Autumn 2009 • ISSUE 71

acdm
association for clinical data management

# DataMatters

## NEWS & VIEWS
Updates from the Committees and SIGs

## ACDM PEOPLE
Lesley Phoenix

SEE PAGE 5 FOR MORE DETAILS

## ACDM COLLEGE WEEK

2-6 November 2009

Training Committee

## ARTICLES

How to Manage the Successful Introduction of a New EDC System

Should ICH GCP be Reviewed & Revised?

Awakening a Sleeping Giant – Thoughts for EDC Vendors to Support Medical Device Trials

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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 |
|---|---|---|
| Winter 2009/10 | 4 December | 1 February |

## ACDM E-shots

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

## ACDM ADVERTISING

ACDM offers advertising in the quarterly online Newsletter – *Data Matters* – and/or on the ACDM website at *www.acdm.org.uk*

*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.

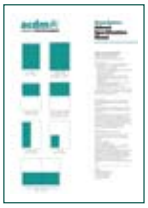
*www.acdm.org.uk* provides a classifieds section where your advertisement can be uploaded in a matter of hours. Not only will your advertisement reach all ACDM members but also the wider community of data management and other professionals who access the website.

## ACDM ADVERTISING RATES

Effective from 1st August 2009

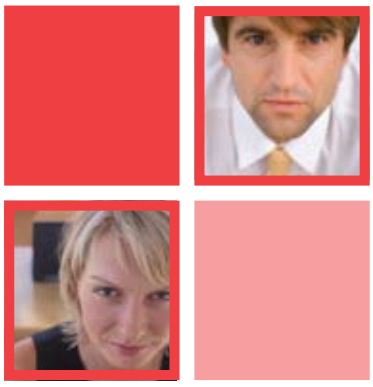
| | | |
|---|---|---|
| **Newsletter** | Full Page Colour* | £1000 |
| | Half Page Colour* | £800 |
| | Quarter Page Colour* | £450 |
| **Web advertising** | One month* | £350 |
| | Renewal per month (no changes) | £250 |
| | Annual advert (up to 6 updates) | £2000 |

* 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**



**ACDM COLLEGE WEEK**

**2-6 November 2009**

Training Committee

## CONTENTS



# A New Greener ACDM

**By the time you read this, most of you would have had a well deserved summer break – and are looking forward to Christmas already – some of you may have even started (or completed) your Christmas shopping. I have just come back from mine nevertheless can't wait for Christmas.**

As you are aware, this is the second edition of electronic Data Matters to be published. We will be interested in your feedback on how you are finding this newer, greener ACDM mode of communication. In case you missed the reasons for making this change, the Board decided to look for ways to reduce costs as part of our 3 year strategic plan. With reduction in advertising revenue and the increase on postage, it was decided to go green and make this change.

Talking about feedback, there is now a Linkedin group for the ACDM at **www.linkedin.com**. Managed by Ian Pinto and Gail Kniveton you will find several postings of interest – we are looking for as many people to join as we would like to hear your opinions on many of these topics. Though this is not a substitute for **www.acdm.org.uk**, it allows for easy sharing of information and requesting opinions. There are two in particular worth contributing to. The call for conference papers for our 2010 conference and a poll on "The ACDM Newsletter 'Data matters' has gone 'green' and now only available online BUT which is your preference?" By becoming a member of this group, you can also follow and contribute to the following subgroups (CDISC, Coding and Dictionaries, Project Management, Data Management, Laboratory Data and Electronic Data)

The 2010 conference will again be at Whittlebury Hall in March (21-23). It is early days yet, but the conference committee is aiming to put on a good show once again. Please put this in your calendar and don't miss it.

At last year's conference, you voted on the motion to offer discounts for joining the Society for Clinical Data Management (SCDM) and have a reciprocal agreement for SCDM members. Since then we have had a number of low level discussions with the Board of the SCDM and are looking at more ways to collaborate. Our first formal meeting was in September. We hope to be able to report progress in the next newsletter and also at the conference in March

The training committee have been working hard in the last year and we can now offer instructor led web based courses as well as the formal classroom based courses. In 2010 the following courses are being planned:

- Managing a Busy Workload
- Medical Terminology, Basics of Human Physiology and Pharmacology
- Understanding Statistics
- Assertiveness Skills for CDMs
- Regulatory Update Essentials for CDM
- Understanding the Roles of Other CR Professionals

Finally, the newsletter committee are looking for new members. As you would appreciate, the association runs on the members contributing their time. As a member you will help write or source articles for the newsletter. Please contact any member of the board if you are able to give some personal time to the newsletter or any of our other SIGs and Committees.

***Tracy Fells & Fred Daniels, Joint ACDM Chairs***

Website
*Committee*

# Analysing www.acdm.org.uk

The website committee has been busy this month analysing figures (which we all know data managers love doing) from the recent Eshots to see if people are opening the Eshots and clicking on the links. This was of particular interest to the newsletter committee as well, as they were keen to see the figures for the E-Newsletter.

The report shows that the Eshot gets delivered to 1217 members and of these members 379 (31%) opened the email. This may seem quite low but according to our website designers most companies would expect an open rate of 25%...

The majority of people seem to open the email the same day they receive it probably early morning or late in the day when work tends to wind down.

The 24th August Eshot featured links to the 2010 Conference, information on training courses, a link to the new E-Data Matters and information on upcoming CDISC and Senior Forums. The report shows that the most clicked on links were regarding the Conference (30% of the clicks) and the new E-Data Matters (22%).

As we continue to send out the fortnightly Eshots we will be monitoring the click through figures to try to ensure we are tailoring the Eshots to subjects that **you** the members want to hear about, but don't worry we're not Big Brother – we can't identify who is looking at which pages...

In the future we may even be able to send you automatic emails with extra information in depending on which link you clicked, watch this space...

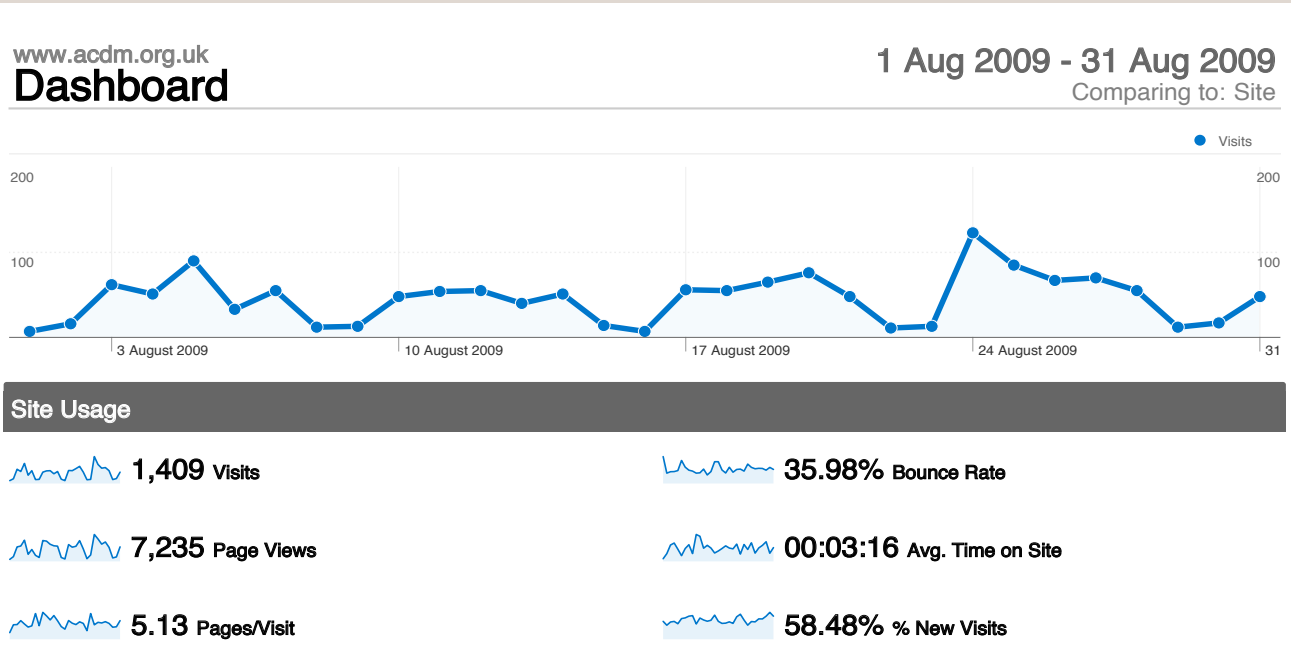
In the meantime please continue to open the Eshots, as it is our way of getting important information re upcoming events, training courses and future SIG/committee meetings to you. If there is anyway you feel we could improve these Eshots then please email admin@acdm.org.uk with your suggestions.

Thanks

***The Website Committee***

As you can see from the graph the website **www.acdm.org.uk** gets an increase in hits when the Eshot is released, with a peak of 102 people visiting on 24th August. On an average month the website has over 1000 people log on and the most visited pages are the resources, events and training pages. It also attracts a number of different nationalities seeking out information on DM with the top 3 countries being UK, US and India. The ACDM have used this information when looking at new training courses and this is why you will see a number of webinars being introduced so our international colleagues can attend these without travelling overseas. If you are experiencing difficulties with the website or have any feedback please email **www.acdm.org.uk** and we will try to rectify the problem ASAP. Thanks

***The Website Committee***



Training
*Committee*

# To Train or Not to Train ...an Update from the Training Committee

College Week is running Monday 2nd – Friday 6th November. We hope that we will see many of you there as feedback from previous College Weeks has been very positive! It's a week of excellent training courses run by experienced trainers who are experts in their field. The course will be run at a venue near Maidenhead in Berkshire, UK with easy access via the transport network. This can be residential so that you can attend all week or you can just attend the modules that suit you best. There is also the added flexibility of being able to send different individuals on different days.

**Here is the schedule of upcoming training events, including College Week:**



## ACDM College Week – 2-6 November 2009

Training
*Committee*

| | |
|---|---|
| **Mon 2 & Tues 3 Nov** | Delivering Successful Projects |
| **Mon 2 & Tues 3 Nov** | Guiding Principles of CDM |
| **Wed 4 Nov** | Managing Projects & Alliances for all Clinical Phases of DM |
| **Wed 4 Nov** | Working as Part of an Effective Project Team |
| **Thurs 5 Nov** | Essential Guide to Oncology |
| **Thurs 5 Nov** | The ABC's of Standards: A CDISC Primer for Data Managers |
| **Thurs 5 Nov** | Effective Design of Data Collection Tools |
| **Fri 6 Nov** | Successful Trials – eClinical Technology |
| **Fri 6 Nov** | The Regulatory Environment and its Impact on the Management of Clinical Data |

**Book your place online NOW! Don't miss it....**

## Other training events

Training
*Committee*

| | |
|---|---|
| **Wed 18 Nov** | Preparing for a Regulatory Inspection (Webinar) |
| **Wed 9 Dec** | GCP / EU Directive Update (Webinar) |

Further details on the content of these courses can be found on the website www.acdm.org.uk.

The committee has also been reviewing the training schedule for 2010 and this will be published soon.

Did you also know that the training committee now also offer customised training courses for our clients at their sites? At a time when budgets are restricted, this excellent option will suit companies with groups of individuals to train without having to pay for travel and accommodation on top.

The ACDM Conference Committee are presenting at the e-Clinical DIA conference on "To Train or Not to Train". We are presenting our rationale for revamping the ACDM training courses. We are also planning to present this again at the ACDM conference at Whittlebury Hall 21st-23rd March 2010.

**For more information on College Week, our schedule for 2010 or customised training courses then please contact us via the ACDM website www.acdm.org.uk or email training@acdm.org.uk**




# Driving Success ...an Update from the Conference Committee

Conference *Committee*

## The dates are set: March 21st-23rd at Whittlebury Hall. The theme is "Driving Success" to fit in with the location at Silverstone.

This year we are revising the format of the conference based on your feedback and ideas. The call for speakers was issued in September and although we can't give you details yet, this does promise to have some excellent speakers from experts in many areas of clinical trials. We will be publishing this in the next newsletter.

**Some of the areas that we are planning to cover include:**

- Data Integration
- Electronic Patient Reported Outcomes
- Oncology and Data Management
- Uniting Data Management and Biostatisticians – how can we work optimally together?
- CRA/DM – role convergence – what works and what doesn't when it comes to remote trial management and data quality?
- Regulatory updates
- Site and CRA views on eCRFs and e-clinical trials
- CTCAE and other hot topics in coding
- Impact of IVRS, EDC and EPRO on clinical DM operations
- Pharmacovigilance and data integration with data management
- Effects of medical ethics on Data Management
- Central and local lab Data Management in an EDC environment

We also promise to have some excellent entertainment during the conference and chances for you to network with people from other companies and areas of clinical trials. The conference also has the JC Amos Poster competition. This is a great opportunity to submit a poster about something that you have worked on and want to share. Individuals or team can enter this. This is suitable for all levels of entry and a prize is offered to the winners. The standard has been great in previous years so we hope that this will continue.

***For more information on the Conference, Sponsorship or to book now then please reach us on: www.acdm.org.uk***

# The Magic of Coding

Coding & Dictionaries
*Special Interest Group*

It's been over a year since the Coding & Dictionary SIGs last face-to-face live meeting. During the last year we did get together for a morning on a conference call to discuss the 'magic' of coding, but there's nothing like meeting up in the flesh and networking with industry colleagues!

The next Live meeting will be taking place at Roche in Welwyn Garden City thanks to ACDM and Coding SIG member Peta Small. Roche have always been keen supporters of the ACDM and especially the SIG (Jane Knight being the founding member and former SIG chair) so thank you once again. The meeting will be on 13th of November 2009. If you would like to attend (even if you're not currently a Coding & Dictionary SIG member) then please email ian.slack@parexel.com and book your place early as numbers are strictly limited. By the time this article goes out there may only be a few places left since the meeting will have already been communicated to the current SIG members.

The meeting will be an all day affair jam-packed full of agenda items such as 'Insulin coding', 'Handling problem terms', 'Labelling' and more! We're also lucky enough to have support from the MSSO (Maintenance and Support Services Organisation) at the meeting and will have a guest speaker providing an overview of SMQ's (Standardised MedDRA Queries) and if that wasn't enough we may also have another 'surprise guest speaker'!

If you'd like to know more about the SIG or would like to take a look at previous meetings / presentations then get yourself over to the ACDM website and the Coding & Dictionaries SIG page www.acdm.org.uk/grp13_home.aspx

If you can't make this particular meeting but would still like to join the SIG member list then please get in touch. It would be great to have you on board.

***Ian Slack***
***Email: ian.slack@parexel.com***

# Stats from the ACDM Secretary

**Membership**

Membership of the ACDM stood as follows on 31st August 2009, with comparison to the previous year:

| | 2007/2008 | | | | 2008/2009 | | | |
|---|---|---|---|---|---|---|---|---|
| | **O** | **A** | **Hon** | **Aff** | **O** | **A** | **Hon** | **Aff** |
| UK | 694 | 75 | 3 | 14 | 713 | 79 | 5 | 20 |
| Non-UK | 126 | 15 | 1 | 1 | 132 | 21 | 1 | 1 |
| **Total** | **929** | | | | **972** | | | |

O = Ordinary Member, A = Associate Member, Hon = Honorary Member, Aff = Affiliate Member

The total number of members has increased slightly compared to the previous year. The Board of Directors continues to monitor membership numbers and are looking at various ways to increase membership numbers.

**Board of Directors**

The Board of Directors has had a full quota for the year, with the following membership/responsibilities:

| | | Other Responsibilities |
|---|---|---|
| **Chairperson(s)** | Fred Daniels / Tracy Fells | Newsletter Committee / Website Committee |
| **Treasurer** | David Baker | |
| **Secretary** | Paul Fardy | |
| | Harshad Sodha | Training Committee |
| | Susan Gales | Conference Committee |
| | Ian Pinto | PR Committee |
| | David Walpole | Senior Forum Committee / Technical Meetings |
| | Andrew Green | International Collaboration / Special Interest Groups / Working Parties |

The Board has met on a regular basis since the AGM in March. The minutes of these meetings are available on the ACDM website.

**Administration Activities**

Our management company, KSAM, have continued to support the ACDM in its administrative activities.

***Paul Fardy, ACDM Secretary***

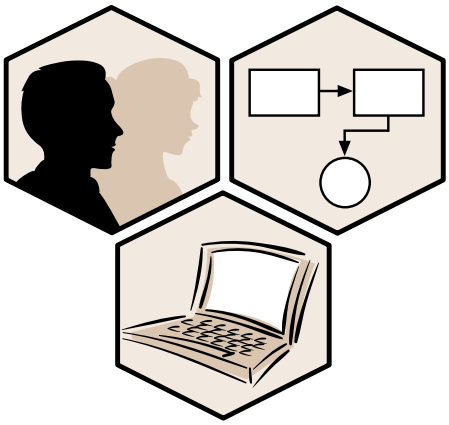
# How to Manage the Successful Introduction of a New EDC System

**Bärbel Fotteler and Usha Parekh, Roche**

Today the use of electronic data capture (EDC) is commonplace across the pharmaceutical industry. However, early adopters of EDC, having already made the difficult journey away from a paper-based environment, are now faced with the new challenge of introducing the latest web-based EDC solutions into their organizations.

Roche selected their first EDC tool in 1997. At that time they selected an offline application that integrated with Oracle Clinical (OC) as the backend system. This EDC model was fully implemented across the organization and was a significant change management achievement.

Ten years after selecting this first EDC tool, Roche launched the EDC Next Gen-



eration (EDC NG) Initiative. The goal was to ensure that Roche capitalized on the best EDC technology to address existing limitations of the old system and to meet future needs.

In this article we would like to share our approach and experience with the selection and implementation of a 2nd generation EDC tool for Roche Clinical Research and Exploratory Development (CRED).

We feel the key to our successful implementation was to ensure alignment across people, systems and processes.

## The Approach

### Objectives and Business Requirements Definition

The main objectives for the EDC NG project for CRED were to support:

- Timely sponsor decisions by making complete, high quality data available in time
- Short study setup timelines
- High flexibility
- Reduced resource/cost

Based on these objectives, the user requirements were collected and reviewed within a cross-functional project team, including critical input from subject matter experts in their respective functions (data management, study management, science, biostatistics, investigational sites, informatics, quality assurance).

## Vendor Selection Process

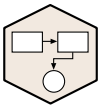
With such an extensive range of EDC solutions available in the marketplace, we started off with 26 potential vendors. Using a staged approach, and pre-defined selection criteria derived from the user requirements, this was reduced to a short list of 4. The top 4 vendors were then invited to present their system in an interactive workshop over a 2 day period. Roche participants in the workshop scored each aspect of the system functionality which led to the selection of a preferred and a backup vendor.

## First Pilot Studies

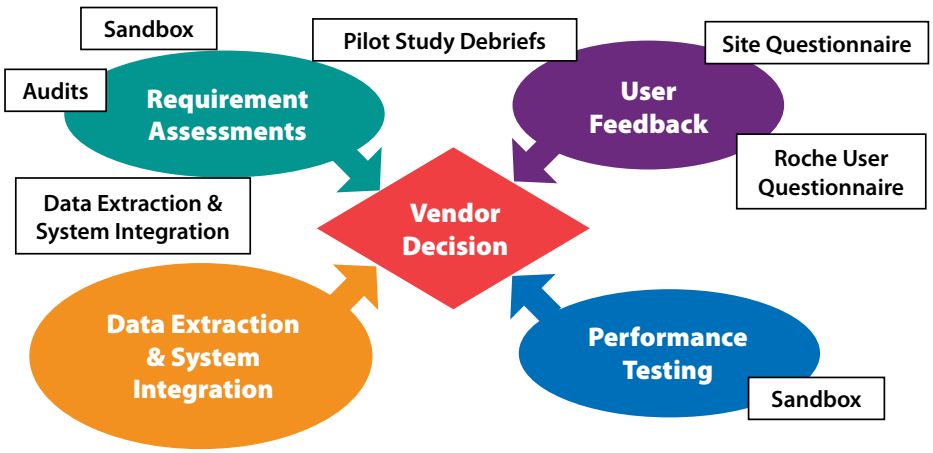
Shortly after the selection process Roche embarked on running 3 pilot studies using the preferred system. These studies were built by the vendor working in an Application Service Provider (ASP) capacity. Alongside this, a "sandbox" assessment was conducted to thoroughly test the performance and technical capabilities of the preferred tool. **An extensive assessment was conducted by 4 different teams looking into the various aspects of the tools:**

As a result of positive conclusions from the pilot studies and the sandbox assessment, Roche made the final vendor decision and proceeded to contract negotiation with Medidata Solutions for their Rave electronic data capture, management and reporting system.

## Process Development



Once the first pilot studies were underway, a process development team was

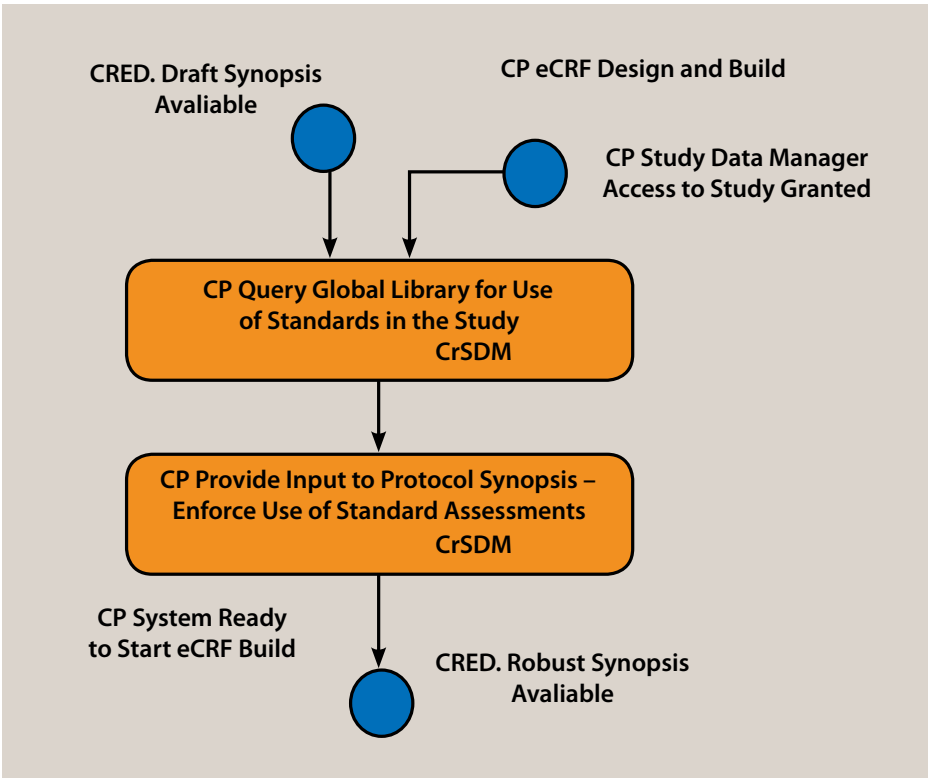


formed. Their goal was to develop streamlined, simplified processes to improve flexibility, efficiency and speed. In only 3 months, this cross-functional process team developed 29 process maps describing in detail how to run a CRED study using the new EDC tool. Lack of technical knowledge by the process development team about the new EDC tool itself was addressed by involving experts from Medidata Solutions in the process design workshops. All processes were mapped in System Architect (software by IBM-Telelogic) using a standard notation (BPMN: Business Process Modeling Notation). This allowed us to publish the process maps in various formats and supported detailed, critical analysis of the processes, including the production of responsibilities lists for the different roles.

## Process Pilots

In order to fully test our proposed new processes before embarking on full roll-out, CRED conducted 3 'Process Pilot' studies. For these studies all study build work was performed in-house by CRED Data Management. This allowed our teams to develop more comprehensive experience of the system. An EDC Advisor Network (EAN), who previously supported the old EDC system, was engaged at this time to provide coaching and support to the Study Management Teams on the process pilots.

At this stage, parallel work started on a training strategy, data extraction techniques and data standards based on the industry standard defined by the Clinical Data Interchange Standards Consortium (CDISC).




## Restructure of the Department

Implementation of the new EDC system and developing new business processes was used as a catalyst and opportunity to revisit the structure of the CRED Data Management Department. New roles were defined using System Architect for full alignment with the new processes. This resulted in fewer hand-offs between roles and functions within Data Management and with partners in the Study Management Team and other functions across Roche.

CRED edc

In April 2009, the full roll-out of CRED EDC was initiated. CRED EDC describes the complete business environment, including:

- People: New roles based on the restructure in 2009 and EAN
- Systems: Medidata Rave® and related tools
- Processes: Process maps and supporting documentation.

Since April, more than 30 CRED studies have been setup using CRED EDC.

## What made CRED EDC a success?

As stated above, we think that the key to the success of CRED EDC was that we focused on three parallel activity streams: People, Systems and Processes and the relationships among these.

### Our People

The early involvement of subject matter experts from all functions and Roche sites in vendor selection, piloting and process development was crucial. This ensured the definition of accurate, high quality requirements and clear selection criteria. It also increased organisational acceptance for the selected tool and new globally aligned business processes.

The various implementation teams were empowered by management to make decisions and design processes. This increased the sense of project and task ownership and increased motivation.

During the piloting phases, the teams were able to learn and experience the new environment first hand and provide real-time input to improving processes and system configuration. The involvement of the EAN was also vital to support

*Continued on page 10*

the learning and knowledge sharing.

A change management training program was established, covering both technical and soft skills, in order to support the implementation of the new system and to help people adjust to any changes in job roles.

A CRED EDC intranet site was rolled out as the primary EDC communication tool within the function, as well as being a valuable source of information for our partners and colleagues from other functions.

However, none of this would have been possible without the individuals from across the organisation being ready and willing to change, fast learners, very knowledgeable, highly committed, dedicated and excellent communicators.

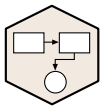
**The System**

In contrast to our legacy EDC system, the new EDC environment is based around a single database. This is a significant simplification for study setup and data management. Medidata Rave® offers a fully web-based front-end for EDC which replaces installing and shipping laptops to investigational sites and allows direct access to data on-line.

Jointly with colleagues from the biostatistics department, the process for transferring data for statistical analysis and reporting was optimized through the adoption of end-to-end data standards and the creation of a single data transformation tool. The cross-functional approach to data standards ensures a good fit between the data collection models in the CRED EDC system and the reporting data structures in SAS. CDISC Study Data Tabulation Model (SDTM) has been used as the basis for these harmonised standards.

Another strategic technology decision was to initially implement Medidata Rave® with minimal integration to other internal Roche systems. Rather than lock ourselves into maintaining potentially costly and inflexible system interfaces, we decided to adopt a lighter touch using semi-automated and manual processes for our CRED studies. In the future we will implement some system integrations leveraging Rave's data access tools, but will design these around standard data interchange techniques to maintain a flexible system architecture.

**The Process**



The benefits of the new processes include removal of unnecessary hand-offs and clarification of the interfaces with partnering functions.

Mapping processes in System Architect gave the opportunity for detailed analysis of the tasks involved in running EDC studies in CRED and to clarify roles and responsibilities in support of the department restructure.

System Architect offers the possibility to produce outputs in various formats from the same source database. Both Word-based process manuals and interactive HTML outputs could be produced for user training and as reference material.

The EAN developed a CRED EDC branding template for documents and presentations. This was an important change management tool to underline the characteristics, uniqueness and quality of CRED EDC.

The EAN also produced process support documents. These were developed iteratively in collaboration with active EDC study teams as they followed the new processes. This ensured that the supporting documents truly met the needs of the teams and did not just introduce unnecessary paperwork. It also ensured that revised documents could be ready in time for the next study in line.

## Conclusion

The 2 years from vendor identification to roll-out in CRED were not always easy, and there is still some way to go until the new EDC environment and processes are fully optimised. However, the progress we have made in only 2 years is remarkable and we are convinced that with the support of the talented people in our organisation we are ready for the next part of this journey.

## Acknowledgement

***EDC Next Generation Team***
***EDC Advisor Network***
***Extraction Team***
***Interim Data Standards Team***
***CRED Data Management***
***Medidata Solutions***

# 'The Evolution of Clinical Data Management'

## 17-18 November 2009
## Munich, Germany

VIBpharma presents the 2nd Annual 'The Evolution of Clinical Data Management' on 17-18 November 2009. This year's event will further the networking opportunities and provide delegates with a wealth of practical ideas and tools to improve their processes with handling the vast amount of data generated by clinical trials.

Through a series of interactive discussions and presentations by the leading manufacturers, the agenda will cover these following key topics and more:

- Utilising EDC tools to integrate data across multiple sites to reduce the risk of data loss
- Assessing collaboration between partners during the trials process for seamless sharing of information without comprising confidentiality and data integrity
- Understanding CDISC standards and implementation challenges to develop improved data management standards and reduce the time to market for new treatments
- Making the right decision on cost and outcomes in data management when outsourcing and working with service providers in emerging markets

Located in Munich, a central hub of the manufacturing and CRO industry, VIBpharma's Data Management in Clinical Trials conference will provide a high-level platform to generate ideas and solutions to make the best use of data management resources and improve processes during clinical trials through to submissions for regulatory approval.

Register at **www.vibevents.com/pharma/data/register.htm** and don't forget to reference code: ACDM. Don't just take our word for it, here's what a previous attendee thought of 'The Evolution of Clinical Data Management':

**Josep Bassa Logistic Director at Roche Diagnostic**

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# Still Relevant After All These Years? Should ICH GCP be Reviewed & Revised?

**Compiled by Andrew Smith**

**Keywords:** Data integrity, Data protection, Essential documents, Good Clinical Practice, ICH GCP, Patient protection, Periodic review

**ICH guideline E6 (ICH-GCP)** is, along with the **Declaration of Helsinki**, arguably the most important document in clinical research. Although neither has any direct status in the legislation of most countries where clinical research is conducted, their principles (and in many cases more substantive details) set the tone for how pretty much everyone conducts clinical research. Since its adoption in 1996 (in Europe; 1997 in the USA and Japan), ICH GCP has been the 'bible' for CRAs, auditors and other clinical research professionals worldwide. Since 1996...

The world of clinical research has moved on quite some way in the past 13 years, and even more so when you consider the period of several years that was taken for the drafting, consulting, reviewing and negotiating prior to the guideline's finalisation. Other guidelines (most notably the Declaration of Helsinki) have been updated several times in the past decades, and have a timeline for regular review every few years.

So, following a remark made by **Professor Richard Gray** when speaking at the ICR Annual Conference earlier this year, we wondered whether ICH E6 should be reviewed and potentially revised. We put a poll on the front page of the ICR website, and were rather surprised by the result: over 80% thought that it should be reviewed (although from an admittedly small sample). Following on from that, we undertook a qualitative survey, asking all Chartered Scientist (CSci) and Clinical Research (FICR) members what elements of the guideline should be updated and/or what should be added that did not exist in 1996. Here we present some of the most interesting and provocative comments.

## Assessing the need for change

Many of the respondents to our survey suggested specific areas where further clarification would reduce variability in interpretation, and aspects where science and working practice have moved on substantially since ICH GCP was adopted. These suggestions are discussed later in this article. First, though, comes the thorny question of whether we should even consider reforming the guideline. According to **Paul Chester MICR CSci**, *"I think this discussion is overdue and very relevant. Whenever I talk about GCP, I feel it is important to point out that ICH GCP is now 13 years old and getting older every day, so it must be read in light of new regulation and guidance."*

Not everyone agrees on this question. There are two main arguments against attempting to update ICH GCP, which are themselves diametrically opposed. One is the widespread feeling that it is so successful, so entrenched after 13 years and so fundamental to modern clinical research that any attempt to change it would be futile and would produce more confusion and political turmoil than any changes might resolve. **Prof. David Hutchinson FICR CSci** holds this view: *"I do not think that ICH GCP guidelines need to be changed. They have stood the test of time and remain perfectly reasonable. It should be remembered that these are a global standard and seem to fit the practices in most parts. The ICH GCP guidelines present clear requirements for sponsors, investigators and ethics committees. They protect subjects and they facilitate the collection of credible data backed up with good documentation."*

The other point of view is that ICH GCP's era of dominance has in fact been ended, in the EU at least, by EU Directives and national legislation that call for the guideline's principles to be taken into consideration but shy away from giving it any direct legal force. One person who took this line in a phone conversation with me was **Joan Perou HonFICR**. However, Prof. Hutchinson reminds us that *"in both the UK/Europe and USA, the ICH GCP guidelines are still used as an inspection standard and are still very much part of our research. In Japan a slight modification to the ICH GCP is still the chosen standard."*

Interestingly, **Tina Barton HonFICR CSci** suggests that *"the perception of issues with ICH GCP may be more related to the EU Clinical Trials Directive and/or the national legislation. The bigger issue may be the lack of a common view of users. Since its adoption, regulators (in particular the FDA and EMEA) are more closely aligned and in broad agreement of the application of this guidance, which has brought many benefits to the research community."*

**Nigel Crossland FICR CSci** holds the guideline in similarly high esteem, commenting that *"despite new requirements such as EU regulation, the ICH GCP Guideline has never been superseded,"* but adds that he thinks *"consideration should be given to review and update of the ICH GCP Guideline."* **Dipti Amin MICR CSci** agrees, saying *"I believe the fundamental premise of GCP is sound and still applicable. It serves as a good base for providing guidance around the processes and requirements for carrying out research particularly for those new to conducting research and those otherwise apt to cut corners. It helps achieve some degree of uniformity in expectations and sets the independently expected standard for all involved in clinical drug research."*

**Rod Owen FICR CSci** nicely sums up a pragmatic approach taken by many respondents: *"It is my view that the Principles of ICH GCP (ie, clauses 2.1-2.13) should remain unchanged as they are absolutely fundamental to the practice of internationally accepted ethical research. However, any minor 'tweaks' elsewhere within Guideline E6 would be perfectly acceptable and indeed logical"*. **Mark Elsley MICR CSci** has a similar view: *"ICH GCP has revolutionised the pharmaceutical industry to improve the quality of clinical data and assure patient safety. As such, I do not believe ICH GCP should undergo radical changes but there are some are some areas where I think further clarification is required"*.

**Dr Arun Bhatt HonFICR** expressed this most strongly, saying *"The current ICH GCP guidelines are too broad and general to proactively manage today's scientific and ethical issues. There is a need to make ICH GCP more explicit, specific and stringent"*. However, perhaps we should be wary of making ICH GCP too prescriptive at the cost of making it overly complex, cautions **Jacqueline Briggs MICR CSci**, *"I would not be keen to see ICH GCP changed into something more complex and confusing as I think its summary layout is helpful and practically applicable."*

Others argue that even keeping ICH GCP unchanged should be a conscious decision rather than a default. This sort of periodic review is the policy adopted by the World Medical Association with regard to the Declaration of Helsinki. **Anita Lindsay FICR CSci** supports the process of regular consideration, *"I would be reassured to know that ICH GCP had been reviewed on a regular basis to ensure that it is still meeting the needs of patients, clinicians and the industry (even if there were no resultant changes, it would also be good to know that there was a process behind the scenes). A review would also raise the profile of ICH again."*

However, **Neil Sharpe MICR CSci** reminds us that *"subject safety and data integrity should remain the founding principles of GCP: any changes made to reflect current practices should not compromise these principles."*

## Specific areas for change

The ICR members who responded to this call for contributions had many suggestions of specific areas to change in a hypothetical revision of ICH GCP. Here is a selection of their recommendations:

### Harmonisation & globalisation

One of the most significant changes in the way clinical trials are conducted since the early 1990s has been the opening up of many new countries as locations for clinical research, and the acceleration of 'off-shoring' large clinical trials to these locations. Dr Bhatt highlights one of the major issues arising as a consequence of this: *"There are also new concerns [to be met by ICH GCP, such as the] use of poor illiterate populations from developing countries as trial subjects."* Although outside the core ICH countries (EU, USA and Japan), ICH GCP plays a major role in these countries. Prof. Hutchinson reminds us that *"We have to think outside the national (UK)/European box and realise that researchers in many countries have only the ICH GCP principles to work with. There are some other GCP codes but these tend to be modelled on the successful ICH GCP standard."*

### Clarifications

Perhaps more troublesome than any other aspect, the potential for differing interpretations of can lead to local variations, bureaucracy and confusion. While ICH GCP is generally considered relatively successful in avoiding this, there are areas that contributors think could be improved.

Tina Barton comments, *"Countries generally stick to the intent of ICH GCP, but there are different interpretations of some details and greater clarity around these would be helpful to assure a more consistent adoption of specifics, often increased by the legislative requirements and the interpretation of those into the everyday activities."*

**Adam Jacobs FICR CSci** notes that *"the section on informed consent of trial subjects, while undoubtedly well-intentioned, can be a bit over the top in some circumstances, resulting in information overload for subjects, which then compromises the validity of the whole informed consent process."*

Dipti Amin comments that *"from time to time the interpretation sometimes placed by those utilizing it in the conduct of clinical research causes unnecessary bureaucracy without adding anything to promote the safety, rights and well being of study participants or in ensuring the integrity of study data. Also, there could be more flexibility in terms of the wording around monitoring which currently suggests that central monitoring should be the exception whereas in reality it's applicability depends on study design, indication, and study purpose as well as level of site experience in conducting research."*

Mark Elsley thinks that *"there should be more guidance about how much SDV to do as the definition in ICH-GCP is rather vague. Some companies do 100% and others take a risk-based approach, without any clear statement of what is acceptable."*

Dr Bhatt suggests that some of the terms used could be clarified to remove ambiguity, such as *"persistent non-compliance and protocol deviations vs violation".*

## Scientific developments

Paul Chester, Dr Bhatt and Mark Elsley all highlight the area of clinical pharmacology, particularly from the point of view of integrating (or at least citing) the guidance on first-in-man studies developed after the TGN-1412 incident.

Anita Lindsay adds *"The big step forward since the mid-90s for me is personalised healthcare (including the requirements of the UK Human Tissue Act etc.); reference to human tissue collection is sparse in E6. Biologics have also emerged as a major component in drug development and E6 might need a refresh in this regard."* This latter point is also echoed by Paul Chester and Dr Bhatt.

Another correspondent who prefers to remain anonymous suggests that *"The definition of Standard Operating Procedure may need to be amended in view of the increasing use of business process software and workflows instead of written instructions."*

## Data protection

**Barbara Hepworth-Jones HonFICR** feels that *"the area of greatest need is that ICH GCP is woefully lacking in data protection requirements. The increase in electronic data systems since ICH GCP came in to being and the potential for misuse of personally identifiable information mean that there is a real need for this to be added."*

Mark Elsley also notes the lack of provision for EDC: *"Many investigators now use electronic systems for recording source data. What should be the minimum requirements for these systems and who is responsible for them?"*

Barbara Hepworth-Jones adds *"I appreciate that in many countries there are data protection laws, inspectors and auditors can use those to supplement GCP, so in practice it can be covered. But if it is not covered in GCP, then subjects' rights and well being are not totally protected by GCP."*

## Essential documents

**Karen Roy HonFICR CSci** told me that exploring the area of essential documents is one area she's closely involved with *"This is the focus of a DIA special interest group I co-chair with Lisa Mulcahy in the US. Basically, the group exists because the Essential Documents are not enough and because auditable documents are more than the Trial Master File (TMF). Our goal is to come up with a standard list of TMF and auditable documents, standard naming, standard structure and standard metadata (for eTMF). This could be adopted by industry worldwide."*

Nigel Crossland suggests that *"areas of improvement could include making section 8, which is used by many as an effective 'checklist checklist', better match up with the details in the preceding sections. There aren't many, but there are several requirements which are not included in section 8. For example:*

1. *The requirement to have amongst the essential documents the investigator's written application to the Ethics Committee (see 4.4.1)*
2. *An IMP inventory at site showing details of quantities, batch numbers, expiry dates etc. of all IMP received (see 4.6.3)*
3. *Details of SOPs used by the sponsor in the conduct of the trial (see 5.1.1)"*

## Other suggestions

The key area that Jacqueline Briggs would like to see discussed *"is recognition of the whole research team rather than just the PI. I totally understand that the PI is ultimately responsible, but in all aspects of healthcare the roles of other health professionals have developed and been recognised. It is important we recognise this in clinical research, and the first step of changing physician consent in the Declaration of Helsinki helps pave the way. Also I would like to see more focus on the study organiser and their protocol development requirements (ie, including people with on-the-ground expertise) and ensuring the protocol is deliverable, with an understanding that GCP needs to link with other policies and procedures in the many different organisations where it is applied."*

Adam Jacobs mentions that one area he considers *"ripe for an update is the section on data management (5.5). Although it's not bad and covers the main points of data management, it's a bit light on detail, and I have sometimes found it hard to argue with a client that their data management systems were not GCP compliant when I know that they were certainly way below best professional standards. There is also nothing at all on statistical analysis of data (even a reference to ICH E9 would be better than nothing ), and I also think the section on writing CSRs could do with being beefed up."*

Nigel Crossland adds that *"there has always been a shortage of details concerning equipment and testing apparatus used at the investigational site and laboratories used by the investigator. This whole area has been recognised by BARQA who issued a guideline some time ago on the requirements that should be in place in clinical laboratories. I have always thought that Clinical QA personnel should be familiar with the "pick and mix" approach to application of GLP standards in the clinical setting and to avoid areas being mistakenly omitted from clinical site audits."*

## Reform & harmonisation of... something

Several contributors also suggested that revision of ICH GCP should be done in the context of a wider harmonisation of global guidelines and regulations, trying to 'smooth out' differences between the various other 'flavours' of GCP (eg, as defined in the EU GCP Directive etc.), the current version of the Declaration of Helsinki etc.

Paul Chester fears *"this would be much more difficult than the original production. Why? Mainly because we now have a legislative framework across Europe that was*

*not in place at the time ICH GCP was implemented. Any changes would need to take into account the variations between countries. Furthermore the legislative framework covers all trials with IMPs while ICH GCP applies only to trials destined for use in licence applications."*

This is echoed by **Susan Ollier Hon-FICR CSci,** who wonders *"why do we still not have a set of basic GCP principles, agreed internationally, that apply to all clinical research in humans? We currently have the globally accepted ICH-GCP which originally applied to commercial drug trials (and is now widely accepted for non-commercial drug trials), plus the various interpretations of GCP into national or regional laws (21CRF, EC/20/2001, Schedule Y etc.) which also largely apply to (interventional) drug trials. For device research, GCP is based upon ISO standards, not-for-profit organisations have occasionally written their own GCP standards (eg, the UK's MRC GCP) and institutions setting standards for internal research governance again make their own interpretations. GCP would be easier to train upon, understand and use if we had a single guideline which covered the basic principles common to all human research; ethics, data quality issues, subject rights, the need to obtain applicable approvals, maintenance and storage of documentation and so on."*

However, as Tina Barton points out, *"changing ICH would only have 'teeth' if those changes were incorporated into CT Directive and national legislation."*

## Conclusion

In conducting the research for this article, it has become clear to me that there are many areas in which the guidelines underpinning modern clinical research could (and, indeed, should) be updated to provide a more coherent environment for global clinical research, take account of developing science and operations/management practices, provide clear definitions and minimise the need for local interpretation.

We currently have a patchwork of guidelines, Directives, legislation and standard ways of working. In the past, it has proved politically impossible in some situations to agree key points between global regions, countries and even individual organisations. Looking at the situation pragmatically, it would seem equally impossible to move from this to a single, coherent guideline, and even more impossible to repeat the feat every few years to take account of further development in the field. As such, while we can each have our own idealised version of ICH GCP, it seems to me that the only way forward with this patchwork is to extend the patchwork further, filling in gaps and agreeing clarifications in subsidiary documents agreed by the stakeholders who need to use them. This could be done by ICH, but could equally be attempted by other groups of organisations, perhaps involving ICR.

Although this has been something of a theoretical exercise, it is still useful to consider which aspects of contemporary clinical research are poorly served by the current fragmented global network of regulation and guidelines, and how different ICH GCP would look if it were being created in 2009. Let's continue this discussion: I'm interested to hear what you think...

**Andrew Smith (andrew.smith@crfocus.org) is Editor of Clinical Research focus.** **He is grateful to the many contributors quoted above, and to any whose comments we were unable to use. This article was originally published in the September 2009 issue of Clinical Research focus (http://www.icr-global.org/crfocus/2009/20-09/) and is republished with permission.**

# Awakening a Sleeping Giant – Thoughts for EDC Vendors to Support Medical Device Trials

**Chris McEleney, David Shah and Gladys Masi, Ethicon**

After years of expectation, EDC seems to finally be fulfilling its potential across the pharmaceutical industry with a number of companies now utilising this technology.

It is estimated that half of all pharmaceutical clinical trials set-up in 2007 were using some form of EDC technology[1]. While this increased uptake seems to be evident in the pharmaceutical industry, it does not seem to be the case currently within medical device trials, best demonstrated by the fact it seems impossible to get figures of EDC use within this sector! From personal experience it seems that often medical device trials may be using some form of EDC technologies for large scale observational studies, or registries, however most regulatory studies or post-market approval studies tend to follow the traditional paper methods.

There is no question that the well known benefits of EDC are just as applicable for medical device trials as they are to our pharmaceutical trial counterparts.

- Reduces paper administration of CRF pages and queries.
- Online edit checks allow cleaner data to be captured directly at the site.
- Reduction in the number of queries
- Allows "real-time" access to data – helping maintain subject safety.
- Less storage space required at study sites that already have little room.
- Reduces sponsor resource requirements in terms of data entry and data cleaning.

A review of the literature published by all EDC vendor shows that nearly all reference cost saving references and figures are from pharmaceutical companies alone. While there are a number of similarities, medical device trials are in many ways unique from pharmaceutical trials, and these benefits and cost savings are not always a direct comparison – a distinction that is often not understood by some EDC vendors and is leading to the medical device sector lagging behind their pharmaceutical counterparts in the uptake of EDC. This is leading to something of a "sleeping giant" within the medical device trial community for an EDC vendor who fully understands the needs of the medical device trial market.

EDC vendors coming to present their software to our medical device company often quote one large benefit of their system that of reducing cycle time, and reducing time between Last Patient Visit (LPV) and database lock – However this is not as applicable for smaller scale medical device trials. There is little doubt that this is certainly an advantage in trials where you have thousands of patients, however the majority of regulatory or post market medical device trials we work on are much smaller (often less than a few hundred patients). In these cases database lock is often dependent on the LPV of only one or two patients, which can have their CRF's faxed into the sponsor, and queries turned around on the same day. This means the database can be locked very shortly after the LPV (often on the same day) and so there really is little benefit of EDC in reducing cycle time in this environment. EDC vendors can sometimes try and break into medical device companies based on this benefit, not understanding that it is not universally applicable, and in our environment they should be focusing on the other benefits EDC can bring in order to have some resonance with management.

The cost structures of many EDC software systems are also normally prohibitive for medical device companies. Most medical device companies operate on a fraction of the budget that major pharmaceutical companies can wield and so can not commit to the large cost of running a number of EDC systems.

There are also the technical issues, which arguably have a larger impact on smaller medical device companies compared to larger pharmaceutical companies. It is still the case that some EDC software still requires software downloads onto local site computers (although this is largely being phased out). Pharmaceutical companies can get around this by offering the sites their own laptop PC's, however this would be an increased cost issue for medical device companies with already limited resources and budgets. Also it appears that hospital IT groups are more technologically advanced than in the past and in some cases will not allow non standard software to be installed on their computers, where as in the past this may have been easier to manage.

Then there is the issue of training. EDC often brings the need for site staff training and ongoing training for new staff, which requires additional sponsor resources which will be seen as a negative reflection for utilising EDC and in a recent survey this was seen as the least favoured aspect of adopting EDC[2]. For paper studies the "training" on how to complete a CRF could be done in an hour or two during the site initiation visit by a CRA, however with EDC there is now often large scale, expensive, user training required before site staff can use the system. We need to keep in perspective that site staff (certainly in Western Europe and the US) are often familiar with using the internet for banking or shopping which they did not require large scale training to use and so EDC systems need to be simple enough that these staff can use the systems with

minimal training. The purpose of EDC is to make the process simpler, not more complicated and so begs the question why do we now require more training than the system used previously? The ongoing requirement of training can be a huge drain on already limited budgets. This is a universal issue that also impacts pharmaceutical trials; however has an arguably larger impact on EDC adoption within the Medical Device industry due to the restrained budgets.

EDC often also brings a number of user questions that are normally resolved though the use of helpdesks. These are an expensive option that offers services that can often be automated. Often a large number of helpdesk calls received pertain to password administration issues. Again all online banking and shopping sites have an option to retrieve or reset account details so surely this must be a reasonably simple solution for our EDC systems.

In summary it seems clear that there are a number of potential actions for EDC vendors to help. The pricing structure for smaller scale, less complex medical device trials studies needs to be addressed in order to make these more viable options for medical device trials. The technology needs to be assessed to be made as user-friendly as possible so that EDC companies can look at reducing the need or complexity of training in their systems. We must be looking to roll EDC systems out to sites with minimal training, however remain confident that they will use the software correctly. Also in order to reduce costs to make EDC systems more attractive to medical device (and other small trial companies), alternative methods to an expensive helpdesk option should also be explored, with suitable online methods to reset user accounts and passwords.

In order for EDC to really take off within the medical device sector, EDC companies must gain an understanding of these trials. It does appear that the market leaders are listening and some are making great strides towards this, however at present some vendors treat medical device trials similar to the pharmaceutical trials and while there are clear similarities; the differences are causing problems and delays in the adoption of this technology and are keeping the sleeping giant dozing.

*1 – "EDC adoption in clinical trials: A 2008 analysis" Centrewatch, February 2008*
*2 – "What monitors think of EDC – results of a survey of US monitors" Rod M. Saponjic, Scott Freedman, and Ali Sadighian*

# Time Traveller – Technology Changes My Life

NAME: Lesley Phoenix
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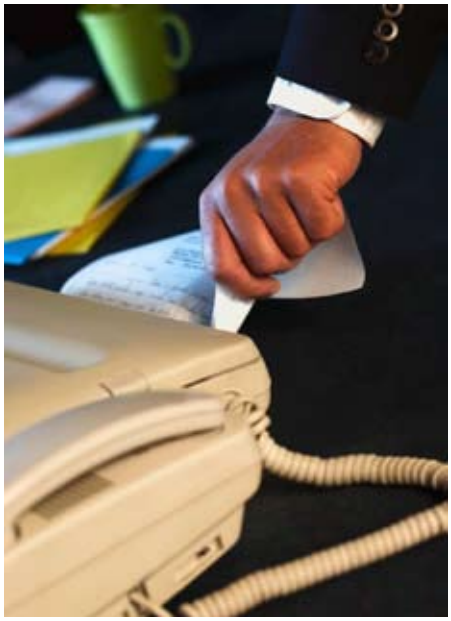
My first job in the pharmaceutical industry was as a Documentation Co-ordinator for Roche Products Ltd in the UK back in 1989. I was responsible for the archiving and retrieval of clinical study documentation and was surprised to see the vast amount of documentation that was required to be kept for clinical studies. This was in the days when we did not have PDF's or CD's and my department was just looking into storing data on microfiche.

After several years I progressed onto the role of trainee Clinical Research Assistant in late phase clinical development which involved the monitoring of clinical studies. Having gained experience in late phase development I then moved into early phase development in the Clinical Pharmacology Department as a Study Co-ordinator, which was the last position in this phase of my life at Roche. This included producing clinical study protocols, designing CRF's and setting up, monitoring and closing Clinical Pharmacology studies.



This was before CRF design software had been introduced and I had to design and produce study specific CRF forms by cutting and pasting modules from previous CRF's onto a blank A4 sheet of paper, or by physically writing what was required onto the paper itself. It's amazing to think back at the ways we used to do things in the past and how technology has changed the way we work to-day.

I left Roche in 1997 to start a new career down in Brighton which is on the South coast of England. Brighton is a lively seaside town, with a pier and Regency heritage. It has good restaurants, shops, nightlife, arts and culture. A little something for everyone. After a few years in the town I moved to a sleepy village in the Sussex South Downs where I had the best of both worlds – still close to the sea and fantastic countryside. This was also the beginning of my love for Persian cats and I rescued two Persians during my time in Sussex.

In 1999 I joined Covance as a Clinical Data Manager. This opened my eyes to the fast moving pace of the CRO world. I learned a lot in a short amount of time about Data Management, the responsibilities of a Study Data Manager and working with clients. I hadn't yet experienced the EDC world but we were starting to use a scanning system for CRF data.

After eight years of being down in Sussex my life turned full circle and I came back to Roche Products in Hertfordshire as a contract Study Data Manager in the Clinical Pharmacology Department,

*Continued from page 19*

working predominantly on Phase 1 studies. After one year I was offered a permanent position and have now progressed to the position of Team Manager for the Study Data Management group.

One of my responsibilities since being back at Roche was as an EDC advisor for our Macro system. This involved supporting and advising Study Management teams and Data Management colleagues on how to set up, conduct and lock studies using Macro.

After the decision had been made to select a new EDC system I became the co-lead of a cross functional process re-design team. Our goal was to develop streamlined, simplified processes to improve flexibility, efficiency and speed. This was a very demanding and challenging project and in 3 months we had produced 29 process maps detailing how to run Clinical Research and Exploratory Development studies using the new Medidata Rave EDC tool. My involvement in this project helped me to gain a good understanding of the new EDC tool and all the processes required for an EDC study. I also had to learn how to document our new processes in a new software system called System Architect. Since the initial development of these processes we have rolled out two versions of the published process maps and, with the further experience that has been gained, we are currently working on publishing our third version. We still have some way to go until the processes are fully optimised but with each study we are gaining a better understanding of the ways in which we can be more efficient in setting up and running our EDC studies.




I am convinced that our tools and our environment will continue to change and with it the role and tasks of a Data Manager. So my journey in the pharmaceutical industry and especially in Data Management will continue and I am sure that there will be very interesting and challenging changes ahead of me. So let's see what comes after paper – microfiche – scanning – CDs – internet and wireless...

As Charles Darwin said "It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change".

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### 2-6

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### 13

**ACDM**
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### 18

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## DECEMBER

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### 9

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## FEBRUARY 2010

### 24

**ACDM**
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### 8-10

**DIA**
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*San Antonio, Texas, USA*

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*Whittlebury Hall, Northamptonshire*

## APRIL 2010

### 19-20

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### 28-29

**CDISC**
CDISC Interchange Europe
*Royal Lancaster Hotel, London*

## JUNE 2010

### 13-17

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### 17-20

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