Package 'SampleSize4ClinicalTrials'

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Type Package

Title Sample Size Calculation for the Comparison of Means or Proportions in Phase III Clinical Trials

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Description
There are four categories of Phase III clinical trials according to different research goals, including (1) Testing for equality, (2) Superiority trial, (3) Non-inferiority trial, and (4) Equivalence trial. This package aims to help researchers to calculate sample size when comparing means or proportions in Phase III clinical trials with different research goals.

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SampleSize4ClinicalTrials *Sample Size Calculation for the Comparison of Means or Proportions in Phase III Clinical Trials*

Description

There are four categories for Phase III clinical trials according to different research goals, including (1) Testing for equality, (2) Superiority trial, (3) Non-inferiority trial, and (4) Equivalence trial. This package aims to help researchers to calculate sample size when comparing means or proportions in Phase III clinical trials with different research goals.

Author(s)

Hongchao Qi, Fang Zhu

ssc_meancomp *Sample Size Calculation for the Comparison of Means in Phase III Clinical Trials*

Description

This function aims to calculate sample size for the comparison of means in Phase III clinical trials.

Usage

```
ssc_meancomp(design, ratio, alpha, power, sd, theta, delta)
```

Arguments

design	The design of the clinical trials. 1L Testing for equality 2L Superiority trial 3L Non-inferiority trial 4L Equivalence trial.
ratio	The ratio between the number of subjects in the treatment arm and that in the control arm
alpha	Type I error rate
power	Statistical power of the test (1-type II error rate)
sd	The standard deviation of observed outcomes in both arms
theta	The true mean difference between two arms
delta	The prespecified superiority, non-inferiority or equivalence margin

Value

samplesize

References

Chow S, Shao J, Wang H. 2008. Sample Size Calculations in Clinical Research. 2nd Ed. Chapman & Hall/CRC Biostatistics Series.

Yin, G. 2012. Clinical Trial Design: Bayesian and Frequentist Adaptive Methods. John Wiley & Sons.

Examples

```
##The comparison of means, a non-inferiority trial and the non-inferiority margin is -0.05
ssc_meancomp(design = 3L, ratio = 1, alpha = 0.05, power = 0.8, sd = 0.1, theta = 0, delta = -0.05)
```

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ssc_propcomp *Sample Size Calculation for the Comparison of Proportions in Phase III Clinical Trials*

Description

This function aims to calculate sample size for the comparison of proportions in Phase III clinical trials.

Usage

```
ssc_propcomp(design, ratio, alpha, power, p1, p2, delta)
```

Arguments

design	The design of the clinical trials. 1L Testing for equality 2L Superiority trial 3L Non-inferiority trial 4L Equivalence trial.
ratio	The ratio between the number of subjects in the treatment arm and that in the control arm.
alpha	Type I error rate
power	Statistical power of the test (1-type II error rate)
p1	The true mean response rate of the treatment arm
p2	The true mean response rate of the control arm
delta	The prespecified superiority, non-inferiority or equivalence margin

Value

samplesize

References

Chow S, Shao J, Wang H. 2008. Sample Size Calculations in Clinical Research. 2nd Ed. Chapman & Hall/CRC Biostatistics Series.

Yin, G. 2012. Clinical Trial Design: Bayesian and Frequentist Adaptive Methods. John Wiley & Sons.

Examples

```
##The comparison of proportions, an equivalence trial and the equivalence margin is 0.2
ssc_propcomp(design = 4L, ratio = 1, alpha = 0.05, power = 0.8, p1 = 0.75, p2 = 0.80, delta = 0.2)
```

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