

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