

Chapter 582

Confidence Intervals for the Bland-Altman Range of Agreement using Expected Half-Width

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 allows you to choose between two criteria for determining sample size: expected width or assurance probability.

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 here 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 defined as

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

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

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

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

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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 Expected Half-Width

The method of determining an optimum sample size used in this procedure is determine an N that guarantees that the expected half-width of the confidence interval is less than a boundary value, δ . That is, we select N so that $E(H) \leq \delta$, where H is the half-width of the confidence interval. This leads to the following expression from which the desired N can be determined by a simple search.

$$\frac{g_{P^*, 1-\alpha, N-1}}{c} \leq \frac{\delta}{\sigma}$$

where

$$c = \frac{\Gamma\left(\frac{N-1}{2}\right) \sqrt{\frac{N-1}{2}}}{\Gamma\left(\frac{N}{2}\right)}$$

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 expected half-width criterion. The value of P^* is set to 0.9 and 0.95.

The value of the standard deviation is unknown at this time, so the researchers will set it to 1.0 and specify δ in standard deviation units. The value of δ 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 ($1 - \alpha$) **0.95**
 δ (Upper Bound of Expected Half-Width)..... **2.2 2.3 2.4 2.5**
 P^* (Central Proportion Covered) **0.9 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 \(N\)](#)
 E(H) Requirement: $E(H) \leq \delta$
 Interval Type: Two-sided, equal-tailed tolerance interval

Confidence Level $1 - \alpha$	Sample Size N	Central Proportion Covered P^*	Upper Bound of Expected Half-Width		Standard Deviation σ	Odeh Owen Factor g''
			Target δ_T	Actual δ_A		
0.95	42	0.90	2.2	2.192	1	2.206
0.95	219	0.95	2.2	2.200	1	2.203
0.95	32	0.90	2.3	2.291	1	2.310
0.95	116	0.95	2.3	2.299	1	2.304
0.95	26	0.90	2.4	2.382	1	2.406
0.95	74	0.95	2.4	2.397	1	2.405
0.95	21	0.90	2.5	2.493	1	2.524
0.95	52	0.95	2.5	2.497	1	2.509

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- 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.
 δT The target upper bound of the expected half-width of the tolerance interval.
 δA The actual upper bound of the expected half-width of the tolerance interval. 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 0.9. The population standard deviation is assumed to be 1. To produce a confidence interval with an expected confidence interval half-width that is no more than 2.2, 42 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%	42	53	11
20%	219	274	55
20%	32	40	8
20%	116	145	29
20%	26	33	7
20%	74	93	19
20%	21	27	6
20%	52	65	13

- 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, 53 subjects should be enrolled to obtain a final sample size of 42 subjects.

References

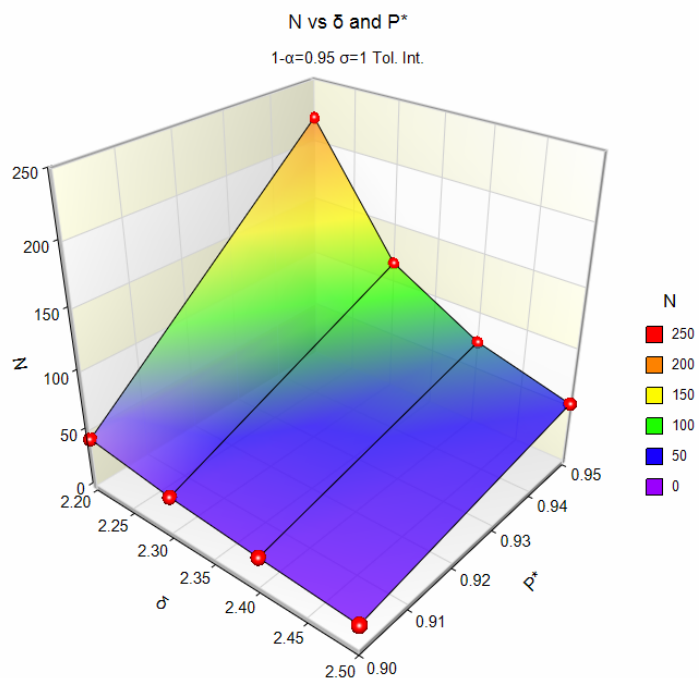
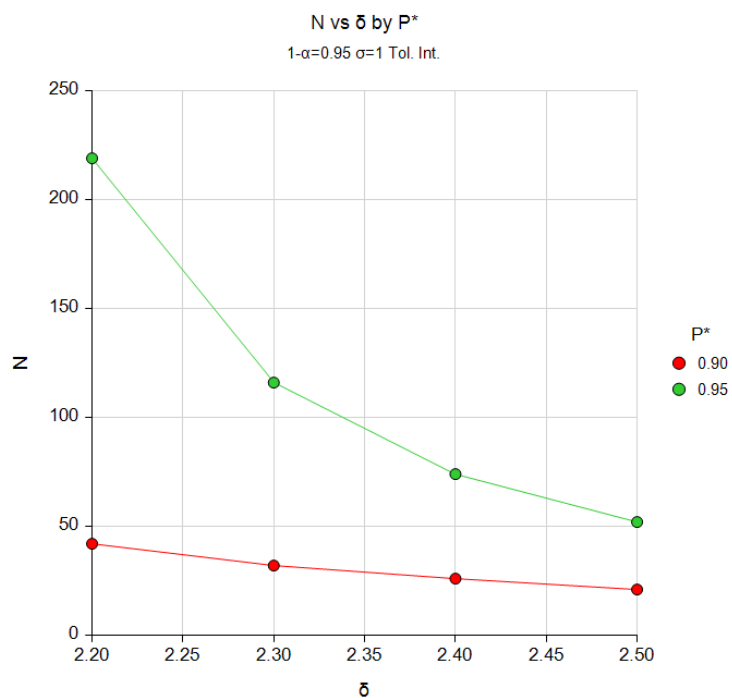
- Jan, S.L. and Shieh, G. 2018. 'The Bland-Altman range of agreement: Exact interval procedure and sample size determination.' Computers in Biology and Medicine. Vol 100, Pages 247-252.
 Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.
 Odeh, R.E. and Owen, D.B.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

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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%, P^* as 0.95, the standard deviation is 19.61, and the upper bound of the expected half-width is 44.1225. The sample size is found to be 155.

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 ($1 - \alpha$) **0.95**
 δ (Upper Bound of Expected Half-Width) **44.1225**
 P^* (Central Proportion Covered) **0.95**
 σ (Standard Deviation) **19.61**

Output

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

Numeric Results

Solve For: [Sample Size \(N\)](#)
 E(H) Requirement: $E(H) \leq \delta$
 Interval Type: Two-sided, equal-tailed tolerance interval

Confidence Level $1 - \alpha$	Sample Size N	Central Proportion Covered P^*	Upper Bound of Expected Half-Width		Standard Deviation σ	Odeh Owen Factor g''
			Target δ_T	Actual δ_A		
0.95	155	0.95	44.1225	44.1113	19.61	2.253

PASS has also calculated a sample size of 155. Thus, the procedure is validated.