This test is useful for the types of tests known as *non-inferiority* and *superiority* tests. Whether the null hypothesis represents 'non-inferiority' or 'superiority' depends on the context and whether the non-inferiority/superiority margin, δ, is positive or negative. In this setting, we wish to test whether a mean, μ, is non-inferior/superior to a reference value, μ0. The idea is that statistically significant differences between the mean and the reference value may not be of interest unless the difference is greater than a threshold, δ. This is particularly popular in clinical studies, where the margin is chosen based on clinical judgement and subject-domain knowledge. The hypotheses to test are

$$H_0 : \mu - \mu_0 \leq \delta$$
$$H_1 : \mu - \mu_0 > \delta$$

and δ is the superiority or non-inferiority margin.

Formulas

This calculator uses the following formulas to compute sample size and power, respectively:

$$n = \left(\sigma \frac{z_{1-\alpha} + z_{1-\beta}}{\mu - \mu_0 - \delta}\right)^2$$

$$1 - \beta = \Phi\left(z - z_{1-\alpha}\right) + \Phi\left(-z - z_{1-\alpha}\right) \quad , \quad z = \frac{\mu - \mu_0 - \delta}{\sigma/\sqrt{n}}$$

where

n is sample size
σ is standard deviation
Φ is the standard Normal distribution function
Φ^{-1} is the standard Normal quantile function
α is Type I error
β is Type II error, meaning $1 - \beta$ is power
δ is the testing margin

References

Chow S, Shao J, Wang H. 2008. Sample Size Calculations in Clinical Research. 2nd Ed. Chapman & Hall/CRC Biostatistics Series. page 52.