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# BOOK REVIEW
## Editor: Petra Macaskill

0. SAMPLE SIZE CALCULATIONS IN CLINICAL RESEARCH (2nd edn). Shein-Chung Chow, Jun Shao and Hansheng Wang, Chapman & Hall/CRC, Boca Raton, FL, 2008. No. of pages: xiv + 465 (hardcover). Price: $89.95. ISBN 1-58488-982-9

The aim of this book is to provide the reader with a comprehensive and unified presentation of the statistical concepts and methods for sample size calculation in various situations in clinical research, focusing on the interactions between biostatisticians and clinicians that often occur during the various phases of clinical research and development. It is also intended to give a summary of current and emerging clinical issues and recently developed methodologies in the area of sample size calculation in clinical research. The intended audience is biostatisticians, clinical researchers, pharmaceutical scientists, clinical or medical research associates and clinical programmers or data coordinators in the areas of clinical research and development, in regulatory agencies and in academia.

After a short introductory chapter that gives an overview of the regulatory requirements, basic considerations and different procedures for sample size calculations, and a chapter discussing the necessary considerations that should be taken into account prior to sample size calculation, the remaining 13 chapters are devoted to methods for sample size calculation for different kinds of statistical procedures or tests. Chapter 3 discusses methods for tests that compare means, Chapters 4 and 5 cover large sample and exact tests for proportions, respectively, Chapter 6 is devoted to tests for goodness-of-fit and contingency tables, while Chapter 7 treats comparisons of time-to-event data. Group sequential methods is the topic of Chapter 8, comparing variabilities is discussed in Chapter 9, bioequivalence testing is the subject of Chapter 10, while dose response and microarray studies are treated in Chapters 11 and 12, respectively. Finally, the three last chapters are devoted to Bayesian sample size calculation, nonparametric tests and sample size calculation in some special areas, such as quality of life studies, bridging studies and vaccine clinical trials.

The discussion of a specific test usually follows a standardized procedure: After a discussion of the design and setup of a test, and how to estimate the parameters of the test, the null and alternative hypotheses are given, followed by the test statistic and its rejection region. After this the power of the test is given, and from this the sample size calculation is derived, usually given by an explicit formula. This procedure is repeated for different kinds of null and alternative hypotheses for the same test. Usually three kinds of hypotheses are discussed: Equality, non-inferiority/superiority and equivalence or similarity. This is followed by a numerical example where the application of the methods is illustrated, and sometimes by a section discussing further aspects of the sample size calculation, such as, e.g. variants of the testing procedure. All necessary formulas for parameter estimations, test statistics, rejection regions, power functions and sample size calculations are given. Tables of sample sizes or numerical methods for obtaining the necessary sample size are given when no explicit formulas for sample size calculations are available. The book is well written and easy to read.

In summary, this book provides a useful comprehensive reference of sample size calculation procedures for clinical research. It should be a valuable reference book for biostatisticians and clinical scientists in medical or pharmaceutical research.

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