Clinical Development

Galantamine

Gal-Int-7

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.
- Empty Remark data will be submitted due to sensitivity of data.
- Datasets containing insignificant information will not be submitted. (eg. CODE,TRLRAND,TRLLIST)
- Dataset containing investigator information is sensitive and hence will not be submitted. (eg.INVEST).
- Empty dataset will not be submitted(eg. DIAGNOS, LABNOR).
- 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-7 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INITIALS, MEDNO, ZINVEST, COINVEST, ZCOINVES, BIRTH_D, HEIGHT, HEIGHT_U, PRVTRIAL ,PRVCRFID, BATCHNO 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)

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
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned Site No. for De-identity

Variable	Type	Label	Codes	Comments
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
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.
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((REF.DATE – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.

1.4.2. Alzheimer's Disease Assessment Scale – ADAS

Dataset	ADAS
Creating program	adas.sas
Description	Alzheimer's Disease Assessment Scale
Unique identifier	DCRFID, VISIT, ADTYPE, ADTRIAL, ADITEM
Sorted by	DCRFID, VISIT, ADTYPE, ADTRIAL, ADITEM
Notes	Below listed variables will be dropped from dataset due to missing values: SORT_NO

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.

1.4.3. Administration of Trial Medication – ADMMED

Dataset	ADMMED
Creating program	admmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID, AMFROMDY, AMSEQ
Sorted by	DCRFID, AMFROMDY, AMSEQ
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, NUMFORM

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.
AMSEQ	num	ADMMED SEQUENCE NUMBER		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.
ZAMREAS	char	REGIMEN CHANGE REASON CODE		Collected at CRF.
AMDOSE	num	DOSE SCHEDULE		Collected at CRF.
AMDOSE_U	char	DOSE SCHEDULE UNIT		Collected at CRF.

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

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: AE_V, AEINCL, 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.
PHASE	char	TRIAL PHASE		Collected at CRF.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESEV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.

Variable	Type	Label	Codes	Comments
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.Resource Use: Caregiver Counseling – CARCONS

Dataset	CARCONS
Creating program	carcons.sas
Description	Resource Use: Caregiver Counseling
Unique identifier	DCRFID, VISIT, CARCONS
Sorted by	DCRFID, VISIT, CARCONS
Notes	

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
CARCONS	char	CAREGIVERS CONSULTANT		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. Resource Use: Caregiver Time – CARETIME

Dataset	CARETIME
Creating program	caretime.sas
Description	Resource Use: Caregiver Time
Unique identifier	DCRFID, VISIT, CRACTIV, CRSEQNO
Sorted by	DCRFID, VISIT, CRACTIV, CRSEQNO
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.

Variable	Type	Label	Codes	Comments
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	CARETIME SEQUENCE NUMBER		Collected at CRF.
CRNOTDNE	char	DONE		Collected at CRF.
CRTMHR	num	DAILY HOURS SPENT ON ACTIVITY		Collected at CRF.
CRTMMIN	num	DAILY MINUTES SPENT ON ACTIVITY		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.7. Concomitant Medication – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Medication
Unique identifier	DCRFID, CTTYPE, RXPREF, CTSEQNO
Sorted by	DCRFID, CTTYPE, RXPREF, CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CONRX_V, CTIND_V, CTFROM_D, CTTO_D, 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.
CTIND	char	CT INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.
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 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-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE).Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D- REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE).Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D- REF.DATE) +1.

1.4.8.DAD -Scale – DAD

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

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

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

1.4.9.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 or due to missing values: DEATH_D, DTREAS_V

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

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.

1.4.10. Resource Use: Dependence Scale – DEPENDS

Dataset	DEPENDS
Creating program	depends.sas
Description	Resource Use: 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	DEPEND SYMPTOM		Collected at CRF.

Variable	Type	Label	Codes	Comments
DEPRESP	char	RESPONSE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.11. 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	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION CODE		Collected at CRF.

1.4.12. Diseases – DISEASES

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned Crf ID for De-identity
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.
DISEASE	char	DISEASE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.13. ECG Overall Interpretation – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ECG Overall Interpretation
Unique identifier	DCRFID, EGLIMIT, SEGRELCHA, ECG_DY
Sorted by	DCRFID, EGLIMIT, SEGRELCHA, 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 COMMENTS		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.

1.4.14. 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

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.
ECGOTH_V	char	ECG OTHER ABN. (VERB.)		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. ECG Description – ECGEVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ECG Description
Unique identifier	DCRFID, EEASPECT, EEEVAL, ECG_DY
Sorted by	DCRFID, EEASPECT, EEEVAL, 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
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEEVAL	char	ECG EVALUATION		Collected at CRF.
ECD_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECD_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 Measurements – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG Measurements
Unique identifier	DCRFID, ZECGPAR, ECG_DY
Sorted by	DCRFID, ZECGPAR, 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.
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.

1.4.17. Inclusion and Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion and Exclusion Criteria
Unique identifier	DCRFID, IETYPE, ZIECRIT
Sorted by	DCRFID, IETYPE, ZIECRIT
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.

1.4.18. Resource Use: Institutionalization – INSTITUT

Dataset	INSTITUT
Creating program	institut.sas
Description	Resource Use: Institutionalization
Unique identifier	DCRFID, VISIT, ZINSTTYP
Sorted by	DCRFID, VISIT, ZINSTTYP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INFROM_D, INTO_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
INSTTYPE	char	TYPE OF INSTITUTION		Collected at CRF.
ZINSTTYP	num	TYPE OF INSTITUTION CODE		Collected at CRF.
WARDTYPE	char	TYPE OF WARD		Collected at CRF.
ZWARDTYP	char	TYPE OF WARD CODE		Collected at CRF.
INSEQNO	num	INSTITU SEQUENCE NUMBER		Collected at CRF.
INPRIOR	char	ONGOING FROM		Collected at CRF.
INONGO	char	ONGOING TO		Collected at CRF.

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

1.4.19. Laboratory Comments – LABCOM

Dataset	LABCOM
Creating program	labcom.sas
Description	Laboratory Comments
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LABID, ZLABID, LABREFNO

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.
LABCOM	char	LAB COMMENTS		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 Requisition Numbers – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory Requisition Numbers
Unique identifier	DCRFID, LSRELCHA, LFTYPE, SAMPLEDY
Sorted by	DCRFID, LSRELCHA, LFTYPE, 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, LABREFNO, LABID, ZLABID, LSSAME

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

1.4.21. Laboratory Results - Clinical Chemistry – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results - Clinical Chemistry
Unique identifier	DCRFID, LABTEST, LABTSTNO, LABVAL, SAMPLEDY
Sorted by	DCRFID, LABTEST, LABTSTNO, LABVAL, SAMPLEDY
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 LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
LABTST_U	char	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.

1.4.22. Laboratory Sample Info – LABSAM

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

1.4.23. Laboratory Urine Results – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urine Results
Unique identifier	DCRFID, ZLABTEST, LUVAL, SAMPLEDY
Sorted by	DCRFID, ZLABTEST, LUVAL, SAMPLEDY
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.
LUVAL	char	URINE VALUE		Collected at CRF.
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
LABTSTNO	num	LAB. TEST NUMBER		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.24. Resource Use: Outpatient Services – OUTPAT

Dataset	OUTPAT
Creating program	outpat.sas
Description	Resource Use: Outpatient Services
Unique identifier	DCRFID, VISIT, SERVICE
Sorted by	DCRFID, VISIT, SERVICE
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
SERVICE	char	OUTPATIENT SERVICE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SERVUSED	char	SERVICE USED?		Collected at CRF.
SERVNO	num	SERVICE NUMBER		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.25. General Well-Being Index – PGWBI

Dataset	PGWBI
Creating program	pgwbi.sas
Description	General Well-Being Index
Unique identifier	DCRFID, VISIT, PGITEM
Sorted by	DCRFID, VISIT, PGITEM
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
PGITEM	char	GENERAL WELL-BEING ITEM		Collected at CRF.
PGSCORE	char	GENERAL WELL-BEING SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZPGSCORE	num	GENERAL WELL-BEING SCORE CODE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.26. 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	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.

1.4.27. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID, VISIT, PESYSTEM
Sorted by	DCRFID, VISIT, PESYSTEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXAM_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
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
EXAM	char	PHYS. EXAM.		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.28. 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.

1.4.29. 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	REMARK LINE NO.		Empty dataset will be submitted
REMARKDY	num	RELATIVE REMARK DAY		Empty dataset will be submitted

1.4.30. Trial Description – TRLDESC

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

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

1.4.31. Trial Regimen – TRLREGM

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		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	TRIAL REGIMEN ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.
ZTMROUTE	char	ADMIN. ROUTE CODE		Collected at CRF.
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.32. Trial Termination – TRLTERM

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

1.4.33. 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 or due to missing values: VISIT_D, CARQUEST, CARBIR_D, ADAS_D, DAD_D, GWBS_D, INITGWBS

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.
OUTPATNT	char	OUTPATIENT SERVICE USED		Collected at CRF.
INSTITUT	char	STAYED IN INSTITUTION?		Collected at CRF.
CARFAM	char	CAREGIVER INFORMAL OR FAMILY		Collected at CRF.
CARSEX	char	CAREGIVERS SEX		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
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.
ECGNOB	char	ECG OBTAINED		Collected at CRF.
LABNOB	char	LABO OBTAINED		Collected at CRF.
ADAS_T	num	ADAS TIME		Collected at CRF.
PSYCHED	char	PSYCHOTROPIC MEDICATION 48 HRS		Collected at CRF.
ADASREF	char	COMPLETE ADAS REFUSED		Collected at CRF.
CARDAD	char	DAD SCALE : CAREGIVER AVAILABLE		Collected at CRF.
CARGWBS	char	GWBS : CAREGIVER AVAILABLE ?		Collected at CRF.
CARAGE	char	CAREGIVERS AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving CARAGE, element derivation follows below rule: CARAGE= int((REF.DATE – CARBIR_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.

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.
ADAS_DY	num	RELATIVE ADAS DAY		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.
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.

1.4.34. Vital Signs – VITSIGN

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

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