Design and Analysis of Non-Inferiority Trials (Chapman Hall/CRC Biostatistics Series)

Mark D. Rothmann, Brian L. Wiens, Ivan S.F. Chan
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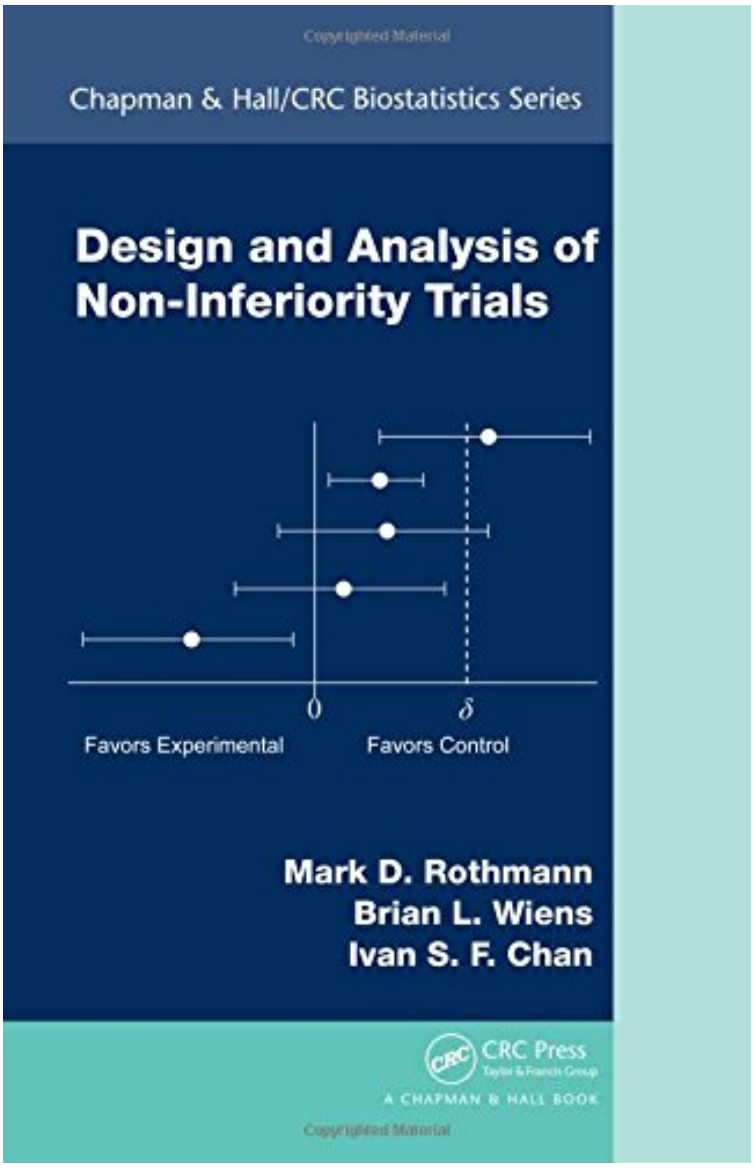

#1932124 in Books Chapman and Hall/CRC 2011-07-12Original language:EnglishPDF # 1 9.21 x 1.00 x 6.14l, 1.70 #File Name: 1584888040454 pages | File size: 30.Mb

Mark D. Rothmann, Brian L. Wiens, Ivan S.F. Chan : Design and Analysis of Non-Inferiority Trials (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Design and Analysis of Non-Inferiority Trials (Chapman Hall/CRC Biostatistics Series):

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Kindle readers support loading this book - for example it will not load into my Kindle Touch nor can it be read with the Kindle Cloud Reader (e.g. in a browser window). In addition, at least when read on an iPad or a Mac, there are certain symbols which are not rendered (a blank appears) making it difficult to make sense of some formulas.I cannot believe that even after over 2 years and the issue being brought to the attention of the publishers at convention booths that this has still not been fixed! Not having all symbols rendered correctly is rather critical in mathematical technical books.0 of 1 people found the following review helpful. Four StarsBy pa106051354Great book with very comprehensive approach buyer must know what they are looking for it is very specliased

The increased use of non-inferiority analysis has been accompanied by a proliferation of research on the design and analysis of non-inferiority studies. Using examples from real clinical trials, Design and Analysis of Non-Inferiority Trials brings together this body of research and confronts the issues involved in the design of a non-inferiority trial. Each chapter begins with a non-technical introduction, making the text easily understood by those without prior knowledge of this type of trial. Topics covered include: A variety of issues of non-inferiority trials, including multiple comparisons, missing data, analysis population, the use of safety margins, the internal consistency of non-inferiority inference, the use of surrogate endpoints, trial monitoring, and equivalence trials Specific issues and analysis methods when the data are binary, continuous, and time-to-event The history of non-inferiority trials and the design and conduct considerations for a non-inferiority trial The strength of evidence of an efficacy finding and how to evaluate the effect size of an active control therapy A comprehensive discussion on the purpose and issues involved with non-inferiority trials, Design and Analysis of Non-inferiority Trials will assist current and future scientists and statisticians on the optimal design of non-inferiority trials and in assessing the quality of non-inferiority comparisons done in practice.

"This important book is relevant because this type of trial is preferred when an approved treatment is available and a conventional placebo-controlled trial would be difficult to justify. These trials are complex and this book goes a long way toward helping the investigator with the issues that arise. This book is comprehensive and includes extensive coverage of every topic. It includes both frequentist and Bayesian approaches as appropriate. Throughout every chapter, topics are fully explained and examples are completely worked out, including statistical formulas and results. a modern and thorough compendium for anyone involved in the design and analysis of noninferiority trials."Mark Bailey, Technometrics, November 2014 " it offers unique perspectives and insights from three renowned experts in clinical trials who work at the U.S. Food and Drug Administration (FDA) and in the pharmaceutical industry. It is refreshing to see FDA and industry perspectives blended thoughtfully, as in this book. Written clearly and concisely, the book is a pleasure to read. Although there are some technical discussions intended for statisticians, most of the book is readily accessible to medical researchers with little statistical training. We recommend the book to anyone interested in NI trialsstatisticians and nonstatisticians alike."Zhiwei Zhang and Lei Nie, Journal of the American Statistical Association, March 2014 "It is a pleasure to see a book completely devoted to the challenging arena of non-inferiority trials. I am very impressed with its depth and breadth, and believe that it will be an important resource for anyone involved in designing non-inferiority trials. The authors weave in many examples, primarily in oncology, as well as a large set of references from the now substantial statistical literature on non-inferiority designs. This book is a must-have resource for those involved in non-inferiority trials for the pharmaceutical industry, and a must-read for those new to non-inferiority trials. A portion of a special topics course in a biostatistics department could be built around this book, and this exposure would be especially valuable for students considering a career in or around the pharmaceutical industry."Erica Brittain, Australian New Zealand Journal of Statistics, May 2012 "This is the first book which is devoted solely to non-inferiority studies. All three authors have published several papers on that topic over the last years. This comprehensive book covers in more than 400 pages nearly all aspects about non-inferiority trials, and beyond. It is also an excellent source of references about non-inferiority studies. recommended for anyone working with clinical trials and in particular for those working in late phase drug development. It is an excellent source of concepts and statistical methods relevant for biostatisticians, clinical epidemiologists and students. This book also is a good source for non-inferiority studies for scientists from the clinical field."Steffen Witte, Journal of Biopharmaceutical Statistics, 2012About the AuthorDr. Mark Rothmann earned his Ph. D. in Statistics at the University of Iowa. He taught several years as a professor and has worked at the U. S. Food and Drug Administration. He has done research in many areas involving the design and analysis of clinical trials. Dr. Brian L. Wiens, received his MS in statistics from Colorado State University and his Ph.D. in statistics from Temple University. He has worked at several pharmaceutical, biotechnology and medical device companies since 1991. He has published research in several areas of design and analysis of clinical trials. Dr. Wiens is a Fellow of the American Statistical Association. Dr. Ivan S.F. Chan received his M.S. in Statistics from The Chinese University of Hong Kong and his Ph.D. in Biostatistics from University of Minnesota. He has worked at Merck Research Laboratories since 1995 and is currently Senior Director and Franchise Head for vaccines, leading the statistical support for all vaccine clinical research programs at Merck. Dr. Chan has published research in many areas of statistics including exact inference,

analysis of non-inferiority trials, and methodologies for clinical trials.