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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.