Clinical Development

JNJ-17080102

Topmatpep3001i1

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	24 JAN 2017

Table of contents

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.
- Comments dataset will be submitted with zero observations.
- Dataset PCCONC is empty as input and will not be submitted.
- Datasets containing insignificant information will not be submitted. (e.g. BOTL3001, CARD3001 , CODELIST ,DLSCOMM)
- Dataset containing investigator information is sensitive and hence will not be submitted. (e.g. INVEST).
- DMINFDT in DEMOG dataset will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

1.3. Data Files

The Topmatpep3001i1 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics (DM)– DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics (DM)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, DMACTDT, DMSCRDT, SUBJINIT, IVFINIT, IVNAME, BIRTHDT, DMINFDT, IVID, RACESPEC, COUNTRYC, CIVNAME

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACEC	num	Race Code		Collected at CRF.
RACE	char	Race		Collected at CRF.
DCOUNTRY	char	De-Identify Country		Group element to protect PII.
ETHNICC	num	Ethnicity Code		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and REF.DATE not missing then perform below logic to calculate DMACTDY, If DMACTDT less than REF.DATE then (DMACTDT - REF.DATE). Else if DMACTDT is greater than equal to REF.DATE then (DMACTDT- REF.DATE) +1.
DMSCRDY	num	Relative Day First Trial Related Proc		If DMSCRDT and REF.DATE not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than REF.DATE then (DMSCRDT - REF.DATE). Else if DMSCRDT is greater than equal to REF.DATE then (DMSCRDT- REF.DATE) +1.

1.4.2.Adverse Event (AE) – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event (AE)
Unique identifier	DUSUBJID,AEDECOD,AEBODSYS,VISIT,AESEQ
Sorted by	DUSUBJID,AEDECOD,AEBODSYS,VISIT,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,AETERM,AESTDT,AEENDT,AESTDTC,AEENDTC,AESERREF,AEREFSEQ, AESTATC,AESTAT,AESTTM,AEENDTM,AETOXC,AESEX,SOC2,SOC3

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AEBODSYS	char	WHO Body System		Collected at CRF.
AEDECOD1	char	WHO Included Term		Collected at CRF.
AEACTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AEACTTRT	char	Action Taken with Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AEBODSYC	char	Body System Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDECOD	char	WHO Preferred Term		Collected at CRF.
SOC1	char	AE System Organ Class 1		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.

1.4.3. Blister Scheme (BS) – BSCHEME

Dataset	BSCHEME
Creating program	bscheme.sas
Description	Blister Scheme (BS)
Unique identifier	STAGE,TIME,ACT_PILS
Sorted by	STAGE,TIME,ACT_PILS
Notes	

Variable	Type	Label	Codes	Comments
STAGE	char	Stage		Collected at CRF.
TIME	char	Time (AM or PM)		Collected at CRF.
ACT_PILS	num	Active pills		Collected at CRF.

1.4.4. Laboratory Data (CHEM) – CHEM

Dataset	CHEM
Creating program	chem.sas
Description	Laboratory Data (CHEM)
Unique identifier	DUSUBJID, PHASE, LBTYPE, LBTEST, VISIT, LBSEQ
Sorted by	DUSUBJID, PHASE, LBTYPE, LBTEST, VISIT, LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STDNRC, STDRESC, LABSPEC, LBACTDT, LBFAST, LBFASTC, LBPRVID, LBPRVIDC, LBPTM, LBREF, PERIOD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
VISIT	char	Visit		Collected at CRF.
UNITCODE	num	Laboratory unit		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
BATCHID	num	Central LAB batch identifier		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSAMSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBSIGHI	num	Significant Range High		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, If LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

1.4.5.Comments (CT) – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments (CT)
Unique identifier	
Sorted by	
Notes	Comments dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Empty dataset will be submitted
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Empty dataset will be submitted
DSUBJID	char	Subject Number Assigned for De-Identity		Empty dataset will be submitted
DSITEID	char	Site ID Assigned For De-Identity		Empty dataset will be submitted
VISITNUM	num	Visit Number		Empty dataset will be submitted
VISIT	char	Visit		Empty dataset will be submitted
PRDNUM	num	Period Number		Empty dataset will be submitted
PHASENUM	num	Phase Number		Empty dataset will be submitted
PHASE	char	Phase		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
PAGNUM	num	Page Number		Empty dataset will be submitted
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted
DOMAIN	char	Domain of Origin		Empty dataset will be submitted
CTACTDY	num	Relative Actual Day of Comment		Empty dataset will be submitted

1.4.6. Concomitant Meds (CM) – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Meds (CM)
Unique identifier	DUSUBJID, PHASE, CMTYPE, CMGROUP, VISIT, CMSEQ, CMSTDY
Sorted by	DUSUBJID, PHASE, CMTYPE, CMGROUP, VISIT, CMSEQ, CMSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, CMSTDT, CMTERM, CMREAS, CMENDT, CMENDTM, CMPRNC, CMPRN, CMPRIORC, CMPRIOR, CMNONE, CMSTDTC, CMENDTC, CMSTATC, CMSTAT, CMCAUSC, CMCAUS

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMGROUPC	num	Medication Group		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMREGIM	char	Regimen (Dose & Frequency)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMROUTE	char	Route		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
CMCONT	char	Medication Continuing		Collected at CRF.
CMSTTM	num	Start Time of Medication		Collected at CRF.
CMDOSE	char	Dosage		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
CMCLASC	char	ATC Code		Collected at CRF.
BASEAEDC	num	Baseline AEDs Identifier Code		Collected at CRF.
BASEAED	char	Baseline AEDs Identifier		Collected at CRF.
CMCLASC0	char	ATC Code 0		Collected at CRF.
CMCLASC1	char	ATC Code 1		Collected at CRF.
CMCLASC2	char	ATC Code 2		Collected at CRF.
CMCLASC3	char	ATC Code 3		Collected at CRF.
CMCLASC4	char	ATC Code 4		Collected at CRF.
CMCLASC5	char	ATC Code 5		Collected at CRF.
CMCLASC6	char	ATC Code 6		Collected at CRF.
CMCLASC7	char	ATC Code 7		Collected at CRF.
CMCLASC8	char	ATC Code 8		Collected at CRF.
CMCLASC9	char	ATC Code 9		Collected at CRF.
CMCLAS0	char	ATC Text 0		Collected at CRF.
CMCLAS1	char	ATC Text 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCLAS2	char	ATC Text 2		Collected at CRF.
CMCLAS3	char	ATC Text 3		Collected at CRF.
CMCLAS4	char	ATC Text 4		Collected at CRF.
CMCLAS5	char	ATC Text 5		Collected at CRF.
CMCLAS6	char	ATC Text 6		Collected at CRF.
CMCLAS7	char	ATC Text 7		Collected at CRF.
CMCLAS8	char	ATC Text 8		Collected at CRF.
CMCLAS9	char	ATC Text 9		Collected at CRF.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
CMCLAS	char	ATC Text		Collected at CRF.
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.

1.4.7. Disposition (DS) – DS

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition (DS)
Unique identifier	DUSUBJID, DSTYPE, DSREAS, DSSTAT, DSACTDY
Sorted by	DUSUBJID, DSTYPE, DSREAS, DSSTAT, DSACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, DSSCRNC, DSSCRN, DSENDC, DSEND, DSACTDT, DEATHDT, DSRABKRS, PREGDUDT, DSSEQ

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSRSOTH	char	Other Reason - Specify		Collected at CRF.
DSRABKDT	num	Actual Date Randomization Code		Collected at CRF.
DSOLC	num	Continue into Open Label Code		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSACTDY	num	Relative Actual Day Trial Completion		If DSACTDT and REF.DATE not missing then perform below logic to calculate DSACTDY, If DSACTDT less than REF.DATE then (DSACTDT - REF.DATE). Else if DSACTDT is greater than equal to REF.DATE then (DSACTDT- REF.DATE) +1.
DEATHDY	num	Relative Actual Day of Death		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.

1.4.8.Study Drug Info (DI) – DRUGINFO

Dataset	DRUGINFO
Creating program	druginfo.sas
Description	Study Drug Info (DI)
Unique identifier	DUSUBJID, PHASE, VISIT
Sorted by	DUSUBJID, PHASE, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, DIDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
DICHGC	num	Study drug change info Code		Collected at CRF.
DICHG	char	Study drug change info		Collected at CRF.
DISEQ	num	Study drug Date sequence		Collected at CRF.
DIACTC	num	Study drug info action Code		Collected at CRF.
DIACT	char	Study drug info action		Collected at CRF.
DIDY	num	Relative Study drug info Day		If DIDT and REF.DATE not missing then perform below logic to calculate DIDY, If DIDT less than REF.DATE then (DIDT - REF.DATE). Else if DIDT is greater than equal to REF.DATE then (DIDT-REF.DATE) +1.

1.4.9.Electrocardiogram (EG) – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram (EG)
Unique identifier	DUSUBJID, PHASE, EGPOS, EGTEST, EGVTYPE, VISIT
Sorted by	DUSUBJID, PHASE, EGPOS, EGTEST, EGVTYPE, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, EGREF, EGDT, EGPTM, EGQUAL, EGSTRESC, EGPRVID, EGPRVIDC, EGLEAD, EGND, EGCHGC, EGCHG, EGINTOTH, EGCHGOTH

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	Planned Time Point Number		Collected at CRF.
EGACTTM	num	Actual Time of ECG		Collected at CRF.
EGPOS	char	Position		Collected at CRF.
EGTEST	char	ECG Test		Collected at CRF.
EGSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
EGSTUNIT	char	Standard Units		Collected at CRF.
EGORRESN	num	Numeric Result in Original Units		Collected at CRF.
EGORUNIT	char	Original Units		Collected at CRF.
EGINTPC	num	Interpretation Code		Collected at CRF.
EGINTP	char	Interpretation		Collected at CRF.
EGSEQ	num	ECG Sequence Number		Collected at CRF.
EGREADC	num	ECG Reader Code		Collected at CRF.
EGREAD	char	ECG Reader		Collected at CRF.
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF.
EGVTYPE	char	ECG Visit Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
BATCHID	num	Central ECG batch identifier		Collected at CRF.
EGDY	num	Relative Actual Day of ECG		If EGDT and REF.DATE not missing then perform below logic to calculate EGDY, If EGDT less than REF.DATE then (EGDT - REF.DATE). Else if EGDT is greater than equal to REF.DATE then (EGDT-REF.DATE) +1.

1.4.10. Eligibility Information (EL) – ELIGIBLE

Dataset	ELIGIBLE
Creating program	eligible.sas
Description	Eligibility Information (EL)
Unique identifier	DUSUBJID,ELREAS,ELRDTL,ELPHASE,VISIT
Sorted by	DUSUBJID,ELREAS,ELRDTL,ELPHASE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,ELWITHDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
ELNEXTC	num	Subject in next portion of trial Code		Collected at CRF.
ELNEXT	char	Subject in next portion of trial		Collected at CRF.
ELPHASEC	num	Study phase Code		Collected at CRF.
ELPHASE	char	Study phase		Collected at CRF.
ELREASC	num	Reason for withdrawal Code		Collected at CRF.
ELREAS	char	Reason for withdrawal		Collected at CRF.
ELRDTLC	num	Screen failure category Code		Collected at CRF.
ELRDTL	char	Screen failure category		Collected at CRF.
ELSPEC	char	Specify other reason for screen failure		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESEQ	num	AE Sequence Number		Collected at CRF.
ELWITHDY	num	Relative Day of withdrawal		If ELWITHDT and REF.DATE not missing then perform below logic to calculate ELWITHDY, If ELWITHDT less than REF.DATE then (ELWITHDT - REF.DATE). Else if ELWITHDT is greater than equal to REF.DATE then (ELWITHDT- REF.DATE) +1.

1.4.11. Enrollment (EN) – ENROLL

Dataset	ENROLL
Creating program	enroll.sas
Description	Enrollment (EN)
Unique identifier	DUSUBJID, PHASE, VISIT, ENCRES, ENCRIT, ENSEQ
Sorted by	DUSUBJID, PHASE, VISIT, ENCRES, ENCRIT, ENSEQ
Notes	Below listed variables will be dropped from dataset due to missing values: PERIOD, ENACTDT, ENCMETC, ENCMET

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
ENCRIT	char	Inclusion or Exclusion Criterion		Collected at CRF.
ENSEQ	num	Criterion Sequence Number		Collected at CRF.
ENCRESC	num	Criterion Result Code		Collected at CRF.
ENCRES	char	Criterion Result		Collected at CRF.
ENTEXT	char	Criterion Text		Collected at CRF.

1.4.12. Exit/Escape Criteria (ES) – ESCAPE

Dataset	ESCAPE
Creating program	escape.sas
Description	Exit/Escape Criteria (ES)
Unique identifier	DUSUBJID,PHASE,ESESCAP,ESEXIT,VISIT
Sorted by	DUSUBJID,PHASE,ESESCAP,ESEXIT,VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: PERIOD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGNUM	num	Page Number		Collected at CRF.
ESESCAPC	num	Did subject meet escape criteria Code		Collected at CRF.
ESESCAP	char	Did subject meet escape criteria		Collected at CRF.
ESEXITC	num	Did subject exit Code		Collected at CRF.
ESEXIT	char	Did subject exit		Collected at CRF.
ESCRITC	num	Exit criteria Code		Collected at CRF.
ESCRIT	char	Exit criteria		Collected at CRF.

1.4.13. Exposure (EX) – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure (EX)
Unique identifier	DUSUBJID, PHASE, EXBOTLE1, EXVOMIT, VISIT
Sorted by	DUSUBJID, PHASE, EXBOTLE1, EXVOMIT, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, EXSTDT, EXENDT, EXSTTM, EXENDTM, EXCARD1, EXCARD2, EXOTHER, EXBOTLE1, EXBOTLE2, DOSEFREQ, ACTTRT, ROUTE, DOSE, DOSEUNIT, EXGIVEN, EXTMLBL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXDISPS	char	Drug Dispensed Time Point		Collected at CRF.
EXDOSE1	num	Dose administered		Collected at CRF.
EXDUNIT1	char	Dose administered unit		Collected at CRF.
EXVOMITC	num	Did Subject Vomited Code		Collected at CRF.
EXVOMIT	char	Did Subject Vomited		Collected at CRF.
EXADMINC	num	Dose Readministered Code		Collected at CRF.
EXADMIN	char	Dose Readministered		Collected at CRF.
EXDOSE2	num	Dose readministered		Collected at CRF.
EXDUNIT2	char	Dose readministered unit		Collected at CRF.
EXTAKENC	num	Dose taken Code		Collected at CRF.
EXTAKEN	char	Dose taken		Collected at CRF.
EXTITRC	num	Did up-titration follow protocol Code		Collected at CRF.
EXTITR	char	Did up-titration follow protocol		Collected at CRF.
EXTIREAC	num	Reason for Change Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXTIREA	char	Reason for Change		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDT less than REF.DATE then (EXSTDT - REF.DATE). Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.

1.4.14. Laboratory Data (HEMAT) – HEMAT

Dataset	HEMAT
Creating program	hemat.sas
Description	Laboratory Data (HEMAT)
Unique identifier	DUSUBJID, LBDESCR, LBABBR, VISIT, LBACTDY
Sorted by	DUSUBJID, LBDESCR, LBABBR, VISIT, LBACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STDNRC, STDRESC, LABSPEC, LBACTDT, LBFAST, LBFASTC, LBPRVID, LBPRVIDC, LBPTM, LBREF, PERIOD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
VISIT	char	Visit		Collected at CRF.
UNITCODE	num	Laboratory unit		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
BATCHID	num	Central LAB batch identifier		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSAMSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBSIGHI	num	Significant Range High		Collected at CRF.
LBSIGLO	num	Significant Range Low		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, If LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

1.4.15. Intake (IT) – INTAKE

Dataset	INTAKE
Creating program	intake.sas
Description	Intake (IT)
Unique identifier	DUSUBJID,PHASE,ITTYPE,ITVOMIT,ITADMIN,VISIT
Sorted by	DUSUBJID,PHASE,ITTYPE,ITVOMIT,ITADMIN,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,ITACTDT,TPTNUM,TPT,ITCARD1, ITCARD2,ITORRES, ITBOTLE1, ITBOTLE2,ITORRESN,ITORRESU,ACQREF,ITPRVIDC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
ITTREAT	num	Current treatment		Collected at CRF.
ITTRUNIT	char	Current treatment unit		Collected at CRF.
ITSEQ	num	Intake Sequence Number		Collected at CRF.
ITTYPE	char	Intake Type		Collected at CRF.
ITACTTM	char	Actual Time of Intake		Collected at CRF.
ITDOSE1	num	Dose administered		Collected at CRF.
ITDUNIT1	char	Dose administered unit		Collected at CRF.
ITVOMITC	num	Did Subject Vomited Code		Collected at CRF.
ITVOMIT	char	Did Subject Vomited		Collected at CRF.
ITADMINC	num	Dose Readministered Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
ITADMIN	char	Dose Readministered		Collected at CRF.
ITTAKENC	num	Dose taken Code		Collected at CRF.
ITTAKEN	char	Dose taken		Collected at CRF.
ITDOSE2	num	Dose readministered		Collected at CRF.
ITDUNIT2	char	Dose readministered unit		Collected at CRF.
ITACTDY	num	Relative Actual Day of Intake		If ITACTDT and REF.DATE not missing then perform below logic to calculate ITACTDY, If ITACTDT less than REF.DATE then (ITACTDT - REF.DATE). Else if ITACTDT is greater than equal to REF.DATE then (ITACTDT- REF.DATE) +1.

1.4.16. Lab Norms (LN) – LABNORM

Dataset	LABNORM
Creating program	labnorm.sas
Description	Lab Norms (LN)
Unique identifier	SEX,LBTEST,LNSEQ
Sorted by	SEX,LBTEST,LNSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LBPRVIDC,LBPRVID, LBSIFACT,LBSIGHI, LBSIGLO, STDNRC, STDNRHI, STDNRLO

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
LNSEQ	num	Lab Normal Sequence Number		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LNSTDT	num	Lab Normal Range Start Date		Collected at CRF.
LNENDT	num	Lab Normal Range End Date		Collected at CRF.
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
LNHIAGE	num	High Age		Collected at CRF.
LNLOAGE	num	Low Age		Collected at CRF.

Variable	Type	Label	Codes	Comments
LNAGUNIT	char	Age Unit		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
LBTTERM	char	Lab Test Term		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.

1.4.17. Measurement History (HI) – MEASHIST

Dataset	MEASHIST
Creating program	meashist.sas
Description	Measurement History (HI)
Unique identifier	DUSUBJID, PHASE, HITESTCD, VISIT, HISEQ, HIDY
Sorted by	DUSUBJID, PHASE, HITESTCD, VISIT, HISEQ, HIDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, HIDTC, HIDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
HISTATC	num	Measurement history availability Code		Collected at CRF.
HISTAT	char	Measurement history availability Code		Collected at CRF.
HISEQ	num	Sequence number		Collected at CRF.
HITESTCD	char	Measurement test		Collected at CRF.
HIORRESN	num	Measurement result		Collected at CRF.
HIORUNIT	char	Units of measurement		Collected at CRF.
HIDY	num	Relative Day of measurement history		If HIDTC and REF.DATE not missing then perform below logic to calculate HIDY, If HIDTC less than REF.DATE then (HIDTC - REF.DATE). Else if HIDTC is greater than equal to REF.DATE then (HIDTC-REF.DATE) +1.

1.4.18. Measurements (ME) – MEASUR

Dataset	MEASUR
Creating program	measur.sas
Description	Measurements (ME)
Unique identifier	DUSUBJID,SUBJID,SITEID,PAGNUM,MEHEAD,MELEN1,VISIT
Sorted by	DUSUBJID,SUBJID,SITEID,PAGNUM,MEHEAD,MELEN1,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,MEDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
MEHEAD	num	Head circumference		Collected at CRF.
MEHUNIT	char	Measurement of head unit		Collected at CRF.
MELEN1	num	Length of infant 1		Collected at CRF.
MELUNIT1	char	Length unit 1		Collected at CRF.
MELEN2	num	Length of infant 2		Collected at CRF.
MELUNIT2	char	Length unit 2		Collected at CRF.
MELEN3	num	Length of infant 3		Collected at CRF.
MELUNIT3	char	Length unit 3		Collected at CRF.
MEDY	num	Relative Measurements Day		If MEDT and REF.DATE not missing then perform below logic to calculate MEDY, If MEDT less than REF.DATE then (MEDT - REF.DATE). Else if MEDT is greater than equal to REF.DATE then (MEDT-REF.DATE) +1.

1.4.19. Medical History (MH) – MEDHIST

Dataset	MEDHIST
Creating program	medhist.sas
Description	Medical History (MH)
Unique identifier	DUSUBJID, MHBODSYC, PHASE, VISIT, MHACTDY
Sorted by	DUSUBJID, MHBODSYC, PHASE, VISIT, MHACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, MHACTDT, MHTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.
MHBODSYC	num	Body System Code		Collected at CRF.
MHBODSYS	char	Body System		Collected at CRF.
MHSTATC	num	Condition Code		Collected at CRF.
MHSTAT	char	Condition		Collected at CRF.
MHACTDY	num	Relative Actual Day of Collection		If MHACTDT and REF.DATE not missing then perform below logic to calculate MHACTDY, If MHACTDT less than REF.DATE then (MHACTDT - REF.DATE). Else if MHACTDT is greater than equal to REF.DATE then (MHACTDT- REF.DATE) +1.

1.4.20. Neurologic Examination (NR) – NEUREXAM

Dataset	NEUREXAM
Creating program	neurexam.sas
Description	Neurologic Examination (NR)
Unique identifier	DUSUBJID, NREXAM, NRTYPE, NRSTAT, PHASE, VISIT, NRACTDY
Sorted by	DUSUBJID, NREXAM, NRTYPE, NRSTAT, PHASE, VISIT, NRACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, NRACTDT, NRVTYPEC, NRVTYPE, NRDSCR

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
NRSEQ	num	Neuroexam Sequence Number		Collected at CRF.
NREXAMC	num	Neuroexam Code		Collected at CRF.
NREXAM	char	Neuroexam Description		Collected at CRF.
NRTYPEC	num	Type of Examination Code		Collected at CRF.
NRTYPE	char	Type of Examination		Collected at CRF.
NRSTATC	num	Status		Collected at CRF.
NRSTAT	char	Status		Collected at CRF.
NRACTDY	num	Relative Actual Day of Neurological Exam		If NRACTDT and REF.DATE not missing then perform below logic to calculate NRACTDY, If NRACTDT less than REF.DATE then (NRACTDT - REF.DATE). Else if NRACTDT is greater than equal to REF.DATE then (NRACTDT- REF.DATE) +1.

1.4.21. Persisting Adverse Event (PA) – PAE

Dataset	PAE
Creating program	pae.sas
Description	Persisting Adverse Event (PA)
Unique identifier	DUSUBJID,PHASE,AEDECOD1,VISIT,AEENDY
Sorted by	DUSUBJID,PHASE,AEDECOD1,VISIT,AEENDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,AETERM,AEENDT,AEENDTC,AESTDT,AESTDTC,PAELCDT,SOC2,SOC3

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
AEBODSYS	char	WHO Body System		Collected at CRF.
AEBODSYC	char	Body System Code		Collected at CRF.
AEDECOD1	char	WHO Included Term		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDECOD	char	WHO Preferred Term		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AESEVC	num	Severity of Event Code		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PROTOCOL	char	Protocol		Collected at CRF.
SOC1	char	SOC1		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
PAELCDY	num	Relative Day of Last Contact		If PAELCDT and REF.DATE not missing then perform below logic to calculate PAELCDY, If PAELCDT less than REF.DATE then (PAELCDT - REF.DATE). Else if PAELCDT is greater than equal to REF.DATE then (PAELCDT- REF.DATE) +1.

1.4.22. Pccnc – PCCNC

Dataset	PCCNC
Creating program	pccnc.sas
Description	Pccnc
Unique identifier	DUSUBJID,PCCAT,PCPRMTYP,VISIT,PCSTDY
Sorted by	DUSUBJID,PCCAT,PCPRMTYP,VISIT,PCSTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SPPRVID,TPT,SPPRVIDC,ACQREF,PCENTM,PCNRHI,PCNRLO,PCORRES, PCORRESN,PCORUNIT,PCPRVID,PCPRVIDC,PCSPCOM,PCSPEC,PCSTDT, PCSTRESC,PCSTRESN,PCSTUNIT,PCTEST,PERIOD,SAMREF

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TPTNUM	num	Planned Time Point Number		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PCCAT	char	Category for Test or Examination		Collected at CRF.
PCENDT	num	End Date of Specimen Collection		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
PCSEQ	num	Sample Sequence Number		Collected at CRF.
PCSTAT	char	Sample Collection Status		Collected at CRF.
PCSTATC	num	Sample Collection Status Code		Collected at CRF.
PCSTTM	num	Start Time of Specimen Collection		Collected at CRF.
PCVTYPE	char	PK/PD Sample Visit Type		Collected at CRF.
PCVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
PCSTDY	num	Relative Start Day Specimen Collection		If PCSTDT and REF.DATE not missing then perform below logic to calculate PCSTDY, If PCSTDT less than REF.DATE then (PCSTDT - REF.DATE). Else if PCSTDT is greater than equal to REF.DATE then (PCSTDT- REF.DATE) +1.

1.4.23. PKPD Sample (SP) – PCSAMP

Dataset	PCSAMP
Creating program	pcsamp.sas
Description	PKPD Sample (SP)
Unique identifier	DUSUBJID,PHASE,SPCAT,SPVTYPE,VISIT
Sorted by	DUSUBJID,PHASE,SPCAT,SPVTYPE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,SPPRVIDC,SPPRVID,ACQREF,SAMREF,TPT,SPSTDT,SPENDT,SPENTM, SPCOM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
SPCAT	char	Category for Test or Examination		Collected at CRF.
SAMMAT	char	Sample Material		Collected at CRF.
TPTNUM	num	Planned Time Point Number		Collected at CRF.
SAMSEQ	num	Sample Sequence Number		Collected at CRF.
SPSTTM	num	Start Time of Specimen Collection		Collected at CRF.
SPVTYPEC	num	PK/PD Sample Visit Type Code		Collected at CRF.
SPVTYPE	char	PK/PD Sample Visit Type		Collected at CRF.
PCPRMTYP	char	Parameter Type		Collected at CRF.
SPSTATC	num	Sample Collection Status Code		Collected at CRF.
SPSTAT	char	Sample Collection Status		Collected at CRF.
SPSTDY	num	Relative Start Day Specimen Collection		If SPSTDT and REF.DATE not missing then perform below logic to calculate SPSTDY, If SPSTDT less than REF.DATE then (SPSTDT - REF.DATE). Else if SPSTDT is greater than equal to REF.DATE then (SPSTDT- REF.DATE) +1.

1.4.24. Physical Exam (PE) – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Exam (PE)
Unique identifier	DUSUBJID, PHASE, VISIT, PEACTDY
Sorted by	DUSUBJID, PHASE, VISIT, PEACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, PEACTDT, PESYSOTH, PEFIND, PEVTYPEC, PEVTYPE, PEND

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.
PEBODSYC	num	Body System Code		Collected at CRF.
PEBODSYS	char	Body System		Collected at CRF.
PESTATC	num	Exam Result Code		Collected at CRF.
PESTAT	char	Exam Result		Collected at CRF.
PEACTDY	num	Relative Actual Day of Phys Exam		If PEACTDT and REF.DATE not missing then perform below logic to calculate PEACTDY, If PEACTDT less than REF.DATE then (PEACTDT - REF.DATE). Else if PEACTDT is greater than equal to REF.DATE then (PEACTDT- REF.DATE) +1.

1.4.25. Phone (PO) – PHONE

Dataset	PHONE
Creating program	phone.sas
Description	Phone (PO)
Unique identifier	DUSUBJID, POCALLC, PHASE , VISIT, POSEQ
Sorted by	DUSUBJID, POCALLC, PHASE , VISIT, POSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, POACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
POSEQ	num	Call Sequence		Collected at CRF.
POCALLC	num	Phone Call Code		Collected at CRF.
POCALL	char	Phone Call		Collected at CRF.
POACTDY	num	Relative Phone Call Day		If POACTDT and REF.DATE not missing then perform below logic to calculate POACTDY, If POACTDT less than REF.DATE then (POACTDT - REF.DATE). Else if POACTDT is greater than equal to REF.DATE then (POACTDT- REF.DATE) +1.

1.4.26. Premature Status (PR) – PRESTAT

Dataset	PRESTAT
Creating program	prestat.sas
Description	Premature Status (PR)
Unique identifier	DUSUBJID, PHASE, PAGNUM, PRAGE, VISIT
Sorted by	DUSUBJID, PHASE, PAGNUM, PRAGE, VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: PERIOD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGNUM	num	Page Number		Collected at CRF.
PRSTATC	num	Was the Subject Born Preterm Code		Collected at CRF.
PRSTAT	char	Was the Subject Born Preterm		Collected at CRF.
PRAGE	num	Subject Gestational Age at Delivery		Collected at CRF.
PRAGUNIT	char	Age Unit		Collected at CRF.

1.4.27. Protocol Description (PD) – PROTDESC

Dataset	PROTDESC
Creating program	protdesc.sas
Description	Protocol Description (PD)
Unique identifier	COMPND,BLINDING,ACTCONTR,DESIGN
Sorted by	COMPND,BLINDING,ACTCONTR,DESIGN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DEVPROID,SPECPOP

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
COMPND	char	Compound Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMPNDC	char	Compound Number		Collected at CRF.
BLINDING	char	Blinding Level		Collected at CRF.
ACTCONTR	char	Active Control		Collected at CRF.
PLACONTR	char	Placebo Control		Collected at CRF.
DESIGN	char	Trial Design		Collected at CRF.
MULTCENT	char	Multi Center		Collected at CRF.
INDICAT	char	Indication		Collected at CRF.
AGEGRP	char	Age Group		Collected at CRF.
SUBJTYPE	char	Subject Type		Collected at CRF.
PROCSTUD	char	Preceding Study Id		Collected at CRF.
STUDPHAS	char	Phase of Study		Collected at CRF.
CRDMVR	char	CRDM Version Number		Collected at CRF.

1.4.28. Protocol Deviation (PV) – PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviation (PV)
Unique identifier	DUSUBJID,PVDECOD,PHASENUM,PVSEQ
Sorted by	DUSUBJID,PVDECOD,PHASENUM,PVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PVTERM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

1.4.29. Randomization (RA) – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization (RA)
Unique identifier	DUSUBJID, PHASE, PAGNUM, TRTGRP, VISIT, RAACTDY
Sorted by	DUSUBJID, PHASE, PAGNUM, TRTGRP, VISIT, RAACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, RAACTDT, RANDNUM, RAUBDT, STRATUM2, STRATUM3

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
STRATUM1	char	Stratum 1		Collected at CRF.
RASEQ	num	Randomization Sequence Number		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
REGIMEN	char	Regimen Code		Collected at CRF.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and REF.DATE not missing then perform below logic to calculate RAACTDY, If RAACTDT less than REF.DATE then (RAACTDT - REF.DATE). Else if RAACTDT is greater than equal to REF.DATE then (RAACTDT- REF.DATE) +1.

1.4.30. Randomization (RS) – RANDOMPS

Dataset	RANDOMPS
Creating program	randomps.sas
Description	Randomization (RS)
Unique identifier	DUSUBJID, PHASE, VISIT, RAACTDY
Sorted by	DUSUBJID, PHASE, VISIT, RAACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, RAACTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and REF.DATE not missing then perform below logic to calculate RAACTDY, If RAACTDT less than REF.DATE then (RAACTDT - REF.DATE). Else if RAACTDT is greater than equal to REF.DATE then (RAACTDT- REF.DATE) +1.

1.4.31. Renal Ultrasound (RU) – RSOUND

Dataset	RSOUND
Creating program	rsound.sas
Description	Renal Ultrasound (RU)
Unique identifier	DUSUBJID,PHASE,RUPARAM,RUABPRE,VISIT,RUSEQ
Sorted by	DUSUBJID,PHASE,RUPARAM,RUABPRE,VISIT,RUSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,RUDT, RUDESCR

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
RUSEQ	num	Renal ultrasound sequence		Collected at CRF.
RUPARAMC	char	Renal Ultrasound parameters Code		Collected at CRF.
RUPARAM	char	Renal Ultrasound parameters		Collected at CRF.
RUSTATC	num	Renal Ultrasound Status Code		Collected at CRF.
RUTM	num	Time of renal ultrasound		Collected at CRF.
RUSTAT	char	Renal Ultrasound Status		Collected at CRF.
RUKIDSP	char	Kidney Malformation Specify		Collected at CRF.
RUSIDE	char	Abnormality Side		Collected at CRF.
RUABPREC	num	Absent / Present Code		Collected at CRF.
RUABPRE	char	Absent / Present		Collected at CRF.

Variable	Type	Label	Codes	Comments
RULOCAC	num	Location of the stone Code		Collected at CRF.
RULOCA	char	Location of the stone		Collected at CRF.
RUDIA	num	Maximim stone diameter		Collected at CRF.
RUDUNIT	char	Stone diameter unit		Collected at CRF.
RUGRADEC	num	Grade Code		Collected at CRF.
RUGRADE	char	Grade		Collected at CRF.
RUHYDGC	char	Hydroureter Grade Code		Collected at CRF.
RUDY	num	Relative Day of renal ultrasound		If RUDT and REF.DATE not missing then perform below logic to calculate RUDY, If RUDT less than REF.DATE then (RUDT - REF.DATE). Else if RUDT is greater than equal to REF.DATE then (RUDT-REF.DATE) +1.

1.4.32. Other Safety Evaluations (SA) – SAFEVAL

Dataset	SAFEVAL
Creating program	safeval.sas
Description	Other Safety Evaluations (SA)
Unique identifier	DUSUBJID,PHASE,SASTAT,VISIT
Sorted by	DUSUBJID,PHASE,SASTAT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,SADT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
SASTATC	num	Other Safety Evaluations Status Code		Collected at CRF.
SASTAT	char	Other Safety Evaluations Status		Collected at CRF.
SADY	num	Relative Day Other Safety Evaluations		If SADT and REF.DATE not missing then perform below logic to calculate SADY, If SADT less than REF.DATE then (SADT - REF.DATE). Else if SADT is greater than equal to REF.DATE then (SADT-REF.DATE) +1.

1.4.33. Seizure History (SH) – SEIZHIST

Dataset	SEIZHIST
Creating program	seizhist.sas
Description	Seizure History (SH)
Unique identifier	DUSUBJID,PHASE,SHSZGR,SHSZTYP, VISIT,SHSEQ
Sorted by	DUSUBJID,PHASE,SHSZGR,SHSZTYP,VISIT, SHSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,SHSZDT,SHSZDTC,SHEPDT,SHEPDTC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
SHSEQ	num	Sequence Number		Collected at CRF.
SHSZGR	char	Seizure Group		Collected at CRF.
SHSZTYPC	num	Seizure Type Code		Collected at CRF.
SHSZTYP	char	Seizure Type Description		Collected at CRF.
SHNONEC	num	None Code		Collected at CRF.
SHNONE	char	None		Collected at CRF.
SHOTHER	char	Other Specify		Collected at CRF.
SHSZNUM	num	Record number in the past 3 month		Collected at CRF.
SHSZDY	num	Relative Day of first seizure (Char)		If SHSZDTC and REF.DATE not missing then perform below logic to calculate SHSZDY, If SHSZDTC less than REF.DATE then (SHSZDTC - REF.DATE). Else if SHSZDTC is greater than equal to REF.DATE then (SHSZDTC- REF.DATE) +1.
SHEPDY	num	Relative Day epilepsy diagnosis (Char)		If SHEPDTC and REF.DATE not missing then perform below logic to calculate SHEPDY, If SHEPDTC less than REF.DATE then (SHEPDTC - REF.DATE). Else if SHEPDTC is greater than equal to REF.DATE then (SHEPDTC- REF.DATE) +1.

1.4.34. Seizure Log (SL) – SEIZLOG

Dataset	SEIZLOG
Creating program	seizlog.sas
Description	Seizure Log (SL)
Unique identifier	DUSUBJID,PHASE,SLSZGR,SLSZTYP, VISIT ,SLSEQ
Sorted by	DUSUBJID,PHASE,SLSZGR,SLSZTYP, VISIT ,SLSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,SLSZDT,SLENDT,SLOTHER

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGNUM	num	Page Number		Collected at CRF.
SLREPRTC	num	Experience any Seizures Code		Collected at CRF.
SLREPRT	char	Experience any Seizures Code		Collected at CRF.
SLNONEC	num	None Code		Collected at CRF.
SLNONE	char	None		Collected at CRF.
SLSEQ	num	Sequence Number		Collected at CRF.
SLSZGR	char	Seizure Group		Collected at CRF.
SLSZTYPC	num	Type of Seizure code		Collected at CRF.
SLSZTYP	char	Type of Seizure		Collected at CRF.
SLNUMSZ	num	Number of Seizure		Collected at CRF.
SLSZDY	num	Relative Seizure Day		If SLSZDT and REF.DATE not missing then perform below logic to calculate SLSZDY, If SLSZDT less than REF.DATE then (SLSZDT - REF.DATE). Else if SLSZDT is greater than equal to REF.DATE then (SLSZDT-REF.DATE) +1.
SLENDY	num	Relative End Day of Seizure		If SLENDT and REF.DATE not missing then perform below logic to calculate SLENDY, If SLENDT less than REF.DATE then (SLENDT - REF.DATE). Else if SLENDT is greater than equal to REF.DATE then (SLENDT-REF.DATE) +1.

1.4.35. Surgery (SG) – SURGERY

Dataset	SURGERY
Creating program	surgery.sas
Description	Surgery (SG)
Unique identifier	DUSUBJID,PHASE,PAGNUM,SGREPRT,VISIT
Sorted by	DUSUBJID,PHASE,PAGNUM,SGREPRT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,SGPLNDTC,SGPLNDT,SGPROC, SGINDIC

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGNUM	num	Page Number		Collected at CRF.
SGREPRTC	num	Are any Surg/Proc. Planned Code		Collected at CRF.
SGREPRT	char	Are any Surg/Proc. Planned		Collected at CRF.
SGSEQ	num	Sequence Number		Collected at CRF.
SGBODSYC	num	Surgery Body System Code		Collected at CRF.
SGBODSYS	char	Surgery Body System		Collected at CRF.
SGPLNDY	num	Relative Character Day Planned Surgery		If SGPLNDTC and REF.DATE not missing then perform below logic to calculate SGPLNDY, If SGPLNDTC less than REF.DATE then (SGPLNDTC - REF.DATE). Else if SGPLNDTC is greater than equal to REF.DATE then (SGPLNDTC- REF.DATE) +1.

1.4.36. Treatment (TR) – TRTMENT

Dataset	TRTMENT
Creating program	trtment.sas
Description	Treatment (TR)
Unique identifier	DUSUBJID, PHASE, TRTREAT, VISIT
Sorted by	DUSUBJID, PHASE, TRTREAT, VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: PERIOD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGNUM	num	Page Number		Collected at CRF.
TRTREATC	num	Treatment formulation Code		Collected at CRF.
TRTREAT	char	Treatment formulation		Collected at CRF.
TRCATC	num	Treatment category Code		Collected at CRF.
TRCAT	char	Treatment category		Collected at CRF.

1.4.37. Laboratory Data (URINE) – URINE

Dataset	URINE
Creating program	urine.sas
Description	Laboratory Data (URINE)
Unique identifier	DUSUBJID, PHASE, LBTEST, LBTYPE, LBVTYPE, VISIT, LBACTDY
Sorted by	DUSUBJID, PHASE, LBTEST, LBTYPE, LBVTYPE, VISIT, LBACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STDNRC, STDRESC, LABSPEC, LBACTDT, LBFAST, LBFASTC, LBPRVID, LBPRVIDC, LBPTM, LBREF, LBSIGHI, LBSIGLO, PERIOD

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject ID for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
VISIT	char	Visit		Collected at CRF.
UNITCODE	num	Laboratory unit		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STDNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
STDNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
BATCHID	num	Central LAB batch identifier		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
LBSAMSEQ	num	Laboratory Sample Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBTMLBL	char	Label of Planned Collection Time		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
NRIND	char	Normal Range Indicator		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRDNUM	num	Period Number		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, If LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

1.4.38. Veeg (VE) – VEEG

Dataset	VEEG
Creating program	veeg.sas
Description	Veeg (VE)
Unique identifier	DUSUBJID, PHASE, VISIT, VESTDY
Sorted by	DUSUBJID, PHASE, VISIT, VESTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, VEDT, VELABEL, VEENDDT, VESPEC, VESTDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
VECLONIC	num	Number of Tonic-Clonic Seizures		Collected at CRF.
VEENDTM	num	VEEG end time		Collected at CRF.
VEOTHNUM	num	Number of OTHER seizures		Collected at CRF.
VESPASM	num	Number of Infantile spasms		Collected at CRF.
VESTTM	num	VEEG start time		Collected at CRF.
VETONIC	num	Number of Tonic Seizures		Collected at CRF.
VEUINTHR	num	Number of Uninterpretible Hours		Collected at CRF.
VEUNINT	char	VEEG uninterpretible		Collected at CRF.
VEWITH	num	# Partial Seizures 2ndary Generalization		Collected at CRF.
VEWTHOUT	num	Number of Partial Seizures		Collected at CRF.

Variable	Type	Label	Codes	Comments
VEDY	num	Relative VEEG start day - CRF		If VEDT and REF.DATE not missing then perform below logic to calculate VEDY, If VEDT less than REF.DATE then (VEDT - REF.DATE). Else if VEDT is greater than equal to REF.DATE then (VEDT-REF.DATE) +1.
VEENDDY	num	Relative VEEG end day		If VEENDDT and REF.DATE not missing then perform below logic to calculate VEENDDY, If VEENDDT less than REF.DATE then (VEENDDT - REF.DATE). Else if VEENDDT is greater than equal to REF.DATE then (VEENDDT- REF.DATE) +1.
VESTDY	num	Relative VEEG start day - Nordli		If VESTDT and REF.DATE not missing then perform below logic to calculate VESTDY, If VESTDT less than REF.DATE then (VESTDT - REF.DATE). Else if VESTDT is greater than equal to REF.DATE then (VESTDT- REF.DATE) +1.

1.4.39. Vineland Scale of Adaptive Behavior (VN) – VINLAND

Dataset	VINLAND
Creating program	vinland.sas
Description	Vineland Scale of Adaptive Behavior (VN)
Unique identifier	DUSUBJID, PHASE, VNMAIN, VNEXAM, VISIT
Sorted by	DUSUBJID, PHASE, VNMAIN, VNEXAM, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, VNDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VNMAINC	num	Domain of Adaptive Behavior Code		Collected at CRF.
VNMAIN	char	Vineland Domain		Collected at CRF.
VNEXAMC	num	Vineland exam Code		Collected at CRF.
VNEXAM	char	Vineland Exam		Collected at CRF.
VNSCORE	char	Subdomain Raw Score		Collected at CRF.
VNSEQ	num	Sequence Number		Collected at CRF.
VNDY	num	Relative Day of Vinland Exam		If VNDT and REF.DATE not missing then perform below logic to calculate VNDY, If VNDT less than REF.DATE then (VNDT - REF.DATE). Else if VNDT is greater than equal to REF.DATE then (VNDT-REF.DATE) +1.

1.4.40. Visit Date [VI] – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit Date [VI]
Unique identifier	DUSUBJID, PHASE, VISIT, VISITDY
Sorted by	DUSUBJID, PHASE, VISIT, VISITDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD, VISITDT

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE). Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

1.4.41. Vital Signs (VS)– VITAL

Dataset	VITAL
Creating program	vital.sas
Description	Vital Signs (VS)
Unique identifier	DUSUBJID,VSTEST,VSTESTCD,VSVTYPE,VISIT,VSACTDY
Sorted by	DUSUBJID,VSTEST,VSTESTCD,VSVTYPE,VISIT,VSACTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,VSACTDT,VSACTTM,VSSTRESN,VSSTRESC,VSTMLBL

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assigned For De-Identity		Randomly assigned unique subject ID for De-Identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-Identity
DSITEID	char	Site ID Assigned For De-Identity		Randomly assigned site ID for De-Identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PAGNUM	num	Page Number		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSLOC	char	Location		Collected at CRF.
VSORRES	char	Result in Original Units		Collected at CRF.
VSORUNIT	char	Original Units		Collected at CRF.
VSORRESN	num	Numeric Result in Original Units		Collected at CRF.
VSSTUNIT	char	Standard Units		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and REF.DATE not missing then perform below logic to calculate VSACTDY, If VSACTDT less than REF.DATE then (VSACTDT - REF.DATE). Else if VSACTDT is greater than equal to REF.DATE then (VSACTDT- REF.DATE) +1.