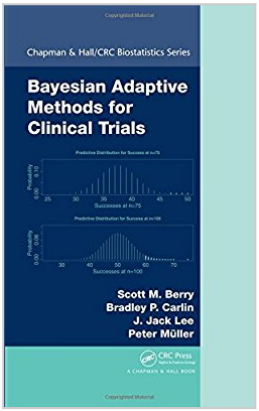


# Bayesian Adaptive Methods for Clinical Trials (Chapman & Hall/CRC Biostatistics Series, Vol. 38)

*By Scott M. Berry, Bradley P. Carlin, J. Jack Lee, Peter Muller*



**Bayesian Adaptive Methods for Clinical Trials (Chapman & Hall/CRC Biostatistics Series, Vol. 38)** By Scott M. Berry, Bradley P. Carlin, J. Jack Lee, Peter Muller

Already popular in the analysis of medical device trials, adaptive Bayesian designs are increasingly being used in drug development for a wide variety of diseases and conditions, from Alzheimer’s disease and multiple sclerosis to obesity, diabetes, hepatitis C, and HIV. Written by leading pioneers of Bayesian clinical trial designs, **Bayesian Adaptive Methods for Clinical Trials** explores the growing role of Bayesian thinking in the rapidly changing world of clinical trial analysis.

The book first summarizes the current state of clinical trial design and analysis and introduces the main ideas and potential benefits of a Bayesian alternative. It then gives an overview of basic Bayesian methodological and computational tools needed for Bayesian clinical trials. With a focus on Bayesian designs that achieve good power and Type I error, the next chapters present Bayesian tools useful in early (Phase I) and middle (Phase II) clinical trials as well as two recent Bayesian adaptive Phase II studies: the BATTLE and ISPY-2 trials. In the following chapter on late (Phase III) studies, the authors emphasize modern adaptive methods and seamless Phase II–III trials for maximizing information usage and minimizing trial duration. They also describe a case study of a recently approved medical device to treat atrial fibrillation. The concluding chapter covers key special topics, such as the proper use of historical data, equivalence studies, and subgroup analysis.

For readers involved in clinical trials research, this book significantly updates and expands their statistical toolkits. The authors provide many detailed examples drawing on real data sets. The R and WinBUGS codes used throughout are available on supporting websites.

Scott Berry talks about the book on the CRC Press YouTube Channel.

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## Editorial Review

Review

… researchers/statisticians who work in oncology clinical trials would especially benefit from this book. Having said that, much of the book should be accessible to nonstatistician readers with interest/involvement in clinical trials across different disease areas, while even Bayesian medical statistician readers should find the book to be a helpful resource. The authors, while clearly advocating the use of Bayesian approaches, nevertheless take a very pragmatic approach to the issue. They argue for Bayesian methods that demonstrate good frequentist properties and that are practical to use. This is a refreshing change from some other books and papers that also advocate Bayesian methods, but which while theoretically interesting, are difficult to implement in practice. In summary, I found this book to be well written and interesting. It is very timely given the interest in adaptive designs, and should be a useful resource for statisticians and nonstatisticians alike interested in adaptive clinical trials from a Bayesian perspective.
?*Biometrics*, 67, September 2011

This is the first serious text on adaptive designs using the Bayesian approach. … This is the right book to get if you are interested in Bayesian methods for adaptive designs.
?Michael R. Chernick, *Technometrics*, August 2011

… a rich introduction to Bayesian clinical trial design in general. It is written in an extremely readable style and is furnished with numerous examples and a great deal of helpful supplementary code. … This work provides a good overall look at the Bayesian approach to clinical trials. It covers the theoretical framework, provides software for the many excellent examples, and even delves into the practical regulatory issues that arise with the use of the designs. The book would be a worthy addition to the practicing statistician’s library.
?*Journal of Statistical Software*, November 2010, Volume 37

This fine book represents the most recent and exciting developments in this area, and gives ample justification for the power and elegance of Bayesian trial design and analysis. … This book, based on the many years of cumulative experience of the authors, manages to deal with [ideological, bureaucratic, practical and pragmatic] difficulties. Adaptive studies are a perfect application for a Bayesian approach, and I am confident that this book will be a major contribution to the science and practice of clinical trials.
?From the Foreword by David J. Spiegelhalter, MRC Biostatistics Unit, University of Cambridge, UK

"This excellent book can be recommended to any biostatistician with a professional interest in clinical trials, who has mainly applied frequentist methods up to now and who wants to gain a better understanding of the Bayesian methodology. The book can also be recommended to clinical investigators and regulators who have a minimum level of formal training. The practice-oriented and real-problem-solving approach of the book shows the strengths, potentials, difficulties, and yes, also weaknesses of the Bayesian adaptive approach for drug and medical device development. The book is well written, contains a lot of real life examples, and provides web links to software code (WinBUGS and R). In short, it is a fine practical handbook."
?Harald Heinzl, *Zentralblatt MATH 1306*

About the Author

**Scott M. Berry** is the President and Senior Statistical Scientist at Berry Consultants, a statistical consulting

group specializing in adaptive clinical trial design in pharmaceutical and medical device research and development.

**Bradley P. Carlin** is Mayo Professor in Public Health and Head of the Division of Biostatistics at the University of Minnesota.

**J. Jack Lee** is Professor of Biostatistics at the University of Texas M.D. Anderson Cancer Center.

**Peter Müller** is a Robert R. Herring Distinguished Professor in Clinical Research in the Department of Biostatistics at the University of Texas M.D. Anderson Cancer Center.

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