Chapter 577

Confidence Intervals for the Bland-Altman Range of Agreement using Assurance Probability

Introduction

This procedure calculates the sample size necessary for the Bland-Altman range of agreement when the underlying data distribution is normal. The range of agreement is represented by the central proportion of the paired differences. The procedure using the exact confidence interval method of Jan and Shieh (2018) which they show to be superior to the approximate method of Lu *et al.* (2016) which is also available in **PASS**.

This procedure uses assurance probability to determine the optimum sample size.

Technical Details

The results used in this procedure come from Jan and Shieh (2018). This article reports the results of extensive simulations that show that this exact method should be adopted rather than the classical Bland-Altman method to find the confidence interval for the range of agreement. The exact method is based on results of Odeh and Owen (1980) which actually predates the original article by Bland and Altman (1986), so it has been around for a while.

Confidence Interval

Suppose that a study is being planned of paired differences whose distribution is reasonably close to $N(\mu, \sigma^2)$. The analysis involves calculating the range of agreement which is defined as a confidence interval of the central portion of these differences. This central portion is defined as the area between the 100_{1-p}th and 100_{p}th percentiles.

Let X represent a paired difference. Suppose that a random sample of N pairs will be obtained and the usual mean and standard deviation $(\bar{X}, S)$ will be used to estimate the two percentiles as follows

$$\theta_{1-p} = \mu + z_{1-p}\sigma \text{ and } \theta_p = \mu + z_p\sigma$$

where z_p is the 100pth percentile of the standard normal distribution $N(0,1)$.

An exact two-sided, 100(1 – α)% confidence interval for the range of agreement can be defined as

$$\Pr\left(\hat{\theta}_{1-p} < \theta_{1-p} \text{ and } \theta_p < \hat{\theta}_p\right) = 1 - \alpha$$

The confidence interval recommended by Jan and Shieh (2018) is the equal-tailed interval given by

$$(\bar{X} - dS, \bar{X} + dS)$$

where $d = g_{P*,1-\alpha,N-1}$, $P^* = 2p - 1$, and g is calculated so that the above exact confidence interval holds as long as the paired differences are normally distributed. The values of g are tabulated as g'' in Odeh and Owen (1980) and Hahn and Meeker (1991).

Sample Size Based on the Assurance Probability

The method of determining an optimum sample size used in this procedure is determine an N that guarantees with specified lower bound on the assurance probability $(1 - \gamma)$ that a particular half-width of the confidence interval is less than a boundary value, ω. That is, we select N so that $\Pr(H \leq \omega) \geq 1 - \gamma$. This leads to the following expression from which the desired N can be determined by a simple search.

$$\psi(\eta) \geq 1 - \gamma$$

where $\psi(\cdot)$ is the cumulative distribution function of a chi-square random variable with N – 1 degrees of freedom and $\eta = (N-1)\left(\frac{\omega}{g\sigma}\right)^2$.

Example 1 – Finding Sample Size

Suppose a study is planned in which the researcher wishes to construct a two-sided, 95% confidence interval for the range of agreement. The goal is to determine the necessary sample size. The sample size calculation will use the assurance probability criterion. The value of P* is set to 0.95.

The value of the standard deviation is unknown at this time, so the researchers will set it to 1.0 and specify ω in standard deviation units. They set the assurance probability to 0.90 and 0.95. The value of ω is set to range between 2.2 and 2.5.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure window. 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	**Sample Size (N)**
Confidence Level (1 - α)	**0.95**
1 - γ (Lower Bound of Assurance Probability)	**0.9 0.95**
ω (Upper Bound of Assurance Half-Width)	**2.2 2.3 2.4 2.5**
P* (Central Proportion Covered)	**0.95**
σ (Standard Deviation)	**1**

Annotated Output

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

Numeric Results

Numeric Results

Solve For: Sample Size (N)
Assurance Requirement: Pr(H ≤ ω) ≥ 1 - γ
Interval Type: Two-Sided, Equal-Tailed Tolerance Interval

Confidence Level 1 - α	Sample Size N	Central Proportion Covered P*	Upper Bound of Assurance Half-Width ω	Lower Bound of Assurance Probability Target 1 - γT	Lower Bound of Assurance Probability Actual 1 - γA	Std Dev σ	Odeh Owen Factor g''
0.95	504	0.95	2.2	0.90	0.9001	1	2.115
0.95	606	0.95	2.2	0.95	0.9501	1	2.101
0.95	263	0.95	2.3	0.90	0.9000	1	2.180
0.95	316	0.95	2.3	0.95	0.9503	1	2.159
0.95	165	0.95	2.4	0.90	0.9013	1	2.243
0.95	197	0.95	2.4	0.95	0.9502	1	2.217
0.95	115	0.95	2.5	0.90	0.9025	1	2.306
0.95	137	0.95	2.5	0.95	0.9510	1	2.274

Report Definitions
1 - α is the confidence level of the confidence interval of the range of agreement (tolerance interval).
N is the sample size of the study.
P* is the central proportion of the data distribution covered. It is the proportion of observations that fall between the limits. For example, a value of 0.95 indicates that 95% of the variable's values fall between the limits.
ω is the upper bound of the assurance half-width. The sample size guarantees (assures) that 100(1 - γ)% of interval half-widths will be less than this value.
1 - γ_T is the target lower bound of the assurance probability. The assurance probability is the probability that the study half-width will be less than ω.
1 - γ_A is the actual lower bound of the assurance probability achieved by this sample size. It may be different from the target value because of the discrete nature of N.
σ is the population standard deviation of the variable being studied.
g'' is the factor that will be used to construct the tolerance interval. This value is tabulated in Odeh and Owen (1980).

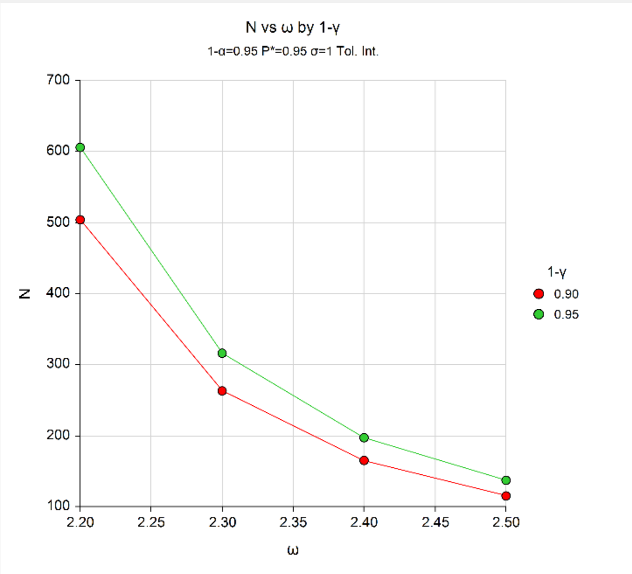
References
Jan, S.L. and Shieh, G. 2018. 'The Bland-Altman range of agreement: Exact interval procedure and sample size determination.' Computers in Biology and Medicine. Vol 100, Pages 247-252.
Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.
Odeh, R.E. and Owen, D.B. 1980. Tables for Normal Tolerance Limits, Sampling Plans, and Screening. Marcel Dekker, Inc. New York, NY.

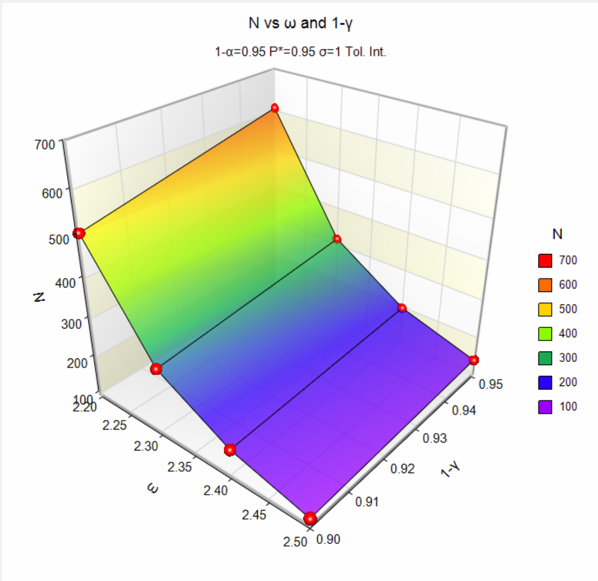
Summary Statements
A sample size of 504 produces a two-sided 95% confidence interval of the range of agreement. This interval is also called an equal-tailed tolerance interval. Given that the data are normally distributed with a standard deviation of 1, the central portion of 0.95 of the distribution will be included in the interval at the stated level of confidence. The design criterion is composed of an assurance probability and associated boundary. Specifically, it is that the interval half-width of an individual study will be less than 2.2 with probability 0.9.

This report shows the calculated sample size for each of the scenarios.

Chart Section

Chart Section





These plots show the sample sizes required for the various scenarios.

Example 2 – Validation using Jan and Shieh (2018)

Jan and Shieh (2018) page 251 give an example of a sample size calculation for a confidence interval based on the assurance probability criterion. They set the confidence coefficient is 95%, the standard deviation is 1, the assurance level is 0.90, P* is 0.95, and the assurance half-width boundary is 2.25. The sample size is listed as 354.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure window. 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 (N)**
Confidence Level (1 - α)	**0.95**
1 - γ (Lower Bound of Assurance Probability)	**0.9**
ω (Upper Bound of Assurance Half-Width)	**2.25**
P* (Central Proportion Covered)	**0.95**
σ (Standard Deviation)	**1**

Output

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

Numeric Results

Numeric Results

Solve For: Sample Size (N)
Assurance Requirement: Pr(H ≤ ω) ≥ 1 - γ
Interval Type: Two-Sided, Equal-Tailed Tolerance Interval

Confidence Level 1 - α	Sample Size N	Central Proportion Covered P*	Upper Bound of Assurance Half-Width ω	Lower Bound of Assurance Probability Target 1 - γT	Lower Bound of Assurance Probability Actual 1 - γA	Std Dev σ	Odeh Owen Factor g''
0.95	354	0.95	2.25	0.9	0.9007	1	2.147

PASS has also calculated a sample size of 354. Thus, the procedure is validated.