Clinical Development

JnJ-17335630

ALZ3005

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.
- Comments dataset will be submitted with zero observation due to sensitivity of data.
- Due to sensitive information INVEST dataset will be removed.
- Due to sensitive information MEDKIT datasets will be removed.
- DEMOG.DMINFDT will be used as Reference Date (referred as REF.DATE in the document) to derive relative day.

1.3.   Data Files

The ALZ3005 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics (DM) – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics (DM)
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
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: SUBJINIT,DMACTDT,IVID,IVNAME,BIRTHDT,BIRTHDTC,DMINFDT, RACEW, RACEB, RACEA , RACEAI , RACENH ,RACESPEC,COUNTRYC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
RACE	char	Race		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.
DMACTDY	num	Relative Actual Day of Demography		If DMACTDT and DMINFDT not missing then perform below logic to calculate DMACTDY, If DMACTDT less than DMINFDT then (DMACTDT - DMINFDT). Else if DMACTDT is greater than equal to DMINFDT then (DMACTDT- DMINFDT) +1.

1.4.2. Adverse Events (AE) – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events (AE)
Unique identifier	DUSUBJID,AEDECOD,AESTDY,AESEQ
Sorted by	DUSUBJID,AEDECOD,AESTDY,AESEQ
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: AETERM,AEMODIFY,AESTDTC,AESTDT,AEENDTC,AEENDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEACTTRC	num	Action Taken With Treatment Code		Collected at CRF.
AEACTTRT	char	Action Taken With Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.
AEOUT	char	Outcome of Event		Collected at CRF.
AERELC	num	Relationship to Treatment Code		Collected at CRF.
AEREL	char	Relationship to Treatment		Collected at CRF.
AESERC	num	Seriousness Criteria Code		Collected at CRF.
AESER	char	Seriousness Criteria		Collected at CRF.
AESHOSPR	char	Requires Hospitalization		Collected at CRF.
AESHOSPP	char	Prolonged Hospitalization		Collected at CRF.
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESCONG	char	Congenial Anomaly or Birth Defect		Collected at CRF.
AESMIE	char	Other Medicaly Important Serious Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESEVC	num	Severity of Event Code		Collected at CRF.
AESEV	char	Severity of Event		Collected at CRF.
AECONTRC	num	Concomitant/Additional Treatment Code		Collected at CRF.
AECONTRT	char	Concomitant/Additional Treatment		Collected at CRF.
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDT and DMINFDT not missing then perform below logic to calculate AESTDY, If AESTDT less than DMINFDT then (AESTDT - DMINFDT). Else if AESTDT is greater than equal to DMINFDT then (AESTDT- DMINFDT) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDT and DMINFDT not missing then perform below logic to calculate AEENDY, If AEENDT less than DMINFDT then (AEENDT - DMINFDT). Else if AEENDT is greater than equal to DMINFDT then (AEENDT- DMINFDT) +1.

1.4.3. APAS - CarB – APASCB

Dataset	APASCB
Creating program	apascb.sas
Description	APAS - CarB
Unique identifier	DUSUBJID,VISITNUM,APPERDY,APSEQ
Sorted by	DUSUBJID,VISITNUM,APPERDY,APSEQ
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: APACOTH,APPERDT,APPERDTC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
APREPRT	char	Were There Any Supported Accomodation		Collected at CRF.
APREPRTC	num	Supported Accomodation Code		Collected at CRF.
APSEQ	num	Sequence Number		Collected at CRF.
APACTYP	char	Type of Accomodation		Collected at CRF.
APACTYPC	num	Type of Accomodation Code		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
APSTAYC	num	Type of Stay Code		Collected at CRF.
APSTAY	char	Type of Stay		Collected at CRF.
APATEMP	num	Temporary Stay(Number of Days)		Collected at CRF.
APADDR	char	Same Address		Collected at CRF.
APADDRC	num	Address Code		Collected at CRF.
APDAYS	num	Days Spent in the Past		Collected at CRF.
APSPVSN	char	Supervision		Collected at CRF.
APSPVSNC	num	Supervision Code		Collected at CRF.
APTMESP	char	Time Spent for Relative		Collected at CRF.
APTMESPC	num	Time Spent for Relative Code		Collected at CRF.
AP1HOUR	num	Hours Spent per Day (B3)		Collected at CRF.
AP1MIN	num	Minutes Spent per Day (B3)		Collected at CRF.
AP2HOUR	num	Hours Spent per Day (B4)		Collected at CRF.
AP2MIN	num	Minutes Spent per Day (B4)		Collected at CRF.
AP3HOUR	num	Hours Spent per Day (B6)		Collected at CRF.
AP3MIN	num	Minutes Spent per Day (B6)		Collected at CRF.

Variable	Type	Label	Codes	Comments
AP4HOUR	num	Hours Spent per Day (B8)		Collected at CRF.
AP4MIN	num	Minutes Spent per Day (B8)		Collected at CRF.
AP5HOUR	num	Hours Spent per Day (B9)		Collected at CRF.
AP5MIN	num	Minutes Spent per Day (B9)		Collected at CRF.
APPERDY	num	Relative Permanent Stay Day		If APPERDT and DMINFDT not missing then perform below logic to calculate APPERDY, If APPERDT less than DMINFDT then (APPERDT - DMINFDT). Else if APPERDT is greater than equal to DMINFDT then (APPERDT- DMINFDT) +1.

1.4.4. Alzheimers Disease History – AZDISHIS

Dataset	AZDISHIS
Creating program	azdishis.sas
Description	Alzheimers Disease History
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
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: DHSTDT,DHDGNDT,DHSTDTC,DHDGNDTC,DHPCSTDT,DHPCSDTC,DHPCENDT, DHPCEDTC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASE	char	Phase		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DHRELAD	char	First Degree Relat. With Alzheimers		Collected at CRF.
DHRELADC	num	First Degree Relat. With Alzheimers Code		Collected at CRF.
DHPSTCH	char	Has the Subject Taken Cholinomimetics		Collected at CRF.
DHPSTCHC	num	Has the Subj Taken Cholinomimetics Code		Collected at CRF.
DHREGM	char	Regimen (example: 500 mg bid)		Collected at CRF.
DHROUTE	char	Route		Collected at CRF.
DHTERM	char	Drug/Therapy		Collected at CRF.
DHSTDY	num	Relative Onset of Cognitive Problem Day		If DHSTDT and DMINFDT not missing then perform below logic to calculate DHSTDY, If DHSTDT less than DMINFDT then (DHSTDT - DMINFDT). Else if DHSTDT is greater than equal to DMINFDT then (DHSTDT- DMINFDT) +1.
DHDGNDY	num	Relative Diagno of Probable Alzheim Day		If DHDGNDT and DMINFDT not missing then perform below logic to calculate DHDGNDY, If DHDGNDT less than DMINFDT then (DHDGNDT - DMINFDT). Else if DHDGNDT is greater than equal to DMINFDT then (DHDGNDT- DMINFDT) +1.

Variable	Type	Label	Codes	Comments
DHPCSTDY	num	Relative Start Day		If DHPCSTDT and DMINFDT not missing then perform below logic to calculate DHPCSTDY, If DHPCSTDT less than DMINFDT then (DHPCSTDT - DMINFDT). Else if DHPCSTDT is greater than equal to DMINFDT then (DHPCSTDT- DMINFDT) +1.
DHPCENDY	num	Relative End Day		If DHPCENDT and DMINFDT not missing then perform below logic to calculate DHPCENDY, If DHPCENDT less than DMINFDT then (DHPCENDT - DMINFDT). Else if DHPCENDT is greater than equal to DMINFDT then (DHPCENDT- DMINFDT) +1.

1.4.5. Comments (CT) – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Comments (CT)
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Empty dataset will be submitted
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Empty dataset will be submitted
DSITEID	char	Site Id Assigned for De-Identity		Empty dataset will be submitted
DOMAIN	char	Domain of Origin		Empty dataset will be submitted
CTSEQ	num	Comment Sequence Number		Empty dataset will be submitted
CTACTDY	num	Relative Actual Day of Collection		Empty dataset will be submitted

1.4.6. Concomitant Meds (CM) – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Meds (CM)
Unique identifier	DUSUBJID,CMDECOD1,CMSTDY,CMSEQ
Sorted by	DUSUBJID,CMDECOD1,CMSTDY,CMSEQ
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 or due to missing values: CMTERM,CMREAS,CMCLASC9,CMCLAS9,CMSTDT,CMSTDTC,CMENDT, CMENDTC,CMCAUSC,CMCAUS,CMGROUP, CMMODIFY

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMCLASC	char	ATC Code		Collected at CRF.
CMCLAS	char	ATC Text		Collected at CRF.
CMCLASC0	char	ATC Code 0		Collected at CRF.
CMCLASC1	char	ATC Code 1		Collected at CRF.
CMCLASC2	char	ATC Code 2		Collected at CRF.
CMCLASC3	char	ATC Code 3		Collected at CRF.
CMCLASC4	char	ATC Code 4		Collected at CRF.
CMCLASC5	char	ATC Code 5		Collected at CRF.
CMCLASC6	char	ATC Code 6		Collected at CRF.
CMCLASC7	char	ATC Code 7		Collected at CRF.
CMCLASC8	char	ATC Code 8		Collected at CRF.
CMCLAS0	char	ATC Text 0		Collected at CRF.
CMCLAS1	char	ATC Text 1		Collected at CRF.
CMCLAS2	char	ATC Text 2		Collected at CRF.
CMCLAS3	char	ATC Text 3		Collected at CRF.
CMCLAS4	char	ATC Text 4		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMCLAS5	char	ATC Text 5		Collected at CRF.
CMCLAS6	char	ATC Text 6		Collected at CRF.
CMCLAS7	char	ATC Text 7		Collected at CRF.
CMCLAS8	char	ATC Text 8		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMREGIM	char	Regimen (Dose + Frequency)		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
CMCONT	char	Medication Continuing		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDT and DMINFDT not missing then perform below logic to calculate CMSTDY, If CMSTDT less than DMINFDT then (CMSTDT - DMINFDT). Else if CMSTDT is greater than equal to DMINFDT then (CMSTDT- DMINFDT) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDT and DMINFDT not missing then perform below logic to calculate CMENDY, If CMENDT less than DMINFDT then (CMENDT - DMINFDT). Else if CMENDT is greater than equal to DMINFDT then (CMENDT- DMINFDT) +1.

1.4.7. Disability Assessment for Dementia – DAD

Dataset	DAD
Creating program	dad.sas
Description	Disability Assessment for Dementia
Unique identifier	DUSUBJID,DAITEM,VISITNUM,DAACTDY
Sorted by	DUSUBJID,DAITEM,VISITNUM,DAACTDY
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: DAACTDT,DAACTDTC,DACGI

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DASEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAITEM	char	Disability Assessment Item		Collected at CRF.
DAGROUP	char	Disability Assessment Group		Collected at CRF.
DASTAT	char	Condition		Collected at CRF.
DASTATC	num	Condition Code		Collected at CRF.
DAACTDY	num	Relative Day of Assessment		If DAACTDT and DMINFDT not missing then perform below logic to calculate DAACTDY, If DAACTDT less than DMINFDT then (DAACTDT - DMINFDT). Else if DAACTDT is greater than equal to DMINFDT then (DAACTDT- DMINFDT) +1.

1.4.8. Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
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: DTCAOTH,DEATHDT,DEATHDTC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DTCAUS	char	Cause of Death		Collected at CRF.

Variable	Type	Label	Codes	Comments
DTCAUSC	num	Cause of Death Code		Collected at CRF.
DEATHDY	num	Relative Death Day		If DEATHDT and DMINFDT not missing then perform below logic to calculate DEATHDY, If DEATHDT less than DMINFDT then (DEATHDT - DMINFDT). Else if DEATHDT is greater than equal to DMINFDT then (DEATHDT- DMINFDT) +1.

1.4.9. Disposition (DS) – DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition (DS)
Unique identifier	DUSUBJID,DSTYPE
Sorted by	DUSUBJID,DSTYPE
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: DSACTDT,DSRSOTH,DSACTDTC,DSDOSEDT,DSDOSDTC, DSRABKDT, DSRABKRS, PREGDUDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSSCRNC	num	Reason for Screen Failure Code		Collected at CRF.
DSSCRN	char	Reason for Screen Failure		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSCONT	char	Continue Following		Collected at CRF.
DSCONTC	num	Continue to Follow-up Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSCARE	char	Started Standard of Care		Collected at CRF.
DSCAREC	num	Started Standard of Care Code		Collected at CRF.
DSTERM1	char	Therapy Name 1		Collected at CRF.
DSTERM2	char	Therapy Name 2		Collected at CRF.
DSSEQ	num	Disposition Sequence Number		Collected at CRF.
DSACTDY	num	Relative Actual Day Trial Comple/Withdr		If DSACTDT and DMINFDT not missing then perform below logic to calculate DSACTDY, If DSACTDT less than DMINFDT then (DSACTDT - DMINFDT). Else if DSACTDT is greater than equal to DMINFDT then (DSACTDT- DMINFDT) +1.
DSDOSEDY	num	Relative Day of Last Dose Taken		If DSDOSEDT and DMINFDT not missing then perform below logic to calculate DSDOSEDY, If DSDOSEDT less than DMINFDT then (DSDOSEDT - DMINFDT). Else if DSDOSEDT is greater than equal to DMINFDT then (DSDOSEDT- DMINFDT) +1.
DSRABKDY	num	Relative Actual Day Randomization Code		If DSRABKDT and DMINFDT not missing then perform below logic to calculate DSRABKDY, If DSRABKDT less than DMINFDT then (DSRABKDT - DMINFDT). Else if DSRABKDT is greater than equal to DMINFDT then (DSRABKDT- DMINFDT) +1.

1.4.10.   DNA Demog Data – DNADEMOG

Dataset	DNADEMOG
Creating program	dnademog.sas
Description	DNA Demog Data
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DNINFDT,DNDT,DNREAS

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study ID		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DNSEQ	num	Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DNCNSNT	char	DNA Informed Consent Form		Collected at CRF.
DNCNSNTC	num	DNA Informed Consent Form Code		Collected at CRF.
DNSTUDY	char	DNA Study Specific Testing		Collected at CRF.
DNSTUDYC	num	DNA Study Specific Testing Code		Collected at CRF.
DNSTORE	char	Sample Storage for Future Testing		Collected at CRF.
DNSTOREC	num	Sample Storage for Future Testing Code		Collected at CRF.
DNREGUL	char	Length Limit of the Storage Sample		Collected at CRF.
DNREGULC	num	Length Limit of the Storage Sample Code		Collected at CRF.
DNLIMIT	char	Regulations Limit		Collected at CRF.
DNLIMITC	num	Regulations Limit Code		Collected at CRF.
DNLIMOTH	char	Storage Limit Others		Collected at CRF.
DNSAMP	char	Blood Sample for DNA Testing		Collected at CRF.
DNSAMPC	num	Blood Sample for DNA Testing Code		Collected at CRF.
DNEDU	char	Highest Level of School Education		Collected at CRF.
DNEDUC	num	Highest Level of School Education Code		Collected at CRF.
DNHDINJ	char	Sustain Head Injury or Stroke		Collected at CRF.
DNHDINJC	num	Sustain Head Injury or Stroke Code		Collected at CRF.
DNDIAB	char	Diagnosis of Diabetes		Collected at CRF.

Variable	Type	Label	Codes	Comments
DNDIABC	num	Diagnosis of Diabetes Code		Collected at CRF.
DNHYPTN	char	Diagnosis of Hypertension		Collected at CRF.
DNHYPTNC	num	Diagnosis of Hypertension Code		Collected at CRF.
DHCHOL	char	Diagnosis of High Cholesterol		Collected at CRF.
DHCHOLC	num	Diagnosis of High Cholesterol Code		Collected at CRF.
DNERTH	char	Estrogen Replacement Therapy		Collected at CRF.
DNERTHC	num	Estrogen Replacement Therapy Code		Collected at CRF.
DNINFDY	num	Relative DNA Informed Consent Day		If DNINFDT and DMINFDT not missing then perform below logic to calculate DNINFDY, If DNINFDT less than DMINFDT then (DNINFDT - DMINFDT). Else if DNINFDT is greater than equal to DMINFDT then (DNINFDT- DMINFDT) +1.
DNDY	num	Relative Day of Blood Sample Obtained		If DNDT and DMINFDT not missing then perform below logic to calculate DNDY, If DNDT less than DMINFDT then (DNDT - DMINFDT). Else if DNDT is greater than equal to DMINFDT then (DNDT- DMINFDT) +1.

1.4.11. Exposure (EX) – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Exposure (EX)
Unique identifier	DUSUBJID,VISITNUM,EXSTDY,EXSEQ
Sorted by	DUSUBJID,VISITNUM,EXSTDY,EXSEQ
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: EXSTDT,EXSTDTC,EXENDT,EXENDTC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSE	num	Dose per Administration		Collected at CRF.
DOSEC	num	Dose per Administration Code		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
EXGIVEN	num	Number of Pills, etc Given		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and DMINFDT not missing then perform below logic to calculate EXSTDY, If EXSTDT less than DMINFDT then (EXSTDT - DMINFDT). Else if EXSTDT is greater than equal to DMINFDT then (EXSTDT- DMINFDT) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDT and DMINFDT not missing then perform below logic to calculate EXENDY, If EXENDT less than DMINFDT then (EXENDT - DMINFDT). Else if EXENDT is greater than equal to DMINFDT then (EXENDT- DMINFDT) +1.

1.4.12. Habit of Tobacco Use – HABIT

Dataset	HABIT
Creating program	habit.sas
Description	Habit of Tobacco Use
Unique identifier	DUSUBJID,HAITEM
Sorted by	DUSUBJID,HAITEM
Notes	

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
HASEQ	num	Sequence Number		Collected at CRF.
HAITEM	char	Habit of Tobacco Use Item		Collected at CRF.

Variable	Type	Label	Codes	Comments
HAITEMC	num	Habit of Tobacco Use Item Code		Collected at CRF.
HASTAT	char	Condition		Collected at CRF.
HASTATC	num	Condition Code		Collected at CRF.
HACIGRT	num	Number of Cigarettes per Day		Collected at CRF.
HACIGAR	num	Number of Cigars per Day		Collected at CRF.
HAPIPE	num	Number of Pipes per Day		Collected at CRF.
HAYRS	num	Number of Years		Collected at CRF.

1.4.13.   Inclusion/Exclusion Exceptions (IE) – IE

Dataset	IE
Creating program	ie.sas
Description	Inclusion/Exclusion Exceptions (IE)
Unique identifier	DUSUBJID,IETEST
Sorted by	DUSUBJID,IETEST
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IEDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.
IESPID	char	Sponsor-Defined Identifier		Collected at CRF.
IETEST	char	Inclusion/Exclusion Criterion		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IEORRES	char	Exception Criterion Original Result		Collected at CRF.
IESTRESC	char	Exception Criterion Result in Std Format		Collected at CRF.
IEMETC	num	Overall Criteria Met Code		Collected at CRF.
IEMET	char	Overall Criteria Met		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDT and DMINFDT not missing then perform below logic to calculate IEDY, If IEDT less than DMINFDT then (IEDT - DMINFDT). Else if IEDT is greater than equal to DMINFDT then (IEDT-DMINFDT) +1.

1.4.14.   Institutionalization Status – INSTST

Dataset	INSTST
Creating program	instst.sas
Description	Institutionalization Status
Unique identifier	DUSUBJID,ISCNT,VISIT
Sorted by	DUSUBJID,ISCNT,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: ISCNTDT,ISSTDT,ISSTDTC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ISCNT	char	Type of Contact		Collected at CRF.

Variable	Type	Label	Codes	Comments
ISCNTC	num	Type of Contact Code		Collected at CRF.
ISSTAT	char	Subject Institutionalization		Collected at CRF.
ISSTATC	num	Subject Institutionalization Code		Collected at CRF.
ISDIE	char	Subject Death		Collected at CRF.
ISDIEC	num	Subject Death Code		Collected at CRF.
ISCNTDY	num	Relative Day of Contact		If ISCNTDT and DMINFDT not missing then perform below logic to calculate ISCNTDY, If ISCNTDT less than DMINFDT then (ISCNTDT - DMINFDT). Else if ISCNTDT is greater than equal to DMINFDT then (ISCNTDT- DMINFDT) +1.
ISSTDY	num	Relative Subj Institutionalization Day		If ISSTDT and DMINFDT not missing then perform below logic to calculate ISSTDY, If ISSTDT less than DMINFDT then (ISSTDT - DMINFDT). Else if ISSTDT is greater than equal to DMINFDT then (ISSTDT- DMINFDT) +1.

1.4.15.   IVRS Data – IVRS

Dataset	IVRS
Creating program	ivrs.sas
Description	IVRS Data
Unique identifier	DSUBJID,TRTGPR,VISITNUM,VISITDY
Sorted by	DSUBJID,TRTGPR,VISITNUM,VISITDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISITDT,RANDNUM,KITNUM

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
VISITNUM	num	Visit Number		Collected at CRF.
KITTYPE	char	Medkit Type		Collected at CRF.
TRTGPR	char	Treatment Group		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and DMINFDT not missing then perform below logic to calculate VISITDY, If VISITDT less than DMINFDT then (VISITDT - DMINFDT). Else if VISITDT is greater than equal to DMINFDT then (VISITDT- DMINFDT) +1.

1.4.16. Medical History (MH) – MEDHIST

Dataset	MEDHIST
Creating program	medhist.sas
Description	Medical History (MH)
Unique identifier	DUSUBJID,MHBODSYS
Sorted by	DUSUBJID,MHBODSYS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MHTERM,MHACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MHBODSYC	num	Body System Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
MHBODSYS	char	Body System		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.
MHSTATC	num	Condition Code		Collected at CRF.
MHSTAT	char	Condition		Collected at CRF.
MHACTDY	num	Relative Actual Day of Collection		If MHACTDT and DMINFDT not missing then perform below logic to calculate MHACTDY, If MHACTDT less than DMINFDT then (MHACTDT - DMINFDT). Else if MHACTDT is greater than equal to DMINFDT then (MHACTDT- DMINFDT) +1.

1.4.17. Mini-Mental State Examination – MMSE

Dataset	MMSE
Creating program	mmse.sas
Description	Mini-Mental State Examination
Unique identifier	DUSUBJID,MMGRP,MMITEM,VISIT,MMSEQ
Sorted by	DUSUBJID,MMGRP,MMITEM,VISIT,MMSEQ
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: MMSEDTC,MMSEDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
MMSEQ	num	Sequence Number		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
MMITEM	char	Mini Mental Examination Item		Collected at CRF.
MMITEMC	char	MMSE Code		Collected at CRF.
MMEVAL	char	Evaluation Performed		Collected at CRF.
MMEVALC	num	Evaluation Performed Code		Collected at CRF.
MMGRP	char	Question Group		Collected at CRF.
MMRESP	char	Patient Response		Collected at CRF.
MMSTAT	char	Result		Collected at CRF.
MMSTATC	num	Result Code		Collected at CRF.
MMFINAL	num	Final Score		Collected at CRF.
MMSCORE	num	Total Score		Collected at CRF.
MMSEDY	num	Relative Day of Evaluation		If MMSEDT and DMINFDT not missing then perform below logic to calculate MMSEDY, If MMSEDT less than DMINFDT then (MMSEDT - DMINFDT). Else if MMSEDT is greater than equal to DMINFDT then (MMSEDT- DMINFDT) +1.

1.4.18.   Neurological Examination – NE

Dataset	NE
Creating program	ne.sas
Description	Neurological Examination
Unique identifier	DUSUBJID,NESTAT,NEBODSYS,VISIT
Sorted by	DUSUBJID,NESTAT,NEBODSYS,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: NEACTDT,NEFIND

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
NESEQ	num	NE Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
NEBODSYC	num	NE Body System Code		Collected at CRF.
NEBODSYS	char	NE Body System		Collected at CRF.
NESTAT	char	Condition		Collected at CRF.
NESTATC	num	Condition Code		Collected at CRF.
NEACTDY	num	Relative Actual Day		If NEACTDT and DMINFDT not missing then perform below logic to calculate NEACTDY, If NEACTDT less than DMINFDT then (NEACTDT - DMINFDT). Else if NEACTDT is greater than equal to DMINFDT then (NEACTDT- DMINFDT) +1.

1.4.19.   Physical Exam (PE) – PE

Dataset	PE
Creating program	pe.sas
Description	Physical Exam (PE)
Unique identifier	DUSUBJID,PESTAT,PEBODSYS,VISIT,PESEQ
Sorted by	DUSUBJID,PESTAT,PEBODSYS,VISIT,PESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PEACTDT,PEFIND

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PEBODSYC	num	Body System Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PEBODSYS	char	Body System		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.
PESTATC	num	Exam Result Code		Collected at CRF.
PESTAT	char	Exam Result		Collected at CRF.
PEACTDY	num	Relative Actual Day of Physical Exam		If PEACTDT and DMINFDT not missing then perform below logic to calculate PEACTDY, If PEACTDT less than DMINFDT then (PEACTDT - DMINFDT). Else if PEACTDT is greater than equal to DMINFDT then (PEACTDT- DMINFDT) +1.

1.4.20.   Phase – PHASE

Dataset	PHASE
Creating program	phase.sas
Description	Phase
Unique identifier	PHASE,KEY
Sorted by	PHASE,KEY
Notes	Below listed variables will be dropped from dataset due to missing values: SUBJID,CYCLENUM,CYCLE

Variable	Type	Label	Codes	Comments
KEY	char	Key		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
PRDNUM	num	Period Number		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.

1.4.21.   Protocol Description (PD) – PROTDESC

Dataset	PROTDESC
Creating program	protdesc.sas
Description	Protocol Description (PD)
Unique identifier	STUDYID
Sorted by	STUDYID
Notes	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
COMPND	char	Compound Name		Collected at CRF.
COMPNDC	char	Compound Number		Collected at CRF.
BLINDING	char	Blinding Level		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTCONTR	char	Active Control		Collected at CRF.
PLACONTR	char	Placebo Control		Collected at CRF.
DESIGN	char	Trial Design		Collected at CRF.
MULTCENT	char	Multi Center		Collected at CRF.
INDICAT	char	Indication		Collected at CRF.
DEVPROID	char	Development Program Id		Collected at CRF.
AGEGRP	char	Age Group		Collected at CRF.
SPECPOP	char	Special Population		Collected at CRF.
SUBJTYPE	char	Subject Type		Collected at CRF.
PROCSTUD	char	Preceding Study Id		Collected at CRF.
STUDPHAS	char	Phase of Study		Collected at CRF.
CRDMVR	char	CRDM Version Number		Collected at CRF.

1.4.22. Protocol Deviation – PROTDEV

Dataset	PROTDEV
Creating program	protdev.sas
Description	Protocol Deviation
Unique identifier	DUSUBJID,PVDECOD,PVSEQ
Sorted by	DUSUBJID,PVDECOD,PVSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PVTERM,PHASE

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.

1.4.23.   Randomization (RA) – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	Randomization (RA)
Unique identifier	DUSUBJID,REGIMEN,TRTGRP
Sorted by	DUSUBJID,REGIMEN,TRTGRP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RAACTDT,RANDNUM,RASOURCE

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
RASEQ	num	RA Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
REGIMEN	char	Regimen Code		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and DMINFDT not missing then perform below logic to calculate RAACTDY, If RAACTDT less than DMINFDT then (RAACTDT - DMINFDT). Else if RAACTDT is greater than equal to DMINFDT then (RAACTDT- DMINFDT) +1.

1.4.24.   Surgery (SG) – SURGERY

Dataset	SURGERY
Creating program	surgery.sas
Description	Surgery (SG)
Unique identifier	DUSUBJID,SGPLNDY
Sorted by	DUSUBJID,SGPLNDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SGPLNDT,SGINDIC,SGPROC

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SGSEQ	num	Sequence Number		Collected at CRF.
SGBODSYC	num	Surgery Body System Code		Collected at CRF.
SGBODSYS	char	Surgery Body System		Collected at CRF.
SGREPRTC	num	Are any Surg/Proc. Planned Code		Collected at CRF.
SGREPRT	char	Are any Surg/Proc. Planned		Collected at CRF.
SGPLNDY	num	Relative Day of Planned Surgery/Proced		If SGPLNDT and DMINFDT not missing then perform below logic to calculate SGPLNDY, If SGPLNDT less than DMINFDT then (SGPLNDT - DMINFDT). Else if SGPLNDT is greater than equal to DMINFDT then (SGPLNDT- DMINFDT) +1.

1.4.25.   Trial Inclusion – TI

Dataset	TI
Creating program	ti.sas
Description	Trial Inclusion
Unique identifier	IETEST
Sorted by	IETEST
Notes	

Variable	Type	Label	Codes	Comments
IESPID	char	Sponsor -Defined Identifier		Collected at CRF.
IECAT	char	Inclusion / Exclusion Category		Collected at CRF.
IETEST	char	Inclusion / Exclusion Criterion		Collected at CRF.
IETESTCD	char	Inclusion/Exclusion Criterion Short Name		Collected at CRF.
IELN	num	Line Number		Collected at CRF.

1.4.26.   Visit (VI) – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit (VI)
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VISITDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT	char	Visit		Collected at CRF.
VISITDY	num	Relative Visit Day		If VISITDT and DMINFDT not missing then perform below logic to calculate VISITDY, If VISITDT less than DMINFDT then (VISITDT - DMINFDT). Else if VISITDT is greater than equal to DMINFDT then (VISITDT- DMINFDT) +1.

1.4.27.   Vital Signs (VS) – VITAL

Dataset	VITAL
Creating program	vital.sas
Description	Vital Signs (VS)
Unique identifier	DUSUBJID,VSTEST,VSPOS,VISIT
Sorted by	DUSUBJID,VSTEST,VSPOS,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VSACTDT

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-Identity		Randomly assigned subject number for De-identity.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-Identity		Randomly assigned unique subject Id for De-identity.
DSITEID	char	Site Id Assigned for De-Identity		Randomly assigned site Id for De-identity.
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF.
VSORRES	char	Result in Original Units		Collected at CRF.
VSORRESN	num	Numeric Result in Original Units		Collected at CRF.
VSORUNIT	char	Original Units		Collected at CRF.
VSSTRESC	char	Character Result in Standard Units		Collected at CRF.
VSSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
VSSTUNIT	char	Standard Units		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
VSACTDY	num	Relative Actual Day of Vital Signs		If VSACTDT and DMINFDT not missing then perform below logic to calculate VSACTDY, If VSACTDT less than DMINFDT then (VSACTDT - DMINFDT). Else if VSACTDT is greater than equal to DMINFDT then (VSACTDT- DMINFDT) +1.