

Package: pscDesign (via r-universe)

June 8, 2026

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>

Config/pak/sysreqs
cmake make libicu-dev libjpeg-dev libpng-dev libuv1-dev libxml2-dev libssl-dev libnode-dev

Repository <https://richjjackson.r-universe.dev>

Date/Publication 2026-01-23 16:54:37 UTC

RemoteUrl <https://github.com/richjjackson/pscdesign>

RemoteRef HEAD

RemoteSha 115e71798bd67de24e63d809496873d87a42c960

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| | |
|--------|---|
| covSim | <i>Simulate covariates from a Counter factual model</i> |
|--------|---|

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

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 recForecast() function. If specified, recTime will be ignored. |

Details

The datSim function simulates a dataset including sampled covariates 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 | <i>Generate a cumulative hazard function from a flexible parametric model</i> |
|------|---|

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 | <i>Generate a survival function from a flexible parametric model</i> |
|---------|--|

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 Gemcitabine patients from ESPAC-3. A generated model with a survival endpoint and a cumulative 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' containing 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 returns either the input value (if positive) or zero (if negative)

Usage

```
modp(x)
```

Arguments

x a numeric vector

Details

A function which returns a version of x with negative values replaced with 0

Value

a numeric vector with negative values replaced with 0

 postEval

A function to evaluate posterior distribution

Description

postEval evaluates a distribution 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

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 recForecast() 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 level 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)
```

| | |
|-------------|--|
| recForecast | <i>Estimating recruitment rates based on the number of sites and average site recruitment rates.</i> |
|-------------|--|

Description

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

Usage

```
recForecast(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 initial month for each site (defaults to penal=0.5) |
| plot | should results be plotted? |
| ... | additional 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

```
recForecast(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 results

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 recForecast() 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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