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Descrizione fisica	1 online resource (574 p.)
Disciplina	610.72/7
Soggetti	Medicine - Research - Statistical methods Clinical trials - Methodology
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	A Chapman and Hall book.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front Cover; Contents; List of Figures; List of Tables; Preface; Early History of the Deming Conference; Some Nonstatistical Reminiscences of My 44 Years of Chairing the Deming Conference; Contributors; Section I: Emerging Issues in Clinical Trial Design and Analysis; Chapter 1: Emerging Challenges of Clinical Trial Methodologies in Regulatory Applications; Chapter 2: Review of Randomization Methods in Clinical Trials; Chapter 3: First Dose Ranging Clinical Trial Design: More Doses? Or a Wider Range?; Chapter 4: Thorough QT/QTc Clinical Trials; Chapter 5: Controversial (Unresolved) Issues in Noninferiority Trials; Section II: Adaptive Clinical Trials; Chapter 6: Adaptive Designs in Drug Development; Chapter 7: Optimizing Group-Sequential Designs with Focus on Adaptability: Implications of Nonproportional Hazards in Clinical Trials; Chapter 8: Group Sequential Design in R; Section III: Clinical Trials in Oncology; Chapter 9: Issues in the Design and Analysis of Oncology Clinical Trials; Chapter 10: Competing Risks and Their Applications in Cancer Clinical Trials; Chapter 11: Dose Finding with Escalation with Overdose Control in Cancer Clinical Trials; Chapter 12: Interval-Censored Time-to-Event Data and Their Applications in Clinical Trials; Section IV: Multiple Comparisons in Clinical Trials; Chapter 13: Introduction to Multiple Test Problems, with Applications to Adaptive Designs; Chapter 14:

Graphical Approaches to Multiple Testing; Chapter 15: Pairwise Comparisons with Binary Responses: Multiplicity-Adjusted P-Values and Simultaneous Confidence Intervals  
Chapter 16: Comparative Study of Five Weighted Parametric Multiple Testing Methods for Correlated Multiple Endpoints in Clinical Trials  
Section V: Clinical Trials in a Genomic Era; Chapter 17: Statistical Analysis of Biomarkers from -Omics Technologies; Chapter 18: Understanding Therapeutic Pathways via Biomarkers and Other Uses of Biomarkers in Clinical Studies; Chapter 19: Statistical Evaluation of Surrogate Endpoints in Clinical Studies; Back Cover

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Sommario/riassunto

Since 1945, The Annual Deming Conference on Applied Statistics has been an important event in the statistics profession. In *Clinical Trial Biostatistics and Biopharmaceutical Applications*, prominent speakers from past Deming conferences present novel biostatistical methodologies in clinical trials as well as up-to-date biostatistical applications from the pharmaceutical industry. Divided into five sections, the book begins with emerging issues in clinical trial design and analysis, including the roles of modeling and simulation, the pros and cons of randomization procedures, the design of Phase II dose-ranging trials, thorough QT/QTc clinical trials, and assay sensitivity and the constancy assumption in noninferiority trials. The second section examines adaptive designs in drug development, discusses the consequences of group-sequential and adaptive designs, and illustrates group sequential design in R. The third section focuses on oncology clinical trials, covering competing risks, escalation with overdose control (EWOC) dose finding, and interval-censored time-to-event data. In the fourth section, the book describes multiple test problems with applications to adaptive designs, graphical approaches to multiple testing, the estimation of simultaneous confidence intervals for multiple comparisons, and weighted parametric multiple testing methods. The final section discusses the statistical analysis of biomarkers from omics technologies, biomarker strategies applicable to clinical development, and the statistical evaluation of surrogate endpoints. This book clarifies important issues when designing and analyzing clinical trials, including several misunderstood and unresolved challenges. It will help readers choose the right method for their biostatistical application. Each chapter is self-contained with references--Provided by publisher.

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