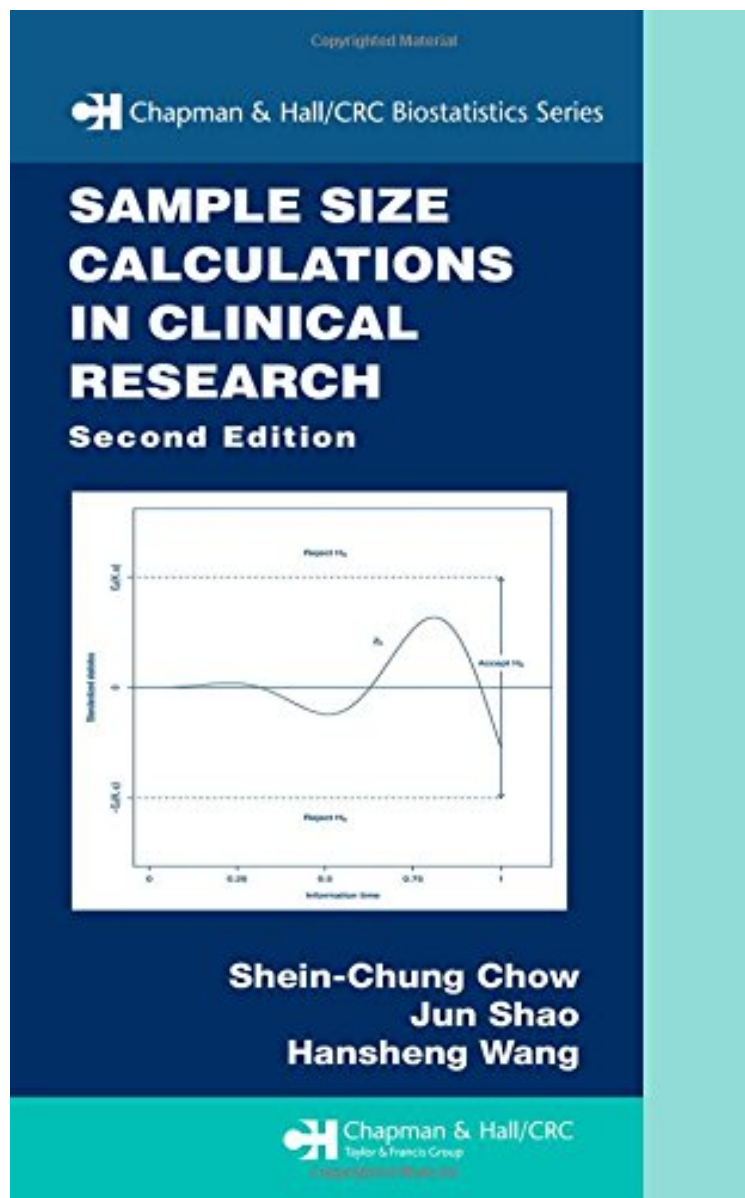


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Sample Size Calculations in Clinical Research, Second Edition (Chapman Hall/CRC Biostatistics Series)

Shein-Chung Chow, Hansheng Wang, Jun Shao
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Shein-Chung Chow, Hansheng Wang, Jun Shao : Sample Size Calculations in Clinical Research, Second Edition (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Sample Size Calculations in Clinical Research, Second Edition (Chapman Hall/CRC

Biostatistics Series):

19 of 19 people found the following review helpful. This *could* have been great...By Mitchell MA
At first browse, this book looks a bit like one of Julius Bendat's excellent texts on time series analysis: dense in formulas, but rewarding the wade. And then I tried to actually _work through_ their examples. A formula-rich book is NO place for typos. I don't mind when the text uses "lossed" for "lost;" I can quickly figure out what was meant. I resent having to do forensics to rebuild what formulas and/or results I should have seen in the examples. That three-star rating reflects two things: the potential this book could have had, and my expectation that sooner or later there will be an ERRATA listing that helps sort this beast out. 0 of 0 people found the following review helpful. Four Stars
By June Sewer
Good reference
31 of 31 people found the following review helpful. 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.

Focusing on an integral part of pharmaceutical development, *Sample Size Calculations in Clinical Research, Second Edition* presents statistical procedures for performing sample size calculations during various phases of clinical research and development. It provides sample size formulas and procedures for testing equality, noninferiority/superiority, and equivalence. A comprehensive and unified presentation of statistical concepts and practical applications, this book highlights the interactions between clinicians and biostatisticians, includes a well-balanced summary of current and emerging clinical issues, and explores recently developed statistical methodologies for sample size calculation. Whenever possible, each chapter provides a brief history or background, regulatory requirements, statistical designs and methods for data analysis, real-world examples, future research developments, and related references. One of the few books to systematically summarize clinical research procedures, this edition contains new chapters that focus on three key areas of this field. Incorporating the material of this book in your work will help ensure the validity and, ultimately, the success of your clinical studies.

" an excellent resource, and the added material (which amounts to roughly 100 pages) more than justifies the publication of the second edition." Joseph Cavanaugh, University of Iowa, *Journal of the American Statistical Association*, March 2009
"The second edition book presents on a total of 465 pages a comprehensive derivation of sample size formulae for a wide variety of testing scenarios from many different clinical research topics well written and easy to read due to the uniform organizational structure of all chapters. Each chapter contains a detailed description of the statistical test problems, the adequate statistical formulae for sample size calculations, numerical examples as well as practical issues this book is recommended to biostatisticians and clinical scientists in medical or pharmaceutical research and provides a comprehensive reference of sample size calculations covering a wide range of different clinical research topics." Iris Burkholder, *Zentralblatt MATH*, 2009
"The second edition has been carefully updated from the first edition. One of the strengths of the book is the organizational structure. Each chapter contains comprehensive references, examples, and practical considerations. The book is clearly laid out and easy to read. The table of contents and the index are comprehensive, which makes the book quite useful as a reference. In summary, this is a useful, comprehensive compendium of almost every possible sample size formula. The strong organization and carefully defined formulae will aid any researcher designing a study." *Biometrics*, December 2008
This impressive book contains formulae for computing sample size in a wide range of settings. One-sample studies and two-sample comparisons for quantitative, binary, and time-to-event outcomes are covered comprehensively, with separate sample size formulae for testing equality, non-inferiority, and equivalence. Many less familiar topics are also covered, including sample size for comparing k samples, bioequivalence, dose response studies, and (new in this second edition) microarray studies and Bayesian sample size determination. Overall, this is a useful reference for the mathematical

statistician Ian White (Medical Research Council Biostatistics Unit), Journal of the Royal Statistical Society " The book is well written and easy to read. 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."Statistics in Medicine, 2008 "This book gives excellent coverage to the many types of study design and aims that are likely to be encountered. The main strength of the book is the vast collection of sample size calculations from many different areas of clinical research an excellent reference for people involved in the designing of clinical research projects."The Journal of Perioperative Practice, September 2008 "This text provides procedures and formulae for the determination of sample size and the appropriate calculation of power for the hypotheses that reflect study objectives under a valid study design. this second edition will appeal to both practitioners and students alike."International Statistical , 2008 Praise for the First Edition This well-composed book contains sample size formulas and examples. a good reference book for researchers in clinical trials. Journal of Statistical Computation and Simulation, Vol. 74, No. 5, May 2004 The reference list contains details of an excellent collection of articles. The examples are clearly illustrated. This is a fascinating book, and applied statisticians and health and medical researchers will like it a lot. Statistical consultants will be fond of the book as a reference guide. Journal of Statistical Computation and Simulation, Vol. 75, No. 9, September 2005