Package 'pscDesign'

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Type Package

Title Study Design for Personalised Synthetic Controls

Version 1.0.0

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Description Tools for the design of prospective studies using Personalised Synthetic Controls. Can be used in either single arm or randomised studies.

License GPL-3

Encoding UTF-8

LazyData true

RoxygenNote 7.3.3

Depends R (>= 4.0.0), survival

Imports psc (>= 2.0.0), S7

Suggests knitr

VignetteBuilder knitr

URL https://github.com/richJJackson/pscDesign

BugReports https://github.com/richJJackson/pscDesign/issues

NeedsCompilation no

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Repository CRAN

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Contents

`covSim` *Simulate covariates from a Counter factual model*

Description

A function to simulate covariate values from a Counter Factual Model

Usage

```
covSim(CFM, n = 100)
```

Arguments

`CFM`	a Counter-Factual model
`n`	number of observation

Details

This functions extracts the covariates form a counter factual model and samples from them in order to create a simulated dataset.

Value

A cumulative Hazard function

`dataSim` *Study design using Personalised Synthetic Controls*

Description

pscDesign performs the simulations required to estimate the Power of a study designed using personalised synthetic controls.

Usage

```
dataSim(CFM, n0 = 0, n1 = 100, beta = 0, fuTime, recTime, rec = NULL)
```

Arguments

CFM	a Counter-Factual model
n0	number of patients allocated to the control arm (defaults to 0 - i.e. single arm study).
n1	number of patients allocated to the experimental arm
beta	the (log) HR used in the study design
fuTime	Follow up time for the study design
recTime	Recruitment time for the study design
rec	a study recruitment estimate obtained using the recForcast() function. If specified, recTime will be ignored.

Details

The datSim function simulates a dataset including sampled covariatees and outcome data from a counterfactual model

Time parameters (fuTime, recTime) should be expressed on the same scale on which they are specified in the Counter Factual Model. One of recTime or rec must be specified. If rec is specified, recTime will be ignored.

Value

A data frame intended for use with the CFM including covariate and outcome data

Examples

```
gemCFM <- pscDesign::gemCFM
dataSim(gemCFM,n0=10,n1=20,beta=log(0.7),fuTime=12,recTime=12)
```

---

fpmH *Generate a cumulative hazard function from a flexible parametric model*

Description

A function to estimate the survival function based on parameter estimates.

Usage

```
fpmH(CFM, maxTime = 24)
```

Arguments

CFM	a Counter-Factual model
maxTime	maximum time used in the estimation

Details

This functions extracts the baseline (cumulative) hazard parameters from a counter factual model. This is used in the simulation of datasets.

Value

A cumulative Hazard function

`fpmSurv` *Generate a survival function from a flexible parametric model*

Description

A function to estimate the survival function based on parameter estimates.

Usage

```
fpmSurv(CFM, beta = NULL, lp = NULL, maxTime = 24)
```

Arguments

`CFM`	a Counter-Factual model
`beta`	parameter with which to adjust the baseline function (defaults to beta=0)
`lp`	a linear predictor which if supplies will be used to adjust the parameters of the survival function
`maxTime`	maximum time used in the estimation

Details

This functions extracts the baseline (cumulative) hazard parameters from a counter factual model and uses these to construct survival estimates. This is used in the simulation of datasets. If a (log) hazard ratio, beta, or a linear predictor, lp, are supplied - these will be used to adjust the baseline estimates.

Value

A survival function

gemCFM *gemCFM*

Description

Model for a survival outcome based on Gemcitbine patients from ESPAC-3. A generated model with a survival endpoint and a cuymulative hazard function estimated using flexible parametric splines. Data for the model were obtained from the ESPAC-3 trials

Usage

```
gemCFM
```

Format

A model of class 'pscCFM' containg a 'flexsurvreg' model:

gamma cumulative baseline hazard parameters

nodes negative (n=1) or positive (n=2) lymph nodes

grade tumour grade (1,2 or 3)

lca199 log transformed ca19.9

ResecM Resection Margins)

Source

simulated

modp *modp*

Description

A function which rrturns either the input value (if positive) or zero (if negative)

Usage

```
modp(x)
```

Arguments

x	a numberic vector

Details

A fucntion which returns a version of x with negative values replacd with 0

Value

a numeric vector with negative values replaced with 0

`postEval` *A function to evaluate posterior distribution*

Description

postEval evaluated a distribition based on given mean and standard deviation

Usage

```
postEval(mn, sd, bound = 0, direction = "greater")
```

Arguments

`mn`	distribution mean
`sd`	distribution sd
`bound`	The bound to use in the posterior evaluation (defaults to 0)
`direction`	The direction which specifies superiority of the efficacy parameter

---

`pscDesign` *Study design using Personalised Synthetic Controls*

Description

pscDesign performs the simulations required to estimate the Power of a study designed using personalised synthetic controls.

Usage

```
pscDesign(
  CFM,
  n0 = 0,
  n1,
  beta,
  fuTime,
  recTime,
  rec = NULL,
  nsim = 4,
  nsim.psc = 500,
  burn.psc = 200,
  bound = 0,
  direction = "greater",
  alpha_eval = c(0.01, 0.025, 0.05, 0.1, 0.15, 0.2)
)
```

Arguments

CFM	a Counter-Factual model
n0	number of patients allocated to the control arm (defaults to 0 - i.e. single arm study).
n1	number of patients allocated to the experimental arm
beta	the (log) HR used in the study design
fuTime	Follow up time for the study design
recTime	Recruitment time for the study design
rec	a study recruitment estimate obtained using the recForcast() function. If specified, recTime will be ignored.
nsim	number of simulations
nsim.psc	number of simulations to use in psc estimation
burn.psc	burn in to use in psc estimation
bound	The bound to use in the posterior evaluation (defaults to 0)
direction	The direction which specifies superiority of the efficacy parameter
alpha_eval	Alpha values at which to evaluate the study design.

Details

The pscDesign function performs a simulation study to estimate the design parameters for a study using personalised synthetic controls.

Time parameters (fuTime, recTime) should be expressed on the same scale on which they are specified in the Counter Factual Model. One of recTime or rec must be specified. If rec is specified, recTime will be ignored.

Value

A list containing a summary of the simulated datasets and estimated type-II error rates (Power) against leveld of significance (alpha-levels)

Examples

```
gemCFM <- pscDesign::gemCFM
pscDesign(gemCFM,n0=0,n1=100,beta=log(0.7),fuTime=12,recTime=12,nsim=2,
    nsim.psc=300,burn.psc=100)
```

recForcast *Estimating recruitment rates based on the number of sites and average site recruitment rates.*

Description

Estimating recruitment rates based on the number of sites and average site recruitment rates.

Usage

```
recForcast(N.site, rpm, open.rate, Max.Time, penal = 0.5, plot = TRUE, ...)
```

Arguments

N.site	The number of recruiting sites
rpm	The average recruitment per site per month
open.rate	the rate at which sites are expected to open to recruitment
Max.Time	maximum time used in the estimation
penal	A penalising factor for the recruitment in the intial month for each site (defaults to penal=0.5)
plot	shoud results be plotted?
...	aditional arguments passed to plot

Details

This functions estimates monthly recruitment rates based on the number of sites and the average monthly recruitment rate. The resulting dataset can be passed to pscDesign to improve estimation of design parameters.

Value

A dataset giving the monthly recruitment rate

Examples

```
recForcast(N.site=5,rpm=1,open.rate=1,Max.Time=12)
```

`trialSamp` *Evaluation of a sampled dataset within pscDesign*

Description

trialSamp evaluates a sampled dataset and returns the reuslts

Usage

```
trialSamp(
  CFM,
  n0,
  n1,
  beta,
  fuTime,
  recTime,
  rec,
  nsim.psc = 750,
  burn.psc = 250
)
```

Arguments

`CFM`	a Counter-Factual model
`n0`	number of patients allocated to the control arm (defaults to 0 - i.e. single arm study).
`n1`	number of patients allocated to the experimental arm
`beta`	the (log) HR used in the study design
`fuTime`	Follow up time for the study design
`recTime`	Recruitment time for the study design
`rec`	a study recruitment estimate obtained using the recForcast() function. If specified, recTime will be ignored.
`nsim.psc`	number of simulations to use in psc estimation
`burn.psc`	burn in to use in psc estimation

Value

The number of events as well as estimates of the posterior mean and standard deviation

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