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DATA BASICS

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2003 Winter

Promoting Clinical Data Management Excellence

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

Letter from the Editors

Dear SCDM Members,

As many of you know, the role of Data Basics editor is a two year appointed position. There are two of us, and our terms overlap, to ensure the most effective knowledge transmission from year to year. December 2003 marks the end of Cherie's two year term. I, Kit, would personally like to thank her for her tremendous contributions to the publication, and for all the support, encouragement and wisdom she has passed along to me over the past year. As is our custom, she will continue to serve on the Publications Committee for the next year as our Chair. At this time, I would also like to welcome Lynda Hunter, who is assuming Cherie's post as Data Basics co-editor, for the 2004-2005 term. Lynda has plentiful experience on journal boards and with other publications, and will bring a wealth of knowledge to our newsletter.

This issue of Data Basics is focused on the Fall Conference. Those who attended encountered a wide array of presentations centered on the theme of 'The People Side of Data Management'. While the slides from many of the presentations are available on SCDM's web site, several presenters have also contributed articles that examine their premises in more detail. We hope this will be a growing trend, as our meetings become ever more meaty.

The next issue of Data Basics will focus on Lab Data, including what it is, why it is collected, the challenges of handling it, different approaches to "databasing" it, and examination of central vs. local labs, and so on. Our intent is to create a primer on lab data that will be of use to you in the future as well as the present. If you would like to contribute an article or other piece, please let us know.

Finally, you will note that the first item in the current issue is a guest editorial. Mr. Elliot Clark was the keynote speaker at the Fall Conference, and he raised some very important, if highly controversial, points. In his editorial, he outlines those points, and sounds a call to action for all Data Managers. We might do well to listen.

Regards,
Kit and Cherie

The Only Constant is Change

Elliot Clark, (Kenexa Corporation)

It was originally Albert Einstein who offered the new age proverb that "The only constant is change." Of course, rumors persisted that he was watching his wife pick wallpaper when he was struck by this cosmic insight.

But Einstein saw the universe differently than most people. Einstein saw a system governed by immutable laws of physics and chemistry, yet a system that was dynamically evolving at every instant of time.

Business is also constantly evolving and it is governed by immutable laws. Most paramount among these is that companies engaged in commerce seek to maximize profits.

Hence, the argument for outsourcing as a profit driver has raged within the pharmaceutical industry for many decades. Data management is now considered potentially fair game for outsourcing. Data management has been seen as an outsourcing opportunity for decades by CROs. It has become accepted

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This Issue

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Submission Deadlines (Articles and Advertising Art Work)

Our quarterly publication schedule for the next three issues requires the following input deadlines:

Volume 10, #1 (Spring)	27 February 2004
Volume 10, #2 (Summer)	26 April 2004
Volume 10, #3 (Fall)	27 July 2004
Volume 10, #4 (Winter)	25 October 2004

Publication Policy

We welcome submission of previously unpublished materials for publication in *Data Basics*. Materials should preferably be submitted in electronic form (MS Word). Acceptance of materials for publication will be at the sole discretion of the Editorial Board. The decision will be based primarily upon professional merit and suitability (i.e. publication may be edited at the discretion of the Editorial Board.

Niether SCDM nor the Data Basics Editorial Board endorses any commercial vendors or systems mentioned or discussed in any materials published in *Data Basics*.

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The Only Constant is Change

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practice for CROs to be the outsourced service provider for projects or large trials, etc. But now outsourcing has taken on a new and more menacing pattern. One of the top pharma companies has outsourced Data Management as an operation. Data Management is outsourced completely to a service provider. Of course, I am speaking about Wyeth and Accenture.

I recently spoke at the SCDM Annual Meeting in Colorado Springs, CO. It was a lovely meeting and a lovely setting. As the keynote speaker, I was afraid I was delivering a particularly unlovely message. In fact, I joked with the individuals sitting at my table during the keynote luncheon that I was afraid the crowd response to my message would be righteous indignation followed by a biblical stoning.

The message I delivered was that outsourcing was a growing trend and individuals in Data Management had to factor that into their career planning. I understand from feedback I received (after I safely left the building) that my speech had sparked considerable controversy and I am glad.

Let's examine the trend for what it is. There are several factors driving the growth of outsourcing. First, the global Internet has changed business, politics and the human experience. The global Internet is more than an interconnection of servers and network protocols; it facilitates a new era of data collection, and it is the very embodiment of globalization.

The Internet also makes operations "placeless". I travel a great deal. I recently received an e-mail from my sister who lives on the west coast. The message began, "How are you, where are you?" When I get to respond I could be anywhere. My company is small by pharma standards, but I can access our e-mail and databases through web browsers from anywhere in the world. Globalization of operations is a growing trend. Globalization of drug trials has already occurred and worldwide registration is a reality. Cross-national organization charts are now commonplace.

The Internet offers the outsourcing community the opportunity to offer services to pharmaceutical companies from infrastructure that exists outside the walls of the pharma industry's vaunted internal research institutes. One of the related highlights of outsourcing is that the providers offer clients access to the outsourced providers' infrastructure. The cost of this infrastructure can be shared across many different companies. For example, no company would recreate the payroll production capability of ADP, but they can hire ADP to run a national payroll and share the cost of ADP's technology with thousands of other customers.

Outsourced providers also sell the concept of the "SLA". This acronym stands for Service Level Agreement. Conceptually, the argument is that most companies do not manage internal resources to the same level of productivity as they will external vendors. For internal resources they defend this spiritual "*en garde*" with references to quality, but the fact that outsourced providers are willing to offer the services with this guarantee at a lower cost than internal resources becomes a significant factor in the decision. Profit always wins.

The Internet is an expression of the globalization of information. It has facilitated outsourcing and particularly "off-shoring" or the sending of jobs overseas. Significant economic savings due to differences in global compensation rates makes this financially attractive, but as the President of one of the larger Indian "off-shoring" operations said at the Outsourcing World Summit in Palm Springs, California just six months ago, "Companies went to India because of cost but they stayed because of quality". Transactional operations like data entry are prime candidates for transfer to less expensive economies. It is not a passing phase. It is a new reality.

What must executives in the data management field do to meet this new reality? They must become global thinkers. They must understand the advantages and disadvantages of global operations. I remember doing a search about 10 years ago for Sterling Winthrop which was then allied to Sanofi Recherché based in Paris. Their profile for a Director of Data Management was unremarkable by comparison with the exception of one attribute. Without the inclusion of that one attribute I could have produced more than a dozen candidates for Sterling. The attribute was the candidate had to speak fluent French. I found one executive in the entire U.S. senior enough to do the job and global enough to say "Bon Jour". Please note the ability and gracefulness of communicating to another in their native language is deeply appreciated. We all remember JFK at the Berlin wall saying "Ich bin ein Berliner". It is probably his most famous quote and it is not English (or even good German).

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The Only Constant is Change

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Executives of the future must learn English if they are not from an English speaking country because it the most common business language in use. English speaking professionals must learn other languages to communicate on a personal and social level with their colleagues from other countries and other cultures. In addition, we must proactively learn to be diplomatic and culturally sensitive in a global economy. Otherwise, the responsibility of management will go offshore with the operations.

Let us face some other troubling facts. First, clinical data management is not a core strategic function of a biopharmaceutical company. Arguably, the only core function is the marketing and sale of pills and potions.

So strategically, the function of data management could be outsourced. Second, one way that outsourcing providers have driven cost reduction in the past is to suppress salary and benefits levels when compared to the labor costs of the functions before outsourcing. This effect is not as true of the executives, but certainly it is of the rank and file employees. Neither one of these facts is palatable for many people. For the CROs it means new competition from enormous global firms, and for pharma personnel, it means your career as an employee of the sponsor company may end.

So what must Data Management professionals do? There have been companies that have withstood the assault of the outsourcing providers. What can data management executives learn from those experiences? You must learn how to create value the way outsourcing providers do. The Data Management executive within the Pharma industry of the future must be an extremely competent business professional. They must understand process engineering, they must be able to manage a budget effectively and strategically plan for the future. Outsourcing providers sell the concept of "increased quality, increased speed and decreased cost". Data Management executives must beat them at their own game.

Data Management executives must focus on managing down costs. They must focus on maximizing productivity. They must become very budget-conscious in order to support their own internal value proposition and compete for the business. They must be more proactively strategic in their thinking than their competitors. You must abandon the thought process of a "cost center" and focus on "return on investment". The Data Management executive of the future must exhibit exemplary customer service orientation, they must embrace new technology, they must drive higher standards of performance and yes, they must even explore off-shore operations. These business skills will benefit you whether you work in pharma or wind up as an executive in an outsourced provider. Regardless of whether you work for a sponsor company or an outsourcing provider, the following immutable law must now be true for your career planning:

Technical skills will continue to have relevance, but it will be business skills that become the pre-eminent weapon of survival.

You do not have to be an Einstein to recognize that change is constant and we all need to be prepared.

Letter from the Chair of the Society for Clinical Data Management

Marianne Plaunt, Chair

As we welcome the New Year, I'd like to take a moment to reflect upon the activities and accomplishments of the past year as well as to take a glimpse into the future at what we can expect for SCDM in 2004.

The Society's accomplishments for 2003 included:

- Association Management change
- Strategic Planning Initiative
- GCDMP was Copyrighted
- Certification Program reached the Beta Test Phase Milestone
- Editorial Changes in DataBasics
- Online Discussion Forums
- Spring Forum – Interdisciplinary Interactions
- Fall Conference – The People Side of Data Management
- International CDM Network Participation

Additional details for each of these were shared during the annual business meeting held during the Fall Conference. The complete meeting presentation is available on the member's page of our web site.

All of these things would not have been possible without the support and dedication of our numerous volunteers. I would like to say "Thank You" to those who have recently ended their term on the Board of Trustees: Sally Cassells (chair), Hugh Donovan (past-chair), Judy Kasperczyk (Treasurer), David Sabritt (Trustee) and Cherie Stabell (Co-Editor). Each of these people has contributed greatly to the goals of the society over the last several years. We are also fortunate that each of them has already agreed to continue volunteering their time on other important SCDM committees and initiatives. New members of the Board of Trustees include Lisa Freeman (Trustee), Jane Hiatt (Trustee), Jill Vath (Trustee) and Audra McRae (Treasurer). We look forward to working with them and to their contributions to the society.

SCDM has many activities and initiatives planned for 2004. We begin each year with an annual planning meeting in the first part of January. At this meeting, we will review all of our current policies, identify, review and discuss the key initiatives for the upcoming year and finalize a budget. Recently the membership was asked to participate in a survey to gather input for the feasibility of an international peer-reviewed journal devoted to Clinical Data Management. We are anxious to evaluate those results. In March we will hold our Spring Forum – *Data Quality: Definitions, Requirements and Practice,* in San Antonio. The Beta Test for our certification program is currently underway with anticipation of enough participation in the first quarter to finalize the "cut score" and release the final version by mid-year. Our membership committee continues to identify and research topics important to each of you. This year please watch for a general membership survey, information regarding the development of local CDM groups and the potential of different membership levels and types. Plans for the Fall Conference – *Global Clinical Data Management*, to be held in Toronto, are also well underway.

Thank you all for your continued interest and support of SCDM. I look forward to an exciting and productive year.

CALENDAR OF EVENTS

March 21-23, 2004
Spring Forum
La Mansion del Rio Hotel
San Antonio, Texas

October 3-6, 2004
Fall Conference
Royal York Hotel
Toronto, Canada

March 13-15, 2005
2005 Spring Forum
Grand Hyatt Buckhead
Atlanta, GA

October 9-12, 2005
2005 Fall Conference
Sheraton San Diego Hotel & Marina
San Diego, California

October 8-11, 2006
2006 Fall Conference
Wyndahm Palace Resort & Spa
Orlando, Florida

September 16-19, 2007
2007 Fall Conference
Hyatt Regency
Chicago, Illinois

CDM as a Customer Service Organization

Ellen Coull, (PRA International)

If your data management department is typical of most, your employees probably come from a mixture of backgrounds with life sciences, nursing, allied health or computer science degrees. Unless they also bring retail selling or other customer based experience to the job, the odds are that customer service may not be part of their developed skill set. However, setting expectations for quality and customer service is an important part of every department in every organization. Even though the newest version of the Good Clinical Data Management Practices document published by SCDM does not include this topic, that does not mean it isn't required for data managers.

So, what is customer service? In a nutshell, it is providing customers what they need, when they need it and at (or above) a level of quality they have come to expect. It sounds simple enough. But, who is your customer? External customers would include the FDA and other regulatory authorities, the sponsor if you are a CRO or vendor service provider, or even corporate investors. It is our internal customers who do not quite get the focus of our customer service skills. Every time you hand off a deliverable to another person or department, you have a customer at the receiving end of your work. That would mean that data management's customers may include biostats, project management, business development and clinical or regulatory departments. Interacting with those contacts and delivering our product with customer service skills has taken a back seat to meeting deadlines, implementing processes, troubleshooting software and complying with SOPs.

If we are meeting our timelines, does *how* we deliver really make a difference? In the framework of the external customer, it is unquestionable that the perception of being able to deliver a quality product on time and within budget will impact the client relationship. Repeat business with the same customer often represents well over 50 percent of new contracts awarded. Should our internal customers expect the same? It's not as if they have a choice about which data management department to go to. The impact of poor customer service with internal customers will be more subtle, much more likely to manifest itself in terms of avoidance, a passive-aggressive shuffling of priorities, and absenteeism, none of which contribute to meeting goals or encouraging team work.

Customer skills can easily be encouraged within your department, but the first step needs to be an evaluation of where you currently stand. It can be as formal as setting up a task force to meet this initiative or as informal as soliciting feedback from your direct contacts. What a CDM manager may perceive as adequate may be perceived by a project manager as merely fair, but the steps needed to improve may be very easy to implement. This does not need to be a manager-driven effort. Suggestions from the line staff will most often reveal the best ideas for improving the daily processes they work with.

Customer service is a skill set that can be taught and developed. While it is possible to have workshops or other classroom settings to introduce these skills, just raising awareness as an agenda item at your department meetings may be sufficient to get the ball rolling. The emphasis needs to be on choosing the right words, delivered at the right time, using the right medium. 'To whom do you report,' may not be the best closing statement when making a request for additional staff to contribute to meeting an urgent deadline. The 'passing in the hallway' conversation may not be the best place to discuss a difficult deliverable. In our e-mail-dependent environment we neglect the personal touch of thanking staff in person for Herculean efforts that may have come at a personal expense. Develop the skill of anticipating what your customers may need and being ready to provide it. Data management should be able to make a reasonable projection of what a project manager or biostatistician will ask them for, and meeting those standard expectations should be part of the package.

As with any habit you are trying to encourage, positive reinforcement of the delivery of good customer service is a must. Most employees look for recognition of their good work as a major factor in job satisfaction. Positive feedback also adds to pride in the organization, but it must be specific. A generic 'good job' needs to be replaced with the specifics of what is recognized as good service. How different does it sound to the employee when it's phrased as 'I appreciated the way you worked with central documents to track down that missing shipment, it really helped save the timeline".

Be sure to practice what you preach and model the skills you want other employees to emulate. You do not need to be a senior level executive to have a positive attitude towards your work and encourage that approach within your department.

Customer Service: How Does Data Management Provide Customer Service when Sponsor and CRO Work Together?

A perspective from Pfizer Ann Arbor and Kendle

Deb Cole (Kendle) & Ann Rauschl (Pfizer)

[Ann Rauschl] Once the Pfizer Ann Arbor location had determined the core competencies for the data management department, the decision to outsource the discrepancy management was not difficult.

Of course, these decisions impact not just the data management department, but also the internal customers that sit at the workgroup table. One of Pfizer's first tasks was to explain core competencies and why outsourcing would help the company to work more efficiently, allowing concentration on more valued tasks. Formal presentations to teams and workgroups seemed to be the best method of communication. These presentations demonstrated that workgroups should notice a positive impact on timelines, workload and handoff's. Afterward, data managers fielded questions.

As with any project, tools are necessary. The tools needed include people, technology and various work instructions and information templates. The time between Pfizer Ann Arbor initiating the decision and the deadline for Kendle to go active was very short. Therefore, the department had to work efficiently. The tools were beneficial, but as time progressed and we had more experience with the outsource model, the tools were improved. Some examples include:

- The liaison role
- Project management details document
- Checklist for outsourcing
- Process work instructions
- Technical issues log
- Shared communication space
- Regularly scheduled teleconferences

These tools were the cornerstones of the effective customer service that Pfizer Ann Arbor was able to provide to Kendle. The outsource model would never have worked if communication broke down.

On the other side, there were documents that Kendle needed to develop to ensure effective customer service to the team at Pfizer. Some of them are:

- The liaison role
- Metric/status reports
- Budget reports

You might ask "What is a liaison?" In this case it is primary contact for Pfizer at Kendle, and internally at Kendle, it is the one source of information from Pfizer. You can think of this role as a gatekeeper. By having one person disseminating information, you can ensure that everyone gets the same information at the same time, all questions are seen by the same people and issues are not "lost" in a round robin email amongst multiple team members.

[Deb Cole] Metric reports are another way to ensure communication. There are metric reports that Pfizer wanted that they programmed for Kendle to run. Also, there are reports that Kendle's management team wanted that Pfizer had to create and run weekly. Finally, there are the budget reports that Kendle's accounting group uses. When I worked in pharma, I could not have told you what the budget for any of my studies was and how my team was doing against that budget; it was simply not something that was tracked at my level. Now that I am in a CRO , it is important to know what my budget is on a weekly basis. I need to know how we are doing against that budget and if there is anything that needs to be addressed with the sponsor in terms of change in scope. Changes in scope are created when the work being done, or that we are asked to do, is not covered in the contract. Some examples of this are the increased number of patients, protocol amendments and additional data transfers. Each of these tasks and associated tasks has a cost and discussions with a sponsor should occur whenever tasks are deemed to be out of scope.

[Ann Rauschl] Well, here we are about nine months into this endeavor and it is time to reflect. We pat ourselves on the back for lots of success and make a mental note of challenges we faced. For the challenges, we now know that one or two presentations at the beginning, to our internal customers were not sufficient. The outsource decision should have been discussed a little more often and further into the study process. This change was lost in a sea of other changes. More frequent reminders would have been helpful. Also, the workgroup and the monitoring team were confused by the multiple Kendle locations and finally we inflicted training- and information-overload on Kendle. It was too much for a one-day session.

We also look back and notice many things that worked very well. The greatest tool created from this entire project was the role of 'liaison'. The Pfizer liaison role was responsible in large part for pulling most of the project together . The appropriate individual was definitely selected for this position. Even though the Kendle training was intense, the documents given to Kendle for reference proved to be very helpful. Also, because the outsource model redefined the data management responsibilities to some extent, new opportunities opened up and we could help redefine what data management looks like today. The best-laid plans sometimes get sidetracked. In our case, it turned out to be a blessing. The initial idea was to send six studies to Kendle immediately. Due to technical problems and workgroup decisions, only one study made it to Kendle for the first four months. However, during these four months, Kendle and Pfizer had the opportunity to find the glitches, improve process and truly define communication. Rather than experimenting on six studies, one study paved the way for the others and today twelve studies run very efficiently.

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Customer Service: How Does Data Management Provide Customer Service when Sponsor and CRO Work Together?

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[Deb Cole] As we at Kendle look back on the last nine months, we too see the challenges that have been overcome as we have worked with Pfizer. Throughout the entire process, communication has been the key to success. The documentation that Pfizer provided is simply incredible. Their realization that we would need to know everything that a new data manager at Pfizer would need to know, is a testament to their foresight. With the documentation that they provided from day one, this partnership could have been filled with many areas of frustration. They provided a liaison and we mirrored it here at Kendle. This allowed both partners to have one point of contact and one route for disseminating information. Email and shared workspaces were used to communicate issues, status reports were used to keep everyone updated, and telecons were held regularly and with regular agendas. Communication is the key; the success in working with a partner will be compromised if the communication fails in any area.

[Ann Rauschl] I'd like to share with you my observation of the partnership between a Sponsor and CRO; it is much like having a house built. Let's suppose that you have enough money to build two houses. For one house you hire a builder and an architect and just tell them "build me a house". For the other house, you hire a builder and an architect and you bring them pictures of what you want, you call daily, you stop by the building site daily and you pick the materials for the house. When both houses are finished, which house do you think you would really like? An honest opinion would probably reveal a stronger liking for the house that involved the most communication with the builder and architect. Outsourcing work is similar and maybe more important. We are all working toward a database that allows the statisticians to show that the medicine is safe and efficacious. If you do not communicate with the CRO, provide documentation for them to use and orientate the CRO, you will struggle to get the database that you really want. It is easier to spend the time up-front on these issues rather then wait until the study is operational to address them.

Lean Thinking – A Simple Technique to Examine Your Data Management Process

By Gail Scherer and Derek Perrin, (Pfizer Global Research and Development)

What is Lean Thinking?

Lean Thinking is a method for examining process. It is used when analyzing an existing work process, or creating a new one. The goal of Lean Thinking is to remove any wasteful, non-value adding steps from your process. The key to this approach is defining the value of each step from your customer's perspective.

Initial work examining processes began in manufacturing environments, with inventory and motion studies. Lean Thinking was first applied specifically to the automotive industry. Toyota enhanced their performance and productivity using a Lean Production approach.

This technique may also be applied to service industries, and in our context, to data management. It is important to approach the analysis of your process from your customer's perspective, therefore, it is important to define who your specific customers are. As Data Managers, your customers include the clinical teams, internal regulatory groups, regulatory agencies, and ultimately the patient who will receive the drugs. You must then ask yourself the question, "What do our customers expect from us and how can we best provide it to them?" Every step that you can take to optimize processes gets the drug into the patient's hands that much faster!

What is waste?

The key component to the Lean Thinking mindset is to eliminate waste. Simply defined, waste is the opposite of value. Waste includes anything that gets in the way of moving a process forward. Types of waste to consider include:

Errors – The biggest error is what keeps us all employed as Data Managers...data errors! However, consider the other types of errors that are within your control to address and correct.

Over-processing – How could you get it "right the first time" and avoid the painful cycle of double or triple checking work? Is the amount of checking you do appropriate? Is it too much?

Batch processing – Do CRFs accumulate at the site before they are brought in-house? Does Data Entry wait until they have a batch of CRFs before entering them? How can you eliminate batching and keep work flowing at a steady stream?

Motion – This addresses specifics such as excess data entry keystrokes or movement of the CRFs. Are your CRFs carried around to different parts of the building to be scanned, and the entered? How efficient are your routing systems?

Processing time – How much time is required to run edit checks? Do you run database updates only overnight?

Transportation – This might include the shipment of CRFs from the investigator sites. The obvious solution here is EDC. You might also consider the physical transportation of monitors to the site to verify source data and collect the CRFs. While this may be necessary, are there ways that you can make this more efficient?

Waiting – Do you wait for investigator signatures on CRFs? How long does it take to turn queries around? This might also include system down time, which may be unavoidable.

Objectives of Lean Thinking:

Shift the focus of management from the *organization* and *assets* to the *product* or *service* you provide. You must remain flexible to meet the customer's service needs. Organizations continually evaluate and adjust their structures and head count to optimize the business. However, given how frequently organizational structures change, it is apparent that companies still haven't identified the "magic bullet". The concept of Lean Thinking suggests that your key product or service should define the structures supporting it. Design the process to efficiently create your product, and then design the organization to support the process.

Start with the actions that affect the product, not the organization or the technology. As we have all experienced, or are experiencing, organizations often evolve to better meet the product or service goals. An example of this is the widespread growth in EDC use, which helps to significantly reduce waste in terms of transportation time and batch processing. While EDC is a tool or asset to the organization, it should not define our process or service. The process should be clearly defined before supporting tools or technology are selected. While technology that enables process improvement is beneficial towards achieving Lean Thinking, one must be careful not to over engineer processes to fit a specific technology. That is, in itself, wasteful.

Define the value of each step in your process from the perspective of the customer. As an example, do your customers really care that you have five quality checks that are required before CRFs can be shipped for a study? Probably not! They want the CRFs sent to the site ASAP! Have you asked your customers recently what they really want and expect from data management?

Enhance the value and remove waste by looking back in the process, not forward. An example of this is incorporating edits at the earliest point possible. Using edits in EDC so the data correction can happen right at the site or source of the data is far better than waiting until further down the line in the process when the data are already in the database. Then the database and the source CRF will both need to be corrected. Always ask, "Where is the earliest point in the process where this problem can be addressed?"

Put creativity before capital and process before technology!

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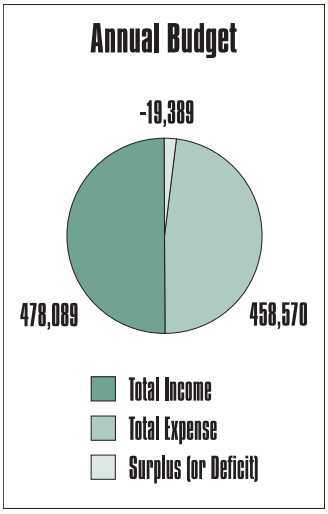
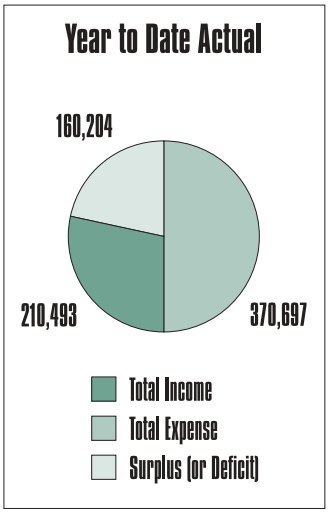
SCDM Financial Report Fiscal Year 2003 Through 9/30/03

SCDM is in sound financial shape.



The planned deficit for the year reflects the plan to use some of our reserve funds to start-up CDM Certification.



The Year to Date Surplus reflects the fact that the income has been received for the Fall Conference, but not all of the expenses have been received as of 9/30/03.

The major income generators for SCDM are the membership dues, Fall Conference, job postings and advertising. These items represent 83% of out total budgeted income. Our major expense items are the Fall Conference, Management Services, Data Basics, and Certification. These items represent 78% of our budgeted expenses.

Lean Thinking – A Simple Technique to Examine Your Data Management Process

Continued from page 9

Steps to apply Lean Thinking

Take a reasonable portion of your overall process and apply these steps:

1. Map your current process.
2. Examine each step and classify it as process, or one of the forms of waste mentioned previously (e.g., transportation, process delay or batch delay).
3. Identify the value stream, the steps that are critical to your end product.
4. Map your future process, eliminating the non-value adding steps.
5. Make the process flow. Remove as much waiting and transportation as possible. Think about a "just-in-time" inventory approach.
6. Pursue perfection. Lean Thinking is a continuous exercise. Always look for ways to streamline the process!

The Lean Thinking approach will help you reduce cycle times for critical milestones, break down organizational silos and strengthen alignment with other functions.

Lean Thinking allows you to see your process in a new light, and makes it easy to identify what steps you need to revise or eliminate from your process. Data managers are important contributors to the clinical trial process and what we do is often on the critical path of a clinical trial or submission. Bringing Lean Thinking to your organization will not only increase your contribution, it may even make your work easier!

References

Lean Thinking: Banish Waste and Create Wealth in Your Corporation, James P. Womack and Daniel T. Jones, Simon and Schuster, 1996.

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Which Way Do I Go?

Career Paths for Data Managers

Lisa Freeman, (Corus Pharmaceuticals)
SCDM Fall 2003 Conference

The days of working for one company our entire career, are in the past. Today's "dog eat dog" world consists of merger madness and the threat of computerized systems replacing professionals. In addition, many of us feel the need to acquire new skills in an effort to create a more fulfilling work environment. Career diversification is not only a great benefit, but a necessity.

What skills and backgrounds do we as a data management community possess? How can those skills can be redirected and how can we acquire the tools needed to guide the direction and focus of our careers?

It is wise to step back and assess one's goals and lifestyle before making a major career change. For example, the long-term goals of a single parent and the goals of an individual without parental commitment may be the same, but their lifestyles and willingness to travel are probably very different. When contemplating a career change, certain factors such as travel time, commuting vs. working from home, time available outside of work for education, etc., must be considered. The Myers Briggs Test (MTBI), Monster's "Discover your Perfect Career Quiz" and Keirsey Temperment Sorter are examples of self-assessment tools available to assist in evaluating one's personality type and lifestyle.

The next step is to evaluate one's skill set. Data managers come from a variety of backgrounds such as lab personnel, nursing, site coordination, CRAs, data programming, data entry and other professions. In conjunction with the skills acquired in former positions, data managers acquire a myriad of skills when performing standard daily tasks. Listed below is a sampling of the responsibilities of the data manager:

- Project and Query Management
- CRF Development
- Medical Coding
- Database Programming
- Electronic Data Capture Principles
- Management
- Training
- Data Entry
- Medical Terminology and Writing
- Knowledge of Regulatory Requirements

Once one's goals and skill set have been established, it is time to decide what direction to go with one's career. Many data managers may decide that they do not wish to switch careers at all because they enjoy the field of data management! Data management must prove that services are a good risk on investment to a company. In order to remain in data management, we as individuals must adopt this philosophy and make ourselves the most marketable data manager possible. This can be achieved by diversifying one's skill set. Those that have been doing the same tasks day in and day out for years should look for opportunities to do different things in their department. Taking on new responsibilities and learning new technologies add to one's skill set or "marketability". The ability to become involved by remaining current with what's going on in the field of data management as well as what's going on in one's department and company, provides foresight on the direction of what skill sets might be needed in the future.

Other options outside of data management are also available, can be organized into four categories: Medical/Clinical, Programming, Management and "Something Different". Suggested career choices in these categories are as follows:

Medical/Clinical
- CRA/Clinical
- Site Personnel
- Medical Writing
- Regulatory
- Medical Coding
- Medical Careers

Programming
- Database Programmer
- Database Administrator
- Technical Support for Software Vendor
- Information Technology
- Biostatistician

Management
- Global Development
- Project Management
- General Management

Continued on page 13

SCDM Committees

The following are currently active Committees within the Society for Clinical Data Management.

Certification Committee
Chair : Armelde Pitre
Phone: (860) 732-5642
E-mail: pitrea@snet.com

GCDMP Committee
Chair : Christine Little
Phone: (919) 408-8000
E-mail: clittle@rhoworld.com

Membership Committee
Chair : Brenda Hoeper
Phone: (513) 984-0450
E-mail:
Brenda.Hoeper@quintiles.com

New Technology Committee
Chair: Sally Cassells
Phone: (781) 237-4491
E-mail: sally.cassells@
lincolntechnologies.com

Publication Committee
Chair: Cherie Stabell
Phone: (650) 225-7672
E-mail: stabell@gene.com

Web Site Committee
Chair: David Borbas
E-mail: dave@borbas.net

Web Sites to Check Out

ACDM - www.acdm.org.uk
CDISC - www.cdisc.org
FDA - www.fda.gov
ICH - www.ich.org

There are more links to be found on our web site!
SCDM - www.scdm.org

Please let the Editorial Board know about any other "hot" web sites that you feel would be of interest to the SCDM membership.

Making the Transition from Data Management to Project Management

Sharon Seitz (Innovus Researc, Inc.)

After making the transition from data management to project management, I came to the realization that most of the insights I possessed in terms of running large, multi-center, national and international clinical trials, came from years of experience in the Data Management department. Applying talents obtained in data management have proven invaluable in providing me with informed decision-making skills regarding many of the areas for which a Project Manager is ultimately responsible.

One of the first advantages of a data management background I noted was that I had insight with regard to proposal writing and developing study budgets involving data, monitoring and statistical analysis. Knowing the data management process well, I was able to understand fully the resources and time required to collect, clean, monitor and analyze data. This insight helped to provide realistic quotes for proposals and ensure that adequate budgets were acquired to complete the tasks at hand.

Having a data management background also allowed me to assist Clinical Research Associates with data clean-up issues. I was able to provide guidance to site staff regarding protocol issues dealing with data reporting. The added understanding I had regarding data proved invaluable at study completion, as many potential problems (such as data interpretation issues) had been avoided.

Experience in data management has also allowed me to have meaningful, informed conversations with staff assigned to the study team in the areas of data management, programming and statistics. Knowledge of these processes allow for greater insight into what it takes to set-up a study database, write a statistical analysis plan and program reports and analysis tables. I was able to offer valuable insight into CRF design and how to streamline the collection and processing of data for clinical sites, CRAs and the data management staff. I was aware of the steps to be completed prior to locking a database and the resources required to complete this task quickly and efficiently.

Finally, through my data management experience, I obtained an acute awareness of the process of Spontaneous Adverse Event (SAE) reporting and in some studies, the adjudication of endpoint data for which the Project Manager may be ultimately responsible. As well, I had a good understanding of the coding process for safety data and subsequently, the time and staffing requirements to complete this very important task.

In conclusion, the experience I obtained from my years in data management helped tremendously when I decided to make the transition into project management. I had a far greater appreciation and understanding of the "data world" and how decisions made from a project management perspective may have an impact on the final product, the study results, which ultimately come from the data itself.

Which Way Do I Go?

Continued from page 12

Something Different

- FDA/QA Auditor
- Training
- Author
- Consultant
- Sales for Software, Device, CROs or Pharma/Biotech Companies

As previously discussed, one's ability to travel, set up a home office, and time availability for outside education are some of the factors that should be evaluated when considering a career change. Once a direction is chosen for a career change, one should perform a "gap analysis" of their current skill set to the skill set that is needed for the new position. Networking and attending professional meetings and career planning seminars are a great place to start when assessing how and what is needed to improve one's skill set. Online research can also be very helpful. An excellent way to obtain the skill set needed for a new position is to engage in cross-training at one's current job. This allows firsthand information of the needed skill set to be obtained from experienced personnel. Other ways to obtain the information needed is to take classes or participate in an internship program or moonlighting. (Obviously, any confidentiality or conflict of interest issues should be addressed prior to participating in the latter suggestions.)

In summary, we are each in charge of our own destiny when it comes to career choices. In today's world, the only certain thing is change. Career change is ranked among the highest stresses that we as a society face today. Those who have assessed their long-term goals; that are aware of their strengths and weaknesses; and who prepare for such changes, will be in the optimal position for handling the changes that one will face in the future.

The future belongs to those who believe in the beauty of their dreams.

— Eleanor Roosevelt

From Safe Harbor to Open Sea - The Transformation of a Post-Merger Spin-Off into a Full Size CRO

Herbert Noack, (Covidence GmbH, Frankfurt, Germany)

A decade ago, a pharmaceutical company was seen as a safe harbor for employees. At that time, no one could have predicted that a merger would transform the Frankfurt-based company Hoechst into the international company, Hoechst-Marion-Roussel (HMR), which was later to become a "merger of equals" to form Aventis, that then would spin off its clinical development site at Frankfurt into a full sized CRO named 'Covidence'. Nowadays it's all open sea and the question that arises is, "Are you able to navigate with knowledge and 'good fortune' on the open sea?"

Spin-offs in Europe compared with the U.S. are different because of the job legislations and the lower employee turnover rate in Europe. In the U.S., it is possible to announce an acquisition of an entire development organization on December 14th with it becoming effective on January 1st. In Europe, the most elegant way is to convince all the people involved to agree to the transition - that is, elegant with respect to keeping the knowledge and group together and to having a smooth transition without interruption of work. Such a process may last between six months and two years in Europe and if you are not convincing enough, people will decline the offer or leave the group — the result being a total project failure. The capital of the new company is the knowledge of the people.

What arguments have convinced 120 very experienced people, most of them with more than ten years in the pharmaceutical industry to join a new CRO, Covidence? We have regarded ourselves as a very productive site, which had contributed a lot to the success of HMR and Aventis. Fortunately, Aventis made it clear early on, that they wanted to continue to work with the Frankfurt group and to build on our expertise in cardiovascular, diabetes, oncology, rheumatology, dermatology and other indications. Aventis management sincerely wanted to collaborate with the group on an optimal solution. The following departments were initially involved at Frankfurt: clinical development, medical writing, pharmacovigilance, biostatistics and data management. No Information Technology, no clinical monitors, just a torso of a CRO, so different business scenarios were evaluated. And our people: We wanted to stay together, we believed in our strength and abilities, i.e. Phase I to Phase III trials and submissions. We thought very early on that with our experience and our productivity we would be able to survive as a new CRO and to build up the additional functions we would need.

The two department heads from clinical and biostats, together with Aventis representatives, led an 18 month effort which was known as the 'CRO-Project Frankfurt'. There was active participation from many members in this process; we formed 12 transition teams looking at different organizational aspects. Open and clear communication throughout the whole group was a key factor. An optimal framework was negotiated for Aventis and our group with entrepreneurship. A key issue for the new CRO was the full operational independence from Aventis, therefore a capital investor (3i) was found in very short time. Management, as well as the whole group were included in the ownership. In total, 37 contracts had to be negotiated and signed between Covidence and Aventis to make this happen. The new company's name 'Covidence' was selected through an employee contest. We found a new building just ten miles away, close to Frankfurt and the Frankfurt Airport, which was an acceptable distance for everyone and we moved out of the Aventis industrial area.

Looking at these two years of preparation, we were able to keep the group together, and without increased attrition rate. Ninety-seven percent of the employees agreed to the transition, and in total 120 very experienced people formed Covidence on January 1st 2002.

In the intervening time, we have grown from 120 people to 220 people and have built up additional functions, such as business development, accounting, QA, and clinical monitoring. We now have a complete quality management system in place, our own Oracle Clinical and Clintrial instances are fully validated and productive, as is our Argus Safety database. Our servers are hosted in an ISO-9001 certified data center, with the highest possible physical data security with backup and recovery procedures. Our data management group has more than 80 Clintrial and Oracle Clinical users, making it one of the largest in Europe. We are very active in CDISC and we are a certified CDISC solution provider.

Is it really different to work for pharma as compared to a CRO?

Continued on page 15

From Safe Harbor to Open Sea - The Transformation of a Post-Merger Spin-Off into a Full Size CRO

Continued from page 14

First, with respect to our sponsor Aventis, the answer is yes and no. No, because in the years before, we had already worked with their Global Drug Development Center in New Jersey and there is not much difference between being an operational site of Aventis and being a partner CRO. Yes, there is a difference because we are included in discussions but not in decisions of the sponsor. In the past 20 months there are many examples of how pleased this sponsor is with our work and how well the whole solution is working for them and us.

Second, with respect to other sponsors yes, there are different expectations between sponsors. To listen very carefully, to discuss in detail the expectations, processes and deliverables are absolutely crucial. Although we have just started, we already have repeat business with other sponsors. This is the best demonstration that we can meet our client's expectations.

LEadership And Development: LEADing the Way for Professional Growth

Cristina Gonzalez, MHSA, RHIA, (Quintiles)

LEAD is a program designed to develop leadership skills by providing professional growth opportunities for higher level associates. It is a program that can easily be adapted to any organization. It requires creativity, flexibility, and a commitment from both participating associates and management.

Background

Upon hiring new associates, organizations focus on developing basic skill sets necessary to perform the essential functions of a job. Emphasis is placed on policies and procedures, technologies and project-specific processes. There is a combination of formal training and mentoring as associates develop a solid knowledge base that can support increased responsibilities.

Increased responsibility results in new experiences and learning opportunities, which in turn leads to a wider knowledge base. Over time, experts and leaders emerge within the organization. These associates require different skill sets in order to succeed as leaders.

LEAD

LEAD aims to develop the leadership skills of higher level associates so they will be more effective in their current roles. Exclusivity is considered to be a key success factor in creating a program that is a reward rather than an obligation. Participants are nominated by their managers and are given the opportunity to accept or decline the nomination. Associates must make a commitment to themselves to complete a curriculum of over 100 hours. Managers must make a commitment to the associate by making training a priority over the course of the year.

Curriculum: The current curriculum consists of monthly activities averaging approximately 10 hours per month. Many opportunities for training already exist within organizations. LEAD takes some of these opportunities and makes them required. To account for different learning styles, the curriculum includes audio distance learning, self study courses, instructor-led courses, in-house training and off-site seminars.

There are modules on communication, coaching, and team management. Each of the modules includes multiple activities, taking advantage of existing resources. In addition to the classroom-like instruction, guest speakers are invited to share their thoughts on leadership with the participants. Speakers include both members from within the organization and the community.

After each module, a LEAD meeting is held. The participants are each given the opportunity to share what they have learned and how they have incorporated new skills into their every day activities. The LEAD meetings allow participants to learn from one another.

LEAD participants are also encouraged to read. There is a frequent distribution of articles on leadership, communication, empowerment, and management skills. The articles come from a variety of sources and subscriptions including newsletters, journals, and the internet. Participants also complete two book report presentations during the year. They are given the choice of reading books, listening to books on tape or watching leadership videos. The presentation once again offers an opportunity to learn from one another while practicing presentation skills.

Graduation: December will be the culmination of an intensive year of leadership skill development. To celebrate the accomplishment of the LEAD participants, they will be presented with a certificate of completion and will be invited to a celebration luncheon with the management team. Associates will continue to work closely with their managers to target additional growth opportunities. The commitment to continue learning is expected to continue beyond graduation.

The Committee:
Kevin Coughlin, Chair
Shari Clark
Cristina Gonzalez
Susan McMillan

SCDM Fall Conference Session Summaries

The SCDM Fall Conference this year focused on the 'People Side of Data Management.' It was well attended, and featured some excellent presentations. Following are a few session summaries, along with some photos.

Session Name: Managing Career Development Through Professional Certification

Session Chair: Armelde Pitre, (Pfizer)
Presenters were: Armelde Pitre, Judy Pyke of Kendle International and Colleen Cox of Carestat

The session was focused on sharing information on how the certification program was developed and what the next steps are. Additionally, practical tips and advice were offered on a variety of topics such as "How to Develop an Application for Sr. CDM Certification" and "Why Companies Should Support Certification of their CDMs."

A sample of the questions and answers raised during the session include:

Q: When will sample questions be available?
A: Most people want sample questions for two primary reasons: 1st. To get a sense for the content and difficulty level of questions, and 2nd. To gain familiarity with the format of the exam.

To address the first area, we have published a detailed list of exam objectives on the website. To address the second area, we will use those questions that will not be used in the final exam, but were developed for use in the beta exam. These may require refinement, based on the feedback we receive from the beta test. If the beta test period is completed by Jan 2004, sample test questions could be available as early as April 2004. The exam objectives are available now.

Q: When will a study guide be available?
A: The certification committee's priority has been focused on release of the certification exam as well as compiling and publishing a list of training and resource materials. We will turn our attention to developing either training or study guides in 2004. We are evaluating options such as building partnerships with training vendors to help expedite the delivery of these materials.

Keynote speaker, Elliot Clark

Q: Are the Board of Trustees (BoT) going to be certified?
A: The BoT is favorably inclined to include this as a policy or requirement for Board members to be certified. We are currently discussing the implementation process.

Q: Has the certification committee given any thought to certifying performance at a task level or role level such as 'coding' or 'safety

Continued on page 19

Conference attendees take in one of the nine sessions offered.

Seated left to right, Larry Hauser, Larry Hunter, Gail Scherer. Standing left to right, Derek Perrin, Theresa Vieira-Brisson and Stefanie Alfano of Session IV: Novel Ways to Improve Process.

SCDM Fall Conference Session Summaries

Continued from page 18

data management' instead of a comprehensive certification of all tasks on the SCDM task list?
A: Yes, many factors such as development and membership costs versus benefits were considered. For a more complete summary of this topic, please see the editorial section of Data Basics, Volume 8 Number 2 Summer 2002.

The certification committee has published the full list of Questions and Answers on the SCDM website. Click on 'certification' button and then on the link "Frequently Asked Questions."

Left to right, Tomo Cummings, Scott Rodgers, Rita Nespeca, Dawn Collette and Stephen Linhares of Session III: People Issues around Introducing Technology.

Attendees feasted on wild game specialties at the SCDM Rocky Mountain Networking Dinner.

Conference co-chair, David Sabritt

Session Name: Career Development for the Data Manager

Session Chair: Christine Little, (Rho, Inc.)

The only panel discussion of the conference, this session provided the audience members the opportunity to ask the career-related questions that were on their minds rather than respond to the material presented - where have we been, where are we going, and how do we get there - and to learn from experienced professionals. The panelists, many past SCDM Board of Trustees members and all having excellent qualifications, including longevity, to address the topic, included Murray Barnhart, Bristol-Myers Squibb; Paul Courtney, BioInformatics; Hugh Donovan, Aventis Pharmaceuticals; Kaye Fendt, Independent Consultant; Brenda Hoeper, Kendle; and Susanne Prokscha, Independent Consultant.

Continued on page 20

The Cheyenne Mountain Resort provided breathtaking views of the Rocky Mountains.

Fall Conference 2004—Call for Abstracts

Clinical Data Management in a Global Environment

Oct. 3-6, 2004 • Fairmont Royal York Hotel, Toronto, Canada

The theme of the 2004 Fall Conference is Clinical Data Management in a Global Environment. Increasingly the world of drug development involves international clinical trials, project teams in many time zones and organizations that span continents. How have these changes affected the processes you use to ensure data quality, the technologies you deploy, the way in which you interact with your team members and your outlook? How do you cope with not always harmonized, occasionally contradictory regulatory requirements? Where do you go for help?

The 2004 Fall Conference Program Committee is seeking abstracts for presentations that explore these issues and beyond. For more information, please visit our website at www.scdm.org for events.

SCDM Fall Conference Session Summaries

Continued from page 19

The session focus was on the career of a *Clinical Data Manager* within the context of the information already presented at the conference, current and future offerings of the SCDM, the overall history of data management in the clinical trials setting, the professional histories of the panelists, what the panelists know about the current state of clinical data management and what they can predict about the future state of clinical data management. The audience tossed out questions and moved the discussion into and around data management in academia, project management, the "old days", the "old" data manager in current times, the future data manager, and expectations of the qualifications needed.

Panelists suggested that emerging roles and responsibilities for the CDM include more data orchestration than data management as we know it now, more data integration, due to multiple sources of data, more project management, especially in the context of outsourcing, technical training of site personnel and, of course, bringing along the newest members of the profession. The GCDMP and CDM Certification are both extremely important and must be kept current, but they are not all that is needed by the good data manager when trying to balance business efficiency, competency, competition and the personal well-being of self and staff.

The panel's conclusions seemed right in step with many of the offerings of the Fall Conference: Today's CDM should be flexible and balanced and should expend effort to educate the newcomers as well as the rest of the industry. Although changing, the role of CDM is integral now and into the future, especially within a data management outsourcing model and given emerging technologies. The CDM must remain current and must have the business sense needed to protect and promote the company and the department. As one of the panelists said, reflecting the comments of the keynote speaker, "CDM Executives have to think like business people!"

Left to right, Lisa Morton, Charlene Dark and Lisa Freeman of Session VI: Career Paths.

Left to right, Armelde Pitre, Judy Pyke, and Colleen Cox of Session V: Managing Career Development through Professional Certification.

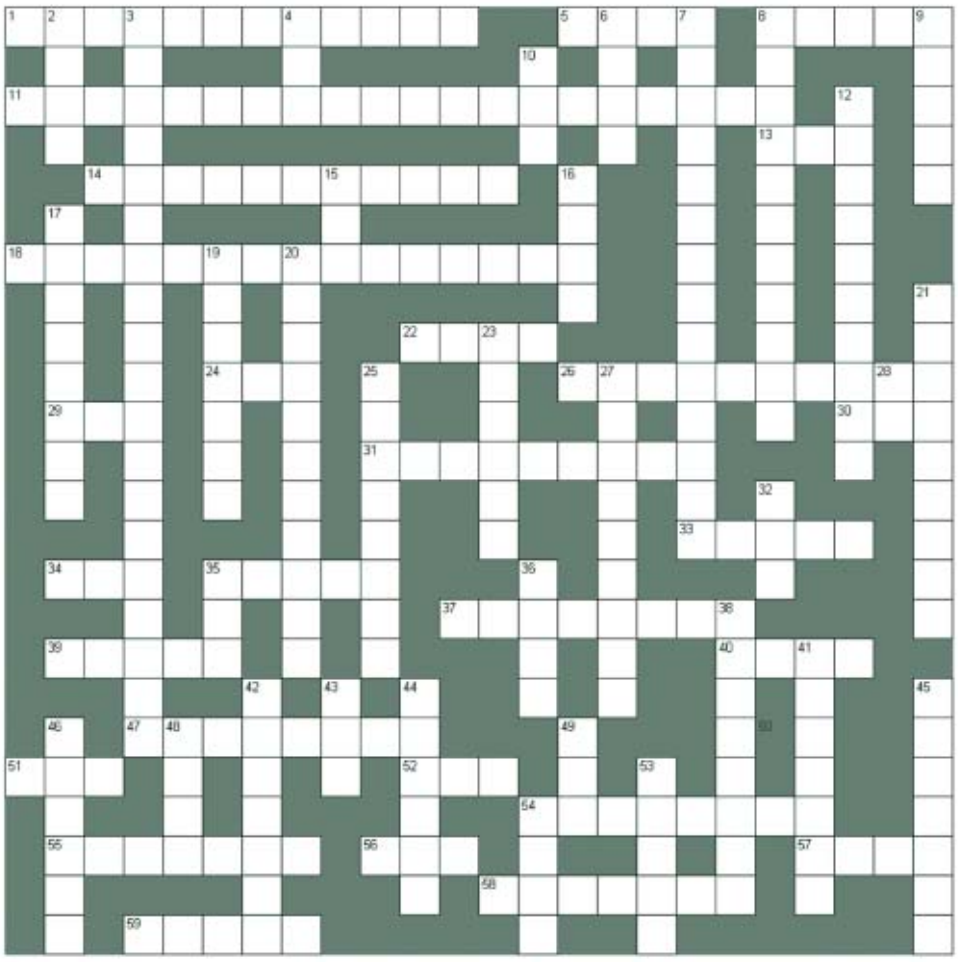
Journal of Clinical Data Management: Status Update

Author: Kit Howard, (Kestrel Consultants)

As many of you have seen in a recent issue of SCDM's e-newsletter Data Connections, SCDM is exploring the creation of a peer-reviewed international journal. The Publications Committee has taken on the responsibility of leading this exploration, and progress has been made. A three-major-milestone approach is being taken, with board approval required at each step. The first milestone will involve the completion of a feasibility and marketing survey, sent to all SCDM members and a variety of other individuals and organizations. This survey will help us understand the level of interest in a journal, and what kinds of content and delivery media are most popular. These results, along with a preliminary budget analysis, will be presented to the SCDM Board of Trustees at the January Board meeting for approval. Assuming that it passes, the first quarter of 2004 will be spent fleshing out the content categories, job descriptions, advertising requirements, editorial and review guidelines, and the like. We will also do some market research into potential advertisers. The Board will have an opportunity to see and approve the results at the Spring Forum Board meeting. If approval is again obtained, then the Journal Publications Subcommittee will begin active solicitation of articles and advertising, recruitment of key editorial and review board members, and finalization of procedures and guidelines, with a goal of publishing the first issue in the first quarter of 2005. This is a very ambitious goal, especially considering that all participants are volunteers, with full-time jobs elsewhere, and the membership is fully international. That said, the opportunity to make a significant impact on our professional body of knowledge is immense, and well worth the effort. We will need more assistance as the task lists become more organized. If you would like to help, please send an email to Alec Vardy (Journal Champion, alec.vardy@cvt.com) or Kit Howard (Journal Organizer, kit@kestrelconsultants.com), or any of the Publications Committee members, and we will involve you at the appropriate time.

Fun Stuff

This issue's fun activity is a crossword puzzle using words that should be familiar to all CDMs. There are no puns nor anagrams, nor any of the other dirty tricks that make some crosswords so difficult! The key will be published in the next issue of DataBasics. Have fun!



Across

1. Anything unexpected happening to a patient
5. "Untrue" estimate
8. US industry trade group to which companies can belong
11. Document that details all known information about a drug
13. Budget _____ can lead to project delays
14. Write up of trial results
18. What subjects sign saying they understand what will happen in the trial
22. Amount of study drug
24. Group of people who protect rights of study subjects
26. Government rule covering many aspects of clinical trials
29. Common analysis language
30. European guideline defining electronic standards for clinical trials
31. Aim of a study
33. Clinical experiment
34. Document that requests permission to market a drug
35. Group that defined submission data standards
37. When a drug is first tested in humans
39. Law allowing FDA to collect user fees from pharmaceutical companies
40. What companies want the FDA to be in reviewing submissions
47. The event that defines success or failure of a subject in a trial
50. Ignore this clue
51. Internal company rules for how to perform a set of tasks
52. Patients with this condition pressured passage of accelerated NDA approvals
54. Electronic file containing study data
55. One goal of a trial is often to do this
56. European clinical trials standards
57. Federal body responsible for reviewing ethical drug applications
58. To be used in a submission, data must be good _____
59. Question about data

Down

2. "Above all, _____ _____ harm", part of Hippocratic Oath
3. Focus of 21CFR11
4. One of the core safety data domains
6. One kind of vital signs data is measured in this
7. Original information sometimes transcribed onto forms
8. Name for studies in which drug is tested in animals
9. Activity designed to assess process compliance
10. Document on which clinical data are often captured
12. Methodology for assessing trial results
15. Alternative to capturing data on paper
16. Information
17. Results assessment
19. Person who examines clinical data at an investigative site
20. Study design in which no one knows who receives what treatment
21. To assign a subject to a treatment group impartially
23. Risk/benefit profile of a product
25. Document detailing how a study will be conducted
27. Computer program designed to identify data anomalies
28. Lots of this is put in when a big deadline is approaching
32. Industry group to which individuals can belong
35. Same as 19 Down
36. Same as 16 Down
38. "How a treatment works in ideal circumstances"
41. Person participating in a clinical trial
42. Company running a clinical trial
43. Proposal submitted by a CRO
44. Principles
45. Not patented
46. Behave in accordance with
48. The hypothesis that the treatment will not work
49. US regulatory body
53. Same as 40 Across
54. Study compound

Election results

The Society for Clinical Data Management is happy to announce the results of the 2003 Board of Trustees election. New members of the Board of Trustees include:

Lisa Freeman, Corus Pharma (Trustee),
Jane Hiatt, Schering Plough Research Institute (Trustee),
Jill Vath, Genentech (Trustee),
Audra McRae, Pharma Research Corporation (Appointed Treasurer).

Additionally, we would like to recognize and thank the trustees who have recently ended their terms. They include:

Sally Cassells, Lincoln Technologies (Chair)
Hugh Donovan, Aventis Pharmaceuticals (Past Chair)
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Each will continue to volunteer their time on other important SCDM committees & initiatives.

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