

Clinical Development

**Paliperidone<sup>®</sup>**

BIM3004

Anonymisation Data Derivation Specification Document

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<b>Status and Version</b>	<b>Release Date</b>	<b>Summary of Key Changes</b>

## 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.
- CODELIST dataset will not be submitted since it does not contain subject level information.
- 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.
- Dataset with zero observation will not be submitted (ex. IMMUNO).
- Due to sensitive information INVEST dataset will be removed.
- MEDKIT dataset will not be submitted as it contains medical kit allocated related information.
- DEMOG.DMINFDT will be used as Reference Date(referred as REF.DATE in the document) to derive relative day.

### 1.3. Data Files

The BIM3004 Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics (DM) – DEMOG

<b>Dataset</b>	DEMOG
<b>Creating program</b>	demog.sas
<b>Description</b>	Demographics (DM)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	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,DMSCRDT,IVNAME,BIRTHDT,IVID, DMINFDT,RACESPEC, COUNTRYC

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACEC	num	Race Code		Group element to protect PII.
RACE	char	Race		Group element to protect PII.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
ETHNICC	num	Ethnicity Code		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
AGE	char	Age		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 REF.DATE not missing then perform below logic to calculate DMACTDY, If DMACTDT less than REF.DATE then (DMACTDT - REF.DATE). Else if DMACTDT is greater than equal to REF.DATE then (DMACTDT- REF.DATE) +1.
DMSCRDY	num	Relative Day of First Trial Related Proc		If DMSCRDT and REF.DATE not missing then perform below logic to calculate DMSCRDY, If DMSCRDT less than REF.DATE then (DMSCRDT - REF.DATE). Else if DMSCRDT is greater than equal to REF.DATE then (DMSCRDT- REF.DATE) +1.



## 1.4.2. Adverse Events (AE) – AE

<b>Dataset</b>	AE
<b>Creating program</b>	ae.sas
<b>Description</b>	Adverse Events (AE)
<b>Unique identifier</b>	DUSUBJID,AECODE,AESTDY,AESEQ
<b>Sorted by</b>	DUSUBJID,AECODE,AESTDY,AESEQ
<b>Notes</b>	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,AESTDTC,AESTDT,AEENDTC,AEENDT,AESERREF

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
AEREPRC	num	Were Any AEs Reported Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEREPR	char	Were Any AEs Reported		Collected at CRF.
AESEQ	num	AE Sequence Number		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.
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.
AESCONG	char	Congenital Anomaly or Birth Defect		Collected at CRF.
AESDISAB	char	Persist or Signif Disability/Incapacity		Collected at CRF.
AESDTH	char	Results in Death		Collected at CRF.
AESHOSPR	char	Hospitalization required		Collected at CRF.
AESHOSPP	char	Prolonged hospitalization		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESLIFE	char	Is Life Threatening		Collected at CRF.
AESMIE	char	Other Medicaly Important Serious Event		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower Level Term		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AESTDY	num	Relative Actual Start Day of Event		If AESTDTC and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDTC less than REF.DATE then (AESTDTC - REF.DATE). Else if AESTDTC is greater than equal to REF.DATE then (AESTDTC- REF.DATE) +1.
AEENDY	num	Relative Actual End Day of Event		If AEENDTC and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDTC less than REF.DATE then (AEENDTC - REF.DATE). Else if AEENDTC is greater than equal to REF.DATE then (AEENDTC- REF.DATE) +1.

## 1.4.3.AIMS (AI) – AIMS

<b>Dataset</b>	AIMS
<b>Creating program</b>	aims.sas
<b>Description</b>	AIMS (AI)
<b>Unique identifier</b>	DUSUBJID,PHASENUM,VISITNUM,AIITEM,AIACTDY
<b>Sorted by</b>	DUSUBJID,PHASENUM,VISITNUM,AIITEM,AIACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AIRATERI,AIACDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
AIVTYPEC	num	AIMS Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AIVTYPE	char	AIMS Visit Type		Collected at CRF.
AIGROUP	char	AIMS Group		Collected at CRF.
AIITEM	char	AIMS Item		Collected at CRF.
AISCOREC	num	AIMS Score Code		Collected at CRF.
AISCORE	char	AIMS Score		Collected at CRF.
AIACTDY	num	Relative Actual Day of AIMS		If AIACTDT and REF.DATE not missing then perform below logic to calculate AIACTDY, If AIACTDT less than REF.DATE then (AIACTDT - REF.DATE). Else if AIACTDT is greater than equal to REF.DATE then (AIACTDT- REF.DATE) +1.

## 1.4.4. Barnes Akathisia Scale (BA) – BARS

<b>Dataset</b>	BARS
<b>Creating program</b>	bars.sas
<b>Description</b>	Barnes Akathisia Scale (BA)
<b>Unique identifier</b>	DUSUBJID ,VISITNUM,BAITEM,BAACTDY
<b>Sorted by</b>	DUSUBJID ,VISITNUM,BAITEM,BAACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BARATERI,BAACTDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
BAVTYPEC	num	BARS Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
BAVTYPE	char	BARS Visit Type		Collected at CRF.
BAGROUP	char	BARS Group		Collected at CRF.
BAITEM	char	BARS Item		Collected at CRF.
BASCOREC	num	BARS Score Code		Collected at CRF.
BASCORE	char	BARS Score		Collected at CRF.
BAACTDY	num	Relative Actual Day of BARS		If BAACTDT and REF.DATE not missing then perform below logic to calculate BAACTDY, If BAACTDT less than REF.DATE then (BAACTDT - REF.DATE). Else if BAACTDT is greater than equal to REF.DATE then (BAACTDT- REF.DATE) +1.

## 1.4.5. CCASA (CC) – CCASA

<b>Dataset</b>	CCASA
<b>Creating program</b>	ccasa.sas
<b>Description</b>	CCASA (CC)
<b>Unique identifier</b>	DUSUBJID,VISIT,CCRPTDY
<b>Sorted by</b>	DUSUBJID,VISIT,CCRPTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CCRPTDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
CCCOMPL	char	C-CASA Completed		Collected at CRF.



Variable	Type	Label	Codes	Comments
CCSCORC	num	C-CASA Score code		Collected at CRF.
CCSCORE	char	C-CASA Score		Collected at CRF.
CCRPTDY	num	Relative C-CASA Reported Day		If CCRPTDT and REF.DATE not missing then perform below logic to calculate CCRPTDY, If CCRPTDT less than REF.DATE then (CCRPTDT - REF.DATE). Else if CCRPTDT is greater than equal to REF.DATE then (CCRPTDT- REF.DATE) +1.

#### 1.4.6.CGI (CG) – CGI

<b>Dataset</b>	CGI
<b>Creating program</b>	cgi.sas
<b>Description</b>	CGI (CG)
<b>Unique identifier</b>	DUSUBJID,VISIT,CGTYPE,CGACTDY
<b>Sorted by</b>	DUSUBJID,VISIT,CGTYPE,CGACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CGRATERI,CGACTDT

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

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
CGTYPE	char	CGI Type		Collected at CRF.
CGSEVC	num	CGI Severity Code		Collected at CRF.
CGSEV	char	CGI Severity		Collected at CRF.
CGACTDY	num	Relative Actual Day of CGI		If CGACTDT and REF.DATE not missing then perform below logic to calculate CGACTDY, If CGACTDT less than REF.DATE then (CGACTDT - REF.DATE). Else if CGACTDT is greater than equal to REF.DATE then (CGACTDT- REF.DATE) +1.

## 1.4.7.LAB (LB) – CHEM

<b>Dataset</b>	CHEM
<b>Creating program</b>	chem.sas
<b>Description</b>	LAB (LB)
<b>Unique identifier</b>	DUSUBJID,PHASENUM,VISITNUM,LBTEST,LBACTDY
<b>Sorted by</b>	DUSUBJID,PHASENUM,VISITNUM,LBTEST,LBACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LBPRVIDC,LBPRVID,ACCNUM,LBREF,LBACTDT,LBTMLBL,LBENDT,LBENTM, LBSTAT,TSTCOM,STDNRC,LBTOXGR,LBTOX,LBSEQ,LBSIFACT,LBCVFACT, LBREASND

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 Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject 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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASCTC	num	Fasting Status Code		Collected at CRF.
LBFASCT	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	Conventional Reference Range Low		Collected at CRF.
CNVNRHI	num	Conventional Reference Range High		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range in Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range in Upper Limit in Std Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
NRIND	char	Reference Range Indicator		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, If LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

## 1.4.8. Comments (CO) – COMMENTS

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Empty data will be submitted.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty data will be submitted.
DSUBJID	char	Subject Id Assigned for De-identity		Empty data will be submitted.
DSITEID	char	Site Id Assigned for De-identity		Empty data will be submitted.
PHASENUM	num	Phase Number		Empty data will be submitted.
PHASE	char	Phase		Empty data will be submitted.
VISITNUM	num	Visit Number		Empty data will be submitted.
VISIT	char	Visit		Empty data will be submitted.
CTSEQ	num	Comment Sequence Number		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
DOMAIN	char	Domain of Origin		Empty data will be submitted.
PERIOD	char	Period		Empty data will be submitted.
PRDNUM	num	Period Number		Empty data will be submitted.
CTACTDY	num	Relative Actual Day of Comment		Empty data will be submitted.

#### 1.4.9. Concomitant Meds (CM) – CONMED

<b>Dataset</b>	CONMED
<b>Creating program</b>	conmed.sas
<b>Description</b>	Concomitant Meds (CM)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,CMGROUP,CMDECOD1,CMSTDY,CMSEQ
<b>Sorted by</b>	DUSUBJID,VISITNUM,CMGROUP,CMDECOD1,CMSTDY,CMSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CMTERM, CMREAS,CMSTDTC,CMSTDT,CMENDTC,CMENDT,CMCLASC

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity

Variable	Type	Label	Codes	Comments
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.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMDOSE	num	Dosage		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
CMREGIM	char	Regimen (Dose & Frequency)		Collected at CRF.
CMROUTE	char	Route of Administration		Collected at CRF.
CMCAUSC	num	Given for AE Code		Collected at CRF.
CMCAUS	char	Given for AE		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
AESEQ1	num	AE Sequence Number 1		Collected at CRF.



Variable	Type	Label	Codes	Comments
AESEQ2	num	AE Sequence Number 2		Collected at CRF.
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF.
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
CMCONT	char	Medication Continuing		Collected at CRF.
CMCLASC	char	ATC Code		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.
CMCLASC9	char	ATC Code 9		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.
CMCLAS9	char	ATC Text 9		Collected at CRF.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
CMCLAS	char	ATC Text		Collected at CRF.
CMSTDY	num	Relative Actual Start Day of Medication		If CMSTDTC and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDTC less than REF.DATE then (CMSTDTC - REF.DATE). Else if CMSTDTC is greater than equal to REF.DATE then (CMSTDTC- REF.DATE) +1.
CMENDY	num	Relative Actual End Day of Medication		If CMENDTC and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDTC less than REF.DATE then (CMENDTC - REF.DATE). Else if CMENDTC is greater than equal to REF.DATE then (CMENDTC- REF.DATE) +1.

## 1.4.10. Continuation Confirmation (CF) – CONTCONF

<b>Dataset</b>	CONTCONF
<b>Creating program</b>	contconf.sas
<b>Description</b>	Continuation Confirmation (CF)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,CFACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,CFACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CFACTDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
CFITEM	char	Item Continuation Confirmation		Collected at CRF.

Variable	Type	Label	Codes	Comments
CFSCORE	char	Score Continuation Confirmation		Collected at CRF.
CFACTDY	num	Relative Actual Day Continuation Confirm		If CFACTDT and REF.DATE not missing then perform below logic to calculate CFACTDY, If CFACTDT less than REF.DATE then (CFACTDT - REF.DATE). Else if CFACTDT is greater than equal to REF.DATE then (CFACTDT- REF.DATE) +1.

#### 1.4.11. Diagnosis (DG) – DIAGNOS

<b>Dataset</b>	DIAGNOS
<b>Creating program</b>	diagnos.sas
<b>Description</b>	Diagnosis (DG)
<b>Unique identifier</b>	DUSUBJID,VISITNUM, DGACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM, DGACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DGDT,DGACTDTC,DGACTDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
DIAGNOSC	num	Primary Diagnosis Code		Collected at CRF.
DIAGNOS	char	Primary Diagnosis		Collected at CRF.
DGTYPEC	num	Current Episode Code		Collected at CRF.
DGTYPE	char	Current Episode		Collected at CRF.
DGCSREAC	num	Course Specifier - seasonal pattern		Collected at CRF.
DGCSREA	char	Course Specifier - seasonal pattern		Collected at CRF.
SDIAGN1	char	Secondary Diagnosis 1		Collected at CRF.
DGCSEPIC	num	Course Specifier - episode recovery		Collected at CRF.
DGCSEPI	char	Course Specifier - episode recovery		Collected at CRF.
SDIAGN2	char	Secondary Diagnosis 2		Collected at CRF.
SDIAGNC1	num	Secondary Diagnosis Code 1		Collected at CRF.
SDIAGN3	char	Secondary Diagnosis 3		Collected at CRF.
SDIAGNC2	num	Secondary Diagnosis Code 2		Collected at CRF.
SDIAGNC3	num	Secondary Diagnosis Code 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
DGDY	num	Relative Day of Collection		If DGDT and REF.DATE not missing then perform below logic to calculate DGDY, If DGDT less than REF.DATE then (DGDT - REF.DATE). Else if DGDT is greater than equal to REF.DATE then (DGDT - REF.DATE) +1.
DGACTDY	num	Relative Actual Day of Diagnosis		If DGACTDTC and REF.DATE not missing then perform below logic to calculate DGACTDY, If DGACTDTC less than REF.DATE then (DGACTDTC - REF.DATE). Else if DGACTDTC is greater than equal to REF.DATE then (DGACTDTC - REF.DATE) +1.

#### 1.4.12. Diabetes Related History (DH) – DIAHIST

<b>Dataset</b>	DIAHIST
<b>Creating program</b>	diahist.sas
<b>Description</b>	Diabetes Related History (DH)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,DHDIAG,DHACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,DHDIAG,DHACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DHCHILD, DHACTDT

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
DHDIAG	char	Diagnosis		Collected at CRF.
DHHISTC	num	Diabetes History Code		Collected at CRF.
DHHIST	char	Diabetes History		Collected at CRF.
DHAGE	char	Age at Diagnosis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DHACTDY	num	Relative Act Day of Diabetes Related His		If DHACTDT and REF.DATE not missing then perform below logic to calculate DHACTDY, If DHACTDT less than REF.DATE then (DHACTDT - REF.DATE). Else if DHACTDT is greater than equal to REF.DATE then (DHACTDT- REF.DATE) +1.

## 1.4.13. Disposition (DS) – DISPOSIT

<b>Dataset</b>	DISPOSIT
<b>Creating program</b>	disposit.sas
<b>Description</b>	Disposition (DS)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,DSCMRS,DSSTAT,DSACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,DSCMRS,DSSTAT,DSACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DSACTDT,PREGDUDT,DEATHDT,DSRSOTH,DSRABKDT,DSRABKRS

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.



Variable	Type	Label	Codes	Comments
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSCMRSC	num	Completion Reason Code		Collected at CRF.
DSCMRS	char	Completion Reason		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		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.
DSRABKTM	num	Time of Code Break		Collected at CRF.
DSACTDY	num	Relative Actual Day Trial Compl/Withdraw		If DSACTDT and REF.DATE not missing then perform below logic to calculate DSACTDY, If DSACTDT less than REF.DATE then (DSACTDT - REF.DATE). Else if DSACTDT is greater than equal to REF.DATE then (DSACTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DEATHDY	num	Relative Actual Day of Death		If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT- REF.DATE) +1.
DSRABKDY	num	Relative Actual Day Random Code Broken		If DSRABKDT and REF.DATE not missing then perform below logic to calculate DSRABKDY, If DSRABKDT less than REF.DATE then (DSRABKDT - REF.DATE). Else if DSRABKDT is greater than equal to REF.DATE then (DSRABKDT- REF.DATE) +1.

## 1.4.14. DNA Result (DN) – DNRSLT

<b>Dataset</b>	DNRSLT
<b>Creating program</b>	dnrslt.sas
<b>Description</b>	DNA Result (DN)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,DNSEQ
<b>Sorted by</b>	DUSUBJID,VISITNUM,DNSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DNINFDT,DNDT,DNPRVIDC,DNPRVID,ACQREF,DNSAMREF,FG_ID,DNREAS, DNDSTRDT,DNDSTRYC,DNGENCD,DNTESTCD,DNTEST,DNGENAM, DNASSAY,DNORRES,DNSTRESC,DNSTRESN,DNRSLTYP

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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
DNSEQ	num	DNA Sample Sequence Number		Collected at CRF.
DNCNSNT	char	Informed Consent Signed		Collected at CRF.
DNCNSNTC	num	Informed Consent Signed Code		Collected at CRF.
DNSTUDY	char	Scope - Study-Specific Testing		Collected at CRF.
DNSTUDYC	num	Scope - Study-Specific Testing Code		Collected at CRF.
DNSAMP	char	Sample Obtained		Collected at CRF.
DNSAMPC	num	Sample Obtained Code		Collected at CRF.
DNSTORE	char	Scope - Storage for Future Use		Collected at CRF.
DNSTOREC	num	Scope - Storage for Future Use Code		Collected at CRF.
DNSAMMAT	char	Sample Material		Collected at CRF.
DNDSTRY	char	Sample Destroyed		Collected at CRF.
DNINFYD	num	Relative Day of Sign on Informed Consent		If DNINFDT and REF.DATE not missing then perform below logic to calculate DNINFYD, If DNINFDT less than REF.DATE then (DNINFDT - REF.DATE). Else if DNINFDT is greater than equal to REF.DATE then (DNINFDT- REF.DATE) +1.
DNDY	num	Relative Day of Sample		If DNDT and REF.DATE not missing then perform below logic to calculate DNDY, If DNDT less than REF.DATE then (DNDT - REF.DATE). Else if DNDT is greater than equal to REF.DATE then (DNDT- REF.DATE) +1.

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

#### 1.4.15. Electrocardiogram (EG) – ECG

<b>Dataset</b>	ECG
<b>Creating program</b>	ecg.sas
<b>Description</b>	Electrocardiogram (EG)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,EGPTMNUM,EGTEST,EGVTYPE,EGDY,EGSEQ
<b>Sorted by</b>	DUSUBJID,VISITNUM,EGPTMNUM,EGTEST,EGVTYPE,EGDY,EGSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EGREF,EGDT,EGPOS,EGPRVIDC,EGPRVID,EGND,EGCHGC,EGCHG,BATCHID, EGINTOTH,EGCHGOTH,XSUBJINT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
EGPTMNUM	num	Planned Time Point Number		Collected at CRF.
EGPTM	char	Planned Time Point Name		Collected at CRF.
EGACTTM	num	Actual Time of ECG		Collected at CRF.
EGQUAL	char	Qualifier		Collected at CRF.
EGTEST	char	ECG Test		Collected at CRF.
EGSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
EGSTUNIT	char	Standard Units		Collected at CRF.
EGSTRESC	char	Character Result in Standard Units		Collected at CRF.
EGORRESN	num	Numeric Result in Original Units		Collected at CRF.
EGORUNIT	char	Original Units		Collected at CRF.
EGINTPC	num	Interpretation Code		Collected at CRF.
EGINTP	char	Interpretation		Collected at CRF.
EGLEAD	char	Lead Used for Measurement		Collected at CRF.
EGSEQ	num	ECG Sequence Number		Collected at CRF.
EGREADC	num	ECG Reader Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGREAD	char	ECG Reader		Collected at CRF.
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF.
EGVTYPE	char	ECG Visit Type		Collected at CRF.
MDS_CODE	char	MDS Code		Collected at CRF.
EGDY	num	Relative Actual Day of ECG		If EGDT and REF.DATE not missing then perform below logic to calculate EGDY, If EGDT less than REF.DATE then (EGDT - REF.DATE). Else if EGDT is greater than equal to REF.DATE then (EGDT - REF.DATE) +1.

#### 1.4.16. Exposure (EX) – EXPOSURE

<b>Dataset</b>	EXPOSURE
<b>Creating program</b>	exposure.sas
<b>Description</b>	Exposure (EX)
<b>Unique identifier</b>	DUSUBJID,EXSTDY
<b>Sorted by</b>	DUSUBJID,EXSTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXSTDT,EXENDT

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
EXGIVENA	num	Number of A Capsules Taken		Collected at CRF.
EXGIVENB	num	Number of B Capsules Taken		Collected at CRF.
EXGIVENC	num	Number of C Capsules Taken		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDT less than REF.DATE then (EXSTDT - REF.DATE). Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.
EXENDY	num	Relative End Day of Exposure		If EXENDT and REF.DATE not missing then perform below logic to calculate EXENDY, If EXENDT less than REF.DATE then (EXENDT - REF.DATE). Else if EXENDT is greater than equal to REF.DATE then (EXENDT- REF.DATE) +1.



## 1.4.17. Family History (FH) – FAMHIST

<b>Dataset</b>	FAMHIST
<b>Creating program</b>	famhist.sas
<b>Description</b>	Family History (FH)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,FHDTYPE,FHACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,FHDTYPE,FHACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: FHACTDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
FHHISTC	num	Relatives History of Diabetes Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
FHHIST	char	Relatives History of Diabetes		Collected at CRF.
FHMEM	char	Family Member		Collected at CRF.
FHDTYPE	char	Diabetes Types		Collected at CRF.
FHACTDY	num	Relative Actual Day of Collection		If FHACTDT and REF.DATE not missing then perform below logic to calculate FHACTDY, If FHACTDT less than REF.DATE then (FHACTDT - REF.DATE). Else if FHACTDT is greater than equal to REF.DATE then (FHACTDT- REF.DATE) +1.

#### 1.4.18. GAF (GA) – GAF

<b>Dataset</b>	GAF
<b>Creating program</b>	gaf.sas
<b>Description</b>	GAF (GA)
<b>Unique identifier</b>	DUSUBJID,PHASENUM,GAACTDY
<b>Sorted by</b>	DUSUBJID,PHASENUM,GAACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: GAACDT, GARATERI

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
GASCORE	num	GAF Score		Collected at CRF.
GAACTDY	num	Relative Actual Day of GAF		If GAACTDT and REF.DATE not missing then perform below logic to calculate GAACTDY, If GAACTDT less than REF.DATE then (GAACTDT - REF.DATE). Else if GAACTDT is greater than equal to REF.DATE then (GAACTDT- REF.DATE) +1.

## 1.4.19. Smoking Habit (HA) – HABIT

<b>Dataset</b>	HABIT
<b>Creating program</b>	habit.sas
<b>Description</b>	Smoking Habit (HA)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,HASMOCUC,HAACDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,HASMOCUC,HAACDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: HAACDT,HAENDTC

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
HASMOCUC	num	Does Subject Currently Smoke Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
HASMOCU	char	Does Subject Currently Smoke		Collected at CRF.
HACGNUM	num	Number of Cigarettes		Collected at CRF.
HACGRNUM	num	Number of Cigars		Collected at CRF.
HAPIPNUM	num	Number of Pipes		Collected at CRF.
HASMOPSC	num	Has Subject Smoked in the Past Code		Collected at CRF.
HASMOPS	char	Has Subject Smoked in the Past		Collected at CRF.
HAYEAR	num	Number of Years Subject Has Smoked		Collected at CRF.
HAACTDY	num	Relative Actual Day of Smoking Habit		If HAACTDT and REF.DATE not missing then perform below logic to calculate HAACTDY, If HAACTDT less than REF.DATE then (HAACTDT - REF.DATE). Else if HAACTDT is greater than equal to REF.DATE then (HAACTDT- REF.DATE) +1.

## 1.4.20. LAB (LB) – HEMAT

<b>Dataset</b>	HEMAT
<b>Creating program</b>	hemat.sas
<b>Description</b>	LAB (LB)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,LBTEST,LBACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,LBTEST,LBACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LBPRVIDC,LBPRVID,ACCNUM,LBREF,LBACTDT,LBTMLBL,LBENDT,LBENTM, LBSTAT,TSTCOM,STDNRC,LBTOXGR,LBTOX,LBSEQ,LBSIFACT,LBCVFACT, LBREASND

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 Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject 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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBDESCR	char	Full Test Description		Collected at CRF.
TSTCOM	char	Test Level Comments		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	Conventional Reference Range Low		Collected at CRF.
CNVNRHI	num	Conventional Reference Range High		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range in Lower Limit in Std Units		Collected at CRF.
STDNRHI	num	Normal Range in Upper Limit in Std Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
NRIND	char	Reference Range Indicator		Collected at CRF.



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

#### 1.4.21. Hospitalization (HO) – HOSPITAL

<b>Dataset</b>	HOSPITAL
<b>Creating program</b>	hospital.sas
<b>Description</b>	Hospitalization (HO)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,HODISCHC,HOSTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,HODISCHC,HOSTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: HOSTDT,HOSTDTC,HOENDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity

Variable	Type	Label	Codes	Comments
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.
HODISCHC	num	Is Subject Discharged from Hospital		Collected at CRF.
HODISCH	char	Is Subject Discharged from Hospital		Collected at CRF.
HOSTDY	num	Relative Admission Day of Hospitalization		If HOSTDTC and REF.DATE not missing then perform below logic to calculate HOSTDY, If HOSTDTC less than REF.DATE then (HOSTDTC - REF.DATE). Else if HOSTDTC is greater than equal to REF.DATE then (HOSTDTC- REF.DATE) +1.
HOENDY	num	Relative Discharge Day of Hospitalization		If HOENDT and REF.DATE not missing then perform below logic to calculate HOENDY, If HOENDT less than REF.DATE then (HOENDT - REF.DATE). Else if HOENDT is greater than equal to REF.DATE then (HOENDT- REF.DATE) +1.

## 1.4.22. Inclusion/Exclusion Exceptions (IE) – IE

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

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
IEMETC	num	Overall Criteria Met Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
IEMET	char	Overall Criteria Met		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	num	Exception Criterion Result in Std Format		Collected at CRF.
IEDY	num	Relative Day of Collection		If IEDT and REF.DATE not missing then perform below logic to calculate IEDY, If IEDT less than REF.DATE then (IEDT - REF.DATE). Else if IEDT is greater than equal to REF.DATE then (IEDT - REF.DATE) +1.

## 1.4.23. Intake (IT) – INTAKE

<b>Dataset</b>	INTAKE
<b>Creating program</b>	intake.sas
<b>Description</b>	Intake (IT)
<b>Unique identifier</b>	DUSUBJID,VISITNUM,ITSTYPEC,ITTYPE,ITACTDY
<b>Sorted by</b>	DUSUBJID,VISITNUM,ITSTYPEC,ITTYPE,ITACTDY
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ITACTDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
ITTYPE	char	Intake Type		Collected at CRF.

Variable	Type	Label	Codes	Comments
ITSTYPEC	num	Intake Sub Type Code		Collected at CRF.
ITSTYPE	char	Intake Sub Type		Collected at CRF.
ITACTTM	num	Actual Time of Intake		Collected at CRF.
ITACTDY	num	Relative Actual Day of Intake		If ITACTDT and REF.DATE not missing then perform below logic to calculate ITACTDY, If ITACTDT less than REF.DATE then (ITACTDT - REF.DATE). Else if ITACTDT is greater than equal to REF.DATE then (ITACTDT- REF.DATE) +1.

#### 1.4.24. MADRS (MA) – MADRS

<b>Dataset</b>	MADRS
<b>Creating program</b>	mads.sas
<b>Description</b>	MADRS (MA)
<b>Unique identifier</b>	DUSUBJID,PHASE,MAITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,MAITEM,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MAACTDT,MARATERI

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
MAITEM	char	MADRS Item		Collected at CRF.
MASCOREC	num	MADRS Score Code		Collected at CRF.
MASCORE	char	MADRS Score		Collected at CRF.
MAACTDY	num	Relative Actual Day of MADRS		If MAACTDT and REF.DATE not missing then perform below logic to calculate MAACTDY, If MAACTDT less than REF.DATE then (MAACTDT - REF.DATE). Else if MAACTDT is greater than equal to REF.DATE then (MAACTDT- REF.DATE) +1.

## 1.4.25. Medical History (MH) – MEDHIST

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

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
MHSEQ	num	MH Sequence Number		Collected at CRF.



Variable	Type	Label	Codes	Comments
MHBODSYC	num	Body System Code		Collected at CRF.
MHBODSYS	char	Body System		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 REF.DATE not missing then perform below logic to calculate MHACTDY, if MHACTDT less than REF.DATE then (MHACTDT - REF.DATE). Else if MHACTDT is greater than equal to REF.DATE then (MHACTDT- REF.DATE) +1.

## 1.4.26. Physical Exam (PE) – PE

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

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
PESEQ	num	Phys Sequence Number		Collected at CRF.

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

#### 1.4.27. Protocol Description (PD) – PROTDESC

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

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
COMPNDC	char	Compound Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMPND	char	Compound Name		Collected at CRF.
BLINDING	char	Blinding Level		Collected at CRF.
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.

## 1.4.28. Protocol Deviation (PV) – PROTDEV

<b>Dataset</b>	PROTDEV
<b>Creating program</b>	protdev.sas
<b>Description</b>	Protocol Deviation (PV)
<b>Unique identifier</b>	DUSUBJID,PVDECOD,PVSEQ
<b>Sorted by</b>	DUSUBJID,PVDECOD,PVSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: PVTERM

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.

## 1.4.29. Psychiatric History (PY) – PSYHIST

<b>Dataset</b>	PSYHIST
<b>Creating program</b>	psyhist.sas
<b>Description</b>	Psychiatric History (PY)
<b>Unique identifier</b>	DUSUBJID,PYDIAG,PYHOSP,PYDGDY,PYSEQ
<b>Sorted by</b>	DUSUBJID,PYDIAG,PYHOSP,PYDGDY,PYSEQ
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: PYDGDTC,PYDGDY

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PYDIAG	char	Diagnosis		Collected at CRF.
PYHOSPC	num	Hospitalizations for Psychosis Code		Collected at CRF.
PYHOSP	char	Hospitalizations for Psychosis		Collected at CRF.
PYDGDY	num	Relative Day of Diagnosis		If PYDGDTC and REF.DATE not missing then perform below logic to calculate PYDGDY, If PYDGDTC less than REF.DATE then (PYDGDTC - REF.DATE). Else if PYDGDTC is greater than equal to REF.DATE then (PYDGDTC - REF.DATE) +1.

#### 1.4.30. Randomization (RA) – RANDOM

<b>Dataset</b>	RANDOM
<b>Creating program</b>	random.sas
<b>Description</b>	Randomization (RA)
<b>Unique identifier</b>	DUSUBJID,PHASE,TRTGRP
<b>Sorted by</b>	DUSUBJID,PHASE,TRTGRP
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RAACTDT,RANDNUM,SUB

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
RASEQ	num	Randomization Sequence Number		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
REGIMEN	char	Regimen Code		Collected at CRF.
RAACTDY	num	Relative Actual Day of Randomization		If RAACTDT and REF.DATE not missing then perform below logic to calculate RAACTDY, If RAACTDT less than REF.DATE then (RAACTDT - REF.DATE). Else if RAACTDT is greater than equal to REF.DATE then (RAACTDT- REF.DATE) +1.



## 1.4.31. Recurrence (RC) – RECUR

<b>Dataset</b>	RECUR
<b>Creating program</b>	recur.sas
<b>Description</b>	Recurrence (RC)
<b>Unique identifier</b>	DUSUBJID,RCTYPE
<b>Sorted by</b>	DUSUBJID,RCTYPE
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RCRECDT,RCOTHER

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
RCTYPEC	num	Type of Recurrence Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
RCTYPE	char	Type of Recurrence		Collected at CRF.
RCREASC	num	Reason Code		Collected at CRF.
RCREAS	char	Reason		Collected at CRF.
RCRECDY	num	Relative Day of Recurrence		If RCRECDT and REF.DATE not missing then perform below logic to calculate RCRECDY, If RCRECDT less than REF.DATE then (RCRECDT - REF.DATE). Else if RCRECDT is greater than equal to REF.DATE then (RCRECDT- REF.DATE) +1.

#### 1.4.32. SARS (SR) – SARS

<b>Dataset</b>	SARS
<b>Creating program</b>	sars.sas
<b>Description</b>	SARS (SR)
<b>Unique identifier</b>	DUSUBJID,PHASE,SRITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,SRITEM,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SRRATERI,SRACTDT

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
SRVTYPEC	num	SARS Visit Type Code		Collected at CRF.
SRVTYPE	char	SARS Visit Type		Collected at CRF.
SRITEM	char	SARS Item		Collected at CRF.
SRSCOREC	num	SARS Score Code		Collected at CRF.
SRSCORE	char	SARS Score		Collected at CRF.
SRACTDY	num	Relative Actual Day of SARS		If SRACTDT and REF.DATE not missing then perform below logic to calculate SRACTDY, If SRACTDT less than REF.DATE then (SRACTDT - REF.DATE). Else if SRACTDT is greater than equal to REF.DATE then (SRACTDT- REF.DATE) +1.

## 1.4.33. SF36 (SF) – SF36

<b>Dataset</b>	SF36
<b>Creating program</b>	sf36.sas
<b>Description</b>	SF36 (SF)
<b>Unique identifier</b>	DUSUBJID,PHASE,SFGROUP,SFITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,SFGROUP,SFITEM,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SFACTDT,SFRATERI

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
SFGROUP	char	SF36 Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
SFITEM	char	SF36 Item		Collected at CRF.
SFSCOREC	num	SF36 Score Code		Collected at CRF.
SFSCORE	char	SF36 Score		Collected at CRF.
SFACTDY	num	Relative Actual Day of SF36		If SFACTDT and REF.DATE not missing then perform below logic to calculate SFACTDY, If SFACTDT less than REF.DATE then (SFACTDT - REF.DATE). Else if SFACTDT is greater than equal to REF.DATE then (SFACTDT- REF.DATE) +1.

#### 1.4.34. SSI (SS) – SSI

<b>Dataset</b>	SSI
<b>Creating program</b>	ssi.sas
<b>Description</b>	SSI (SS)
<b>Unique identifier</b>	DUSUBJID,PHASE,SSITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,SSITEM,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SSACTDT,SSRATERI

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
SSITEM	char	SSI Item		Collected at CRF.
SSSCOREC	num	SSI Score Code		Collected at CRF.
SSSCORE	char	SSI Score		Collected at CRF.
SSACTDY	num	Relative Actual Day of SSI		If SSACTDT and REF.DATE not missing then perform below logic to calculate SSACTDY, If SSACTDT less than REF.DATE then (SSACTDT - REF.DATE). Else if SSACTDT is greater than equal to REF.DATE then (SSACTDT- REF.DATE) +1.

## 1.4.35. Surgery (SG) – SURGERY

<b>Dataset</b>	SURGERY
<b>Creating program</b>	surgery.sas
<b>Description</b>	Surgery (SG)
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SGPROC,SGINDIC,SGPLNDTC,SGPLNDT

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
SGREPRC	num	Are any Surg/Proc. Planned Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
SGREPR	char	Are any Surg/Proc. Planned		Collected at CRF.
SGSEQ	num	Sequence Number		Collected at CRF.
SGBODSY	num	Surgery Body System Code		Collected at CRF.
SGBODSYS	char	Surgery Body System		Collected at CRF.
SGPLNDY	num	Relative Day of Planned Surgery/Proc		If SGPLNDTC and REF.DATE not missing then perform below logic to calculate SGPLNDY, If SGPLNDTC less than REF.DATE then (SGPLNDTC - REF.DATE). Else if SGPLNDTC is greater than equal to REF.DATE then (SGPLNDTC- REF.DATE) +1.

#### 1.4.36. Trial Inclusion/Exclusion Criteria (TI) – TI

<b>Dataset</b>	TI
<b>Creating program</b>	ti.sas
<b>Description</b>	Trial Inclusion/Exclusion Criteria (TI)
<b>Unique identifier</b>	IETESTCD
<b>Sorted by</b>	IETESTCD
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
IECAT	char	Inclusion/Exclusion Category		Collected at CRF.



Variable	Type	Label	Codes	Comments
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.

#### 1.4.37. LAB (LB) – URINE

<b>Dataset</b>	URINE
<b>Creating program</b>	urine.sas
<b>Description</b>	LAB (LB)
<b>Unique identifier</b>	DUSUBJID,PHASE,LBTEST,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,LBTEST,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: LBPRVIDC, LBPRVID, ACCNUM, LBREF, LBACTDT, LBTMLBL, LBENDT, LBENTM, LBSTAT, TSTCOM, STDNRC, LBTOXGR, LBTOX, LBSEQ, LBSIFACT, LBCVFACT, LBREASND

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 Id Assigned for De-identity		Randomly assigned Subject Id for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject 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.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBSPECMN	char	Specimen Type		Collected at CRF.
AGEATCOL	char	Subject Age at Collection		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
AGEU	char	Subject Age Units		Collected at CRF.
LBFASTC	num	Fasting Status Code		Collected at CRF.
LBFAST	char	Fasting Status		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
LBABBR	char	Lab Test Abbreviation		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBDESCR	char	Full Test Description		Collected at CRF.
TSTCOM	char	Test Level Comments		Collected at CRF.
ORGRES	char	Character Result in Original Units		Collected at CRF.
ORGRESN	num	Numeric Result in Original Units		Collected at CRF.
ORGNRLO	num	Normal Range Lower Limit in Orig Units		Collected at CRF.
ORGNRHI	num	Normal Range Upper Limit in Orig Units		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
REPUNIT	char	Original Units		Collected at CRF.
CNVRESC	char	Conventional Text Result		Collected at CRF.
CNVRESN	num	Conventional Numeric Result		Collected at CRF.
CNVNRLO	num	Conventional Reference Range Low		Collected at CRF.
CNVNRHI	num	Conventional Reference Range High		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
STDRESC	char	Character Result in Standard Units		Collected at CRF.
STDRESN	num	Numeric Result in Standard Units		Collected at CRF.
STDNRLO	num	Normal Range in Lower Limit in Std Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
STDNRHI	num	Normal Range in Upper Limit in Std Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
NRIND	char	Reference Range Indicator		Collected at CRF.
LBACTDY	num	Relative Actual Day of Sample		If LBACTDT and REF.DATE not missing then perform below logic to calculate LBACTDY, if LBACTDT less than REF.DATE then (LBACTDT - REF.DATE). Else if LBACTDT is greater than equal to REF.DATE then (LBACTDT- REF.DATE) +1.

#### 1.4.38. Sleep VAS Scale Scores (VA) – VAS

<b>Dataset</b>	VAS
<b>Creating program</b>	vas.sas
<b>Description</b>	Sleep VAS Scale Scores (VA)
<b>Unique identifier</b>	DUSUBJID,PHASE,VASCALE,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,VASCALE,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VAACDT

Variable	Type	Label	Codes	Comments
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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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.
VASCALE	char	VAS Scale		Collected at CRF.
VASCORE	num	VAS Score (mm)		Collected at CRF.
VAACTDY	num	Relative Actual Day of VAS		If VAACTDT and REF.DATE not missing then perform below logic to calculate VAACTDY, If VAACTDT less than REF.DATE then (VAACTDT - REF.DATE). Else if VAACTDT is greater than equal to REF.DATE then (VAACTDT - REF.DATE) +1.

## 1.4.39. Visit (VI) – VISIT

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

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned 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
VISITDY	num	Relative Visit Day		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE). Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

#### 1.4.40. Vital Signs (VS) – VITAL

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

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity

Variable	Type	Label	Codes	Comments
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.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
VSWEIGHT	num	Weight		Collected at CRF.
VSWTUNIT	char	Weight Unit		Collected at CRF.
VSWAIST	num	Waist Circumference		Collected at CRF.
VWSUNIT	char	Waist Circumference Unit		Collected at CRF.
VSHEIGHT	num	Height		Collected at CRF.
VSHUNIT	char	Height Unit		Collected at CRF.
PULSE	num	Pulse Rate (bpm)		Collected at CRF.
SYSBP	num	Systolic Blood Pressure (mmHg)		Collected at CRF.
DIABP	num	Diastolic Blood Pressure (mmHg)		Collected at CRF.
TEMP	num	Temperature		Collected at CRF.
TEMPUNIT	char	Temperature Unit		Collected at CRF.



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

## 1.4.41. YMRS (YM) – YMRS

<b>Dataset</b>	YMRS
<b>Creating program</b>	ymrs.sas
<b>Description</b>	YMRS (YM)
<b>Unique identifier</b>	DUSUBJID,PHASE,YMITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PHASE,YMITEM,VISIT
<b>Notes</b>	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: YMACTDT,YMRATERI

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
DSUBJID	char	Subject Id Assigned for De-identity		Randomly assigned Subject Id for De-identity
DSITEID	char	Site Id Assigned for De-identity		Randomly assigned Site Id for De-identity

Variable	Type	Label	Codes	Comments
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.
YMITEM	char	YMRS Item		Collected at CRF.
YMSCOREC	num	YMRS Score Code		Collected at CRF.
YMSCORE	char	YMRS Score		Collected at CRF.
YMACTDY	num	Relative Actual Day of YMRS		If YMACTDT and REF.DATE not missing then perform below logic to calculate YMACTDY, If YMACTDT less than REF.DATE then (YMACTDT - REF.DATE). Else if YMACTDT is greater than equal to REF.DATE then (YMACTDT- REF.DATE) +1.