Package ‘ADCT’

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<td>Title</td>
<td>Adaptive Design in Clinical Trials</td>
</tr>
<tr>
<td>Version</td>
<td>0.1.0</td>
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<tr>
<td>Author</td>
<td>Yalin Zhu</td>
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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

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BioInfo.Power  

*Power calculation for Biomarker-Informed Design with Hierarchical Model*

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**Description**

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

**Usage**

```r
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` (critical 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**

Examples

```r
## 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)
```

---

**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**

OneArm.CondPower

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

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")

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

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(mu1, mu12, mu21, mu22, rho, tau, 
alpha1, alpha2, alternative, Nmax, B)

Arguments

mu1 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


Examples

# Example in Chang (2014) page 275
TwoGrpCopriEndpt.SimPower(mu1=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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