Chapter 683

Required Sample Size to Detect a Problem in a Pilot Study

Introduction

Other PASS routines on sample size for external pilot studies are based on a desire to account for uncertainty in, and provide an estimate of, the standard deviation.

This routine provides a sample size estimate for the case in which you want a trial run to find and correct any one of a number of problems that might occur. It obtains the sample size of an external pilot study based on the probabilities that each subject has an equal probability of having the problem and the probability that at least one of the subjects exhibits the problem in the pilot study. Hence, the sample size is determined with a desire to detect and correct any one of a number of problems that might occur in the main study.

The procedure is based on the formulas of Viechtbauer *et al.* (2015).

Technical Details

Sample Size to Detect a Problem in a Pilot Study

Assume that a particular problem (or set of problems) has a probability of occurring in a potential subject of P. Further assume that the probability that this problem occurs in a pilot study of N individuals is C which is

$$C = 1 - (1 - P)^N$$

Hence C is analogous to the confidence level in a confidence internal.

Solving this formula for N

$$N = \frac{\ln(1 - C)}{\ln(1 - P)}$$

Produces an expression for calculating the pilot sample size based on P and C.

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

This option specifies the parameter to be solved for from the other parameters.

Sample Size

N (Pilot Study Sample Size)

Enter one or more values of the pilot study's sample size. The range of N is any positive integer. Typical values range from 10 to 200.

You can enter a single value such as *24* or a series of values such as *20 30 40 70* or *10 to 90 by 10*.

Probabilities

P (Probability Problem Exists)

Enter one or more values of the probability that a study participant actually has the problem of interest. The 'problem' can refer to a single problem or to any one of several problems. These are problems that are expensive to correct once the main study begins. They are problems that reasonably could occur.

Range of P

$0 < P < 1$. Typical values include 0.01, 0.05, 0.1, and 0.15.

You can enter a single value such as *0.05* or a series of values such as *0.01 0.05 0.1 0.15* or *0.01 to 0.10 by 0.01*.

C (Probability Problem Occurs)

Enter one or more values for the probability that the problem occurs at least once in the pilot study.

Range of C

$0 < C < 1$. Typical values include 0.8, 0.85, 0.9, 0.95, 0.99.

You can enter a single value such as 0.90 or a series of values such as *0.8 0.9 0.95* or *0.8 to 0.96 by 0.02*.

Example 1 – Calculating the pilot study sample size

Suppose you want to find appropriate pilot study sample sizes when P = 0.02 0.05 0.07 0.1 and C = 0.80 0.90 0.95 0.99.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Required Sample Size to Detect a Problem in a Pilot Study** procedure. You may then make the appropriate entries as listed below, or open **Example 1** by going to the **File** menu of the procedure window and choosing **Open Example Template**.

Option   **Value**

Design Tab
Solve For .... **NPILOT (Pilot Sample Size)**
P (Probability Problem Exists) **0.02 0.05 0.07 0.1**
C (Probability Problem Occurs) **0.80 0.90 0.95 0.99**

Annotated Output

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

Numeric Results

Numeric Results ————————————————————————————————————

Pilot Study Sample Size NPILOT	Probability Problem Exists P	Probability Problem Occurs C
79.7	0.0200	0.8000
114.0	0.0200	0.9000
148.3	0.0200	0.9500
227.9	0.0200	0.9900
31.4	0.0500	0.8000
44.9	0.0500	0.9000
58.4	0.0500	0.9500
89.8	0.0500	0.9900
22.2	0.0700	0.8000
31.7	0.0700	0.9000
41.3	0.0700	0.9500
63.5	0.0700	0.9900
15.3	0.1000	0.8000
21.9	0.1000	0.9000
28.4	0.1000	0.9500
43.7	0.1000	0.9900

Report Definitions
NPILOT is the sample size of the pilot study.
P is the probability that a subject has the problem of interest.
C is the probability that at least one problem occurs in the pilot study.

References
Viechtbauer, W., Smits, L., Kotz, D., Bude, L., Spigt, M., Serroyen, J., Crutzen, R. 2015. 'A simple formula for the calculation of sample size in pilot studies'. Journal of Clinical Epidemiology. Vol 68. Pages 1375-1379.

Required Sample Size to Detect a Problem in a Pilot Study

Summary Statements ——
A pilot study sample size of 79.7 has a probability of at least 0.8000 that a problem will
occur in at least one of the participants. This assumes that each individual has a probability
of 0.0200 of exhibiting the problem.

This report shows the calculated sample size for each of the scenarios. You can round the sample size to an integer as appropriate.

Plots Section
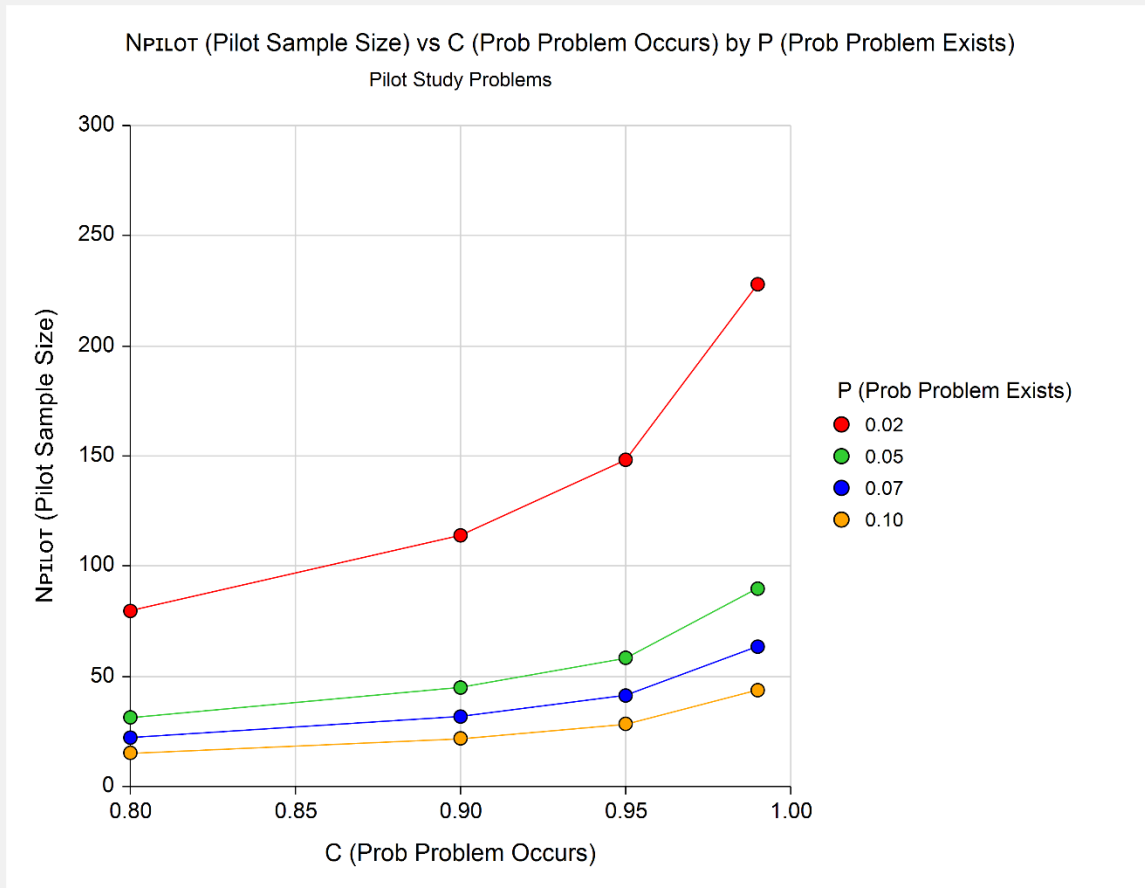
This plot shows the various values of the pilot sample size for various values of the probabilities.

Example 2 – Validation using Viechtbauer *et al*. (2015)

Viechtbauer *et al*. (2015) page 1376 give an example in which P = 0.15 and C = 0.95. They find the sample size to be 18.43.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Required Sample Size to Detect a Problem in a Pilot Study** procedure. You may then make the appropriate entries as listed below, or open **Example 2** by going to the **File** menu of the procedure window and choosing **Open Example Template**.

Option   **Value**

Design Tab
Solve For .... **NPILOT (Pilot Sample Size)**
P (Probability Problem Exists) **0.15**
C (Probability Problem Occurs) **0.95**

Output

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

Numeric Results

Numeric Results ───

Pilot Study Sample Size NPILOT	Probability Problem Exists P	Probability Problem Occurs C
18.4	0.1500	0.9500

PASS matches the pilot sample size.