

Clinical Development

Galantamine

Gal-Int-6

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.
- Complete missing value variables will be removed.
- Partial date’s relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset containing investigator information, which is sensitive. Hence this dataset will not be submitted(ex. INVEST).
- Remarks dataset will be submitted with zero observation due to sensitivity of data.
- CODE dataset contains CODELIST information which is not required for further analysis hence this data set will not be submitted
- Datasets containing insignificant information will not be submitted(ex. TRLRAND, TRLLIST, RANDGRP, MAP, RELATED).
- Datasets with zero observation will not be submitted (ex. DIAGNOS, LABCOM)
- 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-6 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: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,CMSCAN_D,INIT_B,BREAK_D, BREAK_V,COINV,ZCOINV,COGPRB_M, COGPRB_Y</p> <p>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: DSITEID (Source: INVEST dataset) RANDCODE (Source: TRLRAND dataset) RANDGRP (Source: TRLLIST 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

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.
CHOLINOM	char	TRIALSWITH CHOLINOMIMETICS?		Collected at CRF.
BREAK	char	CODE BROKEN ?		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
BATCHNO	num	BATCH NO.		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
INLCR1	char	INCLUSION CRITERION 1		Collected at CRF.
DSITEID	char	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		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{int}((\text{REF.DATE} - \text{BIRTH_D}) / 365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>
CMSCANDY	num	RELATIVE DAY SCAN PERFORMED		<p>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.</p>
BREAK_DY	num	RELATIVE DAY CODE BREAKING		<p>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.</p>

1.4.2. Alzheimer's Disease Assessment Scale - ADAS

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

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
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. Administration of Trial Medication - ADMMED

Dataset	ADMED
Creating program	admmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID,AMREAS,AMSEQ,SEGMENT,BOX,NUMFORM,AMFROMDY
Sorted by	DCRFID,AMREAS,AMSEQ,SEGMENT,BOX,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,AMFREQ,AMDOSE,AMDOSE_U

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	TRIAL SEGMENT SEQ.		Collected at CRF.
BOX	char	BOX		Collected at CRF.
AMSEQ	num	SEQUENCE NUMBER		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		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. 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, 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, 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.
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.
AECNRX	char	AE CO-RX START		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.
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. Brain MRI - CMRI

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

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
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.

1.4.6. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,RXPREF,ATCCODE1,CTSCHED,CONRX,CTPRIOR,CTFROMDY,CTTO_DY
Sorted by	DCRFID,RXPREF,ATCCODE1,CTSCHED,CONRX,CTPRIOR,CTFROMDY,CTTO_DY
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,ATCCODE9,ATCTEXT9

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
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	INDICATION		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.
CTTO_C	char	CO-RX END CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCCODE8	char	ATC CODE 8		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
ATCTEXT3	char	ATC TEXT 3		Collected at CRF.
ATCTEXT4	char	ATC TEXT 4		Collected at CRF.
ATCTEXT5	char	ATC TEXT 5		Collected at CRF.
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
ATCTEXT8	char	ATC TEXT 8		Collected at CRF.
RXPREF	char	PREFERRED NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFROMDY	num	RELATIVE CO-RXSTART 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-RXEND 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.

1.4.7. DAD-Scale - DAD

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
DASYMP	char	SYMPTOM		Collected at CRF.
DASEV	char	SEVERITY		Collected at CRF.

1.4.8. 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.

1.4.9. Protocol Deviation – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Protocol Deviation
Unique identifier	DCRFID,DVTYPE,DEVIAT,ZDEVIAT
Sorted by	DCRFID,DVTYPE,DEVIAT,ZDEVIAT
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.

Variable	Type	Label	Codes	Comments
ZDEVIAT	char	DEVIATION CODE		Collected at CRF.
DVTYPE	char	TYPE OF DEVIATION		Collected at CRF.

1.4.10. Medical History – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Medical History
Unique identifier	DCRFID, DSCOND, DSSYSTEM, DSSEQNO
Sorted by	DCRFID, DSCOND, DSSYSTEM, DSSEQNO
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
DSSEQNO	num	DS SEQUENCE NUMBER		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.

1.4.11. ECG Overall Interpretation - ECG

Dataset	ECG
Creating program	ecg.sas
Description	ECG Overall Interpretation
Unique identifier	DCRFID, ECGSRCE, EGLIMITS, ECG_DY
Sorted by	DCRFID, ECGSRCE, EGLIMITS, 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
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.
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.

1.4.12. ECG Abnormalities - ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Abnormalities
Unique identifier	DCRFID,ECGSRCE,EASEQNO,ECG_DY
Sorted by	DCRFID,ECGSRCE,EASEQNO,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	TRIALID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EASEQNO	num	EA SEQUENCE NUMBER		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.

1.4.13. ECG Evaluation – ECGEVAL

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

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG Measurements
Unique identifier	DCRFID, ECGPAR, ECGSRCE, ECGVAL, EPSEQNO, ECG_DY
Sorted by	DCRFID, ECGPAR, ECGSRCE, ECGVAL, EPSEQNO, 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.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EPSEQNO	num	EP SEQUENCE NUMBER		Collected at CRF.
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ECGPAR_U	char	ECG MEASUREMENT UNIT		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. 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	TRIALID.		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	ELIGIBILITY EXPR.		Collected at CRF.

1.4.16. 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
TRIAL	char	TRIALID.		Collected at CRF.
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.
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.
AGE_U	char	AGE UNIT		Collected at CRF.
SEX	char	SEX		Collected at CRF.

1.4.17. Laboratory Requisition Numbers – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory Requisition Numbers
Unique identifier	DCRFID,LSRELCHA,LFTYPE
Sorted by	DCRFID,LSRELCHA,LFTYPE
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,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. SIGNIFICANT CHANGES		Collected at CRF.
LFTYPE	char	TYPE OF SAMPLE		Collected at CRF.

1.4.18. Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results
Unique identifier	DCRFID, LABCLASS, LABTEST, SAMPLEDY, SAMPLE_T
Sorted by	DCRFID, LABCLASS, LABTEST, 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
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.
LABUPP	num	UPPER NORMAL LIMIT		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.19. Laboratory Sample Info – LABSAM

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

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.
LSRELCHA	char	CLIN. SIGNIFICANT CHANGES		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.

1.4.20. Laboratory Urine Results – LABURI

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

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.

1.4.21. Mini-Mental State Examination – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	Mini-Mental State Examination
Unique identifier	DCRFID,MMITEM
Sorted by	DCRFID,MMITEM
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.
MMITEM	char	MMSE ITEM		Collected at CRF.
MMSCORE	num	MMSE SCORE		Collected at CRF.

1.4.22. Neurological Examination – NEUREXAM

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

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
NESEQNO	num	NEUR. EXAM. SEQ. NO		Collected at CRF.
NESYSTEM	char	NEUR. EXAM. BODY SYSTEM		Collected at CRF.
NERESULT	char	NEUR. EXAM. RESULT		Collected at CRF.

1.4.23. Neuropsychiatric Inventory – NPI

Dataset	NPI
Creating program	npi.sas
Description	Neuropsychiatric Inventory
Unique identifier	DCRFID,NPSYMP,NPNA,NPNO,NPFREQ,NPSEV,NPDIS,VISIT
Sorted by	DCRFID,NPSYMP,NPNA,NPNO,NPFREQ,NPSEV,NPDIS,VISIT
Notes	

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
VISIT	num	VISIT		Collected at CRF.
NPSYMP	char	NPI SYMPTOMS		Collected at CRF.
NPNA	char	NPI NAP		Collected at CRF.
NPNO	char	NPI NO		Collected at CRF.
ZNPNO	num	NPI NO CODE		Collected at CRF.
NPFREQ	num	NPI FREQUENCY		Collected at CRF.
NPSEV	num	NPI SEVERITY		Collected at CRF.
NPDIS	num	NPI DISTRESS		Collected at CRF.

1.4.24. Physical Examination – PHYSEXAM

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

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
VISIT	num	VISIT		Collected at CRF.
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.

1.4.25. 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	TRIALID.		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.

1.4.26. 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	TRIALID.		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
REMARKDY	num	RELATIVE REMARKDAY		Empty dataset will be submitted

1.4.27. Totals – TOTALS

Dataset	TOTALS
Creating program	totals.sas
Description	Totals
Unique identifier	DCRFID,TOGROUP,TOITEM,TOSCORE
Sorted by	DCRFID,TOGROUP,TOITEM,TOSCORE
Notes	

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
TOGROUP	char	TOTAL GROUP		Collected at CRF.
TOITEM	char	TOTAL ITEM		Collected at CRF.
TOSCORE	num	TOTAL SCORE		Collected at CRF.

1.4.28. Trial Description - TRLDDESC

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIALID.		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.
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.

Variable	Type	Label	Codes	Comments
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.29. Trial Regimen - TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Regimen
Unique identifier	TRIAL,TREAT,BLINDING,RANDGRP,BOX,SEGMENT
Sorted by	TRIAL,TREAT,BLINDING,RANDGRP,BOX,SEGMENT
Notes	

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.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
BOX	char	BOX		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.

1.4.30. Trial Disposition – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	Trial Disposition
Unique identifier	DCRFID,TTTYPE,TTREAS
Sorted by	DCRFID,TTTYPE,TTREAS
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	TRIALID.		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.
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.

1.4.31. 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,ADAS_D,CIBIC_D,DAD_D

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
VISIT	num	VISIT		Collected at CRF.
PSYCHED	char	PSYCHOTROPICMEDICATION 48 HRS		Collected at CRF.
PREGRES	char	RESULT OF PREGNANCY TEST		Collected at CRF.
PRIMCAR	char	PRIMARY CAREGIVER INTERVIEWED?		Collected at CRF.
BASECAR	char	PRIMARY CAREGIVER BASELINE?		Collected at CRF.
ADAS_T	num	ADAS TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
CIBIC	char	CIBIC : GLOBAL IMPRESSION CHANGE		Collected at CRF.
ZCIBIC	num	CIBIC : GLOBAL IMPRESSION CHANGE CODE		Collected at CRF.
CARDAD	char	CAREGIVER NOT AVAILABLE		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.
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 CIBICDAY		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 DAD DAY		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.

1.4.32. Vital Signs - VITSIGN

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

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
VISIT	num	VISIT		Collected at CRF.
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	DIASTOLICBP, mmHg		Collected at CRF.