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

Shein-Chung Chow, Hansheng Wang, Jun Shao
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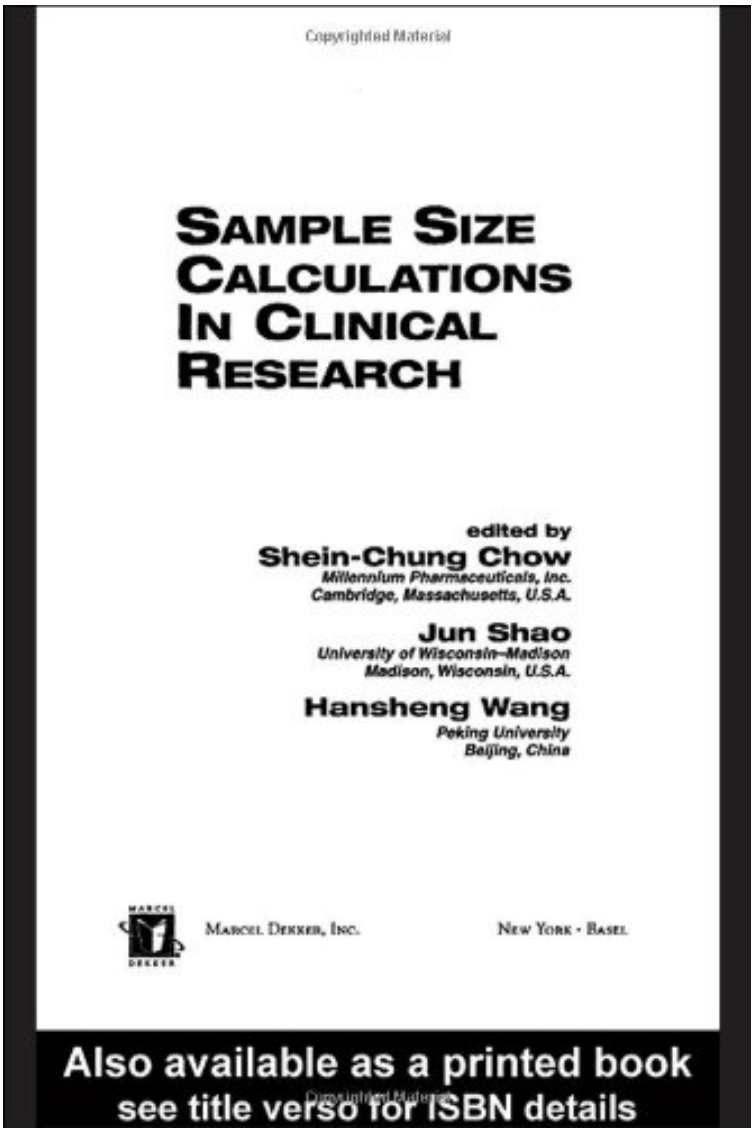

#5001050 in Books 2003-03-04Original language:EnglishPDF # 1 .85 x 6.38 x 9.44l, 1.25 #File Name: 0824709705358 pages | File size: 33.Mb

Shein-Chung Chow, Hansheng Wang, Jun Shao : Sample Size Calculations in Clinical Research (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 (Chapman Hall/CRC Biostatistics Series):

19 of 19 people found the following review helpful. This *could* have been great...By Mitchell MAt 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 StarsBy June SewerGood reference31 of 31 people found the following review helpful. sample size an important aspect of trial designBy Michael R. ChernickThe 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 appoaches 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 Crunchersand 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.

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.

This well composed book contains sample size formulas and examples. [A] good reference book for researchers in clinical trials. - Journal of Statistical Computation Simulation, Vol. 74, No. 5, May 2004The 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.-Journal of Statistical Computation and Simulation, Vol. 75, No. 9, Sept 2005