

# DataMatters

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Nazma Ahmed  
Natalie Oliver  
Ali Green  
Jean Cornhill





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## Guidelines for Contributors

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

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

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

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

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

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

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## NEWSLETTER DEADLINES AND PUBLICATION DATES

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

Issue	Copy Deadline	Publication
Winter 2010/2011	13 December 2010	7 February 2011
Spring	21 March 2011	2 May 2011
Summer	21 June 2011	1 August 2011
Autumn	19 September 2011	7 November 2011

## ACDM eShots

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

## ACDM ADVERTISING

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

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

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

## ACDM ADVERTISING RATES

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Annual advert (up to 6 updates)	£700

### Website Banner advert – Home page

One month	£200
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# Planning for 2011

It's now the end of summer, nights are drawing in and the central heating has been cranked up – at least in most households except mine.

Summer ended a month and half ago courtesy of my wife and the heating has been on since. This is also the time that the conference committee start detailed planning for next year's conference. The theme next year is “Working Smarter”, which continues where last year's conference left off. In the next few weeks, you should receive details in the post. Hope you make it a point to attend, especially if you have not been to conference for a while.

Many of you may be aware that the ACDM has a sister association in the US – The Society of Clinical Data Management. For some time now, we have had in place, reciprocal agreements with them on promoting their training, conferences etc. ACDM members have also reviewed chapters of the most detailed and current manual for Data Managers *Good Clinical Data Management Practices* (GCDMP) published. The board are strengthening links between the two associations and have had several teleconferences this year. I am excited by the potential we can offer each other. – watch this space

*Fred Daniels, ACDM Chair*

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

For more information visit [www.acdm.org.uk](http://www.acdm.org.uk)

# You must be “poking”! Social Networking with the ACDM

Connections are everything these days and online social networking sites have become a foundation for thousands of businesses and individuals alike. Crucial utilities such as LinkedIn and Facebook are now integral to many parts of a professional lifestyle. Those who do not have an active online presence are getting left in the dust by the competition.

“Poking” has become the new handshake. Making friends or renewing old ones is easy, and staying in contact is a major benefit of social networking sites.

As a professional, they offer the opportunity to create a positive self-image that others can see by putting your best qualities “out there”, showing that you care about your reputation and what your peers or future employers think of you.

For this reason, the ACDM Public Relations committee consulted regular users within the membership and decided to venture down this avenue to create a thriving online community centred around the ACDM, providing opportunities for clinical data management professionals around the globe to make connections with people with similar interests and goals, connect with or meet people you may not have had the opportunity to do so before. Communication with this community is now easier than ever, enabling users to interact, share, and be informed about activities and events.

The association benefits from an international brand awareness and recognition in the wider industry, and facilitates in the building of membership.

## So, where are we now?

Since its inception in Apr 2009, we have seen a rapid growth in membership to the ACDM LinkedIn site. In those 18 months over 900 people have joined, covering a huge variety of roles from countries around the globe. It demonstrates the enthusiasm for CDM professionals to want to network.

Around July 2009, we expanded the ACDM group to include the ACDM special interest groups (SIGs) as subgroups. As you can see below, each of these are also becoming successful in attracting professionals.

ACDM LinkedIn Special Interest Groups	Number of Members
Coding and Dictionaries	78
Electronic Data	65
CDISC	54
Laboratory Data	17
Project Management in DM	17

## Networking Tips

Both companies and individuals can benefit in a variety of ways from finding the right job to increasing brand recognition for your company or department.

Join groups, and start discussions, answer some questions, post a news article because it’s human nature to enjoy gossip, but above all be an “active” group member – don’t just build a profile. You have to make things happen, and ask yourself “what value can I add today?” Take an interest in others, find a similar hobby or something in common, get to know people, offer your services, volunteer, follow people in your locality or industry. Interact because you will be amazed how much people will recognise and appreciate the sharing of your knowledge, even as simple as providing a tip.

By simply making yourself visible, valuable and memorable – others will want to make you a part of their network and follow you.

With the ACDM networking sites below, we’re hoping that our community becomes stronger, and recognises what the association has to offer. So keep an eye out for invitations to join our membership, come to our 2011 conference, join our special interest groups and senior forums. Also, watch out for those development opportunities where we will be inviting you to a variety of training courses, and of course interesting articles and news from our eShots and “Data Matters” newsletter.

**Ian Pinto**  
ACDM Director – Public Relations



# Footloose

In July this year, I took a week off from my job as a Clinical Data Manager at Cmed to moonlight as an actress and tread the boards; playing the leading lady in a production of 'Footloose – The Musical' at the Queen's Theatre in North Devon. The musical is based on the classic 80s film, and tells of a small American town where all dancing is banned following a tragic accident. That is, until city boy Ren McCormack arrives on the scene and sets about convincing the locals to bring dancing back, and cut footloose!

I played the local vicar's daughter, Ariel Moore. She wasn't a very nice character – but it was fun to act as a petulant teenager again for a few days. Being slightly too young to have experienced the 80s the first time around, this was a great opportunity to put on some leg warmers, crimp my hair, and indulge in the dubious fashion of the era!

The show features some of the big hits from the original film, such as Let's Hear It for the Boy, Holding Out For A Hero, and of course, Footloose!

Rehearsals started in March of this year, and the cast just had a brilliant time from day one, which I think really came across in the final production. I've always been more of a singer than a dancer, and found the dancing in this show a massive challenge. For a show based on a town where dancing is banned, you'd be surprised how much of it they

can squeeze in! It was physically hard work, with our choreographer working everyone into the ground. There were many days where I ached from using muscles I didn't know I had...I think during the show I was the fittest I'd ever been!!

We had a great reception from the audiences and local press...they all seemed to enjoy the show and especially the megamix at the end when the glowsticks came out. It was so much fun to be a part of and as well as the adrenaline rush from performing; you get a great sense of camaraderie with the other cast members.

This was my first lead role in a show, having started doing musical theatre when I was at University, and it's definitely given me the bug to do more. I can't wait for the next show which will be 'The Producers' in July 2011

*Natalie Oliver*



# eSource in Early Phase

## What does the Future Hold?

The idea is surely intriguing – capture clinical data electronically at the bedside where it happens and provide clean ‘Source data’ to data management in real time without any interface layer. Reduce ‘queries’ and time to database lock by minimising manual input using barcode labels, interfaced medical devices and pre-set electronic forms e.g. for laboratory requests. This is the theory behind electronic source data capture systems – briefly eSource – thus differing quite a bit from the commonly known EDC (or eCRF) systems.

But does the eSource model actually speed up data processing? What are the challenges? Does it help or hinder data management? Finally how does eSource relate to current eCRF and EDC concepts in this ever changing environment? What are the opportunities for evolution into the future? Topics discussed in this article are based on more than 10 years of PAREXEL’s data management experience specifically with regard to early phase drug development.

In the beginning of electronic support systems for the conduct of phase-I studies in the late nineties, the main focus was to provide quality assurance at the bedside. By bar-coding all three entities involved in clinical studies – volunteers with a unique identifier, staff with their personal identification (ID) and clinical supplies (such as sampling tubes) with unique, system generated numbers – and verifying the right volunteer with the right data, including server based time-stamps to all captured data, it was possible to largely avoid entry errors. By setting up a study timetable from the protocol schedule of events/procedures, it was possible to create a list for each volunteer detailing each protocol assessment to be performed throughout the study and when it was to be done. This proved particularly beneficial for the operational staff in larger, busy CROs, which usually ran multiple studies at the same time, challenging them to stay on top of the timely operational require-

ments of each study.

Early on it was clear that manual entries had to be reduced to the minimum to avoid transcription errors, thus creating clean data at the origin. To this end, interfaces to the most common medical devices like ECG, vital signs monitors, spirometry, body scales, interfaces to clinical laboratories and the like were added.

The inevitable standardisation of both procedures and medical equipment in the clinical units using the system is a desired ‘by-product’ in this equation, much appreciated by sponsors, quality departments and supporting staff.

### Integrated systems serve all departments

Market leading eSource systems have a high grade of integration, covering the complete workflow of a Phase-I unit. Project managers involved in study planning and recruitment organisers gather volunteer medical data from a database, which can be easily searched for study subjects meeting certain criteria. Core elements furthermore comprise study preparation, conduct and reporting tools. Systems thereby strictly follow the “Single Source of Truth” principle, keeping each piece of information in one place and relating to it from any other.

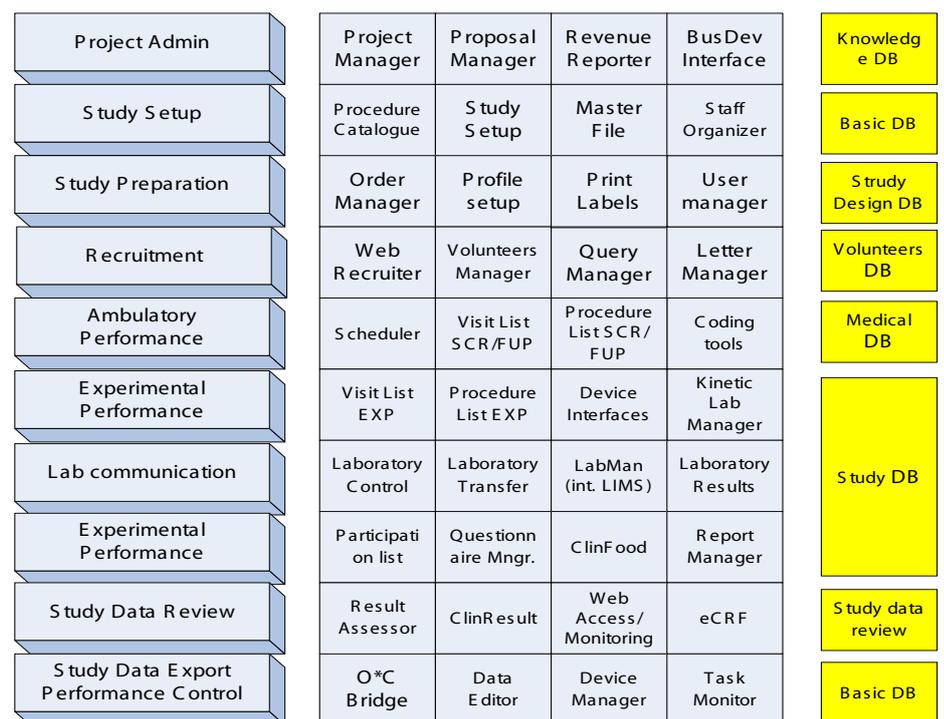


Figure 1: Workflow oriented module distribution

The use of standard procedure forms, which have to just be ‘clicked’ into a study setup and edited for their relative performance times makes protocol-required compilation of the study processes fast and reliable. Likewise, laboratory profiles (or panels) are compiled from test catalogues relating to the interfaced clinical laboratories. Upon body fluid sampling, electronic requests based on validated profiles are sent to labs without manual interference, pulling header data directly from the volunteers database and provided with automatic time stamps and staff authentication data. Should the protocol require non-standard data, individually created data entry masks are easily generated. Data forms present with simple validation checks on completeness and plausibility for their data fields, though inter-procedure checks still require additional programming outside eSource systems.

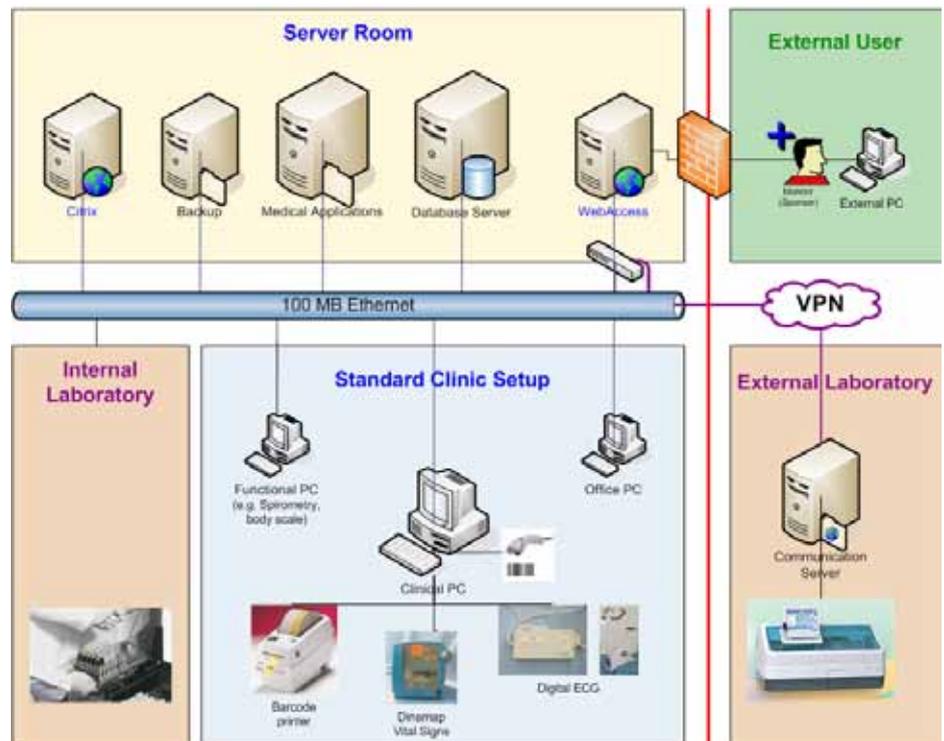
Though highly standardised, any system must be extremely flexible to accommodate a sponsor’s requirements with respect to study design and data formats. While most systems are compliant with the first requirement, the latter is more challenging to obtain. In some systems, for instance, set-up is organised into periods, study – or trial – days, treatments and groups, not allowing similar setups. Moreover, it is the nature of eSource systems to capture system-inherent proprietary data, which are not strictly required per protocol. This can be challenging for external data management teams, which may be unfamiliar with the proprietary data structure provided.

**Trial performance**

After a study is set up, validated and released for production, the remainder of the preparation for the study includes printing off barcode labels (bearing unique numeric identifiers) for fluid sampling and drug containers. The procedure schedule to operate from is automatically provided for each volunteer in each treatment group and supplied on each ward.

The performance of a time-giving event (usually dosing) triggers the insertion of

Figure 2: Typical hardware setup in eSource systems



schedule times to the listed procedures (work list) according to pre-set relative times, individually for each participant. The performance time is checked real time by the system, which enforces comments if out of the agreed time window.

After starting a procedure from the work list, procedure performance consists of scanning the subject ID (confirming the right participant), scanning of the barcodes of the medical supply (to confirm right tubes for the right timepoint). A second scan of the blood tubes after the clinical task is completed serves to record the time. Lastly, the staff authenticates their action with their personal bar-coded ID. Manual entry is only foreseen in non – standard events or procedures like demographics, medical history or adverse event (AE) questioning. The latter two are interfaced with coding tools in order to capture coded symptoms or diagnoses (MedDRA) or treatments (WHO Drug List) at origin.

The lab especially benefits from the support of the electronic tools. Scanned centrifugation times, pipetting surveillance, freezing and storage details are documented in an automated manifest along

with environmental monitoring reports, contributing to process security, ease of documentation and quality control.

**Review and assessment**

Easy to use review tools are paramount for system acceptance. A dedicated module presents all results due for medical assessment and offers batch signature for efficient performance. All trial results are presented by topic related data reports with configurable views in a dedicated module. In this module, templates are provided for data export. Based on the content usually found in CRFs, a specially configured template provides anonymous data tables via a web interface and allows remote monitoring, query management and external upload of raw data.

Database lock is done as usual at the end of the cleaning process and medical coding approval. Although for the sake of their ‘history reporting’ features, eSource systems do not archive data or delete content from the database. PDF-reports (similar to an eCRF print-out) are used to store trial data including additional documentation such as ECG tracings, spirometry reports or third party results.

**Implications for Data Management**

Though clinical teams are fond of the study management features, paperless operation and logistical support, and monitors like the total data transparency in eSource programs, data managers are not always satisfied with the data obtained from the standardised systems. For example, the data formats as well as grouping of data fields on capture forms and reports are often different from initial expectations. The broad market penetration of EDC systems during the last several years has raised awareness in sponsor companies of the manifold options that EDC can offer. EDC systems are designed and programmed strictly according to protocol and data format requirements of the recipient. Independent of what the source documentation looks like, the clinical operations function is responsible for filling in the provided eCRF fields appropriately. An eSource system in contrast, due to the high grade of processes standardisation (e.g. through hieratic device interfaces) and forms (needed for a continued documentation history throughout diverse studies) is often challenged to comply with individual sponsor requirements, which can differ from study to study. While used to dealing with CRF data, which usually come into Data Man-

agement (DM) pre-cleaned and in the sponsor-requested formats, standardised eSource data have to be reconciled and mapped by DM into the required formats, which inevitably increases the effort within the process.

Hence, while study setup of phase-I studies can be done very efficiently (usually not more than 1 week), the processing and ‘transformation’ of clinical data in DM may take an estimated 25% longer than with common EDC systems.

Moreover, data cleaning to some extent differs from the usual query process. In eSource systems there is one set of data only, which may have fairly good quality due to automated uptake, although the human factor cannot be ruled out. The question arises as to where data are edited during the query process. Obviously in these systems only source data can be modified with a reliable audit trail. A change of paradigms in DM departments has been necessary to understand and accept this technological change and to develop adequate, regulatory compliant reporting structures as well as amending timelines to account for ‘changes to a data system outside the control of DM’.

**The future of eSource capturing**

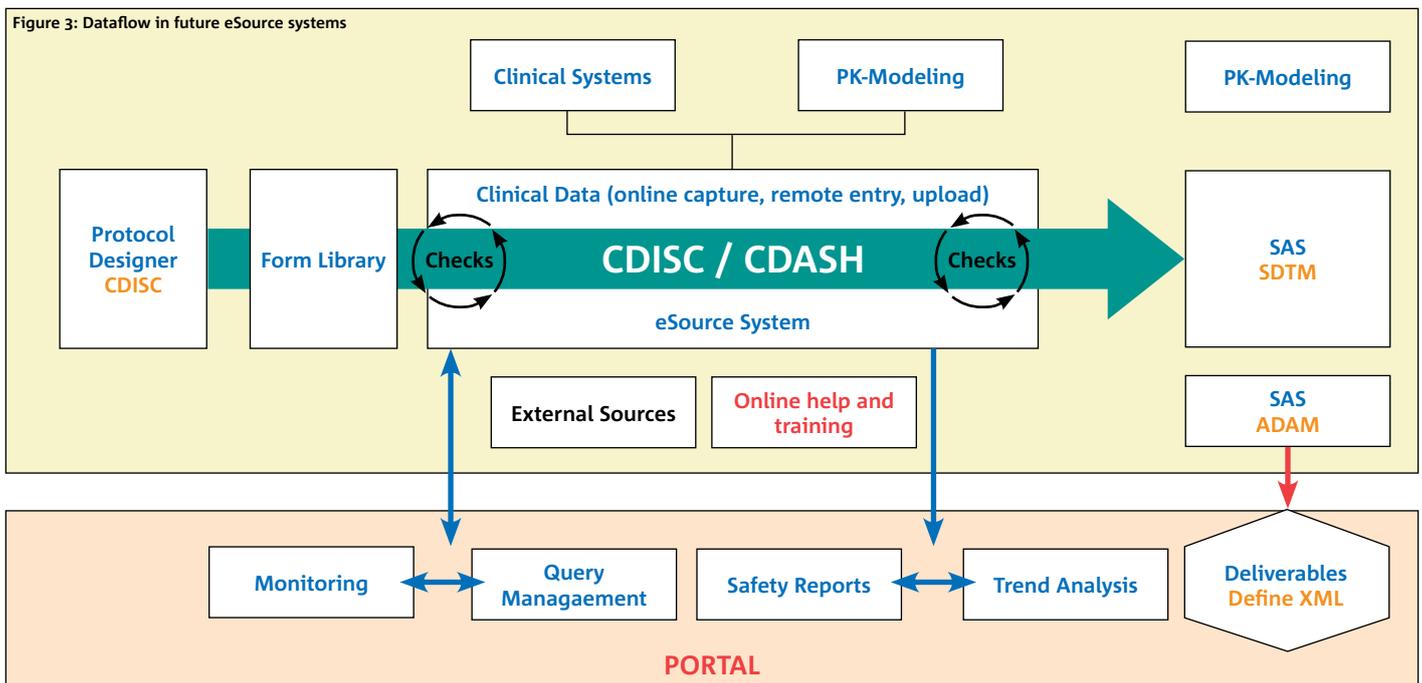
Currently this is the dilemma: eSource

systems are accepted by clinicians due to their ability to provide efficiency gains and support data quality, whereas data managers may view these systems as somewhat inflexible in their ability to accommodate sponsor required formats and the need for extra processing efforts, which is unnecessary in EDC systems.

While it makes good sense to continue direct electronic data capture at the bedside (the alternative would be ‘back-to-paper’) the shortcomings of current eSource systems should readily be remediated in order to strengthen their acceptance in the industry.

Future system development should be based on the CDISC data structure, starting with protocol creation, continued via data capture (i.e. CDASH) and ending in a smooth, highly comparable data steam into DM (i.e. SDTM) and Biostatistics departments (i.e. ADaM). This advancement would accommodate industry expectations as well as the requirements of international authorities. Therefore, clinical databases could have two layers—one which captures data from interfaced systems or devices in multiple formats, and a second layer, in which these original data are immediately mapped into the CDISC-defined format.

Benefits could also be expected from pro-



grammable checks, common in EDC programs, when built into a modern eSource system, anticipating many of the queries currently only created in DM after the delivery of final data sets, hence heavily streamlining data processing. Online coding, a feature most eSource systems provide, should be supported with study-specific catalogues already during data capture.

**Conclusion:**

Phase-I studies can benefit from standardised data capture due to their similar trial objectives (i.e. safety, tolerability, pharmacokinetics). eSource systems cap-

ture data at their origin from independent sources such as interfaced devices, thus saving the hassle of paper documentation and error-prone transcription processes. Currently Data Management teams are challenged with proprietary formats of these systems and increased processing time and efforts.

Solutions for early phase data capture systems point to a hybrid system between eSource and eCRF, composed of direct data capture features in one database layer and study specific data formats using CDISC in a second parallel layer. This combination would provide both paper-

less study management support and the streamlining of data processing, expected and required in data management.

**The author**

HD Wolfstaedter, MD, is a trained clinical pharmacologist, working in electronic data capture for the last 12 years. He leads the department of technical services that support PAREXEL's Early Phase units worldwide. His team is responsible for maintenance, support and validation of clinical systems as well as for technical innovation in the early phase clinical environment.

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# Implementation of e-Sources in a Phase I Clinical Trials Environment

Electronic case report forms (eCRFs) have gained wide acceptance in the clinical trials industry as a valuable tool to accelerate data processing and improve availability of study data. However, the initial capture of clinical data generally still involves paper-based source documents, whereas electronic source documents (eSources; source data captured initially into a permanent electronic record) are rarely employed. In this article the benefits are described of the use of eSources to increase both the quality and early availability of clinical trial data in a phase I environment. The article also gives an overview of the experience of the Early Development Services (EDS) at PRA with implementing eSources

Direct entry of source data into an eCRF can accelerate the data management process in different ways. Obviously, time is saved by removing the need to transcribe source data from paper into electronic form. In addition the source document verification step largely becomes redundant. Another time-saving feature is the potential to accelerate query resolution and thus improving the quality of the data sooner. Data entry in the eCRF is no longer performed by data entry operators separated from the clinical process in time and (usually) space, but becomes an integral part of the clinical process, to be performed immediately upon completion of each procedure and completed by the nurses and physicians directly involved. Consequently, many of the discrepancies signalled by automated data entry checks at this point can be resolved immediately by the person who triggered the query. Benefits of this are self-evident. Not only are details of the executed procedure still fresh in mind, but also the direct feedback provided by the system prevents the creation of new queries of the same type.

## Phase I clinical trials

Especially in Phase I trials, fast database lock and opportunity for early decision making are of great importance. As a Phase I/IIa clinical research organisation with clinical facilities located in the United States, The Netherlands and Central Europe, we at the Early Development

Services (EDS) unit of PRA International were convinced that to obtain the full potential benefits from the introduction of an eCRF system, this implementation had to be accompanied by introduction of the use of eSources suitable for online bedside entry as well.

Phase I clinical trials are well-suited for such an approach as these trials tend to be highly structured and each clinical procedure is scheduled at fixed time points. Having our own clinical facilities also meant that we could train clinical staff not only in medical procedures but in data capture processes too. The additional benefit is that an in-house clinic, data management and IT-services makes it easy to comply with regulations that source data remain under control of the investigator rather than the sponsor.

## Experience of PRA Early Development Services

Since December 2006 PRA EDS has conducted more than 85 trials successfully with direct entry at the bedside

of the volunteer. From the onset it was recognised that the clinical staff are an important stakeholder in making this implementation a success. Their acceptance of the system largely depended on two conditions.

The use of the system had to be no more effort than the collection on paper documents.

The clinical staff should be satisfied and confident in their use of the system.

In order to achieve this, both the infrastructure and the use of the system had to be adapted to fit the processes in the clinic seamlessly. To realise this at PRA EDS we have introduced wireless tablets, a workflow oriented design and standardisation.

## Wireless tablets

For the nurses in the clinic it was important that working with eSources/eCRFs did not limit their mobility. To allow real time access to the eSource/eCRF while retaining the required mobility of clinical staff, we chose to invest in hardware for the clinic. The phase I clinics were provided with secure wireless LAN access to the eSource/eCRF server, using laptops as clients. To allow maximum flexibility for clinical staff the laptops can be used either as tablets or as desktop.

## Workflow oriented design

When a system is used for direct entry in the system, the design of the pages should support this process in the clinic.



**A GOOD UNDERSTANDING AND EVALUATION OF YOUR CLINICAL PROCESSES AS WELL AS INVOLVING THE CLINICAL STAFF IS THE KEY TO SUCCESS**

Most eCRF pages are designed in the same way as the original paper CRF. What is on paper is now electronically available for entry. What is often lacking is the workflow. It is essential that the clinical staff who need to enter data immediately after they performed their procedure can do this quickly and easy, without a lot of clicking and searching in the system. The importance of this can not be underestimated. Most clinical staff are unfamiliar with computers, and sometimes have to enter the data in hectic situations, for example during dosing. Therefore the workflow of the eSources/eCRFs needs to be logical and support the work processes of the clinical staff.

Phase I studies have their own dynamic and differ from Phase III/IV studies. In a phase I study small groups of volunteers come in a phase I clinic at the same time for a number of days, sometimes weeks. The activities are planned to the minute. It is exactly known when a subject is dosed, when blood samples need to be drawn and when a vital sign is taken. Nurses perform the same procedure for all volunteers sequentially and don't perform multiple procedures for one volunteer in a row. This means the study nurse does not take an ECG of subject 1, then a blood pressure of subject 1 and finally a PK sample of subject 1.

Instead the workflow in a Phase I study is procedure oriented: an ECG of subject 1 and then an ECG of subject 2. Another nurse will take the blood pressures of all subjects and a third will take all blood samples. At PRA EDS, in order to match

the eSource/eCRF to this workflow, separate pages are created for each procedure on each scheduled time point instead of having an ECG and a blood pressure on one and the same page. This way each nurse will have their own page for entry and can see which page has already been entered and which not.

### **Standardisation and accessibility of pages**

Standardisation of pages for nurses is an essential step to improve familiarisation with pages and thus helps answering the questions on them. Using computers in daily life is becoming more and more natural. However, it is our experience that clinical staff generally have low affinity with computer work, and often have to enter data under hectic situations. Taking this into consideration, we took several measures to make the handling of the eSources/eCRF as easy to comply with as possible.

First, we chose to design most eCRF pages in the same way as the original paper CRF. As a result, the only difference between the paper CRF and the electronic CRF is that data is not written down, but typed into the system. This way it is easy for the clinical staff to become familiar with the new system.

Second thing we did was assign the clinical study groups to different study sites to increase rapid accessibility of pages in the system. Pages of different subjects need to be quickly accessible, so opening the blood sample page for the next subject does not take more time than opening the next page with the next procedure for the same subject. Each study site represents a group of subjects that is the same clinical study group, who have their procedures taken at the same time. This way nurses can select a study site to only visualise the pages of subjects they actually have to do procedures for. This makes navigation from subject to subject much easier and faster. The system used in PRA EDS, Oracle Clinical RDC, also supports the (de-)selection of individual subjects, giving the nurse the opportunity to

deselect the subjects who dropped out of the study, and those pages are not shown anymore. This way nurses can create a set pages that only consist of the pages they need for their procedures.

The third thing we did was to make sure that pages were named the same way each time for nurses to recognise them easily. This all may sound very logical, but is easier said than done. With a lot of people designing databases, communication is important to design in the same way, especially when new pages need to be created. Sponsors sometimes ask to change the layout of pages, or their order because they mistakenly assume this is of influence on the way they receive their final data electronically. This assumption is not true. Changing the layout or order of pages has no influence on the final presentation of the data, but it does create a potential risk for the quality of data collection. Having strict rules for the naming of pages not only benefits the clinical staff, but also the data managers and database programmers who are responsible for setting up a study. Standardisation of pages also results in a quicker database setup, with study elements that can be used for new studies.

### **Role of the data manager**

The data manager has an important role in this process. The data managers are the intermediate between the clinic, the database programmers and the sponsor. They have to make sure the wishes from the sponsor are evaluated and translated to the database programmer (for technical implementation) and the use in the clinic (regarding the layout/workflow of the eSource/eCRF). For the database programmer it is important not only to set up pages as required by the clinic, but also to maintain enough flexibility in the setup of the database, to implement amendments of the protocol in the most efficient way whenever they become applicable.

### **Common misunderstandings**

As stressed earlier, the way the eCRF is



**NOT ONLY ARE DETAILS OF THE EXECUTED PROCEDURE STILL FRESH IN MIND, BUT ALSO THE DIRECT FEEDBACK PROVIDED BY THE SYSTEM PREVENTS THE CREATION OF NEW QUERIES OF THE SAME TYPE**

designed has no influence on the way sponsors will receive their data electronically at the end of the trial (after locking the database). It is important for people to understand that the setup of the database leaves complete flexibility regarding the final data transfer, but can be of major effect on both quality and efficiency of the data collection in the clinic.

It should also be clear from the beginning, what pages are eSource pages only and what pages are not only eSource, but also marked as eCRF page. Some sponsors are still reluctant to use eSource in a clinical trial, also for a Phase I trial.

There are several returning arguments used in this discussion. First, there is the undocumented fear of losing data. However, backups are in place and it is much more difficult to lose an electronic record than a piece of paper. It is also assumed that clinical staff will make more errors

electronically than on paper. But truth is that a paper source accepts all entries while real time discrepancies are created when using eSource. Reluctant sponsors also doubt if eSources comply with regulations. But they do. See for example the document “Leveraging the CDISC Standards to Facilitate the use of Electronic Source Data within Clinical Trials” (20 November 2006). In this document twelve requirements are described for conducting regulated clinical research using eSource data collection in the context of existing regulations. They provide the basis for acceptability of eSource data. Recently the GCP Inspectors Working Group has sorted these 12 requirements into 5 topics and the document represents the current expectations of the GCP Inspectors on using eSources: “Any departure would need to be justified.” See “Reflection paper on expectations for electronic source data and data tran-

scribed to electronic data collection tools in clinical trials – GCP Inspectors Working Group (GCP IWG) – 09 Jun2010”.

**Conclusion**

The conclusion is that an eCRF can be used in a phase I situation to collect data electronically at the bedside and therefore becoming an eSource as well. eSources are an opportunity to increase both quality and rapid availability of your data. It is important to understand that implementing an eSource for direct data collection is much more than just buy, validate and start using the system. A good understanding and evaluation of your clinical processes as well as involving the clinical staff is the key to success.

**Anja Koster**  
**Senior Data Management Specialist**  
**(Early Development Services)**  
**PRA International**

 **Website**  
*Committee*

## Making Progress

With only two members we are still finding it hard to progress things quickly however we have made some progress this month:

- We have identified some new banner images which will be updated onto the website shortly
- We will be amending the home page banner shortly to enable us to display multiple images at once and so hopefully attract more advertising
- We are hoping to implement a job search functionality on the home page – look out for this in the future.
- We are also in talks with the newsletter committee on ways to make the newsletter more interactive – if you have any ideas please contact us

As usual we continue to send reports to the PR committee and BoD on website traffic and eShot opening rates – you will hear more about this shortly.

**As usual if you know of anyone who is interested in joining our committee or if you would like to send us some feedback on the website please email [admin@acdm.org.uk](mailto:admin@acdm.org.uk)**

 **Training**  
*Committee*

## Update from...the Training Committee

The training committee have been busy assessing which courses to offer over the next year. They are particularly interested in receiving feedback from SIGs (Special Interest Groups) and identifying ‘hot topics’ on which new training courses can be developed. The committee are also working on how best to promote the courses that are currently available.

The team are currently exploring various options for making recordings of webinars available and are looking into the logistics of how to provide this as a cost effective and flexible service

In the near future, the committee will also be looking to revamp the training section on the ACDM website, so watch this space!

**For more information on the current training courses offered by the ACDM, please visit: [www.acdm.org.uk/generic\\_6.aspx](http://www.acdm.org.uk/generic_6.aspx)**

# Perls of Wisdom: Using Regular Expressions in SAS V9 to Catch text of Special Interest

Although both adverse event data and concomitant medications are more often than not coded to make it easy to identify particular events or medications of interest, there can be times when this is not the case and all that is available are free text fields. Similarly, there may be comment fields for other types of data that contain valuable information, for example a particular reason for withdrawing from a study may only be collected in the comment field when 'Other' is checked on the withdrawal page of a CRF.

Free text fields are far from ideal when programming, as they can contain spelling mistakes plus numerous variations of spelling the same thing. Although there have always been ways of identifying specific text from a text field, such as INDEX, SCAN and SUBSTR functions, regular expressions allow for much more accuracy and flexibility.

This article aims to provide a number of practical examples of identifying items of special interest from free text fields using perl regular expressions functions available in SAS® v9.

## What are PERL Regular Expressions in SASv9?

**Regular Expressions (regex or regexp)** *'provide a concise and flexible means for matching strings of text, such as particular characters, words, or patterns of characters. A regular expression is written in a formal language that can be interpreted by a regular expression processor, a program that either serves as a parser generator or examines text and identifies parts that match the provided specification.'*

The simplest form of a regular expression is just a word or a phrase for which to search.

The following are few examples of text which could be expressed as the regular expression `"/Hypertension/"`

- Hypertension
- Arterial Hypertension
- Arterial Hypertension [170/100 mm Hg]

`"/Hypertension/"` would be the simplest form of a regular expression for the word 'Hypertension'.

This regular expression would not identify mixed case variations or common spelling mistakes such as:

- Arterial hlpertension
- Aggravation of arterial hypertension
- The patient had high arterial HYPERTENSION (190/90, 200/100) during 4 days

`"/h(y|i)ptension/i"` would be more successful in indentifying these. (A break down in what the brackets, i and | mean will be

described later in the article whilst discussing the examples.)

SAS functions that implement regular expressions called RX functions have been around for quite some time when SAS® v8.1 was released in 2000. However, the introduction of PRX functions in SAS® v9 when it was released in 2008 gave the user nearly all of the Perl regular expression functionality. The benefits of PRX functions being; that they are faster, flexible and the syntax is very similar to Perl itself.

## Down to Basics

### Two-Step process

The PRX functions that this article focuses on are [PRXPARSE](#) and [PRXMATCH](#).

**Step 1:** Before a regular expression can be used it needs to be defined. This can be done by using the [PRXPARSE](#) function. Once the variable using [PRXPARSE](#) function is created, it can be used as an argument to other PRX functions, such as the [PRXMATCH](#) function.

In the following SAS code the PRXPARSE function is used to create the variable `hypertension_regex`, which contains a number that identifies the regular expression `"/h(y|i)ptension/i"`.

```
retain hypertension_regex hurt_regex;
**create regular expressions **;
if _n_ = 1 then do;
  hypertension_regex = PRXPARSE("/h(y|i)ptension/i");
/*Number 1 */
```

```
hurt_regex = PRXPARSE("/headache/i"); /*Number 2 */
end;
```

The first regular expression that is created using the `PRXPARSE` is given the number '1', the second is given the number '2' and so on. The second regular expression in the example above, `hurt_regex`, is not used in this example but just given for illustrative purposes.

USUBJID	AETERM	hypertension_regex
TEST0697146189	Arterial Hypertension [170/100 mm Hg]	1
TEST0697146190	Increased libido	1
TEST0697146193	hemorrhoidal bleeding	1
TEST0697146208	Cold	1
TEST0697146211	Arterial Hyertension	1
TEST0697146215	Arterial Hypertension	1
TEST0964294931	Aggravation of arterial hypertension	1
TEST0964294932	Back Pain	1
TEST0964296315	arterial hypertension	1
TEST0964296315	abdominal pain	1
TEST0964296316	weakness	1
TEST0964296320	hyperthermia	1
TEST0964296320	ALT elevation	1

Both the `DO` loop and the `RETAIN` statement are only required to save processing time and memory. (The expression would be parsed new for every record with them.)

**Step 2:** Use the variable `hypertension_regex` created using `PRXPARSE` as the first argument to the function `PRXMATCH` with the text field to be searched (`aeterm` in this case) as the second argument.

```
**search the regular expressions in the text string **;
if PRXMATCH(hypertension_regex,aeterm)>0 then flag=1;
else flag=0;
```

`PRXMATCH` returns the start position of the pattern defined by the regular expression `hypertension_regex` found in the text, `aeterm`. Hence, a flag can be created.

The dataset below also including the variable `PRX` to illustrate, that `prx = PRXMATCH(hypertension_regex,aeterm);` returns the start position of the pattern defined by the regular expression `hypertension_regex` found in the text within `aeterm`.

USUBJID	AETERM	hypertension_regex	prx	flag
PRX_TEST537146189	Arterial Hypertension [170/100 mm Hg]	1	10	1
PRX_TEST537146215	Arterial Hypertension	1	10	1
PRX_TEST358911610	hypertension	1	1	1
PRX_TEST358911811	Cold	1	0	0
PRX_TEST384294931	Aggravation of arterial hypertension	1	25	1
PRX_TEST384265428	The patient had high arterial hypertension (190/90, 200/100) during 4 days,	1	32	1
PRX_TEST399468510	arterial hypertension	1	10	1
PRX_TEST399468553	crisis of arterial hypertension	1	20	1
PRX_TEST423666972	Acceleration of hypertension	1	17	1

### The Rules

Already mentioned was the fact that `"/Hypertension/"` would be the simplest form of a regular expression for the word 'Hypertension'. This is however very inflexible and would not pick out all possibilities of 'Hypertension' within a free text field. `"/h(y|i) pertension/"` is slightly better, not perfect but a start for trying to explain what the various regular expression syntax rules are.

The table below provides descriptions of some regular expression syntax rules:

Regular expressions in SAS are enclosed with forward slashes to denote the beginning and end of the expression.	/	/hypertension/
The "i" after the second slash tells the parser to ignore case when matching the expression.	i	/hypertension/i
The vertical bar separates alternatives. So hypertension can be spelt 'hypertension' or mistakenly 'hipertension'.		/h(y i)pertension/i
The parentheses group the alternation, so the 'y' or 'i' can only come after h and before 'pertension'.	(y i)	/h(y i)pertension/i
The optional indicator "?" tells the parser that the character immediately proceeding "?" may or may not occur.	?	/hy?pertension/i
The dot "." is a wildcard that matches any single character.	.	/hyper.tension/i
The "\" Indicates that the last character is a literal period and the dot, "." should not be matched as a wildcard.	\.	/hypertension\./i
An asterisk indicates that any number of the preceding character(s) is allowed but none are required.	*	/hypertension.Hg/i

These are a few examples of rules that can be applied when working with regular expressions. Combinations of the above rules are used to illustrate their use in clinical trials data in the following examples.

### EXAMPLE 1

Throughout a study we would like to monitor the number of subjects with hypertension. The data is coded but coding is not up to date. This is an example of using SAS v9 perl regular expressions to identify all the records where subjects have hypertension recorded in the AETERM variable within the AE dataset.

```
data hypertension_1 ;
set derived.ae_rx (keep=usubjid aeterm );
retain hypertension_regex ;

**1.create regular expressions **;
if _n_ = 1 then do;
hypertension_reg_ex = PRXPARSE("/h?(y|i)?p?(er)?-?(ten|i?o?n)/i");
end;
```

"y" or "i" may or may not occur.

There maybe a 'p' or 'er' or '-' in that order after 'hy' or 'hi'

The text needs to include 'ten' but 'i' may or may not be after. Similary 'o' and 'n'.

```
**2.search the regular expressions in the text string **;
if PRXMATCH(hypertension_regex,aeterm)>0 then flag=1;
else flag=0;

*alternative;
flag_test = min(PRXMATCH(hypertension_regex,aeterm),1);
run;
```

Subject ID	Hypertension	Flag
1	Adverse hypertension (170) Fit not fit	1
2	Adverse Blood	0
3	Adverse Blood	0
4	Adverse Blood	0
5	Adverse hypertension	1
6	Adverse hypertension	1
7	Adverse of Carotid neck death	0
8	Adverse Blood	0
9	Adverse Blood	0
10	Adverse Blood	0
11	Adverse Blood	0
12	Adverse Blood	0
13	Adverse Blood	0
14	Adverse Blood	0
15	Adverse Blood	0
16	Adverse Blood	0
17	Adverse Blood	0
18	Adverse Blood	0
19	Adverse Blood	0
20	Adverse Blood	0
21	Adverse Blood	0
22	Adverse Blood	0
23	Adverse Blood	0

### EXAMPLE 2

Throughout a study we would like to monitor the number of subjects with headache. The data is coded but coding is not up to date. This is an example of using SAS v9 perl regular expressions to identify all the records where subjects have headache recorded in the AETERM variable within the AE dataset.

```
*** Identify Headache using Perl RX ***;
data headache (where=(flag=1));
set derived.ae_rx (keep=usubjid aeterm );
retain headache_regex;

**1.create regular expressions **;
if _n_ = 1 then do;
headache_regex = PRXPARSE("/h(a|e)?e?a?d|?-?.(ache)/i");
end;
```

dot "." is a wildcard that matches any single character, so you could have 'headzache' for example but would normally be used for a blank space.

The text needs to include 'ache' .

```
**2.search the regular expressions in the text string **;
if PRXMATCH(headache_regex,aeterm)>0 then flag=1;
else flag=0;
run;
```

Subject ID	Headache	Flag
1	Head ache	1
2	Headache	1
3	Head ache	1
4	Headache	1
5	Headache	1
6	Headache	1
7	Head ache	1
8	Headache	1
9	Headache	1
10	Headache	1
11	Headache	1
12	Headache	1
13	Headache	1
14	Headache	1
15	Headache	1
16	Headache	1
17	Headache	1
18	Headache	1
19	Headache	1
20	Headache	1
21	Headache	1
22	Headache	1
23	Headache	1

**EXAMPLE 3**

‘Lost to follow-up’ was not recorded as a check box on the CRF, it was only possible to identify subjects who were ‘Lost to follow-up’ within a free text field. This is an example of using SAS v9 perl regular expressions to identify all the records where subjects have ‘Follow-up’ recorded in the DSTERM variable with the DS dataset.

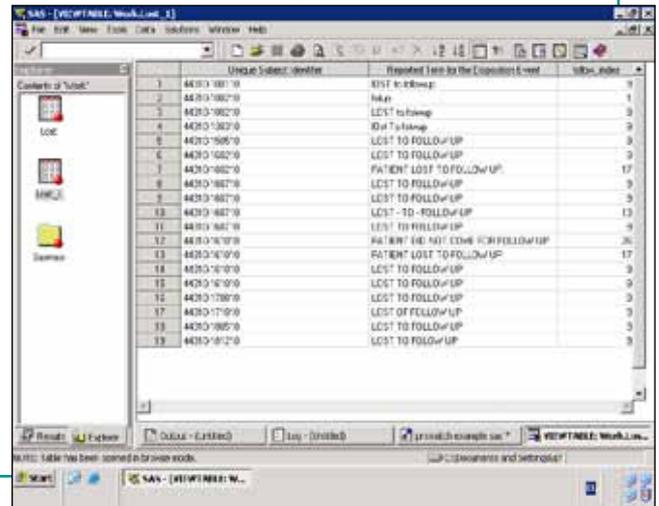
```

*** Identify Lost to Follow-up using Perl RX ***;
data lost (where=(follow_index>0) keep = usubjid dsterm follow follow_index);
set derived.ds_rx (keep=usubjid dsterm);
retain follow ;

**create regular expressions **;
if _n_ = 1 then do;
follow = PRXPARSE("/fol?!?o?w?.??.(up)/i");
end;

**end if first iteration of dataset**;
**search the regular expressions in the text string **;
follow_index =PRXMATCH(follow,dsterm);
run;
    
```

‘i’ allows for mixed case .



**Conclusion**

Regular expressions can be a very powerful tool when trying to capture data of particular interest from text fields, and can help you obtain useful information from data that due to inconsistent spellings and formats is usually very difficult to obtain anything useful from. Using this knowledge could allow us to create simple standard macros that could be created as search tools.

This article has only scratched the surface of what we can achieve with perl regular expressions but I hope it will inspire you to investigate further and allow you to begin your searches using them with more confidence.

**Contact Information**

Your comments and questions are valued and encouraged.

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 www.quintiles.com**

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**References**

- Wikipedia [http://en.wikipedia.org/wiki/Regular\\_expression](http://en.wikipedia.org/wiki/Regular_expression)
- ‘An Introduction to Regular Expressions with Examples from Clinical Data’ Richard Pless, Ovation Research Group, Highland Park, IL <http://www2.sas.com/proceedings/sugi29/043-29.pdf>

## So Much to Learn and Share

NAME: Nazma Ahmed  
 ACDM POSITION: Secretary, Newsletter Committee  
 COMPANY: GlaxoSmithKline



### Provide a brief summary of your life/education etc to date

I got my first exposure into the pharmaceutical industry during my university placement at Roche Products Ltd. during '2003-2004, where I worked as a Global Clinical Trial Assistant (GCTA) on Phase II-IV studies. I really enjoyed the year and gained a real insight into the drug development process. After graduating with a Biochemistry degree from the University of Hertfordshire, I knew I wanted to go back to working for a pharmaceutical company. Being a new graduate, I had the mentality of finding any scientific job than not having a job at all! As a result, I took the position of a Clinical Data Scientist in Clinical Data Management for GSK in 2006 (which I accepted immediately as I was completely unaware of what I was letting myself in for!). I have now been at GSK for nearly 5 years (the time has definitely flown by...) and continue to work as a data scientist in the Oncology department.

I have been on the ACDM newsletter committee since 2006. I enjoy networking with people from different companies – there is so much to learn and share from each other's experiences!

### If you were not in the job you are in, what would you do?

I would like to be a Travel writer... It would be fantastic to experience all the different cultures and traditions across the globe (and sample different cuisines of course!)

Or even better I would love to have the power to be a 'Jumper' as seen in the film 'Jumper'. It would be amazing to

be able to teleport yourself anywhere in the world in the blink of an eye through your own personal wormhole. How great would that be...?

### What has been your greatest achievement to date?

My little girl

### What lesson has life taught you so far?

There is a lot more to life than just work... make the time to enjoy it!

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

I asked my colleague sitting next to me and she said I don't have one....

### What is your greatest fear?

Creepy-crawlies.....urgh!

### If you were on a desert island, which three things would you take with you and why?

Food... I love to eat....

Book – I enjoy reading but just don't have the time...

A hat – for shade from the sun

### What do you do to relax / what are your hobbies?

Doing activities with my daughter, socialising with friends and family, reading, watching TV (when I get a chance!)

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## I wanted to be an Astronaut!

NAME: **Natalie Oliver** ACDM POSITION: **Newsletter Committee**  
COMPANY: **Cmed (Clinical Research Services) Ltd**



### Provide a brief summary of your life/education etc to date

I am still fairly new to Data Management, having graduated from the University of Portsmouth with a Biology degree in 2007. I started working for Cmed in November 2007 and have had nearly three (already?) enjoyable years there to date, with plenty of challenges and rewarding experiences so far. I currently work from home in North Devon.

### If you were on a desert island, which three things would you take with you and why?

Music – I couldn't cope without it! Pen and Paper – so I could write the novel I've always wanted to. A Speedboat – so I could get back to civilisation

### What has been your greatest achievement to date?

I spent three months in Namibia, Africa with a charity in 2004, as part of a school building project. It was an amazing

time, seeing the impact we had made on the community and exploring this fantastic country. We slept out under the stars every night, developed a really close team bond and saw some breathtaking landscapes and wildlife every day. I would go back tomorrow.

### If you were not in the job you are in, what would you do?

Astronaut (despite having a massive fear of flying...which might be a little bit of a problem). When I was younger I genuinely believed I was going to be an astronaut when I grew up.

### What makes you happy?

Being with people I love, music and sunshine. And eating!

### What famous person in history or present day would you most like to meet and why?

John Lennon – I'm a huge fan of The Beatles.

## Making a difference

NAME: **Ali Green** ACDM POSITION: **Editor/Chair, Newsletter Committee**  
COMPANY: **Nutricia Liverpool**



### Provide a brief summary of your life / education etc to date

I grew up in Suffolk and Essex, moving to London when I was 18 to study for a degree in Applied Biology at the University of Greenwich. I was introduced to Data Management via my sandwich year placement in the Clinical Data Management department at GlaxoWellcome (as it was then). I returned to university to complete my degree and then was lucky enough to be offered a job as a Data Manager at GlaxoWellcome. I stayed at GSK for quite a few years, working for a brief spell in the GSK UK offices, I worked in a variety of therapeutic areas – HIV, Infectious diseases, Migraine, Smoking Cessation and Respiratory to name a few! I followed my partner up North and took a job as a Senior Data Management Technology Analyst at AstraZeneca. Following the birth of my second child, I worked briefly at the Christie Hospital in Manchester before finding my current role as the Clinical Data Manager at Nutricia Liverpool. I now work in clinical trials for Foods for Special Medical Purposes (also known as medical foods), in areas such as allergy (mainly infant formulas for children with cows milk allergy), and inherited metabolic disorders such as PKU. It's a very interesting job

and the regulations that govern the clinical trials in non-IMPs are different to IMPs so there has been much to learn. I have been on the Newsletter committee for about 6 years and have been editor /chair from 2006 – 2008 and returned as editor/chair at the end of 2009.

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

I must say 'cool' about 100 times a day..

### If you were not in the job you are in, what would you do?

I like being creative and enjoying making cards and cakes, although maybe these are best kept as hobbies!

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

Making a difference

### What makes you happy?

Listening to the kids talk in such an excited manner about something that I can't understand a word they are saying! It always brings a smile

## Tables turn on the Birdwoman!

NAME: Jean Cornhill

ACDM POSITION: Lead Proofer, Newsletter Committee

COMPANY: PAREXEL International Limited



The tables have been turned – instead of me asking others for a profile for the newsletter, I have been asked to provide one of my own. So, here goes...

My working life started in 1977 as a Secretary, until the birth of our Son in 1988 (in between these two dates, I married Ken in 1981 and moved from Berkshire to Kent at the start of married life). We decided that I should be a full time Mum until George started school and this turned out to be a very special time, being around for all the important baby and toddler milestones, as well as the small everyday ones.

Once George started infant school, I had spare time on my hands. As I knew how to type very fast and accurately, I landed a casual data entry position for a CRO called asru, located on the campus of the University of Kent at Canterbury. During my interview, I was asked if I would have a problem working to Standard Operating Procedures – my answer was I didn't think so, little knowing at that time how important SOPs would become to my working life. This casual job developed into a full time permanent Data Entry position, transforming into a job as a Clinical Data Manager and Data Entry Supervisor responsible for a dedicated data entry team, mostly made up of casuals. After more than seven years with asru, we decided to move from Kent back to my birth town of Newbury in Berkshire, where, in September 2000, I started a Data Manager position with Phoenix International, which became part of MDS Pharma Services three weeks later. The role of Data Entry Supervisor was also added to my DM role after a year or so.

In 2003, my supervisor attended the ACDM Conference and, on her return to the office, suggested that I should join the Newsletter Committee as they had been recruiting for new members. Committee members have come and gone, but we have always worked extremely well as a team to meet the quarterly challenge of sourcing articles to fill the space in the next newsletter. My 'eye for detail' as a data manager and more recently as an auditor has proved invaluable as proof-reader of the newsletter. Around the end of last year, I was 'promoted' to Lead Proofer.

At the beginning of 2004, a QA auditor position became available at MDS. It is still strange to be treated differently once people know that you are an auditor. I will always remember the reaction of a delegate at the 2006 ACDM Conference. She noted my delegate badge with my company name and asked about my job position – on hearing that I was

a QA Auditor, she took one step back and said, "Really?"

Since March 2009, I have worked for PAREXEL, travelling to many worldwide destinations. My previous experience as a Data Manager has been put to good use and my auditing focus is mainly on DM and Statistics, although I am involved in a variety of auditing activities. As I have a very understanding husband, who is more than capable of looking after himself, and a grown up son, who is married with a four year old daughter, I am very flexible and take things as they come because schedules can change suddenly. I am writing this profile in a Berlin hotel, having spent an unplanned weekend sightseeing between audit activities at our German office – I was to have been sightseeing in Poland prior to an audit the following week, but, as I mentioned, schedules can change suddenly!

Well, that has covered the working side of my life, as well as something about my family.

As to what I do in my free time – previous readers of ACDM newsletters may remember that I am a Samaritan volunteer and have been known to jump off Bognor Pier to raise funds for my local branch (in a previous newsletter I was labelled as the ACDM Birdwoman of Bognor); I enjoy reading, travelling, photography, keeping pets and spending quality time with my family, when circumstances allow.

There – profile complete, without even having to answer questions such as "What 3 things would I take with me on a desert island?" or "Which 6 famous people would I invite to a dinner party?"



## NOVEMBER

**31 Oct – 5 Nov**  
**CDISC**CDISC Interchange  
North America  
*Renaissance Harborplace  
Hotel, Baltimore, US***3**  
**ACDM**Essential Skills for  
Supervisors & Line  
Managers  
*Webinar***3-5**  
**DIA**8th DIA Annual  
Canadian Meeting  
*Westin Ottawa Hotel,  
Ottawa, Canada***3-5**  
**ISoP**Autumn US Workshop/  
Meeting  
*Fort Lauderdale,  
Florida***1-5**  
**TOPRA**Autumn Regulatory  
Affairs Introductory  
Course  
*Andels Hotel, Prague,  
21 Stroupežnického  
150 00, Prague,  
Czech Republic***2-5**  
**BARQA**2010 Annual  
Conference  
*The Queens Hotel,  
Leeds, UK***3-6**  
**ISoP**10th Annual  
Meeting  
*The Palm Royal Beach  
hotel, Accra, Ghana,  
Africa*

## NOVEMBER

**7 Nov – 3 Dec**  
**SCDM**Project Management  
for the Clinical Data  
Manager  
*Online***11-13**  
**DIA**4th Annual Clinical  
Forum  
*Lisboa Congress Centre,  
Lisboa, Portugal***11-18**  
**SCDM**CDISC  
*Webinar***17**  
**ISoP**BoF: CDISC Experiences  
(4th discussion)  
*Teleconference***23**  
**ACDM**Preparing for a  
Regulatory Inspection  
*Webinar***23-25**  
**TOPRA**MSc in Regulatory  
Affairs: Module  
5 – Regulatory  
Control of Clinical  
Operations  
*The Bull Hotel, Oxford  
Road, Gerrards Cross,  
Buckinghamshire,  
SL9 7PA, UK***24**  
**TOPRA**Basics of Regulatory  
Affairs  
*Crowne Plaza Brussels, Le  
Palace, Rue Gineste 3,  
1210 Brussels, Belgium*

## NOVEMBER

**24-25**  
**PSI**Introduction To  
Pharmacokinetics and  
Bioequivalence  
*De Vere Denham Grove,  
Tilehouse Lane, Denham,  
Buckinghamshire,  
UB9 5DU, UK***29-30**  
**DIA/ EMA**2nd Joint DIA/  
European Medicines  
Agency Innovation  
Forum  
*Marriott West India Quay,  
London, UK***30 Nov – 1 Dec**  
**PSI**Introduction To R for  
Statisticians in the  
Pharma Industry  
*De Vere Denham Grove,  
Tilehouse Lane, Denham,  
Buckinghamshire,  
UB9 5DU, UK*

## DECEMBER

**1**  
**PSI**Non-Inferiority  
Trials – Latest  
Perspectives  
*Glazier's Hall, 9 Montague  
Close, London Bridge,  
SE1 9DD, UK***1-3**  
**DIA**11th Conference  
on European  
Electronic Document  
Management  
*Hotel Le Meridien,  
Nice, France*

## DECEMBER

**6-7**  
**TOPRA**The Annual European  
Medicines Agency  
Review of the Year and  
Outlook for 2011 and  
beyond  
*The Marriott Hotel  
Grosvenor Square,  
Grosvenor Square,  
W1K 6JP London,  
UK***7**  
**ACDM**Recent Developments  
in GCP &  
Regulations  
*Webinar***7-9****TOPRA**  
MSc MTRA: Module  
6 – Regulation of Drug-  
Device Combinations  
and other Medical  
Technology Products  
*Cranfield University,  
Cranfield, UK***8**  
**TOPRA**CRED: Introduction to  
eCTD  
*TOPRA Office, Bellerive  
House, 3 Muirfield  
Crescent, E14 9SZ,  
London, UK*

## FEBRUARY

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

## MARCH

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

## APRIL

**5-7**  
**TOPRA**MSc in Regulatory  
Affairs: Module 12  
– Medical Device  
Regulatory Affairs  
*De Vere, Tilehouse Lane,  
Denham nr Uxbridge,  
Buckinghamshire  
UB9 5DU, UK***11-15**  
**CDISC**CDISC Interchange  
Europe 2011  
*Crowne Plaza Brussels  
– Le Palace, Rue Gineste  
3, B-1210 Brussels,  
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## JUNE

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