Data Matters

acdm
association for clinical data management

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ACDM NEWS

News and views from around the committees

ARTICLES

What to expect at this years ACDM Annual Conference...

Ideas to help trade associations and societies communicate effectively

ACDM Training – Confidence in Competence

acdm
association for **clinical data management**

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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
Spring 2017	31 March 2017	2 May 2017
Summer 2017	30 June 2017	7 August 2017
Autumn 2017	29 September 2017	6 November 2017
Winter 2017/18	22 December 2017	5 February 2018

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

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A warm welcome to Data Matters

This is really a transition period for the ACDM. As always in this industry, we are experiencing constant change across the clinical data management landscape – geographies, regulations, enabling technologies, evolving roles and of course, mergers and acquisitions. The ACDM strategies are further developing to support a much broader market, specifically, more focussed training for clinical research professionals in wider diverse academic networks, Clinical Research Units and NHS research groups. We are passionate about our profession and will continue to build on our more traditional UK base, extending to groups across Europe and beyond. We are also building on industry collaborations, for example, the NHS R&D Forum, to forge closer links with all professionals involved in the management of clinical trial data.

Of course, professional development has always been a cornerstone of the ACDM. The ACDM has provided a variety of training solutions and formats over many years and has driven key strategies to build on this framework in a more formal and recognised way. The ACDM has engaged an internationally-recognised, robust accreditation system that focuses on learning outcomes and verification of competence, providing a meaningful and professional offering to professional Clinical Data Managers.

The ACDM has partnered with the International Academy of Clinical Research, achieving Authorised Centre status, delivering accreditation of the course trainers and supporting definition and rigorous review of the learning outcomes for each course in the program to ensure that they are mapped to the appropriate level for the target group of learners. This drives benefits for employees and their professional development and of course for employers, ensuring talent retention, maintaining a high level of workforce quality and of course driving efficiency and profitability.

Of course, we continue to run Hot Topic sessions which provide a unique forum for the open sharing of information and ideas. We encourage all of you to continue to attend and propose topics of interest. Also, if you or a colleague would like to be part of one of our committees, the Board or even start a new one we would like to speak with you. We are all volunteers. We provide our time freely to further develop and support our Association, providing a valuable forum for the continuous professional development of colleague in our industry. Playing a role in the ACDM provides a unique opportunity to develop new skills, build networks and contribute to our strategies and goals to provide the best service we can to our members and to the profession in general.

Join us.

Kind regards,

Jon Wood, Chair ACDM

Jon Wood has a degree in physiology and began his career in clinical trials and data management in 1989. Jon brings industry experience across project management, biometrics and strategic sourcing roles within large pharma, biotech and Contract Research Organisations. He has direct experience in preparing for and participating in successful regulatory inspections and is currently operating as Senior Vice President and Biometrics Head at Accelsiors, based in Budapest, Hungary. Jon has been actively involved in the ACDM for a number of years serving on the Board of Directors and has recently taken up the position of Chair for the ACDM. His passion is training and continuous professional development in clinical data management as a profession.

Newsletter
Committee

Newsletter Committee Report

There are vacancies on the Newsletter committee

Are you interested in writing and/or investigating topics relevant to DM or good at approaching people for articles or input. Do you have a keen eye and would be good at proof reading?

There are many advantages to joining the ACDM newsletter committee.

**If you're interested in joining the committee, contact Ali Roskell Tel: 0161 918 7944 Email: Alexandra.Roskell@christie.nhs.uk**

Committees & special interest groups (SIGs)

Committees and SIGs are in need of new members – why not take 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.

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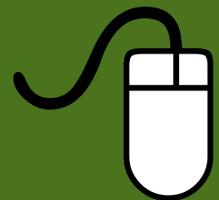
If you have something to say, whether it's a comment on an article or just to let off some steam, we would like to know. Email us at editor@acdm.org.uk

What to expect at this years ACDM Annual Conference...

The ACDM conference will be held this year at The President Park Husa Hotel, Brussels, Belgium on 14th March, book your place at www.acdm.org.uk

Risk-Based Monitoring, Remote Monitoring and eSource: The Unattainable Trilogy of Monitoring?

Author: Stephanie Langouet

Abstract

The number, complexity and cost of clinical trials has kept increasing over the last decade. With Regulatory Agencies now onboard for more effective monitoring strategies, the time is right to change. With new technology available, better operational processes and decades of experience, a flexible combination of RBM, Remote Monitoring and eSource is the solution to reduce costs and run smarter trials.

Biography

Stephanie Langouet has over 20 years' experience in clinical research and has worked for Biotechnology, Pharma and CROs in 5 different countries. She is passionate about fostering dynamic environments where real solutions are implemented. Her global leadership experience is continuously applied to operational efficiencies and the use of technology.

Synopsis

The number, complexity and cost of clinical trials has kept increasing over the last decade. With Regulatory Agencies now onboard for more effective monitoring strategies, the time is right to change. With new technology available, better operational processes and decades of experience, a flexible combination of RBM, Remote Monitoring and eSource is the solution to reduce costs and run smarter trails.

Learning objectives

- Various monitoring strategies – from traditional 100% SDV to RBM and increased remote review
- The role of data management at the heart of central reviews and development of analystics tools
- Benefits from eSource in comparison to EMR systems

BMS Centralized Monitoring dedicated team – Lessons learned after a year in effect

Authors: Patricia Clerton, Oksana Gecha, Ioannis Karageorgos

Abstract

The purpose of the presentation is to share the mission statement and lessons learned by the first few quarters of a fully dedicated Centralized Monitoring Function in effect in BMS. Stemming from the guiding principles established by TransCelerate, we'll dive in the progress made in defining and clarifying tasks, roles, responsibilities, values and engagement rules for a CMN (Central Monitor) as they join the Trial or Program conduct team. We'll share best practices but also the systematic methodology instilled in Risk Based Approaches from the perspective of the CMN and the penetration and impact on the global clinical trial workload. As importantly, we'll share lessons learned and the experience of a team of already solid, veteran central monitors.

ICH E6 (GCP) Addendum – The impact on Pharma and CDM

Author: William Andrew Lawton

Abstract

ICH E.6 (GCP) Addendum was released in December last year and is due to be implemented in mid 2017. ICH E.6 forms the basis for companies to undertake clinical trials and so it is essential that preparations are made to build the changes from the addendum into our processes, and yet a large number of companies have not fully addressed the changes. The changes are perceived to be just RBM, but they are more extensive. The focus of this presentation are in the area of data monitoring and the introduction of quality tolerance limits.

Biography

Andy Lawton has extensive experience in computing, statistics, data management, RDE/RDC, system design, RBA in CSV and clinical trials. He is currently consultant and director of Risk Based Approach Ltd. Previously, Andy held a variety of

positions in 30 years at Boehringer Ingelheim and ended in the position of Global Head of Clinical Data Management.

He was a Founding Committee Member of ACDM, Member of TransCelerate RBM work stream and numerous other external commitments. He won "best author of the year 2015 and 2016" from the DIA, for the TransCelerate papers on SDV and central monitoring in the TIRS Journal.

Synopsis

ICH E.6 (GCP) Addendum was released in December last year and is due to be implemented in mid 2017. ICH E.6 forms the basis for companies to undertake clinical trials and so it is essential that preparations are made to build the changes from the addendum into our processes, and yet a large number of companies have not fully addressed the changes.

The changes are perceived to be just RBM, but they are more extensive. The focus of this presentation are in the area of data monitoring and the introduction of quality tolerance limits.

Learning objectives
- Understand the changes in ICH E.6 and the drivers for them
- Impact on sponsors
- Impact on CDM

Real-world data for post marketing surveillance in eight European countries: how using an eCRF helped a mid-size medical device company streamline this non-interventional study? How was data security handled in the Cloud?
Author: Bertrand Le Bourgeois
Abstract
We will present how using a multi-lingual Cloud-based eCRF helped STENTYS streamline this non-interventional study. Major Adverse Cardiac Events (MACE) were recorded and monitored. We will then explain how data security and access security was handled in the Cloud, present the first results, and what will be the next steps of the study.

Biography
Bertrand Le Bourgeois graduated as an engineer from Ecole Centrale in France, with a marketing specialisation from HEC. He has spent his career in IT Consulting, with the last 15 years in the healthcare and pharma industries. Now Bertand acts as sales and marketing manager for Medsharing, a solution provider for eCRF and randomisation software.

Synopsis
- Stentys, the company

- Challenges
- Solutions
- First results
- Next steps

Learning objectives
Participants will learn:
- How to conduct a non-interventional study in tight delays while complying with regulations and guidelines?
- How to address data security in a cloud environment?
- Tips for facilitating user adoption of a Cloud clinical software solution in a quick time in several countries

GxP and Regulatory Considerations for Cloud Implementations
Author: Dr Anil Dhiri
Abstract
The focus of this presentation will focus on Good Clinical Practices and regulatory compliance requirements when implementing clinical systems in the cloud. Clinical institutions are increasingly being convinced to move from on premise applications to Software as Service (SaaS) and/or Platform as Services (PaaS) that are maintained by vendors. This is being driven by the need to reduce maintenance costs, and optimise IT systems, thereby allowing clinical institutions to focus on their core scientific business. This presentation will focus on 6 keys areas to consider when planning to move to a cloud offering:
- Vendor viability
- Where is my data store and regulatory implications?
- How secure is my data?
- Compliance and regulations
- How, who and when to access data centre
- Service delivery

Biography
Dr Anil Dhiri an entrepreneurial Project Manager with over 34 years' experience in drug development, believes in Rapid Economic Justification (REJ) for forging alliances between IT and Business. A change agent influencer to optimise business processes thorough enablement of appropriate technologies.

Synopsis
GxP and Compliance of Cloud Based Applications
- Ð Vendor viability
- Ð Where is my data store and regulatory implications?
- Ð How secure is my data?
- Ð Compliance and regulations
- Ð How, who and when to access data centre
- Ð Service delivery

Learning objectives

- Best prcatices for implementing application in the cloud
- Types of cloud offerings
- Data security and implications

Big Data to Smart Data
Author: Srinivas Karri

Abstract

This presentation provides an overview of the emerging challenges with the utility of using Big Data for clinical R&D decision making. New and effective algorithmic approaches for processing big data is increasingly attractive when leading to 'smart data' that is of far greater value for clinical R&D. This presentation will consider one such approach - Statistical natural language processing for the identification of new Adverse Drug Events - and how it can be used to improve the safety of clinical trial.

Biography

Srinivas Karri is a Director of Clinical Data Warehousing Platforms at Oracle Heath Sciences. He has worked in the clinical R&D industry for over 17 years, having worked for F. Hoffman La Roche managing validated systems and clinical applications used across clinical R&D. More recently he has been developing cloud platforms to manage Big Data in clinical R&D.

Synopsis

This presentation provides an overview of the emerging challenges with the utility of using Big Data for clinical R&D decision making. New and effective algorithmic approaches for processing big data is increasingly attractive when leading to 'smart data' that is of far greater value for clinical R&D.

This presentation will consider one such approach - Statistical natural language processing for the identification of new Adverse Drug Events - and how it can be used to improve the safety of clinical trial.

Learning objectives

- Understand the fundamental concepts around big data
- Understand the current algorithmic approaches to managing clinial data specifically machine learning, statistical natural language processing and information retrieval
- See the application of statistical natural language processing as part of a real-world case study on big data to create smart data.

Design Clinical Data Management KPIs - The S.M.A.R.T Way
Author: Hari Priya

Abstract

Key Performance Indicators (KPIs) in Clinical Data Management (CDM) are critical to effectively measure and monitor performance, improve efficiencies and outcomes of a clinical study. S.M.A.R.T (Specific, Measurable, Achievable, Relevant, Time-bound) design of the KPIs improvise the tracking and feasibility of clinical trials which ultimately aids in significant decrease in time from drug development to marketing.

Biography

Curently, Global Data Manager with Kelly OCG providing services to Janssen Pharmeceutica . A certified Medidata RAVE Professional experienced in core Clinical Data Management activities with strong Project Management Skills applying Six Sigma strategies within several Phases of Clinical Research across multiple therapeutic areas to drive operational execellence.

Synopsis

Key Performance Indicators (KPIs) in Clinical Data Management (CDM) are critical to effectively measure and monitor performance, improve efficiencies and outcomes of a clinical study. S.M.A.R.T (Specific, Measurable, Achievable, Relevant, Time-bound) design of the KPIs improvise the tracking and feasibility of clinical trials which ultimately aids in significant decrease in time from drug development to marketing.

Learning objectives

- The design of S.M.A.R.T metrics usage in Clinical Data Management Key Performance Indicators.
- Ways of analyzing and interpreting the data in a way that leads to beneficial change.
- Feasibility of the project.

Implementing Risk-Based Monitoring: supporting tools
Authors: Marika Zanin & Giulia Zardi

Abstract

Risk-based monitoring (RBM) is coming into its own as an effective and pragmatic methodology to enhance patient safety and data quality. With the application of electronic Case Report Forms, it is possible to develop tools to support RBM by monitoring data and taking into account risk factors tracking study progression and proactively addressing potential critical situations. The key is to determine which factors correlate with increased risk. As there are subtle different types of risk, different metrics are required to monitor each type of risk. The use of a

Central Statistical Monitoring (CSM) tool adds a level of objectivity using statistical algorithms to check the quality of the data. The assignment of a risk score to each site involved in a clinical trial using this advanced and sophisticated statistical approach combined with the more established RBM approach allows visual exploration of these risk indicators, highlighting anomalies in a database and permitting fast intervention to improve data quality.

Transforming data to knowledge and the Question: Is Clinical Data Big (Data)?
Author: Oliver Herrmann

Abstract
Understanding the difference between data and knowledge and how valid computerised systems, defined and managed correctly, can support data-driven decision-making in a regulated GxP environment. When addressing the hot topic of Big Data in clinical research, considering whether or not clinical data as it is currently collected and processed is truly "Big Data" is an important question when evaluating how computerized systems can help process such data.

Biography
Oliver Herrmann has an engineering degree in computer science with a special emphasis on business process and workflow management. Over more than 10 years of activity within the GxP-regulated industries, he has gained extensive experience in planning, development, execution, documentation, and auditing of QM/QA strategies, projects and controls for GxP regulated environments.

Synopsis
Understanding the difference between data and knowledge and how valid computerised systems, defined and managed correctly, can support data-driven decision-making in a regulated GxP environment. When addressing the hot topic of Big Data in clinical research, considering whether or not clinical data as it is currently collected and processed is truly "Big Data" is an important question when evaluating how computerized systems can help process such data.

Learning objectives
- Understand Big Data, the value of data and the Increasing Data Volumes in Clinical Research
- Explain the relation between Data, Information and Knowledge and understand the Role of Computerized Systems in this context
- Address the Current Situation and Future Issues arising around Big Data and knowledge management

eSource beyond EDC and data management
Author: Mathias Poensgen

Abstract
eSource is mainly discussed in the context of EDC and from a data management perspective. However, the EMA made it clear in its reflection paper on GCP compliance in relation to trial master files that the concept of electronic source data needs to be considered in other areas; e.g., in the context of trial master files (TMF). This talk will provide an overview on the general aspects of eSource and how they apply to TMFs.

Biography
Mathias worked 13 years in various positions in clinical operations in the pharmaceutical industry. He was responsible for a program to replace all key systems in clinical operations, pharmacovigilance and data management for a mid sized pharma company. He then joined Aris Global and is now working as product manager

Synopsis
eSource is mainly discussed in the context of EDC and from a data management perspective. However, the EMA made it clear in its reflection paper on GCP compliance in relation to trial master files that the concept of electronic source data needs to be considered in other areas; e.g, in the context of trial master files (TMF). This talk will provide an overview on the general aspects of eSource and how they apply to TMFs.

Learning objectives
- Participant will be able to understand the effect eSource has on trial master files.
- Understand the difference in how eSource impacts EDC and eTMF.

Standardised CRF design in non-interventional studies

Authors: Alastair Simpson, Michele Pavlovic, Hannah Sharp

Abstract

Non-interventional studies (NIS) are becoming increasingly common in the industry. Gilead DM has seen the number of new studies rise from 1 in 2010 to 15 in 2015. To support this growth, a standardised CRF design has been implemented. Gilead DM will present an overview of NIS data capture considerations and our development of a NIS specific Global Library. This will be followed by an open discussion on standardisation and CRF design methodology in NIS.

Biography

Alastair Simpson is responsible for EU Late Phase data management operations at Gilead Sciences and has over 15 years of industry experience. He has worked in a variety of different CRO/Pharma organisations across Europe and the US, and has a particular technical interest in electronic data capture usage.

Synopsis

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Gilead DM will present an overview of NIS data capture considerations and our development of a NIS specific Global Library. This will be followed by an open discussion on standardisation and CRF design methodology in NIS.

Learning objectives

- Understand some of the challenges faced in CRF design for non-interventional studies
- Learn about how other industry peers have addressed these challenges
- See potential benefits that standardisation in NIS can provide

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Ideas to help trade associations and societies communicate effectively

A Simple Planning Formula

Does one structure fit all? Well, no. Communications fulfill a myriad of purposes. But most written materials that trade associations and societies write can be put together using an easily remembered formula. It's not complicated: you can keep it in mind with an acrostic, PR-MATE: PROPOSITION–RESEARCH–MEDIUM–AUDIENCE–THEME–EXECUTION. In the rest of this short piece, I'll set out how to use this handy memory aid.

1. PROPOSITION

You've seen them: the trade association submission or newsletter that's supposed to be focused, but ends up covering everything on members' minds. You don't have to do it like that. Before you write your piece, identify and agree a clear objective. This is your 'proposition'. Ask yourself: if the member, official or member of the public who reads this remembers one thing only, what should it be? Then write it down. It might never appear in the piece itself, but remember it and focus on it like a laser, throughout.

2. RESEARCH

Let's say you're crafting a consultation response. For all the talk of evidence-based policy, when association professionals first enter the political world, they can be shocked by how public policy can be based on scant research. The key is to start early enough to have that extra time to marshal an array of quality facts and figures. If you can, you'll be ahead of 50% of the competition. The scope to find the right sort of material online expands every year. And don't forget more traditional methods: call that member and quiz them; sit down with that colleague; ring that official.

3. MEDIUM

Good written communications are just that; whatever the medium. But a little thought can boost effectiveness. For example, on email: spend time getting the subject line right, keep essential content 'above the fold' (think preview pane) and, if you know the person, mention shared views and experiences. For reports: vary paragraph length and be consistent with body text and heading font. For presentations: don't use slides as handouts; start with a written document; hand that out; and consider distilling one killer fact or image per slide, or 20 words, or three bullets, tops.

4. AUDIENCE

You've defined the proposition, carved out time for research and thought about the medium. Just as important is to think about who you're talking to. It might be a member you know well, an official you don't know at all or a raft of members of the public. Sales professionals talk about the importance of 'rapport'. Face-to-face, that means matching their client's body and verbal language. You can do the same in written communications. Drop in a few choice words - being careful to fit them into the flow - that show the audience you understand their world.

For members, it might be an allusion to tough operating conditions or illustrating your copy with real examples of their business challenges.

For officials, it might be structuring your piece as a short 'briefing' with annexes, as they might do for a minister or showing you understand the importance of evidence-based policy; for MPs, you might number paragraphs from 1 to x, as a select committee might do in a report.

5. THEME

In an advertising agency, we'd be talking about 'concept'. Most association or society communications are more pedestrian, but the advertising world can still offer tips. Can you put an overall theme to the piece? Try to craft an overarching storyline to slot your material under. You can make a list of general approaches to see if any generates a suitable idea. It could be presenting a series of surprising facts and using each as a sub-heading to get your message across. You could challenge convention: while everybody is talking about emerging markets, you tell a story about how your sector is focusing on growth at home. Or comparison: you use a feature, on a successful automotive company, to tell the story of the historical mistakes made in the UK car industry and show how your firm avoided them.

5. EXECUTION

Then it comes to actually writing it. There's plenty to say there on structure, style and how to persuade and I plan to write another piece on that. I hope you enjoyed this short piece and that it sparked one or two ideas for your own writing.

Rob Siddall is a former trade association professional, who has served as a policy director and chief executive. He now works for himself as 'Anglo Corporate', helping trade associations and societies, small and large, communicate and operate more effectively. Anglo-Corporate can offer a 100% reliable, flexible and affordable addition to your in-house resources.

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ACDM Training – Confidence in Competence

There is no end to education. It is not that you read a book, pass an examination and finish with education. The whole of life, from the moment you are born to the moment you die, is a process of learning. Jiddu Krishnamurti

As an industry, we are not always great at documenting our professional training and development – take a good hard look at your Training Record – does it really represent your skills and experience effectively? Can an inspector or auditor really assess just how competent you are to do your job? A Training record supported by a credible role-based curriculum, clearly defined learning outcomes and independent professional verification is a powerful endorsement of continuing professional development, instilling confidence in your workforce.

As per ICH Guidelines (2.8), "Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s)". How do we best demonstrate this?

Experience of course does not provide evidence of competence and Regulators are increasingly requesting evidence of competence across the project teams. Training is no longer a box ticking exercise for organisations.

The term, Continuing Professional Development (CPD) comprises any educational activity which helps to maintain, develop or increase knowledge, problem-solving, technical skills or professional performance standards. This may comprise reading and understanding a Standard Operating Procedure, training in programming languages, learning how to use new systems, gaining new knowledge in different therapeutics areas or further developing soft skills in presenting, negotiation or effective time management.

As a professional, you have a responsibility to keep your skills and knowledge up to date. CPD helps you turn that accountability into a positive opportunity to identify and achieve your own career objectives and drive personal and organisational performance.

CPD is not a fixed process, one size does not fill all however there are certain basic approaches. The key focus is about setting yourself objectives and the development and charting of your progress towards achieving them. CPD is about capturing valuable experiences and assessing the practical benefits of this learning as you progress along your career path.

Managing your own CPD also supports:
- Building confidence and credibility
- Showcasing your achievements and support for appraisal reviews
- Achievement of your career goals
- Coping positively with change

Taking things to the next level, the process of accreditation promotes a mark of quality for the training that organisations have already put in place. In addition to being an investment for the organisation itself and its employees, accreditation is also viewed as a framework to organisational success. As companies grow and develop, first-class training becomes a vital component of an organisation's consistency towards working standards and practices, driving efficiency and quality, key in clinical data management and drug development.

Accreditation is of course highly valued across a wide set of industries – from private to public sector and ranges in format from role-based training to e-learning modules and specially modelled programmes. Options in the pharmaceutical sector for formal accredited training have been somewhat varied and limited.

A training programme can be accredited to provide external verification of the quality of the training. This can help participants meet continuing professional development requirements as well as providing the company with valuable industry benchmarking and advice and support on maximising the value of its training programmes.

The ACDM has provided a variety of training solutions and formats over many years and was keen to build on this framework in a more formal and recognised way. The ACDM was keen to engage an internationally-recognised, robust accreditation system that focuses on learning outcomes and verification of competence, providing a meaningful and professional offering to professional Clinical Data Managers.

The ACDM has partnered with the International Academy of Clinical Research (IAoCR), achieving Authorised Centre status, delivering accreditation of the course trainers and supporting definition and rigorous review of the learning outcomes for each course in the program to ensure that they are mapped to the appropriate level for the target group of learners.

The vision for the IAoCR and the ACDM is to drive:
• A globally consistent standard for clinical research organisations
• Evidence of independent assessment of workforce competence
• Reassurance that the organisation is following current best practice
• Transparency for sponsors and differentiation for CROs
• A clearly recognizable quality mark

IAoCR accreditations are mapped to various international qualifications frameworks, quality assured by bodies regulated by Ofqual (Office for Qualifications and Examinations Regulation). Levels are recognised within the ISCED framework (International Standard of Education) framework produced by UNESCO (United Nations Educational, Scientific and Cultural Organisation).

The ACDM Accredited Courses in Clinical Data Management aim to deliver a solid foundation in clinical data management skills starting with core fundamentals, progressing to technical and advanced skills through to project leadership, empowering professional Clinical Data Managers and enabling them to develop their career path in the pharmaceutical industry.

The courses are mapped to staff new to the clinical data management role, those looking to develop core technical skills and those taking on project leadership roles.

This drives benefits for employees and their professional development and for employers, ensuring talent retention, maintaining a high level of workforce quality and of course driving efficiency and profitability.

ACDM Accredited Courses are delivered using a mix of Webinar and face-to-face sessions.

During and on completion of the training course, there is a comprehensive assessment of the learning evidence provided in the workbooks by each learner to demonstrate that they have achieved the desired learning outcomes of the course. The evidence is collected both during the course and more importantly, after the course, in the workplace environment. The learning evidence is assessed by the course trainer and then undergoes a two-stage verification process via the IAoCR. If the evidence is satisfactory and meets the assessment criteria, then a certificate of accreditation is awarded to the learner. This is considerably more than a multiple choice test, the assessment is based on the defined learning outcomes and learners must clearly demonstrate a comprehensive understanding. The courses are designed to deliver the
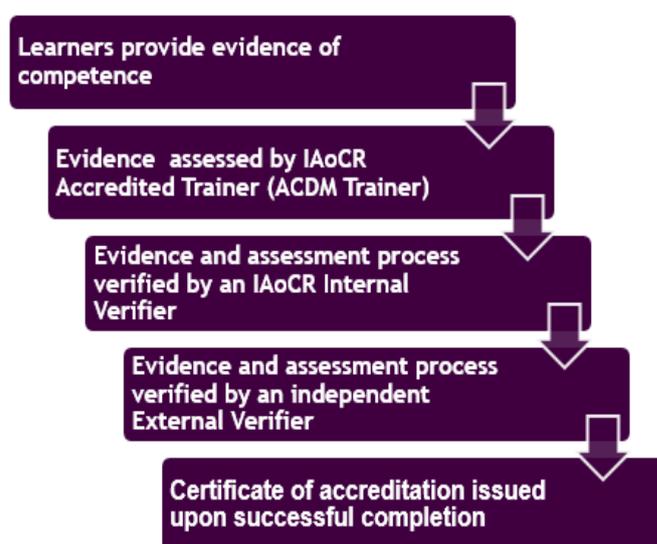
information and also to promote interactivity and hands on exercises based on real project scenarios. Independent internal and external verification is a key differentiator for the ACDM training programme and the comprehensive working materials and feedback sessions are key to demonstrating competence against the assessment criteria.

The benefits to individuals and companies is clear, promoting a robust framework for skills training and verification of competency for its staff.

Accreditation is an assurance that the professionals who work in our industry have a solid educational foundation and are capable of leading the way in drug development innovation, emerging technologies and in anticipating the needs of both internal and external customers.

Of course, competent clinical research professionals enable organisations to reduce time and costs and protect the rights and wellbeing of clinical trial subjects. This programme aims to deliver the confidence to Regulators, employees and employers.

Accreditation is value.

Watch for updates on the 2017 program via the ACDM

Demonstrates ACDM commitment to providing development opportunities

Demonstrates ACDM commitment to building a benchmark career map

Learners achieving accredited status will be entitled to use designatory letters

Enhances ACDM reputation as membership organisation of choice for CDM

website and social media outlets.

Try to learn something about everything and everything about something.

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