

**SAVE  
15% IF BOOKED  
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# WORKING SMARTER



**acdm**   
association for **clinical data management**

## **ACDM Annual Conference 2011**

Whittlebury Hall Hotel  
Northamptonshire  
6-8 March 2011



Conference  
Committee



## Sunday 06 March – Evening

**Evening Entertainment – Buffet meal and Stand up Comedy**

## Monday 07 March – Day 1

**Session Title: Change and Balance**

**Session Chair: Emmet Browne, Head of DMO, Romania, Cmed Research**

**09:15-09:30**

### Welcome Speech

**Fred Daniels, ACDM Chair, Vivienne Yeap, Senior Study Data Manager, Roche Products Ltd and Vicky Wiggins, Project Manager, i3 Statprobe**

**09:30-10:15**

### Keynote Speaker – Life is Change. Growth is Optional. Choose Wisely

**Mark Elsley, Head of Data Management, Novo Nordisk**

Increasing globalisation, improved clinical trials systems and offshoring are just some factors leading to a diminishing demand for the traditional Data Manager in the UK. This presentation will start with a light-hearted look at change and how it affects us and then venture where no Data Manager has ever been before with a thought provoking insight into how data management is likely to change and what new opportunities there are for those who choose wisely.

**10:15-10:45**

### Balancing the Books

**Mark Campbell, Project Management Consultant, CROS NT**

Delivering projects to budget has become a predominate performance metric in clinical trials as organisations look to cut costs, reduce time to market, and CROs in particular, seek to compete in a highly competitive market. Delivering projects on budget and sacrificing time, quality or the employee satisfaction, customers and peers is a paradox afflicting organisations, which can be avoided. This presentation brings focus to project budget without distracting from quality, collaboration and timelines, making on-budget the by-product of sound judgement and effective management.

**10:45-11:00**

### Coffee

**Session Title: AGM and Panel Discussion INCDMA**

**Session Chair: Fred Daniels, ACDM Chair**

**11:00-12:30**

**Main Room**  
AGM/INCDMA

**Breakout 1**  
EDC Vendor

**Breakout 2**  
EDC Vendor

**11:00-11:45**

### AGM

**11:45-12:30**

### The Yin and Yang of Clinical Data Management – can this help us to work smarter?

**INCDMA (International Network of Clinical Data Management Associations) Panel Discussion**

**12:30-13:45**

### Lunch

**Session Title: Planning**

**Session Chair: Harshad Sodha, Global Head of Clinical Data Management, Cmed Research**

**13:45-15:25**

**Main Room**  
Planning

**Breakout 1**  
Senior Forum

**Breakout 2**  
EDC Vendor



<p><b>13:45-14:10</b></p>	<p><b>How does a Smart Data Manager Think in 2011 and Beyond</b>  <b>Monica Pimazzoni, Head of Data Management, CROS NT</b>          Evolving markets, new technologies, early decision-making needs, pressure to cut time to market a drug, demanding project teams, increasing complexity in study designs, fusion studies etc, these are just some of the problems or situations that anyone in a project or study team has happened to experience, and Data Managers are included.</p>		
<p><b>14:10-14:35</b></p>	<p><b>How does Quality Risk Management Work in Practice?</b>  <b>Peter Schiemann, Clinical Quality Assurance, F. Hoffmann – La Roche Ltd.</b>          The new approach of Quality Risk Management using existing data to identify areas with increased quality risk. How this can help in study management. SQA objectives and scope are discussed. Risk Assessment categories are defined. Continuous Risk Assessment looks at process and uses key risk indicators to identify compliance. Data driven risk assessment process represents the backbone of QEM. Example report also given.</p>		
<p><b>14:35-15:00</b></p>	<p><b>Using Advanced, Next-generation EDC Functionality to Simplify Workflow</b>  <b>Paula McHale, Senior Director, Product Management, Data Management Solutions, Perceptive Informatics</b>          Major advances in EDC systems are taking place to introduce functionalities that enable sponsors to not only accelerate collection of clean data but also in a way that dramatically simplifies user workflows while enhancing strategic decision making. The next-generation web-based study design tool helps effectively transform a protocol into an EDC study through facilitating centralized libraries and cross-user collaboration for a faster study build.</p>		
<p><b>15:00-15:25</b></p>	<p><b>Six Sigma Process Improvements for On-boarding of new Data Managers and missing CRF Pages</b>  <b>Adam Baumgart, Senior Director Clinical Data Management, Covance</b>          This presentation will outline the Six Sigma process excellence approach and in particular, two Data Management case studies. The first case study will focus on the provision of IT tools, applications and access for new data management employees. The second will focus on the real issue of missing pages in paper and EDC studies. Real examples will be used so attendees will appreciate the tangible impact of stringent process improvement techniques and their results.</p>		
<p><b>13:45 – 15:25</b></p>	<p><b>Breakout 1 – Senior Forum – Smart Project Management Across the Globe</b></p>		
<p><b>15:25-16:00</b></p>	<p><b>Coffee</b></p>		
<p><b>Session Title: Oncology and Senior Forum Feedback</b>  <b>Session Chair: Andrew Green, Project Data Manager, Pfizer</b></p>			
<p><b>15:25-16:30</b></p>	<p><b>Main Room</b>          Oncology and Senior Forum Feedback</p>	<p><b>Breakout 1</b>          EDC Vendor</p>	<p><b>Breakout 2</b>          EDC Vendor</p>
<p><b>16:00-16:30</b></p>	<p><b>Oncology Trials: Where Independent Review of Data is one of the Primary Endpoints how we can Improve the Cost, Quality and Speed of Obtaining this Information.</b>  <b>Alex Franklin, Instream Process Owner, Principal Data Scientist – Oncology, GSK</b>          I currently work in Oncology Data Management and a large number of our trials have independent review data as one of the primary endpoints. Over the last couple of years GSK has been looking at how we receive this data and how we can improve the cost, quality and speed of obtaining this information.</p>		



<b>16:30-17:00</b>	<b>Senior Forum Feedback</b> An opportunity for us all to get feedback from the Senior Forum Meeting held earlier today.
<b>17:00</b>	<b>Day 1 Round-up</b> <b>Vivienne Yeap, Senior Study Data Manager, Roche Products Ltd and Vicky Wiggins, Project Manager, i3 Statprobe</b>
<b>19:00</b>	<b>Champagne Reception</b>
<b>19:30</b>	<b>Gala Dinner</b>

## Tuesday 08 March – Day 2

**Session Title: Cloud Computing**

**Session Chair: Ian Slack, Global Coding Manager, Vertex Pharmaceuticals**

<b>09:30-09:35</b>	<b>Welcome Speech</b> <b>Vivienne Yeap, Senior Study Data Manager, Roche Products Ltd and Vicky Wiggins, Project Manager, i3 Statprobe</b>
<b>09:35-10:15</b>	<b>Cloud Computing</b> <b>Daniel Chappell, General Manager &amp; Practice Lead Cognizant Life Sciences, Europe</b> Cloud computing has the potential to offer great advantage to processes in Life Sciences as it can be used to automate manual activities, reduce the amount of repetition and provide a solution to lack of project & workflow systems. In this talk, we will address what cloud computing is, how it can be used and we will focus on some work we have undertaken to look at some of the challenging processes in Clinical Data Management that involve multiple parties, systems and processes and that could be addressed through cloud.
<b>10:15-11:00</b>	<b>Coffee</b>

**Session Title: The Debate and Working Smarter**

**Session Chair: Gail Kniveton, Director, Business Services: i3 Pharma Resourcing**

<b>11:00-12:30</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;"><b>Main Room</b> Debate</td> <td style="width: 33%; text-align: center;"><b>Breakout 1</b> Coding SIG and UMC</td> <td style="width: 33%; text-align: center;"><b>Breakout 2</b> EDC Vendor</td> </tr> </table>	<b>Main Room</b> Debate	<b>Breakout 1</b> Coding SIG and UMC	<b>Breakout 2</b> EDC Vendor
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<b>11:00-12:00</b>	<b>Debate led by Julianne Hull, Senior Director, Global Clinical Data Services, Pfizer</b> <b>Debaters Paul Fardy, Senior Director Clinical Data Management, Eisai, Rob King, Data Management, Icon Research and two speakers to be confirmed</b> This house believes the supremacy of e-mail as the primary tool of communication in the clinical research industry has caused us to work less smart rather than smarter – TBC.			
<b>12:00-12:30</b>	<b>Working Smart but not Longer</b> <b>Stuart Cook, Principal Data Analyst, PharmaNet</b> The advent of Electronic Data Capture brings with it increased opportunities for efficiencies in start-up, conduct and close-out. In this presentation we will look at efficiencies and how they can be pragmatically adopted in a clinical EDC trial such as specialist teams, expanded working days, and incremental cleaning and locking of data.			
<b>12:30-13:35</b>	<b>Lunch</b>			



## Day 2 – Continued

**Session Title: Data Warehousing and Working with Partners**

**Session Chair: Vivienne Yeap, Senior Study Data Manager, Roche Products Ltd**

**13:35-15:15**

**Main Room**  
Data Warehousing  
Working with Partners

**Breakout 1**  
PM SIG

**Breakout 2**  
EDC Vendor

**13:35-14:00**

**Data Management and Biostatistics: A Synergistic Relationship**

**Pratik Kulkarni, Data Manager, Syne Qua Non**

It is proposed that this would be presented by Pratik Kulkarni (DM) with support from a statistician. With interactive role play the presentation would show the negative impact on cost in getting the interaction wrong vs. the positive benefits of getting it right.

**14:00-14:25**

**Liberating Data**

**Andrew Davy, Manager, IT Systems and Pauline Allen, Manager, CRF Design, Syne Qua Non**

This would cover the use of CDISC ODM based standards as the technological backbone with the concept of library eCRF, Data Management, Statistics and reporting objects that dramatically simplify the data management and clinical process. Using this foundation the presentation would look at 'liberating the data' by allowing structured access to the data meeting the needs of all those involved in the clinical process. It is proposed that the presentation will be full of examples and real life experiences in this area intermixed with some fun and humour.

**14:25-14:50**

**How Online Endpoint Adjudication System (EAS) Technology Optimizes the Entire Endpoint Assessment Process**

**Simon Hawken, Business Development Director, KIKA-CS**

Clinical Endpoint Committees (CECs) require the collection & compilation of multiple types of data and documents to make the robust decisions necessary as adjudication outcomes. The use of an "end-to-end" electronic management system provides them with the ability to collaborate in a single environment to optimize the entire endpoint process. This session will show how online Endpoint Adjudication System (EAS) technology reduces endpoint cycle times allowing Sponsors to achieve database lock in a more timely & efficient manner.

**14:50-15:15**

**Clinical Data Warehousing and Reporting Environments: Approaches and Considerations for Small and Medium-sized Companies**

**Mike Grossman, Vice President, Clinical Data Warehousing and Analytics, BioPharm Systems**

Having overcome many of the challenges of the transactional systems that support the capture and management of data in clinical studies, organisations are increasingly focused on combining data across multiple studies and data sources to get deeper insight in to their data. This can range from a simple low cost reporting environment to a complete overview of all clinical trials management data and subject data. By gaining further insight in the available data, a company can reduce overall operational costs by running the business more efficiently. In addition, proper subject data monitoring can allow for more rapid decision making therefore decreasing company and subject risk and reducing overall costs of running a clinical program.



<b>15:15-15:30</b>	<b>Coffee</b>		
<b>Session Title: ePRO</b> <b>Session Chair: Ian Pinto, Program Data Leader, Roche Products Ltd</b>			
<b>15:30-16:30</b>	<b>Main Room</b> ePRO	<b>Breakout 1</b> PM SIG	<b>Breakout 2</b> EDC Vendor
<b>15:30-16:00</b>	<b>Optimising clinical monitoring and data management with ePRO</b> <b>John Jordan, Senior Vice President of eClinical Technologies, CRF Health and Mary Monahan, Regional Associate Director, Clinical Operations, Merck</b> Clinical Operations groups within sponsor organisations are being exposed to many different technologies being used in clinical studies. Not only do the Clinical Monitors/CRA's need to understand multiple technologies ranging from EDC and ePRO to portable ECG's and respiratory devices, however the Clinical Data Management groups must also be aware and cognizant of the technical components and the impact they have on their processes.		
<b>16:00-16:30</b>	<b>Getting Better Data Out of Patient Reported Outcomes with Web-based ePRO</b> <b>Scott Dixon, Vice President, Phase Forward</b> Hand-held PDA devices were the first wave of dedicated electronic PRO (ePRO) technology designed to improve the data quality coming from patients and provide reviewers with more immediate access to data. While this solution has advantages over distributing paper, the small PDA screens can possibly restrict the information patients provide, and are costly to distribute and maintain. Other electronic options, EDC and IVR, also have inherent problems that can constrict accurate data collection, limiting widespread adoption of these technologies for late phase research and ePRO.		
<b>16:30</b>	<b>Round up and Close Conference</b> <b>Fred Daniels, ACDM Chair</b>		

## How to Book

To register on-line for the ACDM Annual Conference  
visit our website [www.acdm.org.uk](http://www.acdm.org.uk).

If you have any questions or would like to exhibit please contact  
us by Email [admin@acdm.org.uk](mailto:admin@acdm.org.uk) or by telephone **01727 896080**.

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