Clinical Research Manual

Chapters and Authors

1. Drug Discovery
   Charles J R Hedgecock - Biovitrum, Sweden

2. The Planning of International Development of New Medicines
   D Michael Humphreys - Boehringer Ingelheim Ltd, UK

3. Pharmacokinetics
   Stephen I Ankier - Ankier Associates, UK

4. Product Registration in the UK and Europe
   Janice Kirby-Smith - NDA Regulatory Science Ltd, UK

5. Regulatory Processes in the USA
   Thomas L Pituk - Pharmakopius International Inc, USA

6. Japanese Regulatory Requirements
   Richard Smith - Pharmakopius International Inc, UK

7. Ethical and Legal Aspects of Clinical Research
   Arundel McDougal, Camilla Hoffman and Jo-Anne Powell - Ashurst, UK

8. Monitoring the Safety of Medicines
   Ronald D Mann - University of Southampton, UK

9. Study Design
   Alan Davies and John Whittaker - Kendle International Inc, UK

10. Recruitment of Investigators
    Jacqueline Karmel and Roy Shentall - Millennium Pharmaceuticals Ltd and
    Lancashire Teaching Hospitals NHS Trust, UK

11. Clinical Trial Monitoring
    Gareth Hayes - Phlexglobal Ltd, UK

12. Good Clinical Research Practice
    David Talbot - LEO Pharma, UK
13. Standard Operating Procedures
   Pauline Arnott - DAR Ltd, UK

14. Clinical Trial Supplies
   Sue Miles - Brecon Pharmaceuticals Ltd, UK

15. Statistics
   Anne Wiles and Dennis Chanter - BRI International Ltd, UK

16. Quality Assurance and Clinical Research
   Rita Hattemer-Apostel - Verdandi AG, Switzerland

17. Report Writing
   Janet Gough - Documentation, Systems, and Training, USA

18. Socioeconomics in Healthcare
   M Sam Salek and Brian B Godman - University of Wales, UK

19. Research Fraud and Misconduct
   Jane Barrett - Medico-Legal Investigations Ltd, UK

20. Effective Budgeting of Clinical Research Studies
   David W Dalton - Ixion Consulting Ltd, UK