Chapter 836

Reliability Demonstration Tests of One Proportion with Adverse Events

Introduction

This routine calculates the sample size needed for a *reliability demonstration test* based on the binomial distribution. These tests may be conducted by comparing a one-sided confidence bound for a proportion and with a pre-determined reliability standard or by comparing the number of adverse events to a calculated minimum value. It may be used to find a sample size and/or power for studies of *rare events*.

Power Not Used

This is one of the few procedures in **PASS** in which the sample calculation does not use power. Instead, a value for power is implied by the specified value of the maximum number of adverse events. Optionally, the power of the design can be calculated.

Technical Details

This procedure is primarily based on results in Guenther (1977), Hahn and Meeker (1991), and Abernethy (2006). Conceptually, the test compares the number of adverse events to a critical value which is chosen to guarantee a certain significance level. 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

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

The minimum sample size is found by finding the smallest value of N the obeys the inequality

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

The power of this test may be calculated using

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

where *power* is the probability of a successful demonstration, P_{MIN} is the reliability standard that must be met, 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 parameter values.

Alpha

The probability of a successful demonstration when the population is actually unreliable.

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 Maximum Adverse Events

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 0.001 to 0.02.

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*.

C (Maximum Adverse Events)

This is the number of nonconforming events that are tolerated while still concluding a successful demonstration. It is sometimes called the maximum failures allowed. If the number of adverse events in the study is greater than c, reliability is not demonstrated. Otherwise, it is.

You can enter any non-negative integers. Often, a value less than 5 is used.

You can find the sample size for a *zero acceptance* study by entering a zero here.

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 calculation is $0 < P_{MIN} < 0.999999$. Above 0.999999, the calculations become unstable. Typical values range from 0.8 to 0.999.

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*.

Calculate Power (Probability of a Successful Demonstration)

Check this option if you want to calculate the power. Note that calculating power will not impact the parameter solved for (Sample Size or Alpha).

If you want to calculate power, you will need to enter a value for P_{TRUE}.

True Reliability (P_{TRUE})

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

The permissible range of P_{TRUE} is $P_{MIN} < P_{TRUE} < 1$. Typical values range from P_{MIN} 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*.

Example 1 – Calculating Sample Size

Suppose a study is planned to determine the sample size required for a reliability demonstration study for values of c from 0 to 4. The other values are $P_{MIN} = 0.9$ and Alpha = 0.05.

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 with Adverse Events** 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**
C (Maximum Adverse Events)................	**0 1 2 3 4**
P$_{MIN}$	**0.9**
Calculate Power.....................................	**Not Checked**

Annotated Output

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

Numeric Results

Numeric Results for the Reliability Demonstration Test using a Fixed c
Solved for Sample Size

Minimum Reliability P$_{MIN}$	Target Alpha	Actual Alpha	Sample Size N	Maximum Adverse Events c
0.9000	0.050	0.047	29	0
0.9000	0.050	0.048	46	1
0.9000	0.050	0.049	61	2
0.9000	0.050	0.047	76	3
0.9000	0.050	0.050	89	4

References
Abernethy, Robert B. 1996. The New Weibull Handbook, Second Edition. Robert B. Abernethy, Florida.
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. It is the required proportion conforming.
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 is 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.
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.'

Summary Statements
A test of a single proportion is used to demonstrate conformance with a minimum reliability standard of 0.9000. The study sample size is 29. The target significance level is 0.050. The significance level actually achieved is 0.047. The maximum number of adverse events allowed with a successful demonstration is 0.

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

Plots Section
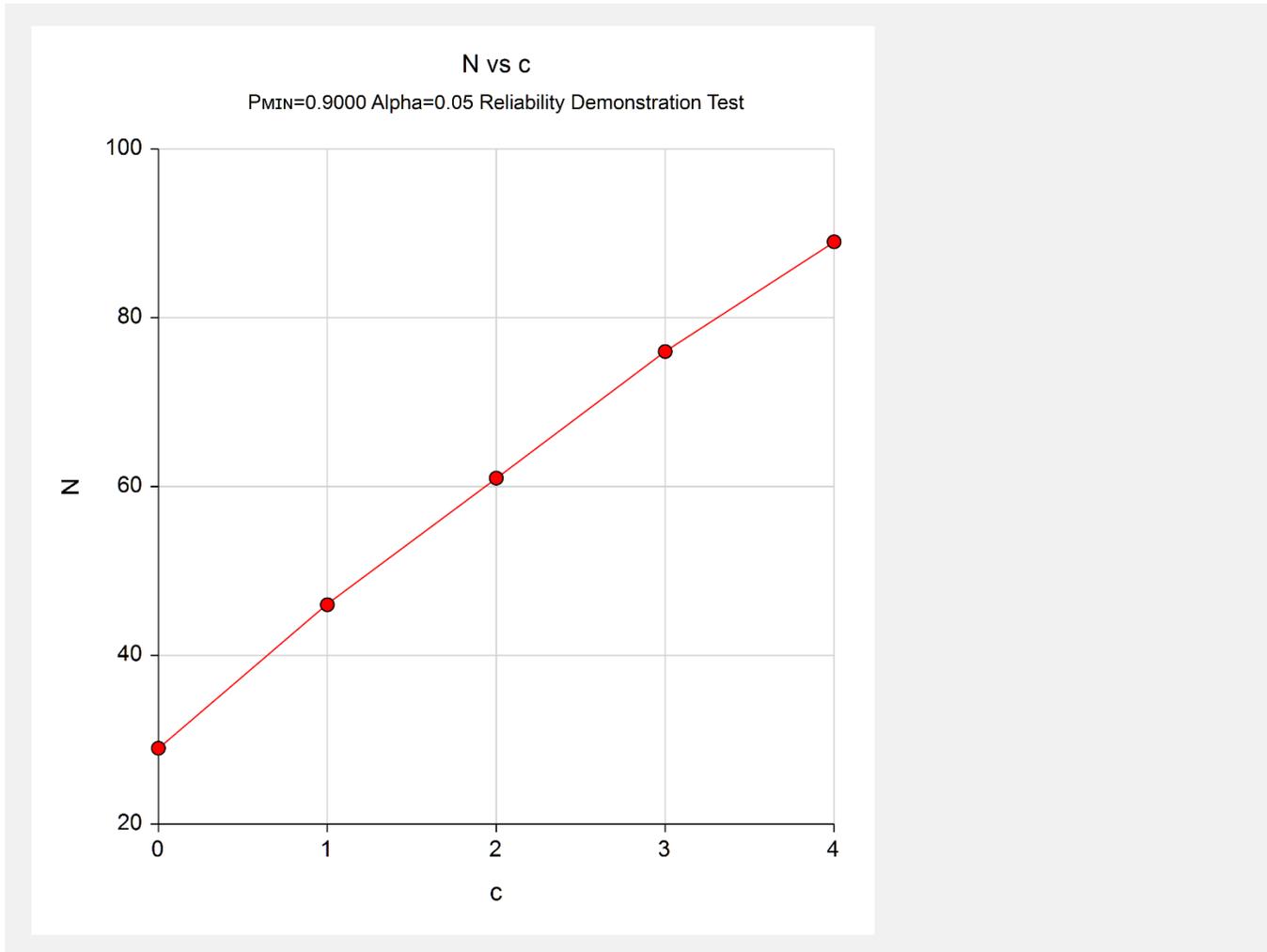
This plot shows the sample size for various value of c.

Example 2 – Validation using Abernethy (1996)

Abernethy (1996) page 8-5 presents a table of sample sizes when c, the number of failures, is zero. One line of the table is for $P_{MIN} = 0.99$ and various confidence level values from 0.5 to 0.9999. These confidence levels are transformed into alpha values using alpha = 1 – confidence level. The resulting sample sizes are 69, 92, 120, 161, 230, 299, 459, 688, and 917.

To show off the additional capabilities of **PASS**, we will also display the power when $P_{TRUE} = 0.999$. These results are not available in Abernethy (1996), but they are very enlightening.

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 with Adverse Events** 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... **0.0001 0.001 0.01 0.05 0.1 0.2 0.3 0.4 0.5**
C (Maximum Adverse Events)................ **0**
P_{MIN} **0.99**
Calculate Power...................................... **Checked**
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 using a Fixed c
Solved for Sample Size ignoring Power

Minimum Reliability P_{MIN}	True Reliability P_{TRUE}	Target Alpha	Actual Alpha	Power	Sample Size N	Maximum Adverse Events c
0.9900	0.9990	0.0001	0.0001	0.6005	917	0
0.9900	0.9990	0.0010	0.0010	0.4976	688	0
0.9900	0.9990	0.0100	0.0099	0.3682	459	0
0.9900	0.9990	0.0500	0.0495	0.2586	299	0
0.9900	0.9990	0.1000	0.0991	0.2056	230	0
0.9900	0.9990	0.2000	0.1983	0.1488	161	0
0.9900	0.9990	0.3000	0.2994	0.1131	120	0
0.9900	0.9990	0.4000	0.3967	0.0879	92	0
0.9900	0.9990	0.5000	0.4998	0.0667	69	0

Note that **PASS** found the same sample size values as Abernethy (1996). Also note that the computed power of these designs shows them to be under-powered.