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Nota di contenuto	- Part I: Introduction to the Estimand Framework -- 1. Aligning Trial Planning, Design, Conduct, Analysis, and Interpretation -- 2. Estimands, Estimators, and Estimates -- 3. Implementation the Estimand Thinking Process Through Multidisciplinary Collaborations -- 4. Documentation of Estimands and Reporting of Results -- 5. Estimands and Causal Inference -- 6. Global Initiatives Since the Release of ICH E9(R1) -- Part II: Case Studies Under the Estimand Framework -- 7. Applying the Estimand Framework: Case Studies in Oncology and Hematology -- 8. Applying the Estimand Framework: Case Studies in Immunology and Inflammation -- 9. Applying the Estimand Framework: Case Studies in Neuroscience -- 10. Applying the Estimand Framework: Case Studies in Cardiology, Respiratory, Infection Diseases and Vaccines -- Part III: Regulatory Guidelines and Their Relationship to the Estimand Framework -- 11. ICH Guidelines and Their Relationship to the Estimand Framework -- 12. EMA Guidelines and Their Relationship to the Estimand Framework -- 13. FDA Guidelines and Their Relationship to the Estimand Framework -- 14. NMPA Guidelines and Their Relationship to the Estimand Framework --

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Sommario/riassunto

This book provides a comprehensive, up-to-date, and practical introduction to the estimand framework and its application in clinical trials. Since its introduction by the International Council for Harmonisation (ICH) through the E9(R1) guideline in 2019, the estimand framework has led to a significant shift in the design, conduct, analysis, and interpretation of clinical trials. By explicitly aligning trial objectives with the clinical question of interest—and by carefully accounting for intercurrent events—the framework facilitates greater transparency and interpretability of trial results. In recent years, its adoption has supported improved scientific and regulatory dialogue, more targeted trial designs and analysis methods, and a better understanding of treatment effects across drug development programs. This book reflects both the conceptual underpinnings of the estimand framework and the growing body of experience gained by the scientific and regulatory community since the release of the ICH E9(R1) guideline. Emphasis is placed on practical implementation across a wide range of clinical and therapeutic settings. Part I introduces the core concepts of the framework and offers detailed guidance on how to describe estimands in clinical trial protocols and related documents. Part II presents a wide range of case studies from various therapeutic areas to support practical implementation. Part III summarizes estimand-related content from regulatory guidelines across different indications. Part IV describes statistical analysis methods and approaches for handling missing data across continuous, binary, recurrent, and time-to-event endpoints. Part V explores the use of the estimand framework in a variety of clinical trial settings. Designed for a broad audience of professionals and students involved in clinical research, this book will be particularly valuable for those engaged in the design, conduct, and analysis of clinical trials across the drug development lifecycle. It serves both as a structured introduction for those new to the field and a detailed reference for experienced professionals. Whether for academic study or practical implementation, this book is an essential resource for advancing the estimand framework and promoting more robust, informative clinical trials.