Winter 2010/2011 • ISSUE 76

acdm
association for clinical data management

DataMatters

ACDM Annual Conference 2011

Whittlebury Hall Hotel
Northamptonshire
6-8 March 2011

ARTICLES
Bringing Bioengineering into Data Management

FOCUSSING ON...
The Conference Committee

ACDM TRAINING
Training Schedule 2011

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Guidelines for Contributors

Articles range from 700 words to over 2,000. Photographs, diagrams and illustrations help to break up large areas of text. News items can range from 80 – 400 words to include photographs if relevant. Profiles can range from 300-600 words, and photographs will enhance these pages.

Photographs – We need good quality digital images taken at the highest resolution possible. With digital photography the more mega pixels the camera has, the better.

Illustrations – Charts and diagrams drawn in Excel or Word will normally need to be redrawn for the printing process. If images are embedded in Word documents they need to be supplied as separate jpegs as well.

Preferably, articles should be sent via Email or CD. Plain ASCII text is best, but many WP formats can be imported. Contact the Editor for help if you are unsure.

All articles should be sent to the Editor in good time for the copy deadline. Articles may need to be edited to fit the constraints of publishing, with full text available on request. All articles are subject to editorial approval.

The opinions expressed within this newsletter are those of the individuals concerned and not necessarily those of their employers or of ACDM. All advertisements included with it are done so independently and the Editor reserves the right to refuse any, which, in his opinion, do not conform with ethical advertising standards.

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NEWSLETTER DEADLINES AND PUBLICATION DATES

If you would like to submit an article to the Newsletter or include an advertisement, then the following dates will help you plan:

Issue	Copy Deadline	Publication
Spring	21 March 2011	2 May 2011
Summer	21 June 2011	1 August 2011
Autumn	19 September 2011	7 November 2011

ACDM eShots

ACDM notices can be included in our twice monthly eShots sent around the 1st and 15th of each month. ACDM advertisements should be emailed to the ACDM office 6 working days in advance.

ACDM ADVERTISING

You can now advertise with the ACDM in the following ways:

- eShots are informative email communications sent to all registered members and non-members, highlighting relevent news and events from the ACDM and across the industry. Your advertisement will be included at least twice a month.
- *Data Matters* features articles on industry news and issues and ensures your advertisement will be viewed by an active audience of more than 1,200 data management professionals.
- Web Site *www.acdm.org.uk* now provides prime banner advertising space as well as the classifieds section where your advertisements cannot fail to be noticed.

Not only will your advertisement reach all ACDM members but also the wider community of data management and other professionals who access the website directly or click through from our eShot.

ACDM ADVERTISING RATES

Effective from 1st February 2010

Newsletter

Full Page Colour* £300
Half Page Colour* £200

Web Advertising (under recruitment or services)

One month* £150
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

Website Banner advert – Home page

One month £200
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

Website Banner advert – other pages (excluding home page)

One month £150
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

eShot advertising

One month (eShot sent at least twice a month) £150

* bulk discounts available – please contact the ACDM office for details (Tel: +44 (0) 1727 896080, email: admin@acdm.org.uk)

Download the latest advert specification sheet from the adverts section of www.acdm.org.uk

All items, excluding membership and publications, will be subject to VAT

CONTENTS

What did Father Christmas really have for me in 2010

This time last year we were all concerned about the credit crunch, its impact on our industry in general and data management in particular. Fast forward twelve months and a lot has changed and a lot has remained the same. Here are some of the data management related highlights for the year.

Though for many of us, EDC has been the norm, personally, I think 2010 was the year EDC and ePRO moved into mainstream. Until last year, I was constantly being asked by many sponsors on the pros and cons of EDC or E diaries. Could it be the credit crunch has made the most conservative of sponsors rethink and embrace technology? I hope we can look back in a few years time and think the credit crunch may have had a few silver linings for the industry.

Two of the largest Clinical Data Management Systems, Oracle Clinical and Phase Forward merged – who saw that coming? This could be a game changer. I wonder if this is the beginning of some sort of convergence as we have had in the mobile phone.

The association also prepared to meet the credit crunch by revising our goals and objectives which members can review on the website. At January's board meeting we looked back at how we have done (the topic was postponed from December's meeting due to bad weather). Quarterly reviews show some progress on this front. There will be more on this at the conference in 2011.

What I hope Father Christmas will give me in 2011:

The training committee has completed the work they started a few years ago and we currently have over 20 different courses planned for 2011. To acknowledge the potential impact of the credit crunch, courses can be run by webinar and we offer various payment options. A good year would be to have excellent attendance at these courses right through the year.

I wish for a successful 2011 conference at Whittlebury Hall with excellent speakers and a few more volunteers to help with the various committees and groups activities. Many of the groups including the newsletter and website committees are looking for more volunteers. If you are able to make this wish come true, please see the last page of this newsletter on who to contact.

Oh, one last wish for 2011 – I would also like a Lamborghini Gallardo please (just in case Father Christmas works in data management when he is not busy making presents)

Fred Daniels, ACDM Chair

ACDM Newsletter Competition

Newsletter Committee

Thank you to everyone who entered the recent newsletter quiz to win a fabulous PenCam mini camera and recorder.

The answers are:

1) One of the newsletter committee members wanted to be an astronaut according to her profile in this newsletter but what role did she play in her recent Musical performance 'Footloose' ?

Answer = The local Vicar's daughter /Ariel Moore

2) You must be 'Poking' in the world of social networking, but can you name the three social networking sites set up by the ACDM ?

Answer = Facebook, LinkedIn and Twitter

3) What is the missing word from this sentence taken from the article 'eSource in early phase' ?

Market Leading eSource systems have a high grade of ....., covering the complete workflow of a Phase-I unit

Answer = Integration

4) What is the AETERM for USUBJID = 'TEST0964296316' mentioned in the article 'Pearls of Wisdom' ?

Answer = weakness

Entries were marked and the correct ones were put into a hat where the winner's name was pulled out by an independent person.

A big congratulations goes to:

SAM GARTHSIDE , Clinical Program Lead working in Data Management of Early Phase Trials at GlaxoSmithKline.

When asked 'What are you most looking forward to using the PenCam for?', Sam replied 'Hmm, I am tempted to do a little domestic espionage – i.e. see what my 11 year old son is doing when he "says" he's doing homework but I think I'd rather not know! I am sure I will find some use for it...'

Well Sam, enjoy your prize, we hope it brings you lots of entertainment!

Thanks go to Ian Pinto for devising the questions and providing the prize and Jacqui Ward-Jones for being our independent person. Look out for more exciting prizes in 2011.

Ali Green on behalf of the ACDM Newsletter Committee

Bringing Bioengineering into Data Management with Applications in Automatic ECG Handling and Interpretation

Bioengineering is a science which refers to the applicability of engineering principles in many biological and medical challenges. It is used to design hardware devices, medical devices, diagnostic devices, biocompatible materials, and to fulfill many more medical needs that can aid the improvement of the standard of life in our society.

How can bioengineering relate to data management, pharma and biotechnology research? I can think of a most useful and stringent example in our trials nowadays – the interpretation of ECGs.

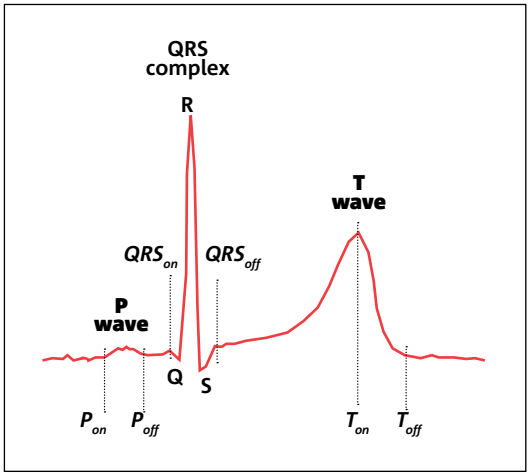
Clinical trials are very much dependant on electrocardiography which is the process of assessing the transthoracic interpretation of the electrical activity of the heart over time captured and externally recorded by skin electrodes. It is well known that cardiac safety is a critical issue in the pharmaceutical industry, and that a significant amount of effort is spent in the early stages of drug development to ensure cardiac safety and detect pathological entities which can be easily seen on the ECG traces. A few examples would be:

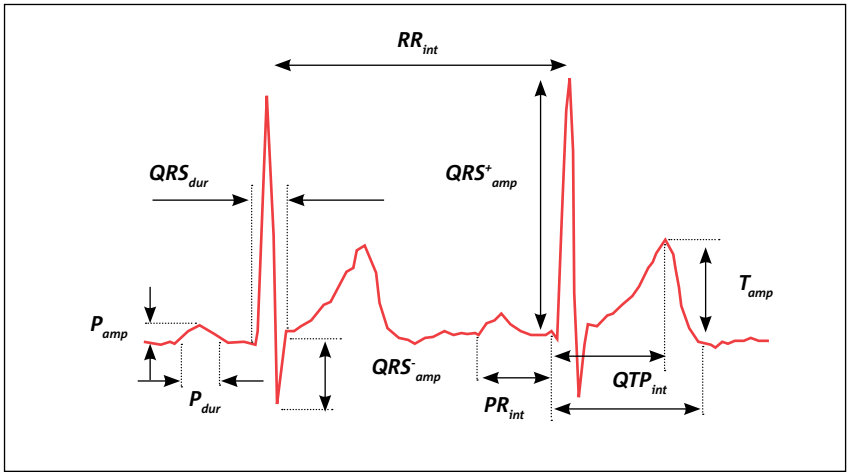
- A prolonged QT interval may be caused by hypocalcaemia,
- Flattened or inverted T waves possibly caused by coronary ischemia, hypertrophy or study drugs
- Hyper acute T waves may possibly be the first manifestation of acute myocardial infarction, etc.

The FDA and European Medicines Agency published their recommendations for ECG QT/QTc studies which evaluate the pro-arrhythmic potential of non-antiarrhythmic drugs in the ICH E14, EMEA, 2005. The assumption behind the document was that the QT-interval is a sufficient biomarker for the arrhythmogenic potential of drugs. Therefore a sophisticated, future-ready data management system which can not only enhance the ability of interpreting, managing and storing ECG data, but can also measure and track heterogeneity, (the measurement of the amount of variance between two ECG waveforms) is considered necessary.

With these requirements and specifications in mind, bioengineering – along with informatics – can simplify ECG data management by providing tools for accurate automated/semi-automated interpretation of ECGs. This must be in pursuance with all relevant standards, including the FDA Specification for Annotated Electrocardiographic Waveform Data in Electronic Format, the FDA 21 CFR, Part 11 guidelines for electronic data storage and electronic signatures and Good Clinical Practice standards.

The challenges are big when developing an algorithm and a system for ECG interpretation – the QT interval duration can be affected by direct inhibition of repolarisation as well as by normal





benign changes in the automatic state, so an accurate identification of the nature of QT signal (benign or potentially dangerous) is critical in order to avoid costly mistakes in drug development. Even if a linear formula to correct the heart rate is applied to the conventional QT analyses, generating a corrected value (which can be Bazzett, Fridericia, Framingham corrections, etc), this method works well only when a patient's heart rate does not significantly deviate from approximately 60 beats per minute. Additionally, if the study drug will cause even minor changes to the heart rate, this will totally distort the attributes of the QT interval over the drug, and according to further studies, this affects about 25% of drugs in development.

Identifying the exact location of the waves is the most difficult step in analysing ECGs. The determination of the wave's amplitudes and shapes is much simpler. The strategy for finding the exact location of the waves is to first filter the ECG signal and then recognise the QRS complex, which has a sharper slope. T wave is recognised next and finally the P wave is recognised, which is usually the smallest wave in amplitude.

Algorithms may vary in vision and architecture, but an algorithm should always be able to classify the ECGs into normal or abnormal. To do this, several parameters (can be thousands) need to be considered and assessed, or one can limit to the parameters requested in a specific study as per Data Transmission Specifications.

Furthermore, the ECG needs to be compared to the baseline ECG of the patient under evaluation and any change in parameters will be analysed. If the change found is more than an agreed range, then the ECG should be immediately classified as abnormal, even if the absolute value of QTc is still in the normal range.

Additionally, and also importantly, the system which incorporates the algorithms should enable several options for the user: to view, measure, compare and annotate the ECG waveforms, adjustable zoom facilities, generating listings and status reports which can be filtered, a facility for uploading ECG data from a variety of sources in a variety of formats (XML, CSV, PDF), and system security management.

The merits of ECG centralisation and ECG automatic interpretation are plenty from the perspective of a data manager or a CRA: replacing the manual, ad-hoc and paper-based procedures with a well-defined set of clear features and processes, like automatic receipt, storage, interpretation, management, review, analysis, formatting for transmittal and archiving ECG and descriptive data.

The market and the research in this domain are still in an early phase. There is a continuous trend in migrating from local labs to central ECG labs. However, even when working with vendors from central labs, the facilities for handling ECG data aren't numerous.

Bioengineering can provide the tools and gadgets to revolutionise ECG data handling.

The only thing left to do is a concerted effort, across the whole industry and within academic institutions to generate data sets large enough to validate fully automatic procedures and implement complex systems in order to output accurate results and make clinical research easier.

Octavia Morancea
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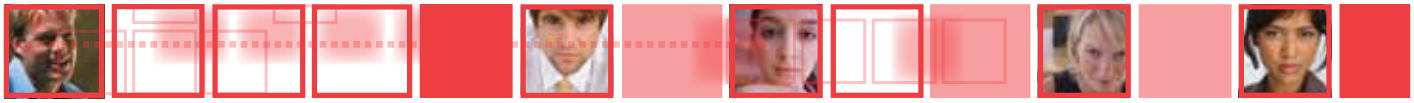

WORKING **SMARTER** – ACDM 2011 Conference

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
13:45-14:10	**How does a Smart Data Manager Think in 2011 and Beyond** **Monica Pimazzoni, Head of Data Management, CROS NT** 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.		

14:10-14:35	**How does Quality Risk Management Work in Practice?** **Peter Schiemann, Clinical Quality Assurance, F. Hoffmann – La Roche Ltd.** 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.
14:35-15:00	**Using Advanced, Next-generation EDC Functionality to Simplify Workflow** **Paula McHale, Senior Director, Product Management, Data Management Solutions, Perceptive Informatics** 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.
15:00-15:25	**Six Sigma Process Improvements for On-boarding of new Data Managers and missing CRF Pages** **Adam Baumgart, Senior Director Clinical Data Management, Covance** 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.
13:45 – 15:25	**Breakout 1 – Senior Forum – Smart Project Management Across the Globe**
15:25-16:00	**Coffee**
Session Title: Oncology and Senior Forum Feedback **Session Chair: Andrew Green, Project Data Manager, Pfizer**	
15:25-16:30	**Main Room** Oncology and Senior Forum Feedback **Breakout 1** EDC Vendor **Breakout 2** EDC Vendor
16:00-16:30	**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.** **Alex Franklin, Instream Process Owner, Principal Data Scientist – Oncology, GSK** 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.
16:30-17:00	**Senior Forum Feedback** An opportunity for us all to get feedback from the Senior Forum Meeting held earlier today.
17:00	**Day 1 Round-up** **Vivienne Yeap, Senior Study Data Manager, Roche Products Ltd and Vicky Wiggins, Project Manager, i3 Statprobe**
19:00	**Champagne Reception**
19:30	**Gala Dinner**

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 us by Email **admin@acdm.org.uk** or by telephone **01727 896080**.

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Tuesday 08 March – Day 2

Session Title: Cloud Computing
Session Chair: Ian Slack, Global Coding Manager, Vertex Pharmaceuticals

09:30-09:35	**Welcome Speech** **Vivienne Yeap, Senior Study Data Manager, Roche Products Ltd and Vicky Wiggins, Project Manager, i3 Statprobe**
09:35-10:15	**Cloud Computing** **Daniel Chappell, General Manager & Practice Lead Cognizant Life Sciences, Europe** 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.
10:15-11:00	**Coffee**

Session Title: The Debate and Working Smarter
Session Chair: Gail Kniveton, Director, Business Services: i3 Pharma Resourcing

11:00-12:30	**Main Room** Debate	**Breakout 1** Coding SIG and UMC	**Breakout 2** EDC Vendor
11:00-12:00	**Debate led by Julianne Hull, Senior Director, Global Clinical Data Services, Pfizer** **Debators Paul Fardy, Senior Director Clinical Data Management, Eisai, Rob King, Data Management, Icon Research and two speakers to be confirmed** 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.		
12:00-12:30	**Working Smart but not Longer** **Stuart Cook, Principal Data Analyst, PharmaNet** 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.		
12:30-13:35	**Lunch**		

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.		

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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.
15:15-15:30	**Coffee**
Session Title: ePRO **Session Chair: Ian Pinto, Program Data Leader, Roche Products Ltd**	
15:30-16:30	**Main Room** ePRO | **Breakout 1** PM SIG | **Breakout 2** EDC Vendor
15:30-16:00	**Optimising clinical monitoring and data management with ePRO** **John Jordan, Senior Vice President of eClinical Technologies, CRF Health and Mary Monahan, Regional Associate Director, Clinical Operations, Merck** 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.
16:00-16:30	**Getting Better Data Out of Patient Reported Outcomes with Web-based ePRO** **Scott Dixon, Vice President, Phase Forward** 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.
16:30	**Round up and Close Conference** **Fred Daniels, ACDM Chair**

"TO ME, WORKING SMARTER IS WORKING EFFICIENTLY TO ACHIEVE THE GOAL NOT WORKING LONGER
ANONYMOUS

"IT'S OK TO SAY NO SOMETIMES. ALWAYS SAYING YES AND THEN FAILING TO DELIVER IS NOT SMART WORKING
TRACY FELLS

"REMEMBER THE THREE P'S:
- PLAN
- PRIORITISE
- PRAY

TRACY FELLS

"TO WORK SMARTER, WE NEED TO GIVE OURSELVES TIME TO THINK. WORKING SMARTER IS ALLOWING YOUR RIGHT BRAIN THINKING TO SHINE THROUGH THE GLOOMY CLUTTER OF AN OVERFULL TASK LIST.
TRACY FELLS

"THINK MORE..DO LESS..
EMMET BROWNE – CMED

"THINK FIRST...DO SECOND
EMMET BROWNE – CMED

"TO WORK SMARTER YOU NEED TO EMBRACE INDUSTRY CHANGE, SUPPORT TECHNOLOGY ADVANCES AND ADAPT TO THE EVER CHANGING LANDSCAPE OF AN INFORMATION MANAGER.
EMMET BROWNE – CMED

"TO ME WORKING SMARTER MEANS STOPPING AT THE OUTSET OF AN ACTIVITY AND MAKING SURE I AM ONLY PROVIDING EXACTLY WHAT IS NEEDED AND NOTHING MORE
JANE TUCKER – GSK

"TO WORK SMARTER, WE MUST BE CLEAR ON THE END GOAL AND WHAT IS REALLY REQUIRED TO MEET IT. ONLY THEN CAN WE ENSURE WE DRIVE PROCESS AND TECHNOLOGY IMPROVEMENTS TO MEET THOSE GOALS EFFICIENTLY.
NIC REED – PAREXEL

"WORKING SMARTER IS IMPORTANT TO THE DM INDUSTRY BECAUSE WE HOLD THE KEY TO PROVIDING VISIBILITY INTO DATA AND RAPID ACCESS TO COMPLETE DATA FOR ANALYSIS. OUR WORK IS CRITICAL TO THE SUCCESS OF THE ONGOING AND COMPLETED TRIAL.
NIC REED – PAREXEL

Focussing on: Conference Committee

NAME: Gail Kniveton
ACDM POSITION: ACDM Conference Committee
POSITION & COMPANY: Director, Business Services at i3

Job history
Gail Kniveton has worked in clinical trials since 1996 starting in data management. Gail has worked in Business Development and in Recruitment for many areas of clinical trials and associated services for the past 14 years. She has been involved in the development of innovative recruitment and outsourcing solutions for many clients. This has included the set-up of offices, recruitment, onboarding, training and retention of teams.

Likes / dislikes
Likes: playing "Just Dance" on the wii a lot more than I should. I think I might be unbeatable.
Dislikes: apathy, a lack of progress

What you enjoy most about being in the conference committee
Working with the committee team, ACDM, Board and our speakers. I like the people side of the conference.....less so the logistics...

NAME: Ian Slack
ACDM POSITION: ACDM Conference Committee
POSITION & COMPANY: Manager, Vertex Pharmaceuticals

Job history
For the last 11 and a half years I have been with PAREXEL, joining first as a coder and then becoming UK coding lead, subsequently WW Coding consultant within Data Management and then a year ago I moved into Quality Management which meant a step away from day to day operations with more focus on Quality, process and technology implementation. I started my new role at Vertex on 1st Feb as the global coding manager which will bring about some exciting new challenges!

Likes / dislikes
Likes – Music (all kinds but especially Rock and Indie), Sports (I am a season ticket holder at Barnsley FC), Singing and Acting. Dislikes – Snow, Cats, Wasps, tag graffiti, thieves and ignorance in its many forms.

What you enjoy most about being in the conference committee
I am new to the committee but I enjoy being part of something which benefits the ACDM membership and am looking to bring something different to this year's conference!

NAME: Vivienne Yeap
ACDM POSITION: ACDM Conference Committee
POSITION & COMPANY: Senior Study Data Manager, Roche Products

Job history

Started working life in the NHS with a number of roles ranging from Pathology Assistant to Mortuary Manager. Industry life began at GSK in 2002 as a Data Manager until March 2005 when I moved to Statwood Ltd (a small CRO) as a Study Data Manager/Project Manager. In January 2006 I joined Data Management at Roche Products Ltd where I still am today.

Likes / dislikes

I play a lot of netball and badminton. I run a Netball League of 36 teams, Captain one team and play for 2 other netball teams throughout the week. I also run a badminton club with 24 members. I like to shop, watch movies and read when I can. My dislikes are having my photo taken (hence the struggle to find a photo of me on my own!) and singing in public!

What you enjoy most about being in the conference committee

Meeting new people and working with a great team

NAME: Jo Marshall
ACDM POSITION: ACDM Conference Committee
POSITION & COMPANY: Managing Director, MDSL International

Job history

I started in Clinical Data Management straight from university and worked for Searle, Pharmacia and Pfizer all whilst sitting in the same office. I joined MDSL International in 2003 as Assistant Director and have been the Managing Director since 2008.

Likes / dislikes

I like scuba diving and mountain walking and I dislike not having enough time in the day to do everything I want to do.

What you enjoy most about being in the conference committee

learning new things, getting to know data managers from other companies and 'giving something back'.

NAME: Vicky Wiggins
ACDM POSITION: ACDM Conference Committee
POSITION & COMPANY: PM, i3 Statprobe

Job history

My name is Vicky Wiggins, current co-chair of the Conference Committee along with Viv Yeap. I work as a Data Services Project Manager at a large global CRO, i3 Statprobe, home based but attached to the Maidenhead office. My job history stretches back to the last century (love saying that). I've worked in South Africa for the Medical Research Council as a mycologist, at GSK as a microbiologist, secondary schools as an IT system administrator, before I moved into Data Management. I have worked at Boehringer Ingelheim, Wyeth, Accenture, Clinical Research Centre, PRA International, then for the last 2 years at Ingenix, contracting at GSK and now working as a PM for the Statprobe CRO. I have had many incarnations from Data Manager to Head of DM and Statistics. I enjoy being surrounded by my family which comprises my husband, 2 grown up sons plus my 2 pet snakes (that usually causes some reactions!!).

What you enjoy most about being in the conference committee

It's great being part of the conference committee, everyone is friendly and we manage to get everything done despite the challenges of the "day job". I hope you have enjoyed conferences in the past and intend to come along in March to find out about "Working Smarter".

TRAINING SCHEDULE **2011**

The ACDM provides a variety of training courses and webinars to support the development of clinical data management professionals throughout their careers. All our courses are written by experienced clinical data managers in conjunction with learning and development professionals.

In 2011 the ACDM will be offering a Level One Certificate in Clinical Data Management. This will replace our previous "Fundamentals of Clinical Data Management" course and is intended for those relatively new to the field. This may be attended as either a two day course or as eight webinar sessions. The certificate will be awarded on successful completion of the final exam.

INTERACTIVE CLASSROOM TRAINING

Month	Course	Venue
21 & 22 June	Level One Certificate in CDM (includes exam)	Berkshire, Moor Hall
27 & 28 September	Project Management for CDM	Berkshire, Moor Hall
12 October	CDISC for Data Managers: How to make sense of the standards revolution	Berkshire, Moor Hall
19th October	Understanding the Roles of Other CR Professionals	Berkshire, Moor Hall

To find out more about any of our courses please visit **www.acdm.org.uk/training.aspx** or email **training@acdm.org.uk**
Please note that all course dates are currently provisional.

WEBINARS

Month	Course
19 January	Level One Certificate in CDM – Part 5
20 January	Management & Integration of Non CRF Data
16 February	Medical Terminology, Basics of Human Physiology and Pharmacology
23 February	Understanding the Impact of Statistics on the Design, Conduct & Reporting of Clinical Trials
23 February	Level One Certificate in CDM – Part 6
9 March	Interpretation of laboratory data from a data management perspective
23 March	Level One Certificate in CDM – Part 7
6 April	Therapeutic Area Training - Pain (run twice)
7 April	Therapeutic Area Training - Oncology (run twice)
13 April	DEFINE.XML - How does it relate to SDTM and ADaM
20 April	Level One Certificate in CDM – Part 8
11 May	Data Management and medical diagnostic procedures
8 June	Effective EDC Training Strategies
7 September	CDISC SHARE Project Update
13 September	Level One Certificate in CDM – Part 1
21 September	Therapeutic Area Training - Oncology (run twice)
5 October	Data Management for Non Data Managers
6 October	Therapeutic Area Training - Pain (run twice)
11 October	Level One Certificate in CDM – Part 2
8 November	Level One Certificate in CDM – Part 3
16 November	Preparing for a Regulatory Inspection from a Data Management Perspective
6 December	Recent Developments in GCP & Regulations from a Data Management Perspective
13 December	Level One Certificate in CDM – Part 4

FEBRUARY

7-8 February
Cambridge Healthtech Institute's Third Annual Conference
Electronic Data in Clinical Trials: Optimize Clinical Trials through Improved Data Collection and Utilization
Westin Colonnade Coral Gables – Miami, FL

8-10
TOPRA
MSc in Regulatory Affairs: Module 6 – Regulatory Strategy: The Market Place
Macdonald Holyrood Hotel, 81 Holyrood Road, Edinburgh, Midlothian EH8 8AU, Scotland

MARCH

6-8
ACDM
Annual Conference 2011 – Working Smarter
Whittlebury Hall Hotel, Northamptonshire

21-22 March
ICR
32nd Annual Conference and Exhibition
Brighton Hilton Metropole, Brighton, UK

28-30 March
DIA
23rd Annual Euro Meeting
Palexpo, Geneva, Switzerland

APRIL

5-7
TOPRA
MSc in Regulatory Affairs: Module 12 – Medical Device Regulatory Affairs
De Vere, Tilehouse Lane, Denham nr Uxbridge, Buckinghamshire UB9 5DU, UK

11-15
CDISC
CDISC Interchange Europe 2011
Crowne Plaza Brussels – Le Palace, Rue Gineste 3, B-1210 Brussels, Belgium

JUNE

19-23 June
DIA
47th Annual Meeting
McCormick Place, Chicago, IL

21-23
TOPRA
MSc in Regulatory Affairs: Module 7 – Regulatory Strategy for Established Active Substances
NH Tropen Hotel, Linnaeusstraat 2c, 1092 CK Amsterdam, The Netherlands

July

12-15
CDISC
CDISC Interchange Japan 2011
Tokyo, Japan

September

11-14
SCDM
2011 Annual Conference
Marriott Baltimore Waterfront, Baltimore, US

October

9-15
CDSIC
CDISC Interchange North America 2011
Renaissance Harborplace Hotel, 202 Pratt Street, Baltimore, MD 21202

13-14
TOPRA
The 8th Annual TOPRA Symposium
Rome, Italy

26-28
ISoP
11th Annual Meeting
Harbiye Military Museum, Istanbul, Turkey

9-15
CDISC
CDISC Interchange North America 2011
Renaissance Harborplace Hotel, 202 Pratt Street, Baltimore, MD 21202

ACDM events can be booked online at www.acdm.org.uk

For ACDM events contact:
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ACDM membership can be applied for via the internet at www.acdm.org.uk, or call the ACDM Office for an application form.

For ACDM events: **www.acdm.org.uk**
For BARQA events: **www.barqa.com**
For CDISC events see: **www.cdisc.org**
For CR-CSV events: **www.cr-csv.org**
For DIA events: **www.diahome.org**
For eClinical Forum events: **www.eclinicalforum.com**
For ICR events: **www.instituteofclinicalresearch.org**
For ISoP events: **www.isoponline.org**
For MHRA events: **www.mhra.gov.uk**
For PSI events: **www.psiweb.org**
For SCDM events: **www.scdm.org**
For TOPRA events: **www.topra.org**

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