Statistical Methodology in the Pharmaceutical Sciences

Edited by
DONALD A. BERRY
School of Statistics
University of Minnesota
Minneapolis, Minnesota

MARCEL DEKKER, INC. New York and Basel
## Contents

**Preface**

**Contributors**

1. Basic Principles in Designing and Analyzing Clinical Studies  
   *Donald A. Berry*  
   Page 1

2. Bioavailability: Designs and Analysis  
   *Bruce E. Rodda*  
   Page 57

3. Analysis of Repeated-Measures Designs  
   *George A. Milliken*  
   Page 83

4. Dose-Response: Relating Doses and Plasma Levels to Efficacy and Adverse Experiences  
   *Bruce P. Ekholm, Terrance L. Fox, and James A. Bolognese*  
   Page 117

5. Population Models  
   *Amy Racine-Poon and Adrian F. M. Smith*  
   Page 139

6. Linear and Nonlinear Regression  
   *R. Dennis Cook and Sanford Weisberg*  
   Page 163

7. Design and Analysis of Multicenter Trials  
   *Judith D. Goldberg and Kenneth J. Koury*  
   Page 201

8. Crossover Versus Parallel Designs  
   *Andrew P. Grieve*  
   Page 239

9. Handling Dropouts and Related Issues  
   *Richard G. Cornell*  
   Page 271
10. Group Sequential Methods in Clinical Trials
   Peter C. O'Brien

11. Survival Analysis
   John D. Kalbfleisch and James O. Street

12. Robust Data Analysis
   Robert V. Hogg, Stephen J. Ruberg, and Lianng Yuh

13. Categorical Data Analysis
   Gary G. Koch, Gregory J. Carr, Ingrid A. Amara, Maura E. Stokes, and Thomas J. Uryniak

14. Causality Assessment for Adverse Drug Reactions
   David A. Lane

15. Bayesian Metaanalysis
   William DuMouchel

16. Inferential Problems in Postmarketing Surveillance
   David A. Lane and Nigel S. B. Rawson

Index