Chapter 753

Assurance for Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design

Introduction

This procedure calculates the assurance of equivalence tests comparing the proportions of two groups (populations) when the data are collected in a cluster-randomized design. The calculation is based on a user-specified prior distribution of the effect size parameters. This procedure may also be used to determine the needed sample size to obtain a specified assurance.

The methods for assurance calculation in this procedure are based on O'Hagan, Stevens, and Campbell (2005).

Cluster-randomized designs are often adopted when there is a high risk of contamination if cluster members were randomized individually. For example, it may be difficult for an instructor to use two methods of teaching individuals in the same class. The price of randomizing by clusters is a loss of efficiency - the number of subjects needed to obtain a certain level of precision in a cluster-randomized trial is usually much larger than the number needed when the subjects are randomized individually. Hence, the standard methods of sample size estimation cannot be used.

Assurance

The assurance of a design is the expected value of the power with respect to one or more prior distributions of the design parameters. Assurance is also referred to as *Bayesian assurance*, *expected power*, *average power*, *statistical assurance*, *hybrid classical-Bayesian procedure,* or *probability of success*.

The power of a design is the probability of rejecting the null hypothesis, conditional on a given set of design attributes, such as the test statistic, the significance level, the sample size, and the effect size to be detected. As the effect size parameters are typically unknown quantities, the stated power may be very different from the true power if the specified parameter values are inaccurate.

While power is conditional on individual design parameter values, and is highly sensitive to those values, assurance is the average power across a presumed prior distribution of the effect size parameters. Thus, assurance adds a Bayesian element to the frequentist framework, resulting in a hybrid approach to the probability of trial or study success. It should be noted that when it comes time to perform the statistical test on the resulting data, these methods for calculating assurance assume that the traditional (frequentist) tests will be used.

The next section describes some of the ways in which the prior distributions for effect size parameters may be determined.

Elicitation

In order to calculate assurance, a suitable prior distribution for the effect size parameters must be determined. This process is called the *elicitation* of the prior distribution.

The elicitation may be as simple as choosing a distribution that seems plausible for the parameter(s) of interest, or as complex as combining the informed advice of several experts based on experience in the field, available pilot data, or previous studies. The accuracy of the assurance value depends on the accuracy of the elicited prior distribution. The assumption (or hope) is that an informed prior distribution will produce a more accurate estimate of the probability of trial success than a single value estimate. Because clinical trials and other studies are often costly, many institutions now routinely require an elicitation step.

Two reference texts that focus on elicitation are O'Hagan, Buck, Daneshkhah, Eiser, Garthwaite, Jenkinson, Oakley, and Rakow (2006) and Dias, Morton, and Quigley (2018).

Two-Sample Z-Test of Proportions

Our formulation comes from Donner and Klar (2000). Denote a binary observation by Y_{gkm} where g = 1 or 2 is the group, k = 1, 2, ..., K_g is a cluster within group g, and m = 1, 2, ..., M_g is an individual in cluster k of group g. The results that follow assume an equal number of individuals per cluster. When the number of subjects from cluster to cluster are about the same, the power and sample size values should be fairly accurate. In these cases, the average number of subjects per cluster can be used.

Equivalence Test Hypotheses

The statistical hypothesis that is tested concerns the difference between the two group proportions, P_1 and P_2. When necessary, we assume that group 1 is the treatment group and group 2 is the control group. With a simple modification, all of the large-sample sample size formulas that are listed in the module for testing two proportions can be used here.

PASS follows the *two one-sided tests* (TOST) approach described by Schuirmann (1987) and Phillips (1990). Let $D = P_1 - P_2$ represent the difference between the two group proportions. Lower and upper equivalence bounds, $D_{0.L}$ and $D_{0.U}$, define the region of equivalence.

With $D_{0.L} < 0$ and $D_{0.U} > 0$, the null hypothesis of non-equivalence is

$$H_0: D \leq D_{0.L} \text{ or } D \geq D_{0.U}.$$

The alternative hypothesis of equivalence is

$$H_1: D_{0.L} < D < D_{0.U}.$$

When the individual subjects are randomly assigned to one of the two groups, the variance of the sample proportion is

$$\sigma_{S,g}^2 = \frac{P_g(1 - P_g)}{N_g}$$

When the randomization is by clusters of subjects, the variance of the sample proportion is

$$\sigma_{C,g}^2 = \frac{P_g(1 - P_g)(1 + (M_g - 1)\rho)}{K_g M_g}$$

$$= \sigma_{S,g}^2 [1 + (M_g - 1)\rho]$$

$$= F_{g,\rho} \sigma_{S,g}^2$$

The factor $[1 + (M_g - 1)\rho]$ is called the *inflation factor*. The Greek letter ρ is used to represent the *intracluster correlation coefficient (ICC)*. This correlation may be thought of as the simple correlation between any two subjects within the same cluster. If we stipulate that ρ is positive, it may also be interpreted as the proportion of total variability that is attributable to differences between clusters. This value is critical to the sample size calculation.

The asymptotic formulas that were used in comparing two proportions (see Chapter 200, "Tests for Two Proportions") may be used with cluster-randomized designs as well, as long as an adjustment is made for the inflation factor. The basic form of the two z-tests is

$$z = \frac{\widehat{D} - D_0}{\hat{\sigma}_{\widehat{D}}}$$

where

$$\widehat{D} = \hat{p}_1 - \hat{p}_2$$

$$D_0 = D_{0.L} \text{ or } D_{0.U}$$

$\hat{\sigma}_{\widehat{D}}$ depends on whether the test is pooled or unpooled.

Z-Test (Pooled)

The proportions are pooled (averaged) in computing the standard error. The formula used for the standard deviation in the power computations is

$$\sigma_{Pooled} = \sqrt{\bar{P}(1 - \bar{P}) \left(\frac{F_{1,\rho}}{N_1^*} + \frac{F_{2,\rho}}{N_2^*} \right)}$$

where

$$\bar{P} = \frac{N_1^* P_1 + N_2^* P_2}{N_1^* + N_2^*}$$

$$N_g^* = \frac{N_g}{F_g}, \qquad g = 1,2$$

Z-Test (Unpooled)

This test statistic does not pool the two proportions in computing the standard error. The formula used for the standard deviation in the power computations is

$$\sigma_{Unpooled} = \sqrt{\left(\frac{P_1(1 - P_1)}{N_1^*} + \frac{P_2(1 - P_2)}{N_2^*} \right)}$$

where

$$N_g^* = \frac{N_g}{F_g}, \qquad g = 1,2$$

Power Calculations

A large sample approximation is used that is most accurate when the values of N_1 and N_2 are large. 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 and P_2 under the alternative hypothesis, computing the appropriate standard deviation, and then computing the power based on the normal distribution. The sample sizes are adjusted to account for the subject clustering.

Assurance Calculation

The assurance computation described here is based on O'Hagan, Stevens, and Campbell (2005).

Let $P_p(H|P_1, P_2, \rho, M_1, M_2)$ be the power function described above where H is the event that null hypothesis is rejected conditional on the values of the parameters. The specification of the parameters is critical to the power calculation, but the actual values are seldom known. Assurance is defined as the expected power where the expectation is with respect to a joint prior distribution for the parameters. Hence, the definition of assurance is

$$Assurance = E_{P_1, P_2, \rho, M_1, M_2} \left(P_p(H|P_1, P_2, \rho, M_1, M_2) \right)$$

$$= \int \int \int \int \int P_p(H|P_1, P_2, \rho, M_1, M_2) f(P_1, P_2, \rho, M_1, M_2) dP_1 \dots dM_2$$

where $f(P_1, P_2, \rho, M_1, M_2)$ is the joint prior distribution of the parameters.

In **PASS**, the joint prior distribution can be specified as either a discrete approximation to the joint prior distribution, or as individual prior distributions, one for each parameter.

Specifying a Joint Prior Distribution

If the joint prior distribution is to be specified directly, the distribution is specified in **PASS** using a discrete approximation to the function $f(P_1, P_2, \rho, M_1, M_2)$. This provides flexibility in specifying the joint prior distribution. In the five-parameter case, six columns are entered on the spreadsheet: five for the parameters and one more for the probability. Each row gives a value for each parameter and the corresponding parameter-combination probability. The accuracy of the distribution approximation is controlled by the number of points (spreadsheet rows) that are used.

An example of entering a joint prior distribution is included at the end of the chapter.

Specifying Individual Prior Distributions

Ciarleglio, Arendt, and Peduzzi (2016) suggest that more flexibility is available if the joint prior distribution is separated into two independent distributions as follows:

$$f(P_1, P_2, \rho, M_1, M_2) = f_1(P_1)f_2(P_2)f_3(\rho)f_4(M_1)f_5(M_2)$$

where $f_1(P_1)$ is the prior distribution of P_1 and so forth. This method is also available in **PASS**. In this case, the definition of assurance becomes

$$Assurance = E_{P_1, P_2, \rho, M_1, M_2}\left(P_p(H|P_1, P_2, \rho, M_1, M_2)\right)$$

$$= \int \int \int \int \int P_p(H|P_1, P_2, \rho, M_1, M_2)f_1(P_1)f_2(P_2)f_3(\rho)f_4(M_1)f_5(M_2)dP_1 \dots dM_2$$

Using this definition, the assurance can be calculated using numerical integration. There are a variety of pre-programmed, univariate prior distributions available in **PASS**.

Fixed Values (No Prior) and Custom Values

For any given parameter, **PASS** also provides the option of entering a single fixed value for the prior distribution, or a series of values and corresponding probabilities (using the spreadsheet), rather than one of the pre-programmed distributions.

Numerical Integration in PASS (and Notes on Computation Speed)

When the prior distribution is specified as independent univariate distributions, **PASS** uses a numerical integration algorithm to compute the assurance value as follows:

The domain of each prior distribution is divided into M intervals. Since many of the available prior distributions are unbounded on one (e.g., Gamma) or both (e.g., Normal) ends, an approximation is made to make the domain finite. This is accomplished by truncating the distribution to a domain between the two quantiles: $q_{0.001}$ and $q_{0.999}$.

The value of M controls the accuracy and speed of the algorithm. If only one parameter is to be given a prior distribution, then a value of M between 50 and 100 usually gives an accurate result in a timely manner. However, if two parameters are given priors, the number of iterations needed increases from M to M^2. For example, if M is 100, 10000 iterations are needed. Reducing M from 100 to 50 reduces the number of iterations from 10000 to 2500.

The algorithm runtime increases when searching for sample size rather than solving for assurance, as a search algorithm is employed in this case. When solving for sample size, we recommend reducing M to 20 or less while exploring various scenarios, and then increasing M to 50 or more for a final, more accurate, result.

List of Available Univariate Prior Distributions

This section lists the univariate prior distributions that may be used for any of the applicable parameters when the Prior Entry Method is set to Individual.

No Prior

If 'No Prior' is chosen for a parameter, the parameter is assumed to take on a single, fixed value with probability one.

Beta (Shape 1, Shape 2, a, c)

A random variable X that follows the beta distribution is defined on a finite interval [a, c]. Two shape parameters (α and β) control the shape of this distribution. Two location parameters a and c give the minimum and maximum of X.

The probability density function of the beta distribution is

$$f(x|\alpha, \beta, a, c) = \frac{\left(\frac{x-a}{c-a}\right)^{\alpha-1}\left(\frac{c-x}{c-a}\right)^{\beta-1}}{(c-a)B(\alpha, \beta)}$$

where $B(\alpha, \beta) = \Gamma(\alpha)\,\Gamma(\beta)/\Gamma(\alpha+\beta)$ and $\Gamma(z)$ is the gamma function.

The mean of X is

$$\mu_X = \frac{\alpha c + \beta a}{\alpha + \beta}$$

Various distribution shapes are controlled by the values of α and β. These include

Symmetric and Unimodal

$\alpha = \beta > 1$

U Shaped

$\alpha = \beta < 1$

Bimodal

$\alpha, \beta < 1$

Uniform

$\alpha = \beta = 1$

Parabolic

$$\alpha = \beta = 2$$

Bell-Shaped

$$\alpha = \beta > 2$$

Gamma (Shape, Scale)

A random variable X that follows the gamma distribution is defined on the interval $(0, \infty)$. A shape parameter, κ, and a scale parameter, θ, control the distribution.

The probability density function of the gamma distribution is

$$f(x|\kappa, \theta) = \frac{x^{\kappa-1} e^{-\frac{x}{\theta}}}{\theta^{\kappa} \Gamma(\kappa)}$$

where $\Gamma(z)$ is the gamma function.

The mean of X is

$$\mu_X = \frac{\kappa}{\theta}$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Inverse-Gamma (Shape, Scale)

A random variable X that follows the inverse-gamma distribution is defined on the interval $(0, \infty)$. If $Y \sim$ gamma, then $X = 1 / Y \sim$ inverse-gamma. A shape parameter, α, and a scale parameter, β, control the distribution.

The probability density function of the inverse-gamma distribution is

$$f(x|\alpha, \beta) = \frac{\beta^{\alpha} x^{\alpha-1} e^{-\frac{\beta}{x}}}{\Gamma(\alpha)}$$

where $\Gamma(z)$ is the gamma function.

The mean of X is

$$\mu_X = \frac{\beta}{\alpha - 1} \text{ for } \alpha > 1$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Logistic (Location, Scale)

A random variable X that follows the logistic distribution is defined on the interval $(-\infty, \infty)$. A location parameter, μ, and a scale parameter, s, control the distribution.

The probability density function of the logistic distribution is

$$f(x|\mu, s) = \frac{e^{-\frac{x-\mu}{s}}}{s\left(1 + e^{-\frac{x-\mu}{s}}\right)^2}$$

The mean of X is

$$\mu_X = \mu$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where Min and Max are two truncation bounds.

Lognormal (Mean, SD)

A random variable X that follows the lognormal distribution is defined on the interval $(0, \infty)$. A location parameter, $\mu_{\log(X)}$, and a scale parameter, $\sigma_{\log(X)}$, control the distribution. If Z ~ standard normal, then $X = e^{\mu + \sigma Z} \sim$ lognormal. Note that $\mu_{\log(X)} = E(\log(X))$ and $\sigma_{\log(X)} = Standard\ Deviation(\log(X))$.

The probability density function of the lognormal distribution is

$$f(x|\mu, \sigma) = \frac{e^{-\frac{1}{2}\left(\frac{\log x - \mu}{\sigma}\right)^2}}{x\sigma\sqrt{2\pi}}$$

The mean of X is

$$\mu_X = e^{\mu + \frac{\sigma^2}{2}}$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where Min and Max are two truncation bounds.

LogT (Mean, SD)

A random variable X that follows the logT distribution is defined on the interval $(0, \infty)$. A location parameter, $\mu_{\log(X)}$, a scale parameter, $\sigma_{\log(X)}$, and a shape parameter, ν, control the distribution. Note that ν is referred to as the *degrees of freedom*.

If t ~ Student's t, then $X = e^{\mu + \sigma t} \sim$ logT.

The probability density function of the logT distribution is

$$f(x|\mu, \sigma, \nu) = \frac{\Gamma\left(\frac{\nu + 1}{2}\right)}{x\Gamma\left(\frac{\nu}{2}\right)\sigma\sqrt{\nu\pi}}\left(1 + \frac{1}{\nu}\left(\frac{\log x - \mu}{\sigma}\right)^2\right)^{\left(\frac{-\nu-1}{2}\right)}$$

The mean of X is not defined.

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Normal (Mean, SD)

A random variable X that follows the normal distribution is defined on the interval $(-\infty, \infty)$. A location parameter, μ, and a scale parameter, σ, control the distribution.

The probability density function of the normal distribution is

$$f(x|\mu, \sigma) = \frac{e^{-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2}}{\sigma\sqrt{2\pi}}$$

The mean of X is

$$\mu_X = \mu$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

T (Mean, SD, DF)

A random variable X that follows Student's t distribution is defined on the interval $(-\infty, \infty)$. A location parameter, μ, a scale parameter, σ, and a shape parameter, ν, control the distribution. Note that ν is referred to as the *degrees of freedom* or *DF*.

The probability density function of the Student's t distribution is

$$f(x|\mu, \sigma, \nu) = \frac{\Gamma\left(\frac{\nu + 1}{2}\right)}{\Gamma\left(\frac{\nu}{2}\right)\sigma\sqrt{\nu\pi}}\left(1 + \frac{1}{\nu}\left(\frac{x - \mu}{\sigma}\right)^2\right)^{\left(\frac{-\nu-1}{2}\right)}$$

The mean of X is μ if $\nu > 1$.

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Triangle (Mode, Min, Max)

Let a = minimum, b = maximum, and c = mode. A random variable X that follows a triangle distribution is defined on the interval (a, b).

The probability density function of the triangle distribution is

$$f(x|a, b, c) = \begin{cases} \dfrac{2(x - a)}{(b - a)(c - a)} & \text{for } a \le x < c \\[2mm] \dfrac{2}{b - a} & \text{for } x = c \\[2mm] \dfrac{2(b - x)}{(b - a)(b - c)} & \text{for } c < x \le b \end{cases}$$

The mean of X is

$$\frac{a + b + c}{3}$$

Uniform (Min, Max)

Let a = minimum and b = maximum. A random variable X that follows a uniform distribution is defined on the interval $[a, b]$.

The probability density function of the uniform distribution is

$$f(x|a, b) = \begin{cases} \dfrac{1}{b - a} & \text{for } a \le x \le b \end{cases}$$

The mean of X is

$$\frac{a + b}{2}$$

Weibull (Shape, Scale)

A random variable X that follows the Weibull distribution is defined on the interval $(0, \infty)$. A shape parameter, κ, and a scale parameter, λ, control the distribution.

The probability density function of the Weibull distribution is

$$f(x|\kappa, \lambda) = \frac{\kappa}{\lambda} \left(\frac{x}{\lambda}\right)^{\kappa - 1} e^{-\left(\frac{x}{\lambda}\right)^{\kappa}}$$

The mean of X is

$$\mu_X = \kappa \Gamma\left(1 + \frac{1}{\kappa}\right)$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \le X \le Max)$ where *Min* and *Max* are two truncation bounds.

Custom (Values and Probabilities in Spreadsheet)

This custom prior distribution is represented by a set of user-specified points and associated probabilities, entered in two columns of the spreadsheet. The points make up the entire set of values that are used for this parameter in the calculation of assurance. The associated probabilities should sum to one. Note that custom values and probabilities can be used to approximate any continuous distribution.

For example, a prior distribution of X might be

X_i	P_i
10	0.2
20	0.2
30	0.3
40	0.2
50	0.1

In this example, the mean of X is

$$\mu_X = \sum_{i=1}^{5} X_i P_i$$

Example 1 – Assurance Over a Range of Sample Sizes

Suppose that a cluster randomized, equivalence study is being planned in which *P1* = 0.5; *P2 = 0.5*; *D0.L* = -0.05; *D0.U* = 0.05; ρ = 0.02; *M1* and *M2* = 7; *alpha* = 0.05; and *K1* and *K2* is in the range 100 to 500. Power is to be calculated for a pooled equivalence test using the TOST procedure.

To complete their sample size study, the researchers want to run an assurance analysis for a range of group sample sizes from 100 to 500. An elicitation exercise determined that the prior distribution of the P1 should be normal with mean 0.5 and standard deviation 0.02, the prior distribution of P2 should be a normal with mean 0.5 and standard deviation 0.01, the prior distribution of the ICC should be a normal with mean 0.02 and standard deviation 0.004, the prior distribution of the cluster size of group 1 should be a normal with mean 7 and standard deviation 1.5, and the prior distribution of the cluster size of group 2 should be a normal with mean 7 and standard deviation 1.5.

To reduce the runtime of this example, the number of computation points is set to 10. In practice, we recommend setting this value to 20 or more for the most accurate results.

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	**Assurance**
Prior Entry Method	**Individual (Enter a prior distribution for each applicable parameter)**
Test Type	**Z-Test (Pooled)**
Alpha	**0.05**
K1 (Number of Clusters)	**100 200 300 400 500**
Prior Distribution of M1	**Normal (Mean, SD)**
Mean	**7**
SD	**1.5**
Truncation Boundaries	**None**
K2 (Number of Clusters)	**K1**
Prior Distribution of M2	**Normal (Mean, SD)**
Mean	**7**
SD	**1.5**
Truncation Boundaries	**None**
D0.U (Upper Equivalence Difference)	**0.05**
D0.L (Lower Equivalence Difference)	**-0.05**
Prior Distribution of P1	**Normal (Mean, SD)**
Mean	**0.5**
SD	**0.02**
Truncation Boundaries	**None**
Prior Distribution of P2	**Normal (Mean, SD)**
Mean	**0.5**
SD	**0.01**
Truncation Boundaries	**None**

Assurance for Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design

Prior Distribution of ρ ....**Normal (Mean, SD)**	
Mean...**0.02**	
SD...**0.004**	
Truncation Boundaries...................................**None**	

Options Tab

Number of Computation Points for each........**10**
  Prior Distribution
Maximum K1 in Sample Size Search.............**1000**

Output

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

Numeric Reports

Numeric Results
───
Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: Z-Test (Pooled)
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U   vs.   H1: D0.L < P1 - P2 < D0.U
Prior Type: Individual Univariate Distributions

Prior Distributions
M1: Normal (Mean = 7, SD = 1.5).
M2: Normal (Mean = 7, SD = 1.5).
P1: Normal (Mean = 0.5, SD = 0.02).
P2: Normal (Mean = 0.5, SD = 0.01).
ρ: Normal (Mean = 0.02, SD = 0.004).
───

		Sample Size			Number of Clusters			Cluster Size		Proportions		Equivalence Differences	Intracluster Correlation	
Assurance*	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(P1)	E(P2)	D0.L | D0.U	E(ρ)	Alpha
0.07119	0.09782	700	700	1400	100	100	200	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05
0.41378	0.60753	1400	1400	2800	200	200	400	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05
0.58199	0.84352	2100	2100	4200	300	300	600	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05
0.67583	0.94133	2800	2800	5600	400	400	800	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05
0.73436	0.97900	3500	3500	7000	500	500	1000	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05

───
* The number of points used for computation of the prior(s) was 10.
‡ Power was calculated using M1 = E(M1) = 7, M2 = E(M2) = 7, P1 = E(P1) = 0.5, P2 = E(P2) = 0.5, and ρ = E(ρ) = 0.02.

Assurance	The expected power where the expectation is with respect to the prior distribution(s).
Power	The power calculated using the means of the prior distributions as the values of the corresponding parameters.
N1	The number of subjects in group 1.
N2	The number of subjects in group 2.
N	The total sample size. N = N1 + N2.
K1	The number of clusters in group 1.
K2	The number of clusters in group 2.
K	The total number of clusters.
E(M1)	The expected average number of items (subjects) per cluster in group 1.
E(M2)	The expected average number of items (subjects) per cluster in group 2.
E(P1)	The expected response proportion in group 1 assumed by H1.
E(P2)	The expected response proportion in group 2.
DO.L | D0.U	The lower and upper equivalence difference margins.
E(ρ)	The expected intracluster correlation (ICC).
Alpha	The probability of rejecting a true null hypothesis.

Summary Statements
──

A parallel two-group cluster-randomized design will be used to test whether the Group 1 (treatment) proportion (P1) is equivalent to the Group 2 (control) proportion (P2), with proportion difference equivalence bounds of -0.05 and 0.05 (H0: P1 - P2 ≤ -0.05 or P1 - P2 ≥ 0.05 versus H1: -0.05 < P1 - P2 < 0.05). The comparison will be made using two one-sided pooled variance Z-tests with an overall Type I error rate (α) of 0.05. The prior distribution used for the average cluster size in Group 1 is Normal (Mean = 7, SD = 1.5). The prior distribution used for the average cluster size in Group 2 is Normal (Mean = 7, SD = 1.5). The prior distribution used for the response proportion in Group 1 is Normal (Mean = 0.5, SD = 0.02). The prior distribution used for the response proportion in Group 2 is Normal (Mean = 0.5, SD = 0.01). The prior distribution used for the intracluster correlation coefficient is Normal (Mean = 0.02, SD = 0.004). With 100 clusters (700 total subjects) in Group 1 (treatment) and 100 clusters (700 total subjects) in Group 2 (control), the assurance (average power) is 0.07119.
──

References
──

O'Hagan, A., Stevens, J.W., and Campbell, M.J. 2005. 'Assurance in clinical trial design'. Pharmaceutical Statistics, Volume 4, Pages 187-201.

Ciarleglio, M.M., Arendt, C.D., and Peduzzi, P.N. 2016. 'Selection of the effect size for sample size determination for a continuous response in a superiority clinical trial using a hybrid classical and Bayesian procedure'. Clinical Trials, Volume 13(3), pages 275-285.

Dias, L.C., Morton, A., and Quigley, J. 2018. Elicitation, The Science and Art of Structuring Judgement. Springer.

Campbell, M.J. and Walters, S.J. 2014. How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research. Wiley. New York.

Ahn, C., Heo, M., and Zhang, S. 2015. Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research. CRC Press. New York.

Donner, A. and Klar, N. 1996. 'Statistical Considerations in the Design and Analysis of Community Intervention Trials'. J. Clin. Epidemiol. Vol 49, No. 4, pages 435-439.

Donner, A. and Klar, N. 2000. Design and Analysis of Cluster Randomization Trials in Health Research. Arnold. London.

Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. 2018. Sample Size Calculations in Clinical Research, Third Edition. Taylor & Francis/CRC. Boca Raton, Florida.
──

This report shows the assurance values obtained by the various sample sizes.

Plots Section

Plots
_____
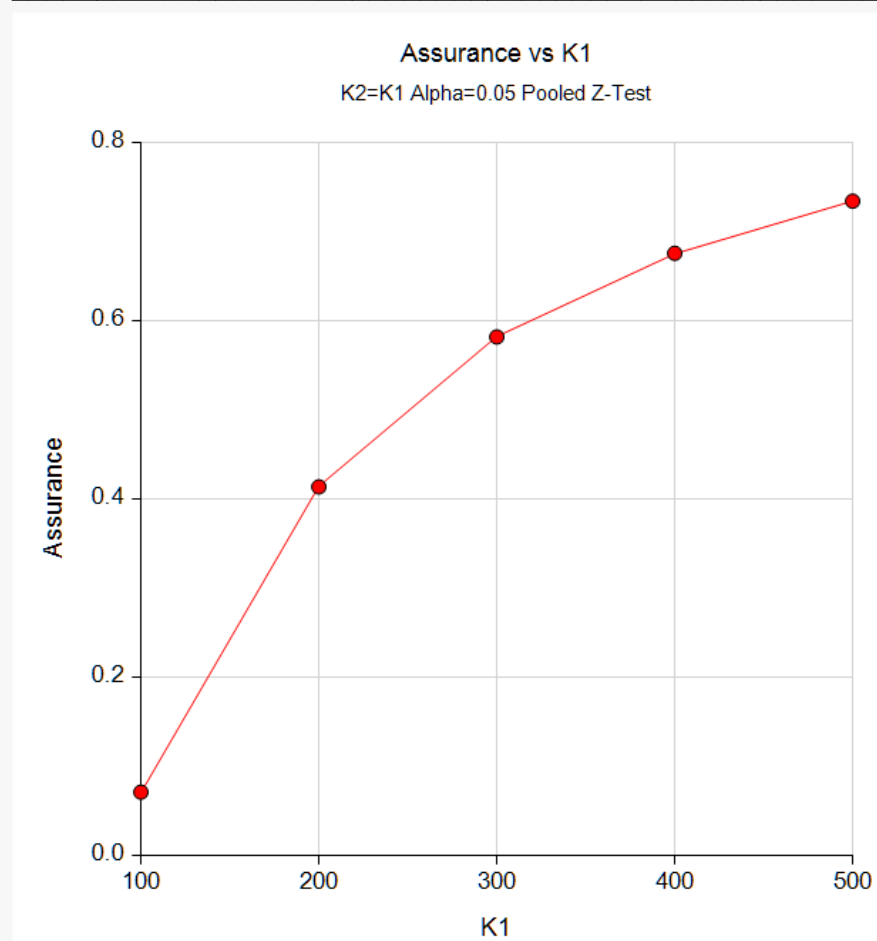
This plot shows the relationship between the assurance and sample size.

Comparison Plots Section

Comparison Plots
_____
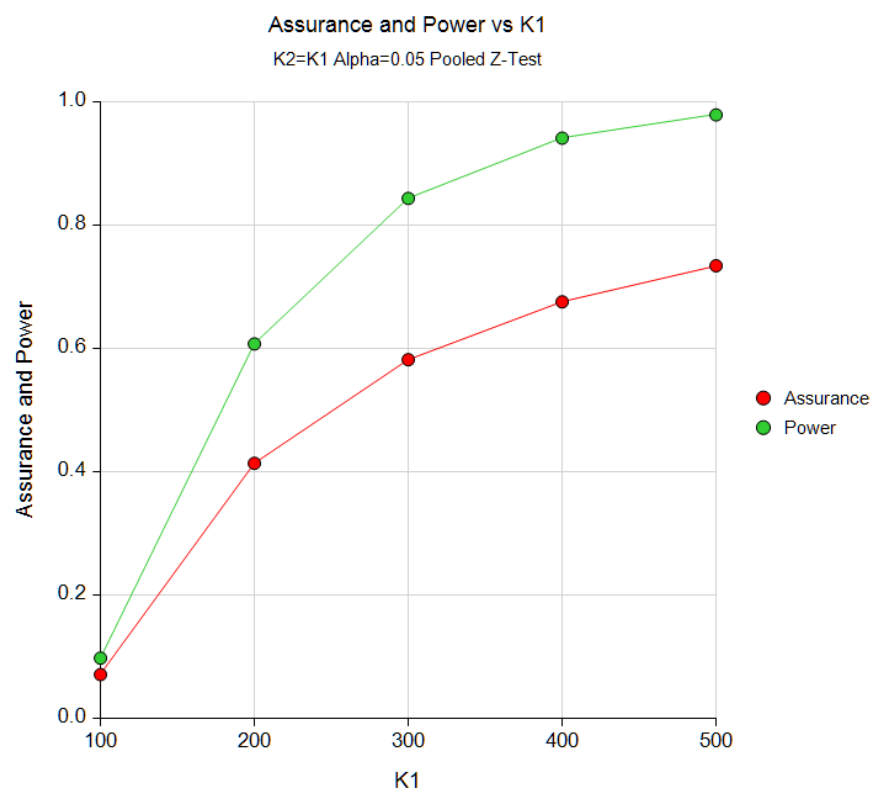
This plot compares the assurance and power across values of sample size.

Example 2 – Validation using Hand Computation

We could not find a validation example in the literature for procedure, so we have developed a validation example of our own.

Suppose two, one-sided, pooled z-tests will be used to test equivalence. Further suppose that K1 = K2 = 300, the significance level is 0.05, D0.L = -0.05 and D0.U = 0.05.

The prior distribution of P1 is approximated by the following table. These are loaded into C1 and C2.

P1	Prob
0.49	0.4
0.51	0.6

The prior distribution of the P2 is approximated by the following table. These are loaded into C3 and C4.

P2	Prob
0.49	0.4
0.51	0.6

The prior distribution of the ρ is approximated by the following table. These are loaded into C5 and C6.

ρ	Prob
0.01	0.5
0.02	0.5

The prior distribution of the M1 is approximated by the following table. These are loaded into C7 and C8.

M1	Prob
7	0.5
9	0.5

The prior distribution of the M2 is approximated by the following table. These are loaded into C9 and C10.

M2	Prob
7	0.5
9	0.5

To run this example, the spreadsheet will need to be loaded with the following 10 columns corresponding to the values listed above.

C1	C2	C3	C4	C5	C6	C7	C8	C9	C10
0.49	0.4	0.49	0.4	0.01	0.5	7	0.5	7	0.5
0.51	0.6	0.51	0.6	0.02	0.5	9	0.5	9	0.5

The *Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design* procedure is used to compute the power for each of the 32 combinations the parameters. The results of these calculations are shown next.

Numeric Results

Solve For: Power
Groups: 1 = Treatment, 2 = Reference
Test Statistic: Z-Test (Pooled)
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U   vs.   H1: D0.L < P1 - P2 < D0.U

	Number of Clusters			Average Cluster Size		Total Sample Size	Proportion			Difference			
							Equivalence	Actual	Reference	Equivalence	Actual	Intracluster Correlation	
Power	K1	K2	K	M1	M2	N	P1.L | P1.U	P1.1	P2	D0.L | D0.U	D1	ICC	Alpha
0.86719	300	300	600	7	7	4200	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.01	0.05
0.90711	300	300	600	7	9	4800	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.01	0.05
0.84370	300	300	600	7	7	4200	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.02	0.05
0.88551	300	300	600	7	9	4800	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.02	0.05
0.90711	300	300	600	9	7	4800	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.01	0.05
0.94143	300	300	600	9	9	5400	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.01	0.05
0.88551	300	300	600	9	7	4800	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.02	0.05
0.92282	300	300	600	9	9	5400	0.44 | 0.54	0.49	0.49	-0.05 | 0.05	0.00	0.02	0.05
0.59335	300	300	600	7	7	4200	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.01	0.05
0.63551	300	300	600	7	9	4800	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.01	0.05
0.57213	300	300	600	7	7	4200	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.02	0.05
0.61153	300	300	600	7	9	4800	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.02	0.05
0.63551	300	300	600	9	7	4800	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.01	0.05
0.68269	300	300	600	9	9	5400	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.01	0.05
0.61153	300	300	600	9	7	4800	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.02	0.05
0.65532	300	300	600	9	9	5400	0.46 | 0.56	0.49	0.51	-0.05 | 0.05	-0.02	0.02	0.05
0.59335	300	300	600	7	7	4200	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.01	0.05
0.63551	300	300	600	7	9	4800	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.01	0.05
0.57213	300	300	600	7	7	4200	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.02	0.05
0.61153	300	300	600	7	9	4800	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.02	0.05
0.63551	300	300	600	9	7	4800	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.01	0.05
0.68269	300	300	600	9	9	5400	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.01	0.05
0.61153	300	300	600	9	7	4800	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.02	0.05
0.65532	300	300	600	9	9	5400	0.44 | 0.54	0.51	0.49	-0.05 | 0.05	0.02	0.02	0.05
0.86719	300	300	600	7	7	4200	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.01	0.05
0.90711	300	300	600	7	9	4800	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.01	0.05
0.84370	300	300	600	7	7	4200	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.02	0.05
0.88551	300	300	600	7	9	4800	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.02	0.05
0.90711	300	300	600	9	7	4800	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.01	0.05
0.94143	300	300	600	9	9	5400	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.01	0.05
0.88551	300	300	600	9	7	4800	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.02	0.05
0.92282	300	300	600	9	9	5400	0.46 | 0.56	0.51	0.51	-0.05 | 0.05	0.00	0.02	0.05

The assurance calculation is made by summing the quantities

$$\left[(power_{i,j,k,l,m})p(P1_i)p(P2_j)p(\rho_k)p(M1_l)p(M2_m)\right]$$

as follows

$$Assurance = (0.86719 \times 0.4 \times 0.4 \times 0.5 \times 0.5 \times 0.5) + (0.90711 \times 0.4 \times 0.4 \times 0.5 \times 0.5 \times 0.5) + \cdots$$
$$+ (0.92282 \times 0.6 \times 0.6 \times 0.5 \times 0.5 \times 0.5)$$
$$= 0.76528.$$

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 ....**Assurance**
Prior Entry Method..**Individual (Enter a prior distribution for each applicable parameter)**
Test Type...**Z-Test (Pooled)**
Alpha..**0.05**
K1 (Number of Clusters) **300**
Prior Distribution of M1 ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C7**
Column of Pr(Values)....................................**C8**
K2 (Number of Clusters) **K1**
Prior Distribution of M2 ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C9**
Column of Pr(Values)....................................**C10**
D0.U (Upper Equivalence Difference)............**0.05**
D0.L (Lower Equivalence Difference) ....**-0.05**
Prior Distribution of P1 ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C1**
Column of Pr(Values)....................................**C2**
Prior Distribution of P2.................................**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C3**
Column of Pr(Values)....................................**C4**
Prior Distribution of ρ ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C5**
Column of Pr(Values)....................................**C6**

Options Tab

Number of Computation Points for each........**10**
  Prior Distribution
Maximum K1 in Sample Size Search.............**1000**

Input Spreadsheet Data

Row	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10
1	0.49	0.4	0.49	0.4	0.01	0.5	7	0.5	7	0.5
2	0.51	0.6	0.51	0.6	0.02	0.5	9	0.5	9	0.5

Output

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

Numeric Results

Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: Z-Test (Pooled)
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U   vs.   H1: D0.L < P1 - P2 < D0.U
Prior Type: Individual Univariate Distributions

Prior Distributions
M1:   Point List (Values = C7, Probs = C8).
  C7:   7 9
  C8:   0.5 0.5
M2:   Point List (Values = C9, Probs = C10).
  C9:   7 9
  C10:   0.5 0.5
P1:   Point List (Values = C1, Probs = C2).
  C1:   0.49 0.51
  C2:   0.4 0.6
P2:   Point List (Values = C3, Probs = C4).
  C3:   0.49 0.51
  C4:   0.4 0.6
ρ: Point List (Values = C5, Probs = C6).
  C5:   0.01 0.02
  C6:   0.5 0.5

		Sample Size			Number of Clusters			Cluster Size		Proportions		Equivalence Differences	Intracluster Correlation	
Assurance	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(P1)	E(P2)	D0.L | D0.U	E(ρ)	Alpha
0.76528	0.90118	2400	2400	4800	300	300	600	8	8	0.502	0.502	-0.05 | 0.05	0.015	0.05

‡ Power was calculated using M1 = E(M1) = 8, M2 = E(M2) = 8, P1 = E(P1) = 0.502, P2 = E(P2) = 0.502, and ρ = E(ρ) = 0.015.

PASS has also calculated the assurance as 0.76528 which validates the procedure.

Example 3 – Finding the Sample Size Needed to Achieve a Specified Assurance

Continuing with Example 1, the researchers want to investigate the sample sizes necessary to achieve assurances of 0.5, 0.6, and 0.7.

In order to reduce the runtime during this exploratory phase of the analysis, the number of points in the prior computation is reduced to 10. This slightly reduces the accuracy, but greatly reduces the runtime.

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 3** 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**
Prior Entry Method..**Individual (Enter a prior distribution for each applicable parameter)**
Test Type...**Z-Test (Pooled)**
Assurance..**0.5 0.6 0.7**
Alpha..**0.05**
Prior Distribution of M1 ....**Normal (Mean, SD)**
Mean..**7**
SD..**1.5**
Truncation Boundaries.................................**None**
K2 (Number of Clusters) **K1**
Prior Distribution of M2 ....**Normal (Mean, SD)**
Mean..**7**
SD..**1.5**
Truncation Boundaries.................................**None**
D0.U (Upper Equivalence Difference)............**0.05**
D0.L (Lower Equivalence Difference) ....**-0.05**
Prior Distribution of P1 ....**Normal (Mean, SD)**
Mean..**0.5**
SD..**0.02**
Truncation Boundaries.................................**None**
Prior Distribution of P2.................................**Normal (Mean, SD)**
Mean..**0.5**
SD..**0.01**
Truncation Boundaries.................................**None**
Prior Distribution of ρ ....**Normal (Mean, SD)**
Mean..**0.02**
SD..**0.004**
Truncation Boundaries.................................**None**

Options Tab

Number of Computation Points for each **10**
  Prior Distribution
Maximum K1 in Sample Size Search **1000**

Output

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

Numeric Reports

Numeric Results
───
Solve For: Sample Size
Groups: 1 = Treatment, 2 = Control
Test Statistic: Z-Test (Pooled)
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U   vs.   H1: D0.L < P1 - P2 < D0.U
Prior Type: Individual Univariate Distributions

Prior Distributions
M1: Normal (Mean = 7, SD = 1.5).
M2: Normal (Mean = 7, SD = 1.5).
P1: Normal (Mean = 0.5, SD = 0.02).
P2: Normal (Mean = 0.5, SD = 0.01).
ρ: Normal (Mean = 0.02, SD = 0.004).
───

|		Sample Size			Number of Clusters			Cluster Size		Proportions		Equivalence Differences	Intracluster Correlation	
Assurance*	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(P1)	E(P2)	D0.L | D0.U	E(ρ)	Alpha
0.50132	0.73579	1708	1708	3416	244	244	488	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05
0.60053	0.86576	2212	2212	4424	316	316	632	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05
0.70046	0.95969	3059	3059	6118	437	437	874	7	7	0.5	0.5	-0.05 | 0.05	0.02	0.05

* The number of points used for computation of the prior(s) was 10.
‡ Power was calculated using M1 = E(M1) = 7, M2 = E(M2) = 7, P1 = E(P1) = 0.5, P2 = E(P2) = 0.5, and ρ = E(ρ) = 0.02.

This report shows the required sample size for each assurance target.

Plots Section

Plots
_____
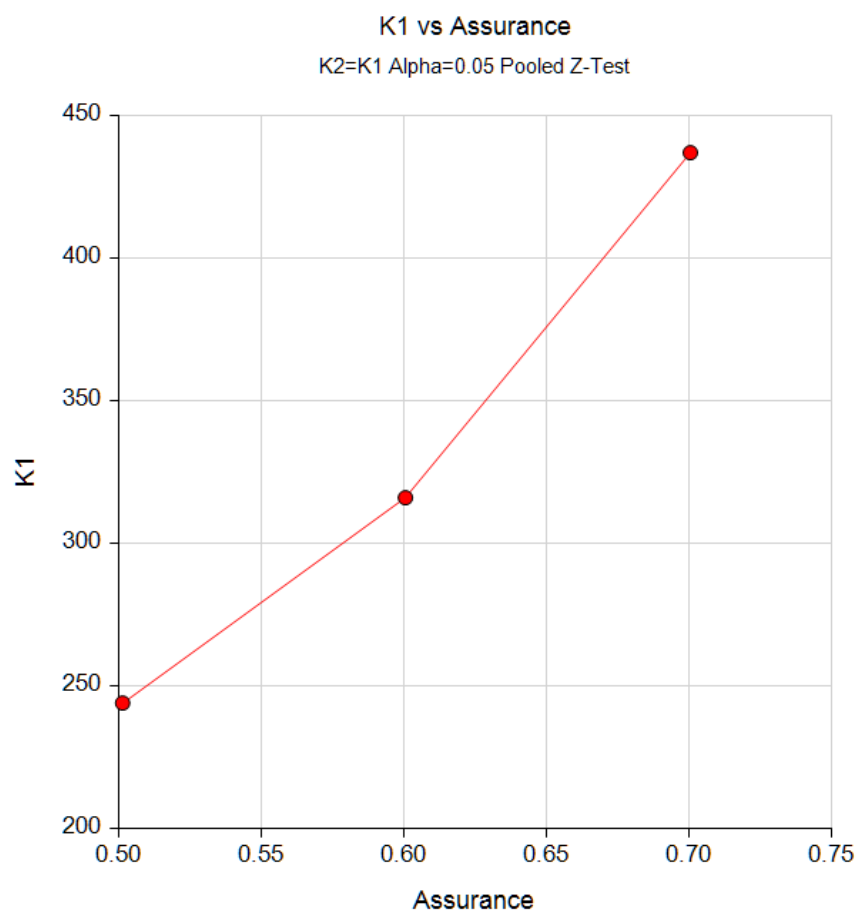
This plot shows the relationship between the sample size and assurance.

Example 4 – Joint Prior Distribution

Suppose a superiority by a margin, pooled z-test will be used in which K1 = K2 = (100, 150, 200, 250, 300), D0.L is -0.04, D0.U is 0.04, and the significance level is 0.05.

The joint prior distribution of the parameters is approximated by the following table. Note that the labels in parentheses identify the corresponding column of the spreadsheet. Also note that the prior probabilities in C6 will be automatically rescaled so that they sum to one.

P1 (C1)	P2 (C2)	ρ (C3)	M1 (C4)	M2 (C5)	Prob (C6)
0.60	0.60	0.01	5	5	0.25
0.61	0.60	0.02	10	10	0.2
0.59	0.59	0.01	5	5	0.35
0.58	0.59	0.02	10	10	0.3
0.58	0.58	0.01	5	5	0.45
0.59	0.58	0.02	10	10	0.4
0.57	0.57	0.01	5	5	0.65
0.56	0.57	0.02	10	10	0.6
0.56	0.56	0.01	5	5	0.55
0.57	0.56	0.02	10	10	0.5
0.55	0.55	0.01	5	5	0.35
0.54	0.55	0.02	10	10	0.3
0.54	0.54	0.01	5	5	0.25
0.55	0.54	0.02	10	10	0.2
0.53	0.53	0.01	5	5	0.25
0.52	0.53	0.02	10	10	0.2

To run this example, the spreadsheet will need to be loaded with the above data.

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 4** 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 ....**Assurance**

Prior Entry Method.......................................**Combined (Enter parameter values and probabilities on spreadsheet)**

Test Type..**Z-Test (Pooled)**

Alpha...**0.05**

K1 (Number of Clusters) **100 200 300 400 500**

Column of M1 Values...................................**C4**

K2 (Number of Clusters) **K1**

Column of M2 Values...................................**C5**

D0.U (Upper Equivalence Difference)............**0.04**

D0.L (Lower Equivalence Difference) ....**-0.04**

Column of P1 Values **C1**
Column of P2 Values **C2**
Column of ρ Values **C3**
Column of Pr(Values).....................................**C6**

Options Tab
_____

Number of Computation Points for each........**10**
  Prior Distribution
Maximum K1 in Sample Size Search.............**1000**

Input Spreadsheet Data
_____

Row	C1	C2	C3	C4	C5	C6
1	0.60	0.60	0.01	5	5	0.25
2	0.61	0.60	0.02	10	10	0.20
3	0.59	0.59	0.01	5	5	0.35
4	0.58	0.59	0.02	10	10	0.30
5	0.58	0.58	0.01	5	5	0.45
6	0.59	0.58	0.02	10	10	0.40
7	0.57	0.57	0.01	5	5	0.65
8	0.56	0.57	0.02	10	10	0.60
9	0.56	0.56	0.01	5	5	0.55
10	0.57	0.56	0.02	10	10	0.50
11	0.55	0.55	0.01	5	5	0.35
12	0.54	0.55	0.02	10	10	0.30
13	0.54	0.54	0.01	5	5	0.25
14	0.55	0.54	0.02	10	10	0.20
15	0.53	0.53	0.01	5	5	0.25
16	0.52	0.53	0.02	10	10	0.20

_____

Output

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

Numeric Results
───
Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: Z-Test (Pooled)
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U   vs.   H1: D0.L < P1 - P2 < D0.U
Prior Type: Joint Multivariate Distribution

Prior Distribution
Point Lists
M1:   C4:   5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10
M2:   C5:   5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10
P1:   C1:   0.6 0.61 0.59 0.58 0.58 0.59 0.57 0.56 0.56 0.57 0.55 0.54 0.54 0.55 0.53 0.52
P2:   C2:   0.6 0.6 0.59 0.59 0.58 0.58 0.57 0.57 0.56 0.56 0.55 0.55 0.54 0.54 0.53 0.53
ρ: C3:   0.01 0.02 0.01 0.02 0.01 0.02 0.01 0.02 0.01 0.02 0.01 0.02 0.01 0.02 0.01 0.02
Prob: C6:   0.25 0.2 0.35 0.3 0.45 0.4 0.65 0.6 0.55 0.5 0.35 0.3 0.25 0.2 0.25 0.2
───

		Sample Size			Number of Clusters			Cluster Size		Proportions		Equivalence Differences	Intracluster Correlation	
Assurance	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(P1)	E(P2)	D0.L | D0.U	E(ρ)	Alpha
0.00618	0.00000	733	733	1466	100	100	200	7.3	7.3	0.56638	0.56655	-0.04 | 0.04	0.01466	0.05
0.26310	0.34391	1466	1466	2932	200	200	400	7.3	7.3	0.56638	0.56655	-0.04 | 0.04	0.01466	0.05
0.52646	0.63983	2199	2199	4398	300	300	600	7.3	7.3	0.56638	0.56655	-0.04 | 0.04	0.01466	0.05
0.69682	0.81015	2932	2932	5864	400	400	800	7.3	7.3	0.56638	0.56655	-0.04 | 0.04	0.01466	0.05
0.80812	0.90306	3664	3664	7328	500	500	1000	7.3	7.3	0.56638	0.56655	-0.04 | 0.04	0.01466	0.05

‡ Power was calculated using M1 = E(M1) = 7.3, M2 = E(M2) = 7.3, P1 = E(P1) = 0.56638, P2 = E(P2) = 0.56655, and ρ =
  E(ρ) = 0.01466.

PASS has calculated the required number of clusters to achieve each assurance goal.

Example 5 – Joint Prior Distribution Validation

The problem given in Example 2 will be used to validate the joint prior distribution method. This will be done by running the individual-prior scenario used in that example through the joint-prior method and checking that the assurance values match.

In Example 2, the prior distribution of P1 is given as follows.

P1	Prob
0.49	0.4
0.51	0.6

The prior distribution of the P2 is approximated by the following table.

P2	Prob
0.49	0.4
0.51	0.6

The prior distribution of the ρ is approximated by the following table.

ρ	Prob
0.01	0.5
0.02	0.5

The prior distribution of the M1 is approximated by the following table.

M1	Prob
7	0.5
9	0.5

The prior distribution of the M2 is approximated by the following table.

M2	Prob
7	0.5
9	0.5

The joint prior distribution can be found by multiplying the independent probabilities. This results in the following discrete probability distribution.

M1 (C1)	M2(C2)	P1 (C3)	P2 (C4)	ρ (C5)	Prob (C6)
7	7	0.49	0.49	0.01	0.02
7	9	0.49	0.49	0.01	0.02
7	7	0.49	0.49	0.02	0.02
7	9	0.49	0.49	0.02	0.02
9	7	0.49	0.49	0.01	0.02
9	9	0.49	0.49	0.01	0.02
9	7	0.49	0.49	0.02	0.02
9	9	0.49	0.49	0.02	0.02
7	7	0.49	0.51	0.01	0.03
7	9	0.49	0.51	0.01	0.03
7	7	0.49	0.51	0.02	0.03
7	9	0.49	0.51	0.02	0.03
9	7	0.49	0.51	0.01	0.03
9	9	0.49	0.51	0.01	0.03
9	7	0.49	0.51	0.02	0.03

9	9	0.49	0.51	0.02	0.03
7	7	0.51	0.49	0.01	0.03
7	9	0.51	0.49	0.01	0.03
7	7	0.51	0.49	0.02	0.03
7	9	0.51	0.49	0.02	0.03
9	7	0.51	0.49	0.01	0.03
9	9	0.51	0.49	0.01	0.03
9	7	0.51	0.49	0.02	0.03
9	9	0.51	0.49	0.02	0.03
7	7	0.51	0.51	0.01	0.045
7	9	0.51	0.51	0.01	0.045
7	7	0.51	0.51	0.02	0.045
7	9	0.51	0.51	0.02	0.045
9	7	0.51	0.51	0.01	0.045
9	9	0.51	0.51	0.01	0.045
9	7	0.51	0.51	0.02	0.045
9	9	0.51	0.51	0.02	0.045

To run this example, the spreadsheet is loaded with the above data.

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 5** 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 ....**Assurance**
Prior Entry Method...**Combined (Enter parameter values and probabilities on spreadsheet)**
Test Type..**Z-Test (Pooled)**
Alpha..**0.05**
K1 (Number of Clusters) **300**
Column of M1 Values......................................**C1**
K2 (Number of Clusters) **K1**
Column of M2 Values......................................**C2**
D0.U (Upper Equivalence Difference)............**0.05**
D0.L (Lower Equivalence Difference) ....**-0.05**
Column of P1 Values **C3**
Column of P2 Values **C4**
Column of ρ Values **C5**
Column of Pr(Values)......................................**C6**

Options Tab

Number of Computation Points for each........**10**
  Prior Distribution
Maximum K1 in Sample Size Search.............**1000**

Input Spreadsheet Data

Row	C1	C2	C3	C4	C5	C6
1	7	7	0.49	0.49	0.01	0.020
2	7	9	0.49	0.49	0.01	0.020
3	7	7	0.49	0.49	0.02	0.020
4	7	9	0.49	0.49	0.02	0.020
5	9	7	0.49	0.49	0.01	0.020
6	9	9	0.49	0.49	0.01	0.020
7	9	7	0.49	0.49	0.02	0.020
8	9	9	0.49	0.49	0.02	0.020
9	7	7	0.49	0.51	0.01	0.030
10	7	9	0.49	0.51	0.01	0.030
11	7	7	0.49	0.51	0.02	0.030
12	7	9	0.49	0.51	0.02	0.030
13	9	7	0.49	0.51	0.01	0.030
14	9	9	0.49	0.51	0.01	0.030
15	9	7	0.49	0.51	0.02	0.030
16	9	9	0.49	0.51	0.02	0.030
17	7	7	0.51	0.49	0.01	0.030
18	7	9	0.51	0.49	0.01	0.030
19	7	7	0.51	0.49	0.02	0.030
20	7	9	0.51	0.49	0.02	0.030
21	9	7	0.51	0.49	0.01	0.030
22	9	9	0.51	0.49	0.01	0.030
23	9	7	0.51	0.49	0.02	0.030
24	9	9	0.51	0.49	0.02	0.030
25	7	7	0.51	0.51	0.01	0.045
26	7	9	0.51	0.51	0.01	0.045
27	7	7	0.51	0.51	0.02	0.045
28	7	9	0.51	0.51	0.02	0.045
29	9	7	0.51	0.51	0.01	0.045
30	9	9	0.51	0.51	0.01	0.045
31	9	7	0.51	0.51	0.02	0.045
32	9	9	0.51	0.51	0.02	0.045

Output

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

Numeric Results
───
Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: Z-Test (Pooled)
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U   vs.   H1: D0.L < P1 - P2 < D0.U
Prior Type: Joint Multivariate Distribution

Prior Distribution
Point Lists
M1:   C1:   7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9
M2:   C2:   7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9 7 9
P1:   C3:   0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.51 0.51 0.51 0.51 0.51 0.51 0.51 0.51 0.51 0.51
            0.51 0.51 0.51 0.51 0.51 0.51
P2:   C4:   0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.51 0.51 0.51 0.51 0.51 0.51 0.51 0.51 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.49 0.51 0.51
            0.51 0.51 0.51 0.51 0.51 0.51
ρ: C5:   0.01 0.01 0.02 0.02 0.01 0.01 0.02 0.02 0.01 0.01 0.02 0.02 0.01 0.01 0.02 0.02 0.01 0.01 0.02 0.02 0.01 0.01 0.02 0.02 0.01 0.01
            0.02 0.02 0.01 0.01 0.02 0.02
Prob: C6: 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.03 0.045
            0.045 0.045 0.045 0.045 0.045 0.045 0.045
───

		Sample Size			Number of Clusters			Cluster Size		Proportions		Equivalence Differences	Intracluster Correlation	
Assurance	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(P1)	E(P2)	D0.L | D0.U	E(ρ)	Alpha
0.76528	0.90118	2400	2400	4800	300	300	600	8	8	0.502	0.502	-0.05 | 0.05	0.015	0.05

‡ Power was calculated using M1 = E(M1) = 8, M2 = E(M2) = 8, P1 = E(P1) = 0.502, P2 = E(P2) = 0.502, and ρ = E(ρ) = 0.015.

PASS has calculated the assurance as 0.76528 which matches the result in Example 2. This validates the joint prior method.