

Clinical Development

**PALIPERIDONE<sup>®</sup>**

R076477-SCH-701

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
- Subject and center/site numbers will be assigned in a random manner so they are not matching the subject and center/site numbers that were used in the actual trial
- 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+).
- 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.
- Complete missing value variables will be removed.

- 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..
- Dataset “KCOMMENT” will be submitted with zero observation.
- Lab Name and Lab Identifier information will not be provided.
- Rater’s Initial or Patient’s Initial will not be provided as it is sensitive. (eg. AIRATERI etc.)
- Variables with completely missing values will not be submitted.
- Dataset containing DNA related information is sensitive and hence will not be submitted. (ex. KDNRSLT)
- For Randomized subjects, RFSTDT will be used as Reference Date (Referred as REF.DATE in the document) to derive relative day. For Screen Failure subjects, "Informed Consent Date" (DMINFDT) from KDEMOG dataset will be used as a reference date(Referred as REF.DATE in the document) to derive relative days.

### 1.3. Data Files

The R076477-SCH-701 CSR Clinical Study Report (CSR) data should be used for converting to de-identification.

## 1.4. Data Domains

### 1.4.1. Demographics – KDEMOG

<b>Dataset</b>	KDEMOG
<b>Creating program</b>	kdemog.sas
<b>Description</b>	Demographics
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PCENTERC,RFENDT,RFSTDT,SUBJINIT,IVID,IVNAME,BIRTHDT,RACESPEC,COUNTRYC,PAGNUM,DMSCRDT,DMACTDT,DMINFDT,RAACTDT,RANDNUM,RIEXSTD DT,RIEXENDT,SBEXSTD,SBEXENDT,DBEXSTD,DBEXENDT,RISTDT,SBSTD,DBSTD,RIENDT,SBENDT,DBENDT,PYEPIDT,HAPIPNUM,REGION,REGIONC,CEREA GE,OLEXSTD,OLEXENDT,DSACTDT,OLSTD,OLENDT</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
AGEUNIT	char	Age Unit		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.

Variable	Type	Label	Codes	Comments
HEIGHTCM	num	Baseline(RI) Height (cm)		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
DPCENTER	char	Pooled Center Assigned for De-identity		Randomly assigned Pooled Center for De-identity
SAFETY	char	Safety		Collected at CRF.
WEIGHTKG	num	Baseline(RI) Weight (kg)		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SEXC	num	Sex Code		Collected at CRF.
SEX	char	Sex		Collected at CRF.
RACEC	num	Race Code		Collected at CRF.
RACE	char	Race		Collected at CRF.



Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
ETHNICC	num	Ethnicity Code		Collected at CRF.
ETHNIC	char	Ethnicity		Collected at CRF.
PSTUDYID	char	Previous Study Id		Collected at CRF.
AGEGRP	char	Age Group		Collected at CRF.
DRUGID	char	Compound Name		Collected at CRF.
DRUGIDC	char	Compound Number		Collected at CRF.
TRTGRP2	char	Run-In/Stabilization Treatment		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
DGTYPEC	num	Schizophrenia Type Code		Collected at CRF.
DGTYPE	char	Schizophrenia Type		Collected at CRF.
DIAGNOSC	num	Diagnosis Code		Collected at CRF.
DIAGNOS	char	Diagnosis		Collected at CRF.
DGAGE	char	Age at Diagnosis of Schizophrenia (yrs)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
PRIORHSP	num	Prior Hospitalizations for Psychosis		Collected at CRF.
HASMOCU	char	Does subject currently smoke?		Collected at CRF.
HACGTNUM	num	Number of Cigarettes Per Day		Collected at CRF.
HACGRNUM	num	Number of Cigars Per Day		Collected at CRF.

Variable	Type	Label	Codes	Comments
HASMOPS	char	Has Subject Smoked in the Past?		Collected at CRF.
HAYEAR	num	Number of Years Subject Has Smoked		Collected at CRF.
SCRNFAIL	char	Screen Failure Subjects		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
SBTRT	char	Safety Subjects for SB		Collected at CRF.
RICOMP	char	Run-In Completer		Collected at CRF.
TRTGRP2C	num	Run-In/Stabilization Treatment Code		Collected at CRF.
TOTCG	num	Amount of Smoking per Day		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
AGE	char	Age (years)		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
BASEBMI	num	Baseline(RI) BMI (kg/m2)		Collected at CRF.
BMIGRP	char	Baseline(RI) BMI Group		Collected at CRF.
BMIGRPC	num	Baseline(RI) BMI Group Code		Collected at CRF.
AGEGRPC	num	Age Group Code		Collected at CRF.
DURPSYCH	num	Time Since Last Psychotic Episode (days)		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
RIPNSS	num	Baseline(RI) Total PANSS		Collected at CRF.
BASEPNSS	num	Baseline (DB) total PANSS		Collected at CRF.
RICGIC	num	Baseline(RI) CGI-S Code		Collected at CRF.
RICGI	char	Baseline(RI) CGI-S		Collected at CRF.
BASECGIC	num	Baseline (DB) CGI-S Code		Collected at CRF.
BASECGI	char	Baseline (DB) CGI-S		Collected at CRF.
BASEPSP	num	Baseline (DB) PSP		Collected at CRF.
RIVAS1	num	Baseline(RI) VAS(Quality of Sleep)		Collected at CRF.
BASEVAS1	num	Baseline(DB) VAS(Quality of Sleep)		Collected at CRF.
RIVAS2	num	Baseline(RI) VAS(Daytime Drowsiness))		Collected at CRF.
BASEVAS2	num	Baseline(DB) VAS(Daytime Drowsiness))		Collected at CRF.
BASESQLS	num	Baseline (DB) total SQLS-R4		Collected at CRF.
PHOSPDUR	num	Duration of Recent Hospitalization, days		Collected at CRF.
PHSPDURS	num	Duration of Recent Hosp Prior to Scrn		Collected at CRF.
DIABETES	char	Diabetes		Collected at CRF.
HYPERTEN	char	Hypertension		Collected at CRF.
DYSLIPID	char	Dyslipidemia		Collected at CRF.

Variable	Type	Label	Codes	Comments
CARDIOVA	char	Cardiovascular Disease		Collected at CRF.
CEREBROV	char	Cerebrovascular Disease		Collected at CRF.
HEPATITI	char	Hepatitis		Collected at CRF.
GESTATIO	char	Gestational Diabetes		Collected at CRF.
IRREGULA	char	Irregular Menses, Acne, or Hirsutism		Collected at CRF.
HAS_THE	char	Has the Subject Borne Children?		Collected at CRF.
DIABAGE	char	Age at Diagnosis with Diabetes		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HYPEAGE	char	Age at Diagnosis with Hypertension		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
DYSLAGE	char	Age at Diagnosis with Dyslipidemia		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
CARDAGE	char	Age at Diag with Cardiovascular Disease		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HEPAAGE	char	Age at Diagnosis with Hepatitis		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
FHHISTC	char	Relatives History of Diabetes Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
FHHIST	char	Family History of Diabetes		Collected at CRF.
SOMNDB	char	Subjects with somnolence in DB Phase		Collected at CRF.
SOMNRI	char	Subjects with somnolence in RI/SB Phases		Collected at CRF.
ANTI HIST	char	Use of Anti-histamines		Collected at CRF.
ANTIDPST	char	Use of Antidepressant		Collected at CRF.
RECURYN	char	Recurrence Status		Collected at CRF.
RICPEP	num	Baseline(RI) C-PEPTIDE Concentration (pmol/l)		Collected at CRF.
RIHGB	num	Baseline(RI) HbA1C Concentration		Collected at CRF.
RIGLUTOL	char	Baseline(RI) Glucose Tolerance Test		Collected at CRF.
RIPLT	char	Baseline(RI) Prolactin Level		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
DSOLC	num	Continue into Open Label Code		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.

Variable	Type	Label	Codes	Comments
BAS2PNSS	num	Baseline(OL) total PANSS		Collected at CRF.
BAS2CGIC	num	Baseline(OL) CGI-S Code		Collected at CRF.
BAS2CGI	char	Baseline(OL) CGI-S		Collected at CRF.
BAS2PSP	num	Baseline(OL) PSP		Collected at CRF.
BAS2SQLS	num	Baseline(OL) total SQLS-R4		Collected at CRF.
BAS2BMI	num	Baseline(OL) BMI (kg/m2)		Collected at CRF.
BMIGRP2	char	Baseline(OL) BMI Group		Collected at CRF.
BMIGRP2C	num	Baseline(OL) BMI Group Code		Collected at CRF.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- 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.
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.

Variable	Type	Label	Codes	Comments
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.
RIEXSTDY	num	Relative Run-In Start Day		If RIEXSTDY and REF.DATE not missing then perform below logic to calculate RIEXSTDY, If RIEXSTDY less than REF.DATE then (RIEXSTDY - REF.DATE). Else if RIEXSTDY is greater than equal to REF.DATE then (RIEXSTDY- REF.DATE) +1.
RIEXENDY	num	Relative Run-In End Day		If RIEXENDY and REF.DATE not missing then perform below logic to calculate RIEXENDY, If RIEXENDY less than REF.DATE then (RIEXENDY - REF.DATE). Else if RIEXENDY is greater than equal to REF.DATE then (RIEXENDY- REF.DATE) +1.
SBEXSTDY	num	Relative Stabilization Start Day		If SBEXSTDY and REF.DATE not missing then perform below logic to calculate SBEXSTDY, If SBEXSTDY less than REF.DATE then (SBEXSTDY - REF.DATE). Else if SBEXSTDY is greater than equal to REF.DATE then (SBEXSTDY- REF.DATE) +1.
SBEXENDY	num	Relative Stabilization End Day		If SBEXENDY and REF.DATE not missing then perform below logic to calculate SBEXENDY, If SBEXENDY less than REF.DATE then (SBEXENDY - REF.DATE). Else if SBEXENDY is greater than equal to REF.DATE then (SBEXENDY- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBEXSTDY	num	Relative Double Blind Start Day		If DBEXSTDT and REF.DATE not missing then perform below logic to calculate DBEXSTDY, If DBEXSTDT less than REF.DATE then (DBEXSTDT - REF.DATE). Else if DBEXSTDT is greater than equal to REF.DATE then (DBEXSTDT- REF.DATE) +1.
DBEXENDY	num	Relative Double Blind End Day		If DBEXENDT and REF.DATE not missing then perform below logic to calculate DBEXENDY, If DBEXENDT less than REF.DATE then (DBEXENDT - REF.DATE). Else if DBEXENDT is greater than equal to REF.DATE then (DBEXENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
PYEPIDY	num	Relative Day of Last Acute Symptom		If PYEPIDT and REF.DATE not missing then perform below logic to calculate PYEPIDY, If PYEPIDT less than REF.DATE then (PYEPIDT - REF.DATE). Else if PYEPIDT is greater than equal to REF.DATE then (PYEPIDT- REF.DATE) +1.
OLEXSTDY	num	Relative Open Label Start Day		If OLEXSTDY and REF.DATE not missing then perform below logic to calculate OLEXSTDY, If OLEXSTDY less than REF.DATE then (OLEXSTDY - REF.DATE). Else if OLEXSTDY is greater than equal to REF.DATE then (OLEXSTDY- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLEXENDY	num	Relative Open Label End Day		If OLEXENDT and REF.DATE not missing then perform below logic to calculate OLEXENDY, If OLEXENDT less than REF.DATE then (OLEXENDT - REF.DATE). Else if OLEXENDT is greater than equal to REF.DATE then (OLEXENDT- REF.DATE) +1.
DSACTDY	num	Relative Act Day Trial Compl/Withdrawal		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.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

### 1.4.2. Adverse Events – KAE

<b>Dataset</b>	KAE
<b>Creating program</b>	kae.sas
<b>Description</b>	Adverse Events
<b>Unique identifier</b>	DUSUBJID,AEDECOD,AESTDY,AESEQ
<b>Sorted by</b>	DUSUBJID,AEDECOD,AESTDY,AESEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>AESTDT,ARFENDT,ARFSTDT,RFENDT,RFSTDT,USUBJTRT,PAGNUM,AETERM,AEENDT,AESTDTC,AEENDTC,AESERREF,AEENDTIP,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

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.
AESEQ	num	AE Sequence Number		Collected at CRF.
AEACTDOS	char	Onset Dose		Collected at CRF.
AEACTSDY	num	Actual Day of AE Onset		Collected at CRF.
AEDOSUNT	char	Onset Dose Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
AEDUR	num	Duration		Collected at CRF.
AEDYONDS	char	Days on Onset Dose		Collected at CRF.
AETEFLAG	char	Treatment Emergent Flag		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
PPHASE	char	Protocol Phase		Collected at CRF.
TRT	char	Assigned Treatment per Phase		Collected at CRF.
ONSETFLG	char	Onset Phase Flag		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
AEREPRTC	num	Were Any AEs Reported Code		Collected at CRF.
AEREPRT	char	Were Any AEs Reported		Collected at CRF.
AECTTRC	num	Action Taken with Treatment Code		Collected at CRF.
AECTTRT	char	Action Taken with Treatment		Collected at CRF.
AEOUTC	num	Outcome of Event Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
AECODEW	char	AE Dictionary Code		Collected at CRF.
AEDCOD1W	char	WHO Included Term		Collected at CRF.
AEDECODW	char	WHO Preferred Term		Collected at CRF.
AEBODSCW	char	Body System Code		Collected at CRF.
AEBODSYW	char	Body System		Collected at CRF.
SOC1W	char	AE System Organ Class 1		Collected at CRF.
SOC2W	char	AE System Organ Class 2		Collected at CRF.
SOC3W	char	AE System Organ Class 3		Collected at CRF.
AECODE	char	AE Dictionary Code		Collected at CRF.
AEDICTDM	char	Adverse Events Dictionary		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
AEBODSYC	char	Body System or Organ Class Code		Collected at CRF.
AEHLGT	char	High Level Group Term		Collected at CRF.
AEHLT	char	High Level Term		Collected at CRF.
AEBODSYS	char	Body System or Organ Class		Collected at CRF.
AEDECOD	char	Dictionary-Derived Term		Collected at CRF.
AEDECOD1	char	Dictionary-Derived Lower-Level Term		Collected at CRF.
AEDICT	char	Adverse Events Dictionary		Collected at CRF.
AESTDTIP	char	AE Onset Date Impute Flag		Collected at CRF.
AERELSDY	num	AE Onset Relative Day		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
ACTTRT	char	Drug/Therapy		Collected at CRF.
INREACH	num	Date within Reach, Out of Phase		Collected at CRF.
TRTC	num	Assigned Treatment per Phase Code		Collected at CRF.
EPSCAT	char	EPS Related Adverse Event		Collected at CRF.
GLCCAT	char	Glucose Related Adverse Event		Collected at CRF.
PLTCAT	char	Potentially Prolactin Related Adverse Event		Collected at CRF.
MEPSCAT	char	EPS Related Adverse Event		Collected at CRF.

Variable	Type	Label	Codes	Comments
MGLCCAT	char	Glucose Related Adverse Event		Collected at CRF.
MPLTCAT	char	Prolactin Related MedDRA Adverse Event		Collected at CRF.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT - REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT - REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT - REF.DATE) +1.



Variable	Type	Label	Codes	Comments
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.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT - REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.

### 1.4.3. Abnormal Involuntary Movement Scale – KAIMS

<b>Dataset</b>	KAIMS
<b>Creating program</b>	kaims.sas
<b>Description</b>	Abnormal Involuntary Movement Scale
<b>Unique identifier</b>	DUSUBJID,VISITNUM,AITEM
<b>Sorted by</b>	DUSUBJID,VISITNUM,AITEM
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PAGNUM,AIRATERI,AIACDT,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBS TDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUN TRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
AIRELDY	num	AIMS Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
AIVTYPEC	num	AIMS Visit Type Code		Collected at CRF.
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	Score		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ZAIITEM	char	Parameter Char. Code		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.

Variable	Type	Label	Codes	Comments
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		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.

Variable	Type	Label	Codes	Comments
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

## 1.4.4. Barnes Akathisia Rating Scale– KBARS

<b>Dataset</b>	KBARS
<b>Creating program</b>	kbars.sas
<b>Description</b>	Barnes Akathisia Rating Scale
<b>Unique identifier</b>	DUSUBJID,VISITNUM,BAGROUP,BAITEM
<b>Sorted by</b>	DUSUBJID,VISITNUM,BAGROUP,BAITEM
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PAGNUM, BARATERI, BAACTDT, RFSTDT, RFENDT, ARFSTDT, ARFENDT, RISTDT, SBSTDT, DBSTDT, DBENDT, OLSTDT, OLENDT, IVNAME, SEXC, SEX, RACEC, RACE, COUNTRYC, COUNTRY, RIENDT, SBENDT, AGE, REGION, REGIONC, OLF, DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
BARELDY	num	BARS Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
BAVTYPEC	num	BARS Visit Type Code		Collected at CRF.
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	Score		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ZBAITEM	char	BARS Item Code		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.

Variable	Type	Label	Codes	Comments
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		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.

Variable	Type	Label	Codes	Comments
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.



### 1.4.5.Clinical Global Impression-Severity– KCGI

<b>Dataset</b>	KCGI
<b>Creating program</b>	kcgi.sas
<b>Description</b>	Clinical Global Impression - Severity
<b>Unique identifier</b>	DUSUBJID,VISITNUM
<b>Sorted by</b>	DUSUBJID,VISITNUM
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>CGRATERI,PAGNUM,CGACTDT,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
CGRELDY	num	CGI-S Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
CGSEVC	num	CGI Severity Code		Collected at CRF.
CGSEV	char	CGI Severity		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		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.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

### 1.4.6. Concomitant Medication/Therapy – KCMED

<b>Dataset</b>	KCMED
<b>Creating program</b>	kcmed.sas
<b>Description</b>	Concomitant Medication/Therapy
<b>Unique identifier</b>	DUSUBJID,CMCAT,CMSTDY,VISIT
<b>Sorted by</b>	DUSUBJID,CMCAT,CMSTDY,VISIT
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>ARFENDT,ARFSTDY,RFENDT,RFSTDY,PAGNUM,CMSTDY,CMTERM,CMENDT,CMSTDTC,CMENDTC,AESEQ,RISTDT,SBSTDY,DBSTDY,DBENDT,OLSTDY,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
APHASE	char	Analysis Phase		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
CMACTSDY	num	Actual Day of Medication Start		Collected at CRF.
CMDUR	num	Duration of Medication in Days		Collected at CRF.
CMCAT	char	Generic Term Category		Collected at CRF.



Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
CMREPRTC	num	Were Any Meds Administered/Changed Code		Collected at CRF.
CMREPRT	char	Were Any Meds Administered/Changed		Collected at CRF.
CMGROUPC	num	Medication Grouping Code		Collected at CRF.
CMGROUP	char	Medication Grouping		Collected at CRF.
CMTYPEC	num	Prior/Concomitant Medication Code		Collected at CRF.
CMTYPE	char	Prior/Concomitant Medication		Collected at CRF.
CMSEQ	num	Conmed Sequence Number		Collected at CRF.
CMDECOD1	char	Medication Specified Term		Collected at CRF.
CMREAS	char	Reason for Medication		Collected at CRF.
CMREGIM	char	Regimen (Dose And Frequency)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMROUTE	char	Route		Collected at CRF.
CMCONTC	num	Medication Continuing Code		Collected at CRF.
CMCONT	char	Medication Continuing		Collected at CRF.
CMPRIORC	num	Med Started Prior to Trial Code		Collected at CRF.
CMPRIOR	char	Med Started Prior to Trial		Collected at CRF.
CMCAUSC	num	Cause of Concom/Drug/Therapy Code		Collected at CRF.
CMCAUS	char	Cause of Concom/Drug/Therapy		Collected at CRF.
CMDOSE	num	Dosage		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
CMCODE	char	Medication Dictionary Code		Collected at CRF.
CMDECOD	char	Medication Generic Term		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
CMRELSDY	num	Conmeds Start Relative Day		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.

Variable	Type	Label	Codes	Comments
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
OLEFLG	char	Open-Label Extension flag		Collected at CRF.
RESETFG	char	DB Reslote to STAB		Collected at CRF.
DRUGCAT	char	Psychotropic Drug Category		Collected at CRF.
PRIPSYRI	char	Psychotropic Medication Prior to RI		Collected at CRF.
PRIPSYDB	char	Psychotropic Medication Prior to DB		Collected at CRF.

Variable	Type	Label	Codes	Comments
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
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.

Variable	Type	Label	Codes	Comments
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.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT - REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT - REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.

### 1.4.7. Anti-Depression and Rescue Med. Summary – KCMEDS

<b>Dataset</b>	KCMEDS
<b>Creating program</b>	kcmeds.sas
<b>Description</b>	Anti-Depression and Rescue Med. Summary
<b>Unique identifier</b>	DUSUBJID,CMCAT
<b>Sorted by</b>	DUSUBJID,CMCAT
<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: RFENDT,RFSTDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,S EXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,RE GIONC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
CMGROUP	char	Medication Grouping		Collected at CRF.
CMCAT	char	Generic Term Category		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
CMUNIT	char	Dose Unit		Collected at CRF.
EXTRTDUR	num	Duration of Medication in Days		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXMEANB	num	Mean Dose (Days on Drug Only)		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.



Variable	Type	Label	Codes	Comments
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
OLEFLG	char	Open-Label Extension flag		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

## 1.4.8. Comments – KCOMMENT

<b>Dataset</b>	KCOMMENT
<b>Creating program</b>	kcomment.sas
<b>Description</b>	Comments
<b>Unique identifier</b>	Not Applicable
<b>Sorted by</b>	Not Applicable
<b>Notes</b>	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Empty data will be submitted.
STUDYID	char	Study Id		Empty data will be submitted.
DSUBJID	char	Subject Number Assigned for De-identity		Empty data will be submitted.
DSITEID	char	Site 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 Id		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.
STUDYIND	char	Indication		Empty data will be submitted.
STUDYTYP	char	Study Type		Empty data will be submitted.
ALLRAND	char	All Randomized Subjects		Empty data will be submitted.
ITT	char	Intent-to-Treat		Empty data will be submitted.
SAFETY	char	Safety		Empty data will be submitted.
ARM	char	Treatment Arm		Empty data will be submitted.
PTRTGRP	char	Previous Treatment Group		Empty data will be submitted.
TRTGRP	char	Treatment Group		Empty data will be submitted.
DSOL	char	Continue into Open Label		Empty data will be submitted.
RITRT	char	All Treated		Empty data will be submitted.
PTRTGRPC	num	Previous Treatment Group Code		Empty data will be submitted.
ARMC	num	Treatment Arm Code		Empty data will be submitted.
OLSAFETY	char	Safety		Empty data will be submitted.
OLITT	char	Intent-to-Treat		Empty data will be submitted.
OLNODB	char	OL subjects w/o DB treatment		Empty data will be submitted.
TRTGRPC	num	Treatment Group Code		Empty data will be submitted.
SMDUR	num	Total Duration of Study Medication (Day)		Empty data will be submitted.

Variable	Type	Label	Codes	Comments
CTACTDY	num	Relative Actual Day of Comment		Empty data will be submitted.
RFENDY	num	Relative Reference End Day		Empty data will be submitted.
RFSTDY	num	Relative Reference Start Day		Empty data will be submitted.
RISTDY	num	Relative Reference Start Day (RI)		Empty data will be submitted.
SBSTDY	num	Relative Reference Start Day (SB)		Empty data will be submitted.
DBSTDY	num	Relative Reference Start Day (DB)		Empty data will be submitted.
RIENDY	num	Relative Reference End Day (RI)		Empty data will be submitted.
SBENDY	num	Relative Reference End Day (SB)		Empty data will be submitted.
DBENDY	num	Relative Reference End Day (DB)		Empty data will be submitted.
OLSTDY	num	Relative Reference Start Day (OL)		Empty data will be submitted.
OLENDY	num	Relative Reference End Day (OL)		Empty data will be submitted.

## 1.4.9. Diabetes Related History – KDIAHIST

<b>Dataset</b>	KDIAHIST
<b>Creating program</b>	kdiahist.sas
<b>Description</b>	Diabetes Related History
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>PAGNUM, DHACTDT, RFENDT, RFSTDT, IVNAME, SEXC, SEX, RACEC, RACE, COUNTRYC, COUNTRY, RISTDT, SBSTDT, DBSTDT, RIENDT, SBENDT, DBENDT, AGE, REGION, REGIONC, OLSTDT, OLENDT</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
DHDIAGC	num	DH Diagnosis Number		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DHCHILD	num	Number of Children Born Weight >10 lbs		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.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.



Variable	Type	Label	Codes	Comments
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
DHACTDY	num	Relative Act Day Diabetes Rel History		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.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT - REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT - REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

### 1.4.10. Disposition/Termination – KDISPO

<b>Dataset</b>	KDISPO
<b>Creating program</b>	kdispo.sas
<b>Description</b>	Disposition/Termination
<b>Unique identifier</b>	DUSUBJID,VISITNUM
<b>Sorted by</b>	DUSUBJID,VISITNUM
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>ARFENDT,ARFSTDT,RFENDT,RFSTDT,DSACTDT,DSRSOTH,DSRABKDT,DEATHDT,PREGDUDT,DSRABKRS,PAGNUM,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
APHASE	char	Analysis Phase		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
DSRELDY	num	Relative Day		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
DSTYPEC	num	End of Treatment or Trial Code		Collected at CRF.
DSTYPE	char	End of Treatment or Trial		Collected at CRF.
DSREASC	num	Reason for Withdrawal/Termination Code		Collected at CRF.
DSREAS	char	Reason for Withdrawal/Termination		Collected at CRF.
DSSTATC	num	Subject Completed Treatment/Trial Code		Collected at CRF.
DSSTAT	char	Subject Completed Treatment/Trial		Collected at CRF.
DSOLC	num	Continue into Open Label Code		Collected at CRF.
DSRABKTM	num	Randomization Code Broken Time		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSSCRNC	num	Screen Failure Code		Collected at CRF.
DSSCRN	char	Screen Failure		Collected at CRF.
AESEQ	num	AE Sequence Number		Collected at CRF.
DSCMRSC	num	Completion Reason Code		Collected at CRF.
DSCMRS	char	Completion Reason		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT - REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT - REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DSACTDY	num	Relative Act Day Trial Compl/Withdrawal		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.
DSRABKDY	num	Relative Act Day Rand 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.
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.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDY and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDY less than REF.DATE then (SBSTDY - REF.DATE). Else if SBSTDY is greater than equal to REF.DATE then (SBSTDY - REF.DATE) +1.



Variable	Type	Label	Codes	Comments
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.

#### 1.4.11. Planned Dose – KDOSE

<b>Dataset</b>	KDOSE
<b>Creating program</b>	kdose.sas
<b>Description</b>	Planned Dose
<b>Unique identifier</b>	TRTGRP,PHASE
<b>Sorted by</b>	TRTGRP,PHASE
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
ACTTRT	char	Drug/Therapy		Collected at CRF.
DOSEFREQ	num	Frequency		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
STRENGTA	num	Strength for Column A		Collected at CRF.
STRENGTHB	num	Strength for Column B		Collected at CRF.
STRENGTHC	num	Strength for Column C		Collected at CRF.

### 1.4.12. Electrocardiogram – KECG

<b>Dataset</b>	KECG
<b>Creating program</b>	kecg.sas
<b>Description</b>	Electrocardiogram
<b>Unique identifier</b>	DUSUBJID,EGTEST,EGACTDY,VISITNUM,EGSEQ
<b>Sorted by</b>	DUSUBJID,EGTEST,EGACTDY,VISITNUM,EGSEQ
<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 or due to missing values: EGREF,EGDT,EGPOS,EGPRVIDC,EGPRVID,EGND,EGCHGC,EGCHG,EGINTOTH,E GCHGOTH,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBSTDT,DBSTDT,DBEN DT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIE NDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG,DBASE

Variable	Type	Label	Codes	Comments
EGTESTCD	char	ECG Test Short Name		Collected at CRF.
SLOPE	num	Slope to Calculate QTCLD		Collected at CRF.
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity

Variable	Type	Label	Codes	Comments
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EGPTMNUM	num	Label of Planned Elapsed Time		Collected at CRF.
EGPTM	char	Planned Elapsed Time of ECG		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	Result Numeric in Standard Units		Collected at CRF.
EGSTUNIT	char	Standard Units		Collected at CRF.
EGSTRESC	char	Result Character		Collected at CRF.
EGORRESN	num	Result Numeric in Original Units		Collected at CRF.
EGORUNIT	char	Original Units		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.
EGREAD	char	ECG Reader		Collected at CRF.
EGVTYPEC	num	ECG Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
EGVTYPE	char	ECG Visit Type		Collected at CRF.
MDS_CODE	char	MDS Code		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
EGRELDY	num	Relative Day		Collected at CRF.
EGACTDY	num	Actual Day of ECG Collection		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
EGDRVFL	char	Derived Record		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE3	num	Value at Baseline(db)		Collected at CRF.
DBASE3	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE3	num	Change from Baseline(db)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE	num	Value at Average Predose		Collected at CRF.
CHANGE	num	Change from Average Predose		Collected at CRF.
PCHANGE	num	Percent Change from Average Predose		Collected at CRF.
EGSIGLO	num	ECG Significant Range Low		Collected at CRF.
EGSIGHI	num	ECG Significant Range High		Collected at CRF.
EGSIGIND	char	ECG Abnormal N/L/H Indicator		Collected at CRF.
EGCAT	char	Category for ECG		Collected at CRF.
EGMAFLAG	char	Markedly Abnormal Flag (RI)		Collected at CRF.
EGMAFLG2	char	Markedly Abnormal Flag (OL)		Collected at CRF.
EGMAFLG3	char	Markedly Abnormal Flag (DB)		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.



Variable	Type	Label	Codes	Comments
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

### 1.4.13. Inclusion Exclusion – KENROLL

<b>Dataset</b>	KENROLL
<b>Creating program</b>	kenroll.sas
<b>Description</b>	Inclusion Exclusion
<b>Unique identifier</b>	DUSUBJID,VISIT,ENSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,ENSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>PAGNUM,ENACTDT,RFENDT,RFSTDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTR YC,COUNTRY,RISTDT,SBSTDT,DBSTDT,RIENDT,SBENDT,DBENDT,AGE,REGION, REGIONC,OLSTDT,OLENDT</p>

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
ENCRIT	char	Inclusion or Exclusion Criterion		Collected at CRF.
ENSEQ	num	Criterion Sequence Number		Collected at CRF.
ENCRESC	num	Criterion Result Code		Collected at CRF.
ENCRES	char	Criterion Result		Collected at CRF.
ENTEXT	char	Criterion Text		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
ENACTDY	num	Relative Actual Day of Enrollment		If ENACTDT and REF.DATE not missing then perform below logic to calculate ENACTDY, If ENACTDT less than REF.DATE then (ENACTDT - REF.DATE). Else if ENACTDT is greater than equal to REF.DATE then (ENACTDT - REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY - REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.



### 1.4.14. Drug Exposure – KEXPO

<b>Dataset</b>	KEXPO
<b>Creating program</b>	kexpo.sas
<b>Description</b>	Drug Exposure
<b>Unique identifier</b>	DUSUBJID,EXSTDY,EXSEQ
<b>Sorted by</b>	DUSUBJID,EXSTDY,EXSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>EXSTDT, MEDENDT, MEDSTDT, PAGNUM, EXENDT, IMPRFDT, EXIMFLAG, RFENDT, RFSTDT, IVNAME, SEXC, SEX, RACEC, RACE, COUNTRYC, COUNTRY, RISTDT, DBSTDT, RIENDT, DBENDT, AGE, REGION, REGIONC, OLSTDT, OLENDT</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
TRTGRP	char	Treatment Group		Collected at CRF.
DOSETOT	num	Total Daily Dose		Collected at CRF.
EXACTEDY	num	Actual Day of End of Dose		Collected at CRF.
EXACTSDY	num	Actual Day of Start of Dose		Collected at CRF.
EXDUR	num	Duration		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		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.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
DSOLC	num	Continue into Open Label Code		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
ACTTRT	char	Drug/Therapy		Collected at CRF.
DOSEFREQ	num	Frequency		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
STRENGTA	num	Strength for Column A		Collected at CRF.
STRENGTB	num	Strength for Column B		Collected at CRF.
STRENGTC	num	Strength for Column C		Collected at CRF.
EXGIVEN	num	Total Number of Pills		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
EXSTDY	num	Relative Start Day of Exposure		If EXSTDY and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDY less than REF.DATE then (EXSTDY - REF.DATE). Else if EXSTDY is greater than equal to REF.DATE then (EXSTDY- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE). Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDT less than REF.DATE then (MEDSTDT - REF.DATE). Else if MEDSTDT is greater than equal to REF.DATE then (MEDSTDT- 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.
IMPRFDY	num	Relative Actual Day of Vital Signs		If IMPRFDT and REF.DATE not missing then perform below logic to calculate IMPRFDY, If IMPRFDT less than REF.DATE then (IMPRFDT - REF.DATE). Else if IMPRFDT is greater than equal to REF.DATE then (IMPRFDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

## 1.4.15. Exposure Summary – KEXPOS

<b>Dataset</b>	KEXPOS
<b>Creating program</b>	kexpos.sas
<b>Description</b>	Exposure Summary
<b>Unique identifier</b>	DUSUBJID, EXLSTDY
<b>Sorted by</b>	DUSUBJID, EXLSTDY
<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: MEDENDT, MEDSTDT, EXFRSDT, EXLSTDT, RFENDT, RFSTDT, IVNAME, SEXC, SEX, RACE, RACE, COUNTRYC, COUNTRY, RISTDT, DBSTDT, RIENDT, DBENDT, AGE, REGION, REGIONC, OLSTDT, OLENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
STUDYID	char	Study Id		Collected at CRF.
PHASENUM	num	Phase Number		Collected at CRF.
EXMAX	num	Maximum Dose (days on/off drug)		Collected at CRF.
EXMAXB	num	Maximum Dose (days on drug only)		Collected at CRF.
EXMEAN	num	Mean Dose (days on/off drug)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXMEANB	num	Mean Dose (days on drug only)		Collected at CRF.
EXMIN	num	Minimum Dose (days on/off drug)		Collected at CRF.
EXMINB	num	Minimum Dose (days on drug only)		Collected at CRF.
EXMODE	num	Mode Dose (days on/off drug)		Collected at CRF.
EXMODEB	num	Mode Dose (days on drug only)		Collected at CRF.
EXTOTDUR	num	Total Duration, Days		Collected at CRF.
EXTRTDUR	num	Treatment Duration, Days		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
ACTTRT	char	Drug/Therapy		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.



Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
DSOLC	num	Continue into Open Label Code		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE). Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT - REF.DATE) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDY and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDY less than REF.DATE then (MEDSTDY - REF.DATE). Else if MEDSTDY is greater than equal to REF.DATE then (MEDSTDY - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
EXFRSDY	num	Relative Start Day of Exposure		If EXFRSDT and REF.DATE not missing then perform below logic to calculate EXFRSDY, If EXFRSDT less than REF.DATE then (EXFRSDT - REF.DATE). Else if EXFRSDT is greater than equal to REF.DATE then (EXFRSDT - REF.DATE) +1.
EXLSTDY	num	Relative End Day of Exposure		If EXLSTDY and REF.DATE not missing then perform below logic to calculate EXLSTDY, If EXLSTDY less than REF.DATE then (EXLSTDY - REF.DATE). Else if EXLSTDY is greater than equal to REF.DATE then (EXLSTDY - REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY - REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

## 1.4.16. Study Medication Summary – KEXPOSSM

<b>Dataset</b>	KEXPOSSM
<b>Creating program</b>	kexpossm.sas
<b>Description</b>	Study Medication Summary
<b>Unique identifier</b>	DUSUBJID,EXLSTDY
<b>Sorted by</b>	DUSUBJID,EXLSTDY
<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: MEDENDT, MEDSTDT, EXFRSDT, EXLSTDT, RFENDT, RFSTDT, IVNAME, SEXC, SEX, RACE, RACE, COUNTRYC, COUNTRY, RISTDT, DBSTDT, RIENDT, DBENDT, AGE, REGION, REGIONC, OLSTDT, OLENDT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
STUDYID	char	Study Id		Collected at CRF.
EXMAX	num	Maximum Dose (days on/off drug)		Collected at CRF.
EXMAXB	num	Maximum Dose (days on drug only)		Collected at CRF.
EXMEAN	num	Mean Dose (days on/off drug)		Collected at CRF.
EXMEANB	num	Mean Dose (days on drug only)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXMIN	num	Minimum Dose (days on/off drug)		Collected at CRF.
EXMINB	num	Minimum Dose (days on drug only)		Collected at CRF.
EXMODE	num	Mode Dose (days on/off drug)		Collected at CRF.
EXMODEB	num	Mode Dose (days on drug only)		Collected at CRF.
EXTOTDUR	num	Total Duration, Days		Collected at CRF.
EXTRTDUR	num	Treatment Duration, Days		Collected at CRF.
ACTTRT	char	Drug/Therapy		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
SMMEAN	num	Mean Dose (days on/off drug)		Collected at CRF.
MEDENDY	num	Relative Last Medication Day		If MEDENDT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDT less than REF.DATE then (MEDENDT - REF.DATE). Else if MEDENDT is greater than equal to REF.DATE then (MEDENDT- REF.DATE) +1.
MEDSTDY	num	Relative First Medication Day		If MEDSTDY and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDY less than REF.DATE then (MEDSTDY - REF.DATE). Else if MEDSTDY is greater than equal to REF.DATE then (MEDSTDY- REF.DATE) +1.
EXFRSDY	num	Relative Actual Start Day of Medication		If EXFRSDY and REF.DATE not missing then perform below logic to calculate EXFRSDY, If EXFRSDY less than REF.DATE then (EXFRSDY - REF.DATE). Else if EXFRSDY is greater than equal to REF.DATE then (EXFRSDY- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
EXLSTDY	num	Relative Actual End Day of Medication		If EXLSTDT and REF.DATE not missing then perform below logic to calculate EXLSTDY, If EXLSTDT less than REF.DATE then (EXLSTDT - REF.DATE). Else if EXLSTDT is greater than equal to REF.DATE then (EXLSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.



## 1.4.17. Family History – KFAMHIST

<b>Dataset</b>	KFAMHIST
<b>Creating program</b>	kfamhist.sas
<b>Description</b>	Family History
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>PAGNUM, FFACTDT, RFENDT, RFSTDT, IVNAME, SEXC, SEX, RACEC, RACE, COUNTRYC, COUNTRY, RISTDT, SBSTDT, DBSTDT, RIENDT, SBENDT, DBENDT, AGE, REGION, REGIONC, OLSTDT, OLENDT</p>

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
FHHISTC	num	Relatives History of Diabetes Code		Collected at CRF.
FHHIST	char	Relatives History of Diabetes		Collected at CRF.
FHMEM	char	Family Member		Collected at CRF.
FHDTYPE	char	Diabetes Types		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		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.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT - REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

## 1.4.18. Smoking History – KHABIT

<b>Dataset</b>	KHABIT
<b>Creating program</b>	khabit.sas
<b>Description</b>	Smoking History
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>PAGNUM, HAENDTC, HAACDT, RFENDT, RFSTDT, IVNAME, SEXC, SEX, RACEC, RACE, COUNTRYC, COUNTRY, RISTDT, SBSTDT, DBSTDT, RIENDT, SBENDT, DBENDT, AGE, REGION, REGIONC, OLSTDT, OLENDT</p>

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
HASMOCUC	num	Does Subject Currently Smoke Code		Collected at CRF.
HASMOCU	char	Does Subject Currently Smoke		Collected at CRF.
HACGTNUM	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.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
HAENDY	num	Relative Stop Day of Smoking		If HAENDTC and REF.DATE not missing then perform below logic to calculate HAENDY, If HAENDTC less than REF.DATE then (HAENDTC - REF.DATE). Else if HAENDTC is greater than equal to REF.DATE then (HAENDTC - REF.DATE) +1.
HAACTDY	num	Relative Actual Day of Collection		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.



Variable	Type	Label	Codes	Comments
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

## 1.4.19. Hospitalization – KHOSP

<b>Dataset</b>	KHOSP
<b>Creating program</b>	khosp.sas
<b>Description</b>	Hospitalization
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>PAGNUM,HOSTDT,HOENDT,RFENDT,RFSTDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RISTDT,SBSTDT,DBSTDT,RIENDT,SBENDT,DBENDT,AGE,REGION,REGIONC,OLSTDT,OLENDT</p>

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
HODISCHC	num	Was the Subject Discharged Code		Collected at CRF.
HODISCH	char	Was the Subject Discharged		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
HOSTDY	num	Relative Admission Day of Hosp		If HOSTDT and REF.DATE not missing then perform below logic to calculate HOSTDY, If HOSTDT less than REF.DATE then (HOSTDT - REF.DATE). Else if HOSTDT is greater than equal to REF.DATE then (HOSTDT- REF.DATE) +1.
HOENDY	num	Relative Discharge Day		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.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT - REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT - REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

### 1.4.20. Laboratory Data – KLABS

<b>Dataset</b>	KLABS
<b>Creating program</b>	klabs.sas
<b>Description</b>	Laboratory Data
<b>Unique identifier</b>	DUSUBJID, LBTESTC, LBACTDY, VISITNUM, LBSEQ
<b>Sorted by</b>	DUSUBJID, LBTESTC, LBACTDY, VISITNUM, LBSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values:</p> <p>ARFENDT, ARFSTD, RFENDT, RFSTD, LBPRVIDC, LBPRVID, LBACTDT, LBREF, LBFASTC, LBFAST, RISTDT, SBSTD, DBSTD, DBENDT, OLSTD, OLENDT, IVNAME, SEXC, SEX, RACEC, RACE, COUNTRYC, COUNTRY, RIENDT, SBENDT, AGE, REGION, REGIONC, OLFG, DBFG, DBASE, DBASE2, DBASE3</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
LBTESTC	num	Lab Test Code		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.



Variable	Type	Label	Codes	Comments
APHASEC	num	Analysis Phase Code		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
LBMAFLAG	char	Markedly Abnormal Flag		Collected at CRF.
LBRELDY	num	Relative Day		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
LBTMLBL	char	Pre-determined collection times		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
LBSEQ	num	RSM unique record id within protocol		Collected at CRF.
LBACTTM	num	Actual Time of Lab Sample		Collected at CRF.
LBVTYPEC	num	Lab Visit Type Code		Collected at CRF.
LBVTYPE	char	Lab Visit Type		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBDESCR	char	Full Test Description		Collected at CRF.
LBABBR	char	Lab Abbreviation		Collected at CRF.
ORGNRHI	num	Upper limit for the lab normal range		Collected at CRF.
ORGNRLO	num	Lower limit for the lab normal range		Collected at CRF.
ORGRES	char	Character lab result		Collected at CRF.
ORGRESN	num	Numeric lab result		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
NRIND	char	High/Low Lab Value Flag		Collected at CRF.
STDNRLO	num	S.I. lower limit		Collected at CRF.
STDRESN	num	S.I. numeric result		Collected at CRF.
STDNRHI	num	S.I. upper limit		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
LAGE	char	Age: time of visit		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
LAGEUNIT	char	Age Unit (M or Y)		Collected at CRF.
LBPTM	num	Planned Collection Time		Collected at CRF.
LBTYPE	char	Lab Type		Collected at CRF.
LBTYPEC	num	Lab Type Code		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBCVRES	num	Result in Conventional Units		Collected at CRF.
LBCVUNIT	char	Conventional Units		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.

Variable	Type	Label	Codes	Comments
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		Collected at CRF.
LBSIGLO	num	Clinically Significant Low in STD Unit		Collected at CRF.
LBSIGHI	num	Clinically Significant High in STD Unit		Collected at CRF.
LBSIGIND	char	Clinically Significant Indicator		Collected at CRF.
LBMAFLG2	char	Markedly Abnormal Flag (Base OL)		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBMAFLG3	char	Markedly Abnormal Flag (Base RI)		Collected at CRF.
TENRIND	char	TE Normal Range Indicator (DB)		Collected at CRF.
TENRIND2	char	TE Normal Range Indicator (OL)		Collected at CRF.
TENRIND3	char	TE Normal Range Indicator (RI)		Collected at CRF.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.

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.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDY and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDY less than REF.DATE then (SBSTDY - REF.DATE). Else if SBSTDY is greater than equal to REF.DATE then (SBSTDY - REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDY and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDY less than REF.DATE then (DBSTDY - REF.DATE). Else if DBSTDY is greater than equal to REF.DATE then (DBSTDY - REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDY and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDY less than REF.DATE then (DBENDY - REF.DATE). Else if DBENDY is greater than equal to REF.DATE then (DBENDY - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.

### 1.4.21. Lab Markedly Abnormal Low/High – KLBSIGRG

<b>Dataset</b>	KLBSIGRG
<b>Creating program</b>	klbsigr.g.sas
<b>Description</b>	Lab Markedly Abnormal Low/High
<b>Unique identifier</b>	LBTESTC,PARAM
<b>Sorted by</b>	LBTESTC,PARAM
<b>Notes</b>	Below listed variables will be dropped from dataset due to repetition of the information: SEX

Variable	Type	Label	Codes	Comments
LBTEST	char	Lab Test Name		Collected at CRF.
LBTESTC	num	Lab Test Code		Collected at CRF.
UNIT	char	SAP Specified Unit		Collected at CRF.
OLBSIGLO	char	SAP Specified Clinically Significant Low		Collected at CRF.
OLBSIGHI	char	SAP Specified Clinically Signi High		Collected at CRF.
ORGUNIT	char	Original Units		Collected at CRF.
STDUNIT	char	Standard Units		Collected at CRF.
LBSIFACT	num	Std. Intl. Conversion Factor		Collected at CRF.



Variable	Type	Label	Codes	Comments
PARAM	char	Laboratory Parameter		Collected at CRF.
STDCFACT	num	Derived Conversion Factor		Collected at CRF.
LBSIGLO	char	Clinically Significant Low in STD Unit		Collected at CRF.
LBSIGHI	char	Clinically Significant High in STD Unit		Collected at CRF.

## 1.4.22. Medical History – KMHIST

<b>Dataset</b>	KMHIST
<b>Creating program</b>	kmhist.sas
<b>Description</b>	Medical History
<b>Unique identifier</b>	DUSUBJID,MHBODSYS,VISIT,MHSEQ
<b>Sorted by</b>	DUSUBJID,MHBODSYS,VISIT,MHSEQ
<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 or due to non significant elements:  PAGNUM,MHTERM,MHACTDT,RFENDT,RFSTDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RISTDT,SBSTDT,DBSTDT,RIENDT,SBENDT,DBENDT,AGE,REGION,REGIONC,OLSTDT,OLENDT

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.
VISITNUM	num	Visit Id		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity

Variable	Type	Label	Codes	Comments
PHASE	char	Phase		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
MHSEQ	num	MH Sequence Number		Collected at CRF.
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.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		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.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT - REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

## 1.4.23. Positive and Negative Syndrome Scale – KPANSS

<b>Dataset</b>	KPANSS
<b>Creating program</b>	kpanss.sas
<b>Description</b>	Positive and Negative Syndrome Scale
<b>Unique identifier</b>	DUSUBJID,PARAMC,PAITEM,VISIT
<b>Sorted by</b>	DUSUBJID,PARAMC,PAITEM,VISIT
<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 or due to non significant elements or due to missing values:  PAGNUM,PARATERI,PAACTDT,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
PARELDY	num	PANSS Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PAGROUP	char	PANSS Group		Collected at CRF.
PAITEM	char	PANSS Item		Collected at CRF.
PASCOREC	num	PANSS Score Code		Collected at CRF.
PASCORE	char	PANSS Score		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ZPAITEM	char	PANSS Item Code		Collected at CRF.
IMPUTE	char	PANSS Score Impute Flag		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.



Variable	Type	Label	Codes	Comments
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		Collected at CRF.
DRVPCHNG	num	Derived Percent Change for Total PANSS		Collected at CRF.
PAACTDY	num	Relative Actual Day of PANSS		If PAACTDT and REF.DATE not missing then perform below logic to calculate PAACTDY, If PAACTDT less than REF.DATE then (PAACTDT - REF.DATE). Else if PAACTDT is greater than equal to REF.DATE then (PAACTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

## 1.4.24. Physical Examination – KPE

<b>Dataset</b>	KPE
<b>Creating program</b>	kpe.sas
<b>Description</b>	Physical Examination
<b>Unique identifier</b>	DUSUBJID,PARAM,PEBODSYS,VISIT,PEACTDY,PESEQ
<b>Sorted by</b>	DUSUBJID,PARAM,PEBODSYS,VISIT,PEACTDY,PESEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>ARFENDT,ARFSTDT,RFENDT,RFSTDT,PAGNUM,PEFIND,PEACTDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAM	char	Parameter		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERELDY	num	Relative Day		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PESEQ	num	Phys Sequence Number		Collected at CRF.
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.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.

Variable	Type	Label	Codes	Comments
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDY and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDY less than REF.DATE then (ARFSTDY - REF.DATE). Else if ARFSTDY is greater than equal to REF.DATE then (ARFSTDY - REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDY and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDY less than REF.DATE then (RFENDY - REF.DATE). Else if RFENDY is greater than equal to REF.DATE then (RFENDY - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY - REF.DATE) +1.
PEACTDY	num	Relative Actual Day of Phys Exam		If PEACTION and REF.DATE not missing then perform below logic to calculate PEACTION, If PEACTION less than REF.DATE then (PEACTION - REF.DATE). Else if PEACTION is greater than equal to REF.DATE then (PEACTION - REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDY and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDY less than REF.DATE then (RISTDY - REF.DATE). Else if RISTDY is greater than equal to REF.DATE then (RISTDY - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

## 1.4.25. Protocol Description – KPROTDES

<b>Dataset</b>	KPROTDES
<b>Creating program</b>	kprotdes.sas
<b>Description</b>	Protocol Description
<b>Unique identifier</b>	STUDYID
<b>Sorted by</b>	STUDYID
<b>Notes</b>	Below listed variables will be dropped from dataset due to missing values: SPECPOP

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

Variable	Type	Label	Codes	Comments
AGEGRP	char	Age Group		Collected at CRF.
SUBJTYPE	char	Subject Type		Collected at CRF.
PROCSTUD	char	Proceeding Study Id		Collected at CRF.
STUDPHAS	char	Phase of Study		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.

## 1.4.26. Protocol Deviation – KPROTDEV

<b>Dataset</b>	KPROTDEV
<b>Creating program</b>	kprotdev.sas
<b>Description</b>	Protocol Deviation
<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 or due to repetition of the information: PVTERM,RFENDT,RFSTDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNT RY,RISTDT,SBSTDT,DBSTDT,RIENDT,SBENDT,DBENDT,AGE,REGION,REGIONC, OLSTDT,OLENDT

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

Variable	Type	Label	Codes	Comments
PVSEQ	num	Protocol Deviation Seq Number		Collected at CRF.
PVDECOD	char	Protocol Deviation Coded Term		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

### 1.4.27. Personal and Social Performance Scale – KPSP

<b>Dataset</b>	KPSP
<b>Creating program</b>	kpsp.sas
<b>Description</b>	Personal and Social Performance Scale
<b>Unique identifier</b>	DUSUBJID,PARAM,PSPITEM,PSACTDY,VISIT
<b>Sorted by</b>	DUSUBJID,PARAM,PSPITEM,PSACTDY,VISIT
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PSRATERI,PAGNUM,PSACTDT,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
PSRELDY	num	PSP Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PSSCORE	num	PSP Score		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
PSPITEM	char	PSP Item		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.

Variable	Type	Label	Codes	Comments
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
PSACTDY	num	Relative Actual Day of PSP		If PSACTDT and REF.DATE not missing then perform below logic to calculate PSACTDY, If PSACTDT less than REF.DATE then (PSACTDT - REF.DATE). Else if PSACTDT is greater than equal to REF.DATE then (PSACTDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT - REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT - REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.

### 1.4.28. Psychosis History – KPSYHIST

<b>Dataset</b>	KPSYHIST
<b>Creating program</b>	kpsyhist.sas
<b>Description</b>	Psychosis History
<b>Unique identifier</b>	DUSUBJID,VISIT,PYSEQ
<b>Sorted by</b>	DUSUBJID,VISIT,PYSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:</p> <p>PAGNUM,PYEPIDTC,PYEPIDT,PYSTDT,PYSTDTTC,PYENDTC,PYENDT,DMSCRDT,R FENDT,RFSTDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RISTDT, SBSTDT,DBSTDT,RIENDT,SBENDT,DBENDT,AGE,REGION,REGIONC,OLSTDT,OLE NDT</p>

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



Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
PYSEQ	num	Psychiatric History Sequence Number		Collected at CRF.
PYDIAG	char	Diagnosis		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
PHOSPDUR	num	Duration of Recent Hospitalization, days		Collected at CRF.
PHSPDURS	num	Duration of Recent Hosp Prior to Scrn		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
PYEPIDY	num	Relative Day of Last Acute Symptom		If PYEPIDTC and REF.DATE not missing then perform below logic to calculate PYEPIDY, If PYEPIDTC less than REF.DATE then (PYEPIDTC - REF.DATE). Else if PYEPIDTC is greater than equal to REF.DATE then (PYEPIDTC - REF.DATE) +1.
PYSTDY	num	Relative Start Day of Psychosis Trt		If PYSTDTC and REF.DATE not missing then perform below logic to calculate PYSTDY, If PYSTDTC less than REF.DATE then (PYSTDTC - REF.DATE). Else if PYSTDTC is greater than equal to REF.DATE then (PYSTDTC - REF.DATE) +1.
PYENDY	num	Relative End Day of Psychosis Treatment		If PYENDTC and REF.DATE not missing then perform below logic to calculate PYENDY, If PYENDTC less than REF.DATE then (PYENDTC - REF.DATE). Else if PYENDTC is greater than equal to REF.DATE then (PYENDTC - 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.

Variable	Type	Label	Codes	Comments
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

### 1.4.29. Simpson Angus Scale – KSARS

<b>Dataset</b>	KSARS
<b>Creating program</b>	ksars.sas
<b>Description</b>	Simpson Angus Scale
<b>Unique identifier</b>	DUSUBJID,PARAMC,SRITEM,VISIT,SRACTDY
<b>Sorted by</b>	DUSUBJID,PARAMC,SRITEM,VISIT,SRACTDY
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PAGNUM,SRRATERI,SRACTDT,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
SRRELDY	num	SARS Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		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	Score		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
ZSRITEM	char	Parameter Char. Code		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		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.



Variable	Type	Label	Codes	Comments
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

### 1.4.30. SQLS-R4 Analysis Dataset– KSQLSR4

<b>Dataset</b>	KSQLSR4
<b>Creating program</b>	ksqlsr4.sas
<b>Description</b>	SQLS-R4 Analysis Dataset
<b>Unique identifier</b>	DUSUBJID,PARAMC,SQITEM,VISIT,SQACTDY,SQSEQ
<b>Sorted by</b>	DUSUBJID,PARAMC,SQITEM,VISIT,SQACTDY,SQSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PAGNUM,SQACTDT,SQND,RFSTDT,RFENDT,ARFSTDT,ARFENDT,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
PARAMC	num	Parameter Code		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
SQRELDY	num	SQLSR Relative Day		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SQSEQ	num	SQLSR4 Sequence Number		Collected at CRF.
SQITEM	char	SQLSR4 Item		Collected at CRF.
SQSCOREC	num	Score Code		Collected at CRF.
SQSCORE	char	Score		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.

Variable	Type	Label	Codes	Comments
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.

Variable	Type	Label	Codes	Comments
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		Collected at CRF.
SQACTDY	num	Relative Actual Day of SQLS-R4		If SQACTDT and REF.DATE not missing then perform below logic to calculate SQACTDY, If SQACTDT less than REF.DATE then (SQACTDT - REF.DATE). Else if SQACTDT is greater than equal to REF.DATE then (SQACTDT - REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDT and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDT less than REF.DATE then (ARFSTDT - REF.DATE). Else if ARFSTDT is greater than equal to REF.DATE then (ARFSTDT- REF.DATE) +1.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT - REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT - REF.DATE) +1.

### 1.4.31. Surgery – KSURGERY

<b>Dataset</b>	KSURGERY
<b>Creating program</b>	ksurgery.sas
<b>Description</b>	Surgery
<b>Unique identifier</b>	DUSUBJID
<b>Sorted by</b>	DUSUBJID
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>PAGNUM,SGPLNDT,SGPLNDTC,SGPROC,SGINDIC,RFENDT,RFSTDT,IVNAME,SEX, XC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RISTDT,SBSTDT,DBSTDT,RIENDT,SB ENDT,DBENDT,AGE,REGION,REGIONC,OLSTDT,OLENDT</p>

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

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Id		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
SGREPRTC	num	Are any Surg/Proc. Planned Code		Collected at CRF.
SGREPRT	char	Are any Surg/Proc. Planned		Collected at CRF.
SGSEQ	num	Sequence Number		Collected at CRF.
SGBODSYC	num	Surgery Body System Code		Collected at CRF.
SGBODSYS	char	Surgery Body System		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
OLSAFETY	char	Safety		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		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.
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDY and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDY less than REF.DATE then (RFSTDY - REF.DATE). Else if RFSTDY is greater than equal to REF.DATE then (RFSTDY- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.

### 1.4.32. Unique Subject Treatment – KTREAT

<b>Dataset</b>	KTREAT
<b>Creating program</b>	ktreat.sas
<b>Description</b>	Unique Subject Treatment
<b>Unique identifier</b>	DUSUBJID,TRT
<b>Sorted by</b>	DUSUBJID,TRT
<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: USUBJTRT,IVNAME,SEX,RACE,COUNTRY,RISTDT,SBSTDT,AGE,REGION,REGIONC

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
TRT	char	Assigned Treatment per Phase		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.



Variable	Type	Label	Codes	Comments
TRTGRP	char	Treatment Group		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
TRTGRP2	char	Run-In/Stabilization Treatment		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
SCRNFAIL	char	Screen Failure Subjects		Collected at CRF.
TRTGRP2C	num	Run-In/Stabilization Treatment Code		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.
TRTC	num	Assigned Treatment per Phase Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT - REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDY and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDY less than REF.DATE then (SBSTDY - REF.DATE). Else if SBSTDY is greater than equal to REF.DATE then (SBSTDY - REF.DATE) +1.

### 1.4.33. Vital Signs – KVITAL

<b>Dataset</b>	KVITAL
<b>Creating program</b>	kvital.sas
<b>Description</b>	Vital Signs
<b>Unique identifier</b>	DUSUBJID,VSTESTCD,VISIT,VSACTDY,VSSEQ
<b>Sorted by</b>	DUSUBJID,VSTESTCD,VISIT,VSACTDY,VSSEQ
<b>Notes</b>	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values:</p> <p>VSACTDT,ARFENDT,ARFSTDT,RFENDT,RFSTDT,PAGNUM,RISTDT,SBSTDT,DBSTDT,DBENDT,OLSTDT,OLENDT,IVNAME,SEXC,SEX,RACEC,RACE,COUNTRYC,COUNTRY,RIENDT,SBENDT,AGE,REGION,REGIONC,OLFG,DBFG</p>

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject Id Assign for De-identity		Randomly assigned Unique Subject Id for De-identity
VISITNUM	num	Visit Id		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
PARAMC	num	Parameter Code		Collected at CRF.
PARAM	char	Parameter		Collected at CRF.
VSTEST	char	Vital Signs Test Name		Collected at CRF.
VSTESTCD	char	Vital Signs Test Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSORRESN	num	Numeric Result in Original Units		Collected at CRF.
VSSTRESN	num	Numeric Result in Standard Units		Collected at CRF.
VSORUNIT	char	Numeric Result in Original Units		Collected at CRF.
VSSTUNIT	char	Standard Units		Collected at CRF.
VALUE	num	Numeric Value		Collected at CRF.
DVALUE	char	Character Value		Collected at CRF.
APHASE	char	Analysis Phase		Collected at CRF.
APHASEC	num	Analysis Phase Code		Collected at CRF.
VSRELDY	num	Relative Day		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.
DSUBJID	char	Subject Number Assigned for De-identity		Randomly assigned Subject Number for De-identity
DSITEID	char	Site Assigned for De-identity		Randomly assigned Site for De-identity
PHASENUM	num	Phase Number		Collected at CRF.
PHASE	char	Phase		Collected at CRF.
VISIT	char	Visit		Collected at CRF.
VSSEQ	num	Vital Signs Sequence Number		Collected at CRF.
VSVTYPEC	num	Vital Signs Visit Type Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSVTYPE	char	Vital Signs Visit Type		Collected at CRF.
VSPOS	char	Position		Collected at CRF.
STUDYIND	char	Indication		Collected at CRF.
STUDYTYP	char	Study Type		Collected at CRF.
SAFETY	char	Safety		Collected at CRF.
RITRT	char	All Treated		Collected at CRF.
OLSAFETY	char	Safety		Collected at CRF.
ALLRAND	char	All Randomized Subjects		Collected at CRF.
ITT	char	Intent-to-Treat		Collected at CRF.
ARM	char	Treatment Arm		Collected at CRF.
PTRTGRP	char	Previous Treatment Group		Collected at CRF.
TRTGRP	char	Treatment Group		Collected at CRF.
DSOL	char	Continue into Open Label		Collected at CRF.
PTRTGRPC	num	Previous Treatment Group Code		Collected at CRF.
ARMC	num	Treatment Arm Code		Collected at CRF.
OLITT	char	Intent-to-Treat		Collected at CRF.
OLNODB	char	OL subjects w/o DB treatment		Collected at CRF.
TRTGRPC	num	Treatment Group Code		Collected at CRF.
SMDUR	num	Total Duration of Study Medication (Day)		Collected at CRF.

Variable	Type	Label	Codes	Comments
RESETFG	char	Record Reslote to Previous Phase		Collected at CRF.
DBBASEFG	char	BASE (DB) from STAB (END)		Collected at CRF.
OLBASEFG	char	BASE (OPEN) from DB (END)		Collected at CRF.
BASE	num	Value at Baseline(db)		Collected at CRF.
DBASE	char	Character Value at Baseline(db)		Collected at CRF.
CHANGE	num	Change from Baseline(db)		Collected at CRF.
PCHANGE	num	Percent Change from Baseline(db)		Collected at CRF.
BASE2	num	Value at Base(open)		Collected at CRF.
DBASE2	char	Character Value at Base(open)		Collected at CRF.
CHANGE2	num	Change from Base(open)		Collected at CRF.
PCHANGE2	num	Percent Change from Base(open)		Collected at CRF.
BASE3	num	Value at Baseline(run-in)		Collected at CRF.
DBASE3	char	Character Value at Baseline(run-in)		Collected at CRF.
CHANGE3	num	Change from Baseline(run-in)		Collected at CRF.
PCHANGE3	num	Percent Change from Baseline(run-in)		Collected at CRF.
VSSIGLO	num	Vital Sign Significant Range Low		Collected at CRF.

Variable	Type	Label	Codes	Comments
VSSIGHI	num	Vital Sign Significant Range High		Collected at CRF.
VSSIGIND	char	Vital Sign Sig. N/L/H Indicator (DB)		Collected at CRF.
VSSIGIN2	char	Vital Sign Sig. N/L/H Indicator (OL)		Collected at CRF.
VSSIGIN3	char	Vital Sign Sig. N/L/H Indicator (RI)		Collected at CRF.
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.
ARFENDY	num	Relative Analysis Reference End Day		If ARFENDT and REF.DATE not missing then perform below logic to calculate ARFENDY, If ARFENDT less than REF.DATE then (ARFENDT - REF.DATE). Else if ARFENDT is greater than equal to REF.DATE then (ARFENDT - REF.DATE) +1.
ARFSTDY	num	Relative Analysis Reference Start Day		If ARFSTDY and REF.DATE not missing then perform below logic to calculate ARFSTDY, If ARFSTDY less than REF.DATE then (ARFSTDY - REF.DATE). Else if ARFSTDY is greater than equal to REF.DATE then (ARFSTDY - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
RFENDY	num	Relative Reference End Day		If RFENDT and REF.DATE not missing then perform below logic to calculate RFENDY, If RFENDT less than REF.DATE then (RFENDT - REF.DATE). Else if RFENDT is greater than equal to REF.DATE then (RFENDT- REF.DATE) +1.
RFSTDY	num	Relative Reference Start Day		If RFSTDT and REF.DATE not missing then perform below logic to calculate RFSTDY, If RFSTDT less than REF.DATE then (RFSTDT - REF.DATE). Else if RFSTDT is greater than equal to REF.DATE then (RFSTDT- REF.DATE) +1.
RISTDY	num	Relative Reference Start Day (RI)		If RISTDT and REF.DATE not missing then perform below logic to calculate RISTDY, If RISTDT less than REF.DATE then (RISTDT - REF.DATE). Else if RISTDT is greater than equal to REF.DATE then (RISTDT- REF.DATE) +1.
SBSTDY	num	Relative Reference Start Day (SB)		If SBSTDT and REF.DATE not missing then perform below logic to calculate SBSTDY, If SBSTDT less than REF.DATE then (SBSTDT - REF.DATE). Else if SBSTDT is greater than equal to REF.DATE then (SBSTDT- REF.DATE) +1.
DBSTDY	num	Relative Reference Start Day (DB)		If DBSTDT and REF.DATE not missing then perform below logic to calculate DBSTDY, If DBSTDT less than REF.DATE then (DBSTDT - REF.DATE). Else if DBSTDT is greater than equal to REF.DATE then (DBSTDT- REF.DATE) +1.



Variable	Type	Label	Codes	Comments
DBENDY	num	Relative Reference End Day (DB)		If DBENDT and REF.DATE not missing then perform below logic to calculate DBENDY, If DBENDT less than REF.DATE then (DBENDT - REF.DATE). Else if DBENDT is greater than equal to REF.DATE then (DBENDT- REF.DATE) +1.
OLSTDY	num	Relative Reference Start Day (OL)		If OLSTDT and REF.DATE not missing then perform below logic to calculate OLSTDY, If OLSTDT less than REF.DATE then (OLSTDT - REF.DATE). Else if OLSTDT is greater than equal to REF.DATE then (OLSTDT- REF.DATE) +1.
OLENDY	num	Relative Reference End Day (OL)		If OLENDT and REF.DATE not missing then perform below logic to calculate OLENDY, If OLENDT less than REF.DATE then (OLENDT - REF.DATE). Else if OLENDT is greater than equal to REF.DATE then (OLENDT- REF.DATE) +1.
RIENDY	num	Relative Reference End Day (RI)		If RIENDT and REF.DATE not missing then perform below logic to calculate RIENDY, If RIENDT less than REF.DATE then (RIENDT - REF.DATE). Else if RIENDT is greater than equal to REF.DATE then (RIENDT- REF.DATE) +1.
SBENDY	num	Relative Reference End Day (SB)		If SBENDT and REF.DATE not missing then perform below logic to calculate SBENDY, If SBENDT less than REF.DATE then (SBENDT - REF.DATE). Else if SBENDT is greater than equal to REF.DATE then (SBENDT- REF.DATE) +1.

## 1.4.34. Analysis Window – KWINDOW

<b>Dataset</b>	KWINDOW
<b>Creating program</b>	kwindow.sas
<b>Description</b>	Analysis Window
<b>Unique identifier</b>	APHASE,WINDOW
<b>Sorted by</b>	APHASE,WINDOW
<b>Notes</b>	

Variable	Type	Label	Codes	Comments
APHASE	char	Analysis Phase		Collected at CRF.
WINREF	num	Target Time Value		Collected at CRF.
WINUNIT	char	Time Interval Unit		Collected at CRF.
WINDOW	char	Time Interval		Collected at CRF.
WINDOWC	num	Time Interval Code		Collected at CRF.
WINLOWER	num	Lower Limit of Time Interval		Collected at CRF.
WINUPPER	num	Upper Limit of Time Interval		Collected at CRF.
DATASET	char	Analysis Data Set		Collected at CRF.
STUDYID	char	Study Id		Collected at CRF.