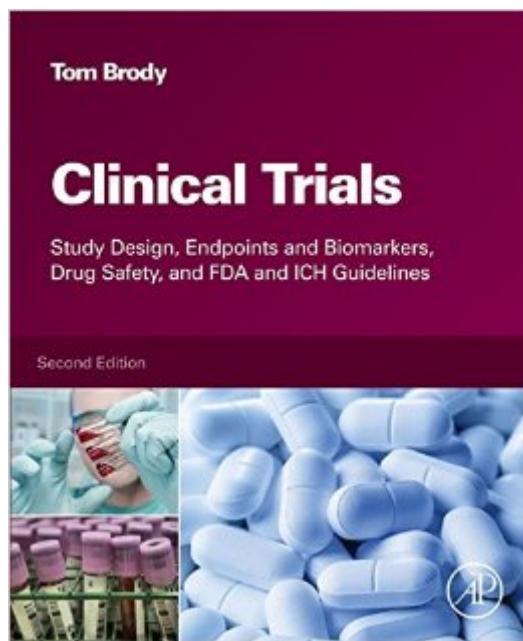


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Clinical Trials: Study Design, Endpoints And Biomarkers, Drug Safety, And FDA And ICH Guidelines



Synopsis

Clinical Trials, Second Edition, offers those engaged in clinical trial design a valuable and practical guide. This book takes an integrated approach to incorporate biomedical science, laboratory data of human study, endpoint specification, legal and regulatory aspects and much more with the fundamentals of clinical trial design. It provides an overview of the design options along with the specific details of trial design and offers guidance on how to make appropriate choices. Full of numerous examples and now containing actual decisions from FDA reviewers to better inform trial design, the 2nd edition of Clinical Trials is a must-have resource for early and mid-career researchers and clinicians who design and conduct clinical trials. Contains new and fully revised material on key topics such as biostatistics, biomarkers, orphan drugs, biosimilars, drug regulations in Europe, drug safety, regulatory approval and more. Extensively covers the "study schema" and related features of study design. Incorporates laboratory data from studies on human patients to provide a concrete tool for understanding the concepts in the design and conduct of clinical trials. Includes decisions made by FDA reviewers when granting approval of a drug as real world learning examples for readers.

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Customer Reviews

I have recently evaluated this comprehensive guidebook, which describes all aspects of design, conduct, and interpretation of clinical research studies, and am highly impressed with both its scope and detail. Each chapter focuses on a different topic, all germane to the development of pharmaceuticals, and very useful to have collected together in one resource. The introductory material sets the stage, including helpful background on the structures of various types of drugs, the design and interpretation of animal models, and discussions of biosimilars and orphan drugs. The following two chapters detail the actual design of clinical trials, including extremely detailed advice for development of the overall study schema, the writing of the Clinical Trial Protocol, the determination of appropriate control groups, and the development of the important "run-in" period prior to treatment. Chapters 4 through 8 cover the critical trial design topics of inclusion/exclusion criteria, blinding, use of placebo groups, and the determination of "intent to treat" versus "per protocol" analysis. A further two chapters (8 and 9) also regard data analyses, with a fascinating -- and easy to understand -- discussion of biostatistics for the interpretation of trial results.

Kaplan-Meier plots and One- or Two-tailed T-tests, for example, are not only explained in detail, but results from actual drug development trials are provided and placed in context. As the choice of endpoints for a clinical trial are critical for obtaining useful information regarding the actual activity of a possible therapeutic compound, Chapters 11 to 24 completely cover this topic, ranging from oncology, to immune and infectious diseases, and even "quality of life" studies.

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