

Package ‘OptGS’

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Type Package

Title Near-Optimal Group-Sequential Designs for Continuous Outcomes

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Description Optimal group-sequential designs minimise some function of the expected and maximum sample size whilst controlling the type I error rate and power at a specified level. ‘OptGS’ provides functions to quickly search for near-optimal group-sequential designs for normally distributed outcomes. The methods used are described in Wason, JMS (2015) <[doi:10.18637/jss.v066.i02](https://doi.org/10.18637/jss.v066.i02)>.

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all.class*Different generic functions for class OptGS*

Description

Generic functions for summarising an object of class OptGS

Usage

```
## S3 method for class 'OptGS'
print(x,...)
## S3 method for class 'OptGS'
plot(x,ylim=NULL,...)
```

Arguments

<code>x</code>	An output object of class OptGS
<code>ylim</code>	y limits to be passed to plot
<code>...</code>	Additional arguments to be passed.

Details

`print.OptGS` gives the group-size, stopping boundaries, and operating characteristics of the design
`plot.OptGS` produces a plot of the expected sample size as the standardised treatment effect differs

Value

Screen or graphics output.

optgs*Finding optimal and balanced group-sequential designs*

Description

`optgs` is used to find a one-sided multi-stage design that balances four optimality criteria for a RCT with normally distributed outcomes

Usage

```
optgs(delta0 = 0, delta1 = 1/3, J = 2, sigma = 1, sd.known = TRUE,
      alpha = 0.05, power = 0.9, weights = c(0.95, 0, 0, 0.05),
      initial = NULL)
```

Arguments

<code>delta0</code>	mean difference in treatment effect under the null hypothesis (default: 0)
<code>delta1</code>	clinically relevant difference used to power the trial (default: 1/3)
<code>J</code>	number of stages in the trial (default: 2)
<code>sigma</code>	assumed standard deviation of treatment responses (default: 1)
<code>sd.known</code>	logical value indicating if sigma will be treated as known; if FALSE, a quantile substitution method will be used to modify the stopping boundaries (default TRUE)
<code>alpha</code>	one-sided type-I error rate required (default: 0.05)
<code>power</code>	power required (default: 0.9)
<code>weights</code>	vector of length 4 giving the weights put on the four optimality criteria (default: c(0.95,0,0,0.05)). See details for more information
<code>initial</code>	starting values for the Nelder-Mead algorithm if the user wishes to override the default (default: NULL). Initial values must be specified as a two-dimensional vector where both entries are between -0.5 and 0.5.

Details

`optgs` uses the extended power-family of group-sequential tests, and searches for the values of the futility and efficacy shape parameters that optimise the specified weighting. A description of the extended power-family and `optgs` is provided in Wason (2012). The ‘weights’ argument corresponds to the weight put on: 1) the expected sample size at $\delta=\delta_0$; 2) the expected sample size at $\delta=\delta_1$; 3) the maximum expected sample size; 4) the maximum sample size (i.e. $J \times \text{groupsize}$).

Value

<code>groupsize</code>	the number of patients required per arm, per stage
<code>futility</code>	the futility boundaries for the design
<code>efficacy</code>	the efficacy boundaries for the design
<code>ess</code>	the expected sample size at the δ_0 ; the expected sample size at the δ_1 ; and the maximum expected sample size
<code>typeIerror</code>	the actual type-I error rate of the design
<code>power</code>	the actual power of the design

References

Wason, J.M.S. OptGS: an R package for finding near-optimal group-sequential designs. Journal of Statistical Software, 66(2), 1-13. <https://www.jstatsoft.org/v66/i02/>

Examples

```
##Find a three-stage design that minimises the maximum expected sample size.
threestagedeltaminimax=optgs(J=3,weights=c(0,0,1,0))
plot(threestagedeltaminimax)
```

powerfamily

*Finding extended power-family group-sequential designs***Description**

`powerfamily` is used to find a one-sided extended power-family group-sequential design

Usage

```
powerfamily(futility = 0, efficacy = 0, delta0 = 0, delta1 = 1/3,
           J = 2, sigma = 1, sd.known = TRUE, alpha = 0.05, power = 0.9)
```

Arguments

<code>futility</code>	shape parameter for futility boundaries (default: 0)
<code>efficacy</code>	shape parameter for efficacy boundaries (default: 0)
<code>delta0</code>	mean difference in treatment effect under the null hypothesis (default: 0)
<code>delta1</code>	clinically relevant difference used to power the trial (default: 1/3)
<code>J</code>	number of stages in the trial (default: 2)
<code>sigma</code>	assumed standard deviation of treatment responses (default: 1)
<code>sd.known</code>	logical value indicating if sigma will be treated as known; if FALSE, a quantile substitution method will be used to modify the stopping boundaries (default TRUE)
<code>alpha</code>	one-sided type-I error rate required (default: 0.05)
<code>power</code>	power required (default: 0.9)

Details

`powerfamily` uses the extended power-family of group-sequential tests. A description of the extended power-family is provided in Wason (2012).

Value

<code>groupsize</code>	the number of patients required per arm, per stage
<code>futility</code>	the futility boundaries for the design
<code>efficacy</code>	the efficacy boundaries for the design
<code>ess</code>	the expected sample size at the <code>delta0</code> ; the expected sample size at the <code>delta1</code> ; and the maximum expected sample size
<code>typeIerror</code>	the actual type-I error rate of the design
<code>power</code>	the actual power of the design

References

Wason, J.M.S. OptGS: an R package for finding near-optimal group-sequential designs. *Journal of Statistical Software*, 66(2), 1-13. <http://www.jstatsoft.org/v66/i02/>

Examples

```
##Find a three-stage design that has shape parameters -0.5 and 0.5.  
threestagedesign=powerfamily(J=3,futility=-0.5,efficacy=0.5)  
plot(threestagedesign)
```

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