

# Package ‘SampleSize4ClinicalTrials’

January 9, 2021

**Type** Package

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

**Version** 0.2.3

**Author** Hongchao Qi, Fang Zhu

**Maintainer** Hongchao Qi <hcqi1992@gmail.com>

## **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.

**Encoding** UTF-8

**LazyData** true

**RoxygenNote** 7.1.1

**License** GPL-3

**NeedsCompilation** no

**Repository** CRAN

**Date/Publication** 2021-01-09 00:20:09 UTC

## **R topics documented:**

SampleSize4ClinicalTrials . . . . .	2
ssc_meancomp . . . . .	2
ssc_propcomp . . . . .	3

<b>Index</b>	<b>5</b>
--------------	----------

---

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)
```

---

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)
```

# Index

SampleSize4ClinicalTrials, [2](#)

ssc\_meancomp, [2](#)

ssc\_propcomp, [3](#)