

Clinical Development

Galantamine

GALUSA010

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.
- Due to sensitive information INVEST dataset will be removed.
- For Randomized subjects, SUBJCHAR.RAND_D ("Randomization Date") will be used as Reference Date to derive relative days. For Screen Failure subjects, VISIT.VISIT_D (WHEN VISIT=1) will be used as a Reference date (referred as REF.DATE in the document) to derive relative days.

1.3. Data Files

The GALUSA010 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MEDNO,INVEST,ZINVEST,INITIALS,BIRTH_D,COGPRB_D,CMSCAN_D,BREAK_D, BREAK_V,COINVEST,RAND_D</p> <p>Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment related information in the de-identified datasets:</p> <p>AGE (Source: XPLASMA2 dataset) RANDGRP (Source: XPLASMA2 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 crfid for De-identity

Variable	Type	Label	Codes	Comments
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned site no. for De-identity
SEX	char	SEX		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
RELATIVE	char	FIRST DEGREE RELATIVES WITH AD		Collected at CRF.
CHOLINUM	char	SUBJECT TAKEN CHOLINOMIMETICS		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
PREGNANT	char	PREGNANT		Collected at CRF.
DNAAPPR	char	APPROVAL FROM ETHICAL COMMITTEE		Collected at CRF.
DNACONST	char	INFORMED CONSENT OBTAINED		Collected at CRF.
DNAAPOE	char	OBTAINED FOR APO E GENOTYPING		Collected at CRF.
DNASTOR	char	OBTAINED FOR STORAGE		Collected at CRF.
RAND	char	RANDOMIZED AT END OF RUN-IN		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
RACE	char	RACE		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
CMSCANDY	num	RELATIVE DAY SCAN PERFORMED		If CMSCAN_D and REF.DATE not missing then perform below logic to calculate CMSCANDY, If CMSCAN_D less than REF.DATE then (CMSCAN_D - REF.DATE). Else if CMSCAN_D is greater than equal to REF.DATE then (CMSCAN_D- REF.DATE) +1.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and REF.DATE not missing then perform below logic to calculate BREAK_DY, If BREAK_D less than REF.DATE then (BREAK_D - REF.DATE). Else if BREAK_D is greater than equal to REF.DATE then (BREAK_D- REF.DATE) +1.

1.4.2. Alzheimer's Disease Assessment Scale1 – ADAS1

Dataset	ADAS1
Creating program	adas1.sas
Description	Alzheimer's Disease Assessment Scale1
Unique identifier	DCRFID,ADTYPE,ADTRIAL,ADITEM,VISIT
Sorted by	DCRFID,ADTYPE,ADTRIAL,ADITEM,VISIT
Notes	Below listed variables will be dropped from dataset due to missing values: ADVALUE

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 crfid for De-identity
ADTYPE	char	TEST		Collected at CRF.
ADTRIAL	char	TRIAL NUMBER		Collected at CRF.
ADITEM	char	ITEM		Collected at CRF.
ADSCORE	char	SCORE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.3. Alzheimer's Disease Assessment Scale2 – ADAS2

Dataset	ADAS2
Creating program	adas2.sas
Description	Alzheimer's Disease Assessment Scale2
Unique identifier	DCRFID,ADTYPE,ADTRIAL,ADITEM,VISIT
Sorted by	DCRFID,ADTYPE,ADTRIAL,ADITEM,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 crfid for De-identity
ADTYPE	char	TEST		Collected at CRF.
ADTRIAL	char	TRIAL NUMBER		Collected at CRF.
ADITEM	char	ITEM		Collected at CRF.
ADSCORE	char	SCORE		Collected at CRF.
ADVALUE	char	VALUE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.4. Alzheimer's Disease Assessment Scale3 – ADAS3

Dataset	ADAS3
Creating program	adas3.sas
Description	Alzheimer's Disease Assessment Scale3
Unique identifier	DCRFID,ADTYPE,ADTRIAL,ADITEM,VISIT
Sorted by	DCRFID,ADTYPE,ADTRIAL,ADITEM,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 crfid for De-identity
ADTYPE	char	TEST		Collected at CRF.
ADTRIAL	char	TRIAL NUMBER		Collected at CRF.
ADITEM	char	ITEM		Collected at CRF.
ADSCORE	char	SCORE		Collected at CRF.
ADVALUE	char	VALUE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.5.AdI – ADL

Dataset	ADL
Creating program	adl.sas
Description	AdI
Unique identifier	DCRFID,ALITEM,VISIT
Sorted by	DCRFID,ALITEM,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 crfid for De-identity
ALITEM	char	ITEM		Collected at CRF.
ALYESNO	char	YES/NO/DON'T KNOW		Collected at CRF.
ALSCORE	char	SCORE		Collected at CRF.

1.4.6. Administration of Trial Medication – ADMMED

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid 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.
ZAMREAS	char	REGIMEN CHANGE REASON (CODE)		Collected at CRF.
SEGMENT	num	SEGMENT		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.

1.4.7. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,AESOC,AEPREF,AEFROM_D,AESEQNO
Sorted by	DCRFID,AESOC,AEPREF,AEFROM_D,AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AE_V,AEINCL,PHASE,AEFROM_D,AEFROM_C,AETO_D,AETO_C,SAEREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
AESEQNO	num	AE SEQ.		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.
AERELAT	char	AE DRUG RELATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
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 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.

1.4.8. Apoeus10 – APOEUS10

Dataset	APOEUS10
Creating program	apoeus10.sas
Description	Apoeus10
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FG_NR

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
APOE_CON	char	APOE Consent		Collected at CRF.
STORAGE	char	STORAGE CONSENT		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
APOE_GEN	char	APOE GENOTYPE		Collected at CRF.
CYP2D6_B	char	CYP2D6 B/T ALLELES		Collected at CRF.
CYP2D6_A	char	CYP2D6 A ALLELE		Collected at CRF.
CYP2D6_G	char	CYP2D6 GENOTYPE		Collected at CRF.
CYP2D6_P	char	CYP2D6 PREDICTED PHENOTYPE		Collected at CRF.

1.4.9.CIBIC-Plus – CIBIC

Dataset	CIBIC
Creating program	cibic.sas
Description	CIBIC-Plus
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 crfid for De-identity
CIBIC	char	SUBJECTS STATUS COMPARED TO BASELINE		Collected at CRF.
ZCIBIC	num	SUBJ STATUS COMPARED TO BASELINE (CODE)		Collected at CRF.

1.4.10. CMRI – CMRI

Dataset	CMRI
Creating program	cmri.sas
Description	CMRI
Unique identifier	DCRFID,CMSYMP
Sorted by	DCRFID,CMSYMP
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 crfid for De-identity
CMSYMP	char	PARAMETERS		Collected at CRF.
CMSEV	char	RESPONSE		Collected at CRF.
CMNUM	char	NUMBER		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.11. Concomitant Medication – COTHER

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

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid 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	INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCCODE0	char	ATC CODE 1		Collected at CRF.
ATCCODE1	char	ATC CODE 2		Collected at CRF.
ATCCODE2	char	ATC CODE 3		Collected at CRF.
ATCCODE3	char	ATC CODE 4		Collected at CRF.
ATCCODE4	char	ATC CODE 5		Collected at CRF.
ATCCODE5	char	ATC CODE 6		Collected at CRF.
ATCCODE6	char	ATC CODE 7		Collected at CRF.
ATCCODE7	char	ATC CODE 8		Collected at CRF.
ATCCODE8	char	ATC CODE 9		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D- REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D- REF.DATE) +1.

1.4.12. Death – DEATH

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

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

1.4.13. 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 crfid for De-identity
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	OTHER DEVIATION		Collected at CRF.

1.4.14. Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset due to repetition of the information: DIAGMON,DIAGYR

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

1.4.15. Diseases – DISEASES

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

1.4.16. ECG Overall Interpretation – ECG

Dataset	ECG
Creating program	ecg.sas
Description	ECG Overall Interpretation
Unique identifier	DCRFID,EGLIMITS,ECG_DY
Sorted by	DCRFID,EGLIMITS,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BIRTH_D,INITIALS,ECG_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 crfid for De-identity
ECG_T	num	ECG TIME		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
ECGSRCE	char	SOURCE ECG COMMENTS		Collected at CRF.
EGCLREL	char	CLINICAL SIGNIFICANCE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGSGNCH	char	SIGNIFICANT CHANGE		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.17. ECG Abnormalities – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Abnormalities
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: ECG_D,ECGOTH_V,ECOTH1_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 crfid for De-identity
ECG_T	num	ECG TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.

1.4.18. ECG Evaluation – ECGINTRP

Dataset	ECGINTRP
Creating program	ecgintrp.sas
Description	ECG Evaluation
Unique identifier	DCRFID,EGABNCLS,EGABN,ECG_DY
Sorted by	DCRFID,EGABNCLS,EGABN,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.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
ECG_T	num	ECG TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGABNCLS	char	ECG ABNORMALITY CLASS		Collected at CRF.
EGABN	char	ECG ABNORMALITY		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.19. ECG Measurements – ECGPAR

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

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

Variable	Type	Label	Codes	Comments
ECG_T	num	ECG TIME		Collected at CRF.
ECGP	char	ECG PARAMETER		Collected at CRF.
ZECGP	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.

1.4.20. Ecgref – ECGREF

Dataset	ECGREF
Creating program	ecgref.sas
Description	Ecgref
Unique identifier	DCRFID,ECGSGNCH,ECG_DY
Sorted by	DCRFID,ECGSGNCH,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.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSGNCH	char	SIGNIFICANT CHANGE		Collected at CRF.
ECG_DY	num	RELATIVE ECG VISIT 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.

1.4.21. Cigarette Smoking – HABIT

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

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

1.4.22. 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 crfid for De-identity
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	char	SELECTION CRITERIA		Collected at CRF.
IEYN	char	NON-ELIGIBILITY EXPR.		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.23. Laboratory Chemistry Results – LABRC

Dataset	LABRC
Creating program	labrc.sas
Description	Laboratory Chemistry Results
Unique identifier	DCRFID,LABTEST,SAMPLEDY
Sorted by	DCRFID,LABTEST,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 crfid for De-identity
LABTEST	char	LAB. TEST		Collected at CRF.
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.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABLOW	num	LAB. LOW		Collected at CRF.
LABUPP	num	LAB. HIGH		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.

1.4.24. Laboratory Requisition Numbers – LABREF

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

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

1.4.25. Laboratory Haematology Results – LABRH

Dataset	LABRH
Creating program	labrh.sas
Description	Laboratory Haematology Results
Unique identifier	DCRFID,LABTEST,SAMPLEDY
Sorted by	DCRFID,LABTEST,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,ENZYME

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
LABTEST	char	LAB. TEST		Collected at CRF.
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.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
LABLOW	num	LAB. LOW		Collected at CRF.
LABUPP	num	LAB. HIGH		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.
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,SAMPLE_D
Sorted by	DCRFID,SAMPLE_D
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,ZLABID,LABREFNO,LSSAME,LSRELCHA

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
FASTED	char	SUBJECT FASTED		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D- REF.DATE) +1.

1.4.27. Laboratory Urine Results – LABURI

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

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

1.4.28. 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.
VISIT	num	VISIT		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
MMITEM	char	MMSE ITEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
MMSCORE	num	MMSE 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,NERESULT
Sorted by	DCRFID,NESYSTEM,NERESULT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NEUR_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 crfid for De-identity
NESYSTEM	char	TEST/SIGNS		Collected at CRF.
NERESULT	char	RESPONSE		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.30. NPI – NPI

Dataset	NPI
Creating program	npi.sas
Description	NPI
Unique identifier	DCRFID,NPSYMP,VISIT
Sorted by	DCRFID,NPSYMP,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 crfid for De-identity
NPSYMP	char	SYMPTOM		Collected at CRF.
NPNO	num	NO		Collected at CRF.
NPSYSFRQ	num	FREQUENCY		Collected at CRF.
NPSEV	num	SEVERITY		Collected at CRF.
NPDIST	num	DISTRESS		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.31. Physical Examination – PHYSEXAM

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

1.4.32. Date Doses Missed – PKMISSED

Dataset	PKMISSED
Creating program	pkmissesd.sas
Description	Date Doses Missed
Unique identifier	DCRFID,PKMISSED,PKMISSDY,PKSEQNO
Sorted by	DCRFID,PKMISSED,PKMISSDY,PKSEQNO
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 crfid for De-identity
PKSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PKMISSED	char	AM/PM DOSE MISSED		Collected at CRF.
PKMISSDY	num	RELATIVE DAY DOSE MISSED		If PKMISS_D and REF.DATE not missing then perform below logic to calculate PKMISSDY, If PKMISS_D less than REF.DATE then (PKMISS_D - REF.DATE). Else if PKMISS_D is greater than equal to REF.DATE then (PKMISS_D- REF.DATE) +1.

1.4.33. Drug Administration Before Sampling – PLAADM

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

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

1.4.34. Plasma Results – PLARES

Dataset	PLARES
Creating program	plares.sas
Description	Plasma Results
Unique identifier	DCRFID,PLASMADY
Sorted by	DCRFID,PLASMADY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INITIALS,LABID,PLASMA_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
TRIAL	char	TRIAL ID.		Collected at CRF.
DRUG	char	STUDY DRUG		Collected at CRF.
VISIT	char	VISIT		Collected at CRF.
PRVAL	num	PLASMA MEASUREMENT		Collected at CRF.
PRFLAG	char	DATA FLAG		Collected at CRF.
PRVAL_U	char	PLASMA UNIT		Collected at CRF.
PRDETECT	num	DETECTION LIMIT		Collected at CRF.
ANALYTE	char	PLASMA SUBSTANCE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PLASMA_T	num	PLASMA SAMPLING TIME		Collected at CRF.
PLASMADY	num	RELATIVE PLASMA SAMPLING DAY		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.

1.4.35. Plasma Samples – PLASAM

Dataset	PLASAM
Creating program	plasam.sas
Description	Plasma Samples
Unique identifier	DCRFID,PLASMADY
Sorted by	DCRFID,PLASMADY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PLREFNO,PLASMA_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
PLASMA_T	num	TIME OF PLASMA SAMPLING		Collected at CRF.

Variable	Type	Label	Codes	Comments
PLASMSEQ	char	PLASMA SEQUENCE		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.

1.4.36. 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
Sorted by	DCRFID,RATYPE
Notes	

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

1.4.37. 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 crfid for De-identity
TTTYPE	char	TERM. TYPE		Collected at CRF.
TTREAS	char	TERM. REASON		Collected at CRF.
TTFROMDY	num	RELATIVE DISCON STDY MED/LST 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.

1.4.38. Visit – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
Unique identifier	DCRFID,VISIT_DY
Sorted by	DCRFID,VISIT_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISIT_D,ADRATER,ADVIS_D,NPRATER,NPDATE_D,CIBIC_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 crfid for De-identity
ADVIS_T	num	ADAS TIME		Collected at CRF.
MISSDOSE	char	MISSED DOSES		Collected at CRF.
NPRMCARE	char	PRIMARY CAREGIVER INTERVIEWD (NPI)		Collected at CRF.
NPRMCAR1	char	SAME CAREGIVER AT BASELINE? (NPI)		Collected at CRF.
VSND	char	VITAL SIGNS NOT DONE		Collected at CRF.
LABND	char	LAB REF NOT DONE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGND	char	ECG NOT DONE		Collected at CRF.
PEND	char	PHYS EXAM NOT DONE		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.
ADVIS_DY	num	RELATIVE ADAS VISIT DAY		If ADVIS_D and REF.DATE not missing then perform below logic to calculate ADVIS_DY, If ADVIS_D less than REF.DATE then (ADVIS_D - REF.DATE). Else if ADVIS_D is greater than equal to REF.DATE then (ADVIS_D- REF.DATE) +1.
NPDATEDY	num	RELATIVE NPI VISIT DAY (NPI)		If NPDATE_D and REF.DATE not missing then perform below logic to calculate NPDATEDY, If NPDATE_D less than REF.DATE then (NPDATE_D - REF.DATE). Else if NPDATE_D is greater than equal to REF.DATE then (NPDATE_D- REF.DATE) +1.
CIBIC_DY	num	RELATIVE CIBIC VISIT DAY		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.

1.4.39. 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 crfid for De-identity
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.
PULSE	num	PULSE, 1/MIN		Collected at CRF.
SBP	num	SYSTOLIC BP, mmHg		Collected at CRF.
DBP	num	DIASTOLIC BP, mmHg		Collected at CRF.

1.4.40. Population PK to PK Grp – XPLASMA1

Dataset	XPLASMA1
Creating program	xplasma1.sas
Description	Population PK to PK Grp
Unique identifier	DCRFID,TIMESEQ,VISIT
Sorted by	DCRFID,TIMESEQ,VISIT
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: INITIALS,XRACE,DATE

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned site no. for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
XAGE	char	AGE IN YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
XTIME	char	TIME INTERVAL		Collected at CRF.
CREATINI	num	CREATININE CONC(MG/DL)		Collected at CRF.
WEIGHT	num	WEIGHT(KG) WEEK4 WEIGHT FROM SCREENING		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
MODEXTDD	char	MODE XTDD 15 DAYS PRIOR TO PLADM_D		Collected at CRF.
MODEDUR	num	DURATION OF MODE DOSE		Collected at CRF.
XTDD	char	TOTAL DAILY DOSE		Collected at CRF.
XPTDD	char	PREVIOUS TOTAL DAILY DOSE		Collected at CRF.
DSLENGTH	num	PLASMA_D - AMFROM_D +1		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
PRVAL	num	PLASMA MEASUREMENT		Collected at CRF.
HR_ELAPS	num	HOURS BETWEEN BLOOD SAMPLE AND MED TIME		Collected at CRF.
RELDAY	num	PLASMA_D - FIRST AMFROM_D +1		Collected at CRF.
XSDD	num	SINGLE SCHEDULED DOSE		Collected at CRF.
XPSDD	num	PREVIOUS SINGLE SCHEDULED DOSE		Collected at CRF.
CLCR	num	CREATININE CL FORMUMLA BY SEX		Collected at CRF.
XSEX	num	0:FEMALE 1:MALE		Collected at CRF.
XSMOKE	num	0:NOT SMOKE 1:YES		Collected at CRF.
TIMSEQ	num	1:DOSE TIME 2:BLOOD SAMPLE TIME		Collected at CRF.
TIME	num	PLASMA_T OR PLADM_T		Collected at CRF.

Variable	Type	Label	Codes	Comments
SS	num	0: PLASMA AVAILABLE 1: OTHERWISE		Collected at CRF.
INTERVAL	num	INTERVAL		Collected at CRF.
SAMPLEDY	num	RELATIVE PLASMA SAMPLING/DRUG ADMIN DAY		If DATE and REF.DATE not missing then perform below logic to calculate DY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE-REF.DATE) +1.

1.4.41. Plasma Conc. with Demo Saf Eff to PK Grp – XPLASMA2

Dataset	XPLASMA2
Creating program	xplasma2.sas
Description	Plasma Conc. with Demo Saf Eff to PK Grp
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 repetition of the information: DATE,DATE_ADM,RACE,DATE_BL

Variable	Type	Label	Codes	Comments
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid for De-identity

Variable	Type	Label	Codes	Comments
AE_MSWKA	num	MUSCLE WEAKNESS(13ITEMS) ONSET DURING TR		Collected at CRF.
AE_MSWKB	num	MUSCLE WEAKNESS ONSET DURING TREAT 1=YES		Collected at CRF.
AE_NAUSE	num	NAUSEA ONSET DURING TREAT 1=YES		Collected at CRF.
AE_VOMIT	num	VOMITING ONSET DURING TREAT 1=YES		Collected at CRF.
AE_SYNCNCP	num	SYNCOPE ONSET DURING TREAT 1=YES		Collected at CRF.
AE_WTLOS	num	WEIGHT LOSS ONSET DURING TREAT 1=YES		Collected at CRF.
AE_ANORE	num	ANOREXIA ONSET DURING TREATMENT 1=YES		Collected at CRF.
AE_FALL	num	FALL ONSET DURING TREATMENT 1=YES		Collected at CRF.
AE_BRADY	num	BRADYCARDIA ONSET DURING TREATMENT 1=YES		Collected at CRF.
DU_MSWKA	num	TOTAL DURATION MUSCLE WEAKNESS(13ITEMS)		Collected at CRF.
DU_MSWKB	num	TOTAL DURATION MUSCLE WEAKNESS DURING TR		Collected at CRF.
DU_NAUSE	num	TOTAL DURATION NAUSEA DURING TREAT(DAYS)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DU_VOMIT	num	TOTAL DURATION VOMITING DURING TREAT(DAY		Collected at CRF.
DU_SYNCP	num	TOTAL DURATION SYNCOPE DURING TREAT(DAYS		Collected at CRF.
DU_WTLOS	num	TOTAL DURATION WEIGHT LOSS DURING TREAT(Collected at CRF.
DU_ANORE	num	TOTAL DURATION ANOREXIA DURING TREAT(DAY		Collected at CRF.
DU_FALL	num	TOTAL DURATION FALL DURING TREAT(DAYS)		Collected at CRF.
DU_BRADY	num	TOTAL DURATION BRADYCARDIA DURING TREAT(Collected at CRF.
XTIME	char	TIME INTERVAL		Collected at CRF.
ADAS10_B	num	ADAS-COG/10 BASELINE		Collected at CRF.
ADAS10_E	num	ADAS-COG/10 AT THE VISIT		Collected at CRF.
ADAS10_D	num	ADAS-COG/10 CHANGE FROM BASELINE		Collected at CRF.
ADAS11_B	num	ADAS-COG/11 BASELINE		Collected at CRF.
ADAS11_E	num	ADAS-COG/11 AT THE VISIT		Collected at CRF.
ADAS11_D	num	ADAS-COG/11 CHANGE FROM BASELINE		Collected at CRF.
ADAS13_B	num	ADAS-COG/13 BASELINE		Collected at CRF.
ADAS13_E	num	ADAS-COG/13 AT THE VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADAS13_D	num	ADAS-COG/13 CHANGE FROM BASELINE		Collected at CRF.
ADASM_B	num	ADAS-COG/MEM BASELINE		Collected at CRF.
ADASM_E	num	ADAS-COG/MEM AT THE VISIT		Collected at CRF.
ADASM_D	num	ADAS-COG/MEM CHANGE FROM BASELINE		Collected at CRF.
PR_BAS	num	PR INTERVAL BASELINE		Collected at CRF.
PR_END	num	PR INTERVAL AT THE VISIT		Collected at CRF.
PR_DIF	num	PR INTERVAL CHANGE FROM BASELINE		Collected at CRF.
QTC_BAS	num	QTC BAZETT BASELINE		Collected at CRF.
QTC_END	num	QTC BAZETT AT THE VISIT		Collected at CRF.
QTC_DIF	num	QTC BAZETT CHANGE FROM BASELINE		Collected at CRF.
QRS_BAS	num	QRS INTERVAL BASELINE		Collected at CRF.
QRS_END	num	QRS INTERVAL AT THE VISIT		Collected at CRF.
QRS_DIF	num	QRS INTERVAL CHANGE FROM BASELINE		Collected at CRF.
CIBIC_D	char	CIBIC-PLUS DECODED VALUE		Collected at CRF.
CIBIC_V	num	CIBIC-PLUS CODED VALUE		Collected at CRF.
ADL_BAS	num	TOTAL ADL BASELINE		Collected at CRF.
ADL_END	num	TOTAL ADL AT THE VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADL_DIF	num	TOTAL ADL CHANGE FROM BASELINE		Collected at CRF.
NPI_BAS	num	TOTAL NPI SCORE BASELINE		Collected at CRF.
NPI_END	num	TOTAL NPI SCORE AT THE VISIT		Collected at CRF.
NPI_DIF	num	TOTAL NPI SCORE CHANGE FROM BASELINE		Collected at CRF.
DSITEID	char	SITE NO. ASSIGNED FOR DE-IDENTITY		Randomly assigned site no. for De-identity
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
AGE	char	AGE IN YEARS		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HEIGHT	num	HEIGHT, CM		Collected at CRF.
MORTALIT	num	MORTALITY 1=YES 0=NO		Collected at CRF.
SAE_30D	num	SAE W/I 30 DYS AFTER LAST MED. 1=YES 0=N		Collected at CRF.
T_STATUS	num	TRIAL COMPLETION 1=COMPLETE 0=DROPOUT		Collected at CRF.
WT_BAS	num	WEIGHT(kg) BASELINE(FROM SCREENING)		Collected at CRF.
WT_END	num	WEIGHT(kg) AT VISIT(WK4 DATA FROM SCREEN)		Collected at CRF.
WT_DIF	num	WEIGHT(kg) CHANGE FROM BASELINE		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
TIME_ADM	num	DRUG ADMIN. TIME		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
DAY_1STC	num	# OF DAYS FROM CURRENT DOSE TO DATE_BL		Collected at CRF.
RESULT	num	PLASMA CONCENTRATION		Collected at CRF.
PRXTDD	char	TOTAL DAILY DOSE ON THE DAY PRIOR TO DAT		Collected at CRF.
HR_ELAPS	num	HRS BETWEEN LAST DOSE AND BLOOD WITHDRAW		Collected at CRF.
DAY_1ST	num	# OF DAYS FROM FIRST TRIAL RX TO DATE_BL		Collected at CRF.
XSDDD	num	SCHEDULED TOTAL DAILY DOSE		Collected at CRF.
CLCR_END	num	CREATININE CLEARANCE AT EACH VISIT		Collected at CRF.
SEX	num	SEX 0=FEMALE 1=MALE		Collected at CRF.
CLCR_BAS	num	CREATININE CLEARANCE BASELINE		Collected at CRF.
CLCR_DIF	num	CREATININE CLEARANCE CHANGE FROM BASELIN		Collected at CRF.
TIME_BL	num	TIME OF BLOOD WITHDRAWAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT_DY	num	RELATIVE VISIT DAY FROM ADAS OR VS PAGE		If DATE and REF.DATE not missing then perform below logic to calculate VISIT_DY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE- REF.DATE) +1.
ADMDY	num	RELATIVE DRUG ADMIN. DAY		If DATE_ADM and REF.DATE not missing then perform below logic to calculate ADMDY, If DATE_ADM less than REF.DATE then (DATE_ADM - REF.DATE). Else if DATE_ADM is greater than equal to REF.DATE then (DATE_ADM- REF.DATE) +1.
BLDY	num	RELATIVE DAY OF BLOOD WITHDRAWAL		If DATE_BL and REF.DATE not missing then perform below logic to calculate BLDY, If DATE_BL less than REF.DATE then (DATE_BL - REF.DATE). Else if DATE_BL is greater than equal to REF.DATE then (DATE_BL- REF.DATE) +1.