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DATA BASICS

Volume 9
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2003 Fall

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

Welcome to the Fall issue of Data Basics! This issue is devoted to the changing ways we do our business. We may do more of this in the future, but this issue is a start.

Looking forward, the Winter issue will expand on the topic of the Fall Conference in Colorado Springs, CO, which should have just ended as you read this. Please note that the deadline for submission for the Winter issue has been extended to Nov. 14, 2003.

Already we on the Editorial Board are looking towards next year. We have received several good topic suggestions from our membership on the SCDM Website Discussion Forum. Based on the ideas and discussions presented on the forum, we have decided on the topic of Labs & Lab Normals for the Spring 2004 issue, to be followed by a Quality Control based issue in the summer. Thank you so much for your suggestions, and keep those ideas coming! With that said, if you have ideas for specific articles or experiences you'd like to share on either of these topics, please contact one of the co-editors. We'd love to get you involved!

We hope you enjoy this issue of Data Basics, and as always, we look forward to your suggestions and input on how to continue making this publication of interest and of value to you!

Regards,
Cherie and Kit

Outsourcing Descrepancy Management and the CRO

Wanda Doles and Lynda Hunter
PRA International

There are many scenarios in which a pharmaceutical or biotechnology company outsources discrepancy management on a study:

- insufficient personnel to handle additional trials;
- complex, global trials;
- lack of a data management department;
- lack of an Information Technology infrastructure and defined methodology to support a trial; and/or
- Rescue efforts for a mismanaged trial.

Projects that are overdue in the pipeline, have timelines that would overload internal departments, or simply require too many resources for the company to function and still maintain a viable business, are targeted for outsourcing. A new start-up company or a company with all investments allocated for one or two drugs may also not be in a position to host a large trial due to the costs. Implementation of a Data Management department can be prohibitive due to the expense of producing a series of standard documents plus database production, maintenance and validation.

Contract Research Organizations (CROs) have a wide variety of services and practical knowledge based on all of the projects that they represent. They are in a unique position to evaluate many different approaches during research trials. This environment gives CROs a vast number of opportunities within the research community to explore different methods for cleaning data. CROs develop data management documents based on knowledge from previous clinical trials and from their experienced personnel – many from pharma companies – to clean the data effectively. Data Managers in CROs have developed a wide repertoire of expertise in many therapeutic areas, since they are involved with studies for several

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This Issue

DATA BASICS Editorial Policies

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(also known as Publications Committee)

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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 9, Issue #4 (Winter)	November 14, 2003
Volume 10, Issue #1 (Spring)	Feburary 2, 2004
Volume 10, Issue # 2 (Summer)	April 26, 2004
Volume 10, Issue #3 (Fall)	July 26, 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. topic, scope, and perceived interest to SCDM membership). Materials accepted for publication may be edited at the discretion of the Editorial Board.

Neither SCDM nor the *Data Basics* Editorial Board endorses any commercial vendors or systems mentioned or discussed in any materials published in *Data Basics.*

Advertising Policy

AD RATES**

Size	Inches	Costs (USD)
Quarter Page	3 5/8 x 4 5/8	$240
Half Page-vertical	3 5/8 x 9 ½	$400
Half Page-horizontal	7 ½ x 4 5/8	$400
Full Page	7 ½ x 9 ½	$ 575

** Ads are net, non-commissionable

MECHANICAL REQUIREMENTS: Do not send logos/photos/images from word processing software, presentation software, or Web sites. Files should be saved in the native application/file format in which they were created. Photos/images should be high resolution and received in the file size you wish to have it printed.

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Acceptable file formats include AI, EPS, and high resolution PDF, PSD, JPEG, and/or TIFF.

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Please submit all forms, artwork, and payments to:

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Fax: 1 (414) 276-3349
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Web site: www. scdm.org

Comments from the Membership

As hoped, this section of *Data Basics* continues to provide a forum for controversy. The following letter was sent to SCDM under the condition that it be published anonymously. "Thank You" to our secret contributor for this issue!

To the Editors,

Am I the only one out there in CDM-land who is sick to the stomach of the "used-car salesman" techniques being used by EDC vendors and their hangers-on in trying to persuade us of the advantages of EDC?

A press release I saw recently neatly captures this point. To quote: "*Comparing these two methods* (EDC and paper) *of edit checking, the question is whether one wishes to see their clean data in nine seconds or nine months*". Let's explore the "nine seconds" claim a little. I will admit that any edit checks that can be fired based **solely** on the data captured by the EDC system can be resolved quickly, but some checks (and some important ones) cannot be fired immediately. In recent trials in which I have been involved, queries have been raised about ambiguity of adverse event reported terms, about dates supplied to the clinical database by the site that did not match those supplied by the same site to the central laboratory, and adverse events reported by the site which were not confirmed by results received from external sources (safety laboratory results, ECGs, etc). Now if any of my fellow CDM professionals can code their adverse events and import data from external sources every nine seconds, I take my hat off to you. I cannot, and neither would I wish to. In most of the trials in which I am involved, it is simply impossible to get **all** the queries to the sites within nine seconds, let alone have them resolved so that the data are clean. And since the data from adverse events and external sources are generally key efficacy or safety data, there's no way I'm going to approve the lock of a database until these queries have been resolved. **In other words, the concept of clean data in nine seconds is a myth.**

On the other side of the coin, if "clean data in nine months" were the paper-process routine in my career, I would expect (justifiably) to be out of a job and most of the companies for which I have worked to be out of business. I can envisage only two situations in which such a protracted data cleaning process would be acceptable: a very-low priority study, or one in which monitoring visits are very infrequent. Given the nature and (lack of) importance of such studies, in neither case would the use of EDC instead of paper have more than a minor impact on the speed of internal decision-making or time to market, claims usually made in its support. Typically, CDM tries (and in my experience generally succeeds) to complete its paper data processing activities so that the site or CRA has the queries for resolution at one monitoring visit from the data collected at the previous visit. Further, the expectation is that most of the queries are resolved at the first available visit; while for various reasons this is not always achieved, if queries are still outstanding after two monitoring visits, most of the companies I have worked for would be urgently trying to rectify this unacceptable situation. Given that a typical interval between monitoring visits is four to six weeks, this implies **the expectation that data are clean in two to three months**, rather than the nine suggested by the press release.

Now let's introduce SDV (Source Data Verification) into the equation. SDV is the process by which the CRA ensures the completeness and accuracy of the data in the database by comparing them against the source data in the patient records at the site. A recent EDM Forum survey reported that only 14% of data collected in EDC studies is immediately entered into the eCRF, so SDV is almost as much a part of the EDC process as it is of the paper process. Implicit in the site monitoring SOPs of many companies is the assumption that the data cannot be "completely trusted" until SDV has been accomplished. The data on the EDC database may pass all the edit checks, but if they are found during SDV to be inaccurate or incomplete, can they really be called clean - draw your own conclusions.

Which brings me to a presentation I heard recently. This presenter informed me that SDV in the paper process is **mandatory** before any data can be delivered to the CDM unit for processing. On the other hand, he claimed that SDV and data cleaning can occur in parallel with EDC systems, thus reducing the interval from data acquisition to data declared clean. I will readily admit that errors uncovered by SDV are easy to correct on most EDC systems, and far less so with the paper process if the CRFs have already been sent to CDM. But if monitoring visits are relatively frequent, and, towards the end of the study, timed to coincide with final patient visits, the time lost in the paper process by waiting for SDV to be completed is very limited.

I borrowed from a colleague the binder from last year's SCDM Fall Conference in Atlanta (EDC, Making It Real), hoping to find a few more realistic comparisons of EDC and paper processes, but I was disappointed. Two statements in particular raised the hairs on the back of my neck: "the data manager prints query reports 8 – 10 weeks after receiving CRFs", and "significant lag time between subject visit and data availability – average 3 months, as long as 6 months". Such statements clearly point to problems far beyond the choice of technology.

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Comments from the Membership

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But there was one bright spot in this binder. In a presentation from two employees of a fairly large pharmaceutical company, one of the "efficiencies we hope to gain" was a 50% reduction in time from LPO (last patient out) to lock a database, from four weeks to two weeks. Yes, I have transcribed correctly – four weeks (not nine months) to two weeks (not nine seconds)!

The two-week lock time with EDC appears reasonable. There is so much to do after the final patient visit that it would be difficult to achieve lock routinely (although it may be possible for "special" studies) in less than two weeks. But if these speakers are to be believed (and I have no reason to doubt this), their company's average lock time with the paper process was **four weeks**. This seems fast to me, but not by much – I would estimate that the average time for studies on which I have worked has been around six weeks.

So if there are people out there for whom a nine-month cleaning process is not unusual, or where it is typical for the data manager to take 8 – 10 weeks to print query reports, or who have to wait three to six months after the subject visit to see their data, my advice would be: you can do much better than this even with a paper process – examine and fix your process before you embark upon the challenges of EDC. But I am more inclined to believe that what I am reading is a deliberate comparison of the best EDC examples against the worst nightmares of the paper process.

I would not want your readers to conclude from what I have written that I am "anti-EDC". I have used EDC technology successfully in the past, and expect to use it more and more in the future. Many vendors, some with whom I have worked – many others with whom I have talked, are sincere in their acknowledgement and understanding of the challenges faced in implementing EDC, and are prepared to work diligently and professionally to meet these challenges. These vendors typically understand the limitations of what their products can achieve, will try to understand the rationale behind the CDM process that their customers wish to implement, and do not over-sell their technology.

What I object to, as I said at the beginning of this letter, are the shoddy "used-car salesman" techniques. I have quoted a few examples, and I am (sadly) sure that there are more that I have missed. Speaking personally, I am far less likely to approach the vendors who make what I see as outrageous statements, so hopefully these people are "shooting themselves in the foot". The discipline of Clinical Data Management, of which I am proud to be a member, is a professional scientific discipline, and should be treated as such. Let me close by asking the SCDM, as our profession's North American mouthpiece, whether it is content to allow such contemptible advertising to reach its members' eyes and ears without doing anything to set the record straight? Would it be possible to design a survey to investigate some of these claims, so that **reliable** metrics can be offered to its membership with which to counter the excesses with which we are frequently confronted?

Signed,
Anonymous

Letter from the Chair of the Society for Clinical Data Management

Sally Cassells - *Lexington Clinical Data Systems*

On September 1, thanks to the extraordinary efforts of Armelde Pitre, the certification committee and dozens of Subject Matter Experts, the SCDM Clinical Data Management Certification Test was made available as a beta test. This is an important milestone in a process that began several years ago and that will lead to the first ever Certified Clinical Data Managers.

The certification program grew out of a Board of Trustees planning retreat held in 1997. On June 20 of this year, the BOT held its second–ever planning retreat at the STATPROBE facility in Ann Arbor, Michigan (many thanks to Vice Chair Marianne Plaunt).

The strategic planning process began with BOT members identifying unique activities and programs offered by SCDM. We then identified and reviewed some of the major trends that affect the current CDM working environment – changes in technology, emergence of new data standards, role changes brought about by corporate mergers or cost cutting measures, and increasingly global drug development processes. The task was then to focus on identifying programs and activities that SCDM could offer to help our members survive and thrive in the face of the challenges posed by fast-paced, forever changing world of drug development.

BOT members divided into two groups – one focused on internal/membership oriented issues, the other focused on external issues – most specifically, relationships with other organizations. It will probably surprise none of you that these were very lively sessions!

The result of the internal issues discussion was identification of three new focus areas for SCDM:

1) Establish a local chapters program to encourage and enable more Clinical Data Managers to join and become actively involved.
2) Develop training programs to support the CDM Certification program
3) Develop a CDM journal – to replace or supplement our current printed newsletter and e-newsletter activities

The externally focused group looked first at why it is important to develop relationships with other organizations and then reviewed issues relating to liaisons with several key organizations including the DIA, CDISC, PhRMA, INCDMA and the FDA. Our relationships with these organizations stand to benefit CDMs by

1) Building greater awareness of the value CDMs bring to the drug development process.
2) Aligning our interests with those of other stakeholders in the industry.

You will hear more about our new programs as we continue to develop our strategic plan and use it to set objectives for next year.

Some of you will have already noticed a recent change in SCDM. As of June 1, our administrative operations were transitioned to Executive Director Incorporated (EDI) – a leading association management organization located in Milwaukee Wisconsin. We are very excited about this change. EDI's level of professionalism and their extensive experience managing other scientific and medical associations will help SCDM continue to grow and to foster Clinical Data Management excellence. The SCDM BOT, the committee chairs and the staff both at PMA and at EDI have been working hard to help make the transition a smooth one. If you attend any of our upcoming meetings, please drop by and introduce yourself to Kim Breitbach, our Executive Director, and others from the EDI staff.

Has your e-mail address changed recently?

SCDM is utilizing e-mail to disseminate information of interest to the membership, via the e-Newsletter and other announcements. Don't miss out.

Be sure SCDM@PMA (e-mail: info@scdm.org) has current e-mail information where you prefer to receive SCDM information. You can also use the members only section of the Web site to update your information (www.SCDM.org)

Ongoing Changes in CDM Roles and Responsibilities

Natasha Ostavnenko, Nancy Roth, Kristen Clemenzi, Christine Hobbs and Lisa Dye
Medical Device Consultants, Inc.
Department of Data Management, Clinical Services

Traditionally, the standard duties of the Clinical Data Manager were limited to reconciling data entered into a database with the corresponding data collected on Case Report Forms (CRFs), generating data queries, coding toxicities, and recording adverse events. Data Managers may have had little or no time for involvement in database design, programming, or performing electronic data checks, generating client-requested data summaries and reports, or the development of CRFs in the first place. As technology has continued to advance and client demands have broadened, there have been significant changes to the Data Manager's role in the clinical research environment.

The advent of sophisticated and powerful data management software tools has had a significant impact on the daily activities of the Data Manager. In the past, older data management software required the Data Manager to resolve differences between databases subsequent to independent double data entry. In this type of system, one data discrepancy report could result in pages and pages of corrections and edits requiring hours of data management time. This translated into little time, if any, for programming automated quality checks, data consistency checks, CRF tracking and patient accountability, or the preparation of client-requested reports. With the implementation of more sophisticated database software, which allows most discrepancies to be resolved at the point of second data entry, Data Managers have experienced a shift of their responsibilities to include other tasks previously handled by programmers or statisticians.

Inasmuch as the data entry and reconciliation steps have been streamlined and simplified by more advanced software, the shift of responsibilities has required Data Managers to obtain more training, technical expertise, and a greater depth of knowledge in many areas. Database design, development and validation have become part of the Data Manager's role, and decisions regarding data storage for appropriate retrieval and filtering capabilities are now in the hands of the Data Manager. Tasks of this nature require a more thorough comprehension of overall study design, specific study protocol and endpoint familiarity, as well as knowledge about the requirements for final analyses and reporting. The expanding role of the Data Manager requires knowledge of relational databases, Sequel Query Language (SQL) or its equivalent, and of reporting tools such as Crystal Reports, to retrieve data from multiple tables within a database in order to create sophisticated statistical and summary reports to satisfy client needs.

If brought into the process during the development phase of a project, data managers with this extended knowledge are able to provide valuable input on the development of case report forms. Working with the Project Manager and the Study Sponsor at this stage of CRF design allows the Data Manager to eliminate potential problems with the CRFs and to provide the client with a high quality database that captures the study endpoints and reflects the study protocol most accurately.

The complex data storage schemes of more advanced data management software have enhanced the effect of the Data Manager's role as gatekeeper in charge of communication between Project Managers, Clinical Research Associates (CRAs), Statisticians and Study Sponsors. The Data Manager sits in a unique position and can control and monitor the quality of the study data. The Data Manager can monitor incoming data for errors and inconsistencies that may need to be communicated to the CRAs or Study Coordinators at specific sites, thus improving the overall quality of the study database.

In addition, the reporting demands of clients are steadily increasing, both in scope and in frequency, requiring effective communication between the Project Manager and Data Manager, and in some cases between the Data Manager and the client. Many studies involve the incorporation of additional data that have been collected and stored by another party such as a central laboratory or another contract research organization. Often it is the Data Manager's responsibility to facilitate the transfer of this type of external data, ensure its accuracy, and resolve any discrepancies or issues with the independent third party. It is apparent that excellent communication skills and the ability to interact with a variety of individuals on many levels are now necessary requirements for an effective Data Manager.

As the role of the Data Manager continues to diversify, there is an ongoing need for greater technical and interpersonal skills. As the majority of data management responsibilities shift from database reconciliation to proactive data management, data managers must continue to increase their technical proficiency and participate as integral members of the clinical project team.

Implementing Data Management Core Competencies at Pfizer Ann Arbor

By: Doug Schantz, Director, Development Transition Management

With significant contributions from: Christine Enciso, Manager, Clinical Study and Data Management, Kelley Purdom, Manager, Clinical Study and Data Management

In early 2002, the Clinical Data Acquisition and Management (CDAM) groups at Pfizer's four major global research and development (PGRD) sites* began implementation of a core competencies model that redefined the role of the project data manager.

The Case for Change

The impetus for developing data manager core competencies was simple. Looking at the realistic future of patient data management systems, it was apparent to the CDAM Leadership Team (LT) that electronic data capture (EDC) was developing to a point that three common tasks done in the data management department would become nearly obsolete in the foreseeable future. Data entry, done at the time by both in-house staff and partially outsourced, would be replaced by data entry at the investigator sites. Imaging of individual CRFs would dwindle as trials became less encumbered by paper. Management of data clarification forms (DCFs), at least to the point of query generation and entry of resolutions if not beyond, would be replaced by interactive edits. This presented us with an excellent opportunity to define the competencies needed by data managers in the future.

This was a pretty radical shift from the role of the traditional data manager. Without good communication and context building, we risked alienating colleagues rather than developing them in their careers. Without a commonly understood vision of the future, we risked not adequately preparing our business to meet project needs (for example, technology deployment, hiring and training). Without a good understanding of our current and future processes, we risked compromising data quality (for example, who checks data across patients, decides when and when not to issues queries, etc.).

Simple Doesn't Necessarily Mean Easy

The strategy for implementing data manager core competencies, dubbed CDAM Strategic Direction, would be to outsource tasks determined to not be core competencies and increase the breadth of data managers' jobs to include not only data management but also database development and forms design; we felt these would better prepare colleagues for the tasks needed in an EDC world. The global CDAM LT was to have begun planning for implementation of CDAM Strategic Direction on September 11, 2001. Fortunately, the many CDAM colleagues who were traveling that day were all safe somewhere, but the chaos and ensuing corporate travel ban limited the rate at which we reached consensus and worked out important details. By February of 2002, we had reached a point where we were ready to have our strategy approved by our management and introduce the concept to the next level of management.

Whereas the notion of developing competencies for the future seems noble to management (who devise them), springing the concept on innocent project data managers did not necessarily result in unconditional acceptance. Change is difficult enough when you understand the end state and worse when presented with having to give up things to which you were accustomed and learn new and sometimes intimidating tasks.

Communicate, Communicate, Communicate

Communication planning was very important to our implementation. We developed a list of stakeholders and determined communication points for each group. Since this was considered a significant change, we were careful to develop consistent messages to be delivered at each site.

You're Going to do What?

The reactions to CDAM Strategic Direction depended on the audience to whom we were presenting it:

- Our management: How much will this save? Fortunately, we were able to show a fairly significant cost savings, but it was an afterthought. We knew we were dead in the water if it cost more!
- Our management teams: Thought of all the things we didn't and predicted that colleagues weren't going to be receptive without understanding what it "looked like" better.

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Good Clinical Data Management Practices Committee July Update

Christine Little, *GCDMP Committee Chair*

The GCDMP committee has been working on obtaining copyright for Version 3. We are very close to having received all the necessary signatures. Going forward, authors will be asked to agree to the conditions for obtaining copyright on future versions before writing commences. We have formed a Lifetime Maintenance sub-committee, members of which have been meeting to draft a Lifetime Maintenance Plan for the GCDMP. Other sub-committees have been working on reformatting the document for ease of use and on obtaining comments via the SCDM website. The committee continues to edit the Metrics section.

Visit us at www.scdm.org

Introducing … INCDMA:

The International Network of Clinical Data Management Associations

By Alec Vardy

Clinical Data Management is practised wherever pharmaceutical research and development is conducted. And Clinical Data Managers the world over are faced with essentially similar issues and challenges. Just as several other disciplines involved in pharmaceutical R&D have found it beneficial to collaborate across national boundaries there is now a formal international forum for Clinical Data Managers, the INCDMA.

The initial "seed" for the INCDMA was "planted" by the UK-based Association for Clinical Data Management (ACDM) and the French Data Management Biomedical (DMB) in the year 2000. Contacts were established with representatives of associations that encompassed Clinical Data Management in Germany, the Nordic region, Australia and the US, and an informal network of e-mail contacts and quarterly teleconferences was initiated. In the teleconferences, "hot" topics (e.g. EDC, MedDRA, etc.) were discussed and information on the activities organised by the member associations was shared.

During 2002, the network participants expressed a growing desire for the organisation to become more autonomous. While wishing to continue the information exchange and discussions of relevance to our member associations, we also felt it important to establish the identity of a truly international body, recognised by the "outside world" as capable of making contact with and gaining information and feedback from literally thousands of Clinical Data Managers through these member associations. And so the INCDMA was born.

Last year saw the INCDMA initiate a number of activities, some of which will be completed in 2003. Four teleconferences were held; CDM associations were identified in four additional countries, and initial contacts were established; contacts with the DIA were made in both Europe and the USA. Special topics included in the teleconferences were reports from member associations' meetings and conferences, a presentation of the EDM Forum, and an update on CDISC activities in Europe

The INCDMA has established the goals for 2003, and is working hard to bring these to fruition. The following main categories summarize the goals, and there are several objectives within each category:

- Continue to improve the internal functioning of INCDMA
- Promote the INCDMA in the Clinical Data Management arena worldwide
- Advance knowledge of CDM outside Clinical Data Management
- Provide global input to relevant regulatory documents
- Provide general guidance in the area of Clinical Data Management area

Links to the web sites of the INCDMA's member associations can be found on the SCDM's web site, www.scdm.org, in the 'Links' link.

CALENDAR OF EVENTS

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

October 10-13, 2004
Fall Conference
Royal York Hotel
Toronto, Canada

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
Orlando, Florida

FAQs about Professional Certification (Part 2)

by Leigh Smith, Wyeth
SCDM Certification Committee

Below are frequently asked questions pertaining to professional certification. We hope that this list will address your questions and concerns. If not, please do not hesitate to forward all questions or concerns to Armelde Pitre (chair, SCDM Certification Committee) at pitrea@groton.pfizer.com or myself at smithL13@wyeth.com.

Q: I heard that there are multiple sections to the exam - what happens if someone does not pass all the sections? Do they have to sit for the entire exam again?

A: The exam contains 26 sections divided into 3 parts. Upon completion of the exam, the participant will be notified what sections they answered correctly and incorrectly. If the participant does not obtain a sufficient number of correct responses (i.e. make the cut-score), then they need retake only part(s) containing those sections with incorrect responses. This will considerably reduce the length of time needed to retake the exam.

Q: Will a reduced price be offered to companies who register in bulk?

A: We are not able to offer a reduced price this at this time. The cost of the exam was established to cover administrative processing costs, cost of exam delivery and cost of development. Both exam delivery and administrative costs are on a per-seat basis. The exam delivery agent, Prometric, does not offer any bulk discounts. If these discounts become available in the future, the reduced costs will be passed on to participants. (Please see *Data Basics* Volume 8, Number 2, Summer 2002 for a full disclosure of our exam pricing policy.)

Q: What are other ways to get the reduced cost?

A: An individual may elect to take the beta test. The beta test is being offered the cost of $195 (US) to the first 100 people who qualify. This price passes only the administrative processing and exam delivery costs onto the test taker. The reduced price is being offered because it is expected that the beta test will take longer than the final exam. We are offering the reduced price to encourage people to participate in the beta test process.

Q: When will the beta testing be offered?

A: We are currently targeting September 2003 for beta test release.

Q: How will we know when the beta test will be offered?

A: Both SCDM and the DIA will be sending an electronic notice to their membership. Additionally, you can periodically check www.prometric.com for a listing of test offerings. Once the SCDM CDM Certification Exam is available, it will be listed on their website.

Q: If I helped to create test questions or helped to validate the test questions am I able to take the professional certification exam?

A: Yes. Any qualified person may sit for the exam.

Q: Would people who created or validated test questions have an advantage?

A: Experts in exam development have ascertained that this is not the case. This is usually due to two reasons: first, there are over 300 questions. Second, the questions went through multiple reviews and would have most likely been modified from their original form.

Q: How long will it take to hear if I passed the exam?

A: After the beta test period is completed, there are three additional steps in the process:

- Blinded psychometric evaluation of test results
- Setting the cutscore
- Application of the cutscore to the unblinded results

Notification of certification results to the participants may occur after this final step. We anticipate that the beta test period will last between one and three months. An additional six to eight weeks are needed to complete the remaining steps. Beta test candidates will be notified of their results in writing by US mail.

Upon release of the final exam, the candidate will be notified immediately (i.e. upon completion of the exam) of their certification status.

Q: Will the testing be offered outside North America?

A: The test delivery process is substantially different for other countries. The cost structure is also different. Therefore, at this time we have no plans to offer the exam outside North America. The exam delivery policy will be reevaluated in one year after we have more experience with the current process.

Please feel free to forward any questions or concerns in reference to professional certification to Leigh Smith at or directly to the chair of the certification committee: Armelde Pitre at. We will address all new questions or concerns in the next issue.

Outsourcing Descrepancy Management and the CRO

Continued from cover

different clients.

CROs use this background information in developing common processes to ensure that successful outcomes on one project can be repeated on subsequent projects. They also take advantage of defined methodologies and templates with the flexibility to be easily adapted to each new project, yet provide a foundation for consistency in application.

Initial planning is standardized and includes documents to specify electronic data checks, reconciliation of serious adverse events, identification of critical variables, coding conventions, components of and standards for quality control, data conversion specifications and data transfers, etc. Communication of these critical components with the client assures the essentials of data management meet their expectations.

Lead Data Managers provide identification and communication on potential issues to clients for their input. Through ongoing involvement with the sponsor, they develop an intimate understanding of the client's philosophy and requirements.

CROs are service industries oriented to time – to develop the plan for data management activities, to review a CRF, to produce and resolve queries, and to ensure the data is clean. By networking with CRAs and Biostatisticians, the data management part of the timeline can be expedited.

Although companies in pharma are subject to high turnover, due to the competitive nature of the industry, there is typically stability in data management departments. A low turnover in data management is a predictor for proficiency. The ability to have flexibility in resourcing of staff assures that data will be reviewed consistently as it is received.

Through documented study specific training and ongoing quality control of each individual's data review, the quality of data cleaning is specified and maintained.

Companies working with CROs know the cost to produce a clean database prior to beginning work on a project. The scope of work is clearly identified and associated costs negotiated. For sponsors with little experience in data management, overhead expenses (disaster recovery, storing essential data management documents, storing CRFs, etc.) can be overwhelming. CROs are able to customize the output of the data to a client's specifications, so integration of the data conforms to a pharma company with a historical or established database scheme.

Double data entry and independent verification of any inconsistencies is the beginning for assuring quality. The validation documents for database set-up, electronic checks, data conversion and transfer of data produced during the planning process verify a 21 CFR Part 11 compliant system. Multiple and ongoing quality control during discrepancy management provides accountability.

Because outcomes are our future, CROs are very responsive to maintaining the high regard and respect of our pharmaceutical and biotechnology clients. Our role is to support the sponsor's vision – a product that will produce for them a revenue stream (livelihood) for the next 7 to 10 years. The patent on unique drug products is now relatively short. As a result, even before the current investigational product is providing revenue for the company, investments are being gathered to support new research for the next compound or line extension. CROs support the drug industry to allow them the means to turn their attention to what they are experts at – discovery and enabling a compound for market.

SCDM Committees

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

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Web Site Committee
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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.

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- Our colleagues: Not receptive without understanding what it "looked like" better.

Moving Ahead

Once we had set direction with our staff, we had plenty of work to do.

We decided that in order to start implementing our strategy as quickly as possible, we would work independently to choose an initial CRO to which we would outsource rather than trying to take time to harmonize requirements, which would take longer. Sites varied on costing models (paying for full-time equivalents vs. paying for units of work) and extent of work outsourced. This proved to be a learning point, as we all ended up negotiating different things with the same CRO.

A task force was established across sites to assess training needs in order to bring colleagues up to speed with required competencies as quickly as possible. In order to pilot the process of outsourcing discrepancy management, Ann Arbor formed a discrepancy management team with current staff which was separate from projects; this proved to be useful learning. From this experience, we were able to better define what parts of discrepancy management were to be outsourced and which were left for in-house staff, resource models and communication pathways from the teams.

So What's Left?

The biggest misconception about CDAM Strategic Direction was that it was born as an outsourcing strategy rather than a core competencies strategy. Unfortunately, in order to develop core competencies, we had to outsource some tasks first, which initially diverted our attention from helping colleagues understand the future role of the data manager. A group of CDAM management at each site began to assess their staff:

- Assessment of current competencies
- Gaps from future state
- Planning training and career development needed to address gaps
- Training and coaching using subject matter experts

We also needed a better description of what the data management part of being a data manager "looked like." Cleaning data (as the readers of *Data Basics* certainly know) has its levels of complexity and it was important to emphasize to colleagues that we were not abandoning the data cleaning process but rather outsourcing those parts that we saw were easy to automate with EDC, allowing us to maintain control of data quality and integrity. A group of early adopters who had demonstrated ability as change agents and had

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subject-matter expertise was convened to develop a list of descriptors for the data management role. This description was subsequently presented to staff and is being incorporated into role descriptions.

Current State

We have successfully implemented CDAM Strategic Direction for a portion of studies at all four PGRD sites; in Ann Arbor, non-core competency tasks for about 90% of studies are either outsourced or plans are in place to outsource. Some studies that were near completion or studies where it cost more to outsource than it does to keep the work in house were not outsourced. Approximately 45% of data management staff in Ann Arbor have been functioning in the role of combined data manager, database developer and forms designer. CDAM is no longer a group at Pfizer, recently having been combined with the Study Management function; the data manager core competency strategy is being carried forward using a somewhat different staffing model.

Lessons Learned

Since the majority of "flawless execution" examples live primarily in the management literature fairy tales, we learned some things from this experience.

First, actively court colleagues who are resistant to change. Your first reaction may be that we suggest this in order to convert them to early adopters (which would be pleasant and beneficial as well); consider the value that these colleagues may bring to test your model, in reasonable doses, of course. In addition to those resistant to change, consider a diverse group to give input (stakeholders, customers, different levels of colleagues, etc.) to help you identify things you missed.

Second, if you are working across multiple sites, it may be beneficial to coordinate implementation strategy. While we were successful with a fast implementation model, particularly since it was significant change and we didn't want to let it languish, other models may be worth considering (ie, taking the time to plan extensively).

Third, we would have gained acceptance more quickly if we emphasized the core competencies aspect of CDAM Strategic Direction more loudly than the outsourcing aspect of the strategy. Unfortunately, in order to get to the former and still do the work, you have to pay attention to the latter.

Finally, communicate, communicate, communicate. Give staff frequent updates and repeatedly draw them back to the reason for moving to your strategy in the first place.

The Future of Data Management

While this was a significant shift for Pfizer, others in our industry have arrived at comparable conclusions. Other companies have employed similar outsourcing strategies (in fact, we found that Pharmacia, which became part of Pfizer in April 2003, had a similar strategy) and Wyeth has partnered with Accenture to provide their entire suite of clinical data management services. Core competencies will be determined, either through what's desired or less optimally, what's left over. Increasing awareness of the benefits of data management and improving professional standing of the data manager may influence senior management to increase the likelihood that we're sitting at the table to determine the path forward.

*Ann Arbor, Michigan, Groton/New London, Connecticut, La Jolla, California and Sandwich, United Kingdom

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Do you have an opinion or concern about some activity of one of SCDM's various committees?

Do you have a question you feel needs more discussion or a more in-depth answer?

Have you been wishing for a way to express yourself to both the society membership and those serving on a specific committee?

Well the wait is OVER!

Your opportunity to express yourself is here.

Data Basics has created the "**Comments from the Membership**" column in order to give you that opportunity. We want to hear from you, the membership, on any data management or society related topic that interests you.

All letters should be submitted for publication to *Data Basics* co-editors Cherie Stabell (stabell@gene.com) or Kit Howard (kit.howard@pfizer.com). Materials are requested to be submitted in electronic form (MS Word) but may be submitted via e-mail, fax, or by mail. Acceptance for publication will be at the sole discretion of the Editorial Board. The decision to publish will be based primarily upon professional merit and suitability (i.e., topic, scope, and perceived interest to SCDM membership). Materials accepted for publication may be edited at the discretion of the Editorial Board (principally for formatting and grammar/spelling).

Ode to the Clinical Data Management Certificate Program

By Paul Joseph Erickson, CDM

From drug discovery, to development, oh…how many elements,
Through phases I…II…III… and IV, wow! What a metaphor.

From protocol design, to quality control,
Here we'll see more than one pitfall.

Between database validation, through safety reconciliation,
My, what a revelation.

By using GCP and ICH guidelines, we will do just fine.

During CRF and database design, I thought I might resign.

Then along comes CDISC, which helps us to define,
Though paper data capture, brings us pure rapture
With 21 CFR 11, we thought we went to heaven.

We design our databases, like our family trees,
We use what's called an entity relationship diagram, to help us see the leaves.

We annotate our CRFs to ease the data flow,
We validate our data schemes, and the code we load.

There will be queries down the road, this you surely know,
Why this is… with all the rules, I really just don't know,
In any event we planned ahead, it's called a CRF/DCF tracking tool,
Hey…this is cool!

With edit checks and data specs, there's nothing to neglect,
We've done our job through and through this is what reflects.

Lab data plays a part; it's where you go….to check your heart.

Reference Ranges are obscene, they can't decide between two means,
Units are important too; it's always fun when they're askew.

Conversions help the process flow; it's just what version that's tough to show,
We have a choice of where to go, there's always Central, don't you know,
But if we take the local route, we may end up a mental bout.

We love to map our subject data
It's all so very orchestrated
The preferred term for us is MedDra,
It's like the many-headed Hydra.

We strive to keep our subjects safe, alas; this is not always the case,
We have a place for SAEs; this is what we sometimes see.
Reconciliation is the key; it leads to safety summaries
We have to tell the FDA; after all, it is their way.

Auditing is a process too; it's how we check to prove we're true,
Un-blinding is what happens next,
It's the findings we might regret.

Locking is the last in line; we really hope our data's fine,
Closure is all that's left; it's when we ship to the Medical reps.

Soft skills is the term, for which we're all concerned
Team building is the goal, it brings us all into the shoal.

Communication is our way, for all to see a brighter day
And feedback is a funny game, which helps us to achieve…
The **ultimate** gain.

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Please contact info@scdm.org if you have questions about registration for upcoming meetings, advertising, renewal of membership, or if you need to provide updated mailing/contact information.

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