



# Sample Size Calculations in Clinical Research

By Shein-Chung Chow, Jun Shao, Hansheng Wang

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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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### **Review**

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 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, health and medical researchers will like it a lot.

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