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DATA BASICS

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Summer 2002

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 Summer issue of Data Basics! With Tam and our continued support from a great Editorial Board, we hope Data Basics will continue to be a worthwhile "read" for our members. This issue features new information from several committees, as well as our feature article packed with the proceedings of a very exciting Fall Conference. Thanks to **Jean Mazalewski** and **Karen Klingler**, the conference co-chairs, for putting this conference together!

Be sure to check out the summary of the SCDM Annual Business Meeting in case you weren't able to attend. It is full of interesting information and highlights of SCDM's accomplishments in the last year.

Regards, *Cherie & Tam*

SCDM 2001 Annual Business Meeting Summary

(Editor's note: The 2001 Annual Business Meeting was held Monday, February 4, 2002 prior to the first General Session of the 2001 Fall Conference.)

Let's face it, one of the objectives for someone running an annual business meeting is to avoid excitement rather than create it to a degree. Having to coordinate 57 PowerPoint slides from 13 speakers begs smooth predictability rather than spontaneity and surprise!

That said, it's hard to get anyone excited.

The goal for our annual business meeting, kicked off with the questions ***"Why Are We Doing This and Why Should You Care?",*** set the tone that SCDM is really all about the work of its committees and the annual meeting gives our membership the chance to hear about the meaningful work that they do and ask questions. As an added feature, **Caroline Fenning** spoke about the Association for Clinical Data Management (ACDM), our sister organization based in the United Kingdom. Above all, truth be told, we're required to have an annual membership meeting by our rules of incorporation.

Here's a brief overview of the presentations given.

2001 Accomplishments:

Doug Schantz, 2001 Chair, gave an overview of 2001 accomplishments. These included advancing GCDMP to Version 2.0, making key decisions to move the Professional Certification program towards reality, starting the e-Newsletter, increasing advertising opportunities and enhancing our web site.

Officers for 2002 were introduced:

- ***Hugh Donovan*** *(Aventis)* – Chair
- ***Sally Cassells*** *(Lexington Clinical Data Systems)* – Vice Chair
- ***Meredith Nahm*** *(Duke Clinical Research Institute)* – Secretary
- ***Judy Kasperczyk*** *(TAP Pharmaceuticals)* – Treasurer

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THIS ISSUE

Comments from the Membership

As hoped, this new section of *Data Basics* has provided a forum for controversy already. The discussion generated at the 2001 Fall Conference continues as the chairperson of the Certification Committee offers her responses to the first two letters originally published in the *Comments from the Membership* column of the Spring issue of *Data Basics* this year. The following items were sent to SCDM. "Thank You" to the contributors for this issue!

Dear Editors,

"In the last issue of *Data Basics,* readers raised two questions about certification that I would like to address. The first question raised was 'Has the certification committee considered allowing CDMs to certify in niche areas and over time work towards a full certification status?' The second question raised was 'Why use the same name (certification) for two different things?'

"In response to the first question regarding multiple certifications, the answer is "yes," the committee did seriously consider this option. At first, this option seemed more attractive since it would better reflect the industry's organization of the roles and responsibilities in CDMs (especially in larger organizations.) However, after investigating the cost of developing and maintaining separate exams, the cost to members to take separate tests ($295 per test), and the cost of maintaining a database to track the various tests and certificants' status, we decided that this option was cost prohibitive to both the certificants and SCDM. In comparison, over an eight-year period, the costs for a single exam are estimated to be $500,000, while the costs over a similar period for maintaining separate exams were estimated at $2,250,000. Additionally, this option would have necessitated several separate certification titles for each area in which the CDM attained certification. Therefore, CDM's business card would read like alphabet soup: Mary Jones, MPH, CCLDM, CCSDM, CCFD, CCDD. Translated as: Mary Jones, Master in Public Health, Certified Clinical Lab Data Manager, Certified Clinical Safety Data Manager, Certified Clinical Forms Designer, and Certified Clinical Database Designer. Mary's certification would have cost her $1,180. In contrast, the certified CDM is simply: Mary Jones, MPH, CCDM. Translated as: Mary Jones, Master Public Health, Certified Clinical Data Manager. The cost of certification to Mary is $295."

"In response to the second question regarding terminology, the answer is that the committee had investigated the established definitions of various terms. Both accreditation and certification are part of a credentialing process. Here are the formal definitions for each term.

- Accreditation is formally defined as the confirmation by a professional organization that a certain institution, educational course, or program meets certain established qualifications or standards (Pennel, Proffit & Hatch (1971.)
- Certification is the process for granting recognition to an individual who has met certain predetermined qualifications as specified by an organization (HEW 1971a.)
- A certification program may or may not incorporate training leading toward professional certification.
- A certificate program (often offered by an accredited institution) is a training program.
- A certificant is a person attempting to obtain professional certification.
- A Certified CDM is a person who has achieved professional certification status or credentials."

"In other words: Institutions or organizations become accredited; people become certified. Certification and accreditation are NOT synonymous but they are related."

Respectfully,

Armelde Pitre,
Chair SCDM Certification Committee

Notes from the Chair of the Society For Clinical Data Management

Hugh Donovan – *Aventis*

It does not seem possible that this is my third letter to the membership. The year is going by so quickly but the SCDM has been able to make significant progress so far this year. One particular success was the Fall Conference postponed from September 2001. This edition of *Data Basics* concentrates on reports from the conference so I will not focus on it. Also we have held another in a long line of valuable Spring Forums, allowing topics to be discussed in much more detail. Plans are already well under way for the 2003 Spring Forum, which will focus on interactions with other disciplines, such as Clinical and Biostatistics.
I recommend that each company try to send a representative.

Another important event, coinciding with the conference, was the release of the second version of the Good Clinical Data Management Practices document, with additional chapters and updates of existing chapters. For the first time the GCDMP document has been made available to all visitors to the SCDM website (www.scdm.org), consistent with our recently developed mission statement, 'Promoting Clinical Data Management Excellence'. Through the recently formed International Clinical Data Management Network, where the SCDM is represented by Board of Trustee (BOT) member, **Alec Vardy**, other CDM organizations are now involved in reviewing and contributing to the document. At a recent BOT teleconference we agreed to make the next version of the document the first one to have incorporated comments from other associations before its release, a major step forward towards global CDM harmonization.

The Certification initiative has taken a major step forward, with the signing of the contract with Galton Associates to implement the testing infrastructure, and the two successful training programs for the volunteer question setters. We are still planning to have beta testing in conjunction with the Fall Conference in Atlanta.

Discussions have been ongoing with the FDA and the DIA to increase collaboration. Also the Membership committee is busy planning the next membership survey, and the Website committee is focusing on the dual goals of on-line discussion forums and on-line balloting, which we are targeting for this year's BOT ballot.

So you can see that many things are happening but we are asking for more assistance from our membership. One relevant area is *Data Basics*. We are seeking in-depth articles and the potential topics are many. Is anyone out there willing to contribute a review of the privacy laws, both the HIPAA legislation in the US and the European Privacy Directive, and the potential impact on CDM? We have many recruiters in our membership; perhaps one of you would be willing to describe the current market place for data management professionals and what you see happening in the future. Outsourcing is always a topic that is of interest to our members. It would be good to see some articles on the topic, in particular, the side of the equation not often addressed, namely what can sponsors do to improve outsourcing from a CRO's perspective. If any of you have recently moved to the US, it would be good to hear of your experiences and comparisons with working elsewhere. Also for those of you just returned from working overseas, what were your experiences? These are just a few examples of how you can help share your valuable experience with your fellow members.

The various committees are all active but can always use additional assistance. Please visit our website to see what activities interest you or contact me for more information.

I wish you all a great summer and hope that you have the chance to recharge your batteries with a well-deserved vacation. I look forward to seeing many of you in Atlanta. Please register early; based on the amount of interest being shown, it seems that the conference is going to be very popular so book early to ensure a hotel room. As always, it you have any comments or questions, feel free to contact me at hugh.donovan@aventis.com

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SCDM 2001 Annual Business Meeting Summary

Financial Report:

Judy Kasperczyk discussed the Society's finances, reporting that for 2001, the organization was in good financial health and ready to support programs planned for 2002.

Committee Reports:

The committee chairs gave overviews of their groups' activities and acknowledged participation from their committee membership:

- **Certification Committee – *Armelde Pitre:*** The group accomplished many tasks that will lead up to a beta certification test to be offered at the 2002 Fall Conference in Atlanta.
- **Membership Committee – *Marianne Plaunt:*** The committee had several campaigns during the year, including follow up with CDM managers. Membership was up overall for the year and a survey will be sent to members over the next few months.
- **Effective Use of Technology Committee – *Ken Carlson:*** A survey conducted last year was analyzed by the group and presented at the 2001 Fall Conference. The committee plans to examine area where it can make the most impact in 2002.
- **Good Clinical Data Management Practices – *Meredith Nahm:*** Version 2.0 was delivered, thanks to the participation of many writers and reviewers. The group is gearing up for Version 3.0 and offered opportunities for membership input during the conference.

- **Web Site Committee – *Greg Dziem:*** Job postings, on-line registration, membership renewal and lots of maintenance were accomplished by the committee in 2001. Look forward to increased use of the web site for an information resource, on-line voting and discussion forums in 2002.
- ***Data Basics – Tam Blackstone:*** Expanded editions last year, which incorporated advertising. Desperately seeking articles from members! Please consider writing for *DataBasics* as a way to contribute to the data management profession.

Retiring Board of Trustees Members:

Hugh Donovan recognized the following retiring Board members for their accomplishments:

- ***Becki Filice***
- ***Kaye Fendt***
- ***Jean Mazalewski***
- ***Cathie Muza***
- ***Doug Schantz*** (to serve as Past Chair)
- ***Annette Schmit***

New Board of Trustees Members:

Hugh introduced the Board of Trustees joining this year:

- ***Greg Dziem***, *Amgen*
- ***Meredith Nahm,*** *Duke Clinical Research Institute*
- ***Marianne Plaunt,*** *STATPROBE*
- ***Alec Vardy,*** *PPD Development (appointed)*
- ***Judy Kasperczyk,*** *TAP* (Treasurer)
- ***Cherie Stabell,*** *Genentech* (*Data Basics* Co-Editor)

2002 Objectives:

Hugh discussed this year's objectives for the Society. They include:

- Building on the GCDMP document
  - Globalization
  - Additional Chapters
  - FDA Input
  - Implementing the beta-test of Certification program
  - Defining and implementing regulatory interaction strategy, to discuss issues related to DM with focus on ICH-GCP, 21CFR11 and electronic submissions.
  - Defining and implementing interaction strategy with other associations with CDM activities (e.g. DIA, ACRP in North America, ACDM in UK)
- Increasing communication:
  - Continuing to grow *DataBasics*, with additional in-depth articles
  - Increasing the use of the Internet (Discussion forums, balloting)
  - Increasing content of e-newsletter
  - Extending Advertising
- Improving control over administrative aspects
- Conducting Membership survey to determine value of current offerings and future needs
  - Reviewing long term strategy
  - If appropriate, identifying new initiatives based on membership desires and long term strategy
- Achieving full attendance at Spring Forum
- Holding 2 'Fall' Conferences with over 400 attendees at each & exhibition space sold out

As you can see, we've got a lot of work to do and our active membership can make it happen!

Call for Letters TO the Editors

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?

Have you been looking for a way to do any of this anonymously?

Well the wait is OVER! Your opportunity to express yourself is here, and "no," you don't have to publish your comments with your name.

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 Tam Blackstone (tblackstone@allos.com) or Cherie Stabell (stabell@gene.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).

SCDM Board of Trustees

Challenges for CDM in the 21st Century

Conference Overview

We would like to thank everyone who attended and participated in the rescheduled Fall 2001 Conference, February 3rd - 6th, 2002 in Seattle, Washington. We had a great turnout with over 500 attendees and a record 55 exhibitors. There was wonderful participation from the session chairs, the speakers and the audience. Seattle is a fun city, the weather cooperated and on a clear day you could see Vancouver, Canada. The hotel was located within walking distance of many nice restaurants, shops and local attractions. The monorail to the Seattle Space Needle was right outside the hotel's front door!

It's been said that technology changes every eighteen months and from the time that the planning began for the September 2001 Fall conference until the conference actually happened, we had many changes not only for the agenda but for the world itself. These changes, especially regarding technology, were reflected in the Fall 2001 Conference.

One third of the session chairs were replaced as well as almost one-half of the scheduled speakers due to schedule changes and reluctance to travel. The focus of the conference changed from a broader topic of Challenges for CDM in the 21st Century to a narrower focus and multiple presentations on EDC (Electronic Data Capture) and its implementation, acceptance, role changes and maintenance. It was not all EDC though; other topics covered during the conference were Training, Certification of CDM, GCDMP (Good Clinical Data Management Practices) and CROs. Despite all the changing and rearranging, and last minute substitutions, the conference was a major success and once again we would like to thank all those who attended.

The conference started off on Sunday afternoon with a pre-conference tutorial, "CDISC," led by **Kaye Fendt** and **Sally Cassells.** Sixty (60) people attended the tutorial.

The Welcome Reception was held off-site at Seattle's Odyssey Maritime Discovery Center. On Sunday evening buses brought everyone to the Discovery Center, an interactive museum where people could actively participate in exhibits featuring maritime themes, have a few drinks and enjoy the buffet. Since it was Superbowl Sunday, a large TV screen was put inside the Discovery Center so that everyone could watch and cheer (or boo) the 2nd half of the game.

Jean Mazalewski, Co-Chair

The conference began officially Monday morning with a "Welcome" by **Jean Mazalewski**, co-chair, and the annual SCDM Business Meeting. Brief presentations were given by different committees to bring the audience up to date with the working status of SCDM. As a bonus we also had a speaker, **Caroline Fenning**, from ACDM, the UK Data Management organization.

Keynote Speakers *David Lubinski* and *Steve T. Chin* with SCDM Conference Co-Chair *Karen L. Klinger*

The Future of Clinical Data Management: Opportunities and Challenges

Speakers: **David Lubinski,** Practice Manager, Microsoft Consulting Services
Steve T. Chin, Worldwide Pharmaceutical Industry Manager, Enterprise & Partner Group, Microsoft Corporation

Our keynote speakers for the conference were **David Lubinski** of Microsoft Consulting Services and **Steve T. Chin** of Microsoft Corporation. They shared the topic *"The Future of Clinical Data Management: Opportunities and Challenges"*. They touched on the progressive use of technology in the Pharmaceutical Industry. They provided a look to the future where integrated healthcare will include MDs, insurers, pharmaceutical employees, the government with the consumer in the middle.

The keynote address contained a short film depicting a person experiencing a minor accident. The film illustrated how optimizing the use of information technology could have an immediate and beneficial impact on the consumer's experience of health care and treatment. The vision included real-time referral service and scheduling of office visits, immediate and comprehensive transfer of medical records from anywhere to anywhere, and on-line crisis management.

The speakers discussed implications for the pharmaceutical industry. The audience had several questions about how Microsoft planned to address current regulatory trends and privacy concerns about data sharing. The speakers responded by stating that such questions were exactly the types of issues that Microsoft would be interested in exploring and that forming partnerships within the industry to solve such problems and to bring about their vision would be beneficial to the industry and the consumer.

One of the driving forces as this technology moves forward will be the sharing of data across a common platform. But the provocative question remains – how will this improve patient safety and improve patient confidentiality?

The Impact of E-Business on CDM

Moderator: **David Kim**, Executive Director, Scirex Corp.

Speakers: **Kenneth D. Carlson**, Director, Strategic Operations, Pfizer Inc
Jonathan R. Andrus, Senior Validation Consultant, Taratec Development Corporation
Tom Mahler, Director, Business Development, Phoenix Data Systems
A. Brooke Hinkskon, Project Manager, Client Services, PHT Corporation
Pam S. Hrubey, Director, eData Management, Eli Lilly and Company
Linda M. Talley, Manager Clinical Pharmacology/eData Management, Eli Lilly and Company

Over the last couple of decades, the Internet has significantly impacted business operation in numerous industries. Other areas have been impacted as well… The pharmaceutical industry has been affected in the areas of electronic data capture (EDC), electronic clinical trials management (eCTM), and electronic submissions. The future holds even more exciting possibilities with electronic source data, wireless and mobile technology integrations, etc. This session focused more specifically on the impact of e-business on clinical data management.

Ken Carlson and **Jonathan Andrus** started the session with a presentation titled ***"Analysis of Current and Future Trends in Technology"***. This was a summary of a survey conducted by the SCDM Effective Use of Technology Committee between the fall of 2000 and spring of 2001. Sixty seven % of the responders represented pharmaceutical or biotechnology organizations. The survey concluded that 77% are utilizing a commercial package for a clinical data management system (CDMS). Oracle Clinical appeared to be the most popular (43%). Only 30% of the organizations surveyed use web-based data collection tools. Of these companies, the majority of the work is still accomplished through paper-based solutions. According to the survey, the largest web-based data collection vendor was PhaseForward followed by homegrown systems. Approximately 38% of the other organizations are planning to pilot an EDC solution in the next twelve months. 21% of the responders indicated use of electronic patient diary tools. Percentage of use within those organizations was still very low (<25%). 15% of the other organizations stated that they planned to pilot an electronic patient diary tool within the next 12 months. The conclusion from the survey was that a few people have started using newer technology innovations, but there still are significant growth potentials.

Then **Brooke Hinkson** spoke on ***"Electronic Data Capture Within the Pharmaceutical Industry"***. She highlighted how organizations successfully adapted new technologies with modification and clarification of roles, responsibilities, and procedures. Within the realm of EDC, the clinical data manager will be drawn into data standards development, the electronic case report form development, and data integration. One of the main differences between EDC and traditional paper trials is the focus on start up activities. The requirements and workflow must be defined early in the process so that the EDC system can be configured and validated before patients are enrolled into the study. The requirements include data dictionary, codelists, derivations, data transfer specifications, workflow, user roles and permissions, e-signature implementation, and privacy protection. In order to execute an EDC study successfully, proper technical assessment of the clinical sites is necessary. This needs to be followed up with hands-on training. Brooke closed her presentation with the benefits derived from the EDC process as well as a continued need for standardization.

Pam Hrubey and **Linda Talley** closed off the session with ***"Unleash the Power of Data"***. They began the presentation with the perceived benefits of EDC over traditional paper-based trials. A recent Forrester/ACRP study noted that 53% of the responders expected to be online for at least 20% of their trials by 2003. There are numerous and significant barriers to building an "e-Pharma world" such as critical need for global data standards, somewhat immature technologies (relative to the pharmaceutical industry customization), an enormous number of vendors, and the requirement of significant organization changes and transitioning. Eli Lilly utilized the work of the Clinical Data Interchange Standards Consortium (CDISC) as a launching pad for their standardization initiative. They focused on process, data, and methodologies. Pam and Linda also relayed the fact that the new CDISC website has added a section that provides clinical research professionals a way to share data elements and processes to encourage and support industry-wide standards. Pam and Linda then focused on Lilly's experience within the three-year initiative to integrate all aspects of clinical data, associated business processes/systems/tools through real-time data management. Some of Lilly's keys to success included managing scope, on-time delivery, external focus, change management, and upper management sponsorship. To highlight the promise of EDC, Pam and Linda shared that they were able to achieve an interim lock in their first EDC trial within 11 hours.

Roles, Processes and New Technology

Moderator: **June Guseman**, Phase I CDM, DuPont Pharmaceuticals

Speakers: **David Rosa**, invivodata, Inc.
Donna Helstein, CM Technologies Inc.
Sharon Miller, Medical Consultant, Eli Lilly and Company

"New Opportunities for Clinical Data Managers as Provided by Experience, Science and Handheld Technology" was the subject of the first presentation given by **Dave Rosa** from invivodata, inc. Dave gave a great presentation about the advantages of new technology and the effects that cleaner data earlier in the study would have on data managers. The data are cleaner upon receipt, so sources of error are reduced, and patient compliance is then optimized. The current tasks of data cleaning are turned more towards data interpretation and trend analysis, which take advantage of the significant knowledge that data managers have of their databases. While the current tasks are about 30% planning, 60% execution and 10% analysis, the new model consists of 30% planning, 10% execution and 60% analysis. The point of this discussion is that the overall focus of data managers shifts from managing data to managing patients, which is really the focus that we should have.

The second presentation in this session was called *"EDC – Changing the Role of the Data Manager",* and was presented by **Donna Hellsten** of CB Technologies, Inc. Donna discussed the types of EDC architectures that are currently in use such as hybrid, thin-client, portals, and hand-held devices. She talked about the challenges of using each system and what companies could do to overcome some of them. She also discussed 21 CFR 11 compliance in regard to electronic records, and what some of the key issues are with FDA regulations. In addition Donna provided a good overview of what things to consider when purchasing an EDC package, such as performance issues, security, static vs. dynamic data, regulatory issues, and the differences between off the shelf products and custom built applications.

Finally, **Sharon Miller** from Eli Lilly and Co. gave a presentation called *"CDM Process Re-Engineering and Role Re-Definition in These Rapidly Changing Times"*. Sharon provided a lot of detail and critical information about business process re-design, which EDC has required of data management departments where it is heavily employed. Sharon gave us the key steps to success in re-aligning functional groups within the department to achieve maximum productivity. She also shared some of the key lessons learned during implementation of new technology, and discussed the critical importance of communication. The overall message that Sharon gave us was that the implementation of new technology is relatively simple, but the challenge of dealing with the people and process aspects require much more planning, time and attention.

SCDM Exhibit Hall

Change Management, Changing Roles and Recognition of Data Managers

Moderator: **Madeline Quarto**, Clinical Operations Scientist, GlaxoSmithKline Biologicals

Speakers: **Michael Crayne**, CEO, Phoenix Data Systems
David Sabritt, Immunex Corporation
Kay Fendt, Independent
Susan K. Howard, Therapeutic Area Manager, GlaxoSmithKline Pharmaceuticals

In this session, speakers presented pertinent information on the impact of technology change on the data manager. **Michael Crayne** discussed the common myths of EDC and RSM. He also discussed practical application of new technologies, the elimination of some standard paper practices and the rational expectations of more technically based methods. The moral is that EDC may not be a competitive advantage if your competitors are using it, it's a business necessity and it can work. **Kaye Fendt** gave a comprehensive presentation on the regulatory aspects of Change Management. She presented an overview of FDA, ICH, HIPAA and HCCFA regulations where they impact the use of advanced technologies in the conduct of clinical trials and emphasized awareness of the impact as the data management practices are changing. **David Sabritt** contributed to this session by discussing some of the factors which have promoted, and inhibited, the adoption of technology changes, including impacts on the roles of data managers and site personnel.

Certification of Data Managers

Moderator: **Armelde Pitre**, Senior Associate Director, Pfizer Inc

Speakers: **Patricia A. Teden**, Independent Consultant
Karen Fitzpatrick, Data Management Training Manager, MTRA/AAI
Colleen M. Cox, Manager, Data Management,
Harvard Clinical Research Institute

Three members of the Certification Committee presented at the Fall 2001 conference held in Seattle. **Pat Teden**, Director of Program Management at Pfizer, presented a summary of the certification process; **Colleen Cox**, Manager of Data Management at CareStat, presented the Code of Ethics; and **Karen Fitzpatrick**, Training Manager at AAI International, presented the process recommended by the SCDM Certification Committee for meeting the training needs for Clinical Data Managers (CDM). The full sets of slides are available on the SCDM web site. Each presentation is summarized below.

Certification Process: What's involved besides the test?

Pat began with a description of the two levels of CDMs who can apply for certification. The Certified CDM is targeted at those CDMs who can perform tasks at a competent level across the broad spectrum of SCDM tasks. A Senior Certified CDM level is targeted at those who are considered 'expert' in many aspects of the CDM role. Pat outlined the planned qualification and application process for each level. Also discussed was the process for appealing decisions of the certification process. Lastly, a summary of the outcome of the debate on continuing education requirements for maintaining certification status was presented. Pat's presentation closed with a discussion of another process for recognizing those professionals who are more advanced in their careers. The concept of a lifetime achievement award was introduced. The certification committee will develop a recommendation for this award and its process this year.

Code of Ethics:

Colleen outlined the process for creating the Code of Ethics including a statement of why professional CDMs need a Code of Ethics. The committee has also recommended a process for dealing with violations of the code. This recommendation includes a review and investigation by the Board. The process will be finalized during this year. The Code of Ethics was presented during this session and is now posted on the SCDM web site.

Meeting the Training Needs of CDMs:

Karen presented the committee's recommended approach for addressing the training needs of CDMs seeking certification. She outlined the status of training in the industry. The committee's recommendation is to post an initial set of training options on the SCDM web site and allow members to add their comments and views about the training. Training providers will also be given the option of posting links and summaries of their training programs. The SCDM cannot endorse specific training programs but will make information available to its members.

Questions and Answers:

Questions from the audience were taken at the close of the session. Questions asked fell into two main categories. The most frequently raised question was raised by senior CDMs who would like to become certified as soon as possible. Under the current process and schedule, a senior CDM would first take the certification exam to become a certified CDM. They could apply for senior certified CDM only after successfully passing the certification exam a second time. The current process addresses the pathway towards certification for those entering the profession and rising through the ranks. The certification committee is reevaluating this process for CDMs who are already at a senior level. A recommendation to the BOT will be developed this year. Also discussed was the significance between the title "senior CDM" commonly used in the industry and Senior Certified CDM. It was reiterated that not all senior CDMs would likely qualify for "Senior Certified CDM" since this is considered an elite status, acquired after a career in the field. The second had to do with the fee structure for the examination. As promised in the session, the certification committee is making the income and costs clear to all SCDM members. In this issue of Data Basics, an income statement for the certification exam is provided.

Taking Advantage of Good Clinical Data Management Practices

Moderator: **Janet Ralstin**, Manager, Clinical Data Coordination, PRA, Inc.

Speakers: **Christine Little**, Director, Clinical Data Management, Rho, Inc.
Susan Howard, Therapeutic Area Manager, GlaxoSmithKline Pharmaceuticals
Ellen Coull, Manager, Clinical Data Management, PRA International
Carolyn Darrel, System Administrator, PRA International
Jeanina Worden, Database Programmer II, PRA International

This section focused on the development of the Good Clinical Data Management Practices (GCDMP) and the practical application of these guidelines to data management practice.

Christine Little, Chair of the GCDMP Committee and Director, Clinical Data Management, Rho, Inc, started the session with an overview of the progress over the past year of the committee and the release of Version 2 of the GCDMP. Future areas of focus were discussed.

Susan Howard, Therapeutic Area Manager, Glaxo-SmithKline Pharmaceuticals, reviewed the process and requirements of moving forward on electronic data capture. She focused on issues and benefits for the data manager and other functional areas within the pharmaceutical company or CRO, and also for the investigator site. Emphasis was placed on adequate training and preparation.

Practical application of GCDMPs was discussed in two final presentations. **Ellen Coull**, Manager, Clinical Data Management, PRA International presented her experience with using the GCDMP document as a reference when negotiating procedural differences between sponsors and CRO. **Carolyn Darrell**, System Administrator and **Jeanina Worden**, Database Programmer II, of PRA International outlined a method of standardization of database structure and incorporating imported non-case report form data utilizing GCDMP guidelines.

Janet Ralstin, Manager, Clinical Data Management, PRA International moderated the session.

SCDM Exhibit Hall

Data Management and Crossover Roles

Moderator: **Samir Shah**, Director, Strategic Development, ReSearch Pharmaceutical Services, Inc.

Panel: **A. Brook Hinkson**, Project Manager, Client Services, PHT Corporation
Sharon A. Miller, Medical Consultant, Eli Lilly and Company
Alice Robertson, VP, Clinical Operations, Etrials, Inc.
Heidi E. Shea, Manager, Clinical Data Management, ViroPharma Incorporated

Samir gathered a panel of experts on implementing and using EDC in clinical trials from the speaker list. This panel discussion centered on the impact that EDC has on the traditional data management methods and team roles and responsibilities. The general trend illuminated in the discussions was one of data managers taking on stronger project management, coordination and site communication roles - assuring critical path items are resolved, troubleshooting, watching for trends and doing much of the technical set up work for a study.

2001 Fall Conference Sponsor Recognition

AstraZeneca Pharmaceuticals LP
Educational Program Sponsor

Blue Ridge Consulting
Tuesday Morning Refreshment Break

The Cambridge Group
Monday Morning Refreshment Break

Eli Lilly and Company
Monday Evening Cocktail Reception in the Exhibit Hall

Etrials, Inc.
Sunday Evening Welcome Reception and Dinner at Seattle's Odyssey Maritime Discovery Center

Genentech, Inc.
Monday Speaker Breakfast

Immunex Corporation
Educational Program Co-Sponsor
Fall Conference Promotional Brochure

Integrated Clinical Systems, Inc.
Tuesday Luncheon in the Exhibit Hall

invivodata, inc.
Monday Afternoon Refreshment Break

Kendle International Inc.
Monday Luncheon in the Exhibit Hall

LifeTree Technology, LLC
Sunday Evening Shuttle Busses
Fall Conference Syllabus
Educational Program Technology
Fall Conference Photography

PHT Corporation
Educational Program

Placemart Personnel Service
Educational Program Co-Sponsor

Quintiles, Inc.
Tuesday Afternoon Refreshment Break

Schering Plough
Tuesday Speaker Breakfast

Smith Hanley
Signage

TAP Pharmaceutical Products Inc.
Monday Continental Breakfast

Different Methods of Working with CROs and Vendors

Moderator: **Jill Vath**, Associate Director, Medical Affairs, Genentech, Inc.

Speakers: **Samir Shah**, ReSearch Pharmaceutical Services, Inc.
Jana Lamb, Manager, Quality Standards, Pfizer Inc
Jay Lodge, Operations Director, Integic Corporation

Samir Shah began this session with a high level presentation entitled ***"Different Methods of Working with CROs and Vendors"*** that set the stage for the rest of the session. In his presentation Samir shared examples of outsourcing from other industries and challenged us learn from these industries and to think outside the box, considering non-traditional options and new models of outsourcing. A key point was made that the option chosen must fit within the strategic vision of the company.

In the second presentation entitled ***"The Quality Deliverables System (QDS): Leveraging the CRO Partnership"*** **Jana Lamb** provided an overview of QDS at Pfizer and some specific details on processes and tools used in the system. The QDS was developed in response to the need to ensure consistent quality of CRO biometrics deliverables. It defines details and timing of specific CRO and sponsor quality control activities. The system employs three process-specific forms; 1) a Quality Deliverables Specification Form that defines the quality steps the CRO is expected to perform as part of a specific process including required deliverables, 2) a Transmittal Form used to transmit and track deliverables and metrics, and 3) a Verification Form which describes the actions Pfizer personnel take in verifying the quality of the CRO deliverables. To date QDS forms have been developed and utilized for a number of data management processes with much success, as seen in deliverables that have the expected level of quality with less iteration and rework and fewer out-of-scope charges.

In the final presentation entitled ***"Orchestrating the Virtual Research Organization (VRO)"*** **Jay Lodge** described some of the relationship challenges that are typically present in sponsor/CRO processes and interactions and how these challenges can be addressed using work process automation and portal technology to create a VRO. In creating a VRO it is important to define clearly processes and implement a solid technical infrastructure. The benefits a VRO can provide are clarity around processes, improved communication, removal of distance-related boundaries and facilitation of a common purpose.

SCDM Exhibit Hall

Optimizing Training for the New Century

Moderator: **Joann Masi**, Director, Clinical Data Management Operations, Wyeth

Speakers: **Hemant Mistry**, Data Manager, Pfizer Global Research & Development
Karen Fitzpatrick, Data Management Training Manager, MTRA/AAI
Dominique Barbeau, Associate Manager, Clinical Data Management, Quintiles, Inc.
Lisa Freeman, Biometrics Training Coordiation, Immunex Corporation

The Clinical Data Management profession has long felt the lack of a specific training program for becoming a Clinical Data Manager. The Clinical Data Management Certificate Program (CDMCP) was formed to fill this educational need. **Hemant Mistry's** presentation entitled ***"Comprehensive Training: Mission Possible"*** was a quick insight into the program. Hemant's presentation began with explaining the need for the program and then provided an overview of the program structure. The first training session of the CDMCP was conducted between June 2001 and August 2001. The experience, learning and results were also presented, which emphasized that the program was successful.

The next speaker, **Karen Fitzpatrick,** presented ***"Training Foundations: Are We Ready For the 21st Century?"*** As we enter into the 21st century, the application of technology within the training industry is on the rise. While there are numerous new technologies available today to assist managers and education-related personnel with training initiatives, Karen emphasized that we must not forget to ensure our training approach and programs have a solid foundation. This foundation must be in place prior to dazzling training participants with fancy materials and leading edge technologies. Otherwise, regardless of the technology used, the training may be at risk of not meeting the needs of the employer or the employee. A solid training foundation should take into account two key concepts. The first is that of metrics. An organization's training initiatives/program should be developed in a manner that encourages measurement of the effectiveness of the training provided. The information gathered should be relevant, manageable and informative. Types of metrics that may be captured include cost-based, efficiency-based and quality-based measures. The second training foundation requiring focus on is that of learning – differentiating between training and learning. Karen concluded by stating that for true learning to occur employees must be fully supported by management. This support is shown in the form of time, human resources, money and most importantly, a positive, learning-focused environment.

Dominique Barbeau's presentation was entitled ***"Communication within the Project Environment."*** Dominique expressed the importance of effective communication and how it is key to success. Sharing her Quintiles experience in the project environment with a CRO and sponsor, she provided tips on improving communication as well as ways to develop a communication plan. Dominique also shared the training philosophy and program at Quintiles. She emphasized the need for training in order to manage constant change. At Quintiles, they have tried to optimize not just training but learning.

Lisa Freeman ended the session by presenting ***"Process Development and Training: Standard Operating Procedures."*** Lisa suggested taking a process development approach to SOP creation, which allows the SOP Coordinator to make a significant contribution to the direction and education of the department. Her presentation focused on the need for and the positive results obtained from developing SOPs. Examples of SOP topics and standard content were included. She emphasized that at the beginning of the project, the SOP Coordinator must identify the target goal, including the steps to be put into effect in order to reach that goal. This target goal consists of not only a list of SOPs to be created or revised but also a schedule for project implementation. The process development approach elicits the involvement and support of key individuals in all functional areas impacted by the project. Such individuals must be familiar with the current processes as well as industry standards, codes and regulations. Finally, training and implementation of the new or revised SOPs is critical to the overall success of the project. Lisa emphasized that regulations required that individuals be not only trained on the process but that they understand and follow such documented processes.

Merging Regulatory, GCP and Technology

Moderator: **John Larus**, Vice President and Chief Technology Officer, PharmaLink FHI

Panel: **Mark C. Anderson**, Director, Clinical Data Management, Immunex Corporation
Ralph J. Russo, Project Manager, Schering-Plough Research Institute

Due to the rescheduling of the SCDM conference and a shifting of the speakers available, this session focused on issues of EDC implementation within pharmaceutical companies.

John Larus from PharmaLinkFHI presented a discussion on the changing role of data managers within an EDC organization. John reviewed how EDC has lessened the data review and querying responsibilities of data managers and he proposed that this evolution allows data management to adopt a new role as the interface between the clinical needs of a project team and the technical requirements of the EDC software. John also pointed out that data managers are now constructing systems that will be seen not only by internal team members but also by external clinical users and he discussed how this change impacted the processes and skills need by data managers.

Mark Anderson from Immunex then discussed a case study of the decision to conduct a study using EDC. Mark's talk focused on practical issues in making the decision to conduct an EDC study. Mark suggested that the four most important areas that must be evaluated before committing to an EDC study are the cost benefit of the switch, the impact of the study design on the software, the impact of the technology on the organization and the expectations of senior management. Focusing on these areas Mark then reviewed the Immunex experience in implementing an EDC study.

Ralph Russo from the Schering-Plough Research Institute discussed re-engineering clinical research for EDC in a large pharmaceutical company. Ralph presented a view of clinical research in which EDC was only a small component of a much larger integrated system of electronic data that followed throughout clinical development and allowed the organization to make decisions *"@ the speed of thought"*. Using this model as his goal, Ralph then discussed the organizational, structural and physical changes that need to occur for clinical research to realize this vision.

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Contact Jeff Sadik
(sadikj@immunex.com)
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ACDM	**http://www.acdm.org.uk**
CDISC	**http://www.cdisc.org**
FDA	**http://www.fda.gov**
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There are more links to be found on our web site!

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

Welcome Reception & Dinner

Odyssey Maritime Discovery Center

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Tamela Blackstone, ***Co-editor***
Allos Therapeutics, Inc.
Phone: 720-540-5274
E-mail: tblackstone@allos.com

Cherie Stabell, ***Co-editor***
Genentech, Inc.
Phone: 650-225-7672
E-mail: stabell@gene.com

Cathie Muza, ***Chair, Newsletter Committee***
Averion, Inc.
Phone: 508-416-2629
E-mail: cmuza@averion.com

Kathy Meyer
Pfizer Inc
Phone: 743-622-7572
E-mail: kathy.meyer@pfizer.com

Felicia Ford-Rice
AtheroGenics, Inc.
Phone: 678-336-2713
E-mail: ffrice@atherogenics.com

Kit Howard
Pfizer Inc
Phone: 734-622-7848
E-mail: kit.howard@pfizer.com

Lynda Hunter
PRA International
Phone: 913-577-2972
E-mail: hunterlynda@praintl.com

Saru Salvi
Coding Plus
Phone: 760-966-6858
E-mail: saru.salvi@codingplus.com

Submission Deadlines (Articles and Advertising Art Work)

Our quarterly publication schedule for the next 4 issues requires the following input deadlines:

Volume 8, Issue #3 (Fall)	July 31, 2002
Volume 8, Issue #4 (Winter)	October 25, 2002
Volume 9, Issue #1 (Spring)	February 3, 2003
Volume 9, Issue #2 (Summer)	April 28, 2003

Each issue is mailed to the membership approximately 6 – 7 weeks after the corresponding submission deadline and posted on the SCDM web page (www.SCDM.org).

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.

Advertising Policy

AD RATES**

Size	Inches	Costs (USD)
Quarter Page	3 5/8 x 4 5/8	$240
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Half Page-horizontal	7 1/2 x 4 5/8	$400
Full Page	7 1/2 x 9 1/2	$575

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Fax: 908-359-7619
E-mail: info@scdm.org

Calendar of Events

October 6-9, 2002
EDC: Is it the Real Thing?
2002 Fall Conference
Grand Hyatt Buckhead
Atlanta, GA

March 16-18, 2003
2003 Spring Forum
Palm Springs Marquis
Conference Resort
Palm Springs, CA

September 21-24, 2003
2003 Fall Conference
Cheyenne Mountain
Conference Resort
Colorado Springs, CO

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

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

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

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 a current e-mail address 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).

Making the Costs of CDM Certification Clear

By Armelde Pitre, *Chair, SCDM Certification Committee*

Why will the certification exam cost its members $295 when the costs of administering the test are only $195 per test? What will SCDM do with the extra money?

The answers to these questions are summarized in the income statement below. Initial SCDM development costs will be recovered through any income derived through test administration (i.e. $100 per test). As shown below, initial development costs may be recovered as early as the fifth year of operations provided the projected target number of CDMs apply for certification. Steady state will not be achieved until the eighth year of operation (2002). Costs below include test maintenance but do not include costs for creating or maintaining a certificants database. This database will be used to track the status of applications and certificants. The certification committee is still evaluating options for this process. In the interim, a SCDM certification board will process applications, so there are no additional program administration costs.

Operating Year	2002	2003	2004	2005	2006	2007	2008	2009	2010
Income									
100 beta testers @ $195	19500								
250 certificants @ $295		73750	66375	59000	51625	44250	36875	29500	29500
initially gradually									
decreasing to 100/yr									
100 recertifications @ $195				19500	19500	19500	19500	19500	19500
TOTAL INCOME	19500	73750	66375	78500	71125	63750	56375	49000	49000
Expenses									
1-time test development									
Job Task Analysis	4000								
Test Development	50360								
Mentoring	3000								
Galton travel expenses	2500								
Ongoing test maintenance									
Test Maintenance		32720		32720		32720		32720	
Additional Mentoring & workshops		9250		9250		9250		9250	
Test Delivery - beta test	12500								
Test Delivery - live test (certificants + recert)		31250	28125	37500	34375	31250	28125	25000	25000
Reports - estimate		5000	5000	5000	5000	5000	5000	5000	5000
TOTAL EXPENSES	72360	78220	33125	84470	39375	78220	33125	71970	30000
Net	-52860	-4470	33250	-5970	31750	-14470	23250	-22970	19000
Internal Rate of Return by Operating Year			-25%	>-30%	1%	-11%	5%	>-30%	3%

Assumptions:
0% inflation - price increases are passed onto certificants
24 mentoring sessions for intial test development
10 mentoring sessions for test maintenance
Test maintenance cycle = every other year
Total number of new certificants over 8 years = 1450

SCDM@PMA

Professional Management Associates (PMA) provides professional management support to the SCDM organization in the following areas: administrative tasks, communications, financial, mailings, meeting arrangements (including registration), membership database, newsletter, printing and tracking.

Please contact SCDM @ PMA if you have questions about registration for upcoming meetings or if you need to provide updated mailing/contact information.

Society For Clinical Data Management, Inc.
c/o Professional Management Associates, LLC
203 Towne Centre Drive
Hillsborough, NJ 08844
Phone: 908-359-0623
Fax: 908-359-7619
E-mail: info@scdm.org

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