

Package ‘OptGS’

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Type Package

Title Near-Optimal and Balanced Group-Sequential Designs for Clinical Trials with Continuous Outcomes

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Description Functions to find near-optimal multi-stage designs for continuous outcomes.

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all.class	<i>Different generic functions for class OptGS</i>
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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

x	An output object of class OptGS
ylim	y limits to be passed to plot
...	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

delta0	mean difference in treatment effect under the null hypothesis (default: 0)
delta1	clinically relevant difference used to power the trial (default: 1/3)
J	number of stages in the trial (default: 2)
sigma	assumed standard deviation of treatment responses (default: 1)
sd.known	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)
alpha	one-sided type-I error rate required (default: 0.05)

power	power required (default: 0.9)
weights	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
initial	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. $J*\text{groupsize}$).

Value

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

futility	shape parameter for futility boundaries (default: 0)
efficacy	shape parameter for efficacy boundaries (default: 0)
delta0	mean difference in treatment effect under the null hypothesis (default: 0)
delta1	clinically relevant difference used to power the trial (default: 1/3)
J	number of stages in the trial (default: 2)
sigma	assumed standard deviation of treatment responses (default: 1)
sd.known	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)
alpha	one-sided type-I error rate required (default: 0.05)
power	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

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