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

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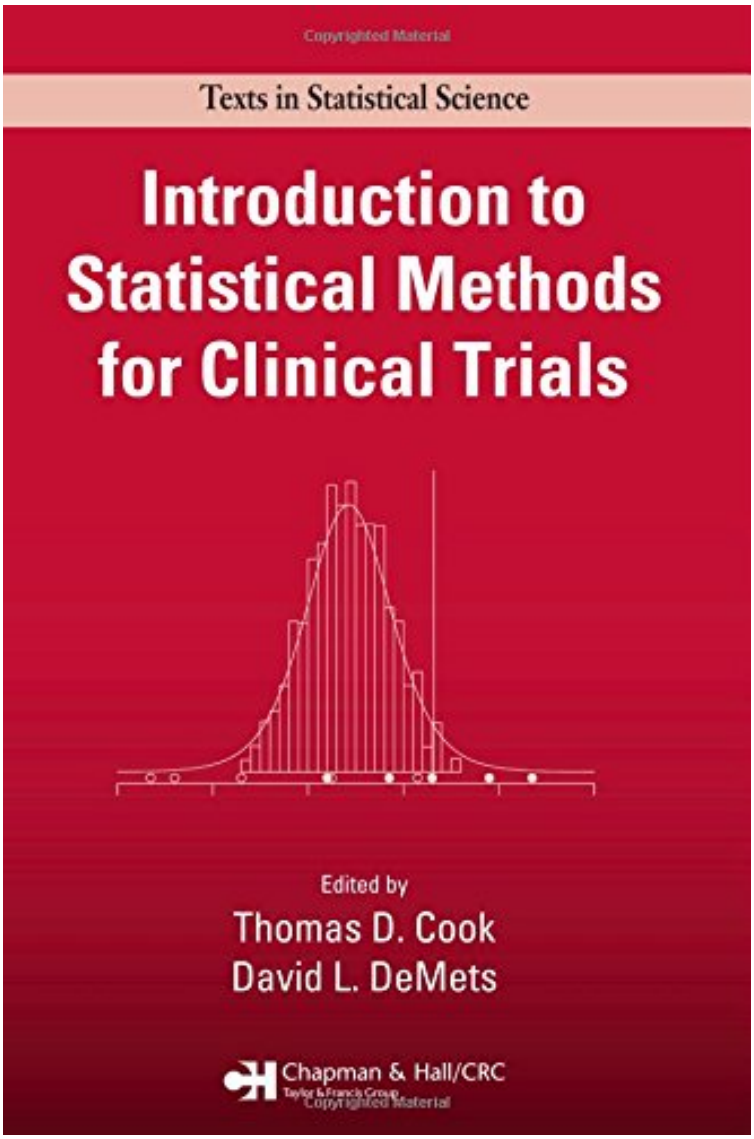

#1116518 in Books Chapman Hall CRC 2007-11-19Original language:EnglishPDF # 1 9.30 x 1.20 x 6.40l, 1.70 #File Name: 1584880279464 pagesChapman Hall CRC | File size: 22.Mb

From Chapman Hall CRC : Introduction to Statistical Methods for Clinical Trials (Chapman Hall/CRC Texts in Statistical Science) before purchasing it in order to gage whether or not it would be worth my time, and all praised Introduction to Statistical Methods for Clinical Trials (Chapman Hall/CRC Texts in Statistical Science):

2 of 3 people found the following review helpful. enjoy reading this book !By JulianeThis book is very well written.

As a statistician in pharma industry, in my opinion, this is a very good introduction book for clinical trial stat.54 of 54 people found the following review helpful. great introduction but not elementaryBy Michael R. ChernickThe author are very accomplished statisticians with many years of clinical trial experience and research. DeMets along with Gordon Lan is famous for the alpha spending function approach that allowed added flexibility to group sequential trials. In addition to authoring several chapters of the book, Cook and Demets edited the book and invited other prominent researchers to contribute to the chapters. The other contributors are Robin Bechhofer, T. Charles Casper, Richard Chappell, Jens Eickhoff, Jan Feyzi, Marian Fisher, Kyungmann Kim, Rebecca Koscik, Mary Lindstrom, and Ellen Roecker.The book covers a wide variety of topics and starts from the basics. But although some people equate introductory in a title to mean elementary that would be a wrong conclusion in this case. Many of the topics are advanced and involve state-of-the-art methodology. The area of adaptive designs is, for example, a very hot topic these days and is the subject of a great deal of research.The chapters are very well written and include most of the crucial topics that come up in trial design and development. For example, in the first chapter randomization is discussed in detail as are issues of trial organization, ethical issues, the reasons why randomized clinical trials are important and some regulatory issues.Chapter 2 covers problem definition, composite outcomes and the use of surrogate endpoints. Chapter 3 covers trial design for all phases of clinical trials and includes sections on early phase trials, phase III trials and the phase IV postmarketing trials. Methodology includes non-inferiority, screening , prevention, therapeutic and adaptive designs.Chapter 4 deals with the important issue of sample size determination primarily using frequentist approaches. This chapter includes the sticky issues of how to deal with clustered data, survival data and censoring due to loss to follow-up and non-adherence to the protocol.This is followed by complete chapters on randomization including response-adaptive randomization, data collection and data quality control, survival analysis. longitudinal data, quality of life data and instrument development, data monitoring and interim analysis, a chapter dealing with missing data, subgroup analysis, multiple testing and ways to avoid bias. The final chapter deals with the very important practical issues on how to close out a trial and prepare and report results.I like this book both as a possible introductory text and as a reference for clinical trial statisticians. The appendix provide sophisticated methods of inference including Brownian motion, information theory, asymptotic theory and the delta method.My only criticism of the book is lack of discussion of software. Statistical software pakages are crucial to the analysis of clinical trials with SAS being the most frequently used. Also there are now a number of fine packages for sample size determiniation and the design of group sequential trials. In this regard Demets and Lan have their own software product and Cytel has East which is now entering the area of adaptive trial design as is AddPlan by Wassmer and the software package produced by Mark Chang. So for a practical text on clinical trials the absence of coverage of the available software along with recommendations of what to use and how to use it is the one glaring omission of the book.I especially recommend this book because from the methodologic viewpoint there is no other book with more depth or broader coverage. Longitudinal analysis and repeated measure designs are very important in clinical trials but are not often covered in introductory biostatistics courses. Chapter 8 covers random effects models, population-average, and subject-specific models and various sophisticated estimation techniques including restricted maximum likelihood estimation, two-stage estimation and generalized estimating equations.0 of 0 people found the following review helpful. Introductory, Not ElementaryBy DallasIt may have been an introduction, but I did not find it to be elementary. I was hired at a new job and first introduced to clinical trials. I got this book hoping it would help me out. I am sure it has a good information, but it was a lot of information and most of it went over my head. I wish they would have given more formulas for sample size calculations rather than theoretical discussions. The book is too wordy--meaning there is a lot of text with very few formulas or workable examples.Overall, it is a pretty good book, but I would not recommend it if you have little or no background in clinical trials (even though it says "introduction" in the title). It does have good topics to get you thinking, but you might have to find other sources to really understand the material.

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.

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, 2008About the AuthorUniversity of Wisconsin, Madison, USA University of Wisconsin, Madison, USA