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We have been gratified by the reception of the first edition of this book, and this new edition offers the opportunity to respond to the many suggestions we have received for further improving and clarifying certain sections. In most cases the changes have consisted in expanding the text, to reflect new developments in research.

Chapters have been reorganised, to follow a more logical sequence for teaching. Thus sample size estimation has been moved to Part C, Clinical Trials, because it is needed for trial design. In the first edition it followed the chapters about analysis where we discussed choice of statistical tests, because the sample size computation depends on the test that will be used.

Health-related quality of life is a rapidly evolving field of research, and this is illustrated by shifting names and identity: quality of life (QoL) outcomes are now also commonly called patient- (or person-) reported outcomes (PROs) to reflect more clearly that symptoms and side effects of treatment are included in the assessments; we have adopted that term as part of the subtitle. Drug regulatory bodies have also endorsed this terminology, with the USA Food and Drug Administration (FDA) bringing out guidance notes concerning the use of PROs in clinical trials for new drug applications; this new edition reflects the FDA (draft) recommendations.

Since the first edition of this book there have been extensive developments in item response theory and, in particular, computer adaptive testing; these are addressed in a new chapter. Another area of growth has been in systematic reviews and meta-analysis, as evinced by the formation of a Quality of Life Methods Group by the Cochrane Collaboration. QoL presents some particular challenges for meta-analysis, and this led us to include the final chapter.

We are very grateful to the numerous colleagues who reported finding this book useful, some of whom also offered constructive advice for this second edition.

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June 2006