# Package 'dejaVu'

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Type Package

Title Multiple Imputation for Recurrent Events

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**License** GPL ( $\geq 2$ )

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ConstantRateDrop 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\*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 = $0$

#### copy\_reference

#### Value

A DropoutMechanism object

#### 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

#### Examples

```
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

 $A \; \texttt{DropoutMechanism.object}$ 

## 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, typically c("censored.time","observed.events","arm")
impute	A function which takes a SingleSimFit object and outputs the details for a single 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 vector numeric( $\emptyset$ ) 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

CreateScenario

## 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

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

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.

#### 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

# 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

# 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

# Examples

dejaData <- MakeDejaData(covar.df,arm="arm",Id="Id")</pre>

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## Impute

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

fit	it A SingleSimFit object		
impute.mechanism			
	An ImputeMechanism object		
Ν	The number of data sets to impute		

#### Value

An 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)</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 single 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 vector 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

# Examples

j2r <- weighted\_j2r(trt.weight=0)</pre>

ImputeSim.object 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

GetImputedDataSet

ImputeSimFit.object 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

summary.ImputeSimFit summary.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 <sup>2</sup> , see description section

## Value

A DropoutMechanism object

#### See Also

DropoutMechanism.object

#### Examples

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

MakeDejaData

## 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 DejaData to import a data set, see ImportSim)

# Value

A DejaData object

# Examples

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

## Description

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

## Usage

numberSubjects(x)

#### simData

#### 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)
```

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

# 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

#### 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

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#### SimulateDropout

#### 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

simComplete A SingleSim object (with status="complete")
drop.mechanism A DropoutMechanism object

# Value

A SingleSim object with status='dropout'

#### Examples

SingleSim.object 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

print.SingleSim and 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.mechani	sm	
	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 gener- ated 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

## 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

S	ingleSim	The SingleSim object to which a model has been fitted
m	odel	The model which has been fitted
g	enCoeff.funct:	ion
		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
e	qual	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

Х

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)
```

summary.ImputeSimFit.object

summary.ImputeSimFit 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

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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=TRI 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	5
	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 empirical.rates	The total time at risk for each arm
	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.effe	ct
	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

#### 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)
```

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 multiplied 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

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

#### Examples

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