



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

By Shein-Chung Chow, Hansheng Wang, Jun Shao



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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.



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### Editorial Review

#### Review

"... 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 America 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 Review*, 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

### **Users Review**

#### **From reader reviews:**

#### **Lisa Maurer:**

As people who live in the modest era should be revise about what going on or details even knowledge to make all of them keep up with the era that is always change and advance. Some of you maybe may update themselves by reading books. It is a good choice to suit your needs but the problems coming to you actually is you don't know what type you should start with. This Sample Size Calculations in Clinical Research, Second Edition (Chapman & Hall/CRC Biostatistics Series) is our recommendation to make you keep up with the world. Why, because book serves what you want and wish in this era.

#### **Daniel Gordon:**

The knowledge that you get from Sample Size Calculations in Clinical Research, Second Edition (Chapman & Hall/CRC Biostatistics Series) is the more deep you looking the information that hide into the words the more you get considering reading it. It doesn't mean that this book is hard to know but Sample Size Calculations in Clinical Research, Second Edition (Chapman & Hall/CRC Biostatistics Series) giving you joy feeling of reading. The article writer conveys their point in specific way that can be understood by anyone who read it because the author of this publication is well-known enough. This book also makes your personal vocabulary increase well. Therefore it is easy to understand then can go to you, both in printed or e-book style are available. We propose you for having this Sample Size Calculations in Clinical Research, Second Edition (Chapman & Hall/CRC Biostatistics Series) instantly.

#### **Veronica Lopez:**

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