Winter 2013/2014 • ISSUE 88

acdm
association for clinical data management

DataMatters

ARTICLES

Straight from the Horse's Mouth: Is this the Future of Post Marketing Adverse Event Reporting?

Key Points in Setting-up and Conducting a Clinical Trial from a Monitor and Data Manager Perspective

TRAINING NEWS

Community of Trainers

PROFILES

Andrada Pasca, Ian Marlow, Jean Cornhill and Anamaria Cristine Stancu

Newsletter Committee
Email to the Editor: editor@acdm.org.uk

Jean Cornhill (Chairperson/Editor)
PAREXEL International Limited
Tel: 01895 614539
Email: jean.cornhill@parexel.com

Andrada Pasca
Cmed Clinical Services
Tel: +40 (0) 356 433 916
Email: apasca@cmedresearch.com

Cristine Stancu
Cmed Clinical Services
Tel: +40 (0) 356 433 970
Email: cristine_stancu@yahoo.com

Ian Marlow
CK Associates Limited
Tel: 01438 743047
Email: imarlow@ckclinical.co.uk

Guidelines for Contributors

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

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

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

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

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

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

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

NEWSLETTER DEADLINES AND PUBLICATION DATES

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

Issue	Copy Deadline	Publication
Spring 2014	14 March	5 May
Summer 2014	13 June	4 August
Autumn 2014	12 September	3 November
Winter 2014/2015	12 December	2 February 2015

ACDM eShots

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

ACDM ADVERTISING

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

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

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

ACDM ADVERTISING RATES

Effective from 1st February 2010

Newsletter

Full Page Colour* £300
Half Page Colour* £200

Web Advertising (under recruitment or services)

One month* £150
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

Website Banner advert – Home page

One month £200
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

Website Banner advert – other pages (excluding home page)

One month £150
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

eShot advertising

One month (eShot sent at least twice a month) £150

* bulk discounts available – please contact the ACDM office for details (Tel: +44 (0) 1727 896080, email: admin@acdm.org.uk)

Download the latest advert specification sheet from the adverts section of www.acdm.org.uk

All items, excluding membership and publications, will be subject to VAT

CONTENTS

Paul Fardy – ACDM Chair

Looking Ahead...

As we welcome in the New Year, I would like to wish everyone a happy and healthy 2014. It is at this time people look back over the last year, recall what they have achieved and what they were unable to do. It's also the time to look ahead and make resolutions and plans.

During the last year we had an excellent conference, very well received, and content rich. Having now seen the published agenda, this year's conference promises to be even better, with respected speakers from our industry delivering presentations aligned to developmental objectives. Please make sure that you take the opportunity to be part of this important event of the calendar year.

Our training offerings go from strength to strength and, as well as the public courses, we have seen a large uptake to run company specific courses. 2014 will see the introduction of an accreditation scheme, which will increase the reputation of data management as a career choice as well as enhancing individual opportunities.

I have mentioned in previous newsletters the establishment of an eClinical sub-committee; this will start to take shape in the New Year. It will provide a multi-disciplinary forum which I would like to see redefine and evolve the role of data managers.

Our association with the Computer System Validation (CSV) group continues and we are proud to sponsor the new CSV Guidelines that are due to be released early in 2014.

This will be my last newsletter as ACDM Chair, so I would like to thank the Board of Directors for their help and support during my tenure, as well as the Committees and SIGs that continue to play an important role in providing members with the opportunity to share thoughts, ideas and best practices. If you haven't already, please make it one of your resolutions to join one of these groups.

Newsletter
Committee

Newsletter Committee Report


Jean Cornhill

NEWSLETTER COMMITTEE

Great news! I am pleased to inform you that three members have joined the Newsletter Committee.

Cristine Stancu and Andrada Pasca, both from Cmed Clinical Services, and also Ian Marlow (from CK Clinical) are welcomed – please read their profiles in this newsletter to learn more about them – I have also updated my profile to complete the Committee Profiles. Having more Committee Members means that we can share out some of the responsibilities.

However, it would still be great to have at least a few more bodies on the Committee so if you are interested or know somebody who would like to become involved, please send an email to editor@acdm.org.uk.

ACDM CONFERENCE 2014

If you are able to attend the next ACDM Conference, please consider writing an article. This could be a write up on one of the presentations or your Conference experience as a new delegate or a regular attendee. The Conference Special is always packed full of articles and photos – in order to achieve this, we need input from delegates to provide write ups as these will be of special interest to all members.

NEWSLETTER ARTICLES

Remember that you do not need to wait to be approached before you write an article – you may submit an article at any time to the editor's email address (editor@acdm.org.uk). As mentioned before, articles can be on almost any subject – either industry related or something more personal. This could be a 'Day in the Life of ….' so that you can explain a typical, or perhaps not so typical, day in your job role. You may like to make everybody jealous and report on a wonderful holiday destination. It may be on a life-changing experience which you are happy to share with members.

The Newsletter Committee have decided to try out some ideas in forthcoming Newsletters:

- There will be a series of articles similar to a 'Day in the Life of ….'. This will follow some of the key areas and roles involved in Clinical Research as follows:
  - Project Management/Regulatory/Safety/Medical Writing
  - Study Start Up/Sites
  - Data Management
  - Statistics/Programming
  - Medical Writing (Clinical Study Report)/Quality Assurance
  - Post Marketing

The intention is to collect articles from those people involved in the various roles, so if you wish to participate in writing any articles in the listed areas, please let us know so that we can contact you. We hope that this series of articles will be interesting and also help some people understand where everything fits in and the interaction between different groups. It is hoped that articles can be included from both Pharmas and CROs to cover the whole aspect.

There will be a regular Q&A section called 'Ask the Recruiter' – if there are questions you would like to ask on recruiting, conduct of recruitment agencies or finding a job, please let us know.

Thank you for your time and I hope that you enjoy reading the rest of the Newsletter.

JEAN CORNHILL, Chair/Editor – Newsletter Committee

J C AMOS ARTICLE OF THE YEAR AWARD

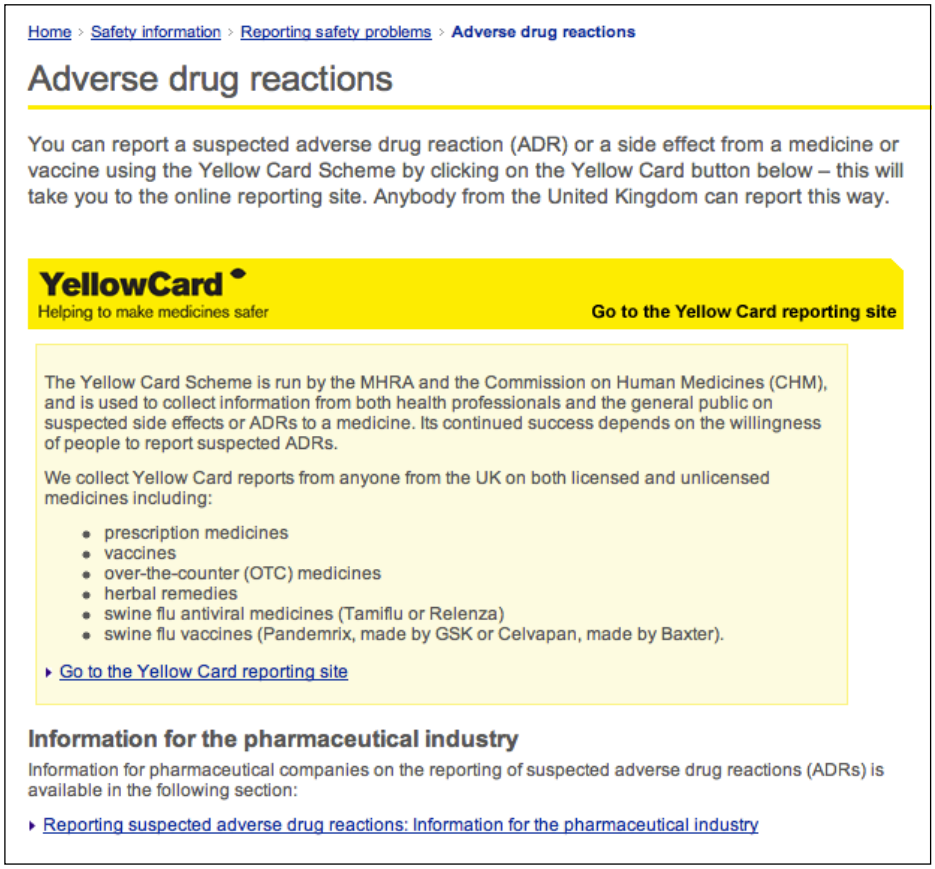
Articles included in this Newsletter are the last to be put forward and considered for the J C Amos Articles of the Year Award. The Newsletter Committee will be reviewing all articles submitted and published in Data Matters since last year's Conference (issues 85-88) against the terms and conditions included in issue 87. The winner(s) will be announced and the prize presented at the next ACDM Conference – due to take place 9-11 March 2014 at Wokefield Park, Reading.

Straight from the Horse's Mouth: Is this the Future of Post Marketing Adverse Event Reporting?

It's during these winter months when all the cold and 'flu bugs are rife that we are most likely to take over-the-counter medicines, or ultimately resort to antibiotics from a GP.

If you experienced any unexpected symptoms after taking one of these medicines, what would you do? Or, would you go to a pharmacist or doctor and ask them to report it on your behalf? Would you telephone the company and tell them about your experiences? Both of these options sound like a lot of bother, especially when you are feeling below par. Wouldn't it be a lot easier to report adverse events direct to the company or even your local regulatory authority through a website? We routinely book travel online, research everything imaginable and shop for absolutely anything, so why not also report our adverse drug reactions? Well... we can..... Yes, that option is available in the UK as well as in some other European countries.

Since the 'flu epidemic several years ago when companies producing drugs to shorten the illness were obliged to offer consumers a website for reporting adverse events efficiently, it has been becoming increasingly common for patients and health care professionals to report post-marketing problems online.



Home › Safety information › Reporting safety problems › Adverse drug reactions

Adverse drug reactions

You can report a suspected adverse drug reaction (ADR) or a side effect from a medicine or vaccine using the Yellow Card Scheme by clicking on the Yellow Card button below – this will take you to the online reporting site. Anybody from the United Kingdom can report this way.

YellowCard
Helping to make medicines safer
Go to the Yellow Card reporting site

The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines (CHM), and is used to collect information from both health professionals and the general public on suspected side effects or ADRs to a medicine. Its continued success depends on the willingness of people to report suspected ADRs.

We collect Yellow Card reports from anyone from the UK on both licensed and unlicensed medicines including:

- prescription medicines
- vaccines
- over-the-counter (OTC) medicines
- herbal remedies
- swine flu antiviral medicines (Tamiflu or Relenza)
- swine flu vaccines (Pandemrix, made by GSK or Celvapan, made by Baxter).

Go to the Yellow Card reporting site

Information for the pharmaceutical industry

Information for pharmaceutical companies on the reporting of suspected adverse drug reactions (ADRs) is available in the following section:

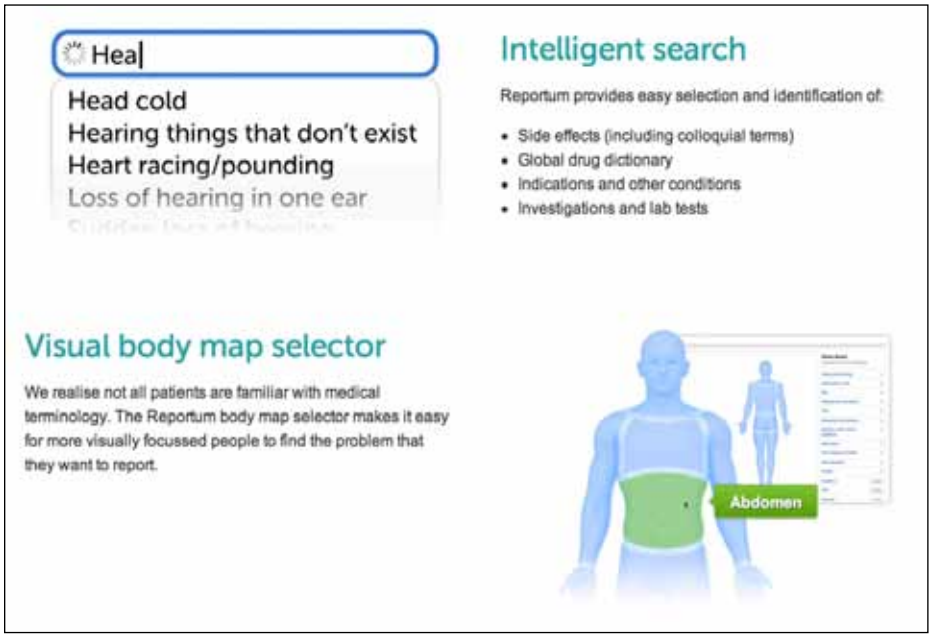
Reporting suspected adverse drug reactions: Information for the pharmaceutical industry

Availability of online reporting sites

In the Netherlands in 2003, the national regulatory agency, Medicines Evaluation Board (MEB), was one of the first countries in the world to implement direct reporting by patients and healthcare providers. At first health care professionals submitted most of the reports but over time, the number from patients has been gradually increasing. The forms allow only free text entry of an adverse event that is then coded to MedDRA by specialist coders in Lareb, an independent foundation assigned by the MEB to collect and assess reports of adverse drug reactions.

In the UK, the MHRA (Medicines and Healthcare products Regulatory Agency) operate an electronic yellow card scheme where the reporter uses a website to enter details of their problem and related information about medical history and concomitant medications. The reporter even reports by selecting a MedDRA term from among the 71,000 Lowest Level Terms (LLTs), removing the need for subsequent coding. Anecdotal evidence seems to suggest that the quality of the reports is no worse than that received from Pharma companies.

Following the apparent success of



regulatory authority sites, several companies have looked to offer this option and there are some commercial products available, such as Reportum, created by MyMeds&Me, (www.mymedsandme.com) which partners with a Pharma company to design and host reporting sites. Creative design of tools no longer requires the reporter to select the correct term from all available LLTs, but instead include intelligent solutions to guide consumers towards accurate reporting through visuals such as body maps and colloquial patient-friendly language. Purist coders may be shocked to even consider anything other than free-text reporting, but research by MyMeds&Me has shown that 85% of consumer reports are accounted for by only around 2,000 MedDRA LLTs so offering an alternative to free text may help patients navigate their way through what could be an overwhelmingly confusing maze of online forms and MedDRA terms.

Do the benefits outweigh any risks?

There are benefits of these online reporting solutions including efficiency for both patients, who can report in their own time from the comfort of their own home, as well as for the company or regulator who need fewer collection centre staff to answer the telephone, data enter the cases and apply standardized terminology such as a Drug Dictionary or MedDRA. Cases are entered more quickly which allows for faster signal detection and ultimately enhanced patient safety.

It could also be claimed that the information reported will be more accurate if it is reported directly without transcription or interpretation during case processing. Many patients have good knowledge of their illness, especially in the case of chronic conditions. It could also be possible to report a case in the reporter's local language, an option supported by the availability of MedDRA in 11 different languages globally. Web technology offers the possibility for interactive sites which can present triggered questions and guided questionnaires prompted by the information being entered as a way to further investigate problems of particular interest for a specific drug. Patients can also be offered advice electronically on how to manage their symptoms or test the functioning of a drug delivery device.

Critics might argue that the risks outweigh these benefits and the data are likely to be less accurate if a patient is selecting a MedDRA term without having clinical knowledge to back up their choice. Or, even more shocking is the scenario that a patient performs an internet search in order to diagnose their symptoms and subsequently enters their perceived diagnosis as the reported event. Research has shown that patient literacy of medical terms is far below that perceived by physicians. For example, 72% of patients surveyed thought that hypertension was a condition of extreme nervousness.[1] Another study found that when presented with names of medical conditions, patients did not realise that some common words were synonyms.[2] Research in Europe and the United States has consistently demonstrated similar findings over the past 50 years.

Another fear commonly highlighted is that not all patients may be familiar with technology and, therefore, be discouraged from reporting if presented with a seemingly endless series of online forms for completion. In addition, it may not be easy to contact online reporters for clarification or follow up information. All of these concerns are valid, but almost all can be mitigated through good design of online reporting tools to maximise ease of use and promote accuracy of reported or selected verbatim terms.

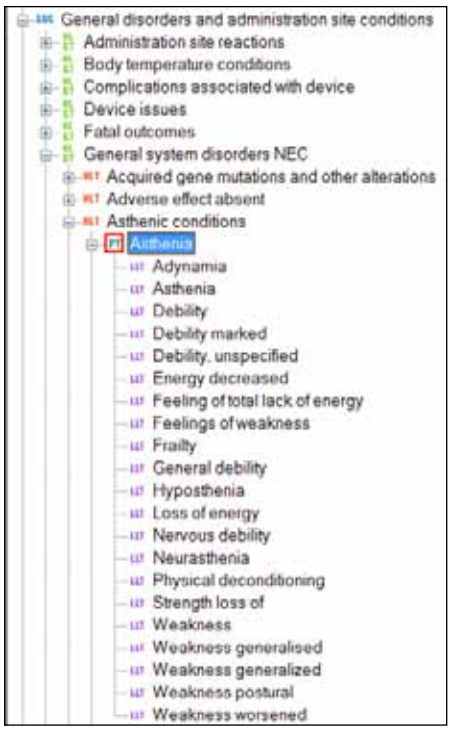
Names of Medical Conditions presented to patients		Patients failing to recognise synonyms
Bleeding	Haemorrhage	79%
Broken bone	Fractured bone	78%
Heart attack	Myocardial infarction	74%
Stitches	Sutures	38%

Impact of Online Reporting for Medical Coding

As already mentioned, online reporting may obviate the need for medical coding if a reporter selects terms from a standardized terminology. Whilst this prospect may scare us coders sufficiently to

go running to update our CVs, in reality there is unlikely to ever be the situation where direct consumer term selection is the only method for reporting without the option for online free text or telephone reporting. From a regulatory and a practical perspective, I believe this would not be ethically or logistically feasible. Even at the MHRA which require an online reporter to select the closest LLT, consumers are given the option to use a downloadable paper form. Use of an online reporting option may instead reduce the number of terms received for coding so that coder time becomes focused on the more complex conditions requiring greater clinical knowledge and familiarity with MedDRA. This is no bad thing if it removes the multiple verbatim terms reporting a headache, rash or nausea – thus enhancing job satisfaction for specialist coders.

In relation to coding of concomitant medications, the patient can accurately select the generic or proprietary name for their drugs, if a comprehensive list of marketed medicines is available as both generic and trade names, ideally presented in their local language. This would increase reporting accuracy and reduce the work for coders when processing the case.



> “I believe this is an exciting time to be involved in direct consumer reporting and in particular to be a specialist-skilled coder working in this field.
> Jane Knight – ACDM Member”

When a patient selects a MedDRA term, the inclusion of such a large number of LLTs means that it is likely a close match to the intended wording will be available. This is because the Lowest Level Term level of MedDRA comprises largely synonyms, variations in word order and colloquial expressions for the medical concepts represented by the associated parent Preferred Terms (PTs). There are some instances, however, where a patient-friendly equivalent of the medical concept is not available and it is here that the risk of inaccuracy of term selection may arise. Misunderstanding of clinical terms and use of the internet for reference may increase this risk.

At other times, a patient may report an abnormal laboratory result, such as ‘High cholesterol’ which codes into the Investigations System Organ Class (SOC) in MedDRA, or similarly the report may fall into the Social Circumstances SOC which some coders may prefer not to use when coding adverse events.

If the reporter uses an online free text option, the verbatim may present more of a challenge for coding especially if a patient describes how they are feeling without specifying symptoms, for example ‘feel like I’m having a heart attack’. This is no different from the poor quality terms received via telephone reporting except that there is no live conversation in which to ask them to clarify their intended meaning.

The future of direct consumer reporting

It is impossible to predict how this shift towards patient and health care provider reporting will evolve but personally, I believe it likely to only move forward. As advancements in web technologies increase, this is an exciting area with great potential for improved accuracy with clear benefits to patient safety.

Terminologies like MedDRA and drug dictionaries may evolve over time to accommodate the technological shift and facilitate patient reporting. MedDRA could expand the LLT level to incorporate more terms expressing patient-friendly language. However, the current challenge this presents is that colloquial expressions and patient-friendly terms tend to be culturally specific and to not translate meaningfully into all eleven language versions of MedDRA.

Coders may have fewer terms for manual coding but there will be new opportunities to apply MedDRA and drug dictionary knowledge in working with in-house and commercial software and website developers. This recognition of specialist coding skills can only increase the profile, skill set and perceived value of medical coders to an organisation. Overall, I believe this is an exciting time to be involved in direct consumer reporting and in particular to be a specialist-skilled coder working in this field.

Jane Knight
ACDM Member

1 Hadlow, J. & Pitts, M. (1991). The understanding of common health terms by doctors, nurses and patients. *Social Science & Medicine* Vol. 32, No. 2., pp 193-196.

2 Lerner, E. B., Jehle, D. V. K., Janicke, D. M. & Moscati, R. M. (2000). Medical Communication: Do our patients understand? *American Journal of Emergency Medicine*, Nov 18 (7), 764-6.

Community of Trainers

Being a trainer for the ACDM requires a special set of skills to uphold the reputation and standard for which the Association has become renowned over the years.

The training committee also recognises that it is beneficial to have new talent joining the community of trainers bringing with them fresh ideas and widening the range of practical experience. Following a recent call for potential new trainers from among the members, two new trainers have been selected to join the community.

The Training Committee is very pleased to welcome Karen Thedinga and Ellen Wieting as new ACDM trainers. Both have extensive experience in the field of Data Management and related specialist roles. Their passion to share experience and knowledge whilst supporting others to learn make them both valuable additions to the Association's pool of trainers.

With a background in Biochemical research, Karen is now a Senior Data Manager, Project Manager and Quality Officer at a University based Trial Co-ordination Centre in Groningen, the Netherlands. In addition to the skills needed for this comprehensive role, she has a range of clinical programming expertise and experience.

Ellen is the manager of a Data

Let us introduce you to Karen.....

Where do you live?

We live in Haren, a small village just south of Groningen. I love it because it is a wonderful combination of a green and quiet country village with a university city just 7 km up north with cinemas and bookstores! And of course I go there on my bicycle!

What do you enjoy doing in your spare time?

I like to read, I love to go to the cinema, and my favourite holiday is to walk in the Swiss mountains. I have two daughters aged 20 and 17. The elder studies pharmacy at university. The younger is doing A-levels this year and hopes to study at the university next year. And I have a sister who lives in England near Brighton.

What is your professional background?

I studied Biology at the University of Amsterdam and did a one-year traineeship at the Centre for Bio Pharmaceutical Sciences in Leiden. After a short traineeship at Ciba Geigy in Basel and 3 years working in one of their research labs, I made the switch to computer programming and data management. After living in Switzerland for 10 years I returned to the Netherlands and took a short break as a fulltime mother, after which I started working as a data manager again 10 years ago for a small CRO that is associated with the University of Groningen (UMCG).

What made you choose to join the ACDM Training Team?

Last year I was looking for a way to 'certify' my knowledge and experience as a data manager. Since the ACDM is an organisation that is active on an international level, I look at their programme and found they offered exactly the right course for me. I thought the course was very inspiring and a great way to share knowledge so when I saw that you were looking for trainers I only had to think once before I sent in my application! And I am so honoured to be part of the ACDM team.

What is it that you are most keen to bring to our training programme?

I plan to bring enthusiasm for our profession and my experience, in both industry and an academic setting.

What do you believe makes a 'good' training event become 'outstanding'?

It happens by listening to the trainees. On the Level 2 Certificate course, the trainees are no longer novices and have experience so the best way to learn at that stage is to discuss your experiences, get feedback, ask 'why-'questions etc. Also it takes love and enthusiasm for our work, of course!

> One of the priorities for coming months is to strengthen links between trainers across Europe and to ensure that the demands to deliver training are rewarded beyond monetary compensation.

Coordination group based in Marburg, Germany, having worked as a Senior Data Coordinator leading all Data Management activities on a clinical trial. She has in depth experience across study management, study coordination, data coordination and site monitoring. She has managed studies with a wide range of clinical indications in all phases of drug trials.

Like other sections of the Association, the training area relies heavily on voluntary contributions of expertise, time and goodwill by its trainers. One of the priorities for coming months is to strengthen links between trainers across Europe and to ensure that the demands to deliver training are rewarded beyond monetary compensation.

An ACDM Trainer Forum launched this month will allow individuals to learn from one another and attend events supporting their own personal development. The aim is also that they can keep abreast of new training formats, techniques and media and share ideas for applying this to future ACDM training offerings. It is hoped that in time, this new community will link up with the SIGs to support and collaborate across the boundaries of ACDM activity groups.

If you are involved in training activities within a SIG or in other areas of your life and are interested in the activities of the forum, Jane Knight – knight.jane@gmail.com or Susy Laws, email susy.laws@sldsolutions.co.uk would love to hear from you

And we'd like you to meet Ellen....

Where do you live?
I live and work in Marburg, which is an hour to the north of Frankfurt. Marburg has a very well known University and a beautiful old town. The area is hilly with lots of forests.

What do you enjoy doing in your spare time?
I am the singer in a female jazz combo. That's a lot of fun! And of course, I like to spend my time with my husband and my two kids who are 7 and 9 years old.

What is your professional background?
I have been working in clinical research for more than 20 years starting out as a monitor and I have a professional certification as a Medical Documentation Specialist. Since 2003 I have been working in Data Management. Currently, I am heading the Accovion DM team in Marburg and I also work as a Project Manager. I have worked in different therapeutic areas: Severe Haemophilia A, Venous Thromboembolism, COPD, Medical Devices, Immunology, Alzheimer's Disease,...

What has been the highlight of your career?
I worked as a CRA in the US for 4 years. It was a highlight of my career, since I had the chance of working and living in another culture. I learned a lot and now feel very comfortable working in multinational teams.

Which of your achievements was the most fulfilling?
That's a difficult question! I don't feel I can point out one single achievement. The most satisfying for me is, when a project has been completed successfully and all the team members have given their best.

What made you choose to join the ACDM Training Team?
I always have a lot of fun when training and mentoring new employees. Last year I started giving training outside of our company and I thought that it could be something I'd like to do more often. When I heard about the ACDM looking for new members of their Training team, I wanted to take the chance; especially, since I had got to know the ACDM as a provider of high quality and relevant training for Clinical Data Managers.

What is it that you are most keen to bring to our training programme?
I have a lot of experience in Data Management of drug and medical device studies in different therapeutic areas. Also, I like to look beyond my own nose, that's why I have a good understanding of the other functions involved in the clinical research process.

What do you believe makes a 'good' training event become 'outstanding'?
This can be done by making the training relevant to the learners' daily work.

The Next Big Challenge

NAME: Andrada Pasca
ACDM POSITION: ACDM Newsletter Committee Member
COMPANY: Cmed Clinical Services

I am based in Timisoara, Romania and I studied Management at University Politehnica Timisoara. After college I worked in numerous roles until I began working for Cmed in Data management in 2008. When I began there were only a small number of people in our office and we didn't really know what Data management was about, however since then the office has expanded adding more and more functions and people.

I began my career in the CRF data coordination group but quickly progressed into managing this group and from there I have been involved in study management, also including line management and recruiting. Working as a global team with different cultures had its challenges in the beginning, however it was great visiting the UK offices and meeting my colleagues face to face. It is really great to put a face to a name, especially in situations where you are working with someone abroad and on a long term project.

Although I am very excited to have the opportunity to be part of the ACDM newsletter committee I will need to put this activity on the back burner for the next couple of months as I am starting maternity leave in March. The birth of my first child is the next big challenge for me but I can see myself surpassing this quickly and coming back to data management in no time. I am looking forward to observing the progress of the clinical trial industry in the next year.

I enjoy travelling, especially in sunny warm locations (still wishing Cmed will open an office in the Caribbean!). As I am a big cat lover I am hoping that in the future I will be able to add a furry companion for my little girl.

Andrada Pasca
Email: apasca@cmedresearch.com

Bringing a contrasting view

NAME: Anamaria Cristine Stancu
ACDM POSITION: ACDM Newsletter Committee Member
COMPANY: Cmed Clinical Services

I am an extremely motivated professional with thorough knowledge of Data and Project Management, with a positive and active response to challenges and pressure. I studied economics – Market Research at West University of Timisoara. After university I worked in various roles, including Project Management for almost five years, until I began working for Cmed in Data Management in 2011.

I began my career in Data Management Operations acting as a Clinical Data Associate – performing tasks as a Deputy Trial Manager, however I rapidly progressed into Clinical Data Manager where I have been involved in Project Managing all trial data management activities.

I am very enthusiastic about the opportunity that was offered to me to be part of the ACDM Newsletter Committee and I hope that my ability of focusing on research and details, in addition to my enthusiasm, will bring a contrast view upon the practical side of the data manager needs and concerns.

In my spare time I am keen on reading fiction novels, I am passionate about nations' origins and evolution, about archaeology and ancient civilisations history. I also like travelling the world, discovering other cultures' habits and customs. My artistic side is also interested in interior design and landscaping.

Anamaria Cristine Stancu
Email: cristine_stancu@yahoo.com

View from the Consultant

NAME: Ian Marlow
ACDM POSITION: ACDM Newsletter Committee Member
COMPANY: CK Clinical

My name is Ian Marlow and I work for CK Clinical. I have been recruiting within Data Management for the last 10 years both in the UK and Mainland Europe. I have been married to my wife Angela coming 3 years and we are expecting our first child any day now!

I am very keen to become involved in the ACDM and when Ian (Public Relations/Website Committee) and then Jean (Newsletter) contacted me, I was delighted to have the chance to put the consultant's view across and really help from that side of things, as well as the chance to show there are very much ethical and professional recruiters out there always able to help, NOT harass or hinder!

So, look out for the regular slot to be included in Data Matters where you can ask questions relating to recruitment or where you can find out more about ethical recruitment practices.

Ian Marlow
Senior Biometrics Consultant II
CK Associates Limited

Birdwoman of Bognor... Update

NAME: Jean Cornhill
ACDM POSITION: ACDM Newsletter Committee Chair/Editor
COMPANY: PAREXEL International

In order to provide profiles on the whole Newsletter Committee, I have updated my profile which was previously submitted back in 2010.

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 proofreader 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 (as well as a grown up Son, we have two Grandchildren), when circumstances allow. Actually, a change in circumstances allowed me to spend more time at home – in May last year, I broke several bones in my foot, so found my leg in plaster from May to October, with an operation in July .... Or should I say two operations – as, before signing the informed consent form for surgery, my surgeon informed me that he was to take a bone graft from my hip to help with the fusion of my foot bones. Even making and carrying a cup of tea was a challenge with crutches (eventually solved with use of a travel mug in a bag which could be carried on the crutch handle). After a while of restricted mobility, a visit to the local supermarket was an exciting outing for me. It was also a valuable experience as people looked down on me and openly showed an expression of pity to see me in a wheelchair or disregarded me completely when hobbling towards them on crutches, expecting me to move out of their way. There were also two occasions when I was nearly run over – once by a tractor hurtling through a country village at great speed and once by a reversing car driver without a glance in the rear view mirror!

Luckily, my job allows me to work remotely, so there was minimal time off required following my injury and subsequent healing process. At least now I can now drive my car again, rather than have to wait for others to help out. However, it could be up to another six months before the swelling has gone down completely, but at least I can walk now. Patience and physio exercises are a virtue!

Since the previous profile, I now have the position of Chairperson/Editor of the Newsletter Committee. Three new committee members have recently joined, but we are in need of two or three new recruits.

There – profile updated, still 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?"

Jean Cornhill, Senior Auditor, PAREXEL International
Chairperson/Editor, ACDM Newsletter Committee

FEBRUARY

12

ACDM Webinar
Effective EDC Training Strategies
12:00 – 13:30 GMT

25 & 26

ACDM
Level Two Certificate in Clinical Data Management
2 day course + exam
Maidenhead, UK

MARCH

5

ACDM Webinar
Understanding the Impact of Statistics on the Design, Conduct & Reporting of Clinical Trials
12:00 – 13:30 GMT

9-11

ACDM Annual Conference 2014
Reading, UK

14 Mar 2014

MHRA
Pharmacovigilance Inspections Symposium
The London Marriott Hotel, Grosvenor Square, London

12 & 26

ACDM Webinar
CDISC Fundamentals for Data Managers
12:00 – 13:30 GMT

25-27

DIA/26th Annual EuroMeeting Vienna 2014
ACV. Vienna, Austria

APRIL

03-04

ISoP
Proactive Pharmacovigilance, Risk Management & Pharmacovigilance in the Era of Personalised Medicine
Zagreb, Croatia

09

MHRA
The Quality of Medicines – Future Evolution
The Church House Conference Centre, Westminster Abbey, London

15

ACDM Webinar
ECG and Holter Data Explained
12:00 – 13:30 GMT

7-11

CDISC/CDISC Europe Interchange 2014
Paris, France

MAY

11-14

PSI / PSI
2014 Conference
The Tower Hotel, Tower Bridge, London

14

ACDM Webinar
RECIST Criteria a Practical Guide for Data Managers
12:00 – 13:30 GMT

MAY

8-10

DIA/7th European Conference on Rare Diseases & Orphan Products
Andel's Hotel Berlin, Landsberger Allee 106, 10369 Berlin, Germany

JUNE

17-18

ACDM
Level One Certificate in CDM (includes exam)
2 day course + exam
Maidenhead, UK

SEPTEMBER

10 & 24

ACDM
CDISC Fundamentals for Data Managers
12:00 – 13:30 UK
Webinar

16-17

ACDM
Level Three Project Management for Clinical Data Management Accredited Program
09:00 – 17:00 UK
Horsham, UK

28-1 Oct

SCDM/SCDM 2014 20th Anniversary Annual Conference
Las Vegas, Nevada, USA

OCTOBER

8

ACDM
Data Management for Non-Data Managers
12:00 – 13:30 UK
Webinar

13-15 Oct 2014

TOPRA
The 11th TOPRA Annual Symposium 2014
The Square, Brussels, Belgium

18-22 Oct 2014

ISoP
(International Society of Pharmacovigilance) / Annual Meeting
Tianjin, China

NOVEMBER

11

ACDM
Recent Developments in GCP & Regulations
12:00 – 13:30 UK
Webinar

DECEMBER

9

ACDM
Preparing for a Regulatory Inspection
12:00 – 13:30 UK
Webinar

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

For ACDM events contact:
Association for Clinical Data Management
105 St Peter's Street
St Albans, Herts AL1 3EJ
Tel: +44 (0) 1727 896080
Fax: +44 (0) 1727 896026
Email: admin@acdm.org.uk

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

acdm
association for clinical data management

Association for Clinical Data Management
105 St Peter's Street, St Albans, Herts AL1 3EJ
Tel: +44 (0) 1727 896080 • Fax: +44 (0) 1727 896026
Email: admin@acdm.org.uk • www.acdm.org.uk

ACDM DIRECTORS

	Paul Fardy CROS NT	**Tel** 07557 388581 **Email** paul.fardy@crosnt.com
	Emmet Browne Cmed	**Tel** 07776 213884 (mobile) **Email** ebrowne@cmedresearch.com
	Andrew Green INC Research	**Email** andyogreen@aol.com.
	Andrew McGarvey CROS NT	**Email** andrew.macgarvey@crosnt.com
	Ian Pinto Roche Products Ltd	**Tel** 01707 365904 **Fax** 01707 384513 **Email** ian.pinto@roche.com
	Jon Wood Syne Qua Non	**Email** jon.wood@synequanon.com

COMMITTEES

Conference	**Laurence Ghafar** Roche Products Ltd	**Tel** 01707 366000 **Fax** 01707 384513 **Email** laurence.ghafar@roche.com
International Collaboration	**Eva Hammarström-Wickens** Orion, UK	**Tel** 0115 948 7116 **Fax** 0115 948 7119 **Email** eva.hammarstrom-wickens@orionpharma.com
Newsletter	**Jean Cornhill** PAREXEL International	**Tel** 01895 614539 **Fax** ..... **Email** jean.cornhill@parexel.com
Public Relations & Website	**Ian Pinto** Roche Products Ltd	**Tel** 01707 365904 **Fax** 01707 384513 **Email** ian.pinto@roche.com
Training	**Susy Laws** SLD Solutions Limited	**Tel** 07973 820519 **Email** susy.laws@sldsolutions.co.uk
Senior Forum	**Andrea Robinson-Smith** Amgen Ltd	**Tel** 01223 436281 **Email** andrea@amgen.com

SPECIAL INTEREST GROUPS

CDISC	**Alan Cantrell** PAREXEL International	**Tel** 01142 251351 **Fax** 0114 225 1001 **Email** Alan.cantrell@parexel.com
Coding & Dictionaries	**Josephine Staniforth** Roche Products Ltd	**Tel** 01707 366000 **Fax** 01707 323222 **Email** josephine.staniforth@roche.com
eClinical	**Emmet Browne** Cmed	**Tel** 07776 213884 (mobile) **Email** ebrowne@cmedresearch.com
Project Management in Data Management	Chair position open	**Tel** ..... **Fax** ..... **Email** .....