Clinical Development

RISPERIDONE

RIS-INT-24

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	12 Jan 2017

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset containing investigator related information is sensitive and hence will not be submitted. (ex. AAINVEST)
- AAREMARK i.e. Remarks dataset will be submitted with zero observation due to sensitivity of data.
- AALABREF dataset will not be submitted as it contains Lab reference number (LABREFNO) which after removed, no significant information is available for further analysis.
- AAVISIT.DATE_VIS (when VISIT =1) will be used as a Reference Date to derive relative days (referred as REF.DATE in the document).
- XPLASMA and AAECGVCM dataset will not be submitted since they do not contain any information for further analysis.

1.3. Data Files

The RIS-INT-24 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demography - AAPAT

Dataset	AAPAT
Creating program	aapat.sas
Description	Demography
Unique identifier	DPATIENT
Sorted by	DPATIENT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INVEST,INITIALS,BIRTHDAT,ONS_DEMM,ONS_DEMY,ONS_BEHM,ONS_BEHY, DAT_HOSM,DAT_HOSY,DAT_CUR,ENTRYCOM Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment related information and Country information in the de-identified datasets: DCOUNTRY (Source: AAINVEST dataset)

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
DSITEID	num	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
CIMSCNTR	char	CIMS Country code		Collected at CRF.
ACIMSCNT	char	CIMS Country code		Collected at CRF.
CIMSSTUD	num	CIMS Study number		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.
HEIGHT	num	Height		Collected at CRF.
HEIGHTUN	char	Height unit		Collected at CRF.
HOSP_PRE	num	Number of prev. hosp.		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 – BIRTHDAT)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
CUR_DY	num	Relative Day of current inst.		If DAT_CUR and REF.DATE not missing then perform below logic to calculate CUR_DY, If DAT_CUR less than REF.DATE then (DAT_CUR - REF.DATE). Else if DAT_CUR is greater than equal to REF.DATE then (DAT_CUR- REF.DATE) +1.

1.4.2. Administration of Trial Medication - AAADMIN

Dataset	AAADMIN
Creating program	aaadmin.sas
Description	Administration of Trial Medication
Unique identifier	DPATIENT,SEQ_ADM,ADFROMDY
Sorted by	DPATIENT,SEQ_ADM,ADFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: FROM_ADM,TO_ADM,NUM_ADM,FREQ_ADM,ROUT_ADM,AROUT_AD, FORM_ADM

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TYPE_ADM	char	Type		Collected at CRF.
SEQ_ADM	num	Sequence number		Collected at CRF.
ADFROMDY	num	Relative Start day of admin.		If FROM_ADM and REF.DATE not missing then perform below logic to calculate ADFROMDY, If FROM_ADM less than REF.DATE then (FROM_ADM - REF.DATE). Else if FROM_ADM is greater than equal to REF.DATE then (FROM_ADM- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ADTODY	num	Relative End day of admin.		If TO_ADM and REF.DATE not missing then perform below logic to calculate ADTODY, If TO_ADM less than REF.DATE then (TO_ADM - REF.DATE). Else if TO_ADM is greater than equal to REF.DATE then (TO_ADM- REF.DATE) +1.

1.4.3.Adverse Events - AAAE

Dataset	AAAE
Creating program	aaae.sas
Description	Adverse Events
Unique identifier	DPATIENT,PREFTERM,SEQ_AE,AEFROMDY,AETODY
Sorted by	DPATIENT,PREFTERM,SEQ_AE,AEFROMDY,AETODY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: V_AE,FROM_AE,TO_AE,NUMADREM,VISIT,ONSUN_AE,DUR_AE,DRUN_AE, REPORTED,YN_AE,ONSET_AE

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity

Variable	Type	Label	Codes	Comments
SEQ_AE	num	Sequence number		Collected at CRF.
SEV_AE	char	Severity		Collected at CRF.
FREQ_AE	char	Frequency		Collected at CRF.
RELATION	char	Drug relationship		Collected at CRF.
ACT_AE	char	Action taken		Collected at CRF.
OUTCOME	char	Outcome		Collected at CRF.
SOUR_AE	char	Source		Collected at CRF.
AE	char	Adverse experience		Collected at CRF.
PREFTERM	char	Preferred term		Collected at CRF.
BODYSYS	char	System Organ Class		Collected at CRF.
HOF_ASS	char	Head Office Assessment		Collected at CRF.
PHASE	char	Study phase		Collected at CRF.
AEFROMDY	num	Relative AE start day		If FROM_AE and REF.DATE not missing then perform below logic to calculate AEFROMDY, If FROM_AE less than REF.DATE then (FROM_AE - REF.DATE). Else if FROM_AE is greater than equal to REF.DATE then (FROM_AE- REF.DATE) +1.
AETODY	num	Relative AE end day		If TO_AE and REF.DATE not missing then perform below logic to calculate AETODY, If TO_AE less than REF.DATE then (TO_AE - REF.DATE). Else if TO_AE is greater than equal to REF.DATE then (TO_AE- REF.DATE) +1.

1.4.4. Behavioural Pathology in Alzheimers - AABEHAVE

Dataset	AABEHAVE
Creating program	aabehave.sas
Description	Behavioural Pathology in Alzheimers
Unique identifier	DPATIENT,AD_SYM,VISIT
Sorted by	DPATIENT,AD_SYM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
VISIT	num	Visit		Collected at CRF.
AD_SYM	char	AD Symptomatology		Collected at CRF.
AAD_SYM	char	AD Symptomatology (code)		Collected at CRF.
AD_SEV	char	Severity		Collected at CRF.
AAD_SEV	num	Severity (code)		Collected at CRF.

1.4.5. Cohen-Mansfield Agitation Inventory - AACMAI

Dataset	AACMAI
Creating program	aacmai.sas
Description	Cohen-Mansfield Agitation Inventory
Unique identifier	DPATIENT,CMAI_SYM,VISIT
Sorted by	DPATIENT,CMAI_SYM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
VISIT	num	Visit		Collected at CRF.
CMAI_SYM	char	Symptom		Collected at CRF.
ACMAI_SY	char	Symptom (code)		Collected at CRF.
CMAI_SEV	char	Severity		Collected at CRF.
ACMAI_SE	num	Severity (code)		Collected at CRF.

1.4.6. Concomitant Therapy - AACOTHE

Dataset	AACOTHE
Creating program	aacothe.sas
Description	Concomitant Therapy
Unique identifier	DPATIENT,TYPE_COT,COTHER,SEQ_COT,COFROMDY,COTODY
Sorted by	DPATIENT,TYPE_COT,COTHER,SEQ_COT,COFROMDY,COTODY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: V_COTHER,FROM_COT,TO_COT,VISIT,PHASE,IND_COT

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TYPE_COT	char	Type of concomitant medication		Collected at CRF.
ATYPE_CO	char	Type of concomitant medication (code)		Collected at CRF.
SEQ_COT	num	Sequence number		Collected at CRF.
V_INDCOT	char	Primary indication (verbatim)		Collected at CRF.
DOSE_COT	char	Dose		Collected at CRF.
ROUT_COT	char	Route of administration		Collected at CRF.

Variable	Type	Label	Codes	Comments
AROUT_CO	char	Route of administration (code)		Collected at CRF.
PRIO_COT	char	Start prior to study		Collected at CRF.
ONGO_COT	char	Ongoing at end of study		Collected at CRF.
COTHER	char	Concomitant therapy		Collected at CRF.
SOUR_COT	char	Source		Collected at CRF.
COFROMDY	num	Relative Cother start day		If FROM_COT and REF.DATE not missing then perform below logic to calculate COFROMDY, If FROM_COT less than REF.DATE then (FROM_COT - REF.DATE). Else if FROM_COT is greater than equal to REF.DATE then (FROM_COT- REF.DATE) +1.
COTODY	num	Relative Cother end day		If TO_COT and REF.DATE not missing then perform below logic to calculate COTODY, If TO_COT less than REF.DATE then (TO_COT - REF.DATE). Else if TO_COT is greater than equal to REF.DATE then (TO_COT- REF.DATE) +1.

1.4.7. Psychiatric History - AADIAGN

Dataset	AADIAGN
Creating program	aadiagn.sas
Description	Psychiatric History
Unique identifier	DPATIENT,DIAGN
Sorted by	DPATIENT,DIAGN
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
DIAGN	char	Diagnosis		Collected at CRF.
ADIAGN	char	Diagnosis (code)		Collected at CRF.
DIAG_PER	char	Diagnosis period onset		Collected at CRF.
ADIAG_PE	char	Diagnosis period onset (code)		Collected at CRF.

1.4.8. Disorder - AADISORD

Dataset	AADISORD
Creating program	aadisord.sas
Description	Disorder
Unique identifier	DPATIENT,SEQ_DIS,TYPE_DIS
Sorted by	DPATIENT,SEQ_DIS,TYPE_DIS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: V_DISORD,FROM_DIS,TO_DIS,PHASE,VISIT,DISORDER,YN_DIS

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
SEQ_DIS	num	Sequence number		Collected at CRF.
TYPE_DIS	char	Type		Collected at CRF.
SOUR_DIS	char	Source		Collected at CRF.

1.4.9.Abnormalities - AAELIG

Dataset	AAELIG
Creating program	aaelig.sas
Description	Abnormalities
Unique identifier	DPATIENT
Sorted by	DPATIENT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
V_NELIG	char	Non-eligibility (verbatim)		Collected at CRF.
YN_CRIT	char	Yes/No		Collected at CRF.

1.4.10. Extrapyramidal Symptom Rating Scale - AAESRS

Dataset	AAESRS
Creating program	aaesrs.sas
Description	Extrapyramidal Symptom Rating Scale
Unique identifier	DPATIENT,ESRS_SYM,VISIT
Sorted by	DPATIENT,ESRS_SYM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
VISIT	num	Visit		Collected at CRF.
ESRS_SYM	char	ESRS symptom		Collected at CRF.
AESRS_SY	char	ESRS symptom (code)		Collected at CRF.
ESRS_SEV	num	ESRS severity		Collected at CRF.

1.4.11. Physical Examination - AAEXAM

Dataset	AAEXAM
Creating program	aaexam.sas
Description	Physical Examination
Unique identifier	DPATIENT,SYS_EXA,VISIT
Sorted by	DPATIENT,SYS_EXA,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
VISIT	num	Visit		Collected at CRF.
SYS_EXA	char	Body system		Collected at CRF.
YN_EXA	char	Normal/Abnormal		Collected at CRF.
V_EXAM	char	Physical examination (verbatim)		Collected at CRF.

1.4.12. Family History - AAFAMILY

Dataset	AAFAMILY
Creating program	aafamily.sas
Description	Family History
Unique identifier	DPATIENT,FAM_MEM,FAM_DIS
Sorted by	DPATIENT,FAM_MEM,FAM_DIS
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
FAM_MEM	char	Family member		Collected at CRF.
FAM_DIS	char	Disease of family member		Collected at CRF.

1.4.13. Functional Assessment Staging - AAFAST

Dataset	AAFAST
Creating program	aafast.sas
Description	Functional Assessment Staging
Unique identifier	DPATIENT,FAST_SYM,VISIT
Sorted by	DPATIENT,FAST_SYM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
VISIT	num	Visit		Collected at CRF.
FAST_SYM	char	FAST Symptom		Collected at CRF.
AFAST_SY	char	FAST Symptom (code)		Collected at CRF.
FAST_PRS	char	Symptom present?		Collected at CRF.
AFAST_PR	char	Symptom present? (code)		Collected at CRF.

1.4.14. Laboratory Results - AALABRES

Dataset	AALABRES
Creating program	aalabres.sas
Description	Laboratory Results
Unique identifier	DPATIENT,TEST,VALUE,SAM_DY
Sorted by	DPATIENT,TEST,VALUE,SAM_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DATE_SAM

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TEST	char	Laboratory test		Collected at CRF.
VALUE	num	Measurement		Collected at CRF.
V_RESULT	char	Test result (verbatim)		Collected at CRF.
UNIT	char	Unit of measurement		Collected at CRF.
LOWLIMIT	num	Lower limit		Collected at CRF.
UPPLIMIT	num	Upper limit		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAM_DY	num	Relative Day of sampling		If DATE_SAM and REF.DATE not missing then perform below logic to calculate SAM_DY, If DATE_SAM less than REF.DATE then (DATE_SAM - REF.DATE). Else if DATE_SAM is greater than equal to REF.DATE then (DATE_SAM- REF.DATE) +1.

1.4.15. Laboratory Samples - AALABSAM

Dataset	AALABSAM
Creating program	aalabsam.sas
Description	Laboratory Samples
Unique identifier	DPATIENT,SAM_DY,TIME_SAM
Sorted by	DPATIENT,SAM_DY,TIME_SAM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DATE_SAM,LABO,ALABO,ANADATE,LABREFNO

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TIME_SAM	num	Time of sampling		Collected at CRF.

Variable	Type	Label	Codes	Comments
HEMOLYS	char	Sample hemolysed		Collected at CRF.
FASTED	char	Fasted		Collected at CRF.
PHASE	char	Study phase		Collected at CRF.
SAM_DY	num	Relative Day of sampling		If DATE_SAM and REF.DATE not missing then perform below logic to calculate SAM_DY, If DATE_SAM less than REF.DATE then (DATE_SAM - REF.DATE). Else if DATE_SAM is greater than equal to REF.DATE then (DATE_SAM- REF.DATE) +1.

1.4.16. Mini-Mental State Examination - AAMMS

Dataset	AAMMS
Creating program	aamms.sas
Description	Mini-Mental State Examination
Unique identifier	DPATIENT,MMS_SYM,VISIT
Sorted by	DPATIENT,MMS_SYM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity

Variable	Type	Label	Codes	Comments
VISIT	num	Visit		Collected at CRF.
MMS_SYM	char	MMS Symptom		Collected at CRF.
AMMS_SYM	char	MMS Symptom (code)		Collected at CRF.
MMS_SEV	num	Symptom score		Collected at CRF.

1.4.17. Phase Details - AAPHASE

Dataset	AAPHASE
Creating program	aaphase.sas
Description	Phase Details
Unique identifier	DPATIENT,PHASE
Sorted by	DPATIENT,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FROM_PHA,TO_PHA

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
PHASE	char	Study phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHFROMDY	num	Relative Phase start day		If FROM_PHA and REF.DATE not missing then perform below logic to calculate PHFROMDY, If FROM_PHA less than REF.DATE then (FROM_PHA - REF.DATE). Else if FROM_PHA is greater than equal to REF.DATE then (FROM_PHA- REF.DATE) +1.
PHTODY	num	Relative Phase end day		If TO_PHA and REF.DATE not missing then perform below logic to calculate PHTODY, If TO_PHA less than REF.DATE then (TO_PHA - REF.DATE). Else if TO_PHA is greater than equal to REF.DATE then (TO_PHA- REF.DATE) +1.

1.4.18. Dose Administration - AAPLAADM

Dataset	AAPLAADM
Creating program	aaplaadm.sas
Description	Dose Administration
Unique identifier	DPATIENT,DOSE_ADM,ADM_DY,TIME_ADM
Sorted by	DPATIENT,DOSE_ADM,ADM_DY,TIME_ADM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DATE_ADM

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TIME_ADM	num	Time of administration test drug		Collected at CRF.
DOSE_ADM	num	Dose of test drug (ml)		Collected at CRF.
ADM_DY	num	Relative Day of admin test drug		If DATE_ADM and REF.DATE not missing then perform below logic to calculate ADM_DY, 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.

1.4.19. Plasma - AAPLASAM

Dataset	AAPLASAM
Creating program	aaplasam.sas
Description	Plasma
Unique identifier	DPATIENT,PLA_DY
Sorted by	DPATIENT,PLA_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DATE_PLA

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TIME_PLA	num	Time plasma sample taken		Collected at CRF.
PLA_DY	num	Relative Day plasma samp taken		If DATE_PLA and REF.DATE not missing then perform below logic to calculate PLA_DY, If DATE_PLA less than REF.DATE then (DATE_PLA - REF.DATE). Else if DATE_PLA is greater than equal to REF.DATE then (DATE_PLA- REF.DATE) +1.

1.4.20. Medication at Selection - AAPRETHE

Dataset	AAPRETHE
Creating program	aaprethe.sas
Description	Medication at Selection
Unique identifier	DPATIENT,TYPE_PRE,DOSE_PRE,PRETHER,SEQ_PRE
Sorted by	DPATIENT,TYPE_PRE,DOSE_PRE,PRETHER,SEQ_PRE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: V_PRETHE,INJECT,FROM_PRE,TO_PRE,INTERVAL

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
TYPE_PRE	char	Type previous therapy		Collected at CRF.
SEQ_PRE	num	Sequence number		Collected at CRF.
DOSE_PRE	char	Dose		Collected at CRF.
ROUT_PRE	char	Route previous therapy		Collected at CRF.
AROUT_PR	char	Route previous therapy (code)		Collected at CRF.
SOUR_PRE	char	Source		Collected at CRF.
PRETHER	char	Previous therapy		Collected at CRF.

Variable	Type	Label	Codes	Comments
INJECTDY	num	Relative Day of last injection		If INJECT and REF.DATE not missing then perform below logic to calculate INJECTDY, If INJECT less than REF.DATE then (INJECT - REF.DATE). Else if INJECT is greater than equal to REF.DATE then (INJECT- REF.DATE) +1.
PREFRMDY	num	Relative Start day		If FROM_PRE and REF.DATE not missing then perform below logic to calculate PREFRMDY, If FROM_PRE less than REF.DATE then (FROM_PRE - REF.DATE). Else if FROM_PRE is greater than equal to REF.DATE then (FROM_PRE- REF.DATE) +1.
PRETODY	num	Relative End day		If TO_PRE and REF.DATE not missing then perform below logic to calculate PRETODY, If TO_PRE less than REF.DATE then (TO_PRE - REF.DATE). Else if TO_PRE is greater than equal to REF.DATE then (TO_PRE- REF.DATE) +1.

1.4.21. Remarks - AAREMARK

Dataset	AAREMARK
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
RANDLIST	num	Randomization list		Empty dataset will be submitted
DPATIENT	num	Patient Assigned for De-identity		Empty dataset will be submitted
PAGE_REM	num	Page		Empty dataset will be submitted
TYPE_REM	char	Context		Empty dataset will be submitted
SEQ_REM	num	Line number		Empty dataset will be submitted

1.4.22. Randomization Groups - AARNDGRP

Dataset	AARNDGRP
Creating program	aarndgrp.sas
Description	Randomization Groups
Unique identifier	RANDLIST,RANDGRP
Sorted by	RANDLIST,RANDGRP
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
RANDGRP	char	Study group code		Collected at CRF.
STUDYGRP	char	Study group		Collected at CRF.

1.4.23. Randomization List - RANDLIST

Dataset	AARNDLST
Creating program	aarndlst.sas
Description	Randomization List
Unique identifier	RANDLIST
Sorted by	RANDLIST
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
RNDCODE	char	Randomization list code		Collected at CRF.
DESCRIPT	char	Description		Collected at CRF.
CIMSDRUG	char	CIMS Drug code		Collected at CRF.
ACIMSDRU	char	CIMS Drug code (code)		Collected at CRF.
DESIGN	char	Study design		Collected at CRF.
BLKSIZE	num	Block size		Collected at CRF.

1.4.24. Subject Randomisation - AARNDPAT

Dataset	AARNDPAT
Creating program	aarndpat.sas
Description	Subject Randomisation
Unique identifier	DPATIENT
Sorted by	DPATIENT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
RANDGRP	char	Study group code		Collected at CRF.

1.4.25. Trial Details - AARNDPHA

Dataset	AARNDPHA
Creating program	aarndpha.sas
Description	Trial Details
Unique identifier	RANDLIST,RANDGRP,PHASE
Sorted by	RANDLIST,RANDGRP,PHASE
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
RANDGRP	char	Study group code		Collected at CRF.
PHASE	char	Study phase		Collected at CRF.
SEQ_RND	num	Sequence number		Collected at CRF.
SEQ_PHA	num	Sequence of phase		Collected at CRF.
TREATM	char	Treatment		Collected at CRF.
NUMFORM	num	Number per intake		Collected at CRF.
STRENGTH	num	Strength		Collected at CRF.
STRENGUN	char	Strength unit		Collected at CRF.
FREQ_RND	char	Frequency of administration		Collected at CRF.
ROUT_RND	char	Route of administration		Collected at CRF.

Variable	Type	Label	Codes	Comments
AROUT_RN	char	Route of administration (code)		Collected at CRF.
FORM_RND	char	Formulation		Collected at CRF.

1.4.26. Inclusion/Exclusion Criteria - AAVALID

Dataset	AAVALID
Creating program	aavalid.sas
Description	Inclusion/Exclusion Criteria
Unique identifier	DPATIENT,VALID,SPEC_VAL
Sorted by	DPATIENT,VALID,SPEC_VAL
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
SPEC_VAL	char	Validation (specification)		Collected at CRF.
VALID	char	Validation		Collected at CRF.
AVALID	char	Validation (code)		Collected at CRF.

1.4.27. Visits - AAVISIT

Dataset	AAVISIT
Creating program	aavisit.sas
Description	Visits
Unique identifier	DPATIENT,VISIT
Sorted by	DPATIENT,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DATE_VIS,DATE_ECG

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
VISIT	num	Visit		Collected at CRF.
WEIGHT	num	Weight		Collected at CRF.
WEIGHTUN	char	Weight unit		Collected at CRF.
ECG	char	ECG result		Collected at CRF.
CGI_I	char	Clin. gl. impression - investig.		Collected at CRF.
ACGI_I	char	Clin. gl. impression - investig.		Collected at CRF.
CGI_C	char	Clin. gl. impression - caregiver		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACGI_C	char	Clin. gl. impression - caregiver		Collected at CRF.
SEDATION	char	Sedation		Collected at CRF.
ASEDATIO	char	Sedation		Collected at CRF.
DOSE	num	Dose (ml)		Collected at CRF.
CGI_CH_I	char	CGI Condition change - investig.		Collected at CRF.
ACGI_CH_	char	CGI Condition change - investig.		Collected at CRF.
CGI_CH_C	char	CGI Condition change - caregiver		Collected at CRF.
TH_EFF_I	char	Therapeutic effect - investig.		Collected at CRF.
ATH_EFF_	char	Therapeutic effect - investig.		Collected at CRF.
TH_EFF_C	char	Therapeutic effect - caregiver		Collected at CRF.
SE_I	char	Side effect - investigator		Collected at CRF.
ASE_I	char	Side effect - investigator		Collected at CRF.
SE_C	char	Side effect - caregiver		Collected at CRF.
ASE_C	char	Side effect - caregiver		Collected at CRF.
PQ	num	PQ (msec)		Collected at CRF.
QRS	num	QRS (msec)		Collected at CRF.
QT	num	QT (msec)		Collected at CRF.
HR_ECG	num	Heart rate ECG		Collected at CRF.
PHASE	char	Study phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
VIS_DY	num	Relative Visit day		If DATE_VIS and REF.DATE not missing then perform below logic to calculate VIS_DY, If DATE_VIS less than REF.DATE then (DATE_VIS - REF.DATE). Else if DATE_VIS is greater than equal to REF.DATE then (DATE_VIS- REF.DATE) +1.
ECG_DY	num	Relative Day of ECG taken		If DATE_ECG and REF.DATE not missing then perform below logic to calculate ECG_DY, If DATE_ECG less than REF.DATE then (DATE_ECG - REF.DATE). Else if DATE_ECG is greater than equal to REF.DATE then (DATE_ECG- REF.DATE) +1.

1.4.28. Vital Signs - AAVITAL

Dataset	AAVITAL
Creating program	aavital.sas
Description	Vital Signs
Unique identifier	DPATIENT,POS_VIT,HR_VIT,SBP_VIT,DBP_VIT,SEQ_VIT,VISIT
Sorted by	DPATIENT,POS_VIT,HR_VIT,SBP_VIT,DBP_VIT,SEQ_VIT,VISIT
Notes	

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATIENT	num	Patient Assigned for De-identity		
VISIT	num	Visit		Collected at CRF.
POS_VIT	char	Position of measurement		Collected at CRF.
SEQ_VIT	num	Sequence of reading		Collected at CRF.
SBP_VIT	num	SBP (mmHg)		Collected at CRF.
DBP_VIT	num	DBP (mmHg)		Collected at CRF.
HR_VIT	num	HR (bpm)		Collected at CRF.

1.4.29. Disposition - AAWHYADM

Dataset	AAWHYADM
Creating program	aawhyadm.sas
Description	Disposition
Unique identifier	DPATIENT,WHY_ADM,ADFROMDY
Sorted by	DPATIENT,WHY_ADM,ADFROMDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FROM_ADM,V_WHYADM

Variable	Type	Label	Codes	Comments
RANDLIST	num	Randomization list		Collected at CRF.
DPATIENT	num	Patient Assigned for De-identity		Randomly assigned Patient for De-identity
SEQ_ADM	num	Sequence number		Collected at CRF.
WHY_ADM	char	Reason		Collected at CRF.
AWHY_ADM	char	Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADFROMDY	num	Relative Start day		If FROM_ADM and REF.DATE not missing then perform below logic to calculate ADFROMDY, If FROM_ADM less than REF.DATE then (FROM_ADM - REF.DATE). Else if FROM_ADM is greater than equal to REF.DATE then (FROM_ADM- REF.DATE) +1.

1.4.30. Plasma - XXPLASMA

Dataset	XXPLASMA
Creating program	xxplasma.sas
Description	Plasma
Unique identifier	DPATIENT
Sorted by	DPATIENT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SAMPLE_D, LSTDO_D, INVEST

Variable	Type	Label	Codes	Comments
TRIAL	Char	PROTOCOL NUMBER		Collected at CRF.
TREAT	Char	TREATMENT		Collected at CRF.
LSTDO_T	Char	LAST DOSE ADMINISTRATION TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
LSTDO	Num	LAST DOSE ADMINISTRED		Collected at CRF.
LSTDO_U	Char	LAST DOSE ADMINISTRATION UNIT		Collected at CRF.
LSTDDO	Num	TOTAL DOSE ADMINISTRED PER DAY		Collected at CRF.
LSTDDO_U	Char	TOTAL DOSE ADMINISTRED PER DAY UNIT		Collected at CRF.
SAMPLE_T	Char	BLOOD SAMPLING TIME		Collected at CRF.
VISIT	Num	VISIT NUMBER		Collected at CRF.
SUBST	Char	SUBSTANCE		Collected at CRF.
BRVAL	Num	CONCENTRATION VALUE(NUMERIC)		Collected at CRF.
BRVAL_V	Char	CONCENTRATION VALUE(TEXT)		Collected at CRF.
BRVAL_U	Char	CONCENTRATION VALUE UNIT		Collected at CRF.
BRQUANT	Num	QUANTIFICATION LIMIT		Collected at CRF.
SEX	Char	SEX		Collected at CRF.
RACE	Char	RACE		Collected at CRF.
HEIGHT	Num	HEIGHT		Collected at CRF.
WEIGHT	Num	WEIGHT		Collected at CRF.
DPATIENT	Char	PATIENT ASSIGNED FOR DE-IDENTITY		Randomly assigned Patient for De-identity
AGE	Char	AGE IN YEARS		If age greater than 89+ years then will be grouped as per HIPAA rules.
DCOUNTRY	Char	DE-IDENTIFY COUNTRY		Element will be grouped to protect PII.

Variable	Type	Label	Codes	Comments
LSTDODY	Num	RELATIVE BLOOD SAMPLING DAY		If LSTDO_D and REF.DATE not missing then perform below logic to calculate LSTDODY, If LSTDO_D less than REF.DATE then (LSTDO_D - REF.DATE). Else if LSTDO_D is greater than equal to REF.DATE then (LSTDO_D - REF.DATE) +1.
SAMPLEDY	Num	RELATIVE LAST DOSE ADMINISTRATION 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.