Chapter 835

Reliability Demonstration Tests of One Proportion

Introduction

This routine calculates the sample size needed for a *reliability demonstration test* based on the binomial distribution. These tests are conducted by calculating a one-sided confidence bound for a proportion and checking whether the bound is greater than a pre-determined reliability standard. It may be used to find a sample size and/or power for studies of *rare events*.

Technical Details

This procedure is primarily based on results in Guenther (1977) and Hahn and Meeker (1991). Conceptually, the test compares a one-sided confidence bound to the reliability standard. However, the sample size formulas are based on using an exact binomial test of one proportion.

A binomial variable should exhibit the following four properties:

1. The variable is binary --- it can take on one of two possible values.

2. The variable is observed a known number of times. Each observation or replication is called a Bernoulli trial. The number of replications is *n*. The number of times that the outcome of interest is observed is *r*. Thus *r* takes on the possible values 0, 1, 2, ..., *n*.

3. The probability, *P*, that the outcome of interest occurs is constant for each trial.

4. The trials are independent. The outcome of one trial does not influence the outcome of the any other trial.

A binomial probability is calculated using the formula

$$b(r; n, P) = \binom{n}{r} P^r (1 - P)^{n-r}$$

where

$$\binom{n}{r} = \frac{n!}{r!(n-r)!}$$

Following Guenther (1977) define the cumulative binomial as

$$Bi(c; N, P) = Pr(X \leq c) = \sum_{x=0}^{c} b(x; N, P) = \sum_{x=0}^{c} \binom{N}{x} P^x (1 - P)^{N-x}$$

The minimum sample size is found by solving the following two inequalities simultaneously

$$Bi(c; N, 1 - P_{MIN}) \leq \alpha$$

$$Bi(c; N, 1 - P_{TRUE}) \geq Power$$

where *Power* is the probability of a successful demonstration, P_{MIN} is the reliability standard, and P_{TRUE} is the reliability value at which *Power* is calculated.

Procedure Options

This section describes the options that are specific to this procedure. These are located on the Design tab. For more information about the options of other tabs, go to the Procedure Window chapter.

Design Tab

The Design tab contains most of the parameters and options that you will be concerned with.

Solve For

Solve For

Select the parameter you want to solve for. The parameter you select here will be shown on the vertical axis in the plots.

Sample Size

A search is conducted for the minimum sample size that adheres to the two inequalities. Remember that the search is based on two inequalities, so the particular values of the confidence level and *Power* are seldom met exactly.

Power (Prob of Successful Demonstration)

A search is conducted to find the value of *Power* for the values of the other parameters.

Sample Size

N (Sample Size)

Enter one or more values for the sample size. This is the number of individuals selected at random from the population to be in the study.

You can enter a single value or a range of values.

Alpha and Power

Alpha

Specify alpha, the probability of concluding reliability when in fact the object under study is not reliable. Reliability is defined as the probability of a success.

In this procedure, one minus alpha is interpreted as the confidence level of a one-sided confidence bound for the reliability. The demonstration test is may be carried-out by comparing a one-sided lower confidence bound of the reliability to a specified minimum requirement (P_{MIN}). If the confidence bound is larger than P_{MIN}, reliability is demonstrated.

The demonstration test may also be carried out by noting whether the number of adverse events is less than or equal to c, the maximum allowed adverse events.

Alpha ranges from 0 to 1. Typical values range from 0.2 to 0.001.

You can enter a single value such as *0.05* or a series of values such as *0.1 0.05 0.01* or *0.05 to 0.20 by 0.01*.

Power

The power is the probability that the test demonstrates conformance to the reliability standard (P_{MIN}) when the object's reliability is actually greater than P_{MIN}. The power is calculated using the cumulative binomial distribution with $P = P_{TRUE}$, the assumed true reliability.

The range of this parameter is from 0 to 1. Typical values range from 0.8 to 0.999.

You can enter a single value such as *0.95* or a series of values such as *0.9 0.95 0.99* or *0.8 to 0.95 by 0.01*.

Reliability

P_{MIN} (Minimum Reliability)

Enter P_{MIN}, the minimum reliability (proportion of population conforming) that has been set as the standard or requirement.

If the lower confidence bound of the proportion conforming computed from the study is greater than P_{MIN}, reliability is demonstrated. Otherwise, it is not.

The range of this parameter is $0 < P_{MIN} < 0.999999$.

Often, one of the values 0.80, 0.90, 0.95, 0.99, 0.999, or 0.9999 is used.

You can enter a single value such as 0.9 or a series of values such as 0.9 0.95 0.99 or 0.8 to 0.95 by 0.01.

P_{TRUE} (True Reliability)

Enter P_{TRUE}, the assumed true value of the reliability (proportion of population conforming). This is the value of P used to calculate power using the binomial probability distribution.

The range of this parameter is between P_{MIN} and 1. Typical values range from P_{MIN} to 0.9999.

You can enter a single value such as *0.95* or a series of values such as *0.9 0.95 0.99* or *0.8 to 0.95 by 0.01*.

Example 1 – Calculating Sample Size

Suppose a study is planned to determine the sample size required for a reliability demonstration study in which $P_{MIN} = 0.9$, $P_{TRUE} = 0.95$, 0.99, or 0.999, the significance level is 0.05, and the probability of a successful demonstration must be at least 0.95.

Setup

This section presents the values of each of the parameters needed to run this example. First load the **Reliability Demonstration Tests of One Proportion** 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**
Alpha..	**0.05**
Power..	**0.95**
P_{MIN}	**0.9**
P_{TRUE}	**0.95 0.99 0.999**

Annotated Output

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

Numeric Results

Numeric Results for Reliability Demonstration Test
Solved for Sample Size

Minimum Reliability P_{MIN}	True Reliability P_{TRUE}	Target Power	Actual Power	Target Alpha	Actual Alpha	Sample Size N	Maximum Adverse Events c
0.9000	0.9500	0.9500	0.9542	0.050	0.049	298	21
0.9000	0.9900	0.9500	0.9766	0.050	0.049	61	2
0.9000	0.9990	0.9500	0.9714	0.050	0.047	29	0

References
Guenther, William C. 1977. Sampling Inspection in Statistical Quality Control. Griffin's Statistical Monographs, Number 37. London.
Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.
Meeker, W.Q. and Escobar, L.A. 1998. Statistical Methods for Reliability Data. John Wiley & Sons. New York.

Report Definitions
Minimum Reliability, P_{MIN}, is the reliability standard or requirement. It is the required proportion of the population conforming and is used to calculate alpha.
True Reliability, P_{TRUE}, is the reliability (proportion conforming) that is assumed to be 'true' and is used to calculate power.
Power is the probability of rejecting the null hypothesis of unreliability when it is false. In reliability demonstration studies, power is often called the probability of successful demonstration of conformity. It is calculated using P_{TRUE}.
Target Power is the power the design is meant to achieve.
Actual Power is the power the design actually achieves. It is calculated using P_{TRUE}.
Alpha is the significance level of this one-sided test. It is the probability of rejecting the null hypothesis of unreliability when it is true. The demonstration test can be carried-out by comparing a one-sided lower confidence bound of the reliability with a confidence level of one minus alpha to a specified minimum requirement (P_{MIN}). If the confidence bound is larger than P_{MIN}, reliability is demonstrated. The demonstration test can also be carried-out by comparing the number of adverse events to a maximum allowed value, c.
Target Alpha is the significance level the design is meant to achieve.
Actual Alpha is the significance level the design actually achieves. It is calculated using P_{MIN}.
Sample Size, N, is the number of subjects in the study.
Maximum Adverse Events, c, is the number of nonconforming events that are tolerated while still concluding a successful demonstration. It is sometimes called the 'maximum failures allowed.'

Reliability Demonstration Tests of One Proportion

Summary Statements

A test of a single proportion used to demonstrate conformance with a reliability standard
computed from a sample of 298 observations with a minimum reliability requirement of 0.9000 at
a 0.050 significance level. The probability that such a study will have a successful
demonstration is 0.9500 assuming a true reliability of 0.9500. The maximum number of adverse
events allowed with a successful demonstration is 21.

Dropout-Inflated Sample Size

	Sample Size	Dropout-Inflated Enrollment Sample Size	Expected Number of Dropouts
Dropout Rate	**N**	**N'**	**D**
20%	298	373	75
20%	61	77	16
20%	29	37	8

Definitions

Dropout Rate (DR) is 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").
N is the evaluable sample size at which the tolerance 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 tolerance interval.
N' is the total number of subjects that should be enrolled in the study in order to end up with 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., and Wang, H. (2008) pages 39-40.)
D is the expected number of dropouts. D = N' - N.

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

Plots Section
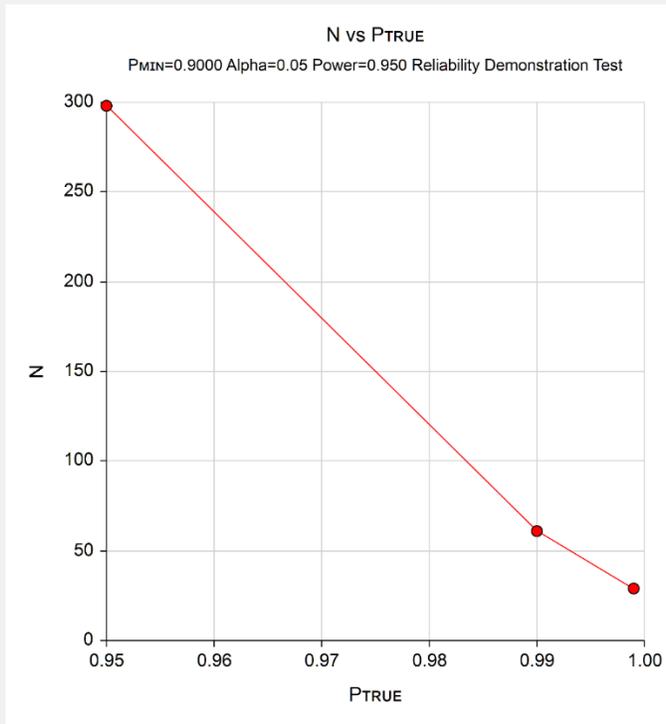
This plot shows the sample size versus the three values of P_{MIN}.

Example 2 – Validation using Hahn and Meeker (1991)

Hahn and Meeker (1991) page 171 find the sample size requirements for a reliability demonstration study in which $P_{MIN} = 0.99$, $P_{TRUE} = 0.999$, the confidence level is 0.9 (alpha = 0.1), and the probability of a successful demonstration (power) must be at least 0.95. They calculated a sample size of 531 with c = 2.

Setup

This section presents the values of each of the parameters needed to run this example. First load the **Reliability Demonstration Tests of One Proportion** 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**
Alpha.. **0.1**
Power.. **0.95**
P_{MIN} **0.99**
P_{TRUE} **0.999**

Output

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

Numeric Results

Numeric Results for the Reliability Demonstration Test
Solved for Sample Size

Minimum Reliability P_{MIN}	True Reliability P_{TRUE}	Target Power	Actual Power	Target Alpha	Actual Alpha	Sample Size N	Maximum Adverse Events c
0.9900	0.9990	0.9500	0.9832	0.100	0.100	531	2

PASS has also calculated the sample size as 531 and c = 2.