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*.

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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

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	**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**

Output

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

Numeric Reports

Numeric Results

Solve For: NPILOT (Pilot Sample Size)

Pilot Study Sample Size NPILOT	Probability that Problem Exists P	Probability that Problem Occurs C
79.7	0.02	0.80
114.0	0.02	0.90
148.3	0.02	0.95
227.9	0.02	0.99
31.4	0.05	0.80
44.9	0.05	0.90
58.4	0.05	0.95
89.8	0.05	0.99
22.2	0.07	0.80
31.7	0.07	0.90
41.3	0.07	0.95
63.5	0.07	0.99
15.3	0.10	0.80
21.9	0.10	0.90
28.4	0.10	0.95
43.7	0.10	0.99

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

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Required Sample Size to Detect a Problem in a Pilot Study

Summary Statements

A pilot study will be used to detect (and correct) problems with the subjects. It is assumed that each subject has an equal probability of the problem of interest. If the probability for each subject to have the problem of interest is 0.02, and the probability is 0.8 that the problem occurs at least once among all the individuals of the pilot study, the corresponding pilot study sample size is 79.7.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size NPILOT	Dropout-Inflated Enrollment Sample Size NPILOT'	Expected Number of Dropouts D
20%	79.7	100	20.3
20%	114.0	143	29.0
20%	148.3	186	37.7
20%	227.9	285	57.1
20%	31.4	40	8.6
20%	44.9	57	12.1
20%	58.4	73	14.6
20%	89.8	113	23.2
20%	22.2	28	5.8
20%	31.7	40	8.3
20%	41.3	52	10.7
20%	63.5	80	16.5
20%	15.3	20	4.7
20%	21.9	28	6.1
20%	28.4	36	7.6
20%	43.7	55	11.3

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.
NPILOT	The evaluable sample size at which power is computed. If NPILOT subjects are evaluated out of the NPILOT' subjects that are enrolled in the study, the design will achieve the stated power.
NPILOT'	The total number of subjects that should be enrolled in the study in order to obtain NPILOT evaluable subjects, based on the assumed dropout rate. After solving for NPILOT, NPILOT' is calculated by inflating NPILOT using the formula NPILOT' = NPILOT / (1 - DR), with NPILOT' 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 = NPILOT' - NPILOT.

Dropout Summary Statements

Anticipating a 20% dropout rate, 100 subjects should be enrolled to obtain a final sample size of 79.7 subjects.

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.

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

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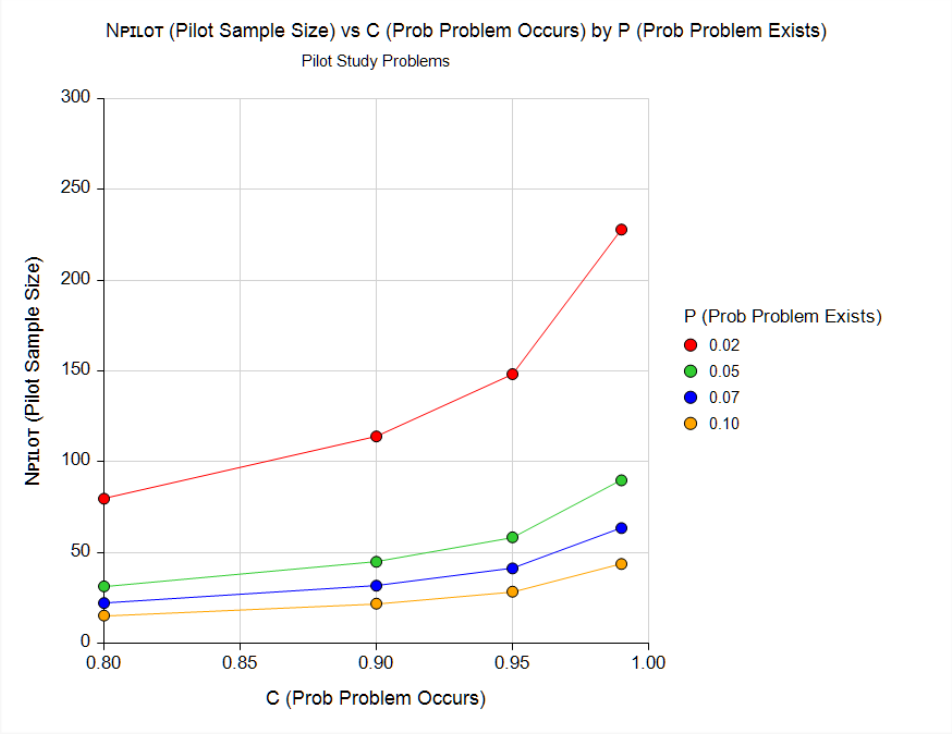
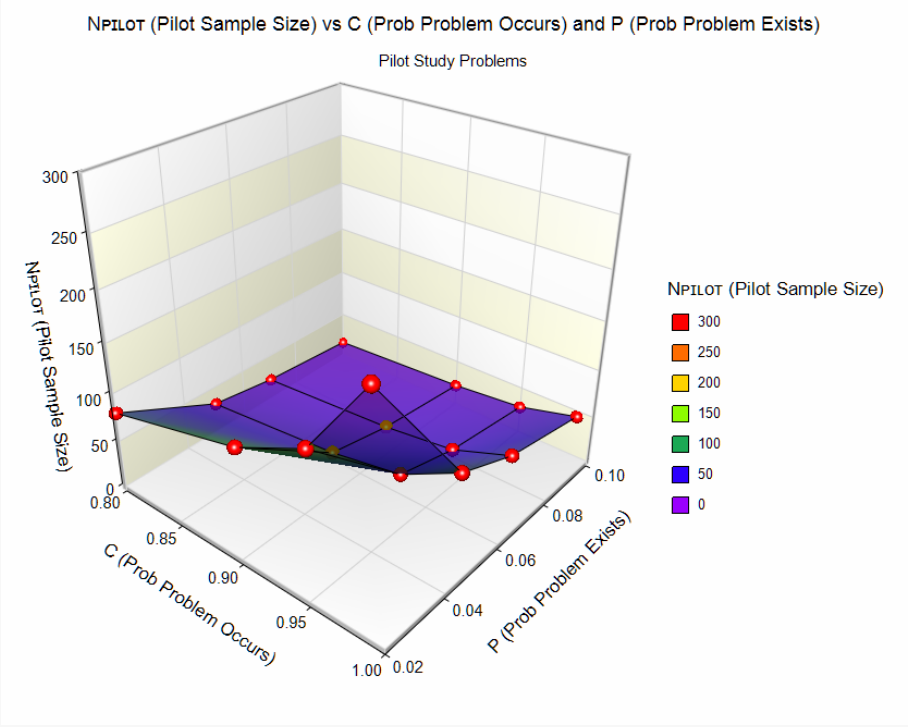
Plots Section

Plots





These plots show the various values of the pilot sample size for various values of the probabilities.

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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

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	**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

Solve For: NPILOT (Pilot Sample Size)

Pilot Study Sample Size NPILOT	Probability that Problem Exists P	Probability that Problem Occurs C
18.4	0.15	0.95

PASS matches the pilot sample size.

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