

# 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.

**License** GPL (>= 3)

**Encoding** UTF-8

**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
)

```



```

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,
  EXPTNUM = 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

*LB*

---

### 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

**LBTPN** 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,
  EXTPPTNUM = 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,
  EXPTNUM = 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.



```
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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