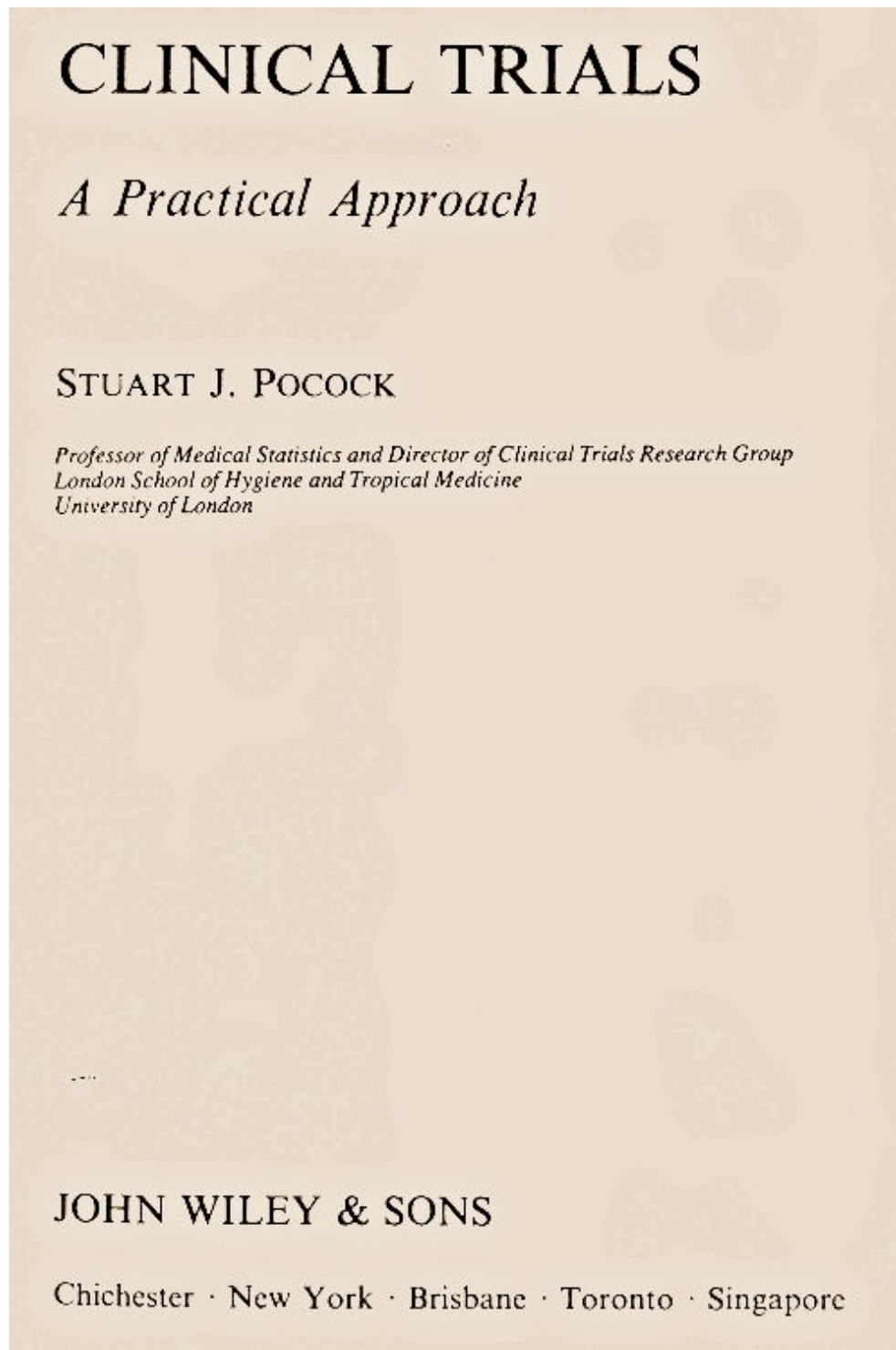


**Pocock SJ (1983).** Clinical trials: a practical approach. Chichester: John Wiley.

**Title pages**

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# Preface

There is an ever-increasing number of treatment innovations which require proper investigation to see if they are of genuine benefit to patients. The randomized controlled clinical trial has become widely regarded as the principal method for obtaining a reliable evaluation of treatment effect on patients. The purpose of this book is to explain in practical terms the basic principles of clinical trials. Particular emphasis is given to their scientific rationale, including the relevance of statistical methods, though ethical and organizational issues are also discussed in some detail.

My intention has been to present the methodology of clinical trials in a style which is comprehensible to a wide audience. I hope the book proves to be especially useful to clinicians and others who are involved in conducting trials and it would be particularly gratifying if this text encouraged more clinicians to undertake or collaborate in properly designed trials to resolve relevant therapeutic issues.

Pharmaceutical companies have a fundamental role in the organization of trials for drug therapy. I have tried to give a balanced view of their activities in this area and hope that my approach to clinical trials is conducive to maintaining high standards of research in the clinical testing of new drugs. However, I wish to emphasize that randomized controlled trials should also be applied to assessing other (non-drug) aspects of therapy and patient management.

The practice of medicine poses a need to interpret wisely the published findings from clinical trials. Accordingly, the medical profession at large and others concerned with the treatment and management of patients may benefit from an increased understanding of how clinical trials are (and should be) conducted.

The proper use of statistical methods is important at the planning stage of a clinical trial as well as in the analysis and interpretation of results. I also recognize that many clinicians and others without mathematical training experience some difficulty in understanding statistical concepts. Hence, I have used a straightforward non-mathematical approach in describing those statistical issues that I consider of relevance to the practice of clinical trials. In particular,

I would like to think that the basic principles of statistical analysis described in chapter 13 may be of more general interest beyond clinical trials. Indeed, some readers who are unfamiliar with statistical terms may find it instructive to begin with this chapter.

My own experience in teaching undergraduate medical students has encouraged me to believe that the introduction of clinical trials and related statistical ideas is a useful aspect of preclinical education. Accordingly, my approach to such courses is reflected in much of this book.

As a medical statistician I believe that clinical trials require a successful collaboration of clinical, organizational and statistical skills. I feel that my profession needs to strive harder to achieve effective communication of our ideas to non-statistical colleagues and I would be delighted if this book could persuade other statisticians towards a commonsense and less theoretical approach to medical research. In this respect, students of biostatistics may find this book a useful antidote to their more mathematical courses!

Lastly, my policy has been always to introduce each concept via actual examples of clinical trials. In this way, the reader should experience the reality of clinical trials, not as an abstract collection of methods, but as a practical contribution to furthering medical knowledge.

I greatly appreciate the contributions of Sheila Gore and Austin Heady who read the book in draft and made many suggestions for improvement. I am also grateful to Tom Meade and Simon Thompson for their helpful comments on the draft. I am indebted to Peter Armitage for first stimulating the publishers to realize the need for such a book. I wish to express sincere thanks to Yvonne Ayton for typing the manuscript and to other colleagues for their invaluable support. Lastly, this whole project was made easier by the help and encouragement of my wife Faith.