

# PREFACE

According to Sir David Cox, the randomised controlled clinical trial is perhaps the outstanding contribution of statistics to 20th century medical research. Nowadays about 8000 such trials are undertaken annually in all areas of medicine from the treatment of acne to the prevention of cancer. Although the vast majority of these trials take place away from the glare of public interest, some deal with issues that are controversial enough to make even the popular press; an obvious example is the use of AZT for the treatment of AIDS.

There are many excellent books available which give comprehensive accounts of how clinical trials should be carried out and organised. Our aim is somewhat different; we attempt to give relatively concise descriptions of the more statistical aspects of the design and analysis of clinical trials, particularly those methods developed over the last decade or so. Topics discussed in this text include randomisation, interim analyses, sample size determination, the analysis of longitudinal data, Bayesian methods, survival analysis and meta-analysis. Many examples are included alongside some of the necessary technical material, the more difficult parts of which are confined to tables. An Appendix gives details of relevant software. We hope that our book will be useful to medical statisticians and others faced with the often difficult problems of designing and analysing clinical trials.

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