DEFINITION OF DATASET VARIABLES

| **Variable** | **Categorization** | **Description** | **Values** | **Units** | **Format** | **Comment** |
| --- | --- | --- | --- | --- | --- | --- |
| C | Flag | Flag to comment unused records | C = unused record |  | Character |  |
| NSTUDY | Identification | Subject study | 1 = STUDYID |  | Numeric |  |
| SUBJID | Identification | Unique subject ID label |  |  | Numeric |  |
| ID | Identification | Subject ID counting number |  |  | Numeric |  |
| ATFD | Time | Actual time since first dose |  | days | Numeric |  |
| ATLD | Time | Actual time since last dose |  | days | Numeric |  |
| NTFD | Time | Nominal time since first dose |  | days | Numeric |  |
| NTLC |  |  |  | days | Numeric |  |
| NTLD | Time | Nominal time since last dose |  | days | Numeric |  |
| NDAY | Time | Nominal study day |  | days | Numeric |  |
| TPT | Time | Nominal timepoint |  | days | Numeric |  |
| EVID | NONMEM-required | Event identification number | 0 = Observation event |  | Numeric |  |
| 1 = Dose event |  |
| MDV | NONMEM-required | Missing dependent variable flag | 0 = DV not missing |  | Numeric |  |
| 1 = DV is missing |  |
| CMT | NONMEM-required | Compartment number | 0 = BP (Dose) | mg/dl | Numeric |  |
| 1 = CHOL (Dose) | mg/dl |
| 2 = WT (Dose) | mg/dl |
| 3 = BP (Dose) | mg/dl |
| 5 = WT (Dose) | mg/dl |
| 6 = BP (Dose) | mg/dl |
| 0 = BP (PK) | mg/dl |
| 1 = CHOL (PK) | mg/dl |
| 2 = WT (PK) | mg/dl |
| 3 = BP (PK) | mg/dl |
| 5 = WT (PK) | mg/dl |
| 6 = BP (PK) | mg/dl |
| DVID | Endpoint | Dependent variable ID number | 1 = BP |  | Numeric |  |
| 2 = WT |  |
| 3 = CHOL |  |
| AMT | Dose | Administered drug amount |  | mg/dl | Numeric |  |
| ODV | Endpoint | Original dependent variable |  |  | Numeric |  |
| LDV | Endpoint | Natural log transformed dependent variable |  |  | Numeric |  |
| BLQ | Endpoint | Below limit of quantification flag | 0 = observation not BLQ |  | Numeric |  |
| 1 = BLQ observation (pre-dose) |  |
| 2 = BLQ observation (post-dose) |  |
| LLOQ | Endpoint | Lower limit of quantification of dependent variable |  |  | Numeric |  |
| DOSENUM | Dose | Latest dose event number |  |  | Numeric |  |
| DOSEA | Dose | Actual administered dose amount |  | mg/dl | Numeric |  |
| NROUTE | Dose | dose route | 1 = ORAL |  | List |  |
| NROUTE |  | Subject NA | 1 = ORAL |  | List |  |
| NFRQ | Dose | dose frequency | 1 = QD |  | List |  |
| NFRQ |  | Subject NA | 1 = QD |  | List |  |
| BAGE | Covariate | Baseline age |  |  | List |  |
| BAGE |  | Baseline NA |  |  | List |  |
| PDOSEF | Flag | Flag for records prior to first dose | 0 = At or after first dose |  | Numeric |  |
| 1 = Prior to first dose |  |
| TIMEF | Flag | Flag for records with missing ATFD | 0 = ATFD not missing |  | Numeric |  |
| 1 = ATFD is missing |  |
| AMTF | Flag | Flag for dose records with missing AMT | 0 = AMT not missing |  | Numeric |  |
| 1 = AMT is missing |  |
| DUPF | Flag | Flag for duplicated records | 0 = Not duplicated |  | Numeric |  |
| 1 = At least one duplicate |  |
| NOEXF | Flag | Flag for subjects with no dose records | 0 = At least one dose |  | Numeric |  |
| 1 = No dose |  |
| NODV1F | Flag | Flag for subjects with no observation records | 0 = At least one observation (DVID = 1) |  | Numeric |  |
| 1 = No observations (DVID = 1) |  |
| NODV2F | Flag | Flag for subjects with no observation records | 0 = At least one observation (DVID = 2) |  | Numeric |  |
| 1 = No observations (DVID = 2) |  |
| NODV3F | Flag | Flag for subjects with no observation records | 0 = At least one observation (DVID = 3) |  | Numeric |  |
| 1 = No observations (DVID = 3) |  |
| SDF | Flag | Flag for subjects with a single dose | 0 = Multi-dose subject |  | Numeric |  |
| 1 = Single-dose subject |  |
| PLBOF | Flag | Flag for records referencing a placebo dose | 0 = Not placebo |  | Numeric |  |
| 1 = Placebo |  |
| SPARSEF | Flag | Flag for records with sparse sampling design | 0 = Serial sampling |  | Numeric |  |
| 1 = Sparse sampling |  |
| TREXF | Flag | Flag for trailing dose records after last observation | 0 = At least one future observation |  | Numeric |  |
| 1 = No future observations |  |
| IMPEX | Flag | Flag for previous dose record with imputed ATFD | 0 = Dose time not imputed |  | Numeric |  |
| 1 = Dose time imputed |  |
| IMPDV | Flag | Flag for observations with imputed ATFD and ATLD | 0 = Observation time not imputed |  | Numeric |  |
| 1 = Observation time imputed |  |
| LINE | Flag | Dataset row number |  |  | Numeric |  |
| USUBJID | Identification | Unique subject ID label |  |  | Character | Dropped in control stream |
| NSTUDYC | Identification | Subject study label |  |  | Character | Dropped in control stream |
| VISIT | Time | Visit label |  |  | Character | Dropped in control stream |
| TPTC | Time | Timepoint label |  |  | Character | Dropped in control stream |
| DOMAIN | Label | Record domain |  |  | Character | Dropped in control stream |
| DVIDC | Label | Dependent variable label |  |  | Character | Dropped in control stream |
| DVIDU | Units | Dependent variable units |  |  | Character | Dropped in control stream |
| TIMEU | Units | Time units |  |  | Character | Dropped in control stream |
| NROUTEC |  | Subject NA label |  |  | Character | Dropped in control stream |
| NFRQC | Dose | dose frequency catagorical |  |  | List |  |
| NFRQC |  | Subject NA label |  |  | List |  |
| BAGEU | Covariate | Baseline Age Units |  |  | List |  |
| BAGEU |  | Baseline NA units |  |  | List |  |
| DTIM | Time | Date and time of record |  |  | Character | Dropped in control stream |
| FDOSE | Time | Date and time of subject's first dose |  |  | Character | Dropped in control stream |
| VERSN | Version | pk\_build() function version number |  |  | Character | Dropped in control stream |
| BUILD | Version | Dataset creation date |  |  | Character | Dropped in control stream |
| \*NA parameters and missing character-type covariates labeled with "." | | | | | | |
| \*\*Missing numeric-type covariates labeled with -999 | | | | | | |