

Package ‘gen2stage’

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Author Seongho Kim
Maintainer Seongho Kim <biostatistician.kim@gmail.com>
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](https://doi.org/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)

Seongho Kim <biostatistician.kim@gmail.com>

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 against 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 error)
-----	---

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	<i>Two-stage boundary operating characteristics</i>
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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 termination 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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