Summer 2012 • ISSUE 82

acdm
association for clinical data management

# DataMatters

## FORWARD PLANNING AND STRATEGIC THINKING THIS SUMMER

NEWS & VIEWS

**J.C. AMOS AWARD WITH A DIFFERENCE!**

**FIRST TIME ATTENDEE AT THE ACDM CONFERENCE**

**PROJECT MANAGEMENT ACROSS THE GLOBE**

HOT TOPIC

**HOW REAL ARE REPORTED AES AND CONMEDS**

**CDISC – IS IT WORTH IT?**

ARTICLES

**DATA MANAGEMENT VERSUS THE INTERNET**

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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.

Designed and Produced by Character Design
Tel. 01981 541154 • info@characterdesign.co.uk

# 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 2012 | 21st September 2012 | 5th November 2012 |
| Winter 2012-13 | 14th December 2012 | 4th February 2013 |
| Spring 2013 | 5th April 2013 | 6th May 2013 |
| Summer 2013 | 21st June 2013 | 5th August 2013 |

## 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



# Forward planning and strategic thinking

So, summer has arrived, and it's time for the sound of leather on willow, the grunts and groans at Wimbledon and for one of the very few times in the UK, the Olympics.

All of these activities take forward planning, strategic thinking and a lot of hard work. Something that the Board of Directors are continuing to do in order to ensure that the Association moves ahead in the direction that will benefit its members. One of the most important factors in all of the above events is participation, not only by the competitors but also for those spectating. Getting involved at any level is crucial to the success of the event, and the same is true of the ACDM. The Association needs volunteers to ensure its continued success and future development. So whatever you're up to this summer, please consider what you can offer as an active member. And let's see how successful all of our British competitors will be during the many events taking place over the summer period.

I thought I would remind you of the members of the Board of Directors:

Chairperson.....Paul Fardy (Independent)
Vice-Chairperson.....Emmet Brown (Cmed)
Treasurer.....Andrew Green (INC Research)
Secretary.....Sara Alalouff (Roche)
Director.....Gail Kniveton (i3 Pharma Resourcing)
Director.....Andrew MacGarvey (CROS NT)
Director.....Ian Pinto (Roche)
Director.....Nic Reed (Parexel International)
Director.....Vanessa Tierney (Independent)
Director.....David Walpole (GlaxoSmithKline)
Director.....Jon Wood (Syne Qua Non)

The schedule of BoD meetings for the rest of the year are as follows:

- 19th September – Cmed, Horsham
- 24th October – teleconference
- 28th November – GSK, Harlow
- 9th January 2013 – teleconference
- 13th February 2013 – INC Research
- 13th March 2013 – KSAM

I hope you have an enjoyable few months, and look forward to reporting back on activities in the next newsletter.

***Paul Fardy – ACDM Chair***

# J.C. Amos award to be presented with a difference in 2013!

**The J.C.Amos Award will be presented for the 'Best ACDM newsletter article' written in 2012. All articles published in this newsletter and future issues up to Winter 2012-13 will be entered into the competition for a chance to win an award for their article. So get writing and email your articles to editor@acdm.org.uk**

# What do you think?

**Send us your views –** If you have something to say, whether it's a comment on an article or just to let off some steam, we would like to know.
Email us at editor@acdm.org.uk

# First time attendee at the ACDM Conference

This was the first year I attended the ACDM conference, I was particularly interested in attending this year because I was excited by the 'Future Fit' theme and diverse agenda for the meeting. The presentations delivered during the two day meeting were both engaging and thought provoking. I particularly enjoyed Ayd Instone's 'Don't tell the Dinosaurs', Ayd conveyed his message by using a mixture of humour and songs and this very different style and approach thoroughly captivated, energised and inspired the audience on the morning of the second day of the meeting.

The meeting enabled me to network with likeminded individuals and to gain an insight into how current industry wide challenges are being addressed by other companies. I thoroughly enjoyed the experience, it offered participants a great opportunity to share knowledge, have fun and socialise. I would strongly encourage everyone in the industry to attend a future meeting.

***Margo Horgan – Roche Products Ltd***




# Why not join one of the ACDM Special Interest Groups?

For more information visit www.acdm.org.uk

# Want to Join the ACDM Newsletter Committee?

**Would you like to broaden your network and increase your profile throughout the Data Management community? We are looking for data managers to join us on the newsletter committee to share skills and experiences with other data managers from across the UK. As a newsletter committee member, there are quarterly meetings to attend and you will be liaising with internal & external Data Management partners to gather articles on hot topics in our field. Your creative ideas will also be welcomed for future newsletter themes.**

**If you are interested in this great opportunity, please email editor@acdm.org.uk**


Senior Forum & Postgraduate *Committee*

# Project Management across the Globe

Senior Forums are an ideal opportunity for experienced data managers to network and find out what others in the industry are doing for the topic under discussion.

The next ACDM Senior Forum will be on Wednesday October 10th at GSK, Stockley Park and will cover Project Management across the Globe.

The session will be led by Jane Rippon, Senior Manager, Clinical Data Management, Amgen, and will cover the principles of Project Management in the Data Management environment, including PRINCE2 methodology.

Case studies will be presented from both the Pharma and CRO perspective covering key areas such as:

- Managing multiple disciplines to the same milestones
- Communication between functions and across timezones
- Right People, Right Place, Right Time?
- Cost effective strategic planning
- Ensuring quality is not compromised

Attendance at Senior Forums is FREE of charge for ACDM members.

If you are interested in attending this or other forums in the future please contact Andrea Robinson-Smith (andrea@amgen.com) for further information.

## Are you interested in promoting and developing the professional status of clinical data managers worldwide?

## If so the ACDM Training Committee needs you!

For more information visit www.acdm.org.uk

HOTTOPIC

# How real are reported AEs and Conmeds

Most know from experience with ePRO (electronic Patient Reported Outcome) data that patients often have to recall information in between visits. Various data collection tools such as eDiaries tell us that ePROs cannot be trusted completely as patients don't always recall something that happened a few days or weeks ago. Also, studies show existence of discrepancies between SAEs and ConMeds recorded in ePRO and what the subjects may inform the investigator. It is commonly observed that during SDV (Source Document Verification) for data delivery efforts, an increase is usually seen in the volume of ConMeds and AE/SAEs being reported in the eCRF.

Most data managers believe that they could perhaps do more but are not sure what could be done. The collection of ConMeds is vital in forming a safety portfolio for the drug and is used to look at drug-drug interactions. Some data managers recalled when they first joined the Pharmaceutical industry many years ago, there was a push to do drug-related interactions in addition to patient safety. This was not conducted on an ad-hoc basis but data managers would look at drug-drug interaction on an ongoing basis as specified in the protocol. If there was an AE, again data managers would go back and look at any drug-related interactions. Companies were being encouraged to look at drug-related interactions at a global level.

Most data managers believe that too much information is collected for ConMeds. They argue that data managers have to spend a lot of time trying to resolve ConMed data queries when Statisticians are not really going to utilise this information but will present the data as a listing. So what is the use of collecting and cleaning this data? A potential solution to this should be to collect minimal details such as the medication name, start/ stop date (time if applicable). Whilst it is recognised that regulatory agencies may ask about the study drug type and the category of drugs specified in the protocol. Statisticians could use the actual tables & categories of these drugs and cross-reference with AEs to check for signals. The discussion group was unaware of any standard regulatory guidelines on this.

Some trials have developed a targeted approach to limiting ConMed collection by asking 'Is the patient taking any of the following: <listing a broad category of drugs> to select from. This would help to limit the effort put into cleaning that data again and potentially decrease the risk of losing safety information. From a coding perspective on collecting ambiguous ConMeds, it is important to collect as much information as possible since licensing authorities do look at trade names globally and this is recognised by the Coding group. The drug administration details can be very helpful in identifying the treatment e.g. the administration route of a medicine can help indication by using ATC codes. The ATC codes allow correct coding of ConMeds which is pivotal in data analysis.

The volume and detail of information being collected for AEs within the industry was felt to be about right. One question that did arise was 'Should there be a focussed approach to AE/SAE collection?' Sometimes the investigator may create an AE/SAE by asking the patient about specific symptoms or conditions since they look for particular events to report. The collection of AEs can also vary greatly across sites since data reporting and eCRF entry is dependent on hospital staff capturing the information and whether they classify it as an event. There are studies with evidence that show how some investigators will report an event whereas other investigators may not consider it to be an event. For example, some investigators may report 'facial redness' as an AE and others don't. So we can have excessive or very little reporting of AE/SAEs by investigators since it is really up to the investigators discretion. Maybe patients should enter events into an ePRO system themselves...? To ensure events are free from any investigator bias. This then brings up the patient confidentiality issue, the public view of the Pharmaceutical industry is not as positive as it should be. Patients do not want their details given out hence the Pharmaceutical industry needs to convince the public that data is not abused and to build trust with them.

> "MOST DATA MANAGERS BELIEVE THAT THEY COULD PERHAPS DO MORE BUT ARE NOT SURE WHAT COULD BE DONE.

Cleaning of AE and ConMed data can be a resource intensive activity that is very much dependent upon how clean you want the data. For example, there are numerous records with cold/flu as an AE but no reference to any flu-related medication e.g. Paracetamol. If we truly want to capture the fine detail, how accurate are we? Data Managers need to remain careful to avoid issuing leading queries, potentially resulting in bias reporting of the event. The sites are provided with data entry guidance via eCRF completion guidelines.

Merging different types of data together from different electronic

systems is not always straightforward e.g. combining the Conmed and AE data together. Even if other ePRO data is not required, should the merging of AE & ConMed data be made standard? Looking at the developed world, eSolutions Health Records continue to develop that natural extension into ConMeds and AEs.

In additional, there could be the scenario that we go beyond every AE and ConMed possible but create another problem in addition to resolving one.

Money is considered to be an important factor in stopping data collection. The Pharma industry should try to collect as much data as possible on late phase studies. The combination of money and process systems may prevent data from being collected and quality may not be included at all.

In conclusion, data managers agree that we do need to do more in terms of increasing interaction with sites but felt that too much caution is taken on capturing ConMed details. Interesting, no one said this is the case with AE reporting. One way is to have ePRO with subject entering the data themselves to ensure we have the most real-time information.

We are certainly not neglecting our duty as data managers. The team felt we are doing our best with the technology; we have to allow easy data collection and reporting.

***Nazma Ahmed***
***Principal Clinical Data Scientist, GSK***

HOTTOPIC

**What do you think?**

Send us your views

**If you have something to say, whether it's a comment on an article or just to let off some steam, we would like to know.**
**Email us at editor@acdm.org.uk**

HOTTOPIC

# CDISC – Is it worth it?

**Should everyone use CDISC?**

- CDISC does not change very much in DM – we have always had standards
- Sometimes we have another therapy standards / company standards / CDISC standards
- Mapping from sponsor data is not always smooth to CDISC SDTM
- Company vs CDISC – standards – usually a larger scope of sponsor standards vs. SDTM standards
- We do need CDISC standard – once people are using it – it offers benefits
- In long term offers advantages to sponsors and CROs in expediting data delivery
- Helps organisation structure resource – resources may be shared across projects easier if working to the same standards
- Some sponsors use the implementation guide as their standard and send out to vendors – the benefit is data is faster to process from sponsor's side and can use some programs again and again
- Vendors / early phase providing data to sponsors – sponsors have seen the quality of data since CDISC improving
- Same for every study

**People's experiences**

- Own implementation guide based on CDISC – covers loose area
- quality of data is better, 5 years, have seen improvement in quality
- teething issues at the start
- feeding back comments to CDISC was unclear
- For CROs working with multiple sponsors implementing CDISC standards – helps reuse of standards / work across studies
- Helps CROs understand quickly other sponsor's data when in a known standard
- Data specific to therapeutic areas is currently difficult to map and not a fixed standard for most data, so is not really standard
- Doesn't need to be familiar with all the domains

**Conclusion**

- Group agreed that CDISC offers benefits to companies implementing the standards
- DM (ACDM) perhaps need guidance / awareness on CDISC as the work such as SDTM is done by more technical groups such as database and statistical programming
- Group were interested to know how to feedback issues / comments to CDISC
- Group wanted to find out more about CDISC
- Group agreed that awareness needs to be increased

***Alan Cantrell, Parexel***

# Data Management versus the Internet

On 28th of March 2011, an old lady from Georgia stopped all Internet connections in her country as well as in Armenia for 12 hours! Apparently, the old lady cut off a bunch of optic fibers while she was looking for metals to sell.

As much as hilarious the story is, it is also very true and the poor lady was convicted to 7 years of jail for this. The event makes you think that if one can black out the internet in a whole country without the smallest intention, what could a terrorist organisation do? If this sounds a bit too conspiring, think that there might be other events and factors that can leave our world Internet-less, such as natural disasters, solar explosions, censorship in some countries, etc.

We all know that in a space of fewer than five years, the great global network of computer networks called the Internet has blossomed from an arcane tool used primarily by academics and government researchers into a worldwide mass communications medium that is rapidly becoming a backbone of business-to-business communications.

No previous telecommunications advance – not the telephone, the television set, cable television, the VCR, the facsimile machine, nor the cell phone – has penetrated public consciousness and secured widespread public adoption this quickly. The integration of the Internet and the World Wide Web into conventional social and economic processes is taking place so rapidly, in fact, that even many of those in the industry have a hard time keeping up. So, if the rise of the Internet is definitely considered a (positive?) black swan event for the technology, imagine what would happen if the Internet would disappear in an industry where it was already said that the 'golden days' are over in terms of healthy profitability.

We all know our work as Data Managers, but are we truly aware of how much we rely on internet nowadays or what will we do in case such undesirable, unwelcome and unattractive event happens?

Not that long ago, most of the clinical trials were paper based. We all thank well-designed eDC systems for their improvements in clinical research compared with paper data collection because of the elimination of duplicate data entry, edit checks to flag faults, eCRFs, eMonitoring, time and

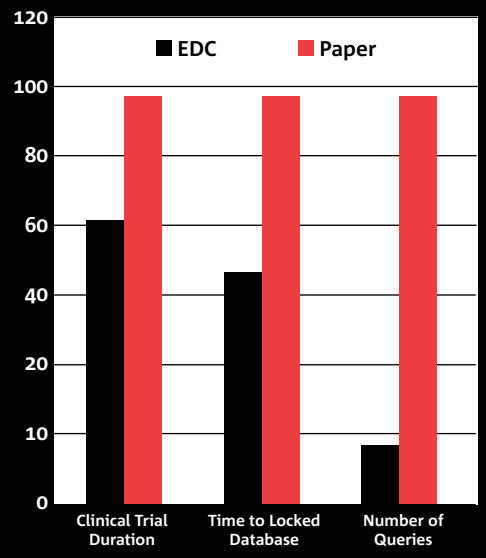



**Figure 1. Comparison of Efficiency of eDC vs Paper data collection**

costs savings, reduction of queries generated, elimination of printing, binding, shipping costs, reduction of space at trial sites, reduction of travel costs, and much more. No internet will mean none of these!

Studies showed that the eDC studies efficiency versus paper studies is translated into percentages (and figurative) as follows:

- Clinical trial duration – 30%
- Time to locked database – 43%
- Number of queries – 86%

It is very clear how important the efficiency is in terms of releasing a drug on the market. No Internet and no possibility of accessing electronic data capturing systems will definitely decrease this. Furthermore, if we look deeper at the meaning of 'efficiency' term, we can identify the issues that can cause a lack of efficiency in a paper-based world. Different studies ran on more phase III trials, show that in a confrontation eDC/paper, the ratio looks like this:

- Percentage of enrolled subjects that are invalid: 7.5%/15%
- Cost of raising and resolving a query: 10$/60$
- Number of queries/subject: 0.25-1/5-20
- Percentage of data requiring correction: 0.05 – 0.1%/1-2%
- Percentage of queries caused by missing data: 0%/48%
- Percentage of queries caused by inconsistent data: 5%/35%
- Percentage of queries caused by out-of-range data: 0.1%/8%
- Percentage of queries requesting clarification: 0%/6%
- Percentage of queries due to invalid data: 0.05%/0.1%

On the other hand, there is a lot to be said for literally being able to see the data in black and white documents that are solid and easily accessed under all circumstances (for example, in cases when the internet crashes). The reality is that many

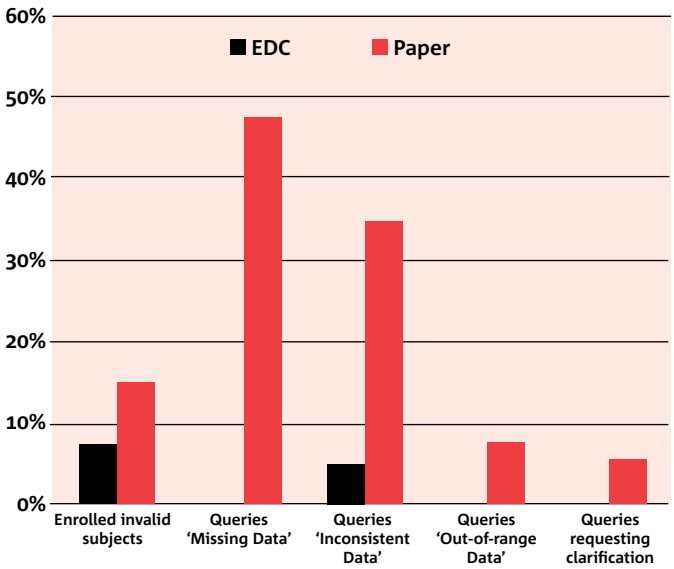
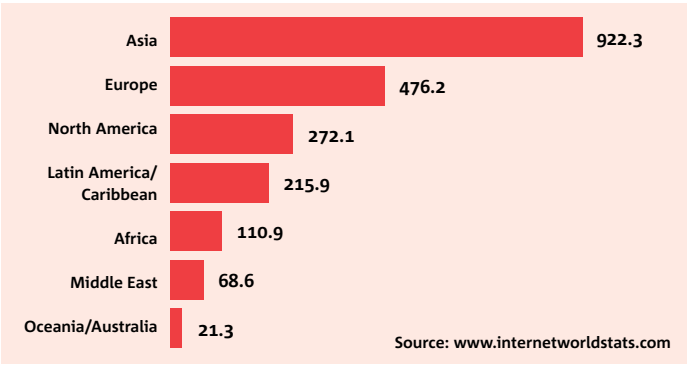



**Figure 2: Data Quality Comparison – eDC vs Paper data collection**

**Figure 3: Internet Users in the World, 2011 (Millions of users)**




worldwide sites still have barriers to eDC usage, whether through unreliable Internet connectivity or other technical obstacles. (i.e. sites in Oceania/Australia, Africa, etc). Just as a matter of curiosity and to picture the highest and lowest number of internet users, the figure below shows the spread across globe. This mapping often dictates sites selection and industry development.

As both eDC and paper trials have their pluses and minuses, we can definitely say that the eDC trials are much more efficient nowadays, in terms of time and security. Almost everything is based on using the Internet for monitoring the data, sending and receiving information and also for communication all over the world.

All in all, clearly the Internet has an important role in clinical trials and the cessation of it, has a great impact over the Data Management and, also – the most important part – on the efficacy of releasing a drug on the market.

A world without internet is hardly imagined in our work and in our day to day life now. This analysis underlines the value of internet usage and electronic data capturing as a cost and time-saving instrument in modern clinical research.

## Bibliography


- Comparison of Electronic Data Capture with Paper Data Collection – Is There Really an Advantage, Dr Thomas Bart
- J Moser, "Links Between Drug Company Profitability and Investments in Research: A Fact Sheet", Galen Institute, July, 2002
- N Banik, "Evaluation of EDC versus Paper in a Multinational Asthma Trial", Presented at the DIA European Data Management Meeting, Berlin, October 1998.
- C Spink, "Electronic Data Capture (EDC) as a means for e-clinical trial success", IBM Global Services, Pharmaceutical Clinical Development, March 2002.
- eDC, Past, Present and Future, white paper, Alex O'Toole


***Andra Chiticaru, Delia Georgescu, Octavia Morancea, Sandra Stanescu, Cmed Research SRL***

# acdm conference

NETWORKING | EDUCATION | SUPPORT 2013

## 17th-19th March

## new format!

The new 2013 ACDM Conference Committee has already begun planning for your conference in 2013. While building on the solid foundations of previous conferences, the move to a new venue brings a whole host of fresh and inventive ideas designed to improve this year's conference experience.

Replacing the 'themed' conferences of the past is a new conference brand and logo. The logo represents the commitment to integrate our new conference into the existing structure of the ACDM, utilising the skills, knowledge, experience and enthusiasm of its members. It also signifies that along with this change and improvement comes a commitment to continue to deliver on the very principles that have made the conference such a huge success in the past, Networking, Education and Support.

## new venue!

An exciting new venue has been already been selected for your new look conference. Wokefield Park is set among 250 acres of landscaped gardens and has the unique ability to offer both a state of the art conference facility tied in with an impressive, traditional mansion house setting.

Situated in Berkshire it is easily accessible from the M4 and very close to Reading for direct trains to and from London. Heathrow is just a stone's throw away for our ever welcome international delegates and speakers.

www.deverevenues.co.uk/locations/wokefield-park.html

## new agenda!

We have strengthened and improved our links into the existing ACDM structure. Drawing on the expertise of our Special Interest Groups (SIGS), 'Hot Topic' discussion forums and Training Groups, we are confident we can bring you a more current, interesting and varied agenda.

Lively panel debates, interactive key note speakers, an extensive list of exhibitors and the well-established and popular breakout sessions all reflect a clear dedication from us to increase the potential for interaction and knowledge sharing between our delegates.

Every agenda item will be linked to a specific purpose, learning or development objective to ensure our delegates leave the conference with a tangible sense of achievement. By making these objectives transparent you can link your attendance into your current training and development needs. We also trust that this will make it easier for decision makers to determine who to send to the conference. With attendance potentially adding so much value and benefit to your staff's development, you will now have a solid business case to send more delegates than in previous years.

## new people?

We are currently seeking talented individuals from within the industry to be an active part of this exciting new conference. With no theme this year the subject matter is not restricted so if you feel you can add value to our members as a speaker, discussion panellist or breakout session host, then please email your idea or brief outline of your presentation to admin@acdm.org.uk before the 01 Sept 2012. Exhibitor interest can also be sent to the above address.

**If you feel you can add value as a speaker, discussion panellist, exhibitor or breakout session host, then please send your details to our email address admin@acdm.org.uk**

# ACDM 2012-13 Course Schedule

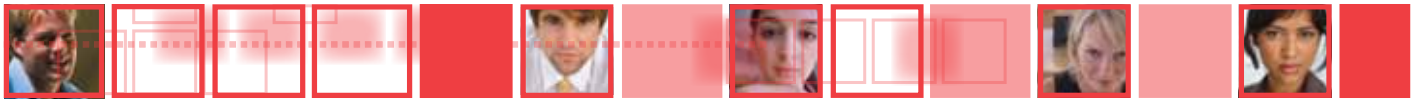
| Course | Trainer | Date | Time | Location |
|---|---|---|---|---|
| Level One Certificate in CDM Part 1 of 8 | Cliona O'Donovan | 07 September 2012 | 12:00 – 13:30 | Webinar |
| Training Course – Project Management | Adam Baumgart | 18 – 19 September 2012 | 09:30 – 16:30 | Moor Hall Conference Centre, Thames Valley |
| Level One Certificate in CDM Part 2 of 8 | Cliona O'Donovan | 05 October 2012 | 12:00 – 13:30 | Webinar |
| Data Management for Non Data Managers | Susy Laws | 12 October 2012 | 12:00 – 13:30 | Webinar |
| Level One Certificate in CDM Part 3 of 8 | Cliona O'Donovan | 09 November 2012 | 12:00 – 13:30 | Webinar |
| Recent Developments in GCP & Regulations from a Data Management Perspective | Cliona O'Donovan | 23 November 2012 | 12:00 – 13:30 | Webinar |
| Preparing for a Regulatory Inspection | David Baker | 04 December 2012 | 12:00 – 13:30 | Webinar |
| Level One Certificate in CDM Part 4 of 8 | Cliona O'Donovan | 07 December 2012 | 12:00 – 13:30 | Webinar |
| ACDM Annual Conference 2013 | Various | 18-19 March 2013 | All day | Wokefield Park, Goodboys Lane, Mortimer, Berkshire, Reading RG7 3AH |

If you would like to attend a Webinar but are not available at the scheduled date and time then we may be able to run additional sessions – please contact us at training@acdm.org.uk to discuss. More courses will be scheduled for the remainder of 2012 shortly and if you have a particular interest in a topic not listed, please do get in contact.

**ACDM events can be booked online at www.acdm.org.uk or contact:**
ACDM Administrator, 105 St Peter's Street, St Albans, Herts, AL1 3EJ
Tel: +44 (0) 1727 896080 • Fax: +44 (0) 1727 896026 • Email: admin@acdm.org.uk

**For ACDM events see: www.acdm.org.uk**





# Fresh Thinking

NAME: Vanessa Tierney
ACDM POSITION: ACDM Board of Directors
COMPANY: Freelance

Leaving Brunel University with a BSc in Applied Biochemistry in the bag and a future husband in tow, I've spent the last twenty five years in medicines development at GlaxoSmithKline. During this time I worked in a variety of clinical trial roles across the disciplines of data management, study management and site monitoring. I have worked across phases I to III, witnessed the shift from paper to electronic data capture and more process re-design than I care to recall, as well as being involved in two major mergers . I now enjoy using the breadth and depth of my experience to generate fresh thinking to optimise people, process and systems. Having just left GSK, I am currently freelance, specialising in strategic data management resourcing, off-shore start-up and capability change management.

After a previous term of office in the nineties, I have re-joined the ACDM Board of Directors to be part of driving the organisation forward to help ensure it remains relevant and supportive to its members. It would be a matter of regret if the ACDM withers on the vine and is only missed by its members (both lapsed and present) when it is gone. However, to avoid that outcome, those members need to reciprocate with their support before it is too late.

Greatest achievement? Well, it is a source of constant surprise to me that I somehow now find myself having grown up into a 'respectable pillar of the community' without having seemingly tried ...two children, two cars, two houses, one dog, one husband, PTA Chair and WI member!

My most used (and abused!) phrase – 'I won't be a minute'.

Hidden talent? Is knitting a talent? If yes, that's mine.

For fun and relaxation, regular barbeques on Chesil Beach with family and friends, rain or shine, works for me.

My Favourite music is hard to pin down... I know exactly what I like, but most of it stopped being made by the mid-eighties, although seeing Macy Gray at the Jazz Café in London last week comes close.

My hobbies have always been home crafts and gardening with some rowing and cycling thrown in but the balance of time and pleasure each brings is shifting over time!

A dinner party for six would have to be Joe Strummer, Vivienne Westwood, Richard Harris, Morrissey, Shakespeare and my husband.

If I were a musical instrument, I'd be unplayable!

## SEPTEMBER

**07**
**Level One Certificate in CDM – Part 1 of 8**
Cliona O'Donovan,
12:00 – 13:30
*Webinar*

**18-19**
**Training Course – Project Management**
Adam Baumgart, 09:30 – 16:30
*Moor Hall Conference Centre, Thames Valley*

**19**
**PSI**
Therapeutic Area Meeting: Oncology
*Glazier's Hall, 9 Montague Close, London Bridge, London SE1 9DD*

**22-25**
**SCDM**
2012 Annual Conference
*J.W. Marriott Los Angeles L.A. LIVE, 900 West Olympic Boulevard, Los Angeles, CA 90015, Los Angeles, CA, USA*

## OCTOBER

**01-03**
**TOPRA**
TOPRA Symposium 2012
*Venue tbc, Dublin, Ireland*

**05**
**Level One Certificate in CDM – Part 2 of 8**
Cliona O'Donovan, 12:00 – 13:30
*Webinar*

**12**
**Data Management for Non Data Managers**
Susy Laws, 12:00 – 13:30
*Webinar*

## OCTOBER

**21-26**
**CDISC**
CDISC Interchange North America 2012
*Renaissance Harborplace Hotel, 202 Pratt Street, Baltimore, MD 21202*

## NOVEMBER

**07-09**
**BARQA**
2012 Annual Conference
*The Midland Hotel, Manchester, UK*

**09**
**Level One Certificate in CDM – Part 3 of 8**
Cliona O'Donovan,
12:00 – 13:30
*Webinar*

**23**
**Recent Developments in GCP & Regulations from a Data Management Perspective**
Cliona O'Donovan, 12:00 – 13:30
*Webinar*

**30 Oct – 02 Nov**
**ISoP**
12th ISoP Annual Meeting
*JW Marriott Resort & Spa, Cancun, Mexico*

## DECEMBER

**07**
**Level One Certificate in CDM – Part 4 of 8**
Cliona O'Donovan, 12:00 – 13:30
*Webinar*

## JUNE 2013

**23 – 27**
**DIA**
49th Annual Meeting
*Boston, MA, USA*

## ONLINE COURSES

**16 August**
**SCDM**
*Clinical Research Trials for Infectious Diseases*

**18 October**
SCDM
*Managing a Blinded Study for the CDM*

**01 – 28 October**
**SCDM**
*Managing Clinical Trials Utilizing Electronic Data Capture (EDC)*

**05 November – 8 December**
**SCDM**
*Database Lock and Randomisation*

**15 November**
**SCDM**
*Preparing for and Surviving an Audit*

**= ACDM Training Course Schedule**
If you would like to attend a Webinar but are not available at the scheduled date and time then we may be able to run additional sessions – please contact us at training@acdm.org.uk to discuss. More courses will be scheduled for the remainder of 2012 shortly and if you have a particular interest in a topic not listed, please do get in contact. ACDM events can be booked online at www.acdm.org.uk

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**For ACDM events contact:**
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St Albans, Herts AL1 3EJ
Tel: +44 (0) 1727 896080
Fax: +44 (0) 1727 896026
Email: admin@acdm.org.uk

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

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

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| | | |
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