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 $100_{1\text{-}p}$th and 100_pth 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

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

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

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 (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**

Output

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

Numeric Reports

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	Standard Deviation 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

1 - α The confidence level of the confidence interval of the range of agreement (tolerance interval).
N The sample size of the study.
P* 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 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 - γT 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 - γA 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 The population standard deviation of the variable being studied.
g'' The factor that will be used to construct the tolerance interval. This value is tabulated in Odeh and Owen (1980).

Summary Statements

A paired (two-measurement) design will be used to obtain a two-sided 95% confidence interval for the Bland-Altman range of agreement. The methodology described in Jan and Shieh (2018) will be used in the (exact) confidence interval calculations. It is assumed that the underlying data distribution is Normal. The central proportion of the paired differences covered is assumed to be 0.95. The population standard deviation is assumed to be 1. To produce a confidence interval with 0.9 probability that the confidence interval half-width will be no more than 2.2, 504 subjects will be needed.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	504	630	126
20%	606	758	152
20%	263	329	66
20%	316	395	79
20%	165	207	42
20%	197	247	50
20%	115	144	29
20%	137	172	35

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.
N The evaluable sample size at which the confidence interval is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated confidence interval.
N' The total number of subjects that should be enrolled in the study in order to obtain N evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' 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.)
D The expected number of dropouts. D = N' - N.

Dropout Summary Statements

Anticipating a 20% dropout rate, 630 subjects should be enrolled to obtain a final sample size of 504 subjects.

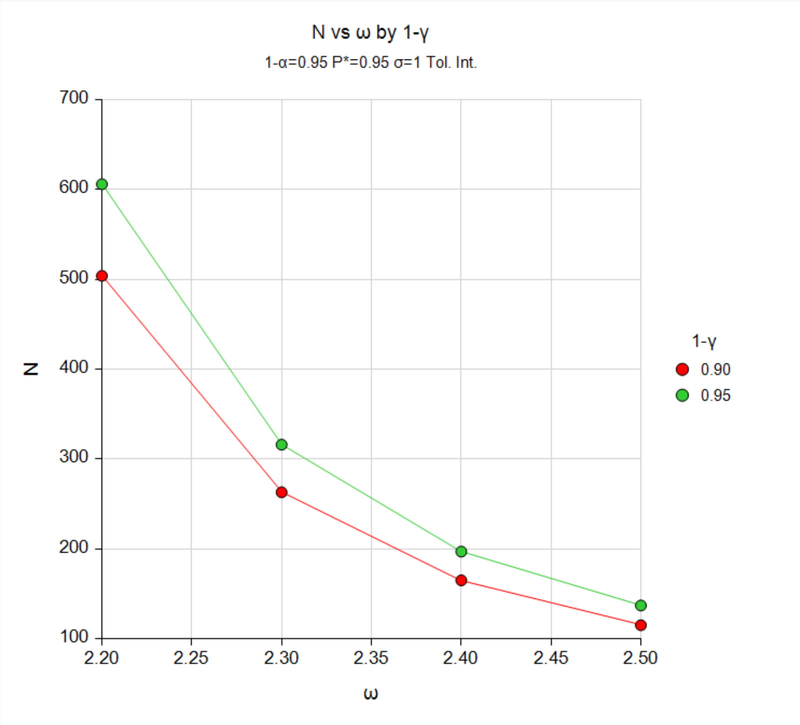
References

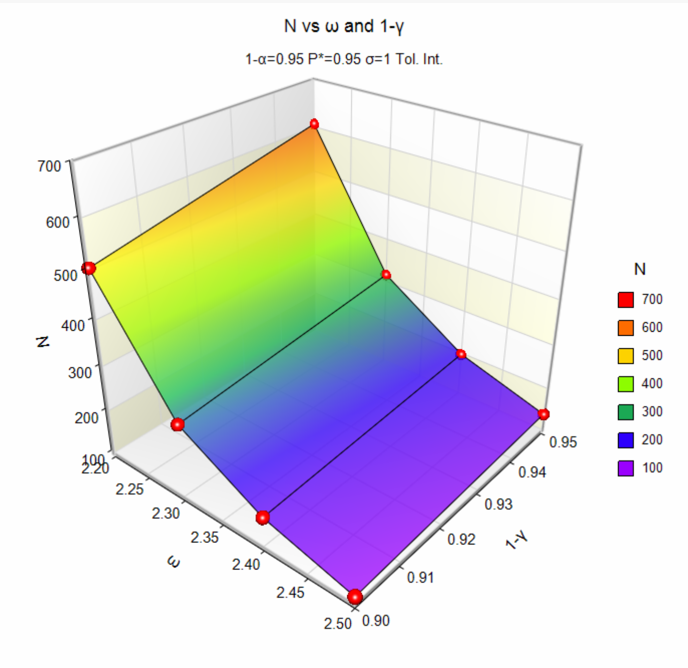
Jan, S.L. and Shieh, G. 2018. 'The Bland-Altman range of agreement: Exact interval procedure and sample size determination.' Computers in Biology and Medicine. Vol 100, Pages 247-252.
Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.
Odeh, R.E. and Owen, D.B. 1980.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

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

Plots Section

Plots





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

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 (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

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	Standard Deviation 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.