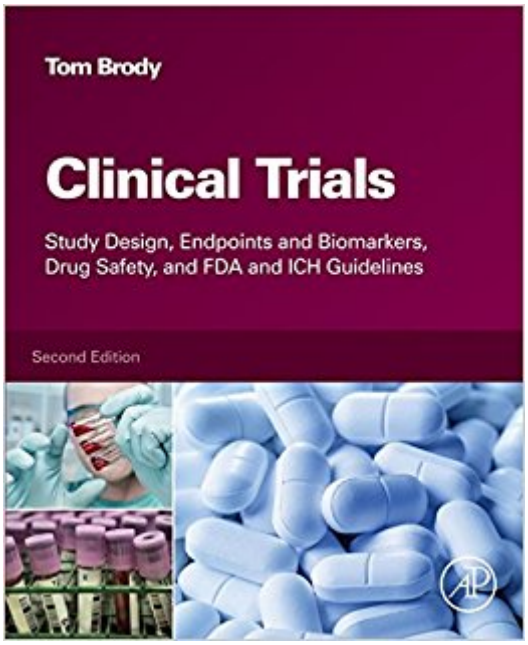
Clinical Trials: Study Design, Endpoints And Biomarkers, Drug Safety, And FDA And ICH Guidelines



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 moreExtensively covers the "study schema" and related features of study designIncorporates laboratory data from studies on human patients to provide a concrete tool for understanding the concepts in the design and conduct of clinical trialsIncludes decisions made by FDA reviewers when granting approval of a drug as real world learning examples for readers

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Customer Reviews

Clear, well-structured,up-to-date

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. The ensuing chapters include other diverse and important topics for the pharmacological investigator: drug safety and mechanism of action, with separate detailed chapters for cancers, immune disorders, and infectious diseases. As clinical trials cannot be run without patient understanding and agreement, "consent forms" are covered in Chapter 30. Information regarding requirements for information provided in a package insert is given in Chapter 31. Chapter 32 provides detailed descriptions of the various types of FDA warning letters and their consequences; for example the significance of Institutional Review Boards (IRBs) and Data Monitoring Committees (DMCs). The approval, or non-approval, of a drug is considered in Chapter 34, including the types of approval which can be sought. The final chapter is a fascinating discussion of the topic of drug patenting. In all, I find this reference book to be an exhaustive and essential tool for anyone learning about clinical trials, designing or conducting clinical trials, or involved in any aspect of therapeutic development. An additional positive point about this book is that the reference citations are provided at the bottom of

each page, for ease of referral.

I would strongly recommend this book for those beginning a career in the pharmaceutical industry or for those already working in industry for use as a reference. It is especially useful in the oncology therapeutic area and for its explanations of frequently-used statistical analyses. It is thorough, broad in scope, and well-referenced. After more than 20 years of working in industry, I find it relevant and extremely useful. It would be a wonderful text book for a graduate-level introduction to clinical research in industry.I'm very glad to have invested in this addition to my reference library!

Lippincott’s Dental Drug Reference)