Package 'p2oncology'

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Title Single Arm Phase 2 Oncology Trial

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Description Single arm phase 2 oncology trial. For more details see P. Gao (2024) <doi:10.1080/10543406.2024.2341673>.

Depends clinfun, mvtnorm, doParallel

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Encoding UTF-8

Imports foreach, dplyr, jsonlite

Config/roxygen2/version 8.0.0

URL https://github.com/innovatiostat/rcode

BugReports https://github.com/innovatiostat/rcode/issues

NeedsCompilation no

Repository CRAN

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Contents

`asd_ci_est_one_arm_2_stage` *Final analysis: two stage design, with sample size change*

Description

Final analysis: two stage design, with sample size change

Usage

```
asd_ci_est_one_arm_2_stage(p_0, n_1, n_2, r_1_e, r_2, n_new, x_1, x_new, alpha)
```

Arguments

`p_0`	Response rate indicating low activity with insufficient clinical benefit.
`n_1`	Number of patients at first look.
`n_2`	Number of patients at second look.
`r_1_e`	The trial would be stopped for superiority if at least r_1_e responses are observed at the first look.
`r_2`	If no more than r_2 responses are observed at the second look, then the null hypothesis will not be rejected.
`n_new`	New sample size after the interim analysis.
`x_1`	Number of responses at the first look.
`x_new`	Number of responses at the final visit.
`alpha`	One-sided type I error.

Value

UL: upper limit of confidence interval.

LL: lower limit of confidence interval.

The results with continuity correction are not necessarily different from those with continuity correction.

The need for continuity correction can be determined through simulations on type I error (see Gao, Zhang, 2004).

References

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Gao, P., L. Liu, and C. Mehta. 2013 Oct 15. Exact inference for adaptive group sequential designs. Statistics in Medicine 32(23):3991–4005. doi:10.1002/sim.5847.

Examples

```
asd_ci_est_one_arm_2_stage( p_0=0.2,n_1=100,n_2=105,r_1_e=33,r_2=29,n_new=115,
x_1=28,x_new=34,alpha=0.025)
```

---

asd_ci_est_one_arm_3_stage

Final analysis: three stage design, with sample size change

Description

Final analysis: three stage design, with sample size change

Usage

```
asd_ci_est_one_arm_3_stage(
  p_0,
  n_2,
  n_3,
  r_2_e,
  r_2,
  r_3,
  n_new,
  x_2,
  x_new,
  alpha
)
```

Arguments

p_0	Response rate indicating low activity with insufficient clinical benefit.
n_2	Number of patients at second look.
n_3	Number of patients at third look.
r_2_e	The trial would be stopped for superiority if at least r_2_e responses are observed at the second look. If r_2_e was not used in the design, enter NA.
r_2	If no more than r_2 responses are observed at the second look, then the trial would be stopped for futility.

r_3	If no more than r_3 responses are observed at the third look, then the null hypothesis will not be rejected.
n_new	New sample size after the interim analysis (at the second look).
x_2	Number of responses at the second look.
x_new	Number of responses at the final visit.
alpha	One-sided type I error.

Value

UL: upper limit of confidence interval.

LL: lower limit of confidence interval.

The results with continuity correction are not necessarily different from those with continuity correction.

The need for continuity correction can be determined through simulations on type I error (see Gao, Zhang, 2004).

References

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Gao, P., L. Liu, and C. Mehta. 2013 Oct 15. Exact inference for adaptive group sequential designs. Statistics in Medicine 32(23):3991–4005. doi:10.1002/sim.5847.

Examples

```
asd_ci_est_one_arm_3_stage( p_0=0.2,n_2=105,n_3=110,r_2_e=33,r_3=29,n_new=115,
x_2=28,x_new=34,alpha=0.025)
```

EXP_3_stg_sz *Three-stage design*

Description

Three-stage design

Usage

```
EXP_3_stg_sz(alpha, beta, p_0, p_low, p_1, d_23_cut)
```

Arguments

alpha	One-sided type I error.
beta	Type II error.
p_0	Response rate indicating low activity with insufficient clinical benefit.
p_low	Minimally clinically beneficial response rate.
p_1	Assumed response rate.
d_23_cut	Min(n3-n2) sets the minimal difference between n3 and n2 for the design.

Value

n1: Number of patients at first look. n1 for the three-stage design is the from Simon's design with p=p_1.

n_2: Number of patients at second look. n_2 for the three-stage design is the n1 from Simon's design with p=p_low.

r1: If no more than r1 responses are observed at the first look, then the trial would be stopped for futility.

r_2: The null hypothesis will be rejected if at least r_2 responses are observed at the end of the trial.

EN(p0) is the expected sample size under the null hypothesis.

PET(p0) is the probability of early termination under the null hypothesis.

PET_p is the probability of early termination under p=p_1.

PET_p_low is the probability of early termination under p=p_low.

power_p_1 is the power under p=p_1.

power_p_low is the power under p=p_low.

Type I error is the probability of rejecting the null hypothesis under p<=p_0.

The minimax design has the smallest n_2 among all possible choices of (n1,r1,n_2,r_2).

The optimal design has the smallest EN(p0) among all possible choices of (n1,r1,n_2,r_2).

The n1 and n_2 for the average design is the average of n1's and n_2's from the minimax and the optimal designs.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Examples

```
EXP_3_stg_sz(alpha=c(0.001,0.024),beta=0.1,p_0=0.2,p_low=0.33,p_1=0.4,d_23_cut=5)
```

`gsd_ci_est_2_stage` *Final analysis: two stage design, no sample size change*

Description

Final analysis: two stage design, no sample size change

Usage

```
gsd_ci_est_2_stage(p_0, n_1, n_2, r_1_e, r_2, x_last, last_vt, alpha)
```

Arguments

`p_0`	Response rate indicating low activity with insufficient clinical benefit.
`n_1`	Number of patients at first look.
`n_2`	Number of patients at second look.
`r_1_e`	The trial would be stopped for superiority if at least r2e responses are observed at the second look.
`r_2`	If no more than r_2 responses are observed at the second look, then the null hypothesis will not be rejected.
`x_last`	Number of responses at the final visit.
`last_vt`	1.
`alpha`	One-sided type I error.

Value

UL: upper limit of confidence interval.

LL: lower limit of confidence interval.

The results with continuity correction are not necessarily different from those with continuity correction.

The need for continuity correction can be determined through simulations on type I error (see Gao, Zhang, 2004).

References

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Gao, P., L. Liu, and C. Mehta. 2013 Oct 15. Exact inference for adaptive group sequential designs. Statistics in Medicine 32(23):3991–4005. doi:10.1002/sim.5847.

Examples

```
gsd_ci_est_2_stage(p_0=0.2,n_1=100,n_2=105,r_1_e=NA,r_2=29,x_last=31,last_vt=1,alpha=0.025)
```

gsd_ci_est_3_stage *Final analysis: three stage design, no sample size change*

Description

Final analysis: three stage design, no sample size change

Usage

```
gsd_ci_est_3_stage(p_0, n_2, n_3, r_2_e, r_3, x_last, last_vt, alpha)
```

Arguments

p_0	Response rate indicating low activity with insufficient clinical benefit.
n_2	Number of patients at second look.
n_3	Number of patients at third look.
r_2_e	The trial would be stopped for superiority if at least r_2_e responses are observed at the second look. If r_2_e was not used in the design, enter NA.
r_3	If no more than r_3 responses are observed at the third look, then the null hypothesis will not be rejected.
x_last	Number of responses at the final visit.
last_vt	1.
alpha	One-sided type I error.

Value

UL: upper limit of confidence interval.

LL: lower limit of confidence interval.

The results with continuity correction are not necessarily different from those with continuity correction.

The need for continuity correction can be determined through simulations on type I error (see Gao, Zhang, 2004).

References

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Gao, P., L. Liu, and C. Mehta. 2013 Oct 15. Exact inference for adaptive group sequential designs. Statistics in Medicine 32(23):3991–4005. doi:10.1002/sim.5847.

Examples

```
gsd_ci_est_3_stage(p_0=0.2,n_2=100,n_3=105,r_2_e=31,r_3=29,x_last=31,last_vt=3,alpha=0.025)
```

hybrid_sz *Two-stage design: the hybrid design*

Description

Two-stage design: the hybrid design

Usage

```
hybrid_sz(alpha, beta, p_0, p_low, p_1, d_12_cut)
```

Arguments

alpha	One-sided type I error.
beta	Type II error.
p_0	Response rate indicating low activity with insufficient clinical benefit.
p_low	Minimally clinically beneficial response rate.
p_1	Assumed response rate.
d_12_cut	Min(n2-n1) sets the minimal difference between n2 and n1 for the design.

Value

n1: Number of patients at first look.

n_2: Number of patients at second look. n_2 is also the total sample size.

r1: If no more than r1 responses are observed at the first look, then the trial would be stopped for futility.

r_2: The null hypothesis will be rejected if at least r_2 responses are observed at the end of the trial.

EN(p0) is the expected sample size under the null hypothesis.

PET(p0) is the probability of early termination under the null hypothesis.

PET_p is the probability of early termination under p=p_1.

PET_p_low is the probability of early termination under p=p_low.

power_p is the power under p=p_1.

power_p_low is the power under p=p_low.

Type I error is the probability of rejecting the null hypothesis under p<=p_0.

The minimax design has the smallest n2 among all possible choices of (n1,r1,n_2,r_2).

The optimal design has the smallest EN(p0)) among all possible choices of (n1,r1,n_2,r_2).

The n1 for the average design is the average of n1's from the minimax and the optimal designs.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Examples

```
hybrid_sz(alpha=c(0.001,0.024),beta=0.1,p_0=0.2,p_low=0.4,p_1=0.55,d_12_cut=0)
```

---

interim_analysis *The interim analysis can be conducted for both two-stage and three-stage designs*

Description

The interim analysis can be conducted for both two-stage and three-stage designs

Usage

```
interim_analysis(p_0, r_final, n_inter, n_final, x_inter, beta, N_max)
```

Arguments

p_0	Response rate indicating low activity with insufficient clinical benefit.
r_final	For two-stage designs, r_final=r2. For the three-stage design, r_final=r3.
n_inter	Number of patients at the interim look. For two-stage designs, n_inter=n1. For the three-stage design, n_inter=n2.
n_final	For two-stage designs, n_inter=n2. For the three-stage design, n_inter=n3.
x_inter	Number of responses observed at the interim look.
beta	The conditional type II error. 1-beta is the desired conditional power.
N_max	Pre-selected maximum sample size.

Value

n_new: is the new sample size.

r_new (without continuity correction) and r_new (with continuity correction) are thresholds such that the null hypothesis will be rejected at n_new if at least r_new responses are observed. Simulations on type I error will help to determine if continuity correction is needed.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

P. Gao, J.H. Ware, C. Mehta, (2008), Sample size re-estimation for adaptive sequential designs. Journal of Biopharmaceutical Statistics, 18: 1184–1196, 2008.

Examples

```
interim_analysis(p_0=0.2,r_final=17,n_inter=22,n_final=56,x_inter=7,beta=0.1,N_max=120)
```

`midpnt_sz` *Two-stage design: the midpoint design*

Description

Two-stage design: the midpoint design

Usage

```
midpnt_sz(alpha, beta, p_0, p_low, p_1, q, d_12_cut)
```

Arguments

`alpha`	One-sided type I error.
`beta`	Type II error.
`p_0`	Response rate indicating low activity with insufficient clinical benefit.
`p_low`	Minimally clinically beneficial response rate.
`p_1`	Assumed response rate.
`q`	0<q<1.
`d_12_cut`	Min(n2-n1) sets the minimal difference between n2 and n1 for the design.

Value

n1: Number of patients at first look.

n_2: Number of patients at second look. n_2 is also the total sample size.

r1: If no more than r1 responses are observed at the first look, then the trial would be stopped for futility.

r_2: The null hypothesis will be rejected if at least r_2 responses are observed at the end of the trial.

EN(p0) is the expected sample size under the null hypothesis.

PET(p0) is the probability of early termination under the null hypothesis.

PET_p is the probability of early termination under p=p_1.

PET_p_low is the probability of early termination under p=p_low.

power_p is the power under p=p_1.

power_p_low is the power under p=p_low.

Type I error is the probability of rejecting the null hypothesis under p<=p_0.

The minimax design has the smallest n_2 among all possible choices of (n1,r1,n2,r2).

The optimal design has the smallest EN(p_0)) among all possible choices of (n1,r1,n_2,r_2).

The n1 for the average design is the average of n1's from the minimax and the optimal designs.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Examples

```
midpnt_sz(alpha=c(0.001,0.024),beta=0.1,p_0=0.2,p_low=0.33,p_1=0.4,q=0.5,d_12_cut=5)
```

`one_arm_ad_3_stg_binary`

Simulations: adaptive three stage design

Description

Simulations: adaptive three stage design

Usage

```
one_arm_ad_3_stg_binary(
  p_1,
  p_0,
  n_1,
  r_1,
  n_2,
  r_2,
  r_2_e = NA,
  n_3,
  r_3,
  N_max,
```

```
  beta,
  sim_num
)
```

Arguments

p_1	The assumed response rate.
p_0	Response rate indicating low activity with insufficient clinical benefit.
n_1	Number of patients at first look.
r_1	If no more than r_1 responses are observed at the first look, then the trial would be stopped for futility.
n_2	Number of patients at second look.
r_2	If no more than r_2 responses are observed at the second look, then the trial would be stopped for futility.
r_2_e	The trial would be stopped for superiority if at least r_2_e responses are observed at the second look. If r_2_e is not used in the design, enter NA.
n_3	Number of patients at third look.
r_3	If no more than r_3 responses are observed at the third look, then the null hypothesis will not be rejected.
N_max	Maximum sample size for the trial.
beta	Type II error. The target power is 1-beta.
sim_num	Purpose of simulation: To verify type I error control by setting p_1=p_0, To evaluate the operating characteristics of the adaptive design and to determine if continuity correction is necessary.

Value

Average sample size is EN(p_1).

Rate of termination is PET(p_1)

If rejection rate without continuity correction does not exceed alpha, the continuity correction is not needed for this group of parameters p_0,n_1,r_1,n_2,r_2,r_2_e,n_3,r_3. Otherwise, continuity correction should be applied.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

P. Gao, J.H. Ware, C. Mehta, (2008), Sample size re-estimation for adaptive sequential designs. Journal of Biopharmaceutical Statistics, 18: 1184–1196, 2008.

Examples

```
one_arm_ad_3_stg_binary(p_1=0.2,p_0=0.2,n_1=37,r_1=8,n_2=100,r_2=22,r_2_e=33,
n_3=105,r_3=29,N_max=150,beta=0.1,sim_num=100000)
```

`one_arm_ad_two_stg_binary` *Simulations: adaptive two stage design*

Description

Simulations: adaptive two stage design

Usage

```
one_arm_ad_two_stg_binary(
  p_1,
  p_0,
  n_1,
  r_1,
  r_1_e = NA,
  n_2,
  r_2,
  N_max,
  beta,
  sim_num
)
```

Arguments

`p_1`	The assumed response rate.
`p_0`	Response rate indicating low activity with insufficient clinical benefit.
`n_1`	Number of patients at first look.
`r_1`	If no more than r_1 responses are observed at the first look, then the trial would be stopped for futility.
`r_1_e`	The trial would be stopped for superiority if at least r_1_e responses are observed at the first look. If r_1_e is not used in the design, enter NA.
`n_2`	Number of patients at second look.
`r_2`	If no more than r_2 responses are observed at the second look, then the null hypothesis will be rejected.
`N_max`	Maximum sample size for the trial.
`beta`	Type II error. The target power is 1-beta.
`sim_num`	Purpose of simulation: To verify type I error control by setting p_1=p_0, To evaluate the operating characteristics of the adaptive design and to determine if continuity correction is necessary.

Value

Average sample size is EN(p_1).

Rate of termination is PET(p_1)

If rejection rate without continuity correction does not exceed alpha, the continuity correction is not needed for this group of parameters p_0,n_1,r_1,r_1_e,n_2,r_2. Otherwise, continuity correction should be applied.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

P. Gao, J.H. Ware, C. Mehta, (2008), Sample size re-estimation for adaptive sequential designs. Journal of Biopharmaceutical Statistics, 18: 1184–1196, 2008.

Examples

```
one_arm_ad_two_stg_binary(p_1=0.2,p_0=0.2,n_1=37,r_1=9,r_1_e=NA,n_2=53,r_2=16,
N_max=140,beta=0.1,sim_num=100000)
```

---

one_arm_rej_2_stg_binary

Simulations: Two stage fixed expanded Simon's design: either hybrid or mid-point design

---

Description

Simulations: Two stage fixed expanded Simon's design: either hybrid or mid-point design

Usage

```
one_arm_rej_2_stg_binary(p_1, p_0, n_1, r_1_f, r_1_e = NA, n_2, r_2, sim_num)
```

Arguments

p_1	The assumed response rate.
p_0	Response rate indicating low activity with insufficient clinical benefit.
n_1	Number of patients at first look.
r_1_f	If no more than r_1 responses are observed at the first look, then the trial would be stopped for futility.

r_1_e	The trial would be stopped for superiority if at least r_1_e responses are observed at the first look. If r_1_e is not used in the design, enter NA.
n_2	Number of patients at second look.
r_2	If no more than r_2 responses are observed at the second look, then the null hypothesis will be rejected.
sim_num	Purpose of simulation: To verify type I error control by setting p_1=p_0, To verify the parameters n_1,r_1_f,r_1_e,n_2,r_2 are correctly chosen, such that the rejection rate matches that from the design table from either the hybrid design or the mid-point design.

Value

Average sample size is EN(p_1).

Rate of termination is PET(p_1)

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

P. Gao, J.H. Ware, C. Mehta, (2008), Sample size re-estimation for adaptive sequential designs. Journal of Biopharmaceutical Statistics, 18: 1184–1196, 2008.

Examples

```
one_arm_rej_2_stg_binary(p_1=0.2,p_0=0.2,n_1=100,r_1_f=25,r_1_e=33,
n_2=105,r_2=29,sim_num=100000)
```

---

one_arm_rej_3_stg_binary

Simulations: Expanded Simon's design: the three stage design, no sample size change

---

Description

Simulations: Expanded Simon's design: the three stage design, no sample size change

Usage

```
one_arm_rej_3_stg_binary(
  p_1,
  p_0,
  n_1,
  r_1,
  n_2,
  r_2_f,
  r_2_e = NA,
  n_3,
  r_3,
  sim_num
)
```

Arguments

p_1	The assumed response rate.
p_0	Response rate indicating low activity with insufficient clinical benefit.
n_1	Number of patients at first look.
r_1	If no more than r_1 responses are observed at the first look, then the trial would be stopped for futility.
n_2	Number of patients at second look.
r_2_f	If no more than responses are observed at the second look, then the trial would be stopped for futility.
r_2_e	The trial would be stopped for superiority if at least r_2_e responses are observed at the first look. If r_2_e is not used in the design, enter NA.
n_3	Number of patients at third look.
r_3	If at least r_2 responses are observed at the third look, then the null hypothesis will be rejected.
sim_num	Purpose of simulation: To verify type I error control by setting p_1=p_0, To verify the parameters n_1,r_1,n_2,r_2_f,r_2_e,n_3,r_3 are correctly chosen, such that the rejection rate matches that from the design table of the three-stage design.

Value

Average sample size is EN(p_1).

Rate of termination is PET(p_1)

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673.

To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

P. Gao, J.H. Ware, C. Mehta, (2008), Sample size re-estimation for adaptive sequential designs. Journal of Biopharmaceutical Statistics, 18: 1184–1196, 2008.

Examples

```
one_arm_rej_3_stg_binary(p_1=0.2,p_0=0.2,n_1=37,r_1=8,n_2=100,r_2_f=22,r_2_e=33,
n_3=105,r_3=29,sim_num=100000)
```

`one_arm_rej_simon_binary`

Simulations: two stage fixed Simon's design

Description

Simulations: two stage fixed Simon's design

Usage

```
one_arm_rej_simon_binary(p_1, p_0, n_1, r_1, n_2, r_2, sim_num)
```

Arguments

`p_1`	The assumed response rate.
`p_0`	Response rate indicating low activity with insufficient clinical benefit.
`n_1`	Number of patients at first look.
`r_1`	If no more than r_1 responses are observed at the first look, then the trial would be stopped for futility.
`n_2`	Number of patients at second look.
`r_2`	If no more than r_2 responses are observed at the second look, then the null hypothesis will be rejected.
`sim_num`	Purpose of simulation: To verify type I error control by setting p_1=p_0, To verify the parameters n_1,r_1,n_2,r_2 are correctly chosen, such that the trial has 1-beta power if the true response rate is p_1.

Value

Average sample size is EN(p_1).

Rate of termination is PET(p_1)

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

P. Gao, J.H. Ware, C. Mehta, (2008), Sample size re-estimation for adaptive sequential designs. Journal of Biopharmaceutical Statistics, 18: 1184–1196, 2008.

Examples

```
one_arm_rej_simon_binary(p_1=0.4,p_0=0.2,n_1=37,r_1=9,n_2=53,r_2=16,sim_num=100000)
```

`simon_ph2_sz` *Two-stage design: Simon's design*

Description

Two-stage design: Simon's design

Usage

```
simon_ph2_sz(alpha, beta, p_0, p_1)
```

Arguments

`alpha`	One-sided type I error.
`beta`	Type II error.
`p_0`	Response rate indicating low activity with insufficient clinical benefit.
`p_1`	Assumed response rate.

Value

r1: If no more than r1 responses are observed at the first look, then the trial would be stopped for futility.

n1: Number of patients at first look.

r_2: The null hypothesis will be rejected if at least r_2 responses are observed at the end of the trial.

n_2: Number of patients at second look. n_2 is also the total sample size.

EN(p_0) is the expected sample size under the null hypothesis.

PET(p_0) is the probability of early termination under the null hypothesis.

PET_p_1 is the probability of early termination under p=p_1.

power_p_1 is the power under p=p_1.

Type I error is the probability of rejecting the null hypothesis under p<=p_0.

The minimax design has the smallest n_2 among all possible choices of (n1,r1,n_2,r_2).

The optimal design has the smallest EN(p_0) among all possible choices of (n1,r1,n_2,r_2).

The average design is an augmentation of the original Simon's design (Gao, Zhang. 2024). The n1 for the average design is the average of n1's from the minimax and the optimal designs.

References

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

P. Gao & W. Zhang (15 Apr 2024): Adaptive sequential design for phase II single-arm oncology trials: an expansion of Simon's design, Journal of Biopharmaceutical Statistics, DOI: 10.1080/10543406.2024.2341673. To link to this article: https://www.tandfonline.com/doi/full/10.1080/10543406.2024.2341673.

Examples

```
simon_ph2_sz(alpha=0.025,beta=0.1,p_0=0.2,p_1=0.33)
```

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