

Practical Considerations for Adaptive Trial Design and Implementation (Statistics for Biology and Health)



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This edited volume is a definitive text on adaptive clinical trial designs from creation and customization to utilization. As this book covers the full spectrum of topics involved in the adaptive designs arena, it will serve as a valuable reference for researchers working in industry, government and academia. The target audience is anyone involved in the planning and execution of clinical trials, in particular, statisticians, clinicians, pharmacometricians, clinical operation specialists, drug supply managers, and infrastructure providers. In spite of the increased efficiency of adaptive trials in saving costs and time, ultimately getting drugs to patients sooner, their adoption in clinical development is still relatively low. One of the chief reasons is the higher complexity of adaptive design trials as compared to traditional trials. Barriers to the use of clinical trials with adaptive features include the concerns about the integrity of study design and conduct, the risk of regulatory non-acceptance, the need for an advanced infrastructure for complex randomization and clinical supply scenarios, change management for process and behavior modifications, extensive resource requirements for the planning and design of adaptive trials and the potential to relegate key decision makings to outside entities. There have been limited publications that address these practical considerations and recommend best practices and solutions. This book fills this publication gap, providing guidance on practical considerations for adaptive trial design and implementation. The book comprises three parts: Part I focuses on practical considerations from a design perspective, whereas Part II delineates practical considerations related to the implementation of adaptive trials. Putting it all together, Part III presents four illustrative case studies ranging from description and discussion of specific adaptive trial design considerations to the logistic and regulatory issues faced in trial implementation.

Bringing together the expertise of leading key opinion leaders from pharmaceutical industry, academia, and regulatory agencies, this book provides a balanced and comprehensive coverage of practical considerations for adaptive trial design and implementation.

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