Society for Clinical Data Management
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Data Basics

To advance excellence in the management of clinical data

A PUBLICATION SUPPORTED BY AND FOR THE MEMBERS OF THE SOCIETY FOR CLINICAL DATA MANAGEMENT, INC.

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Letter from the Editors

Chandra Wooten and Rehana Blunt

It's hard to believe half the year has passed and we are already sharing the Summer issue of *Data Basics*. It's been a challenging year between the state of the economy and companies in our industry changing their structures, goals and priorities to better weather this economic storm. On the brighter side, change creates opportunities to break out of old patterns and re-invent yourself and your career. This can be your summer of renewal.

We've made some changes as well; the SCDM Web site has a new look and this is the second *Data Basics* e-publication. You'll find some interesting information about project management in this quarter's issue. Maybe you're interested in expanding your skill set and considering a career in technical clinical project management. Or perhaps you're looking to save commute time and gas money and are considering working remotely. This is your issue.

You've still got some time to plan your travel for the SCDM Annual Conference in Seattle. But if you can't make it to the SCDM Annual Conference this year, there are plenty of online webinars and courses available to hone your skills. And of course, the Publications Taskforce is eager to review articles submitted for publication in *Data Basics*; writing from your area of expertise is a great way to connect with your CDM colleagues (and having an article to your credit makes a nice addition to your resume, too!). The Fall issue will focus on ePRO and Other Patient Reported Data so dust off your typing fingers and share your thoughts, processes, questions and exciting stories.

On behalf of the Publications Taskforce, have a safe and relaxing summer. ■

Mind Mapping

Martin Robinson, BSc, PhD

Ever been asked to write an article and not known where to start? Being faced with a blank piece of paper and having committed to write 1,000 words can be quite daunting. Nineteenth century English poet Samuel Taylor Coleridge solved his particular problem of writer's block by taking laudanum – a potent mixture of opium and alcohol. Sadly he had completed only 54 lines of his famous unfinished work, *Kubla Khan*, before his stream of free-flowing thought was interrupted by the call of a visitor to his house.

Nowadays a more reliable and less addictive method of releasing the brain's potential is a technique known as Mind Mapping. This is a process designed to liberate the brain's energy and creativity. It involves capturing freewheeling ideas on a piece of paper. Lines are drawn between associated ideas and a Mind Map is created. The map usually has a radial appearance with interrelated thoughts emanating out from a central theme.

The mapping of ideas in a diagram seems to have been used as early as the third century. The Phoenician philosopher Porphyry of Tyre applied the technique to show the structure of the main themes of Aristotle's work *Categories*. American psychologist Tony Buzan claims to have invented the modern technique in the 1960s. Frustrated with taking copious notes as

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This Issue

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Letter from the Chair

Linda M. Talley, CCDM

Summer greetings to all!

I am excited to report that there continues to be tremendous progress in SCDM toward our objectives and goals for 2009.

Data Basics provides SCDM members with educational information each quarter to keep you current on industry trends. But reading peer-reviewed articles doesn't replace the experience of in-person learning.

Apparently, you agree. More than 50 percent of respondents to our polling indicated that they prefer meetings and conferences over other forms of education – including webinars, online courses and publications.

The upcoming 2009 SCDM Annual Conference, October 4-6 in Seattle, is certain to justify our status as the premier educational event in the clinical data management industry.

This year's schedule focuses on the changes and challenges in clinical data management, with presentations from the Food and Drug Administration, the Metrics Champion Consortium (MCC) and industry experts on project management, new technology and other topics.

If you haven't already, make sure to register soon for the Annual Conference. You can register online at www.scdm.org/events/fall2009. Early registration discounts apply through July 17.

Just because we're so excited about our upcoming conference doesn't mean we're not investing in other learning opportunities. In fact, we're continuing to improve our educational programs to provide you with the quality and innovation you expect from SCDM. Here's a quick look at some of our recent initiatives:

In cooperation with the Japan Pharmaceuticals Manufacturers Association, *Good Clinical Data Management Practices*, our award-winning resource, will be translated into Japanese. This project will improve consistency and establish standards for clinical data management across the globe.

We have formed a partnership with CDISC to provide exceptional professional development opportunities to members of both organizations. We've already hosted two webinars in conjunction with CDISC. A third, titled CDASH User Guide, will be held in October.

Our first online course, on data management plans, is underway with 20 students. A second course, on project management, is set to begin in September. These courses are led by industry leaders and have a flexible schedule to fit the busy lifestyles of our members. Learn more on these opportunities through the education portal section of the SCDM Web site.

Social networking via Twitter, Facebook and LinkedIn provides SCDM members with convenient forums to network. You can access any of these groups by creating a free account on the social networking site and searching "SCDM."

I hope that you are as excited about these new opportunities as I am. I look forward to seeing all of you in Seattle!

Wishing you happy times this summer!

Cheers,
Linda M. Talley, CCDM
Chair, SCDM Board of Trustees

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Mind Mapping

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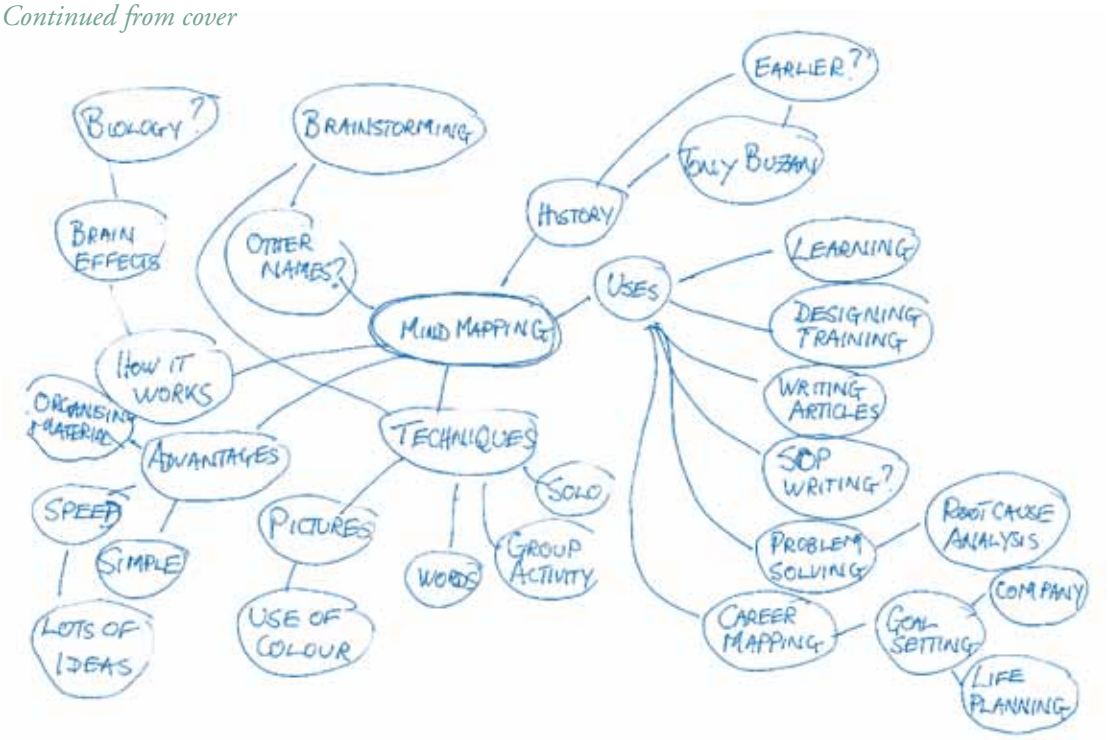

a student during lectures at university, Buzan used the technique to organize his thoughts and capture ideas. He found that not only was Mind Mapping a more efficient way of taking notes, but it also enabled him to memorize the material. Since then, Mind Mapping has been developed as a tool for preparing presentations, creating written work, goal setting, problem solving, decision making and as a method for memory retention.

The power of Mind Mapping comes from the way the technique reflects the way the brain processes information naturally. Traditional note making is considered to inhibit creative thought. This is because laying out ideas in a linear way uses left brain thinking only. This part of the brain is dominated by logical, ordered and detailed thinking. Mind Mapping is supposed to stimulate the use of the right brain, which releases a stream of consciousness and uses symbolism and large-scale pictorial thinking.

Let's look at one of the applications of Mind Mapping — the creating of ideas for a magazine article like this one. Start the process by getting a blank piece of paper. Try to avoid lined material. It might make it too tempting to create a list! Size A4 will do and it is preferable to use the page in landscape mode. Write the word describing the central topic or title of the article in the middle of the paper and circle it. If your chosen topic was Mind Mapping you might start thinking about its uses, history, techniques, how it works, etc. Write these ideas as you think of them as single words or short phrases, circling and connecting them with lines to the central theme. Each of these secondary ideas will lead to further thoughts which you can write down as you think of them. The ideas will not come in any particular logical order and your mind might jump from one concept to another. It is this free-wheeling stream of thought which allows your brain to generate lots of ideas in a relatively short period of time.

Some people find using color helps. Different shades are used to illustrate the various concepts which radiate from the central theme. This can help stimulate the imagination into creative thought. Sometimes drawing simple pictures can be useful. To give you an idea of what a Mind Map might look like, the one I used to start writing this article is shown in the illustration. It took me about 10 minutes to create this, as I was sitting on a crowded train on the way to an assignment.

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Mind Mapping

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Mind Mapping can also be used to help design presentations or training courses. I find it particularly helpful if I have to create a course on a potentially dry topic such as Good Clinical Practice. Once the main ideas are created, the material can then be selected and put in a logical order so it makes sense for the participants and flows smoothly.

Mind Mapping is sometimes called 'brainstorming for one.' It can also be a very powerful tool when used by small teams. Usually no more than six to eight people per group works best. In one of my previous companies, we used the group technique very successfully to conduct a type of root cause analysis. The challenge was to find out why people don't use Standard Operating Procedures. We posed this as a central question on a piece of flipchart paper and came up with numerous reasons. As well as the obvious, several of the more obscure issues came to light, some of which proved to be valid. With group Mind Mapping one person should act as a facilitator. This role involves ensuring the team freewheels lots of ideas without judgement. The rationalization, analysis and, most important, the action plan, can be developed later.

Mind Mapping can also be used for goal-setting. Businesses can apply the technique for exploring the potential for new markets or for generating ideas for innovative products. By looking at how to use its current assets in unexploited areas, a company can maximize the potential of its workforce and its resources.

Mind Mapping can be applied to individual goal-setting too. People have used it for analyzing both their careers and private lives. By identifying likes and dislikes about your life in and outside work and reflecting on where you want to go, you can create an individual plan to help you realize your aims and desires!

As you might imagine, Mind Mapping software has been developed. There are a number of organizations who offer this. Various packages related to the different uses of Mind Mapping are available, including tools for studying, creative thinking and project management. There are copious books on the subject and a quick search on the internet will reveal numerous titles. Nevertheless, one of the beauties of Mind Mapping remains its simplicity. A pen, a piece of paper and a little time is all you need. Have a go and see where it takes you! ■

Martin Robinson, BSc, PhD, is principal training consultant at the Institute of Clinical Research. In the past he has been involved in clinical research in a number of roles including training and development, and clinical study project management. Martin has authored a book and monographs on clinical research subjects. He has also had fictional short stories published and is currently working on a larger project. Martin frequently uses Mind Mapping for the design of training courses and the creation of written work.

The Institute of Clinical Research is a not-for-profit membership organization. It is well established as the largest professional clinical research body in Europe and India. Its aims are to provide opportunities for learning and development, to enhance professional competence in clinical research. Services for members include discussion forums, information resources, training courses, conferences and publications.

This article was previously published in the Autumn 2008 issue 67 of Association for Clinical Data Management's *Data Matters*.

Outsourcing Trends and Business Models in Clinical Data Management

Nimita Limaye, PhD

The global clinical trials business is currently worth an estimated $10 billion (USD). With over a thousand CROs worldwide, the top five account for 45 percent of the market share. While leading CROs serve as one-stop shops, the data management niche is increasingly being eroded by the business process outsourcing (BPO)/Information Technology Enabled Services (ITES) sector. Scalability, process expertise and direct access to sponsors through other verticals such as financials and software give this sector the necessary foothold.

Companies are also gradually evolving from the Fully Integrated Pharmaceutical Company (FIPCO) to the Virtual Pharma Company (VIPCO). Rapidly expiring patents, shrinking pipelines, increasing drug development costs and timelines, and fluctuating business needs are consistently driving companies to carefully evaluate core responsibilities – and to outsource those that are non-core. Traditionally, all activities were performed in-house – the FIPCO model. But as companies transition to the VIPCO model, non-core activities, such as clinical data management and clinical operations, are outsourced to contract research organizations (CROs).

Current outsourcing trends include:

- Offshore service providers are choosing the path of inorganic growth – mergers and acquisitions are the method of choice.
- Labor arbitrage is rapidly diminishing thanks to wage inflation.
- Asia-Pacific, Eastern Europe and Latin America are key outsourcing destinations.
- Contracts are increasingly demanding that process improvements translate to fixed cost savings.
- Mega-deals are expected to diminish.

The advantages of outsourcing include converting fixed costs (e.g., head count, infrastructure) to variable costs, allowing the vendor to bear the costs of handling peaks and troughs in work volumes and eliminating the need to build expensive domain expertise in-house in areas that are non-core. A step further is the formation of virtual CROs (vCROs), which utilize a small team with high levels of domain expertise, to play more of a consultancy role and further subcontract to niche CROs.

Outsourcing dilemmas faced by companies include:

- Defining what is core and non-core and, hence, what should be outsourced
- Whether to outsource to a business process outsourcing (BPO), knowledge process outsourcing (KPO) or CRO CROs have the advantage of clinical domain expertise across the clinical trial spectrum, whereas BPOs stand out in terms of process expertise and scalability. KPOs position themselves as niche high-end players, with a narrow focus in a core area
- Whether to pursue functional outsourcing/cherry-picking or to look for a one-stop shop
- Which business model to follow
- Whether to outsource or offshore. While the cost advantages of offshoring are pretty obvious, issues that come up include concerns regarding time zones, communication difficulties, cultural differences and the need to perform a thorough due diligence to ensure data security, etc. Vendors may attempt to partly address these issues by establishing onsite project management
- Whether to approach top global CROs of established repute or opt for smaller, less expensive, local CROs with local expertise
- Which approach should be followed for short-listing vendors – the routine RFI/RFP option, followed by a bid defense, or the reverse auction process (a type of an auction in which the role of the buyer and seller are reversed, with the primary objective to drive purchase prices downward through a dynamic real-time online bidding process)

What works and what doesn't

Some of the common sources of conflict between sponsors and CROs include:

- Mismatched expectations and poor communication between the sponsor and the CRO
- Excessive micromanagement from the sponsor
- Changing needs from the sponsor during the course of the engagement
- A lack of transparency from the CRO regarding problems that arise during the study
- Staff showcased by the CRO during the bidding process not constituting a part of the actual study team
- High levels of employee turnover at the CRO resulting in continuous changes to the study team

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- Inability of the CRO to meet timelines or commit to quality standards
- Inadequate planning or risk management by the CRO
- Differential treatment by the CRO towards large and small sponsors

Factors contributing to the success of CRO-sponsor relationships include:

- Well established and effective issue escalation and communication plans
- Onsite project management
- High levels of transparency of what the CRO can and cannot deliver
- Thorough compliance with the contract
- Ensuring a well-serviced relationship with senior management commitment from both ends
- A genuine commitment from the sponsor to make the CRO team feel a part of the sponsor team. This drives both commitment and quality

Options for Business Models

There are a number of business models that can be followed to meet the unique needs of the company and/or project. These include:

Individual Project Outsourcing

This is the simplest and most routinely followed model, wherein a single project or a small set of activities are outsourced to a vendor. This model is usually pursued in the initial stages of a sponsor-vendor relationship and at the stage at which the sponsor is testing the waters – it is a confidence-building exercise. This model is typically employed by smaller pharmas.

Full Time Equivalent (FTE)

This is an extension of the contract staffing model, wherein the vendor provides the sponsor with a dedicated number of FTEs per the sponsor's requirements. Costing is per resource. This is a better model to opt for when there is a clear visibility of work volumes and the number of FTEs that are required.

Functional Service Provider (FSP)

This is a more advanced model, wherein there are a dedicated number of resources, but costing is done at an hourly rate. The advantage of this model to the sponsor is where work loads fluctuate significantly. The sponsor needs to pay only for the productive billable hours of the resources. Thus, it is the vendor who bears the cost of the slack in work volumes.

Both the FTE and FSP models are usually pursued by larger pharmas and thus provide the vendor with visibility as well as a steady inflow of revenue.

Build Operate Transfer (BOT) and Build Own Operate Transfer (BOOT)

These models are useful when a sponsor wants to set up its own operations in a new country and is not well versed with the lay of the land. In this model, the vendor sets up operations from scratch and, over a period of time, the facility and the resources are taken over by the sponsor. This is a model that is usually not preferred by vendors since, at the end of the day, the resources that have been recruited and trained by the vendor are taken over by the sponsor. In addition, since these resources are going to constitute sponsor head count, sponsors tend to be more intrusive in this matter.

Captive

This model is usually pursued for more high-end research and development, such as drug discovery, wherein the sponsor establishes its own operations. The investment and the challenges of independently establishing one's own operations in a new geography are high; however, when control over IP becomes critical, this often is considered the method of choice. Here, of course, outsourcing does not come into the picture.

At the end of the day, there will be a maturing of vendor-sponsor relationships, resulting in service provider consolidation, and a transition from a service provider relationship to a strategic partner relationship – wherein risk-sharing and profit-sharing come into the picture. The partner that may be chosen may not necessarily be the lowest-bid provider, but one that provides long-term efficiencies, minimizes out-of-scope costs and ensures performance improvements that would potentially surpass short-term cost savings. ■

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This article is derived from a session originally presented at the 2008 SCDM Annual Conference.

Upcoming Webinars

Patient Reported Outcomes
August 13 & 20

Database Validation & Surviving an Audit
October 22 & 29

Project Management Toolbox
November 5, 12 & 19

Tech(Cli)nical Project Managers and Their Role in eCDM

Suresh Sharma

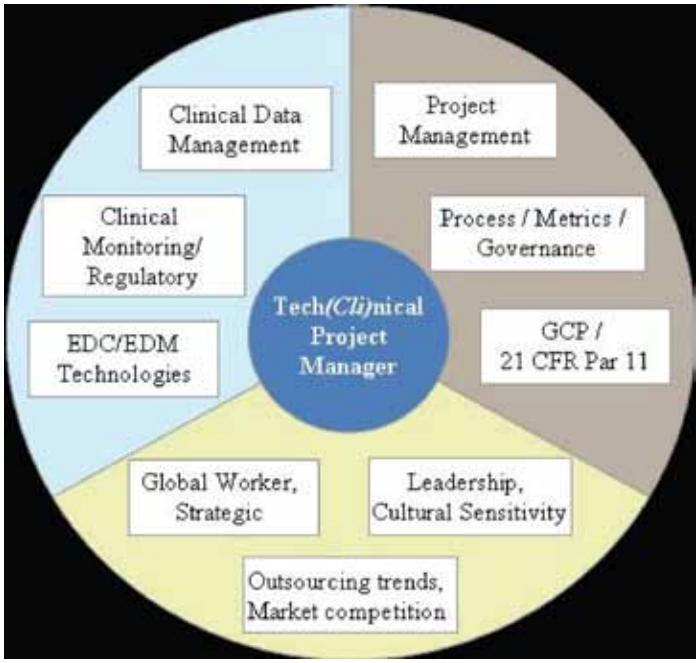
According to a recent market report, spending on EDC solutions is expected to increase at 11.6 percent compound annual growth rate (CAGR) and total more than $3.25 billion for 2007-2012. In 2009, spending on Phase I-III studies alone will exceed $523 million[1]. Wider electronic data capture (EDC) adoption has been driven by increased acceptance by large pharma and as a result, the EDC market is expected to grow 16 percent CAGR and approach $700 million by 2012. EDC has also created opportunities in expanding the role of the clinical research associate (CRA) and the clinical data manager (CDM), not just bridging it. CRAs and CDMs of the 21st century operate in environments quite unlike those they first entered years ago. They must regularly update their skills (clinical advancements, project management, technical and behavioral) to meet the challenges of a dynamic global clinical research market that includes outsourcing and off shoring.

Pharmaceutical companies have always opted for EDC (with CROs IT Enabled-Services Business Process Outsourcing (ITES-BPOs) developed in-house leading EDC vendors) to carry out large multinational, multi-center clinical trials, primarily to improve quality of data, shorten study timelines and reduce project costs. Advancements in technology that capture and manage volumes of clinical trial data from multiple sources have added more complexity to the processes involved in conducting an EDC study. Project teams must possess the necessary skills and competencies to handle these challenges.

A clinical development professional with a blend of both technical and clinical expertise, coupled with strong project management skills, can understand the complexities in handling EDC trials. He or she can provide innovative solutions and process improvements and translate them into actionable items for project teams. These professionals are called 'Tech(Cli)nical' Project Managers or '*TC*PMs'.

Who can become a TCPM?

Clinical research professionals and project data managers who have hands-on experience in most aspects of clinical data management and have managed the delivery of large global/multi-country and multi-center clinical trial databases are ideal candidates for the role of TCPMs. TCPMs are seen mostly in pharmaceutical companies rather than CROs due to their exposure in handling multiple therapeutic areas, collaborating with third-party vendors for data transfers and data reconciliation, and working with clinical project teams on study inputs/amendments/modifications with stringent budgets and timelines for submissions to regulatory authorities.



Competencies of a TCPM

The competencies of a TCPM typically should cover:

Technical:

- Clinical research methodologies
- Clinical data management
- EDC technologies
- Project management
- Information technology

Behavioral:

- Leadership
- Strong cross-cultural communication
- People management
- Planning and organization
- Innovation and creativity
- Networking

Strategic:

- Outsourcing trends
- Department/business goals
- Market competition
- Cost competition
- Vendor management/procurement
- Pharma-IT integration

Roadmap to Bridge Skill Gap

A clinical research professional must chart his career map by doing a Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis of himself. If after analysis the role of TCPM is fascinating, below are a few steps to help achieve it.

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Tech(Cli)nical Project Managers and their Role in eCDM

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Technical skill gaps

Technical skills in CDM can be improved by preparing to take certification exams such as Certified Clinical Data Manager (CCDM®) offered by the Society for Clinical Data Management (SCDM) or Project Management Professional (PMP®) offered by Project Management Institute (PMI). Additionally, skills can be honed by working on EDC trials, participating or leading the design and implementation of a tool/software that automates any clinical data management process, or by project managing a large phase III, trial that includes data handling with third-party vendors (IVRS, lab, ECG, CT-SCAN, etc.).

Behavioral skills gaps

Behavioral skills can be enhanced by nominating deserving professionals to attend leadership development seminars and workshops. Skills can also be improved by providing opportunities to work on project teams that have different cultures, styles of working, communication and time zones. It is often seen that participation in face-to-face project team meetings like investigator meetings, CRA trainings and EDC set-up meetings enables individuals to learn, adapt and understand the behaviors and objectives of every stakeholder involved in making the project a success. Another networking forum where diverse cultures, thoughts and ideas can be experienced is at international conferences and seminars organized by professional bodies like SCDM, Drug Information Association (DIA) and Association of Clinical Data Management (ACDM) among others.

Strategic skill gaps

Tactical skills can be enhanced by providing opportunities to review and give input into the department's overall strategic plan. Taking a strategic priority that is hindered and brainstorming what changes could be made to the process and policy around it also aligns with strategic priorities. Reading industry and organizational business reports and summarizing information about current business trends for decision making helps gain corporate mileage.

So, after all this hard work, do you want to be a Technical PM, Clinical PM or TCPM? ■

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Bio of the Author:

Suresh Sharma has been in clinical data management for more than 10 years with prior experience in a multinational pharmaceutical company and a leading multinational CRO in India. He is currently working as operations director in the life sciences and pharma BPO at TATA Consultancy Services, India, and manages the delivery of outsourced clinical development services for a global pharmaceutical client. Besides operations, he also supports business development and market research/intelligence in the life sciences and pharma vertical of TCS.

Remote Possibilities

The Benefits and Challenges of Working Remotely

Mary Belgard, MMHS

Have you ever considered working remotely? You are not alone. There is growing interest from both employers and employees in non-traditional work environments. For greatest success, however, this shift must be approached with strategic evaluation of the advantages and disadvantages, as well as careful assessment of employees and managers.

The advantages for an employee working remotely may seem obvious:

- The ability to expand professional options without relocating. You may have an opportunity to work in a position that provides more visibility or opportunity for advancement, but it's on the opposite coast. This means uprooting the kids from school and friends; your spouse/significant other would need to find a position as well. Suddenly, the opportunity doesn't seem so wonderful – unless you can work remotely.
- Reducing or eliminating time spent commuting and the associated costs.
- The ability to enhance work/life balance. Eliminating a daily commute can make a significant impact on quality of life – the difference between making dinner or picking up takeout, having the time and energy to help with homework, spending time at the gym or devoting time to other activities.

The advantages to an organization also seem obvious:

- Attracting great talent from a wider geographical area without the cost of relocation.
- Expanding service area without necessarily increasing real estate or facility costs.
- Increasing resources without adding to the "space race" in existing facilities.

According to a white paper published by the Work Design Collaborative in 2008, Sun Microsystems, Cisco Systems and IBM were able to reduce their investment in real estate and facilities by up to 50 percent by allowing employees to work remotely – a substantial cost savings.

For all intents and purposes, this sounds like the ultimate win-win scenario. There are, however, challenges that accompany remote work. Organizations must consider connectivity (DSL vs. dial-up), security (authentication methods for VPN access) and the ability to support the remote employee (tools that allow IT to investigate and address problems remotely, software compatibility).

Communication and relationship building must also be addressed. Remote employees and managers do not have the chance to have unplanned hallway conversations; they do not meet at the coffee maker or walking from the parking lot. Communication becomes more formal and centers on the project or task.

A traditional work environment provides managers with a better sense of productivity and quality of their direct reports. For managers and personnel functioning in a remote environment, there may be a gap between perception and reality. Key to bringing perception closer to reality is a process of communication and relationship building. Effective communication yields quality results; expectations need to be clear. Effective communication in combination with a solid relationship yields a trusting relationship – one where both parties are comfortable questioning and clarifying. The Work Design Collaborative estimated a 15 percent gain in productivity among remote workers and attributed this to a reduction of what they term "time wasters" – distractions, interruptions and disturbances that are inherent in the workplace. Without clear expectations and the ability to measure performance, this anticipated productivity gain may never be realized or, if gained, may not be noticed. Failure, by either the manager or the employee, to plan for or manage these challenges virtually guarantees a suboptimal outcome.

It is also critical to acknowledge that not everyone has the personality, skill set or experience for remote work and not every role lends itself to being done remotely. Some individuals need the interaction of an office environment. Some may be easily distracted or have difficulty managing time. More junior level employees may benefit from working closely with a team or may require more guidance or training. Not all managers can effectively manage remote employees – they may come to their positions with innate trust issues or they may fall into the "out of sight out of mind" trap, neglecting to disseminate information or bypassing a remote worker for an assignment. Roles that require frequent face-to-face meetings or trials that are run using a paper-based system are not amenable to remote work solutions.

The key to making a remote work scenario a success is determining fit. Whether you are hiring a new employee, or evaluating a current employee for a remote position, there are certain characteristics that should be present. A candidate who is a good fit will be focused and self-motivated. They will possess good problem-solving ability and will actively seek additional information if needed. They will be experienced in their role and comfortable with the organization. While these are characteristics that are desirable in any employee, they are critical for a remote employee.

How can you determine whether a candidate is a good fit for a position? The techniques listed here are commonly employed

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Remote Possibilities

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for both onsite and remote positions, but hiring managers must keep in mind the unique challenges posed by an off-site position.

Begin with a phone screen. Spell out the requirements of the position – is a set schedule needed or is there some degree of flexibility; will the candidate be expected to be on site periodically? Who will the candidate interact with on a regular basis – only colleagues within data management, or will they work with an interdisciplinary team? Will they interact with clinical sites, or in the case of a CRO or consulting group, with a client? Try to evaluate the candidate's verbal communication skills as this is the primary method they will employ in the position. Are their responses clearly stated and on topic? Did they ask for clarification or further definition? Ask if they prefer written or verbal communication – while both are necessary, knowing this personal preference will promote an effective working relationship.

A face-to-face interview allows both the hiring manager and the candidate an opportunity to establish a relationship, for both parties to assess 'fit' with the team and the company culture. This interview offers the opportunity to lay a solid foundation upon which to build.

Personality assessment tools help to gauge the candidate's profile as it is, not necessarily the one that is presented during the interview. The Predictive Index, DiSC, or Myers-Briggs tools help identify a candidate's strengths. Knowledge of a candidate's or employee's preferences can help a manager understand how to best motivate, lead and leverage a person's strengths. In my organization, we have found that sharing these profiles within a team aids in understanding how team members complement each other's strengths and helps the team develop a shared, common language.

Another goal during the interview process is to assess whether the candidate has a suitable working environment. Discuss the logistics and the expectations of the position. What will the candidate be expected to provide (e.g., separate office area, secure storage for confidential information, DSL); what will the company provide (laptop, cell phone) or reimburse (dedicated phone line, office supplies, software)?

What management skills are needed when working with remote staff? The manager needs to communicate – clearly, consistently, and often. The manager needs to make conscious efforts to build rapport with each team member and to facilitate team building. When balancing a heavy workload it may be easy to focus on your onsite employees and overlook the needs of a remote employee – but it is not acceptable. Ongoing support is required, even when all is running smoothly. Setting a time for a regular phone call or face-to-face meeting (if possible) keeps the lines of communication open. The manager needs to measure performance on an ongoing basis and provide feedback. Performance should be both metric based (e.g., time from LPLV to lock) as well as gauged by customer satisfaction (internal team or sponsor/client).

Issues need to be addressed in a timely fashion. Many people find it difficult to address a negative issue directly. The temptation to let issues ride is exacerbated when the employee is remote – again the "out of sight out of mind" trap. It is a disservice to the organization – and to the employee – to indulge in this behavior. Proceeding without intervention typically worsens the situation. When the issue is finally addressed, it is perceived by the employee as a sudden course correction of a long standing behavior (the "why now?" scenario).

It is just as important to celebrate success as it is to address issues. Both are learning processes. Acknowledgement of a team success can enhance an employee's profile and further incorporate the remote worker into the larger unit.

If remote work is adopted by an organization, periodically assessing the success of this strategy is advisable. Identifying strengths and, perhaps more importantly, weaknesses can facilitate rapid response and process improvement.

Remote work environments provide great opportunities for both individuals and organizations. They also require careful definition of roles and responsibilities; careful screening for best fit; communication of expectations; and intentional, consistent management of both performance and relationships. ■

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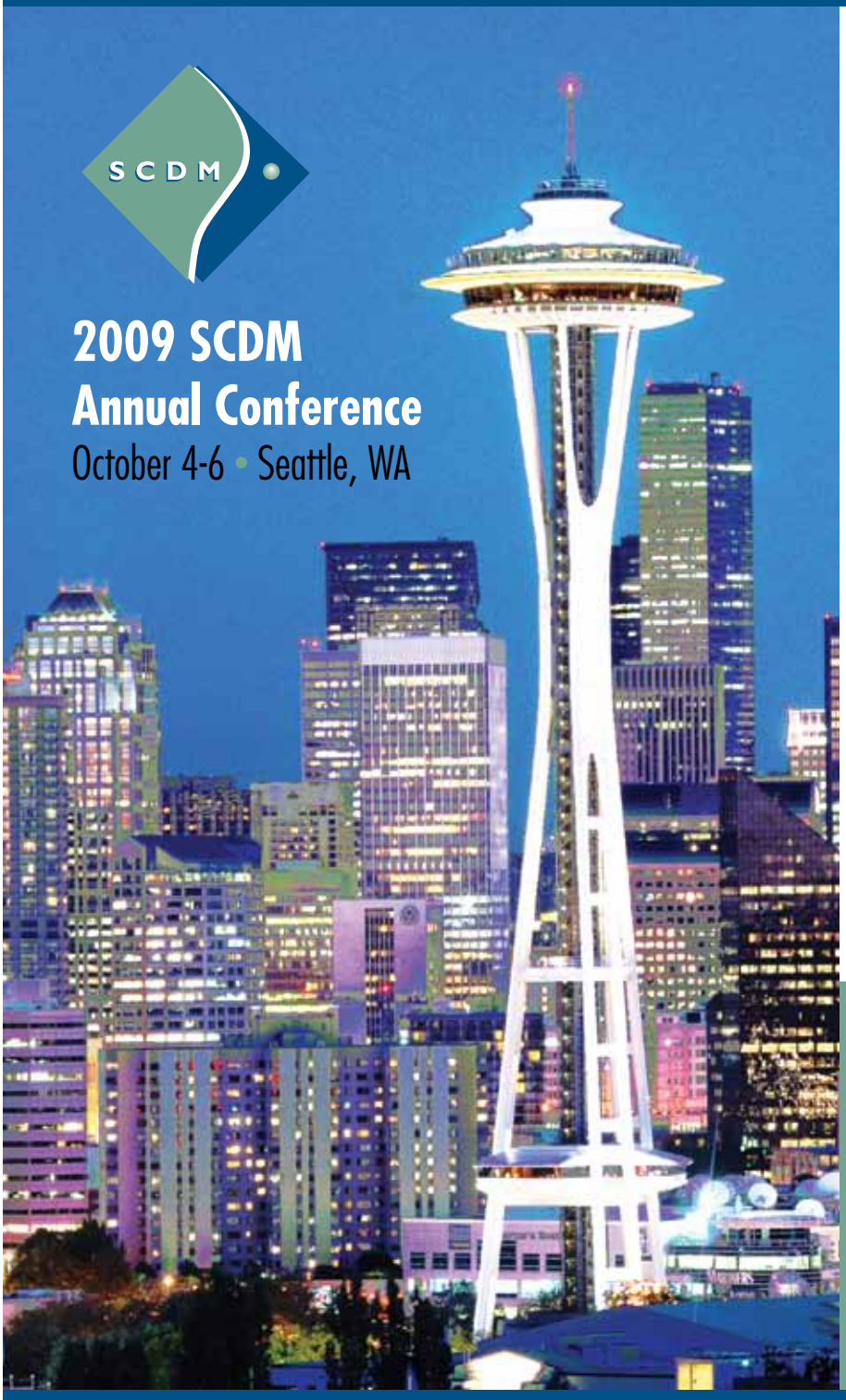

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An Analysis of Requirements for Metadata in Metadata Driven Mapping Projects and Organizations

Dimitri Kutsenko, MSc/MA

The metadata-based data processing brings numerous advantages. By defining the structure and content of the target data in advance, the probability of errors in the data framework is significantly reduced and the data framework consistency is increased. If meaningful, metadata allow for data validation against metadata definitions leading to improved data quality – one of the major advantages of the metadata-based approach.

This forward approach allows for better planning of study structures and improves data comparability and transparency: through easier pooling of standardized intra- and inter-study data, organizations are able to make analysis statistically more reliable through a broader data base for informed decisions.

From the process perspective, a significant advantage is the separation of data structure definition and data acquisition. Thus statistical programmers can start developing analysis programs even before study data are available, thereby taking the definition of metadata off the critical path. Moreover, standardized structures would allow creation of standard algorithms which can be made available to and reused by others involved in the data definition, transformation, analysis and reporting process. By collecting and providing the developed standard metadata items, structures and algorithms in a company-wide library, organizations eliminate redundant work and save valuable expert time.

Moreover, standard metadata significantly reduce training efforts in an organization and community. Once trained and familiar with standard metadata items and their descriptions, those involved can more easily interpret the data and develop analysis programs, even if data are structured differently in particular studies.

However, in order to establish a true metadata driven organization and to benefit from the metadata foundation, a number of requirements with regard to metadata must be fulfilled.

When dealing with multiple clinical trials over longer time periods, organizations perform a balancing act between the variation and standardization of study structures and consequent study metadata descriptions — each study's metadata are and will remain specific, reflecting particular study characteristics. Moreover, life sciences organizations usually collect for internal purposes more information than required for submission. This additional information is not included in submission packages, but is essential and has to be managed in a consistent way together with the submission relevant items.

How much metadata does an organization need to organize the processes in an efficient way? Which metadata items should be included in the standardized model at the organizational level and which should be maintained at the study level? Every organization which implements metadata-based processes has to answer these questions first. The questions are especially significant for large organizations with a broad spectrum of studies. If you try to include all possible metadata and study-specific metadata in the standardized model, the model becomes incomprehensible and leads to "metadata inflation." This is also true for the company-specific implementations of CDISC models with regard to structural issues (e.g., definition of additional domains, selection of attributes that must be included in supplemental qualifiers) and terminology usage.

Consequently, the metadata handling within an organization must be flexible, to allow the integration of both standardized (e.g., CDISC-compliant) and specific metadata into the company-wide model. On the other hand, metadata models must be extensible to cope with future changes (e.g., new CDISC versions). Change management must be supported to allow simultaneous and consistent work with different versions of metadata models and data dictionaries due to study duration.

To make numerous organization-wide metadata items comprehensive and easy to use, means to organize them in groups or classes are required. Moreover, it should be possible to define metadata hierarchically at different levels — be it project, study, domain or attributes. It should be possible to link metadata to data dictionaries and catalogs in order to provide for consistent data definition, to check the data and to compare it to the dictionaries later on. The possibility of specifying dependencies between objects at all available levels would reduce the complexity and allow for automated processing such as on-the-fly generation of define.xml with all corresponding hyperlinks. Different types of entity relations must be supported - not only 1:1, but also 1:N and M:N. The metadata handling mechanism should support transfer between data and metadata as well, which is required in case of supplemental qualifiers.

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An Analysis of Requirements for Metadata in Metadata Driven Mapping Projects and Organizations

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In order to use metadata in steering processes, metadata need to be accessible at runtime.

Metadata must be made available throughout the organization to all concerned parties, for example, via a central repository. One must be able to reuse metadata definitions already developed without requiring that they be rewritten from scratch thus eliminating redundant work in each new study. It should be possible to access available metadata in external systems or automatically derive metadata from existing (legacy) datasets. Reusability must be available for different metadata types such as object metadata, structure definitions or transformation algorithms.

The multi-stage data definition, transformation, analysis and submission process involves multiple organizational roles (e.g. data managers and statistical programmers), usually distributed over separate units. Significant communicational loss and friction emerge at the interfaces between roles and units without proper tool support.

Effective and efficient team collaboration tools are required in a metadata driven environment that would reduce tension between the participants: setting up controlled workflows is one of them. Due to the fact that workflows might differ from study to study, and that they depend on the particular object type, workflow definition based on metadata (instead of hard-coded workflows) would bring required flexibility.

Finally, addressing the strict requirements applicable to life sciences, the process of metadata handling has to be transparent, traceable, repeatable and well documented from metadata creation through metadata-based data conversion and analysis up to reporting and submission in order to fulfill the regulatory requirements like FDA 21 CFR part 11 (FDA, 2000).

CDISC has already made the first steps toward the described metadata vision by having started standards harmonization initiatives (CDISC, 2008) and providing model metadata in a public domain repository (NCI, 2009). The effort of establishing a metadata-driven organization will not be adequate if it is not possible to automate major metadata handling processes. Only in this case would the advantages connected with introducing complex metadata oriented models surpass the costs of manual data maintenance.

With consistent publicly available and company-own standard metadata and efficient support of the tools for metadata handling already available on the market, a metadata driven project organization has become a reality – share the vision and take off now! ■

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Certification Corner

Welcome to the very first release of the Certification Corner! We've created this special section of *Data Basics* for CCDMs and those interested in certification as a forum for sharing fun facts, updates and CCDM tips.

CCDMs have established themselves as professionals dedicated to career advancement and industry improvement, as evidenced by their membership in various professional associations.

Some fun facts for you:

As of April'09:

- We have 388 CCDMs of whom approximately 70% are females
- Eight represent either medical professionals or doctorates
- Approximately one-eighth of the CCDMs represents senior management (Asst Director and above)
- 58 of the CCDMs are from California, 34 from North Carolina, 24 from Maryland, 36 from Philadelphia, 20 from Texas
- We also have 20 CCDMs from Canada, 18 from India, 17 from South Africa – that's SCDM going global and a clear global need for professional certification
- 185 of the 388 members have acquired beta certification
- About 20 of the CCDMs have over nine years of experience in the field of data management
- 78 members have one to three years and 43 have four to five years of work experience in the field of data management
- Almost all the members with over 11 years of experience in the field of data management opted for the beta certification
- Close to 100 CCDMs were also members of the DIA; about 28 were members of the ACDM and several CCDMs were also members of SOCRA, ACRP and a few other associations

With respect to membership from 2009:

- Close to 40 percent of our membership is organizational, not individual
- There is a 3:2 female to male gender distribution
- More than 15 percent of the membership for 2009 represents international members – indicative of an organization going global
- Of the domestic membership, representing 28 states across the US, California leads in membership, followed by Maryland, New Jersey, North Carolina and Pennsylvania
- With members joining from 16 countries apart from the US in 2009, Canada, followed by India, Germany and Denmark had the highest membership. Five Asian countries, namely India, China, Japan, Singapore and Thailand represented more than one-fourth of the new membership
- CROs represented almost half of the membership with biotechs and pharmas representing approximately 8 percent and 9 percent respectively
- A vast chunk of the membership has two to five years of experience

We welcome your comments, tips and brainstorming for the next release of the Certification Corner – do write in to Sue Abrahms at sabrahms@scdm.org!

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