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Nota di contenuto	CLINICAL TRIALS; CONTENTS; Preface; Preface to the First Edition; 1 Preliminaries; 1.1 Introduction; 1.2 Audience and Scope; 1.3 Other Sources of Knowledge; 1.3.1 Terminology; 1.3.2 Review of Notation and Terminology Is Helpful; 1.4 Examples, Data, and Programs; 1.5 Summary; 2 Clinical Trials as Research; 2.1 Introduction; 2.1.1 Clinical Reasoning Is Based on the Case History; 2.1.2 Statistical Reasoning Emphasizes Inference Based on Designed Data Production; 2.1.3 Clinical and Statistical Reasoning Converge in Research; 2.2 Defining Clinical Trials Formally 2.2.1 Mixing of Clinical and Statistical Reasoning Is Recent2.2.2 Clinical Trials Are Rigorously Defined; 2.2.3 Experiments Can Be Misunderstood; 2.2.4 Clinical Trials as Science; 2.2.5 Trials and Statistical Methods Fit within a Spectrum of Clinical Research; 2.3 Practicalities of Usage; 2.3.1 Predicates for a Trial; 2.3.2 Trials Can Provide Confirmatory Evidence; 2.3.3 Clinical Trials Are Unwieldy, Messy, and Reliable; 2.3.4 Other Methods Are Valid for Making Some Clinical Inferences; 2.3.5 Trials Are Difficult to Apply in Some

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 4.3.2 Are Devices Different from Drugs?

## Sommario/riassunto

Learn rigorous statistical methods to ensure valid clinical trialsThis Second Edition of the critically hailed Clinical Trials builds on the text's reputation as a straightforward and authoritative presentation of statistical methods for clinical trials. Readers are introduced to the fundamentals of design for various types of clinical trials and then skillfully guided through the complete process of planning the experiment, assembling a study cohort, assessing data, and reporting results. Throughout the process, the author alerts readers to problems that may arise during the course of