SCDM

DATABASICS

Volume 6
Number 4
Winter 2000

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

Letter from the Editors

Welcome Tamela Blackstone as our new co-editor! 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 is jam packed with our feature article of the proceedings of a very exciting Fall Conference. Thanks to Ken Carlson and Jean Mazalewski, the conference co-chairs, in putting this all together. Look also for Part 3 in our continuing series on other data management organizations around the world. You will also notice a new addition to our newsletter…the inclusion of advertising. We hope this too will be of help to our membership, as well as providing some revenue, which will allow us to continue to improve and grow our publication. We expect advertisers will see a benefit too in reaching a very eager audience. Please support them!

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,
Cathie and Tam

SCDM Annual Business Meeting Summary

The SCDM Annual Business Meeting was held Monday, October 16, 2000 prior to the first General Session of the 2000 Fall Conference.

SCDM 2000

Pat Teden, 2000 Board of Trustees Chair, opened the meeting with a review of SCDM accomplishments for 2000. This was a very active year for the SCDM. The Professional Certification Committee made great progress toward development of the program that will certify Clinical Data Managers. The SCDM web site was expanded to provide more information for the membership. *Data Basics* now supports advertising. The Society By-Laws were rewritten. Finally, there was an increase in the SCDM membership and an increase in the number of members participating in various SCDM sponsored committees. Additionally, the Board of Trustees felt very positive about the strong slate of candidates for this year's elections to the Board and about the great progress in collaboration with both the Association for Clinical Data Management (ACDM in the UK) and the Clinical Data Interchange Standards Consortium (CDISC). The most notable milestone achieved this year was the completion of the first version of the Good Clinical Data Management Practices (GCDMP) document. Special acknowledgement was given to the GCDMP committee members for their unrelenting dedication in pursuing the finalization of this document.

Pat also introduced the Board of Trustee Officers for 2001. They are Doug Schantz from Pfizer, Chair, Hugh Donovan from Aventis, Vice Chair and Brenda Hoeper from Kendle International, Secretary.

SCDM 2001: Looking Ahead

Doug Schantz briefly discussed SCDM opportunities for 2001. Members have career development opportunities through participation in SCDM initiatives, professional certification progress and opportunities to write and present to fellow data management professionals. The

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SCDM Annual Business Meeting Summary

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data management profession will continue to build influence through the GCDMPs. SCDM will provide service to the membership through the Spring Forum, the Fall Conference, *Data Basics* (and advertising therein) and the web site.

Financial Report

Annette Schmit presented the treasurer's report. The Society has a positive cash flow. A financial audit was conducted in July 2000. Copies of financial information, including the audit report, are available to any member upon request.

Certification Committee Update

Armelde Pitre, Committee Chair, shared the committee's objectives and the extensive progress that has been made since just last year. This coming year the committee will be working to develop a project plan outlining the steps to deliver the key components of the Certification Program. The committee has developed a survey that was included in the conference registration packet as well as made available on the SCDM web site, to solicit feedback to facilitate moving the efforts of this committee forward.

Membership Committee

Catherine Celingant, Committee Chair, presented the goals of this committee and the methods and activities used to achieve them. Due to efforts of this committee the SCDM membership continues to increase. As of October 2000 the SCDM had 1,167 members.

New Technology Committee

Ken Carlson, Committee Chair, outlined the objective and activities of this committee. The committee's objective is to monitor technology trends within the industry and to identify effective system evaluation and implementation practices. The committee is currently conducting a survey to gain insight into the current use and future trends of data management tools and technologies. The results of this survey will be published in an upcoming issue of *Data Basics*. This committee will also be writing a paper outlining the project management techniques proven to be effective in selecting and implementing new systems.

Good Clinical Data Management Practices (GCDMP)

Meredith Nahm, Committee Chair, briefly discussed the efforts of the GCDMP committee. A plenary session was held on Sunday, October 15th prior to the conference. This session was very well attended. This group will now focus their efforts on evaluation feedback (collected through the SCDM web site and conference documentation) and incorporating the feedback in the next version of GCDMP. Meredith also asked for additional volunteers to help carry this committee into the next phase.

Web Site

Doug Schantz, Committee Board Liaison, reported that the primary web site activity this past year has been maintenance. New features added to the web site this past year include a secure member only area and an on-line membership directory. One planned future enhancement is the posting of job announcements.

Doug concluded with special thanks to Sandy Ricciardi for his continued support of the web site and an open invitation for new committee members. Individuals do **not** need to have web development experience in order to volunteer and make valuable contributions to this ongoing effort.

New and Retiring Board Members

Doug Schantz, 2001Board of Trustees Chair, introduced the new Board of Trustee Members for 2001. Jean Mazalewski from Novartis, Sally Cassells from PPD Informatics, David Sabritt from Immunex and Tam Blackstone (appointed as co-editor of *Data Basics*). Anette Schmit will continue to function as Treasurer.

Special recognition was given to retiring Board of Trustee members. Pat Teden (will now serve as Past Chair), Ken Carlson, Susan Bornstein and Lana Turner. The contributions made by these Trustees were enormous and their efforts felt and appreciated by all.

2001 Spring Forum

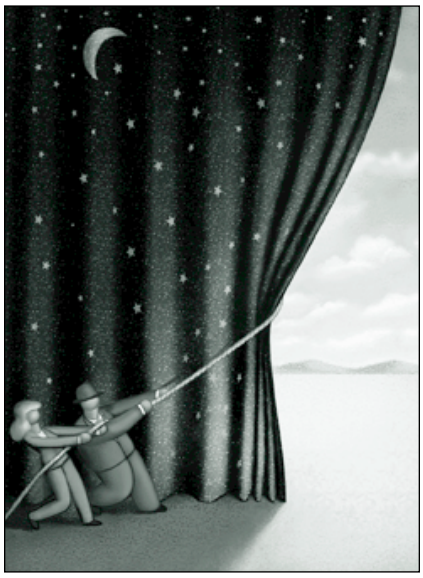
Pat Teden, conference chair for the Spring Forum scheduled March 18 – 20, 2001 in Galveston, Texas, discussed the goal of this conference. The theme is "Clinical Data Management as a Profession". This conference will be a working meeting and the goal is to provide direction for the Professional Certification and future GCDMP efforts. CDM managers and directors who are responsible for the professional development of clinical data managers were urged to register for participation in this conference.

2001 Fall Conference

Jean Mazalewski, 2001 Fall Conference co-chair, announced that next year's Fall Conference will be at the Westin Hotel in Seattle, Washington on September 23–26, 2001. The theme for this conference is currently being developed and members are invited to share ideas for the theme and sessions. Karen Klingler is the co-chair for this event.

Meeting Conclusion

Pat Teden concluded the meeting by providing those attending the opportunity to ask questions and outlining the numerous opportunities that exist for clinical data management professionals to participate in the SCDM. There are various forms and surveys being distributed to the membership to facilitate member input and every committee would welcome new volunteers.



The State of Clinical Data Management as the Millennium Unfolds

Conference Overview

The Sixth Annual SCDM Fall Conference held October 15–18th, had 292 conference attendees and 91 exhibitors represented at 37 booths. The conference was held just outside of Washington DC, at the Crystal Gateway Marriott in Arlington VA. The hotel provided wonderful accommodations, and attendees could walk underground from the hotel to a subway that connected them to the sights in our nation's capital. The conference opened on Sunday with a tutorial on Quality Control Steps in Data Management, followed by a Plenary Session on the Good Clinical Data Management Practices guidance and the Gala Reception. Monday morning started with the Annual SCDM Business meeting. The highlight of the day was the keynote address by Dr. Janet Woodcock, Director of CDER at the FDA. Excellent presentations followed throughout the conference. Attendance stayed strong until the conference closed at noon on Wednesday. Everyone departed, saying goodbye for now, and looking forward to meeting again in Seattle next year at the SCDM 2001 Fall Conference!

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

Keynote Speaker Summary

Dr. Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, Food and Drug Administration, gave the keynote address titled "Regulatory and Social Factors Affecting Clinical Data Management". In this presentation she stated that factors outside the discipline would affect Clinical Data Management into the New Millennium. Major forces affecting Clinical Data Management will be: Societal Distrust, "Biomedical-Industrial" Complex, cost containment, scientific innovation, data standardization outside of the Clinical Trial realm, and electronic processing and its regulation.

The concern that the whole enterprise of clinical trials is not conducted in the best interest of patients calls for greater controls, i.e. IRB, use of placebos, incentives for enrollment, reimbursement of investigators and better control of data. In response, the HHS and FDA has moved the Office for Protection from Research Risks from NIH to HHS, the FDA is establishing a human subject protection function at the Commissioner's Office level.

It is imperative that trials be conducted to the highest ethical standards. Open and ongoing dialog about issues that are raised in clinical trials research is encouraged. The IRB and institutional oversight must be strengthened. "Time = money", so there will be a push for speed, and efficiency in the clinical area will be a necessity. When dealing with cost containment, a narrow emphasis on speed and efficacy may be shortsighted. Efficiencies could be gained through standardization/paring of data collection. We need to look at the whole system.

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Calendar of Events

March 18-20, 2001
Spring Forum
The Tremont House Hotel
Galveston, TX

Clinical Data Management as a Profession

September 23-26, 2001
Fall Conference
The Westin Seattle
Seattle, WA

March 10-12, 2002
Spring Forum
Radisson Bahia Mar Beach Resort
Fort Lauderdale, FL

October 6-9, 2002
Fall Conference
Grand Hyatt Buckhead
Atlanta, GA

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

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

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

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

The State of Clinical Data Management as the Millennium Unfolds

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Dr. Woodcock referenced the IOM workshop report, "Assuring Data Quality & Validity in Clinical Trials for Regulatory Decision Making"(1999). Lack of cross-industry standards for CRFs was noted as confusing investigation and increasing errors. Excessive data collection also increases errors and the cost of both collection and "cleanup".

Stating that scientific innovations now make it easy to develop candidate drugs, she emphasized that there must be a drive for more efficient ways to do trials, i.e., health care delivery systems. Automated medical records and electronic processing and its regulations provide tremendous promise for efficiency, effectiveness and learning. Data standards are needed for maximum impact. Security, integrity, validity will remain concerns (21 CFR Part 11).

The FDA plans include rulemaking for required electronic submission starting with adverse event reports and drug package inserts. They will increase the level of standardization of other electronic submissions. This will include a common technical document and proposed data standards based on private standard-setting efforts. Part 11 requirements will be clarified.

In conclusion, a great public and health benefit can accrue from more automated, standardized data collection and management. But changes must occur in a way that retains public confidence.

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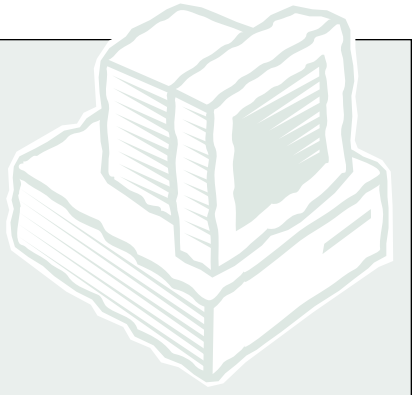
GOT A WEBSITE?



Want to support SCDM?

Please feel free to place a link on your web site to www.scdm.org!

Contact Doug Schantz (douglas.schantz@wl.com) if you need more information.

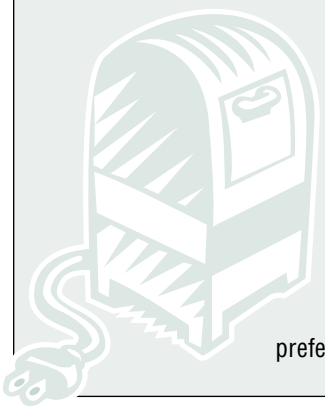
Web Sites to Check Out

ACDM	**http://www.acdm.org.uk**
CDISC	**http://www.cdisc.org**
FDA	**http://www.fda.gov**
ICH	**http://www.ich.org**.

There are more links to be found on our web site!

SCDM http://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.



Has your e-mail address changed recently?

SCDM is utilizing e-mail to disseminate information of interest to the membership.

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.

SPECIAL PLENARY GCDMP SESSION

Merideth Nahm, Wendy Cuthbert, Kaye Fendt, Christine Little, and Angel Lazarov

Moderator:

Kaye Fendt, Independent Consultant

Speakers:

Wendy Cuthbert, Director, Data Management, North America, MTRA/AAI

Christine Little, Director, Data Management, Rho, Inc.

Meredith Nahm, Manager, Data Management, Duke Clinical Research Institute

Anthony J. Costello, Data Manager, Nextrials Inc.

Angel Lazarov, Manager, Data Management, MDS Pharma Services

Kaye Fendt started this session with an introduction to Good Clinical Data Management (GCDM) and the Good Clinical Data Management Practices guidance. Stating that GCDM is not a new concept, she emphasized that the need for GCDM continues, the needs change over time, and that the needs have become even more important now that regulatory bodies rely more heavily on electronically transmitted data for critical data-based decision making. The SCDM mission includes "…promotion of standards of good practice within Clinical Data Management." In alignment with this part of the mission the SCDM Board of Trustees established a committee in 1998 to determine Standards for Good Clinical Data Management Practices. The GCDMP committee objectives are to develop, publish, and recommend use of Good Clinical Data Management Practices by providing guidance on accepted practices for the many areas of CDM that are not covered by existing regulations and guidance documents, and to remain consistent with regulatory practices in related areas of clinical research. The GCDMP guidance is thus provided as a special service to the SCDM membership. It is intended to provide assistance to the data managers in their implementation of high quality data management processes and provide managers in data management with a guide for planning training and education for new clinical data management staff.

Wendy Cuthbert summarized the contents of the GCDMP guidance. Minimum Standards and Best Practices were given for each of the sections: Data Acquisition, Data Storage, Database Validation/ Programming and Standards, Data Processing, Laboratory/External Data, Measuring Data Quality, Assuring Data Quality, Database Closure, and Vendor Management.

Christine Little reported on the consensus building process by which the guidance was developed. Nineteen independent responses were received from the 50 identified beta reviewers. These comments were summarized and the committee met weekly to review and determine action. Feedback from the beta readers included requests for more discussion of metrics, statements that there was redundancy within the document, requests for less focus on the paper processes, and identification of inconsistencies across the sections of the document in terms of theory and detail.

Meredith Nahm then provided the audience with a look into the future. Potential topics for future versions of the guidance include: CDM presentation at investigator meetings, CRF printing and distribution, CRF completion guidelines, creation and maintenance of data dictionaries and codelists, electronic CDM processes, electronic submission management, metrics, randomization scheme generation and maintenance, breaking the blind, IVR support, review of analysis tables and listings, SAE reconciliation, training and piloting new technologies. Plans for the future include sharing information more actively with regulatory authorities. Meredith encouraged all attendees to visit the SCDM web site, review the document, and send comments and questions to the committee. The GCDMP guidance document will be updated annually based on these comments. The committee will meet again at the 2001 SCDM Spring Forum where they will address comments, update the document and then release a new version at the 2001 SCDM Fall Conference.

Session Chair – Lora Todd

Measuring Timelines, Quality and Productivity in CDM

Moderator:

Lora E. Todd, Manager – Regional Data Management, Eli Lilly and Company

Speakers:

Susan M. Bornstein, Director of Data Management, Serono, Inc.

Neil Kamler, Data Management Coordinator, Merck & Co. Inc.

Jonathan Kfoury, Data Manager, Boston Biostatistics, Inc.

Sharon Miller, Associate Clinical Data Management Consultant, Eli Lilly and Company

Linda Talley, Product Phase Team Leader, Clinical Data Management, Eli Lilly and Company

Neil Kamler, Jonathan Kfoury, Sharon Miller, and Linda Talley

Susan Bornstein's presentation was entitled "Project Team Roles and Responsibilities – Timeline Goals and How to Get There". She began by giving an overview of drug development today. Susan reviewed MTRA/AAI and Serono's corporate strategy for developing aggressive timelines and roles and responsibilities. MTRA/AAI utilized internal benchmarking to best understand roles and responsibilities in the clinical trial process and then was able to set-up aggressive timelines. Serono implemented the Clinical Trials Optimization Process (CTOP) which streamlined the planning, conduct and reporting of clinical research from Phase I to submission by utilizing an eight step project approach. Both of these processes gave some helpful insights on how to optimize all activities related to clinical trials and translate them into timeline savings.

Neil Kamler presented on "Guidelines for Improved Quality and Efficiency of a Data Management Meeting". Neil talked about the participants, their roles and responsibilities, and the structure of effective data management meetings. A list of ten tips was provided as a way to improve the quality and efficiency of the meetings. He indicated that efficient meetings occur when there are stated objectives and everyone can participate equally.

Jonathan Kfoury discussed "The Study Coordinator's Impact on Data Quality: Time Limitations and Pre-study Preparation Examined". His presentation focused on the main issues surrounding time constraints and study preparation. Jonathan suggested that open and on-going communication between CRAs and DM is important to ensure proper training of coordinators. He also suggested that the sites receive follow-up training, study specific examples of potential CRF errors and e-mail training updates as a means to improve quality of data. Ultimately, issues that affect a coordinator's ability to provide clean data will eventually impact a study's success.

Sharon Miller and Linda Talley provided information on "Metrics and the Quest for Rapid Database Lock". Sharon began by reviewing the importance of establishing meaningful metrics targets and measures and making sure that all factors, within and outside your company, are considered. She also commented that it is very important to re-evaluate those targets and measures periodically to make sure that they are still aligned with your business. Linda provided a case study where there was a need to redesign a process for managing clinical trial data due to unacceptable cycle time, lack of accountability and lack of standardization. She focused on the use of data to drive the improvements that are necessary, as well as utilizing data later to measure the progress of the improvement.

Session Chair – Sally Cassells

New Technologies in Support of Data Management

Moderator:

Sally Cassells, Executive Director, PPD Informatics

Speakers:

Jim Comer, Medical Data Systems Consultant, Glaxo Wellcome, Inc.

Jeffrey Klofft, Vice President, Products and Technology, Phase Forward Inc.

Arien Malec, Director, Strategic Development, Fast Track

Jim Comer, Sally Cassells, Jeffrey Klofft, and Arien Malec

The speakers in this session shared their contributions to technologies for the present, near term and long term futures.

Jim Comer started this session with a presentation "Automating the Production of Electronic Submissions, Part11". He described a system developed at Glaxo that provides significant automation in generating Case Report Tabulations for Item 11 of an electronic NDA. This system generates SAS Transport files with input data from any platform, generates documentation describing the datasets, makes it easy to map variables to the CRF pages where they are collected, automatically generates the hypertext links and stores them in a compliant directory structure. This allows them to spread the work of generating the links over the timeline of the project rather than forcing a crunch in the end phase of a submission project. Many in the audience felt this application was a great example of a use of technology that would provide immediate benefits to their organizations.

Jeffrey Klofft talked about "Designing User Friendly Electronic Data Capture." Jeff gave many examples of choices to be made in CRF design to improve ease of use and navigation. He stressed that it is important to design user interfaces, both so they are easy to learn and use in the beginning, but also so that experienced 'power users' can gain efficiency as they learn the system. As use of Electronic Data Capture grows, data managers will increasingly find themselves designing electronic CRF pages for investigator use. Jeff gave showed several examples of good user interfaces from popular software packages and explained how they illustrated ease of use factors.

Arien Malec described an electronic trial scenario of the future where an intelligent electronic model of a protocol and a knowledge-based architecture can help to improve the level of integration between the diverse organizations that contribute to a clinical trial. Ultimately this technology will support rapid design and execution of smaller and more targeted genomics-based trials, point of care protocol compliance and safety monitoring and more innovation in trial designs. This talk gave us a glimpse of some technology that may someday play a significant role in automating the entire clinical trial process.

BOARD OF TRUSTEES *(left)*

Susan Bornstein, Tamela Blackstone, Karen Klingler, Doug Schantz, Annette Schmit, Jean Mazalewski, Kaye Fendt, Hugh Donovan, Pat Teden, Ken Carlson, Brenda Hoeper, (missing Sally Cassells, Becki Filice, Cathie Muza, David Sabritt, Lana Turner)

EXHIBIT HALL *(right)*

Innovative Approaches to Capturing Data Without CRFs

Moderator:

Larry Hauser, Vice President, Data Management North America, Quintiles, Inc.

Speakers:

Anne Wiles, Executive Vice President, e-Business, Quintiles Transnational

Rebecca Kush, President, CDISC and CSO NextPhase

Jeff Finkeldey, Clinical Data Manager, Oral Care, Procter & Gamble Company

Beth Stout

This session covered a broad range of perspectives and experience on Electronic Data Capture (EDC). Presentations began with a general discussion of industry pressure to increase speed, efficiency, standards, quality, and implementation of innovative technology, and moved to examples of the successful application of EDC technology for actual clinical trials.

The session included four presentations; Anne Wiles – "Quality Improvement from the Interface between Job Functions, Tasks, and Data Systems," Rebecca Kush – "Clinical Data from the Source: Data Conception vs. Data Duplication," Jeff Finkeldey – "Use of the Internet for Data Capture and More," and Beth Stout – "Web Solutions: a Quintiles and Sepracor Evaluation."

Rebecca Kush's presentation was formed through flow charts indicating that today's data acquisition typically involves the entry of data at seven points: completion of the source document, completion of the CRF, first and second pass data entry into an operational database, entry of information into a site tracking database, entry of information into a project management database, and entry of information into an AE tracking database. Much of this data/information is duplicated. The potential benefits of 'lean clinical trials', in particular collecting high quality data from the source and entering the data once, were explored. These included leveraging technology, process efficiencies, standardization and quality. Key benefits include the ability to support true online monitoring, to have early access to decision-making information, and to reduce transcription and data entry duplication.

It's clear a lot is expected of data management in the future. Not the least of which is to process more data, in a shorter period of time, with less people, and with the highest level of quality. We were cautioned by several of our presenters that technology is only a part of the solution. The solution must also include new integrated streamlined processes, use of standards such as CDISC, and new job roles as well. One thing is clear, this shift to the use of EDC requires more effort up-front, more technical training, and considerable investigator site cooperation. Based on the results of the case studies presented, however, "real-time" access to the data, fewer manual queries, and higher quality data are significant potential advantages. As we continue to learn from these experiences with EDC, we will meet many expectations and set new ones.

Session Chair – Deborah Cole

Madeline Quarto and Suzanne Silver

Developing, Training and Motivating People to Excel in CDM

Moderator:

Deborah Cole, Data Coordinator, Pfizer Global Research and Development, Ann Arbor Laboratories

Speakers:

Meredith Nahm, Manager, Data Management, Duke Clinical Research Institute

Katherine Voss, Independent Consultant

Derek Perrin, Supervisor, Data Coordination, Pfizer Global Research and Development, Ann Arbor Laboratories

Gail Scherer, Manager, Data Coordination, Pfizer Global Research and Development, Ann Arbor Laboratories

Madeline Quarto, In-House Clinical Research Associate, SmithKline Beecham Biologicals

Suzanne Silver, AstraZeneca

Meredith Nahm, Katherine Voss, Derek Perrin and Gail Scherer

Meredith Nahm started this session by speaking on "Design, Development and Administration of a Comprehensive Clinical Data Management Training Program". Her presentation spoke to the time commitment and the investment that an organization needs to make upfront when considering how to develop team members and the benefits that implementing such development program bring. Some basics points from her presentation were: it is important for the new colleague to have access to e-mail on the first day, spending eight hours a day in training is too much, and too many classes in the first week is a recipe for disaster. A final note from the presentation was that no matter how complex your training needs are, you can develop and implement a training program in less than two years.

Katherine Voss spoke on the job opportunities available for the data manager who wants a change. The skills that we develop as we do our day to day work as data managers, open doors to a number of different jobs, such as programmers, medical coders, DBAs and others. One important take away from this presentation is that in the end WE are responsible for our professional development and we need to act on this knowledge.

Derek Perrin and Gail Scherer presented an overview of "ClinPharm University: a High Throughput Data Management Training Program". ClinPharm University allows a new colleague to quickly learn all aspects of a data manager's job and to apply these newly learned skills in a real life situation. The time investment for the new colleague is eight hours a week for two 4-week periods. Some of the take aways from this presentation were that is important to recognize the colleague for completing the program and that giveaways are always appreciated.

Madeline Quarto and Suzanne Silver spoke on teams and behaviors that are needed in order for the team to succeed in their presentation titled "A Win-Win Approach to Managing and Motivating CDM Teams". They shared the example of having to complete a major project with a team comprised of 85% new colleagues and very tight timelines. Some take aways from this presentation were that micromanaging a team is not good, delegating is good and that even with an inexperienced team and tight timelines, you can have a successful project completion.

Session Chair – Greg Johnson

Novel Processes in Support of CDM

Moderator:

Greg A. Johnson, Product Director, PRA International

Speakers:

Abdelhak Oualim, Group Head Project Data Managers, Aventis Pharma

Wayne Walker, System Administrator, PRA International

Margaret Goad, System Administrator, PRA International

John Rodermund, Associate Director, Clinical Data Management, Gilead Sciences

Dean Gittleman, Associate Director, Strategic Projects, Pfizer, Inc.

Abdelhak Oualim, Margaret Goad, Wayne Walker, John Rodermund and Dean Gittleman

Abdelhak Oualim began this session with a presentation on "Global Simultaneous Submissions: Data Management Standards and Global Integrated Database, Two of the Success Factors". Abdelhak gave an overview of the project, which had the goal of submitting the same dossier and database to both the FDA and the EMEA within one month of each other, and within four months of locking the last database. The submission contained data from 42 Phase I and III studies, performed in Europe and the U.S., and was also intended to support later submission to the Japanese regulatory authorities. Abdelhak emphasized the need to define in advance a single submissions database, and to develop a process to include databases before they were locked. He offered several suggestions from the experience, including a reminder to not underestimate the effort of including Phase I data, and to initiate early contact with the FDA to identify special requests such as preferred file formats.

Margaret Goad and Wayne Walker presented on "Supporting a Distributed Global Clinical Data Management System". Their presentation included a discussion of the systems that are used for tracking application issues to ensure prompt resolution and compliance with 21 CFR Part 11 change controls. In addition to discussing the tools that are used to provide support for users who are geographically dispersed, Margaret and Wayne discussed the role of the system administrator in distributing information to system users and providing a communication channel for sharing best practices.

John Rodermund followed with a talk about "The Team Approach to Locking a Quality Clinical Database". John's presentation focused on how to accomplish database lock as a true project team, while maintaining controls to avoid bias. John discussed the roles of the various members of the project team, and the importance of the Statistical Analysis Plan for identifying what variables are critical to the study analysis. He closed by emphasizing the importance of not over-relying on computerized data checks, and the usefulness of a full team review of draft tables, figures and listings prior to database lock.

Dean Gittleman finished the session with an informative and entertaining presentation called "Fun and Profit with Subject IDs". Dean made the case for eliminating the use of two distinct subject identifiers (such as "screening" and "randomization") that both refer to the same study subject but at different time points. He recommended instead the use of a single identifier assigned at the point of first contact and treating the randomization code as a study attribute, in the manner that other attributes such as "date of birth" and "gender" are currently handled.

David Olson, Steven Nelson, Nikki Bonnell, and Ernie Trent

Working with CROs and Vendors

Moderator:

Steve Nelson, Director Outsourcing Operations, Clinical Data Operations, Pfizer, Inc.

Speakers:

David C. Olson, Advisor, Data Communique

Nikki Bonnell, Senior Project Manager, MiniDoc, Inc.

Ernie Trent, Director, Outsourcing Operations, Clinical Data Operations, Pfizer, Inc.

David Olson spoke first in the first session entitled: "Niche Providers – Selecting and Establishing Effective Partnerships." David described what a niche provider is in the pharmaceutical industry and gave several examples. He described the importance and place they fill in sponsor's choices, as well as how one may identify and select suitable niche providers. Lastly he described the differences in working with smaller niche providers and gave some concrete do's and don'ts. Overall the talk covered many important partnership tips.

The second speaker, Nikki Bonnell gave a talk titled "The Importance of Customer Support When Selecting a Vendor or CRO." Nikki discussed how to evaluate customer support in vendors from perspectives of communication, flexibility and scalability. She described the importance of vendor reporting capabilities and state of the art customer support technologies.

The last of the speakers, Ernie Trent, spoke on the topic of "Strategic Outsourcing in Biometrics." Ernie first described Strategic Outsourcing at Pfizer, specifically the Biometrics area. He spoke on the importance of Pre-Planning, Process Maps, Quality Gates, and Benchmarking internal requirements. He eloquently summarized Pfizer's Effective Outsourcing Network (EON); a process for identification, selection, and evaluation of CROs. He spoke on general Pfizer contracting strategies as well as how to manage vendor relationships.

2000 SCDM Fall Conference Sponsor Recognition

The Advanced Group
Educational Program Co-Sponsor

Boston Biostatistics Inc.
Tuesday Continental Breakfast

Boston Scientific Corporation
Monday Morning Refreshment Break

The Cambridge Group
Monday Afternoon Refreshment Break

Coding Plus
Monday Luncheon in the Exhibit Hall

Covance
Promotional Brochures

Domain Pharma
Monday Evening Cocktail Reception

Genentech, Inc.
Monday Continental Breakfast

Health Care Online
Sunday Gala Welcome Reception

INC Research
Wednesday Continental Breakfast

IntraSphere Technologies Inc.
Monday Evening Cocktail Reception

invivodata, inc.
Tuesday Afternoon Refreshment Break and Wednesday Morning Refreshment Break

MTRA/AAI
Tuesday Morning Refreshment Break

Placemart Personnel Service
Educational Program Co-Sponsor

Quintiles, Inc.
Tuesday Luncheon in the Exhibit Hall and Conference Syllabus

Smith Hanley
Signage

Geoffrey Gordon, Barbara Tardiff and Rebecca Kush

Regulatory Considerations in CDM

Moderator:

Rebecca D. Kush, Ph.D., President, CDISC and CSO, NextPhase

Speakers:

Barbara Tardiff, M.D., M.S., M.Phil., Assistant Professor of Anesthesiology and Director Clinical Data Integration, Duke Clinical Research Institute

Geoffrey Gordon, Vice President, Engineering, PHT Clinical Networks

Barbara Tardiff's talk was entitled "Standards and their Impact on Quality". Dr. Tardiff began by defining 'standard', then drew a relationship among the interaction of consumers, the nature of food, and the regulatory environment. She gave a historical perspective on consistency and its association with quality and provided the specific example of the Guild Act in the Eleventh Century. Her premise that 'the need for certainty about what constitutes good quality has led to physical and written standards' was carried throughout the talk: "What is good and right?" To relate this to data management, the corresponding interaction is among the nature of the study, the user, and the regulatory requirements; the intersection of these three is the 'quality practices of clinical data management'. Dr. Tardiff then discussed sources of errors in data collection and reporting and the causes of poor quality. She concluded her talk by providing real world examples of what setting standards can do, i.e. allowing the measurement of what is 'good and right', increasing the likelihood that the product is 'right', and increasing the likelihood that the product is what the user is expecting.

Geoffrey Gordon's talk was entitled "Using XML for Interchange and Archiving of Clinical Data". He covered the work of a CDISC team that has applied extensible markup language (XML) to produce a draft Document Type Definition (DTD) to represent clinical trials data and metadata to support the acquisition, interchange and archive of electronic data. Mr. Gordon began with the requirements for data integrity, extended data retention requirements, and rigorous audit and review requirements for data from clinical trials. The numerous incompatible data sources we deal with can benefit from a standards-based solution. Mr. Gordon then discussed the rationale for choosing an XML foundation to support data acquisition and archive. He presented the progress to date within CDISC to produce a Version 1.0 DTD, which is posted on the CDISC website for review (www.cdisc.org). To close his talk, Mr. Gordon discussed the actual development of compliant systems, and the associated implementation, functionality and advantages of such a data interchange model.

Call for Session Chairs for the Year 2001 Fall Conference

The 2000 Fall Conference was successful because of the hard work of people who volunteered their time to make it a success. As anyone in CDM knows, the key to success is careful planning. So...The planning for the year 2001 conference is already starting! It will be held September 23 – 26, 2001 at the Westin Seattle in Seattle, Washington.

At this time, the SCDM is seeking people who would like to participate as session chairs. Session chairs play a key role in shaping the conference, as they select the speakers who will present in their session. Anyone interested in volunteering for this important role should contact Karen Klingler or Jean Mazalewski as outlined below:

Karen Klingler
klinglk@war.wyeth.com
610-902-1429

Jean Mazalewski
jean.mazalewski@pharma.novartis.com
973-781-8475

Nellie Hudson, Marysasser Hendrick Holloway, Sandy Saposnik, and Tammy Giametta

Collecting and Processing Laboratory Data

Moderator:

Tammy Giametta, Quality Process Manager, Novartis Pharmaceuticals

Speakers:

Thomas Morrow, Associate Medical Consultant, Eli Lilly and Company

Marysasser Hendrick Holloway, Clinical Data Management Coordination Specialist, Quintiles, Inc.

Sandy Saposnik, Medical Data Coordinator, Merck & Co., Inc.

Nellie Hudson, Medical Data Project Leader, Glaxo Wellcome Inc.

Thomas Morrow, started the session with a presentation called "Overview of Centralized Clinical Diagnostic Data Management". Thomas presented the audience with the trends in the pharmaceutical industry and their impact on the laboratory data support needed for clinical trials. Thomas followed that up with how Eli Lilly has evolved in this area over the past 14 years in order to support these trends. With emphasis on the volume of laboratory data within a clinical trial, the huge need for dedicated support was quite apparent.

Marysasser Hendrick Holloway talked about "How Does It Fit In?". Each type of laboratory data was identified as a puzzle piece and the logistics on how to make each piece a unique fit into the laboratory data puzzle was discussed. As each of us has at one time had to find the right match for each puzzle piece, Marysasser provided some general guidelines to ease the handling of laboratory data and some common problems one can expect to encounter.

Sandy Saposnik gave a comprehensive view of Merck's approach to handling central laboratory data. Planning as the underlying theme of Sandy's presentation, was captured up front in the title "Facilitating the Collecting and Processing of Central Vendor Laboratory Data". By making the right decisions and following those decisions on an ongoing basis the task of collecting and processing central laboratory data can run smoothly.

Nellie Hudson, the final presenter for this session, provided insight into how Glaxo Wellcome strives to make handling laboratory data fun. With the development of standard working practices, processes, programs and good communication, the processing time for laboratory data can be reduced. Glaxo Wellcome took the team approach to development of their laboratory data processing system.

Professional Identity of Clinical Data Management — Spring Forum 2001

The next Spring Forum will be held on March 18 – 20, 2001 at The Tremont House Hotel in Galveston, Texas. The overall theme is "Clinical Data Management as a Profession".

Key topics covered will include:

- What does it mean to be a "professional"?
- How will the SCDM-sponsored clinical data management professional certification program be structured?
- What direction should the Good Clinical Data Management guidance take?
- How will this program affect the professional lives of SCDM members?
- What is the link between certification and training?
- What challenges lie ahead for our profession?

As with other Spring Forums, the SCDM will organize a special event on Sunday evening. Check out http://www.galvestonhistory.org to learn about Galveston and get an idea of the types of events being considered.

Do not miss this! Mark these dates on your calendar and plan to attend.

Ellen Loonan and Colleen Cox

The State of the Art in Coding of Clinical Data

Moderator:

Colleen M. Cox, Manager, DM System Development, MTRA/AAI

Speakers:

Joann Medbery, MedDRA MSSO

Ellen Loonan, Director, Clinical Projects, DZS Computer Solutions Inc.

Andras Kornai, Principal Scientist, PPD Informatics/Belmont Research

Joann Medbery opened the session with a presentation entitled, "MedDRA in the Millennium". She gave a brief history of MedDRA and a recap of the activity that has occurred within the first year. These activities included: addition of new terminology, review of several SOC categories for consistency and/or re-mapping. The activity within the first year included both simple changes that occurred every quarter and completed changes that were implemented in version 3.1. Simple changes include changes that affect the preferred and lower level terms. Complex changes involve the preferred term and above. Joann also described what activities the MedDRA MSSO is currently undertaking. These activities include spelling clean up (of the preferred term), maintenance and utilization rules, and documents to discuss recommendations for MedDRA versioning. Future directions include a complex change release that will include: application of updated maintenance and utilization rules and both a SOC-by-SOC review and a cross-SOC review. This release is scheduled for late 2001.

Ellen Loonan followed with a presentation focused on the development, implementation and maintenance of a coding system: "Experiences in Coding Using a SAS® Based State of the Art Coding System". Ellen started with a description of the existing coding situation that included a basic encoder with exact matches and the reliance on manual coding. SAS® was used as the base software to allow for creation of transport files, to ensure continuity with existing systems, to utilize flexible reporting features and to handle large data, such as the MedDRA dictionary. The incorporation of the autoencoder increased the hit rate, reduced coding time and provided consistency. In addition, advanced autocoding matching techniques such as the incorporation of a synonym table, elimination of trivial words and non-exact term matching also added enhanced capabilities. Manual coding was streamlined through the use of search tools: "sounds like", contains and exact phrase and pattern searches.

Andras Kornai ended the session with his presentation, "Automatic Coding of Omissions". Andras's presentation focused on the integration of artificial neural networks (ANNs) as a mechanism to improve the coding of omitted terms. Artificial neural networks are based on units (neurons) arranged in network, the numerical connection strength between units. For coding, units are defined as words and phrases, the connection strengths are based on previously coded terminology. The same algorithm can be used on multiple dictionaries. ANNs can be used as part of a generalized model and with existing synonym tables. They can be used in an interactive setting, as part of MedDRA training or during database merging or harmonization.

Other Data Management Organizations:

Parlez-vous Clinical Data Management ?

The third in our series looking at other data management associations focuses on the Data Management Biomedical (DMB), a French society founded in 1995. It currently has approximately 150 members, working in pharmaceutical companies or CROs.

The aims of DMB are to promote data management activities, notably by:

- bringing together, and making easier, exchanges between interested people
- making the profession known through publications, presentations, conferences, and training
- optimizing working methods and anticipating evolutions
- having a special relationship with the authorities, software providers, and CROs
- establishing relationships with other data management associations in Europe and in the World

The council of DMB is composed of 14 elected members, with a main Committee composed of six elected members. Also there are five working groups producing documents or organizing meetings:

- Biological data
- Quality assurance
- Coding
- New technologies
- Training

One particular area of expertise, which may be of interest to the SCDM membership, is conversion factors for laboratory tests. The group has developed and maintains a comprehensive list of conversion factors, from the familiar to the exotic. If you need to convert FT3 from ng/l to pmol/l the DMB has the answer.

The DMB holds an annual meeting in Paris. Recent themes have included coding and blinded review. The 2001 meeting will focus on new technologies.

Contacts:

- Université de Marne la Vallée – IFIS/DMB – Cité Descartes – 5 Boulevard Descartes – CHAMPS sur MARNE – 77454 MARNE LA VALLEE Cedex 2
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  E-mail : joris.cauquil@pierre-fabre.com

DATA BASICS

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We've had some very promising writers answer the call! Look for their articles in upcoming issues! However, the search continues...!

Please submit any articles, ideas, etc. for publication to the Editorial Board.
Submit advertising as indicated in the Advertising policy section below.

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Submission Deadlines

(Articles and Advertising Art Work)

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

Volume 7, Issue #1 (Spring)	February 1, 2001
Volume 7, Issue #2 (Summer)	April 27, 2001
Volume 7, Issue #3 (Fall)	July 31, 2001
Volume 7, Issue #4 (Winter)	October 26, 2001

Each issue is mailed to the membership approximately 6 – 7 weeks after the corresponding submission deadline.

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 7/8	$240
Half Page-vertical	3 5/8 x 10	$400
Half Page-horizontal	7 1/2 x 4 7/8	$400
Full Page	7 1/2 x 10	$575

**Ads are net, non-commissionable

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Please submit all forms, artwork, and payments to:

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$1.8 Million Federal Grant Awarded for a Bio-Science Training Project

(reprinted compliments of Pfizer)

Armelde Pitre has long been aware that Clinical Data Management positions were hard to fill, partly because many potentially good candidates simply lacked the necessary training and experience. "We found that there were limited positions for new graduates and we normally needed to recruit CDMs from other pharmaceutical companies. We simply didn't have the resources or time to train inexperienced people from scratch."

At one point, a candidate asked Armelde where she could get the necessary training or acquire the skills needed to become a CDM. When she looked into it, she found that while there were numerous training sessions available, there were no comprehensive CDM training programs in the United States. Furthermore, she wanted to find a program that had industry-wide acceptance and recognition. Again, none were available.

So she took the initial steps toward creating such a program.

"I submitted a proposal to launch an exploratory project," she said. She began by contacting five colleges in her region — Connecticut College, University of Connecticut, Mitchell, Three Rivers, and Eastern Connecticut State University (ECSU) — to explore their level of interest in a joint project to develop a CDM non-credited training program and potentially longer-term formal degree program. "The colleges responded enthusiastically to my request," she said.

Based on various criteria, ECSU was chosen. Next there was the issue of funding to develop and launch this program. Armelde researched various options and identified an opportunity to raise the necessary funds through government grants. Together with ECSU and the Workforce Investment Board of Southeastern Connecticut, a grant proposal was submitted to the U.S. Department of Labor. Armelde said the criteria on

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$1.8 Million Federal Grant

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which ECSU was chosen included such considerations as completeness of the proposal, cost to the students, staff support, parking, housing, computers and other available resources, and provisions made to attract women and other underrepresented minorities.

In July, a $1.8 million federal grant was awarded to Workforce Investment Board of Southeastern Connecticut for a Bio-Science Training Project. The Workforce Development Board will manage distribution of the grant monies. ECSU will develop and deliver the training. Pfizer will coordinate industry participation.

Next steps include gaining the support of industry. Armelde would like to see Pfizer, along with other industry partners, provide overall guidance in curriculum development, internship opportunities and mentoring. The SCDM membership can play a key role in this process.

"I envision a program that consists of a simulated work environment in which the student is taken all the way through the clinical trials development process, from the perspective of a Clinical Data Manager," Armelde said. "There will be lectures, lab work and team work. The teams will meet with their program advisors to review protocols and case report forms, develop clinical databases and edit checks, issue queries, close databases, and prepare reports for an NDA submission." They will receive feedback on their work before proceeding to the next topic area.

The first full-time classes are scheduled to launch next June. Future classes will be offered in various formats (such as on a part-time basis). Participants might include bioscience workers, underemployed workers and students. The program will prepare them for high-skill jobs in pharmaceutical and clinical research companies, health maintenance organizations and insurance companies.

"I envisioned a 'win-win-win' for everyone involved," Armelde said. "It's a win for Pfizer and other pharmaceutical companies as it will provide us with a pool of potential candidates for hire, and also a resource to help bridge any internal skills gap that our employees may have. It's a win for the community because these skills are currently in demand and are highly transferable to other related occupations, such as HMOs and insurance companies. It gives people in the community with degrees in computer science and nursing additional career options."

Finally, she said, it's a win for the colleges. Although the program will launch in ECSU other area colleges are already involved. Eventually, Armelde expects the project to be launched nationally. "Other colleges around the country have already expressed an interest," she said.

This fall, a program coordinator will be hired to manage all the program logistics. We're continuing work on curriculum development and assembling a team of reviewers from internal and external clinical data management positions. Armelde would like the curriculum development to be closely linked to other SCDM initiatives such as Professional Certification and Good Clinical Data Management Practices. Additionally, instructors will be recruited from both the industry and academia. If all goes according to plan, screening for applicants and mentors will begin in February 2001.

Anyone interested in participating in the program or its development should contact Armelde Pitre at pitrea@groton.pfizer.com.

Professional Certification Technical Capabilities Questionnaire

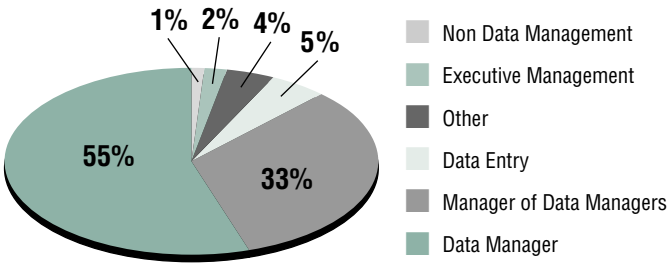
Introduction

Certification of Clinical Data Managers (CDMs) is largely dependent on determining those technical capabilities or competencies that are required and those that are optional. Ultimately, using a standardized assessment tool, CDMs will assess their own technical capabilities against the norm. To develop an assessment tool and to establish norms, the Certification Committee developed a DRAFT detailed description of the capabilities expected of CDMs and Senior CDMs for each of the tasks listed in the CDM task list. This list was published in the Fall1999 Volume 5 Number 3 Issue of *Data Basics*. During the Fall 2000 SCDM conference, attendees completed a 13 page questionnaire (much to our amazement and gratitude!) This questionnaire was used to gather feedback for the Certification Committee's CDM capabilities definitions as well as to determine which capabilities were considered core and which were considered optional. The questionnaire content and results are presented herein.

Questionnaire Results

There were a total of 147 completed questionnaires. The respondents fell into the following job categories:

Distribution of Questionnaire Response By Job Category



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Professional Certification Technical Capabilities Questionnaire

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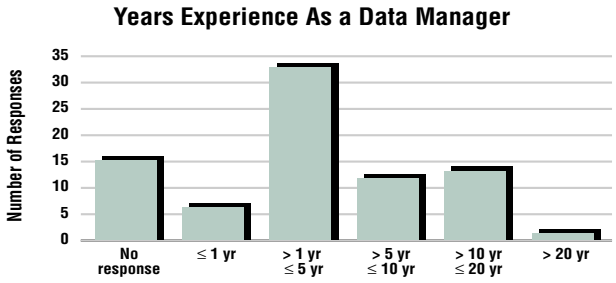
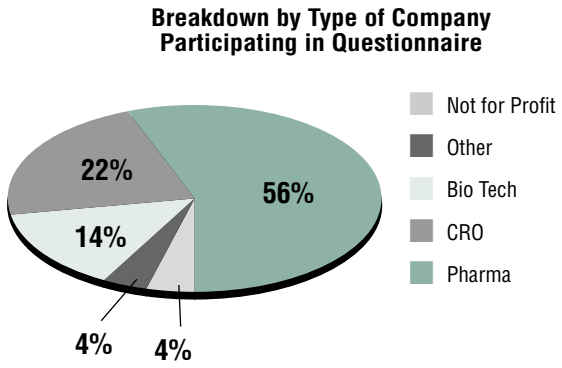
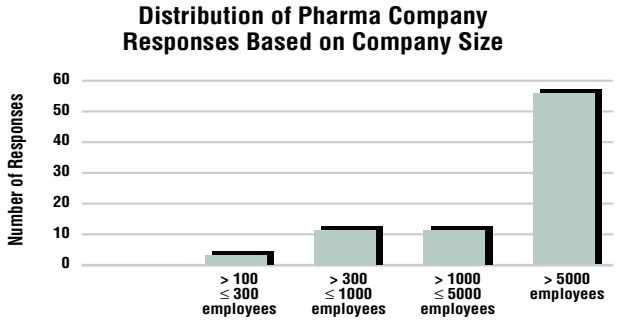
By far, the largest group of respondents was data managers (eighty in all). Their experience ranged from less than one year to over twenty years. The distribution was as follows:

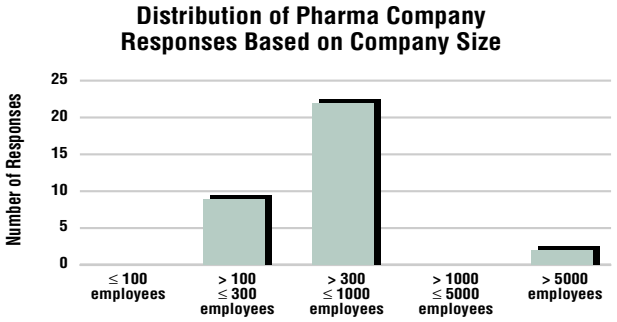


Members from all types of organizations participated in completing the questionnaire. The following distribution was noted:



The largest number of respondents was from Pharmaceutical Companies and CROs. The following company size demographics were also collected.





The results have been recently tabulated and analyzed in accordance with the above demographics. For convenience and the sake of brevity in this article, SCDM members may access the results in the SCDM web site's Certification Committee page. From these results, readers may determine the norms regarding both core and optional capabilities for Clinical Data Managers, Senior Clinical Data Managers. The SCDM Certification Committee thanks fall conference attendees for taking the time to complete this questionnaire and provide us with valuable information to frame the remainder of our work.

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.

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