Winter 2008/2009 • ISSUE 68

acdm
association for clinical data management

# DataMatters

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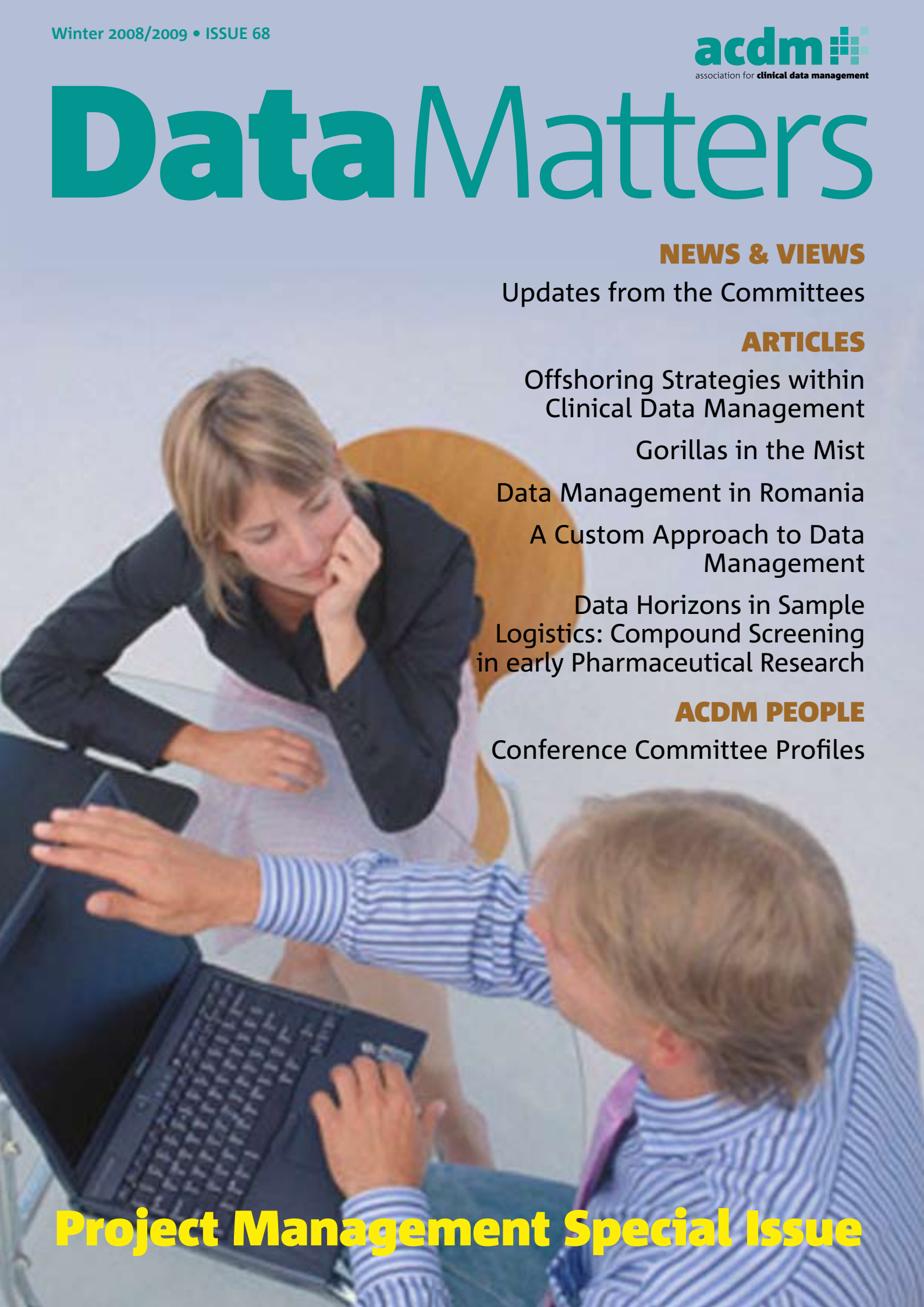

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**Guidelines for Contributors**

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.



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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 | Delivery of mailing |
|---|---|---|
| Spring 2009 | 20 March | 4 May |
| Summer 2009 | 12 June | 3 August |

# ACDM MONTHLY MAILINGS

A mailshot is sent to every ACDM member in the first week of each month. If you wish to have any material included in the monthly mailing you must:

- confirm by fax or letter to the ACDM Office by 10th of the month
- supply 1200 copies to the ACDM Office by the deadline below

Deadlines for recruitment adverts and master copies of ACDM notices, flyers etc:

| Month | Deadline for Masters/Flyers | Delivery of mailing |
|---|---|---|
| **February** | 15 January | 2 February* |
| **March** | 16 February | 2 March |
| **April** | 16 March | 1 April |
| **May** | 15 April | 4 May* |
| **August** | 15 July | 3 August |

* Distributed with Newsletter.

See Advertising Rates below for different pricing options.

ACDM notices only (eg ACDM meetings, SIGs, Committee or Sub-Committee correspondence, AGM information, etc): A master copy should be sent to the ACDM Office, for photocopying and distribution. This must arrive by the deadline above.

**ACDM E-shots**

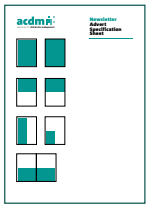
ACDM notices can be included in our twice monthly e-shots sent on the 1st and 15th of each month (only on the 15th of the month where a quarterly mailing is sent out). ACDM notices should be emailed to the office 6 working days in advance.

# ACDM ADVERTISING RATES

Effective from 1st November 2008

| | | |
|---|---|---|
| **Newsletter** | Sponsorship of Newsletter *(includes double centre page colour advertisement and company name and logo on inside cover)* | £2500 |
| | Sponsorship of Newsletter *(includes full page colour advertisement and company name and logo on inside cover)* | £1500 |
| | Full Page Colour* | £1000 |
| | Half Page Colour* | £800 |
| | Quarter Page Colour* | £450 |
| **Flyers** (distribution only) | A4 Flyer* | £700 |
| | A5 Flyer* | £550 |
| **Web advertising** | One month* | £350 |
| | Renewal per month (no changes) | £250 |

* 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**



# Supporting events and activities

**I hope the credit crunch has not bitten too hard and everyone enjoyed their Christmas break, got plenty of presents, had enough turkey, and sprouts to eat and no family members were murdered.....**

I would like to start my letter with a mention of the ACDM's aims and objectives. As you may be aware, the Board of Directors, together with all of the committees and Special Interest Group (SIG) chairs, met in the summer and set a variety of goals for each committee based around a set of core visions for the organisation as a whole. These visions are:

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

Around these visions the Board of Directors and Committees have set a number of objectives. This visions and objectives document can be found on the ACDM website.

The main visible progress that can be seen with these objectives is the rebranding of the ACDM with the new logo, the redesigned website and the revamped newsletter. I trust you agree that all of these are an improvement and enhance our efforts with the promotion of the ACDM.

Other objectives are being pursued through the Training Committee who will launch a new training strategy and programme in the new year looking at some more bespoke standalone courses in addition to College Week. The Training Committee is looking at a Continuous Professional Development (CPD) approach to training alongside a role-based training programme. They are also working with the Institute of Clinical Research (ICR) to collaborate with the running and promotion of some courses.

This work with outside organisations such as the ICR is continued by our International Collaboration Committee chaired by Eva Hammarström-Wickens (Orion Pharmaceuticals) who regularly meet with other data management organisations throughout the world and also by the Board of Directors who have been meeting with the Society for Clinical Data Management (SCDM) in the USA and looking at ways of working more closely together.

If you would like to get involved with any of these objectives then please contact the ACDM office.

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# Are You Confused? Feel Isolated? Is EDC Getting You Down?

Electronic Data
*Special Interest Group*

**Well fear not good Data Manager, help is at hand... THE EDC SIG**

As part of the EDC SIG we strive to share knowledge in order to, hopefully, standardise the expectations and implementation of EDC.

If you have a lust for life, an insatiable thirst for knowledge then the EDC SIG might be the place for you. For as little as your ACDM membership fee you can join the group where a good time is had by all. Don't just take our word for it! Check out the recent meeting minutes from our face to face meeting at the Waldorf Hilton (Thanks again Takeda!!) and see for yourself. New members always welcome.

We are a reasonably sized SIG, with over 90 members from all walks of life including large Pharma, small Pharma, biotech companies, CROs and technology vendors. We have organised ourselves into sub-teams consisting of Project Management, Training and Technology. Under our fearless leader, Chairman Richard Young (who incidentally is up for re-election soon so if you would like to run against him please contact us), we have developed some objectives to ensure that all our targets and meetings actually produce some outputs.

Even if you don't decide to join in (oh, how we wish you would), you don't have to miss out. We intend to utilise the ACDM website to its full potential to ensure that the materials produced from our SIG are made public. Also, at the 2009 ACDM Annual Conference we will be hosting a break out session, be sure to stop by.

Please remember, it doesn't matter if you're Sponsor, CRO or Vendor – all kinds are catered for at the EDC SIG!

***Kerry McCarthy, Daiichi Sankyo Development Ltd and ACDM EDC SIG Communications Subgroup***

# The CR-CSV Working Party

CR-CSV
*Working Party*

The Association for Clinical Data Management (ACDM) and Statisticians in the Pharmaceutical Industry (PSI) were approached by the Association of the British Pharmaceutical Industry (ABPI) to investigate the need for an industry-wide guideline on the subject of Computerised System Validation (CSV).

In August 1995, a joint working party was formed with the remit to create this guideline and nine authors with Pharmaceutical Data Management, Statistical and Quality Assurance/ Regulatory backgrounds were brought together to form the first ACDM/PSI Working Party with the objective of producing and publishing the first edition of the guideline.

Following the success of the first edition of the guideline, and due to many changes in the compliance and regulatory landscape, a second edition was planned. The Working Party expanded to include fifteen authors to meet these new challenges and now included input from members of the British Association of Quality Assurance (BARQA) and the Institute of Clinical Research (ICR).

As well as input from members of these highly respected organisations, advice and input was also sought from CSV practitioners in industry so that 'front-line' experience and need also shaped the construction of the guideline.

The activities of the Working Party were, and are, not solely restricted to the guidance though. Other activities of the membership currently include:

- Special interest forums.
- These include debates and networking opportunities for CSV practitioners, consultants and regulatory specialists as well as many other stakeholders, e.g. Competent Authorities and Health Authorities.
- Development and presentation of training materials in support of guideline contents.

The Working Party now needs the assistance of new authors, new ideas and approaches to meet the challenges faced by sponsors and their niche and academic partners alike to carry out effective, efficient, economical and ethical clinical research.

In preparation for our next publication: CSV Lite, our next forum (25th March 2009 – see advertisement/flier/website) aims to discuss practical, quality solutions to establishing evidence of robust business processes and is open to representatives of corporate as well as niche and academic organisations.

This Forum will focus on:

- The attendance of representatives from across the pharmaceutical industry – corporate pharma, CROs, niche support organisations and academia.
- The ability to shape the development of a possible new edition of the guideline and / or development of new guidance for specialist suppliers.

We anticipate and look forward to meeting you all in the near future.

***David Smith and Jane Tucker***
***Co-Chairs of the CR-CSV Working Party***

# Senior Clinical Data Managers' Forum

Senior Forum *Committee*

The ACDM Senior Clinical Data Managers' Forum is sponsored by the ACDM Senior Forum and Postgraduate Qualification Committee. Under the guidance of this Committee, meetings are set up on a regular basis (usually 3-4 per year) to share experiences and discuss specific items of interest. Senior Forum members are encouraged to suggest and present on topics that they feel would be beneficial for discussion with other experienced colleagues in Clinical Data Management from other companies. The Senior Forum is an excellent way to exchange ideas and keep up to date with issues in the constantly changing world of Clinical Data Management.

Meetings are usually held in London from midday, continuing into the evening with discussion over dinner.

A wide variety of past topics have included:

- Motivating a Composite Workforce.
- Cultural Awareness in International Teams.
- Developing and Assessing Personal Skills in Data Managers.
- Cost Effective Data Management Strategies for the Future.
- Data Quality – What's it Worth?
- The Flexible Workforce.
- CDM Resource Strategies.
- Role of the Data Manager as a Project Manager.
- Offshoring Strategies within Clinical Data Management.

Information about Senior Forum events is usually sent only to members of the Senior Forum. Application for membership of the Senior Forum is open to **all** ACDM members who have been working in Clinical Data Management for a minimum of 5 years and have either line or project management experience. If you would like to join the mailing list for this group, please contact admin@acdm.org.uk.

The next Senior Forum will be held on **Wednesday, 25th February 2009** at The Royal Statistical Society in London, with the topic of **Assessing Risks and Contingency Planning**. Jane Tucker, Validation Consultant – Lifecycle Quality Management Team at GSK will be the keynote speaker for this event. Jane has extensive experience in risks assessment and helping others to plan contingencies in case such risks occur. She plans to cover such topics as:

- What is risk?
- What sorts of risk are involved?
- What does doing a Risks Assessment involve?
- Are there right and wrong times to do risks assessments?
- What is the regulatory impact of risks assessments?
- What are the benefits of doing a risks assessment?
- How does Risks Assessment link into Contingency Planning?

Jane's fellow presenters will provide case studies on two real life cases of risks assessment, planning contingencies and what actually happened. One case will feature the use of electronic diaries, whilst the other will focus on a staff resource scenario. Attendance at Senior Forums is a very cost effective way of ensuring your continuing professional development – in fact to attend this next Forum we are pleased to offer a very attractive registration fee of two places at the Forum for a total fee of only £200! If you would like to come along to this next Forum, please contact **admin@acdm.org.uk**.

Meanwhile, if you are still not sure if the Senior Forum is for you, please read the article in this Newsletter about our last Senior Forum and also have a look at some of the quotes provided by attendees!

***The ACDM Senior Forum and Postgraduate Qualification Committee***

*Continued from page 3*

The annual ACDM Conference is rapidly approaching. The venue is again Whittlebury Hall with a conference theme this year of "Mapping the Future". Tom O'Leary and the Conference Committee have put together this innovative programme and I would urge you to go to the website to view it and hopefully book your place. The gala evening event will attract many Daniel Craigs, Sean Connerys and Pussy Galores with its "007" theme.

The coming year of 2009 will prove to be a hard one for a lot of companies and people alike and the ACDM will also not be immune. Being a voluntary organisation, it is times like this more than ever that we need the members and their companies to continue to support the events and activities of the ACDM. Without this support the activities of the ACDM will not be of the level we all want so please make the effort.

***David Baker – ACDM Chair***
***Email: david.baker@chiltern.com***

acdm association for clinical data management

**Mapping the future**

**ACDM Annual Conference**
8-10 March 2009
Whittlebury Hall Hotel,
Northamptonshire

# Offshoring Strategies within Clinical Data Management

ACDM Senior Forum 8th October 2008

Although I have been a member of the ACDM for many years this was the first time I had participated at a Senior Clinical Data Managers Forum. I found it to be an extremely useful, topical and interesting afternoon. There was an informal, friendly atmosphere which encouraged interactive and open discussion. The forum started with a buffet lunch, followed by the afternoon forum and then dinner. There were approximately 15 participants from a variety of companies and it was held at the Novartis Foundation in London, where there is also the facility for participants from out of the area to stay overnight.

The keynote speaker at the forum was Vanessa Tierney, Global Head ClinPharm Data Sciences (CPDS), Development Operations, GSK. Vanessa presented the business case for having an offshoring strategy. This was then followed by presentations and break-out sessions lead by Harshad Sodha (Omnicare) and Lisa Goodwin (AstraZeneca) of how such a strategy is being implemented in both CRO and Pharma companies.

Lisa Goodwin provided us with an insightful overview of AstraZeneca's approach to the Data Management transition. This was followed by the first break out session where we were divided into 3 groups to consider and feedback on the following:

- *What would you see as being the key challenges / risks to successful implementation for a project of this scale and how would you manage these?*
- *How would you structure the Data Management transition project: What skills and sub-teams would be required to manage this change?*
- *How would you plan the implementation of the new Data Management model: what would be your approach to the transition of ongoing studies versus new studies and what timescales would you apply?*

Harshad Sodha introduced the second break out session where we were provided with a case study of a mid-size CRO considering offshoring Clinical Data Management (CDM) services. In our groups we discussed suitable implementation strategies for such a company and presented back our recommended approaches. The following implementation considerations were discussed: Geography, Structure, Operating Model, Recruitment, Training, Quality and Issue Management. Harshad then presented the Omnicare Experience and how they approached and implemented such a project.

It was interesting to see how the business drivers, strategy and considerations for offshoring differ between CRO and Pharma. There were certainly a lot of discussion and it was good to discuss and share ideas on addressing the common challenges that we all face in our current DM environment. The senior forum was a good opportunity to meet other senior ACDM members and also the ACDM committee members in person. For me, it was definitely a rewarding experience which I would recommend to other senior members who have not yet attended a senior forum.

***Joanne Archer, Alliance Manager,***
***TCS – Data Management,***
***F. Hoffmann-La Roche Ltd***

## Quotes from the October 2008 Senior Forum:

***"Thought-provoking discussions. Good opportunities to network"***

***"We could do with some wine at this end of the table!"***

***"I've just realised what I've been missing"***

***"Great way of informally sharing knowledge and networking"***

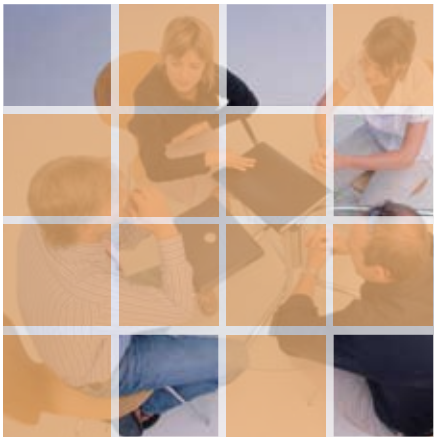
***"Banana Foster? Well at least it isn't lavender ice cream!"***

***"It was a great opportunity to listen to like-minded folk and share ideas, strategies and discuss the changing world of data management. I will certainly come again if I survive the night at the Novartis Foundation and if the committee let me in again!"***

***"Great opportunity to discuss 'here and now' topics that affect Data Management globally"***

***"Thank you – it's been a great day!"***

Senior Forum
*Committee*



# Senior Clinical Data Managers Forum

## Assessing Risks and Contingency Planning

**Royal Statistical Society • London**
**Wednesday 25th February, 2009 • 13.00 – 20.00**

The actual forum will be from 13.30 – 18.00
Registration will from 13.00
Dinner will be served from 18.00 – 20.00

**Jane Tucker – Validation Consultant – Lifecycle Quality Management Team, GSK**
Jane will be the keynote speaker at this forum and will present the business case for having a risks assessment strategy. This will be followed by discussions of how such a strategy is being implemented in both CRO and Pharma companies.

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# Gorillas in the Mist

**The morning of September 27th was shrouded in fog, the unmistakable silhouette of Tower Bridge just visible over the Thames. As the sun rose and the mist dispersed the sound of strange creatures could be heard emerging from the streets and alleyways of the ancient City of London. Then, as if transported from the mountains of Africa, massed ranks of hundreds of gorillas appear, running past the Tower of London and on for seven kilometres as the Great Gorilla Run gets underway!**


**Hertford, July 2008**

I'm not really sure how I got involved in this but I do know that I've never fancied running much. I'm fairly active and play football a couple of times a week but running has always seemed a bit, well, dull. Maybe it was the opportunity to wear a gorilla suit, maybe our glorious hot summer affected my thinking, but one way or another I found myself signed up for the Great Gorilla Run.

Training began in earnest. I persuaded a friend to run with me but he was already in shape ready for an upcoming half marathon, whereas I had a lot of work to do as it's one thing running seven kilometres but quite another to do it in a furry, heavy gorilla suit. However, training went well and I found that I actually quite enjoyed it – running along the canal paths around Hertford in the sun was rather pleasant. I even made a training montage video which is still on YouTube! (I'm the one in white) **www.youtube.com/watch?v=hrS_rXhdZKc**. As the sponsorship started to come in, so the pressure mounted but gradually I pushed myself further and faster until as race day approached I felt ready. Just one doubt remained – I knew I could make the distance in shorts and t-shirt, but could we run dressed as gorillas?

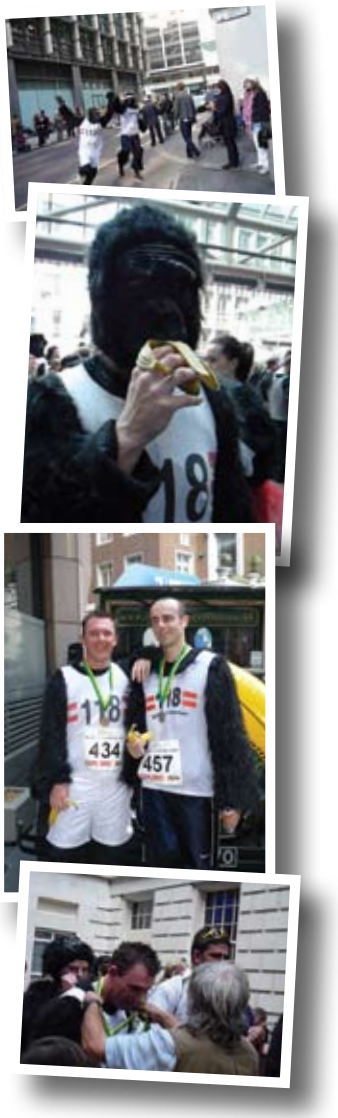
**London, September 27th 2008**

By the time we arrived at the registration desks the sun had broken through the early morning fog and a unique sight unfolded – hundreds of people, all in gorilla costumes and every single one with fancy dress over the top. The atmosphere was incredible and everyone was monkeying around, some dancing, some climbing the railings, and the rest just grunting and hooting at pretty much anything. Having arrived in human form we changed into our gorilla costumes and revealed the highly imaginative and difficult to pull off "118 118" fancy dress that we had spent the last couple of months perfecting. Then soon enough it was time to line up for the start – we took our places somewhere between the Ghostbuster gorillas and the gorillas in Borat mankinis. With everyone in place celebrity starter Bill Oddie said a few words of encouragement and we were off!

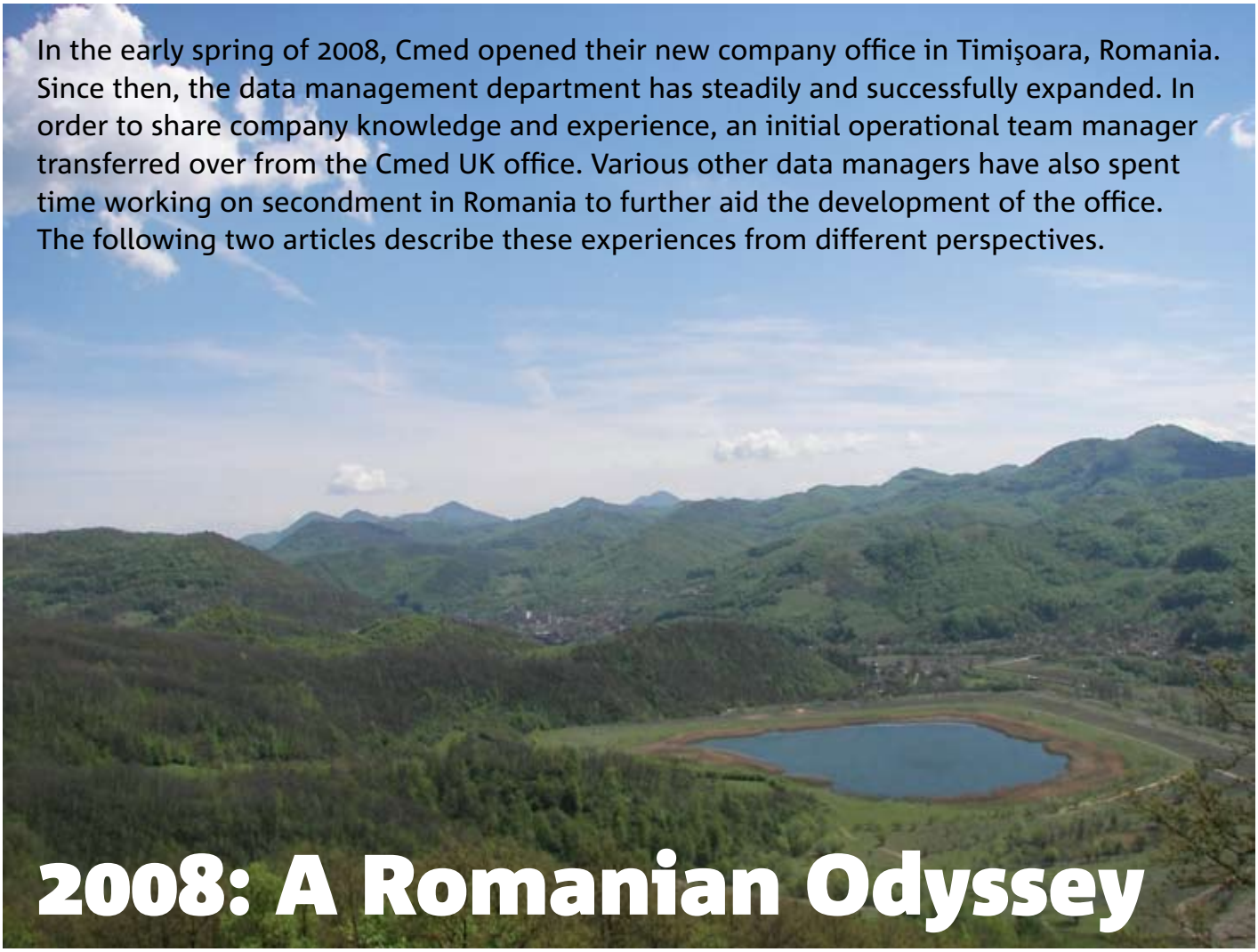
As it turns out running in a full gorilla costume is a bit tricky – it is impossible to see anything which isn't directly infront of you so minor collisions are inevitable until the crowd thins out. Then we realised that unlike the marathon or other running events you may have seen there was no roped off course and we found ourselves running around pedestrians and at one point waiting for the green man so we could cross the road! As we got to Tower Bridge the field started to thin out and we got into our stride, waving at onlookers as we jogged along the South bank. The route criss-crossed the Thames four times and the final crossing took us over Blackfriars Bridge so once over that we knew we were on the home stretch. Despite struggling a bit toward the end we crossed the finish line a respectable 146th and 147th out of 720, then proudly (and it must be said rather sweatily) collected our medals from Bill.

All in all this was a great experience and I raised over £550 for the Gorilla Organisation (massive thanks to everyone who sponsored me). Plus it seems that this is merely the beginning for me and running – last week I did my first 10k (in sleet and mud around Hatfield House) and there is even talk of doing a triathlon next year. The icing on the cake is the news that came through after the race that I am now a world record holder! Bizarrely there is a world record for "number of people dressed as gorillas" and this year the 720 of us broke the previous world record...so far I have not received anything from the good people at Guinness though...

***Phil Moggridge***
***GSK***




**You can find out more about the Great Gorilla Run at www.greatgorillas.org**



In the early spring of 2008, Cmed opened their new company office in Timişoara, Romania. Since then, the data management department has steadily and successfully expanded. In order to share company knowledge and experience, an initial operational team manager transferred over from the Cmed UK office. Various other data managers have also spent time working on secondment in Romania to further aid the development of the office. The following two articles describe these experiences from different perspectives.

# 2008: A Romanian Odyssey

The yellow Dacia taxi weaved its way through the dark streets of Timişoara. Sodium and neon offered fleeting glimpses of the new world I was about to inhabit for the next 12 months. On the surface, it seemed similar to other cities I had visited; high-rise apartment buildings, shops, banks, bars and restaurants. Yet, I could tell this was not quite the same as anywhere else I had ever been to. This was my first proper visit to eastern Europe. This was my first visit to Romania.

The Cmed office is located in a large, newly built 5-star office block in the city centre. The building has proved to be a tremendous success for the developers, testified to by an additional building of the same design currently in the latter stages of construction next door. I had already met my new colleagues during their several weeks of training undertaken in the Cmed UK office. Having found all of them to be extremely friendly, professional and motivated, I was very much looking forward to working with them. With a mixture of emotions, I walked into the office to begin the first operational day in March 2008. The Facilities team had done a fantastic job in fitting out the office. There were


inevitable IT issues that arose, but even within this first working day we started processing live trial data, and interacting with our colleagues in the other offices. A new era had begun.

The initial few weeks were very much based around finding our respective feet. It was as much a new experience for me working with a Romanian team as it was for them to be working with a UK manager. We soon learned the best way to work together, and discovered many interesting cultural differences. Ever since I began here, all the people I have met and interacted with have been amongst the friendliest and most hospitable I have ever encountered. More than anything, this has made my time here rewarding and indeed the whole venture the success it has been.

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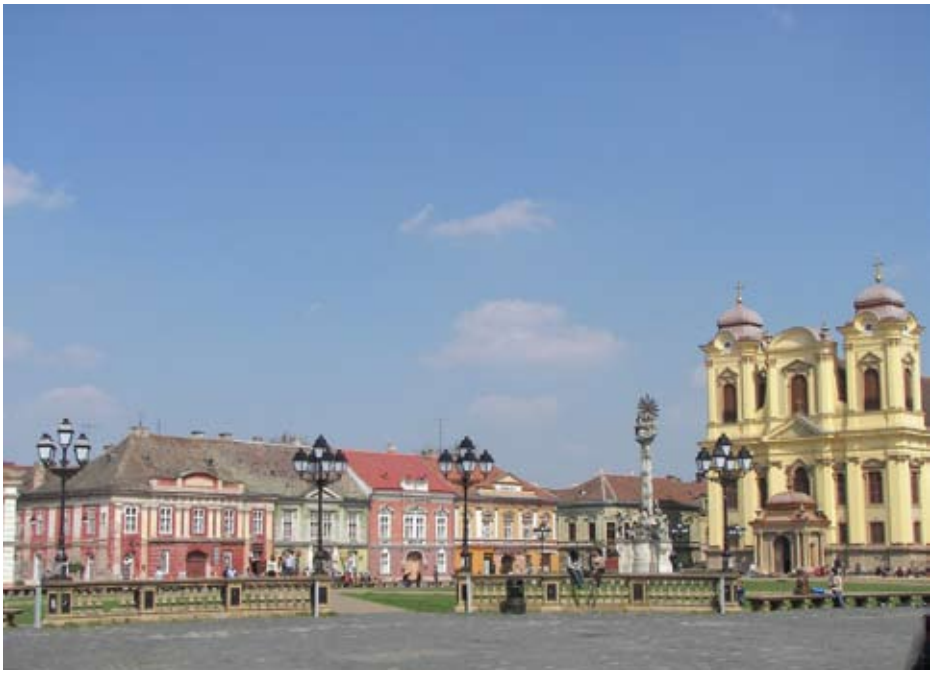


I also began to find my way around the city itself, sensibly deciding to purchase a map rather than navigate by self-discovery! Timişoara is a city of many contrasts. The centre is adorned with gothic architecture, grand squares and cathedrals. Indeed, the city is nicknamed "Little Vienna", with good reason. Most of the buildings are lovingly maintained in their original condition, but some are a little more neglected. Many visitors feel a distinctive Italian influence in the culture; the two countries are very much linked historically, the name Romania being an obvious reference point. There are traditional markets, stalls and shops, selling a wealth of local produce. Large projection screen television sets in the main squares display a variety of local information and culture. These were best employed during the recent European Football Championships, which proved to me beyond all doubt that this is the national sport and passion of Romania!

Further out of the city centre, there is extensive development work ongoing, new office and residential buildings are springing up everywhere. These juxtapose with the imposing original grey concrete structures, to create a truly unique skyline. A massive new shopping mall, gymnasium and cinema complex attracts

visitors from far and wide. The roads are filled with trams, buses, and cars ranging from 30+ years old to brand new exotic and executive models. Native Romanians make up the majority of the population demographic, but there is also a considerable population of inhabitants from various other parts of Europe.

**"Ever since I began here, all the people I have met and interacted with have been amongst the friendliest and most hospitable I have ever encountered. More than anything, this has made my time here rewarding and indeed the whole venture the success it has been"**

There is also evidence of difficult times gone by. The Romanian revolution occurred in 1989 when infamous communist leader Nicolae Ceauşescu was overthrown. The revolution started in the centre of Timişoara itself. The powerful sense of pride amongst the residents is still very much evident to this day. The local food, culture and nightlife are plentiful and varied. I enrolled in a course of Romanian language lessons, and started to truly feel part of my surroundings.

Summertime arrived, and showed just how truly beautiful a city Timişoara is. The warm climate was an added bonus of being here, but admittedly a very welcome one! Visits to the surrounding countryside showed a very different view to city life; jagged mountains, sheer gorges, winding rivers, and villages where the horse-drawn cart is still the primary method of transport. I marvelled at just what a diverse country I was living in.

The data management team were rapidly developing an excellent reputation within the company, and so further expansion was undertaken. We were inundated with top quality candidate CVs, and had some difficult decisions to make regarding who exactly to recruit. The next influx of staff changed the dynamic of the office, in a wholly positive way. The pieces all started to fall into place, personalities became established, and a true sense of team spirit emerged.

Additional opportunities were made available for some of my UK colleagues to spend short term secondments in Romania. This sharing of experience helped to strengthen the team even further. So impressive was the success, Cmed senior management decided to subsequently expand even more quickly than anticipated. Further rounds of interviewing yielded an even greater variety of talent.

The next phase of expansion proved to be the most challenging. A rapid increase in head count had meant a corresponding rapid growth in trial work to be performed. Learning, training and mentoring became the most important

concepts for everyone. My own knowledge and experience proved to be invaluable, although it was proving to be far and away the biggest challenge of my career to date. The emphasis from the very beginning in the Romania office has been on demonstrating and maintaining the highest level of quality. This concept became embedded with the team psyche, and their reputation within the company prospered. Of course, things did not always go according to plan. If mistakes were made, they were recognized, discussed and resolved. Knowledge was shared and the entire team benefitted as a result.

As of December 2008, the data management team comprised 17 people including myself, with further expansion planned for the start of 2009. Discussions are already in progress for additional departments to be formed, such as Biostatistics, Database Configuration and Medical Coding.

Romanians are a passionate, proud and hard-working people. Joining the European Union on 1st January 2007 was a major landmark for the country. Development and progress is occurring rapidly in many areas. Cmed are just one of a number of recent "western" companies to establish a presence here. I feel an immense sense of pride to have been a part of the new office from the very beginning. With such a pride reflected in all the people I work with, Cmed can only become ever more successful as the office continues to expand and develop. It is an experience that has changed my life, and one I would recommend to anyone given a similar opportunity.

***Alastair Simpson,***
***Data Management Team Manager for Cmed SRL, Timişoara, Romania.***

Timişoara is a city that is steeped in a rich and diverse history. You can clearly see, when walking around this striking city, the influences of its past etched on its buildings. Examples of this can be found in Piata Victoriei (Victory Square) – you can notice visible remnants of the difficult times that occurred during the revolution. Piata Victoriei was one of the core places in Timişoara where the revolution began in 1989.

A short term secondment to Timişoara allows you to experience the culture, history, beauty and the hospitality of the people. Those whom I met during my two months in Timişoara were warm and friendly; the majority work for Cmed SRL. They are a hard working, intelligent and conscientious people who made me feel very welcome. I was always invited to join them for lunch and socialise outside of work so they could show me around Timişoara.

Timişoara is a developing city which blends the traditional and the modern. It has excellent business facilities whilst still maintaining its charm and traditions. Cmed SRL is based in the City Business Centre in Timişoara. The building is well equipped and offers highly professional amenities with excellent working conditions. There is a stylish restaurant on the very top level of the building which provides a quick and accessible break for lunch and serves very delectable food.

Having spent two months in Timişoara I really see potential in the city to become of great interest for both businesses and tourists alike. I feel that in future it will become a well publicised and thriving destination.

I would highly recommend anyone to visit Timişoara and experience the culture and lifestyle for themselves. I had a fantastic time and gained valuable experience. I am very proud of what Cmed SRL has achieved in a short period of time. It is a testament to the hard working staff who seem to always strive for the best achievements possible whilst maintaining a warm and friendly environment. This way of being embodies the feelings and beliefs of Cmed as a whole and I am excited to be a part of it.

***Gemma Millar, Cmed Clinical Data Manager based in Timişoara during September and October 2008.***

# Choosing the Best Strategy: A Custom Approach to Data Management

**Data management is a very simple and straightforward exercise. Regardless of the specifications of any individual study, there is a "one size fits all" approach that can always be implemented that will allow for effective and timely data cleaning. Right? ...Wrong.**

While it has long been acknowledged in the pharmaceutical industry that there are always specific nuances relating to regulatory affairs strategy, biostatistical techniques, or clinical research methodology, it remains a common misconception for many in the industry that data management is very simple. The reality is somewhat different. There are many different factors and parameters that can affect the way that the data management aspects of a trial are to be handled. In line with colleagues in other departments, data management teams must also look at the unique characteristics of each study and treat each one differently. No two studies will ever be identical in how they are handled.

The way that these factors are managed and customized on an individual study basis can have significant influence on the ease and effectiveness of the processes, the total cost of data management activities and, eventually, the timeliness of clean data being made available for analysis. By the same token, the selection of the wrong data collection tool, the wrong data management system, or the wrong country in which to complete the work can also adversely affect those same items.

It is vital that the data management team (typically represented by a "lead" data manager) be included in all activities related to starting a study, from the initial costing activities to the internal and sponsor kick off meetings. It is only by their inclusion and involvement in the discussions within the entire study team that the optimal, customized approach can be agreed upon. Planning for database lock needs to start on the day that the trial is awarded.

A multi-disciplined approach is always required to best suit the needs of the study. Experienced staff will recognize that each trial has individual needs, requirements, and challenges; no two trials are the same, and "one size fits all" is not an approach that maximizes either efficiency or cost.

## Study Definition

### Phase and Therapeutic Area

A non-registrational global late phase registry study with many sites and subjects will require a different strategy from a single-site Phase II oncology trial whose data will be submitted to the appropriate regulatory authorities. The use of subjects as opposed to healthy volunteers can also affect:

- the number of blood draws
- the number of (serious) adverse events
- the number of medical terms to be coded, and so on.

### Monitoring and Recruitment Strategies

Different strategies affect the query rate and by consequence the workload of the data management team, the clinical research associates (CRAs), and the investigative sites:

- Not all studies are monitored—if the study is monitored, the source document verification (SDV) may or may not be 100%; non-monitored studies will likely generate more queries than monitored studies, as will studies with reduced SDV
- Monitoring could be face-to-face or via telephone and scheduled weekly or quarterly. Sites that do not complete the case record form (CRF) pages regularly usually do not benefit from lessons learned from initial query rounds
- Sites included in the study may be specialized care units with much experience of many clinical trials or they could be research-naïve general practitioners (GPs) with minimal trial experience who may require extra help when responding to queries.

### Staff Experience and Background

A major factor in the assignment of staff is their level of experience, either within:

- A specific therapeutic background—a given therapeutic area may be important if particular aspects of a given CRF that are peculiar to one disease area (for instance, the use of many different rating scales in neurology trials, or the high number of coded terms associated with oncology trials); or
- A given job role—it might be appropriate for a junior data manager to lead activities on a small Phase I trial, but it is less appropriate for them to lead a global oncology Phase III electronic data capture (EDC) trial.

### Study Timelines

If the first subject first visit (FPFV) date for an accelerated start-up is required (a subject may need to be recruited by a given date to meet a corporate timeline), a paper CRF might be easier.

Initial CRF design activities can be fast-tracked and screening/baseline visits can be sent out separately to allow recruitment to begin. Subsequent visits can follow at a later date.

If EDC technology is required, time is required to complete technology assessments of the sites, and then the eCRF can be constructed on a visit-by-visit basis—with or without full validation

programming of online checks and full user acceptance testing.

The database lock target is another important factor. If required timelines between last subject last visit and database lock are two weeks or less then EDC technology will probably be required to accomplish them, but a more relaxed timeframe of four-plus weeks could be equally as well achieved with a paper CRF.

**Preferred Location of Staff**

The data management activities can be led in several ways:

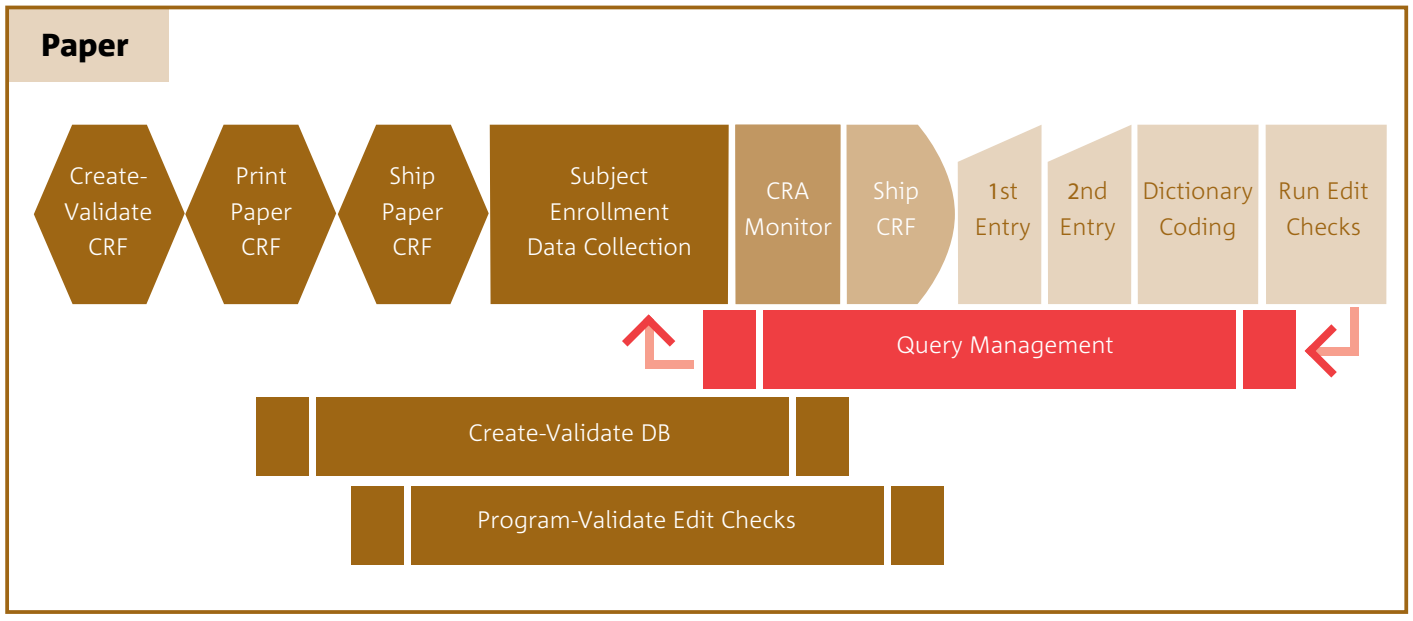
- Close to the sponsor and/or the clinical team
- With a lead data manager in each geographical region for global trials—certain activities can be "off-shored"; scanning and imaging technology for paper studies and EDC technology mean that location becomes much less of an issue from a processing/cleaning perspective, with appropriately trained and equipped staff able to complete data cleaning tasks from any location
- The need for multiple languages to talk with the sites or local CRAs may dictate where the work is placed.

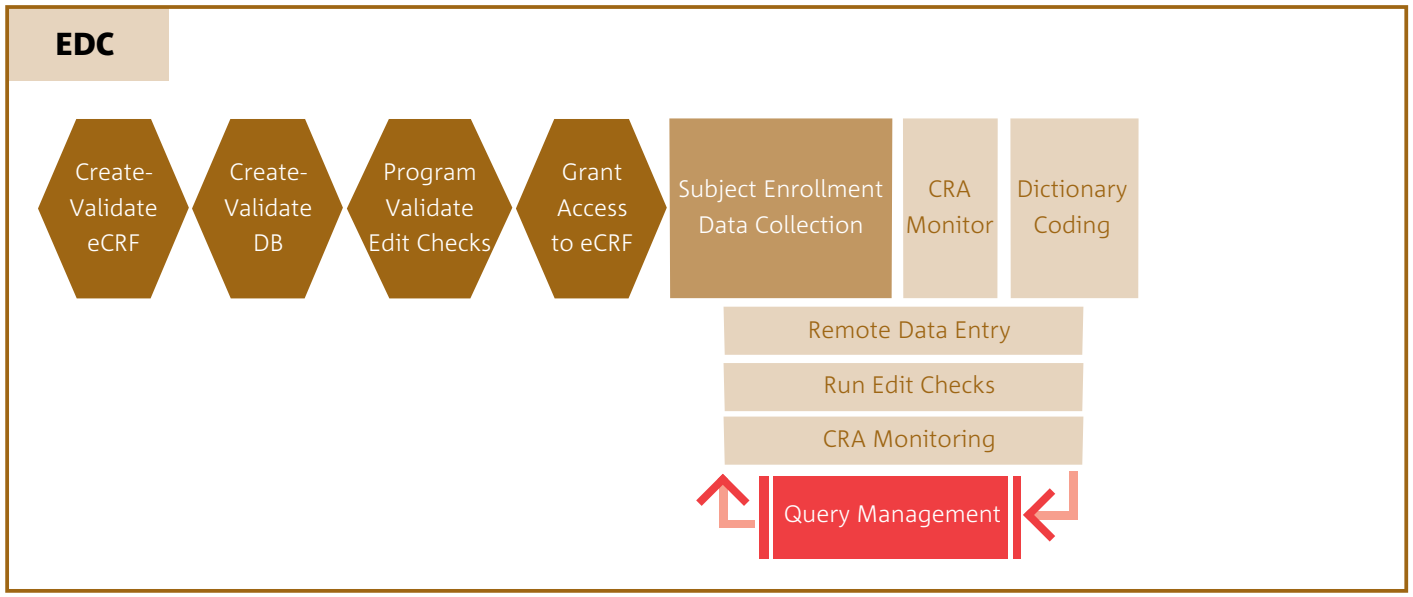
## Technical Issues and Study Conduct

**eCRF Design and Study Methodology**

The study could be EDC, paper, or hybrid. A combination of both EDC and paper within the same study, possibly due to some sites not being equipped to run EDC trials, would provide the option of using traditional paper CRFs and the associated processes to clean the data. Or, alternatively, the EDC study may have a paper diary completed by subjects whose data needs to be entered into the same study.

Paper studies can be "fax-back" or optical character recognition-based. A database that reads and enters the data automatically combined with toll-free fax lines can greatly facilitate the entry and receipt of data. However, poor fax quality, fax machines running out of paper, and a limited number of



*Continued from page 13*
fax lines can all hamper this process. Similarly, there are still countries in the world where toll-free fax lines are still not available.

**Database Management System Selection**

Sometimes there is a specific requirement for a certain database system to be used. But if SAS® datasets are the only deliverable, then maybe the specific database used may be inconsequential.

A client might need to import a complete database from a CRO system into its own, and on that basis needs to re-use database objects and items that have successfully been used before in previous studies.

If a client wants a CRO to work in its own database system, this can be done remotely or actually at the sponsor's site.

It may be that the study makes up a small part of a larger program of studies and there is a requirement to remain consistent with previous systems and naming conventions utilized. The reuse of items that have already been designed, reviewed, validated, and used successfully can make a large difference in terms of efficiencies to be gained on a study. The recent increase in interest and use of Clinical Data Interchange Standards Consortium (CDISC) standards has stemmed from the desire of the industry to be more consistent in naming and labelling across the board, thereby making the data review of the regulatory agencies easier and faster.

**Electronic Data Capture and Applications Support**

The use of EDC brings a set of unique challenges, but if the system and strategy are planned and implemented correctly there are many benefits to be had for the whole team from making use of the available technology.

A huge part of EDC trials relates to the technology and support aspects of the system. The different technologies and methodologies are well documented:

- The technology assessment for sites may be completed by the system owner or by a specialist third-party provider.
- The sponsor may decide to provision lap-tops or upgrade the communications lines to sites in the trial to allow them to use EDC or not; the provision of lap-tops itself can result in issues for import licences into certain countries.
- Costing and resourcing of the applications support can also be affected in several different ways, such as:
  - The availability of the help desk
  - The expected number of support calls for EDC system
  - How many of these calls will be covered by study CRA/data managers
  - Whether the help desk is available 24/7/365—anything less than this can cause issues in global trials with the complications of different time zones, different national holidays, and different weekend days, all potentially requiring cover
  - The languages covered by the help desk—global trials in several continents may require the availability of multiple languages.

**Validation Programming**

Validation programming can be tweaked according to the study to maximise benefits:

- "Simple" studies' (those with minimal text fields and many check boxes) programs will almost be limited to missing data; there are few other CRF fields against which responses can be confirmed
- The amount of data on a page will directly influence the number of checks to be programmed, and by the same token the number of programs checked will influence the number of queries
- The use of self-evident corrections (SEC) can also affect the query rate; the more SECs employed, the fewer queries will go to site.

**Review of and Access to Data**

Clients frequently request and expect access to their data, either on an ad hoc basis or for formal review of coding or subsets of the study data at deliverable times. The time required for this review can add to the timelines and affect the database lock. For EDC studies they will likely have access to the system to see some information, and it is not unusual for them to want to see listings and filtered data on an ongoing basis. The frequency and format of these listings and deliverables will need to be agreed up front. Some CROs have portals set up to aid this requirement. They can be completely customisable, secure (user name and password required), and available 24/7/365. Reports included may be real time or may be generated on an every-24-hours basis. Great care needs to be taken by the study team as to who has access to this data, and what it is used for; in a blinded study clearly there are going to be some team members of the team who should not be privy to the information included.

Another common concern when data are transferred before the end of a study is how "clean" the data are at any given time. Many an email and "dirty data" discussion have occured when a person reviewing data assumes that it is clean. This is even more likely if real time reports are being used. It may be that the discrepant data in question were just entered that same morning a few minutes prior to the review.

The team and, in particular, the Lead Data Manager must carefully define the status of the data to the reviewer.

**Metrics**

Sophisticated metrics show real time data trends in queries can make it possible for a huge amount of progress to be made early in a study in terms of resolving the issues that would otherwise cause a lot of work for everyone, and thereby prevent a larger problem later in the trial. Typical useful metrics can include:

- The number of queries per site

- The number of queries per CRA
- The average time to resolution of queries.

Regular discussion of these metrics can allow the team to make recommendations as to the refinement of validation checks being used, or of less-well-performing sites/CRAs based on query rate or on query text that needs to be modified. These metrics can also be used in a wider sense, such as inclusion in investigator newsletters or presented in study close-out or lessons learned meetings.

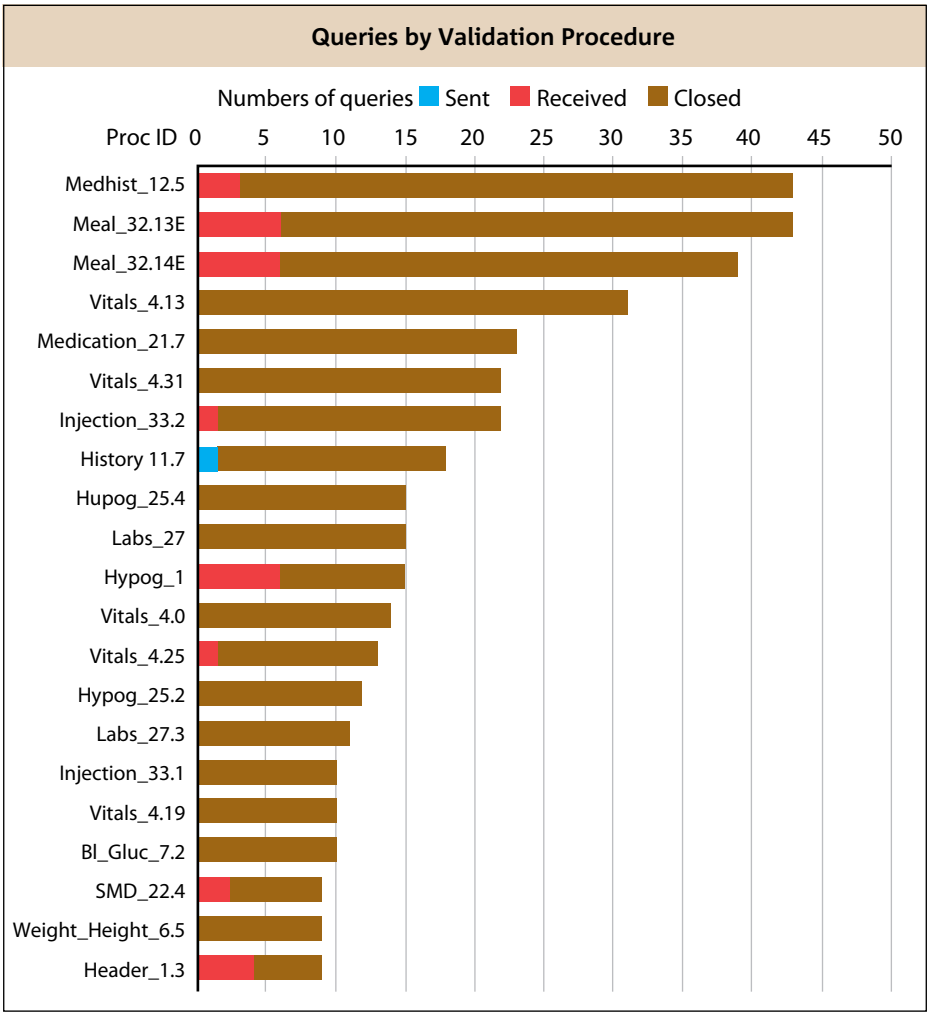
### Quality Control Steps and Error Rates

For paper CRF studies, there is often a final Quality Control (QC) step at the time of lock involving a manual check of database output against the original CRFs, related queries, and study documentation.

The sample size chosen and the nature of the data to be included in this step can take a very long time. There are always discussions for increasing the sample size and scope of the QC based on the trial—non-registrational, Phase I, and healthy volunteer studies may not need the same level of attention.

Teams need to be realistic and decide which data being checked adds the most value. It is not logical to QC data for a registry study to the same degree as for a study whose data will be sent to the appropriate regulatory authorities. Safety, demography and efficacy are often included and comments and subject diaries are often omitted, but this will differ between studies. The inclusion of concomitant medication and or lab data needs to be carefully handled.

Some companies choose a small random sample of root n+1 or similar, while others will choose five percent, 10 percent, or up to 100 percent of some subjects or some datasets.




QC for EDC studies is not possible in the traditional sense. Listings form the database and the eCRF are one and the same thing. In this instance, QC can be restricted to checking that the data extracts are working correctly.

### Conclusion

The above discussion covers the main topics that require decisions from the data management team.

There are of course myriad other topics that, while also requiring decisions to be made, may be deemed to have a lower impact on the conduct of the entire trial—including interim analyses, data monitoring committees (DMCs), frequency of QC, frequency of data loads, the communication plan, meeting attendance, selection of coding dictionaries, third-party data, subject diaries (paper or electronic), and SAE reconciliation—but the principle remains the same. Project teams need to take all of the above parameters into consideration when deciding how best to run the data management aspects of any trial.

By customising the approach and optimizing the processes and assumptions for data management, efficiency can be maximised, cost reduced, and timeliness improved upon.

To summarise, data management is a very simple and straightforward exercise. Regardless of the specifications of any individual study, there is a "one size fits all" approach that can always be implemented that will allow for effective and timely data cleaning...right?

***Steve Mitchell, B.Sc.(Hons.), M.Sc.***
***Senior Director, Global Clinical Data Management, i3 Statprobe***

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# Mapping

**ACDM Annual Conference • 9-10 March 2009**

The events being experienced in the world today are truly global in their impact, gone are the days where the impact was only experienced nationally or regionally. Mapping the Future for Data Management presents similar challenges and consequences, but given how Data Managers have evolved their roles and responsibilities to date, the future remains an exciting and challenging place for Data Management professionals.

The 2009 Conference brings together an exciting mix of presentation, discussion and debate where a number of contributors will share their experiences and how they see the future being mapped.

The agenda has been designed with topics of interest for data managers who are new to the profession as well as those who have many years of experience within the industry. The conference will include a range of exhibitors and there are sponsorship opportunities available. The ACDM also invites you to submit a poster for the "John C Amos Award for Clinical Data Management Innovation" sponsored by Merck at the ACDM Annual Conference.

## Conference Programme

### Day 1 – 9th March

**9:15** **Welcome Speech**
*David Baker, ACDM Chair*

**Session Chair** – Brian Gennery, Pharmaceutical medicine consultant with a special interest in early stage development and paediatric drug development.

**9:30** **"Mapping the Future" Guest Speaker**
*Phil Hammond*

Phil Hammond is a GP, writer, speaker and broadcaster. He graduated at Cambridge University at St Thomas' Hospital, London in 1987. Phil has taught frequently about the complexities of Medical decision making, he co-wrote and fronted six series of "Trust Me, I'm a Doctor" an award winning BBC 2 health series promoting evidence based patient choice and his book of the same series is a best seller. Phil Hammond will provide us with some interesting views on how he sees the future of healthcare being mapped out.

**10:15** **Randomisation in Everyday Clinical Care – The New Epidemiological Tool**
*John Parkinson, MHRA*

The full electronic, coded, recording of data has for many years been the quest of researchers who use observational data. The era is upon us where many clinical trials could be conducted using these electronic records as the source of the clinical trial data. The presentation will show how everyday clinical data now has a major role in enabling a whole range of both observational and interventional studies.

**11:00** **Coffee Break**

**11:45** **Break-Out Sessions**
*Choose from one of the two options below:*

- SAE Handling in EDC systems
- MHRA Audits

# the Future

- Whittlebury Hall Hotel, Northamptonshire

**12:45** **Lunch**

Session Chair – Harshad Sodha, Vice President, CDM Operations, Omnicare Clinical Research.

**14:00** **AGM**

**15:00** **Managing a Successful Offshore Data Management Unit**
*DilliBabu Shunmugam, ICON Clinical Research*

A presentation outlining how Data Management activities can be successfully off-shored, the challenges to be embraced and how success is measured and recognised.

**15:30** **Tea Break**

**16:00** **Phase IV Clinical Trials**
*Stephen Dorman, CTEP*

Discover how niche EDC providers are continuing to adapt their technologies to meet the ever increasing demands of Phase IV trials. Understand what sites are looking for in EDC technologies in order to conduct Phase IV trials successfully.

**16:30** **ePRO Evolution and its Impact on Clinical Data Management**
*Adam Wood, Invivodata*

This presentation will focus on the changes in ePRO that are directly relevant to clinical data managers, including the evolution of modern ePRO, the role of psychometric and linguistic validation, and how regulatory bodies, such as the U.S. FDA are impacting clinical data management, through it's Draft Guidance on PROs in Clinical Research.

**17:00** **How eSOURCE is Driving Changes in our Industry**
*Richard Young, Cmed*

This presentation will provide a detailed review of how eSource can drive a huge shift in the industry, from changing roles and responsibilities to costs and processes.

**17:30** **End of day one session**

**19:00** **Champagne Reception**

**19:30** **Gala Dinner**
"James Bond" – 007 theme night.

## Day 2 – 10th March

**8:45** **Welcome Speech**
*Tom O'Leary, ICON Clinical Research*

Session Chair – Gail Kniveton, Director, Data Services, i3 Pharma Resourcing.

**9:00** **EDC & ePRO Solutions**
*Gilbert Bellachen, Oracle Corp*

Learn more about how e-technologies will converge in the future and how data will be integrated across various technologies. This presentation will consider how services in clinical trials maybe orchestrated to allow flexible processes in the future.

**9:45** **Debate**
'This house believes that the huge advances in technology have not led to any significant increase in the quality of data" – Julianne Hull,Senior Director, Global Development Data Operations, Wyeth Research will chair this entertaining and exciting debate.

# Mapping the Future

**ACDM Annual Conference** • 9-10 March 2009
Whittlebury Hall Hotel, Northamptonshire

**10:30** **Tea Break**

**11:15** **The New Clinical Trials Landscape: eSource, Adaptive Trials and The iPhone Revolution**
*Richard Young, Cmed*

This presentation will consider the latest technologies in the market place and highlight the challenges facing the eDC industry.

**11:45** **Breakout Sessions**
*Choose from one of the two options below:*

- EDC Special Interest Group
- CDISC

**12:45** **Lunch**

Session Chair – David Walpole Therapy Programme Manager, Clinical Data Management, GSK.

**14:00** **Electronic Data Capture + Effective Training = High Quality Data**
*Paul Millard, Phase Forward*

Experience has taught Phase Forward that effective Investigator training can have a direct influence on the timeliness and quality of data entered into eClinical systems. This talk will discuss the most appropriate methods of training for a number of real-life scenarios.

**14:30** **Quality and How it can be Impacted**
*Ian Clarke*

This presentation will explore the meaning of quality in clinical trial data, what factors effect quality and how quality can be achieved by the steps taken up-stream in a clinical trial.

**15:00** **EDC Training for Investigators and Site Staff – The Optimum Delivery**
*Stuart Cook, Pharmanet*

Increasingly, Investigator Meetings are becoming more and more condensed in terms of agenda and available time. Therefore a paradigm occurs where EDC application training and CRF Completion Guidelines can be delivered to most if not all site staff at an Investigator Meeting yet there is often little time available. This presentation will review the optimal approach to successful EDC training at Investigators Meetings.

**15:30** **Closing Remarks**

## How to Book

To register on-line for the ACDM Annual Conference visit our website www.acdm.org.uk.

If you have any questions please contact us by email (admin@acdm.org.uk) or by telephone (01727 896080).

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acdm
association for **clinical data management**

# So what is it exactly that you do?

**How can I convey to family and friends, without slipping into a badly thought-through interview question response, what my job entails? Jon Milton trys to answer the question.**

A very good friend, and someone for whom I have a lot of respect, once told me to *"turn your brain off dear!"* Fast-forward a few weeks. Imagine the scene; a beautiful autumnal day. Two thousand and eight had been a year beset with changeable weather conditions; an environment that had effortlessly stolen yet another English summer (is there such a thing?) whilst simultaneously giving us some of the most intensely stunning leaf colours I have ever witnessed. As I drove my car through this dramatic scenery, numerous thoughts (and the road) were vying for my full attention. The one thought, however, that continued to thrust to the forefront of my mind was simply this: how can I convey to family and friends, without slipping into a badly thought-through interview question response, what my job entails? I know that many of my colleagues can empathise with this predicament, hence why I decided to write this article. I, for one, have been asked the question far too many times, yet it is something that has continually (for eight-and-a-half years!) elicited an obtuse, inconsistent and often incoherent, response. I decided it was time to put a halt to the mad ramblings that so often ensue upon receipt of this very question. So I had a think. I quickly determined that in order to be able to answer this question, I really needed to understand a) why I had chosen this path and b) what had prompted my friend to tell me to turn off my brain. The rest would logically follow, or so I thought.

Young boys typically have the utmost respect for their grandfathers. I didn't buck the trend. With a certain, but at the same time unjust, inevitability, I lost my paternal grandfather to Parkinson's disease, and my maternal grandfather to a stroke and subsequent complications. Both suffered from protracted periods of illness, which I, as a young boy, struggled to understand and could do little (or more accurately, nothing) about. Helplessness is not a nice feeling. To see the people who you love (and admire) suddenly become so vulnerable (and suffer) is probably the worst feeling. Circumstances can have a profound affect on a life. Until this time, I had a penchant for writing and languages, but the allure of science, the unknown and more importantly – some answers – took an unwavering hold of me, and to date its grip has not let go.

Many people "fall into" data management, invariably owing to the fact that they have been disillusioned with the laboratory work aspect of their scientific degree course. I fall into this category, and by virtue of this I can probably safely say that I did indeed fall into data management. This does not mean that I am not passionate about the job, nor should it detract from the inherent importance of our job; clinical trial data, after all, drive important regulatory decisions, ultimately determining whether a drug is efficacious and safe for human use. If these clinical trial data are not "clean", then the aforementioned decisions could be tragically flawed. It is this, and the subsequent impact that we can have on people's lives, that I believe unites us in a common quest and gives us the drive and commitment to deliver quality data. So this is an important job. Perhaps this is, or is part of, the response? However, surely all jobs are important – we all make a difference – so how would this response distinguish me from, say, a Fire Fighter? What is more, Fire Fighters save lives and more significantly, they are visible when doing so – people know what they do, there's no need to ask. Conversely, we adopt more of an unsung hero approach, quietly working and occasionally seeking refuge in our data. We are not an obvious public service (yet surely we are in a way?); as such, people struggle to relate. Take Fireman Sam, for example; my three year old son knows what he does, but at the same time thinks that I spend all day playing with the little stress (and juggling) balls that adorn my desk. Now there's a thought.

If we take a moment to think about the fundamental principles that govern our daily work, and thereby consider ICH GCP, we immediately see numerous references to the accuracy and credibility of data. We know these guidelines, we understand them and should we be asked about them we can extrapolate the principles to our everyday work and in so doing we can communicate sensible and succinct responses. These guidelines are of real benefit to us in our daily work, and especially when we're unfortunate enough to be involved in an audit or inspection situation. They are not as useful, nor as effective, at a children's Halloween birthday party, for instance. So, now I'm struggling. What do we do? We push a lot of e-mails here and there, we irritate sites with queries. We even find ourselves burning the midnight oil (it was this that prompted the *"turn your brain off dear"* quote) in pursuit of something. But what exactly? I'm not sure it's definable.

I set out writing this with the ultimate aim of generating a stock sentence that I could a) share and b) learn and recite at will. It's taken some soul-searching to appreciate that I cannot do this. What is more, I don't want to do this, even if it means no stifling, and hence madder rambling to come. In all seriousness, each and every one of us will have our own story; our own motivation. Please take a few minutes to reflect on yours. It helps. When I next get asked the question, I'll think about the times that I spent on the beach or the allotment, and then I'll think about my son and hope that he gets the chance to enjoy more time with his grandfathers. We do make a difference, and however little, and however indiscernible, it is still a difference. Take comfort in this. Rambling is not all bad.

***www.parkinsons.org.uk/default.aspx***

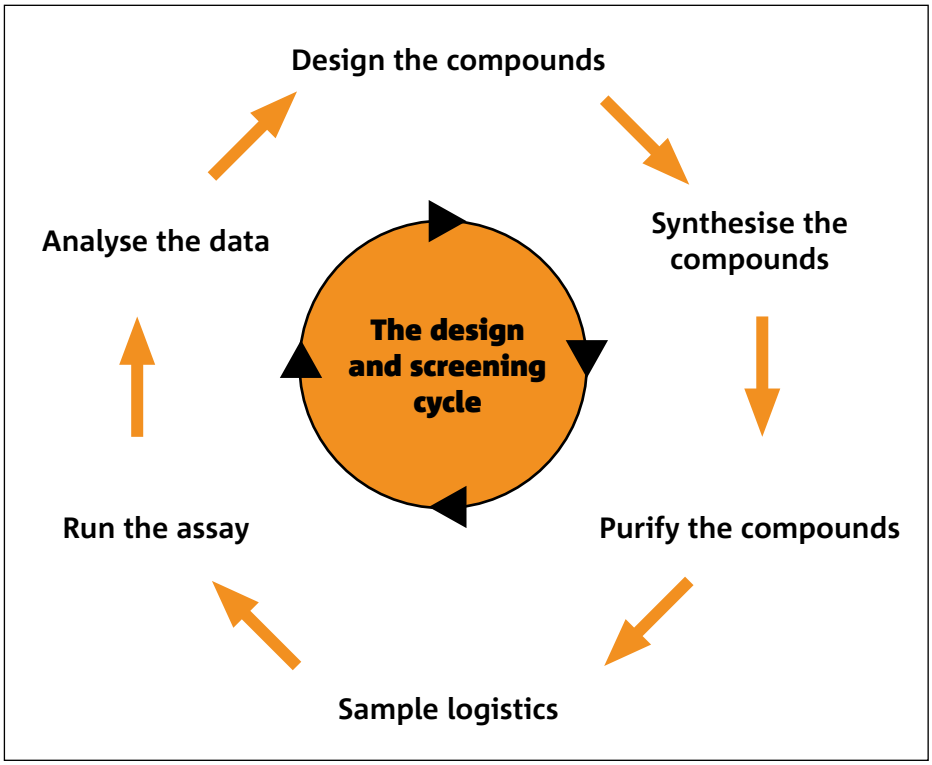
***Jon Milton, Pfizer***

# Data Horizons in Sample Logistics: Compound Screening in early Pharmaceutical Research

Early pharmaceutical research (idea to clinical candidate) has often been portrayed as a rather linear process, progressing from Idea, through High Throughput Screen (HTS), Lead identification and optimisation and later, candidate selection. Largely speaking this is true, however buried within that is a more complex picture, especially post HTS where multiple often parallel knowledge generation loops are performed – compounds are designed, synthesised, purified and assayed to generate new data which informs the next round of compound designs and experiments.

In this way, and usually through multiple iterations, a low potency, non-selective compound perhaps with poor or uncharacterised pharmacokinetic or safety characteristics can be improved and optimised to reach a point where meaningful testing in an animal model or ultimately a human population can be contemplated – with the appropriate safety testing, of course. At Pfizer, this process is referred to as the Design and Screening Loop. As an approach, this has been the central paradigm in use in Drug Discovery for many decades, albeit as a low throughput process.

However the last 10 years has seen a revolution – large investments in robotics and Information Technology (IT) have seen this process industrialised, illustrated most powerfully by a 20 fold increase in the number of data points generated, with fewer experimentalists. It's also become increasingly complex, for instance in a typical month at Pfizer's Sandwich Research facility in the UK, many thousands of compounds will be tested, across any one of 100 or so assays in support of perhaps 30 or 40 different drug discovery projects – a complex logistical and data management exercise. So what has allowed us to manage this new industrial process? It has been the development of sophisticated sample logistic processes and IT – basically very good systems to track the compounds from the moment they are synthesised through to assay. However we didn't get here overnight, in fact it's been a path that's taken over 20 years...




Twenty-one years ago, HTS was in its infancy barely recognisable by today's standards. Then, a sample logistics group was really focussed around a dry compound inventory, manual weighing and a basic computer system for sample logging. A biologist would receive a dry sample and would spend significant time performing repetitive manual sample preparation for their assay, rather than doing science, limiting throughput of compounds and data generation. With the establishment of the first HTS group at Sandwich processes started to change, a computer system for a basic electronic inventory and submission tracking was developed and we started to participate for the first time in liquid rather than solid handling, signalling the beginning of an evolution toward a centrally managed sample logistics function dramatically driving the efficiency of the Design and Screening Loop. So, what were the challenges that, then, drove the further development of sample logistics?

About 10 years ago, the onset of library and combinatorial chemistry sent the numbers of compounds to be screened into 6 figures/year. Efficiency became an ever stronger driver – simply due to the number of compounds being made and much work was done at this time to remove undesirable or low value compounds so reducing the number of samples that had to

be screened. Emerging new technologies from companies such as Tecan and Cybio allowed yet higher throughput and more flexibility. At the same time, IT investment built the connectivity between local automation and centralised corporate databases, thus opening up the data to the wider organisation.

In Sandwich, we focussed on Sample Logistics as a distinct part of the Discovery process separated from the Biology and Screening diciplines. The Sample Logistics team was to embrace the skills, knowledge and development time needed to add value to the inventory and logistics of getting samples to screen and thus generate more timely results and consequently more information and knowledge. This led to the beginning of a collaboration with a software company in London that was to evolve over the next 10 years into a full partnership. That company was Titian Software Limited. Titian provided Pfizer with a method of integrating automation and our inventory database allowing us to easily access plates of liquid samples and flexibly combine them into sets for investigation or follow-up. Cherrypicking allowed us to re-classify our liquid file into specific sets without the need to re-process new samples which drove whole new set of screening paradigms such as specific set of diverse compounds or those that were focussed around specific gene families.

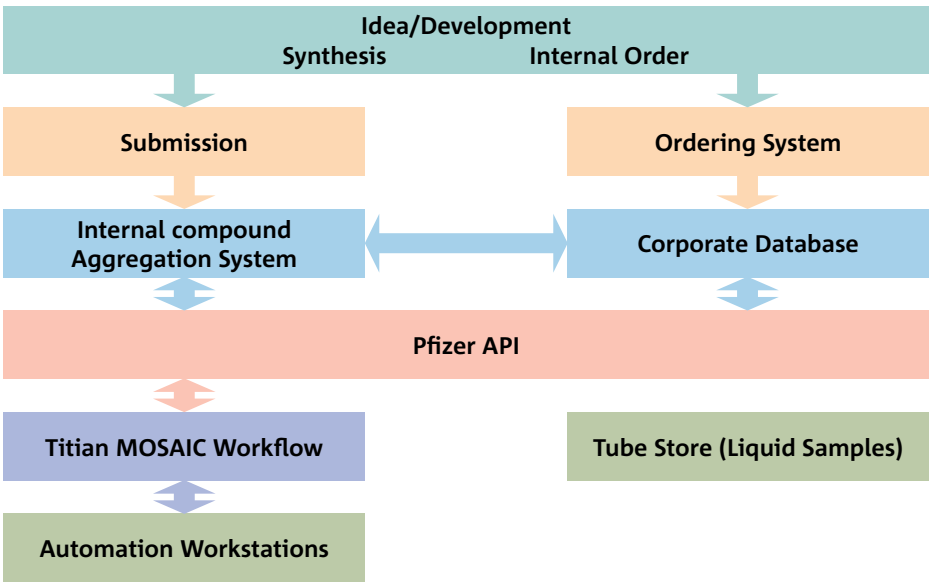
However, up until 5 years ago, all samples were still being submitted dry and required a minimum of 20mg of samples to support the early stages of screening. Our response was to review the whole 'submission' process to reduce sample use per screen, and improve the efficiency of sample plating and delivery.

Globally, Pfizer recognised the need to fully integrate our ordering system and compound submission process closely with the liquid handling infrastructure developed, thus streamlining the whole submission process and truly embedding the 'Design Cycle' research strategy into the work process. Pfizer Research worked with our in-house Informatics team, and Titian Software to develop a system where the scientists stated their requirements for Assay Ready Plates (ARPs) in an internal system to create a 'Deliverable Set'. Compounds synthesised in-house or compound library derived materials can be submitted in bar-coded tubes and associated with one or more groups of screens through a simple user interface. Samples are automatically directed to the Sample Logistics group and, after solubilisation, loaded into an automated sample tube store. Our internal systems aggregate the orders and Titian's MOSAIC Workflow Management System integrates to the in-house ordering and 'Compound Aggregation' systems to validate the requests and determine the optimal liquid handling required. Most of the sample logistics automation systems are logged into Titian's MOSAIC software system along with their liquid handling properties. Rules have been built into the MOISAIC workflow manager that allows the system to decide the best workflow to get the desired plates, with the flexibility to account for any currently unavailable automation. Re-submissions can be incorporated into the system from any of the Global Pfizer stores.

With the link between compound registration, screen submission, liquid handling, sample tracking, and subsequent screening in the sample logistics arena, the group have supplied the missing link to create a sample flow and tracking system that allows the Research chemist to keep track of their team's ideas. Most recently, now that our platform is mature, we are starting to use the data in entirely new ways to, for instance drive continuous improvement intitiatives using real data to drive future improvements.

In summary, we've some dramatic changes in the last 20 years, from a purely manual process handing small numbers of dry compounds through to today's scenario where, from their computer screen a scientist can select which compound should be screened in which assays at what time and after submission of that request our systems and robotics drive the whole process through to data generation whilst at the same time providing real time tracking of compound status. We've seen a dramatic increase in productivity through, efficiency gains and quality and as a result an integrated sample logisitics function has become an integral part of the Research process.

**Simplified Data Diagram**




***Bill Skinner and Jerry Lanfear,***
***Research Data Support & Management,***
***Pfizer Global Research & Development,***
***Ramsgate Road, Sandwich,***
***Kent CT13 9NJ. UK.***

# 21st Century Evolution? – Red Apple becomes Peach!

On 8th September 2008, Drug Information Association (DIA) Headquarters in Horsham PA, saw 90+ representatives from pharmaceutical companies, CROs and support organisations, and all major regulatory authorities gather to launch the Peach initiative. As a continuation from the Red Apple (1980s) and Red Apple II (2006) initiatives, which were both directed at non-clinical computerised systems; the core committee's aim was to write the previously planned document to address the use of computerised systems in the clinical research arena. It will be titled – Computerised Systems in Clinical Research: Current Quality and Data Integrity Concepts.

Prior to 8th September the Core committee had put in 2 years of hard work to establish the planned structure of the publication and to appoint a team of Chapter Chairs. These Chapter Chairs would work together, to ensure that all the individually written chapters would eventually hang together to create a cohesive whole.

The initiative was planned to address the fact that the increasing use of computerised systems in clinical research may result in a risk that data quality and integrity may be affected adversely; and also to raise general levels of awareness of this fact. Building on Red Apple and Red Apple II it was readily acknowledged that clinical research is more complex arena than manufacturing and non-clinical activities, so may require different strategies. However it was decided to stick with the basic development methodology used previously i.e. gathering a group of individuals together and setting them tight deadlines for producing the first drafts, then utilising an editorial team to craft those drafts into the final document.

The Core team had already written the 6 part Preface with background to the initiative and guidance on the structure of the publication; and under their guidance the 17 individual Chapter Teams set out to produce the content of their individual sections.

The first 5 chapters set out to define the basic principles of the core topics:

- Clinical Research
- Data Integrity
- The Systems Life Cycle and Computer Validation
- Quality
- Risk

The following 12 chapters took those basic principles and established more precise guidance on how they should be implemented within clinical research activities. Those 12 chapters are entitled:

- Computer Systems Validation in Clinical Trials
- Computer Systems Validation in Clinical Records and Records Retention
- Impact of Computerised Systems on Data Integrity
- Quality – QC and QA in Clinical Research
- Risk in Clinical Research
- Infrastructure
- Security (Managing Security of eProcesses)
- Outsourcing
- Programming Languages and other related software
- Data Collection Techniques, Tools, and source data
- Medical and Diagnostic Equipment
- Bio-analytic and Central Laboratories

The objective of the book is to establish best practice guidance across the whole of the clinical research process, integrating, where necessary, guidance's which may already exist in other publications, that perhaps focus on one particular area. The aim was to develop a benchmark for design, testing, implementation and retirement of computerised systems used in clinical research – i.e. across the whole computer system lifecycle. However a new lifecycle concept was also developed, that of a lifecycle for data from creation to archiving, migration or deletion and this is also explained and expanded.

Three basic concepts are developed throughout each chapter of the book – Data Integrity, Data Quality and Risk. When using computerised systems in the complex field of clinical research the industry's challenge is to:

- Establish and maintain data integrity
- Ensure data quality
- Identify and mitigate risk ...the final output from the Peach initiative will aim to provide guidance and best practices to meet those three challenges!

Following the initial writing activities prior to and during the September meeting there will be time spent reviewing the contents for accuracy and eliminating any potential duplication of content. There will be wide ranging review of the whole document for style and format then any necessary editing will be performed. It is planned that the final document will be published in late 2009. For more information about the Peach initiative – visit **www.diahome.org**.

Final Note – why Peach? – the initial meetings among the Core Team took place in Georgia – apparently known as the 'Peach State'!

***Jane Tucker (GSK) & Dave Smith (Roche), Co-Chairs Clinical Research Computer Systems Validation Working Party***

There will be no charge for attendance

# CR-CSV FORUM

Wednesday 25th March 2009
KSAM, London EC1

CR CSV

## *"Pragmatically meeting regulatory expectations for Niche companies and/or Academic organisations when supporting large Pharma"*

Sponsors and their niche and academic partners often struggle to communicate and or appreciate the challenges they jointly face working together to carry out clinical research.

The value that these partnerships deliver may be diminished due to limited awareness of how to implement fit for purpose validation strategies that address process and technologies.

This forum aims to discuss practical, quality solutions to establishing evidence of robust business processes.

In preparation for our next publication: CSV Lite, this will be a working forum open, on a first come first served basis, to representatives of corporate as well as niche and academic organisations.

The output will form the foundation for the structure of this new groundbreaking guideline.

**Attendees may include (but are not limited to) people involved in:**

- **Support and management of Clinical Trials**
- **Data Management**
- **IT and support services**
- **Development or customisation of computerised systems**
- **Statistical programming and analysis**
- **QA**

**The meeting will be from 12.00 – 5.00pm and will be followed by a buffet**

**For further information or to register to attend please send an email to: david.smith.ds1@roche.com Before 9th March 2009**

**Please pass details of this meeting to your colleagues especially those in Niche Companies and/or Academic Organisations**

# Data Management to Clinical Project Management

**My current role is as a Clinical Project Manager (CPM) at Pfizer. According to the job description, a role that is responsible for the full delivery of clinical studies, from protocol synopsis to completion of clinical study report, to time, cost and quality goals through use of Project Management and leadership skills of internal and external resources.**

My background prior to this role is that of data management – and proud of it. This article is to try and give a flavour of what I found were the key skills developed as a data manager that helped my transition to this role with responsibilities for the delivery of entire studies. It is also to share what I feel is required from the data managers I work with (as well as every other group) to help make a clinical study successful – not just superb data management skills but the ability to lay out clear detailed plans and deliver them through exquisite project management!

I gained my grounding in data management at Covance (then Besselaar), before moving to Pfizer just over 10 years ago. Within Pfizer, opportunities presented themselves to take on leadership roles supervising data managers and leading the data management activities across multiple protocols. It was at this time within Pfizer, and across the industry, that the 'Cost' of the 'Time / Cost / Quality' triangle began to rise in significance. In fact, at the same point, 'Time' also grew in importance along with Quality. Essentially, the whole Time / Cost / Quality triangle grew in size and significance to become a very visible element of daily work and a core goal of every study.

At this time, there was little planning or project management within the data management function. Teams had project managers but they operated at a high level looking across a whole program, not at the detailed work of a protocol team. There was little emphasis on early planning and setting out a single, integrated study plan, with each team member accountable for their tasks. As a data manager you got your discrepancy checks programmed for approximately when you believed the first data was due in house and you tried to keep pace as the often exponential data flow occurred between first and last patient!

By today's standards, this was not resource efficient and certainly didn't use fundamental good planning and project management techniques; producing a clear model of what's intended to happen before you start, monitor the current status against that plan regularly, provide early warnings of (possible) deviations and give yourself time to implement real time corrective actions. Having clear plans set-out also gives one the ability to make learnings on how you delivered to them and to implement improvements next time; essential to keep pace with the ever growing pressures on Time / Cost / Quality.

Detailed forward planning and project management had to become a core part of the data managers (and all project team members) skills set, especially as outsourcing and off-shoring data management activities grew. Within the DM group at Pfizer, a range of avenues were explored; some successful, some not – but all added to the mindset of the importance to become better at planning and managing the available resources to deliver our work

By now, many of you may have switched off this article as I come across as some old fashioned fool, talking about the old days for skills that are now bread and butter of DM teams. A message that Jurgen Groebbler, GB rowing team coach, gives after each Olympics: simply training as hard for 4 more years in order to reproduce the same time that won these Olympics, will not be sufficient to even get you to the start of the next Olympic final. Whatever staple project planning and project management techniques you do now, they need to be constantly reviewed, refined and improved to meet the ever increasing pressures on project delivery to that Time / Cost / Quality triangle

That brings me to my current role as a CPM at Pfizer. If I was to summarise my view of the intention behind this role it would be: studies often fail because they fail to invest detailed time in planning at the start and during a study. Plans fail as team members are unable to work these plans (for myriad of reasons – unrealistic plans, team changes, processes changes, distractions during the study). The CPM role is there to ensure both occur (planning and engagement – not the failure!), thereby reducing chances of problems. However, even the most well organised plans and formed teams can still fail to meet agreed dates and the CPM role is there to support, lend pressure – whatever is needed – to reduce impact.

So, what do I look for from data managers? I've already mentioned exquisite data management knowledge and skills, but what else. Study plans created to manage the overall study can only organise the key tasks. They cannot address the planning and management of the multitude of subtasks underpinning each key task. Take a simple sounding task

such as 'CRF build', and then think about what this really means, the amount of team input from clinicians, programmers, study managers, standards group etc., the number of review cycles and updates, QCs against protocol etc.: like a swan serenely crossing a lake, CRF build may well be moving forward, but this is only possible when underneath there's a whole intense mesh of co-ordinated and carefully timed activities and effort.

The data managers are the experts of these tasks. While studies have project managers specifically to project manage the key tasks, they are reliant on the ability and experiences of the data managers to project manage the subtasks that power this movement. This is even more important with the competition for resources and – often – their location.

I've used above a fairly meaty example of CRF but, to me, the application of good planning and project management extends to even the most innocuous of tasks. For example, a junior data manager seeing that ~200 discrepancies are being generated each day needs to be thinking: can I cope with this workload? Do I need additional help? Was this rate expected or a product of uneven data flow or of training? What's causing this number – what data improvements can be flagged? As a data manger, you are well skilled in accessing and using data repositories with ease therefore able to provide answers to these questions – You are already on your way to implementing valid PM and planning skills into your work that support meeting project goals.

When I was a data manager, the skills I learnt from tinkering around with ideas on different tasks, experimenting with PM techniques I had seen and growing personal experiences of what can (and does) go wrong, were vital to my growth and progression as a data manager. Trying to use these skills seemed logical and was rewarding; updating my manager with clear data, potential risks and plans / strategies to steer around these risks gave me confidence. Those same initial concepts and fundamental mind set that became engrained while a data manager were key to supporting my career progression.

While studies have team members whose job it is to plan and project manage, the only reason that the swan has the potential to cope with a variety of waters is the further detailed planning and project management carried out by each team member. I believe each team member has the responsibility to employ planning and project management techniques to support meeting delivery of their work. I firmly believe that data managers have a high aptitude to do this well and that career growth is directly linked to your ability to deliver which in turn is directly linked to your planning and management.

I also firmly believe – like our Olympic teams already aiming for 2012 – whatever suite of planning and project management techniques you employ today across your activities, I urge you to constantly look to extend it: Use your growing experiences, evaluate how tasks went and look to improve those skills further. The ability to input to a plan with confidence, and then deliver to it, is highly valued and will set you up well for whatever the next challenge may be.

***Rob Freeland,***
***Clinical Project Manager, Pfizer***

# A Marriage made in Heaven or Grounds for Divorce?

## Does Project Management Manage the Data Management and Statistics Functions Effectively?

This meeting of the ICR Project Management Special Interest Group was held at the Institute of Clinical Research on 10 October 2008. The aim of the debate was to explore the interface between project management, data management and statistics.

The motion for the debate was "The data management and statistics functions are well managed by project management" and the session was chaired by Jan Robinson, Director of Clinical Operations at PharmaKodex Ltd.

The aim of the debate was to hold an open discussion, looking at the following:

- What are the keys to improving relationships and ensuring better outcomes? What really works and what does not?
- Are there differences if the two functions are not within the same company and how do you manage that to best effect in both scenarios?
- If you need to make changes how do get buy-in from the stakeholders to implement those changes?
- How would you measure the effect of your improvements?

In order for the debate to be effective, four speakers were asked to represent the case, two in favour and two against – but it was clearly stated that these speakers did not necessarily hold the belief they were presenting!

"Project management" was described as the function of the clinical project leader, i.e. a role outside of Biometrics. Speaking for the motion was:

- Danny Nasmyth-Miller, Director Project Management, Parexel UK.
- Stuart Redding, Vice Chair, ICR Project Management SIP & Director, The Medical Research Network Ltd.

I was one of the two presenters speaking against the motion:

- Tony Rees, Director, Syne Qua Non.
- Tracy Roe, Senior Manager, Data Operations, Kendle.

The meeting was attended by 38 delegates. The table below details their backgrounds relative to the discussion.

| **Total delegates** | **38** |
|---|---|
| Dual PM/DM responsibility | 4 |
| PMs or responsible for project management | 29 |
| DM or responsible for data management/stats | 1 |
| Other | 4 |

The first question before the presentations began was to ascertain from the audience whether they were for or against the motion or wanted to abstain at this stage. Whilst the initial votes were collated, Andrew Smith the facilitator from ICR clarified the aim of the debate and the procedure for voting throughout the afternoon.

| **Before** | | |
|---|---|---|
| For motion | 11 | 29% |
| No opinion/abstain | 14 | 37% |
| Against motion | 13 | 34% |

Danny Nasmyth-Miller started the presentation for the motion highlighting the various drivers around successful project management. His opening statement was "Some of my best friends work in data management and statistics" and he proceeded with the following quote which best described his theory.

*"Management is about getting a group of people together, making it clear what you want to do, empowering them to do it and keep following up to make sure they have done it. It is not a very sophisticated process."*

**Sir Gerry Robinson**

Danny emphasised that project managers try to include data management in the project team but that data management tended to abstain from being fully involved in the process. He proceeded to say that in his experience biometrics has a tendency not to attend key team meetings or teleconferences even though they had been invited, leaving key decisions to be made by the project manager alone.

Stuart Redding then continued the flow of positive attributes for the motion, this time focusing on "What is project management?"

He described project management as a discipline of planning, organizing, and managing resources to bring about the successful completion of specific project goals and objectives. He highlighted that the primary challenge of project management is to achieve all of the project goals and objectives while adhering to classic project constraints-usually scope, quality, time and budget. He then defined a project as a set of activities that use resources (money, people, materials, energy, space, provisions, communication, etc.) to achieve the project goals and objectives.

Tony Rees and I decided upon a different presentation tactic to speak against the motion, presenting as a team and dividing the slides between us. We highlighted solid foundations of evidence such as experiences from previous trials

whereby the following examples of poor project management had occurred:

- Suggestions by biometrics have been ignored.
- Fragmented team, not advised when study team members have left.
- Clinical failure on recruitment targets, resulting in unreasonable deadlines for biometrics (e.g. squeezing 6 months of biometrics work into two months to ensure end deliverable is still achieved).
- The project plan is not shared with biometrics.
- Communication on critical key components has not been received by biometrics, e.g. protocol amendments.
- No willingness to support Biometrics when they have not agreed with set milestones.
- Timeline amendments for database lock from "Last Patient Last Visit" (LPLV) have been agreed upon with the client before checking with Biometrics and getting their approval.
- Project managers do not understand the value Biometrics can bring to a project and that their role is pivotal to the success of the study.
- Poor monitoring resulting in dirtier data means more queries generated (working with data managers to ensure better understanding of the CRF completion would prevent this).
- Making decisions for Biometrics without consulting us first – don't try to do our job, we are the experts in our field.

Our key point was that good leadership gets things done but... the quality of leadership determines the difference between a team passionate about what they are doing versus one that is simply following orders.

**To drive our point home we quoted:**

*"Surround yourself with the best people you can find, delegate authority and don't interfere as long as the policy you've decided upon is being carried out."*

**Ronald Reagan**

At this point the debate opened to the floor, with attendees then sharing the experiences they have had and this resulted in many questions to all four presenters.

Following an extensive question and answer period, the facilitator Andrew Smith took another vote to ascertain if people's views had shifted.

| **After presentations** | | |
|---|---|---|
| For motion | 15 | 39% |
| No opinion/abstain | 3 | 5% |
| Against motion | 20 | 53% |

The four presenters continued to answer questions and defend both for and against the motion.

Many powerful answers and explanations were given to the attendees highlighting the success factors of being a good project manager, including:

- The need to build trust with clients and prove to them their project has the best team.
- Assigning a team with relevant experience and good communication skills.
- Using those who are experienced in their area, and avoiding trying to become the expert in a field in which you are a novice.
- Knowing how to set-up a detailed project plan and then using it.
- Holding regular team meetings and making sure a representative from each functional group is present.
- Sending out timelines and minutes regularly.
- Asking the team for their input and listening to their response.
- Building strategic partnerships.
- Ensuring the team works as one, managing any internal politics between departments and ensuring any issues are not conveyed outside of the internal project team.
- Knowing when to escalate issues to senior management.

In the closing session, all presenters gave their final views and opinions to portray why they should win this debate.

Andrew Smith then gave a final overview before taking the final vote, which yielded the following results:

| **After discussion** | | |
|---|---|---|
| For motion | 18 | 47% |
| No opinion/abstain | 1 | 0% |
| Against motion | 19 | 50% |

The final vote confirmed that the debate had persuaded most of the attendees to form an opinion, as only one delegate remained with no opinion. You could say that the figures throughout the debate showed that those speaking for the motion were actually more persuasive, as 7 attendees swung for the motion whereas only 6 swung against. However, the final score was 19 against the motion – so theoretically we did win!

But was it really a win though? The conclusion that half of the attendees felt that data management and statistics functions are not well managed by project management is not an outcome for which any of us would hope.

The general consensus of all attendees and speakers showed there are faults on both sides and improvements need to be made by both biometrics and clinical project managers.

As a biometrics project leader, I felt communication and ensuring interaction between the functional leads was the key to success moving forward.

Others within the group felt communication was pivotal and that biometrics needs to be included in all project discussions.

Overall, the meeting was very successful as all delegates and speakers were able to understand and see weaknesses and strengths in both biometrics and clinical project management, taking away with them ideas for improvement.

***Tracy Roe,***
***Senior Manager Data Operations,***
***Kendle***

# Managing Non-Standard eData

**From time to time we are tasked with managing a piece of data that is unfamiliar to us. Our ultimate goal is to have this data available for final analysis and reporting, but how do we get it there? I hope my experience is a lesson to all who may have to follow in my footsteps!**

I encountered a compound whose protocols were collecting specialty lab data. You know the data type; the one none of your colleagues has worked with. The beauty of it, so I thought at the time, was that this particular compound was locking 4 studies in the same year so there would be efficiencies gained from 1 study to the next, right? Wrong!

The first study was locked in April and the process for working out the issues with the vendor was laborious. The database lock was delayed a couple of weeks but ultimately the issues and resolutions were well documented. We shared this documentation with the vendor as the next lock was scheduled for August. August came and went and we finally locked in September. The delay for this lock was due to the same issues from the first database lock. It's now October and we are targeting the 3rd and 4th database locks. We're confident the same issues are a thing of the past; until we received what the vendor said was the final data load. Back to square one!

One would think that working through the issues with the vendor and having a lessons learned meeting should have been enough to prevent the same issues from resurfacing from one study to the next. Arriving at database lock and not realizing that your specialty data is missing a few tests based upon the results of other test results provided, is too late. The epiphany, there needed to be more diligence in managing the expectation of the end result and that starts well before database lock.

We've all seen vendor contracts/agreements but they don't always get down to the data and if they do, it may be too technical too understand. At the onset of the study there should be an understanding of the specific data to be transferred. For example, know which tests are expected and the required format of the results. This is now achieved by reviewing the specifications at the start of the study. These specifications would include the analyses to be performed and the format and timing of data transfers.

It is ultimately the data manager's responsibility to ensure this data is as expected yet we are not always the project managers for this data. When it comes to anything data, regardless if you are the vendor liaison or not, it is your responsibility to know what to expect. The way to become immersed is to start with the protocol and any supplemental documentation that details the assessments. From there, if you have any questions, follow-up with the clinician or protocol author and obtain clarification. Meet with the vendor to discuss the project and the processes surrounding data transfer. Be sure to discuss the testing and how results will be formatted. Ask them to be specific and include "if-then" statements. For instance, some tests with positive results require an additional test. You should be aware of the tests which are analyzed in this manner.

As data is transmitted it should be reviewed to ensure expectations are being met and that there are no issues needing to be corrected. Issues flagged during review could include inconsistencies with subject id, visit name, and unexpected test results. When issues are flagged the vendor should be notified to correct them. It's extremely important that careful review is performed upon receipt of corrected loads to ensure the corrections were made.

In summary, managing vendor data does not have to be challenging. It's all in the oversight! If one has an understanding of the format and what is being collected, reconciling and cleaning vendor data can be painless. I recommend including data loaders in these discussions as well. They will know which questions to ask to ensure the data loads occur without any technical difficulty. Developing a process where the Data Loading group provides the vendor with a data format, applicable test codes, visit names, etc. along with a sample file, will lay the foundation for setting the expectations. Once this information is communicated, a test transfer and subsequent QC can be performed before the actual data is transferred. If the testing checks out and is approved then you can be more confident that the actual loads might run smoothly as well.

**"If one has an understanding of the format and what is being collected, reconciling and cleaning vendor data can be painless"**

***Brenda R. Gaines***
***Program Data Manager***
***Pfizer Global Research and Development***
***Email: brenda.r.gaines@pfizer.com***

# Conference Committee Profiles

Conference Committee

## Mr. Tom O'Leary, Global Head of Data Management, ICON Clinical Research

**The formal part...**

Tom is the Global Head of Data Management at ICON Clinical Research. He joined the company in Feb-2001 where he held the position of Manager of Data management in Dublin. He subsequently went on to set-up ICON's process improvement initiative "IMPROVE" and returned to Data Management to become EU VP of Data Management before becoming Global Head of Data Management in 2006.

From 1994-2001 he worked for SmithKline Beecham and later GlaxoSmithKline and held positions in Data Management, Project Management and resource Management. He is a graduate of Kingston University in Surrey and a Member of the Royal Society of Chemistry. He holds a Degree in Medicinal Chemistry and a Masters in Data Management.

**More about me...**

I joined the ACDM Conference Committee in 2006 as I wanted to contribute something back to the organisation and felt that being part of the Conference Committee would be a fun way to do so. I've held the position as chair of the Conference Committee for the past 2 years and have had some great fun working with rest of the conference committee team bringing together the 2008 conference and we are well on our way to the 2009 Conference as we speak. I had previously been a member of the ACDM for more than 10 years but had done little apart from reading the newsletters and attending the conference. Being part of the conference committee provides a great opportunity to shape the agenda for future conferences and gain a better understanding about how the organisation works overall.

Outside work my wife sees that I am kept pretty busy with all sorts of DIY activities but I occasionally get in a round of golf. Like all those with young kids free time tends to get eaten up rapidly, this summer saw the attention of two ponies; I'm starting to think my kids are slowly accumulating a small zoo on the quiet!

## Gail Kniveton, Global Director, i3 Pharma Resourcing

Gail joined the the CRO business as a Data Manager and has been working in Business Development and in Recruitment for data management and clinical services for the past 12 years. Gail has been involved in the development of innovative recruitment and outsourcing solutions for many clients. This has included the set-up of data management offices, recruitment and the training of teams. Gail is currently Global Director for i3 Pharma Resourcing, specialising in the recruitment of data services experts in clinical trials.

## Vicky Wiggins
## i3 Pharma Resourcing

Vicky's experience of Data Management and Clinical Research has extended over twenty years. This is comprised of Mycological Research (South African MRC) and Microbiological Research (Glaxo) plus fourteen years of Data Management experience at two pharmaceutical companies (Boehringer Ingelheim and Wyeth), an IT solutions provider (Accenture), a phase I CRO (Clinical Research Centre) and a top 5 CRO (PRA).

Vicky currently works for i3 Pharma Resourcing, contracting to GSK.

She graduated from Nottingham University with a BSc in Food Science, has been a member of the ACDM since 1995 and a conference committee member since 2006. She's been an active member of the Project Management SIG for about six years and has also attended ACDM SIG meetings for CRF design and Phase I.

I enjoy working on the ACDM conference committee, it gives me an opportunity to shape the conferences and bring interesting and varied speakers into an environment where they would not necessarily be heard by Data Managers.

My home life revolves around my husband, two sons and my two pet snakes. And if you're wondering about the photo – I don't have many of me, this one was taken at my elder son's first graduation, trying his mortar board on, since when I graduated, females did not get to wear one at graduation!!

### Miss Vivienne Yeap
### Study Data Manager
### Roche Products Limited

I graduated with an Honours Degree in Pharmaceutical Sciences from Kingston University in 2000 and went on to gain a Masters in Management of Intellectual Property from Queen Mary and Westfield University of London in 2001. From 2001-2002 I worked for the East and North Herts NHS Trusts before joining Data Management at GlaxoSmithKline in April 2002. I moved on from GSK in March 2005 to a small CRO as a Senior Data Manager/Project Manager/ Team Leader before moving to Roche Products Ltd in January 2006 as a Study Data Manager.

I joined the ACDM Conference Committee in 2007 after attending an impressive ACDM Conference in 2007. I had previously been a member of the ACDM for 6 years but had done little apart from reading the newsletters. I became part of the committee to be able to contribute and influence what is presented at the conferences and to give a little bit back. I subsequently took on the role as treasurer for the committee and haven't looked back since.

Outside work socialising with my friends and family is my first love in life. I am a massive sports fan, I watch pretty much any sport. I play a lot of netball, playing for 3 teams, captaining 2 teams as well as standing as Chair for a league consisting of 36 teams. I also run a badminton club and play twice a week.

### Claire Keith Lucas, Director Operations and Business Support, INC Research

Claire is based in the INC Research offices in Battle, UK. Famous as the site of the Battle of Hastings in 1066 but nowadays a much more peaceful environment!

Claire has been with INC since 2002 and her challenge is to provide a link between the operational DM teams and the Business Development teams globally. Data Management is one of the most complex areas for the Business Development teams to present to sponsors especially now with all the different technology options.

Previously Claire worked for Quintiles where she was fortunate to be given a variety of roles including Data Management, Project Management, Data Management Technical Training and QA Audit Support. She particularly enjoyed her time with the Technical Training group training teams all over Europe. Claire is a graduate of Sussex University with a degree in Biological Sciences. She has been on the ACDM conference committee since 2005 and considers the ACDM conference a great forum to find out how other groups approach data management with all its little twists and complexities.

Outside work activities include racing her old Jag – yes completely mad – sailing, skiing and any other outdoor activities she is allowed to have a go at.


### Dermot Kenny,, Vice President Data Management, ICON Clinical Research

Dermot is based in ICON Clinical Research headquarters in Dublin, Ireland. Dermot joined ICON in April 2001 as a clinical data co-ordinator and during the last 7 and a half years has progressed to the role of VP DM supporting ICON's data management business units in Dublin, India and Australia.

In 1996 Dermot completed a Batchelors Degree in Biotechnology at Dublin City University and after a short period of time working in the food industry Dermot moved to the UK to take up a research position with the Defence Evaluation and Research Agency in Porton Down (now known as DSTL). For the next 4 years he worked on a number of different projects in conjunction with Queen Mary and Westfield College in London and the University of Manchester developing novel antimicrobials to treat victims of potential agents of biological warfare. In 2001, he returned home to Ireland and married his wife (Samantha) before taking up a position in ICON

Outside of work most of his'free' time is spent with his two daughters although when he gets a chance he loves to play a spot of football (goalkeeper with the ICON 6-a-side), a round of golf (handicap too high for publication) or play with whatever his latest gadget is.

## FEBRUARY

### 10-13

**DIA**
22nd Annual DIA Conference for Electronic Document Management
*Philadelphia, USA*

### 25

**ACDM**
Senior CDM Forum – Assessing Risks and Contingency Planning
*Royal Statistical Society, London*

## MARCH

### 9 -10

**ACDM**
AGM & Annual Conference (book online now)
*Whittlebury Hall Hotel, Northampton*

### 9-11

**DIA**
24th Annual DIA DATA Conference & Exhibition
*Philadelphia, USA*

### 15-17

**SCDM**
2009 SCDM Leadership Forum
*Nashville, Tennessee, USA*

### 17-18

**ICR**
30th Annual Conference & Exhibition
*ICC, Birmingham*

## MARCH

### 23-25

**DIA**
21st Annual Euromeeting
*Berlin, Germany*

### 25

**CR-CSV**
CR-CSV Forum – "Pragmatically meeting regulatory expectations for Niche companies and/or Academic organisations when supporting large Pharma"
*KSAM Offices, London*

## APRIL

### 20-22

**eClinical Forum**
eClinical Forum – EU Meeting
*Helsinki, Finland*

### 22-23

**CDISC**
CDISC Interchange Europe – "Standards in Style"
*Corinthia Grand Hotel Royal, Budapest,Hungary*

## MAY

### 17-20

**PSI**
32nd Annual Conference
*Hilton Brighton Metropole Hotel, Brighton*

### 19

**ACDM**
Senior CDM Forum – Developing Strategic Partnerships
*Royal Statistical Society, London*

## JUNE

### 21-25

**DIA**
45th Annual Meeting
*San Diego, USA*

## OCTOBER

### 4-7

**SCDM**
Annual Conference
*Seattle, USA*

### 6-9

**ISOP**
9th Annual Meeting
*Reims, France*

### 7

**ACDM**
Senior CDM Forum
*Royal Statistical Society, London*

### 7-9

**TOPRA**
6th Annual TOPRA Symposium
*Clarion Hotel Stockholm, Sweden*

### 19-23

**DIA**
3rd Annual Clinical Forum
*Nice Acropolis, Nice, France*

### 28-30

**BARQA**
BARQA Annual Conference 2009
*Grand Hotel, Brighton*

## NOVEMBER

### 2-6

**ACDM**
College Week
*Details to be confirmed*



**For ACDM events contact:**
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Registration forms for ACDM events will be sent out to each member approximately three months prior to each event.

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 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**

acdm
association for clinical data management

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| | | |
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| | | |
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