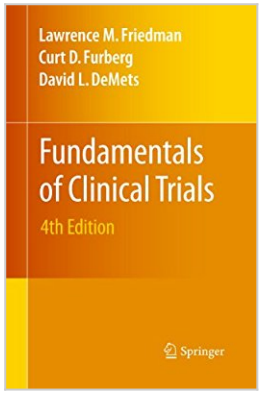

Fundamentals of Clinical Trials

By Lawrence M. Friedman, Curt D. Furberg, David DeMets

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The clinical trial is “the most definitive tool for evaluation of the applicability of clinical research.” It represents “a key research activity with the potential to improve the quality of health care and control costs through careful comparison of alternative treatments” [1]. It has been called on many occasions, “the gold st-dard” against which all other clinical research is measured. Although many clinical trials are of high quality, a careful reader of the medical literature will notice that a large number have deficiencies in design, conduct, analysis, presentation, and/or interpretation of results. Improvements have occurred over the past few decades, but too many trials are still conducted without adequate attention to its fundamental principles. Certainly, numerous studies could have been upgraded if the authors had had a better understanding of the fundamentals. Since the publication of the first edition of this book, a large number of other texts on clinical trials have appeared, most of which are indicated here [2–21]. Several of them, however, discuss only specific issues involved in clinical trials. Additionally, many are no longer current. The purpose of this fourth edition is to update areas in which major progress has been made since the publication of the third edition. We have revised most chapters considerably and added one on ethical issues.

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Fundamentals of Clinical Trials By Lawrence M. Friedman, Curt D. Furberg, David DeMets Bibliography

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Editorial Review

Review

From the reviews of the fourth edition:

“This book is clearly written for students in the arena of health care. Physicians and health care providers can use it as a reference book. … The organization and structure is good and logical. … it deepens the understanding of applications of statistical methods and the analysis of clinical trials. Also, it provides a list of references at the end of each chapter. … In summary, this is an important contribution, providing up-to-date coverage on clinical trial methodology in a logical and systematic manner.” (Technometrics, Vol. 53 (2), May, 2011)

From the Back Cover
This is the fourth edition of a very successful textbook on clinical trials methodology, written by three recognized experts who have long and extensive experience in all areas of clinical trials. Most chapters have been revised considerably from the third edition. A chapter on ethics has been added and topics such as noninferiority and adaptive designs now receive considerable discussion. There is much new material on adverse events, adherence, data monitoring, and issues in analysis. This book is intended for the clinical researcher who is interested in designing a clinical trial and developing a protocol. It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients. The authors use numerous examples of published clinical trials from a variety of medical disciplines to illustrate the fundamentals. The text is organized sequentially from defining the question to trial closeout. One chapter is devoted to each of the critical areas to aid the clinical trial researcher. These areas include pre-specifying the scientific questions to be tested and appropriate outcome measures, determining the organizational structure, estimating an adequate sample size, specifying the randomization procedure, implementing the intervention and visit schedules for participant evaluation, establishing an interim data and safety monitoring plan, detailing the final analysis plan, and reporting the trial results according to the pre-specified objectives. Although a basic introductory statistics course is helpful in maximizing the benefit of this book, a researcher or practitioner with limited statistical background would still find most if not all the chapters understandable and helpful. While the technical material has been kept to a minimum, the statistician may still find the principles and fundamentals presented in this text useful. This book has been successfully used for teaching courses in clinical trial methodology.

About the Author
Lawrence M. Friedman is Marion Rice Kirkwood Professor at Stanford Law School. He is the author, among other works, of A History of American Law; The Legal System: A Social Science Perspective; Crime and Punishment in American History; and The Human Rights Culture.

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