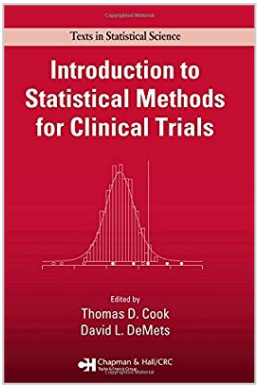

Introduction to Statistical Methods for Clinical Trials (Chapman & Hall/CRC Texts in Statistical Science)

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Clinical trials have become essential research tools for evaluating the benefits and risks of new interventions for the treatment and prevention of diseases, from cardiovascular disease to cancer to AIDS. Based on the authors' collective experiences in this field, **Introduction to Statistical Methods for Clinical Trials** presents various statistical topics relevant to the design, monitoring, and analysis of a clinical trial.

After reviewing the history, ethics, protocol, and regulatory issues of clinical trials, the book provides guidelines for formulating primary and secondary questions and translating clinical questions into statistical ones. It examines designs used in clinical trials, presents methods for determining sample size, and introduces constrained randomization procedures. The authors also discuss how various types of data must be collected to answer key questions in a trial. In addition, they explore common analysis methods, describe statistical methods that determine what an emerging trend represents, and present issues that arise in the analysis of data. The book concludes with suggestions for reporting trial results that are consistent with universal guidelines recommended by medical journals.

Developed from a course taught at the University of Wisconsin for the past 25 years, this textbook provides a solid understanding of the statistical approaches used in the design, conduct, and analysis of clinical trials.

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Editorial Review

Review

… There is much good material in this book. The individual chapters are well written and cover the technical aspects as well. A major strength is the ordering of topics to follow the thought process used in the development and implementation of a protocol from defining the question to reporting results. There are careful discussions on fundamental principles and the pivotal role played by statistics is well brought out. … there is much that practicing pharmaceutical statisticians will find useful in this book. They will find the coverage of fundamental principles useful and the technical content of the book a good reference source. …
?*Pharmaceutical Statistics*, 2010

… fits the need for a contemporary text and handbook that is oriented toward the clinical trial statistician. I highly recommend it and look forward to using it as both a primary and supplemental text in our curriculum, as well as a research resource.
?James J. Dignam, University of Chicago, *JASA*, March 2009

The (technical) statistical content is the main focus of the book and this is what helps it to stand apart from most others on clinical trials (even the more obviously statistically orientated ones). It takes the reader to quite a technical background that would serve him or her well if moving on to research problems in the various areas covered, yet does not lose sight of practical issues. … For those of us with the interest (and need) to grapple with these more statistical issues, I wholeheartedly recommend it.
?*Biometrics*, December 2008

…The book is very well written and clear. … the authors generally strike the right balance for the intended audience. The inclusion of many historically important as well as contemporary examples to illustrate various points throughout the text is a major strength, as is the inclusion of several modern topics not seen in other texts. As a basis for a course in clinical trials for graduate students in biostatistics, this book is outstanding. In addition, statisticians in the pharmaceutical industry, government, or academia … will find this text extremely informative and useful.”
?Michael P. McDermott, University of Rochester Medical Center, *Journal of Biopharmaceutical Statistics*, 2008

About the Author
University of Wisconsin, Madison, USA University of Wisconsin, Madison, USA

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