

Package ‘hctrial’

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Type Package

Title Using Historical Controls for Designing Phase II Clinical Trials

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Description Provides functions for designing phase II clinical trials adjusting for the heterogeneity of the population using known subgroups or historical controls.

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License GPL-2 | GPL-3

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hctrial	<i>hctrial: A package for designing phase 2 clinical trials adjusting for heterogeneous populations.</i>
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Description

The hctrial package provides functions for designing phase 2 clinical trials that adjust for the heterogeneity in the population.

Details

Two different ways are considered for designing a trial: based on known subgroups or based on historical data.

For initializing a stratified trial, use strat_start.

At interim, strat_interim should be used to adjust the trial.

At the end of the study, strat_end is used to adjust the trial again.

hist_start, hist_interim and hist_end work analogously, but are based on historical controls.

hist_end	<i>Adjust a design based on historical controls at the end of the study using the covariate data of the patients accrued in stage 2.</i>
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Description

Adjust a design based on historical controls at the end of the study using the covariate data of the patients accrued in stage 2.

Usage

```
hist_end(interim, stagetwo_data)
```

Arguments

interim An design based on historical controls and adjusted at interim as returned by hist_interim().

stagetwo_data A dataframe containing the relevant covariate data of the patients accrued in stage 2.

Value

A list returning the arguments of the function and the final design of the trial.

Examples

```

X <- abs(rnorm(1000, 0, 1))
Y <- rbinom(1000, 1, 1-exp(-X))
mydata <- data.frame("X" = X, "Y" = Y)
start <- hist_start(mydata, Y~X, c1 = 2)
n1 <- start$des_start[2]
X1 <- abs(rnorm(n1, 0, 1))
dataone <- data.frame("X" = X1)
interim <- hist_interim(start, dataone)
n2 <- interim$des_interim[4]
X2 <- abs(rnorm(n2, 0, 1))
datatwo <- data.frame("X" = X2)
hist_end(interim, datatwo)

```

hist_interim	<i>Adjust a design based on historical controls at interim using the covariate data of the patients accrued in stage 1.</i>
--------------	---

Description

Adjust a design based on historical controls at interim using the covariate data of the patients accrued in stage 1.

Usage

```
hist_interim(start, stageone_data)
```

Arguments

start	An initialized design based on historical controls as returned by hist_start().
stageone_data	A dataframe containing the relevant covariate data of the patients accrued in stage 1.

Value

A list returning the arguments of the function and the preliminary design of a trial based on historical controls adjusted at interim.

Examples

```

X <- abs(rnorm(1000, 0, 1))
Y <- rbinom(1000, 1, 1-exp(-X))
mydata <- data.frame("X" = X, "Y" = Y)
start <- hist_start(mydata, Y~X, c1 = 2)
n1 <- start$des_start[2]
X1 <- abs(rnorm(n1, 0, 1))
dataone <- data.frame("X" = X1)
hist_interim(start, dataone)

```

hist_start	<i>Initializes a design based on historical controls before the start of the study.</i>
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Description

Initializes a design based on historical controls before the start of the study.

Usage

```
hist_start(hist_data, formula, phi = "odds_ratio", c1, modelfit = NULL,
           mean0 = NULL, mean1 = NULL, alpha = 0.05, beta = 0.2)
```

Arguments

hist_data	A data frame containing covariates and binary responses for historical controls.
formula	A formula which is used for fitting a logistic regression model on the historical data.
phi	The relation between the response rate under the null and the response rate under the interesting alternative. "odds_ratio" assumes that the odds ratio (OR) between these response rates is constant with $OR = c1+1$. "difference" assumes that the response rate under the alternative is $c1$ higher than under the null. Can also be specified by the user by providing a function with arguments c and x .
c1	parameter for obtaining the response rate under the alternative, see description of phi.
modelfit	Can be used instead of formula and hist_data to provide an arbitrary fitted model that is compatible with <code>predict(modelfit, type="response")</code> . formula and hist_data are ignored if modelfit is specified.
mean0	Optional: Can be used to overwrite the estimated average response rate under the null of the fitted model.
mean1	Optional: Can be used to overwrite the estimated average response rate under the alternative of the fitted model.
alpha	Specified type I error of the trial.
beta	Specified type II error of the trial.

Value

A list returning the arguments of the function and the preliminary design for starting the stratified trial.

Examples

```
X <- abs(rnorm(1000, 0, 1))
Y <- rbinom(1000, 1, 1-exp(-X))
mydata <- data.frame("X" = X, "Y" = Y)
hist_start(mydata, Y~X, c1 = 2)
```

strat_end	<i>Adjust a subspace stratified design at the end of the study.</i>
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Description

Adjust a subspace stratified design at the end of the study.

Usage

```
strat_end(interim, sub_stagetwo)
```

Arguments

`interim` A preliminary stratified design adjusted at interim as returned by `strat_interim()`.
`sub_stagetwo` The subtypes observed for the patients accrued in stage 2.

Value

A list returning the arguments of the function and the final design of the stratified trial.

Examples

```
p0_sub <- c(0.1, 0.3, 0.5)
p1_sub <- c(0.3, 0.5, 0.7)
distr_sub <- c(1/3, 1/3, 1/3)
start <- strat_start(p0_sub, p1_sub, distr_sub)
n1 <- start$des_start[2]
subone <- sample(c(1,2,3), n1, TRUE)
interim <- strat_interim(start, subone)
n2 <- interim$des_interim[4]
subtwo <- sample(c(1,2,3), n2, TRUE)
strat_end(interim, subtwo)
```

strat_interim	<i>Adjust a subspace stratified design at interim.</i>
---------------	--

Description

Adjust a subspace stratified design at interim.

Usage

```
strat_interim(start, sub_stageone)
```

Arguments

`start` An initialized stratified design as returned by `strat_start()`.
`sub_stageone` The subtypes observed for the patients accrued in stage 1.

Value

A list returning the arguments of the function and the preliminary design of a stratified trial adjusted at interim.

Examples

```
p0_sub <- c(0.1, 0.3, 0.5)
p1_sub <- c(0.3, 0.5, 0.7)
distr_sub <- c(1/3, 1/3, 1/3)
start <- strat_start(p0_sub, p1_sub, distr_sub)
n1 <- start$des_start[2]
subone <- sample(c(1,2,3), n1, TRUE)
strat_interim(start, subone)
```

strat_start

Initializes a subspace stratified design before the start of the study.

Description

Initializes a subspace stratified design before the start of the study.

Usage

```
strat_start(p0_sub, p1_sub, distr_sub, alpha = 0.05, beta = 0.2)
```

Arguments

`p0_sub` A vector, where the i -th entry corresponds to the response rate under the null for the i -th subtype.
`p1_sub` A vector, where the i -th entry corresponds to the response rate under the alternative for the i -th subtype.
`distr_sub` A vector, where the i -th entry corresponds to the prevalence of the i -th subtype in the population.
`alpha` Specified type I error of the trial.
`beta` Specified type II error of the trial.

Value

A list returning the arguments of the function and the preliminary design for starting the stratified trial.

Examples

```
p0_sub <- c(0.1, 0.3, 0.5)
p1_sub <- c(0.3, 0.5, 0.7)
distr_sub <- c(1/3, 1/3, 1/3)
strat_start(p0_sub, p1_sub, distr_sub)
```

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