Statistical Issues in Drug Development
Statistics in Practice

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everyday practical needs. Feedback of views from readers will be most valuable to
monitor the success of this aim.

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To Victoria, Helen and Mark
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Preface to the Second Edition

There have been many developments since the first edition of this book and it was high time for a second. My own period working in the pharmaceutical industry is now a distant memory but the ten years working as an academic since the first edition has had its compensations. I have been fortunate enough to be able to consult for many pharmaceutical companies during this time and this has certainly widened my appreciation of the work that statisticians do within the industry and the problems they face.

Alas, this appreciation is not shared by all. Many take it as almost axiomatic that statistical analysis carried out within the pharmaceutical industry is necessarily inferior to that carried out elsewhere. Indeed, one medical journal has even gone so far as to make it a requirement for publication that analyses from the pharmaceutical industry should be confirmed by an academic statistician, a policy which is as impractical as it is illogical.

Two related developments since the first edition, one of which is personal, are highly relevant. The first is that I have been honoured to succeed Vic Barnett as an editor for Wiley’s *Statistics in Practice* series, in which this book appears. The second is that the series itself, so ably founded by Vic and Helen Ramsey, has been growing steadily and since the first edition now has attracted a number of further volumes that are highly relevant to this one. The chapters that have particularly benefited are listed with the relevant references as follows.

Chapter 6 Allocating treatments to patients in clinical trials (Berger, 2005)
Chapter 7 Baselines and covariate information (Berger, 2005)
Chapter 11 Intention to treat, missing data and related matters (Molenberghs and Kenward, 2007)
Chapter 16 Meta-analysis (Whitehead, 2002)
Chapter 19 Sequential trials (Ellenberg, et al., 2003)
Chapter 20 Dose-finding (Chevret, 2006)
Chapter 22 Bioequivalence studies (Hauschke, et al., 2007)
Chapter 23 Safety data, harms, drug-monitoring and pharmacoepidemiology (Lui, 2004)
Chapter 24 Pharmacoeconomics and portfolio management (Parmigiani, 2002, Willan and Briggs, 2006)

Also extremely useful are two books on Bayesian methods (O’Hagan *et al.*, 2006, Spiegelhalter *et al.*, 2003) and Brown and Prescott’s book on mixed models (Brown and Prescott, 2006), which is already in a second edition. The books on survival analysis and