

Clinical Development

P04807[®]

CNTO312

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 Name will not be provided.
- Date of birth will not be provided, only age in years and 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, Bottle, lot, kit 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.
- Non-randomized and non-treated subjects are not included in the de-identified datasets.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Datasets CLINPTCL, ITEMLBL, LABPCT, PANELS, PHASEDEF will not be provided as these datasets doesn't contain subject level information.
- ACTOR, PFSDV dataset will not be submitted as these have zero observation.
- DCATS, LABINVC, LABSMPL datasets collected for re-conciliation purpose will not be submitted.
- DISHX2 dataset having insufficient information for further analysis, hence not provided.
- Below mentioned datasets will not be provided as it does not contain any significant information for further analysis - ENROLL, EXYERNA1, QUERY, LABSMPCM, SCREEN

1.3. Data Files

The CNTO312 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the CNTO312 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demographics – SUBJINFO

Dataset	SUBJINFO
Creating program	subjinfo.sas
Description	Demographics
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>BIRTHDD,BIRTHDT,BIRTHMM,BIRTHYY,COHORT,EDCKEY,ETHNCTY,FSTDOSDT,INITIALS,JPNBTHCD,JPNGPRNT,JPNPRNT,MATCHID,MODNDIND,OCCUPAT,PAGENBR,PAGERPT,PAGESEC,TX2NDDT,TX2NDTM,TX3RDDT,TX4THDT,TX4THTM, TX5THDT, TX5THTM, TX6THDT, TX6THTM, TX7THDT, TX7THTM, TX8THDT, TX8THTM, TX9THDT, TX9THTM, VISRPT, AGEDAYS</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
AGE	char	Age at Entry		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
FSTDOSTM	char	Subject first treatment dose time		Collected at CRF.
GENDER	char	Gender		Collected at CRF.
RACE	char	Race		Element will be grouped to protect PII.
TX3RDTM	char	Subject third treatment dose time		Collected at CRF.
FSTDOSDY	num	Relative Subject 1st Trt Day of 1st Dose		If FSTDOSDT and RANDDT not missing then perform below logic to calculate FSTDOSDY, If FSTDOSDT less than RANDDT then (FSTDOSDT - RANDDT).Else if FSTDOSDT is greater than equal to RANDDT then (FSTDOSDT- RANDDT) +1.
TX2NDDY	num	Relative Subject 2nd Trt Day of 1st Dose		If TX2NDDT and RANDDT not missing then perform below logic to calculate TX2NDDY, IfTX2NDDT less than RANDDT then (TX2NDDT - RANDDT).Else if TX2NDDT is greater than equal to RANDDT then (TX2NDDT- RANDDT) +1.

Variable	Type	Label	Codes	Comments
TX3RDDY	num	Relative Subject 3rd Trt Day of 1st Dose		If TX3RDDT and RANDDT not missing then perform below logic to calculate TX3RDDY, IfTX3RDDT less than RANDDT then (TX3RDDT - RANDDT).Else if TX3RDDT is greater than equal to RANDDT then (TX3RDDT- RANDDT) +1.
TX4THDY	num	Relative Subject 4th Trt Day of 1st Dose		If TX4THDT and RANDDT not missing then perform below logic to calculate TX4THDY, IfTX4THDT less than RANDDT then (TX4THDT - RANDDT).Else if TX4THDT is greater than equal to RANDDT then (TX4THDT- RANDDT) +1.

1.4.2. Adverse events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse events
Unique identifier	DSUBJID,AELLT,AEDEGDI
Sorted by	DSUBJID,AELLT,AEDEGDI
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: AEASSID,AEBDYLOC,AEDEGDD,AEDEGDT,AEDEGMM,AEDEGYY,AEBSOC,AECABDF,AECD,AEDISAB,AEENDDD,AEENDDT,AEENDMM,AEENDYY,AEINC,AEINCLIT,AELIT,AERELTN1,AETXPROW,EDCKEY,ENCCNFD,ENCDT,ENCMTHD,ENCUSER,MODNDIND,PAGENBR,PAGERPT,PAGESEC,VISRPT

Variable	Type	Label	Codes	Comments
AEDEGHH	num	Hour Began		Collected at CRF.
AEDEGMN	num	Minute Began		Collected at CRF.
AEDEGTM	char	Time Began		Collected at CRF.
AEDEATH	Char	Death		Collected at CRF.
AEDISCON	char	Study Discontinued		Collected at CRF.
AEDISLIT	char	Treatment Discontinued Literal.		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEENDHH	num	Hour Ended		Collected at CRF.
AEENDMN	num	Minute Ended		Collected at CRF.
AEENDTM	char	Time Ended		Collected at CRF.
AEHOSP	char	Hospitalization		Collected at CRF.
AEINTLIT	char	Treatment Interrupted Literal.		Collected at CRF.
AEINTRPT	char	Study Drug Interrupted		Collected at CRF.
AELLTCD	char	Event MedDRA LLT Code		Collected at CRF.
AELLT	char	Event MedDRA LLTerm		Collected at CRF.
AENONE	char	No Data Present Flag		Collected at CRF.
AEONG	char	Ongoing?		Collected at CRF.
AEONONE	char	None		Collected at CRF.
AEOTHRLT	char	Relation to other.		Collected at CRF.
AEPRCIND	char	Therapeutic procedures indicator		Collected at CRF.
AERED	char	Dose Reduced		Collected at CRF.
AEREDLIT	char	Treatment Reduced Literal.		Collected at CRF.
AETHPY	char	Additional Medications		Collected at CRF.
AETXDC	char	Study Drug Discontinued		Collected at CRF.
AETYPCD	num	Adverse Event Type Code		Collected at CRF.
RELATION	num	Relationship		Collected at CRF.
SERIOUS	char	Serious Flag		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEVERITY	num	Severity		Collected at CRF.
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
AEBEGDY	num	Relative Day Began		If AEBEGDT and RANDDT not missing then perform below logic to calculate AEBEGDY, If AEBEGDT less than RANDDT then (AEBEGDT - RANDDT).Else if AEBEGDT is greater than equal to RANDDT then (AEBEGDT- RANDDT) +1.
AEENDDY	num	Relative Day Ended		If AEENDDT and RANDDT not missing then perform below logic to calculate AEENDDY, If AEENDDT less than RANDDT then (AEENDDT - RANDDT).Else if AEENDDT is greater than equal to RANDDT then (AEENDDT- RANDDT) +1.

1.4.3. Screening Assays – ASSAY

Dataset	ASSAY
Creating program	assay.sas
Description	Screening Assays
Unique identifier	DSUBJID,SAMPDY
Sorted by	DSUBJID,SAMPDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>ASACCNBR,ASCOMMT2,ASGTYPE,ASINSTR,ASLABNM,ASLOLIMT,ASQTY,ASRC DVST,ASRLTCD,ASRLVTM,ASRLTXT,ASRSLTTP,ASSAYTXT,ASSPEC,ASTMPRD,ASTSTDD,ASTSTDT,ASTSTMM,ASTSTYY,EDCKEY,INTERFRN,MODNDIND,PAGEN BR,PAGERPT,PAGESEC,RSLTUNT2,SAMPDD,SAMPDT,SAMPHH,SAMPMM,SAMP MN,SAMPPTM,SAMPYTYPE,SAMPYY,TSTRSLT2,VISRPT</p>

Variable	Type	Label	Codes	Comments
ASSAYNM	char	Assay Name		Collected at CRF.
RSLTUNIT	char	Unit for Assay Test Result.		Collected at CRF.
TSTRSLT	num	Test Result for Assay.		Collected at CRF.
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
ASTSTDY	num	Relative Day of Test Reading		If ASTSTDT and RANDDT not missing then perform below logic to calculate ASTSTDY, If ASTSTDT less than RANDDT then (ASTSTDT - RANDDT).Else if ASTSTDT is greater than equal to RANDDT then (ASTSTDT- RANDDT) +1.
SAMPDY	num	Relative Sample day		If SAMPDT and RANDDT not missing then perform below logic to calculate SAMPDY, If SAMPDT less than RANDDT then (SAMPDT - RANDDT).Else if SAMPDT is greater than equal to RANDDT then (SAMPDT- RANDDT) +1.

1.4.4. Subject's Comments – COMMENTS

Dataset	COMMENTS
Creating program	comments.sas
Description	Subject's Comments
Unique identifier	Not Applicable
Sorted by	Not Applicable
Notes	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
COMPATH	char	InForm Data Path		Collected at CRF.
COMREF	char	Area Comment Refers To		Collected at CRF.
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMDY	num	Relative Day Recorded		If COMDT and RANDDT not missing then perform below logic to calculate COMDY, If COMDT less than RANDDT then (COMDT - RANDDT).Else if COMDT is greater than equal to RANDDT then (COMDT- RANDDT) +1.

1.4.5. Previous and Concomitant Medications – CRX

Dataset	CRX
Creating program	crx.sas
Description	Previous and Concomitant Medications
Unique identifier	DSUBJID,WHODRUG,CRXFREQ,CRXDOSE,CRXRTE,CRXBEGDY,CRXLSTDY
Sorted by	DSUBJID,WHODRUG,CRXFREQ,CRXDOSE,CRXRTE,CRXBEGDY,CRXLSTDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>ATCCD,ATCECD,BODYSIDE,CRXAECD,CRXAERSN,CRXASSID,CRXBEGDD,CRXBEGDT,CRXBEGHH,CRXBEGMM,CRXBEGMN,CRXBEGTM,CRXBEGYY,CRXBSOC,CRXECNFD,CRXEDT,CRXEMTHD,CRXEUSER,CRXJNTCD,CRXLIT,CRXLLTCD,CRXLSTD,CRXLSTDY,CRXLSTHH,CRXLSTMM,CRXLSTMN,CRXLSTTM,CRXLSTYY,CRXMDI,CRXMHXIN,CRXOTH,CRXNORM,CRXPREEX,CRXPROPH,CRXRSN,CRXSUPP,CRXTOTDY,EDCKEY,ENCAECNF,ENCAEDT,ENCAEMTH,ENCAEUSR,ENCCNFD,ENCNT,ENCMTHD,ENCUDCNF,ENCUDDT,ENCUDUSR,ENCUMTH,ENCUSER,MODNDIND,PAGENBR,PAGERPT,PAGESEC,URXCD,VISRPT, CRXRSN</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
CRXCONT	char	Continuing?		Collected at CRF.
CRXDOSE	num	Dose		Collected at CRF.
CRXFREQ	char	Frequency of Therapy		Collected at CRF.
CRXNONE	char	No Data Present Flag		Collected at CRF.
CRXRTE	num	Route of Administration		Collected at CRF.
CRXUNT	char	Units for Dose		Collected at CRF.
TXUSE	num	Con Med Therapy Use Type		Collected at CRF.
WHODRGCD	char	Preferred Term for Therapy Code		Collected at CRF.
WHODRUG	char	Preferred Term for Therapy		Collected at CRF.
CRXBEGDY	num	Relative Day Began		If CRXBEGDT and RANDDT not missing then perform below logic to calculate CRXBEGDY, If CRXBEGDT less than RANDDT then (CRXBEGDT - RANDDT).Else if CRXBEGDT is greater than equal to RANDDT then (CRXBEGDT- RANDDT) +1.
CRXLSTDY	num	Relative Day Stopped/Last taken		If CRXLSTDY and RANDDT not missing then perform below logic to calculate CRXLSTDY, If CRXLSTDY less than RANDDT then (CRXLSTDY - RANDDT).Else if CRXLSTDY is greater than equal to RANDDT then (CRXLSTDY- RANDDT) +1.

1.4.6. Report of Subject Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Report of Subject Death
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: AUTPYCD,DTHBSOC,DTHCD,DTHDD,DTHDT,DTHHH,DTHLIT,DTHLLTCD,DTHMM,DTHMN,DTHSUM,DTHTM,DHTXT,DTHYY,EDCKEY,ENCCNFD,ENCDT,ENCMTHD,ENCUSER,PAGENBR,PAGERPT,PAGESEC,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
DTHCTG	num	Cause of Death Category		Collected at CRF.
DTHRELCD	num	Relationship to Study Treatment		Collected at CRF.

1.4.7. Study Treatment Dispense Information– DISPENSE

Dataset	DISPENSE
Creating program	dispense.sas
Description	Study Treatment Dispense Information
Unique identifier	DSUBJID, VISCD, DISPLIT, DISPDY
Sorted by	DSUBJID, VISCD, DISPLIT, DISPDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>ATCCD,ATCECD,BOXNO,DISPBCH,DISPCOMP,DISPDD,DISPDFCD,DISPDGCD,DISPDT,DISPDVCD,DISPKITN,DISPMM,DISPNBRM,DISPNORM,DISPQTY,DISPRET,DISPTXUS,DISPUNT,DISPUS,DISPUSE,DISPY,DPRETUNT,EDCKEY,ENCCNFD,ENCNT,ENCMTHD,ENCUDCNF,ENCUDDT,ENCUDUSR,ENCUMTH,ENCUSER,PAGE NBR,PAGERPT,PAGESEC,UDSCRXCD,VISRPT</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF

Variable	Type	Label	Codes	Comments
MODNDIND	char	Module Not Completed flag		Collected at CRF
DSITENBR	num	Site Number Assigned for De-identity		Randomly Assigned Site Number for De-Identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly Assigned Subject Identifier for De-Identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-Identity
VISCD	num	Visit Identifier		Collected at CRF
DISPLIT	char	Treatment Literal		Collected at CRF
DISPDY	num	Relative Day Dispensed/Returned		If DISPDT and RANDDT not missing then perform below logic to calculate DISPDY, If DISPDT less than RANDDT then (DISPDT - RANDDT).Else if DISPDT is greater than equal to RANDDT then (DISPDT - RANDDT) +1.

1.4.8.Reductions/Interruptions to Dosing – DOSCHG

Dataset	DOSCHG
Creating program	doschg.sas
Description	Reductions/Interruptions to Dosing
Unique identifier	DSUBJID,VISCD,CHGNCRSN,CHGRSNCD,CHGBEGDY
Sorted by	DSUBJID,VISCD,CHGNCRSN,CHGRSNCD,CHGBEGDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>ATCCD,ATCECD,CHGBEGDD,CHGBEGDT,CHGBEGHH,CHGBEGMM,CHGBEGMN,CHGBEGTM,CHGBEGYY,CHGCNFD,CHGDRGCD,CHGENCDT,CHGENDDD,CHGENDDT,CHGENDDH,CHGENDDMM,CHGENDDMN,CHGENDDTM,CHGENDDYY,CHGINNBR,CHGLLTC,CHGMTHD,CHGNORM,CHGRSNTX,CHGSTUNT,CHGTYPE,CHGUSER,DOSFORM,EDCKEY,ENCUDCNF,ENCUDDT,ENCUDUSR,ENCUMTH,PAGENBR,PAGERPT,PAGESEC,RSNBSOC,RSNCD,RSNCNFD,RSNDT,RSNMTHD,RSNUSE R,RSOTHTXT,UDCRXCD,VISRPT</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
CHGNCRSN	num	Non-compliance Reason		Collected at CRF.
CHGQTY	num	Dose Change Amount		Collected at CRF.
CHGRSNCD	num	Reason for Dose Change/Interruption Code		Collected at CRF.
CHGTXLIT	char	Treatment Literal		Collected at CRF.
CHGUNIT	char	Units for Dose Change Amount Code		Collected at CRF.
CHGBEGDY	num	Relative Day Dose Change Begins		If CHGBEGDT and RANDDT not missing then perform below logic to calculate CHGBEGDY, If CHGBEGDT less than RANDDT then (CHGBEGDT - RANDDT).Else if CHGBEGDT is greater than equal to RANDDT then (CHGBEGDT- RANDDT) +1.
CHGENDDY	num	Relative Day Dose Change Ends		If CHGENDDT and RANDDT not missing then perform below logic to calculate CHGENDDY, If CHGENDDT less than RANDDT then (CHGENDDT - RANDDT).Else if CHGENDDT is greater than equal to RANDDT then (CHGENDDT- RANDDT) +1.

1.4.9. Dosing – DOSING

Dataset	DOSING
Creating program	dosing.sas
Description	Dosing
Unique identifier	SUBJID,VISCD,DOSELIT,DOSBEGDY
Sorted by	SUBJID,VISCD,DOSELIT,DOSBEGDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>ATCCD,ATCECD,CHOTHTXT,DLYUNT,DOSBEGDD,DOSBEGDT,DOSBEGMM,DOSBEGSC,DOSBEGTS,DOSBEGYY,DOSEDCD,DOSEFRQ,DOSELOC,DOSENDDD,DOSENDDT,DOSENDMM,DOSENDSC,DOSENDTS,DOSENDYY,DOSERTE,DOSETXT,DOSEVUNT,DOSFORM,DOSLOTH,DOSMXT,DOSNORM,DOSRLSDD,DOSRLSDT,DOSRLSHH,DOSRLSMM,DOSRLSMN,DOSRLSTM,DOSRLSYY,DOSTAVOL,DOSTEVOL,DOSVOLAS,DSBGMTCD,DSEDTMCD,EDCKEY,ENCCNFD,ENCDT,ENCMTHD,ENCUDCNF,ENCUDDT,ENCUDUSR,ENCUMTH,ENCUSER,NONDAYCK,PAGENBR,PAGERPT,PAGESEC,TOTDYQTY,UDOSRXCD,VIALSTR,VIALUNIT,VISRPT</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
DOSBEGHH	num	Hour Dose Begins		Collected at CRF.
DOSBEGMN	num	Minute Dose Begins		Collected at CRF.
DOSBEGTM	char	Time Dose Begins		Collected at CRF.
DOSCHGCD	num	Reason for Change		Collected at CRF.
DOSCYCID	num	Cycle ID		Collected at CRF.
DOSELIT	char	Treatment Literal		Collected at CRF.
DOSENDHH	num	Hour Dose Ends		Collected at CRF.
DOSENDMN	num	Minute Dose Ends		Collected at CRF.
DOSENDTM	char	Time Dose Ends		Collected at CRF.
DOSEUNT	char	Units for Dose		Collected at CRF.
DOSTXASN	num	Treatment Assignment Number.		Collected at CRF.
INCRQTY	num	Incremental Amnt		Collected at CRF.
DOSBEGDY	num	Relative Day Dose Begins		If DOSBEGDT and RANDDT not missing then perform below logic to calculate DOSBEGDY, If DOSBEGDT less than RANDDT then (DOSBEGDT - RANDDT).Else if DOSBEGDT is greater than equal to RANDDT then (DOSBEGDT- RANDDT) +1.

Variable	Type	Label	Codes	Comments
DOSENDDY	num	Relative Day Dose Ends		If DOSENDDT and RANDDT not missing then perform below logic to calculate DOSENDDY, If DOSENDDT less than RANDDT then (DOSENDDT - RANDDT).Else if DOSENDDT is greater than equal to RANDDT then (DOSENDDT- RANDDT) +1.

1.4.10. Protocol Deviations – DV

Dataset	DV
Creating program	dv.sas
Description	Protocol Deviations
Unique identifier	DSUBJID,DVTYPE,DVDY
Sorted by	DSUBJID,DVTYPE,DVDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: DVDD,DVDESCRP,DVDT,DVMM,DVOTHTYP,DVYY,EDCKEY,MODNDIND,PAGENBR,PAGERPT,PAGESEC,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF

Variable	Type	Label	Codes	Comments
DSITENBR	num	Site Number Assigned for De-identity		Randomly Assigned Site Number for De-Identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly Assigned Subject Identifier for De-Identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-Identity
VISCD	num	Visit Identifier		Collected at CRF
DVTYPE	char	Type of Deviation		Collected at CRF
DVWAIVER	char	Was Waiver Received?		Collected at CRF
DVDY	Num	Relative Day of Deviation		If DVDT and RANDDT not missing then perform below logic to calculate DVDY, If DVDT less than RANDDT then (DVDT - RANDDT).Else if DVDT is greater than equal to RANDDT then (DVDT- RANDDT) +1.

1.4.11. Disease Rating Scale – DXSC

Dataset	DXSC
Creating program	dxsc.sas
Description	Disease Rating Scale
Unique identifier	DSUBJID,VISCD,DXCONTXT
Sorted by	DSUBJID,VISCD,DXCONTXT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: DXCONID,DXDSBLNG,DXRLVTM,DXRTDD,DXRTDT,DXRTHH,DXRTMM,DXRTMN,DXRTTM,DXRTTY,DXTYTXT,EDCKEY,PAGENBR,PAGERPT,PAGESEC,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
DXCONXT	char	Condition for rating text		Collected at CRF.
DXRSLT	num	Rating scale result		Collected at CRF.
DXSCNM	char	Scale or instrument for rating		Collected at CRF.
DXSCORE	num	Total of all scale ratings		Collected at CRF.
DXRTDY	num	Relative Day of disease rating		If DXRTDT and RANDDT not missing then perform below logic to calculate DXRTDY, If DXRTDT less than RANDDT then (DXRTDT - RANDDT).Else if DXRTDT is greater than equal to RANDDT then (DXRTDT- RANDDT) +1.

1.4.12. Inclusion / Exclusion with Phase Criteri – INEX2

Dataset	INEX2
Creating program	inex2.sas
Description	Inclusion / Exclusion with Phase criteria
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: EDCKEY,EXCPINDC,INEXPHS,INEXSAMP,INEXSTYP,INEXSUBS,MODNDIND,PAG ENBR,PAGERPT,PAGESEC,SSBEGDD,SSBEGDT,SSBEGMM,SSBEGYY,SENDDDD,S SENDDT,SENDMM,SENDYY,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
INEXCD	char	Criteria met Y/N?		Collected at CRF.

1.4.13. Laboratory Results – LABRSLT

Dataset	LABRSLT
Creating program	labrslt.sas
Description	Laboratory Results
Unique identifier	DSUBJID,GROUPCD,PARMCD,COLLDY,COLLHH,ABSRSLT,LABVISCD
Sorted by	DSUBJID,GROUPCD,PARMCD,COLLDY,COLLHH,ABSRSLT,LABVISCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: ACCNBR,COLLDD,COLLDT,COLLMM,COLLYY,COMMTXT,EDCKEY,LABRFSN,LAB SITE,MODNDIND,PAGENBR,PAGERPT,PAGESEC,RLVTMCD,SECSITE,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
ABSRSLT	num	Absolute conversion result		Collected at CRF.

Variable	Type	Label	Codes	Comments
ALERTCD	char	Out of Range Flag		Collected at CRF.
CLNALERT	char	Percent Alert Code		Collected at CRF.
COLLHH	num	Hour of Lab Collection		Collected at CRF.
COLLMN	num	Minute of Lab Collection		Collected at CRF.
COLLTM	char	Time of Lab Collection		Collected at CRF.
GROUPCD	char	Lab Group Parameter belong to (Lab Area)		Collected at CRF.
HIRANGE	char	Upper Limit of Normal		Collected at CRF.
LABAGE	char	Calculated Subject Age		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LABVISCD	num	Lab visit code		Collected at CRF.
LOWRANGE	char	Lower Limit of Normal		Collected at CRF.
NUMRSLT	num	Numeric Result		Collected at CRF.
OPERCD	char	Operator (<, >)		Collected at CRF.
PARMCD	num	Lab Parameter Code		Collected at CRF.
RLTVRSLT	num	Relative Procedure Result		Collected at CRF.
SIHI	char	Lab SI upper value		Collected at CRF.
SILOW	char	Lab SI lower value		Collected at CRF.
TIHINBR	char	Therapy Specific ULN		Collected at CRF.
TXLOWNBR	char	Therapy Specific LLN		Collected at CRF.
TXTRSLT	char	Text Result		Collected at CRF.

Variable	Type	Label	Codes	Comments
TXTVAL	char	Laboratory Reference Text Value		Collected at CRF.
UNITCD	char	Units for Range		Collected at CRF.
COLLDY	num	Relative Day of Lab Collection		If COLLDT and RANDDT not missing then perform below logic to calculate COLLDY, If COLLDT less than RANDDT then (COLLDT - RANDDT).Else if COLLDT is greater than equal to RANDDT then (COLLDT- RANDDT) +1.

1.4.14. Medical History – MEDHX2

Dataset	MEDHX2
Creating program	medhx2.sas
Description	Medical History
Unique identifier	DSUBJID,MHXLLT,CONDSTAT
Sorted by	DSUBJID,MHXLLT,CONDSTAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: CONDCD,CONDLIT,EDCKEY,ENCCNFD,ENCDT,ENCMTHD,ENCUSER,MEDHXDD, MEDHXDT,MEDHXMM,MEDHXYY,MHXBSOC,MHXCTG,MHXCURTX,MHXDIAY Y,MHXINNUM,MHXTXT,PAGENBR,PAGERPT,PAGESEC,PGTYPCD,VISRPT, MODNDIND

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
CONDSTAT	char	Current Status of Condition		Collected at CRF.
MHLLTCD	char	Condition MedDRA LLT Code		Collected at CRF.
MHLLT	char	Condition MedDRA LLTerm		Collected at CRF.
MHXXNONE	char	No Data Present Flag		Collected at CRF.

1.4.15. Sites participating in the study – PRSITES

Dataset	PRSITES
Creating program	prsites.sas
Description	Sites participating in the study
Unique identifier	DCNTRYCD
Sorted by	DCNTRYCD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: FSTNAME,LSTNAME,PAGESEC,REFSRCCD,SITELRN,SITEPLI,SITEPRN

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DCNTRYCD	char	De-identify Country code		Group element to protect PII.

Variable	Type	Label	Codes	Comments
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity

1.4.16. Questionnaire – QUEST

Dataset	QUEST
Creating program	quest.sas
Description	Questionnaire
Unique identifier	DSUBJID,QSTQID,QSTDY
Sorted by	DSUBJID,QSTQID,QSTDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>EDCKEY,MODNDIND,PAGENBR,PAGERPT,PAGESEC,QSRVWTXT,QSTAROTH,QSTARSP1,QSTARSP2,QSTARSP3,QSTARSP4,QSTARSP5,QSTARSP6,QSTARSP7,QSTARSP8,QSTDD,QSTDT,QSTEXPL1,QSTEXPL2,QSTFSTDD,QSTFSTDT,QSTFSTM M,QSTFSTYY,QSTLSTDD,QSTLSTDT,QSTLSTMM,QSTLSTYY,QSTMM,QSTRLTMM,QSTYY,VISRPT</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
QSTHH	num	Hour of Questionnaire		Collected at CRF.
QSTINSTR	char	Instrument Name		Collected at CRF.
QSTMN	num	Minute of Questionnaire		Collected at CRF.
QSTQID	char	Question Identifier		Collected at CRF.
QSTQTXT	char	Question		Collected at CRF.
QSTRTXT	char	Response		Collected at CRF.
QSTTM	char	Time of Questionnaire		Collected at CRF.
QSTDY	num	Relative Day of Questionnaire		If QSTDY and RANDDT not missing then perform below logic to calculate QSTDY, If QSTDY less than RANDDT then (QSTDY - RANDDT).Else if QSTDY is greater than equal to RANDDT then (QSTDY - RANDDT) +1.

1.4.17. Subject Number Assignment/Randomization– RANDOC2

Dataset	RANDOC2
Creating program	randoc2.sas
Description	Subject Number Assignment/Randomization
Unique identifier	DSUBJID,RNDKITDY
Sorted by	DSUBJID,RNDKITDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values or repetition of information : EDCKEY,MODNDIND,PAGENBR,PAGERPT,PAGESEC,RANDDD,RANDDT,RANDDM,RANDSCRN,RANDYY,RNDDBDD,RNDDBDT,RNDDBMM,RNDDBY,RNDGEND,RNDKITDD,RNDKITDT,RNDKITMM,RNDKITN,RNDKITRN,RNDKITYY,RNDSINIT,SEQCORCT,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF
SITENBR	num	Site Number Assigned for De-identity		Randomly Assigned Site Number for De-Identity
SUBJID	char	Subject Id Assigned for De-identity		Randomly Assigned Subject Identifier for De-Identity
SUBJNBR	char	Subject Number Assigned for De-identity		Randomly Assigned Subject Number for De-Identity
VISCD	num	Visit Identifier		Collected at CRF

Variable	Type	Label	Codes	Comments
ARMCD	char	Arm Code		Collected at CRF
RANDHH	num	Hour of Randomization		Collected at CRF
RANDMN	num	Minute of Randomization		Collected at CRF
RANDTM	char	Time of Randomization		collected at CRF
RNDCRIT1	char	Criteria 1		Collected at CRF
RNDCRIT2	char	Criteria 2		Collected at CRF
STRATA	num	Strata Assigned for De-identity		Randomly Assigned Strata Number for De-identity.
RNDKITDY	num	Relative Day Kit Assigned - Rand. Center		If RNDKITDT and RANDDT not missing then perform below logic to calculate RNDKITDY, If RNDKITDT less than RANDDT then (RNDKITDT - RANDDT).Else if RNDKITDT is greater than equal to RANDDT then (RNDKITDT - RANDDT) +1.

1.4.18. Phase/Visit/Cycle/Status – STATCK

Dataset	STATCK
Creating program	statck.sas
Description	Phase/Visit/Cycle/Status
Unique identifier	DSUBJID,VISCD,ACTTYPE
Sorted by	DSUBJID,VISCD,ACTTYPE
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>ASSESSOR,ATCCD,ATCECD,EDCKEY,ENCUDCNF,ENCUDDT,ENCUDUSR,ENCUMTH,ENTRYDD,ENTRYDT,ENTRYIND,ENTRYMM,ENTRYYY,NEWAECD,NEWBLDEV,NEWCECD,NEWCRXCD,NEWIMMCD,PAGENBR,PAGERPT,PAGESEC,STATCD,STATCNFD,STATCOMP,STATCONT,STATDIAR,STATDOTH,STATDRSN,STATECDT,STATID,STATINF,STATLIT,STATMTH,STATPREF,STATQOL,STATQOTH,STATRSN,STATUSER,TXMODCD,USCRXCD,VISRPT</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
ACTTYPE	char	Activity Type description.		Collected at CRF.
ACTVSNBR	num	Number of Visits for Activity Type.		Collected at CRF.
STATCHK	num	Phase/Cycle/Visit Status		Collected at CRF.
TRIG1	char	Missing Data Trigger		Collected at CRF.

1.4.19. Subject Status – SUBJSTAT

Dataset	SUBJSTAT
Creating program	subjstat.sas
Description	Subject Status
Unique identifier	DSUBJID,PHASECD
Sorted by	DSUBJID,PHASECD
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>DOSENDHH,DOSENDMM,DOSENDTM,EDCKEY,EXTPTCL,FAILRSN,FAILTXT,LSTCNTDD,LSTCNTDT,LSTCNTMM,LSTCNTYY,PAGENBR,PAGERPT,PAGESEC,PERBEGDD,PERBEGDT,PERBEGMM,PERBEGYY,PERENDDD,PERENDDT,PERENDMM,PERENDYY,TX2LSTDD,TX2LSTDY,TX2LSTMM,TX2LSTYY,TX3LSTDD,TX3LSTDY,TX3LSTMM,TX3LSTYY,TX4LSTDD,TX4LSTDY,TX4LSTMM,TX4LSTYY,TX5LSTDD,TX5LSTDY,TX5LSTMM,TX5LSTYY,TX6LSTDD,TX6LSTDY,TX6LSTMM,TX6LSTYY,TX7LSTDD,TX7LSTDY,TX7LSTMM,TX7LSTYY,TX8LSTDD,TX8LSTDY,TX8LSTMM,TX8LSTYY,TX9LSTDD,TX9LSTDY,TX9LSTMM,TX9LSTYY,TXLSTDD,TXLSTDY,TXLSTMM,TXLSTYY,VISRPT,WDRLLD,WDRLLT,WDRLLM,WDRLLY</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
DISCCD	num	Discontinuation Reason		Collected at CRF.
EXTRSNCD	num	Reason for not entering Extension Study.		Collected at CRF.
PHASECD	char	Phase code		Collected at CRF.
STATPERD	num	Period Id		Collected at CRF.
LSTCNTDY	num	Relative Day of last contact		If LSTCNTDT and RANDDT not missing then perform below logic to calculate LSTCNTDY, If LSTCNTDT less than RANDDT then (LSTCNTDT - RANDDT).Else if LSTCNTDT is greater than equal to RANDDT then (LSTCNTDT- RANDDT) +1.
TX2LSTDY	num	Relative 2nd TX, Day of Last Dose.		If TX2LSTDT and RANDDT not missing then perform below logic to calculate TX2LSTDY, IfTX2LSTDT less than RANDDT then (TX2LSTDT - RANDDT).Else if TX2LSTDT is greater than equal to RANDDT then (TX2LSTDT- RANDDT) +1.
TXLSTDY	num	Relative Day of Last Dose		If TXLSTDT and RANDDT not missing then perform below logic to calculate TXLSTDY, If TXLSTDT less than RANDDT then (TXLSTDT - RANDDT).Else if TXLSTDT is greater than equal to RANDDT then (TXLSTDT- RANDDT) +1.

1.4.20. Tobacco Use – TOBACCO2

Dataset	TOBACCO2
Creating program	tobacco2.sas
Description	Tobacco Use
Unique identifier	DSUBJID,TOBAMT,TOBCNONE
Sorted by	DSUBJID,TOBAMT,TOBCNONE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: EDCKEY,PAGENBR,PAGERPT,PAGESEC,TOBBEGDD,TOBBEGDT,TOBBEGMM,TOBBEGYY,TOBCSM,TOBENDDD,TOBENDDT,TOBENDMM,TOBENDYY,TOBPKYRS,TOBQTUNT,TOBTYTXT,VISRPT, MODNDIND

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
TOBAMT	char	Amount of Tobacco Use(d)		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOBCNONE	char	No Current Data Present Flag		Collected at CRF.
TOBCONT	char	Continuing Flag		Collected at CRF.
TOBDUR	num	Duration of Tobacco Use		Collected at CRF.
TOBNONE	char	No Data Present Flag		Collected at CRF.
TOBTYPE	num	Tobacco Type		Collected at CRF.
TOBUNT	char	Units for Duration of Tobacco Use		Collected at CRF.
TOBENDDY	num	Relative Day Smoke Exposure Ended		If TOBENDDT and RANDDT not missing then perform below logic to calculate TOBENDDY, If TOBENDDT less than RANDDT then (TOBENDDT - RANDDT).Else if TOBENDDT is greater than equal to RANDDT then (TOBENDDT- RANDDT) +1.

1.4.21. Therapeutic Procedures or Surgeries – TXPRC

Dataset	TXPRC
Creating program	txprc.sas
Description	Therapeutic Procedures or Surgeries
Unique identifier	DSUBJID, TXPLLT, TXPBEGDY
Sorted by	DSUBJID, TXPLLT, TXPBEGDY
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values:</p> <p>EDCKEY, MODNDIND, PAGENBR, PAGERPT, PAGESEC, TXPBEGDD, TXPBEGDT, TXPBEGHH, TXPBEGMM, TXPBEGMN, TXPBEGTM, TXPBEGYY, TXPBODY, TXPCON, TXPCONU, TXPDURA, TXPENCCF, TXPENCDT, TXPENCMT, TXPENCUS, TXPENDDD, TXPENDDT, TXPENDHH, TXPENDMM, TXPENDMN, TXPENDTM, TXPENDYY, TXPFIND, TXPJOINT, TXPOCQTY, TXPOTTXT, TXPPLTYP, TXPPREF, TXPRCLIT, TXPRCTXT, TXPRCUSE, TXPTRAM, TXPTRAMU, TXPUNIT, TXPRSTXT, VISRPT</p>

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
VISCD	num	Visit Identifier		Collected at CRF.
TXPCONT	char	Continuing?		Collected at CRF.
TXPLLTCD	char	Procedure/Surgery MedDRA LLT Code		Collected at CRF.
TXPLLT	char	Procedure/Surgery MedDRA LLTerm		Collected at CRF.
TXPNONE	char	No Data Present Flag.		Collected at CRF.
TXPSTDIS	char	Therapeutic Procead for Study Disease?		Collected at CRF.
TXPBEGDY	num	Relative Begin Day of Therap Procead/Surg		If TXPBEGDT and RANDDT not missing then perform below logic to calculate TXPBEGDY, If TXPBEGDT less than RANDDT then (TXPBEGDT - RANDDT).Else if TXPBEGDT is greater than equal to RANDDT then (TXPBEGDT- RANDDT) +1.
TXPENDDY	num	Relative End Day of Therap Procead/Surg		If TXPENDDT and RANDDT not missing then perform below logic to calculate TXPENDDY, If TXPENDDT less than RANDDT then (TXPENDDT - RANDDT).Else if TXPENDDT is greater than equal to RANDDT then (TXPENDDT- RANDDT) +1.

1.4.22. Visit Information – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit Information
Unique identifier	DSUBJID,VISCD,ACTVISDY
Sorted by	DSUBJID,VISCD,ACTVISDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: ACTVISDD,ACTVISDT,ACTVISHH,ACTVISMM,ACTVISMN,ACTVISTM,ACTVISYY,BOX2NO,BOX3NO,BOXNO,CONTCTCD,CRANDNO,EDCKEY,ERXCD,INPATCD,PAGENBR,PAGERPT,PAGESEC,RANDNO,VISRPT

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODID	num	Period Id		Collected at CRF.
PHASEID	num	Phase Id		Collected at CRF.
TRTCD	char	Entered Trt code for Open Label Studies		Collected at CRF.
ACTVISDY	num	Relative Day of Visit		If ACTVISDT and RANDDT not missing then perform below logic to calculate ACTVISDY, If ACTVISDT less than RANDDT then (ACTVISDT - RANDDT).Else if ACTVISDT is greater than equal to RANDDT then (ACTVISDT- RANDDT) +1.

1.4.23. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DSUBJID,VISCD,VITALSDY,PULSE
Sorted by	DSUBJID,VISCD,VITALSDY,PULSE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: EDCKEY,EXTRMCD,HEARTRT,HTCM,PAGENBR,PAGERPT,PAGESEC,PLSOXNBR,POSITNCD,RESP,TEMPC,VBMIDRVD,VISRPT,VITALBMI,VITALBSA,VITALMAP,VITALSDD,VITALSDT,VITALSHH,VITALSMM,VITALSMN,VITALSSC,VITALSTM,VITALSTS,VITALSYY,VRLVTM,WTKG

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
MODNDIND	char	Module Not Completed flag		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity

Variable	Type	Label	Codes	Comments
VISCD	num	Visit Identifier		Collected at CRF.
DIASBP	num	Diastolic Blood Pressure		Collected at CRF.
HT	num	Height		Collected at CRF.
HTUNT	char	Height Units		Collected at CRF.
PULSE	num	Pulse		Collected at CRF.
SYSBP	num	Systolic Blood Pressure		Collected at CRF.
TEMP	num	Temperature		Collected at CRF.
TEMPRTE	char	Site of Temperature Measurement		Collected at CRF.
TEMPUNT	char	Temperature Units		Collected at CRF.
WT	char	Weight		Collected at CRF.
WTUNT	char	Weight Units		Collected at CRF.
VITALSDY	num	Relative Day of Vitals Exam		If VITALSDT and RANDDT not missing then perform below logic to calculate VITALSDY, If VITALSDT less than RANDDT then (VITALSDT - RANDDT).Else if VITALSDT is greater than equal to RANDDT then (VITALSDT- RANDDT) +1.

1.4.24. Xray – XRAY2

Dataset	XRAY2
Creating program	xray2.sas
Description	Xray
Unique identifier	DSUBJID
Sorted by	DSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or missing values: BASECHG,BASESIG,CXRVCDD,EDCKEY,MODNDIND,PAGENBR,PAGERPT,PAGESE C,VISRPT,XOTHTXT,XRAYDD,XRAYDT,XRAYMM,XRAYTXT,XRAYTXT2,XRAYYY

Variable	Type	Label	Codes	Comments
CLINPTCL	char	Clinical Protocol Number		Collected at CRF.
DSITENBR	num	Site Number Assigned for De-identity		Randomly assigned Site Number for De-identity
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSUBJNBR	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
VISCD	num	Visit Identifier		Collected at CRF.
RESULTS	num	Xray Results		Collected at CRF.

Variable	Type	Label	Codes	Comments
XSIGRSLT	num	Clin. Significant Results		Collected at CRF.
XRAYDY	num	Relative Day of Xray		If XRAYDT and RANDDT not missing then perform below logic to calculate XRAYDY, If XRAYDT less than RANDDT then (XRAYDT - RANDDT).Else if XRAYDT is greater than equal to RANDDT then (XRAYDT- RANDDT) +1.