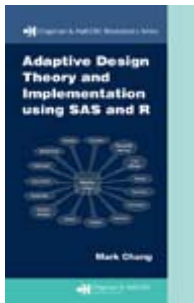


# Adaptive Design Theory and Implementation Using SAS and R

Mark Chang *Millennium Pharmaceuticals, Cambridge, Massachusetts, USA*

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- Covers a broad range of adaptive methods with an emphasis on the relationships among different methods
- Offers a quick way to master different adaptive designs through real-world examples encountered in clinical trials
- Presents current regulatory views and discusses the challenges in planning, executing, analyzing, and reporting adaptive designs
- Features Bayesian decision theory to optimize adaptive designs and programs
- Explores controversial issues surrounding statistical theories as well as fruitful avenues for future research and applications of adaptive designs
- Includes 40 SAS macros and R functions throughout the book to illustrate the design and simulation of adaptive trials
- Provides research problems/questions for both practitioners and students

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-funding, 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.

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