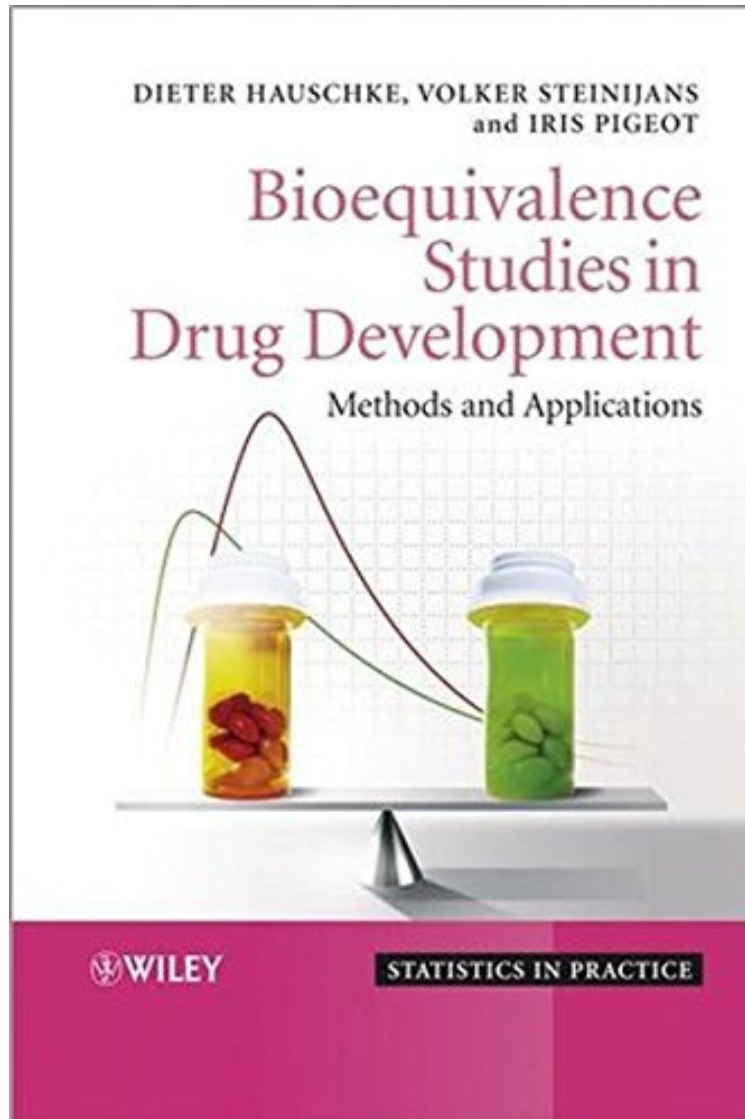


# Bioequivalence Studies in Drug Development: Methods and Applications

*Dieter Hauschke, Volker Steinijans, Iris Pigeot*  
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**Dieter Hauschke, Volker Steinijans, Iris Pigeot : Bioequivalence Studies in Drug Development: Methods and Applications** before purchasing it in order to gage whether or not it would be worth my time, and all praised Bioequivalence Studies in Drug Development: Methods and Applications:

2 of 3 people found the following review helpful. best book on a very important topicBy Michael R. ChernickAs a biostatistician who has written a book on bootstrap methods, been working in the medical device and pharmaceutical

industry since 1995 I feel that I am especially qualified to comment on this book. Bioequivalence is a very important topic. When I was at Auxilium Pharmaceuticals Inc., I actually designed an adaptive cross-over trial for bioequivalence. There are many subtleties that separate bioequivalence trials from other clinical trials. These authors are among the top researchers in this field. For example, I know Iris Pigeot and her fine work with Jun Shao at developing valid and consistent bootstrap tests for individual bioequivalence and for her very excellently written expository papers on the subject which were published in the drug information journal. The authors cover all the models, subtleties and regulatory issues surrounding the three types of bioequivalence, average, individual and population. The statistical community was able to develop successful methods for individual and population bioequivalence at the time when the decision was made to favor individual bioequivalence over average bioequivalence in clinical trial studies for the regulatory authorities. These authors were in the thick of it. They describe all the methods and types of bioequivalence in detail. The book is very well written. I was so excited about the role the bootstrap played as a methodologic tool and as an accepted method by the FDA that I wrote about it in the second edition of my bootstrap book. Unfortunately I soon learned that the FDA had reversed its stand on individual bioequivalence under pressure from the pharmaceutical companies. To me this is a black eye for the industry and the FDA who by and large have done a great job toward bringing safe and effective drugs to market. In the chapter about population and individual bioequivalence the authors provide a detailed description of the events that led the FDA to reverse its decision. My colleague, Terry Hyslop from Thomas Jefferson University Hospital was one of the statisticians who work on parametric methods for individual bioequivalence in her research and her dissertation at Temple University in the 1990s. Here is a woman who did excellent research on a topic that was very exciting to her but has totally moved away from the area after becoming disillusioned by the politics that has affected clinical development. The authors of this book are very authoritative at covering the research literature and Terry's work is covered nicely in the chapter that covers individual and population bioequivalence. The text also does a very good job of covering the pharmacokinetics associated with such studies. For all these reasons I give the book five stars. My only disappointment was that I did not see any discussion of adaptive methods that are now being developed for all phases of clinical trials including sample size reestimation in bioequivalence trials. Well it is a lot to expect everything in one book. This is a book that all biostatisticians should read and perhaps even more so for the FDA statisticians!

Studies in bioequivalence are the commonly accepted method to demonstrate therapeutic equivalence between two medicinal products. Savings in time and cost are substantial when using bioequivalence as an established surrogate marker of therapeutic equivalence. For this reason the design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities. Bioequivalence Studies in Drug Development focuses on the planning, conducting, analysing and reporting of bioequivalence studies, covering all aspects required by regulatory authorities. This text presents the required statistical methods, and with an outstanding practical emphasis, demonstrates their applications through numerous examples using real data from drug development. Includes all the necessary pharmacokinetic background information. Presents parametric and nonparametric statistical techniques. Describes adequate methods for power and sample size determination. Includes appropriate presentation of results from bioequivalence studies. Provides a practical overview of the design and analysis of bioequivalence studies. Presents the recent developments in methodology, including population and individual bioequivalence. Reviews the regulatory guidelines for such studies, and the existing global discrepancies. Discusses the designs and analyses of drug-drug and food-drug interaction studies. Bioequivalence Studies in Drug Development is written in an accessible style that makes it ideal for pharmaceutical scientists, clinical pharmacologists, and medical practitioners, as well as biometricians working in the pharmaceutical industry. It will also be of great value for professionals from regulatory bodies assessing bioequivalence studies.

"The book provides an excellent introduction for researchers approaching the concept of bioequivalence and is a complete and useful compendium for experienced statisticians." (Biometrical Journal, April 2009) "The book provides an important reference providing many worked examples with real data from drug development. Professionals from the pharmaceutical industry and regulatory bodies will particularly appreciate the emphasis made on regulatory guidelines." (Statistical Methods in Medical Research, February 2009) "Bioequivalence Studies in Drug Development: Methods and Applications is an informative, timely, and easy-to-read contribution to bioequivalence and drug-drug/food-drug interaction literature." (Journal of the American Statistical Association, September 2008) "those statisticians working in this area of research will find that this book will serve as an excellent reference for their work..." (Journal of Biopharmaceutical Statistics, January 2008) "This book would be beneficial to both pharmaceutical scientists/researchers and biostatisticians" (Biometrics, September 2007) "For anyone interested in any aspect of bioequivalence, the book is a very valuable reference." (International Statistical, 2007) "my pleasure to review I would like to add this book to my book collection of pharmaceutical research and development." (Biometrics, September 2007) From the Back Cover Studies in bioequivalence are the commonly accepted method to demonstrate therapeutic equivalence between two medicinal products. Savings in time and cost are substantial when using

bioequivalence as an established surrogate marker of therapeutic equivalence. For this reason the design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities. *Bioequivalence Studies in Drug Development* focuses on the planning, conducting, analysing and reporting of bioequivalence studies, covering all aspects required by regulatory authorities. This text presents the required statistical methods, and with an outstanding practical emphasis, demonstrates their applications through numerous examples using real data from drug development. Includes all the necessary pharmacokinetic background information. Presents parametric and nonparametric statistical techniques. Describes adequate methods for power and sample size determination. Includes appropriate presentation of results from bioequivalence studies. Provides a practical overview of the design and analysis of bioequivalence studies. Presents the recent developments in methodology, including population and individual bioequivalence. s the regulatory guidelines for such studies, and the existing global discrepancies. Discusses the designs and analyses of drug-drug and food-drug interaction studies. *Bioequivalence Studies in Drug Development* is written in an accessible style that makes it ideal for pharmaceutical scientists, clinical pharmacologists, and medical practitioners, as well as biometricians working in the pharmaceutical industry. It will also be of great value for professionals from regulatory bodies assessing bioequivalence studies.

About the Author  
Dieter Hauschke, ALTANA Pharma, Konstanz, Germany. Well-respected statistician working in the pharmaceutical industry, specializing in bioequivalence studies, with over 60 publications in leading journals.  
Volker Steinijans, ALTANA Pharma, Konstanz, Germany. Head of the Department of Biometry and Clinical Data Management at ALTANA.  
Iris Pigeot, Institute for Statistics, University of Bremen, Germany. Has over 50 published papers, and also written a number of books in German.