

## 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  $0, 1, 2, \dots, n$ .
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

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

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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.

## Example 1 – Calculating Sample Size

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

### 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 .....	<b>Sample Size</b>
Alpha.....	<b>0.05</b>
Power (Prob of Successful Demonstration) .....	<b>0.95</b>
$P_{MIN}$ (Minimum Reliability) .....	<b>0.90</b>
$P_{TRUE}$ (True Reliability) .....	<b>0.95 0.99 0.999</b>

### Output

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

### Numeric Reports

Numeric Results							
Solve For: <a href="#">Sample Size</a>							
Test Type: Exact Binomial Test							
Power		Sample Size N	Reliability		Alpha		Maximum Adverse Events c
Target	Actual		Minimum $P_{MIN}$	True $P_{TRUE}$	Target	Actual	
0.95	0.9542	298	0.9	0.950	0.05	0.049	21
0.95	0.9766	61	0.9	0.990	0.05	0.049	2
0.95	0.9714	29	0.9	0.999	0.05	0.047	0
Power	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	The power the design is meant to achieve.						
Actual Power	The power the design actually achieves. It is calculated using $P_{TRUE}$ .						
N	Sample Size. The number of subjects in the study.						
$P_{MIN}$	Minimum Reliability. The reliability standard or requirement. It is the required proportion of the population conforming and is used to calculate alpha.						
$P_{TRUE}$	True Reliability. The reliability (proportion conforming) that is assumed to be "true" and is used to calculate power.						

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Alpha	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 <sub>MIN</sub> ). If the confidence bound is larger than P <sub>MIN</sub> , 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	The significance level the design is meant to achieve.
Actual Alpha	The significance level the design actually achieves. It is calculated using P <sub>MIN</sub> .
c	Maximum Adverse Events. 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 single-group reliability demonstration design will be used to test whether the minimum reliability (success proportion) requirement of 0.9 is met (H<sub>0</sub>: P ≤ 0.9 versus H<sub>1</sub>: P > 0.9). The evaluation will be made using a one-sided, one-sample, exact binomial test, with a Type I error rate (α) of 0.05. If the true reliability (proportion of successes) is assumed to be 0.95 and the needed power (probability of a successful demonstration of reliability) is 0.95, a sample size of 298 units (or observations) will be needed. The maximum number of adverse events allowed for a successful demonstration is 21.

**Dropout-Inflated Sample Size**

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

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 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'	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 Lohknygina, Y. (2018) pages 32-33.)
D	The expected number of dropouts. $D = N' - N$ .

**Dropout Summary Statements**

Anticipating a 20% dropout rate, 373 subjects should be enrolled to obtain a final sample size of 298 subjects.

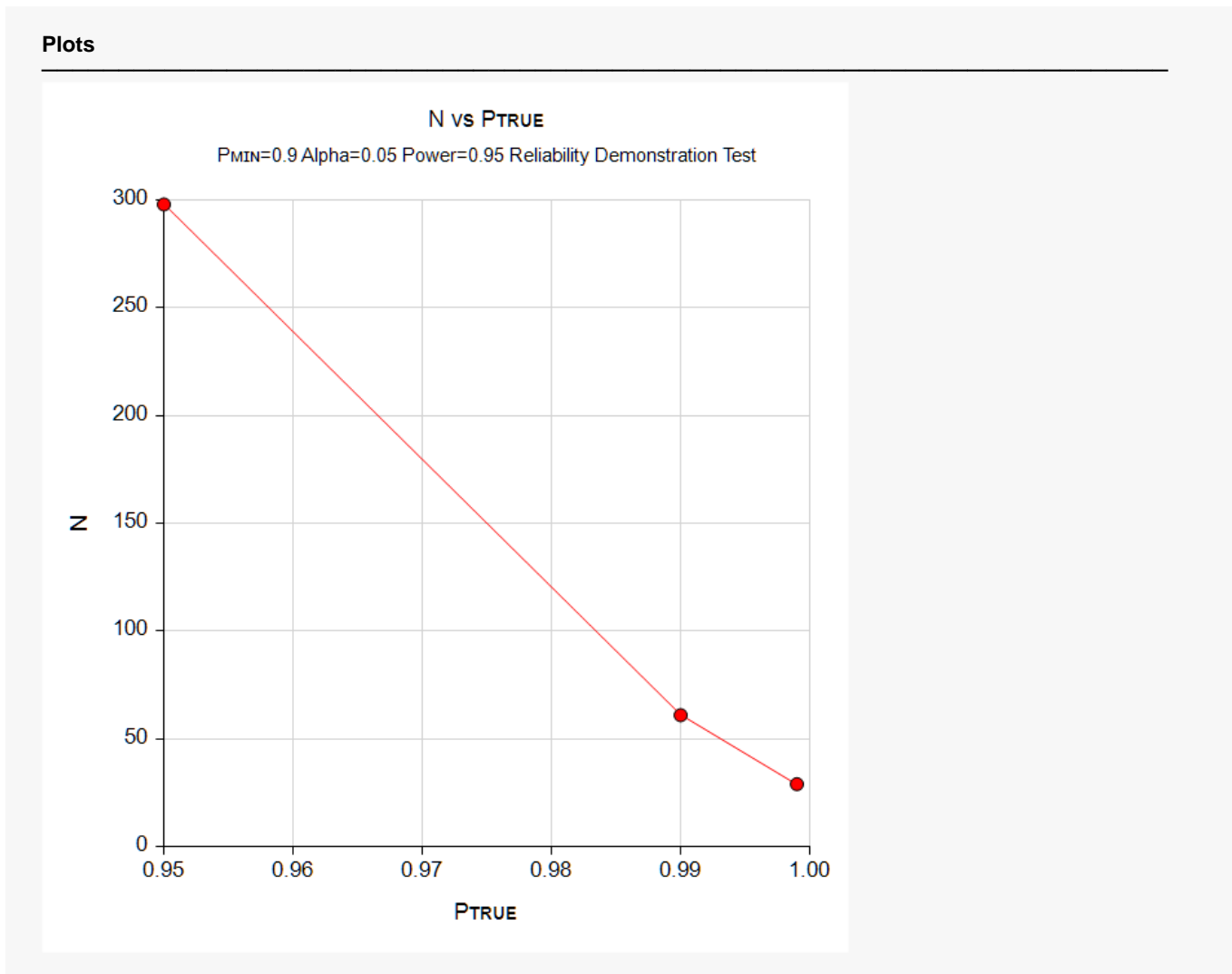
**References**

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.

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

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## 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

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

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Solve For ..... **Sample Size**  
 Alpha.....**0.1**  
 Power (Prob of Successful Demonstration) .....**0.95**  
 $P_{MIN}$  (Minimum Reliability) .....**0.99**  
 $P_{TRUE}$  (True Reliability).....**0.999**

### Output

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

**Numeric Results**

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Solve For: [Sample Size](#)  
 Test Type: Exact Binomial Test

Power		Sample Size N	Reliability		Alpha		Maximum Adverse Events c
Target	Actual		Minimum $P_{MIN}$	True $P_{TRUE}$	Target	Actual	
0.95	0.9832	531	0.99	0.999	0.1	0.1	2

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