Clinical Development

JnJ-17335630

GAL-ALZ-302

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.
- Due to sensitive information datasets will be removed(ex: INVEST, CAREGIVER, ECGABN, NOTES).
- SUBJCHAR.INFORM_D will be used as Reference Date (referred as REF.DATE in the document) to derive relative day.

1.3. Data Files

The GAL-ALZ-302 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.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 missing values: INVEST,INITIALS,BIRTH_D,BIRTH_C,RACE_V,MENSES_C,MENSES_D,SIGDB_C, SIGDB_D,MEDNO,INFORM_D,INFORM_C,CTMRI_D,SIGOL_C,SIGOL_D, COINV_DB,COINV_OL,COINV_SCR,SIGSCR_C,SIGSCR_D,RESCRN,RESCRN_V, OLDCRFID,MEDNO2 Below listed variables were not part of the Raw dataset. These have been added to retain the Demographic related information in the de-identified datasets: SITENO (Source: INVEST dataset) COUNTRY (Source: INVEST dataset)

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

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
SEX	char	SEX		Collected at CRF.
RACE	char	RACE		Collected at CRF.
CHILDPOT	char	CHILDPOT		Collected at CRF.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT_U		Collected at CRF.
CRALZTYP	char	CRALZTYP		Collected at CRF.
DEMENTYN	char	DEMENTYN		Collected at CRF.
CTMRIYN	char	CTMRIYN		Collected at CRF.
CTMRI_C	char	CTMRI_C		Collected at CRF.
DSCRCRFID	char	SCRCRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned scrcrfid assigned for de-identity.
ADRDA_YN	char	ADRDA_YN		Collected at CRF.
AIREN_YN	char	AIREN_YN		Collected at CRF.
CVDSCORE	char	CVDSCORE		Collected at CRF.
HEIGHT2	num	HEIGHT2		Collected at CRF.
HEIGHT2U	char	HEIGHT2_U		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.

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
DSITENO	char	SITENO ASSIGNED FOR DE-IDENTITY		Randomly assigned siteno for De-identity.
SIGDB_DY	num	RELATIVE SIGDB_D DAY		If SIGDB_D and INFORM_D not missing then perform below logic to calculate SIGDB_DY, If SIGDB_D less than INFORM_D then (SIGDB_D - INFORM_D). Else if SIGDB_D is greater than equal to INFORM_D then (SIGDB_D- INFORM_D) +1.
CTMRIDY	num	RELATIVE CTMRI_D DAY		If CTMRI_D and INFORM_D not missing then perform below logic to calculate CTMRIDY, If CTMRI_D less than INFORM_D then (CTMRI_D - INFORM_D). Else if CTMRI_D is greater than equal to INFORM_D then (CTMRI_D- INFORM_D) +1.
SIGOLDY	num	RELATIVE SIGOL_D DAY		If SIGOL_D and INFORM_D not missing then perform below logic to calculate SIGOLDY, If SIGOL_D less than INFORM_D then (SIGOL_D - INFORM_D). Else if SIGOL_D is greater than equal to INFORM_D then (SIGOL_D- INFORM_D) +1.
SIGSCRDY	num	RELATIVE SIGSCR_D DAY		If SIGSCR_D and INFORM_D not missing then perform below logic to calculate SIGSCRDY, If SIGSCR_D less than INFORM_D then (SIGSCR_D - INFORM_D). Else if SIGSCR_D is greater than equal to INFORM_D then (SIGSCR_D- INFORM_D) +1.

1.4.2. Activities of Daily Living – ACTDL

Dataset	ACTDL
Creating program	actdl.sas
Description	Activities of Daily Living
Unique identifier	DCRFID,ADGROUP,ADITEM,VISIT
Sorted by	DCRFID,ADGROUP,ADITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ADSEQNO	char	ADSEQNO		Collected at CRF.
ADGROUP	char	ADGROUP		Collected at CRF.
ADITEM	char	ADITEM		Collected at CRF.
ADSELF	num	ADSELF		Collected at CRF.
ADSUP	num	ADSUP		Collected at CRF.
ADHOUR	num	ADHOUR		Collected at CRF.
ADMIN	num	ADMIN		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,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: AMFROM_D,AMTO_D,AMREM_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
AMFROM_C	char	AMFROM_C		Collected at CRF.
AMTO_C	char	AMTO_C		Collected at CRF.
AMBOX	char	AMBOX		Collected at CRF.
TABDISP	num	TABDISP		Collected at CRF.
TABRET	num	TABRET		Collected at CRF.
AMDOSE	num	AMDOSE		Collected at CRF.
PHASE	char	PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMFROMDY	num	RELATIVE AMFROM_D DAY		If AMFROM_D and INFORM_D not missing then perform below logic to calculate AMFROMDY, If AMFROM_D less than INFORM_D then (AMFROM_D - INFORM_D). Else if AMFROM_D is greater than equal to INFORM_D then (AMFROM_D- INFORM_D) +1.
AMTO_DY	num	RELATIVE AMTO_D DAY		If AMTO_D and INFORM_D not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than INFORM_D then (AMTO_D - INFORM_D). Else if AMTO_D is greater than equal to INFORM_D then (AMTO_D- INFORM_D) +1.

1.4.4. DiagnoofScreenProbableAlzheimer'sDisease – ADRDA

Dataset	ADRDA
Creating program	adrda.sas
Description	DiagnoofScreenProbableAlzheimer'sDisease
Unique identifier	DCRFID,ADTYPE,ADCRIT
Sorted by	DCRFID,ADTYPE,ADCRIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ADSEQNO	num	ADSEQNO		Collected at CRF.
ADYN	char	ADYN		Collected at CRF.
ADCRIT	char	ADCRIT		Collected at CRF.
ADTYPE	char	ADTYPE		Collected at CRF.

1.4.5. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,PT_NAME,AEFROMDY,AESEQNO
Sorted by	DCRFID,PT_NAME,AEFROMDY,AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AE_V,AEFROM_D,AETO_D,SAEREFNO

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

Variable	Type	Label	Codes	Comments
AESEQNO	num	AESEQNO		Collected at CRF.
LLT_NAME	char	LLT_NAME		Collected at CRF.
AEFROM_C	char	AEFROM_C		Collected at CRF.
AETO_C	char	AETO_C		Collected at CRF.
ZAECONRX	num	ZAECONRX (CODE)		Collected at CRF.
AECONRX	char	AECONRX		Collected at CRF.
ZAERELAT	num	ZAERELAT (CODE)		Collected at CRF.
AERELAT	char	AERELAT		Collected at CRF.
ZAEACT	num	ZAEACT (CODE)		Collected at CRF.
AEACT	char	AEACT		Collected at CRF.
ZAEOUT	num	ZAEOUT (CODE)		Collected at CRF.
AEOUT	char	AEOUT		Collected at CRF.
ZAESER	num	ZAESER (CODE)		Collected at CRF.
AESER	char	AESER		Collected at CRF.
ZAESEV	num	ZAESEV (CODE)		Collected at CRF.
AESEV	char	AESEV		Collected at CRF.
LLT_CODE	char	LLT_CODE		Collected at CRF.
PT_CODE	char	PT_CODE		Collected at CRF.
HLT_CODE	char	HLT_CODE		Collected at CRF.
HLGTCODE	char	HLGT_CODE		Collected at CRF.
SOC_CODE	char	SOC_CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PT_NAME	char	PT_NAME		Collected at CRF.
HLT_NAME	char	HLT_NAME		Collected at CRF.
HLGTNAME	char	HLGT_NAME		Collected at CRF.
SOC_NAME	char	SOC_NAME		Collected at CRF.
AEFROMDY	num	RELATIVE AEFROM_D DAY		If AEFROM_D and INFORM_D not missing then perform below logic to calculate AEFROMDY, If AEFROM_D less than INFORM_D then (AEFROM_D - INFORM_D). Else if AEFROM_D is greater than equal to INFORM_D then (AEFROM_D- INFORM_D) +1.
AETO_DY	num	RELATIVE AETO_D DAY		If AETO_D and INFORM_D not missing then perform below logic to calculate AETO_DY, If AETO_D less than INFORM_D then (AETO_D - INFORM_D). Else if AETO_D is greater than equal to INFORM_D then (AETO_D- INFORM_D) +1.

1.4.6. NINDS-AIREN Criteria – AIREN

Dataset	AIREN
Creating program	airen.sas
Description	NINDS-AIREN Criteria
Unique identifier	DCRFID,AIRGROUP,AIRITEM
Sorted by	DCRFID,AIRGROUP,AIRITEM
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
AIR_YN	char	AIR_YN		Collected at CRF.
AIRGROUP	char	AIRGROUP		Collected at CRF.
AIRITEM	char	AIRITEM		Collected at CRF.
AIRSEQNO	char	AIRSEQNO		Collected at CRF.

1.4.7. Use of Health and Social Care Services – CARAVIS

Dataset	CARAVIS
Creating program	caravis.sas
Description	Use of Health and Social Care Services
Unique identifier	DCRFID,RESIDRES, VISIT_DY
Sorted by	DCRFID,RESIDRES, VISIT_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,VISIT_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
VISIT_C	char	VISIT_C		Collected at CRF.
RESIDRES	char	RESIDRES		Collected at CRF.
ATHOSPYN	char	ATHOSPYN		Collected at CRF.
INPATYN	char	INPATYN		Collected at CRF.
OUTPATYN	char	OUTPATYN		Collected at CRF.
MDSINVYN	char	MDSINVYN		Collected at CRF.
NPIINVYN	char	NPIINVYN		Collected at CRF.

Variable	Type	Label	Codes	Comments
RESCOMP	char	RESCOMP		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT_D DAY		If VISIT_D and INFORM_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than INFORM_D then (VISIT_D - INFORM_D). Else if VISIT_D is greater than equal to INFORM_D then (VISIT_D- INFORM_D) +1.

1.4.8. Caregiver – CAREGIV

Dataset	CAREGIV
Creating program	caregiv.sas
Description	Caregiver
Unique identifier	DCRFID,CGTYPE,CGSTRTDY
Sorted by	DCRFID,CGTYPE,CGSTRTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,CGSTRT_D

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

Variable	Type	Label	Codes	Comments
CGSTRT_C	char	CGSTRT_C		Collected at CRF.
CGTYPE	char	CGTYPE		Collected at CRF.
CGSTRTDY	num	RELATIVE CGSTRT_D DAY		If CGSTRT_D and INFORM_D not missing then perform below logic to calculate CGSTRTDY, If CGSTRT_D less than INFORM_D then (CGSTRT_D - INFORM_D). Else if CGSTRT_D is greater than equal to INFORM_D then (CGSTRT_D- INFORM_D) +1.

1.4.9. Concomitant Adverse Events – CONAE

Dataset	CONAE
Creating program	conae.sas
Description	Concomitant Adverse Events
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

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

Variable	Type	Label	Codes	Comments
CTSEQNO	num	CTSEQNO		Collected at CRF.
AESEQNO	num	AESEQNO		Collected at CRF.

1.4.10. Coravis – CORAVIS

Dataset	CORAVIS
Creating program	coravis.sas
Description	Coravis
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 or due to missing values: INVEST,VISIT_C,VISIT_D

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

Variable	Type	Label	Codes	Comments
MMSE_INC	char	MMSE_INC		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT_D DAY		If VISIT_D and INFORM_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than INFORM_D then (VISIT_D - INFORM_D). Else if VISIT_D is greater than equal to INFORM_D then (VISIT_D- INFORM_D) +1.

1.4.11. Concomitant Therapy – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Therapy
Unique identifier	DCRFID,RXPREF,CTFROMDY,CTSEQNO
Sorted by	DCRFID,RXPREF,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,CTTO_D,ATCCODE9,ATCTEXT9

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL		Collected at CRF.
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
CTSEQNO	num	CTSEQNO		Collected at CRF.
CONRX	char	CONRX		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTIND	char	CTIND		Collected at CRF.
CTPRIOR	char	CTPRIOR		Collected at CRF.
CTFROM_C	char	CTFROM_C		Collected at CRF.
CTONGO	char	CTONGO		Collected at CRF.
CTTO_C	char	CTTO_C		Collected at CRF.
CTREGIM	char	CTREGIM		Collected at CRF.
RXPREF	char	RXPREF		Collected at CRF.
RXWHONUM	char	RXWHONUM		Collected at CRF.
ATCCODE0	char	ATCCODE0		Collected at CRF.
ATCCODE1	char	ATCCODE1		Collected at CRF.
ATCCODE2	char	ATCCODE2		Collected at CRF.
ATCCODE3	char	ATCCODE3		Collected at CRF.
ATCCODE4	char	ATCCODE4		Collected at CRF.
ATCCODE5	char	ATCCODE5		Collected at CRF.
ATCCODE6	char	ATCCODE6		Collected at CRF.
ATCCODE7	char	ATCCODE7		Collected at CRF.
ATCCODE8	char	ATCCODE8		Collected at CRF.
ATCTEXT0	char	ATCTEXT0		Collected at CRF.
ATCTEXT1	char	ATCTEXT1		Collected at CRF.
ATCTEXT2	char	ATCTEXT2		Collected at CRF.
ATCTEXT3	char	ATCTEXT3		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCTEXT4	char	ATCTEXT4		Collected at CRF.
ATCTEXT5	char	ATCTEXT5		Collected at CRF.
ATCTEXT6	char	ATCTEXT6		Collected at CRF.
ATCTEXT7	char	ATCTEXT7		Collected at CRF.
ATCTEXT8	char	ATCTEXT8		Collected at CRF.
CTFROMDY	num	RELATIVE CTFROM_D DAY		If CTFROM_D and INFORM_D not missing then perform below logic to calculate CTFROMDY, If CTFROM_D less than INFORM_D then (CTFROM_D - INFORM_D). Else if CTFROM_D is greater than equal to INFORM_D then (CTFROM_D- INFORM_D) +1.
CTTO_DY	num	RELATIVE CTTO_D DAY		If CTTO_D and INFORM_D not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than INFORM_D then (CTTO_D - INFORM_D). Else if CTTO_D is greater than equal to INFORM_D then (CTTO_D- INFORM_D) +1.

1.4.12. CriteriaforDementiaoftheAlzheimer'sType – CRITALZ

Dataset	CRITALZ
Creating program	critalz.sas
Description	CriteriaforDementiaoftheAlzheimer'sType
Unique identifier	DCRFID,CAGROUP,CADETAIL
Sorted by	DCRFID,CAGROUP,CADETAIL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
CARES	char	CARES		Collected at CRF.
CAGROUP	char	CAGROUP		Collected at CRF.
CARESDET	char	CARESDET		Collected at CRF.
CADETAIL	char	CADETAIL		Collected at CRF.

1.4.13. Brain CT/MRI Outcome – CTMRIOUT

Dataset	CTMRIOUT
Creating program	ctmriout.sas
Description	Brain CT/MRI Outcome
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,CTOUT_V,CTMRI_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
CTOUT	char	CTOUT		Collected at CRF.
CTRADYN	char	CTRADYN		Collected at CRF.
CTMRI_C	char	CTMRI_C		Collected at CRF.
CTMRIDY	num	RELATIVE CTMRI_D DAY		If CTMRI_D and INFORM_D not missing then perform below logic to calculate CTMRIDY, If CTMRI_D less than INFORM_D then (CTMRI_D - INFORM_D). Else if CTMRI_D is greater than equal to INFORM_D then (CTMRI_D- INFORM_D) +1.

1.4.14. Deviatn – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Deviatn
Unique identifier	DCRFID,DVTYPE,DEVIAT
Sorted by	DCRFID,DVTYPE,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		Collected at CRF.
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
DVTYPE	char	DVTYPE		Collected at CRF.
ZDEVIAT	char	ZDEVIAT		Collected at CRF.
DEVIAT	char	DEVIAT		Collected at CRF.

1.4.15. Medical & Surg Hist/Concomitant Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Medical & Surg Hist/Concomitant Diseases
Unique identifier	DCRFID,DSSYSTEM,DSCOND,DSSEQNO
Sorted by	DCRFID,DSSYSTEM,DSCOND,DSSEQNO
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
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DISEASE	char	DISEASE		Collected at CRF.
DSCOND	char	DSCOND		Collected at CRF.
DSSEQNO	num	DSSEQNO		Collected at CRF.
DSSYSTEM	char	DSSYSTEM		Collected at CRF.
DSSYST_V	char	DSSYST_V		Collected at CRF.

1.4.16. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID,ECGWNL,VISIT, ECG_DY
Sorted by	DCRFID,ECGWNL,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
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
ECG_C	char	ECG_C		Collected at CRF.
ECGWNL	char	ECGWNL		Collected at CRF.
ECGSIGN	char	ECGSIGN		Collected at CRF.
ECG_DY	num	RELATIVE ECG_D DAY		If ECG_D and INFORM_D not missing then perform below logic to calculate ECG_DY, If ECG_D less than INFORM_D then (ECG_D - INFORM_D). Else if ECG_D is greater than equal to INFORM_D then (ECG_D- INFORM_D) +1.

1.4.17. Electrocardiogram Parameter – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	Electrocardiogram Parameter
Unique identifier	DCRFID,ECGPAR,VISIT
Sorted by	DCRFID,ECGPAR,VISIT
Notes	

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

1.4.18. Evaluation SIB – EVALSIB

Dataset	EVALSIB
Creating program	evalsib.sas
Description	Evaluation SIB
Unique identifier	DCRFID,ESVERBAL,ESMOTOR,VISIT
Sorted by	DCRFID,ESVERBAL,ESMOTOR,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,SIBNAME

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

1.4.19. Eligibility Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Eligibility Criteria
Unique identifier	DCRFID,IECRIT,VISIT
Sorted by	DCRFID,IECRIT,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
IECRIT	char	IECRIT		Collected at CRF.
IESEQNO	char	IESEQNO		Collected at CRF.
IEYN	char	IEYN		Collected at CRF.
IETYPE	char	IETYPE		Collected at CRF.

1.4.20. In Patient – INPAT

Dataset	INPAT
Creating program	inpat.sas
Description	In Patient
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: HOSTYPE_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
HOSTYPE	char	HOSTYPE		Collected at CRF.
STAY	num	STAY		Collected at CRF.
STAYUNK	char	STAYUNK		Collected at CRF.

1.4.21. Laboratory References – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory References
Unique identifier	DCRFID,LSRELABN,SAMPLEDY
Sorted by	DCRFID,LSRELABN,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,LABREFNO,LAB_V,URINE_D,URINE_V,SAMPLE_D,LABID

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
LSRELABN	char	LSRELABN		Collected at CRF.
URINE_C	char	URINE_C		Collected at CRF.
SAMPLE_C	char	SAMPLE_C		Collected at CRF.
URINETM	num	URINE_D Time		If URINE_D contains time part then timepart(URINE_D) else URINETM equal to NULL.

Variable	Type	Label	Codes	Comments
URINEDY	num	RELATIVE URINE_D DAY		If URINE_D and INFORM_D not missing then perform below logic to calculate URINEDY, If URINE_D less than INFORM_D then (URINE_D - INFORM_D). Else if URINE_D is greater than equal to INFORM_D then (URINE_D- INFORM_D) +1.
SAMPLETM	num	SAMPLE_D Time		If SAMPLE_D contains time part then timepart(SAMPLE_D) else SAMPLETM equal to NULL.
SAMPLEDY	num	RELATIVE SAMPLE_D DAY		If SAMPLE_D and INFORM_D not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than INFORM_D then (SAMPLE_D - INFORM_D). Else if SAMPLE_D is greater than equal to INFORM_D then (SAMPLE_D- INFORM_D) +1.

1.4.22. Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory 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: PAGERPT,INVEST,LABID,STIME,SAMPLE_D,ANALYS_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
VISRPT	num	VISRPT		Collected at CRF.
LABTEST	char	LABTEST		Collected at CRF.
LABVAL	num	LABVAL		Collected at CRF.
LABVAL_V	char	LABVAL_V		Collected at CRF.
LABLOW	num	LABLOW		Collected at CRF.
LABUPP	num	LABUPP		Collected at CRF.
LABTST_U	char	LABTST_U		Collected at CRF.

Variable	Type	Label	Codes	Comments
CLASS	char	CLASS		Collected at CRF.
SILABVAL	num	SILABVAL		Collected at CRF.
SIUNIT	char	SIUNIT		Collected at CRF.
ZLABTEST	char	ZLABTEST		Collected at CRF.
SAMPLETM	num	SAMPLE_D Time		If SAMPLE_D contains time part then timepart(SAMPLE_D) else SAMPLETM equal to NULL.
SAMPLEDY	num	RELATIVE SAMPLE_D DAY		If SAMPLE_D and INFORM_D not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than INFORM_D then (SAMPLE_D - INFORM_D). Else if SAMPLE_D is greater than equal to INFORM_D then (SAMPLE_D- INFORM_D) +1.

1.4.23. Laboratory Sample collection – LABSAM

Dataset	LABSAM
Creating program	labsam.sas
Description	Laboratory Sample collection
Unique identifier	DCRFID,VISIT,SAMPLEDY
Sorted by	DCRFID,VISIT,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: INVEST,LABID,SAMPLE_D,LABREQNO,LSREM_V,BARCNO1,BARCNO2, BARCNO3,RECEPT_D1,RECEPT_D2,RECEPT_D3,FASTING,COMMENTS

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SAMPLETM	num	SAMPLE_D Time		If SAMPLE_D contains time part then timepart(SAMPLE_D) else SAMPLETM equal to NULL.
SAMPLEDY	num	RELATIVE SAMPLE_D DAY		If SAMPLE_D and INFORM_D not missing then perform below logic to calculate SAMPLEDY, If SAMPLE_D less than INFORM_D then (SAMPLE_D - INFORM_D). Else if SAMPLE_D is greater than equal to INFORM_D then (SAMPLE_D- INFORM_D) +1.

Variable	Type	Label	Codes	Comments
RECEP1TM	num	RECEPT_D1 Time		If RECEPT_D1 contains time part then timepart(RECEPT_D1) else RECEP1TM equal to NULL.
RECEP1DY	num	RELATIVE RECEPT_D1 DAY		If RECEPT_D1 and INFORM_D not missing then perform below logic to calculate RECEP1DY, If RECEPT_D1 less than INFORM_D then (RECEPT_D1 - INFORM_D). Else if RECEPT_D1 is greater than equal to INFORM_D then (RECEPT_D1-INFORM_D) +1.
RECEP2TM	num	RECEPT_D2 Time		If RECEPT_D2 contains time part then timepart(RECEPT_D2) else RECEP2TM equal to NULL.
RECEP2DY	num	RELATIVE RECEPT_D2 DAY		If RECEPT_D2 and INFORM_D not missing then perform below logic to calculate RECEP2DY, If RECEPT_D2 less than INFORM_D then (RECEPT_D2 - INFORM_D). Else if RECEPT_D2 is greater than equal to INFORM_D then (RECEPT_D2-INFORM_D) +1.

1.4.24. Laboratory Urinalysis – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urinalysis
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: PAGERPT,VISRPT,INVEST,LABID,SAMPLE_D,LUVAL_V,LUTST_U,ANALYS_D, SILUVAL,SIUNIT

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
LUVAL	char	LUVAL		Collected at CRF.
LABTEST	char	LABTEST		Collected at CRF.
ZLABTEST	char	ZLABTEST		Collected at CRF.
CLASS	char	CLASS		Collected at CRF.
SAMPLETM	num	SAMPLE_D Time		If SAMPLE_D contains time part then timepart(SAMPLE_D) else SAMPLETM equal to NULL.

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

1.4.25. Minimum Data Set – MINDSET

Dataset	MINDSET
Creating program	mindset.sas
Description	Minimum Data Set
Unique identifier	DCRFID,MSITEM,MSGROUP,VISIT
Sorted by	DCRFID,MSITEM,MSGROUP,VISIT
Notes	

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

Variable	Type	Label	Codes	Comments
MSGROUP	char	MSGROUP		Collected at CRF.
MSSCORE	char	MSSCORE		Collected at CRF.

1.4.26. Mini-Mental State Examination (MMSE) – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	Mini-Mental State Examination (MMSE)
Unique identifier	DCRFID,METYPE,MEITEM,VISIT
Sorted by	DCRFID,METYPE,MEITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
METYPE	char	METYPE		Collected at CRF.
MESCORE	char	MESCORE		Collected at CRF.
MEITEM	char	MEITEM		Collected at CRF.
MMSE_SU	num	MMSE_SU		Collected at CRF.

1.4.27. Neurological Examination – NEUREXAM

Dataset	NEUREXAM
Creating program	neurexam.sas
Description	Neurological Examination
Unique identifier	DCRFID,NETEST,VISIT,NESEQNO
Sorted by	DCRFID,NETEST,VISIT,NESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NEEXAM_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
NEEXAM	char	NEEXAM		Collected at CRF.
NERESULT	char	NERESULT		Collected at CRF.
NETEST	char	NETEST		Collected at CRF.
NESEQNO	num	NESEQNO		Collected at CRF.

1.4.28. Neurological Questionnaire – NEURQST

Dataset	NEURQST
Creating program	neurqst.sas
Description	Neurological Questionnaire
Unique identifier	DCRFID,NQTYPE,NQITEM,VISIT
Sorted by	DCRFID,NQTYPE,NQITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
NQSEQNO	num	NQSEQNO		Collected at CRF.
NQITEM	char	NQITEM		Collected at CRF.
NQSCORE	char	NQSCORE		Collected at CRF.
NQTYPE	char	NQTYPE		Collected at CRF.

1.4.29. Out Patient – OUTPAT

Dataset	OUTPAT
Creating program	outpat.sas
Description	Out Patient
Unique identifier	DCRFID,VISTYPE,VISIT,VISNO
Sorted by	DCRFID,VISTYPE,VISIT,VISNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,VISTYPE_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
VISTYPE	char	VISTYPE		Collected at CRF.
VISNO	num	VISNO		Collected at CRF.
NOUNK	char	NOUNK		Collected at CRF.

1.4.30. Patbeh – PATBEH

Dataset	PATBEH
Creating program	patbeh.sas
Description	Patbeh
Unique identifier	DCRFID,PBITEM,VISIT
Sorted by	DCRFID,PBITEM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
PBSEQNO	num	PBSEQNO		Collected at CRF.
PBITEM	char	PBITEM		Collected at CRF.
PBNA	char	PBNA		Collected at CRF.
PBFREQ	num	PBFREQ		Collected at CRF.
BPSEV	num	BPSEV		Collected at CRF.
PBDIS	num	PBDIS		Collected at CRF.

1.4.31. Physical Examination – PHYSEXAM

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

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
PERESULT	char	PERESULT		Collected at CRF.
PESYSTEM	char	PESYSTEM		Collected at CRF.
PESEQNO	num	PESEQNO		Collected at CRF.

1.4.32. Randomisation – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomisation
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	

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

1.4.33. Related Adverse Events – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	Related Adverse Events
Unique identifier	DCRFID,RATYPE,RASEQNO
Sorted by	DCRFID,RATYPE,RASEQNO
Notes	

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
RASEQNO	num	RASEQNO		Collected at CRF.
RATYPE	char	RATYPE		Collected at CRF.

1.4.34. Remark – REMARK

Dataset	REMARK
Creating program	remark.sas
Description	Remark
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
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
TRIAL	char	TRIAL		Empty dataset will be submitted
VISIT	num	VISIT		Empty dataset will be submitted
RMPAGE	char	RMPAGE		Empty dataset will be submitted
RMSEQNO	num	RMSEQNO		Empty dataset will be submitted
REMARKDY	num	RELATIVE REMARK_D DAY		Empty dataset will be submitted

1.4.35. Reminder – REMIND

Dataset	REMIND
Creating program	remind.sas
Description	Reminder
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: INVEST,MOVE_D,MOVE_C

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
DIFRESYN	char	DIFRESYN		Collected at CRF.
STOPMED	char	STOPMED		Collected at CRF.
MOVE_DY	num	RELATIVE MOVE_D DAY		If MOVE_D and INFORM_D not missing then perform below logic to calculate MOVE_DY, If MOVE_D less than INFORM_D then (MOVE_D - INFORM_D). Else if MOVE_D is greater than equal to INFORM_D then (MOVE_D- INFORM_D) +1.

1.4.36. Services – SERVICES

Dataset	SERVICES
Creating program	services.sas
Description	Services
Unique identifier	DCRFID,SERVICE,VISIT
Sorted by	DCRFID,SERVICE,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST,SERVIC_V

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SERVICE	char	SERVICE		Collected at CRF.
SUSEDYN	char	SUSEDYN		Collected at CRF.
NOUSEDUN	char	NOUSEDUN		Collected at CRF.
NOUSED	num	NOUSED		Collected at CRF.

1.4.37. Severe Impairment Battery – SIB

Dataset	SIB
Creating program	sib.sas
Description	Severe Impairment Battery
Unique identifier	DCRFID,SBTEST,VISIT,SBSEQNO
Sorted by	DCRFID,SBTEST,VISIT,SBSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: INVEST

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
SBSEQNO	char	SBSEQNO		Collected at CRF.
SBTEST	char	SBTEST		Collected at CRF.
SBSCORE	num	SBSCORE		Collected at CRF.
SBALTER	char	SBALTER		Collected at CRF.

1.4.38. Subjchar_Lab – SUBJCHAR_LAB

Dataset	SUBJCHAR_LAB
Creating program	subjchar_lab.sas
Description	Subjchar_Lab
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: INVEST,INITIALS,BIRTH_D,DIABETIC

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

1.4.39. Trllist – TRLLIST

Dataset	TRLLIST
Creating program	trllist.sas
Description	Trllist
Unique identifier	TRIAL,RANDCODE
Sorted by	TRIAL,RANDCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDNO

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

1.4.40. Trlrand – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Trlrand
Unique identifier	RANDGRP
Sorted by	RANDGRP
Notes	

Variable	Type	Label	Codes	Comments
RANDGRP	char	RANDGRP		Collected at CRF.
RANDCODE	char	RANDCODE		Collected at CRF.
TRIAL	char	TRIAL		Collected at CRF.

1.4.41. Screening Evaluation – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	Screening Evaluation
Unique identifier	DCRFID,TTPHASE
Sorted by	DCRFID,TTPHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TTREAS_V,TTFROM_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
TRIAL	char	TRIAL		Collected at CRF.
TTREAS	char	TTREAS		Collected at CRF.
TTTYPE	char	TTTYPE		Collected at CRF.
TTFROM_C	char	TTFROM_C		Collected at CRF.
TTPHASE	char	TTPHASE		Collected at CRF.
TTFROMDY	num	RELATIVE TTFROM_D DAY		If TTFROM_D and INFORM_D not missing then perform below logic to calculate TTFROMDY, If TTFROM_D less than INFORM_D then (TTFROM_D - INFORM_D). Else if TTFROM_D is greater than equal to INFORM_D then (TTFROM_D- INFORM_D) +1.

1.4.42. 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 or due to missing values: INVEST,VISIT_D,VISIT_C

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
PAGE	char	PAGE		Collected at CRF.
TRIAL	char	TRIAL		Collected at CRF.
VISIT	num	VISIT		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT_U		Collected at CRF.
MMSE_REP	num	MMSE_REP		Collected at CRF.
MMSE_INC	char	MMSE_INC		Collected at CRF.
MMSE_TOT	num	MMSE_TOT		Collected at CRF.
NOSAMPLE	char	NOSAMPLE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURILL	num	DURILL		Collected at CRF.
INST	char	INST		Collected at CRF.
VISIT_DY	num	RELATIVE VISIT_D DAY		If VISIT_D and INFORM_D not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than INFORM_D then (VISIT_D - INFORM_D). Else if VISIT_D is greater than equal to INFORM_D then (VISIT_D- INFORM_D) +1.

1.4.43. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	DCRFID,VS_DY
Sorted by	DCRFID,VS_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VS_D

Variable	Type	Label	Codes	Comments
DCRFID	char	CRFID ASSIGNED FOR DE-IDENTITY		Randomly assigned crfid assigned for de-identity.
PAGE	char	PAGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL		Collected at CRF.
VS_C	char	VS_C		Collected at CRF.
PULSE	num	PULSE		Collected at CRF.
SBP	num	SBP		Collected at CRF.
DBP	num	DBP		Collected at CRF.
VS_DY	num	RELATIVE VS_D DAY		If VS_D and INFORM_D not missing then perform below logic to calculate VS_DY, If VS_D less than INFORM_D then (VS_D - INFORM_D). Else if VS_D is greater than equal to INFORM_D then (VS_D-INFORM_D) +1.