

Clinical Development

Galantamine

Gal-USA-1

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

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

Part II: Variables within dataset

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

1.2. Guidelines for Preparing Data

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

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

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Datasets containing insignificant information will not be submitted. (eg. CODE,RELATED,TRLRAND,TRLLIST,TEMPLATE)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg.INVEST).
- 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-USA-1 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	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,COGPRB_D,CMSCAN_D,BREAK_D,BREAK_V,DRYRUN,COINVEST</p> <p>Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment related information in the de-identified datasets: RANDCODE (Source: TRLRAND dataset) RANDGRP (Source: TRLLIST dataset) DCOUNTRY (Source: INVEST dataset)</p>

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

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
RELATIVE	char	FIRST DEGREE RELATIVE WITH AD		Collected at CRF.
CHOLINUM	char	CLINICAL TRIALS WITH CHOLINOMIMETICS		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
PREGNANT	char	PREGNANT		Collected at CRF.
DNAAPPR	char	APPROVAL FROM ETHICAL COMMITTEE		Collected at CRF.
DNACONST	char	INFORMED CONSENT OBTAINED		Collected at CRF.
DNAAPOE	char	OBTAINED FOR APO E GENOTYPING		Collected at CRF.
DNASTOR	char	OBTAINED FOR STORAGE		Collected at CRF.
DSITEID	num	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned Site No. for De-identity.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Element will be grouped to protect PII.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: $AGE = \text{int}((REF.DATE - BIRTH_D)/365.25)$ If age greater than 89+ years then will be grouped as per HIPAA rules.
CMSCANDY	num	RELATIVE DAY SCAN PERFORMED		If CMSCAN_D and REF.DATE not missing then perform below logic to calculate CMSCANDY, If CMSCAN_D less than REF.DATE then (CMSCAN_D - REF.DATE). Else if CMSCAN_D is greater than equal to REF.DATE then (CMSCAN_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	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
ADTYPE	char	TEST		Collected at CRF.
ADTRIAL	char	TRIAL NUMBER		Collected at CRF.
ADITEM	char	ADAS ITEM		Collected at CRF.
ADSCORE	char	ADAS SCORE		Collected at CRF.
ADVALUE	char	VALUE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.3. Administration of Trial Medication – ADMMED

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
PHASE	char	TRIAL PHASE		Collected at CRF.
NUMFORM	num	TABLETS PER DAY		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		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.

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

1.4.4. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID, AEPREF, AESEQNO
Sorted by	DCRFID, 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, AEFROM_C, AETO_D, AETO_C, ADREMNUM

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.
AESEV	char	AE SEVERITY		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AECONRX	char	AE CO-RX START		Collected at CRF.
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.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC	char	ADVERSE EVENT SYSTEM ORGAN CLASS		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.

1.4.5.Resource Use: Caregiver Time – CARETIME

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

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

Variable	Type	Label	Codes	Comments
CRNOTDNE	char	DONE		Collected at CRF.
CRTMHR	char	DAILY TIME SPENT ON ACTIVITY (HRS)		Collected at CRF.
CRTMMIN	char	DAILY TIME SPENT ON ACTIVITY (MIN)		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.6.CIBIC-Plus – CIBIC

Dataset	CIBIC
Creating program	cibic.sas
Description	CIBIC-Plus
Unique identifier	DCRFID,CIBIC,VISIT
Sorted by	DCRFID,CIBIC,VISIT
Notes	

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

Variable	Type	Label	Codes	Comments
CIBIC	char	SUBJECT STATUS COMPARED TO BASELINE		Collected at CRF.
ZCIBIC	num	SUBJECT STATUS COMPARED TO BASELINE CODE		Collected at CRF.

1.4.7. Brain MRI – CMRI

Dataset	CMRI
Creating program	cmri.sas
Description	Brain MRI
Unique identifier	DCRFID,CMSYMP,VISIT
Sorted by	DCRFID,CMSYMP,VISIT
Notes	

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

Variable	Type	Label	Codes	Comments
CMNUM	char	NUMBER		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.8. Concomitant Medication– COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Medication
Unique identifier	DCRFID,CTTYPE,CTSEQNO
Sorted by	DCRFID,CTTYPE,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,CTIND_V,CTFROM_D,CTFROM_C,CTTO_D,CTTO_C, ATCCODE9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 1		Collected at CRF.
ATCCODE1	char	ATC CODE 2		Collected at CRF.
ATCCODE2	char	ATC CODE 3		Collected at CRF.
ATCCODE3	char	ATC CODE 4		Collected at CRF.
ATCCODE4	char	ATC CODE 5		Collected at CRF.
ATCCODE5	char	ATC CODE 6		Collected at CRF.
ATCCODE6	char	ATC CODE 7		Collected at CRF.
ATCCODE7	char	ATC CODE 8		Collected at CRF.
ATCCODE8	char	ATC CODE 9		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.

1.4.9.DAD-Scale – DAD

Dataset	DAD
Creating program	dad.sas
Description	DAD-Scale
Unique identifier	DCRFID,VISIT,SORT_NO
Sorted by	DCRFID,VISIT,SORT_NO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
DASYMP	char	DAD ITEM		Collected at CRF.
DASEV	char	YES/NO/NA		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.10. Death – DEATH

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

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

1.4.11. Dependence Scale – DEPENDEN

Dataset	DEPENDEN
Creating program	dependen.sas
Description	Dependence Scale
Unique identifier	DCRFID,VISIT,SORT_NO
Sorted by	DCRFID,VISIT,SORT_NO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
DEPEND	char	DEPENDENCE SCALE		Collected at CRF.
DEPRESP	char	RESPONSE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.12. Protocol Deviation – DEVIATN

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		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	OTHER DEVIATION		Collected at CRF.

1.4.13. 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	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
DIAGN	char	DIAGNOSIS		Collected at CRF.

1.4.14. Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Diseases
Unique identifier	DCRFID,DSSYSTEM,DSCOND,SORT_NO
Sorted by	DCRFID,DSSYSTEM,DSCOND,SORT_NO
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	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.15. ECG Overall Interpretation – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ECG Overall Interpretation
Unique identifier	DCRFID,VISIT,ECG_DY
Sorted by	DCRFID,VISIT,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
ECG_T	num	ECG TIME		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
ECGSRCE	char	SOURCE ECG COMMENTS		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGSGNCH	char	SIGNIFICANT CHANGE		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. ECG Abnormalities – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Abnormalities
Unique identifier	DCRFID,VISIT,ECG_DY
Sorted by	DCRFID,VISIT,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D,ECGOTH_V,ECOTH1_V

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

Variable	Type	Label	Codes	Comments
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG COMMENTS		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 Evaluation – ECGINTRP

Dataset	ECGINTRP
Creating program	ecgintrp.sas
Description	ECG Evaluation
Unique identifier	DCRFID,VISIT,EGABNCLS,ECG_DY
Sorted by	DCRFID,VISIT,EGABNCLS,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	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
ECG_T	num	ECG TIME		Collected at CRF.
EGABNCLS	char	ECG ABNORMALITY CLASS		Collected at CRF.
EGABN	char	ECG ABNORMALITY		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.

1.4.18. ECG Measurements – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG Measurements
Unique identifier	DCRFID, ECGPAR, VISIT, ECG_DY
Sorted by	DCRFID, ECGPAR, VISIT, ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
ECG_T	num	ECG TIME		Collected at CRF.
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ZECGPAR	char	ECG PARAMETER CODE		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SORT_NO	num	PREFILL SORT NO		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.

1.4.19. Emergency Room Visits – EMERROOM

Dataset	EMERROOM
Creating program	emerroom.sas
Description	Emergency Room Visits
Unique identifier	DCRFID,ERVIS_DY,ERSEQNO
Sorted by	DCRFID,ERVIS_DY,ERSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ERVIS_D,ERREAS_V

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

Variable	Type	Label	Codes	Comments
ERSEQNO	char	E.R. VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
ERVIS_DY	num	RELATIVE EMERROOM VISIT DAY		If ERVIS_D and REF.DATE not missing then perform below logic to calculate ERVIS_DY, If ERVIS_D less than REF.DATE then (ERVIS_D - REF.DATE). Else if ERVIS_D is greater than equal to REF.DATE then (ERVIS_D- REF.DATE) +1.

1.4.20. General Well-being Schedule – GWBS

Dataset	GWBS
Creating program	gwbs.sas
Description	General Well-being Schedule
Unique identifier	DCRFID,GWBS,VISIT
Sorted by	DCRFID,GWBS,VISIT
Notes	

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

Variable	Type	Label	Codes	Comments
GWBSSEV	char	SCORE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.21. Cigarette Smoking – HABIT

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

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

1.4.22. Hachinski Schemic Score – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	Hachinski Schemic Score
Unique identifier	DCRFID,HOSTYPE,HOSEQNO
Sorted by	DCRFID,HOSTYPE,HOSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: HOPRIOR,HOFROM_D,HOONGO,HOTO_D,HOREAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
HOSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
HOSTYPE	char	TYPE OF HOSPITAL		Collected at CRF.
ZHOSTYPE	num	TYPE OF HOSPITAL CODE		Collected at CRF.
WARDTYPE	char	TYPE OF WARD		Collected at CRF.
ZWARDTYP	char	TYPE OF WARD CODE		Collected at CRF.

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

1.4.23. Inclusion Criteria – INEX

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.

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

1.4.24. Laboratory Normal Ranges– LABNOR

Dataset	LABNOR
Creating program	labnor.sas
Description	Laboratory Normal Ranges
Unique identifier	LABTEST LNSEQNO
Sorted by	LABTEST LNSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABID,ZLABID,WGHTFROM,WGHTTO,WGHT_U

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LNFROM_D	num	RANGE APPLIC. FROM		Collected at CRF.
LNTO_D	num	RANGE APPLIC. TO		Collected at CRF.
LNSEQNO	num	LAB. NORMAL SEQ.		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABLOW	num	LOWER NORMAL LIMIT		Collected at CRF.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
AGEFROM	num	LOWER AGE LIMIT		Collected at CRF.
AGETO	num	UPPER AGE LIMIT		Collected at CRF.
AGE_U	char	AGE UNIT		Collected at CRF.
SEX	char	SEX		Collected at CRF.

1.4.25. Laboratory Requisition Numbers – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory Requisition Numbers
Unique identifier	DCRFID,LATYPE,VISIT
Sorted by	DCRFID,LATYPE,VISIT
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,LABREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
LATYPE	char	DNA SAMPLE		Collected at CRF.
LSRELCHA	char	CLIN. RELEVANT CHANGES		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.

1.4.26. Laboratory Results - Clinical Chemistry – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results - Clinical Chemistry
Unique identifier	DCRFID, LABTEST, LABVAL, SAMPLEDY
Sorted by	DCRFID, LABTEST, LABVAL, SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, LABVAL_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.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
LABTST_U	char	TEST UNIT		Collected at CRF.
LOWPATHO	num	LOWER PATHOLOGICAL LIMIT		Collected at CRF.
UPPPATHO	num	UPPER PATHOLOGICAL LIMIT		Collected at CRF.
CFACTOR	num	CONVERSION FACTOR		Collected at CRF.
SIUNIT	char	STANDARD INTERNATIONAL UNIT		Collected at CRF.
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.
LABCLASS	char	LAB CLASS		Collected at CRF.
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.

1.4.27. Laboratory Sample Info – LABSAM

Dataset	LABSAM
Creating program	labsam.sas
Description	Laboratory Sample Info
Unique identifier	DCRFID,SAMPLEDY
Sorted by	DCRFID,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,LABREFNO,LSSAME,LSRELCHA

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
FASTED	char	SUBJECT FASTED		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.

1.4.28. Laboratory Urine Results – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urine Results
Unique identifier	DCRFID, LABTEST, LUVAL, SAMPLEDY
Sorted by	DCRFID, 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, LUVAL

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LUVAL_V	char	URINE VALUE		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.

1.4.29. Mini-Mental State Examination – MMSE

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
MMSYMP	char	MMSE SYMPTOM		Collected at CRF.
MMSEV	num	MMSE SCORE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.30. Neurological Examination – NEUREXAM

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
NESYSTEM	char	TEST/SIGNS		Collected at CRF.
NERESULT	char	RESPONSE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.31. Nursing Home Admissions – NURSHOME

Dataset	NURSHOME
Creating program	nurshome.sas
Description	Nursing Home Admissions
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: NHFROM_D,NHTO_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
NHSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
NHPRIOR	char	ONGOING (FROM)		Collected at CRF.
NHONGO	char	ONGOING, IF NOT		Collected at CRF.
NHREAS	char	REASON		Collected at CRF.
ZNHREAS	num	REASON CODE		Collected at CRF.

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

1.4.32. Paid Home Help – PAIDHOME

Dataset	PAIDHOME
Creating program	paidhome.sas
Description	Paid Home Help
Unique identifier	DCRFID,VISIT,SORT_NO
Sorted by	DCRFID,VISIT,SORT_NO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PHOTH_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
PHHELPER	char	PAID HOME HELP		Collected at CRF.
PHHELPNU	char	USED		Collected at CRF.
PHVAL	num	NUMBER HOURS/MEALS		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.33. Phone Contact –PHONE

Dataset	PHONE
Creating program	phone.sas
Description	Phone Contact
Unique identifier	DCRFID,VISIT
Sorted by	DCRFID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
PHONE	char	CONTACTED BY PHONE?		Collected at CRF.
PHOUTCME	char	OUTCOME OF PHONE CONTACT		Collected at CRF.
PHANTEM	char	ANTI-EMETICS PRESIBED		Collected at CRF.
PHUNSCHD	char	UNSCHEDULED VISIT PLANNED?		Collected at CRF.

1.4.34. Physical Examination –PHYSEXAM

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.35. Date Doses Missed 3 Days Before Blood Dra – PKMISSED

Dataset	PKMISSED
Creating program	pkmissd.sas
Description	Date Doses Missed 3 Days Before Blood Dra
Unique identifier	DCRFID,PKSEQNO,PKMISSDY
Sorted by	DCRFID,PKSEQNO,PKMISSDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PKMISS_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
PKSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PKMISSED	char	AM/PM DOSE MISSED		Collected at CRF.
PKMISSDY	num	RELATIVE DAY DOSE MISSED		If PKMISS_D and REF.DATE not missing then perform below logic to calculate PKMISSDY, If PKMISS_D less than REF.DATE then (PKMISS_D - REF.DATE). Else if PKMISS_D is greater than equal to REF.DATE then (PKMISS_D- REF.DATE) +1.

1.4.36. Drug Administration Before Sampling – PLAADM

Dataset	PLAADM
Creating program	plaadm.sas
Description	Drug Administration Before Sampling
Unique identifier	DCRFID, PLADMSEQ, PLADM DY
Sorted by	DCRFID, PLADMSEQ, PLADM DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PLREFNO, PLADM_D, TREAT

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

1.4.37. Plasma Results – PLARES

Dataset	PLARES
Creating program	plares.sas
Description	Plasma Results
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: SUBJECT,MEDNO,INITIALS,TUBE,DATE

Variable	Type	Label	Codes	Comments
TRIAL	char	Trial ID.		Collected at CRF.
DRUG	char	GAL		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
VISIT	num	VISIT NO.		Collected at CRF.
PRVAL	num	PLASMA MEASUREMENT		Collected at CRF.
PRFLAG	char	DATA FLAG		Collected at CRF.
PRVAL_U	char	PLASMA UNIT		Collected at CRF.
PRDETECT	num	DETECTION LIMIT		Collected at CRF.
PRSUBST	char	GALANTAMINE		Collected at CRF.
TIME	num	TIME		Collected at CRF.

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

1.4.38. Plasma Samples – PLASAM

Dataset	PLASAM
Creating program	plasam.sas
Description	Plasma Samples
Unique identifier	DCRFID, PLASMADY
Sorted by	DCRFID, PLASMADY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PLREFNO, PLASMA_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.
PLASMA_T	num	TIME OF PLASMA SAMPLING		Collected at CRF.

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

1.4.39. Professional Visit – PROFVIS

Dataset	PROFVIS
Creating program	profvis.sas
Description	Professional Visit
Unique identifier	DCRFID,VISITOR,VISIT
Sorted by	DCRFID,VISITOR,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
VISITOR	char	HEALTH CARE PROFESSIONAL		Collected at CRF.
PFVIS	char	VISIT		Collected at CRF.
PFOFFICE	num	IN OFFICE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PFHOME	num	AT SUBJECTS HOME		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.40. Related AEs for Trial Termination or Death – RELAE

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

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

1.4.41. Subject Socio-Demographics – RESQUEST

Dataset	RESQUEST
Creating program	resquest.sas
Description	Subject Socio-Demographics
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: CARBIR_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
STATUS	char	REFUSED/CAREGIVER NOT AVAIL (A)		Collected at CRF.
LIVSIT	char	USUAL LIVING SITUATION OR HAS CHANGED(A)		Collected at CRF.
SCHOOLED	char	HIGHEST LEVEL OF EDUCATION (A)		Collected at CRF.
PROFVIS	char	VIS. BY OTHER HLTH CARE PRO (B)		Collected at CRF.
PDHMEHLP	char	ANY PAID HOME HELP (C)		Collected at CRF.
DAYCARE	char	SPENT TIME IN DAY CARE (D)		Collected at CRF.

Variable	Type	Label	Codes	Comments
HALFDAY	num	HALF DAY SESSIONS PER WEEK (D)		Collected at CRF.
FULLDAY	num	FULL DAY SESSIONS PER WEEK (D)		Collected at CRF.
RESPCARE	char	SPENT TIME IN RESPITE CARE (D)		Collected at CRF.
NONIGHTS	num	HOW MANY NIGHTS OF RESPITE (D)		Collected at CRF.
ERVISIT	char	VISITED THE EMERGENCY ROOM (E)		Collected at CRF.
HOSPITAL	char	STAYED IN THE HOSPITAL (F)		Collected at CRF.
NURSHOME	char	STAYED IN NURSING HOME (G)		Collected at CRF.
CARSEX	char	CAREGIVERSSEX (H)		Collected at CRF.
CARRELAT	char	CAREGIVERSRELATIONSHIP TO SUBJ (H)		Collected at CRF.
CARLIV	char	CAREGIVER LIVING WITH SUBJECT (H)		Collected at CRF.
CARSCHL	char	HIGHEST LEVEL OF EDUCATION (H)		Collected at CRF.
CARINCM	char	CAREGIVER ANNUAL INCOME (H)		Collected at CRF.
CARPAID	char	CAREGIVER IN PAID EMPLOYMENT?(I)		Collected at CRF.
CARLOSDA	char	LOSE ANY WORKING DAYS (I)		Collected at CRF.
CARNODAY	num	WORKING DAYS LOST (I)		Collected at CRF.
SUPERVIS	char	REQUIRE ROUND-THE-CLOCK SUPERVISION (K)		Collected at CRF.

Variable	Type	Label	Codes	Comments
TMALNHR	char	LEFT ALONE ON TYPICAL DAY (HRS) (K)		Collected at CRF.
TMALNMIN	char	LEFT ALONE ON TYPICAL DAY (MIN) (K)		Collected at CRF.
CARAGE	char	CAREGIVERSAGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving CARAGE, element derivation follows below rule: $CARAGE = \text{int}((REF.DATE - CARBIR_D) / 365.25)$ If age greater than 89+ years then will be grouped as per HIPAA rules.

1.4.42. Trial Description – TRLDDESC

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.

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

1.4.43. Trial Regimen – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Regimen
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	TRIALID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.

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

1.4.44. Trial Disposition – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	Trial Disposition
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TTREAS_V

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

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

1.4.45. Visit General Info – VISIT

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
PSYMED	char	PSYCHOTROPICMEDICATIONS		Collected at CRF.
ADVIS_T	num	ADAS VISIT TIME		Collected at CRF.
ADAS_T	num	TIME LAST STUDY MED DOSE		Collected at CRF.
MISSDOSE	char	MISSED DOSES		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
ADVIS_DY	num	RELATIVE ADASVISIT 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.

1.4.46. 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	TRIALID.		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, 1/MIN		Collected at CRF.
SBP	num	SYSTOLIC BP, MMHG		Collected at CRF.
DBP	num	DIASTOLICBP, MMHG		Collected at CRF.