Preamble
This book was the 43rd in a series of statistics textbooks and monographs edited by DB Owen (Department of Statistics, Southern Methodist University, Dallas, Texas, USA) and RG Cornell (School of Public Health, University of Michigan, Ann Arbor, Michigan, USA, for the publisher Marcel Dekker. It originated from a postgraduate course held at the Villa Monastero in Varenna, Como, Italy, 14-16 November 1977, organised by the Italian Society of Gastroenterology. The individual chapters include comments from discussants.

It is dedicated to the memory of Franz J Ingelfinger (1910-1980), one of the authors, and editor of the New England Journal of Medicine (1967-1976).

Aims
In the recent past randomised clinical trials have had increasing impact on clinical practice and therapeutic decisions. Previously, however, therapeutic decisions were often made without guidance from randomised clinical trials, simply because relevant trials were lacking. This is changing with the increasing number of trials being conducted. What may be more important, however, is that the randomised clinical trial is being accepted as a tool for the solution of therapeutic problems, which in turn represents an approval of the classical scientific approach to clinical practice. The general success of scientific methodology in the acquisition of new knowledge gives promise that the randomised clinical trial will have a significant impact on medical care. In principle, the randomised clinical trial resembles the manner in which clinicians have always gained skills and experience, i.e., by systematic, not random, trial and error. The difference lies in the increase in precision offered by the clinical trial. By systematic collection and analysis of relevant data, the clinical trial attempts to quantify therapeutic effects in comparative terms. The risk of reaching a wrong conclusion is not eliminated, but usually it is smaller (and always better defined) than when therapeutic evaluations are based on general impressions, anecdotal experience, or beliefs. Furthermore, the need for precision regarding criteria for selection of patients and evaluation of therapeutic effects in clinical trials serves to reveal where current diagnostic concepts and therapeutic objectives are inaccurate or irreproducible. This book is not intended to be a handbook on the conduct of clinical trials. It does not intend to give the complete recipe of how to conduct a trial, even though we hope that it will encourage more physicians to engage in such activity. The intention is to provide the consumers and prospective participants, perhaps including patients, with an understanding of the mechanism of a clinical trial and the kind of information it yields, so that they can interpret, evaluate, and apply its results critically (Preface, pages vii and viii).

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