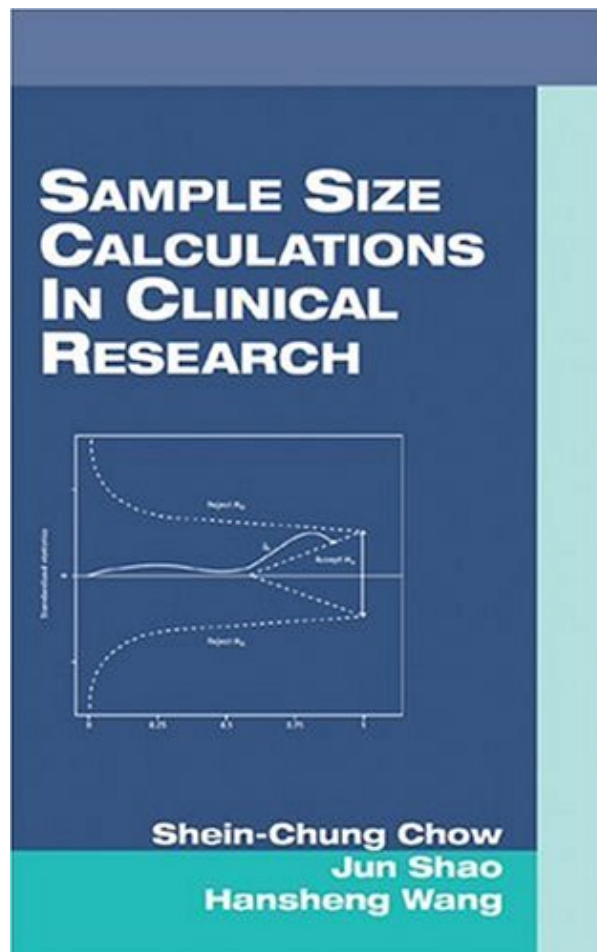


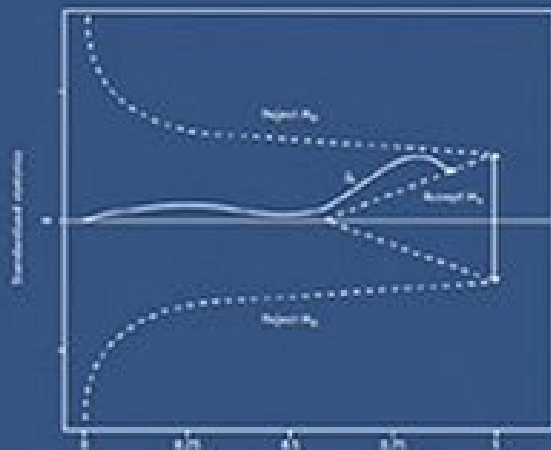
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This well composed book ... contains sample size formulas and examples. ... [A] good reference book for researchers in clinical trials.

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The reference list contains details of an excellent collection of articles. The examples are clearly illustrated. This is a fascinating book, and applied statisticians, health and medical researchers will like it a lot. Statistical consultants will be fond of the book as a reference guide.

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Sample size calculation plays an important role in clinical research. It is not uncommon, however, to observe discrepancies among study objectives (or hypotheses), study design, statistical analysis (or test statistic), and sample size calculation. Focusing on sample size calculation for studies conducted during the various phases of clinical research and development, *Sample Size Calculation in Clinical Research* explores the causes of discrepancies and how to avoid them.

This volume provides formulas and procedures for determination of sample size required not only for testing equality, but also for testing non-inferiority/superiority, and equivalence (similarity) based on both untransformed (raw) data and log-transformed data under a parallel-group design or a crossover design with equal or unequal ratio of treatment allocations. It contains a comprehensive and unified presentation of statistical procedures for sample size calculation that are commonly employed at various phases of clinical development. Each chapter includes, whenever possible, real examples of clinical studies from therapeutic areas such as cardiovascular, central nervous system, anti-infective, oncology, and women's health to demonstrate the clinical and statistical concepts, interpretations, and their relationships and interactions.

The book highlights statistical procedures for sample size calculation and justification that are commonly employed in clinical research and development. It provides clear, illustrated explanations of how the derived formulas and/or statistical procedures can be used.

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- Published on: 2003-03-04
- Released on: 2003-03-04
- Format: Kindle eBook

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sample size an important aspect of trial design

By Michael R. Chernick

The authors of this book have a great deal of clinical trial experience in the pharmaceutical industry as well as strong academic backgrounds. For the clinical trial statistician there is now a rich supply of software products to aid in the determination of sample size for a variety of modeling situations. So knowing formulas is no longer important. What is important is to understand the basis for the formulas. This book provides the industrial perspective and the main fixed sample size designs. In this industry trials are constructed to show superiority, noninferiority and equivalence. These three distinct approaches lead to different results because the null and alternative hypotheses change as you change your goal from superiority to equivalence.

This book makes that important distinction and is very scholarly, providing many of the relevant references. Although most clinical trials are still parallel design randomized controlled trials with fixed sample size, there are more and more trials that allow for sequential decisionmaking and hence the actual total sample size can be subject to randomness. The group sequential trials have been the most successful in this regard. But now there are also more flexible "adaptive designs" that are being used. For group sequential designs see the text by Jennison and Turnbull and for the adaptive designs Chow and Chang and a more recent applied text by Chang are very good sources of information. Software packages that are available to do group sequential and adaptive designs are East by Cytel, Seq+Trials by Insightful Corp., PASS by Number Crunchers and ADDPLAN by a German Company. Also statisticians like Mark Chang and Keaven Anderson have created their own routines for adaptive designs using the R programming language.

29 of 31 people found the following review helpful.

nice coverage of typical sample size problems in clinical trials

By Michael R. Chernick

This is the second edition of a very popular book on sample size estimation that is a valuable reference for any statistician in the industry. we all need to go through such exercises at the beginning of a trial as part of the protocol development.

One disappointment I have with the book is that it does not delineate new topics and other changes/additions from the first edition. Often this is covered by having two Prefaces, the original one from the first edition and a new one from the second edition. The authors unfortunately did not choose to do that. So an owner of the first edition would have to scan through both books to identify the changes.

Another disappointment is the lack of reference to any existing software to do sample size estimation and these days there are a lot of products available. The programs nQuery Advisor and Power and Precision handle equivalence, superiority and noninferiority problems for continuous data. They also provide approximate and exact methods for binomial data. Other packages such as StatXact handle sample size estimation for exact binomial tests as well as for Fisher's Exact test. PASS, S+SeqTrial and East are packages that provide the designs and sample size stopping rules for group sequential procedures and in some cases adaptive designs. Also with the development of version 9 of SAS comes the new procedures power and glmpower that do everything that nQuery can handle.

The value of the book is that it develops the methodology and therefore helps with the understanding of how and when to use the various procedures. Traditional tables that use to be important for sample size calculations are now obsolete given the availability of good software tools. Although the book goes to great lengths to cover almost any application. Most of these applications can be handled these days through the available software packages.

I can definitely recommend this book as a fine reference on sample size estimation for the wide range of trial

applications. I would only try to encourage the authors to drop the use of tables and get up to date by recommending the appropriate software for the various applications.

0 of 0 people found the following review helpful.

Four Stars

By June E. Nezamis

Good reference

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