



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

By Shein-Chung Chow, Jen-pei Liu

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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.

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- Sales Rank: #1584554 in Books
- Brand: Brand: Chapman and Hall/CRC
- Published on: 2008-10-15
- Original language: English
- Number of items: 1
- Dimensions: 9.30" h x 1.50" w x 6.10" l, 2.50 pounds
- Binding: Hardcover
- 760 pages

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Editorial Review

Review

... 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 anybody's 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 Review* (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 Edition

...The 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 2004

About the Author

Duke University School of Medicine, Durham, North Carolina, National Taiwan University, Taipei, Taiwan

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