Record Nr. UNINA9910459136803321 Handbook of adaptive designs in pharmaceutical and clinical **Titolo** 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 Electronic books. 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-

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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.

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