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Const	tantRateDrop Create a Dropout Mechanism with constant dropout rate	

Description

Creates an MCAR DropoutMechanism object where subject i dropout is exponentially distributed with rate Ri where Ri = $C \times \exp(Xi)$ for constant C and Xi a random normal variable with mean 0 and standard deviation sigma

Usage

ConstantRateDrop(rate, var = 0)

Arguments

rate C described in the details

var $sigma^2$ described in the details section, by default = 0

Value

A DropoutMechanism object

copy_reference 3

See Also

DropoutMechanism.object

Examples

```
ConstantRateDrop(rate=0.0025)
ConstantRateDrop(rate=0.0025, var=1)
```

copy_reference

Create a copy reference ImputeMechanism object

Description

Missing counts for subjects in both arms are imputed by assuming the rate before and dropout are both equal to the control (reference) estimated rate. This corresponds to what is usually termed the copy reference assumption.

Usage

```
copy_reference(proper = TRUE)
```

Arguments

proper

If proper=TRUE then proper imputation is performed, in which each imputation is created based on parameters values drawn from the (approximate) posterior distribution of the imputation model. If proper=FALSE, improper imputation is performed. This means all imputed datasets are generated conditional on the maximum likelihood estimates of the parameters.

Value

An ImputeMechanism object

See Also

ImputeMechanism.object

CreateNewDropoutMechanism

A function which creates a DropOut Mechanism object

Description

A function which creates a DropOut Mechanism object

Usage

```
CreateNewDropoutMechanism(
  type,
  text,
  cols.needed = vector("character"),
  GetDropTime,
  parameters = NULL
)
```

Arguments

type The type of mechanism (e.g. "MCAR" or "MNAR")

text A short string describing the mechanism (only used for printing)

cols.needed Which columns in the SingleSim\$data data frame must be included for this drop

out mechanism to work. This option could allow drop out mechanism which

depend on covariates to be included.

GetDropTime A function with two arguments event.times and data, the corresponding entries

from the SingleSim object. This function should return a list of dropout times (if a subject does not dropout its dropout time should be their current censored.time

(i.e. the study follow up time))

parameters A list of named parameters for the mechanism (only used for printing) or NULL

if none

Value

A DropoutMechanism.object

See Also

DropoutMechanism.object

CreateNewImputeMechanism

A function which creates an Impute Mechanism object

Description

A function which creates an Impute Mechanism object

Usage

```
CreateNewImputeMechanism(
  name,
  cols.needed = vector("character"),
  impute,
  parameters = NULL
)
```

Arguments

name The method name (used for printing)

cols.needed which columns of the SingleSim data frame are required by the method, typi-

cally c("censored.time", "observed.events", "arm")

impute A function which takes a SingleSimFit object and outputs the details for a sin-

gle imputed data set, specifically a list with two elements: new.censored.times - a vector of times subjects were censored (after taking into account imputation) and newevent.times - a list of vectors where the vectors contain the imputed event times for the subjects (these vectors do not contain the observed event times before subject drop out). If a subject has no imputed events then the vec-

tor numeric(0) is returned.

parameters A list of named parameters describing the method (used for printing) - or NULL

if none

Value

A ImputeMechanism.object

See Also

ImputeMechanism.object

DejaData.object

Description

Create Scenario object from list of Fit Summaries

Usage

```
CreateScenario(object, description = "")
```

Arguments

object Either a list of summary. SingleSimFit or summary. ImputeSimFit objects

description A character string describing the scenario (used for printing)

Value

A Scenario object

See Also

Scenario.object

DojaData object	Data frame of covariates for simulating recomment events
DejaData.object	Data frame of covariates for simulating recurrent events

Description

This object allows covariates to be included in the simulation procedure The object is created using the MakeDejaData function

Arguments

data	A data frame containing the subject
arm	character the column name of the treatment arm for each subject
rate	character the column name of the rate to be used when simulating
Id	character the column name of subject Id

Structure

The above components must be included in a DejaData Object

DropoutMechanism.object

DropoutMechanism object

Description

An object which defines a specific mechanism which takes a complete SingleSim object and returns a set of drop out times for subjects

Arguments

type The type of mechanism (e.g. "MCAR" or "MNAR")

text A short string describing the mechanism (only used for printing)

cols.needed Which columns in the SingleSim\$data data frame must be included for this drop

out mechanism to work. This option could allow drop out mechanism which

depend on covariates to be included.

GetDropTime A function with two arguments event.times and data, the corresponding entries

from the SingleSim object. This function should return a list of dropout times (if a subject does not dropout its dropout time should be their current censored.time

(i.e. the study follow up time))

parameters A list of named parameters for the mechanism (only used for printing) or NULL

if none

Details

It is possible to create user defined mechanisms, however, certain common mechanisms have already been implemented. For example see ConstantRateDrop and LinearRateChangeDrop

Only the GetDropTime and cols.needed entries are required for calculation, the other entries are used for printing the object

 $\verb|print.DropoutMechanism| methods is defined.$

Structure

The following components must be included in a DropoutMechanism Object

expandEventCount Expand event counts into a list of event times

Description

This function exists to allow clinical trial data which typically gives event counts over time to be plugged into this software, which relies on actual event counts.

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Usage

```
expandEventCount(count, time)
```

Arguments

count a vector of event counts. All entries must be non-negative. time a matching (strictly positive) vector of followup times.

Details

This function always produces a warning: anyone relying on this function to actually analyze data should take great care.

Value

a list of vectors of event times

Examples

```
expandEventCount(count=c(0, 20), time=c(10, 20))
```

extract_results

Extract the results of running a scenario

Description

This function is a wrapper around CreateScenario See the user guide vignette for an example of using this function

Usage

```
extract_results(answer, name, description)
```

Arguments

answer A named list of lists

name The name of the lists of answer which should be extracted and put together into

a sc

description The description parameter to be passed into the CreateScenario function

Value

A Scenario object

See Also

CreateScenario

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 ${\tt GetImputedDataSet}$

Output a single imputed data set

Description

Output a single imputed data set

Usage

```
GetImputedDataSet(imputeSim, index)
```

Arguments

imputeSim A ImputeSim object which contains multiple imputed data sets index numeric, which of the multiple imputed data sets to output

Value

A SingleSim object with status="imputed"

See Also

```
ImputeSim.object
```

Examples

```
sim <- SimulateComplete(study.time=365,number.subjects=50,
event.rates=c(0.01,0.005),dispersions=0.25)
sim.with.MCAR.dropout <- SimulateDropout(sim,
    drop.mechanism = ConstantRateDrop(rate = 0.0025))
fit <- Simfit(sim.with.MCAR.dropout)
imps <- Impute(fit, copy_reference(), 10)
imp1 <- GetImputedDataSet(imps, 1)</pre>
```

ImportSim

Import an existing data frame for use with the package

Description

Import an existing data frame for use with the package

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Usage

```
ImportSim(
  dejaData,
   event.times,
  status,
  study.time,
  censored.time = NULL,
  actual.events = NULL,
  allow.beyond.study = FALSE
)
```

Arguments

dejaData a DejaData object contain the subject covariates and treatment arm

event.times A list of vectors, containing the observed event times of each subject. If no

events are observed then numeric(0) should be used. See example in this help

file for more details

status The status of the data set imported, either "complete" (if all subjects complete

their follow up period) or "dropout" (if not)

study.time The total follow up time according to study protocol

censored.time If status is "dropout", this is a vector of the times at which each subject is cen-

sored

actual.events If status is "dropout" and the total number of events (i.e. not just the number

observed) is known (e.g. if a different simulation procedure was used) a vector of total number of events should be included. If the number is not known or

status is "complete" then this should be set to NULL

allow.beyond.study

Whether or not to allow imported data with events after the nominal end of study.

Value

A SingleSim object

Impute 11

```
study.time=365)

censored.time <- c(365,178,100,245,200,100)

dropout.dataset <- ImportSim(dejaData, event.times, status="dropout", study.time=365, censored.time=censored.time)</pre>
```

Impute

Produce imputed data sets

Description

Given a SingleSimFit object (with impute.parameters not NULL) and an imputation mechanism, create a collection of imputed data sets

Usage

```
Impute(fit, impute.mechanism, N)
```

Arguments

Value

An ImputeSim object

```
sim <- SimulateComplete(study.time=365,number.subjects=50,
    event.rates=c(0.01,0.005),dispersions=0.25)
sim.with.MCAR.dropout <- SimulateDropout(sim,
    drop.mechanism = ConstantRateDrop(rate = 0.0025))
fit <- Simfit(sim.with.MCAR.dropout)
imps <- Impute(fit, copy_reference(), 10)</pre>
```

ImputeMechanism.object

ImputeMechanism object

Description

An object which defines a mechanism for taking a SingleSimFit object and imputing missing data to create a ImputeSim

Arguments

name The method name (used for printing)

cols.needed which columns of the SingleSim data frame are required by the method, typi-

cally c("censored.time", "observed.events", "arm")

impute A function which takes a SingleSimFit object and outputs the details for a sin-

gle imputed data set, specifically a list with two elements: new.censored.times - a vector of times subjects were censored (after taking into account imputation) and newevent.times - a list of vectors where the vectors contain the imputed event times for the subjects (these vectors do not contain the observed event times before subject drop out). If a subject has no imputed events then the vec-

tor numeric(0) is returned.

parameters A list of named parameters describing the method (used for printing) - or NULL

if none

Details

It is possible to create user defined mechanisms, however, common mechanisms have already been implemented. For example see weighted_j2r

A print. ImputeMechanism method is defined.

Structure

The following components must be included in an ImputeMechanism Object

```
j2r <- weighted_j2r(trt.weight=0)</pre>
```

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2put0002t 00 jeet	<pre>ImputeSim.object</pre>	ImputeSim object
-------------------	-----------------------------	------------------

Description

This object contains a collection of imputed data sets derived from a SingleSimFit object and ImputeMechanism

Arguments

singleSim The SingleSim object from which the imputed data sets have been derived impute.mechanism

The ImputeMechanism object used to perform the imputation

imputed.values A matrix with 1 column per imputed data set and two rows: newevent.times

a list of vectors containing the imputed event times (not including the events which were observed) and new.censored.times - a vector containing the times at

which subjects (with imputed data) are now censored

dropout A vector containing the number of subjects who have dropped out in each arm,

for whom data is to be imputed

Use GetImputedDataSet to extract a single imputed data set and use Simfit to

fit a model to the set of data sets

See Also

 ${\tt GetImputedDataSet}$

<pre>ImputeSimFit.object</pre>	ImputeSimFit object	

Description

An object which contains both a set of imputed data sets (ImputeSim object) and a set of models fitted to them

Arguments

imputeSim The ImputeSim object for which models have been fitted

summaries A list of summary. SingleSimFit objects containing the model fits for each of

the imputed data sets

Details

Calling summary. ImputeSimFit will apply Rubin's formula to calculate estimates for the treatment effect and standard error

Functions summary. ImputeSimFit and as.data.frame.ImputeSimFit have been implemented

See Also

 $summary. Impute {\tt SimFit} \ summary. {\tt SingleSimFit}$

LinearRateChangeDrop Create a Dropout Mechanism with drop out rate which changes by a fixed constant after every event

Description

Creates an MAR DropoutMechanism object where subject i has piecewise exponential dropout rate where the rate changes by a constant amount after each event, specifically after j events the subject has rate Rij = Cj*exp(Xij) where Cj=C+j*D for constants C, D and Xij is a standard normal variable with mean 0 and standard deviation sigma

Usage

LinearRateChangeDrop(starting.rate, rate.change, var = 0)

Arguments

starting.rate C, see description section.

rate.change D, see description section. Note if D<0, Cj could be negative for large j, this is

not possible and the rate remains constant if the next change would set Cj<=0

var sigma^2, see description section

Value

A DropoutMechanism object

See Also

DropoutMechanism.object

```
LinearRateChangeDrop(starting.rate=0.0025,rate.change=0.0005)
LinearRateChangeDrop(starting.rate=0.0025,rate.change=-0.00001,var=1)
```

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MakeDejaData	Create a DejaData object	

Description

This object is can be used to create a SingleSim object with subject specific rates

Usage

```
MakeDejaData(data, arm, Id, rate = NULL)
```

Arguments

data	A data frame containing the subject
arm	character the column name of the treatment arm for each subject
Id	character the column name of subject Id
rate	character the column name of the rate to be used when simulating (or NULL, if using DeiaData to import a data set, see ImportSim)

Value

A DejaData object

Examples

numberSubjects

S3 generic to output the number of subjects in a given object

Description

S3 generic to output the number of subjects in a given object

Usage

```
numberSubjects(x)
```

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Arguments

x The object

Value

The number of subjects

Examples

```
sim <- SimulateComplete(study.time=365,number.subjects=50,
event.rates=c(0.01,0.005),dispersions=0.25)
numberSubjects(sim)</pre>
```

Scenario.object

Scenario object

Description

This class contains a collection of model fit summaries and summarizing this object will calculate overall summary statistics such as power/type I error

Arguments

description A string containing a description of the scenario

summaries A list of either summary. ImputeSimFit or summary. SingleSimFit objects

Details

Functions as.data.frame.Scenario and summary.Scenario have been implemented

See Also

CreateScenario

simData

Simulated recurrent event data.

Description

A simulated dataset containing a randomised treatment group, follow-up time, and number of events, for 500 patients. The planned follow-up period for the study was 1 year, but some patients dropped out early and so their follow-up ended prematurely (i.e. before 1 year)

Usage

simData

Simfit 17

Format

A data frame with 500 rows and 3 variables:

z a binary variable indicating randomised treatment group

y number of events observed during patient's follow-up

fupTime the time in years the patient was followed up for ...

Source

Simulated data

Simfit

S3 generic for fitting models

Description

S3 generic for fitting models

Usage

```
Simfit(x, family = "negbin", equal.dispersion = TRUE, covar = NULL, ...)
```

Arguments

x The S3 object

family Either "negbin" for fitting a negative binomial model (using MASS::glm.nb),

"poisson" for fitting a poisson model (glm) or "quasipoisson" for fitting a quasipois-

son model glm

equal.dispersion

logical, should the arms have the same dispersion parameter when fitting nega-

tive binomial models

covar A formula containing the additional covariates to be used when calling glm. nb

if no covariates are included in the model this should be NULL, for example

~covar1 + covar2 See vignette for further details

... Additional arguments to be passed to glm or glm.nb

Value

A SingleSimFit object

See Also

```
SingleSimFit.object
```

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Examples

SimulateComplete

Simulate a complete data set

Description

Simulate a complete data set of a recurrent event clinical trial without dropouts using a negative binomial model with given rates and dispersion parameters

Usage

```
SimulateComplete(
   study.time,
   dejaData = NULL,
   number.subjects = NULL,
   event.rates = NULL,
   dispersions
)
```

Arguments

study.time The study follow up period

dejaData If not NULL this should contain a DejaData object. If this is used then num-

ber.subjects and event.rates arguments are ignored

number.subjects

The number of subjects, if a vector c(a,b) then a subjects on the control arm and b subjects on the active arm. If number subjects is a single number then

both arms have the given number of subjects.

event.rates The rate parameter(s) for the negative binomial model (if single parameter then

it is used for both arms)

dispersions The dispersion parameter(s) for the negative binomial model (if single parameter

then it is used for both arms)

Details

Each subject's events are described by a Poisson process with a subject specific rate given by lambda/study.time where study.time is the study follow up period and lambda has a gamma distribution with shape=1/dispersion and scale=dispersion*event.rate*study.time

Different dispersions, event.rates and number of subjects can be specified for both arms of the trial

SimulateDropout 19

Value

A SingleSim object with status='complete'

See Also

```
SingleSim.object
```

Examples

SimulateDropout

Simulate subject dropout

Description

This function takes a complete recurrent event data set and drop out mechanism and creates a data set set with dropout

Usage

```
SimulateDropout(simComplete, drop.mechanism)
```

Arguments

Value

A SingleSim object with status='dropout'

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SingleSim Object

Description

A class containing the data for a single simulation. Depending on the value of status, this may be a complete data set, a set including subject dropouts or a data set after multiple imputation

 $\verb|print.SingleSim| and \verb|summary.SingleSim| methods are defined.$

Arguments

data	The data frame, one row per subject containing (at least) the following columns Id, arm, censored.time, observed.events and actual.events	
event.times	A list of event times. event.times[[1]] is a list of event times for subject with Id 1 The length of event.times[[1]] = the number of observed events of subject with Id 1	
status	Either "complete", "dropout" or "imputed" denoting the status of the data set.	
subject.rates	A vector of the specific rates used for the Poisson process for subjects when generating the data	
dropout.mechanism		
	If status is not "complete" then this contains the DropoutMechanism object used to perform the subject dropout. See DropoutMechanism.object.	
impute.mechanism		
	If the status is "imputed" then this contains the ImputeMechanism object used to perform the imputation. See ImputeMechanism.object	
study.time	The study follow up period (see SimulateComplete)	
event.rates	The control/active event rates (see SimulateComplete), if data set was generated without using these (e.g. the dejaData argument was used) then this is set to NULL	
dispersions	The control/active dispersion rates (see SimulateComplete)	

Structure

The above components must be included in a SingleSim Object

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SingleSimFit.object SingleSimFit object

Description

A SingleSimFit object is returned from calling Simfit with a SingleSim object. It can be used to both impute data sets or can be summarized

Arguments

singleSim The SingleSim object to which a model has been fitted

model The model which has been fitted

genCoeff.function

A function which returns a list of parameters from the model fit(s) which can be used when performing the gamma imputation. It takes one argument, use uncertainty (by default is TRUE) which if TRUE stochastically incorporates uncertainty into the parameter estimates in preparation for use with imputation If a Poisson/quasi-Poisson model was fitted to the SingleSimFit object then this will be NULL

equal dispersion whether equal dispersions were used when fitting model(s) to the data

Details

A summary. SingleSimFit method has been implemented

subjectsPerArm S3 generic to output the number of subjects in each arm for a given object

Description

S3 generic to output the number of subjects in each arm for a given object

Usage

subjectsPerArm(x)

Arguments

x The object

Value

A vector of the number of subjects in each arm

Examples

```
sim <- SimulateComplete(study.time=365,number.subjects=50,
event.rates=c(0.01,0.005),dispersions=0.25)
subjectsPerArm(sim)</pre>
```

```
summary. Impute Sim Fit. object \\ summary. Impute Sim Fit object
```

Description

The summary of a ImputeSimFit object. Rubin's formula is used to combine the test statistics into a single summary

Arguments

treatment.effect		
	The mean of the estimated treatment.effect from the imputed data	
se	The standard error of the (log) treatment effect calculated using Rubin's formula	
df	The number of degrees of freedom used to calculate the p-value	
adjusted.df	The number of degrees of freedom used to calculate the adjusted p-value (this should be used if the complete data number of degrees of freedom is small)	
dispersion	The mean of the estimated dispersion parameter	
pval	The p-value for the test log(treatment.effect)=0 using Rubin's formula	
adjusted.pval	The p-value for the test log(treatment.effect)=0 using Rubin's formula and the adjusted number of degrees of freedom	
dropout	The number of subjects who drop out (per arm) for this imputed data set	
number.subjects		
	The number of subjects (per arm) for this imputed data set	

Details

A print.summary.ImputeSimFit object has been implemented

summary.Scenario.object

summary.Scenario object

Description

This object contains the overall summary statistics for a specific scenario. It is envisioned that multiple scenarios are run and a set of summary. Scenario objects are created and these can then be used for plotting

Arguments

treatment.effect

The exp(mean(log(individual treatment effects))),

se The mean standard error of the (log) treatment effect

power The proportion of simulations for which the p-value is < alpha

alpha The significance level used when calculating power, by default 0.05 use summary(object,alpha=x)

to use a different p value

use.adjusted.pval

logical, default FALSE should the p values calculated using Rubin's formula

with the adjusted number of degrees of freedom be used. Use summary(object, use.adjusted.pval=TR

to use the adjusted p values

description A string containing a description of the scenario

dropout A list of summary statistics regarding number of subject dropouts

Details

A print.summary.Scenario function has been implemented

summary.SingleSim.object

summary.SingleSim object

Description

The object returned when calling the summary function on a SingleSim object

Arguments

status The status of the SingleSim object

study.time The study.time from the SingleSim object

number.subjects

The number of subjects on each arm

number.dropouts

The number of subjects who dropout on each arm

total.events The total number of events for each arm

time.at.risk The total time

The total time at risk for each arm

empirical.rates

total.events/time.at.risk

The print.summary.SingleSim method has been implemented

summary.SingleSimFit summary.SingleSimFit

Description

The summary object for a SingleSimFit object

Arguments

model.summary The model summary from the fit

treatment.effect

The estimate of treatment effect from the model fit

CI.limit The confidence interval limit (by default 0.95), call summary (object, CI.limit=x)

to use CI of x instead.

CI The confidence interval of the treatment effect

se Estimate for the standard error of (log) treatment effect

dispersion Estimate for the dispersion parameter or numeric(0) if Poisson/quasi-Poisson

model used

rate.estimate Estimate of the event rates from the model a vector c(control arm, treatment

arm)

pval The p value directly from the model fit (this is for the single model fit only, i.e.

not using Rubin's formula)

datastatus The status of SingleSim object to which the fit was applied

df The number of degrees of freedom of the model

dropout The number of dropouts of each arm

number.subjects

The number of subjects in each arm

weighted_j2r 25

Details

A print.summary.SingleSimFit method has been implemented

See Also

```
SingleSimFit.object
```

Examples

```
sim <- SimulateComplete(study.time=365,number.subjects=50,
event.rates=c(0.01,0.005),dispersions=0.25)
fit <- Simfit(sim)
summary(fit)</pre>
```

weighted_j2r

Create a weighted_j2r ImputeMechanism object

Description

Missing counts for a subject in the active treatment arm will be imputed according to a point (determined by trt.weight) between the means of the placebo and treatment arms, conditioned on the number of events. Missing counts for subjects in the placebo arm will be imputed according to the mean of the placebo arm, conditioned on the subject's observed number of events.

Usage

```
weighted_j2r(trt.weight, delta = c(1, 1), proper = TRUE)
```

Arguments

trt.weight See details

delta If trt.weight=1 then delta is a vector of length 2 (control.delta,treatment.delta)

and the mean number of expected events for the imputed missing data is multi-

plied by the appropriate delta

proper If proper=TRUE then proper imputation is performed, in which each imputation

is created based on parameters values drawn from the (approximate) posterior distribution of the imputation model. If proper=FALSE, improper imputation is performed. This means all imputed datasets are generated conditional on the

maximum likelihood estimates of the parameters.

Details

If trt.weight = 0 then imputation using this mechanism will follow the jump to reference (j2r) model whereby missing counts for subjects in both arms will be imputed according to the mean of the placebo arm conditioned on the subject's observed number of events

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If trt.weight = 1 then imputation using this mechanism will follow the MAR model whereby missing counts for subjects in each arm will be imputed according to the event rate of subjects in its treatment group conditioned on the subject's observed number of events

See the User guide vignette for further details

Value

An ImputeMechanism object

See Also

ImputeMechanism.object

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