Package 'ADCT'

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Type Package

Title Adaptive Design in Clinical Trials

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Description Existing adaptive design methods in clinical trials. The package includes power, stopping boundaries (sample size) calculation functions for two-group group sequential designs, adaptive design with coprimary endpoints, biomarker-informed adaptive design, etc.

Imports stats, mvtnorm

Suggests clinfun, gsDesign

License GPL (>= 2)

LazyData TRUE

NeedsCompilation no

Repository CRAN

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Contents

`BioInfo.Power` *Power calculation for Biomarker-Informed Design with Hierarchical Model*

Description

Given the Biomarker-Informed design information, returns the overall power and probability of the arm is selected as the winner.

Usage

```
BioInfo.Power(uCtl, u0y, u0x, rhou, suy, sux, rho, sy, sx, Zalpha, N1, N, nArms, nSims)
```

Arguments

`uCtl`	mean value for the control group.
`u0y`	mean parameter of the group 1 for the parent model.
`u0x`	mean parameter of the group 2 for the parent model.
`rhou`	correlation coefficient between two groups for the parent model.
`suy`	standard deviation of the group 1 for the parent model.
`sux`	standard deviation of the group 2 for the parent model.
`rho`	correlation coefficient between two groups for the lower level model.
`sy`	standard deviation of the group 1 for the lower level model.
`sx`	standard deviation of the group 2 for the lower level model.
`Zalpha`	crtical point for rejection.
`N1`	sample size per group at interim analysis.
`N`	sample size per group at final analysis.
`nArms`	number of active groups.
`nSims`	number of simulation times.

Value

The evaluated power and probability of selecting the arm as the winner.

Author(s)

Yalin Zhu

References

Chang, M. (2014). Adaptive design theory and implementation using SAS and R. *CRC Press*.

Examples

```
## Determine critical value Zalpha for alpha (power) =0.025
u0y=c(0,0,0); u0x=c(0,0,0)
BioInfo.Power(uCtl=0, u0y, u0x, rhou=1, suy=0, sux=0, rho=1, sy=4, sx=4,
 Zalpha=2.772, N1=100, N=300, nArms=3, nSims=1000)
## Power simulation
u0y=c(1,0.5,0.2)
u0x=c(2,1,0.5)
BioInfo.Power(uCtl=0, u0y, u0x, rhou=0.2, suy=0.2, sux=0.2, rho=0.2, sy=4, sx=4,
 Zalpha=2.772, N1=100, N=300, nArms=3, nSims=500)
```

`CopriEndpt.Power` *Power Calculation for Two Coprimary Endpoints.*

Description

Given the group sequential design information, returns the overall power.

Usage

```
CopriEndpt.Power(n, tau, mu1, mu2, rho, alpha1, alpha2, alternative)
```

Arguments

`n`	sample size for the design.
`tau`	information time for the interim analysis.
`mu1`	mean value for coprimary endpoint 1.
`mu2`	mean value for coprimary endpoint 2.
`rho`	correlation coefficient between two coprimary endpoints.
`alpha1`	significant level for the first stage.
`alpha2`	significant level for the second stage.
`alternative`	indicates the alternative hypothesis and must be one of `"two.sided"` or `"two.sided"`.

Value

The evaluated power with attributes and computational error.

Author(s)

Yalin Zhu

References

Chang, M. (2014). Adaptive design theory and implementation using SAS and R. *CRC Press*.

Examples

```
# Example in Chang (2014) page  272
CopriEndpt.Power(n=197, tau=0.5, mu1=0.2, mu2=0.2, rho=0.5,
alpha1=0.0025, alpha2=0.024, alternative="one.sided")
 sapply(c(-0.8,-0.5,-0.2,0,0.2,0.5,0.8),CopriEndpt.Power,
n=197, tau=0.5, mu1=0.2, mu2=0.2, alpha1=0.0025, alpha2=0.024, alternative="one.sided")
```

`OneArm.CondPower` *Conditional power for one-arm, two-stage design with two primary endpoints*

Description

Given the group sequential design information, returns the conditional power.

Usage

```
OneArm.CondPower(mu1, mu2, n1, n2, rho, tau, alpha2, alternative)
```

Arguments

`mu1`	mean value for the first stage (endpoint 1).
`mu2`	mean value for the second stage (endpoint 2).
`n1`	sample size for the first stage.
`n2`	sample size for the second stage.
`rho`	correlation coefficient between two coprimary endpoints.
`tau`	information time for the interim analysis.
`alpha2`	significant level for the second stage.
`alternative`	indicates the alternative hypothesis and must be one of `"two.sided"` or `"two.sided"`.

Value

The evaluated power with attributes and computational error.

Author(s)

Yalin Zhu

References

Chang, M. (2014). Adaptive design theory and implementation using SAS and R. *CRC Press*.

Examples

```
# Example in Chang (2014) page  277
OneArm.CondPower(mu1=0.1333, mu2=0.1605, n1=130, n2=130, rho=0.35,
 tau=0.5, alpha2=0.024, alternative = "one.sided")
OneArm.CondPower(mu1=0.1333, mu2=0.1605, n1=130, n2=414, rho=0.35,
 tau=0.5, alpha2=0.024, alternative = "one.sided")
```

TwoArms.CondPower *Conditional power for two-group design, two-stage design with two primary endpoints*

Description

Given the group sequential design information, returns the conditional power.

Usage

```
TwoArms.CondPower(mu1, mu2, sigma1, sigma2, n1, n2, rho, tau, alpha2, alternative)
```

Arguments

mu1	mean value for the first stage (endpoint 1).
mu2	mean value for the second stage (endpoint 2).
sigma1	standard deviation for the first stage.
sigma2	standard deviation for the second stage.
n1	sample size for the first stage.
n2	sample size for the second stage.
rho	correlation coefficient between two coprimary endpoints.
tau	information time for the interim analysis.
alpha2	significant level for the second stage.
alternative	indicates the alternative hypothesis and must be one of "two.sided" or "two.sided".

Value

The evaluated power with attributes and computational error.

Author(s)

Yalin Zhu

References

Chang, M. (2014). Adaptive design theory and implementation using SAS and R. *CRC Press*.

Examples

```
# Example in Chang (2014) page  278
TwoArms.CondPower(mu1=0.28, sigma1=1.9, mu2=0.35, sigma2=2.2, n1=340, n2=340,
rho=0.3, tau=0.5, alpha2=0.024, alternative = "one.sided")
TwoArms.CondPower(mu1=0.28, sigma1=1.9, mu2=0.35, sigma2=2.2, n1=340, n2=482,
rho=0.3, tau=0.5, alpha2=0.024, alternative = "one.sided")
TwoArms.CondPower(mu1=0.32, sigma1=2, mu2=0.4, sigma2=1.8, n1=340, n2=340,
rho=0.3, tau=0.5, alpha2=0.024, alternative = "one.sided")
```

TwoGrpCopriEndpt.SimPower

Power Simulation for Two Group Two Coprimary Endpoints Group Sequential Design.

Description

Given the group sequential design information, returns the simulated overall power.

Usage

```
TwoGrpCopriEndpt.SimPower(mu11,mu12, mu21, mu22, rho, tau,
 alpha1, alpha2, alternative , Nmax, B)
```

Arguments

mu11	standardized mean value for coprimary endpoint 1 in group 1.
mu12	standardized mean value for coprimary endpoint 2 in group 1.
mu21	standardized mean value for coprimary endpoint 1 in group 2.
mu22	standardized mean value for coprimary endpoint 2 in group 2.
rho	correlation coefficient between two coprimary endpoints.
tau	information time for the interim analysis.
alpha1	significant level for the first stage.
alpha2	significant level for the second stage.
alternative	indicates the alternative hypothesis and must be one of "two.sided" or "two.sided".
Nmax	maximum sample size per group.
B	the simulation iterative time.

Value

The evaluated power with attributes and computational error.

Author(s)

Yalin Zhu

References

Chang, M. (2014). Adaptive design theory and implementation using SAS and R. *CRC Press*.

Examples

```
# Example in Chang (2014) page  275
TwoGrpCopriEndpt.SimPower(mu11=0.2,mu12=0.25, mu21=0.005, mu22=0.015, rho=0.25,
tau=0.5, alpha1=0.0025, alpha2=0.024, alternative = "two.sided",Nmax=584, B=10000)
```

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