Package ‘gen2stage’

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Type Package

Title Generalized Two-Stage Designs for Phase II Single-Arm Studies

Version 1.0

Depends R (>= 2.0.0), graphics, stats, clinfun

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Description One can find single-stage and two-stage designs for a phase II single-arm study with either efficacy or safety/toxicity endpoints as described in Kim and Wong (2019) <doi:10.29220/CSAM.2019.26.2.163>.

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`gen2stage-package` *Generalized Two-Stage Designs for Phase II Single-Arm Studies*

Description

The R package `gen2stage` can generate single-stage and two-stage designs for phase II single-arm efficacy or safety studies.

Details

Package:	gen2stage
Type:	Package
Version:	1.0
Date:	2017-10-05
License:	GPL-2

Author(s)

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References

Kim S and Wong WK. Phase II Two-Stage Single-Arm Clinical Trials for Testing Toxicity Levels. *Commun Stat Appl Methods. 2019 Mar;26(2):163-173.* `https://www.ncbi.nlm.nih.gov/pubmed/31106162`.

Examples

```
# Single-stage safety design with pu (p0) = 0.33 vs. pa (p1) = 0.20
gen2single(0.33, 0.20, 0.05, 0.20)

# Single-stage efficacy design with pu (p0) = 0.67 vs. pa (p1) = 0.80
gen2single(0.67, 0.80, 0.05, 0.20)

# save and print
safety1 = gen2single(0.33, 0.20, 0.05, 0.20)
print(safety1)

# Two-stage safety design with pu (p0) = 0.33 vs. pa (p1) = 0.20
gen2simon(0.33, 0.20, 0.05, 0.20)
gen2simon(0.33, 0.20, 0.05, 0.10, nmax=150)

# Two-stage efficacy design with pu (p0) = 0.67 vs. pa (p1) = 0.80
gen2simon(0.67, 0.80, 0.05, 0.20)
gen2simon(0.67, 0.80, 0.05, 0.10, nmax=150)
```

```
# save, print and plot
safety2 = gen2simon(0.33, 0.20, 0.05, 0.20)
print(safety2)
plot(safety2)
```

`gen2simon` *Generalized Simon's 2-stage phase II design*

Description

Calculates generalized optimal and minimax 2-stage phase II designs based on the R function ph2simon.

Usage

```
gen2simon(pu, pa, ep1, ep2, nmax=100)
## S3 method for class 'gen2simon'
print(x, ...)
## S3 method for class 'gen2simon'
plot(x, ...)
```

Arguments

`pu`	unacceptable response/toxicity rate
`pa`	response/toxicity rate that is desirable
`ep1`	threshold for the probability of declaring drug/treatment desirable under p0
`ep2`	threshold for the probability of rejecting the drug/treatment under p1
`nmax`	maximum total sample size (default 100; can be at most 500)
`x`	object returned by gen2simon
`...`	arguments to be passed onto plot and print commands called within

Value

gen2simon returns a list with pu, pa, alpha, beta and nmax as above and:

`out`	matrix of best 2 stage designs for each value of total sample size n. The 6 columns are: r1, n1, r, n, EN(p0), PET(p0), alpha, beta

The "print" method formats and returns the minimax and optimal designs. The "plot" plots the expected sample size agains the maximum sample size as in Jung et al., 2001

References

Kim S and Wong WK. Phase II Two-Stage Single-Arm Clinical Trials for Testing Toxicity Levels. *Commun Stat Appl Methods. 2019 Mar;26(2):163-173.* `https://www.ncbi.nlm.nih.gov/pubmed/31106162`.

Jung SH, Carey M and Kim KM. (2001). Graphical Search for Two-Stage Designs for Phase II Clinical Trials. *Controlled Clinical Trials* 22, 367-372.

Simon R. (1989). Optimal Two-Stage Designs for Phase II Clinical Trials. *Controlled Clinical Trials* 10, 1-10.

See Also

`oc.gentwostage.bdry`

Examples

```
# Two-stage safety design with pu (p0) = 0.33 vs. pa (p1) = 0.20
gen2simon(0.33, 0.20, 0.05, 0.20)
gen2simon(0.33, 0.20, 0.05, 0.10, nmax=150)

# Two-stage efficacy design with pu (p0) = 0.67 vs. pa (p1) = 0.80
gen2simon(0.67, 0.80, 0.05, 0.20)
gen2simon(0.67, 0.80, 0.05, 0.10, nmax=150)

# save, print and plot
safety2 = gen2simon(0.33, 0.20, 0.05, 0.20)
print(safety2)
plot(safety2)
```

`gen2single` *Generalized exact single stage phase II design*

Description

Calculates the generalized exact one stage phase II design based on the R function ph2single.

Usage

```
gen2single(pu,pa,ep1,ep2,nsoln=5)
## S3 method for class 'gen2single'
print(x, ...)
```

Arguments

`pu`	unacceptable response/toxicity rate
`pa`	response/toxicity rate that is desirable
`ep1`	threshold for the probability of declaring drug/treatment desirable under p0

`ep2`	threshold for the probability of rejecting the drug/treatment under p1
`nsoln`	number of designs with given alpha and beta
`x`	object returned by gen2single
`...`	arguments to be passed onto print command called within

Value

gen2single returns the optimal design with pu, pa, alpha, and beta as above and:

`out`	matrix of the single-stage designs up to nsoln. The 4 columns are: r, n, alpha (type I error), beta (type II erro)

The "print" method formats and returns the optimal design.

References

Kim S and Wong WK. Phase II Two-Stage Single-Arm Clinical Trials for Testing Toxicity Levels. *Commun Stat Appl Methods. 2019 Mar;26(2):163-173.* `https://www.ncbi.nlm.nih.gov/pubmed/31106162`.

See Also

`gen2simon`

Examples

```
# Single-stage safety design with pu (p0) = 0.33 vs. pa (p1) = 0.20
gen2single(0.33, 0.20, 0.05, 0.20)

# Single-stage efficacy design with pu (p0) = 0.67 vs. pa (p1) = 0.80
gen2single(0.67, 0.80, 0.05, 0.20)

# save and print
safety1 = gen2single(0.33, 0.20, 0.05, 0.20)
print(safety1)
```

`oc.gentwostage.bdry` *Two-stage boundary operating characteristics*

Description

Calculates the operating characteristics of a two-stage boundary based on the R function oc.twostage.bdry.

Usage

```
oc.gentwostage.bdry(pu, pa, r1, n1, r, n)
```

Arguments

`pu`	unacceptable response rate
`pa`	response rate that is desirable
`r1`	first stage threshold to declare treatment undesirable
`n1`	first stage sample size
`r`	overall threshold to declare treatment undesirable
`n`	total sample size

Value

oc.gentwostage.bdry returns the type I and II error rates as well as the probability of early temination and expected sample size under pu for a specific boundary.

References

Kim S and Wong WK. Phase II Two-Stage Single-Arm Clinical Trials for Testing Toxicity Levels. *Commun Stat Appl Methods. 2019 Mar;26(2):163-173.* `https://www.ncbi.nlm.nih.gov/pubmed/31106162`.

See Also

`gen2simon`

Examples

```
# Optimal two-stage safety design with pu (p0) = 0.33 vs. pa (p1) = 0.20
oc.gentwostage.bdry(0.33, 0.20, 8, 26, 22, 85)

# Optimal two-stage efficacy design with pu (p0) = 0.67 vs. pa (p1) = 0.80
oc.gentwostage.bdry(0.67, 0.80, 18, 26, 63, 85)
```

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