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Type Package

Title Create Random ADaM Datasets

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Description A set of functions to create random Analysis Data Model (ADaM) datasets and cached dataset. ADaM dataset specifications are described by the Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model Team.

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random.cdisc.data-package
 random.cdisc.data *Package*

Description

Package to create random SDTM and ADAM datasets.

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`apply_metadata`*Apply Metadata*

Description

Apply label and variable ordering attributes to domains.

Usage

```
apply_metadata(  
  df,  
  filename,  
  add_adsl = TRUE,  
  adsl_filename = "metadata/ADSL.yml"  
)
```

Arguments

<code>df</code>	(data.frame) Data frame to which metadata is applied.
<code>filename</code>	(yaml) File containing domain metadata.
<code>add_adsl</code>	(logical) Should ADSL data be merged to domain.
<code>adsl_filename</code>	(yaml) File containing ADSL metadata.

Value

Data frame with metadata applied.

Examples

```
seed <- 1  
adsl <- radsl(seed = seed)  
adsub <- radsub(adsl, seed = seed)  
yaml_path <- file.path(path.package("random.cdisc.data"), "inst", "metadata")  
adsl <- apply_metadata(adsl, file.path(yaml_path, "ADSL.yml"), FALSE)  
adsub <- apply_metadata(  
  adsub, file.path(yaml_path, "ADSUB.yml"), TRUE,  
  file.path(yaml_path, "ADSL.yml")  
)
```

cadab	<i>Cached ADAB</i>
-------	--------------------

Description

Cached ADAB data generated with seed = 1

Usage

```
data(cadab)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 6916 rows and 21 columns.

cadae	<i>Cached ADAE</i>
-------	--------------------

Description

Cached ADAE data generated with seed = 1

Usage

```
data(cadae)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1934 rows and 92 columns.

cadaette	<i>Cached ADAETTE</i>
----------	-----------------------

Description

Cached ADAETTE data generated with seed = 1

Usage

```
data(cadaette)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 3600 rows and 66 columns.

cadcm	<i>Cached ADCM</i>
-------	--------------------

Description

Cached ADCM data generated with seed = 1

Usage

```
data(cadcm)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 3685 rows and 83 columns.

caddv	<i>Cached ADDV</i>
-------	--------------------

Description

Cached ADDV data generated with seed = 1

Usage

```
data(caddv)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 119 rows and 66 columns.

cadeg	<i>Cached ADEG</i>
-------	--------------------

Description

Cached ADEG data generated with seed = 1

Usage

```
data(cadeg)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 13600 rows and 88 columns.

`cadex`*Cached ADEX*

Description

Cached ADEX data generated with seed = 1

Usage

```
data(cadex)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 6400 rows and 79 columns.

`cadhy`*Cached ADHY*

Description

Cached ADHY data generated with seed = 1

Usage

```
data(cadhy)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 20000 rows and 71 columns.

`cadlb`*Cached ADLB*

Description

Cached ADLB data generated with seed = 1

Usage

```
data(cadlb)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 8400 rows and 102 columns.

`cadmh`*Cached ADMH*

Description

Cached ADMH data generated with seed = 1

Usage

```
data(cadmh)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1934 rows and 67 columns.

`cadpc`*Cached ADPC*

Description

Cached ADPC data generated with seed = 1

Usage

```
data(cadpc)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 6640 rows and 72 columns.

`cadpp`*Cached ADPP*

Description

Cached ADPP data generated with seed = 1

Usage

```
data(cadpp)
```

Format

An object of class `data.frame` with 26268 rows and 68 columns.

cadqlqc	<i>Cached ADQLQC</i>
---------	----------------------

Description

Cached ADQLQC data generated with seed = 1

Usage

```
data(cadqlqc)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 116803 rows and 50 columns.

cadqs	<i>Cached ADQS</i>
-------	--------------------

Description

Cached ADQS data generated with seed = 1

Usage

```
data(cadqs)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 14000 rows and 73 columns.

cadrs	<i>Cached ADRS</i>
-------	--------------------

Description

Cached ADRS data generated with seed = 1

Usage

```
data(cadrs)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 3200 rows and 65 columns.

cadsl	<i>Cached ADSL</i>
-------	--------------------

Description

Cached ADSL data generated with seed = 1

Usage

```
data(cadsl)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 400 rows and 55 columns.

cadsub	<i>Cached ADSUB</i>
--------	---------------------

Description

Cached ADSUB data generated with seed = 1

Usage

```
data(cadsub)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 2000 rows and 65 columns.

cadtr	<i>Cached ADTR</i>
-------	--------------------

Description

Cached ADTR data generated with seed = 1

Usage

```
data(cadtr)
```

Format

An object of class `data.frame` with 2800 rows and 76 columns.

cadtte	<i>Cached ADTTE</i>
--------	---------------------

Description

Cached ADTTE data generated with seed = 1

Usage

```
data(cadtte)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 2000 rows and 67 columns.

cadvs	<i>Cached ADVS</i>
-------	--------------------

Description

Cached ADVS data generated with seed = 1

Usage

```
data(cadvs)
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 16800 rows and 87 columns.

mutate_na	<i>Replace Values with NA</i>
-----------	-------------------------------

Description

[Stable]

Replace column values with NAs.

Usage

```
mutate_na(ds, na_vars = NULL, na_percentage = 0.05)
```

Arguments

ds	(data.frame) Any data set.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none">• seed (numeric) The seed to be used for this element - can be NA.• percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
na_percentage	(proportion) Default percentage of values to be replaced by NA.

Value

dataframe without NA values.

radab	<i>Anti-Drug Antibody Analysis Dataset (ADAB)</i>
-------	---

Description

[Stable]

Function for generating a random Anti-Drug Antibody Analysis Dataset for a given Subject-Level Analysis Dataset and Pharmacokinetics Analysis Dataset.

Usage

```
radab(  
  adsl,  
  adpc,  
  constants = c(D = 100, ka = 0.8, ke = 1),  
  paramcd = c("R1800000", "RESULT1", "R1800001", "RESULT2", "ADASTAT1", "INDUCD1",  
    "ENHANC1", "TRUNAFF1", "EMERNEG1", "EMERPOS1", "PERSADA1", "TRANADA1", "BFLAG1",  
    "TIMADA1", "ADADUR1", "ADASTAT2", "INDUCD2", "ENHANC2", "EMERNEG2", "EMERPOS2",  
    "BFLAG2", "TRUNAFF2"),  
  param = c("Antibody titer units", "ADA interpreted per sample result",  
    "Neutralizing Antibody titer units", "NAB interpreted per sample result",  
    "ADA Status of a patient", "Treatment induced ADA", "Treatment enhanced ADA",  
    "Treatment unaffected", "Treatment Emergent - Negative",  
    "Treatment Emergent - Positive", "Persistent ADA", "Transient ADA", "Baseline",  
    "Time to onset of ADA", "ADA Duration", "NAB Status of a patient",  
    "Treatment induced ADA, Neutralizing Antibody",  
    "Treatment enhanced ADA, Neutralizing Antibody",
```

```

    "Treatment Emergent - Negative, Neutralizing Antibody",
    "Treatment Emergent - Positive, Neutralizing Antibody",
    "Baseline, Neutralizing Antibody", "Treatment unaffected, Neutralizing Antibody"),
  avalu = c("titer", "", "titer", "", "", "", "", "", "", "", "", "", "", "weeks",
    "weeks", "", "", "", "", "", "", "", ""),
  seed = NULL,
  na_percentage = 0,
  na_vars = list(AVAL = c(NA, 0.1)),
  cached = FALSE
)

```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
adpc	(data.frame) Pharmacokinetics Analysis Dataset.
constants	(character vector) Constant parameters to be used in formulas for creating analysis values.
paramcd	(character vector) Parameter code values.
param	(character vector) Parameter values.
avalu	(character) Analysis value units.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADAB data cadab should be returned or new data should be generated. If set to TRUE then the other arguments to radab will be ignored.

Details

One record per study per subject per parameter per time point: "R1800000", "RESULT1", "R1800001", "RESULT2".

Value

data.frame

Examples

```
adsl <- rads1(N = 10, seed = 1, study_duration = 2)
adpc <- radpc(adsl, seed = 2, duration = 9 * 7)

adab <- radab(adsl, adpc, seed = 2)
adab
```

radae	<i>Adverse Event Analysis Dataset (ADAE)</i>
-------	--

Description

[Stable]

Function for generating random Adverse Event Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radae(
  adsl,
  max_n_aes = 10L,
  lookup = NULL,
  lookup_aag = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(AEBODSYS = c(NA, 0.1), AEDECOD = c(1234, 0.1), AETOXGR = c(1234, 0.1)),
  cached = FALSE
)
```

Arguments

- adsl (data.frame)
Subject-Level Analysis Dataset (ADSL).
- max_n_aes (integer)
Maximum number of AEs per patient. Defaults to 10.
- lookup (data.frame)
Additional parameters.
- lookup_aag (data.frame)
Additional metadata parameters.
- seed (numeric)
Seed to use for reproducible random number generation.

na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADAE data cadae should be returned or new data should be generated. If set to TRUE then the other arguments to radae will be ignored.

Details

One record per each record in the corresponding SDTM domain.

Keys: STUDYID, USUBJID, ASTDTM, AETERM, AESEQ

Value

data.frame

Examples

```
adsl <- rads1(N = 10, study_duration = 2, seed = 1)

adae <- radae(adsl, seed = 2)
adae

# Add metadata.
aag <- utils::read.table(
  sep = ",", header = TRUE,
  text = paste(
    "NAMVAR, SRCVAR, GRPTYPE, REFNAME, REFTERM, SCOPE",
    "CQ01NAM, AEDECOD, CUSTOM, D.2.1.5.3/A.1.1.1.1 AESI, dcd D.2.1.5.3,",
    "CQ01NAM, AEDECOD, CUSTOM, D.2.1.5.3/A.1.1.1.1 AESI, dcd A.1.1.1.1,",
    "SMQ01NAM, AEDECOD, SMQ, C.1.1.1.3/B.2.2.3.1 AESI, dcd C.1.1.1.3, BROAD",
    "SMQ01NAM, AEDECOD, SMQ, C.1.1.1.3/B.2.2.3.1 AESI, dcd B.2.2.3.1, BROAD",
    "SMQ02NAM, AEDECOD, SMQ, Y.9.9.9.9/Z.9.9.9.9 AESI, dcd Y.9.9.9.9, NARROW",
    "SMQ02NAM, AEDECOD, SMQ, Y.9.9.9.9/Z.9.9.9.9 AESI, dcd Z.9.9.9.9, NARROW",
    sep = "\n"
  ), stringsAsFactors = FALSE
)

adae <- radae(adsl, lookup_aag = aag)

with(
  adae,
  cbind(
```

```

      table(AEDECOD, SMQ01NAM),
      table(AEDECOD, CQ01NAM)
    )
  )

```

radaette

*Time to Adverse Event Analysis Dataset (ADAETTE)***Description****[Stable]**

Function to generate random Time-to-AE Dataset for a given Subject-Level Analysis Dataset.

Usage

```

radaette(
  adsl,
  event_descr = NULL,
  censor_descr = NULL,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(CNSR = c(NA, 0.1), AVAL = c(1234, 0.1)),
  cached = FALSE
)

```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
event_descr	(character vector) Descriptions of events. Defaults to NULL.
censor_descr	(character vector) Descriptions of censors. Defaults to NULL.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA.

- **percentage (proportion)**
Percentage of elements to be replaced with NA. If NA, `na_percentage` is used as a default.
- cached** boolean whether the cached ADAETTE data `cadaette` should be returned or new data should be generated. If set to TRUE then the other arguments to `radaette` will be ignored.

Details

Keys: STUDYID, USUBJID, PARAMCD

Value

`data.frame`

Author(s)

Xiuting Mi

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adaette <- radaette(adsl, seed = 2)
adaette
```

radcm

Previous and Concomitant Medications Analysis Dataset (ADCM)

Description

[Stable]

Function for generating random Concomitant Medication Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radcm(
  adsl,
  max_n_cms = 10L,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(CMCLAS = c(NA, 0.1), CMDECOD = c(1234, 0.1), ATIREL = c(1234, 0.1)),
  who_coding = FALSE,
  cached = FALSE
)
```

Arguments

<code>adsl</code>	(data.frame) Subject-Level Analysis Dataset (ADSL).
<code>max_n_cms</code>	(integer) Maximum number of concomitant medications per patient. Defaults to 10.
<code>lookup</code>	(data.frame) Additional parameters.
<code>seed</code>	(numeric) Seed to use for reproducible random number generation.
<code>na_percentage</code>	(proportion) Default percentage of values to be replaced by NA.
<code>na_vars</code>	(list) A named list where the name of each element is a column name of <code>ds</code> . Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • <code>seed</code> (numeric) The seed to be used for this element - can be NA. • <code>percentage</code> (proportion) Percentage of elements to be replaced with NA. If NA, <code>na_percentage</code> is used as a default.
<code>who_coding</code>	(flag) Whether WHO coding (with multiple paths per medication) should be used.
<code>cached</code>	boolean whether the cached ADCM data <code>cadcm</code> should be returned or new data should be generated. If set to TRUE then the other arguments to <code>radcm</code> will be ignored.

Details

One record per each record in the corresponding SDTM domain.

Keys: STUDYID, USUBJID, ASTDTM, CMSEQ

Value

data.frame

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adcm <- radcm(adsl, seed = 2)
adcm

adcm_who <- radcm(adsl, seed = 2, who_coding = TRUE)
adcm_who
```

raddv	<i>Protocol Deviations Analysis Dataset (ADDV)</i>
-------	--

Description

[Stable]

Function for generating random Protocol Deviations Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
raddv(
  adsl,
  max_n_dv = 3L,
  p_dv = 0.15,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(ASTDt = c(seed = 1234, percentage = 0.1), DVCAT = c(seed = 1234,
    percentage = 0.1)),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
max_n_dv	(integer) Maximum number of deviations per patient. Defaults to 3.
p_dv	(proportion) Probability of a patient having protocol deviations.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.

cached boolean whether the cached ADDV data caddv should be returned or new data should be generated. If set to TRUE then the other arguments to raddv will be ignored.

Details

One record per each record in the corresponding SDTM domain.
Keys: STUDYID, USUBJID, ASTDT, DVTERM, DVSEQ

Value

data.frame

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

addv <- raddv(adsl, seed = 2)
addv
```

radeg	<i>ECG Analysis Dataset (ADEG)</i>
-------	------------------------------------

Description

[Stable]
Function for generating random dataset from ECG Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radeg(
  adsl,
  egcat = c("INTERVAL", "INTERVAL", "MEASUREMENT", "FINDING"),
  param = c("QT Duration", "RR Duration", "Heart Rate", "ECG Interpretation"),
  paramcd = c("QT", "RR", "HR", "ECGINTP"),
  paramu = c("msec", "msec", "beats/min", ""),
  visit_format = "WEEK",
  n_assessments = 5L,
  n_days = 5L,
  max_n_eg = 10L,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(ABLFL = c(1235, 0.1), BASE = c(NA, 0.1), BASEC = c(NA, 0.1), CHG =
    c(1234, 0.1), PCHG = c(1234, 0.1)),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
egcat	(character vector) EG category values.
param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
paramu	(character vector) Parameter unit values.
visit_format	(character) Type of visit. Options are "WEEK" and "CYCLE".
n_assessments	(integer) Number of weeks or cycles.
n_days	(integer) Number of days in each cycle (only used if visit_format is "CYCLE").
max_n_eg	(integer) Maximum number of EG results per patient. Defaults to 10.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADEG data cadeg should be returned or new data should be generated. If set to TRUE then the other arguments to radeg will be ignored.

Details

One record per subject per parameter per analysis visit per analysis date.

Keys: STUDYID, USUBJID, PARAMCD, BASETYPE, AVISITN, ATPTN, DTYPE, ADTM, EGSEQ, ASPID

Value

data.frame

Author(s)

tomlinsj, npaszty, Xuefeng Hou, dipietrc

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adeg <- radeg(adsl, visit_format = "WEEK", n_assessments = 7L, seed = 2)
adeg

adeg <- radeg(adsl, visit_format = "CYCLE", n_assessments = 2L, seed = 2)
adeg
```

radex

Exposure Analysis Dataset (ADEX)

Description**[Stable]**

Function for generating random Exposure Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radex(
  adsl,
  param = c("Dose administered during constant dosing interval",
    "Number of doses administered during constant dosing interval",
    "Total dose administered", "Total number of doses administered"),
  paramcd = c("DOSE", "NDOSE", "TDOSE", "TNDOSE"),
  paramu = c("mg", " ", "mg", " "),
  parcat1 = c("INDIVIDUAL", "OVERALL"),
  parcat2 = c("Drug A", "Drug B"),
  visit_format = "WEEK",
  n_assessments = 5L,
  n_days = 5L,
  max_n_exs = 6L,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(AVAL = c(NA, 0.1), AVALU = c(NA), 0.1),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
paramu	(character vector) Parameter unit values.
parcat1	(character vector) Dose amount categories. Defaults to "Individual" and "Overall".
parcat2	(character vector) Types of drug received. Defaults to "Drug A" and "Drug B".
visit_format	(character) Type of visit. Options are "WEEK" and "CYCLE".
n_assessments	(integer) Number of weeks or cycles.
n_days	(integer) Number of days in each cycle (only used if visit_format is "CYCLE").
max_n_exs	(integer) Maximum number of exposures per patient. Defaults to 6.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADEX data cadex should be returned or new data should be generated. If set to TRUE then the other arguments to radex will be ignored.

Details

One record per each record in the corresponding SDTM domain.

Keys: STUDYID, USUBJID, EXSEQ, PARAMCD, PARCAT1, ASTDTM, AENDTM, ASTDY, AENDY, AVISITN, EXDOSFRQ, EXROUTE, VISIT, VISITDY, EXSTDTC, EXENDTC, EXSTDY, EXENDY

Value

data.frame

Examples

```
adsl <- radsl(N = 10, study_duration = 2, seed = 1)

adex <- radex(adsl, seed = 2)
adex
```

radhy

Hy's Law Analysis Dataset (ADHY)

Description**[Stable]**

Function for generating a random Hy's Law Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radhy(
  adsl,
  param = c("TBILI <= 2 times ULN and ALT value category",
    "TBILI > 2 times ULN and AST value category",
    "TBILI > 2 times ULN and ALT value category",
    "TBILI <= 2 times ULN and AST value category",
    "TBILI > 2 times ULN and ALKPH <= 2 times ULN and ALT value category",
    "TBILI > 2 times ULN and ALKPH <= 2 times ULN and AST value category",
    "TBILI > 2 times ULN and ALKPH <= 5 times ULN and ALT value category",
    "TBILI > 2 times ULN and ALKPH <= 5 times ULN and AST value category",
    "TBILI <= 2 times ULN and two consecutive elevations of ALT in relation to ULN",

    "TBILI > 2 times ULN and two consecutive elevations of AST in relation to ULN",
    "TBILI <= 2 times ULN and two consecutive elevations of AST in relation to ULN",
    "TBILI > 2 times ULN and two consecutive elevations of ALT in relation to ULN",
    "TBILI > 2 times ULN and two consecutive elevations of ALT in relation to Baseline",
    "TBILI <= 2 times ULN and two consecutive elevations of ALT in relation to Baseline",
    "TBILI > 2 times ULN and two consecutive elevations of AST in relation to Baseline",

    "TBILI <= 2 times ULN and two consecutive elevations of AST in relation to Baseline",
    "ALT > 3 times ULN by Period", "AST > 3 times ULN by Period",
    "ALT or AST > 3 times ULN by Period", "ALT > 3 times Baseline by Period",
    "AST > 3 times Baseline by Period", "ALT or AST > 3 times Baseline by Period"),
  paramcd = c("BLAL", "BGAS", "BGAL", "BLAS", "BA2AL", "BA2AS", "BA5AL", "BA5AS",
    "BL2AL2CU", "BG2AS2CU", "BL2AS2CU", "BG2AL2CU", "BG2AL2CB", "BL2AL2CB", "BG2AS2CB",
```



```

      "BL2AS2CB", "ALTPULN", "ASTPULN", "ALTASTPU", "ALTPBASE", "ASTPBASE", "ALTASTPB"),
    seed = NULL,
    cached = FALSE
  )

```

Arguments

<code>adsl</code>	(data.frame) Subject-Level Analysis Dataset (ADSL).
<code>param</code>	(character vector) Parameter values.
<code>paramcd</code>	(character vector) Parameter code values.
<code>seed</code>	(numeric) Seed to use for reproducible random number generation.
<code>cached</code>	boolean whether the cached ADHY data <code>cadhy</code> should be returned or new data should be generated. If set to TRUE then the other arguments to <code>radhy</code> will be ignored.

Details

One record per subject per parameter per analysis visit per analysis date.

Keys: STUDYID, USUBJID, PARAMCD, AVISITN, ADTM, SRCSEQ

Value

data.frame

Author(s)

wojciakw

Examples

```

adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adhy <- radhy(adsl, seed = 2)
adhy

```

radlb	<i>Laboratory Data Analysis Dataset (ADLB)</i>
-------	--

Description

[Stable]

Function for generating a random Laboratory Data Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radlb(  
  adsl,  
  lbcats = c("CHEMISTRY", "CHEMISTRY", "IMMUNOLOGY"),  
  param = c("Alanine Aminotransferase Measurement", "C-Reactive Protein Measurement",  
    "Immunoglobulin A Measurement"),  
  paramcd = c("ALT", "CRP", "IGA"),  
  paramu = c("U/L", "mg/L", "g/L"),  
  aval_mean = c(18, 9, 2.9),  
  visit_format = "WEEK",  
  n_assessments = 5L,  
  n_days = 5L,  
  max_n_lbs = 10L,  
  lookup = NULL,  
  seed = NULL,  
  na_percentage = 0,  
  na_vars = list(LOQFL = c(NA, 0.1), ABLFL2 = c(1234, 0.1), ABLFL = c(1235, 0.1), BASE2 =  
    c(NA, 0.1), BASE = c(NA, 0.1), CHG2 = c(1235, 0.1), PCHG2 = c(1235, 0.1), CHG =  
    c(1234, 0.1), PCHG = c(1234, 0.1)),  
  cached = FALSE  
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
lbcats	(character vector) LB category values.
param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
paramu	(character vector) Parameter unit values.

aval_mean	(numeric vector) Mean values corresponding to each parameter.
visit_format	(character) Type of visit. Options are "WEEK" and "CYCLE".
n_assessments	(integer) Number of weeks or cycles.
n_days	(integer) Number of days in each cycle (only used if visit_format is "CYCLE").
max_n_lbs	(integer) Maximum number of labs per patient. Defaults to 10.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADLB data cadlb should be returned or new data should be generated. If set to TRUE then the other arguments to radlb will be ignored.

Details

One record per subject per parameter per analysis visit per analysis date.

Keys: STUDYID, USUBJID, PARAMCD, BASETYPE, AVISITN, ATPTN, DTYPE, ADTM, LBSEQ, ASPID

Value

data.frame

Author(s)

tomlinjs, npaszty, Xuefeng Hou

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)
```

```
adlb <- radlb(adsl, visit_format = "WEEK", n_assessments = 7L, seed = 2)
```

```
adlb

adlb <- radlb(adsl, visit_format = "CYCLE", n_assessments = 2L, seed = 2)
adlb
```

radmh

Medical History Analysis Dataset (ADMH)

Description

[Stable]

Function for generating a random Medical History Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radmh(
  adsl,
  max_n_mhs = 10L,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(MHBODSYS = c(NA, 0.1), MHDECOD = c(1234, 0.1)),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
max_n_mhs	(integer) Maximum number of MHs per patient. Defaults to 10.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> seed (numeric) The seed to be used for this element - can be NA. percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.

cached boolean whether the cached ADMH data `cadmh` should be returned or new data should be generated. If set to `TRUE` then the other arguments to `radmh` will be ignored.

Details

One record per each record in the corresponding SDTM domain.

Keys: STUDYID, USUBJID, ASTDTM, MHSEQ

Value

`data.frame`

Examples

```
adsl <- radsl(N = 10, study_duration = 2, seed = 1)

admh <- radmh(adsl, seed = 2)
admh
```

radpc

Pharmacokinetics Analysis Dataset (ADPC)

Description

[Stable]

Function for generating a random Pharmacokinetics Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radpc(
  adsl,
  avalu = "ug/mL",
  constants = c(D = 100, ka = 0.8, ke = 1),
  duration = 2,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(AVAL = c(NA, 0.1)),
  cached = FALSE
)
```

Arguments

<code>adsl</code>	(data.frame) Subject-Level Analysis Dataset (ADSL).
<code>avalu</code>	(character) Analysis value units.
<code>constants</code>	(character vector) Constant parameters to be used in formulas for creating analysis values.
<code>duration</code>	(numeric) Duration in number of days.
<code>seed</code>	(numeric) Seed to use for reproducible random number generation.
<code>na_percentage</code>	(proportion) Default percentage of values to be replaced by NA.
<code>na_vars</code>	(list) A named list where the name of each element is a column name of <code>ds</code> . Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • <code>seed</code> (numeric) The seed to be used for this element - can be NA. • <code>percentage</code> (proportion) Percentage of elements to be replaced with NA. If NA, <code>na_percentage</code> is used as a default.
<code>cached</code>	boolean whether the cached ADPC data <code>cadpc</code> should be returned or new data should be generated. If set to TRUE then the other arguments to <code>radpc</code> will be ignored.

Details

One record per study, subject, parameter, and time point.

Value

`data.frame`

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adpc <- radpc(adsl, seed = 2)
adpc

adpc <- radpc(adsl, seed = 2, duration = 3)
adpc
```

radpp

*Pharmacokinetics Parameters Dataset (ADPP)***Description****[Stable]**

Function for generating a random Pharmacokinetics Parameters Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radpp(
  adsl,
  ppcat = c("Plasma Drug X", "Plasma Drug Y", "Metabolite Drug X", "Metabolite Drug Y"),
  ppspec = c("Plasma", "Plasma", "Plasma", "Matrix of PD", "Matrix of PD", "Urine",
    "Urine", "Urine", "Urine"),
  paramcd = c("AUCIFO", "CMAX", "CLO", "RMAX", "TON", "RENALCL", "RENALCLD", "RCAMINT",
    "RCPCLINT"),
  param = c("AUC Infinity Obs", "Max Conc", "Total CL Obs", "Time of Maximum Response",
    "Time to Onset", "Renal CL", "Renal CL Norm by Dose", "Amt Rec from T1 to T2",
    "Pct Rec from T1 to T2"),
  paramu = c("day*ug/mL", "ug/mL", "ml/day/kg", "hr", "hr", "L/hr", "L/hr/mg", "mg",
    "%"),
  aval_mean = c(200, 30, 5, 10, 3, 0.05, 0.005, 1.5613, 15.65),
  visit_format = "CYCLE",
  n_days = 2L,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(AVAL = c(NA, 0.1)),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
ppcat	(character vector) Categories of parameters.
ppspec	(character vector) Specimen material types.
paramcd	(character vector) Parameter code values.
param	(character vector) Parameter values.
paramu	(character vector) Parameter unit values.

aval_mean	(numeric vector) Mean values corresponding to each parameter.
visit_format	(character) Type of visit. Options are "WEEK" and "CYCLE".
n_days	(integer) Number of days in each cycle (only used if visit_format is "CYCLE").
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADPP data cadpp should be returned or new data should be generated. If set to TRUE then the other arguments to radpp will be ignored.

Details

One record per study, subject, parameter category, parameter and visit.

Value

data.frame

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)
```

```
adpp <- radpp(adsl, seed = 2)
```

```
adpp
```

radqlqc

EORTC QLQ-C30 V3 Analysis Dataset (ADQLQC)

Description

[Stable]

Function for generating a random EORTC QLQ-C30 V3 Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radqlqc(adsl, percent, number, seed = NULL, cached = FALSE)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
percent	(numeric) Completion - Completed at least y percent of questions, 1 record per visit
number	(numeric) Completion - Completed at least x question(s), 1 record per visit
seed	(numeric) Seed to use for reproducible random number generation.
cached	boolean whether the cached ADQLQC data cadqlqc should be returned or new data should be generated. If set to TRUE then the other arguments to radqlqc will be ignored.

Details

Keys: STUDYID, USUBJID, PARCAT1N, PARAMCD, BASETYPE, AVISITN, ATPTN, ADTM, QSSEQ

Value

data.frame

Examples

```
adsl <- radsl(N = 10, study_duration = 2, seed = 1)

adqlqc <- radqlqc(adsl, seed = 1, percent = 80, number = 2)
adqlqc
```

radqs	<i>Questionnaires Analysis Dataset (ADQS)</i>
-------	---

Description

[Stable]

Function for generating a random Questionnaires Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radqs(
  adsl,
  param = c("BFI All Questions", "Fatigue Interference",
    "Function/Well-Being (GF1,GF3,GF7)", "Treatment Side Effects (GP2,C5,GP5)",
    "FKSI-19 All Questions"),
  paramcd = c("BFIALl", "FATIGI", "FKSI-FWB", "FKSI-TSE", "FKSIALl"),
  visit_format = "WEEK",
  n_assessments = 5L,
  n_days = 5L,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(LOQFL = c(NA, 0.1), ABLFL2 = c(1234, 0.1), ABLFL = c(1235, 0.1), CHG2 =
    c(1235, 0.1), PCHG2 = c(1235, 0.1), CHG = c(1234, 0.1), PCHG = c(1234, 0.1)),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
visit_format	(character) Type of visit. Options are "WEEK" and "CYCLE".
n_assessments	(integer) Number of weeks or cycles.
n_days	(integer) Number of days in each cycle (only used if visit_format is "CYCLE").
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADQS data cadqs should be returned or new data should be generated. If set to TRUE then the other arguments to radqs will be ignored.

Details

One record per subject per parameter per analysis visit per analysis date.

Keys: STUDYID, USUBJID, PARAMCD, AVISITN

Value

data.frame

Author(s)

npaszty

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adqs <- radqs(adsl, visit_format = "WEEK", n_assessments = 7L, seed = 2)
adqs

adqs <- radqs(adsl, visit_format = "CYCLE", n_assessments = 3L, seed = 2)
adqs
```

radrs

Tumor Response Analysis Dataset (ADRS)

Description**[Stable]**

Function for generating a random Tumor Response Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radrs(
  adsl,
  avalc = NULL,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(AVISIT = c(NA, 0.1), AVAL = c(1234, 0.1), AVALC = c(1234, 0.1)),
  cached = FALSE
)
```

Arguments

<code>adsl</code>	(data.frame) Subject-Level Analysis Dataset (ADSL).
<code>avalc</code>	(character vector) Analysis value categories.
<code>lookup</code>	(data.frame) Additional parameters.
<code>seed</code>	(numeric) Seed to use for reproducible random number generation.
<code>na_percentage</code>	(proportion) Default percentage of values to be replaced by NA.
<code>na_vars</code>	(list) A named list where the name of each element is a column name of <code>ds</code> . Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • <code>seed</code> (numeric) The seed to be used for this element - can be NA. • <code>percentage</code> (proportion) Percentage of elements to be replaced with NA. If NA, <code>na_percentage</code> is used as a default.
<code>cached</code>	boolean whether the cached ADRS data <code>cadrs</code> should be returned or new data should be generated. If set to TRUE then the other arguments to <code>radrs</code> will be ignored.

Details

One record per subject per parameter per analysis visit per analysis date. SDTM variables are populated on new records coming from other single records. Otherwise, SDTM variables are left blank.

Keys: STUDYID, USUBJID, PARAMCD, AVISITN, ADT, RSSEQ

Value

data.frame

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adrs <- radrs(adsl, seed = 2)
adrs
```

radsaftte	<i>Time to Safety Event Analysis Dataset (ADSAFTTE)</i>
-----------	---

Description

Function to generate random Time-to-Safety Event Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radsaftte(adsl, ...)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
...	Additional arguments to be passed to radaette

Details

Keys: STUDYID, USUBJID, PARAMCD

Value

data.frame

Examples

```
adsl <- rads1(N = 10, seed = 1, study_duration = 2)

adsaftte <- radsaftte(adsl, seed = 2)
adsaftte
```

rads1	<i>Subject-Level Analysis Dataset (ADSL)</i>
-------	--

Description

[Stable]

The Subject-Level Analysis Dataset (ADSL) is used to provide the variables that describe attributes of a subject. ADSL is a source for subject-level variables used in other analysis data sets, such as population flags and treatment variables. There is only one ADSL per study. ADSL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis data sets are submitted.

Usage

```

rads1(
  N = 400,
  study_duration = 2,
  seed = NULL,
  with_trt02 = TRUE,
  na_percentage = 0,
  na_vars = list(AGE = NA, SEX = NA, RACE = NA, STRATA1 = NA, STRATA2 = NA, BMRKR1 =
    c(seed = 1234, percentage = 0.1), BMRKR2 = c(1234, 0.1), BEP01FL = NA),
  ae_withdrawal_prob = 0.05,
  cached = FALSE
)

```

Arguments

N	(numeric) Number of patients.
study_duration	(numeric) Duration of study in years.
seed	(numeric) Seed to use for reproducible random number generation.
with_trt02	(logical) Should period 2 be added.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
ae_withdrawal_prob	(proportion) Probability that there is at least one Adverse Event leading to the withdrawal of a study drug.
cached	boolean whether the cached ADSL data cads1 should be returned or new data should be generated. If set to TRUE then the other arguments to rads1 will be ignored.

Details

One record per subject.

Keys: STUDYID, USUBJID

Value

data.frame

Examples

```
adsl <- radsl(N = 10, study_duration = 2, seed = 1)
adsl

adsl <- radsl(
  N = 10, seed = 1,
  na_percentage = 0.1,
  na_vars = list(
    DTHDT = c(seed = 1234, percentage = 0.1),
    LSTALVDT = c(seed = 1234, percentage = 0.1)
  )
)
adsl

adsl <- radsl(N = 10, seed = 1, na_percentage = .1)
adsl
```

radsub

Subcategory Analysis Dataset (ADSUB)

Description**[Stable]**

Function for generating a random Subcategory Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radsub(
  adsl,
  param = c("Baseline Weight", "Baseline Height", "Baseline BMI", "Baseline ECOG",
    "Baseline Biomarker Mutation"),
  paramcd = c("BWGHTSI", "BHGHTSI", "BBMISI", "BECOG", "BBMRKR1"),
  seed = NULL,
  na_percentage = 0,
  na_vars = list(),
  cached = FALSE
)
```

Arguments

adsl (data.frame)
Subject-Level Analysis Dataset (ADSL).

param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADSUB data cadsb should be returned or new data should be generated. If set to TRUE then the other arguments to radsub will be ignored.

Details

One record per subject.

Keys: STUDYID, USUBJID, PARAMCD, AVISITN, ADTM, SRCSEQ

Value

data.frame

Author(s)

tomlinsj, npaszty, Xuefeng Hou, dipietrc

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)
```

```
adsub <- radsub(adsl, seed = 2)
adsub
```


radtr	<i>Tumor Response Analysis Dataset (ADTR)</i>
-------	---

Description

[Stable]

Function for generating a random Tumor Response Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radtr(  
  adsl,  
  param = c("Sum of Longest Diameter by Investigator"),  
  paramcd = c("SLDINV"),  
  seed = NULL,  
  cached = FALSE,  
  ...  
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
seed	(numeric) Seed to use for reproducible random number generation.
cached	boolean whether the cached ADTR data cadtr should be returned or new data should be generated. If set to TRUE then the other arguments to radtr will be ignored.
...	Additional arguments to be passed to radrs.

Details

One record per subject per parameter per analysis visit per analysis date.
Keys: STUDYID, USUBJID, PARAMCD, BASETYPE, AVISITN, DTYPE

Value

data.frame

Author(s)

tomlinsj, npaszty, Xuefeng Hou, dipietrc

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adtr <- radtr(adsl, seed = 2)
adtr
```

radtte	<i>Time-to-Event Analysis Dataset (ADTTE)</i>
--------	---

Description

[Stable]

Function for generating a random Time-to-Event Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radtte(
  adsl,
  event_descr = NULL,
  censor_descr = NULL,
  lookup = NULL,
  seed = NULL,
  na_percentage = 0,
  na_vars = list(CNSR = c(NA, 0.1), AVAL = c(1234, 0.1), AVALU = c(1234, 0.1)),
  cached = FALSE
)
```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
event_descr	(character vector) Descriptions of events. Defaults to NULL.
censor_descr	(character vector) Descriptions of censors. Defaults to NULL.
lookup	(data.frame) Additional parameters.
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.

na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none">• seed (numeric) The seed to be used for this element - can be NA.• percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADTTE data cadtte should be returned or new data should be generated. If set to TRUE then the other arguments to radtte will be ignored.

Details

Keys: STUDYID, USUBJID, PARAMCD

Value

data.frame

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

adtte <- radtte(adsl, seed = 2)
adtte
```

radvs	<i>Vital Signs Analysis Dataset (ADVS)</i>
-------	--

Description

[Stable]
Function for generating a random Vital Signs Analysis Dataset for a given Subject-Level Analysis Dataset.

Usage

```
radvs(  
  adsl,  
  param = c("Diastolic Blood Pressure", "Pulse Rate", "Respiratory Rate",  
            "Systolic Blood Pressure", "Temperature", "Weight"),  
  paramcd = c("DIABP", "PULSE", "RESP", "SYSBP", "TEMP", "WEIGHT"),  
  paramu = c("Pa", "beats/min", "breaths/min", "Pa", "C", "Kg"),  
  visit_format = "WEEK",  
  n_assessments = 5L,  
  n_days = 5L,
```

```

    seed = NULL,
    na_percentage = 0,
    na_vars = list(CHG2 = c(1235, 0.1), PCHG2 = c(1235, 0.1), CHG = c(1234, 0.1), PCHG =
      c(1234, 0.1), AVAL = c(123, 0.1), AVALU = c(123, 0.1)),
    cached = FALSE
  )

```

Arguments

adsl	(data.frame) Subject-Level Analysis Dataset (ADSL).
param	(character vector) Parameter values.
paramcd	(character vector) Parameter code values.
paramu	(character vector) Parameter unit values.
visit_format	(character) Type of visit. Options are "WEEK" and "CYCLE".
n_assessments	(integer) Number of weeks or cycles.
n_days	(integer) Number of days in each cycle (only used if visit_format is "CYCLE").
seed	(numeric) Seed to use for reproducible random number generation.
na_percentage	(proportion) Default percentage of values to be replaced by NA.
na_vars	(list) A named list where the name of each element is a column name of ds. Each element of this list should be a numeric vector with two elements: <ul style="list-style-type: none"> • seed (numeric) The seed to be used for this element - can be NA. • percentage (proportion) Percentage of elements to be replaced with NA. If NA, na_percentage is used as a default.
cached	boolean whether the cached ADVS data cadvs should be returned or new data should be generated. If set to TRUE then the other arguments to radvs will be ignored.

Details

One record per subject per parameter per analysis visit per analysis date.

Keys: STUDYID, USUBJID, PARAMCD, BASETYPE, AVISITN, ATPTN, DTYPE, ADTM, VSSEQ, ASPID

Value

data.frame

Author(s)

npaszty

Examples

```
adsl <- radsl(N = 10, seed = 1, study_duration = 2)

advs <- radvs(adsl, visit_format = "WEEK", n_assessments = 7L, seed = 2)
advs

advs <- radvs(adsl, visit_format = "CYCLE", n_assessments = 3L, seed = 2)
advs
```

rel_var

Related Variables: Assign

Description

Assign values to a related variable within a domain.

Usage

```
rel_var(df, var_name, related_var, var_values = NULL)
```

Arguments

df	(data.frame) Data frame containing the related variables.
var_name	(character) Name of variable related to rel_var to add to df.
related_var	(character) Name of variable within df with values to which values of var_name must relate.
var_values	(any) Vector of values related to values of related_var.

Value

df with added factor variable var_name containing var_values corresponding to related_var.

Examples

```
# Example with data.frame.
params <- c("Level A", "Level B", "Level C")
adlb_df <- data.frame(
  ID = 1:9,
  PARAM = factor(
    rep(c("Level A", "Level B", "Level C"), 3),
    levels = params
  )
)
rel_var(
  df = adlb_df,
  var_name = "PARAMCD",
  var_values = c("A", "B", "C"),
  related_var = "PARAM"
)

# Example with tibble.
adlb_tbl <- tibble::tibble(
  ID = 1:9,
  PARAM = factor(
    rep(c("Level A", "Level B", "Level C"), 3),
    levels = params
  )
)
rel_var(
  df = adlb_tbl,
  var_name = "PARAMCD",
  var_values = c("A", "B", "C"),
  related_var = "PARAM"
)
```

replace_na

*Replace Values in a Vector by NA***Description****[Stable]**

Randomized replacement of values by NA.

Usage

```
replace_na(v, percentage = 0.05, seed = NULL)
```

Arguments

v (any)
Vector of any type.

percentage	(proportion) Value between 0 and 1 defining how much of the vector shall be replaced by NA. This number is randomized by +/- 5% to have full randomization.
seed	(numeric) Seed to use for reproducible random number generation.

Value

The input vector *v* where a certain number of values are replaced by NA.

rtexp	<i>Truncated Exponential Distribution</i>
-------	---

Description**[Stable]**

This generates random numbers from a truncated Exponential distribution, i.e. from $X \mid X > l$ or $X \mid X < r$ when $X \sim \text{Exp}(\text{rate})$. The advantage here is that we guarantee to return exactly *n* numbers and without using a loop internally. This can be derived from the quantile functions of the left- and right-truncated Exponential distributions.

Usage

```
rtexp(n, rate, l = NULL, r = NULL)
```

Arguments

n	(numeric) Number of random numbers.
rate	(numeric) Non-negative rate.
l	(numeric) Positive left-hand truncation parameter.
r	(numeric) Positive right-hand truncation parameter.

Value

The random numbers. If neither *l* nor *r* are provided then the usual Exponential distribution is used.

Examples

```
x <- stats::rexp(1e6, rate = 5)
x <- x[x > 0.5]
hist(x)

y <- rtxexp(1e6, rate = 5, l = 0.5)
hist(y)

z <- rtxexp(1e6, rate = 5, r = 0.5)
hist(z)
```

rtpois*Zero-Truncated Poisson Distribution*

Description**[Stable]**

This generates random numbers from a zero-truncated Poisson distribution, i.e. from $X \mid X > 0$ when $X \sim \text{Poisson}(\text{lambda})$. The advantage here is that we guarantee to return exactly n numbers and without using a loop internally. This solution was provided in a post by [Peter Dalgaard](#).

Usage

```
rtpois(n, lambda)
```

Arguments

n	(numeric) Number of random numbers.
lambda	(numeric) Non-negative mean(s).

Value

The random numbers.

Examples

```
x <- rpois(1e6, lambda = 5)
x <- x[x > 0]
hist(x)

y <- rtpois(1e6, lambda = 5)
hist(y)
```

sample_fct	Create a Factor with Random Elements of <i>x</i>
------------	--

Description

Sample elements from *x* with replacement to build a factor.

Usage

```
sample_fct(x, N, ...)
```

Arguments

- x* (character vector or factor)
If character vector then it is also used as levels of the returned factor. If factor then the levels are used as the new levels.
- N* (numeric)
Number of items to choose.
- ...* Additional arguments to be passed to *sample*.

Value

A factor of length *N*.

Examples

```
sample_fct(letters[1:3], 10)
sample_fct(iris$Species, 10)
```

var_relabel	Primary Keys: Labels
-------------	----------------------

Description

Relabel a subset of variables in a data set.

Usage

```
var_relabel(x, ...)
```

Arguments

- x* (data.frame)
Data frame containing variables to which labels are applied.
- ...* (named character)
Name-Value pairs, where name corresponds to a variable name in *x* and the value to the new variable label.

Value

x (data.frame)
Data frame with labels applied.

Examples

```
adsl <- radsl()
var_relabel(adsl,
  STUDYID = "Study Identifier",
  USUBJID = "Unique Subject Identifier"
)
```

visit_schedule	<i>Create Visit Schedule</i>
----------------	------------------------------

Description

Create a visit schedule as a factor.

Usage

```
visit_schedule(visit_format = "WEEK", n_assessments = 10L, n_days = 5L)
```

Arguments

visit_format	(character)
	Type of visit. Options are "WEEK" and "CYCLE".
n_assessments	(integer)
	Number of weeks or cycles.
n_days	(integer)
	Number of days in each cycle (only used if visit_format is "CYCLE").

Details

X number of visits, or X number of cycles and Y number of days.

Value

A factor of length n_assessments.

Examples

```
visit_schedule(visit_format = "WEEK", n_assessments = 10L)
visit_schedule(visit_format = "CYCLE", n_assessments = 5L, n_days = 2L)
```

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