Design and Analysis of Bioavailability and Bioequivalence Studies, Third Edition (Chapman Hall/CRC Biostatistics Series)

Shein-Chung Chow, Jen-pei Liu
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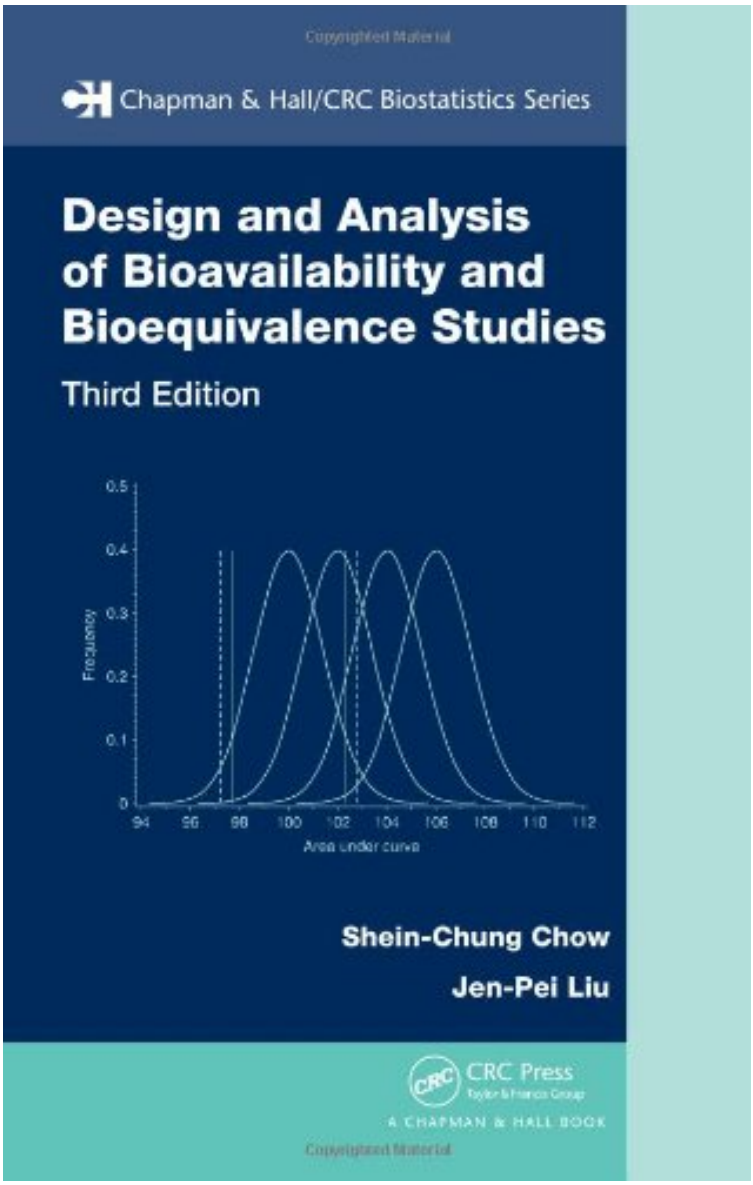

#1598256 in Books Chapman and Hall/CRC 2008-10-15Original language:EnglishPDF # 1 9.30 x 1.50 x 6.10l, 2.50 #File Name: 1584886684760 pages | File size: 16.Mb

Shein-Chung Chow, Jen-pei Liu : Design and Analysis of Bioavailability and Bioequivalence Studies, Third Edition (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 Bioavailability and Bioequivalence Studies, Third Edition

(Chapman Hall/CRC Biostatistics Series):

4 of 4 people found the following review helpful. could be the bible on bioequivalenceBy Michael R. ChernickIt has been over 9 years since the second edition of this book came out. In that time there has been a lot of new research and developments in regulatory guidelines regarding individual and population bioequivalence. I was particularly interested in the bootstrap confidence interval approaches to individual bioequivalence and for a time the FDA 1997 Guidance recommended the bootstrap approach. But in recent years the old standby, average bioequivalence is back in favor. All these events are chronicled in this book. The book is greatly expanded and contains 4 new chapters and around 100 new references. Most topics are covered in great detail and the text appears to be highly detailed.One thing that did bother me though was the large number of references to the 1993 paper by Schall and Luus in Statistics in Medicine. In the paper they provide a bootstrap approach that Shao and Pigeot proved was not consistent. It surprises me that Pigeot's survey articles in the DIJ and the joint work of Shao and Pigeot are not referenced and I did not see any disclaimers about the Schall and Luus procedure.I was also disappointed that there was no discussion of an adaptive design for bioequivalence. I did such a two-stage design while working at Auxilium. It involved sample size reestimation at an interim time point using an AB/BA crossover design.Nevertheless this book is a fantastic reference for bioavailability and bioequivalence and is definitely worth having. To every method there are numerical examples given with real data. Methods for individual and population bioequivalence are complicated and the authors cover all the complications in detail.Now even if there were no updates in the first 16 chapters I would still buy the book because Chapters 17-20 are totally new chapters and are very enlightening. I particularly enjoyed Chapter 19. The book seems to be guided by the FDA research and a lot of emphasis is placed on the regulatory guidance and guidelines related to the various types of bioequivalence studies by the FDA and the EMEA. But in Chapter 19 the authors take an independent look and are critical of some of the guidances based on statistical research in the literature. For instance the use of log transformations is brought into question for AUC and Cmax and back transforming to the original scale can create biases when the analysis is properly done on the log scale.Another nice feature of the book is that all the latest statistical methods that have a place here are mentioned. This includes mixed effects linear and non-linear models, generalized estimating equations, the bootstrap and other nonparametric approaches. Also the complications of ocnfoundiong in crossover trials and the many subtle issues associated with equivalence testing and crossover designs are covered. Nothing is avoided deliberately.Topics that I was not familiar with that interested me were generalized p-values, the linearization approach of Hyslop et al. for parametric estimation of individual bioequivalence, bioequivalence meta-analyses,and in vivo drug interaction studies for nasal sprays.0 of 0 people found the following review helpful. Nice clinical research book!By Seong-Youn HwangThis is a nice book for clinicians to design their clinical researchs. The merits also include easy calculation of sample size, appropriate examples, etc.

Preeminent Experts Update a Well-Respected Book Taking into account the regulatory and scientific developments that have occurred since the second edition, Design and Analysis of Bioavailability and Bioequivalence Studies, Third Edition provides a complete presentation of the latest progress of activities and results in bioavailability and bioequivalence on regulatory requirements, scientific and practical issues, and statistical methodology. New to the Third Edition Four new chapters that present a thorough account of novel developments in the field New and updated sections that reflect recent advances in the statistical methodology in the design and analysis of bioavailability and bioequivalence studies Reorganization of the material into five parts, making it easier to access related information together Over 100 new references from the literature Like its bestselling predecessors, this edition covers all of the statistical problems that may occur in the various stages of design and data analysis. Keeping the mathematics and statistics at a fundamental level, it continues to focus on practical concepts rather than technical details.

the improvement in the table of contents makes it easier to navigate around the book. The new addition has added many new and extra chapters, which does a more comprehensive job of covering the subject of bioavailability and bioequivalence. The SAS examples are better laid out in the new edition and these provide good resources in analyzing these studies. The first and second editions of this book have been invaluable for me and I think it would be a good addition to anybodys shelf. I would encourage anybody working in the industry to ensure there is a copy in their company. The mathematics in the book is not so complex as to make it unreadable for a nonmathematical person. It offers good insight into the workings of the regulatory guidelines and gives good practical advice in dealing with difficult situations.Alun Bedding, Pharmaceutical Statistics, 2010 the book provides an encyclopedic coverage of all these issues and more. [The first] two parts could lead to a good course on bioequivalence and its proxy, namely, bioavailability. International Statistical (2009), 77, 2 The text is well written and rich in all statistical methods In summary, the book provides an important reference covering nearly all of the most relevant literature. Hence, it is a very valuable reference for anyone interested in the statistical aspects of bioequivalence.Journal of Biopharmaceutical Statistics, 2009 Praise for the Second EditionThe second edition brings with it some 170 further pages new material includes sample size determination for higher order cross-over designs, meta-analysis for bioequivalence, and

introduction to population and individual bioequivalence and some regulatory comments. The book is a thorough expose of a subject about which the authors have considerable expert knowledge. Its strengths are its encyclopedic coverage of the subject. Biometrics a useful reference also provides a historical perspective on the evolution of bioequivalence test methods in the context of regulatory policies and public debates on these issues. Detailed description of current statistical concepts, methodology, and underlying assumptions are provided and exemplified. The emphasis of this volume is on statistical concepts and methodology (as it should be). Pharmaceutical Research, 2000 The second edition of the book very substantially revises and expands the contents of the first edition The book is well written and is quite comprehensive. It is useful particularly to statisticians involved in the design and assessment of bioequivalence studies The concepts are presented clearly, and the many numerical illustrations helpfully assist the reader to assimilate the material this is a valuable review of principles and procedures for the statistical assessment of bioequivalence studies. It can be recommended particularly for statisticians involved in these kinds of clinical trials. Non-statisticians interested in the quantitative aspects of these investigations could also benefit from its perusal. ISCB News, June 2004About the AuthorDuke University School of Medicine, Durham, North Carolina, National Taiwan University, Taipei, Taiwan