

Clinical Development

Galantamine

GAL9301

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 with zero observation will not be submitted (ex. INEX).
- VISITE. VISIT_D (VISIT DATE when VISIT=2) will be used as Reference Date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The GAL9301 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. DEMOGRAPHICS – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	DEMOGRAPHICS
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 repetition of the information: MEDNO,INITIALS,BIRTH_D,XHEIGHT

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.
RANDGRP	char	RANDOMIZATION GROUP		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
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.

Variable	Type	Label	Codes	Comments
XDIAGN	char	DIAGNOSIS		Collected at CRF.
XAGE	char	AGE, YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XWEIGHT	num	WEIGHT, KG		Collected at CRF.

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,VISIT
Sorted by	DCRFID,ADTYPE,ADITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
VISIT	num	VISIT NO		Collected at CRF.
ADTYPE	char	TYPE OF ADAS TEST		Collected at CRF.
ADITEM	char	ADAS TEST ITEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADSCORE	char	ADAS TEST ITEM SCORE		Collected at CRF.
ADVALUE	num	ADAS TEST ITEM VALUE		Collected at CRF.
ADTARGET	char	ADAS TEST ITEM TARGET		Collected at CRF.

1.4.3. CIBICOM – CIBICOM

Dataset	CIBICOM
Creating program	cibicom.sas
Description	CIBICOM
Unique identifier	DCRFID,CTYPE,VISIT
Sorted by	DCRFID,CTYPE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CIBIC_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.
VISIT	num	VISIT NO		Collected at CRF.
CTYPE	char	CIBIC-PLUS INTERVIEW SUBJECT		Collected at CRF.

1.4.4.IADL – IADL

Dataset	IADL
Creating program	iadl.sas
Description	IADL
Unique identifier	DCRFID,IADLTYPE,VISIT
Sorted by	DCRFID,IADLTYPE,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf Id for De-Identity.
VISIT	num	VISIT NO		Collected at CRF.
IADLTYPE	char	IADL TYPE		Collected at CRF.
IADLSCOR	num	IADL SCORE		Collected at CRF.

1.4.5.MINI-MENTAL STATE EXAMINATION – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	MINI-MENTAL STATE EXAMINATION
Unique identifier	DCRFID,MMSYMP,VISIT
Sorted by	DCRFID,MMSYMP,VISIT
Notes	Below listed variables will be dropped from dataset due to repetition of the information: PATIENT

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	SYMPTOM		Collected at CRF.
MMSEV	num	MMSE SCORE		Collected at CRF.
VISIT	num	VISIT NO		Collected at CRF.

1.4.6. PROGRESSIVE DETERIORATION SCALE – PDS

Dataset	PDS
Creating program	pds.sas
Description	PROGRESSIVE DETERIORATION SCALE
Unique identifier	DCRFID,PDSITEM,VISIT,PDSSEQ
Sorted by	DCRFID,PDSITEM,VISIT,PDSSEQ
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 NO		Collected at CRF.
PDSSEQ	num	PDS CARERS ASSESSMENT		Collected at CRF.
PDSITEM	char	PDS CHARACTERISTIC		Collected at CRF.
PDSSCORE	num	PDS SCORE		Collected at CRF.
PDSNEVER	char	NEVER DID DUE TO ILLNESS		Collected at CRF.

1.4.7.VISIT – VISITE

Dataset	VISITE
Creating program	visite.sas
Description	VISIT
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,INITADAS,INITCIBI,INITIADL

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 NO		Collected at CRF.
RETTABNO	num	TOTAL NUMBER OF RETURNED TABLETS		Collected at CRF.
CHCOMPL	num	COMPLIANCE CHECK		Collected at CRF.
ADAS_T	num	ASSESSMENT TIME FOR ADAS		Collected at CRF.
CIBIC_T	num	ASSESSMENT TIME FOR CIBIC PLUS		Collected at CRF.
CIBIC	char	CIBIC:EXTENT OF CHANGE		Collected at CRF.
ZCIBIC	num	CIBIC:EXTENT OF CHANGE CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CIBSCORE	num	CIBIC:IMPRESSION AND MENTAL STATUS		Collected at CRF.
IADL_T	num	ASSESSMENT TIME FOR IADL		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.