Clinical Development

JNJ-17080102

YP

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	20 JAN 2017

Table of contents

Clinical Development 1
1. Datasets 6
1.1. Specifications Introduction 6
1.2. Guidelines for Preparing Data 6
1.3. Data Files 7
1.4. Data Domains 8
1.4.1. DEMOGRAPHIC - DEMOG 8
1.4.2. ADVEDTL - ADVEDTL 10
1.4.3. ADVEDUR - ADVEDUR 12
1.4.4. ADVEHDR - ADVEHDR 14
1.4.5. AGES - AGES 15
1.4.6. ANTIEHDR - ANTIEHDR 17
1.4.7. ANTIEPLP - ANTIEPLP 18
1.4.8. ASSIGN - ASSIGN 21
1.4.9. COMMENT - COMMENT 22
1.4.10. COMPDTL - COMPDTL 23
1.4.11. COMPHDR - COMPHDR 25
1.4.12. CURMDTL - CURMDTL 27
1.4.13. CURMHDR - CURMHDR 29
1.4.14. DAILYDOS - DAILYDOS 30
1.4.15. DC_DRUG - DC_DRUG 32
1.4.16. DOSESUM - DOSESUM 33
1.4.17. ECG - ECG 36
1.4.18. EVN_DEFN - EVN_DEFN 38
1.4.19. GLKTEST - GLKTEST 39
1.4.20. GLOBEVAL - GLOBEVAL 42
1.4.21. KEYADVE - KEYADVE 44
1.4.22. KEYANTI - KEYANTI 47
1.4.23. KEYCOMP - KEYCOMP 49
1.4.24. KEYCURM - KEYCURM 51
1.4.25. KEYDATES - KEYDATES 54

1.4.26. KEYDOSE - KEYDOSE 57
1.4.27. KEYECG - KEYECG 60
1.4.28. KEYEFF - KEYEFF 64
1.4.29. KEYEFF28 - KEYEFF28 70
1.4.30. KEYEFF_1 - KEYEFF_1 76
1.4.31. KEYEFF_A - KEYEFF_A 81
1.4.32. KEYGLOB - KEYGLOB 87
1.4.33. KEYLAB1 - KEYLAB1 89
1.4.34. KEYNEURO - KEYNEURO 92
1.4.35. KEYOPEN - KEYOPEN 96
1.4.36. KEYPHYS - KEYPHYS 97
1.4.37. KEYPLAS - KEYPLAS 99
1.4.38. KEYPLASM - KEYPLASM 104
1.4.39. KEYVIT1 - KEYVIT1 107
1.4.40. KEYVIT2 - KEYVIT2 111
1.4.41. LABNORM - LABNORM 115
1.4.42. LABS - LABS 116
1.4.43. MARKL - MARKL 118
1.4.44. MHIST - MHIST 119
1.4.45. MHIST1 - MHIST1 121
1.4.46. MISSSING - MISSSING 122
1.4.47. NEUREXAM - NEUREXAM 124
1.4.48. PAT_INFO - PAT_INFO 128
1.4.49. PERSYRS - PERSYRS 129
1.4.50. PHYS - PHYS 130
1.4.51. PLASMA - PLASMA 132
1.4.52. PLASMACO - PLASMACO 133
1.4.53. PLPLOT - PLPLOT 135
1.4.54. PREREP - PREREP 136
1.4.55. PROFILE - PROFILE 137
1.4.56. PROTOCOL - PROTOCOL 142
1.4.57. RANDOM - RANDOM 144
1.4.58. REGIMEN - REGIMEN 145

1.4.59. ROSS - ROSS 147
1.4.60. SEIZHIST - SEIZHIST 148
1.4.61. SMED - SMED 150
1.4.62. SMEDVW - SMEDVW 152
1.4.63. TOPPLAS - TOPPLAS 153
1.4.64. VITALS - VITALS 156
1.4.65. VITALSVW - VITALSVW 158
1.4.66. VTL - VTL 160
1.4.67. WEEKSEIZ - WEEKSEIZ 163
1.4.68. YPAE - YPAE 165
1.4.69. YPAED - YPAED 166
1.4.70. YPDBSUM - YPDBSUM 167
1.4.71. YPMARKL - YPMARKL 168
1.4.72. YPMFLAG - YPMFLAG 169
1.4.73. YPNORMS - YPNORMS 170

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Comment dataset will be submitted with zero observations.
- Dataset containing investigator information is sensitive and hence will not be submitted. (e.g. INVNAM).
- EVDATE in DEMOG will be used as Reference Date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files

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

1.4. Data Domains

1.4.1. DEMOGRAPHIC - DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	DEMOGRAPHIC
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,EVDATE,EVDAT,BIRTHDT,BIRTHD,TUPID,REC_NUM,RACESPEC Below listed variables were not a part of the Raw dataset. These have been added to retain the Age, Sex, Race related information and Site ID information in the de-identified datasets: DSITEID (Source: INVNAM.INO) AGE (Source: AGES.AGE) RACE (Source: PROFILE. RACEF) SEX (Source: PROFILE.SEXF)

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Group element to protect PII.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
SEX	num	C_SEX		Collected at CRF.
RACE	num	C_RACE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
AGE	char	AGE		Element will be grouped to protect subject PII as per HIPPA rules: If age is greater than 89 then "90+".
DSITEID	char	SITE ID ASSIGNED FOR DE-IDENTITY		Randomly assigned site ID for De-Identity
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.2.ADVEDTL - ADVEDTL

Dataset	ADVEDTL
Creating program	advedtl.sas
Description	ADVEDTL
Unique identifier	DPATNO,ENTRYNO,ADVCODE,PHASE,STOPDY,OUTCOME,ONSETDY
Sorted by	DPATNO,ENTRYNO,ADVCODE,PHASE,STOPDY,OUTCOME,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,VERBATIM,ADVDESC2,ONSETD,ONSETDT,TONSET,STOPD, STOPDT,STOPTIME,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVCODE	char	C_ADVCODE		Collected at CRF.
ADVDESC	char	C_ADVDESC		Collected at CRF.
ADVCODE2	char	C_ADVCODE2		Collected at CRF.
SEVERITY	num	C_SEVERITY		Collected at CRF.
SERIOUS	num	C_SERIOUS		Collected at CRF.
DRUGREL	num	C_DRUGREL		Collected at CRF.
ACTION	num	C_ACTION		Collected at CRF.
CONCOM	num	C_CONCOM		Collected at CRF.
OUTCOME	num	C_OUTCOME		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
ONSETDY	num	RELATIVE C_ONSET DAY		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
STOPDY	num	RELATIVE C_STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.3.ADVEDUR - ADVEDUR

Dataset	ADVEDUR
Creating program	advedur.sas
Description	ADVEDUR
Unique identifier	DPATNO,EVENT_ID,ENTRYNO,ADVCODE,ONSETDY
Sorted by	DPATNO,EVENT_ID,ENTRYNO,ADVCODE,ONSETDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: VERBATIM,ONSETDT,TONSET,STOPDT,STOPTIME

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ADVEXP	num	ADVEXP		Collected at CRF.
PHASE	num	PHASE		Collected at CRF.
ENTRYNO	num	ENTRYNO		Collected at CRF.
ADVCODE	char	ADVCODE		Collected at CRF.
ADVDESC	char	ADVDESC		Collected at CRF.
SEVERITY	num	SEVERITY		Collected at CRF.

Variable	Type	Label	Codes	Comments
SERIOUS	num	SERIOUS		Collected at CRF.
DRUGREL	num	DRUGREL		Collected at CRF.
ACTION	num	ACTION		Collected at CRF.
CONCOM	num	CONCOM		Collected at CRF.
OUTCOME	num	OUTCOME		Collected at CRF.
DURATION	num	DURATION		Collected at CRF.
ONSETDY	num	RELATIVE ONSET DAY		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
STOPDY	num	RELATIVE STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.4.ADVEHDR - ADVEHDR

Dataset	ADVEHDR
Creating program	advehdr.sas
Description	ADVEHDR
Unique identifier	DPATNO,EVENT_ID,ADVEXP
Sorted by	DPATNO,EVENT_ID,ADVEXP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ADVEXP	num	C_ADVEXP		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.5.AGES - AGES

Dataset	AGES
Creating program	ages.sas
Description	AGES
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,EVDATE,BIRTHDT,SEX,RACE,RACESPEC

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
AGE	char	AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.6.ANTIEHDR - ANTIEHDR

Dataset	ANTIEHDR
Creating program	antiehdr.sas
Description	ANTIEHDR
Unique identifier	DPATNO,EVENT_ID,AED
Sorted by	DPATNO,EVENT_ID,AED
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
AED	num	AED		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.7.ANTIEPLP - ANTIEPLP

Dataset	ANTIEPLP
Creating program	antieplp.sas
Description	ANTIEPLP
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,VERBATIM,DRUGDESC,DRUGCOD2,DRUGDES2, STARTD,STARTDT,STOPD,STOPDT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity

Variable	Type	Label	Codes	Comments
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
DRUGCODE	char	C_DRUGCODE		Collected at CRF.
CONT	num	C_CONT		Collected at CRF.
TOTDOSE	char	C_TOTDOSE		Collected at CRF.
PRN	char	C_PRN		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STARTDY	num	RELATIVE C_START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE C_STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.8.ASSIGN - ASSIGN

Dataset	ASSIGN
Creating program	assign.sas
Description	ASSIGN
Unique identifier	DPATNO,REGCODE,PNO
Sorted by	DPATNO,REGCODE,PNO
Notes	Below listed variables will be dropped from dataset due to repetition of the information or due to missing values: SCTRY,PERIOD,SEQUENCE,STRATUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
REGCODE	num	REGCODE		Collected at CRF.
REGIMEN	char	REGIMEN		Collected at CRF.

1.4.9.COMMENT - COMMENT

Dataset	COMMENT
Creating program	comment.sas
Description	COMMENT
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comment dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Empty dataset will be submitted
F_STATUS	char	F_STATUS		Empty dataset will be submitted
DRUG	char	DRUG		Empty dataset will be submitted
TAREA	char	TAREA		Empty dataset will be submitted
PNO	char	PNO		Empty dataset will be submitted
EVENT_ID	char	EVENT_ID		Empty dataset will be submitted
PAG_NAME	char	PAG_NAME		Empty dataset will be submitted
ENTRYNO	num	C_ENTRYNO		Empty dataset will be submitted
MODNAME	char	C_MODNAME		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
PHASE	num	C_PHASE		Empty dataset will be submitted
EVDY	num	RELATIVE C_EVENT DAY		Empty dataset will be submitted

1.4.10. COMPDTL - COMPDTL

Dataset	COMPDTL
Creating program	compdtl.sas
Description	COMPDTL
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,VERBATIM,ADVCODE2,ADVDESC2,TUPID, REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.

Variable	Type	Label	Codes	Comments
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
ADVCODE	char	C_ADVCODE		Collected at CRF.
ADVDESC	char	C_ADVDESC		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.11. COMPHDR - COMPHDR

Dataset	COMPHDR
Creating program	comphdr.sas
Description	COMPHDR
Unique identifier	DPATNO,EVENT_ID,VISNUM
Sorted by	DPATNO,EVENT_ID,VISNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,STATUSD,STATUSDT,OTHRSPEC,DEATHD, DEATHDT,LASTD,LASTDT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
VISNUM	num	C_VISNUM		Collected at CRF.

Variable	Type	Label	Codes	Comments
STATUS	num	C_STATUS		Collected at CRF.
ENTERNXT	num	C_ENTERNXT		Collected at CRF.
REASON	num	C_REASON		Collected at CRF.
DEATH	num	C_DEATH		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
STATUSDY	num	RELATIVE C_STATUS DAY		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
LASTDY	num	RELATIVE C_LAST DAY		If LASTDT and REF.DATE not missing then perform below logic to calculate LASTDY, If LASTDT less than REF.DATE then (LASTDT - REF.DATE). Else if LASTDT is greater than equal to REF.DATE then (LASTDT- REF.DATE) +1.

1.4.12. CURMDTL - CURMDTL

Dataset	CURMDTL
Creating program	curmdtl.sas
Description	CURMDTL
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,VERBATIM,DRUGCOD2,DRUGDES2,STARTD,STARTDT,STOPD, STOPDT,INDICT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUGCODE	char	C_DRUGCODE		Collected at CRF.
DRUGDESC	char	C_DRUGDESC		Collected at CRF.
CONT	num	C_CONT		Collected at CRF.
ROUTE	char	C_ROUTE		Collected at CRF.
TOTDOSE	char	C_TOTDOSE		Collected at CRF.
PRN	char	C_PRN		Collected at CRF.
FORTAE	num	C_FORTAE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
STARTDY	num	RELATIVE C_START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE C_STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.13. CURMHDR - CURMHDR

Dataset	CURMHDR
Creating program	curmhdr.sas
Description	CURMHDR
Unique identifier	DPATNO,EVENT_ID,PHASE
Sorted by	DPATNO,EVENT_ID,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
CONMED	num	C_CONMED		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.14. DAILYDOS - DAILYDOS

Dataset	DAILYDOS
Creating program	dailydos.sas
Description	DAILY DOSAGE
Unique identifier	DPATNO,DAYOFDBT
Sorted by	DPATNO,DAYOFDBT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PERIOD,MEDSTRT,MEDSTOP,STARTDT,STOPDT,SURN,INVNAME,DOSEDATE

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOTDDOSE	num	C_TOTDDOSE		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
DAYOFDBT	num	DAY OF DOUBLE-BLIND THERAPY		Collected at CRF.
PRCTAR	num	PERCENT OF TARGET - DAILY RATE		Collected at CRF.
MGKG	num	MG PER KG - DAILY RATE		Collected at CRF.
REGIMEN	char	REGIMEN		Collected at CRF.
MEDSTRDY	num	RELATIVE DOSE START DAY		If MEDSTRT and REF.DATE not missing then perform below logic to calculate MEDSTRDY, If MEDSTRT less than REF.DATE then (MEDSTRT - REF.DATE). Else if MEDSTRT is greater than equal to REF.DATE then (MEDSTRT- REF.DATE) +1.
MEDSTPDY	num	RELATIVE DOSE STOP DAY		If MEDSTOP and REF.DATE not missing then perform below logic to calculate MEDSTPDY, If MEDSTOP less than REF.DATE then (MEDSTOP - REF.DATE). Else if MEDSTOP is greater than equal to REF.DATE then (MEDSTOP- REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
DOSEDY	num	RELATIVE DOSE DAY		If DOSEDATE and REF.DATE not missing then perform below logic to calculate DOSEDY, If DOSEDATE less than REF.DATE then (DOSEDATE - REF.DATE). Else if DOSEDATE is greater than equal to REF.DATE then (DOSEDATE- REF.DATE) +1.

1.4.15. DC_DRUG - DC_DRUG

Dataset	DC_DRUG
Creating program	dc_drug.sas
Description	DC_DRUG
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity

Variable	Type	Label	Codes	Comments
PNO	char	PNO		Collected at CRF.
DC_DRUG	num	DC_DRUG		Collected at CRF.
DC_DRUGF	char	DC_DRUGF		Collected at CRF.

1.4.16. DOSESUM - DOSESUM

Dataset	DOSESUM
Creating program	dosesum.sas
Description	DOSESUM
Unique identifier	DPATNO,UNITSTRF
Sorted by	DPATNO,UNITSTRF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDSTTDT,MEDSTPDT,NMEDSTRT,TITSTRDT,TITSTPDT,STBSTPDT,DBSTRTDT, DOSTPDT,SURN

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
DAYS	num	DAYS		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
TOTDDOSE	num	C_TOTDDOSE		Collected at CRF.
DOS1TABS	num	C_DOS1TABS		Collected at CRF.
DOS2TABS	num	C_DOS2TABS		Collected at CRF.
UNITSTRF	char	VAR_DAYS		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
MEDSTTDY	num	RELATIVE MEDSTART DAY		If MEDSTTDT and REF.DATE not missing then perform below logic to calculate MEDSTTDY, If MEDSTTDT less than REF.DATE then (MEDSTTDT - REF.DATE). Else if MEDSTTDT is greater than equal to REF.DATE then (MEDSTTDT - REF.DATE) +1.
MEDSTPDY	num	RELATIVE MEDSTOP DAY		If MEDSTPDT and REF.DATE not missing then perform below logic to calculate MEDSTPDY, If MEDSTPDT less than REF.DATE then (MEDSTPDT - REF.DATE). Else if MEDSTPDT is greater than equal to REF.DATE then (MEDSTPDT - REF.DATE) +1.
NMEDY	num	RELATIVE NMEDSTRT DAY		If NMEDSTRT and REF.DATE not missing then perform below logic to calculate NMEDY, If NMEDSTRT less than REF.DATE then (NMEDSTRT - REF.DATE). Else if NMEDSTRT is greater than equal to REF.DATE then (NMEDSTRT- REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRDT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRDT less than REF.DATE then (TITSTRDT - REF.DATE). Else if TITSTRDT is greater than equal to REF.DATE then (TITSTRDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTPDT and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTPDT less than REF.DATE then (TITSTPDT - REF.DATE). Else if TITSTPDT is greater than equal to REF.DATE then (TITSTPDT - REF.DATE) +1.
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STBSTPDT and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STBSTPDT less than REF.DATE then (STBSTPDT - REF.DATE). Else if STBSTPDT is greater than equal to REF.DATE then (STBSTPDT - REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUBLE-BLIND START DAY		If DBSTRTDT and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRTDT less than REF.DATE then (DBSTRTDT - REF.DATE). Else if DBSTRTDT is greater than equal to REF.DATE then (DBSTRTDT - REF.DATE) +1.
DOSTPDY	num	RELATIVE DOSESTOP DAY		If DOSTPDT and REF.DATE not missing then perform below logic to calculate DOSTPDY, If DOSTPDT less than REF.DATE then (DOSTPDT - REF.DATE). Else if DOSTPDT is greater than equal to REF.DATE then (DOSTPDT - REF.DATE) +1.

1.4.17. ECG - ECG

Dataset	ECG
Creating program	ecg.sas
Description	ELECTROCARDIOGRAM
Unique identifier	DPATNO,EVENT_ID,PHASE
Sorted by	DPATNO,EVENT_ID,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,ECGDAT,ECGDATE,OTHRSPEC,TUPID, REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORMAB	num	C_NORMAB		Collected at CRF.
RHYTHM	num	C_RHYTHM		Collected at CRF.
RATE	num	C_RATE		Collected at CRF.
QRS	num	C_QRS		Collected at CRF.
PR	num	C_PR		Collected at CRF.
QT	num	C_QT		Collected at CRF.
SIGNCHG	num	C_SIGNCHG		Collected at CRF.
ADVREC	num	C_ADVREC		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
ECGDADY	num	RELATIVE C_ECG DAY		If ECGDATE and REF.DATE not missing then perform below logic to calculate ECGDADY, If ECGDATE less than REF.DATE then (ECGDATE - REF.DATE). Else if ECGDATE is greater than equal to REF.DATE then (ECGDATE- REF.DATE) +1.

1.4.18. EVN_DEFN - EVN_DEFN

Dataset	EVN_DEFN
Creating program	evn_defn.sas
Description	EVN_DEFN
Unique identifier	DSCR,EVENT_ID
Sorted by	DSCR,EVENT_ID
Notes	Below listed variables will be dropped from dataset due to repetition of the information or due to missing values: SCTRY,ABS_DAYS,REL_DAYS,VAR_DAYS

Variable	Type	Label	Codes	Comments
DSCR	char	DSCR		Collected at CRF.
PNO	char	PNO		Collected at CRF.
SEQ_NO	num	SEQ_NO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PRV_EVEN	char	PRV_EVENT		Collected at CRF.

1.4.19. GLKTEST - GLKTEST

Dataset	GLKTEST
Creating program	glktest.sas
Description	GLKTEST
Unique identifier	DPATNO,DRUGCODE,EVENT_ID,PHASE,DURATION,STUDYDAY
Sorted by	DPATNO,DRUGCODE,EVENT_ID,PHASE,DURATION,STUDYDAY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VERBATM,START,STOP,CSTARTDT,CSTOPDT,FDATE,VERBATIM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
CONMED	num	C_CONMED		Collected at CRF.
CONMEDF	char	CONCOMITANT MEDICATION TAKEN - FORMATTED		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
DRUGCODE	char	C_DRUGCODE		Collected at CRF.
DRUGDESC	char	C_DRUGDESC		Collected at CRF.
CONT	num	C_CONT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ROUTE	char	C_ROUTE		Collected at CRF.
TOTDOSE	char	C_TOTDOSE		Collected at CRF.
INDICT	char	C_INDICT		Collected at CRF.
FORTAE	num	C_FORTAE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
FORTAEF	char	TREATMENT EMERGENT AE		Collected at CRF.
DURATION	num	DURATION OF CONCOMITANT MEDICATION		Collected at CRF.
CONTF	char	DOSE CONTINUING		Collected at CRF.
STUDYDAY	num	STUDY DAY - DAYS FROM MEDSTART		Collected at CRF.
REGDAY	num	REGIMEN DAY		Collected at CRF.
GENDESC	char	GENERIC DESCRIPTION		Collected at CRF.
ATC_CD	char	ATC_CD		Collected at CRF.
ATC_TEXT	char	ATC_TEXT		Collected at CRF.
THERCLAS	char	THERAPEUTIC*CLASS		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGIC*CLASS		Collected at CRF.
STRTDY	num	RELATIVE START DAY		If START and REF.DATE not missing then perform below logic to calculate STRTDY, If START less than REF.DATE then (START - REF.DATE). Else if START is greater than equal to REF.DATE then (START-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STPDY	num	RELATIVE STOP DAY		If STOP and REF.DATE not missing then perform below logic to calculate STPDY, If STOP less than REF.DATE then (STOP - REF.DATE). Else if STOP is greater than equal to REF.DATE then (STOP-REF.DATE) +1.
CSTARTDY	num	RELATIVE CONCOM MEDICATION START DAY		If CSTARTDT and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTARTDT less than REF.DATE then (CSTARTDT - REF.DATE). Else if CSTARTDT is greater than equal to REF.DATE then (CSTARTDT- REF.DATE) +1.
CSTOPDY	num	RELATIVE CONCOM MEDICATION STOP DAY		If CSTOPDT and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOPDT less than REF.DATE then (CSTOPDT - REF.DATE). Else if CSTOPDT is greater than equal to REF.DATE then (CSTOPDT- REF.DATE) +1.
FDY	num	RELATIVE F DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE-REF.DATE) +1.

1.4.20. GLOBEVAL - GLOBEVAL

Dataset	GLOBEVAL
Creating program	globeval.sas
Description	GLOBEVAL
Unique identifier	DPATNO,EVENT_ID,PHASE
Sorted by	DPATNO,EVENT_ID,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
ALERT	num	C_ALERT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTIVITY	num	C_ACTIVITY		Collected at CRF.
SEVERITY	num	C_SEVERITY		Collected at CRF.
ENVIRONS	num	C_ENVIRONS		Collected at CRF.
RESPONSE	num	C_RESPONSE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.21. KEYADVE - KEYADVE

Dataset	KEYADVE
Creating program	keyadve.sas
Description	KEYADVE
Unique identifier	DPATNO,EVENT_ID,TRTMENT,ADVEXP,ADVCODE,REGDAY,SEQNO
Sorted by	DPATNO,EVENT_ID,TRTMENT,ADVEXP,ADVCODE,REGDAY,SEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,EVDATE,BIRTHDT,SEX,RACE,ONSETDT,STOPDT,START,STOP, _ONSETD

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
F_STATUS	char	F_STATUS		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
ADVEXP	num	C_ADVEXP		Collected at CRF.
ADVEXPF	char	ADVEXPF		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADVCODE	char	C_ADVCODE		Collected at CRF.
ADVDESC	char	C_ADVDESC		Collected at CRF.
SEVERITY	num	C_SEVERITY		Collected at CRF.
SERIOUS	num	C_SERIOUS		Collected at CRF.
DRUGREL	num	C_DRUGREL		Collected at CRF.
ACTION	num	C_ACTION		Collected at CRF.
CONCOM	num	C_CONCOM		Collected at CRF.
OUTCOME	num	C_OUTCOME		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
SEVERITF	char	SEVERITF		Collected at CRF.
SERIOUSF	char	SERIOUSF		Collected at CRF.
DRUGRELF	char	DRUGRELF		Collected at CRF.
ACTIONF	char	ACTIONF		Collected at CRF.
CONCOMF	char	CONCOMF		Collected at CRF.
OUTCOMEF	char	OUTCOMEF		Collected at CRF.
DURDAY	num	DURDAY		Collected at CRF.
INCL_TER	char	INCL_TER		Collected at CRF.
SITE_ID	char	SITE_ID		Collected at CRF.
BODY_SYS	char	BODY_SYS		Collected at CRF.
BODYSYS	char	DSCR		Collected at CRF.
BODY_SY1	char	BODY_SY1		Collected at CRF.

Variable	Type	Label	Codes	Comments
BODY_SY2	char	BODY_SY2		Collected at CRF.
RECNO	char	RECNO		Collected at CRF.
SEQNO	char	SEQNO		Collected at CRF.
PREF_TRM	char	PREF_TER		Collected at CRF.
SEXAE	char	SEXAE		Collected at CRF.
ONSETFLG	char	ONSETFLG		Collected at CRF.
STOPDFLG	char	STOPDFLG		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
REGDAY	num	REGDAY		Collected at CRF.
ONSETDY	num	RELATIVE C_ONSET DAY		If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT- REF.DATE) +1.
STOPDY	num	RELATIVE C_STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
STRTDY	num	RELATIVE START DAY		If START and REF.DATE not missing then perform below logic to calculate STRTDY, If START less than REF.DATE then (START - REF.DATE). Else if START is greater than equal to REF.DATE then (START- REF.DATE) +1.

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

1.4.22. KEYANTI - KEYANTI

Dataset	KEYANTI
Creating program	keyanti.sas
Description	KEYANTI
Unique identifier	DPATNO,EVENT_ID,DRUGCODE,CONT,DURATION,REGDAY
Sorted by	DPATNO,EVENT_ID,DRUGCODE,CONT,DURATION,REGDAY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: STARTDT,STOPDT,VERBATM,START,STOP,FDATE,VERBATIM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	PAG_NAME		Collected at CRF.
DRUGCODE	char	C_DRUGCODE		Collected at CRF.
DRUGDESC	char	C_DRUGDESC		Collected at CRF.
CONT	num	C_CONT		Collected at CRF.
TOTDOSE	char	C_TOTDOSE		Collected at CRF.
DURATION	num	DURATION		Collected at CRF.
CONTF	char	CONTF		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
REGDAY	num	REGDAY		Collected at CRF.
STARTDY	num	RELATIVE C_START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE C_STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.
FDY	num	RELATIVE F DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE- REF.DATE) +1.

1.4.23. KEYCOMP - KEYCOMP

Dataset	KEYCOMP
Creating program	keycomp.sas
Description	KEYCOMP
Unique identifier	DPATNO,EVENT_ID,PHASE
Sorted by	DPATNO,EVENT_ID,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: STATUSDT,DEATHDT,VERBATIM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
SEVERITY	num	C_SEVERITY		Collected at CRF.
SERIOUS	num	C_SERIOUS		Collected at CRF.
DRUGREL	num	C_DRUGREL		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
SEVERITF	char	SEVERITF		Collected at CRF.
SERIOUSF	char	SERIOUSF		Collected at CRF.
DRUGRELF	char	DRUGRELF		Collected at CRF.

Variable	Type	Label	Codes	Comments
DURDAY	num	DURDAY		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
REGDAY	num	REGDAY		Collected at CRF.
BODYSYS	char	DSCR		Collected at CRF.
PREF_TRM	char	PREF_TER		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
STATUS	num	C_STATUS		Collected at CRF.
REASON	num	C_REASON		Collected at CRF.
ADVCODE	char	C_ADVCODE		Collected at CRF.
ADVDESC	char	C_ADVDESC		Collected at CRF.
STATUSDY	num	RELATIVE C_STATUS DAY		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.

1.4.24. KEYCURM - KEYCURM

Dataset	KEYCURM
Creating program	keycurm.sas
Description	KEYCURM
Unique identifier	DPATNO,EVENT_ID,ROUTE,TOTDOSE,FORTAE,DRUGCODE,STARTDY
Sorted by	DPATNO,EVENT_ID,ROUTE,TOTDOSE,FORTAE,DRUGCODE,STARTDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: VERBATM,START,STOP,CSTARTDT,CSTOPDT,FDATE,VERBATIM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
CONMED	num	C_CONMED		Collected at CRF.
CONMEDF	char	CONCOMITANT MEDICATION TAKEN - FORMATTED		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
DRUGCODE	char	C_DRUGCODE		Collected at CRF.
DRUGDESC	char	C_DRUGDESC		Collected at CRF.
CONT	num	C_CONT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ROUTE	char	C_ROUTE		Collected at CRF.
TOTDOSE	char	C_TOTDOSE		Collected at CRF.
INDICT	char	C_INDICT		Collected at CRF.
FORTAE	num	C_FORTAE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
FORTAEF	char	TREATMENT EMERGENT AE		Collected at CRF.
DURATION	num	DURATION OF CONCOMITANT MEDICATION		Collected at CRF.
CONTF	char	DOSE CONTINUING		Collected at CRF.
STUDYDAY	num	STUDY DAY - DAYS FROM MEDSTART		Collected at CRF.
REGDAY	num	REGIMEN DAY		Collected at CRF.
GENDESC	char	GENERIC DESCRIPTION		Collected at CRF.
ATC_CD	char	ATC_CD		Collected at CRF.
ATC_TEXT	char	ATC_TEXT		Collected at CRF.
THERCLAS	char	THERAPEUTIC*CLASS		Collected at CRF.
PHRMCLAS	char	PHARMACOLOGIC*CLASS		Collected at CRF.
STRTDY	num	RELATIVE START DAY		If START and REF.DATE not missing then perform below logic to calculate STRTDY, If START less than REF.DATE then (START - REF.DATE). Else if START is greater than equal to REF.DATE then (START-REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STPDY	num	RELATIVE STOP DAY		If STOP and REF.DATE not missing then perform below logic to calculate STPDY, If STOP less than REF.DATE then (STOP - REF.DATE). Else if STOP is greater than equal to REF.DATE then (STOP-REF.DATE) +1.
CSTARTDY	num	RELATIVE CONCOM MEDICATION START DAY		If CSTARTDT and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTARTDT less than REF.DATE then (CSTARTDT - REF.DATE). Else if CSTARTDT is greater than equal to REF.DATE then (CSTARTDT- REF.DATE) +1.
CSTOPDY	num	RELATIVE CONCOM MEDICATION STOP DAY		If CSTOPDT and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOPDT less than REF.DATE then (CSTOPDT - REF.DATE). Else if CSTOPDT is greater than equal to REF.DATE then (CSTOPDT- REF.DATE) +1.
FDY	num	RELATIVE F DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE-REF.DATE) +1.

1.4.25. KEYDATES - KEYDATES

Dataset	KEYDATES
Creating program	keydates.sas
Description	KEYDATES
Unique identifier	DPATNO,BASEDAYS
Sorted by	DPATNO,BASEDAYS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: BASESTRT,BASESTOP,TITSTRT,TITSTOP,STABSTRT,STABSTOP,DBSTRT_S, DBSTOP_S,TAPSTRT,TAPSTOP,TAPDAYS,LTSEIZDT,DBSTRT,DBSTOP

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
BASEDAYS	num	DAYS IN BASELINE PHASE		Collected at CRF.
TITDAYS	num	DAYS IN TITRATION PHASE		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION PHASE		Collected at CRF.
DBDAYS_S	num	DAYS IN DOUBLE-BLIND PHASE		Collected at CRF.
DBFDATE	num	DBFDATE		Collected at CRF.
TOPIDAYS	num	DAYS ON TOPIRAMATE		Collected at CRF.
SEIZDAYS	num	NUMBER OF KOWN SEIZURE DIARY DAYS		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASETRDY	num	RELATIVE BASELINE START DAY		If BASESTRT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASESTRT less than REF.DATE then (BASESTRT - REF.DATE). Else if BASESTRT is greater than equal to REF.DATE then (BASESTRT- REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASESTOP and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASESTOP less than REF.DATE then (BASESTOP - REF.DATE). Else if BASESTOP is greater than equal to REF.DATE then (BASESTOP- REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STABSTRT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STABSTRT less than REF.DATE then (STABSTRT - REF.DATE). Else if STABSTRT is greater than equal to REF.DATE then (STABSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STABSTOP and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STABSTOP less than REF.DATE then (STABSTOP - REF.DATE). Else if STABSTOP is greater than equal to REF.DATE then (STABSTOP- REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUBLE-BLIND START DAY		If DBSTRT_S and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRT_S less than REF.DATE then (DBSTRT_S - REF.DATE). Else if DBSTRT_S is greater than equal to REF.DATE then (DBSTRT_S- REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOP_S and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOP_S less than REF.DATE then (DBSTOP_S - REF.DATE). Else if DBSTOP_S is greater than equal to REF.DATE then (DBSTOP_S- REF.DATE) +1.
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.

1.4.26. KEYDOSE - KEYDOSE

Dataset	KEYDOSE
Creating program	keydose.sas
Description	KEYDOSE
Unique identifier	DPATNO,ADOSE
Sorted by	DPATNO,ADOSE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: MEDSTRTM,MEDSTPTM,PERIOD,DOSESTOP,STARTDT,STOPDT,SURN, INVNAME,RTITLE2,RTITLE3

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
ADOSE	num	AVERAGE TOPIRAMATE DOSE		Collected at CRF.
HDOSE	num	HIGHEST DOSE		Collected at CRF.
LDOSE	num	LOWEST DOSE		Collected at CRF.
IDOSE	num	INITIAL DOSE		Collected at CRF.
FDOSE	num	FINAL DOSE		Collected at CRF.
STABADOS	num	AVERAGE DOSE DURING STABILIZATION PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
STABHDOS	num	HIGHEST DOSE DURING STABILIZATION PHASE		Collected at CRF.
STABLDOS	num	LOWEST DOSE DURING STABILIZATON PHASE		Collected at CRF.
STABFDOS	num	FINAL DOSE DURING STABILIZATION PHASE		Collected at CRF.
PNO	char	PNO		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
TARGET	num	TARGET DOSE		Collected at CRF.
STABMGKG	num	AVERAGE MG PER KG DURING STABILIZATION P		Collected at CRF.
SPCTTARG	num	PERCENT OF TARGET - STABILIZATION PHASE		Collected at CRF.
DBMGKG	num	MG PER KG DURING DOUBLE-BLIND		Collected at CRF.
DPCTTARG	num	DOUBLE-BLIND PERCENT OF TARGET		Collected at CRF.
REGIMEN	char	REGIMEN		Collected at CRF.
RTITLE1	char	TITLE1		Collected at CRF.
THRPYDAY	num	TOTAL DAYS ON THERAPY		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSTPDY	num	RELATIVE LAST DOSE DAY		If DOSESTOP and REF.DATE not missing then perform below logic to calculate DOSTPDY, If DOSESTOP less than REF.DATE then (DOSESTOP - REF.DATE). Else if DOSESTOP is greater than equal to REF.DATE then (DOSESTOP- REF.DATE) +1.
STARTDY	num	RELATIVE MEDICATION START DAY		If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.
STOPDY	num	RELATIVE MEDICATION STOP DAY		If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.

1.4.27. KEYECG - KEYECG

Dataset	KEYECG
Creating program	keyecg.sas
Description	KEYECG
Unique identifier	DPATNO,RATE,TRTMENTF,EVDY
Sorted by	DPATNO, RATE,TRTMENTF,EVDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EVDATE,ECGDATE,OTHRSPEC,EDATE,ECGDTE,DBSTRT_S,DBSTOP_S,LTSEIZDT, AGE,SURN,INVNAME

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
NORMAB	num	C_NORMAB		Collected at CRF.
RHYTHM	num	C_RHYTHM		Collected at CRF.
RATE	num	C_RATE		Collected at CRF.
QRS	num	C_QRS		Collected at CRF.
PR	num	C_PR		Collected at CRF.
QT	num	C_QT		Collected at CRF.
SIGNCHG	num	C_SIGNCHG		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
QTC	num	QTC RATE		Collected at CRF.
DBDAYS_S	num	DOUBLE-BLIND DAYS FOR SAFETY		Collected at CRF.
SEIZDAYS	num	NUMBER OF KOWN SEIZURE DIARY DAYS		Collected at CRF.
BASERATE	num	BASELINE RATE		Collected at CRF.
BASEQRS	num	BASELINE QRS		Collected at CRF.
BASEPR	num	BASELINE PR		Collected at CRF.
BASEQT	num	BASELINE QT		Collected at CRF.
BASEQTC	num	BASELINE QTC		Collected at CRF.
LASTRATE	num	LAST RATE VALUE		Collected at CRF.
LASTPR	num	LAST PR VALUE		Collected at CRF.
LASTQRS	num	LAST QRS VALUE		Collected at CRF.
LASTQT	num	LAST QT VALUE		Collected at CRF.
LASTQTC	num	LAST QTC VALUE		Collected at CRF.
TRTMENTF	char	TREATMENT		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
AGEGRP1	num	AGE GRP FOR MARKEDLY ABNM RATE FLAGS		Collected at CRF.
AGEGRP2	num	AGE GRP FOR MARKEDLY ABNM QT, QTC FLAG		Collected at CRF.
CHGRATE	num	CHANGE IN RATE		Collected at CRF.
CHGPR	num	CHANGE IN PR		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHGQRS	num	CHANGE IN QRS		Collected at CRF.
CHGQT	num	CHANGE IN QT		Collected at CRF.
CHGQTC	num	CHANGE IN QTC		Collected at CRF.
DAYOFDBT	num	DAY OF DOUBLE-BLIND THERAPY		Collected at CRF.
MABNPR	num	MARKEDLY ABNORMAL PR VALUE		Collected at CRF.
MABNQRS	num	MARKEDLY ABNORMAL QRS VALUE		Collected at CRF.
MABNRATE	num	MARKEDLY ABNORMAL RATE VALUE		Collected at CRF.
MABNQT	num	MARKEDLY ABNORMAL QT VALUE		Collected at CRF.
MABNQTC	num	MARKEDLY ABNORMAL QTC VALUE		Collected at CRF.
BESTDAY	num	BEST DAY		Collected at CRF.
DAYDIFF	num	NUMBER OF DAYS		Collected at CRF.
KEEP	num	KEEP		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
ECGDADY	num	RELATIVE C_ECG DAY		If ECGDATE and REF.DATE not missing then perform below logic to calculate ECGDADY, If ECGDATE less than REF.DATE then (ECGDATE - REF.DATE). Else if ECGDATE is greater than equal to REF.DATE then (ECGDATE- REF.DATE) +1.
EDY	num	RELATIVE C_EVENT DAY		If EDATE and REF.DATE not missing then perform below logic to calculate EDY, If EDATE less than REF.DATE then (EDATE - REF.DATE). Else if EDATE is greater than equal to REF.DATE then (EDATE- REF.DATE) +1.
ECGDY	num	RELATIVE DAY OF ECG		If ECGDTE and REF.DATE not missing then perform below logic to calculate ECGDY, If ECGDTE less than REF.DATE then (ECGDTE - REF.DATE). Else if ECGDTE is greater than equal to REF.DATE then (ECGDTE- REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUBLE-BLIND START DAY		If DBSTRT_S and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRT_S less than REF.DATE then (DBSTRT_S - REF.DATE). Else if DBSTRT_S is greater than equal to REF.DATE then (DBSTRT_S- REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOP_S and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOP_S less than REF.DATE then (DBSTOP_S - REF.DATE). Else if DBSTOP_S is greater than equal to REF.DATE then (DBSTOP_S- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.

1.4.28. KEYEFF - KEYEFF

Dataset	KEYEFF
Creating program	keyeff.sas
Description	KEYEFF
Unique identifier	DPATNO,SEIZTYPE
Sorted by	DPATNO,SEIZTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: BASESTRT,BASESTOP,TITSTRT,TITSTOP,STBSTRDT,STBSTPDT,DBSTPDT, LTSEIZDT,SURN,INVNAME,SEX, SEXF,CALSTPDT,CALSTRDT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity

Variable	Type	Label	Codes	Comments
CALCBDAY	num	NUMBER OF KNOWN SEIZURE DIARY DAYS-BASEL		Collected at CRF.
SEIZTYPE	char	C_SEIZTYPE		Collected at CRF.
BTYPSZCT	num	BASELINE SEIZURE COUNT BY TYPE		Collected at CRF.
BLRATE	num	BASELINE SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
STDAYS	num	STABILIZATION DAYS INCLD AFTER WITHD		Collected at CRF.
ASTPSZCT	num	THE SUM, NUMB		Collected at CRF.
AFTSRATE	num	STABILIZATIN SEIZURE RATE BY TYPE -AFTR		Collected at CRF.
TITDAYS	num	DAYS IN TITRATION PHASE		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION PHASE		Collected at CRF.
DBTYSZCT	num	DB SEIZURE COUNT BY TYPE		Collected at CRF.
DBRATE	num	DB SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
PCTREDUC	num	DB PERCENT REDUCTION - BY TYPE		Collected at CRF.
STYPSZCT	num	STABILIZATION SEIZ COUNT BY TYPE		Collected at CRF.
STRATE	num	STABILIZATION SEIZURE RATE-BY SEZURE TPE		Collected at CRF.
STPCTR	num	STABILIZATION PERCENT REDUCTION- BY TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASEDAYS	num	DAYS IN BASELINE PHASE		Collected at CRF.
DBDAYS_S	num	DAYS IN DOUBLE-BLIND PHASE		Collected at CRF.
SEIZDAYS	num	NUMBER OF KNOWN SEIZURE DIARY DAYS		Collected at CRF.
DBTYAFCT	num	DB SEIZURE COUNT BY TYPE AFTER WDRW		Collected at CRF.
DBFRATE	num	DB SEIZURE RATE BY TYPE-INCL AFT WITHDRW		Collected at CRF.
AFPCTRED	num	DB REDUCTION RATE BY TYP-INCD AFT WITDRW		Collected at CRF.
AFSTYRED	num	STABILIZATN % REDUCTIN BY TYPE INCLD AFT		Collected at CRF.
ALLBSZCT	num	BASELINE TOTAL SEIZURE COUNT		Collected at CRF.
ALLBASE	num	BASELINE SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLSSZCT	num	STABILIZATION TOTAL SEIZURE COUNT		Collected at CRF.
ALLSTAB	num	STABILIZATION SEIZURE RATE - ALL TYPES		Collected at CRF.
ALDBSZCT	num	DB TOTAL SEIZURE COUNT		Collected at CRF.
ALDBRATE	num	DB SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLPCTR	num	DB PERCENT REDUCTION - ALL TYPES		Collected at CRF.

Variable	Type	Label	Codes	Comments
ALSTPCTR	num	STABILIZATION PERCENT REDUCTION-ALL TYPE		Collected at CRF.
ALDBAFCT	num	DB TOTAL SEIZURE CT-INCLD AFT WITHDRW		Collected at CRF.
ALLDBAFT	num	DB SEIZURE RATE - INCD AFTWITHDRW		Collected at CRF.
ALAFPCTR	num	DB PERCENT REDUCTION - INCLD AFT WITHDRW		Collected at CRF.
AFTSSZCT	num	STABILIZATN SEIZURE CNT INCLD AFT WITHD		Collected at CRF.
AFALSTAB	num	STABILIZATN SEZURE RATE ALL TYP ICLD AFT		Collected at CRF.
AFSALRED	num	STABILIZATN % REDUCTIN ALL TPE INCLD AFT		Collected at CRF.
TRTMENTF	char	TREATMENT - FORMATTED VALUE		Collected at CRF.
TRTMENT	char	TRTMENT		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
BASETRDY	num	RELATIVE BASELINE START DAY		If BASESTRT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASESTRT less than REF.DATE then (BASESTRT - REF.DATE). Else if BASESTRT is greater than equal to REF.DATE then (BASESTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASESTOP and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASESTOP less than REF.DATE then (BASESTOP - REF.DATE). Else if BASESTOP is greater than equal to REF.DATE then (BASESTOP- REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STABSTRT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STABSTRT less than REF.DATE then (STABSTRT - REF.DATE). Else if STABSTRT is greater than equal to REF.DATE then (STABSTRT- REF.DATE) +1.
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STABSTOP and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STABSTOP less than REF.DATE then (STABSTOP - REF.DATE). Else if STABSTOP is greater than equal to REF.DATE then (STABSTOP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.
CALSTPDY	num	RELATIVE BASELINE STOP - I.E. TITSTRT DAY		If CALSTPDT and REF.DATE not missing then perform below logic to calculate CALSTPDY, If CALSTPDT less than REF.DATE then (CALSTPDT - REF.DATE). Else if CALSTPDT is greater than equal to REF.DATE then (CALSTPDT - REF.DATE) +1.
CALSTRDY	num	RELATIVE BASELINE START - 56 DAY RULE		If CALSTRDT and REF.DATE not missing then perform below logic to calculate CALSTRDY, If CALSTRDT less than REF.DATE then (CALSTRDT - REF.DATE). Else if CALSTRDT is greater than equal to REF.DATE then (CALSTRDT - REF.DATE) +1.

1.4.29. KEYEFF28 - KEYEFF28

Dataset	KEYEFF28
Creating program	keyeff28.sas
Description	KEYEFF28
Unique identifier	DPATNO,SEIZTYPE
Sorted by	DPATNO,SEIZTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: BASETRDT,BASETPDT,TITSTRT,TITSTOP,STBSTRDT,STBSTPDT, DBSTPDT, LTSEIZDT,SURN,INVNAME,SEX,CALSTPDT,CALSTRDT,SEXF

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
CALCBDAY	num	NUMBER OF KNOWN SEIZURE DIARY DAYS-BASEL		Collected at CRF.
SEIZTYPE	char	C_SEIZTYPE		Collected at CRF.
BTYPSZCT	num	BASELINE SEIZURE COUNT BY TYPE		Collected at CRF.
BLRATE	num	BASELINE SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
STDAYS	num	STABILIZATION DAYS INCLD AFTER WITHD		Collected at CRF.

Variable	Type	Label	Codes	Comments
ASTPSZCT	num	THE SUM, NUMB		Collected at CRF.
AFTSRATE	num	STABILIZATIN SEIZURE RATE BY TYPE -AFTR		Collected at CRF.
TITDAYS	num	DAYS IN TITRATION PHASE		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION PHASE		Collected at CRF.
DBTYSZCT	num	DB SEIZURE COUNT BY TYPE		Collected at CRF.
DBRATE	num	DB SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
PCTREDUC	num	DB PERCENT REDUCTION - BY TYPE		Collected at CRF.
STYPSZCT	num	STABILIZATION SEIZ COUNT BY TYPE		Collected at CRF.
STRATE	num	STABILIZATION SEIZURE RATE-BY SEZURE TPE		Collected at CRF.
STPCTR	num	STABILIZATION PERCENT REDUCTION- BY TYPE		Collected at CRF.
BASEDAYS	num	DAYS IN BASELINE PHASE		Collected at CRF.
DBDAYS_S	num	DAYS IN DOUBLE-BLIND PHASE		Collected at CRF.
SEIZDAYS	num	NUMBER OF KNOWN SEIZURE DIARY DAYS		Collected at CRF.
DBTYAFCT	num	DB SEIZURE COUNT BY TYPE AFTER WDRW		Collected at CRF.
DBFRATE	num	DB SEIZURE RATE BY TYPE-INCL AFT WITHDRW		Collected at CRF.

Variable	Type	Label	Codes	Comments
AFPCTRED	num	DB REDUCTION RATE BY TYP-INCD AFT WITDRW		Collected at CRF.
AFSTYRED	num	STABILIZATN % REDUCTIN BY TYPE INCLD AFT		Collected at CRF.
ALLBSZCT	num	BASELINE TOTAL SEIZURE COUNT		Collected at CRF.
ALLBASE	num	BASELINE SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLSSZCT	num	STABILIZATION TOTAL SEIZURE COUNT		Collected at CRF.
ALLSTAB	num	STABILIZATION SEIZURE RATE - ALL TYPES		Collected at CRF.
ALDBSZCT	num	DB TOTAL SEIZURE COUNT		Collected at CRF.
ALDBRATE	num	DB SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLPCTR	num	DB PERCENT REDUCTION - ALL TYPES		Collected at CRF.
ALSTPCTR	num	STABILIZATION PERCENT REDUCTION-ALL TYPE		Collected at CRF.
ALDBAFCT	num	DB TOTAL SEIZURE CT-INCLD AFT WITHDRW		Collected at CRF.
ALLDBAFT	num	DB SEIZURE RATE - INCD AFTWITHDRW		Collected at CRF.
ALAFPCTR	num	DB PERCENT REDUCTION - INCLD AFT WITHDRW		Collected at CRF.

Variable	Type	Label	Codes	Comments
AFTSSZCT	num	STABILIZATN SEIZURE CNT INCLD AFT WITHD		Collected at CRF.
AFALSTAB	num	STABILIZATN SEZURE RATE ALL TYP ICLD AFT		Collected at CRF.
AFSALRED	num	STABILIZATN % REDUCTIN ALL TPE INCLD AFT		Collected at CRF.
TRTMENTF	char	TREATMENT - FORMATTED VALUE		Collected at CRF.
TRTMENT	char	TRTMENT		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
BASETRDY	num	RELATIVE BASELINE START DAY		If BASETRDT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASETRDT less than REF.DATE then (BASETRDT - REF.DATE). Else if BASETRDT is greater than equal to REF.DATE then (BASETRDT - REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STABSTRT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STABSTRT less than REF.DATE then (STABSTRT - REF.DATE). Else if STABSTRT is greater than equal to REF.DATE then (STABSTRT- REF.DATE) +1.
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STABSTOP and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STABSTOP less than REF.DATE then (STABSTOP - REF.DATE). Else if STABSTOP is greater than equal to REF.DATE then (STABSTOP- REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOP_S and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOP_S less than REF.DATE then (DBSTOP_S - REF.DATE). Else if DBSTOP_S is greater than equal to REF.DATE then (DBSTOP_S- REF.DATE) +1.
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CALSTPDY	num	RELATIVE BASELINE STOP - I.E. TITSTRT DAY		If CALSTPDT and REF.DATE not missing then perform below logic to calculate CALSTPDY, If CALCSTOP less than REF.DATE then (CALCSTOP - REF.DATE). Else if CALCSTOP is greater than equal to REF.DATE then (CALCSTOP- REF.DATE) +1.
CALSTRDY	num	RELATIVE BASELINE SART - 56 DAY RULE		If CALSTRDT and REF.DATE not missing then perform below logic to calculate CALSTRDY, If CALSTRDT less than REF.DATE then (CALSTRDT - REF.DATE). Else if CALSTRDT is greater than equal to REF.DATE then (CALSTRDT - REF.DATE) +1.

1.4.30. KEYEFF_1 - KEYEFF_1

Dataset	KEYEFF_1
Creating program	keyeff_1.sas
Description	KEYEFF_1
Unique identifier	DPATNO,SEIZTYPE
Sorted by	DPATNO,SEIZTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: BASETRDT,BASETPDT,TITSTRT,TITSTOP,STBSTRDT,STBSTPDT,DBSTPDT, LTSEIZDT,SURN,INVNAME,SEX,SEXF

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
CALCBDAY	num	NUMBER OF KNOWN SEIZURE DIARY DAYS-BASEL		Collected at CRF.
SEIZTYPE	char	C_SEIZTYPE		Collected at CRF.
BTYPSZCT	num	BASELINE SEIZURE COUNT BY TYPE		Collected at CRF.
BLRATE	num	BASELINE SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
STDAYS	num	STABILIZATION DAYS INCLD AFTER WITHD		Collected at CRF.

Variable	Type	Label	Codes	Comments
ASTPSZCT	num	THE SUM, NUMB		Collected at CRF.
AFTSRATE	num	STABILIZATIN SEIZURE RATE BY TYPE -AFTR		Collected at CRF.
TITDAYS	num	DAYS IN TITRATION PHASE		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION PHASE		Collected at CRF.
DBTYSZCT	num	DB SEIZURE COUNT BY TYPE		Collected at CRF.
DBRATE	num	DB SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
PCTREDUC	num	DB PERCENT REDUCTION - BY TYPE		Collected at CRF.
STYPSZCT	num	STABILIZATION SEIZ COUNT BY TYPE		Collected at CRF.
STRATE	num	STABILIZATION SEIZURE RATE-BY SEZURE TPE		Collected at CRF.
STPCTR	num	STABILIZATION PERCENT REDUCTION- BY TYPE		Collected at CRF.
BASEDAYS	num	DAYS IN BASELINE PHASE		Collected at CRF.
DBDAYS_S	num	DAYS IN DOUBLE-BLIND PHASE		Collected at CRF.
SEIZDAYS	num	NUMBER OF KNOWN SEIZURE DIARY DAYS		Collected at CRF.
DBTYAFCT	num	DB SEIZURE COUNT BY TYPE AFTER WDRW		Collected at CRF.
DBFRATE	num	DB SEIZURE RATE BY TYPE-INCL AFT WITHDRW		Collected at CRF.

Variable	Type	Label	Codes	Comments
AFPCTRED	num	DB REDUCTION RATE BY TYP-INCD AFT WITDRW		Collected at CRF.
AFSTYRED	num	STABILIZATN % REDUCTIN BY TYPE INCLD AFT		Collected at CRF.
ALLBSZCT	num	BASELINE TOTAL SEIZURE COUNT		Collected at CRF.
ALLBASE	num	BASELINE SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLSSZCT	num	STABILIZATION TOTAL SEIZURE COUNT		Collected at CRF.
ALLSTAB	num	STABILIZATION SEIZURE RATE - ALL TYPES		Collected at CRF.
ALDBSZCT	num	DB TOTAL SEIZURE COUNT		Collected at CRF.
ALDBRATE	num	DB SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLPCTR	num	DB PERCENT REDUCTION - ALL TYPES		Collected at CRF.
ALSTPCTR	num	STABILIZATION PERCENT REDUCTION-ALL TYPE		Collected at CRF.
ALDBAFCT	num	DB TOTAL SEIZURE CT-INCLD AFT WITHDRW		Collected at CRF.
ALLDBAFT	num	DB SEIZURE RATE - INCD AFTWITHDRW		Collected at CRF.
ALAFPCTR	num	DB PERCENT REDUCTION - INCLD AFT WITHDRW		Collected at CRF.

Variable	Type	Label	Codes	Comments
AFTSSZCT	num	STABILIZATN SEIZURE CNT INCLD AFT WITHD		Collected at CRF.
AFALSTAB	num	STABILIZATN SEZURE RATE ALL TYP ICLD AFT		Collected at CRF.
AFSALRED	num	STABILIZATN % REDUCTIN ALL TPE INCLD AFT		Collected at CRF.
TRTMENTF	char	TREATMENT - FORMATTED VALUE		Collected at CRF.
TRTMENT	char	TRTMENT		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
BASETRDY	num	RELATIVE BASELINE START DAY		If BASETRDT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASETRDT less than REF.DATE then (BASETRDT - REF.DATE). Else if BASETRDT is greater than equal to REF.DATE then (BASETRDT - REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STBSTRDT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STBSTRDT less than REF.DATE then (STBSTRDT - REF.DATE). Else if STBSTRDT is greater than equal to REF.DATE then (STBSTRDT - REF.DATE) +1.
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STBSTPDT and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STBSTPDT less than REF.DATE then (STBSTPDT - REF.DATE). Else if STBSTPDT is greater than equal to REF.DATE then (STBSTPDT - REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.

1.4.31. KEYEFF_A - KEYEFF_A

Dataset	KEYEFF_A
Creating program	keyeff_a.sas
Description	KEYEFF_A
Unique identifier	DPATNO,SEIZTYPE
Sorted by	DPATNO,SEIZTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: BASETRDT,BASETPDT,TITSTRT,TITSTOP,STBSTRDT,STBSTPDT,DBSTPDT, LTSEIZDT,SURN,INVNAME,SEX,SEXF,CALCTPDY,CALSTRDY

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
CALCBDAY	num	NUMBER OF KNOWN SEIZURE DIARY DAYS-BASEL		Collected at CRF.
SEIZTYPE	char	C_SEIZTYPE		Collected at CRF.
BTYPSZCT	num	BASELINE SEIZURE COUNT BY TYPE		Collected at CRF.
BLRATE	num	BASELINE SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
STDAYS	num	STABILIZATION DAYS INCLD AFTER WITHD		Collected at CRF.

Variable	Type	Label	Codes	Comments
ASTPSZCT	num	THE SUM, NUMB		Collected at CRF.
AFTSRATE	num	STABILIZATIN SEIZURE RATE BY TYPE -AFTR		Collected at CRF.
TITDAYS	num	DAYS IN TITRATION PHASE		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION PHASE		Collected at CRF.
DBTYSZCT	num	DB SEIZURE COUNT BY TYPE		Collected at CRF.
DBRATE	num	DB SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
PCTREDUC	num	DB PERCENT REDUCTION - BY TYPE		Collected at CRF.
STYPSZCT	num	STABILIZATION SEIZ COUNT BY TYPE		Collected at CRF.
STRATE	num	STABILIZATION SEIZURE RATE-BY SEZURE TPE		Collected at CRF.
STPCTR	num	STABILIZATION PERCENT REDUCTION- BY TYPE		Collected at CRF.
BASEDAYS	num	DAYS IN BASELINE PHASE		Collected at CRF.
DBDAYS_S	num	DAYS IN DOUBLE-BLIND PHASE		Collected at CRF.
SEIZDAYS	num	NUMBER OF KNOWN SEIZURE DIARY DAYS		Collected at CRF.
DBTYAFCT	num	DB SEIZURE COUNT BY TYPE AFTER WDRW		Collected at CRF.
DBFRATE	num	DB SEIZURE RATE BY TYPE-INCL AFT WITHDRW		Collected at CRF.

Variable	Type	Label	Codes	Comments
AFPCTRED	num	DB REDUCTION RATE BY TYP-INCD AFT WITDRW		Collected at CRF.
AFSTYRED	num	STABILIZATN % REDUCTIN BY TYPE INCLD AFT		Collected at CRF.
ALLBSZCT	num	BASELINE TOTAL SEIZURE COUNT		Collected at CRF.
ALLBASE	num	BASELINE SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLSSZCT	num	STABILIZATION TOTAL SEIZURE COUNT		Collected at CRF.
ALLSTAB	num	STABILIZATION SEIZURE RATE - ALL TYPES		Collected at CRF.
ALDBSZCT	num	DB TOTAL SEIZURE COUNT		Collected at CRF.
ALDBRATE	num	DB SEIZURE RATE - ALL TYPES		Collected at CRF.
ALLPCTR	num	DB PERCENT REDUCTION - ALL TYPES		Collected at CRF.
ALSTPCTR	num	STABILIZATION PERCENT REDUCTION-ALL TYPE		Collected at CRF.
ALDBAFCT	num	DB TOTAL SEIZURE CT-INCLD AFT WITHDRW		Collected at CRF.
ALLDBAFT	num	DB SEIZURE RATE - INCD AFTWITHDRW		Collected at CRF.
ALAFPCTR	num	DB PERCENT REDUCTION - INCLD AFT WITHDRW		Collected at CRF.

Variable	Type	Label	Codes	Comments
AFTSSZCT	num	STABILIZATN SEIZURE CNT INCLD AFT WITHD		Collected at CRF.
AFALSTAB	num	STABILIZATN SEZURE RATE ALL TYP ICLD AFT		Collected at CRF.
AFSALRED	num	STABILIZATN % REDUCTIN ALL TPE INCLD AFT		Collected at CRF.
TRTMENTF	char	TREATMENT - FORMATTED VALUE		Collected at CRF.
TRTMENT	char	TRTMENT		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
BASETRDY	num	RELATIVE BASELINE START DAY		If BASETRDT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASETRDT less than REF.DATE then (BASETRDT - REF.DATE). Else if BASETRDT is greater than equal to REF.DATE then (BASETRDT - REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STBSTRDT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STBSTRDT less than REF.DATE then (STBSTRDT - REF.DATE). Else if STBSTRDT is greater than equal to REF.DATE then (STBSTRDT - REF.DATE) +1.
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STBSTPDT and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STBSTPDT less than REF.DATE then (STBSTPDT - REF.DATE). Else if STBSTPDT is greater than equal to REF.DATE then (STBSTPDT - REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CALSTPDY	num	RELATIVE BASELINE STOP - I.E. TITSTRT-1 DAY		If CALSTPDT and REF.DATE not missing then perform below logic to calculate CALSTPDY, If CALSTPDT less than REF.DATE then (CALSTPDT - REF.DATE). Else if CALSTPDT is greater than equal to REF.DATE then (CALSTPDT - REF.DATE) +1.
CALSTRDY	num	RELATIVE BASELINE SART - 56 DAY RULE		If CALSTRDT and REF.DATE not missing then perform below logic to calculate CALSTRDY, If CALSTRDT less than REF.DATE then (CALSTRDT - REF.DATE). Else if CALSTRDT is greater than equal to REF.DATE then (CALSTRDT - REF.DATE) +1.

1.4.32. KEYGLOB - KEYGLOB

Dataset	KEYGLOB
Creating program	keyglob.sas
Description	KEYGLOB
Unique identifier	DPATNO,ALERTF,ENVIRONF
Sorted by	DPATNO,ALERTF,ENVIRONF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SEX,SEXF,INO,SURN,INVNAME,EVDATE

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
ALERT	num	C_ALERT		Collected at CRF.
ACTIVITY	num	C_ACTIVITY		Collected at CRF.
SEVERITY	num	C_SEVERITY		Collected at CRF.
ENVIRONS	num	C_ENVIRONS		Collected at CRF.
RESPONSE	num	C_RESPONSE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
ALERTF	char	FORMATED ALERT VALUE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENVIRONF	char	FORMATED ENVIRON VALUE		Collected at CRF.
ACTIVITF	char	FORMATED ACTIVITY VALUE		Collected at CRF.
SEVERF	char	FORMATED SEVERITY VALUE		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.33. KEYLAB1 - KEYLAB1

Dataset	KEYLAB1
Creating program	keylab1.sas
Description	KEYLAB1
Unique identifier	DPATNO,EVENT_ID,LABCODE,RESULT,SAMPTIME
Sorted by	DPATNO,EVENT_ID,LABCODE,RESULT,SAMPTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LABSPEC,SAMPDT,LABLOC,LABNAME,EVDATE,FDATE,AGE,SEXGRP,SEXF, TITSTRT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
LABCODE	char	C_LABCODE		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.
COLLECT	char	C_COLLECT		Collected at CRF.
SAMPTIME	char	C_SAMPTIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
RESULT	num	C_RESULT		Collected at CRF.
CRESULT	char	C_CRESULT		Collected at CRF.
UNITCODE	num	C_UNITCODE		Collected at CRF.
FLAG	char	C_FLAG		Collected at CRF.
AGRP	char	AGRP		Collected at CRF.
COLORD	num	COLORD		Collected at CRF.
COLORDF	char	COLORDF		Collected at CRF.
GRP	num	GRP		Collected at CRF.
LABCLASS	char	TYPE OF LAB		Collected at CRF.
LABDESC	char	FULL LAB DESCRIPTION		Collected at CRF.
LABTST	char	ABBREVIATED LAB DESCRIPTION		Collected at CRF.
UNIT	char	UNIT		Collected at CRF.
BASEFLAG	char	BASEFLAG		Collected at CRF.
ENDPT	char	ENDPT		Collected at CRF.
B_VALUE	num	C_RESULT		Collected at CRF.
CHGBASE	num	CHGBASE		Collected at CRF.
PCTCHG	num	PCTCHG		Collected at CRF.
ALOW	num	ALOW		Collected at CRF.
AHIGH	num	AHIGH		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
BESTDAY	num	BESTDAY		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAYDIFF	num	DAYDIFF		Collected at CRF.
KEEP	num	KEEP		Collected at CRF.
SAMPDY	num	RELATIVE C_SAMP DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
FDY	num	RELATIVE F DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE- REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.

1.4.34. KEYNEURO - KEYNEURO

Dataset	KEYNEURO
Creating program	keyneuro.sas
Description	KEYNEURO
Unique identifier	DPATNO,INO,TRTMENT,EVDY
Sorted by	DPATNO,INO,TRTMENT,EVDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EVDAT,SURN,INVNAME,INO

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
MENTAL	num	C_MENTAL		Collected at CRF.
ORIENT	num	C_ORIENT		Collected at CRF.
CONSLEVL	num	C_CONSLEVL		Collected at CRF.
MOOD	num	C_MOOD		Collected at CRF.
THOUGHT	num	C_THOUGHT		Collected at CRF.
MEMSHORT	num	C_MEMSHORT		Collected at CRF.
MEMREMOT	num	C_MEMREMOT		Collected at CRF.

Variable	Type	Label	Codes	Comments
CALC	num	C_CALC		Collected at CRF.
FUNDKNOW	num	C_FUNDKNOW		Collected at CRF.
CONCENT	num	C_CONCENT		Collected at CRF.
SPEECH	num	C_SPEECH		Collected at CRF.
CRANIAL	num	C_CRANIAL		Collected at CRF.
OLFACTIO	num	C_OLFACTIO		Collected at CRF.
FUNDOSCP	num	C_FUNDOSCP		Collected at CRF.
VISUAL	num	C_VISUAL		Collected at CRF.
CONFRONT	num	C_CONFRONT		Collected at CRF.
EXTRAOCU	num	C_EXTRAOCU		Collected at CRF.
NYSTAGMS	num	C_NYSTAGMS		Collected at CRF.
SENSORY	num	C_SENSORY		Collected at CRF.
MOTOR	num	C_MOTOR		Collected at CRF.
FACIAL	num	C_FACIAL		Collected at CRF.
HEARING	num	C_HEARING		Collected at CRF.
GLOSSOPH	num	C_GLOSSOPH		Collected at CRF.
ACCESSRY	num	C_ACCESSRY		Collected at CRF.
HYPOGLOS	num	C_HYPOGLOS		Collected at CRF.
MOTORSYS	num	C_MOTORSYS		Collected at CRF.
MUSBULK	num	C_MUSBULK		Collected at CRF.
MUSTONE	num	C_MUSTONE		Collected at CRF.

Variable	Type	Label	Codes	Comments
MUSSTREN	num	C_MUSSTREN		Collected at CRF.
SENSRSYS	num	C_SENSRSYS		Collected at CRF.
PAINTEMP	num	C_PAINTEMP		Collected at CRF.
POSITION	num	C_POSITION		Collected at CRF.
VIBRATN	num	C_VIBRATN		Collected at CRF.
ROMBERG	num	C_ROMBERG		Collected at CRF.
TRACRECG	num	C_TRACRECG		Collected at CRF.
GAIT	num	C_GAIT		Collected at CRF.
CASGAIT	num	C_CASGAIT		Collected at CRF.
TANDGAIT	num	C_TANDGAIT		Collected at CRF.
CEREBELL	num	C_CEREBELL		Collected at CRF.
GROSCOOR	num	C_GROSCOOR		Collected at CRF.
FINGNOSE	num	C_FINGNOSE		Collected at CRF.
HEELSHIN	num	C_HEELSHIN		Collected at CRF.
RAPIDMOV	num	C_RAPIDMOV		Collected at CRF.
REFLEXES	num	C_REFLEXES		Collected at CRF.
BICEPS	num	C_BICEPS		Collected at CRF.
TRICEPS	num	C_TRICEPS		Collected at CRF.
KNEE	num	C_KNEE		Collected at CRF.
ANKLE	num	C_ANKLE		Collected at CRF.
PLANTAR	num	C_PLANTAR		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	C_PHASE		Collected at CRF.
DAYOFDBT	num	DAY OF DOUBLE-BLIND THERAPY		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDAT and REF.DATE not missing then perform below logic to calculate EVDATDY, If EVDAT less than REF.DATE then (EVDAT - REF.DATE). Else if EVDAT is greater than equal to REF.DATE then (EVDAT- REF.DATE) +1.

1.4.35. KEYOPEN - KEYOPEN

Dataset	KEYOPEN
Creating program	keyopen.sas
Description	KEYOPEN
Unique identifier	DPATNO,SEIZTYPE
Sorted by	DPATNO,SEIZTYPE
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
SEIZTYPE	char	C_SEIZTYPE		Collected at CRF.
ALLRATE	num	SEIZURE RATE DURING OPEN EXT. - ALL SEIZ		Collected at CRF.
BYRATE	num	SEIZURE RATE DURING OPEN EXT. - BY SEIZ.		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
ALLREDUC	num	PCT. SEIZURE REDUC. DURING OPEN EXT. - A		Collected at CRF.
BYREDUC	num	PCT. SEIZURE REDUC. DURING OPEN EXT. - B		Collected at CRF.

1.4.36. KEYPHYS - KEYPHYS

Dataset	KEYPHYS
Creating program	keyphys.sas
Description	KEYPHYS
Unique identifier	DPATNO,EVENT_ID,ENTRYNO,PHASE
Sorted by	DPATNO,EVENT_ID,ENTRYNO,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: REC_ID,SCTRY,EVDAT,EVDATE,OTHRSPEC,VERBATIM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SYSTEM	num	C_SYSTEM		Collected at CRF.
NORMAB	num	C_NORMAB		Collected at CRF.
CHANGE	num	C_CHANGE		Collected at CRF.
ABNCODE	char	C_ABNCODE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
TUPID	num	C_TUPID		Collected at CRF.
REC_NUM	num	C_REC_NUM		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.37. KEYPLAS - KEYPLAS

Dataset	KEYPLAS
Creating program	keyplas.sas
Description	KEYPLAS
Unique identifier	DPATNO,EVENT_ID,SAMPTIME,MEANCONC,DOUBCONC
Sorted by	DPATNO,EVENT_ID,SAMPTIME,MEANCONC,DOUBCONC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LABSPEC,SAMPDT,LABLOC,LABNAME,EVDATE,FDATE,AGE,SEXGRP,SEXF,GRP, TITSTRT,BASETRDY,BASETPDY,TITSTOP,STABSTRT,STABSTOP,DBSTRT_S, DBSTOP_S,TAPSTRT,TAPSTOP,TAPDAYS,DBFDATE,LTSEIZDT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
LABCODE	char	DRUGCODE		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.
COLLECT	char	C_COLLECT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPTIME	char	SAMPLE TIME		Collected at CRF.
RESULT	num	ORIGINAL NUMERIC VALUE		Collected at CRF.
CRESULT	char	ORIGINAL CHAR VALUE		Collected at CRF.
UNITCODE	num	C_UNITCODE		Collected at CRF.
FLAG	char	C_FLAG		Collected at CRF.
AGRP	char	AGRP		Collected at CRF.
COLORD	num	COLORD		Collected at CRF.
COLORDF	char	COLORDF		Collected at CRF.
LABCLASS	char	TYPE OF LAB		Collected at CRF.
LABDESC	char	DRUGDESC		Collected at CRF.
LABTST	char	ABBREVIATED LAB DESCRIPTION		Collected at CRF.
UNIT	char	UNIT OF LAST DOSE		Collected at CRF.
BASEFLAG	char	BASEFLAG		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
BESTDAY	num	BESTDAY		Collected at CRF.
DAYDIFF	num	DAYDIFF		Collected at CRF.
KEEP	num	KEEP		Collected at CRF.
CONCEN	num	CONCEN		Collected at CRF.
BASEDAYS	num	DAYS IN BASELINE PHASE		Collected at CRF.
TITDAYS	num	DAYS IN TITRATION PHASE		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
DBDAYS_S	num	DAYS IN DOUBLE-BLIND PHASE		Collected at CRF.
TOPIDAYS	num	DAYS ON TOPIRAMATE		Collected at CRF.
SEIZDAYS	num	NUMBER OF KOWN SEIZURE DIARY DAYS		Collected at CRF.
DAYOFDBT	num	DAYOFDBT		Collected at CRF.
DOUBFLAG	num	DOUBFLAG		Collected at CRF.
DOUBLD	num	DOUBLD		Collected at CRF.
PHASE	num	PHASE		Collected at CRF.
MEANCONC	num	MEANCONC		Collected at CRF.
DOUBCONC	num	DB MEAN CONC		Collected at CRF.
SAMPDY	num	RELATIVE C_SAMP DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
FDY	num	RELATIVE F DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.
BASETRDY	num	RELATIVE BASELINE START DAY		If BASETRDT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASETRDT less than REF.DATE then (BASETRDT - REF.DATE). Else if BASETRDT is greater than equal to REF.DATE then (BASETRDT - REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STABSTRT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STABSTRT less than REF.DATE then (STABSTRT - REF.DATE). Else if STABSTRT is greater than equal to REF.DATE then (STABSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STABSTOP and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STABSTOP less than REF.DATE then (STABSTOP - REF.DATE). Else if STABSTOP is greater than equal to REF.DATE then (STABSTOP- REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUBLE-BLIND START DAY		If DBSTRT_S and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRT_S less than REF.DATE then (DBSTRT_S - REF.DATE). Else if DBSTRT_S is greater than equal to REF.DATE then (DBSTRT_S- REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOP_S and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOP_S less than REF.DATE then (DBSTOP_S - REF.DATE). Else if DBSTOP_S is greater than equal to REF.DATE then (DBSTOP_S- REF.DATE) +1.
DBFDY	num	RELATIVE DBF DAY		If DBFDATE and REF.DATE not missing then perform below logic to calculate DBFDY, If DBFDATE less than REF.DATE then (DBFDATE - REF.DATE). Else if DBFDATE is greater than equal to REF.DATE then (DBFDATE- REF.DATE) +1.
LTSEIZDY	num	RELATIVE DAY OF LAST SEIZURE		If LTSEIZDT and REF.DATE not missing then perform below logic to calculate LTSEIZDY, If LTSEIZDT less than REF.DATE then (LTSEIZDT - REF.DATE). Else if LTSEIZDT is greater than equal to REF.DATE then (LTSEIZDT- REF.DATE) +1.

1.4.38. KEYPLASM - KEYPLASM

Dataset	KEYPLASM
Creating program	keyplasm.sas
Description	KEYPLASM
Unique identifier	DPATNO,EVENT_ID,SAMPTIME,AMT,LASTDOSE,DBSTRT_S
Sorted by	DPATNO,EVENT_ID,SAMPTIME,AMT,LASTDOSE,DBSTRT_S
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: EVDATE,SAMPDT,DRUGCODE,DRUGDESC,LASTDT,DBSTRT_S,DBSTOP_S, DBFDATE,EVD,LASTD

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
SAMPTIME	char	C_SAMPTIME		Collected at CRF.
DRUGNAME	char	C_DRUGNAME		Collected at CRF.
LASTDOSE	num	C_LASTDOSE		Collected at CRF.
AMT	num	C_AMT		Collected at CRF.
LUNITS	num	C_LUNITS		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
FLAG	char	FLAG		Collected at CRF.
STUDYDAY	num	STUDYDAY		Collected at CRF.
DOUBFLAG	num	DOUBFLAG		Collected at CRF.
MEANCONC	num	MEANCONC		Collected at CRF.
TITCONC	num	TITCONC		Collected at CRF.
STABCONC	num	STABCONC		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
SAMPDY	num	RELATIVE C_SAMP DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
LASTDY	num	RELATIVE C_LAST DAY		If LASTDT and REF.DATE not missing then perform below logic to calculate LASTDY, If LASTDT less than REF.DATE then (LASTDT - REF.DATE). Else if LASTDT is greater than equal to REF.DATE then (LASTDT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBSTRTDY	num	RELATIVE DOUB-BLIND START DAY		If DBSTRT_S and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRT_S less than REF.DATE then (DBSTRT_S - REF.DATE). Else if DBSTRT_S is greater than equal to REF.DATE then (DBSTRT_S- REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUB-BLIND STOP DAY		If DBSTOP_S and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOP_S less than REF.DATE then (DBSTOP_S - REF.DATE). Else if DBSTOP_S is greater than equal to REF.DATE then (DBSTOP_S- REF.DATE) +1.
DBFDY	num	RELATIVE FINAL DB VISIT DAY		If DBFDATE and REF.DATE not missing then perform below logic to calculate DBFDY, If DBFDATE less than REF.DATE then (DBFDATE - REF.DATE). Else if DBFDATE is greater than equal to REF.DATE then (DBFDATE- REF.DATE) +1.
LASTDDY	num	RELATIVE LASTD DAY		If LASTD and REF.DATE not missing then perform below logic to calculate LASTDDY, If LASTD less than REF.DATE then (LASTD - REF.DATE). Else if LASTD is greater than equal to REF.DATE then (LASTD- REF.DATE) +1.

1.4.39. KEYVIT1 - KEYVIT1

Dataset	KEYVIT1
Creating program	keyvit1.sas
Description	KEYVIT1
Unique identifier	DPATNO,EVENT_ID,TRTMENT,VITAL,EVDY
Sorted by	DPATNO,EVENT_ID,TRTMENT,VITAL,EVDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: EVDATE,RESP,DTEMP,VDATE,COLLECT,SAMPTIME,FDATE,BASETPDT, DBSTRTDT,DBSTOPDT,AGE

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
SYST	num	C_SYST		Collected at CRF.
DIAS	num	C_DIAS		Collected at CRF.
PULS	num	C_PULS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DWGT	num	DWGT		Collected at CRF.
DHGT	num	DHGT		Collected at CRF.
ENDPT	char	POST-THERAPY FLAG		Collected at CRF.
COLORD	num	ORDER OF COLLECTION POINTS		Collected at CRF.
COLORDF	char	ORDER OF COLLECTION POINTS - FORMATTED		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
REGDAY	num	REGIMEN DAY		Collected at CRF.
VITAL	char	VITAL SIGN		Collected at CRF.
VALUE	num	DATA VALUE FOR ECH VITAL VARBLE COLCTD		Collected at CRF.
BASEFLAG	char	BASELINE VALUE FLAG		Collected at CRF.
CHGBASE	num	CHANGE FROM BASELINE VALUE		Collected at CRF.
PCTCHG	num	PERCENT CHANGE FROM BASELINE		Collected at CRF.
DAYOFDBT	num	DAY OF DOUBLE-BLIND THERAPY		Collected at CRF.
AGEGRP1	num	AGE GROUP FOR PLUSE & DIASTOLE		Collected at CRF.
AGEGRP2	num	AGE GROUP FOR SYSTOLE		Collected at CRF.
AGEGRP3	num	AGE GROUP FOR RESPIRATION RATE		Collected at CRF.

Variable	Type	Label	Codes	Comments
MABNSYS	num	MARKEDLY ABNORMAL FLAG FOR SYSTOLE		Collected at CRF.
MABNDIA	num	MARKEDLY ABNORMAL FLAG FOR DIASTOLE		Collected at CRF.
MABNPUL	num	MARKEDLY ABNORMAL FLAG FOR PULSE		Collected at CRF.
BESTDAY	num	BESTDAY		Collected at CRF.
DAYDIFF	num	DAYDIFF		Collected at CRF.
KEEP	num	KEEP		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
VDY	num	RELATIVE V DAY		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.
FDY	num	RELATIVE FINAL DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUBLE-BLIND START DAY		If DBSTRTDT and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRTDT less than REF.DATE then (DBSTRTDT - REF.DATE). Else if DBSTRTDT is greater than equal to REF.DATE then (DBSTRTDT - REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.

1.4.40. KEYVIT2 - KEYVIT2

Dataset	KEYVIT2
Creating program	keyvit2.sas
Description	KEYVIT2
Unique identifier	DPATNO,EVENT_ID,TRTMENT,VITAL,EVDY
Sorted by	DPATNO,EVENT_ID,TRTMENT,VITAL,EVDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: EVDATE,RESP,DTEMP,VDATE,COLLECT,SAMPTIME,FDATE,BASETPDT, DBSTRTDT,DBSTOPDT,AGE

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
SYST	num	C_SYST		Collected at CRF.
DIAS	num	C_DIAS		Collected at CRF.
PULS	num	C_PULS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DWGT	num	DWGT		Collected at CRF.
DHGT	num	DHGT		Collected at CRF.
ENDPT	char	POST-THERAPY FLAG		Collected at CRF.
COLORD	num	ORDER OF COLLECTION POINTS		Collected at CRF.
COLORDF	char	ORDER OF COLLECTION POINTS - FORMATTED		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
STUDYDAY	num	STUDY DAY		Collected at CRF.
REGDAY	num	REGIMEN DAY		Collected at CRF.
VITAL	char	VITAL SIGN		Collected at CRF.
VALUE	num	DATA VALUE FOR ECH VITAL VARBLE COLCTD		Collected at CRF.
BASEFLAG	char	BASELINE VALUE FLAG		Collected at CRF.
CHGBASE	num	CHANGE FROM BASELINE VALUE		Collected at CRF.
PCTCHG	num	PERCENT CHANGE FROM BASELINE		Collected at CRF.
DAYOFDBT	num	DAY OF DOUBLE-BLIND THERAPY		Collected at CRF.
AGEGRP1	num	AGE GROUP FOR PLUSE & DIASTOLE		Collected at CRF.
AGEGRP2	num	AGE GROUP FOR SYSTOLE		Collected at CRF.
AGEGRP3	num	AGE GROUP FOR RESPIRATION RATE		Collected at CRF.

Variable	Type	Label	Codes	Comments
MABNSYS	num	MARKEDLY ABNORMAL FLAG FOR SYSTOLE		Collected at CRF.
MABNDIA	num	MARKEDLY ABNORMAL FLAG FOR DIASTOLE		Collected at CRF.
MABNPUL	num	MARKEDLY ABNORMAL FLAG FOR PULSE		Collected at CRF.
BESTDAY	num	BESTDAY		Collected at CRF.
DAYDIFF	num	DAYDIFF		Collected at CRF.
KEEP	num	KEEP		Collected at CRF.
LSTFLG	num	LSTFLG		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
VDY	num	RELATIVE V DAY		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.
FDY	num	RELATIVE FINAL DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUBLE-BLIND START DAY		If DBSTRTDT and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRTDT less than REF.DATE then (DBSTRTDT - REF.DATE). Else if DBSTRTDT is greater than equal to REF.DATE then (DBSTRTDT - REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.

1.4.41. LABNORM - LABNORM

Dataset	LABNORM
Creating program	labnorm.sas
Description	LABNORM
Unique identifier	LABCODE, LORANGE,HIRANGE,STOPDT,ENTRYDT
Sorted by	LABCODE, LORANGE,HIRANGE,STOPDT,ENTRYDT
Notes	LABLOC,SEX

Variable	Type	Label	Codes	Comments
LABCODE	char	LABCODE		Collected at CRF.
LOAGE	num	LOAGE		Collected at CRF.
HIAGE	num	HIAGE		Collected at CRF.
AGEUNIT	char	AGEUNIT		Collected at CRF.
LORANGE	num	LORANGE		Collected at CRF.
HIRANGE	num	HIRANGE		Collected at CRF.
UNITCODE	num	UNITCODE		Collected at CRF.
STARTDT	num	START DATE		Collected at CRF.
STOPDT	num	STOP DATE		Collected at CRF.
ENTRYDT	num	ENTRY DATE		Collected at CRF.
MODIFYDT	num	MODIFY DATE		Collected at CRF.

1.4.42. LABS - LABS

Dataset	LABS
Creating program	labs.sas
Description	LABORATORY
Unique identifier	DPATNO,EVENT_ID,PAG_NAME,LABCODE,RESULT,SAMPTIME
Sorted by	DPATNO,EVENT_ID,PAG_NAME,LABCODE,RESULT,SAMPTIME
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,LABSPEC,SAMPD,SAMPDT,LABLOC,LABNAME,ACCNO,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
LABCODE	char	C_LABCODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITYPE	num	C_VISITYPE		Collected at CRF.
COLLECT	char	C_COLLECT		Collected at CRF.
SAMPTIME	char	C_SAMPTIME		Collected at CRF.
RESULT	num	C_RESULT		Collected at CRF.
CRESULT	char	C_CRESULT		Collected at CRF.
UNITCODE	num	C_UNITCODE		Collected at CRF.
FLAG	char	C_FLAG		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
BATCHID	num	C_BATCHID		Collected at CRF.
TUPID	num	C_TUPID		Collected at CRF.
SAMPDY	num	RELATIVE C_SAMP DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.

1.4.43. MARKL - MARKL

Dataset	MARKL
Creating program	markl.sas
Description	MARKL
Unique identifier	AGRP,ALOW,AHIGH
Sorted by	AGRP,ALOW,AHIGH
Notes	

Variable	Type	Label	Codes	Comments
LABCODE	char	LABCODE		Collected at CRF.
AGRP	char	AGRP		Collected at CRF.
ALOW	num	ALOW		Collected at CRF.
AHIGH	num	AHIGH		Collected at CRF.

1.4.44. MHIST - MHIST

Dataset	MHIST
Creating program	mhist.sas
Description	MHIST
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,VERBATIM,ABNCODE,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	ENTRYNO		Collected at CRF.
SYSTEM	num	SYSTEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORMAB	num	NORMAB		Collected at CRF.
PHASE	num	PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.45. MHIST1 - MHIST1

Dataset	MHIST1
Creating program	mhist1.sas
Description	MHIST1
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SCTRY,REC_ID,EVDATE,EVDAT,VERBATIM,ABNCODE,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
SYSTEM	num	C_SYSTEM		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORMAB	num	C_NORMAB		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.46. MISSSING - MISSSING

Dataset	MISSSING
Creating program	misssing.sas
Description	MISSSING
Unique identifier	DPATNO,ITM_NAME,F_STATUS,MOD_NAME,PAG_NAME,PKEY1,EVENT_ID
Sorted by	DPATNO,ITM_NAME,F_STATUS,MOD_NAME,PAG_NAME,PKEY1,EVENT_ID
Notes	

Variable	Type	Label	Codes	Comments
ITM_NAME	char	ITM_NAME		Collected at CRF.
F_STATUS	char	F_STATUS		Collected at CRF.
F_NOTE	char	F_NOTE		Collected at CRF.

Variable	Type	Label	Codes	Comments
T_NOTE	char	T_NOTE		Collected at CRF.
MISSREAS	char	MISSREAS		Collected at CRF.
MOD_NAME	char	MOD_NAME		Collected at CRF.
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
PKEY1	char	PKEY1		Collected at CRF.
PKEY2	char	PKEY2		Collected at CRF.
PKEY3	char	PKEY3		Collected at CRF.
PKEY4	char	PKEY4		Collected at CRF.
PKEY1_NA	char	PKEY1_NA		Collected at CRF.
PKEY2_NA	char	PKEY2_NA		Collected at CRF.
PKEY3_NA	char	PKEY3_NA		Collected at CRF.
PKEY4_NA	char	PKEY4_NA		Collected at CRF.

1.4.47. NEUREXAM - NEUREXAM

Dataset	NEUREXAM
Creating program	neurexam.sas
Description	NEUREXAM
Unique identifier	DPATNO,EVENT_ID
Sorted by	DPATNO,EVENT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
MENTAL	num	C_MENTAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
ORIENT	num	C_ORIENT		Collected at CRF.
CONSLEVL	num	C_CONSLEVL		Collected at CRF.
MOOD	num	C_MOOD		Collected at CRF.
THOUGHT	num	C_THOUGHT		Collected at CRF.
MEMSHORT	num	C_MEMSHORT		Collected at CRF.
MEMREMOT	num	C_MEMREMOT		Collected at CRF.
CALC	num	C_CALC		Collected at CRF.
FUNDKNOW	num	C_FUNDKNOW		Collected at CRF.
CONCENT	num	C_CONCENT		Collected at CRF.
SPEECH	num	C_SPEECH		Collected at CRF.
CRANIAL	num	C_CRANIAL		Collected at CRF.
OLFACTIO	num	C_OLFACTIO		Collected at CRF.
FUNDOSCP	num	C_FUNDOSCP		Collected at CRF.
VISUAL	num	C_VISUAL		Collected at CRF.
CONFRONT	num	C_CONFRONT		Collected at CRF.
EXTRAOCU	num	C_EXTRAOCU		Collected at CRF.
NYSTAGMS	num	C_NYSTAGMS		Collected at CRF.
SENSORY	num	C_SENSORY		Collected at CRF.
MOTOR	num	C_MOTOR		Collected at CRF.
FACIAL	num	C_FACIAL		Collected at CRF.
HEARING	num	C_HEARING		Collected at CRF.

Variable	Type	Label	Codes	Comments
GLOSSOPH	num	C_GLOSSOPH		Collected at CRF.
ACCESSRY	num	C_ACCESSRY		Collected at CRF.
HYPOGLOS	num	C_HYPOGLOS		Collected at CRF.
MOTORSYS	num	C_MOTORSYS		Collected at CRF.
MUSBULK	num	C_MUSBULK		Collected at CRF.
MUSTONE	num	C_MUSTONE		Collected at CRF.
MUSSTREN	num	C_MUSSTREN		Collected at CRF.
SENSRSYS	num	C_SENSRSYS		Collected at CRF.
PAINTEMP	num	C_PAINTEMP		Collected at CRF.
POSITION	num	C_POSITION		Collected at CRF.
VIBRATN	num	C_VIBRATN		Collected at CRF.
ROMBERG	num	C_ROMBERG		Collected at CRF.
TRACRECG	num	C_TRACRECG		Collected at CRF.
GAIT	num	C_GAIT		Collected at CRF.
CASGAIT	num	C_CASGAIT		Collected at CRF.
TANDGAIT	num	C_TANDGAIT		Collected at CRF.
CEREBELL	num	C_CEREBELL		Collected at CRF.
GROSCOOR	num	C_GROSCOOR		Collected at CRF.
FINGNOSE	num	C_FINGNOSE		Collected at CRF.
HEELSHIN	num	C_HEELSHIN		Collected at CRF.
RAPIDMOV	num	C_RAPIDMOV		Collected at CRF.

Variable	Type	Label	Codes	Comments
REFLEXES	num	C_REFLEXES		Collected at CRF.
BICEPS	num	C_BICEPS		Collected at CRF.
TRICEPS	num	C_TRICEPS		Collected at CRF.
KNEE	num	C_KNEE		Collected at CRF.
ANKLE	num	C_ANKLE		Collected at CRF.
PLANTAR	num	C_PLANTAR		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.48. PAT_INFO - PAT_INFO

Dataset	PAT_INFO
Creating program	pat_info.sas
Description	PAT_INFO
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT,CTRY,CNO,BASEDT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_AUDIT	char	F_AUDIT		Collected at CRF.
F_ROW_IN	char	F_ROW_INS_AUD		Collected at CRF.
SAFETY	num	SAFETY		Collected at CRF.
EFFICACY	num	EFFICACY		Collected at CRF.
BASEDY	num	RELATIVE BASELINE DAY		If BASEDT and REF.DATE not missing then perform below logic to calculate BASEDY, If BASEDT less than REF.DATE then (BASEDT - REF.DATE). Else if BASEDT is greater than equal to REF.DATE then (BASEDT - REF.DATE) +1.

1.4.49. PERSYRS - PERSYRS

Dataset	PERSYRS
Creating program	persyrs.sas
Description	PERSYRS
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: AGE,SEX,SEXF,STARTDAT,STOPDAT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
DURATION	num	DURATION		Collected at CRF.
STRTADY	num	RELATIVE START DAY		If STARTDAT and REF.DATE not missing then perform below logic to calculate STRTADY, If STARTDAT less than REF.DATE then (STARTDAT - REF.DATE). Else if STARTDAT is greater than equal to REF.DATE then (STARTDAT- REF.DATE) +1.

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

1.4.50. PHYS - PHYS

Dataset	PHYS
Creating program	phys.sas
Description	PHYS
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SCTRY,REC_ID,EVDAT,EVDATE,VERBATIM,ABNCODE,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.
SYSTEM	num	C_SYSTEM		Collected at CRF.
OTHRSPEC	char	C_OTHRSPEC		Collected at CRF.
NORMAB	num	C_NORMAB		Collected at CRF.
CHANGE	num	C_CHANGE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.51. PLASMA - PLASMA

Dataset	PLASMA
Creating program	plasma.sas
Description	PLASMA
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
MEANV	num	MEANV		Collected at CRF.

1.4.52. PLASMACO - PLASMACO

Dataset	PLASMACO
Creating program	plasmaco.sas
Description	PLASMACO
Unique identifier	DPATNO,EVENT_ID,ENTRYNO
Sorted by	DPATNO,EVENT_ID,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,SAMPD,SAMPDT,SAMPTIM,DRUGCODE, DRUGDESC,DRUGCOD2,DRUGDES2,LASTD,LASTDT,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPTIME	char	C_SAMPTIME		Collected at CRF.
DRUGNAME	char	C_DRUGNAME		Collected at CRF.
LASTDOSE	num	C_LASTDOSE		Collected at CRF.
LASTDOST	char	C_LASTDOST		Collected at CRF.
AMT	num	C_AMT		Collected at CRF.
LUNITS	num	C_LUNITS		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
SAMPDY	num	RELATIVE C_SAMP DAY		If SAMPDT and REF.DATE not missing then perform below logic to calculate SAMPDY, If SAMPDT less than REF.DATE then (SAMPDT - REF.DATE). Else if SAMPDT is greater than equal to REF.DATE then (SAMPDT- REF.DATE) +1.
LASTDY	num	RELATIVE C_LAST DAY		If LASTDT and REF.DATE not missing then perform below logic to calculate LASTDY, If LASTDT less than REF.DATE then (LASTDT - REF.DATE). Else if LASTDT is greater than equal to REF.DATE then (LASTDT- REF.DATE) +1.

1.4.53. PLPLOT - PLPLOT

Dataset	PLPLOT
Creating program	plplot.sas
Description	PLPLOT
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
MEANV	num	MEANV		Collected at CRF.
PGROUP	num	PGROUP		Collected at CRF.
STPCTR	num	STABILIZATION PERCENT REDUCTION- BY TYPE		Collected at CRF.
ALSTPCTR	num	STABILIZATION PERCENT REDUCTION-ALL TYPE		Collected at CRF.
TRTMENT	char	TRTMENT		Collected at CRF.
BLDA	num	BLDA		Collected at CRF.
BLALL	num	BLALL		Collected at CRF.

1.4.54. PREREP - PREREP

Dataset	PREREP
Creating program	prerep.sas
Description	PREREP
Unique identifier	TRTMENTF
Sorted by	TRTMENTF
Notes	

Variable	Type	Label	Codes	Comments
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
NSDOS	num	NUMBER OF NONMISSING VALUES, STABMGKG		Collected at CRF.
MSDOS	num	THE MEAN, STABMGKG		Collected at CRF.
STDSDOS	num	THE STANDARD DEVIATION, STABMGKG		Collected at CRF.
MXSDOS	num	THE LARGEST VALUE, STABMGKG		Collected at CRF.
MDSDOS	num	THE MEDIAN, STABMGKG		Collected at CRF.
MNSDOS	num	THE SMALLEST VALUE, STABMGKG		Collected at CRF.
GROUP	char	GROUP		Collected at CRF.
RSDOS	char	RSDOS		Collected at CRF.

1.4.55. PROFILE - PROFILE

Dataset	PROFILE
Creating program	profile.sas
Description	PROFILE
Unique identifier	DPATNO
Sorted by	DPATNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: BIRTHDT,BIRTHD,SEX,SEXF,RACE,RACEF,RACESPEC,FDATE,CNTRY,AGE, BASETRDT,BASETPDT,TITSTRT,TITSTOP,STABSTRT,STABSTOP,DBSTRTDT, DBSTOPDT,INO,TAPSTRT,TAPSTOP,TAPDAYS,DBFDATE,STATUSD,STATUSDT, OTHRSPEC,DEATHD,DEATHDT,LASTD,LAST,FORE,SURN,INVNAME,VDATE, CALCSTOP,CALCSTRT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
AGEUNIT	char	AGE UNIT		Collected at CRF.
BASEDAYS	num	DAYS IN BASELINE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TITDAYS	num	TITRATION DAYS		Collected at CRF.
STABDAYS	num	DAYS IN STABILIZATION		Collected at CRF.
DBDAYS_S	num	DAYS IN DOUB-BLIND		Collected at CRF.
TOPIDAYS	num	DAYS ON TOPIRAMATE		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
STATUS	num	C_STATUS		Collected at CRF.
REASON	num	C_REASON		Collected at CRF.
DEATH	num	C_DEATH		Collected at CRF.
STATUSF	char	STATUS DECODE		Collected at CRF.
DEATHF	char	DEATH DECODE		Collected at CRF.
REASONF	char	REASON DECODE		Collected at CRF.
COMPDAYS	num	DAYS COMPLETED		Collected at CRF.
WGTUNIT	char	C_WGTUNIT		Collected at CRF.
HGTUNIT	char	C_HGTUNIT		Collected at CRF.
BASEHGT	num	BASELINE HEIGHT		Collected at CRF.
BASEWGT	num	BASELINE WEIGHT		Collected at CRF.
CALCBDAY	num	NUMBER OF KNOWN SEIZURE DIARY DAYS-BASEL		Collected at CRF.

Variable	Type	Label	Codes	Comments
BLRATE	num	BASELINE SEIZURE RATE - BY SEIZURE TYPE		Collected at CRF.
ALLBASE	num	ALL SEIZURE TYPES - BASELINE MONTHLY AVG		Collected at CRF.
FDY	num	RELATIVE F DAY		If FDATE and REF.DATE not missing then perform below logic to calculate FDY, If FDATE less than REF.DATE then (FDATE - REF.DATE). Else if FDATE is greater than equal to REF.DATE then (FDATE-REF.DATE) +1.
BASETRDY	num	RELATIVE F BASELINE START DAY		If BASETRDT and REF.DATE not missing then perform below logic to calculate BASETRDY, If BASETRDT less than REF.DATE then (BASETRDT - REF.DATE). Else if BASETRDT is greater than equal to REF.DATE then (BASETRDT - REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STABSTRT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STABSTRT less than REF.DATE then (STABSTRT - REF.DATE). Else if STABSTRT is greater than equal to REF.DATE then (STABSTRT- REF.DATE) +1.
STBSTPDY	num	RELATIVE STABILIZATION STOP DAY		If STABSTOP and REF.DATE not missing then perform below logic to calculate STBSTPDY, If STABSTOP less than REF.DATE then (STABSTOP - REF.DATE). Else if STABSTOP is greater than equal to REF.DATE then (STABSTOP- REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUB-BLIND START DAY		If DBSTRTDT and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRTDT less than REF.DATE then (DBSTRTDT - REF.DATE). Else if DBSTRTDT is greater than equal to REF.DATE then (DBSTRTDT - REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUB-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.

Variable	Type	Label	Codes	Comments
DBFDY	num	RELATIVE FINAL DB VISIT DAY		If DBFDATE and REF.DATE not missing then perform below logic to calculate DBFDY, If DBFDATE less than REF.DATE then (DBFDATE - REF.DATE). Else if DBFDATE is greater than equal to REF.DATE then (DBFDATE- REF.DATE) +1.
STATUSDY	num	RELATIVE C_STATUS DAY		If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT- REF.DATE) +1.
LASDY	num	RELATIVE LAST NAME DAY		If LAST and REF.DATE not missing then perform below logic to calculate LASDY, If LAST less than REF.DATE then (LAST - REF.DATE). Else if LAST is greater than equal to REF.DATE then (LAST- REF.DATE) +1.
VDY	num	RELATIVE V DAY		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.
CALSTPDY	num	RELATIVE BASELINE STOP - I.E. TITSTRT-1 DAY		If CALCSTOP and REF.DATE not missing then perform below logic to calculate CALSTPDY, If CALCSTOP less than REF.DATE then (CALCSTOP - REF.DATE). Else if CALCSTOP is greater than equal to REF.DATE then (CALCSTOP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
CALSTRDY	num	RELATIVE BASELINE START - 56 DAY RULE		If CALCSTRT and REF.DATE not missing then perform below logic to calculate CALSTRDY, If CALCSTRT less than REF.DATE then (CALCSTRT - REF.DATE). Else if CALCSTRT is greater than equal to REF.DATE then (CALCSTRT- REF.DATE) +1.

1.4.56. PROTOCOL - PROTOCOL

Dataset	PROTOCOL
Creating program	protocol.sas
Description	PROTOCOL
Unique identifier	DRUG
Sorted by	DRUG
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: FIRSTDB,DMODIFY

Variable	Type	Label	Codes	Comments
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PROJECT	char	PROJECT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PROTOCOL	char	PROTOCOL		Collected at CRF.
TITLE1	char	TITLE1		Collected at CRF.
TITLE2	char	TITLE2		Collected at CRF.
BLINDED	char	BLINDED		Collected at CRF.
CROSOVER	char	CROSOVER		Collected at CRF.
STDYTYPE	char	STDYTYPE		Collected at CRF.
AGEUNIT	char	AGEUNIT		Collected at CRF.
EVENTUNT	char	EVENTUNT		Collected at CRF.
TOTREGI	num	TOTREGI		Collected at CRF.
ELABTRAN	char	ELABTRAN		Collected at CRF.
RSM	char	RSM		Collected at CRF.
AVAILABL	char	AVAILABL		Collected at CRF.
SHRTPROT	char	SHRTPROT		Collected at CRF.
DSTAMPDT	num	DSTAMP DATE		Collected at CRF.
FINALDB	num	FINALDB DATE		Collected at CRF.

1.4.57. RANDOM - RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	RANDOM
Unique identifier	DPATNO,EVENT_ID
Sorted by	DPATNO,EVENT_ID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,RANDOM,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.58. REGIMEN - REGIMEN

Dataset	REGIMEN
Creating program	regimen.sas
Description	REGIMEN
Unique identifier	CODE
Sorted by	CODE
Notes	Below listed variables will be dropped from dataset due to missing values: TITLE2,TITLE3,SUB_SEQU

Variable	Type	Label	Codes	Comments
CODE	char	CODE		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.

Variable	Type	Label	Codes	Comments
STRENGTH	char	STRENGTH		Collected at CRF.
ROUTE	char	ROUTE		Collected at CRF.
DOSE	char	DOSE		Collected at CRF.
FREQUENC	char	FREQUENCY		Collected at CRF.
DURATION	char	DURATION		Collected at CRF.
INSTRUCT	char	INSTRUCTIONS		Collected at CRF.
TITLE1	char	TITLE1		Collected at CRF.
APPROVAL	char	APPROVAL		Collected at CRF.

1.4.59. ROSS - ROSS

Dataset	ROSS
Creating program	ross.sas
Description	ROSS
Unique identifier	DPATNO,DRUGCODE
Sorted by	DPATNO,DRUGCODE
Notes	

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
PNO	char	PNO		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.
DRUGCODE	char	C_DRUGCODE		Collected at CRF.

1.4.60. SEIZHIST - SEIZHIST

Dataset	SEIZHIST
Creating program	seizhist.sas
Description	SEIZHIST
Unique identifier	DPATNO,ENTRYNO
Sorted by	DPATNO,ENTRYNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,OTHRSPEC,NUMSEIZ,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
SEIZTYPE	num	C_SEIZTYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
PRESENT	num	C_PRESENT		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.61. SMED - SMED

Dataset	SMED
Creating program	smed.sas
Description	SMED
Unique identifier	DPATNO,ENTRYNO,TOTDDOSE,DOS2TABS,EVDY,MEDSTRDY
Sorted by	DPATNO,ENTRYNO,TOTDDOSE,DOS2TABS,EVDY,MEDSTRDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,EVDAT,MEDSTRTM,MEDSTPDT,MEDSTPD,MEDSTPTM, TUPID,REC_NUM,MEDSTRDT,MEDSTRD

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
CARDNUM	num	C_CARDNUM		Collected at CRF.
TOTDDOSE	num	C_TOTDDOSE		Collected at CRF.
PERIOD	num	C_PERIOD		Collected at CRF.
UNITSTRG	num	C_UNITSTRG		Collected at CRF.
OTHRSTRG	num	C_OTHRSTRG		Collected at CRF.
DOS1TABS	num	C_DOS1TABS		Collected at CRF.
DOS2TABS	num	C_DOS2TABS		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
MEDSTRDY	num	RELATIVE C_MEDSTR DAY		If MEDSTRDT and REF.DATE not missing then perform below logic to calculate MEDSTRDY, If MEDSTRDT less than REF.DATE then (MEDSTRDT - REF.DATE). Else if MEDSTRDT is greater than equal to REF.DATE then (MEDSTRDT - REF.DATE) +1.
MEDSTPDY	num	RELATIVE C_MEDSTP DAY		If MEDSTPDT and REF.DATE not missing then perform below logic to calculate MEDSTPDY, If MEDSTPDT less than REF.DATE then (MEDSTPDT - REF.DATE). Else if MEDSTPDT is greater than equal to REF.DATE then (MEDSTPDT- REF.DATE) +1.

1.4.62. SMEDVW - SMEDVW

Dataset	SMEDVW
Creating program	smedvw.sas
Description	SMEDVW
Unique identifier	DPATNO,MEDSTRDY
Sorted by	DPATNO,MEDSTRDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: MEDSTRDT

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
MEDTRDY	num	RELATIVE C_MEDSTR DAY		If MEDSTRDT and REF.DATE not missing then perform below logic to calculate MEDTRDY, If MEDSTRDT less than REF.DATE then (MEDSTRDT - REF.DATE). Else if MEDSTRDT is greater than equal to REF.DATE then (MEDSTRDT- REF.DATE) +1.

1.4.63. TOPPLAS - TOPPLAS

Dataset	TOPPLAS
Creating program	topplas.sas
Description	TOPPLAS
Unique identifier	DPATNO,EVENT_ID,PHASE
Sorted by	DPATNO,EVENT_ID,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DATE,SDATE,EVDATE,TITSTRT,TITSTOP,STABSTRT,DBSTRT_S,DBFDATE

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
CONCEN	num	CONCEN		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PNO	char	PNO		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
REGORDER	num	REGORDER		Collected at CRF.
DAYOFDBT	num	DAYOFDBT		Collected at CRF.
DOUBFLAG	num	DOUBFLAG		Collected at CRF.
DOUBLD	num	DOUBLD		Collected at CRF.

Variable	Type	Label	Codes	Comments
PHASE	num	PHASE		Collected at CRF.
MEANCONC	num	MEANCONC		Collected at CRF.
DOUBCONC	num	DOUBCONC		Collected at CRF.
SDY	num	RELATIVE S DAY		If SDATE and REF.DATE not missing then perform below logic to calculate SDY, If SDATE less than REF.DATE then (SDATE - REF.DATE). Else if SDATE is greater than equal to REF.DATE then (SDATE-REF.DATE) +1.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
TITSTRDY	num	RELATIVE TITRATION START DAY		If TITSTRT and REF.DATE not missing then perform below logic to calculate TITSTRDY, If TITSTRT less than REF.DATE then (TITSTRT - REF.DATE). Else if TITSTRT is greater than equal to REF.DATE then (TITSTRT- REF.DATE) +1.
TITSTPDY	num	RELATIVE TITRATION STOP DAY		If TITSTOP and REF.DATE not missing then perform below logic to calculate TITSTPDY, If TITSTOP less than REF.DATE then (TITSTOP - REF.DATE). Else if TITSTOP is greater than equal to REF.DATE then (TITSTOP- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
STBSTRDY	num	RELATIVE STABILIZATION START DAY		If STABSTRT and REF.DATE not missing then perform below logic to calculate STBSTRDY, If STABSTRT less than REF.DATE then (STABSTRT - REF.DATE). Else if STABSTRT is greater than equal to REF.DATE then (STABSTRT- REF.DATE) +1.
DBSTRTDY	num	RELATIVE DOUB-BLIND START DAY		If DBSTRT_S and REF.DATE not missing then perform below logic to calculate DBSTRTDY, If DBSTRT_S less than REF.DATE then (DBSTRT_S - REF.DATE). Else if DBSTRT_S is greater than equal to REF.DATE then (DBSTRT_S- REF.DATE) +1.
DBFDY	num	RELATIVE FINAL DB VISIT DAY		If DBFDATE and REF.DATE not missing then perform below logic to calculate DBFDY, If DBFDATE less than REF.DATE then (DBFDATE - REF.DATE). Else if DBFDATE is greater than equal to REF.DATE then (DBFDATE- REF.DATE) +1.

1.4.64. VITALS - VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	VITALS
Unique identifier	DPATNO,EVENT_ID,ENTRYNO,PHASE
Sorted by	DPATNO,EVENT_ID,ENTRYNO,PHASE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,TEMP,TEMPUNIT,RESP,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SYST	num	C_SYST		Collected at CRF.
DIAS	num	C_DIAS		Collected at CRF.
PULS	num	C_PULS		Collected at CRF.
WGT	num	C_WGT		Collected at CRF.
WGTUNIT	char	C_WGTUNIT		Collected at CRF.
HGT	num	C_HGT		Collected at CRF.
HGTUNIT	char	C_HGTUNIT		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.65. VITALSVW - VITALSVW

Dataset	VITALSVW
Creating program	vitalsvw.sas
Description	VITALSVW
Unique identifier	DPATNO,EVENT_ID,PHASE,SYST,DIAS
Sorted by	DPATNO,EVENT_ID,PHASE,SYST,DIAS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDATE,TEMP,TEMPUNIT,RESP,DTEMP

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
VISITYPE	num	C_VISITYPE		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.

Variable	Type	Label	Codes	Comments
SYST	num	C_SYST		Collected at CRF.
DIAS	num	C_DIAS		Collected at CRF.
PULS	num	C_PULS		Collected at CRF.
WGT	num	C_WGT		Collected at CRF.
WGTUNIT	char	C_WGTUNIT		Collected at CRF.
HGT	num	C_HGT		Collected at CRF.
HGTUNIT	char	C_HGTUNIT		Collected at CRF.
DWGT	num	DWGT		Collected at CRF.
DHGT	num	DHGT		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.

1.4.66. VTL - VTL

Dataset	VTL
Creating program	vtl.sas
Description	VTL
Unique identifier	DPATNO,SYST,DAYOFDBT
Sorted by	DPATNO,SYST,DAYOFDBT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EVDATE,VDATE, BASETPDT, DBSTOPDT,AGE,SURN,INVNAME

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
SYST	num	C_SYST		Collected at CRF.
DIAS	num	C_DIAS		Collected at CRF.
PULS	num	C_PULS		Collected at CRF.
DWGT	num	DWGT		Collected at CRF.
VBASESYS	num	C_SYST		Collected at CRF.
VBASEDIA	num	C_DIAS		Collected at CRF.
VBASEPUL	num	C_PULS		Collected at CRF.
VBASEWGT	num	DWGT		Collected at CRF.

Variable	Type	Label	Codes	Comments
VCHGSYS	num	VISIT CHANGE IN SYSTOLE		Collected at CRF.
VCHGDIA	num	VISIT CHANGE IN DIASTOLE		Collected at CRF.
VCHGPUL	num	VISIT CHANGE IN PULSE		Collected at CRF.
VCHGWGT	num	VISIT CHANGE IN WEIGHT		Collected at CRF.
AGEGRP1	num	AGE GROUP 1 FLAG		Collected at CRF.
AGEGRP2	num	AGE GROUP 2 FLAG		Collected at CRF.
AGEGRP3	num	AGE GROUP 3 FLAG		Collected at CRF.
MABNSYS	num	MARKEDLY ABNORMAL SYSTOLE FLAG		Collected at CRF.
MABNDIA	num	MARKEDLY ABNORMAL DIASTOLE FLAG		Collected at CRF.
MABNPUL	num	MARKEDLY ABNORMAL PULSE FLAG		Collected at CRF.
DAYOFDBT	num	DAY OF DOUBLE-BLIND THERAPY		Collected at CRF.
BESTDAY	num	BEST DAY FOR RANGING VISITS		Collected at CRF.
DAYDIFF	num	DIFF BTWN VISIT AND BEST DAY		Collected at CRF.
KEEP	num	KEEP FLAG FOR A VISIT		Collected at CRF.
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
TRTMENT	char	TREATMENT		Collected at CRF.

Variable	Type	Label	Codes	Comments
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
VDY	num	RELATIVE VISIT DAY		If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE- REF.DATE) +1.
BASETPDY	num	RELATIVE BASELINE STOP DAY		If BASETPDT and REF.DATE not missing then perform below logic to calculate BASETPDY, If BASETPDT less than REF.DATE then (BASETPDT - REF.DATE). Else if BASETPDT is greater than equal to REF.DATE then (BASETPDT - REF.DATE) +1.
DBSTOPDY	num	RELATIVE DOUBLE-BLIND STOP DAY		If DBSTOPDT and REF.DATE not missing then perform below logic to calculate DBSTOPDY, If DBSTOPDT less than REF.DATE then (DBSTOPDT - REF.DATE). Else if DBSTOPDT is greater than equal to REF.DATE then (DBSTOPDT - REF.DATE) +1.

1.4.67. WEEKSEIZ - WEEKSEIZ

Dataset	WEEKSEIZ
Creating program	weekseiz.sas
Description	WEEKSEIZ
Unique identifier	DPATNO,EVDAY,TOWEEKDY,SEIZTYPE
Sorted by	DPATNO,EVDAY,TOWEEKDY,SEIZTYPE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: REC_ID,SCTRY,EVDAT,EVDATE,FRWEEKD,FRWEEKDT,TOWEEKD,TOWEEKDT, OTHRSPEC,TUPID,REC_NUM

Variable	Type	Label	Codes	Comments
DPATNO	char	PATIENT NUMBER ASSIGNED FOR DE-IDENTITY		Randomly assigned patient number for De-Identity
F_STATUS	char	F_STATUS		Collected at CRF.
DRUG	char	DRUG		Collected at CRF.
TAREA	char	TAREA		Collected at CRF.
PNO	char	PNO		Collected at CRF.
EVENT_ID	char	EVENT_ID		Collected at CRF.
PAG_NAME	char	PAG_NAME		Collected at CRF.
ENTRYNO	num	C_ENTRYNO		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEIZTYPE	char	C_SEIZTYPE		Collected at CRF.
NUMSEIZ	num	C_NUMSEIZ		Collected at CRF.
PHASE	num	C_PHASE		Collected at CRF.
EVDY	num	RELATIVE C_EVENT DAY		If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE- REF.DATE) +1.
FRWEEKDY	num	RELATIVE C_FRWEEK DAY		If FRWEEKDT and REF.DATE not missing then perform below logic to calculate FRWEEKDY, If FRWEEKDT less than REF.DATE then (FRWEEKDT - REF.DATE). Else if FRWEEKDT is greater than equal to REF.DATE then (FRWEEKDT- REF.DATE) +1.
TOWEEKDY	num	RELATIVE C_TOWEEK DAY		If TOWEEKDT and REF.DATE not missing then perform below logic to calculate TOWEEKDY, If TOWEEKDT less than REF.DATE then (TOWEEKDT - REF.DATE). Else if TOWEEKDT is greater than equal to REF.DATE then (TOWEEKDT- REF.DATE) +1.

1.4.68. YPAE - YPAE

Dataset	YPAE
Creating program	ypae.sas
Description	YPAE
Unique identifier	BODYSYS,TERM
Sorted by	BODYSYS,TERM
Notes	

Variable	Type	Label	Codes	Comments
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
BODYSYS	char	DSCR		Collected at CRF.
COUNT	num	FREQUENCY COUNT		Collected at CRF.
PERCENT	num	PERCENT OF TOTAL FREQUENCY		Collected at CRF.
TOP	num	FREQUENCY COUNT		Collected at CRF.
I	num	I		Collected at CRF.
PCT	num	PCT		Collected at CRF.
TPCT	num	TPCT		Collected at CRF.
TOT	num	TOT		Collected at CRF.
TOTPCT	num	TOTPCT		Collected at CRF.
ADVCODE	char	C_ADVCODE		Collected at CRF.
J	num	J		Collected at CRF.

Variable	Type	Label	Codes	Comments
PLAC	char	PLAC		Collected at CRF.
TOPIRA	char	TOPIRA		Collected at CRF.
TOTAL	char	TOTAL		Collected at CRF.
TERM	char	TERM		Collected at CRF.

1.4.69. YPAED - YPAED

Dataset	YPAED
Creating program	ypaed.sas
Description	YPAED
Unique identifier	PAR
Sorted by	PAR
Notes	

Variable	Type	Label	Codes	Comments
TOP1	char	TOP1		Collected at CRF.
TOP2	char	TOP2		Collected at CRF.
TOTA	char	TOTA		Collected at CRF.
PAR	num	PAR		Collected at CRF.

1.4.70. YPDBSUM - YPDBSUM

Dataset	YPDBSUM
Creating program	ypdbsum.sas
Description	YPDBSUM
Unique identifier	TRTMENTF
Sorted by	TRTMENTF
Notes	

Variable	Type	Label	Codes	Comments
TRTMENTF	char	TREATMENT DECODE		Collected at CRF.
NADOS	num	NUMBER OF NONMISSING VALUES, AVDBMGKG		Collected at CRF.
NXDOS	num	NUMBER OF NONMISSING VALUES, MXDBMGKG		Collected at CRF.
MADOS	num	THE MEAN, AVDBMGKG		Collected at CRF.
MXDOS	num	THE MEAN, MXDBMGKG		Collected at CRF.
STDADOS	num	THE STANDARD DEVIATION, AVDBMGKG		Collected at CRF.
STDXDOS	num	THE STANDARD DEVIATION, MXDBMGKG		Collected at CRF.
MXADOS	num	THE LARGEST VALUE, AVDBMGKG		Collected at CRF.
MXXDOS	num	THE LARGEST VALUE, MXDBMGKG		Collected at CRF.

Variable	Type	Label	Codes	Comments
MDADOS	num	THE MEDIAN, AVDBMGKG		Collected at CRF.
MDXDOS	num	THE MEDIAN, MXDBMGKG		Collected at CRF.
MNADOS	num	THE SMALLEST VALUE, AVDBMGKG		Collected at CRF.
MNXDOS	num	THE SMALLEST VALUE, MXDBMGKG		Collected at CRF.

1.4.71. YPMARKL - YPMARKL

Dataset	YPMARKL
Creating program	ypmarkl.sas
Description	YPMARKL
Unique identifier	AGRP,ALOW,AHIGH
Sorted by	AGRP,ALOW,AHIGH
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SEXGRP

Variable	Type	Label	Codes	Comments
LABCODE	char	LABCODE		Collected at CRF.
AGRP	char	AGRP		Collected at CRF.

Variable	Type	Label	Codes	Comments
ALOW	num	ALOW		Collected at CRF.
AHIGH	num	AHIGH		Collected at CRF.

1.4.72. YPMFLAG - YPMFLAG

Dataset	YPMFLAG
Creating program	ypmflag.sas
Description	YPMFLAG
Unique identifier	AGRP,CRIT,L,H
Sorted by	AGRP,CRIT,L,H
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: SEXGRP

Variable	Type	Label	Codes	Comments
LABCODE	char	LABCODE		Collected at CRF.
AGRP	char	AGRP		Collected at CRF.
CRIT	char	CRIT		Collected at CRF.
L	char	L		Collected at CRF.
H	char	H		Collected at CRF.

1.4.73. YPNORMS - YPNORMS

Dataset	YPNORMS
Creating program	ypnorms.sas
Description	YPNORMS
Unique identifier	LOAGE,HIRANGE,LORANGE,STARTDT
Sorted by	LOAGE,HIRANGE,LORANGE,STARTDT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SEX, LABLOC

Variable	Type	Label	Codes	Comments
LABCODE	char	LABCODE		Collected at CRF.
LOAGE	num	LOAGE		Collected at CRF.
HIAGE	num	HIAGE		Collected at CRF.
AGEUNIT	char	AGEUNIT		Collected at CRF.
LORANGE	num	LORANGE		Collected at CRF.
HIRANGE	num	HIRANGE		Collected at CRF.
UNITCODE	num	UNITCODE		Collected at CRF.
STARTDT	num	START DATE		Collected at CRF.
STOPDT	num	STOP DATE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENTRYDT	num	ENTRY DATE		Collected at CRF.
MODIFYDT	num	MODIFY DATE		Collected at CRF.