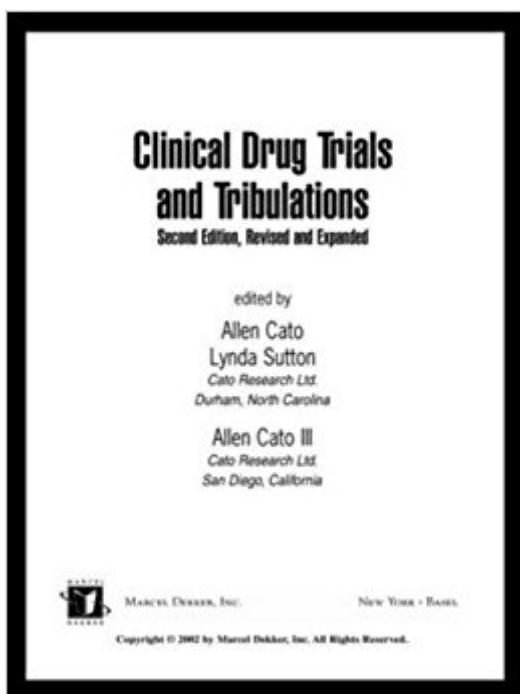


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# Clinical Drug Trials And Tribulations, Revised And Expanded, Second Edition (Drugs And The Pharmaceutical Sciences)



## Synopsis

Aimed at those already involved in drug development or those considering entering the field, Clinical Drug Trials and Tribulations, Second Edition comprehensively addresses the new, day-to-day challenges of drug development with valuable assessments of the areas affecting the conduction of nonclinical and clinical studies. Addressing which decisions should be made during drug development, this updated and expanded text/reference carefully guides readers through the various trials and tribulations that emerge phase-by-phase and are pertinent to all levels of pharmaceutical or clinical drug management. Bringing together the latest information on drug development, the Second Edition contains: new material on international regulation and deregulation, venture capitalist investment, the IND process, informed consent changes in manufacturing, and updated and extended coverage of pediatric drug trial design, the advantages and disadvantages of orphan drug designations, the maximization of package inserts for marketing, post approval safety surveillance, and withdrawals from the drug market. Clinical Drug Trials and Tribulations, Second Edition will prove an invaluable reference for pharmacologists, pharmacists, clinical chemists, clinical coordinators, clinical monitors, government drug regulatory personnel, and bioethicists as well as a useful text for medical or pharmacy school courses on pharmaceutical development and research.

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