Autumn 2014 • ISSUE 91

acdm
association for clinical data management

DataMatters

www.acdm.org.uk

ACDM NEWS
News and views from around the committees

ARTICLES
ACDM Coding SIG Meeting

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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 2014/2015	12 December	2 February 2015
Spring 2015	15 March 2015	5 May 2015
Summer 2015	19 June 2015	3 August 2015
Autumn 2015	11 September 2015	2 November 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

Competence Building

Jon Wood – ACDM Co-Chair

Welcome to the latest ACDM newsletter Chair letter. In Issue 90, Emmet highlighted some of the challenges for our association reflecting the continuing changing landscape of our industry.

Clinical data management continues to evolve as a profession, driven by new technologies, operational approaches such as Risk-Based Monitoring and strategic sourcing initiatives engaging new geographies to deliver high quality data for regulatory submission for innovative new treatments. As a Board, we are continuing to focus on wider European collaboration and to evolve our membership demographic beyond pharma, biotech and CRO sectors into more extensive collaborations with academic research units.

Training continues to be a primary focus moving into 2015. The ACDM continues to be committed to training and its priority is to deliver the value of an accredited program of training to enable organisations to verify the competence of its clinical data management professionals. We have been working hard to develop a robust accreditation framework that will differentiate itself from other training options. Working in partnership with the International Academy of Clinical Research, we are working to ensure that our training delivery provides the focus on proof that the individual can apply their knowledge to the job, supported by robust and independent assessment of competence mapped to international qualifications frameworks. As GCP guides us, "Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s)". The ACDM over many years has developed and delivered training for clinical data management professionals and the accredited program will ensure we can also demonstrate competence. However, the ACDM cannot operate without the valued voluntary contributions provided by you. If you have never been involved with the ACDM before then now is a great time to become involved and gain new experience and expertise contributing to one of our many Committee teams.

Whether you have great organisational skills, training skills or technical skills, we value your contribution. Please reach out to us and help us continue to deliver our goals of bringing best practices in clinical data management to our organisations through professional training and development opportunities.

Remember why we do this job - a competent workforce enables organisations to conduct clinical trials more efficiently and effectively, thus reducing risks, reducing costs, saving time and helping to bring new treatments to patients quicker - that's what we do!

Newsletter
Committee

Newsletter Committee Report


Jean Cornhill

NEWSLETTER & NEWSLETTER COMMITTEE

Unfortunately, the Autumn issue of Data Matters is smaller than usual. In order to make this a Newsletter for all members, we do need input from you to provide articles – so please consider it a New Year Resolution to write even a small article for inclusion in a future issue – this would also put you in line for being considered for the JC Amos Article of the Year Award to the tune of £500. Please refer to the terms and conditions included in issue 87. Remember that all articles submitted and published in Data Matters in issues 89-92) will be considered for the J C Amos Article of the Year Award which will be announced at the ACDM Conference 2015.

You only have a chance of winning £500 or a share of this if you write and submit an article ..... so why not start writing.

If you ever wish to comment or if you have any questions on an article, please send them to the editor.

I am still on the lookout for new committee members so please contact me if you are interested in joining the Committee by sending an email to editor@acdm.org.uk

COMMITTEES & SPECIAL INTEREST GROUPS (SIGs)

Committees and SIGs are desperate for new members – why not have a look at the back page of the newsletter or log on to the ACDM website to see if there is anything of interest to you. The Coding & Dictionaries SIG held a meeting on 8th September – this was attended by members who provided feedback on the meeting – have a look at their comments elsewhere in this newsletter.

NEWSLETTER ARTICLES

We had hoped to publish articles on all stages of clinical trials to improve understanding and awareness of responsibilities of other areas in the clinical research journey. However, If you would like to offer or know of anyone willing to write an article on any stage (e.g. Project Management, Regulatory, Clinical Monitoring, Data Management, Statistics/Programming, Medical Writing, Safety, Quality Assurance, Quality Management, Post Marketing), please let me know. As always, we would like to include articles from both a Pharma and CRO perspective. Articles may not be needed immediately or they could be written now and held for a later publication. However, we would like to start with Project Management and the set up or initiation of a trial.

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.

MEMBER FEEDBACK AND COMMENTS

It would be useful to receive feedback and comments from readers to be shared with those reading Data Matters. If you have anything to say or questions to ask authors or members, please send by email to editor@acdm.org.uk It would be interesting to receive some feedback to share with everyone. Thank you for your time and I hope that you enjoy reading the rest of the Newsletter.

Coding Sig Meeting

I have launched a feedback form which can be used by ACDM SIGs, Committees, Meetings and at the Annual Conference for attendees to provide snippets of feedback to inform members and in turn encourage them to attend future events.

The feedback below was provided to me by those who attended the ACDM Coding SIG Meeting hosted by Roche on 8th September 2014.

It was a lively and busy day, with a packed agenda of presentations, along with an energiser and quiz by Jane Knight (with the MSSO and also on the ACDM Training Committee). We were welcomed by Jo Staniforth, who works at Roche and is also the Co-Chair of the Coding SIG. Jane's energiser woke our brains into thinking of words associated with a coding term. We scored points if we thought of the same words as others sitting at our table. An interesting twist based on Boggle, where you only score points if you have words not on anybody else's list.

The MSSO (Patrick Revelle and Jane Knight) gave an update from the ICH Meeting held in June on the Scope of MedDRA, demonstrated the new MedDRA web-based browser, informed us of training offered by MSSO and gave an update on the Points to Consider document (PTC) from the June Meeting.

Jane's quiz showed us what we did or didn't know on coding – with a prize for the individual winner as well as for the table with the highest average score.

Annay Mistry, Thesaurus Manager with Roche shared his experience with an in-house drug dictionary.

Malin Jakobsson, Product Manager with UMC, gave presentations on standardised drug groupings, ATC coding, WHO Herbal Dictionary as well as the WHO Drug Dictionary China.

Barry Hammond (Standards and Medical Coding Consultant with Terminologeze Limited and Co-Chair of the Coding SIG) gave us an update on ISO IDMP (new medicinal product standards).

Questions were welcomed throughout the day and there were regular supplies of food and refreshments. Roche looked after everyone and was considered an excellent host. Offers were requested from other companies to host future Coding SIGs.

As you can see from the comments below, ACDM members are encouraged to attend future SIGs – it is obviously an excellent way to network and also learn from the experience of others within the industry.

Jean Cornhill – ACDM Newsletter Chair/ Editor

JASON DONNELLY
Principal Clinical Dictionary Analyst, GSK
Expectations: Increase knowledge of MedDRA and Drug Dictionary items, understanding of differences in approach throughout the industry.
Meeting Experience: Expectations were met. Enjoyable and informative presentations and discussions.

JEAN HOGAN
Clinical Coding Specialist, Roche
Expectations: Updates on MedDRA and browser.
Meeting Experience: Expectations were met. Good experience.
Recommendations/Comments for others to attend future events: Needs to be advertised more. Maybe doing an overview of SIG to all ACDM.

LAUREN CAMERON
Senior Clinical Coding Specialist, Roche Products Limited
Expectations: Networking opportunity. Update from dictionary maintenance organisations. Sharing and gathering information with/ from peers.
Meeting experience: I was pleased with the open discussion from a variety of people and supportive atmosphere. Useful information from expert organisations.
Recommendations/Comments for others to attend future events: The greatest benefit comes when there is a variety of attendees from different companies and CROs.

PAKSHA PATEL
Clinical Coding Specialist, Roche
Expectations: Not sure.
Meeting Experience: I did not have any expectations, however, all topics covered were interesting and relevant and the questions/ answers sessions as well as discussions generated were invaluable.
Recommendations/Comments for others to attend future events: Great to interact with others who also code. Networking opportunities. Good learning opportunities to see how other people work/ their systems/conventions.

TRISH SIMS
Senior Coding Specialist, Chiltern International
Expectations: General discussion on MedDRA and WHODD.
Meeting Experience: Very enjoyable, looking forward to next meeting.

JANE KNIGHT
Clinical Associate, MSSO & Freelance Trainer/Coder
Expectations: Interesting presentations and lively, fully participative discussions.
Meeting Experience: Very interactive, as these meetings always are. Relaxed and informal with open slots to discuss audience ideas and topics.
Recommendations/Comments for others to attend future events: Surprising that only a small number of people took the opportunity to network and hear the latest information from key people in MSSOS and UMC. I like the flexibility of the SIG and its agendas to discuss learning issues that attendees want to raise. Meetings are a good way for speakers to hear how users are working in practice.

BARRY HAMMOND
Data Standards & Medical Coding Consultant, Terminologeze
Expectations: Updates on MedDRA and Drug coding. Networking.
Meeting Experience: Exceeded expectations. New information and great presentations. Lot of audience interaction.
Recommendations/Comments for others to attend future events: You need to be at the meeting to get the full value.

PAT REVELLE
Director, MSSO
Expectations: Opportunity to present MSSO initiatives and plans.
Meeting experience: Expectations were met, very much.
Recommendations/Comments for others to attend future events: I would like to do a presentation on the life of a MedDRA change request.

MAXINE TAYLOR
Clinical Coding Specialist, Roche
Expectations: Informative Coding topics or related topics.
Meeting Experience: Yes, expectations were met, very much so – very interesting & relevant.
Recommendations/Comments for others to attend future events: Always try and have at least one well-known figure in the coding world to present – that would be a long draw card.

CHRIS COOMBS
Coding Specialist, Worldwide Clinical Trials
Expectations: Up to date information. Talks from experts.
Meeting Experience: Informative. Interesting. Great talks from guest speakers.

RUCHI SHAH
Senior Clinical Dictionary Analyst, GSK
Expectations: Learn more about MedDRA – MSSO, WHO drug dictionary. ISO IDMP.
Meeting Experience: Very good experience with quizzes which helped me understand more about MedDRA.
Recommendations/Comments for others to attend future events: Would recommend to other team members.

SHEILA MAWHOOD
Clinical Coding Consultant
Expectations: Catch up (1) MedDRA news, (2) WHO news.
Meeting Experience: (1) Yes, definitely, the new MedDRA browser looks great. (2) Presentation was very general, some screenshots would have been useful. Anything else: Need for library space* for paper coding thesaurus(es).
**CHAIR/.EDITOR note: Any suggestions from ACDM members would be useful – let me know.*

JACKIE RICE
Senior Clinical Coder, INC Research
Expectations: Learn about new developments in MedDRA and WHO DRL. Meet colleagues from the industry.
Meeting Experience: Expectations met – very much so! Really enjoyed the Energiser.

PETA SMALL
Principal Coding Specialist, Roche
Expectations: Networking. MSSO updates. Drug coding overview (updates in WHO drug dictionary).
Meeting Experience: Networking – yes (small group, but varied roles/companies. MSSO updates really good (blue ribbon panel. Interested in WHO presentation as currently do not use this.
Recommendations/Comments for others to attend future events: It was great fun to ask questions of the experts. Good to have MSSO particularly. Sharing of expertise and experiences is excellent. Very good agenda!

SUSANNE HENSS
Medical Coding Manager, CSL Behring
Expectations: Information update on MedDRA, WHO DD, sharing experiences.
Meeting Experience: Expectations met in general. Exercises good.
Recommendations/Comments for others to attend future events: Helping for coding personnel (basic knowledge required).

SARAH CUMMINGS
Principal Clinical Dictionary Analyst, GSK
Expectations: Useful information to give me greater knowledge of coding.
Meeting Experience: Great content and it really helped to have the speakers share their experience and take a lot of questions.
Recommendations/Comments for others to attend future events: Very interesting, worwhile. Good to meet people in similar roles.

A desire to contribute to beating Cancer

NAME: Nicola Mockler
ACDM POSITION: ACDM Board Member
COMPANY: Cancer Research

Like many people, I didn't plan Clinical Data Management as a career. During my Ph.D. in Pharmacology, I decided that I wasn't enjoying working in a laboratory, but I did want to stay working within drug development. When I accepted the position of Clinical Data Manager at Axess, who at that point were also a Data Management and Statistics CRO as well as Recruitment agency, I was interested in taking the role so that I could see what other roles existed in clinical development. I worked there for three years, being promoted to a Project Coordinator responsible for delivery of the contracts.

I moved on to GSK Consumer Healthcare, enjoying working as part of a larger project team on many shorter studies. It was great to be able to set studies up and see them through to analysis and reporting. I also had the appreciated learning to design clinical databases and program the checks. This was also my first opportunity to lead process change as I worked with a clinical colleague to review and improve efficiencies across all of our processes. When I left it was to become a Manager in Data Management at what is now inVentive Health, leaving there to join Cancer Research UK Centre for Drug Development in 2006.

My motivation for joining, along with the obvious desire to contribute to beating cancer, was that the change in the regulations in 2004 meant major changes in processes for the data management group. I was keen to update all of the processes, implement them and train the team. Since then I have been involved in the next round of process re-engineering when we implemented EDC. Now I lead the Data Management group, enjoying the constant process change and the challenges of delivering early phase trials of cancer treatments where the IMPs are often first in man and the safety and data complex. Working as a Clinical Data Manager in the not-for-profit sector has its own challenges and I'm hoping that by joining the Board I can highlight these.

What do you think? Send us your views

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

November

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PSI
How Do Data Monitoring Committees Operate
contact PSI@mci-group.com
RSS Offices, Errol Street, London

6-7
DIA
ISPE/DIA Workshop on Computer Systems Compliance
'Maintain Data Integroty to Reduce Risk for the Patient'
Pullman Basel Europe, Basel, Switzerland

10-14
CDISC
International Interchange
Bethesda North Marriott Hotel and Conference Centre, North Bethesda, MD 20852

10-14
TOPRA
The Introductory Course
contact meetings@topra.org
Leonardo Royal Hotel, Berlin, Germany

20
CDISC
Public Webinar Series – Standards Updates and Additions
Webinar 11:00 – 12:30

December

2-3
DIA
15th Annual Conference on Electronic Document Management (eDM)
Maritim Hotel Berlin, Berlin, Germany

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

For ACDM events contact:
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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**

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