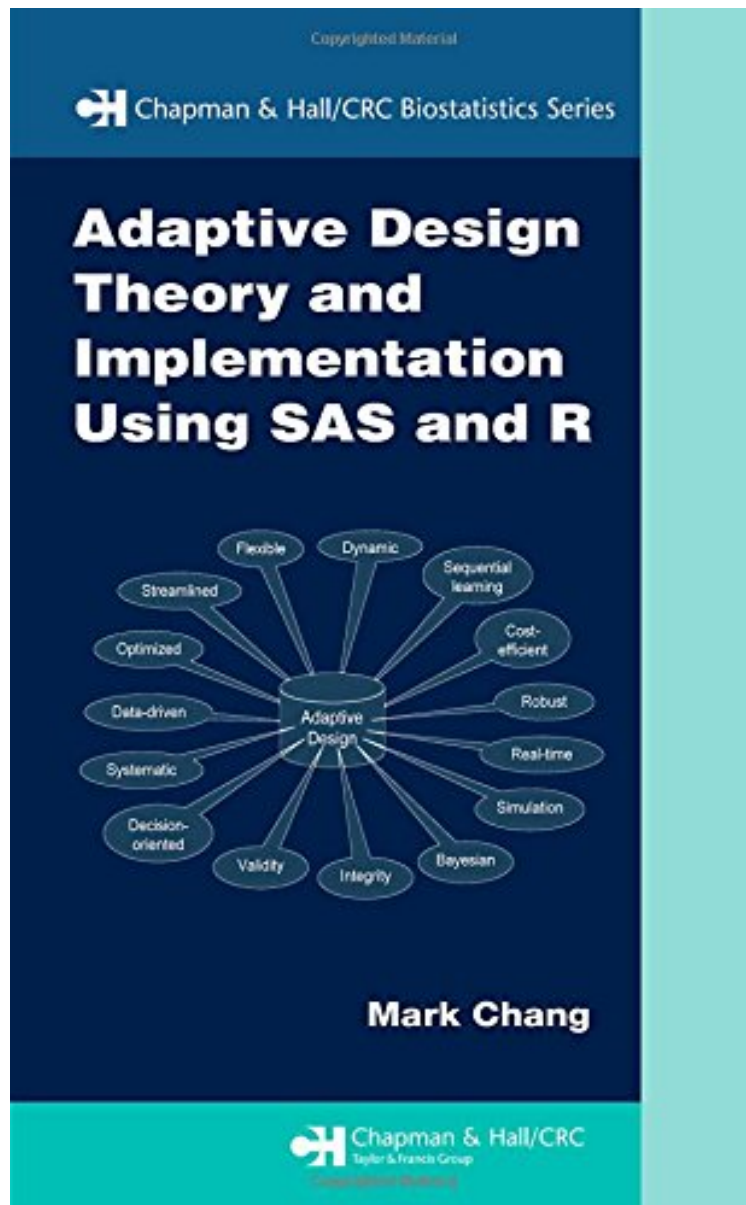


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Adaptive Design Theory and Implementation Using SAS and R (Chapman Hall/CRC Biostatistics Series)

Mark Chang

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Mark Chang : Adaptive Design Theory and Implementation Using SAS and R (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Adaptive Design Theory and Implementation Using SAS and R (Chapman Hall/CRC Biostatistics Series):

34 of 34 people found the following review helpful. excellent topic, well covered, with software for implementation
By Michael R. Chernick
This book just came out but I know a lot about it and about the author before I even got a copy. In November of last year Mark Chang coauthored a book in this Chapman and Hall series that I reviewed with praise because of the importance of the topic and the way it was demonstrated to work in a variety of real problems in pharmaceutical clinical trials. This book is even better as it goes more deeply into the methodology, the controversies and the results from simulation studies. Also it is much more practical because for every case where an application is given a SAS macro is also included to allow the reader to try the methodology for himself. In March of 2007 I actually designed a two-stage adaptive design with sample size reestimation for bioequivalence trials. I met mark at a conference where he presented much of his recent work and he was instrumental in helping me through his first book and his journal articles. This book had already gone to the publisher but he realized that this important design had overlooked. He added it when the copyedited version came to him. The design and the simulations related to it are very close to what I actually used. For those who like to program in R, he provides R code corresponding to each of the SAS macros that he gave. These programs make the new methodology readily available to interested users. The book is very comprehensive in that it covers a wide variety of applications for phase 2, phase 3 and combined phase trials. With the FDAs new initiative to speed up the drug discovery process this book will be an invaluable tool to statisticians in the pharmaceutical industry who would like to learn and apply these methods that along with the group sequential methods are gaining favor within the FDA. 40 of 45 people found the following review helpful.

Comprehensive, concise, unified presentation written by a hands-on statistician with years of adaptive design experiences
By Paradox
There are explosions of adaptive design papers in past several years. This book alone has included about 400 references. It is very confusing to most new researchers in this field. This book use a unified approach to treat the major hypothesis test based adaptive design methods, i.e., view different methods as some forms of stagewise p-values combinations for test statistics. Chapter 1 provides overview of adaptive designs. Chapter 2 provides background for various clinical trials including superior, non-inferiority, equivalence and dose-response trials. The unified approach is presented in chapter 3 for stopping boundary determination, adjusted p-value, early futility and efficacy stopping, expected sample-size and clinical trial duration, conditional power, and futility index. All the formulations for these operating characteristics are presented in multiple-integration forms. In the next several chapters, all the integrations for the operating characteristics are carried out for particular combinations of p-values - lead to particular statistical methods for adaptive designs. In the most cases, the book avoid to using approaches from the original papers when the ideas were first proposed to avoid confusions and reduce the amount of material to be included. Chapter 7 presented another way (conditional error approach) to look at the common and different characteristics among different methods. Almost all methods for adaptive design can be reviewed as the conditional error approach. The difference is that each method uses a different conditional error function. In the chapter, different conditional error function and conditional power formulations are summarized. Chapter 8 discusses the recursive conditional error method so that it can be used for a K-stage adaptive design. Chapters 9 to 14 discuss different types of adaptive trials using the statistical methods that have been discussed in the previous chapters. These trials include sample-size reestimation, drop-loser design, biomarker adaptive design, response-adaptive randomization, adaptive treatment switch, and multiple endpoint issues. Chapters 15 and 16 discuss Bayesian adaptive approach for clinical trials. Chapter 17 talks about implementation issues. Chapter 18 is for readers who are interested in philosophical debates. If you have not read too much adaptive design research papers, you wouldn't be confused, and you may not appreciate the unified approach in this book. For most chapters, computer programs (SAS Macro) are provided with illustrated examples from clinical trials. However, it is not the author's intention to teach to how to implement adaptive design using SAS. The main purpose to include computer programs is to provide tools that you can use to design your adaptive trials since the software for adaptive design is very expensive (some reach [..]annual license for single user). It is not a computer book. Hence the algorithm of the computer program is usually not provided your clinical trials. However, each program is written with clear logic flows and is only about a page long. It should not be a challenge to most readers who have coding knowledge. The corresponding R functions are presented in Appendix. Because they are so similar between a SAS Macro and the corresponding R function. It is wise to put one of them in the appendix. The R functions cover the typical adaptive designs. Others can be directly translated from SAS macros without any difficulties. There are exercises at end of chapters. Some are good, some are OK. This should be enhanced for the revision. For some reasons, Amazon.com does not include the sample pages from the book. I am the author of book; I think it is helpful to use this feature to provide some insight for the readers. More information can be found online, where you can obtain the table of contents and the electronic computer programs. Rank it 5 stars that could be author's bias. 9 of 14 people found the following review helpful. A SAS macro library with attached documentation and a few R functions appended
By andreas
The book, going by the table of contents, provides a fairly comprehensive overview of the field of adaptive designs in drug development. After having read it, I am somewhat disappointed. The topics are in fact all there, and the different approaches are presented. There is no real overview on how the different approaches link together though. I think that other texts like Ting (Dose Finding in Drug Development (Statistics for Biology and Health)) do a much better job at providing the background. The code seems quite useful, but the typesetting is fairly

disastrous. Most functions and macros have many parameters, and they are listed in floating text style instead of a tabular layout, making it very hard to read. The code is typeset in proportional font (where monospace is standard) and does not contain any comments and documentation of particular blocks. Finally, the text comprises 27 SAS programs and only 6 R programs. The SAS programs are in the corresponding chapters, the R programs are all put at the very end of the book in its own appendix chapter. The R code is of fairly low quality, suggesting that the author is a SAS user and transcribed the code into R. Example of some typical and not so great R code: `for(i in 1:nStgs) { TSc[i] = 0}` So the benefit of the book might be in the SAS library. It is not in the introduction to adaptive design theory and certainly not in the small R library, making the title somewhat misleading.

Adaptive design has become an important tool in modern pharmaceutical research and development. Compared to a classic trial design with static features, an adaptive design allows for the modification of the characteristics of ongoing trials based on cumulative information. Adaptive designs increase the probability of success, reduce costs and the time to market, and promote accurate drug delivery to patients. Reflecting the state of the art in adaptive design approaches, *Adaptive Design Theory and Implementation Using SAS and R* provides a concise, unified presentation of adaptive design theories, uses SAS and R for the design and simulation of adaptive trials, and illustrates how to master different adaptive designs through real-world examples. The book focuses on simple two-stage adaptive designs with sample size re-estimation before moving on to explore more challenging designs and issues that include drop-loser, adaptive dose-finding, biomarker-adaptive, multiple-endpoint adaptive, response-adaptive randomization, and Bayesian adaptive designs. In many of the chapters, the author compares methods and provides practical examples of the designs, including those used in oncology, cardiovascular, and inflammation trials. Equipped with the knowledge of adaptive design presented in this book, you will be able to improve the efficiency of your trial design, thereby reducing the time and cost of drug development.

The SAS and R programs are available on the web. This is good news since it avoids painful re-typing and error checking. The book can provide all statisticians interested in the adaptive design field with an overview of the topic and software to run practical examples. *Pharmaceutical Statistics*, 2011, 10 this book covers many of the different forms of adaptive design. The book also provides both SAS and R code to implement the theory, making the implementation of the theory much more accessible to readers. Its strength is that it provides an overview on many different types of adaptive designs, with an excellent source of references. a useful resource in this relatively new and quickly developing field. *Patrick Kelly, Statistics in Medicine*, Vol. 29, 2010 This book provides a thorough overview of adaptive designs in clinical trials similar to another book on adaptive designs coauthored by Dr. Chang (*Chow and Chang*, 2006), but using a more theoretical framework. this book is an excellent addition to the biostatistics book series . It provides a comprehensive summary of adaptive designs that have been developed, and includes about 400 references in the bibliography. The general theory behind most of the adaptive designs is helpful in understanding their advantages over fixed designs, as well as their potential pitfalls. The SAS and R programs associated with each adaptive design make the book practical as well. *Journal of the American Statistical Association*, Vol. 104, No. 487, September 2009 this book provides a systematic introduction to adaptive design theory. It also gives trial examples and computing code to help readers construct a comprehensive understanding of adaptive designs. It is certainly a useful guide and reference for academic and industry statisticians alike. *Feifang Hu, Biometrics*, June 2009 This easy-to-read book provides the reader with a unified and concise presentation of adaptive design theories, together with computer programs written in SAS and R for the design and simulation of adaptive trials. The text, computer programs, and data sets will be of value to both practitioners and students alike. *International Statistical* , 2008 About the Author *Millennium Pharmaceuticals*, Cambridge, Massachusetts, USA