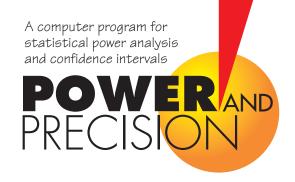
## "Your software is superb!"

— Dr. David Noble, University of Aberdeen



# Find the sample size you need. **FAST**

#### WORK

with confidence

#### GET

the big picture in seconds

#### PRESENT

results profesionally





"I'm using another program. Why should I switch?"

Because with this program

- The interface is a pleasure
- The report is both detailed and clear
- The table and graphs are created effortlessly, and they get it exactly right.

An indispensable resource for grant applications.

#### **EMPOWER YOURSELF**



FOR THE

#### RESEARCHER

This program is incredibly easy to learn and use. The interface is clear and intuitive. The interactive guide will walk you through all steps in the power analysis. The clear instructions ensure that power is computed correctly and the detailed report ensures that it is communicated properly.



FOR THE

#### STATISTICIAN

Spend your time productively and present your results professionally. Create tables and graphs in a matter of seconds rather than hours and incorporate these in study plans for added emphasis and clarity.



FOR THE

## A C A D E M I C I N S T R U C T O R

When students manipulate power interactively the concepts come alive and they "get it". The detailed report serves as an example of how a power analysis should be communicated. The interactive guides, extensive Help system, and worked examples are invaluable resources.

"I've been in love with the earlier version of your program for years, but this one is really amazing."

— Brenda J. Shields, Columbus, OH

This program is universally acclaimed for its clear interface, ease of use and computational accuracy.

The program is currently in use at more than 8,000 institutions including the FDA, CDC, World Health Organization, major universities, pharmaceutical companies, businesses, consulting firms, and medical centers.



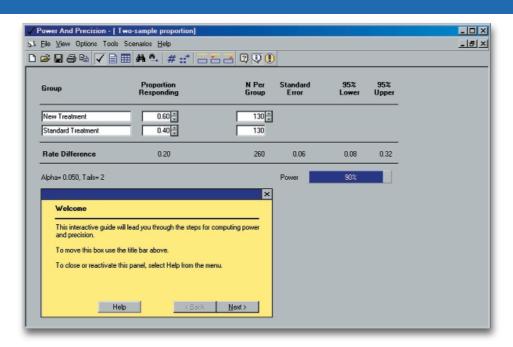






#### Work interactively!

- Interactive guide walks you through all the steps in the power analysis
  - Modify any element in the study and immediately see the impact on power
- Use a wide array of tools to visualize the effect size and to understand the impact of alpha, effect size, and sample size



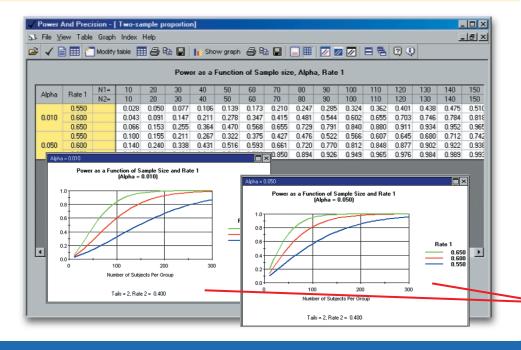
## Create a report with a single click!

- The program generates a lucid, comprehensive report that explains the study design, assumptions, and power.
- The report serves as a teaching tool and may also be used in the statistics section of a study proposal or grant application
  - Export to Word <sup>™</sup> or other word processing program.

#### 51 Elle ⊻iew Help \_|@|×| **☞ ■ ⑤ № ✓ ■ ■** ② Power for a test of the null hypothesis One goal of the proposed study is to test the null hypothesis that the proportion responding is identical in the two populations. The criterion for significance (alpha) has been set at 0.050. The test is 2-tailed, which means that an effect in either direction will be interpreted. With the proposed sample size of 130 and 130 for the two groups, the study will have power of 90.2% to yield a statistically significant result. This computation assumes that the difference in proportions is 0.20 (specifically, 0.60 versus 0.40) This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance. It is also assumed that this effect size is reasonable, in the sense that an effect of this magnitude could be anticipated in this field of research. Precision for estimating the effect size A second goal of this study is to estimate the difference between the two populations. Based on these same parameters and assumptions the study will enable us to report the difference in proportions with a precision (95.0% confidence level) of approximately plus/minus 0.12 points. Specifically, an observed difference of 0.20 would be reported with a 95.0% confidence interval of 0.08 to 0.32.

## Create tables and graphs with a single click!

- Get the big picture in just seconds! Use graphs to quickly evaluate any number of options for study design.
- Export to Word <sup>™</sup>, Excel <sup>™</sup>, PowerPoint<sup>™</sup>
   and other programs.
- Include the graphs in your presentation or grant application to justify your selection of a sample size.



## An Illustrative Example

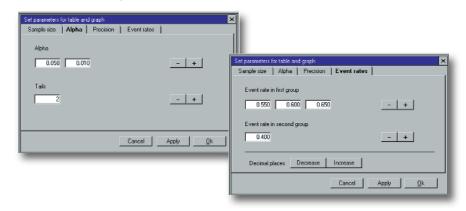
Assume that you are planning a study to compare the proportion of patients responding to two treatments. Patients will be randomly assigned to either the standard treatment or a new treatment.

The standard treatment has a response rate on the order of 40% and the new treatment would be considered useful if it increased the response rate to 60%. What sample size is required to yield power of 90%?

The following steps, which correspond to panels at left, show how you would use the program to quickly compute power and prepare a report and graphs.

Select the module for two independent proportions

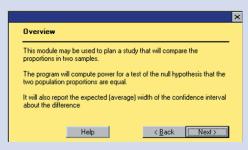
- Enter names for the two groups.
- Enter the response rate for each group (60%, 40%)
- Click on Alpha and select a value (.05)
- Click "Find N" for power of 90%
- The program shows that 130 subjects per group will yield power of 90%
- Click "Make Report" to create the report shown at left. Copy to clipboard and export to Word ® or other word processing program.
- Glick "Make Table" to create the table and graphs. The program picks up the effect size and alpha from the main screen and uses these to automatically select a range of plausible values for sample size. The initial table and graph are created immediately.
- ⊃ Add factors to the table and graphs in seconds! Open the wizard (below), add one or more factors, and click OK. The program automatically nests the factors, adds titles to the tables and graphs, creates legends, sets a new range for the sample size—in an instant.



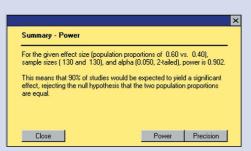
- Pivot the tables and graphs! To modify tables simply drag and drop the columns. All elements of the graphs, including titles and legends, are modified automatically as well.
- Export the report, table and graphs to your word processing program and include then in your study plan or grant application.

How much more impressive would your proposal be with the inclusion of these graphs? Define, create, and export the graphs in less than a minute!

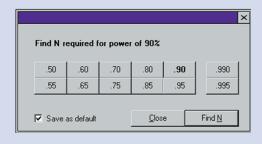
### Tools and Features



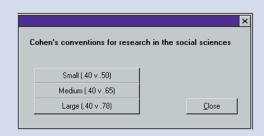
**INTERACTIVE GUIDE.** This guide alerts you to the program's features and offers suggestions for increasing power.



**CONTINUOUS SUMMARY.** This panel provides a running commentary on the current state of the analysis.



FIND THE SAMPLE SIZE AUTOMATICALLY. Click "Find N" and the program displays the sample size required for any level of power. You may specify an allocation ratio (e.g., 2:1) which will be honored in all computations.



#### CONVENTIONS FOR EFFECT SIZE.

If you cannot estimate an effect size, use Cohen's conventions for small, medium, and large effects. Even when you can estimate an effect size, compare it with these values to ensure that your values are realistic.

## SPECIFICATIONS

#### **WORKING WITH RESULTS**

#### Tables

- Print directly
- Copy to clipboard as data and insert into Microsoft Excel® or other spreadsheet

  NEW
- Copy to clipboard as a bitmap and insert into Microsoft Word ® or other word processing program

#### Graphs

- Print directly
- Copy to clipboard as data and insert into Microsoft Word® or other word processing program
- Export as bitmap (BMP), Windows Metafile (WMF) or Windows enhanced Metafile (EMF) and insert into Microsoft Word®, PowerPoint ® or other programs

#### Reports

 Save as RTF file or copy to clipboard and insert into Word ® or other word processing programs.

#### Stored Scenarios (Sensitivity analysis)

- Print directly
- Copy to clipboard as data and insert into Microsoft Excel® or other spreadsheet NEW!
- Copy to clipboard as a bitmap and insert into Microsoft Word ® or other word processing program

#### Tables and graphs

- Pivot the tables interactively NEW!
- Display several graphs at once to assess the impact of factors in isolation or in combination with each other.

  NEW
- Graphs are linked to the tables —
   Drag and drop columns in table, and
   the graphs are updated as well.

  NEW!
- Graphs can be saved as BMP, WMF, EMF files and easily exported to Word, PowerPoint, and other programs.
- Tabulate and graph precision (confidence interval) and standard error as well as power for proportions and means.

#### **TOOLS AND FEATURES**

- Find the sample size for a given level of power
- Assign subjects to groups using allocation ratio
- Store and restore any set of parameters
- Apply Cohen's effect size conventions
- Store scenarios to list (sensitivity analysis)
- Customize the spin control for sample size
- Customize data entry

- Set alpha and tails, link to confidence interval
- Customize the number of decimals displayed
- Display power using digits or bar graph

#### STATISTICAL PROCEDURES

#### t-tests and z-tests

- One group against a null of zero
- One group against a user-specified null
- Paired/change against a null of zero
- Paired/change against a user-specified null
- Two independent groups, enter difference score
- Two independent groups, enter mean for each aroup

#### Proportions

- One group against a null of 50%
- One group against a user-specified null
- Two independent groups (Eight computational options for power including Fisher exact test. Indices include risk difference, relative risk, and odds ratio).
- McNemar test of paired proportions
- KxC test of independent proportions\*
- Sign tests

#### Correlations

- One group against a null of zero
- One group against a user-specified null\*
- Two groups

#### Analysis of variance/covariance

- One way analysis of variance/covariance
- Two way fixed effects factorial anova/ancova
- Three way fixed effects anova/ancova

## Multiple hierarchical linear regression

- Templates for common designs including covariates followed by main effects; main effects followed by interactions; dummy-coded variables; and polynomial regression
- Customize the design with up to 10 sets of variables and up to 99 variables per set
- Computes power for the increment to R-squared at each step and also for the cumulative R-squared at each step
- $\bullet$  Compute power for sequential sets combined

#### Logistic regression\* NEW!

- One continuous covariate
- Two continuous covariates, one partialled
- Two continuous covariates combined
- One categorical covariate up to 5 levels

# POWER AND PRECISION

#### Survival analysis\* NEW!

- Accrual options Prior to study, constant rate, or varies
- Hazard Constant rate or varies
- Attrition (Drop-outs) None, constant rate, or varies

#### Equivalence tests NEW!

- Proportions\*
- Means

#### General Case

 Compute power using the non-central t distribution, non-central F, or non-central chisquare distributions

#### Power, confidence intervals, tolerance intervals

- Compute power for all procedures
- Compute precision (expected width of confidence intervals) for t-tests, z-tests, one sample proportions, two independent sample proportions, and one sample correlation
- Compute tolerance intervals for t-tests

#### Computational Algorithms

Includes exact algorithms for all procedures except where noted by (\*).

#### Help and Technical Support

- Interactive guide
- Continuous summary
- Tip of the day
- Windows Help System including Table of Contents, Index, Step-by-Step Help
- Technical support by e-mail or phone

#### Printed manual

The printed manual explains the logic and proper application of power analysis. It also includes worked examples for each statistical procedure, and details for all algorithms An extensive Help system provides step-by step instructions for each procedure.

## DEVELOPED BY A TEAM OF EXPERTS

Michael Borenstein, Jacob Cohen, Hannah Rothstein, David Schoenfeld, Jesse Berlin, Ed Lakatos

#### Biostat™

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