1. Record Nr. UNINA9910799990703321

Titolo	Handbook of adaptive designs in pharmaceutical and clinical development / / edited by Annpey Pong, Shein-Chung Chow
Pubbl/distr/stampa	Boca Raton : , : CRC Press, , 2011
ISBN	0-429-13066-X 1-283-00453-4 9786613004536 1-4398-1017-6
Descrizione fisica	1 online resource (475 p.)
Altri autori (Persone)	PongAnnpey ChowShein-Chung <1955->
Disciplina	615.5072/4
Soggetti	Clinical trials Drugs - Research - Methodology
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front cover; Contents; Preface; Editors; Contributors; Chapter 1. Overview of Adaptive Design Methods in Clinical Trials; Chapter 2. Fundamental Theory of Adaptive Designs with Unplanned Design Change in Clinical Trials with Blinded Data; Chapter 3. Bayesian Approach for Adaptive Design; Chapter 4. The Impact of Protocol Amendments in Adaptive Trial Designs; Chapter 5. From Group Sequential to Adaptive Designs; Chapter 6. Determining Sample Size for Classical Designs; Chapter 7. Sample Size Reestimation Design with Applications in Clinical Trials Chapter 8. Adaptive Interim Analyses in Clinical TrialsChapter 9. Classical Dose-Finding Trial; Chapter 10. Improving Dose-Finding: A Philosophic View; Chapter 11. Adaptive Dose-Ranging Studies; Chapter 12. Seamless Phase I/II Designs; Chapter 13. Phase II/III Seamless Designs; Chapter 14. Sample Size Estimation/Allocation for Two-Stage Seamless Adaptive Trial Designs; Chapter 15. Optimal Response-Adaptive Randomization for Clinical Trials; Chapter 16. Hypothesis-Adaptive Design; Chapter 17. Treatment Adaptive Allocations in Randomized Clinical Trials: An Overview

Chapter 18. Integration of Predictive Biomarker Diagnostics into Clinical Trials for New Drug DevelopmentChapter 19. Clinical Strategy for Study Endpoint Selection; Chapter 20. Adaptive Infrastructure; Chapter 21. Independent Data Monitoring Committees; Chapter 22. Targeted Clinical Trials; Chapter 23. Functional Genome-Wide Association Studies of Longitudinal Traits; Chapter 24. Adaptive Trial Simulation; Chapter 25. Efficiency of Adaptive Designs; Chapter 26. Case Studies in Adaptive Design; Chapter 27. Good Practices for Adaptive Clinical Trials; Back cover

Sommario/riassunto

This comprehensive guide offers a unified presentation of the principles and methodologies in adaptive design and analysis. It gives a well-balanced summary of current regulatory perspectives and recently developed statistical methods in this area. The handbook provides some insight regarding early phase and later phase adaptive designs. With a focus on the implementation of adaptive methods in clinical trials, it introduces the concepts of role, responsibility, function, and activity of a data safety monitoring board (DSMB) when applying these methods. Other important topics covered in detail include regulatory perspectives and logistics issues in applying adaptive design methods--Provided by publisher.