

Inputs for Power Analysis: Internal Pilot

Course developed by
Deborah H. Glueck and Keith E. Muller

Slides developed by Jessica R. Shaw, Keith E. Muller,
Albert D. Ritzhaupt and Deborah H. Glueck

© Copyright by the Regents of the University of Colorado 1

Learning Objectives

Define internal pilot studies.

Understand the benefits of internal pilot studies.

Understand the limitations of internal pilot studies.

2

An internal pilot design can be a strategy for identifying inputs for power and sample size analysis

An **internal pilot** estimates parameters using data from a portion of the main study.

Coffey and Muller, 1999, 2000, 2003
Coffey et al., 2007
Gurka et al., 2007

3

Internal pilots are conducted in five sequential steps

1. Specify study characteristics
design dimensions
mean differences of a priori interest
planning value standard deviation
recruiting time
2. Collect half of the data (typically)

Coffey and Muller, 1999, 2000, 2003
Coffey et al., 2007
Gurka et al., 2007

4

Internal pilots are conducted in five sequential steps

3. Re-estimate variance based on pilot
4. Re-calculate sample size
5. Collect remaining data and conduct test based on all the data.

Coffey and Muller, 1999, 2000, 2003
Coffey et al., 2007
Gurka et al., 2007

5

Internal pilots are useful for interim power analyses

Using a portion of the main study's data enables better estimation of inputs for power and sample size calculation.

6

Unfortunately, internal pilots have limited applications

Internal pilots are usually not intended for:

- Estimating means or confidence intervals
- Interim data analysis

See Kairalla et al., 2010 for ways to combine internal pilots and interim data analysis.

Kairalla et al., 2010

7

Internal pilots can also inflate the Type I error rate

Recall, Type I error is the probability of incorrectly rejecting the null hypothesis.

Type I error inflation occurs in small studies when the variance is estimated.

For large studies (>~50 participants), no Type I error rate inflation occurs.

Coffey and Muller, 1999, 2000, 2003
Coffey et al., 2007
Gurka et al., 2007

8

Review Summary

- An internal pilot estimates parameters using data from a portion of the main study
- Using a portion of the main study's data enables better estimation of inputs for power and sample size calculation.
- Internal pilots are usually not intended for estimating means, confidence intervals, or interim data analysis

9


