Clinical Development

Galantamine

Gal-Int-11_24m

Anonymisation Data Derivation Specification Document

Document Type	Reference 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	Code list 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 due to sensitivity of the data.
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- 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 “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Catalog number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number 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.
- Datasets with zero observation will not be submitted (ex. LABNOR)
- Dataset containing investigator information is sensitive and hence will not be submitted. (ex. INVEST)
- Dataset containing sensitive information about medication kit will not be submitted. (ex. BOX)
- Remarks dataset will be submitted with zero observation due to sensitivity of data.
- Dataset containing DNA result related sensitive information will not be submitted (ex. APOE4).
- Datasets MAP and TEMPLATE contain information about the attributes (like datatype, length, sequence no. etc.) of other datasets (e.g. ADAS etc.), hence these datasets will not be submitted.
- Datasets containing insignificant information will not be submitted (ex. CODE, TRLRAND, TRLLIST).
- Visit Date (VISIT_D) when Visit=1 from VISIT dataset will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

1.3. Data Files

The Gal-Int-11_24m Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INVEST,ZINVEST,INITIALS,BIRTH_D,COGPRB_D,DNA_D,RAND_D,MEDNO,COINV,ZCOINV,DRYRUN,BREAK_D,BREAK_V Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment and country related information in the de-identified datasets: RANDCODE (Source: TRLRAND dataset) RANDGRP (Source: TRLLIST dataset) DCOUNTRY (Source: INVEST dataset)

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

Variable	Type	Label	Codes	Comments
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned site ID for De-identity
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
PREGRES	char	PREGNANT		Collected at CRF.
RELATIVE	char	FIRST DEGREE RELATIVES WITH AD		Collected at CRF.
CHOLINOM	char	SUBJECT TAKEN CHOLINOMIMETICS		Collected at CRF.
DNACONST	char	INFORMED CONSENT OBTAINED		Collected at CRF.
DNASTOR	char	OBTAINED FOR STORAGE		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DEATHNA	char	EVENT OF DEATH		Collected at CRF.
DNANA	char	DNA NOT APPLICABLE		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((REF.DATE –BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
COGPRBDY	num	RELATIVE ONSET DAY OF COGNITIVE PROBLEMS		If COGPRB_D and REF.DATE not missing then perform below logic to calculate COGPRBDY, If COGPRB_D less than REF.DATE then (COGPRB_D - REF.DATE). Else if COGPRB_D is greater than equal to REF.DATE then (COGPRB_D - REF.DATE) +1.
DNA_DY	num	RELATIVE DNA SAMPLING DAY		If DNA_D and REF.DATE not missing then perform below logic to calculate DNA_DY, If DNA_D less than REF.DATE then (DNA_D - REF.DATE). Else if DNA_D is greater than equal to REF.DATE then (DNA_D - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RAND_DY	num	RELATIVE RANDOMIZATION DAY		If RAND_D and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_D less than REF.DATE then (RAND_D - REF.DATE). Else if RAND_D is greater than equal to REF.DATE then (RAND_D - REF.DATE) +1.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and REF.DATE not missing then perform below logic to calculate BREAK_DY, If BREAK_D less than REF.DATE then (BREAK_D - REF.DATE). Else if BREAK_D is greater than equal to REF.DATE then (BREAK_D - REF.DATE) +1.

1.4.2.Alzheimer's Disease Assessment Scale – ADAS

Dataset	ADAS
Creating program	adas.sas
Description	Alzheimer's Disease Assessment Scale
Unique identifier	DCRFID,ADTYPE,ADITEM,ADTRIAL,VISIT
Sorted by	DCRFID,ADTYPE,ADITEM,ADTRIAL,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
ADTYPE	char	TYPE OF ADAS TEST		Collected at CRF.
ADTRIAL	num	TRIAL SEQUENCE		Collected at CRF.
ADITEM	char	ADAS TEST ITEM		Collected at CRF.
ADSCORE	char	ADAS TEST ITEM SCORE		Collected at CRF.
ADVALUE	num	ADAS TEST ITEM VALUE		Collected at CRF.

1.4.3.Activities Of Daily Living – ADL

Dataset	ADL
Creating program	adl.sas
Description	Activities Of Daily Living
Unique identifier	DCRFID,ALITEM,VISIT
Sorted by	DCRFID,ALITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
ALITEM	char	ITEM		Collected at CRF.
ALYESNO	char	YES/NO/DON'T KNOW		Collected at CRF.
ALSCORE	char	SCORE		Collected at CRF.

1.4.4.Administration Of Trial Medication – ADMMED

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	SEGMENT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON CODE		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMDOSE	num	DOSE		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.

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

1.4.5.Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,AESOC,AEPREF,AESEQNO
Sorted by	DCRFID,AESOC,AEPREF,AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V,AEINCL,PHASE,AEFROM_D,AETO_D,SAEREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
AESEQNO	num	AE SEQ.		Collected at CRF.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESEV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AECONRX	char	AE CO-RX START		Collected at CRF.

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

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

1.4.6. Clinical Dementia Rating – CDR

Dataset	CDR
Creating program	cdr.sas
Description	Clinical Dementia Rating
Unique identifier	DCRFID, VISIT,CDRSCORE
Sorted by	DCRFID, VISIT,CDRSCORE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CDR_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
CDRMEM	num	MEMORY SCORE		Collected at CRF.
CDRSCORE	num	OVERALL SCORE		Collected at CRF.
CDRCONV	char	SUBJECT PROGRESSD TO AD?		Collected at CRF.
CDRMEM2	num	MEMORY SCORE		Collected at CRF.
CDRORIEN	num	ORIENTATION SCORE		Collected at CRF.
CDRJUDGE	num	JUDGEMENT AND PROBLEM SOLVING SCORE		Collected at CRF.
CDRCOMM	num	COMMUNITY AFFAIRS SCORE		Collected at CRF.
CDRHOME	num	HOME AND HOBBIES SCORE		Collected at CRF.
CDRCARE	num	PERSONAL CARE SCORE		Collected at CRF.
CDR_DY	num	RELATIVE CDR PERFORMED DAY		If CDR_D and REF.DATE not missing then perform below logic to calculate CDR_DY, If CDR_D less than REF.DATE then (CDR_D - REF.DATE). Else if CDR_D is greater than equal to REF.DATE then (CDR_D - REF.DATE) +1.

1.4.7.Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,RXPREF,CTSEQNO
Sorted by	DCRFID,RXPREF,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CONRX_V,CTIND_V,CTFROM_D,CTTO_D,ATCCODE1,ATCCODE2,ATCCODE3,ATCCODE4,ATCCODE5,ATCCODE6,ATCCODE7,ATCCODE8,ATCCODE9,ATCTEXT1,ATCTEXT2,ATCTEXT3,ATCTEXT4,ATCTEXT5,ATCTEXT6,ATCTEXT7,ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTIND	char	CT INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTTO_C	char	CO-RX END CODE		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D - REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D - REF.DATE) +1.

1.4.8.Death Report – DEATH

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DTREAS	char	DEATH CAUSE		Collected at CRF.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATH_D and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATH_D less than REF.DATE then (DEATH_D - REF.DATE). Else if DEATH_D is greater than equal to REF.DATE then (DEATH_D - REF.DATE) +1.

1.4.9.Protocol Deviation – DEVIATN

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

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

1.4.10. Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DIAGMON,DIAGYR

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

1.4.11. Previous And Concomitant Diseases – DISEASES

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

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

1.4.12. Digit Symbol Substitution Test – DSST

Dataset	DSST
Creating program	dsst.sas
Description	Digit Symbol Substitution Test
Unique identifier	DCRFID, VISIT,DSSTRES
Sorted by	DCRFID, VISIT,DSSTRES
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DSST_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
DSSTRES	num	NUMBER CORRECT		Collected at CRF.
DSST_DY	num	RELATIVE DSST PERFORMED DAY		If DSST_D and REF.DATE not missing then perform below logic to calculate DSST_DY, If DSST_D less than REF.DATE then (DSST_D - REF.DATE). Else if DSST_D is greater than equal to REF.DATE then (DSST_D - REF.DATE) +1.

1.4.13. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID, EGRELCHA, VISIT, EGLIMITS, ECG_T
Sorted by	DCRFID, EGRELCHA, VISIT, EGLIMITS, ECG_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D, ECGREFNO, ECGINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES (ECG)		Collected at CRF.

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

1.4.14. ECG Other Abnormalities – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Other Abnormalities
Unique identifier	DCRFID,VISIT,ECGOTH_V,ECG_DY
Sorted by	DCRFID,VISIT,ECGOTH_V,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.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity

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

1.4.15. Electrocardiogram Evaluation – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	Electrocardiogram Evaluation
Unique identifier	DCRFID, VISIT, EEASPECT, EEEVAL, ECG_DY, ECG_T
Sorted by	DCRFID, VISIT, EEASPECT, EEEVAL, ECG_DY, ECG_T
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.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEEVAL	char	ECG EVALUATION		Collected at CRF.

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

1.4.16. Electrocardiogram Measurements – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	Electrocardiogram Measurements
Unique identifier	DCRFID, VISIT, ECGPAR, ECG_T
Sorted by	DCRFID, VISIT, ECGPAR, ECG_T
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.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity

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

1.4.17. ECG Reference – ECGREF

Dataset	ECGREF
Creating program	ecgref.sas
Description	ECG Reference
Unique identifier	DCRFID, EGRELCHA, VISIT
Sorted by	DCRFID, EGRELCHA, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECGREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
EGRELCHA	char	CLIN. SIGNIFICANT CHANGES (ECG)		Collected at CRF.

1.4.18. Habits – HABIT

Dataset	HABIT
Creating program	habit.sas
Description	Habits
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
HATYPE	char	HABIT TYPE		Collected at CRF.
HABIT	char	HABIT		Collected at CRF.

1.4.19. Inclusion-Exclusion Criteria – INEX

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

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

1.4.20. Laboratory Results – LABRES

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.

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

1.4.21. Laboratory Urine Results – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urine Results
Unique identifier	DCRFID, VISIT,LABTEST,LUVAL,SAMPLEDY
Sorted by	DCRFID, VISIT,LABTEST,LUVAL,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,SAMREFNO,LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LUVAL	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D - REF.DATE) +1.

1.4.22. Brain MRI – MRIREF

Dataset	MRIREF
Creating program	mriref.sas
Description	Brain MRI
Unique identifier	DCRFID, VISIT, MRI_DY
Sorted by	DCRFID, VISIT, MRI_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MRI_D, MRIREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
MRI_DY	num	RELATIVE DAY SCAN PERFORMED		If MRI_D and REF.DATE not missing then perform below logic to calculate MRI_DY, If MRI_D less than REF.DATE then (MRI_D - REF.DATE). Else if MRI_D is greater than equal to REF.DATE then (MRI_D- REF.DATE) +1.

1.4.23. Brain CT/MRI Results – MRIRES

Dataset	MRIRES
Creating program	mrires.sas
Description	Brain CT/MRI Results
Unique identifier	DCRFID, VISIT1,BRV1,BRV2
Sorted by	DCRFID, VISIT1,BRV1,BRV2
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BIOID,SCAN1_D,SCAN2_D,COMMENTS

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT1	num	VISIT OF SCAN NUMBER 1		Collected at CRF.
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY.		Randomly assigned site ID for De-identity
BRV1	num	BRAIN VOLUME 1		Collected at CRF.
VISIT2	num	VISIT OF SCAN NUMBER 2		Collected at CRF.
BRV2	num	BRAIN VOLUME 2		Collected at CRF.
BBSI	num	WHOLE BRAIN CHANGE(ml)		Collected at CRF.
INTERVAL	num	INTERVAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
REPEAT	char	REPEAT SCAN		Collected at CRF.
QUALITY	num	CODE FOR RELIABILITY OF BBSI RESULT		Collected at CRF.
SCAN1_DY	num	RELATIVE DAY OF SCAN NUMBER 1		If SCAN1_D and REF.DATE not missing then perform below logic to calculate SCAN1_DY, If SCAN1_D less than REF.DATE then (SCAN1_D - REF.DATE). Else if SCAN1_D is greater than equal to REF.DATE then (SCAN1_D - REF.DATE) +1.
SCAN2_DY	num	RELATIVE DAY OF SCAN NUMBER 2		If SCAN2_D and REF.DATE not missing then perform below logic to calculate SCAN2_DY, If SCAN2_D less than REF.DATE then (SCAN2_D - REF.DATE). Else if SCAN2_D is greater than equal to REF.DATE then (SCAN2_D - REF.DATE) +1.

1.4.24. MRI Scan Result – MRIRESA

Dataset	MRIRESA
Creating program	mriresa.sas
Description	MRI Scan Result
Unique identifier	DCRFID, VISIT
Sorted by	DCRFID, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BIOID,SCAN_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY.		Randomly assigned site ID for De-identity
HIPPOR	num	RIGHT HIPPOCAMPUS (MM3)		Collected at CRF.

Variable	Type	Label	Codes	Comments
HIPPOL	num	LEFT HIPPOCAMPUS (MM3)		Collected at CRF.
SCAN_DY	num	RELATIVE SCAN DAY		If SCAN_D and REF.DATE not missing then perform below logic to calculate SCAN_DY, If SCAN_D less than REF.DATE then (SCAN_D - REF.DATE). Else if SCAN_D is greater than equal to REF.DATE then (SCAN_D - REF.DATE) +1.

1.4.25. Neurological Examination Test – NEUREXAM

Dataset	NEUREXAM
Creating program	neurexam.sas
Description	Neurological Examination Test
Unique identifier	DCRFID, NESYSTEM
Sorted by	DCRFID, NESYSTEM
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
NESYSTEM	char	TEST/SIGNS		Collected at CRF.
NERESULT	char	RESPONSE		Collected at CRF.
NEUR_V	char	RESPONSE (VERB.)		Collected at CRF.

1.4.26. NYU Paragraph Recall Test – NYU

Dataset	NYU
Creating program	nyu.sas
Description	NYU Paragraph Recall Test
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NYU_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
NYTCIR	num	TOTAL CORRECT IMMEDIATE RECALL		Collected at CRF.

Variable	Type	Label	Codes	Comments
NYTEIR_T	num	TIME ENDED IMMEDIATE RECALL		Collected at CRF.
NYTCDR	num	TOTAL CORRECT DELAYED RECALL		Collected at CRF.
NYTEDR_T	num	TIME BEGAN DELAYED RECALL		Collected at CRF.
NYU_DY	num	RELATIVE NYU PERFORMED DAY		If NYU_D and REF.DATE not missing then perform below logic to calculate NYU_DY, If NYU_D less than REF.DATE then (NYU_D - REF.DATE). Else if NYU_D is greater than equal to REF.DATE then (NYU_D - REF.DATE) +1.

1.4.27. Physical Examination – PHYSEXAM

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

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

1.4.28. Related AEs For Termination Or Death – RELAE

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

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

1.4.29. Remarks And Comments – REMARK

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Empty dataset will be submitted.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted.
RMSEQNO	num	RM SEQUENCE NUMBER		Empty dataset will be submitted.
RMTYPE	char	REMARK TYPE		Empty dataset will be submitted.

1.4.30. Samples – SAMPLE

Dataset	SAMPLE
Creating program	sample.sas
Description	Samples
Unique identifier	DCRFID, VISIT,SPECIMEN,SAMPLEDY,SAMPLE_T
Sorted by	DCRFID, VISIT,SPECIMEN,SAMPLEDY,SAMPLE_T
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D, LABID,ZLABID,FASTED,SAMREFNO,SASAME,SARELCHA, LABINTNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
SPECIMEN	char	SPECIMEN		Collected at CRF.
SAMTYPE	char	PURPOSE OF SAMPLE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

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

1.4.31. Sample Requisition Numbers – SAMREF

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

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

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

1.4.32. Trial Description – TRLDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	Trial Description
Unique identifier	TRIAL,COMPOND
Sorted by	TRIAL,COMPOND
Notes	Below listed variables will be dropped from dataset due to missing values: SPECPOP

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME CODE		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.

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

1.4.33. Trial Medication Regimens – TRLREGM

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

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

Variable	Type	Label	Codes	Comments
SEGMENT	num	SEGMENT		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	TRIAL REGIMEN ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.
ZTMROUTE	char	ADMIN. ROUTE CODE		Collected at CRF.
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.34. Treatment / Trial Termination – TRTERM

Dataset	TRTERM
Creating program	trterm.sas
Description	Treatment / 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: TRREAS_V,TRFROM_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
TRTYPE	char	TYPE OF TERMINATION		Collected at CRF.
TRSTATE	char	STATE OF TERMINATION		Collected at CRF.
TRREAS	char	TERM. REASON		Collected at CRF.

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

1.4.35. Visits – VISIT

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

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
ADVIS_T	num	ADAS VISIT TIME		Collected at CRF.
CAREYN	char	CAREGIVER NOT AVAILABLE		Collected at CRF.
CARESAME	char	BASELINE CAREGIVER		Collected at CRF.
VSND	char	VITAL SIGNS NOT DONE		Collected at CRF.
LABND	char	LAB REF NOT DONE		Collected at CRF.
ECGND	char	ECG NOT DONE		Collected at CRF.
PEND	char	PHYS EXAM NOT DONE		Collected at CRF.
ASSESS	char	EFFICACY ASSESSMENTS		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and REF.DATE not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than REF.DATE then (VISIT_D - REF.DATE). Else if VISIT_D is greater than equal to REF.DATE then (VISIT_D - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADVIS_DY	num	RELATIVE ADAS VISIT DAY		If ADVIS_D and REF.DATE not missing then perform below logic to calculate ADVIS_DY, If ADVIS_D less than REF.DATE then (ADVIS_D - REF.DATE). Else if ADVIS_D is greater than equal to REF.DATE then (ADVIS_D - REF.DATE) +1.
ADL_DY	num	RELATIVE DAY ADL PERFORMED		If ADL_D and REF.DATE not missing then perform below logic to calculate ADL_DY, If ADL_D less than REF.DATE then (ADL_D - REF.DATE). Else if ADL_D is greater than equal to REF.DATE then (ADL_D - REF.DATE) +1.

1.4.36. Vital Signs – VITSIGN

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
VISIT	num	VISIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, 1/MIN		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.