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| Nota di contenuto | Clinical Testing of a New Drug -- A Frequentist Decision-making Framework -- Characteristics of a Diagnostic Test -- The Parallel Between Clinical Trials and Diagnostic Tests -- Incorporating Information from Completed Trials in Future Trial Planning -- Choosing Metrics Appropriate for Different Stages of Drug Development -- Designing Proof-of-Concept Trials with Desired Characteristics -- Designing Dose-response Studies with Desired Characteristics -- Designing Confirmatory Trials with Desired Characteristics -- Designing Phase 4 Trials -- Other Metrics That Have Been Proposed to Optimize Drug Development Decisions -- Discounting Prior Results to Account for Selection Bias -- Index -- Appendix. |

Sommario/riassunto

This book offers a high-level treatise of evidence-based decisions in drug development. Because of the inseparable relationship between designs and decisions, a good portion of this book is devoted to the design of clinical trials. The book begins with an overview of product development and regulatory approval pathways. It then discusses how to incorporate prior knowledge into study design and decision making at different stages of drug development. The latter include selecting appropriate metrics to formulate decisions criteria, determining go/no-go decisions for progressing a drug candidate to the next stage and predicting the effectiveness of a product. Lastly, it points out common mistakes made by drug developers under the current drug-development paradigm. The book offers useful insights to statisticians, clinicians, regulatory affairs managers and decision-makers in the pharmaceutical industry who have a basic understanding of the drug-development process and the clinical trials conducted to support drug-marketing authorization. The authors provide software codes for select analytical approaches discussed in the book. The book includes enough technical details to allow statisticians to replicate the quantitative illustrations so that they can generate information to facilitate decision-making themselves.