Chapter 215

Equivalence Tests for Two Proportions

Introduction

This module provides power analysis and sample size calculation for equivalence tests in two-sample designs in which the outcome is binary. Users may choose from among eight popular test statistics commonly used for running the hypothesis test.

The power calculations assume that independent, random samples are drawn from two populations.

Four Procedures Documented Here

There are four procedures in the menus that use the program module described in this chapter. These procedures are identical except for the type of parameterization. The parameterization can be in terms of proportions, differences in proportions, ratios of proportions, and odds ratios. Each of these options is listed separately on the menus.

Example

An equivalence test example will set the stage for the discussion of the terminology that follows. Suppose that the response rate of the standard treatment of a disease is 0.70. Unfortunately, this treatment is expensive and occasionally exhibits serious side-effects. A promising new treatment has been developed to the point where it can be tested. One of the first questions that must be answered is whether the new treatment is therapeutically equivalent to the standard treatment.

Because of the many benefits of the new treatment, clinicians are willing to adopt the new treatment even if its effectiveness is slightly different from the standard. After thoughtful discussion with several clinicians, it is decided that if the response rate of the new treatment is between 0.63 and 0.77, the new treatment would be adopted. The *margin of equivalence* is 0.07.

The developers must design an experiment to test the hypothesis that the response rate of the new treatment does not differ from that of the standard treatment by more than 0.07. The statistical hypothesis to be tested is

$$H_0: |p_1 - p_2| \geq 0.07 \text{ versus } H_1: |p_1 - p_2| < 0.07$$

Technical Details

The details of sample size calculation for the two-sample design for binary outcomes are presented in the chapter entitled “Two Proportion Non-Null Case,” and they will not be duplicated here. Instead, this chapter only discusses those changes necessary for equivalence tests.

Approximate sample size formulas for equivalence tests of two proportions are presented in Chow et al. (2003), page 88. Only large sample (normal approximation) results are given there. The results available in this module use exact calculations based on the enumeration of all possible values in the binomial distribution.

Suppose you have two populations from which dichotomous (binary) responses will be recorded. Assume without loss of generality that higher proportions are better. The probability (or risk) of cure in group 1 (the treatment group) is p_1 and in group 2 (the reference group) is p_2. Random samples of n_1 and n_2 individuals are obtained from these two groups. The data from these samples can be displayed in a 2-by-2 contingency table as follows

Group	Success	Failure	Total
Treatment	a	c	m
Control	b	d	n
Totals	s	f	N

The following alternative notation is also used.

Group	Success	Failure	Total
Treatment	x_{11}	x_{12}	n_1
Control	x_{21}	x_{22}	n_2
Totals	m_1	m_2	N

The binomial proportions p_1 and p_2 are estimated from these data using the formulae

$$\hat{p}_1 = \frac{a}{m} = \frac{x_{11}}{n_1} \text{ and } \hat{p}_2 = \frac{b}{n} = \frac{x_{21}}{n_2}$$

Let $p_{1.0}$ represent the group 1 proportion tested by the null hypothesis H_0. The power of a test is computed at a specific value of the proportion which we will call $p_{1.1}$. Let δ represent the smallest difference (margin of equivalence) between the two proportions that still results in the conclusion that the new treatment is equivalent to the current treatment. The set of statistical hypotheses that are tested is

$$\text{H}_0: \left| p_{1.0} - p_2 \right| \geq \delta \text{ versus } \text{H}_1: \left| p_{1.0} - p_2 \right| < \delta$$

These hypotheses can be rearranged to give

$$\text{H}_0: p_{1.0} - p_2 \leq \delta_L \text{ or } p_{1.0} - p_2 \geq \delta_U \text{ versus } \text{H}_1: \delta_L \leq p_{1.0} - p_2 \leq \delta_U$$

This composite hypothesis can be reduced to two one-sided hypotheses as follows

$$\text{H}_{0L}: p_{1.0} - p_2 \leq \delta_L \text{ versus } \text{H}_{1L}: \delta_L \leq p_{1.0} - p_2$$

$$\text{H}_{0U}: p_{1.0} - p_2 \geq \delta_U \text{ versus } \text{H}_{1U}: \delta_U \geq p_{1.0} - p_2$$

There are three common methods of specifying the margin of equivalence. The most direct is to simply give values for p_2 and $p_{1.0}$. However, it is often more meaningful to give p_2 and then specify $p_{1.0}$ implicitly by reporting the difference, ratio, or odds ratio. Mathematically, the definitions of these parameterizations are

Parameter	Computation	Alternative Hypotheses
Difference	$\delta = p_{1.0} - p_2$	$\text{H}_1: \delta_L \leq p_{1.0} - p_2 \leq \delta_U$
Ratio	$\phi = p_{1.0} / p_2$	$\text{H}_1: \phi_L \leq p_{1.0} / p_2 \leq \phi_U$
Odds Ratio	$\psi = Odds_{1.0} / Odds_2$	$\text{H}_1: \psi_L \leq o_{1.0} / o_2 \leq \psi_U$

Difference

The difference is perhaps the most direct method of comparison between two proportions. It is easy to interpret and communicate. It gives the absolute impact of the treatment. However, there are subtle difficulties that can arise with its interpretation.

One difficulty arises when the event of interest is rare. If a difference of 0.001 occurs when the baseline probability is 0.40, it would be dismissed as being trivial. However, if the baseline probability of a disease is 0.002, a 0.001 decrease would represent a reduction of 50%. Thus interpretation of the difference depends on the baseline probability of the event.

Note that $\delta_L < 0$ and $\delta_U > 0$. Usually, $\delta_L = -\delta_U$.

Equivalence using a Difference

The following example might help you understand the concept of an *equivalence* test. Suppose 60% of patients respond to the current treatment method $(p_2 = 0.60)$. If the response rate of the new treatment is no less than five percentage points better or worse than the existing treatment, it will be considered to be equivalent. Substituting these figures into the statistical hypotheses gives

$$\mathrm{H}_0\colon p_{1.0} - p_2 \le -0.05 \text{ or } p_{1.0} - p_2 \ge 0.05 \text{ versus } \mathrm{H}_1\colon -0.05 \le p_{1.0} - p_2 \le 0.05$$

Using the relationship

$$p_{1.0} = p_2 + \delta$$

gives

$$\mathrm{H}_0\colon p_{1.0} \le 0.55 \text{ or } p_{1.0} \ge 0.65 \text{ versus } \mathrm{H}_1\colon 0.55 \le p_{1.0} \le 0.65$$

In this example, when the null hypothesis is rejected, the concluded alternative is that the response rate is between 0.55 and 0.65.

Ratio

The ratio, $\phi = p_{1.0} / p_2$, gives the relative change in the probability of the response. Testing equivalence uses the formulation

$$\mathrm{H}_0\colon p_{1.0} / p_2 \le \phi_L \text{ or } p_{1.0} / p_2 \ge \phi_U \text{ versus } \mathrm{H}_1\colon \phi_L \le p_{1.0} / p_2 \le \phi_U$$

The only subtlety is that for equivalence tests $\phi_L < 1$ and $\phi_U > 1$. Usually, $\phi_L = 1/\phi_U$.

Equivalence using a Ratio

The following example might help you understand the concept of *equivalence* as defined by the ratio. Suppose that 60% of patients $(p_2 = 0.60)$ respond to the current treatment method. If the response rate of a new treatment is within 10% of 0.60, it will be considered to be equivalent to the standard treatment. Substituting these figures into the statistical hypotheses gives

$$\mathrm{H}_0\colon p_{1.0} / p_2 \le 0.9 \text{ or } p_{1.0} / p_2 \ge 1.1 \text{ versus } \mathrm{H}_1\colon 0.9 \le p_{1.0} / p_2 \le 1.1$$

Using the relationship

$$p_{1.0} = \phi_0 p_2$$

gives

$$\mathrm{H}_0\colon p_{1.0} \le 0.54 \text{ or } p_{1.0} \ge 0.66 \text{ versus } \mathrm{H}_1\colon 0.54 \le p_{1.0} \le 0.66$$

Odds Ratio

The odds ratio, $\psi = \left(p_{1.0} / \left(1 - p_{1.0}\right)\right) / \left(p_2 / \left(1 - p_2\right)\right)$, gives the relative change in the odds (o) of the response. Testing equivalence use the formulation

$$\mathrm{H}_0: o_{1.0} / o_2 \le \psi_L \text{ or } o_{1.0} / o_2 \ge \psi_U \text{ versus } \mathrm{H}_1: \psi_L \le o_{1.0} / o_2 \le \psi_U$$

The only subtlety is that for equivalence tests $\psi_L < 1$ and $\psi_U > 1$. Usually, $\psi_L = 1 / \psi_U$.

Power Calculation

The power for a test statistic that is based on the normal approximation can be computed exactly using two binomial distributions. The following steps are taken to compute the power of these tests.

1. Find the critical values using the standard normal distribution. The critical values z_L and z_U are chosen as that value of z that leaves exactly the target value of alpha in the appropriate tail of the normal distribution.
2. Compute the value of the test statistic z_t for every combination of x_{11} and x_{21}. Note that x_{11} ranges from 0 to n_1, and x_{21} ranges from 0 to n_2. A small value (around 0.0001) can be added to the zero-cell counts to avoid numerical problems that occur when the cell value is zero.
3. If $z_t > z_L$ and $z_t < z_U$, the combination is in the rejection region. Call all combinations of x_{11} and x_{21} that lead to a rejection the set *A*.
4. Compute the power for given values of $p_{1.1}$ and p_2 as

$$1 - \beta = \sum_A \binom{n_1}{x_{11}} p_{1.1}^{x_{11}} q_{1.1}^{n_1 - x_{11}} \binom{n_2}{x_{21}} p_2^{x_{21}} q_2^{n_2 - x_{21}}$$

5. Compute the actual value of alpha achieved by the design by substituting $p_{1.0L}$ and $p_{1.0U}$ for $p_{1.1}$ to obtain

$$\alpha_L = \sum_A \binom{n_1}{x_{11}} p_{1.0L}^{x_{11}} q_{1.0L}^{n_1 - x_{11}} \binom{n_2}{x_{21}} p_2^{x_{21}} q_2^{n_2 - x_{21}}$$

and

$$\alpha_U = \sum_A \binom{n_1}{x_{11}} p_{1.0U}^{x_{11}} q_{1.0U}^{n_1 - x_{11}} \binom{n_2}{x_{21}} p_2^{x_{21}} q_2^{n_2 - x_{21}}$$

The value of alpha is then computed as the maximum of α_L and α_U.

Asymptotic Approximations

When the values of n_1 and n_2 are large (say over 200), these formulas take a long time to evaluate. In this case, a large sample approximation can be used. The large sample approximation is made by replacing the values of $\hat{p}_1$ and $\hat{p}_2$ in the z statistic with the corresponding values of $p_{1.1}$ and p_2 and then computing the results based on the normal distribution. Note that in large samples, the Farrington and Manning statistic is substituted for the Gart and Nam statistic.

Test Statistics

Several test statistics have been proposed for testing whether the difference, ratio, or odds ratio are different from a specified value. The main difference among the several test statistics is in the formula used to compute the standard error used in the denominator. These tests are based on the following *z*-test

$$z_t = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0 - c}{\hat{\sigma}}$$

The constant, *c*, represents a continuity correction that is applied in some cases. When the continuity correction is not used, *c* is zero. In power calculations, the values of $\hat{p}_1$ and $\hat{p}_2$ are not known. The corresponding values of $p_{1.1}$ and p_2 can be reasonable substitutes.

Following is a list of the test statistics available in ***PASS***. The availability of several test statistics begs the question of which test statistic one should use. The answer is simple: one should use the test statistic that will be used to analyze the data. You may choose a method because it is a standard in your industry, because it seems to have better statistical properties, or because your statistical package calculates it. Whatever your reasons for selecting a certain test statistic, you should use the same test statistic when doing the analysis after the data have been collected.

Z Test (Pooled)

This test was first proposed by Karl Pearson in 1900. Although this test is usually expressed directly as a chi-square statistic, it is expressed here as a *z* statistic so that it can be more easily used for one-sided hypothesis testing. The proportions are pooled (averaged) in computing the standard error. The formula for the test statistic is

$$z_t = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0}{\hat{\sigma}_1}$$

where

$$\hat{\sigma}_1 = \sqrt{\bar{p}(1-\bar{p})\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}$$

$$\bar{p} = \frac{n_1\hat{p}_1 + n_2\hat{p}_2}{n_1 + n_2}$$

Z Test (Unpooled)

This test statistic does not pool the two proportions in computing the standard error.

$$z_t = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0}{\hat{\sigma}_2}$$

where

$$\hat{\sigma}_2 = \sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}$$

Z Test with Continuity Correction (Pooled)

This test is the same as Z Test (Pooled), except that a continuity correction is used. Remember that in the null case, the continuity correction makes the results closer to those of Fisher's Exact test.

$$z_t = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0 + \frac{F}{2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}{\hat{\sigma}_1}$$

$$\hat{\sigma}_1 = \sqrt{\bar{p}(1-\bar{p})\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}$$

$$\bar{p} = \frac{n_1\hat{p}_1 + n_2\hat{p}_2}{n_1 + n_2}$$

where F is -1 for lower-tailed hypotheses and 1 for upper-tailed hypotheses.

Z Test with Continuity Correction (Unpooled)

This test is the same as the Z Test (Unpooled), except that a continuity correction is used. Remember that in the null case, the continuity correction makes the results closer to those of Fisher's Exact test.

$$z_t = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0 - \frac{F}{2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}{\hat{\sigma}_2}$$

$$\hat{\sigma}_2 = \sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}$$

where F is -1 for lower-tailed hypotheses and 1 for upper-tailed hypotheses.

T-Test of Difference

Because of a detailed, comparative study of the behavior of several tests, D'Agostino (1988) and Upton (1982) proposed using the usual two-sample t-test for testing whether the two proportions are equal. One substitutes a '1' for a success and a '0' for a failure in the usual, two-sample *t*-test formula.

Miettinen and Nurminen's Likelihood Score Test of the Difference

Miettinen and Nurminen (1985) proposed a test statistic for testing whether the difference is equal to a specified, non-zero, value, δ_0. The regular MLE's, $\hat{p}_1$ and $\hat{p}_2$, are used in the numerator of the score statistic while MLE's $\tilde{p}_1$ and $\tilde{p}_2$, constrained so that $\tilde{p}_1 - \tilde{p}_2 = \delta_0$, are used in the denominator. A correction factor of $N/(N\text{-}1)$ is applied to make the variance estimate less biased. The significance level of the test statistic is based on the asymptotic normality of the score statistic.

The formula for computing this test statistic is

$$z_{MND} = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0}{\hat{\sigma}_{MND}}$$

where

$$\hat{\sigma}_{MND} = \sqrt{\left(\frac{\tilde{p}_1\tilde{q}_1}{n_1} + \frac{\tilde{p}_2\tilde{q}_2}{n_2}\right)\left(\frac{N}{N-1}\right)}$$

$$\tilde{p}_1 = \tilde{p}_2 + \delta_0$$

$$\tilde{p}_1 = 2B\cos(A) - \frac{L_2}{3L_3}$$

$$A = \frac{1}{3}\left[\pi + \cos^{-1}\left(\frac{C}{B^3}\right)\right]$$

$$B = \text{sign}(C)\sqrt{\frac{L_2^2}{9L_3} - \frac{L_1}{3L_3}}$$

$$C = \frac{L_2^3}{27L_3^3} - \frac{L_1L_2}{6L_3^2} + \frac{L_0}{2L_3}$$

$$L_0 = x_{21}\delta_0(1-\delta_0)$$

$$L_1 = [N_2\delta_0 - N - 2x_{21}]\delta_0 + M_1$$

$$L_2 = (N + N_2)\delta_0 - N - M_1$$

$$L_3 = N$$

Miettinen and Nurminen’s Likelihood Score Test of the Ratio

Miettinen and Nurminen (1985) proposed a test statistic for testing whether the ratio is equal to a specified value, ϕ_0. The regular MLE’s, $\hat{p}_1$ and $\hat{p}_2$, are used in the numerator of the score statistic while MLE’s $\tilde{p}_1$ and $\tilde{p}_2$, constrained so that $\tilde{p}_1 / \tilde{p}_2 = \phi_0$, are used in the denominator. A correction factor of N/(N-1) is applied to make the variance estimate less biased. The significance level of the test statistic is based on the asymptotic normality of the score statistic.

The formula for computing the test statistic is

$$z_{MNR} = \frac{\hat{p}_1 / \hat{p}_2 - \phi_0}{\sqrt{\left(\frac{\tilde{p}_1\tilde{q}_1}{n_1} + \phi_0^2\frac{\tilde{p}_2\tilde{q}_2}{n_2}\right)\left(\frac{N}{N-1}\right)}}$$

where

$$\tilde{p}_1 = \tilde{p}_2\phi_0$$

$$\tilde{p}_2 = \frac{-B - \sqrt{B^2 - 4AC}}{2A}$$

$$A = N\phi_0$$

$$B = -\left[N_1\phi_0 + x_{11} + N_2 + x_{21}\phi_0\right]$$

$$C = M_1$$

Miettinen and Nurminen's Likelihood Score Test of the Odds Ratio

Miettinen and Nurminen (1985) proposed a test statistic for testing whether the odds ratio is equal to a specified value, ψ_0. Because the approach they used with the difference and ratio does not easily extend to the odds ratio, they used a score statistic approach for the odds ratio. The regular MLE's are $\hat{p}_1$ and $\hat{p}_2$. The constrained MLE's are $\tilde{p}_1$ and $\tilde{p}_2$. These estimates are constrained so that $\tilde{\psi} = \psi_0$. A correction factor of N/(N-1) is applied to make the variance estimate less biased. The significance level of the test statistic is based on the asymptotic normality of the score statistic. The formula for computing the test statistic is

$$z_{MNO} = \frac{\frac{(\hat{p}_1 - \tilde{p}_1)}{\tilde{p}_1\tilde{q}_1} - \frac{(\hat{p}_2 - \tilde{p}_2)}{\tilde{p}_2\tilde{q}_2}}{\sqrt{\left(\frac{1}{N_2\tilde{p}_1\tilde{q}_1} + \frac{1}{N_2\tilde{p}_2\tilde{q}_2}\right)\left(\frac{N}{N-1}\right)}}$$

where

$$\tilde{p}_1 = \frac{\tilde{p}_2\psi_0}{1 + \tilde{p}_2(\psi_0 - 1)}$$

$$\tilde{p}_2 = \frac{-B + \sqrt{B^2 - 4AC}}{2A}$$

$$A = N_2(\psi_0 - 1)$$

$$B = N_1\psi_0 + N_2 - M_1(\psi_0 - 1)$$

$$C = -M_1$$

Farrington and Manning's Likelihood Score Test of the Difference

Farrington and Manning (1990) proposed a test statistic for testing whether the difference is equal to a specified value, δ_0. The regular MLE's, $\hat{p}_1$ and $\hat{p}_2$, are used in the numerator of the score statistic while MLE's $\tilde{p}_1$ and $\tilde{p}_2$, constrained so that $\tilde{p}_1 - \tilde{p}_2 = \delta_0$, are used in the denominator. The significance level of the test statistic is based on the asymptotic normality of the score statistic.

The formula for computing the test statistic is

$$z_{FMD} = \frac{\hat{p}_1 - \hat{p}_2 - \delta_0}{\sqrt{\left(\frac{\tilde{p}_1\tilde{q}_1}{n_1} + \frac{\tilde{p}_2\tilde{q}_2}{n_2}\right)}}$$

where the estimates $\tilde{p}_1$ and $\tilde{p}_2$ are computed as in the corresponding test of Miettinen and Nurminen (1985) given above.

Farrington and Manning's Likelihood Score Test of the Ratio

Farrington and Manning (1990) proposed a test statistic for testing whether the ratio is equal to a specified value, ϕ_0. The regular MLE's, $\hat{p}_1$ and $\hat{p}_2$, are used in the numerator of the score statistic while MLE's $\tilde{p}_1$ and $\tilde{p}_2$, constrained so that $\tilde{p}_1 / \tilde{p}_2 = \phi_0$, are used in the denominator. A correction factor of N/(N-1) is applied to increase the variance estimate. The significance level of the test statistic is based on the asymptotic normality of the score statistic.

The formula for computing the test statistic is

$$z_{FMR} = \frac{\hat{p}_1 / \hat{p}_2 - \phi_0}{\sqrt{\left(\frac{\tilde{p}_1 \tilde{q}_1}{n_1} + \phi_0^2 \frac{\tilde{p}_2 \tilde{q}_2}{n_2} \right)}}$$

where the estimates $\tilde{p}_1$ and $\tilde{p}_2$ are computed as in the corresponding test of Miettinen and Nurminen (1985) given above.

Farrington and Manning's Likelihood Score Test of the Odds Ratio

Farrington and Manning (1990) indicate that the Miettinen and Nurminen statistic may be modified by removing the factor *N*/(*N*-1).

The formula for computing this test statistic is

$$z_{FMO} = \frac{\frac{(\hat{p}_1 - \tilde{p}_1)}{\tilde{p}_1 \tilde{q}_1} - \frac{(\hat{p}_2 - \tilde{p}_2)}{\tilde{p}_2 \tilde{q}_2}}{\sqrt{\left(\frac{1}{N_2 \tilde{p}_1 \tilde{q}_1} + \frac{1}{N_2 \tilde{p}_2 \tilde{q}_2} \right)}}$$

where the estimates $\tilde{p}_1$ and $\tilde{p}_2$ are computed as in the corresponding test of Miettinen and Nurminen (1985) given above.

Gart and Nam's Likelihood Score Test of the Difference

Gart and Nam (1990), page 638, proposed a modification to the Farrington and Manning (1988) difference test that corrects for skewness. Let $z_{FMD}(\delta)$ stand for the Farrington and Manning difference test statistic described above. The skewness-corrected test statistic, z_{GND}, is the appropriate solution to the quadratic equation

$$(-\tilde{\gamma}) z_{GND}^2 + (-1) z_{GND} + \left(z_{FMD}(\delta) + \tilde{\gamma} \right) = 0$$

where

$$\tilde{\gamma} = \frac{\tilde{V}^{3/2}(\delta)}{6} \left(\frac{\tilde{p}_1 \tilde{q}_1 (\tilde{q}_1 - \tilde{p}_1)}{n_1^2} - \frac{\tilde{p}_2 \tilde{q}_2 (\tilde{q}_2 - \tilde{p}_2)}{n_2^2} \right)$$

Gart and Nam's Likelihood Score Test of the Ratio

Gart and Nam (1988), page 329, proposed a modification to the Farrington and Manning (1988) ratio test that corrects for skewness. Let $z_{FMR}(\phi)$ stand for the Farrington and Manning ratio test statistic described above. The skewness-corrected test statistic, z_{GNR}, is the appropriate solution to the quadratic equation

$$(-\tilde{\varphi}) z_{GNR}^2 + (-1) z_{GNR} + \left(z_{FMR}(\phi) + \tilde{\varphi} \right) = 0$$

where

$$\tilde{\varphi} = \frac{1}{6\tilde{u}^{3/2}}\left(\frac{\tilde{q}_1(\tilde{q}_1 - \tilde{p}_1)}{n_1^2 \tilde{p}_1^2} - \frac{\tilde{q}_2(\tilde{q}_2 - \tilde{p}_2)}{n_2^2 \tilde{p}_2^2}\right)$$

$$\tilde{u} = \frac{\tilde{q}_1}{n_1 \tilde{p}_1} + \frac{\tilde{q}_2}{n_2 \tilde{p}_2}$$

Procedure Options

This section describes the options that are specific to this procedure. These are located on the Design tab. For more information about the options of other tabs, go to the Procedure Window chapter.

Design Tab (Common Options)

The Design tab contains the parameters associated with this test such as the proportions, sample sizes, alpha, and power. This chapter covers four procedures, each of which has different options. This section documents options that are common to all four procedures. Later, unique options for each procedure will be documented.

Solve For

Solve For

This option specifies the parameter to be solved for using the other parameters. The parameters that may be selected are *P1.1* (or *D1*, *R1*, or *OR1*), *Alpha*, *Power*, *Sample Size (N1)*, and *Sample Size (N2)*. Under most situations, you will select either *Power* or *Sample Size (N1)*.

Select *Sample Size (N1)*when you want to calculate the sample size needed to achieve a given power and alpha level.

Select *Power* when you want to calculate the power of an experiment.

Test

Test Type

Specify which test statistic is used in searching and reporting. Although the pooled *z*-test is commonly shown in elementary statistics books, the likelihood score test is arguably the best choice.

Note that *C.C.* is an abbreviation for *Continuity Correction*. This refers to the adding or subtracting 1/(2n) to (or from) the numerator of the z-value to bring the normal approximation closer to the binomial distribution.

Power and Alpha

Power

This option specifies one or more values for power. Power is the probability of rejecting a false null hypothesis, and is equal to one minus Beta. Beta is the probability of a type-II error, which occurs when a false null hypothesis is not rejected. In this procedure, a type-II error occurs when you fail to reject the null hypothesis of unequal proportions when in fact they are equivalent.

Values must be between zero and one. Historically, the value of 0.80 (Beta = 0.20) was used for power. Now, 0.90 (Beta = 0.10) is also commonly used.

A single value may be entered here or a range of values such as *0.8 to 0.95 by 0.05* may be entered.

Alpha

This option specifies one or more values for the probability of a type-I error. A type-I error occurs when a true null hypothesis is rejected. In this procedure, a type-I error occurs when you reject the null hypothesis of unequal proportions when in fact they are not equal.

Values must be between zero and one. Historically, the value of 0.05 has been used for alpha. This means that about one test in twenty will falsely reject the null hypothesis. You should pick a value for alpha that represents the risk of a type-I error you are willing to take in your experimental situation.

You may enter a range of values such as *0.01 0.05 0.10* or *0.01 to 0.10 by 0.01*.

Sample Size (When Solving for Sample Size)

Group Allocation

Select the option that describes the constraints on *N1* or *N2* or both.

The options are

- **Equal (N1 = N2)**
  This selection is used when you wish to have equal sample sizes in each group. Since you are solving for both sample sizes at once, no additional sample size parameters need to be entered.

- **Enter N1, solve for N2**
  Select this option when you wish to fix *N1* at some value (or values), and then solve only for *N2*. Please note that for some values of *N1*, there may not be a value of *N2* that is large enough to obtain the desired power.

- **Enter N2, solve for N1**
  Select this option when you wish to fix *N2* at some value (or values), and then solve only for *N1*. Please note that for some values of *N2*, there may not be a value of *N1* that is large enough to obtain the desired power.

- **Enter R = N2/N1, solve for N1 and N2**
  For this choice, you set a value for the ratio of *N2* to *N1*, and then PASS determines the needed *N1* and *N2*, with this ratio, to obtain the desired power. An equivalent representation of the ratio, *R*, is

  $$N2 = R * N1.$$

- **Enter percentage in Group 1, solve for N1 and N2**
  For this choice, you set a value for the percentage of the total sample size that is in Group 1, and then PASS determines the needed *N1* and *N2* with this percentage to obtain the desired power.

N1 (Sample Size, Group 1)

This option is displayed if Group Allocation = "Enter N1, solve for N2"

N1 is the number of items or individuals sampled from the Group 1 population.

N1 must be ≥ 2. You can enter a single value or a series of values.

N2 (Sample Size, Group 2)

This option is displayed if Group Allocation = "Enter N2, solve for N1"

N2 is the number of items or individuals sampled from the Group 2 population.

N2 must be ≥ 2. You can enter a single value or a series of values.

R (Group Sample Size Ratio)

This option is displayed only if Group Allocation = "Enter R = N2/N1, solve for N1 and N2."

R is the ratio of *N2* to *N1*. That is,

$$R = N2 / N1.$$

Use this value to fix the ratio of *N2* to *N1* while solving for *N1* and *N2*. Only sample size combinations with this ratio are considered.

N2 is related to *N1* by the formula:

$$N2 = [R \times N1],$$

where the value *[Y]* is the next integer ≥ *Y*.

For example, setting *R* = 2.0 results in a Group 2 sample size that is double the sample size in Group 1 (e.g., *N1* = 10 and *N2* = 20, or *N1* = 50 and *N2* = 100).

R must be greater than 0. If *R* < 1, then *N2* will be less than *N1*; if *R* > 1, then *N2* will be greater than *N1*. You can enter a single or a series of values.

Percent in Group 1

This option is displayed only if Group Allocation = "Enter percentage in Group 1, solve for N1 and N2."

Use this value to fix the percentage of the total sample size allocated to Group 1 while solving for *N1* and *N2*. Only sample size combinations with this Group 1 percentage are considered. Small variations from the specified percentage may occur due to the discrete nature of sample sizes.

The Percent in Group 1 must be greater than 0 and less than 100. You can enter a single or a series of values.

Sample Size (When Not Solving for Sample Size)

Group Allocation

Select the option that describes how individuals in the study will be allocated to Group 1 and to Group 2.

The options are

- **Equal (N1 = N2)**
  This selection is used when you wish to have equal sample sizes in each group. A single per group sample size will be entered.

- **Enter N1 and N2 individually**
  This choice permits you to enter different values for *N1* and *N2*.

- **Enter N1 and R, where N2 = R * N1**
  Choose this option to specify a value (or values) for *N1*, and obtain *N2* as a ratio (multiple) of *N1*.

- **Enter total sample size and percentage in Group 1**
  Choose this option to specify a value (or values) for the total sample size (*N*), obtain *N1* as a percentage of *N*, and then *N2* as *N* - *N1*.

Sample Size Per Group

This option is displayed only if Group Allocation = "Equal (N1 = N2)."

The Sample Size Per Group is the number of items or individuals sampled from each of the Group 1 and Group 2 populations. Since the sample sizes are the same in each group, this value is the value for *N1*, and also the value for *N2*.

The Sample Size Per Group must be ≥ 2. You can enter a single value or a series of values.

N1 (Sample Size, Group 1)

*This option is displayed if Group Allocation = "Enter N1 and N2 individually" or "Enter N1 and R, where N2 = R * N1."*

N1 is the number of items or individuals sampled from the Group 1 population.

N1 must be ≥ 2. You can enter a single value or a series of values.

N2 (Sample Size, Group 2)

This option is displayed only if Group Allocation = "Enter N1 and N2 individually."

N2 is the number of items or individuals sampled from the Group 2 population.

N2 must be ≥ 2. You can enter a single value or a series of values.

R (Group Sample Size Ratio)

*This option is displayed only if Group Allocation = "Enter N1 and R, where N2 = R * N1."*

R is the ratio of *N2* to *N1*. That is,

$$R = N2/N1$$

Use this value to obtain *N2* as a multiple (or proportion) of *N1*.

N2 is calculated from *N1* using the formula:

$$N2=[R \text{ x } N1],$$

where the value *[Y]* is the next integer ≥ *Y*.

For example, setting *R* = 2.0 results in a Group 2 sample size that is double the sample size in Group 1.

R must be greater than 0. If *R* < 1, then *N2* will be less than N1; if *R* > 1, then *N2* will be greater than *N1*. You can enter a single value or a series of values.

Total Sample Size (N)

This option is displayed only if Group Allocation = "Enter total sample size and percentage in Group 1."

This is the total sample size, or the sum of the two group sample sizes. This value, along with the percentage of the total sample size in Group 1, implicitly defines *N1* and *N2*.

The total sample size must be greater than one, but practically, must be greater than 3, since each group sample size needs to be at least 2.

You can enter a single value or a series of values.

Percent in Group 1

This option is displayed only if Group Allocation = "Enter total sample size and percentage in Group 1."

This value fixes the percentage of the total sample size allocated to Group 1. Small variations from the specified percentage may occur due to the discrete nature of sample sizes.

The Percent in Group 1 must be greater than 0 and less than 100. You can enter a single value or a series of values.

Effect Size – Reference (Group 2)

P2 (Reference Group Proportion)

Specify the value of P2, the reference, baseline, or control group's proportion. The null hypothesis is that the two proportions differ by no more than a specified amount. Since P2 is a proportion, these values must be between 0 and 1.

You may enter a range of values such as *0.1 0.2 0.3* or *0.1 to 0.9 by 0.1*.

Design Tab (Proportion)

This section documents options that are used when the parameterization is in terms of the values of the two proportions, P1 and P2. P1.0 is the value of the P1 assumed by the null hypothesis and P1.1 is the value of P1 at which the power is calculated.

Effect Size – Equivalence Proportions

P1.0U & P1.0L (Upper & Lower Equivalence Proportion)

Specify the *margin of equivalence* directly by giving the upper and lower bounds of P1.0. The two groups are assumed to be equivalent when P1.0 is between these values. Thus, P1.0U should be greater than P2 and P1.0L should be less than P2.

Note that the values of P1.0U and P1.0L are used in pairs. Thus, the first values of P1.0U and P1.0L are used together, then the second values of each are used, and so on.

You may enter a range of values such as *0.03 0.05 0.10* or *0.01 to 0.05 by 0.01*.

Proportions must be between 0 and 1. They cannot take on the values 0 or 1. These values should surround P2.

Effect Size – Actual Proportion

P1.1 (Actual Proportion)

This option specifies the value of P1.1, which is the value of the treatment proportion at which the power is to be calculated. Proportions must be between 0 and 1. They cannot take on the values 0 or 1.

You may enter a range of values such as *0.03 0.05 0.10* or *0.01 to 0.05 by 0.01*.

Design Tab (Difference)

This section documents options that are used when the parameterization is in terms of the difference, P1 – P2. P1.0 is the value of P1 assumed by the null hypothesis and P1.1 is the value of P1 at which the power is calculated. Once P2, D0, and D1 are given, the values of P1.1 and P1.0 can be calculated.

Effect Size – Equivalence Differences

D0.U & D0.L (Upper & Lower Equivalence Difference)

Specify the *margin of equivalence* by specifying the largest distance above (D0.U) and below (D0.L) P2 which will still result in the conclusion of equivalence. As long as the actual difference is between these two values, the difference is not considered to be large enough to be of practical importance.

The values of D0.U must be positive and the values of D0.L must be negative. D0.L can be set to '-D0.U,' which is usually what is desired.

The power calculations assume that P1.0 is the value of P1 under the null hypothesis. This value is used with P2 to calculate the value of P1.0 using the formula: P1.0U = D0.U + P2.

You may enter a range of values for D0.U such as *.03 .05 .10* or *.05 to .20 by .05*.

Note that if you enter values for D0.L (other than '-D0.U'), they are used in pairs with the values of D0.U. Thus, the first values of D0.U and D0.L are used together, then the second values of each are used, and so on.

RANGE:

D0.L must be between -1 and 0. D0.U must be between 0 and 1. Neither can take on the values -1, 0, or 1.

Effect Size – Actual Difference

D1 (Actual Difference)

This option specifies the actual difference between P1.1 (the actual value of P1) and P2. This is the value of the difference at which the power is calculated. In equivalence trials, this difference is often set to 0.

The power calculations assume that P1.1 is the actual value of the proportion in group 1 (experimental or treatment group). This difference is used with P2 to calculate the true value of P1 using the formula: P1.1 = D1 + P2.

You may enter a range of values such as -*.05 0 .5* or -*.05 to .05 by .02*. Actual differences must be between -1 and 1. They cannot take on the values -1 or 1.

Design Tab (Ratio)

This section documents options that are used when the parameterization is in terms of the ratio, P1 / P2. P1.0 is the value of P1 assumed by the null hypothesis and P1.1 is the value of P1 at which the power is calculated. Once P2, R0, and R1 are given, the values of P1.0 and P1.1 can be calculated.

Effect Size – Equivalence Ratios

R0.U & R0.L (Upper & Lower Equivalence Ratio)

Specify the *margin of equivalence* by specifying the largest ratio (P1/P2) above (R0.U) and below (R0.L) 1 which will still result in the conclusion of equivalence. As long as the actual ratio is between these two values, the difference between the proportions is not considered to be large enough to be of practical importance.

The values of R0.U must be greater than 1 and the values of R0.L must be less than 1. R0.L can be set to ‘1/R0.U,’ which is often desired.

The power calculations assume that P1.0 is the value of P1 under the null hypothesis. This value is used with P2 to calculate the value of P1.0 using the formula: P1.0U = R0.U x P2.

You may enter a range of values for R0.U such as *1.1 1.5 1.8* or *1.1 to 2.1 by 0.2*.

Note that if you enter values for R0.L (other than '1/R0.U'), they are used in pairs with the values of R0.U. Thus, the first values of R0.U and R0.L are used together, then the second values of each are used, and so on.

R0.L must be between 0 and 1. R0.U must be greater than 1. Neither can take on the value 1.

Effect Size – Actual Ratio

R1 (Actual Ratio)

This option specifies the ratio of P1.1 and P2, where P1.1 is the actual proportion in the treatment group. The power calculations assume that P1.1 is the actual value of the proportion in group 1. This difference is used with P2 to calculate the value of P1 using the formula: P1.1 = R1 x P2. In equivalence trials, this ratio is often set to 1.

Ratios must be positive. You may enter a range of values such as *0.95 1 1.05* or *0.9 to 1.9 by 0.02*.

Design Tab (Odds Ratio)

This section documents options that are used when the parameterization is in terms of the odds ratios, O1.1 / O2 and O1.0 / O2. Note that the odds are defined as O2 = P2 / (1 – P2), O1.0 = P1.0 / (1 – P1.0), etc. P1.0 is the value of P1 assumed by the null hypothesis and P1.1 is the value of P1 at which the power is calculated. Once P2, OR0, and OR1 are given, the values of P1.1 and P1.0 can be calculated.

Effect Size – Equivalence Odds Ratios

OR0.U & OR0.L (Upper & Lower Equivalence Odds Ratio)

Specify the *margin of equivalence* by specifying the largest odds ratio above (OR0.U) and below (OR0.L) 1 which will still result in the conclusion of equivalence. As long as the actual odds ratio is between these two values, the difference between the proportions is not large enough to be of practical importance.

The values of OR0.U must be greater than 1 and the values of OR0.L must be less than 1. OR0.L can be set to ‘1/OR0.U,’ which is often desired.

The power calculations assume that P1.0 is the value of the P1 under the null hypothesis. This value is used with P2 to calculate the value of P1.0.

You may enter a range of values for OR0.U such as *1.1 1.5 1.8* or *1.1 to 2.1 by 0.2*.

Note that if you enter values for OR0.L (other than '1/OR0.U'), they are used in pairs with the values of OR0.U. Thus, the first values of OR0.U and OR0.L are used together, next the second values of each are used, and so on.

OR0.L must be between 0 and 1. OR0.U must be greater than 1. Neither can take on the value 1.

Effect Size – Actual Odds Ratio

OR1 (Actual Odds Ratio)

This option specifies the odds ratio of P1.1 and P2, where P1.1 is the actual proportion in the treatment group. The power calculations assume that P1.1 is the actual value of the proportion in group 1. This value is used with P2 to calculate the value of P1. In equivalence trials, this odds ratio is often set to 1.

Odds ratios must be positive. You may enter a range of values such as *0.95 1 1.05* or *0.9 to 1.9 by 0.02*.

Options Tab

The Options tab contains various limits and options.

Zero Counts

Zero Count Adjustment Method

Zero cell counts cause many calculation problems. To compensate for this, a small value (called the Zero Count Adjustment Value) can be added either to all cells or to all cells with zero counts. This option specifies whether you want to use the adjustment and which type of adjustment you want to use. We recommend that you use the option 'Add to zero cells only.'

Zero cell values often do not occur in practice. However, since power calculations are based on total enumeration, they will occur in power and sample size estimation.

Adding a small value is controversial, but can be necessary for computational considerations. Statisticians have recommended adding various fractions to zero counts. We have found that adding 0.0001 seems to work well.

Zero Count Adjustment Value

Zero cell counts cause many calculation problems when computing power or sample size. To compensate for this, a small value may be added either to all cells or to all zero cells. This value indicates the amount that is added. We have found that 0.0001 works well.

Be warned that the value of the ratio and the odds ratio will be affected by the amount specified here!

Exact Test Options

Maximum N1 or N2 for Exact Calculations

When either N1 or N2 is above this amount, power calculations are based on the normal approximation to the binomial. When the normal approximation to the binomial is used, the actual value of alpha is not calculated. Currently, for three-gigahertz computers, a value near 200 is reasonable. As computers increase in speed, this number may be increased.

Example 1 – Finding Power

A study is being designed to establish the equivalence of a new treatment compared to the current treatment. Historically, the current treatment has enjoyed a 50% cure rate. The new treatment reduces the seriousness of certain side effects that occur with the current treatment. Thus, the new treatment will be adopted even if it is slightly less effective than the current treatment. The researchers will recommend adoption of the new treatment if its cure rate is within 15% of the standard treatment.

The researchers plan to use the Farrington and Manning likelihood score test statistic to analyze the data. They want to study the power of the Farrington and Manning test at group sample sizes ranging from 50 to 500 for detecting a difference inside 15% when the actual cure rate of the new treatment ranges from 50% to 60%. The significance level will be 0.05.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Differences** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for Two Proportions using Differences**. You may then make the appropriate entries as listed below, or open **Example 1** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Power**
Test Type	**Likelihood Score (Farr. & Mann.)**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
Sample Size Per Group	**50 to 500 by 50**
D0.U (Upper Equivalence Difference)	**0.15**
D0.L (Lower Equivalence Difference)	**-D0.U**
D1 (Actual Difference)	**0.00 0.05 0.10**
P2 (Reference Group Proportion)	**0.5**

Annotated Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Numeric Results for Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U.   H1: D0.L < P1 - P2 = D1 < D0.U.
Test Statistic: Score test (Farrington & Manning)

Power	N1	N2	N	Ref. P2	P1.0L	P1.0U	D0.L	D0.U	D1	Target Alpha	Actual Alpha
0.0000	50	50	100	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	0.0515
0.3793	100	100	200	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	0.0489
0.6689	150	150	300	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	
0.8305	200	200	400	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	
0.9160	250	250	500	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	
0.9594	300	300	600	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	
0.9808	350	350	700	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	
0.9911	400	400	800	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	

(report continues)

Note: Direct Binomial distribution calculations for alpha and power were only used when both N1 and N2 were less than 100. In all other cases, Normal approximation was used.

Report Definitions
Power is the probability of rejecting a false null hypothesis.
N1 and N2 are the number of items sampled from each population.
N is the total sample size, N1 + N2.
P2 is the proportion for Group 2. This is the standard, reference, or control group.
P1.0L is the smallest treatment-group response rate that still yields an equivalence conclusion. P1.0U is the largest treatment-group response rate that still yields an equivalence conclusion.
D0.L is the lowest difference that still results in the conclusion of equivalence. D0.U is the highest difference that still results in the conclusion of equivalence. D1 is the actual difference, P1-P2, at which the power is calculated.
Target Alpha is the input probability of rejecting a true null hypothesis. Actual Alpha is the value of alpha that is actually achieved.

Summary Statements
Sample sizes of 50 in the treatment group and 50 in the reference group achieve 0% power to detect equivalence. The margin of equivalence, given in terms of the difference, extends from -0.1500 to 0.1500. The actual difference is 0.0000. The reference group proportion is 0.5000. The calculations assume that two, one-sided likelihood score (Farrington & Manning) tests are used. Although the significance level is targeted at 0.0500, the level actually achieved is 0.0515.

This report shows the values of each of the parameters, one scenario per row. Note that the actual alpha value is blank for sample sizes greater than 100, which was the limit set for exact computation.

Most of the report columns have obvious interpretations. Those that may not be obvious are presented here.

Prop Grp 2 P2

This is the value of P2, the response rate in the control group.

Lower & Upper Equiv. Grp 1 Prop: P1.0L & P1.0U

These are the margin of equivalence for the response rate of the treatment group as specified by the null hypothesis of non-equivalence. Values of P1 inside these limits are considered equivalent to P2.

Lower & Upper Equiv. Margin Diff: D0.L & D0.U

These set the margin of equivalence for the difference in response rates. Values of the difference outside these limits are considered *non-equivalent*.

Actual Margin Diff D1

This is the value of D1, the difference between the two group proportions at which the power is computed. This is the value of the difference under the alternative hypothesis.

Target Alpha

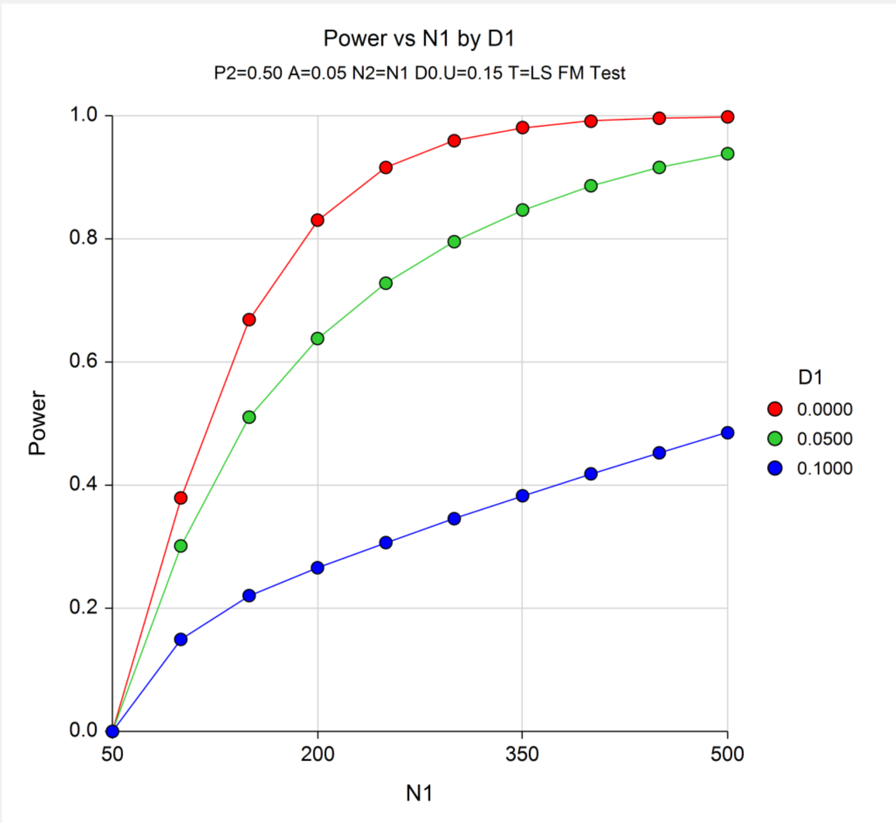
This is the value of alpha that was targeted by the design. Note that the target alpha is not usually achieved exactly. For two-sided tests, this value will usually be 0.05.

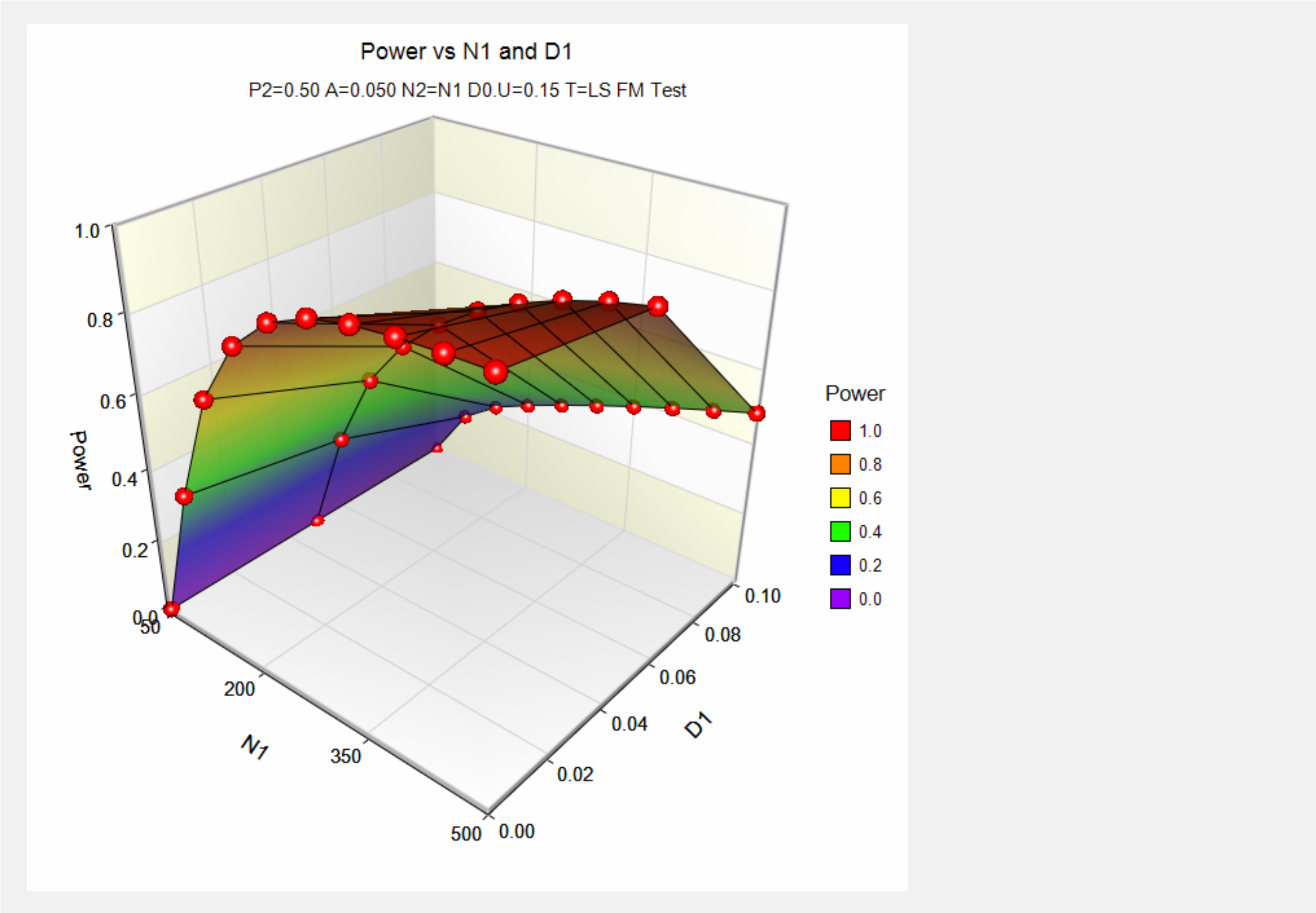
Actual Alpha

This is the value of alpha that was actually achieved by this design. Note that since the limit on exact calculations was set to 100, and since this value is calculated exactly, it is not shown for values of N1 greater than 100.

The difference between the Target Alpha and the Actual Alpha is caused by the discrete nature of the binomial distribution and the use of the normal approximation to the binomial in determining the critical value of the test statistic.

Plots Section





The values from the table are displayed in the above charts. These charts give a quick look at the sample size that will be required for various values of D1.

Example 2 – Finding the Sample Size

Continuing with the scenario given in Example 1, the researchers want to determine the sample size necessary for each value of D1 to achieve a power of 0.80. To cut down on the runtime, they decide to look at approximate values whenever N1 is greater than 100.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Differences** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for Two Proportions using Differences**. You may then make the appropriate entries as listed below, or open **Example 2** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Test Type	**Likelihood Score (Farr. & Mann.)**
Power	**0.80**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
D0.U (Upper Equivalence Difference)	**0.15**
D0.L (Lower Equivalence Difference)	**-D0.U**
D1 (Actual Difference)	**0.00 0.05 0.10**
P2 (Reference Group Proportion)	**0.5**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Numeric Results for Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U. H1: D0.L < P1 - P2 = D1 < D0.U.
Test Statistic: Score test (Farrington & Manning)

Target Power	Actual Power	N1	N2	N	Ref. P2	P1.0L	P1.0U	D0.L	D0.U	D1	Target Alpha	Actual Alpha
0.80	0.8003	188	188	376	0.500	0.350	0.650	-0.150	0.150	0.000	0.0500	
0.80	0.8001	304	304	608	0.500	0.350	0.650	-0.150	0.150	0.050	0.0500	
0.80	0.8001	1202	1202	2404	0.500	0.350	0.650	-0.150	0.150	0.100	0.0500	

The required sample size will depend a great deal on the value of D1. Any effort spent determining an accurate value for D1 will be worthwhile.

Example 3 – Comparing the Power of Several Test Statistics

Continuing with Example 1, the researchers want to determine which of the eight possible test statistics to adopt by using the comparative reports and charts that ***PASS*** produces. They decide to compare the powers and actual alphas for various sample sizes between 50 and 200 when D1 is 0.1.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Differences** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for Two Proportions using Differences**. You may then make the appropriate entries as listed below, or open **Example 3** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Power**
Test Type	**Likelihood Score (Farr. & Mann.)**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
Sample Size Per Group	**50 to 200 by 50**
D0.U (Upper Equivalence Difference)	**0.15**
D0.L (Lower Equivalence Difference)	**-D0.U**
D1 (Actual Difference)	**0.10**
P2 (Reference Group Proportion)	**0.5**
Options Tab	
Maximum N1 or N2 for Exact Calc.	**300**
Reports Tab	
Show Numeric Report	**Not checked**
Show Comparative Reports	**Checked**
Show Summary Statements	**Not checked**
Plots Tab	
Show Plots	**Not checked**
Show Comparative Plots	**Checked**

Output

Click the Calculate button to perform the calculations and generate the following output.

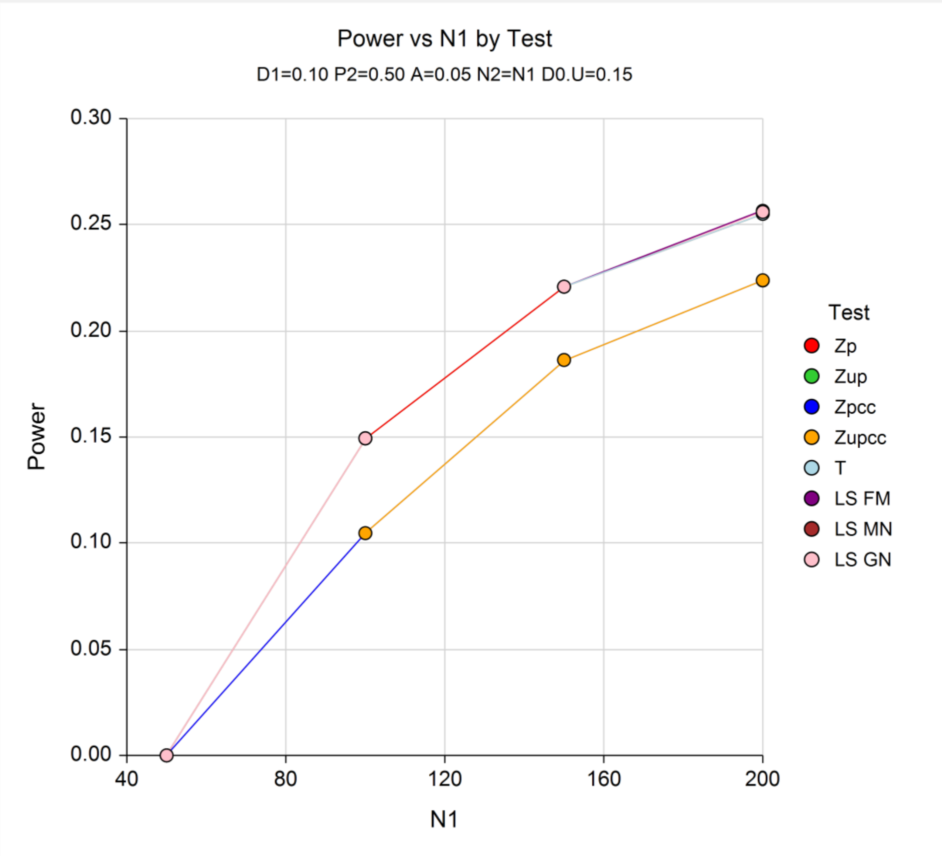
Numeric Results and Plots

Power Comparison of Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U. H1: D0.L < P1 - P2 = D1 < D0.U.

N1/N2	P2	Upper Equiv. Margin D0.U	Target Alpha	Z(P) Test Power	Z(UnP) Test Power	Z(P) CC Test Power	Z(UnP) CC Test Power	T Test Power	F.M. Score Power	M.N. Score Power	G.N. Score Power
50/50	0.5000	0.1500	0.0500	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
100/100	0.5000	0.1500	0.0500	0.1494	0.1494	0.1047	0.1047	0.1493	0.1495	0.1494	0.1494
150/150	0.5000	0.1500	0.0500	0.2208	0.2208	0.1863	0.1863	0.2208	0.2208	0.2208	0.2208
200/200	0.5000	0.1500	0.0500	0.2552	0.2553	0.2238	0.2239	0.2552	0.2566	0.2566	0.2560

Actual Alpha Comparison of Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U. H1: D0.L < P1 - P2 = D1 < D0.U.

N1/N2	P2	Upper Equiv. Margin D0.U	Target Alpha	Z(P) Test Alpha	Z(UnP) Test Alpha	Z(P) CC Test Alpha	Z(UnP) CC Test Alpha	T Test Alpha	F.M. Score Alpha	M.N. Score Alpha	G.N. Score Alpha
50/50	0.5000	0.1500	0.0500	0.0515	0.0515	0.0334	0.0334	0.0514	0.0515	0.0515	0.0515
100/100	0.5000	0.1500	0.0500	0.0486	0.0486	0.0358	0.0358	0.0485	0.0489	0.0487	0.0487
150/150	0.5000	0.1500	0.0500	0.0495	0.0495	0.0386	0.0386	0.0495	0.0495	0.0495	0.0495
200/200	0.5000	0.1500	0.0500	0.0465	0.0468	0.0376	0.0378	0.0465	0.0488	0.0488	0.0481



It is interesting to note that the powers of the continuity-corrected test statistics are consistently lower than the other tests. This occurs because the actual alpha achieved by these tests is lower than for the other tests. An interesting finding of this example is that the regular *t*-test performed about as well as the *z*-test.

Example 4 – Validation using Chow with Equal Sample Sizes

Chow et al. (2003), page 91, present a sample size study in which P2 = 0.75, D0.U = 0.2, D0.L = -0.2, D1 = 0.05, alpha = 0.05, and beta = 0.2. Using the pooled Z test statistic, they found the sample size to be 96 in each group.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Differences** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for Two Proportions using Differences**. You may then make the appropriate entries as listed below, or open **Example 4** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Test Type	**Z Test (Pooled)**
Power	**0.80**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
D0.U (Upper Equivalence Difference)	**0.2**
D0.L (Lower Equivalence Difference)	**-D0.U**
D1 (Actual Difference)	**0.05**
P2 (Reference Group Proportion)	**0.75**
Options Tab	
Maximum N1 or N2 for Exact Calc.	**2 (Set low for a rapid search.)**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Numeric Results for Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U. H1: D0.L < P1 - P2 = D1 < D0.U.
Test Statistic: Z test (pooled)

Target Power	Actual Power	N1	N2	N	Ref. P2	P1.0L	P1.0U	D0.L	D0.U	D1	Target Alpha	Actual Alpha
0.80	0.8028	98	98	196	0.750	0.550	0.950	-0.200	0.200	0.050	0.0500	

PASS found the required sample size to be 98 which is slightly larger than the 96 that Chow obtained. This is mainly due to the rounding to two decimal places that Chow did in this example. We used the exact option in PASS and obtained N1 = 99. Thus, PASS was indeed closer than was Chow.

Example 5 – Validation using Tuber-Bitter with Equal Sample Sizes

Tuber-Bitter et al. (2000), page 1271, present a sample size study in which P2 = 0.1; D0.U = 0.01, 0.02, 0.03; D0.L = -D0.U; D1 = 0.0; alpha = 0.05; and beta = 0.1. Using the pooled Z test statistic, they found the sample sizes to be 19484, 4871, and 2165 in each group.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Differences** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for Two Proportions using Differences**. You may then make the appropriate entries as listed below, or open **Example 5** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Test Type	**Z Test (Pooled)**
Power	**0.90**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
D0.U (Upper Equivalence Difference)	**0.01 0.02 0.03**
D0.L (Lower Equivalence Difference)	**-D0.U**
D1 (Actual Difference)	**0.0**
P2 (Reference Group Proportion)	**0.1**
Options Tab	
Maximum N1 or N2 for Exact Calc.	**2 (Set low for a rapid search.)**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Numeric Results for Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U.   H1: D0.L < P1 - P2 = D1 < D0.U.
Test Statistic: Z test (pooled)

Target Power	Actual Power	N1	N2	N	Ref. P2	P1.0L	P1.0U	D0.L	D0.U	D1	Target Alpha	Actual Alpha
0.80	0.8028	98	98	196	0.750	0.550	0.950	-0.200	0.200	0.050	0.0500	
0.90	0.9000	19480	19480	38960	0.100	0.090	0.110	-0.010	0.010	0.000	0.0500	
0.90	0.9000	4870	4870	9740	0.100	0.080	0.120	-0.020	0.020	0.000	0.0500	
0.90	0.9001	2165	2165	4330	0.100	0.070	0.130	-0.030	0.030	0.000	0.0500	

PASS found the required sample sizes to within rounding error of Tuber-Bitter.

Example 6 – Computing the Power after Completing an Experiment

Researchers are testing a generic drug to determine if it is equivalent to the name-brand alternative. Equivalence is declared if the success rate of the generic brand is no more than 5% from that of the name-brand drug. In a study with 1000 individuals in each group, they find that 774, or 77.4%, are successfully treated using the name-brand drug, and 700, or 70%, respond to the generic drug. An equivalence test (exact test) with alpha = 0.05 failed to declare that the two drugs are equivalent. The researchers would now like to compute the power for actual differences ranging from 0 to 4%. Suppose that the true value for the response rate for the name-brand drug is 77%.

Note that the power is not calculated at the difference observed in the study, 77.4%. In fact, the difference observed in the study is larger than the proposed equivalence difference, 5%. It would make no sense to perform a power calculation for a difference larger than the equivalence difference. It is more informative to study a range of values smaller than or equal to the equivalence difference.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Differences** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for Two Proportions using Differences**. You may then make the appropriate entries as listed below, or open **Example 6** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Power**
Test Type	**Likelihood Score (Farr. & Mann.)**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
Sample Size Per Group	**1000**
D0.U (Upper Equivalence Difference)	**0.05**
D0.L (Lower Equivalence Difference)	**-D0.U**
D1 (Actual Difference)	**0.00 to 0.04 by 0.01**
P2 (Reference Group Proportion)	**0.77**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Numeric Results for Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U. H1: D0.L < P1 - P2 = D1 < D0.U.
Test Statistic: Score test (Farrington & Manning)

Power	N1	N2	N	Ref. P2	P1.0L	P1.0U	D0.L	D0.U	D1	Target Alpha	Actual Alpha
0.6875	1000	1000	2000	0.770	0.720	0.820	-0.050	0.050	0.000	0.0500	
0.6313	1000	1000	2000	0.770	0.720	0.820	-0.050	0.050	0.010	0.0500	
0.4731	1000	1000	2000	0.770	0.720	0.820	-0.050	0.050	0.020	0.0500	
0.2857	1000	1000	2000	0.770	0.720	0.820	-0.050	0.050	0.030	0.0500	
0.1362	1000	1000	2000	0.770	0.720	0.820	-0.050	0.050	0.040	0.0500	

The power of the test ranges from 68.75% if the true difference is actually 0.0% to 13.62% if the true difference is 4%.

Example 7 – Finding the Sample Size using Proportions

A study is being designed to prove the equivalence of a new drug to the current standard. The current drug is effective in 85% of cases. The new drug, however, is cheaper to produce. The new drug will be deemed equivalent to the standard if its success rate is between 78% and 92%. What sample sizes are necessary to obtain 80% or 90% power for actual success rates ranging from 80% to 90%? The researchers will test at a significance level of 0.05 using the Farrington and Manning likelihood score test.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Two Proportions using Proportions** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Proportions**, and then clicking on **Equivalence Tests for Two Proportions using Proportions**. You may then make the appropriate entries as listed below, or open **Example 7** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Test Type	**Likelihood Score (Farr. & Mann.)**
Power	**0.80 0.90**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
P1.0U (Upper Equivalence Prop)	**0.92**
P1.0L (Lower Equivalence Prop)	**0.78**
P1.1 (Actual Proportion)	**0.80 to 0.90 by 0.02**
P2 (Reference Group Proportion)	**0.85**

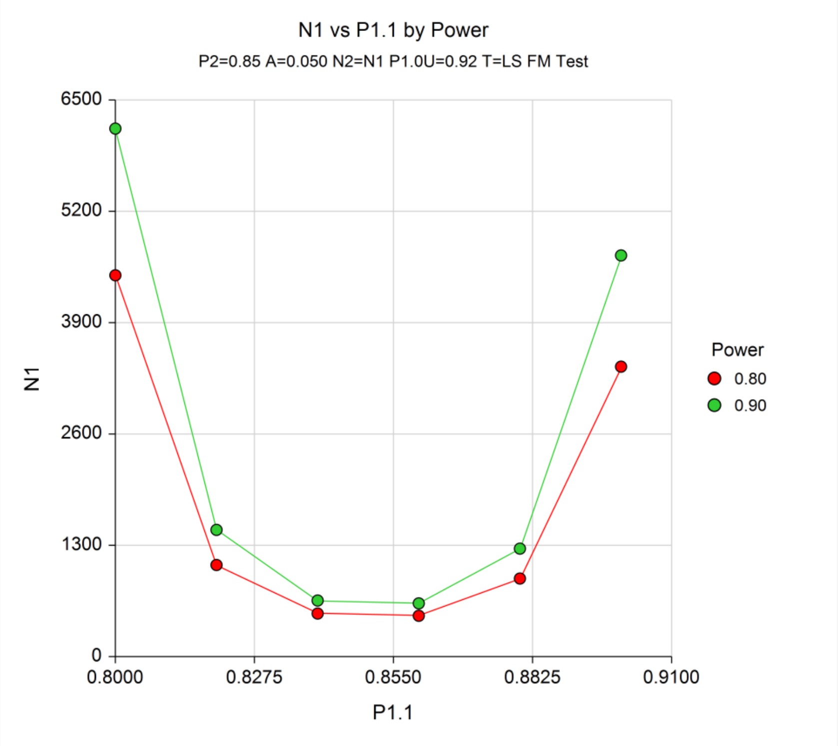
Output

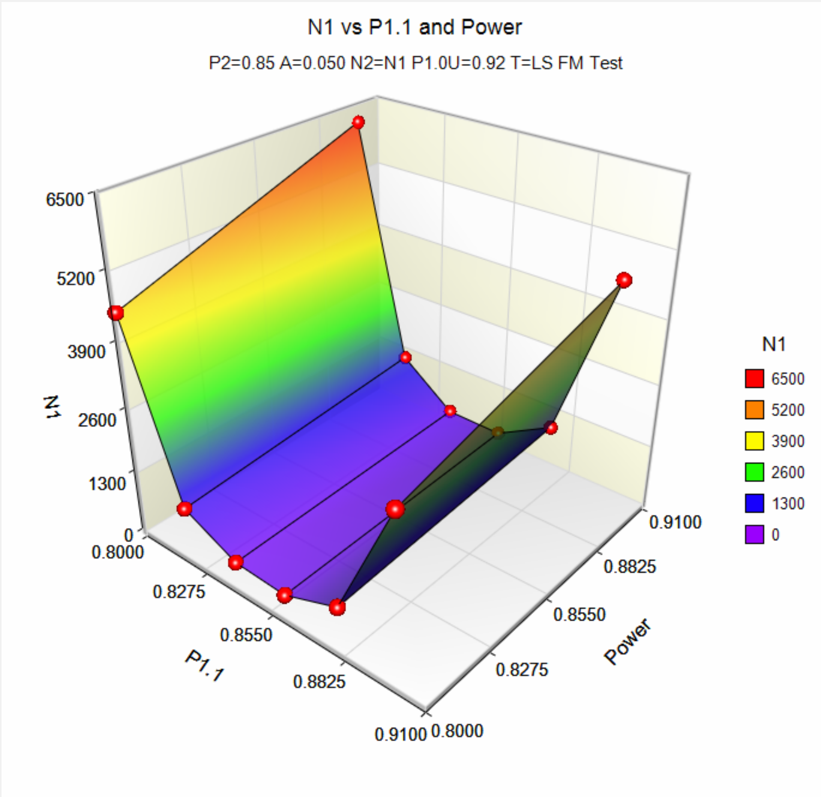
Click the Calculate button to perform the calculations and generate the following output.

Numeric Results and Plots

Numeric Results for Equivalence Tests Based on the Difference: P1 - P2
H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U. H1: D0.L < P1 - P2 = D1 < D0.U.
Test Statistic: Score test (Farrington & Manning)

Target Power	Actual Power	N1	N2	N	Ref. P2	P1.0L	P1.0U	D0.L	D0.U	D1	Target Alpha	Actual Alpha
0.80	0.8001	4453	4453	8906	0.850	0.780	0.920	-0.070	0.070	-0.050	0.0500	
0.90	0.9000	6166	6166	12332	0.850	0.780	0.920	-0.070	0.070	-0.050	0.0500	
0.80	0.8002	1070	1070	2140	0.850	0.780	0.920	-0.070	0.070	-0.030	0.0500	
0.90	0.9000	1480	1480	2960	0.850	0.780	0.920	-0.070	0.070	-0.030	0.0500	
0.80	0.8008	503	503	1006	0.850	0.780	0.920	-0.070	0.070	-0.010	0.0500	
0.90	0.9001	655	655	1310	0.850	0.780	0.920	-0.070	0.070	-0.010	0.0500	
0.80	0.8004	477	477	954	0.850	0.780	0.920	-0.070	0.070	0.010	0.0500	
0.90	0.9004	622	622	1244	0.850	0.780	0.920	-0.070	0.070	0.010	0.0500	
0.80	0.8002	912	912	1824	0.850	0.780	0.920	-0.070	0.070	0.030	0.0500	
0.90	0.9002	1261	1261	2522	0.850	0.780	0.920	-0.070	0.070	0.030	0.0500	
0.80	0.8000	3386	3386	6772	0.850	0.780	0.920	-0.070	0.070	0.050	0.0500	
0.90	0.9000	4685	4685	9370	0.850	0.780	0.920	-0.070	0.070	0.050	0.0500	





It is evident from these results that the sample sizes required to achieve 80% and 90% power depend a great deal on the actual value of the success rate, P1.1.