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realistic assessment of trial size; 9.3 The inadequacy of small trials; 9.4 Multi-centre trials; 9.5 The number of treatments and factorial designs; 10. Monitoring Trial Progress; 10.1 Reasons for monitoring; 10.2 Interim analyses; 10.3 Repeated significance testing: group sequential designs; 10.4 Continuous sequential designs; 11. Forms and Data Management; 11.1 Form design; 11.2 Data management; 11.3 The use of computers; 12. Protocol Deviations; 12.1 Ineligible patients; 12.2 Non-compliance and incomplete evaluation; 12.3 Inclusion of withdrawals in analysis; 13. Basic Principles of Statistical Analysis; 13.1 Describing the data; 13.2 Significance tests; 13.3 Estimation and confidence limits; 14. Further Aspects of Data Analysis; 14.1 Prognostic factors; 14.2 The analysis of survival data; 14.3 Multiplicity of data; 15. Publication and Interpretation of Findings; 15.1 Trial reports and their critical evaluation; 15.2 An excess of false-positives; 15.3 Combining evidence and overall strategy; References; Index

Sommario/riassunto

This comprehensive, unified text on the principles and practice of clinical trials presents a detailed account of how to conduct the trials. It describes the design, analysis, and interpretation of clinical trials in a non-technical manner and provides a general perspective on their historical development, current status, and future strategy. Features examples derived from the author's personal experience.
