

Package ‘apmx’

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Type Package

Title Automated Population Pharmacokinetic Dataset Assembly

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Description Automated methods to assemble population PK (pharmacokinetic) and PKPD (pharmacodynamic) datasets for analysis in 'NONMEM' (non-linear mixed effects modeling) by Bauer (2019) <[doi:10.1002/psp4.12404](https://doi.org/10.1002/psp4.12404)>. The package includes functions to build datasets from SDTM (study data tabulation module) <<https://www.cdisc.org/standards/foundational/sdtm>>, ADaM (analysis dataset module) <<https://www.cdisc.org/standards/foundational/adam>>, or other dataset formats. The package will combine population datasets, add covariates, and create documentation to support regulatory submission and internal communication.

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LazyData true

Imports dplyr, tidyr, purrr, this.path, flextable, officer,
tidyselect, utils, arsenal

RoxygenNote 7.2.3

URL <https://github.com/stephen-amori/apmx>

BugReports <https://github.com/stephen-amori/apmx/issues>

Depends R (>= 4.00)

Suggests rmarkdown, knitr, testthat, tibble

VignetteBuilder knitr

NeedsCompilation no

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cov_apply	<i>Apply covariates to PK(PD) dataset</i>
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Description

Add covariates to a dataset built by pk_build() or pk_combine() Can add subject-level covariates (by any ID variable) or time-varying (by any time variable)

Usage

```
cov_apply(  
  df,  
  cov,  
  id.by = "USUBJID",  
  time.by = NA,  
  direction = "downup",  
  exp = FALSE,  
  ebe = FALSE,  
  cov.rnd = NA,  
  na = -999,  
  demo.map = TRUE,  
  keep.other = TRUE  
)
```

Arguments

df	PK(PD) dataframe generated by pk_build
cov	dataframe of covariates
id.by	id variable to merge covariates
time.by	time variable to merge covariates
direction	fill direction for time-varying covariates
exp	treats new covariates as exposure metrics when TRUE
ebe	treats new covariates as empirical bayes estimates when TRUE
cov.rnd	covariate rounding parameter
na	value to replace NA numeric covariates
demo.map	toggle pre-set numeric values for SEX, RACE, and ETHNIC demographic variables
keep.other	filter to keep or remove other events, EVID = 2

Value

PK(PD) dataset with additional covariates]

Examples

```
## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
```

```

      CMT = 2,
      VISIT = "Day 1",
      PCTPT = c("Pre-dose",
                 "30-min post-dose",
                 "2-hr post-dose"),
      PCTEST = "ABC",
      PCSTRESU = "ug/mL")

## Create with pk_build()
df <- pk_build(ex, pc)

## Simple dm domain for the corresponding study
dm <- data.frame(USUBJID = c("ABC101-001",
                             "ABC101-002",
                             "ABC101-003"),
                 AGE = c(45,
                         37,
                         73),
                 AGEU = "years",
                 SEX = c("Male",
                         "Female",
                         "Male"),
                 RACE = c("White",
                         "White",
                         "Black"),
                 ETHNIC = c("Not Hispanic/Latino",
                           "Not Hispanic/Latino",
                           "Not Hispanic/Latino"))

## Add covariates with cov_apply()
df1 <- cov_apply(df, dm)

```

cov_find

Find covariates of particular types

Description

Can filter for categorical, continuous, or other covariates. Can filter for numeric or character type.

Usage

```
cov_find(df, cov, type)
```

Arguments

df	PK(PD) dataset
cov	covariate distribution
type	covariate type

Value

vector of desired column names

Examples

```
## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
  CMT = 2,
  VISIT = "Day 1",
  PCTPT = c("Pre-dose",
    "30-min post-dose",
    "2-hr post-dose"),
  PCTEST = "ABC",
  PCSTRESU = "ug/mL")

## Create with pk_build()
df <- pk_build(ex, pc)

## Simple dm domain for the corresponding study
dm <- data.frame(USUBJID = c("ABC101-001",
  "ABC101-002",
  "ABC101-003"),
  AGE = c(45,
    37,
    73),
  AGEU = "years",
```

```

SEX = c("Male",
        "Female",
        "Male"),
RACE = c("White",
        "White",
        "Black"),
ETHNIC = c("Not Hispanic/Latino",
           "Not Hispanic/Latino",
           "Not Hispanic/Latino"))

## Add covariates with cov_apply()
df1 <- cov_apply(df, dm)

## Find covariates with cov_find()
cov_find(df1, cov="categorical", type="numeric")
cov_find(df1, cov="categorical", type="character")
cov_find(df1, cov="continuous", type="numeric")
cov_find(df1, cov="units", type="character")

```

DM

DM

Description

Randomly generated demographic data domain

Usage

DM

Format

'DM' A data frame with 22 rows and 12 variables:

STUDYID study label

SITEID site code

SUBJID subject code

USUBJID unique subject ID

SCRFL screen fail flag

ICFDT informed consent date

ICFDTC informed consent date character form

DOBDT date of birth

AGE subject baseline age

SEX subject sex

RACE subject race

ETHNIC subject ethnicity

EX

EX

Description

Randomly generated exposure domain

Usage

EX

Format

'EX' A data frame with 42 rows and 19 variables:

STUDYID study label

SITEID site code

USUBJID unique subject ID

EXCAT domain category

VISIT visit label

EXSTDY numeric study day

VISCRFN visit numeric code

EXTRT treatment label

EXDOSE treatment amount

EXDOSU treatment unit label

EXROUTE treatment route label

EXDOSFRQ treatment frequency

EXDT treatment administration date

EXDTC treatment administration date character form

EXTM treatment administration time

EXTMC treatment administration time character form

EXSTDTC treatment administration date and time

EXTPT treatment timepoint label

EXTPTNUM treatment numeric timepoint

LB	<i>LB</i>
----	-----------

Description

Randomly generated laboratory data domain

Usage

LB

Format

'LB' A data frame with 2159 rows and 16 variables:

STUDYID study label

SITEID site code

USUBJID unique subject ID

LBCAT domain category

LBCOMPFL completion flag

LBDT date of assessment

LBVST visit label

VISCRFN visit numeric code

LBTPT timepoint label

LBTPTN timepoint numeric code

LBPARAMCD parameter code

LBPARAM parameter

LBORRES original parameter result

LBORRESC original parameter result, character form

LBORRESU original parameter unit label

PC

PC

Description

Randomly generated pharmacokinetic observation domain

Usage

PC

Format

'PC' A data frame with 420 rows and 19 variables:

STUDYID study label

SITEID site code

USUBJID unique subject ID

PCCAT domain category

PCTEST analyte category

VISIT visit label

PCDY study numeric day

VISCRFN visit numeric code

PCTPT timepoint label

PCTPTN timepoint numeric code

PCSTAT completion status

PCDT observation date

PCTM observation time

PCTMC observation time character form

PCDTC observation date and time

PCORRES original pharmacokinetic observation

PCORRESU original pharmacokinetic observation unit label

PCSTRESN standardized pharmacokinetic numeric observation

PCSTRESC standardized pharmacokinetic character observation

PCSTRESU standardized pharmacokinetic observation unit label

PCLLOQ standardized pharmacokinetic observation lower limit of quantification

pk_build

*Create a NONMEM PK(PD) dataset***Description**

Input a pre-processed ex and pc domain for combination into a NONMEM dataset. Additional pd endpoints, subject-level covariates, and time-varying covariates can also be added. Other parameters can customize some calculations and formatting.

Usage

```
pk_build(
  ex,
  pc = NA,
  pd = NA,
  sl.cov = NA,
  tv.cov = NA,
  time.units = "days",
  cycle.length = NA,
  na = -999,
  time.rnd = NULL,
  amt.rnd = NULL,
  dv.rnd = NULL,
  cov.rnd = NULL,
  impute = NA,
  BDV = FALSE,
  DDV = FALSE,
  PDV = FALSE,
  sparse = 3,
  demo.map = TRUE,
  tv.cov.fill = "downup",
  keep.other = TRUE
)
```

Arguments

ex	dose event dataframe
pc	pc event dataframe
pd	pd event dataframe
sl.cov	subject-level covariate dataframe
tv.cov	time-varying covariate dataframe
time.units	units for time attributes
cycle.length	cycle length in units of days
na	value for missing numeric items
time.rnd	time attribute rounding parameter

amt.rnd	amount attribute rounding parameter
dv.rnd	dependent variable attribute rounding parameter
cov.rnd	covariate attribute rounding parameter
impute	imputation method
BDV	baseline pd attribute
DDV	change from baseline pd attribute
PDV	percent change from baseline pd attribute
sparse	threshold for sparse sampling
demo.map	toggle pre-set numeric values for SEX, RACE, and ETHNIC demographic variables
tv.cov.fill	time-varying covariate fill direction
keep.other	filter to keep or remove other events, EVID = 2

Value

PK(PD) dataset

Examples

```
## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
  CMT = 2,
```

```

VISIT = "Day 1",
PCTPT = c("Pre-dose",
          "30-min post-dose",
          "2-hr post-dose"),
PCTEST = "ABC",
PCSTRESU = "ug/mL")

## Create with pk_build()
df <- pk_build(ex, pc)

```

pk_combine

combine study level datasets to form population dataset

Description

Input two datasets created by `pk_build()`. Any character descriptions that were numerically mapped will be re-mapped to the whole population.

Usage

```
pk_combine(df1, df2, demo.map = TRUE, na = -999)
```

Arguments

df1	original PK(PD) dataset
df2	additional PK(PD) dataset
demo.map	toggle pre-set numeric values for SEX, RACE, and ETHNIC demographic variables
na	value for missing numeric items

Value

population PK(PD) dataset

Examples

```

## Simple ex domain with 1 subject and 1 dose, study 101
ex101 <- data.frame(STUDYID = "ABC101",
                    USUBJID = "ABC101-001",
                    EXSTDTC = "2000-01-01 10:00:00",
                    EXSTDY = 1,
                    EXTPNUM = 0,
                    EXDOSE = 100,
                    CMT = 1,
                    EXTRT = "ABC",
                    EXDOSU = "mg",
                    VISIT = "Day 1",

```

```

EXTPT = "Dose",
EXDOSFRQ = "Once",
EXROUTE = "Oral")

## Simple ex domain with 1 subject and 1 dose, study 102
ex102 <- data.frame(STUDYID = "ABC102",
  USUBJID = "ABC102-001",
  EXSTDTC = "2001-01-01 08:09:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 200,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "QW",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations, study 101
pc101 <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
  CMT = 2,
  VISIT = "Day 1",
  PCTPT = c("Pre-dose",
    "30-min post-dose",
    "2-hr post-dose"),
  PCTEST = "ABC",
  PCSTRESU = "ug/mL")

## Simple pc domain with 1 subject and 3 observations, study 102
pc102 <- data.frame(USUBJID = "ABC102-001",
  PCDTC = c("2001-01-01 08:05:00",
    "2001-01-01 11:38:00",
    "2001-01-02 08:11:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.125,
    1),
  PCSTRESN = c(NA,
    1150,
    591),
  PCLLOQ = 25,

```

```

CMT = 2,
VISIT = "Day 1",
PCTPT = c("Pre-dose",
           "2-4 hr post-dose",
           "24 hr post-dose"),
PCTEST = "ABC",
PCSTRESU = "ug/mL")

## Create with pk_build()
df101 <- pk_build(ex101, pc101)
df102 <- pk_build(ex102, pc102)

## Combine with pk_combine()
df_combine <- pk_combine(df101, df102)

```

pk_define

*Create definition file from published dataset***Description**

Definition file table can be read into a template word document (.docx) or blank document if desired. Definitions are sourced from a variable list stored separately on your server. Please refer to `apmx::variable_list_export()` for a standard copy of the variable list.

Usage

```

pk_define(
  df,
  file = NULL,
  project,
  data,
  variable.list,
  template = NULL,
  font = "Times New Roman",
  size = 9,
  na = -999
)

```

Arguments

df	apmx analysis dataset
file	optional filepath for definition file (.docx file)
project	project name
data	dataset name
variable.list	reference dataframe for variable definitions
template	optional filepath for definition file template (.docx file)

font	font for table contents
size	font size for table contents
na	value used for missing or na numeric covariates

Value

dataset definition file

Examples

```
## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
  CMT = 2,
  VISIT = "Day 1",
  PCTPT = c("Pre-dose",
    "30-min post-dose",
    "2-hr post-dose"),
  PCTEST = "ABC",
  PCSTRESU = "ug/mL")

## Create apmx dataset with pk_build()
df <- pk_build(ex, pc)

## Create variable definitions with variable_list_create()
vl <- variable_list_create()
```

```
## Create definition file
pk_define(df, variable.list = vl)
```

pk_summarize

Produce summary tables for a PK(PD) dataset

Description

Summarize BLQ distributions, categorical covariates, and continuous covariates in three tables. Outputs are default .csv files, but can also be .docx and/or .pptx. Tables are default stratified by study, but can be stratified by any variable requested by the user.

Usage

```
pk_summarize(
  df,
  dir = NA,
  strat.by = "NSTUDYC",
  ignore.c = TRUE,
  na = -999,
  docx = FALSE,
  pptx = FALSE,
  docx.font = "Times New Roman",
  docx.size = 9,
  docx.template = NULL,
  pptx.template = NULL,
  pptx.font = "Times New Roman",
  pptx.size = 12,
  docx.orientation = "portrait",
  ignore.request = c()
)
```

Arguments

df	dataset produced by pk_build().
dir	filepath for output directory.
strat.by	vector of variables names to stratify the summary tables.
ignore.c	ignores records flagged in the C column when TRUE.
na	numeric value to be interpreted as NA or missing.
docx	creates summary tables as a Word document when TRUE.
pptx	creates summary tables as a PowerPoint document when TRUE.
docx.font	font for the summary tables in the Word document.
docx.size	font size for the summary tables in the Word document.

docx.template filepath for template .docx file. When NULL, the summary tables print to a blank document.

pptx.template filepath for template .pptx file. When NULL, the summary tables print to a blank slide.

pptx.font font for the summary tables in the PowerPoint document.

pptx.size font size for the summary tables in the PowerPoint document.

docx.orientation orientation of .docx files.

ignore.request vector of additional logical expressions to filter the dataset prior to summary.

Value

summary tables as .csv, .docx, and .pptx files

Examples

```
## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
  CMT = 2,
  VISIT = "Day 1",
  PCTPT = c("Pre-dose",
    "30-min post-dose",
    "2-hr post-dose"),
  PCTEST = "ABC",
```

```

PCSTRESU = "ug/mL")

## Create with pk_build()
df <- pk_build(ex, pc)

## Generate summary statistics with pk_summarize()
pk_summarize(df)

```

pk_write

Write PK(PD) dataset to specified location

Description

Dataset created by `pk_build()` or `pk_combine()` will be outputted as a .csv file with NONMEM-standard formatting.

Usage

```
pk_write(df, file)
```

Arguments

df	PK(PD) dataframe
file	filepath

Value

writes dataset to specified location

Examples

```

## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

```

```
## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
                 PCDTC = c("2000-01-01 09:40:00",
                           "2000-01-01 10:29:00",
                           "2000-01-01 12:05:00"),
                 PCDY = 1,
                 PCTPTNUM = c(0, ##Units of hours
                              0.021,
                              0.083),
                 PCSTRESN = c(NA,
                              469,
                              870),
                 PCLLOQ = 25,
                 CMT = 2,
                 VISIT = "Day 1",
                 PCTPT = c("Pre-dose",
                           "30-min post-dose",
                           "2-hr post-dose"),
                 PCTEST = "ABC",
                 PCSTRESU = "ug/mL")

## Create with pk_build()
df <- pk_build(ex, pc)

## Write with pk_write()
name <- "dataset.csv"
pk_write(df, file.path(tempdir(), name))
```

`variable_list_create` *Create a dataframe with standard variable names and definitions*

Description

Variable list should be used as an input to the `apmx::pk_define()` function. The user should add additional definitions to the file for custom columns with `apmx::variable_list_add()`.

Usage

```
variable_list_create(
  variable = NULL,
  categorization = NULL,
  description = NULL,
  comment = NA
)
```

Arguments

variable	vector of variable names
categorization	vector of category names
description	vector of variable descriptions
comment	vector of variable comments (can be left NA)

Value

dataframe of standard variable definitions

Examples

```
v1 <- variable_list_create(variable = c("WEIGHT", "HEIGHT"),
                           categorization = rep("Covariate", 2),
                           description = c("weight", "height"))
```

version_log

Create and maintain a dataset version log

Description

Version log is outputted as a .docx file. Document tracks changes in subject count, record count, new variables, and changing variables. User comments in the word document are preserved between versions.

Usage

```
version_log(
  df,
  name,
  file = NULL,
  prevdata = NULL,
  template = NULL,
  comp_var,
  src_data = "",
  font = "Times New Roman",
  size = 9,
  orient = "landscape"
)
```

Arguments

df	filepath of new dataset
name	name of the dataset (filename with .csv suffix)
file	filepath for version log file (.docx)
prevdata	comparison dataset filepath
template	template docx filepath
comp_var	grouping variables for comparison
src_data	string to describe source data
font	font style
size	font size
orient	document orientation

Value

version log as a .docx file

Examples

```
## Simple ex domain with 1 subject and 1 dose
ex <- data.frame(STUDYID = "ABC101",
  USUBJID = "ABC101-001",
  EXSTDTC = "2000-01-01 10:00:00",
  EXSTDY = 1,
  EXTPTNUM = 0,
  EXDOSE = 100,
  CMT = 1,
  EXTRT = "ABC",
  EXDOSU = "mg",
  VISIT = "Day 1",
  EXTPT = "Dose",
  EXDOSFRQ = "Once",
  EXROUTE = "Oral")

## Simple pc domain with 1 subject and 3 observations
pc <- data.frame(USUBJID = "ABC101-001",
  PCDTC = c("2000-01-01 09:40:00",
    "2000-01-01 10:29:00",
    "2000-01-01 12:05:00"),
  PCDY = 1,
  PCTPTNUM = c(0, ##Units of hours
    0.021,
    0.083),
  PCSTRESN = c(NA,
    469,
    870),
  PCLLOQ = 25,
  CMT = 2,
  VISIT = "Day 1",
```

```
PCTPT = c("Pre-dose",
          "30-min post-dose",
          "2-hr post-dose"),
PCTEST = "ABC",
PCSTRESU = "ug/mL")

## Create with pk_build()
df <- pk_build(ex, pc)

## Document with version_log()
vlog <- version_log(df, name = "PK_DATA_V01.csv")
```

VL	VL
----	----

Description

Variable list with apmx variables and definitions

Usage

VL

Format

‘VL’ A data frame with 66 rows and 4 variables:

Variable Column or variable name

Categorization Column or variable category

Description Column or variable description

Comment NA by default

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