Chapter 169

Multi-Arm Equivalence Tests for the Difference Between Treatment and Control Proportions

Introduction

This module computes power and sample size for multi-arm, equivalence tests of the difference between treatment and control proportions. This procedure is based on the results in Machin, Campbell, Tan, and Tan (2018). In this design, there are *k* treatment groups and one control group. The groups are independent and are sampled using simple random sampling. A proportion is measured in each group. A total of *k* hypothesis tests are anticipated each comparing a treatment group with the common control group using a simple equivalence test of the difference between two proportions.

The Bonferroni multiplicity adjustment of the type I error rate may be optionally made because several tests are being constructed from the same data. Making a multiplicity adjustment is usually recommended, but not always. In fact, Saville (1990) advocates not applying it and Machin, Campbell, Tan, and Tan (2018) include omitting it as a possibility.

Whether you want to test several doses of a single treatment or several types of treatments, good research practice requires that each treatment be compared with a control. For example, a popular three-arm design consists of three groups: control, treatment A, and treatment B. Two tests are run: treatment A versus control and treatment B versus the same control. This avoids having to obtain a second control group for treatment B. Besides the obvious efficiency in subjects, it may be easier to recruit subjects if their chances of receiving a new treatment are better than 50%.

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 the *margin of equivalence* is 0.07. Hence, if the difference between treatment and control proportions is 0.7 or less, the new treatment can be adopted.

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

$$H_0: |P_T - P_C| > 0.07 \quad \text{vs.} \quad H_1: |P_T - P_C| \leq 0.07$$

Technical Details

Suppose you have *k* treatment groups with response probabilities P_i of size N_i and one control group with response probability P_C of size N_C. The total sample size is $N = N_1 + N_2 + \ldots + N_k + N_C$.

The *k* equivalence tests hypotheses are

$$H_{0i}: P_i - P_C \le D_L \quad \text{or} \quad P_i - P_C \ge D_U \quad \text{vs.} \quad H_{1i}: D_L < P_i - P_C < D_U \quad \text{for } i = 1, 2, \ldots, k$$

where D_L and D_U are the equivalence limits.

If we define $D_i = P_i - P_C$, these are equivalent to

$$H_{0i}: D_i \le D_L \quad \text{or} \quad D_i \ge D_U \quad \text{vs.} \quad H_{1i}: D_L < D_i < D_U \quad \text{for } i = 1, 2, \ldots, k$$

For convenience, these hypotheses are collectively referred to as

$$H_0: D \le D_L \quad \text{or} \quad D \ge D_U \quad \text{vs.} \quad H_1: D_L < D < D_U$$

Test Statistics

Several test statistics are available in this routine. Symmetric versions of these tests are presented below.

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

$$z_t = \frac{\hat{p}_i - \hat{p}_C - D}{\hat{\sigma}_1}$$

where

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

$$\bar{p} = \frac{N_i \hat{p}_i + N_C \hat{p}_C}{N_i + N_C}$$

Z Test (Unpooled)

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

$$z_t = \frac{\hat{p}_i - \hat{p}_C - D}{\hat{\sigma}_2}$$

where

$$\hat{\sigma}_2 = \sqrt{\frac{\hat{p}_i(1-\hat{p}_i)}{N_i} + \frac{\hat{p}_C(1-\hat{p}_C)}{N_C}}$$

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.

$$z_t = \frac{\hat{p}_i - \hat{p}_C - D + \frac{F}{2}\left(\frac{1}{N_i} + \frac{1}{N_C}\right)}{\hat{\sigma}_1}$$

where

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

$$\bar{p} = \frac{N_i\hat{p}_i + N_C\hat{p}_C}{N_i + N_C}$$

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.

$$z_t = \frac{\hat{p}_i - \hat{p}_C - D - \frac{F}{2}\left(\frac{1}{N_i} + \frac{1}{N_C}\right)}{\hat{\sigma}_2}$$

where

$$\hat{\sigma}_2 = \sqrt{\frac{\hat{p}_i(1-\hat{p}_i)}{N_i} + \frac{\hat{p}_C(1-\hat{p}_C)}{N_C}}$$

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

Miettinen and Nurminen's Likelihood Score Test

Miettinen and Nurminen (1985) proposed a test statistic for testing whether the difference is equal to a specified, non-zero, value, D. The regular MLE's, $\hat{p}_i$ and $\hat{p}_C$, are used in the numerator of the score statistic while MLE's $\tilde{p}_i$ and $\tilde{p}_C$, constrained so that $\tilde{p}_i - \tilde{p}_C = D$, 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 this test statistic is

$$z_{MND} = \frac{\hat{p}_i - \hat{p}_C - D}{\hat{\sigma}_{MND}}$$

where

$$\hat{\sigma}_{MND} = \sqrt{\left(\frac{\tilde{p}_i\tilde{q}_i}{n_i} + \frac{\tilde{p}_C\tilde{q}_C}{n_C}\right)\left(\frac{N}{N-1}\right)}$$

$$\tilde{p}_i = \tilde{p}_C + D$$

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

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

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

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

$$L_0 = x_{21}D(1-D)$$

$$L_1 = [n_CD - N - 2x_{21}]D + m_1$$

$$L_2 = (N + n_C)D - N - m_1$$

$$L_3 = N$$

$$m_1 = \text{number of successes}$$

Farrington and Manning's Likelihood Score Test

Farrington and Manning (1990) proposed a test statistic for testing whether the difference is equal to a specified value D. The regular MLE's, $\hat{p}_i$ and $\hat{p}_C$, are used in the numerator of the score statistic while MLE's $\tilde{p}_i$ and $\tilde{p}_C$, constrained so that $\tilde{p}_i - \tilde{p}_C = D$, 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

$$z_{FMD} = \frac{\hat{p}_i - \hat{p}_C - D}{\sqrt{\left(\frac{\tilde{p}_i\tilde{q}_i}{N_i} + \frac{\tilde{p}_C\tilde{q}_C}{N_C}\right)}}$$

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

Gart and Nam's Likelihood Score Test

Gart and Nam (1990), page 638, proposed a modification to the Farrington and Manning (1988) difference test that corrects for skewness. Let $z_{FMD}(D)$ 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

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

where

$$\tilde{\gamma} = \frac{\tilde{V}^{3/2}(D)}{6}\left(\frac{\tilde{p}_i\tilde{q}_i(\tilde{q}_i - \tilde{p}_i)}{N_i^2} - \frac{\tilde{p}_C\tilde{q}_C(\tilde{q}_C - \tilde{p}_C)}{N_C^2}\right)$$

Asymptotic Approximation to Power

A large sample approximation is used to compute power. The large sample approximation is made by replacing the values of $\hat{p}_i$ and $\hat{p}_C$ in the z statistic with the corresponding values of P_i and P_C, 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.

Multiplicity Adjustment

Because *k* z-tests between treatment groups and the control group are run when analyzing the results of this study, many statisticians recommend that the Bonferroni adjustment be applied. This adjustment is easy to apply: the value of alpha that is used in the test is found by dividing the original alpha by the number of tests. For example, if the original alpha is set at 0.05 and the number of treatment (not including the control) groups is five, the individual tests will be conducted using an alpha of 0.01.

The main criticism of this procedure is that if there are many tests, the value of alpha becomes very small. To mitigate against this complaint, some statisticians recommend separating the treatment groups into those that are of primary interest and those that are of secondary interest. The Bonferroni adjustment is made by the using the number of primary treatments rather than the total number of treatments.

There are some who advocate ignoring the adjustment entirely in the case of randomized clinical trials. See for example Saville (1990) and the discussion in chapter 14 of Machin, Campbell, Tan, and Tan (2018).

Size of the Control Group

Because the control group is used over and over, some advocate increasing the number of subjects in this group. The standard adjustment is to include $\sqrt{k}$ subjects in the control group for each subject in one of the treatment groups. See Machin, Campbell, Tan, and Tan (2018, pages 231-232). Note that often, the treatment groups all have the same size.

Example 1 – Finding the Sample Size

A parallel-group, clinical trial is being designed to compare three doses of a test compound against the standard therapy using three Gart-Nam equivalence tests. Suppose the standard therapy has a response rate of 60%. The investigators would like a sample size large enough to find statistical significance at an overall 0.05 level and an individual-test power of 0.80. The response rates of group 1 are 60%, 61%, or 62%. The response rate of group 2 is 60%. The response rate of group 3 is 60%. The equivalence margin is 0.06 (10% of the standard therapy response rate).

Following common practice, the control-group sample-size multiplier will be set to $\sqrt{k} = \sqrt{3} = 1.732$ since there are three treatment groups in this design.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab	
Solve For	**Sample Size**
Test Type	**Likelihood Score (Gart & Nam)**
Power of Each Test	**0.8**
Overall Alpha	**0.05**
Bonferroni Adjustment	**Standard Bonferroni**
Group Allocation	**Enter Group Allocation Pattern, solve for group sample sizes**
DU (Upper Equivalence Difference)	**0.06**
DL (Lower Equivalence Difference)	**-DU**
Control Proportion	**0.6**
Control Sample Size Allocation	**1.732**
Set A Number of Groups	**1**
Set A Proportion	**0.60,0.61,0.62**
Set A Sample Size Allocation	**1**
Set B Number of Groups	**1**
Set B Proportion	**0.6**
Set B Sample Size Allocation	**1**
Set C Number of Groups	**1**
Set C Proportion	**0.6**
Set C Sample Size Allocation	**1**
Set D Number of Groups	**0**
More	**Unchecked**

Output

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

Numeric Reports

Numeric Results

Solve For:	Sample Size
Group Allocation:	Enter Group Allocation Pattern, solve for group sample sizes
Hypothesis:	H0: D ≤ DL or D ≥ DU vs. H1: DL < D < DU
Test Type:	Gart & Nam Likelihood Score Test
Number of Groups:	4
Bonferroni Adjustment:	Standard Bonferroni (Divisor = 3)

	Power		Sample Size		Proportion		Difference: Equivalence Limits			Alpha	
Comparison	Target	Actual	Ni	Allocation	Pi|H0 Pi.0	Pi|H1 Pi.1	Lower DL	Upper DU	Actual Di	Overall	Bonferroni-Adjusted
Control			2113	1.732	0.6	0.60					
vs A	0.8	0.80023	1220	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
vs B	0.8	0.80023	1220	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
vs C	0.8	0.80023	1220	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
Total			5773								
Control			2382	1.732	0.6	0.60					
vs A	0.8	0.80033	1375	1.000	0.6	0.61	-0.06	0.06	0.01	0.05	0.016667
vs B	0.8	0.86436	1375	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
vs C	0.8	0.86436	1375	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
Total			6507								
Control			3540	1.732	0.6	0.60					
vs A	0.8	0.80016	2044	1.000	0.6	0.62	-0.06	0.06	0.02	0.05	0.016667
vs B	0.8	0.97767	2044	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
vs C	0.8	0.97767	2044	1.000	0.6	0.60	-0.06	0.06	0.00	0.05	0.016667
Total			9672								

Comparison	The group that is involved in the comparison between the treatment and control displayed on this report line. The comparison is made using the difference.
Target Power	The power desired. Power is probability of rejecting a false null hypothesis for this comparison. This power is of the comparison shown on this line only.
Actual Power	The power actually achieved.
Ni	Sample Size. The number of subjects in the ith group. The total sample size, N, is shown as the last row of the column.
Allocation	The group sample size allocation pattern. The value on each row represents the relative number of subjects assigned to the group.
Pi.0	The response proportion in the ith group assumed by the null hypothesis, H0. Note that Pi.0 = Pc, where Pc is the control group proportion.
Pi.1	The response proportion in the ith group at which the power is calculated. Note that Pi.1 = Pc + Di, where Pc is the control group proportion.
DL	The lower equivalence difference is the smallest negative difference in treatment and control proportions that still results in the conclusion that they are equivalent.
DU	The upper equivalence difference is the largest positive difference in treatment and control proportions that still results in the conclusion that they are equivalent.
Di	The difference between the ith group proportion (Pi.1) and the control group proportion (Pc) at which the power is calculated. The formula is Di = Pi.1 - Pc.
Overall Alpha	The probability of rejecting at least one of the comparisons in this experiment when each null hypothesis is true.
Bonferroni Alpha	The adjusted significance level at which each individual comparison is made.

Summary Statements

A parallel, 4-group design (with one control group and 3 treatment groups) will be used to test whether the proportion for each treatment group is equivalent to the control group proportion, with equivalence difference bounds of -0.06 and 0.06 (H0: $\delta \leq -0.06$ or $\delta \geq 0.06$ versus H1: $-0.06 < \delta < 0.06$, $\delta = Pi - Pc$). Each of the 3 equivalence comparisons will be made using two one-sided, two-sample, Bonferroni-adjusted Gart & Nam Likelihood Score tests. The overall (experiment-wise) Type I error rate (α) is 0.05. The control group proportion is assumed to be 0.6. To detect the treatment proportions 0.6, 0.6, and 0.6 with at least 80% power for each test, the control group sample size needed will be 2113 and the number of needed subjects for the treatment groups will be 1220, 1220, and 1220 (totaling 5773 subjects overall).

Dropout-Inflated Sample Size

Group	Dropout Rate	Sample Size Ni	Dropout-Inflated Enrollment Sample Size Ni'	Expected Number of Dropouts Di
1	20%	2113	2642	529
2	20%	1220	1525	305
3	20%	1220	1525	305
4	20%	1220	1525	305
Total		5773	7217	1444
1	20%	2382	2978	596
2	20%	1375	1719	344
3	20%	1375	1719	344
4	20%	1375	1719	344
Total		6507	8135	1628
1	20%	3540	4425	885
2	20%	2044	2555	511
3	20%	2044	2555	511
4	20%	2044	2555	511
Total		9672	12090	2418

Group	Lists the group numbers.
Dropout Rate	The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
Ni	The evaluable sample size for each group at which power is computed (as entered by the user). If Ni subjects are evaluated out of the Ni' subjects that are enrolled in the study, the design will achieve the stated power.
Ni'	The number of subjects that should be enrolled in each group in order to obtain Ni evaluable subjects, based on the assumed dropout rate. Ni' is calculated by inflating Ni using the formula Ni' = Ni / (1 - DR), with Ni' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)
Di	The expected number of dropouts in each group. Di = Ni' - Ni.

Dropout Summary Statements

Anticipating a 20% dropout rate, group sizes of 2642, 1525, 1525, and 1525 subjects should be enrolled to obtain final group sample sizes of 2113, 1220, 1220, and 1220 subjects.

References

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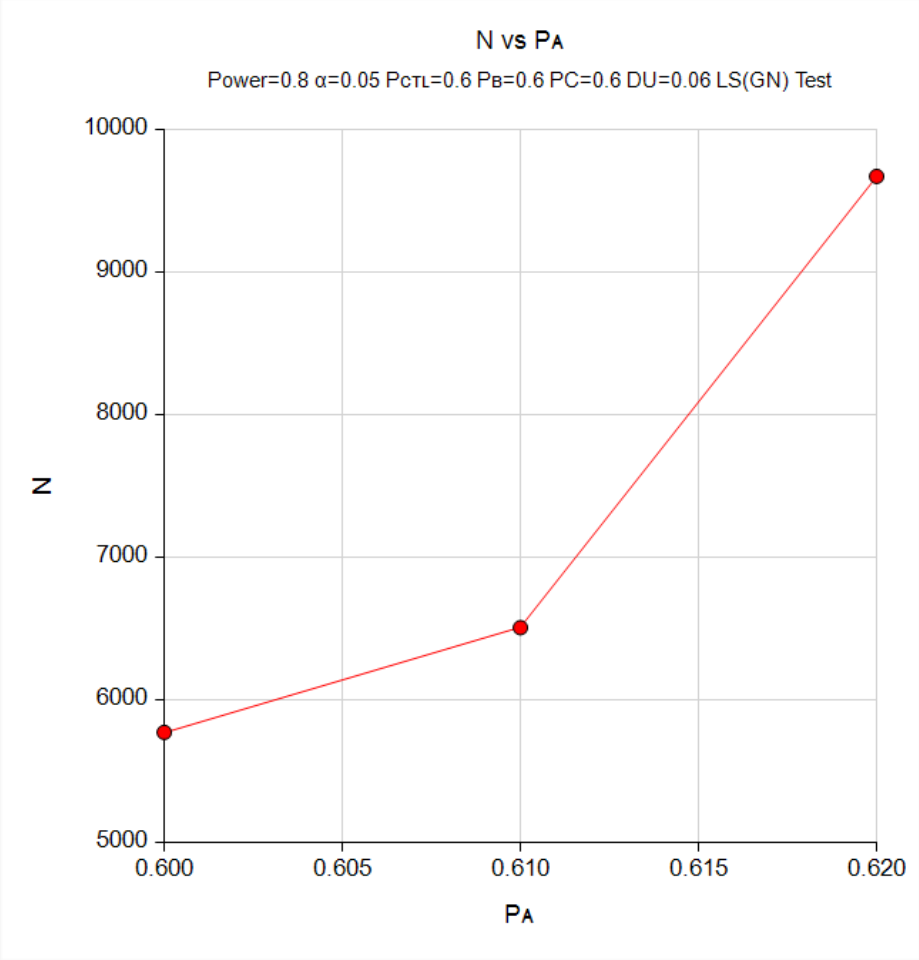
Lachin, J.M. 2000. Biostatistical Methods. John Wiley & Sons. New York.
Machin, D., Campbell, M.J., Tan, S.B, and Tan, S.H. 2018. Sample Sizes for Clinical, Laboratory, and Epidemiology Studies, 4th Edition. Wiley Blackwell.
Miettinen, O.S. and Nurminen, M. 1985. 'Comparative analysis of two rates.' Statistics in Medicine 4: 213-226.
Tubert-Bitter, P., Manfredi,R., Lellouch, J., Begaud, B. 2000. 'Sample size calculations for risk equivalence testing in pharmacoepidemiology.' Journal of Clinical Epidemiology 53, 1268-1274.

This report shows the numeric results of this power study. Notice that the results are shown in blocks of four rows at a time. Each block represents a single design.

Plots Section

Plots



This plot gives a visual presentation to the results in the Numeric Report. We can quickly see the impact on the sample size of increasing the difference between the treatment and control proportions.

Example 2 – Validation using a Previously Validated Procedure

We could not find a validation result in the statistical literature, so we will use a previously validated **PASS** procedure (**Equivalence Tests for the Difference Between Two Proportions**) to produce the results for the following example.

A parallel-group, clinical trial is being designed to compare three doses of a test compound against the standard therapy using three Gart-Nam equivalence tests. Suppose the standard therapy has a response rate of 60%. The investigators would like a sample size large enough to find statistical significance at an overall 0.05 level and an individual-test power of 0.80. The response rate of group 1 is 60%. The response rate of group 2 is 60%. The response rate of group 3 is 60%. The equivalence margin is 0.06 (10% of the standard therapy response rate). The sample sizes of all groups will be equal.

The **Equivalence Tests for the Difference Between Two Proportions** procedure is set up as follows

Design Tab	
Solve For	**Sample Size**
Power Calculation Method	**Normal Approximation**
Test Type	**Likelihood Score (Gart & Nam)**
Power	**0.8**
Alpha	**0.016667** (which is Alpha / k)
Group Allocation	**Equal (N1 = N2)**
Input Type	**Difference and Proportions**
D0.U (Upper Equivalence Difference)	**0.06**
D0.L (Lower Equivalence Difference)	**-D0.U**
P1.1 (Actual Proportion)	**0.6**
P2 (Group 2 Proportion)	**0.6**

This set of options generates the following report.

Numeric Results

Solve For: Sample Size
Test Statistic: Gart & Nam Likelihood Score Test
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U vs. H1: D0.L < P1 - P2 < D0.U

Target Power	Actual Power*	N1	N2	N	Ref. P2	P1.1	P1.0L	P1.0U	D0.L	D0.U	D1	Alpha
0.8	0.80038	1548	1548	3096	0.6	0.6	0.54	0.66	-0.06	0.06	0	0.01667

* Power was computed using the normal approximation method.

In order to maintain a power of 80% for all three groups, it is apparent that the groups will all need to have a sample size of 1548. This table contains the validation values. We will now run these values through the current procedure and compare the results with these values.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab	
Solve For	**Sample Size**
Test Type	**Likelihood Score (Gart & Nam)**
Power of Each Test	**0.8**
Overall Alpha	**0.05**
Bonferroni Adjustment	**Standard Bonferroni**
Group Allocation	**Equal (Nc = N1 = N2 = ...)**
DU (Upper Equivalence Difference)	**0.06**
DL (Lower Equivalence Difference)	**-DU**
Control Proportion	**0.6**
Set A Number of Groups	**1**
Set A Proportion	**0.60**
Set B Number of Groups	**1**
Set B Proportion	**0.6**
Set C Number of Groups	**1**
Set C Proportion	**0.6**
Set D Number of Groups	**0**
More	**Unchecked**

Output

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

Numeric Results

Solve For:	Sample Size
Group Allocation:	Equal (Nc = N1 = N2 = ...)
Hypothesis:	H0: D ≤ DL or D ≥ DU vs. H1: DL < D < DU
Test Type:	Gart & Nam Likelihood Score Test
Number of Groups:	4
Bonferroni Adjustment:	Standard Bonferroni (Divisor = 3)

				Proportion		Difference: Equivalence Limits			Alpha	
	Power		Sample Size	Pi|H0	Pi|H1	Lower	Upper	Actual		
Comparison	Target	Actual	Ni	Pi.0	Pi.1	DL	DU	Di	Overall	Bonferroni-Adjusted
Control			1548	0.6	0.6					
vs A	0.8	0.80038	1548	0.6	0.6	-0.06	0.06	0	0.05	0.016667
vs B	0.8	0.80038	1548	0.6	0.6	-0.06	0.06	0	0.05	0.016667
vs C	0.8	0.80038	1548	0.6	0.6	-0.06	0.06	0	0.05	0.016667
Total			6192							

As you can see, the sample sizes and powers match thus validating this procedure.