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acdm
association for clinical data management

DataMatters

NEWS & VIEWS

Updates from the Committees and SIGs

ARTICLES

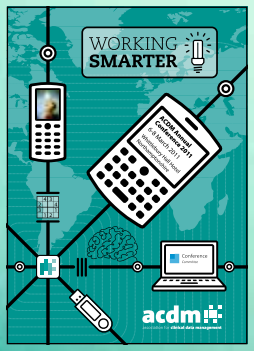
Data Matters and so does Compliance

The future of ePRO and Electronic Data Capture as a Whole

Vendor Conference Experience

CDISC – why is it for me?

FEATURE: The 'Perfect' Project Manager



See page 17

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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
Autumn	13 Sept	1 November
Winter	13 December	7 February 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

Getting down to business

It has been a couple of months since your new board of directors was reconfirmed, since then the board has got down to the business for the year, first appointing new contacts for committees, SIGs and working parties as well as new officers.

You will find details of who is responsible for what at **www.acdm.org.uk/grp12_home.aspx**. We planned what needed to be achieved during this year including updating the VISIONS and AIMS document.

The Visions and Aims document was created in 2008 and here are the main points:

- Enhance and promote the benefits of the ACDM to an increasing global membership
- Create an easily accessible and visible information repository
- Establish an active communication platform for the dissemination of new industry developments
- Develop and execute a professional development and training strategy that meets the changing needs of the membership
- Forge and strengthen links with related industry organisations
- Effectively manage finances to achieve the organisation's aims

Around these visions the Board of Directors and Committees have set a number of objectives and we are pleased that many of these have been achieved though there is more to achieve. This visions and aims document can be found on the ACDM website.

Those who made the conference will recall that we gave an update of our continued discussion with the Society for Clinical Data Management (SCDM) in the US. These discussions are still going on and we have already set a series of teleconferences with them to explore collaboration opportunities. In the meantime as a member, you are able to get a discount on SCDM membership.

Many of the committees and working parties are looking for additional volunteers. If you would like to get involved with any of these objectives then please contact the ACDM office.

Fred Daniels, ACDM Chair

Conference
Committee

ACDM Conference 2010 – Driving Success

Another excellent ACDM Conference was successfully held on 21st-23rd March, this was the 2010 Driving Success Conference. Whittlebury Hall Hotel, Northamptonshire, was once again the chosen venue simply because it constantly delivers a high standard of accommodation, facilities and is ideally located.

Attendance was impressive considering the continuing economic climate (and reduced travel budgets) and numerous overseas participants travelled to the conference despite BA's first cabin crew strike (and thankfully the conference occurred well before the Icelandic volcano chose to erupt!).

The Conference Committee did a great job in promoting the conference and all available stands were booked ensuring the vendor hall was always busy and popular with attendees. The new Bingo game ensured everyone was keen to visit as many stands as possible to have their card stamped for the prize draw. Thanks should also go to the following sponsors of events: Perceptive Informatics (Bingo), Medidata Solutions (pens), Richmond Pharmacology (coffee), Syne Qua Non (pads) and to Oracle and Aris Global who participated in the eDC vendor sessions. Special thanks must go to CRF Health who kindly provided touch pad devices to collect ongoing feedback from delegates throughout the conference (some of the statistics collated from these devices are given at the end of this article).

The conference kicked off with the Sunday networking evening, which was well attended and always a great opportunity to catch-up with old colleagues, share your news and meet some new people too. It's a lovely informal evening and is a chance to relax ahead of the busy, jam-packed eventful two days to come. A delicious buffet kept everyone well nourished whilst the Motor Racing themed quiz tested everyone's driving knowledge. I wisely chose to sit on Claire Keith-Lucas' table (Claire is part of the Conference Committee and also a racing driver in her spare-time!) – a good move as our table won.

Day 1 was launched with Gail Kniveton's opening speech as Conference Chair and then the enthusiastic and engaging Diane Jorkasky accelerated us into the conference with her passionate presentation as Guest Speaker. Diane neatly steered the conference on course with her themed talk on Driving for success but are we driving as smart as we can? The morning continued with Dr. Steven Julius, another lively speaker, and then into a choice of Breakout Sessions leading up to lunch. This year there were multiple consecutive Breakout Sessions to meet everyone's palate: Oncology session (5 talks covering different Oncology topics) continued in the main conference hall, EDC Vendor Demos and a Senior Forum interactive meeting.

After the Annual AGM the afternoon sessions included presentations on Data Coding, Training and then further multiple offerings with Breakout Sessions covering: Personal Development, Project Management SIG, EDC SIG and talks in the main hall on metrics analysis, ePRO and Phase I Data Management. I think all who attended will agree it was a packed first day agenda and there was definitely a happy buzz from all participants as they headed for the evening's Gala Dinner and entertainment.

The Gala Dinner was black tie and champagne flowed freely at the drinks reception. After an excellent dinner the band kept some of the delegates dancing, whilst others tried out giant Scalextric and Mario Kart and the virtual pistol shooting gallery proved very popular (several 007 wannabes looked the part in their tuxedos). Of course there was the usual contingency in the bar...

The ever-popular ACDM Debate chaired by Julianne Hull pumped Day 2 into gear. With both of the debating teams led by members of the ACDM Board of Directors (Fred Daniels and Harshad Sodha) this promised to be a juicy session with the tasty topic of Regulatory Inspections and how they drive (or don't) success. All debaters threw themselves into the spirit of the fight (sorry) debate and lived up to expectations.

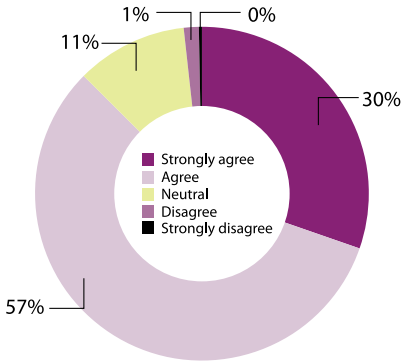
After coffee the session was themed on Lab and other external data with talks on QT studies, ePRO Integration and lab normal range integration within eDC.

Sadly the conference cruised towards its conclusion following the final afternoon's presentations – firstly a variety of talks themed around Data Standards and Quality and rounding off the day with an interactive panel discussion on What will data management look like in 2015? What can we do to prepare?

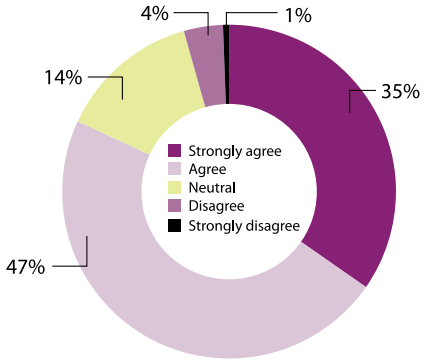
The comments received during the conference were all very positive. It certainly was a relaxed, friendly atmosphere, which is so important to encourage all to actively participate without fear of embarrassment in front of peers (particularly for new attendees). The multiple Breakout Sessions were popular

Feedback from Conference Attendees

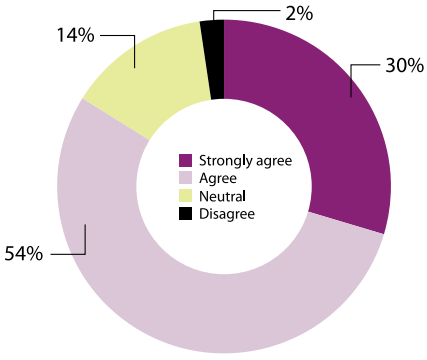
Feedback on presentations: Well presented and clear



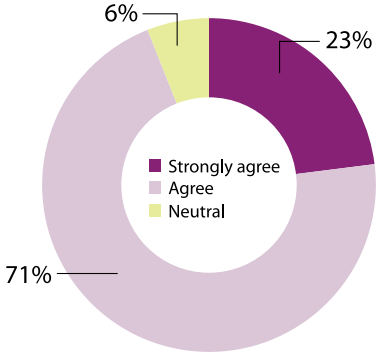
Feedback on presentations: Engaging



Feedback on presentations: Good length and pace



Why attend conference: Papers looked interesting



and many commented on the variety of choice and quality of these sessions.

Please note there are some excellent write-ups of many of this year's Conference talks and Sessions in the ACDM DATA MATTERS Spring Edition (available from website **www.acdm.org.uk**).

Finally many thanks go to all who attended and participated in the ACDM Conference 2010 – Driving Success, it couldn't take place without you! Please keep supporting this fabulous annual event and on behalf of the Conference Committee we look forward to seeing you all in 2011!

Tracy Fells, Consultant, on behalf of the ACDM Conference Committee

CR-CSV
Working Party

CSV Lite

The CR-CSV WP is currently working hard, with volunteers from across the pharma industry, to start drafting the already agreed chapters within their newest publication, whose working title is CSV Lite. This book is designed to help AROs and Niche suppliers work with Sponsors of clinical trials to successfully incorporate their tools/questionnaires/assets etc. into the necessary regulated environment of a clinical trial and its database/analysis etc.

We are planning to hold one Working Forum session this year to which we will invite anyone wanting to advance this area of activity within the industry. We plan to use this forum to start getting a wider audience reviewing draft chapter contents and suggested tools and templates, to provide comments and feedback. We are anxious to make contact with representatives from as many AROs and Niche suppliers as possible to ensure that what we produce really will be written in appropriate terms and be useful to them in working with clinical trial sponsors.

If you have an ARO/Niche supplier that you have used please pass onto them details about the Forum sessions advertised across the ACDM, and perhaps offer to come along with them so that both your voices are added to the discussions.

For more details contact Jane Tucker at jane.e.tucker@gsk.com

Data Matters and so does Compliance

Careful design of eDiaries leads to higher rates of compliance in studies that require patient-reported outcome data – and compliance matters to both sponsors and regulators.

CRF Health kindly provided their handheld devices to collect live feedback from the conference delegates at this year's annual ACDM conference, as discussed in the article by Tracy Fells on behalf of the conference committee. The following article discusses the use of these devices within Clinical Trials. The following article has been edited to fit the constraints of publishing; a full text article is available upon request.

Ali Green, Editor, Data Matters.

A study team spends a great deal of time, care, resources and attention on the design of a clinical trial. The trial design is subjected to rigorous checking and a number of approval processes. Only until the study team is confident that the protocol meets all good clinical practice (GCP) requirements, primary endpoints, and in many cases, agency approval, does a sponsor finalise a protocol and prepare it to send to an Institutional Review Board (IRB), Ethics Committee and Investigators.

When a protocol calls for patient-reported outcome (PRO) measures, the study team pays close attention to the way in which they will capture such patient outcome data. After all the careful planning and meticulous trial design, the study teams and investigators must then rely on unsupervised patient data entry to collect what is often pivotal data. Because trial subjects are not research professionals, the design and number of questions in an eDiary must strike a careful balance. Many study teams would want as much data as possible to be collected. And although unsupervised data entry is an essential part of some trials, the questionnaires utilised must elicit responses that meet the protocol design needs and not place too great a burden on the trial subjects. Electronic Patient Reported Outcome (ePRO) devices can not only facilitate data collection and analysis, but also provide important control over the data recorded.

Key Ideas to Consider for eDiary Data Collection

Keep it simple. That's the key to compliance. Unsupervised data collection should not rely on expecting clinical trial subjects to remember precisely what to do every day within a clinical trial. The eDiary acts as a personal assistant, and essentially guides the patient through the clinical trial and minimises patient burden by providing features such as portability, audible alarms, questionnaire navigation, and privacy for the patient. When subjects hear the alarm, for example, they can log-in to the eDiary (using their password) and respond to easy-to-read questions in their own language. They simply touch the screen to answer those questions. This puts the subjects' experience at the centre of the design, which makes it easy to use and easy to comply.

Keep it reliable. That's the key to good data collection. To prevent bias and to provide the same experience across the study, ensure that every subject receives the same device, one that is suitable for the therapeutic area. And choose a device that can display the languages of every country where the trial is to be conducted. This is important as some devices lack the capability to accept programming in complex Indian, Hebrew, or Japanese languages. Plan ahead. Complex languages might not be required in the early stages of the clinical trial, but an expansion to other countries/languages might be necessary for a variety of reasons; i.e. slow recruitment or changes in study parameters. Adding additional countries not originally planned for can affect the eDiary Design (i.e. screen size limitation or operating system incompatibility due to the addition of complex languages), so it is good to know

the capabilities of your ePRO service provider upfront.

Keep it flexible

That's the key to skillful/proficient eDiary development. With these eDiaries, study teams are able to build in smart branching logic to limit the number of question pages to be viewed. However, here, it is important to remember some diary design rules. For example, when complete answers are not displayed on the screen, it has been shown that some diary users fail to scroll and read all options before entering a response. Smart design can improve compliance rates. Also, study teams should be mindful of the subject's condition when building in certain criteria. You would not necessarily want the alarm to go off if a subject does not enter information exactly on time. You may build in a certain entry time window to allow for subjects that are at work or just need a moment of privacy to enter the data. Since there is a cost to transmitting data, be sure to match the data sending frequency to only meet the actual need of the study team to see the data. The study population and the therapeutic indication under the study drive the timing of diary entries. Diary entries may be event-driven, such as each time a person with asthma uses a rescue inhaler. Also, a study design may require a diary entry at a special time each day (e.g. after taking medication or just before bedtime), or a specific day each week. Some studies may require only completing a questionnaire at each visit to the investigator site. Whatever the criteria, creating a simple experience requires expertise and flexibility in the design and development of a successful ePRO solution.

Keep it strong

A knowledgeable, experienced ePRO service provider team and a solid system behind them is key to a smooth and positive project. The ePRO service provider team helps the study team through the device selection process by reviewing protocol complexity and diary performance requirements. Diary performance is important to achieving high compliance rates, especially for daily diaries. A collaborative design approach is favourable, working with the study team in interactive design meetings and using real-time simulations and prototypes of the eDiary. That kind of collaboration allows the team to visualise what study subjects would face on the eDiary as they work to develop the finalised questionnaire together. This provides a unique opportunity to evaluate the patient experience in real time as the eDiary is designed and built. If screen changes or other diary functionality take too much time, the subject is likely to become frustrated and compliance will suffer. Fast response times have a very strong, positive correlation with assessments of usability of computer systems, and such systems will keep a subject engaged throughout the course of lengthy and/or frequently-administered questionnaires. High quality project management and systems provided by the service provider, gives a study team a great deal of assurance that the data collected is consistent, accurate and reliable.

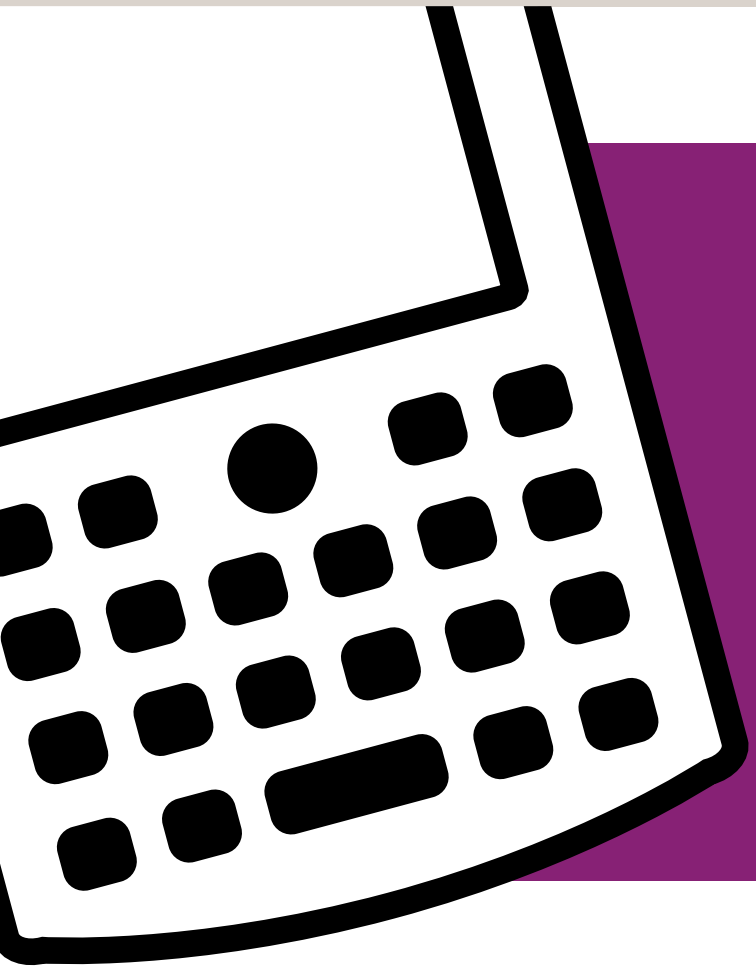
Why Is Compliance So Important?

The FDA's recently published Guidance for Industry on Patient-Reported Outcome Measures emphasises that the agency's focus is on compliance with the protocol. It states, "If a patient diary or some other form of unsupervised data entry is used, we plan to review the clinical trial protocol to determine what steps are taken to ensure that patients make entries according to the clinical trial design and not, for example, just before a clinic visit when their reports will be collected." (**www.crfhealth.com/FDA_Guidance_PRO_Dec2009_Final.pdf**)

With an electronic solution, every patient-reported outcome entry is created with a date/time stamp. That provides important documentation that the data was entered in accordance with the study design. A paper-based approach makes it impossible to know when the subject actually entered the data. Paper lets you see how much data was collected, but there is no way to know when it was collected. That dilutes its value.

As shown above, ePRO can reduce the burden on trial subjects. It can also ease burdens on sites by eliminating the need for double data entry and source data verification. Those reasons plus the lack of extraneous or superfluous data with ePRO solutions (that you may still get with paper), also significantly minimises errors and variability, making overall data cleaner. ePRO provides cleaner data which enhances the scientific decision-making process. Increasingly, it can be integrated into EDC systems. It can shorten the time to database lock. From the early days of the historic Palm-based devices to the now fully wireless slim-designed Windows Mobile® technology, ePRO has evolved during the past 10 years, and as the technology has improved, so have the ePRO solutions.

Chris Barden, Director, Business Development, CRF Health
Gregg Jewett, Senior Director, Strategic Alliances and Partnerships, CRF Health



The future of ePRO and Electronic Data Capture as a whole

I recently attended the ACDM conference 'driving success', where I listened to a presentation on the future of electronic Patient Reported Outcomes by Valdo Arnera. His presentation got me thinking about not only the future of ePRO but the future of all electronic Data Capture.

Our lives today revolve around technology: the internet, email, mobile phones, LCD TVs and so on. We rely on these technological advances to make our lives better and easier. In the pharmaceutical industry, we are building and using advanced technology to aid us in our work – electronic Data Capture (eDC), ePRO, IVRS (Interactive Voice Response System) and wireless devices are just some examples of this.

eDC has revolutionised the way we capture patient data. There are systems, such as Cmed's Timaeus, that can capture patients' vital signs directly from wireless devices in the clinical database with no need for any paper CRF completion, thus making data capture easier and more time-efficient for all parties involved. The quality and accuracy of data is also improved with limited room for human error from a validated system and online real time validation checks.

A Patient-Reported Outcome, or PRO, is a questionnaire used in a clinical trial where the responses are collected directly from the patient. An e-PRO is an electronic form of capturing this information straight from the subject. The development of more advanced technology to meet site demands in clinical trials appears to be the future, so it may be assumed that there would be rapid acceptance with regards to the use of ePROs over paper-based PROs.

Having listened to Valdo Arnera at the ACDM conference 'Driving Success', it would seem that the future is looking bright for ePRO, as the pharmaceutical industry is moving more and more towards eDC for trial data capture. However, there does appear to still be some resistance currently from Sponsors, regulatory authorities and site personnel, to name just a few. Apart from the initial regulatory complications that come with most transitions from paper-based data capture to electronic, it would seem there are other equally challenging factors which are still preventing sponsors moving towards electronic capture for patient data. In this article, I am going to briefly explore a few possible reasons as to why all PRO data are not currently electronic. My thoughts could also be applied as a possible explanation why not all clinical data are currently captured using eDC.

As not all countries have equal technological capability, one factor that comes to mind is that it could depend on the

area of the world in which the patient population is based. For studies conducted with a site / sites in a less technologically developed country, then eDC may be altogether a non-viable proposition. It may be considerably more difficult for some systems (i.e. those that rely on a widely established internet connection or advanced telecommunications structure as a pre-requisite) to capture PRO data electronically, compared with using paper-based data capture. Countries with less advanced technological capacity may contain patient populations who would find ePRO usage more difficult than using paper: there could be potential reluctance to embrace a revolutionary new method of data capture, due to uncertainty in the user friendliness of a technology or possibly a concern about the reliability of the technology. Site staff do not want to be capturing live patient data and have a technical failure. A simple, easy-to-use, robust validated data capture system could rectify this, but there could still be some initial resistance.

Each country develops at its own rate and each prioritises technological development according to the country's needs. Due to this, it may take some time before ePRO is a feasible source of data capture in many countries. What is helping the situation in less technologically advanced countries is the fact that there are evolved systems that can run with minimal pre-requisites.

With the above in mind, I have personal experience of working on studies where the patient population is based in countries that could support ePRO but paper PRO has been chosen. This really perplexed me at first, as I could not understand why, if an electronic option is available, it would not be used by sponsors on their trials. Having researched this, it would appear that cost could be a factor. It may seem that start-up costs for an ePRO based study could be significantly higher than that of a paper based study using PRO, which could dissuade some sponsors from using ePRO. Sites usually have a big say in this decision as well so, depending on the preference of the Investigators and study staff, eDC may not be chosen. The Investigators' and associated study teams' preference for paper or electronic data capture may be based on several factors, such as previous experiences with eDC systems and personal experience, knowledge and comfort with regards to using a new system. Every eDC system around today should be seeking to provide the best possible service to the sites – with positive experience from using an eDC system (with minimal issues, or none) may come confidence, and this may help to ensure future studies are performed using eDC.

Figures in Valdo Arnera's presentation suggest that compliance and accuracy rates are improved when using ePRO over paper-based patient entered data. Even though cost is a major factor for all sponsors in deciding whether or not to use ePRO, time and thought should be invested in whether more accurate data capture would outweigh any potential cost increase to a study.

In the UK, there is a developed internet and telecommunication infrastructure, and email is increasingly more widespread in usage. However, there has always been some resistance to new technology compared with how we are 'used' to doing things. An example of this resistance to new practices is the fact that there is still a considerable amount of written communication that takes place via postal mail and not email. Many sponsors and regulatory authorities could be much more familiar with paper-based data capture, as some people are with postal mail. Companies spend considerable sums of money basing their operation around a system or process and do not like to make changes unless they really have to. A reluctance to deviate from the tried and tested status quo could be coming into play when choosing how to capture data for new trials. I feel that the more widespread ePRO and eDC as a whole becomes, the more sponsors and regulatory authorities will look at the statistics and become more interested in the use of electronic data capture. Having said that, technology resistance, satisfying regulatory authorities and technological capabilities will always be a challenge we face when trying to move forward with any electronic data capture.

Valdo Arnera mentioned that the future may contain eDC on mobile phones as an application. I think this is a wonderful vision, although there are constraints that will come with this, such as the fact that any application should conform to CFR21 standards. This compliance is noted as an industry standard of acceptance for any system. Approval from regulatory authorities is also required, for any new method of capturing clinical trial data. These constraints could mean any potential application is in development for many years before being introduced. The mobile phone world is constantly evolving so custom-made mobile phones could be necessary to support an eDC system. With any application that could contain confidential data, essential security features would be needed, to ensure clinical trial data could not be viewed or altered by anyone other than those authorised to do so.

I believe that the development of technology is the way forward for data capture. There are systems currently available that can capture data in some of the most remote regions of the world, using GPRS technology, with minimal necessity for an advanced internet and telecommunications structure. Paper is still a popular choice for clinical data capture; however, through more widespread knowledge, understanding and acceptance of electronic methods of capturing patient data, such as ePRO, we will see sponsors and regulatory authorities agree and choose to move forward with advanced forms of electronic data capture for all studies in the future.

Gemma Millar
Clinical Data Manager,
Cmed (Clinical Research Services)

Vendor Conference Experience

At first glance, trade shows such as the ACDM Annual Conference, offer vendors such as ourselves a first rate opportunity to showcase our wares and present our latest offerings to the World. The path is well trodden, complete with magical stands that self-assemble, brochures and handouts that meet our every need, and "give-aways" (which are pre-decided... of course we are giving away the new iPad).

So when asked by the ACDM to share my experiences at conferences and trade shows, the question that immediately comes to mind really is does the train depart precisely on time from platform 9¾ or in fact are we fighting a volcanic ash cloud that dictates that our booth stand is in New Jersey and our brochures in Munich, and that give-away, well the iPad is now a $25 iTunes voucher! Despite everyone's best efforts, the reality often remains firmly based in Iceland and only briefly visits Hogwarts.

With some poetic licence, I have attempted to think back over the last ACDM conference and review my experiences, both positive and not so positive, and provide the reader with some sense of the work that goes into a vendor's attendance at a conference such as the one last March.

Day – 180

Medidata's Marketing Department asks me whether I think we should attend this year's conference. In previous years we have met with degrees of both success and indifference, but the over-riding corporate position remains one of resolute commitment towards supporting the ACDM. After all, recognising its usefulness to the data management world, we help run the Special Interest Group for Electronic Data, we submit articles for its magazine, and we offer other assistance wherever we can. The ACDM provides a forum for independent thought and collaboration for the customers and our industry, and as such should be embraced.

It is perhaps appropriate to immediately address a common misconception about conferences. Vendors do not go to a conference expecting to sign contracts and come away with new business. It is very rare to find ourselves in a position where clients are in such urgent need during a conference, and our "getting to know you" stage is a bit longer than the normal conference duration. Nevertheless we also recognise that we can lose an opportunity in the blink of an eye, with poor preparation or inattentive attitudes. Our goals for these conference are as showcases – for us and for you: you can learn about us in a more relaxed, less formal setting than a sales call; we can learn about you and your needs, in our specific product areas or in related topics, giving us ideas to think about and possibly build into our next generation of software that will help you through a pain point. Our goal is to invite the audience in, not to scare you with talk of sales and contracts, to be accepted as trusted advisors and key opinion leaders. Do we work for Medidata? Yes. Are we also there to learn? Yes. So, please, if nothing else, come and say hello – we

> **"ACROSS NATIONAL LINES, ACROSS CONTINENTS, ACROSS SEAS, ALL OUR EFFORTS ARE AIMED AT AVOIDING THE DREADED EMPTY TABLE, AND HAVING TO EXPLAIN TO OUR COLLEAGUES THAT CUSTOMS HAVE DECLINED TO RELEASE OUR SHIPMENT**

are there to meet you, make some new friends, and most of all share ideas.

So with six months to go, the conference planning begins ... the confluence of marketing, product management, business development, account management and professional services activities is a complex meshing of agendas, experiences and ambitions, all geared towards producing a single, coherent message that will take the conference by storm. New products, enhanced features, presentation topics, discussion groups, all form our initial planning agenda – or more simply, "Who? Where? Why?" New clients, current clients, prospective clients, partners or just interested parties – all deserve attention.

Day – 30

150 days have passed since we last spoke... the conference is almost upon us, and it is time to review the plan, and ensure we have not overlooked the obvious. Travel plans are checked, the requisite beer with Mr. Baker is confirmed for 4:00 pm Sunday, and the presentations are drafted and ready for internal review. In truth, the conference season is well under way, and Marketing are coordinating multiple events; stands/materials are being shipped from one location to the next with a precision normally reserved for military matters. Across national lines, across continents, across seas, all our efforts are aimed at avoiding the dreaded empty table, and having to explain to our colleagues that customs have declined to release our shipment.

Day – 7

Final debrief, everyone knows the plan, who is setting up and who is shutting down. I have 87 emails in my in-box confirming attendance and re-affirming that I will meet Mr. Baker at 4:00 pm on Sunday. It is also around this time that Gail calls and asks if I can join the discussion panel on day 2, oh, and by the way can you prepare a back up presentation just in case ?

On a more profound note, I think we should use the ACDM web site to book one-on-one meetings, so we can schedule some quality time between prospective partners. Meeting at the stand is often an intimidating experience, especially if your current vendors are next door! Having the ability to book a one-on-one in advance offers everyone a chance to meet with a greater sense of discretion. This concept of "speed-dating" is not new, and is in many ways very simple, but it does allow for a high quality, focused exchange of requirements, ideas and interests. Just a thought.....

Day – 1

"The stand is where? Customs in Zurich refuse to release it because someone labelled it clinical equipment?"

Day 0 (Sunday 21st March 2010)

Arriving at the hotel is always an experience, the myriad of old friends and acquaintances to greet – one of the things I like about the ACDM Annual Conference is the opportunity for old friends to dispense with their corporate image on Sunday, join in the quiz, and catch up on recent events. For the record, Mr. Baker was not even here this year!

First order of the day however is erecting the stand – find our designated 3x3 spot, locate the various shipped boxes, put it up (this piece goes where?) and get set for tomorrow. Fortunately, Paul is our resident expert at the stand – putting the various IKEA-esque pieces together in minutes.

Day 1 (Monday 22nd March)

Mukhtar (VP, Implementation Services) is presenting today – Integrating a Successful Oncology Data Management System. His presentation is well received, and the stand is immediately busy with oncology specialists wishing to discuss further. This is the main reason we are here, and the questions range from the novice to

> **"I HONESTLY BELIEVE THAT THE ACDM SHOULD REMAIN VENDOR-AGNOSTIC BUT AT THE SAME TIME, THE ACDM NEEDS TO EMBRACE THE VENDORS WHO SUPPORT IT AND REWARD THEM FOR THAT SUPPORT**

expert level. Some of the conversations are firmly at the 30,000 feet level, generic and designed to avoid specificity. Others home in on a minute detail, and call for a technology demonstration. Medidata sent three attendees this year – Mukhtar, as a presenter, Paul and myself. Paul is a Senior Business Consultant for Medidata and takes the lead on all demonstrations. The hope is that we can address everyone's questions in one way or another, through the mixture of skills and knowledge present on the stand, and listen to the underlying concerns that we can take back to our R&D group

The stand is not constantly busy; the session times offer the stand delegates a chance to visit other stands, engage in Business-to-Business (B2B) discussions and follow up on any unanswered questions. I also feel that this really lends itself to my previous point about one-on-one meetings. Paul and I will choose to attend some of the sessions but we can't both leave the stand at once, just in case someone wants to talk – be that a prospective client, an existing partner who is also stand-bound, or even a competitor who wants to kick some ideas around. Allowing users to book sessions and manage our time more pro-actively would add an extra layer of interaction for the vendors.

Overall, day one was successful, with a number of good meetings/discussions and even some potential leads. There were some long periods of downtime, rapidly followed by bursts of rapid activity, but this is expected.

The gala dinner offers an opportunity to dine with some new found friends from ICON, as well as some older friends from times past. This networking opportunity remains a great asset of the ACDM Annual Conference, offering the chance to mingle freely.

Day 2 (Tuesday 23rd March)

The morning after the night before, as for so many, is a rude awakening. Whether it was the run-up to the conference, the lateness of the hour or the drinks consumed last night doesn't really matter. I see it as a question of honour – being on the stand, suited and booted before the first presenter! Two years ago, Roger Small and I were that opening act, and having experienced the challenges of enlivening a recovering audience I feel it only fair that I now take my place in the audience.

> **"I HOPE NEXT YEAR WILL BRING AN EVEN MORE DIVERSE CONFERENCE, AND ONCE AGAIN I WILL BE THERE, ON THE STAND WAITING TO ANSWER YOUR QUESTIONS**

The stand is generally busier on day two, but never too busy. I think it is here that vendors need a forum where they can be more open and provocative – why not introduce a challenge of some description for vendors to construct during the conference, or create a showcase for them to present on their core capabilities? In other conferences I have seen the "EDC Olympics", or a scenario-based discussion panel. We have a poster competition, but this is generally a static scenario, and could surely be taken further. Does the ACDM need to retain such a strong position of vendor neutrality?

To dispel another misconception, vendors pay to attend and have a stand, and they need to demonstrate return on their investment. Consequently, I think it only fair to provide an environment for them to showcase their products. Equally, the meeting should be a forum for sponsor companies to come and learn about the different offerings the marketplace has to offer. I honestly believe that the ACDM should remain vendor-agnostic but at the same time, the ACDM needs to embrace the vendors who support it and reward them for that support. The same principle is also true for the Special Interest Group (EDC), whereby the need to reward the heavy contributors is challenged by the need to remain neutral and impartial. If a particular individual or corporation heavily supports an initiative over a prolonged period, I would reward them through an opportunity to present, or by receiving a special rate for attendance. The ACDM needs vendors to drive these initiatives, just as vendors need sponsor companies to give the initiatives purpose. Let us not lose sight of the simple fact that we, as vendors, offer our subject matter expertise, not just to contribute but also to seek positive feedback for our own organisations.

As such I would also add that the ACDM should encourage additional sponsor attendance. We need to attract new sponsors who will add to our conversations and contribute to future success. This year attendance was too heavily dominated by vendors, and whilst the opportunity for B2B interactions is always well received, it is not the main reason we attend. The question for me is what do sponsors need/want from the conference? Bring the sponsors and vendors will come, but is the reverse true?

This year, I left Whittlebury Hall fairly happy on our ROI. The conference led to some new opportunities, a chance to discuss some keenly debated topics, and we even found time to share a few jokes during the final discussion panel. As with all things, the conference will only be what you make of it. I applaud those who offer to present and/or organise – without them, we would not have a conference. I hope next year will bring an even more diverse conference, and once again I will be there, on the stand waiting to answer your questions.

Richard Young
Medidata Solutions Worldwide

The 'Perfect' Project Manager

Ambitious Target, Unachievable Ideal or Impossibility?

Keywords: Big pharma, Biotech, Communication, Contract Research Organisation (CRO), Decision-making, Leadership, Project management, Skills, Small pharma

Arguably the most important activity in any clinical development programme is the project management of each clinical trial. Having a study plan that is appropriate, affordable and deliverable, and then managing the performance of each activity through to its output is key to the smooth running of the development of any new medicine or medical device.

There has been much talk about where project managers should come from, whether from the ranks of clinical operations or data management, imported from other industries (e.g., construction, aerospace etc.) that are thought to be closer to the 'cutting edge' of project management techniques and tools, or trained from scratch as a function independent of other clinical development roles.

But how much common ground is there between the activities of project managers in different types of organisation? Are different mixes of skills required in different contexts? Indeed, is there such a thing as the 'perfect' project manager? Is it something we can achieve by professional development, a single ideal we can all aspire to but never quite reach, or something that is impossible to even consider because the idea of 'perfection' varies so greatly in different contexts?

Set with the task of identifying what makes the 'perfect project manager', several speakers from across the industry were invited to speak at a ICR Project Management Special Interest Group forum meeting. The aim of the forum was to establish whether the key skills required for project management were the same regardless of the size and type of organisation.

The perfect PM

Noel Landsman, the Deputy Head of Project Management at Guys Drug Research Unit, Quintiles spoke to us about the key skills and character traits one needed to become the 'Perfect Project Manager'. Basing his talk on Winston Churchill, who led some significant projects during his long military and political career, he asked "Is 'perfect' achievable or is the perfect project manager just a dream?"

> "IS 'PERFECT' ACHIEVABLE OR IS THE PERFECT PROJECT MANAGER JUST A DREAM?"

Noel argued that the combination of hard skills, soft skills, functional competencies and personal traits compose the raw material for overall capability as a Project Manager (or, indeed, as a Prime Minister). Even if you are proficient in many of the skill areas, your ability as a PM will be limited if you cannot apply those skills to your day-to-day activities effectively.

He identified several core personality traits and skills a project manager should have if they are to have any hope of approaching perfection. They should have integrity; a consistency of actions and values, and a sense of honesty when it comes to the motivations for their actions. One of the best behavioural traits a PM can become known for is doing what they say they will do; an important factor when leading a team.

Communication

Communication skills are often taken for granted because they seem too obvious, but to be both understood and effective is an important skill for the perfect PM. Communication skills have to be developed, honed and added to on an ongoing basis. Noel argued that to be effective in business you have to communicate well, but to be an effective manager you have to communicate exceptionally well. He cited an example of Churchill, who communicated to his senior staff, "Let it be clearly understood, that all directions emanating from me are made in writing, or should be immediately afterwards confirmed in writing, and that I do not accept any responsibility for matters relating to national defence, on which I am alleged to have given directions, unless they are in writing." This issue of documenting your communications holds strong parallels with the pharmaceutical industry, where creating an audit trail is a critical part of managing clinical trials.

Decisiveness

Noel further argued that the perfect PM should be decisive, and that decision-making is the very essence of leadership. A PM working towards perfection should be able to exercise good judgement to make sound and well-informed decisions, and should be able to perceive the impact of their decisions. He quoted George Canning (1770-1827, British Statesman) who said that "Indecision and delays are the parents of failure", highlighting that the PM should be able to make effective and timely decisions, even when under pressure or when the solutions produce unpleasant consequences. A further skill in this area is the ability to

recognise when a decision is not ready to be made yet, but to still have the ability to move things along.

> **"…THE PM SHOULD BE ABLE TO MAKE EFFECTIVE AND TIMELY DECISIONS, EVEN WHEN UNDER PRESSURE OR WHEN THE SOLUTIONS PRODUCE UNPLEASANT CONSEQUENCES."**

Leadership

Noel went on to discuss how the perfect PM should be capable of taking the position of leader, and driving forward their team. Vision is a key element in this, and successful leaders are known for giving their followers a common goal with which they can fully identify and contribute to. He flagged five tips on effective leadership:

1. They should be able to communicate clearly and routinely
2. They should involve team members in setting and understanding objectives
3. They should give authority to the team and allow them to be accountable
4. They should be accountable themselves
5. They should be trustworthy and extend that trust to the team

Churchill was quoted as having said "I am certainly not one of those who need to be prodded. In fact, if anything, I am a prod.", highlighting the important role the PM has in motivating their team to take both action and responsibility for their actions.

Working in a whole-company context

Steve Donoghue, from Daffodil Consulting LLP, spoke about his perspective of project management from within a company that provides strategic and operational project management to both large and small pharma/biotech.

He argued that large pharma and CROs require very similar skills from their project managers. They should have drug development experience, preferably in multiple areas, and should be trained as a PM, with an understanding of all the relevant tools. They should be well organised, target driven and have the ability to manage teams/meetings, using their personality to help persuade and encourage team members along. They should be able to proactively identify issues, and have the ability to network effectively. Even networking within their own company can prove beneficial when it comes to moving a project along quickly and efficiently.

> **"…A PROJECT MANAGER WORKING IN A SMALL PHARMA COMPANY SHOULD HAVE ALL OF THE ABOVE SKILLS, PLUS MANY MORE."**

Steve went on to discuss how a project manager working in a small pharma company should have all of the above skills, plus many more. In comparison to large pharma companies, where large support networks and resource are more freely available, the small pharma company may not have as much time or money to spend on training and improving their PM, and thus experience is essential. He argued that a PM in such a company would need to be a self-starter and have the self-belief and confidence to move a project along and make decisions without constant oversight. They should be proactive enough to not only look for problems, but enjoy solving them.

Understanding the bigger picture

Being resilient was seen to be critical in an environment where there may be little internal support available, and where you may need to stand up in front of senior management to justify the way you were running your project and spending your budget. A PM in this environment would need to be aware of the big picture within the company, and how this may impact the financial constraints on their study. They may also need to be more aware of funding needs and the critical importance of meeting milestones in order to secure funding from investors.

Steve argued that small pharma looks for these skills in project managers whether as employees or consultants. They may often lack people with PM skills in their own company, and hence may turn to CROs to provide their PMs. There may be a temptation in a small company where money is tight to look for a cheap PM, but this is not necessarily good value. In a small pharma or biotech, one project may be the life or death of the company, and the choice of PM may prove critical to not only the success of the project, but the survival of that company. Steve also highlighted that the failure of a study did not necessarily mean the failure of the PM. If a study is unsuccessful, the quicker it can be shown to be unsuccessful, the less money will be spent; an important fact for investors.

> **"RATHER THAN START AN ELUSIVE QUEST TO BE THE PERFECT PM, PROJECT MANAGERS SHOULD FOCUS ON DOING THE BEST JOB THEY CAN…"**

Steve concluded that the project manager should 'Have no fear of perfection – you'll never reach it'. Rather than start an elusive quest to be the perfect PM, project managers should focus on doing the best job they can, using all their skills, and that how successful they might be depends on the skills they have and the type of company they work in.

Delivering the contract

Jamie Chorlton, then Senior Director of Project Management at Matrix (now Novella), spoke about project management from a CRO perspective, and highlighted the different type of skills project managers needed to have to be successful with the CRO environment. In a CRO, PMs are accountable for the delivery of a project according to the contract. The PM should know the contract inside out, and know what is required of them. To run the varied types of study that a CRO might receive, different levels of experience are required of the PMs, but the core skills remain the same.

Keeping cool and maintaining confidence

The PM should be technically competent and be able to get inside an issue and advise their sponsor on all options available to them. This provides the crucial reassurance to the sponsor that the PM understands the study appropriately. The PM should have outstanding communication skills, the confidence a sponsor has in the PM most often depends on the level of trust they have in the PM, a trust that is earned through easy and open communication.

> "IT IS CRUCIAL TO STILL BE ABLE TO MAKE DECISIONS, KEEP THE RESPECT OF THE PROJECT TEAM, AND KEEP CLIENT CONFIDENCE AT THE MOST DIFFICULT POINTS IN A STUDY."

An ability to stay cool under pressure is another skill critical to the CRO PM. They cannot lose control, no matter how bad it gets. It is crucial to still be able to make decisions, keep the respect of the project team, and keep client confidence at the most difficult points in a study. It is also important for the PM to be good humoured and generous, sharing their glory and praise with the team when things go well. They should look out for opportunities to praise their team members, and should be able to take responsibility when things do not go to plan.

Business-minded

Jamie highlighted how a PM in a CRO environment must be business-minded, looking for repeat business from existing clients, and capitalising on new business opportunities. They should be goal-oriented, and have an ability to 'manage to metrics', focusing on the deliverables of the project. They should also be financially astute, showing an aptitude for budget awareness and an ability to adhere to the contract, minimising out-of-scope activities unless requested by the sponsor.

Jamie concluded that although the core skills required by project managers across different types of company were the same, the PMs working for a CRO need to be more client focused and business-minded, and needed to be flexible and adaptable in their approach to project management in order to adequately meet the needs of their clients.

Many contexts, many ideals

It seems that despite what type of company you work for, all the speakers agreed on the core skills required of an excellent project manager – communication, organisation, leadership, proactive nature, goal-oriented to name but a few.

> "... DIFFERENCES IN TYPES OF SKILLS IN WHICH A PROJECT MANAGER MIGHT NEED TO EXCEL DEPENDING ON THE TYPE OF ORGANISATION THEY WORK FOR."

However, there are differences in types of skills in which a project manager might need to excel depending on the type of

organisation they work for. Those PMs working in small pharma/biotech might need to be more experienced in working without a large support network, and be able to have the confidence to make decisions and push their study along independently. On the other hand, PMs working in a CRO need to be more client focused in their approach to project management, adapting to their client's needs and ensuring rigid adherence to the study contract.

The perfect project manager is perhaps a myth, but the numerous skills required across the different business contexts give us plenty for which to strive.

Katie McGuire MICR is a Project Manager with Nexus Oncology Ltd and a member of the ICR Project Management Special Interest Group.

To comment on this article, email comment@crfocus.org. Comments might be published on the Clinical Research focus web pages, with author's name/affiliation, unless notified otherwise.

Katie McGuire

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CDISC – why is it for me?

As you're reading this, one of two questions are probably whirling around your brain i) "what is CDISC, I've never heard of it?" or ii) "how does CDISC affect me, I'm not a programmer?" Hopefully this article will help you answer these questions and provide you with a base to start from.

Well, let's start with the CDISC mission statement

"The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website."

source: www.cdisc.org

In simpler terms, CDISC aims to create standards to enable us to share data with each other more easily. Most people familiar with CDISC are programmers, but this may be due to the focus on the theoretical and technical aspects of the standards when they began. However, CDISC standards not only affect programmers, they can affect the design of the protocol (protocol model), CRF and database design (CDASH), data cleaning and export activities (SDTM) and the analysis and reporting of the data (ADaM).

So as you can see if you are involved in any of the processes above, there is a good chance that CDISC will affect you in the near future or could even be affecting you now.

Where next?

You can begin by looking at the CDISC website www.cdisc.org. This will provide you with details on the different standards (if the company you work for is a CDISC member, you can even obtain access to the members' area and review further information on the standards). Also by joining the ACDM CDISC SIG and user groups in your location (English speaking (ESUG), German, French, Italian, etc) you can get involved in meetings, attend teleconferences and presentations and increase your understanding.

So why should you get involved in the SIG?

I first started using / encountered CDISC 4 years ago having attended a course on SDTM (study data tabulation model); as a programmer I found it amazing that a group of people had got together from across our industry and decided we required data standards for the transfer and submission of clinical data. I left the course excited that finally the process of transferring data back to the sponsors would be more straight forward. 4 years later and using these standards day to day I can say that I am still learning new things and I still have questions.

However with all the questions I have, one of the great things I have discovered is the fantastic network of individuals and groups of people that feel the same as I do about CDISC. I attended the ACDM conference last year and discovered a room of people who had been using SDTM like me who had questions and wanted answers and so the ACDM CDISC SIG was formed. As a SIG, we wanted to have aims for our group to allow us to meet the needs of our members.

Some of the aims of the SIG are to:

- Provide an opportunity for members to contact other ACDM members with specific experience in CDISC
- Provide articles on relevant topics, such as:
  - What CDISC resources are available
  - How to take advantage of them
- Facilitate feedback on CDISC standards that are out for public review by posting link on SIG website, with an explanation as to why it is important to have data management feedback included in the review
- Coordinate with other SIGs regarding CDISC standards related to their areas to ensure they are aware of these standards
- Provide executive summaries of ESUG F2F and TC discussions
- Provide a forum for information sharing within ACDM on CDISC questions and raise those to the ESUG for consolidated response

So, if you're interested in more information or are already working with CDISC and want to discuss it with like minded people or are new to it altogether and want to get started, feel free to get in touch and join the CDISC SIG.

Alan Cantrell, CDISC SIG Lead
PAREXEL International

CALL FOR SPEAKERS

ACDM Annual Conference 2011

6-8 March 2011
Whittlebury Hall Hotel
Northamptonshire

WORKING **SMARTER**

Call For Speakers

The ACDM conference will once again be held at Whittlebury Hall from 6-8 March 2011. The theme of the conference is "Working Smarter".
We are looking for speakers to cover how we can all be "Working Smarter" in the following areas:

- **Cost effective trial management**
- **Balancing the books – how to run your project within budget**
- **How can Data Management add value to the trial process**
- **Working smarter but not longer!**
- **Smarter fit with the clinical project team**
- **Can new technology bring real savings and efficiencies**
- **Maintaining and increasing quality without increased cost**
- **How does a smart Data Manager think in 2011 and beyond**
- **Surviving financial restraints in an increasingly competitive market**
- **Where process re-engineering has really worked**
- **Innovative processes and technology**

REMEMBER you don't have to be a Data Manager to speak at, contribute or attend the conference!

Please let the ACDM know if there are any additional topics that you would like to speak on or hear about.

EDC, IVRS and EPRO vendor demos:

This year we are again inviting EDC, IVRS, CTMS and ePRO vendors to come along and demo their systems to us. Please contact the ACDM if you are interested.

Debate:

We are interested to receive suggestions for the Debate at the 2011 conference. What is the most controversial topic you would like to debate with your industry colleagues?

Team Break-Out Sessions/Hot Topic panel

We are interested to receive suggestions for the breakout sessions or the hot topic panel discussion at the 2011 conference. What topics are you interested in discussing with your industry peers?

Please send suggestions for the debate, hot topics and break-out sessions to us at admin@acdm.org.uk.

Don't forget to start thinking about your entries for the John Amos poster competition. Details to be published on the website.

Please submit synopsis for papers to admin@acdm.org.uk by 10th September 2010.

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All DMs, please add the date of the conference in your diaries.

Exhibitor space will be available.

For more information please contact ACDM Conference Committee at: admin@acdm.org.uk

www.acdm.org.uk

acdm
association for **clinical data management**

Health is your Wealth

NAME: Emmet Browne
ACDM POSITION: Board of Directors
COMPANY: Cmed

Provide a brief summary of your life / education etc to date.
I grew up in a town called Clonmel in Co. Tipperary, Ireland – Yes, I know it is a long way to Tipperary. I am also very aware that I have the same name as Dr Emmet L Browne in 'Back to the Future'.

I studied/socialised in University College Galway where I received a General Science degree and lots of good stories. However I did receive a Wellcome Trust Vacation Studentship to work in the department of Pharmacology where I carried out studies on the effects of MDMA. I continued my studies at University of Surrey in Guildford, where I received an honours degree in Biochemistry and Toxicology. During this time I also completed a placement year in the Dept of Medicine in University College London where I worked as a research assistant in the Centre for Diabetes and Cardiovascular risk.

My Data Management career began as a CDC1 in ICON Dublin just over 11 years ago. I didn't really know what to expect from the role and intended to stay 6 months, however I ended up staying just under 5 years reaching a level of Project Leader. Life in a CRO was exciting and an excellent learning curve.

After working with many Pharma and Biotech companies during my time at ICON I wanted to experience life on the other side of the fence which led me to Amgen, Cambridge where I set up my own limited company and worked in the DM dept as a contractor for 3 years running oncology supportive care trials globally. During this time I also acquired a small property portfolio which keeps me busy.

Then I moved to Roche in Welwyn Garden City working in the Clinical Pharmacology group managing Phase 1 studies for approx 6 months. During this period I struggled to cope with the pace of the biotech companies and once again I was lured back into the fast-paced, pressurised life-style of the CRO when I accepted a Head of DM, Programming and Statistics at Richmond Pharmacology. This position was definitely the most challenging I have ever been exposed to in my career to date. After a year and 4 months of very long hours and 4 hour daily commutes I decided to move on to Cmed research on the outskirts of the picturesque town of Horsham as a Team Manager in October 2009. I was excited by this role because it is unlike most of the companies I have worked with before; it has a young company feel and we have developed our own technology 'Timaeus' which is unique to Cmed. In the Team Manager role I functionally and line managed staff across all of our global offices as well as managing many Business Process Initiatives within the organisation globally. During my initial months at Cmed I spent a month in our Romanian office in a city called Timisoara, and I was so impressed by the people, culture and the team I took on the Acting Head of DM Romania. In this role I am responsible for the development and consolidation of the DM group.

During my time so far in DM I have worked with some great people and companies and I learn something new everyday. Cheezy as it may sound I am looking forward to the next 10 years in this rapidly evolving industry.

> "DURING MY TIME SO FAR IN DM I HAVE WORKED WITH SOME GREAT PEOPLE AND COMPANIES AND I LEARN SOMETHING NEW EVERYDAY. CHEEZY AS IT MAY SOUND I AM LOOKING FORWARD TO THE NEXT 10 YEARS IN THIS RAPIDLY EVOLVING INDUSTRY.

If you were on a desert island, which three things would you take with you and why?
My Blackberry – so I can communicate with the outside world and keep up to date with all the gossip.
Solar powered charger – to power the blackberry.
Fishing rod – to catch fish.

What has been your greatest achievement to date?
There are so many to choose from I just can't make up my mind....

What word or phrase, do you most over use?
Grand

If you were not in the job you are in, what would you do?
Property developer or an Investment Trader

Continued on page 20

The Master Baker

NAME: Alison Lewis
ACDM POSITION: Board of Directors
COMPANY: PAREXEL International

Provide a brief summary of your life / education to date
Like many of my colleagues in the Pharmaceutical Industry, I 'fell' into Data Management towards the end of my Biostatistics degree at Sheffield Hallam University. I was one of the lucky few who managed to find a permanent job before finishing the course. I always knew I didn't want to be a statistician, and I also had no knowledge of the Industry we all know and love! I applied because the advert made it sound interesting, but it also played to my skills of being highly organised and a logical thinker. The company sounded fun too! What I actually found was that it was extremely hard work, long hours, however, if you put in the graft, I soon found that I got more out of it, and developed very quickly, moving into Management quickly as the company grew. I've now been in the Industry 19 years, and have seen numerous changes both within my own organisation and others.

If you were on a desert island, what 3 things would you take with you and why?
Discs, and something to play them on – Music makes the world go round.....
Moisturiser – An essential to keep those wrinkles at bay! Particularly in the sun.
Lip Balm – Nothing worse than dry lips.

What has been your greatest achievement to date?
It's a cliché, I know... but raising two gorgeous girls

What word or Phrase, do you most over use...
Sorry... Not that I make many mistakes, but I'm always apologising! And for nothing in particular!

If you were not in the job you are in, what would you do?
Well in my spare time (what little I have with working for PAREXEL, and having two daughters), I bake vegetable muffins and American style cupcakes... I bake these for events (weddings, engagements, parties etc), and I love the creative side of it all. It's a little bit of escapism, albeit very hard work. Look out for BBC2's Great British Bake Off in August.... A program similar to masterchef....

What is your greatest fear?
Looking back on life in regret... you only get one chance, so make the most of it.

What makes you happy?
Spending time with the people I love.

What do you do to relax / What are your hobbies?
Baking! running, the gym, I love the cinema, and watching new films when they come out. Relaxing with friends, going to restaurants.... Chillaxing in the sun – when its out!

Continued from page 19

If you could be remembered for something, what would it be?
Curing Cancer

What lesson has life taught you so far?
Health is your wealth and life is what you make of it

What is your idea of perfect happiness?
Beautiful wife and family, and a successful career

What is your greatest fear?
Having regrets on my death bed

What makes you happy?
The simple things in life

What makes you depressed?
Not much

Where would you like to be in 5 years time?
At the top of my game

What do you do to relax?
Socialise with friends, listen to music, go to the gym

What famous person in history or present day would you most like to meet and why?
Elvis – because he is a legend

Bringing a new focus to Clinical Data Management

NAME: Nic Reed
ACDM POSITION: Board of Directors
COMPANY: PAREXEL

Having just joined the ACDM Board of Directors it's about time I let you know a bit about myself. I've been a member of the ACDM almost since I started out in CDM. I've been involved with the Annual Conference for many years by way of working on the PAREXEL stand, I've benefited from several courses and attend as many of the SCDM Forums as I can.

When I was young I wanted to be many things. Firstly, I wanted to be a lorry driver. I thought it would be cool to travel the country in a big rig. Then, I wanted to work in an office. I didn't know doing what, but I remember setting up a desk and neatly stacking papers and pens and feeling organised and efficient. Then, I wanted to be a graphic designer. So, by the time it came to studying for a degree, oh boy, was I confused. Just one discipline? But there were so many options!

I chose Archaeology as it was such a broad discipline. There were lots of options combining the science of dating techniques, archeometallurgy, handling large amounts of data scientifically (see there is a link to CDM after all!), and the art of understanding the pre-history of human evolution. So, please don't ask me anything about the Romans or Egypt, or Time Team and how whole socio-economic theories can possibly be based on the find of one broken pot shard, but the science around our archaeological heritage can be fascinating. My main discovery was that I'm not suited to hard manual labour and think I got away lightly, only ending up in hospital once at a dig. Working in an office became appealing again.

I fell into a role in a lovely little company called S-Cubed in Sheffield in 1997, who took real care of me. I still thank my lucky stars I landed that job otherwise I would still probably be none the wiser about our industry. I was given a solid grounding in all the CDM tasks, back in the day when it was normal to set up the database, write the validation programs, then clean and lock the data as part of one role (with appropriate QC steps of course!). S-Cubed was soon brought under the umbrella of PAREXEL and the Sheffield office saw rapid growth and opportunities to actively take more responsibility and learn new skills kept coming my way.

I moved into a line management position and vowed to try to support staff in the manner that I had been. I still get a kick out of facilitating others' success. Following many changes within PAREXEL I managed the Sheffield CDM group for several years. Although managing locally, by then we were actively embracing a global structure and my teams worked with those both onshore and offshore and of course, working with clients from all over the world (and one just down the road from where I was born).

> **"I DO BELIEVE THERE IS MORE TO LIFE THAN JUST WORK! I PLAY QUITE A LOT OF BADMINTON AND LOVE SKI-ING TRYING TO GO SEVERAL TIMES EACH YEAR, AND THEN SPEND THE REST OF THE YEAR THINKING ABOUT IT.**

My most recent job move was a couple of years ago, still within PAREXEL. An opportunity came up within the evolving Quality structure. I felt like I needed a fold out business card initially as different areas and departments came and went from my remit, but that meant I also had a say in the structure. We now have a well established and robust Quality system and my role is to lead a team of consultants across 8 countries supporting all phases of trials. We support the design and implementation of global processes for CDM and also local 'quality' activity which feeds into those processes, such as supporting resolution of quality issues, audits, inspections and department root cause analyses. It's still CDM, but with a different focus. I'll be undertaking my Green Belt Lean Six Sigma later this year so will be honing my business improvement and analysis skills.

However, I do believe there is more to life than just work! I play quite a lot of badminton, for various district teams and am Secretary for the largest club in Yorkshire. I love ski-ing and try to go several times each year, and then spend the rest of the year thinking about it. I even managed to ski directly after a client meeting once and admit it was hard to focus that day!

If I wasn't in this industry I doubt I'd go off to be a lorry driver or a graphic designer. I can half imagine running a mountain bike friendly B+B in the Yorkshire Dales. It would have to be something completely different. However, I still get a kick out of what I do so I'm not looking to change things any time soon.

OCTOBER

4-6

TOPRA
The 7th Annual TOPRA Symposium
Hilton Park Lane, London

7

ACDM
Senior Forum
TBC

17-20

SCDM
Annual Conference
Hyatt Regency Minneapolis, USA

28-29

DIA
7th DIA Japan Annual Meeting
Tower Hall Funabori, Tokyo, Japan

31 Oct – 5 Nov

CDISC
CDISC Interchange North America
Renaissance Harborplace Hotel, Baltimore, US

NOVEMBER

2-5

BARQA 2010 Annual Conference
The Queens Hotel, Leeds, UK

3-5

DIA
8th DIA Annual Canadian Meeting
Westin Ottawa Hotel, Ottawa, Canada

3-6

ISoP
10th Annual Meeting
The Palm Royal Beach Hotel, Africa

11-13

DIA
4th Annual Clinical Forum
Lisboa Congress Centre, Lisboa, Portugal

29-30

DIA/EMA
2nd Joint DIA/ European Medicines Agency Innovation Forum
Marriott West India Quay, London, UK

DECEMBER

1-3

DIA
11th Conference on European Electronic Document Management
Hotel Le Meridien, Nice, France

2011

11-14 SEPTEMBER

SCDM
Annual Conference
Marriott Baltimore Waterfront, Baltimore, US

OCTOBER

ISoP
11th Annual Meeting
TBC, Istanbul, Turkey

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

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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.

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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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