



Sensible Guidelines for the Conduct of Clinical Trials

Second meeting

5th & 6th September 2009, St. Anne's College, Oxford, UK

The Organising Committee gratefully acknowledges unrestricted grants from:



Bristol-Myers Squibb

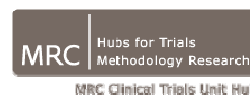


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AGENDA

ARRIVALS: Friday 4th September

- From 16.00 Registration; St Anne's College
19.00-22.00 Buffet supper

DAY 1, Saturday 5th September, 2009

- 08.30 Registration and Coffee; Martin Wood Lecture Theatre
09.00 Introduction to the meeting
Professor Sir John Bell, Chair, Office for Strategic Co-ordination of Health Research (OSCHR)

SESSION 1: Overcoming barriers to initiating trials

Chairs: Professor Sir John Bell, Professor Colin Baigent

- 9.10 Minimising delays within regulatory agencies
Professor Christopher Granger, Professor of Cardiology, Duke University
- 9.40 Reducing delays in institutional approvals
Professor Janet Darbyshire, Professor of Epidemiology, MRC Clinical Trials Unit, University of London
- 10.10 Contracts and insurance in international trials
Professor Jackie Bosch, Population Health Research Institute, McMaster University
- 10.40 Coffee break
- 11.00 Sensible ethics for research ethics review
Professor Mike Parker, Professor of Bioethics, Director of the Ethox Centre, University of Oxford
- 11.30 Panel Discussion: Professor Jackie Bosch, Professor Janet Darbyshire, Dr Brian Davis, Professor Christopher Granger, Dr Richard Liwicki, Dr Dianne Murphy, Professor Mike Parker, Dr Robert Temple
- 12.30 Lunch

SESSION 2: Overcoming barriers to conducting trials

Chairs: Professor Marc Buyse, Dr Philip Devereaux

- 14.00 A Regulatory Perspective from China
Dr Zhang Jingli, Deputy Commissioner, SFDA, China
- 14.30 Problems resulting from privacy laws
Professor Sir Alex Markham, Chair, NHS Connecting for Health Research Capability Programme
- 15.00 How should trials be monitored?
Dr Martin Landray, Reader in Epidemiology, CTSU, University of Oxford
- 15.30 Inspection priorities based on the experience of the MHRA
Mr Ian Oulsnam, Expert Inspector, MHRA
- 16.00 Tea break
- 16.20 How should we monitor safety in trials?
Professor Salim Yusuf, Professor of Medicine, Director of Population Health Research Institute, McMaster University, Hamilton Health Sciences
Professor Robert Califf, Vice Chancellor for Clinical Research, Professor of Medicine, Division of Cardiology, Duke University
- 16.50 Panel Discussion: Professor Robert Califf, Professor Rory Collins, Mr Gerald Heddell, Dr Martin Landray, Professor Sir Alex Markham, Mr Ian Oulsnam, Professor Peter Sandercock, Professor Salim Yusuf
- 18.00 Sensible Guidelines Working Group meeting (by invitation)
- 19.00 Reception at the University Museum
- 20.15 Dinner at St Anne's College

DAY 2, Sunday 6th September, 2009

08.30 Coffee; Martin Wood Lecture Theatre

SESSION 3: Streamlining trials: what needs to change & how do we do it?

Chairs: Professor Robert Califf, Professor Salim Yusuf

Case studies: streamlining trial regulation and governance

09.00 The UK Clinical Research Collaboration

Professor Dame Sally Davies, Director General of Research and Development for the Department of Health and NHS, Chair of the UKCRC Board

09.30 The US FDA's Clinical Trials Transformation Initiative (CTTI)

Dr Judith Kramer, Duke University

10.00 Streamlining Clinical Research

Dr Richard Barker, Director General of The Association of the British Pharmaceutical Industry

10.45 The organisation and management of UK clinical trials: Evidence from the current landscape

Professor Maxine Robertson, Director of Research, School of Business & Management, Queen Mary University of London

11.00 Coffee break

11.20 How can we resolve the current problems with the EU Directive?

Dr Ingrid Klingmann, Project Coordinator, Impact on Clinical Research of European Legislation

How can we facilitate a programme of constructive change in regulations internationally?

11.50 Panel Discussion: Dr Richard Barker, Dr Brian Davis, Professor Dame Sally Davies, Dr James (Terry) Ferguson, Dr Ingrid Klingmann, Dr Judith Kramer, Professor Maxine Robertson, Dr Anders Svensson

13.00 Concluding remarks

Professor Rory Collins, Professor of Medicine and Epidemiology, Co-director CTSU, University of Oxford

13.15 Lunch and departures