAL	num	ECG Measurement		Collected at CRF.
VISIT	num	Visit		Collected at CRF.
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity

Variable	Type	Label	Codes	Comments
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.

1.4.16. Extrapyramidal Symptom Rating Scale (ESRS) – ESRS

Dataset	ESRS
Creating program	esrs.sas
Description	Extrapyramidal Symptom Rating Scale (ESRS)
Unique identifier	DCRFID,RANDDY,DFSEQ
Sorted by	DCRFID,RANDDY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VISITD1,VISITD2,INIT50,INIT51,INIT52,INIT53,INIT54,INIT55,INIT56,INIT150,INIT151,INIT152,INIT153,INIT154,INIT155,INIT156,DFPL150,DFPL151,DFPL152,DFPL153,DFPL154,DFPL155,DFPL156,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PARK01	num	I. Q1		Collected at CRF.
PARK02	num	I. Q2		Collected at CRF.
PARK03	num	I. Q3		Collected at CRF.
PARK04	num	I. Q4		Collected at CRF.
PARK05	num	I. Q5		Collected at CRF.
PARK06	num	I. Q6		Collected at CRF.
PARK07	num	I. Q7		Collected at CRF.
PARK08	num	I. Q8		Collected at CRF.
PARK09	num	I. Q9		Collected at CRF.
PARK10	num	I. Q10		Collected at CRF.
PARK11	num	I. Q11		Collected at CRF.
PARK12	num	I. Q12		Collected at CRF.
BPARK1	num	II. Q1		Collected at CRF.
BPARK2	num	II. Q2		Collected at CRF.
BPARK31	num	II. Q3.1		Collected at CRF.
BPARK32	num	II. Q3.2		Collected at CRF.
BPARK33	num	II. Q3.3		Collected at CRF.
BPARK34	num	II. Q3.4		Collected at CRF.
BPARK4	num	II. Q4		Collected at CRF.
BPARK51	num	II. Q5.1		Collected at CRF.
BPARK52	num	II. Q5.2		Collected at CRF.

Variable	Type	Label	Codes	Comments
BPARK53	num	II. Q5.3		Collected at CRF.
BPARK54	num	II. Q5.4		Collected at CRF.
BPARK55	num	II. Q5.5		Collected at CRF.
BPARK56	num	II. Q5.6		Collected at CRF.
BPARK57	num	II. Q5.7		Collected at CRF.
BPARK58	num	II. Q5.8		Collected at CRF.
BPARK6	num	II. Q6		Collected at CRF.
BPARK7	num	II. Q7		Collected at CRF.
BPARK8	num	II. Q8		Collected at CRF.
CDYST101	num	III. Q1.1		Collected at CRF.
CDYST102	num	III. Q1.2		Collected at CRF.
CDYST103	num	III. Q1.3		Collected at CRF.
CDYST104	num	III. Q1.4		Collected at CRF.
CDYST105	num	III. Q1.5		Collected at CRF.
CDYST106	num	III. Q1.6		Collected at CRF.
CDYST107	num	III. Q1.7		Collected at CRF.
CDYST108	num	III. Q1.8		Collected at CRF.
CDYST109	num	III. Q1.9		Collected at CRF.
CDYST110	num	III. Q1.10		Collected at CRF.
CDYST201	num	III. Q2.1		Collected at CRF.
CDYST202	num	III. Q2.2		Collected at CRF.

Variable	Type	Label	Codes	Comments
CDYST203	num	III. Q2.3		Collected at CRF.
CDYST204	num	III. Q2.4		Collected at CRF.
CDYST205	num	III. Q2.5		Collected at CRF.
CDYST206	num	III. Q2.6		Collected at CRF.
CDYST207	num	III. Q2.7		Collected at CRF.
CDYST208	num	III. Q2.8		Collected at CRF.
CDYST209	num	III. Q2.9		Collected at CRF.
CDYST210	num	III. Q2.10		Collected at CRF.
DDYSK1	num	IV. Q1		Collected at CRF.
DDYSK2	num	IV. Q2		Collected at CRF.
DDYSK3	num	IV. Q3		Collected at CRF.
DDYSK4	num	IV. Q4		Collected at CRF.
DDYSK5	num	IV. Q5		Collected at CRF.
DDYSK6	num	IV. Q6		Collected at CRF.
DDYSK7	num	IV. Q7		Collected at CRF.
FDYSKCGI	num	CGI Severity Dyskinesia		Collected at CRF.
SPARKCGI	num	CGI Severity Parkinsonism		Collected at CRF.
SDYSTCGI	num	CGI Severity Dystonia		Collected at CRF.
ESTAGEP	num	Q8: Stage Parkinsonism		Collected at CRF.
DFPL50	num	Plate 50		Collected at CRF.
DFPL51	num	Plate 51		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL52	num	Plate 52		Collected at CRF.
DFPL53	num	Plate 53		Collected at CRF.
DFPL54	num	Plate 54		Collected at CRF.
DFPL55	num	Plate 55		Collected at CRF.
DFPL56	num	Plate 56		Collected at CRF.
PLTINDEX	num	Pltindex		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE)+1.

1.4.17. Final Laboratory Data – FINALLAB

Dataset	FINALLAB
Creating program	finallab.sas
Description	Final Laboratory Data
Unique identifier	DCRFID, LABTEST, LABVAL, RANDDY, DFSEQ
Sorted by	DCRFID, LABTEST, LABVAL, RANDDY, DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BIRTHD, COLDT, SERVDT, INV, INIT, REQNO, REASON, COM1, LABV, RANDD1, MEDCODE, RREFNO

Variable	Type	Label	Codes	Comments
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
COMPLETE	num	Entire Trial Completed?		Collected at CRF.
COLTM	num	Coltm		Collected at CRF.
TRL_NAME	char	Trl_Name		Collected at CRF.
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
SEX	num	Sex		Collected at CRF.
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.
VISNO	num	Visno		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFSEQ	num	Dfseq		Collected at CRF.
VISNAME	char	Visname		Collected at CRF.
VISTYPE	char	Vistype		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
LABTEST	char	Labtest		Collected at CRF.
LABVAL	num	Labval		Collected at CRF.
LABLOW	num	Lablow		Collected at CRF.
LABUPP	num	Labupp		Collected at CRF.
RFLAG	char	Rflag		Collected at CRF.
LABVALV	char	Labvalv		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
COLDY	num	Relative Col Day		If COLDT and REF.DATE not missing then perform below logic to calculate COLDY, If COLDT less than REF.DATE then (COLDT - REF.DATE). Else if COLDT is greater than equal to REF.DATE then (COLDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SERVDY	num	Relative Serv Day		If SERVDT and REF.DATE not missing then perform below logic to calculate SERVDY, If SERVDT less than REF.DATE then (SERVDT - REF.DATE). Else if SERVDT is greater than equal to REF.DATE then (SERVDT- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.18. Inclusion / Exclusion Criteria – INCLEXCL

Dataset	INCLEXCL
Creating program	inclexcl.sas
Description	Inclusion / Exclusion Criteria
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT1,INIT2,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
INCL1	num	Inclusion Criteria #1		Collected at CRF.
INCL2	num	Inclusion Criteria #2		Collected at CRF.
INCL3	num	Inclusion Criteria #3		Collected at CRF.
INCL4	num	Inclusion Criteria #4		Collected at CRF.
INCL5	num	Inclusion Criteria #5		Collected at CRF.
INCL6	num	Inclusion Criteria #6		Collected at CRF.
INCL7	num	Inclusion Criteria #7		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCL1	num	Exclusion Criteria #1		Collected at CRF.
EXCL2	num	Exclusion Criteria #2		Collected at CRF.
EXCL3	num	Exclusion Criteria #3		Collected at CRF.
EXCL4	num	Exclusion Criteria #4		Collected at CRF.
EXCL5	num	Exclusion Criteria #5		Collected at CRF.
EXCL6	num	Exclusion Criteria #6		Collected at CRF.
EXCL7	num	Exclusion Criteria #7		Collected at CRF.
EXCL8	num	Exclusion Criteria #8		Collected at CRF.
EXCL9	num	Exclusion Criteria #9		Collected at CRF.
EXCL10	num	Exclusion Criteria #10		Collected at CRF.
EXCL11	num	Exclusion Criteria #11		Collected at CRF.
EXCL12	num	Exclusion Criteria #12		Collected at CRF.
DFPL1	num	Plate 1		Collected at CRF.
DFPL2	num	Plate 2		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.19. Principal Investigator's Statement Concerning Data Verification – INVSTMT

Dataset	INVSTMT
Creating program	invstmt.sas
Description	Principal Investigator's Statement Concerning Data Verificat
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: SIGND1,SIGND2,INIT91,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
SIGNED	num	Investigator Signature?		Collected at CRF.
DFPL91	num	Plate 91		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
SIGNDY	num	Relative SAS Day of Signature		If SIGND1 and REF.DATE not missing then perform below logic to calculate SIGNDY, If SIGND1 less than REF.DATE then (SIGND1 - REF.DATE). Else if SIGND1 is greater than equal to REF.DATE then (SIGND1-REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1-REF.DATE) +1.

1.4.20. Laboratory data - Hematology, Biochemistry and Urinalysis – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory data - Hematology, Biochemistry and Urinalysis
Unique identifier	DCRFID,SAMPDY
Sorted by	DCRFID,SAMPDY
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: SAMPD1,SAMPD2,INIT32,INIT132,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
FASTED	num	Subject Fasted?		Collected at CRF.
CHANGES	num	Any Relevant Changes?		Collected at CRF.
DFPL32	num	Plate 32		Collected at CRF.
DFPL132	num	Plate 132		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPDY	num	Relative SAS Sample Lab Day		If SAMPD1 and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPD1 less than REF.DATE then (SAMPD1 - REF.DATE). Else if SAMPD1 is greater than equal to REF.DATE then (SAMPD1- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.21. Labpatho – LABPATHO

Dataset	LABPATHO
Creating program	labpatho.sas
Description	Labpatho
Unique identifier	LABTEST
Sorted by	LABTEST
Notes	

Variable	Type	Label	Codes	Comments
LABTEST	char	Lab Test		Collected at CRF.
SEX	char	Sex		Collected at CRF.

Variable	Type	Label	Codes	Comments
LOWAGE	num	Low Age		Collected at CRF.
HIGHAGE	num	High Age		Collected at CRF.
LOWLIMIT	num	Lower Limit		Collected at CRF.
UPPLIMIT	num	Upper Limit		Collected at CRF.
UNITS	char	Units		Collected at CRF.
CFACTOR	num	Conversion Factor		Collected at CRF.
SIUNIT	char	Standard International Unit		Collected at CRF.

1.4.22. Map – MAP

Dataset	MAP
Creating program	map.sas
Description	Map
Unique identifier	TABLE_NA,SEQ_NO
Sorted by	TABLE_NA,SEQ_NO
Notes	

Variable	Type	Label	Codes	Comments
TABLE_NA	char	Table_Name		Collected at CRF.
TABLE_LA	char	Table_Label		Collected at CRF.
VARIABLE	char	Variable		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABEL	char	Label		Collected at CRF.
DATATYPE	char	Datatype		Collected at CRF.
FORMATLE	num	Formatlength		Collected at CRF.
LENGTH	num	Length		Collected at CRF.
SEQ_NO	num	Seq_No		Collected at CRF.
SORT_NO	num	Sort_No		Collected at CRF.

1.4.23. Nisonger Child Behaviour Rating form: Parent Version – NISONGER

Dataset	NISONGER
Creating program	nisonger.sas
Description	Nisonger Child Behaviour Rating form: Parent Version
Unique identifier	DCRFID,COMPBY,RANDDY,DFSEQ
Sorted by	DCRFID,COMPBY,RANDDY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SPECIALA,SPECIALB,SPECIALC,SPECIALD,INIT45,INIT46,INIT47,INIT48,INIT49, RANDD1,MEDCODE,RREFNO,COMPSP

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity

Variable	Type	Label	Codes	Comments
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
COMPBY	num	Nisonger Completed By		Collected at CRF.
NIS201	num	II. Q1		Collected at CRF.
NIS202	num	II. Q2		Collected at CRF.
NIS203	num	II. Q3		Collected at CRF.
NIS204	num	II. Q4		Collected at CRF.
NIS205	num	II. Q5		Collected at CRF.
NIS206	num	II. Q6		Collected at CRF.
NIS207	num	II. Q7		Collected at CRF.
NIS208	num	II. Q8		Collected at CRF.
NIS209	num	II. Q9		Collected at CRF.
NIS210	num	II. Q10		Collected at CRF.
NIS301	num	III. Q1		Collected at CRF.
NIS302	num	III. Q2		Collected at CRF.
NIS303	num	III. Q3		Collected at CRF.
NIS304	num	III. Q4		Collected at CRF.
NIS305	num	III. Q5		Collected at CRF.
NIS306	num	III. Q6		Collected at CRF.
NIS307	num	III. Q7		Collected at CRF.
NIS308	num	III. Q8		Collected at CRF.

Variable	Type	Label	Codes	Comments
NIS309	num	III. Q9		Collected at CRF.
NIS310	num	III. Q10		Collected at CRF.
NIS311	num	III. Q11		Collected at CRF.
NIS312	num	III. Q12		Collected at CRF.
NIS313	num	III. Q13		Collected at CRF.
NIS314	num	III. Q14		Collected at CRF.
NIS315	num	III. Q15		Collected at CRF.
NIS316	num	III. Q16		Collected at CRF.
NIS317	num	III. Q17		Collected at CRF.
NIS318	num	III. Q18		Collected at CRF.
NIS319	num	III. Q19		Collected at CRF.
NIS320	num	III. Q20		Collected at CRF.
NIS321	num	III. Q21		Collected at CRF.
NIS322	num	III. Q22		Collected at CRF.
NIS323	num	III. Q23		Collected at CRF.
NIS324	num	III. Q24		Collected at CRF.
NIS325	num	III. Q25		Collected at CRF.
NIS326	num	III. Q26		Collected at CRF.
NIS327	num	III. Q27		Collected at CRF.
NIS328	num	III. Q28		Collected at CRF.
NIS329	num	III. Q29		Collected at CRF.

Variable	Type	Label	Codes	Comments
NIS330	num	III. Q30		Collected at CRF.
NIS331	num	III. Q31		Collected at CRF.
NIS332	num	III. Q32		Collected at CRF.
NIS333	num	III. Q33		Collected at CRF.
NIS334	num	III. Q34		Collected at CRF.
NIS335	num	III. Q35		Collected at CRF.
NIS336	num	III. Q36		Collected at CRF.
NIS337	num	III. Q37		Collected at CRF.
NIS338	num	III. Q38		Collected at CRF.
NIS339	num	III. Q39		Collected at CRF.
NIS340	num	III. Q40		Collected at CRF.
NIS341	num	III. Q41		Collected at CRF.
NIS342	num	III. Q42		Collected at CRF.
NIS343	num	III. Q43		Collected at CRF.
NIS344	num	III. Q44		Collected at CRF.
NIS345	num	III. Q45		Collected at CRF.
NIS346	num	III. Q46		Collected at CRF.
NIS347	num	III. Q47		Collected at CRF.
NIS348	num	III. Q48		Collected at CRF.
NIS349	num	III. Q49		Collected at CRF.
NIS350	num	III. Q50		Collected at CRF.

Variable	Type	Label	Codes	Comments
NIS351	num	III. Q51		Collected at CRF.
NIS352	num	III. Q52		Collected at CRF.
NIS353	num	III. Q53		Collected at CRF.
NIS354	num	III. Q54		Collected at CRF.
NIS355	num	III. Q55		Collected at CRF.
NIS356	num	III. Q56		Collected at CRF.
NIS357	num	III. Q57		Collected at CRF.
NIS358	num	III. Q58		Collected at CRF.
NIS359	num	III. Q59		Collected at CRF.
NIS360	num	III. Q60		Collected at CRF.
NIS361	num	III. Q61		Collected at CRF.
NIS362	num	III. Q62		Collected at CRF.
NIS363	num	III. Q63		Collected at CRF.
NIS364	num	III. Q64		Collected at CRF.
NIS365	num	III. Q65		Collected at CRF.
NIS366	num	III. Q66		Collected at CRF.
DFPL45	num	Plate 45		Collected at CRF.
DFPL46	num	Plate 46		Collected at CRF.
DFPL47	num	Plate 47		Collected at CRF.
DFPL48	num	Plate 48		Collected at CRF.
DFPL49	num	Plate 49		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1-REF.DATE)+1.

1.4.24. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID,PESYSTEM,RANDDY,DFSEQ
Sorted by	DCRFID,PESYSTEM,RANDDY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXAMV,CHANGEV,INIT13,INIT113,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESYSTEM	char	Body Part Or System		Collected at CRF.
PERESULT	num	Normal/Abnormal Results		Collected at CRF.
CHRESULT	num	Change/No Change Results		Collected at CRF.
DFPL13	num	Plate 13		Collected at CRF.
DFPL113	num	Plate 113		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.25. Randomization Information – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization Information
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: RANDD1,RANDD2,INIT2,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
DFPL2	num	Plate 2		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1-REF.DATE)+1.

1.4.26. Template – TEMPLATE

Dataset	TEMPLATE
Creating program	template.sas
Description	Template
Unique identifier	DATASET,SEQ
Sorted by	DATASET,SEQ
Notes	

Variable	Type	Label	Codes	Comments
SEQ	num	Sequence Number		Collected at CRF.
VAR	char	Variable Name		Collected at CRF.
LGT	num	Variable Length		Collected at CRF.
TYP	char	Variable Type		Collected at CRF.
FMT	char	Variable Format		Collected at CRF.
INF	char	Variable Informat		Collected at CRF.
LBL	char	Variable Label		Collected at CRF.
DTSLBL	char	Dataset Label		Collected at CRF.
DTSEQ	num	Dataset Sequence		Collected at CRF.
DATASET	char	Dataset Name		Collected at CRF.

1.4.27. Administration of Trial Medication – TRLMED

Dataset	TRLMED
Creating program	trlmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID, TMFROMDY
Sorted by	DCRFID, TMFROMDY
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: TMFROMD1, TMFROMD2, TMTOD1, TMTOD2, TMREASV, INIT60, RANDD1, MEDCODE, RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Trial Meds Page Number		Collected at CRF.
TSEQNO	num	Calculated Sequence Number		Collected at CRF.
TMDOSE	num	Dose Amount (mg/kg/day)		Collected at CRF.
AM	num	AM Dosage		Collected at CRF.
PM	num	PM Dosage		Collected at CRF.
TMREAS1	num	Per Protocol?		Collected at CRF.
TMREAS2	num	Due to AE?		Collected at CRF.

Variable	Type	Label	Codes	Comments
DFPL60	num	Plate 60		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.
TMFROMDY	num	Relative SAS Dose Start Day		If TMFROMD1 and REF.DATE not missing then perform below logic to calculate TMFROMDY, If TMFROMD1 less than REF.DATE then (TMFROMD1 - REF.DATE). Else if TMFROMD1 is greater than equal to REF.DATE then (TMFROMD1- REF.DATE) +1.
TMTODY	num	Relative SAS Dose Ended Day		If TMTOD1 and REF.DATE not missing then perform below logic to calculate TMTODY, If TMTOD1 less than REF.DATE then (TMTOD1 - REF.DATE). Else if TMTOD1 is greater than equal to REF.DATE then (TMTOD1- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.28. 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 or due to repetition of the information: TTFROMD1,TTFROMD2,INIT90,RANDD1,MEDCODE,RREFNO,PROTSP, TTREAS_V

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
COMPLETE	num	Entire Trial Completed?		Collected at CRF.
TTREAS	num	Reason Trial Not Complete		Collected at CRF.
AE1	num	AE Number Causing Termin		Collected at CRF.
AE2	num	AE Number Causing Termin		Collected at CRF.
AE3	num	AE Number Causing Termin		Collected at CRF.
DFPL90	num	Plate 90		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
TTFROMDY	num	Relative SAS Day of Trial Termination		If TTFROMD1 and REF.DATE not missing then perform below logic to calculate TTFROMDY, If TTFROMD1 less than REF.DATE then (TTFROMD1 - REF.DATE). Else if TTFROMD1 is greater than equal to REF.DATE then (TTFROMD1- REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.

1.4.29. Visual Analogue Scale – VAS

Dataset	VAS
Creating program	vas.sas
Description	Visual Analogue Scale
Unique identifier	DCRFID,COMPBY,RANDDY,DFSEQ
Sorted by	DCRFID,COMPBY,RANDDY,DFSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INIT57,INIT157,RANDD1,MEDCODE,RREFNO,COMPSP

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
COMPBY	num	Vas Completed By		Collected at CRF.
SYMPT	char	Most Disturbing Symptom		Collected at CRF.
SEVSYMP	num	Severity of Symptom		Collected at CRF.
DFPL57	num	Plate 57		Collected at CRF.
DFPL157	num	Plate 157		Collected at CRF.

Variable	Type	Label	Codes	Comments
RANDGRP	num	Randomization Group		Collected at CRF.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1-REF.DATE)+1.

1.4.30. Vdates – VDATES

Dataset	VDATES
Creating program	vdates.sas
Description	Vdates
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: VDAT10,SDAT10,VDAT20,SDAT20,VDAT30,SDAT30,VDAT40,SDAT40,VDAT50,SDAT50,VDAT60,SDAT60,VDAT70,SDAT70,FIRSTDOS, LASTDOSE,RANDD1, RANDD2, BIRTHD1,BIRTHD2, TTFROMD1, TTFROMD2, LASTASSM, LASTVD, MEDCODE, RREFNO, TTREAS_V

Variable	Type	Label	Codes	Comments
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
PLT10	num	Plt10		Collected at CRF.

Variable	Type	Label	Codes	Comments
PLT20	num	Plt20		Collected at CRF.
PLT30	num	Plt30		Collected at CRF.
PLT40	num	Plt40		Collected at CRF.
PLT50	num	Plt50		Collected at CRF.
PLT60	num	Plt60		Collected at CRF.
PLT70	num	Plt70		Collected at CRF.
TOT601	num	Total Trial Medication		Collected at CRF.
YN701	num	Any Conmeds?		Collected at CRF.
TOT701	num	Total Concomitant Therapy		Collected at CRF.
YN801	num	Adverse Events?		Collected at CRF.
TOT801	num	Total Adverse Events		Collected at CRF.
AGE	char	Age of Subject		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
SEX	num	Sex		Collected at CRF.
COMPLETE	num	Entire Trial Completed?		Collected at CRF.
TTREAS	num	Reason Trial Not Complete		Collected at CRF.
AE1	num	AE Number Causing Termin		Collected at CRF.
AE2	num	AE Number Causing Termin		Collected at CRF.
AE3	num	AE Number Causing Termin		Collected at CRF.
DFPL90	num	Plate 90		Collected at CRF.
LASTVSQN	num	Last Visit Sequence #		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAYS DRUG	num	Days Subject Received Drug		Collected at CRF.
DCENTRE	char	Centre Number Assigned For De-Identity		Randomly assigned Centre Number For De-Identity
RANDGRP	num	Randomization Group		Collected at CRF.
V10DY	num	Relative Baseline Visit Day		If VDAT10 and REF.DATE not missing then perform below logic to calculate V10DY, If VDAT10 less than REF.DATE then (VDAT10 - REF.DATE). Else if VDAT10 is greater than equal to REF.DATE then (VDAT10 - REF.DATE) +1.
V20DY	num	Relative Visit 2 Day		If VDAT20 and REF.DATE not missing then perform below logic to calculate V20DY, If VDAT20 less than REF.DATE then (VDAT20 - REF.DATE). Else if VDAT20 is greater than equal to REF.DATE then (VDAT20 - REF.DATE) +1.
V30DY	num	Relative Visit 3 Day		If VDAT30 and REF.DATE not missing then perform below logic to calculate V30DY, If VDAT30 less than REF.DATE then (VDAT30 - REF.DATE). Else if VDAT30 is greater than equal to REF.DATE then (VDAT30 - REF.DATE) +1.
V40DY	num	Relative Visit 4 Day		If VDAT40 and REF.DATE not missing then perform below logic to calculate V40DY, If VDAT40 less than REF.DATE then (VDAT40 - REF.DATE). Else if VDAT40 is greater than equal to REF.DATE then (VDAT40 - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
V50DY	num	Relative Visit 5 Day		If VDAT50 and REF.DATE not missing then perform below logic to calculate V50DY, If VDAT50 less than REF.DATE then (VDAT50 - REF.DATE). Else if VDAT50 is greater than equal to REF.DATE then (VDAT50- REF.DATE) +1.
V60DY	num	Relative Visit 6 Day		If VDAT60 and REF.DATE not missing then perform below logic to calculate V60DY, If VDAT60 less than REF.DATE then (VDAT60 - REF.DATE). Else if VDAT60 is greater than equal to REF.DATE then (VDAT60- REF.DATE) +1.
V70DY	num	Relative Final Visit 7 Day		If VDAT70 and REF.DATE not missing then perform below logic to calculate V70DY, If VDAT70 less than REF.DATE then (VDAT70 - REF.DATE). Else if VDAT70 is greater than equal to REF.DATE then (VDAT70- REF.DATE) +1.
FSTDOSDY	num	Relative First Medication Dose Day		If FIRSTDOS and REF.DATE not missing then perform below logic to calculate FSTDOSDY, If FIRSTDOS less than REF.DATE then (FIRSTDOS - REF.DATE). Else if FIRSTDOS is greater than equal to REF.DATE then (FIRSTDOS- REF.DATE) +1.
LSTDOSDY	num	Relative Last Medication Dose Day		If LASTDOSE and REF.DATE not missing then perform below logic to calculate LSTDOSDY, If LASTDOSE less than REF.DATE then (LASTDOSE - REF.DATE). Else if LASTDOSE is greater than equal to REF.DATE then (LASTDOSE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1- REF.DATE) +1.
TTFROMDY	num	Relative SAS Day of Trial Termination		If TTFROMD1 and REF.DATE not missing then perform below logic to calculate TTFROMDY, If TTFROMD1 less than REF.DATE then (TTFROMD1 - REF.DATE). Else if TTFROMD1 is greater than equal to REF.DATE then (TTFROMD1- REF.DATE) +1.
LSTASMDY	num	Relative Last Trial Assessment Day		If LASTASSM and REF.DATE not missing then perform below logic to calculate LSTASMDY, If LASTASSM less than REF.DATE then (LASTASSM - REF.DATE). Else if LASTASSM is greater than equal to REF.DATE then (LASTASSM- REF.DATE) +1.
LASTVDY	num	Relative Last Visit Day		If LASTVD and REF.DATE not missing then perform below logic to calculate LASTVDY, If LASTVD less than REF.DATE then (LASTVD - REF.DATE). Else if LASTVD is greater than equal to REF.DATE then (LASTVD- REF.DATE) +1.

1.4.31. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	DCRFID,VISITDY,DFSEQ
Sorted by	DCRFID,VISITDY,DFSEQ
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: VISITD1,VISITD2,INIT10,INIT11,RANDD1,MEDCODE,RREFNO

Variable	Type	Label	Codes	Comments
DCENTRE	char	Centre Number Assigned for De-Identity		Randomly assigned Centre Number for De-Identity
DCRFID	char	Crf Id Assigned for De-Identity		Randomly assigned Crf Id for De-Identity
DFSEQ	num	Visit Number		Collected at CRF.
WEIGHT	num	Weight (kg)		Collected at CRF.
PULSE	num	Pulse (bpm)		Collected at CRF.
SBP	num	Systolic Blood Pressure		Collected at CRF.
DBP	num	Diastolic Blood Pressure		Collected at CRF.
DFPL10	num	Plate 10		Collected at CRF.
DFPL11	num	Plate 11		Collected at CRF.
RANDGRP	num	Randomization Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative SAS Visit Day		If VISITD1 and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITD1 less than REF.DATE then (VISITD1 - REF.DATE). Else if VISITD1 is greater than equal to REF.DATE then (VISITD1 - REF.DATE) +1.
RANDDY	num	Relative SAS Randomization Day		If RANDD1 and REF.DATE not missing then perform below logic to calculate RANDDY, If RANDD1 less than REF.DATE then (RANDD1 - REF.DATE). Else if RANDD1 is greater than equal to REF.DATE then (RANDD1 - REF.DATE) +1.