Package 'PracticalEquiDesign'

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Title Design of Practical Equivalence Trials

Version 0.0.3

Description
Sample size calculations for practical equivalence trial design with a time to event endpoint.

Depends R (>= 3.5.0)

License GPL-3

Encoding UTF-8

Imports dplyr, ggplot2, methods, numDeriv, stats, Temporal, tidyr

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R topics documented:

ProbCurve *Plot Sample Size Curve*

Description

Plot the probability of selecting the superior treatment as a function of the sample size n.

Usage

```
ProbCurve(
  cens_prop = 0,
  med1 = NULL,
  shape1 = NULL,
  rate1 = NULL,
  med2 = NULL,
  shape2 = NULL,
  rate2 = NULL,
  info_reps = 50,
  delta = 1,
  min_n = 10,
  max_n = 100,
  margin = 0,
  target_prob = 0.8,
  use_exp_calc = TRUE
)
```

Arguments

cens_prop	Expected censoring proportion.
med1	Median for treatment arm 1, assuming shape1 is 1. Overwrites shape and rate if supplied.
shape1	Shape parameter for treatment arm 1.
rate1	Rate parameter for treatment arm 1.
med2	Median for treatment arm 2, assuming shape2 is 1. Overwrites shape and rate if supplied.
shape2	Shape parameter for treatment arm 2.
rate2	Rate parameter for treatment arm 2.
info_reps	Replicates used for estimating the observed information matrix.
delta	Increment between consecutive sample sizes to evaluate.
min_n	Minimum allowable sample size.
max_n	Maximum allowable sample size.
margin	Margin of practical equivalence.
target_prob	Probability of selecting the more effective treatment.
use_exp_calc	If both shape parameters are 1, should the calculations be performed assuming an exponential distribution for the time to event in each arm?

Value

ggplot object.

Examples

```
# Plot the selection probability curve for the case of two exponentials
# with medians of 9 and 12 (e.g.) months, and a 2 month margin of
# practical equivalence.
q <- ProbCurve(
  cens_prop = 0.15,
  med1 = 9,
  med2 = 12,
  margin = 2.0
)
```

SampleSize *Sample Size Estimation*

Description

Estimate the sample size for a practical equivalence trial with a time to event endpoint. The sample size is determined by specifying the time to event distribution of each treatment arm, the margin of practical equivalence, and the desired probability of selecting the superior treatment. The distribution in each treatment arm may be specified either by providing the median, in which case the time to event is assumed to be exponential, or by specifying the shape and rate of a Weibull distribution. For guidance on how to set the shape and rate parameters when using a Weibull calculation, see WeibullSpec.

Usage

```
SampleSize(
  cens_prop = 0,
  med1 = NULL,
  shape1 = NULL,
  rate1 = NULL,
  med2 = NULL,
  shape2 = NULL,
  rate2 = NULL,
  info_reps = 50,
  min_n = 10,
  max_n = 100,
  margin = 0,
  target_prob = 0.8,
  use_exp_calc = TRUE
)
```

Arguments

cens_prop	Expected censoring proportion.
med1	Median for treatment arm 1, assuming shape1 is 1. Overwrites shape and rate if supplied.
shape1	Shape parameter for treatment arm 1.
rate1	Rate parameter for treatment arm 1.
med2	Median for treatment arm 2, assuming shape2 is 1. Overwrites shape and rate if supplied.
shape2	Shape parameter for treatment arm 2.
rate2	Rate parameter for treatment arm 2.
info_reps	Replicates used for estimating the observed information matrix.
min_n	Minimum allowable sample size.
max_n	Maximum allowable sample size.
margin	Margin of practical equivalence.
target_prob	Probability of selecting the more effective treatment.
use_exp_calc	If both shape parameters are 1, should the calculations be performed assuming an exponential distribution for the time to event in each arm? Default is TRUE.

Value

Integer sample size.

Examples

```
# Sample size calculation based on exponentials.
n <- SampleSize(
  cens_prop = 0.15,
  med1 = 9,
  med2 = 12
)

# Sample size calculation based on exponentials with a 2 month margin.
# Note that the required sample size is expected to increase.
n <- SampleSize(
  cens_prop = 0.15,
  med1 = 9,
  med2 = 12,
  margin = 2
)

# Sample size calculation based on Weibulls.
n <- SampleSize(
  cens_prop = 0.15,
  shape1 = 2.8,
  rate1 = 0.10,
  shape2 = 4.0,
  rate2 = 0.08
)
```

SupProb *Superiority Probability*

Description

Probability of selecting the more effective treatment as pr(median2 - median1 >= margin) + 0.5 * pr(abs(median2 - median1) < margin).

Usage

```
SupProb(
  cens_prop,
  n,
  med1 = NULL,
  shape1 = NULL,
  rate1 = NULL,
  med2 = NULL,
  shape2 = NULL,
  rate2 = NULL,
  info_reps = 50,
  margin = 0,
  use_exp_calc = TRUE
)
```

Arguments

cens_prop	Expected censoring proportion.
n	Sample size.
med1	Median for treatment arm 1, assuming shape1 = 1. Overwrites shape and rate if supplied.
shape1	Shape parameter for arm 1.
rate1	Rate parameter for arm 1.
med2	Median for treatment arm 2, assuming shape2 = 1. Overwrites shape and rate if supplied.
shape2	Shape parameter for arm 2.
rate2	Rate parameter for arm 2.
info_reps	Replicates used for estimating the observed information matrix.
margin	Margin of practical equivalence.
use_exp_calc	If both shape parameters are 1, should the calculations be performed assuming an exponential distribution for the time to event in each arm? Default is TRUE.

Value

Numeric equivalence probability.

Examples

```
# Calculation in the case of exponentials with no margin.
prob <- SupProb(
  cens_prop = 0.15,
  n = 100,
  med1 = 9,
  med2 = 12,
)

# Calculation in the case of exponentials with a 2 month margin.
# The probability should be lower than in the absence of a margin.
prob <- SupProb(
  cens_prop = 0.15,
  n = 100,
  med1 = 9,
  med2 = 12,
  margin = 2
)

# Calculation in the case of Weibulls with a 2 month margin.
prob <- SupProb(
  cens_prop = 0.15,
  n = 100,
  shape1 = 2.8,
  rate1 = 0.10,
  shape2 = 4.0,
  rate2 = 0.08,
  margin = 2
)
```

`WeiAvgInfo` *Weibull Average Information*

Description

Estimate the expected information as the average value of the observed information across 'reps' realizations of the data.

Usage

```
WeiAvgInfo(cens_prop, n, shape, rate, reps = 10)
```

Arguments

`cens_prop`	Censoring proportion.
`n`	Sample size.
`shape`	Shape parameter 'alpha'.
`rate`	Rate parameter 'lambda'.
`reps`	Replicates to average.

Value

Numeric information matrix for shape and rate.

`WeibullSpec` *Weibull Specification*

Description

Calculate shape and rate of a Weibull distribution from the value of the survival curve at 2 time points.

Usage

```
WeibullSpec(t1, p1, t2, p2)
```

Arguments

`t1`	First time point.
`p1`	Probability at the first time point.
`t2`	Second time point.
`p2`	Probability at the second time point.

Value

Numeric vector containing the shape and rate.

Examples

```
# Determine the shape and rate parameter of a Weibull distribution
# where survival at 6 (e.g.) months is 80%, and survival at 12
# months is 50%.
theta <- WeibullSpec(t1 = 6, p1 = 0.8, t2 = 12, p2 = 0.5)
```

`WeiMed` *Weibull Median*

Description

Calculate the median of a Weibull distribution from the shape and rate.

Usage

```
WeiMed(shape, rate)
```

Arguments

shape	Shape parameter, ‘alpha‘.
rate	Rate parameter, ‘lambda‘.

Value

Numeric median.

Examples

```
# In the case of shape = 1 and rate = 1, the distribution
# is exponential, and the median is log(2).
med <- WeiMed(shape = 1, rate = 1)
```

Index