



Clinical Trials of Drugs and Biopharmaceuticals

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The pharmaceutical industry is on the verge of an exciting and challenging century. Advances in pharmaceutical sciences have dramatically changed the processes of discovery and development of new therapeutic drugs and, in turn, resulted in an extraordinary increase in the potential prophylactic and therapeutic interventions. In this atmosphere, an intimate understanding of the mechanisms of pharmacokinetic and pharmacodynamic activity and the processes of drug evaluation is essential.

Clinical Trials of Drugs and Biopharmaceuticals provides an overview of current procedures and major issues involved in drug and biopharmaceutical development. The book examines critical biochemical and pharmaceutical considerations for trials conducted during each phase of clinical development. It also reports information related to early pre-clinical evaluations of pharmacological activities and safety before proceeding with initiation of clinical trials. The sections focus on clinical assessments of drugs and biopharmaceuticals such as cardiovascular, respiratory, central nervous system, gastrointestinal and liver, genitourinary, skin, metabolism, and chemotherapeutic drugs as well as vaccines, biotechnology-derived therapeutics, and plant-based medicines.

Practical and informative, this step-by-step guide includes information on all four phases of clinical trials prior to licensure and covers the design of post-marketing studies. The editors examine how recent advances and increased demand for safer and more effective drugs have changed the process by which drugs are developed and approved.

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