

Future Fit



ACDM Annual Conference 2012

Monday 12th & Tuesday 13th March
Whittlebury Hall Hotel, Northamptonshire

Sunday 11th March 2012	
Evening Entertainment including a Buffet Meal and Stand-Up Comedy	
Monday 12th March 2012	
09:15	Conference Opening
09:20	<p>What is Keeping Data Managers Busy Today? <i>Vanessa Tierney, Head Data Quality Practice, GSK R&D</i></p> <p>Look around at data managers today and you'll see a diverse bunch of people, with a variety of backgrounds and a plethora of job accountabilities that are constantly adapting. This has been the case for sometime but with continuing challenges to cost, quality and speed to deliver, coupled with changing technology, the smarter data managers may now be finding ways to bring increased value. This presentation will share observations of how data managers are changing their skills and capabilities. It will take a look at the emerging roles and suggest how and why this is occurring.</p>
09:50	<p>Is the future risky? – What can you do? <i>Jane Tucker, Risk Management Consultant and Trainer, R.J.T Associates</i></p> <p>The future will always contain risks and opportunities. We will investigate how you can ensure that you are always well prepared to identify and manage risks, and importantly, also ready to capitalise on opportunities.</p>
10:20	<p>“PARAs must be fit” <i>Tomás O'Mahoney, Clinical Operations Director, Clinical Trial EndPoint (CTEP) Ltd</i></p> <p>With the development in trials there is an evolving importance for well-documented patient observational studies. This topic will explore the main design elements essential to fast and cost-effective, post-approval clinical studies and what necessary skills and knowledge levels are required to undertake effective, ethical studies without risks to data privacy or any corruption of the electronic data collection (EDC) process. We will also review specific eCRF considerations for post-approval studies.</p>
10:50	REFRESHMENT BREAK

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

11:30	Parallel Sessions	
11:30	<p>Preparing for the Cloud <i>Rich Davies, Solutions Specialist, Oracle Health Sciences</i></p> <ul style="list-style-type: none"> ● Review how the cloud is being used in clinical research today. ● Discuss the benefits of virtualized research in the cloud computing environment. ● Identify key technology workflows and steps to take to prepare for virtualized research. 	<p>Troubleshooting:- Using a System Thinking Approach <i>Mark Campbell, Project Management Consultant</i></p> <p>Data Management has many customers, including the Sponsor or investigational sites and statistics to name a few. In order for data managers to be successful they must be proficient in troubleshooting problems as they arise through the trials they are accountable for. This session will introduce the concept of 'systems thinking' as a core discipline for data managers to utilise when problem solving. The session will use everyday problems faced by data managers and by using the practical application of systems thinking unearth interesting facts about these problems; whilst learning to separate cause from effect in large complex studies.</p>
12:00	<p>The Cost of doing business in the Cloud <i>Steve Tee, CTO/Head of Technology, Clinical Trial EndPoint (CTEP) Ltd</i></p> <p>This paper will focus on the potential cost savings available to organisations who opt to use internet and 'cloud-based' platforms for their clinical trials.</p> <p>The future is premised on a migration of suitable services to software-as-a-service (SaaS)-based, cloud-resident services where an existing business model – such as clinical trial infrastructure – can be adapted and streamlined to suit the customers' requirements. Major savings can be envisaged provided this new environment can be made to work in the pharma context.</p>	
12:30	LUNCH & EXHIBITION	
13:30	<p>"Is Learning A Non-Contact Sport?" <i>Bob Melville</i></p> <p>Summary - In the world of learning and development, there have been huge changes in the way in which solutions have been delivered over the last 10 years, and we can expect further changes as we move forward. Some organisations have been quick to embrace more recent innovations, while in others there is some resistance to new techniques. Is there still a place in this rapidly changing business environment for traditional delivery?</p>	
13:50	ACDM Annual General Meeting	
14:20	International Network of Clinical Data Management Associations <i>Panel Discussion</i>	
15:20	REFRESHMENT BREAK	

15:40	Parallel Sessions	
15:40	<p>Black Swan Events in Clinical Trials and Data Management <i>Octavia Morancea, Clinical Data Manager, Cmed Research</i></p> <p>The theory of Black Swan Events is a metaphor that encapsulates the concept that an event is a surprise (to the observer) and has a major impact. The theory has ancient roots, but it was not long ago developed and adapted to the modern society by Nassim Nicholas Taleb. It is widely accepted that black swans may occur in history, finance, science and technology, but they can also be found in particular domains and sub-domains, even in medicine, pharmacy, clinical trials and data management.</p> <p>The article tries to identify some vulnerable spots in clinical trials and data management domain, where unexpected events with major impact can occur at any time and question how future fit we are in order to minimize unpredicted major effects. The article will debate separately the technological perspective, with a special discussion over electronic data capturing - eDC systems (durability, robustness and cloud computing aspects), as well as statistics (predictability and risk factors, black swans vs. Gauss) and medicine, giving a flavour on how iatrogenics, teratogenicity, SAEs, placebo effects, etc can impact a clinical trial.</p>	<p>Troubleshooting:- Using a System Thinking Approach: <i>Mark Campbell, Project Management Consultant</i></p> <p>Data Management has many customers, including the Sponsor or investigational sites and statistics to name a few. In order for data managers to be successful they must be proficient in troubleshooting problems as they arise through the trials they are accountable for. This session will introduce the concept of 'systems thinking' as a core discipline for data managers to utilise when problem solving. The session will use everyday problems faced by data managers and by using the practical application of systems thinking unearth interesting facts about these problems; whilst learning to separate cause from effect in large complex studies.</p>
16:05	<p>Inspection Readiness: The Sprint to success <i>Sara Alalouff & Laurence Ghafar</i> <i>Clinical Data Management – Biometrics Product Development, Roche Products Ltd</i></p> <p>PROACTIVITY is key to managing inspection preparations, Roche has spent the past year focusing on changing the mindset to one of proactivity as opposed to reactivity. We achieved this through the development of two supportive networks – The Biometrics Inspection Readiness Network (BIRN), whose purpose is to align support to the overall global Biometrics function where Inspection activities are mostly focused - Clinical Data Management, Statistical Programming and Analysis and BioStatistics; and the Process Efficiency & Compliance Oversight Committee (PECOC) – providing a global overarching governance structure to CDM that manages compliance on an ongoing basis and interlinks well with the BIRN to ensure that Inspections and Outcomes are effectively managed. Laurence Ghafar and Sara Alalouff would like to share how you too can be FUTURE FIT for inspections.</p>	
16:30	Closing Remarks	
19:30	Drinks will be served in the Bentley and Aston Rooms, followed by The Gala Dinner in the Grand Prix Suite	

Tuesday 13th March 2012	
09:15	Opening Remarks
09:20	<p>Don't Tell the Dinosaurs <i>Ayd Instone</i> How right-brain thinking will help you cope with change and increase your success in the 'New Economy'. Ayd is an inspirational and motivational speaker who unleashes people's talent, helps them find their creative dynamic and unlocks Thought Innovation. Using humour, original songs (often bespoke to the audience, performed on acoustic guitar) and high energy, Ayd creates a unique, entertaining and inspirational performance.</p>
09:50	<p>Electronic Medical Records (EMRs) and their use in clinical trials: A case Study <i>Faye Jamali and Geraldine Smith</i> The aim of the presentation is to describe the methodology, challenges and key learnings of setting up a clinical study in a 'real-life' setting using integrated patient primary and secondary care electronic medical records.</p>
10:15	REFRESHMENT BREAK
10:30	<p>Risk Based Source Data Verification <i>Shafi Chowdhury, Managing Director, Shafi Consultancy Limited</i> Source Data Verification (SDV) is a must in clinical trials. However, it is not required that all data of every patient is verified. Intelligent use of SDV can ensure the CRAs spend more time on "risky" sites, and less time on sites which are "proven" to be reliable. This will deliver cleaner data using less CRA time, assess quality of sites, and save millions during the conduct of mega trials.</p>

Continued overleaf

How to Book

To register on-line for the ACDM Annual Conference

visit our website **www.acdm.org.uk**.

If you have any questions or would like to exhibit please contact

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11:00 & 11:40

Parallel Sessions

Software as a Service – the Future, or the latest fashion?

Richard Young, Director, Regional Sales (EMEA) Medidata

Software as a service (SaaS), sometimes referred to as “on-demand software,” is a software delivery model in which software and its associated data are hosted centrally and are typically accessed by users using a thin client, normally using a web browser over the Internet; and SaaS has been incorporated into the strategy of virtually all leading enterprise software companies.

This presentation will use real examples, from various industries, to explore the benefits of SaaS-delivered solutions:

- Faster deployment and productivity.
- Streamlined use and management.
- Increased flexibility.
- Better reliability and performance.

The WHO Drug Dictionary in a CDISC Environment

Ola Strandberg, Vendor Liaison Officer, Uppsala Monitoring Centre

This presentation will discuss the structure of the WHO Drug Dictionaries and the CM (concomitant medication) dataset in CDISC SDTM, and best practices for submitting information coded using WHODRUG. How to identify the dictionary and version in define.xml will be covered, as well as how to capture ATC codes and when/how to use a supplemental dataset, including naming of the QNAM/QLABEL variables.

Use the define.xml Standard from the Start for CRF design

Dr. Philippe Verplancke, Managing Director, XClinical GmbH

Many still see the creation of define.xml as a necessary and annoying duty at the end of a clinical trial when delivering the SDTM datasets. However, with define.xml, you are just one click away from the automatic set-up of an EDC/CDM system. A number of EDC/CDM systems are officially certified to be able to import CDISC ODM metadata. Importing define.xml into an EDC system ensures that the data are collected in a way which is compliant to the SDTM standard. define.xml and ODM XML are almost identical as far as the value-level metadata are concerned. If you understand the value of this approach, you'll want to start by building define.xml and odm.xml before you start your next clinical trial.

Multivariate Bayesian Logistic Regression for Analysis of Clinical Trial Safety Issues

William DuMouchel, PhD, Chief Statistician, Oracle Health Sciences

Explanation of multivariate Bayesian logistic regression
Description of how a set of medically related issues can be fit to a parallel logistic regression model so as to allow them to “borrow strength” from one another
Apply method in trials sized for efficacy with sparse response data.

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12:20	LUNCH & EXHIBITION
13:30	Energiser: Preparation for the Olympics and whether weather data is just like clinical data? <i>Including Sarah Keith-Lucas – Broadcast Meteorologist with the BBC and a Data Manager in a previous life.</i>
14:00	What do Adaptive Trials mean to Clinical Data Management <i>Emmet Browne, Director, CMed CRS Limited</i> Adaptive clinical trials have sparked much debate in R&D circles in the last few years. This presentation will provide some real life examples of how adaptive clinical trials really affect all aspects of Clinical Data Management and will explore some aspects of the FDA guidance. The presentation will also provide the concept of an ideal adaptive platform and how the data would flow through the clinical trial process. Ultimately this presentation should provide some insight into how operations can be affected by using an adaptive trial design. The presentation will also call out benefits and potential pitfalls to avoid; hopefully shining some light on the mysterious world of adaptive trials. Finally, there will also be a brief glimpse into what maybe the future of trial data management of the future.
14:30	Phase IV and ePRO – Methods, Benefits, and Execution <i>Rauha Tulkki-Wilke, Director, Product Management, CRF Health</i> Use of ePRO is increasing in Phase IV. Studies in Phase IV need cost efficient ePRO methods that allow managing patient compliance and facilitating retention of patients during long studies. Ease of use at study sites and global availability are also important. This session discusses ePRO methods that are particularly useful in Phase IV studies, the benefits that ePRO offers, and how ePRO is used in large Phase IV trials together with other eClinical technologies.
15:00	REFRESHMENT BREAK
15:15	Proactive management of emerging data quality issues <i>Margaret Seaman, Director of Quality and Compliance Management, GSK Oncology</i> Are we in Data Management being proactive enough in managing quality issues arising from changes in regulatory expectations and findings? Margaret will present on a number of recent issues that have led to changes in data management processes and practices.
15:45	Nutrition Clinical Research: ‘Last but not least’ <i>Hanneke Lankheet & Leontine Peters-van der Burgt, Danone</i> This presentation will discuss the evolution in Nutrition Clinical Research, illustrated by some examples coming from the industry. The requirements to substantiate the efficacy, tolerance and safety of nutrition products, are clearly evolving towards pharma standards. However, nutritional research does not always fit into the pharma standards. For example, from a data management perspective Danone Research proposes additional standards in CDISC. In such a way, food companies respond to expected changing requirements for nutritional research and anticipate any future changes.
16:15	ACDM Board of Directors
16:20	Conference Chair – Closing Remarks

POSTER
COMPETITION

Future Fit



Express your creativity!

The ACDM 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 2012.

John Amos was the Director of Merck's Worldwide Clinical Data Management Organisation in Brussels who sadly passed away unexpectedly on January 31st, 2004. A well known and highly respected individual within the Clinical Data Management arena, it was considered appropriate to set up an annual award, sponsored by Merck Pharmaceuticals, in his memory, in the name of Clinical Data Management innovation.

Poster Specifications

Posters should be developed around a topic related to the 2012 Annual Conference theme of **'Future Fit'**. This year the posters can be submitted electronically in either A3 or A4. All images and logos need to be in high resolution (300dpi), all fonts embedded in the pdf file and the author'(s) names should be displayed.

The posters will be judged for **innovation, creativity, quality** and **originality** by the Board of Directors and a senior Clinical Data Management member of staff from Merck, at the conference.

The Award

The author(s) of the winning poster will receive the 'John C. Amos Award for Clinical Data Management Innovation'. The award will be announced and presented on the first day of the conference. The prize will include **vouchers worth £2,500** for the author(s) to use on any ACDM training courses, conference or technical meetings. Any remaining balance up to a maximum of £250 may be used towards the purchase of ACDM publications and any other scientific publications, books or business software.* In addition to this, **a personal cheque for £500** would also be paid. For posters with more than one author, the prize may be split between the winners.

** Any remaining amounts too small to be used on anything would not be credited to the recipient(s).*

Submitting Your Poster

If you intend to submit a poster, please email a pdf of your poster to the ACDM Office with your title and names of authors no later than Monday 13th February.