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Lingua di pubblicazione	Inglese
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Nota di bibliografia	Includes bibliographical references and index at the end of each chapters.
Nota di contenuto	Preface -- The Need for and the Future of Adaptive Designs in Clinical Development -- Regulatory Guidance Documents on Adaptive Designs: an Industry Perspective -- A Commentary on the U.S. FDA Adaptive Design Draft Guidance and EMA Reflection Paper from a Regulatory Perspective and Regulatory Experiences -- Considerations and optimization of adaptive trial design in clinical development programs -- Optimal Cost-effective Go-No Go Decisions in Clinical Development -- Timing and frequency of interim analyses in confirmatory trials -- Approaches for optimal dose selection for adaptive design trials -- A Review of Available Software and Capabilities for Adaptive Designs -- Randomization Challenges in Adaptive Design Studies -- Response-adaptive randomization for clinical trials -- Implementing Adaptive Designs: Operational Considerations, Putting it all together -- Implementation Issues in Adaptive Design Trials -- Implementing Adaptive Designs; Using Technology to Protect Trial Integrity, Reduce Operational Bias, and Build Regulatory Trust -- Considerations for Interim Analyses in Adaptive Trials, and Perspectives on the Use of

DMCs -- Approaches for Clinical Supply Modelling and Simulation -- Approaches for Patient Recruitment Modeling and Simulation -- A case study for adaptive trial design consideration and implementation -- Design Considerations for a Phase Ib Randomized, Placebo-Controlled, 4-Period Cross-over Adaptive Dose-Finding Clinical Trial -- Continual Reassessment Method for a First-In-Human Trial: From Design to Trial Implementation -- Practical Considerations for a Two-Stage Confirmatory Adaptive Clinical Trial Design and its Implementation: ADVENT Trial.

Sommario/riassunto

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.