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. The ssc function can calculate the sample size with pre-specified type I error rate, statistical power and effect size.

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Author(s)

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Usage

ssc(cat=c("m","p"), design=c(1,2,3,4), ratio, alpha, power, sigma, p1, p2, theta, delta)

Arguments

cat          Type of the outcome for comparison.  
"m"          stands for the comparison of means.  
"p"          stands for the comparison of proportions.  

design       The design of the clinical trials.  
1            Testing for equality  
2            Superiority trial  
3            Non-inferiority trial  
4            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)

sigma: The variance of observed outcomes in both arms (specified in the comparison of means for continuous outcomes)

p1: The response rate of the treatment arm (specified the comparison of proportions for binary outcomes)

p2: The response rate of the control arm

theta: The difference between means or proportions in the two arms

delta: The prespecified non-inferiority or equivalence margin in non-inferiority or equivalence trials

Value
	samplesize

References


Examples

##The comparison of means, a non-inferiority trial with a non-inferiority margin 0.5
##the true treatment difference is assumed to be zero in non-inferiority and equivalence trials
ssc(cat="m",design=3,ratio=1,alpha=0.05,power=0.9,sigma=1,theta=0,delta=0.5)

##The comparison of proportions, a superiority trial
ssc(cat="p",design=2,ratio=3,alpha=0.025,power=0.8,p1=0.4,p2=0.2,theta=0.2)
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