

Clinical Development

Galantamine

Gal-Int-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.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset containing investigator information, which is sensitive and hence will not be submitted. (eg. INVEST, RELATED).
- Dataset contains zero observations hence it will not be submitted. (eg. PLARES)
- Dataset containing pharmacogenetic information will not be submitted. (eg. GENOTYPE)
- REMARK dataset will be submitted with zero observation due to sensitivity of data.
- LABCOM dataset will contain only date and time variables after removing the sensitive information from the dataset. Hence this dataset will be dropped from the de-identified dataset.
- Visit Date(VISIT_D) when Visit=1 will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

1.3. Data Files

The Gal-Int-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: INITIALS, MEDNO, INVEST, ZINVEST, COINVEST, ZCOINVES, BIRTH_D, BREAK_D, BREAK_V, COGPRB_D, CMSCAN_D, GENOTYPE</p> <p>Below listed variables were not a part of the Raw dataset. These have been added to retain the Site and Country related information in the de-identified datasets: DSITEID (SOURCE: INVEST dataset) DCOUNTRY (Source: INVEST dataset)</p>

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
SEX	char	SEX		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	RACE		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
BATCHNO	num	BATCH NUMBER		Collected at CRF.
RELATIVE	char	RELATIVE WITH ALZH.DEMENTIA		Collected at CRF.
CHOLINOM	char	TAKEN PART IN TRIALS WITH CHOLINOM.		Collected at CRF.
PREGNANT	char	PREGNANT		Collected at CRF.
DNAAPPR	char	APPROVAL ETHICAL COMMITTEE OBTAINED		Collected at CRF.
DNACONST	char	HAS INFORMED CONSENT BEEN OBTAINED		Collected at CRF.
DSITEID	char	SITE NO. ASSIGNED FOR DE- IDENTITY		Randomly assigned Site No for De-identity
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element 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.
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.
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.
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.

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,SORT_NO,VISIT
Sorted by	DCRFID,ADTYPE,ADITEM,SORT_NO,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
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.
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, NUMFORM, AMFROMDY
Sorted by	DCRFID, PHASE, 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: 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	UNITS PER ADMIN.		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.

Variable	Type	Label	Codes	Comments
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. TODAY		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, AEWHONUM, AESEQNO
Sorted by	DCRFID, AEPREF, AEWHONUM, 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, 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.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AECONRX	char	AE CO-RX START		Collected at CRF.
ZAECNRX	num	AE CO-RX START CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME CODE		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS CODE		Collected at CRF.
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.
AETO_DY	num	RELATIVE AE TODAY		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. Caregiver Cons – CARCONS

Dataset	CARCONS
Creating program	carcons.sas
Description	Caregiver Cons
Unique identifier	DCRFID,CARCONS,VISIT
Sorted by	DCRFID,CARCONS,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
CARCONS	char	CAREGIVERSCONSULTANT		Collected at CRF.
CCNOTCON	char	CAREGIVER CONSULTED?		Collected at CRF.
CARCONO	num	NUMBER OF CAREGIVER CONS SESSIONS		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.6. Caregiver Time – CARETIME

Dataset	CARETIME
Creating program	caretime.sas
Description	Caregiver Time
Unique identifier	DCRFID, CRACTIV, CRSEQNO, VISIT
Sorted by	DCRFID, CRACTIV, CRSEQNO, 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
CRACTIV	char	ACTIVITIES		Collected at CRF.
CRSEQNO	num	CARE TIME SEQUENCE NUMBER		Collected at CRF.
CRNOTDNE	char	DONE		Collected at CRF.
CRTMHR	num	DAILY HOURSPENT ON ACTIVITY		Collected at CRF.
CRTMMIN	num	DAILY MINUTESPENT ON ACTIVITY		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRACK_V	char	OTHER ACTIVITY		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.7. Brain MRI – CMRI

Dataset	CMRI
Creating program	cmri.sas
Description	Brain MRI
Unique identifier	DCRFID,CMSYMP,CMNUM,CMSEQ
Sorted by	DCRFID,CMSYMP,CMNUM,CMSEQ
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
CMSYMP	char	BRAIN CT/MRI SYMPTOM		Collected at CRF.
CMSEQ	num	SEQUENCE		Collected at CRF.
CMSEV	char	SEVERITY OR LOCALIZATION OF BRAIN CT/MRI		Collected at CRF.
CMNUM	char	BRAIN CT/MRI NUMBER		Collected at CRF.

1.4.8. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,CTTYPE,CONRX,CTSEQNO
Sorted by	DCRFID,CTTYPE,CONRX,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,CTIND,CTFROM_D,CTTO_D,ATCCODE9,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
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTTO_C	char	CO-RX END CODE		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.
ATCTEXT0	char	ATC TEXT 1		Collected at CRF.
ATCTEXT1	char	ATC TEXT 2		Collected at CRF.
ATCTEXT2	char	ATC TEXT 3		Collected at CRF.
ATCTEXT3	char	ATC TEXT 4		Collected at CRF.
ATCTEXT4	char	ATC TEXT 5		Collected at CRF.
ATCTEXT5	char	ATC TEXT 6		Collected at CRF.
ATCTEXT6	char	ATC TEXT 7		Collected at CRF.
ATCTEXT7	char	ATC TEXT 8		Collected at CRF.
ATCTEXT8	char	ATC TEXT 9		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D - REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D - REF.DATE) +1.

1.4.9. DAD-Scale – DAD

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		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
DASYMP	char	SYMPTOM DAD		Collected at CRF.
DASEV	char	SEVERITY		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,DTREAS
Sorted by	DCRFID,DTREAS
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

Variable	Type	Label	Codes	Comments
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 – DEPENDS

Dataset	DEPENDS
Creating program	depends.sas
Description	Dependence Scale
Unique identifier	DCRFID,DEPEND
Sorted by	DCRFID,DEPEND
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
DEPEND	char	SYMPTOM		Collected at CRF.

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

1.4.13. Date of Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Date of 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: DIAGN_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
DIAGN	char	DIAGNOSIS		Collected at CRF.
DIAGN_DY	num	RELATIVE DIAGNOSIS DAY		If DIAGN_D and REF.DATE not missing then perform below logic to calculate DIAGN_DY, If DIAGN_D less than REF.DATE then (DIAGN_D - REF.DATE). Else if DIAGN_D is greater than equal to REF.DATE then (DIAGN_D - REF.DATE) +1.

1.4.14. Medical History – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Medical History
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 or due to missing values: DISEAS_V,DISEASE

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
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, ECG_DY
Sorted by	DCRFID, ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ECG_D, EGRHYTHM, EGINFARC, EGHYPER, EGMORPHO, EGAV, EGLBB, EGRBB

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf Id for De-identity
ECGSRCE	char	SOURCE ECG COMMENTS		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. RELEVANT CHANGES ECG		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, ECG_DY
Sorted by	DCRFID, ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D, ECGOTH_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
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 Measurements – ECGPAR

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

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

1.4.18. Emergency Room Visits – EMERROOM

Dataset	EMERROOM
Creating program	emerroom.sas
Description	Emergency Room Visits
Unique identifier	DCRFID,ERSEQNO,VISIT
Sorted by	DCRFID,ERSEQNO,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ERVIS_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
ERSEQNO	num	EMERGENCY ROOM SEQUENCE NUMBER		Collected at CRF.
ERREAS_V	char	REASON FOR EMERGENCY ROOM		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.

1.4.19. 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	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
GWBS	char	SYMPTOM GWBS		Collected at CRF.
GWBSSEV	num	SEVERITY GWBS		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.20. 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.
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.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.21. Hospitalization – HOSPITAL

Dataset	HOSPITAL
Creating program	hospital.sas
Description	Hospitalization
Unique identifier	DCRFID,HOSPTYPE,WARDTYPE,VISIT
Sorted by	DCRFID,HOSPTYPE,WARDTYPE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HOFROM_D,HOTO_D,HOREAS_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
HOSPTYPE	char	TYPE OF HOSPITAL		Collected at CRF.
ZHOSPTYP	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.
HOSEQNO	num	HOSPITAL SEQUENCE NUMBER		Collected at CRF.
HOPRIOR	char	HOSPITAL ONGOING FROM		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOONGO	char	HOSPITAL ONGOING TO		Collected at CRF.
HOFROMDY	num	RELATIVE HOSPITALISATION 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 TODAY		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.

1.4.22. 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	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.
ZIECRIT	num	SELECTION CRITERIA CODE		Collected at CRF.
IEYN	char	NON-ELIGIBILITY EXPR.		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.23. Laboratory Normal Ranges – LABNOR

Dataset	LABNOR
Creating program	labnor.sas
Description	Laboratory Normal Ranges
Unique identifier	LABTEST,LABLOW,LABUPP,SEX
Sorted by	LABTEST,LABLOW,LABUPP,SEX
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,AGE_U,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.
LNT0_D	num	RANGE APPLIC. TO		Collected at CRF.
LNSEQNO	num	LAB. NORMAL SEQ.		Collected at CRF.
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.

Variable	Type	Label	Codes	Comments
AGETO	num	UPPER AGE LIMIT		Collected at CRF.
SEX	char	SEX		Collected at CRF.

1.4.24. Laboratory Requisition Numbers – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory Requisition Numbers
Unique identifier	DCRFID,TYPE,SAMPLEDY
Sorted by	DCRFID,TYPE,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABREFNO,LABID,ZLABID,SAMPLE_D,SAMPLE_T,HAEMOLYS,FASTED,LSSAME

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
LSRELCHA	char	CLIN. RELEVANT CHANGES		Collected at CRF.
TYPE	char	TYPE		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.

1.4.25. Laboratory Results – LABRES

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

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.

Variable	Type	Label	Codes	Comments
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		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.

1.4.26. Laboratory Sample Info – LABSAM

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

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
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
FASTED	char	SUBJECT FASTED		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		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.

1.4.27. Laboratory Urine Results – LABURI

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

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.

Variable	Type	Label	Codes	Comments
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LUVAL	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
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.

1.4.28. Mini-Mental State Examination – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	Mini-Mental State Examination
Unique identifier	DCRFID,MMSYMP
Sorted by	DCRFID,MMSYMP
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
MMSYMP	char	MINI-MENTAL STATE		Collected at CRF.
MMSEV	num	MINI-MENTAL STATE SCORE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.29. Neurological Examination – NEUREXAM

Dataset	NEUREXAM
Creating program	neurexam.sas
Description	Neurological Examination
Unique identifier	DCRFID,NESYSTEM
Sorted by	DCRFID,NESYSTEM
Notes	Below listed variables will be dropped from dataset due to missing values: NEXAM

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
NESYSTEM	char	NEUR. EXAM. BODY SYSTEM		Collected at CRF.
NERESULT	char	NEUR. EXAM. RESULT		Collected at CRF.
NEXAM_V	char	NEUR. EXAM. (VERB.)		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.30. Nursing Home Admissions – NURSHOME

Dataset	NURSHOME
Creating program	nurshome.sas
Description	Nursing Home Admissions
Unique identifier	DCRFID,NHREAS,NHSEQNO,VISIT
Sorted by	DCRFID,NHREAS,NHSEQNO,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	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
NHSEQNO	num	NURSING HOME SEQUENCE NUMBER		Collected at CRF.
NHPRIOR	char	ONGOING FROM		Collected at CRF.
NHONGO	char	ONGOING TO		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 TP 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.

1.4.31. Paid Home Help – PAIDHOME

Dataset	PAIDHOME
Creating program	paidhome.sas
Description	Paid Home Help
Unique identifier	DCRFID,PHHELPER,PHSEQNO,VISIT
Sorted by	DCRFID,PHHELPER,PHSEQNO,VISIT
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	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
PHHELPER	char	PAID HOME HELPER		Collected at CRF.
PHSEQNO	num	PAID HOME SEQUENCE NUMBER		Collected at CRF.
PHHELPNU	char	PAID HOME HELPER USED?		Collected at CRF.
PHVAL	num	NUMBER OF HOURS/MEALS PER WEEK		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.32. Phone Contact – PHONE

Dataset	PHONE
Creating program	phone.sas
Description	Phone Contact
Unique identifier	DCRFID,PHOUTCOM,VISIT
Sorted by	DCRFID,PHOUTCOM,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
PHONE	char	CONTACTED BY PHONE?		Collected at CRF.
PHOUTCOM	char	OUTCOME OF PHONE CONTACT		Collected at CRF.
PHANTEM	char	ANTI-EMETICS PRESCRIBED		Collected at CRF.
PHUNSCHD	char	UNSCHEDULED VISIT PLANNES		Collected at CRF.

1.4.33. 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_V,EXAM

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
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.

1.4.34. 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,PKMISSED,PKSEQNO,VISIT,PKMISSDY
Sorted by	DCRFID,PKMISSED,PKSEQNO,VISIT,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	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
PKSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PKMISSED	char	DOSE MISSED		Collected at CRF.
PKMISSDY	num	RELATIVE DAY 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.

1.4.35. Drug Administration Before Sampling – PLAADM

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

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
PLREFNO	num	PLASMA REF. NO.		Collected at CRF.
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.

1.4.36. Plasma Samples – PLASAM

Dataset	PLASAM
Creating program	plasam.sas
Description	Plasma Samples
Unique identifier	DCRFID, PLREFNO
Sorted by	DCRFID, PLREFNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: 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
PLREFNO	num	PLASMA REF. NO.		Collected at CRF.
PLASMA_T	num	TIME OF PLASMA SAMPLING		Collected at CRF.
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.

1.4.37. Professional Visit – PROFVIS

Dataset	PROFVIS
Creating program	profvis.sas
Description	Professional Visit
Unique identifier	DCRFID,PVTYPE,VISITOR,VISITED
Sorted by	DCRFID,PVTYPE,VISITOR,VISITED
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
PVTYPE	char	PHYSICIAN OR PROFESSIONAL		Collected at CRF.
VISITOR	char	SPECIFICATION PHYSICIAN OR PROFESSIONAL		Collected at CRF.
VISITED	char	VISITED		Collected at CRF.
INOFFICE	num	NUMBER OF VISITATIONS IN OFFICE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATHOME	num	NUMBER OF VISITATIONS AT SUBJECT'S HOME		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.38. 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.

1.4.39. Remarks – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remarks
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
RCSEQNO	num	REMARKLINE NO.		Empty dataset will be submitted
REMARK	char	REMARK		Empty dataset will be submitted
REMARKDY	num	RELATIVE REMARK DAY		Empty dataset will be submitted

1.4.40. Resource Use Questionnaire – RESQUEST

Dataset	RESQUEST
Creating program	resquest.sas
Description	Resource Use Questionnaire
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,CARBIR_D

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
LIVSIT	char	USUAL LIVING SITUATION		Collected at CRF.
SCHOOLED	char	HIGHEST LEVEL OF REGULAR SCHOOL EDUCAT.		Collected at CRF.
PHYSVIS	char	SUBJECT VISITED BY PHYSICIAN		Collected at CRF.
PROFVIS	char	SUBJECT VISITED BY PROFESSIONAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAIDHOME	char	SUBJECT USED PAID HOME HELP		Collected at CRF.
DAYCARE	char	SPENT TIME IN DAY CARE		Collected at CRF.
HALFDAY	num	HALF DAY SESSIONS PER WEEK		Collected at CRF.
FULLDAY	num	FULL DAY SESSIONS PER WEEK		Collected at CRF.
RESPCARE	char	SPENT TIME IN RESPITE CARE		Collected at CRF.
NONIGHTS	num	HOW MANY NIGHTS OF RESPITE		Collected at CRF.
EMERROOM	char	SUBJECTS VISITED EMERGENCY ROOM		Collected at CRF.
HOSPITAL	char	SUBJECT STAYED IN HOSPITAL		Collected at CRF.
NURSHOME	char	SUBJECT STAYED IN NURSING HOME		Collected at CRF.
CARFAM	char	CAREGIVER INFORMAL OR FAMILY		Collected at CRF.
CARSEX	char	CAREGIVERSSEX		Collected at CRF.
CARRELAT	char	CAREGIVERS RELATIONSHIP TO SUBJECT		Collected at CRF.
CARLIV	char	CAREGIVER LIVING WITH SUBJECT		Collected at CRF.
CARCON	char	CAREGIVER CONSULTED FOR ANY THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
CARPAID	char	CAREGIVER IN PAID EMPLOYMENT		Collected at CRF.
CARLOSDA	char	LOSE ANY WORKING DAYS		Collected at CRF.
CARNODAY	num	WORKING DAY LOST		Collected at CRF.
SUPERVIS	char	REQUIRE ROUND-THE-CLOCK SUPERVISION		Collected at CRF.
THALNHR	num	HOURS ALONE ON TYPICAL DAY		Collected at CRF.
THALNMIN	num	MINUTES ALONE ON TYPICAL DAY		Collected at CRF.
CARAGE	char	CAREGIVERS AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: $\text{CARAGE} = \text{int}((\text{REF.DATE} - \text{CARBIR_D}) / 365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and REF.DATE not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than REF.DATE then (VISIT_D - REF.DATE). Else if VISIT_D is greater than equal to REF.DATE then (VISIT_D - REF.DATE) + 1.

1.4.41. Trial Disposition – TRLTERM

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

1.4.42. Visit (Include CIBIC Score) – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit (Include CIBIC Score)
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,ADAS_D,CIBIC_D,DAD_D,GWBS_D

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
DOSEMISS	char	DOSES MISSED ?		Collected at CRF.
CARQUEST	char	QUEST.SCALE CAREGIVER AVAILABLE		Collected at CRF.
ADAS_T	num	ADAS TIME		Collected at CRF.
ADASREF	char	COMPLETE ADAS REFUSED		Collected at CRF.
CIBIC	char	CIBIC : GLOBAL IMPRESSION OF CHANGE		Collected at CRF.
ZCIBIC	num	CIBIC : GLOBAL IMPRESSION OF CHANGE CODE		Collected at CRF.
CARDAD	char	DAD SCALE : CAREGIVER AVAILABLE		Collected at CRF.
CARGWBS	char	GWBS : INF./FAMILY CAREGIVER AVAILABLE		Collected at CRF.
INITGWBS	char	INITIALS CAREGIVER GWBS		Collected at CRF.
PSYCHED	char	PSYCHOTROPIC MEDICATION 48 HRS		Collected at CRF.
ECGNOB	char	ECG OBTAINED		Collected at CRF.
LABNOB	char	LABO OBTAINED		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
ADAS_DY	num	RELATIVE ADASDAY		If ADAS_D and REF.DATE not missing then perform below logic to calculate ADAS_DY, If ADAS_D less than REF.DATE then (ADAS_D - REF.DATE). Else if ADAS_D is greater than equal to REF.DATE then (ADAS_D- REF.DATE) +1.
CIBIC_DY	num	RELATIVE DAY CIBIC		If CIBIC_D and REF.DATE not missing then perform below logic to calculate CIBIC_DY, If CIBIC_D less than REF.DATE then (CIBIC_D - REF.DATE). Else if CIBIC_D is greater than equal to REF.DATE then (CIBIC_D- REF.DATE) +1.
DAD_DY	num	RELATIVE DAY DAD		If DAD_D and REF.DATE not missing then perform below logic to calculate DAD_DY, If DAD_D less than REF.DATE then (DAD_D - REF.DATE). Else if DAD_D is greater than equal to REF.DATE then (DAD_D- REF.DATE) +1.
GWBS_DY	num	RELATIVE DAY GWBS		If GWBS_D and REF.DATE not missing then perform below logic to calculate GWBS_DY, If GWBS_D less than REF.DATE then (GWBS_D - REF.DATE). Else if GWBS_D is greater than equal to REF.DATE then (GWBS_D- REF.DATE) +1.

1.4.43. Vital Signs – VIT SIGN

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.
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, beats/min		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.