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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 Recent 2.2.2 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 Circumstances; 2.3.6 Randomized Studies Can Be Initiated Early 2.4 Summary 2.5 Questions for Discussion; 3 Why Clinical Trials Are

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3.3.2 High-Profile Mistakes Were Made in the United States  
3.3.3 The Helsinki Declaration Was Widely Adopted; 3.3.4 Other International Guidelines Have Been Proposed; 3.3.5 Institutional Review Boards Provide Ethical Oversight; 3.3.6 Ethical Principles Relevant to Clinical Trials; 3.4 Contemporary Foundational Principles; 3.4.1 Collaborative Partnership; 3.4.2 Scientific Value; 3.4.3 Scientific Validity; 3.4.4 Fair Subject Selection; 3.4.5 Favorable Risk-Benefit; 3.4.6 Independent Review; 3.4.7 Informed Consent; 3.4.8 Respect for Subjects; 3.5 Methodologic Reflections  
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4.3.2 Are Devices Different from Drugs?

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#### Sommario/riassunto

Learn rigorous statistical methods to ensure valid clinical trials  
This 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

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