

A clinical trial, involving evaluation of the safety and efficacy of drugs which may ultimately be administered to millions of people, represents one of the most important applications of the scientific method. However, the design of a valid trial is quite subtle, and misleading results can easily be obtained with poor technique. Immunointervention is the use of pharmacological agents to modify the action of the immune system for the benefit of the patient. The practice is as old as vaccination but, with the recent increase in basic immunological knowledge and the availability of therapeutic quantities of immunological mediators made possible by genetic engineering, the number of clinical trials of such agents will increase dramatically in the 1990s. However, an understanding of immunology is still not widespread among clinical practitioners or those working in the pharmaceutical industry. This book provides guidance on how to test immunological therapies in clinical trials and how to appraise critically the results of such studies. Lessons are drawn from an evaluation of 190 clinical trials of immunotherapeutic agents, in the principle therapeutic areas of cancer, infection, autoimmune disease, and allergy. This guidance is set against an overview of basic immunological mechanisms, the ways in which they are involved in disease, and the practical problems associated with monitoring relevant features of the immune system in a clinical setting.

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