

Conference Programme



Mapping the future

ACDM Annual Conference
9-10 March 2009
Whittlebury Hall Hotel,
Northamptonshire

acdm 
association for **clinical data management**

The events being experienced in the world today are truly global in their impact, gone are the days where the impact was only experienced nationally or regionally. Mapping the Future for Data Management presents similar challenges and consequences, but given how Data Managers have evolved their roles and responsibilities to date, the future remains an exciting and challenging place for Data Management professionals.

The 2009 Conference brings together an exciting mix of presentation, discussion and debate where a number of contributors will share their experiences and how they see the future being mapped.

The agenda has been designed with topics of interest for data managers who are new to the profession as well as those who have many years of experience within the industry. The conference will include a range of exhibitors and there are sponsorship opportunities available. The ACDM also invites you to submit a poster for the “John C Amos Award for Clinical Data Management Innovation” sponsored by Merck at the ACDM Annual Conference.

Conference Programme

Day 1 – 9th March

9:15 **Welcome Speech**

David Baker, ACDM Chair

Session Chair – Brian Gennery, Pharmaceutical medicine consultant with a special interest in early stage development and paediatric drug development.

9:30 **“Mapping the Future” Guest Speaker**

Phil Hammond

Phil Hammond is a GP, writer, speaker and Broadcaster. He graduated at Cambridge University at St Thomas’ Hospital, London in 1987. Phil has taught frequently about the complexities of Medical decision making, he co-wrote and fronted six series of “Trust Me, I’m a Doctor” an award winning BBC 2 health series promoting evidence based patient choice and his book of the same series is a best seller. Phil Hammond will provide us with some interesting views on how he sees the future of healthcare being mapped out.

10:15 **Randomisation in Everyday Clinical Care – The New Epidemiological Tool**

John Parkinson, MHRA

The full electronic, coded, recording of data has for many years been the quest of researchers who use observational data. The era is upon us where many clinical trials could be conducted using these electronic records as the source of the clinical trial data. The presentation will show how everyday clinical data now has a major role in enabling a whole range of both observational and interventional studies.

11:00 **Coffee Break**

11:45 **Break-Out Sessions**

Choose from one of the two options below:

- SAE Handling in EDC systems
- MHRA Audits

the Future

- Whittlebury Hall Hotel, Northamptonshire



12:45 Lunch

Session Chair – Harshad Sodha Vice President, CDM Operations, Omnicare Clinical Research.

14:00 AGM

15:00 Managing a Successful Offshore Data Management Unit

DilliBabu Shunmugam, ICON Clinical Research

A presentation outlining how Data Management activities can be successfully off-shored, the challenges to be embraced and how success is measured and recognised.

15:30 Tea Break

16:00 Phase IV Clinical Trials

Stephen Dorman, CTEP

Discover how niche EDC providers are continuing to adapt their technologies to meet the ever increasing demands on Phase IV trials. Understand what sites are looking for in EDC technologies in order to conduct Phase IV trials successfully.

16:30 ePRO Evolution and its Impact on Clinical Data Management

Adam Wood, Invivodata

This presentation will focus on the changes in ePRO that are directly relevant to clinical data managers, including the evolution of modern ePRO, the role of psychometric and linguistic validation, and how regulatory bodies, such as the U.S. FDA are impacting clinical data management, through it's Draft Guidance on PROs in Clinical Research.

17:00 How eSOURCE is Driving Changes in our Industry

Richard Young, Cmed

This presentation will provide a detailed review of how eSource can drive a huge shift in the industry, from changing roles and responsibilities to costs and processes.

17:30 End of day one session

19:00 Champagne Reception

19:30 Gala Dinner

"James Bond" – 007 theme night.

Day 2 – 10th March

8:45 Welcome Speech

Tom O'Leary, ICON Clinical Research

Session Chair – Gail Kniveton Director, Data Services i3 Pharma Resourcing.

9:00 EDC & ePRO Solutions

Gilbert Bellachen, Oracle Corp

Learn more about how e-technologies will converge in the future and how data will be integrated across various technologies. This presentation will consider how services in clinical trials maybe orchestrated to allow flexible processes in the future.

9:45 Debate

"This house believes that the huge advances in technology have not led to any significant increase in the quality of data" – Julianne Hull, Senior Director, Global Development Data Operations, Wyeth Research will chair this entertaining and exciting debate.

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10:30 **Tea Break**

11:15 **The New Clinical Trials Landscape: eSource, Adaptive Trials and The iPhone Revolution**

Richard Young, Cmed

This presentation will consider the latest technologies in the market place and highlight the challenges facing the eDC industry.

11:45 **Breakout Sessions**

Choose from one of the two options below:

- EDC Special Interest Group
- CDISC

12:45 **Lunch**

Session Chair – David Walpole Therapy Programme Manager, Clinical Data Management, GSK.

14:00 **Electronic Data Capture + Effective Training = High Quality Data**

Paul Millard, Phase Forward

Experience has taught Phase Forward that effective Investigator training can have a direct influence on the timeliness and quality of data entered into eClinical systems. This talk will discuss the most appropriate methods of training for a number of real-life scenarios.

14:30 **Quality and How it can be Impacted**

Ian Clarke

This presentation will explore the meaning of quality in clinical trial data, what factors effect quality and how quality can be achieved by the steps taken up-stream in a clinical trial.

15:00 **EDC Training for Investigators and Site Staff – The Optimum Delivery**

Stuart Cook, Pharmanet

Increasingly, Investigator Meetings are becoming more and more condensed in terms of agenda and available time. Therefore a paradigm occurs where EDC application training and CRF Completion Guidelines can be delivered to most if not all site staff at an Investigator Meeting yet there is often little time available. This presentation will review the optimal approach to successful EDC training at Investigators Meetings.

15:30 **Closing Remarks**

How to Book

To register on-line for the ACDM Annual Conference
visit our website www.acdm.org.uk.

If you have any questions please contact us by
email (admin@acdm.org.uk) or by telephone (01727 896080).