S C D M
S C D M
S C D M
S C D M

DATA BASICS

Volume 5
Number 4
Winter 1999

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

From the Editors

Welcome to the first issue of *Data Basics* on our combined watch. As you may already know or will soon learn from this issue, the editorial responsibilities for the newsletter have changed somewhat. We have lots of new as well as experienced talent to draw from to make the Society's newsletter bigger and better than ever. We hope to use the editing skills, talents, experiences and insights of the newly formed Editorial Board (members identified later in this issue) on an ongoing basis to spread the workload as well as fun around. Now on to the content of this issue!

Now that fall is over and the winter winds are blowing, why not take a few minutes to read through this issue and find out what's new and happening with SCDM. We hope you will find exciting things to peak your interest and involvement as well as to help brighten up what can be dreary winter months for several of us. The feature article on the Fall Conference is terrific thanks to the contributions and efforts of the conference Co-chairs, **Ken Carlson** and **Becki Filice**, as well as all the session moderators. We wish to extend special thanks to **Frannie Rink** for helping with the photo selection and captions.

Be sure to check out the various shorter articles - for examples: committee updates; look ahead to the 2000 Spring Forum; letter from the new SCDM chair – which all help to point out the many initiatives, activities and opportunities there are or will be within SCDM.

Enjoy!
Lana and Cathie

THIS ISSUE

PROCEEDINGS OF THE 1999 SCDM FALL CONFERENCE

Optimizing Clinical Data Management Through People, Processes and Standards

CONFERENCE OVERVIEW

The Fifth Annual SCDM Fall Conference, held September 26-29th, set record attendance with 348 conference attendees, and 78 exhibitors represented at 32 booths. Chicago welcomed us with beautiful, sunny, weekend weather, and the Fairmont Hotel provided wonderful accommodations and a great location from which to explore the city. For the first time, a pre-conference tutorial was held in conjunction with the Fall Conference, drawing 43 attendees on Sunday afternoon. The conference officially kicked off with a Welcome Gala Reception on Sunday evening, providing the opportunity to network with old friends and meet new people. As conference sessions began on Monday morning, Chicago skies turned cloudy and rainy, apparently understanding there was lots of

continued on page 3

Fall Conference Co-chairs, B. Filice and K. Carlson, take a moment to enjoy the satisfaction of "a job very well done!"

Letter from the Chair of the SCDM

Dear Members,

I am delighted to write a few words at the start of my year as Chair of the SCDM. The SCDM is ***HOT*** with a growing list of activities/services and an expanding number of active members. Let's spend a minute to recognize our many successes in 1999 and set a charter for the year 2000.

The vigor in our professional organization comes from a grassroots imperative to strengthen OUR profession of Clinical Data Management. Clarifying and communicating the role and contributions of CDM to regulated product development industries is very important. This implies activities such as the turbo-charged Good Clinical Data Management Practices Committee ably led by **Meredith Nahm** of Duke Clinical Research Institute, and the nascent professional certification development activities led by **Armelde Pitre** of Pfizer. A large group chaired by **Susan Bornstein** of MTRA is addressing training, and is planning additional training opportunities in 2000. These three initiatives are collectively supported by scores of SCDM members.

The new SCDM web site was a big hit at the recent Fall Conference (actually the entire conference was a big hit). Many thanks to the web site creators: **Christine Tattrie, Nick Stamos** and **Doug Schantz**. Welcome to our new webmaster, **Sandy Ricciardi** of Novartis. Send your suggestions for further development via **www.scdm.org**. One common suggestion is for the web site to support job openings. Keep checking for that one. I hope the membership uses the web site to develop a sense of "community" with each other.

The 2000 SCDM Board of Trustees:
Left to right (standing): P. Teden, K. Klingler, A. Schmidt, S. Bornstein, D. Schantz
Left to right (sitting): B. Hoeper, K. Carlson, B. Filice
Not pictured: C. Muza, K. Fendt, L. Turner, K. Buchholz, H. Donovan

SCDM "standard" services are being continued and improved in 2000. ***Data Basics*** is growing. The new co-editing team of **Lana Turner** and **Cathie Muza** is being augmented by an Editorial Board. Look for ***Data Basics*** to offer CDM service providers the opportunity to advertise their services to our professional membership in the near future.

The events of 1999 are a tough act to follow for the year 2000 Spring Forum and Fall Conference planners. Both events in 1999 were well attended and well received by participants. We are in awe of the efforts of **Frannie Rink, Ken Carlson, Becki Filice** and the session chairs, which assured the success of these events. You'll enjoy reading about the Fall Conference in this edition of ***Data Basics***.

SCDM will spend considerable effort in 2000 to strengthen the Society's relationship with the FDA whose appreciation of the importance of clinical data management is growing daily. Special thanks are given to SCDM Board member and FDA employee **Kaye Fendt**.

Expect to see SCDM play a more formal role in supporting the CDISC initiatives this year.

The Board of Trustees is growing. Board members for the year 2000 are:

Susan Bornstein, MTRA		**Karen Klingler**, Wyeth-Ayerst	
Ken Buchholz, INC Research	(Past Chair)	**Cathie Muza**, Boston Biostatistics	
Ken Carlson, Pfizer		**Doug Schantz**, Parke-Davis	(Vice-Chair)
Hugh Donovan, Aventis		**Annette Schmit**	(Treasurer)
Kaye Fendt, FDA		**Pat Teden**, Independent Consultant	(Chair)
Becki Filice, Genentech	(Secretary)	**Lana Turner**, Pharmacia & Upjohn	
Brenda Hoeper, Kendle			

The Board is grateful to retiring Board members, **Ron Copp, Frannie Rink** and **Kristin O'Connor** for their many contributions to the SCDM. We will miss you at Board meetings but LOVE that your active participation in SCDM is continuing! **Ken Buchholz** will carry the torch as Past Chair, for which the Board will be richer.

I hope you agree that the SCDM is "coming into its own" and how important it is for you to be part of the continued success of the SCDM. What can you do to help foster the professional growth of the CDM profession? Simply get involved. Volunteer for one of the existing initiatives, or suggest new ones. Expand the SCDM membership within your company and network of professional colleagues. Attend/support the SCDM activities. Think about running for the Board next year. Write an article for ***Data Basics***. Bring the SCDM your issues, talents and advice.

As tempting as it is, I won't sign off with any saccharin sentiments about the new millennium. Let's just say this coming year is going to be **GOOD!**

Pat Teden, Chair of the SCDM

continued from page 1

Optimizing Clinical Data Management Through People, Processes and Standards

excitement indoors! Highlights of Monday included two great sessions with excellent presentations, a lively panel discussion, a featured keynote speaker, and a Vendor Reception stocked with great food and drink and more networking opportunities. Tuesday continued with more sessions, more excellent presentations, and the SCDM Annual Business Meeting over lunch. Wednesday's half day session continued to draw great attendance, as there was significant interest in the timely topics and valuable presentations. Skies were turning sunny again in Chicago as we said our good-byes and headed home (except the few lucky people staying to enjoy the city a little longer), already looking forward to seeing everyone again next year at SCDM Fall Conference 2000!

W. Leigh Thompson

KEYNOTE SPEAKER SUMMARY

W. Leigh Thompson, PhD, MD, ScD, FACP, FCCM, founder of Profound Quality Resources, was the featured speaker for the Fall Conference, and provided an exciting, energetic end to the day Monday. Leigh, who is from Charleston, South Carolina, has over 30 years of experience in medical and clinical research. He provided the audience with a provocative and entertaining presentation focusing on a potentially different paradigm for drug development that would speed research and decision making, decrease costs, and provide benefits to patients more quickly. He also provided attendees with two Monographs titled *"Interim Analyses: for Ethics, Frugality, and Speed"* and *"Therapeutics in the Third Millennium."*

PRE-CONFERENCE TUTORIAL

A pre-conference tutorial was held from 1-5 pm on Sunday afternoon, September 26th, covering the topic of *"The Data Management Plan and SOP."* The instructors for the tutorial were **Katherine Voss**, Consultant, and **Dr. Louise Murphy**, Senior Director, Data Management, ICON Clinical Research, Inc. The tutorial provided both lecture and hands-on exercises, working with a sample protocol. Data Management Plan details such as building the contact matrix, timelines and milestones, version control and amendments, approvals and signoffs, distribution and archive requirements were covered. Participants also formed smaller groups in which they developed a sample SOP for the creation of the Data Management Plan. At the end of the workshop, participants left with a sample Data Management Plan and a sample SOP to be used as future references.

Left to right (standing):
S. Bornstein,
T. Murphy,
W. Facas
Left to right (sitting):
T. Ockershausen,
J. Edington,
L. Shinaberry,
J. Ralstin

The Diversity of Roles in CDM

Moderator: Terry Murphy, Associate Director CV/CNS Data Management, Pfizer, Inc.

Speakers: Susan Bornstein, Director, Data Management, Medical & Technical Research Associates, Inc.

Wendy Facas, Manager, Clinical Data Management, Pfizer, Inc.

Janet Ralstin, Clinical Data Coordinator, Pharmaceutical Research Associates, Inc.

Theresa Ockershausen, Senior Manager Clinical Data Coordination, Pharmaceutical Research Associates, Inc.

The roles and skills within Clinical Data Management are continually changing and evolving within the industry. This session focused on the diversity of roles within Clinical Data Management.

Susan Bornstein's presentation on "Data Management Self-Directed Core Teams" included the evolution of the self-directed core team concept. This concept is represented by members within each discipline of data management who are empowered to make group decisions and the benefits associated with this concept.

"Redefining the Data Manager," given by **Wendy Facas**, included an overview on the historic role of the data manager, the current role of the data manager, how the role has expanded and become increasingly diverse. She also shared her vision for the future data manager, focusing on opportunities, skill sets, and challenges.

Janet Ralstin and **Theresa Ockershausen** presented "Different Backgrounds Represented in the Clinical Data Management Teams." They described a survey developed to determine if their colleagues and peers believed a diverse community existed within their data management departments worldwide, and whether or not diversity is a positive element that should be part of data management groups. **Jim Edington** and **Lauren Shinaberry** (Pharmaceutical Research Associates, Inc.) participated in the Session III Panel Discussion for this same topic.

The diversity of the data management disciplines represented on the core teams proved to be quite effective in setting priorities, assigning designated backups, streamlining resources and enhancing communication. Redefining the data manager as it pertains to the future role of the data manager presents numerous opportunities for diversifying and expanding upon skills not present in the traditional data manager role. The respondents to the survey looking at diversity all indicated a variety of experiences are beneficial to the data manager position and that cross training between the disciplines should be required. All three presentations concluded that a diversity of education, background, skills, and teamwork is invaluable to data management. The variance and diversity of the data management role can clearly lead to increased efficiency, morale and team contributions.

Call for Session Chairs for the Year 2000 Fall Conference

The 1999 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 up-front planning. Well, the planning for the year 2000 conference is already starting! It will be held October 15-18, 2000 at the Crystal Gateway Marriott in Arlington, Virginia.

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 Ken Carlson as outlined below:

Mail: Pfizer, Inc.
235 East 42nd Street 205/4/5
New York, NY 10017

E-mail: carlsk@pfizer.com
Phone: 212-573-7985

Left to right (standing):
R. Rothmeier,
K. Klingler,
J. Larus,
J-L. Saillo
Left to right (sitting):
N. Stamos,
J. Vath

The Organizational Impact of New Technologies and Processes

Moderator: Ross Rothmeier, Program Manager, Phase Forward, Inc.

Speakers: Nick Stamos, Chief Architect, Phase Forward, Inc.

Jean-Louis Saillo, MD, Sr. Director Clinical Operations, Schering-Plough Research Institute

Karen Klingler, Director of Data Management, Wyeth-Ayerst Research

Jill Vath, Senior Manager, Clinical Data Management, Genentech, Inc.

John Larus, PharmaLink

This session focused on the organizational impact of new technologies - especially Electronic Data Capture (EDC).

Nick Stamos and **Jean-Louis Saillo** presented "Changing Roles and Processes in Web Clinical Data Management." In particular, they described how the data manager could take a leadership role in the development of clinical trial applications. They also shared their vision of the data manager as a data integrator, bringing together data from multiple sources.

Karen Klingler "pinch-spoke" for her Wyeth-Ayerst colleague, Lisa Rossini, who was unable to attend the conference at the last minute. Karen discussed how important it is to establish guiding training principals to ensure that the training takes cultural differences into consideration, as well as new processes, role changes, and different learning styles in this talk titled "New Processes and Technology – Training Strategy for a Global Organization."

Jill Vath discussed "The Organizational Impact Following Implementation of a New Clinical Data Management System." She focused on post-implementation activities and strategies that can help reduce the sometimes negative undertones associated with implementing a new technology. Specifically, the roles of the CDM, CRA, and statisticians were discussed. Frequent cross-functional and department meetings that bring out the people issues of such changes can help your organization move forward. In addition, she stressed ensuring that you have dedicated resources to support post-implementation activities.

This session concluded with **John Larus** speaking on "Electronic Data Capture Systems and Their Impact on Clinical Teams." John suggested that the clinical data manager of the future may be able to play a critical role bridging the growing gap between technical and clinical expertise. By introducing a new technology into the clinical data management environment, we also have an opportunity to create new teams with specialized skill sets.

Annual SCDM Business Meeting Summary

The 1999 Annual Business Meeting for SCDM was held during the Fall Conference on Tuesday, September 28, over lunch. **Pat Teden**, SCDM Board of Trustees Chair, opened the meeting with a review of SCDM goals, structure and accomplishments for the 1998-1999 year. Notable accomplishments included the Spring Forum, Fall Conference and launching of the SCDM Web Site. **Annette Schmit**, Treasurer, provided general information on the main expenses of the Society in the past year. These included: Spring Forum, Fall Conference, Membership Directory, *Data Basics* Newsletter, and Web Site. Following this report, several Society Committees gave updates to the membership.

Membership Committee: **Catherine Celingant** reported a 26% growth in membership in 1998-1999, with current membership at 1107 people.

Education Committee: **Susan Bornstein** reported on the committee's efforts to produce training modules, which would provide topics and materials for pre-conference tutorials. The committee is also focusing on advanced topics for future workshops.

continued on page 14

SESSION III

Panel Discussion with Speakers from Sessions I and II

Moderators: Terry Murphy, Associate Director CV/CNS Data Management, Pfizer, Inc.
Ross Rothmeier, Program Manager, Phase Forward, Inc.

All the speakers from Sessions I and Sessions II returned for a lively panel discussion. The hot topic for questions was Electronic Data Capture via the Web. Two of the presentations from Session II focused on this new technology and the audience was clearly interested in learning more. Questions ranged from specific ones on issues such as data security to more broad based questions on how this new technology might affect the clinical data management profession as a whole. The other major area for questions and discussion was the evolving role of the Clinical Data Manager. The audience clearly enjoyed the opportunity to explore these issues more fully via the panel discussion.

SESSION IV

Left to right:
K. Johnson,
P. Teden,
K. Klingler,
B. Elashoff

CDM in the Product Development Team: Challenges and Opportunities

Moderator: Pat Teden, Independent Consultant

Speakers: Barbara Elashoff, FDA Statistician, FDA/CDER
Kathleen Johnson, Clinical Data Manager, Pharmacia & Upjohn
Karen Klingler, Director of Data Management, Wyeth-Ayerst Research

Barbara Elashoff, a statistical reviewer for CDER, started this session with a presentation called "Data Management in the NDA Review Process: A FDA Reviewer's Perspective." She offered very specific and helpful examples of the types of data issues she has experienced in reviewing 20 different NDAs. Most of the examples caused needless slowdowns in the review process, a process with very tight deadlines. Barbara's message will help data managers represent the FDA's clinical data issues to the product development team. The audience readily received Barbara's message of teamwork with sponsors and her recommendation that data managers be included in phase II+ planning meetings with the FDA.

Kathleen Johnson talked about "Team Roles Post Merger: A Day in the Life of a Data Manager." A quick poll of the audience showed more than half had experienced at least one corporate merger during their CDM career. Kathleen reviewed how Pharmacia & Upjohn organized their global development teams by creating separate strategic/scientific teams and operational teams. She clarified the value data management brings to both teams throughout the life of the study and project.

Karen Klingler gave examples of clinical data managers performing "extraordinary" services in support of the product development team's goals. One of those examples was captured in the presentation's title, "NDA Day," in which data managers were on-call to address FDA questions within minutes/hours during a pre-scheduled review day. Another example had teams of data managers flying to investigative sites to clean/process data onsite during the study's critical path time in order to protect timelines. Yet another example illustrated the value clinical data managers brought to a strategic product submission team in assuring that the team's decisions were data driven. We've all gone that extra mile for the team!

Left to right (standing):
J. Hertz,
G. Dearhammer,
L. Cole,
M. Alioto
Left to right (sitting):
P. Clarkson

Effective Partnering with CROs

Moderator: Paul Clarkson, Manager, Clinical Data Management, Genentech, Inc.

Speakers: Maria Alioto, Senior Clinical Data Coordinator, Genentech, Inc.
Jean Hertz, Manager, Clinical Data Management, Pfizer, Inc.
Louise Cole, Group Leader, Data Management, G.D. Searle & Company
Gregg Dearhammer, Associate Director, CDM, Kendle International, Inc.

Maria Alioto gave this session's first presentation titled "Learning Along The Way: A Sponsor's Journey in Partnering with CROs." Maria discussed some of the steps Genentech has taken to improve its effectiveness in partnering with CROs and to ensure the success of outsourced studies. Some steps taken include a forming a cross-functional CRO Advisory Team; developing written guidelines, documentation and data transfer standards; and increasing access to CRO management-related training opportunities. The CRO Advisory Team was responsible for leading many of these activities as well as serving as a point of contact for interactions with the CRO. Maria concluded her presentation with how data management at Genentech is involved in all stages of outsourced study conduct ranging from CRO selection through participation in end of study evaluation meetings.

Jean Hertz continued to build on the theme of the first talk with her presentation entitled "Defining Expectations: A Key Component to Successful Partnering with CROs." Jean outlined a number of steps taken within her organization to make working with CROs as effective as possible. These steps included providing templates for key deliverables to CROs, having regular meetings with CROs to clearly define (and then later review) task ownership, timelines and important processes. Other steps taken included always documenting all communications with CROs, and taking an active quality assurance role in reviewing CRO quality control activities. The net effect of implementing these steps was to provide clearly defined joint expectations. This required a lot of very detailed up-front work, feedback from the CROs involved, and continuous communication between sponsor and CRO.

The session's final presentation highlighted the need for and value of continuous communication between sponsor and CRO. **Louise Cole** and **Gregg Dearhammer** gave a presentation titled "Developing a Partnership - A Case Study." Louise and Gregg described how they partnered successfully to provide data management for the Celebrex project, which encompassed a total of 47 protocols and 14,000 subjects. Important success factors included delegating responsibility, committing resources, clearly defining expectations and being flexible in the face of change. It was also very important for both sponsor and the CRO to have a single data management contact person. In the end, the success of the project was ensured by honest communication between sponsor and the CRO and the development of a high degree of trust.

Some of the key success factors identified in these presentations included developing a clear understanding of joint expectations, frequent and open communication between sponsor and CRO data managers, developing and using standard documentation and templates, and sharing information on outsourcing experiences internally.

Advertising Opportunities

The SCDM plans to create advertising possibilities within ***Data Basics*** for vendors offering clinical data management services. Plans for advertising opportunities for job openings on the web page are also in the works. Details will follow in the near future.
Hint: Check out the SCDM web page!

Left to right:
G. Moody,
K. Konrad,
C. Cox,
C. Tattrie

Quality Management in CDM: Building and Ensuring Effective Processes

Moderator: Christine Tattrie, Manager, Clinical Data Services, Medical & Technical Research Associates, Inc.

Speakers: Colleen Cox, Data Analyst, Medical & Technical Research Associates, Inc.
Karl Konrad, Senior Medical Data Systems Analyst, Glaxo Wellcome, Inc.
Greg Moody, Versal Technologies

In this session, presenters discussed how the implementation of quality processes can save both time and money.

Colleen Cox presented "Enhancing Effectiveness and Efficiencies During the Transition of an Image-Based to a Facsimile-Based Data Management System." She described how a Task Force was established, consisting of individuals with both industry and data processing experience. The Task Force determined the workflow of the new system and the impact on users, including study coordinators. Many of the details regarding changes in case report form design were mentioned, including bar-coding and the need for cover pages for facsimile receipt. The validation process was also explained. The speaker emphasized the importance of maintaining and streamlining existing processes, as well as the importance of quality within the integration process.

Karl Konrad's talk, "Automating Data Clarification Reports in Four Weeks," focused on obtaining high value with limited resources. Karl described how his initial proposal to management was approved but with less resources than requested. He approached the problem by developing the system in Microsoft Access to realize substantial savings in both cost and time. The system benefits the Clinical Department in that they can easily see which queries are unresolved. Another bonus is that the queries are more accurate and legible than the previous hand-written ones. Karl estimated cost savings of the system to exceed $600,000 annually.

In the "Leveraging Technology to Perfect the Process" presentation, **Greg Moody** spoke about the importance of understanding both the problem and the current process in order to determine where efficiencies can be gained. He mentioned that not all forms of technology work effectively for all problems - it is imperative to know and understand how the proposed technology will assist in solving the current problem. Solutions typically do not address all of the issues, so it's important to prioritize the issues to ensure that most important ones are resolved. He also stressed the importance of training the users to understand the new technology, since that is a large factor in determining the success of new technologies.

Education Committee Update

The Education Committee is happy to welcome a new member, **Armelde Pitre** (Pfizer). This committee is having ongoing discussions on finalization of outlines for future tutorial offerings as well as ideas for workshops in the year 2000. Please forward any suggestions you have for future workshops and tutorials to Susan Bornstein (e-mail: **sbornste@mtra.com**).

Professional CDM Certification Committee Update

Look for information regarding the newly formed Certification Committee in subsequent issues of Data Basics. Please contact **Armelde Pitre** at **pitrea@pfizer.com** if you are interested in learning more about this new committee including opportunities for participation.

SESSION VII

Left to right:
N. Mulligan,
J. Hendricks,
A. Gibson III
Not pictured:
W. Kubrik

Standards Management in CDM

Moderator: Nancy Mulligan, Associate Director, Clinical Data Management, PPD Pharmaco, Inc.

Speakers: Arthur Gibson III, Senior Clinical Data Analyst, PPD Pharmaco, Inc.
Judi Hendricks, Contract Designer
Wayne Kubrik, PROsys LLC

This session opened with **Arthur Gibson** speaking on "Standards Management in CDM." Arthur stressed the importance of maintaining standards for training, documentation, and mentoring in organizations as they prepare for the challenges of the new century.

The second speaker was **Judi Hendricks** who presented "The Need for Standards in Forms Design." Her talk outlined the "do's and don'ts" when designing case report forms to maximize the efficiency of data capture.

This session ended with **Wayne Kubrik** presenting "Facilitating Clinical Development through Data Standardization: The CDISC Strawman Data Model for FDA Submissions." In this presentation, Wayne outlined the CDISC initiative, which is seeking to define a model for standardizing data transfers to the FDA.

DATA BASICS *Call for Articles*

The search continues…!

Please submit any articles, ideas, etc. for publication to the Editorial Board.

Editorial Board

Lana Turner, *Co-editor*
Pharmacia & Upjohn, Inc.
Phone: 616-833-0542
E-mail: lana.f.turner@am.pnu.com

Cathie Muza, *Co-editor*
Boston Biostatistics, Inc.
Phone: 508-416-2629
E-mail: cmuza@bostonbio.com

Tamela Blackstone
Pharmacia & Upjohn, Inc.
Phone: 616-833-0296
E-mail: tamela.a.blackstone@am.pnu.com

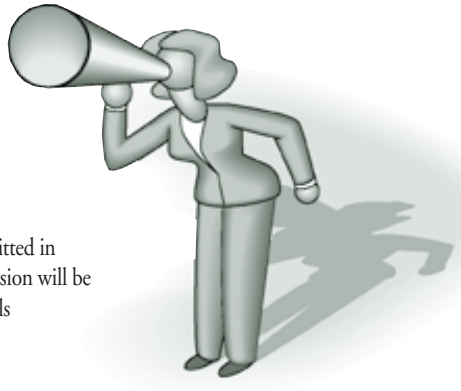
Frannie Rink
Wyeth-Ayerst Research
Phone: 616-341-5693
E-mail: rinkf@labs.wyeth.com

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

Publication Schedule

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

Volume 6, Issue #1 (Spring)	February 1, 2000
Volume 6, Issue #2 (Summer)	April 28, 2000
Volume 6, Issue #3 (Fall)	July 31, 2000
Volume 6, Issue #4 (Winter)	October 26, 2000



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.

SESSION VIII

Left to right:
S. Coull,
B. Caldwell,
K. Howard,
S. Prokscha

Developing a Global Database: People, Process, and Standards

Moderator: Brent Caldwell, Manager, Clinical Data Processing, Biometrics & Data Management, Boehringer Ingelheim Pharmaceuticals, Inc.

Speakers: Sonja Coull, Associate Data Management Coordinator, Merck Research Laboratories

Katherine (Kit) Howard, Manager, Standardization, Leadership & Advisory Team (SLATE), Warner Lambert Parke-Davis

Susanne Prokscha, Principal Consultant, PPD Informatics/Belmont Research, Inc.

This informative session concerned the development of a global database and cross-project standards.

The first presentation, "Managing Activities of a Global Database," was delivered by **Sonja Coull**. She discussed how the migration of legacy data into a new reporting database can be achieved by developing and following standards; by utilizing the appropriate team players; and by developing strategic processes. Since the mapping processes can be quite challenging, future business needs should be evaluated to determine what data are required for conversion and what data are not. Options for legacy data migration included specific conversion programs, as well as, the re-keying of data into a new reporting database.

Kit Howard highlighted the importance of cross-project standards, specifically, "Integrated Protocol Modules (IPMs): A Twist on Traditional Standardization," a standardization tool used at Warner-Lambert Parke-Davis to improve efficiency through reuse. Kit discussed the numerous study tools that were standardized (protocol, CRFs, database structures, derived fields, data entry screens, monitoring guidelines, edit checks, data listings & tabulations, summary tables, analysis plans and research reports). As a result of the broad scope of the standardization effort, multiple processes and departments are involved. The use of IPMs promoted planning, enhanced study quality, fostered teamwork in clinical development and reduced the time required for database development and database lock.

Susanne Prokscha discussed the necessity of "Creating A Global Database After A Corporate Merger." Susanne presented the options for a standard system, points to consider when selecting a standard system, options and considerations concerning standard data storage, what actually should be migrated to the global database, and how to build a team of individuals involved in standard system development. Implementation should be grounded in experience as opposed to theory and priorities should be set for items of greatest importance. Further, it is important to ensure participation of dedicated management, to be aware of political sensitivities inherent in corporate mergers, and to expeditiously create "living" standards that can be revised along the way.

2000 SCDM SPRING FORUM

Building Quality into the Process – From the Management Perspective

Sunday, March 19, through Tuesday, March 21, 2000

Wild Dunes Resort
Isle of Palms,
South Carolina

The Sixth Annual SCDM Spring Forum will bring together leaders in Clinical Data Management for two days of intensive roundtable discussions. The Forum, unlike the Fall Conference, is *limited to 60* attendees and is focused on a single topic considered to be both timely and of significant interest. This year we have selected *Building Quality into the Process.*

Session I: How do we balance quality vs timelines?

Session II: Setting Data Management standards – what do we standardize, why and how?

Session III: How does one lead an organization towards quality? What are the elements of a quality system?

Session IV: How do we enable quality when working across multiple sites? How do we harmonize across sites?

An expert in quality processes will be joining us on the second day.

We are honored to announce the facilitators for these discussions:

- Heidi Shea, Manager Data Management, Medical & Technical Research Associates, Inc.
- Joann Masi, Associate Director, Global CDM Training/Quality Evaluation, Wyeth-Ayerst Research
- Sharon Clay, Project Leader Training, TAP Data Management Services
- Delia Rasmussen, Section Head, Oncology, Clinical Data Management, Glaxo Wellcome, Inc.

Registration fee for the forum is $425.

Kristin O'Connor, Director, Data Management, Boehringer Ingelheim Pharmaceuticals (203-798-4244) is the 2000 Spring Forum Chairperson.

Golf anyone? If you and/or your guest(s) would be interested in participating in an afternoon of golf on one of the ***fabulous courses*** at Wild Dunes - either Sunday or Tuesday - please contact Frannie Rink (610-341-5693 or rinkf@labs.wyeth.com).

SESSION IX

Left to right:
M. Klepper,
G. Johnson,
M. Platt

Experiences with Implementing MedDRA and Other New Standards

Moderator: Merta Platt, Manager, Clinical Data Coordination, Pharmaceutical Research Associates, Inc.

Speakers: Michael Klepper, MD, Integrated Safety Systems, Inc.

Greg Johnson, Senior Systems Program Manager, Pharmaceutical Research Associates, Inc.

Dr. Michael Klepper presented "Experiences With MedDRA Implementation on Clinical Study Data." Dr. Klepper discussed the scope and structure of MedDRA, and clearly demonstrated how the use of MedDRA will result in changes to analysis and reporting of adverse event data by comparing the incidences of clinical study data coded with MedDRA 2.1 and COSTART 5. Emphasis was placed on the importance of collection of unambiguous data from the site, and the necessity for all MedDRA users to have full knowledge of the hierarchical structure of the dictionary. Company wide standardization and coding guidelines will be essential for successful MedDRA implementation.

Greg Johnson gave the last presentation of the conference entitled "Complying With New Industry Guidance on Computerized Systems Used in Clinical Trials." Greg provided an in-depth discussion on FDA guidelines released April 1999, concerning computer systems used to generate, collect, maintain, and transmit clinical data for the purpose of submission. He also outlined how the guidelines related to the FDA regulations on Electronic Records & Electronic Signatures section of 21 CFR. Particular emphasis was placed on how these guidelines and regulations effect data management in terms of SOP creation and compliance, security, and training.

SCDM Conference Sponsors

The Society for Clinical Data Management would like to gratefully acknowledge the support of this year's Fall Conference sponsors.

SPONSOR	ACTIVITY SUPPORTED
Amgen, Inc.	Tuesday Continental Breakfast
Boehringer Ingelheim Pharmaceuticals, Inc.	Tuesday Afternoon Refreshment Break
The Cambridge Group, Ltd.	Tuesday Morning Refreshment Break
Genentech, Inc.	Monday Morning Refreshment Break
Glaxo Wellcome, Inc.	Tuesday Luncheon
	Annual Business Meeting
Kendle	Monday Luncheon in the Exhibit Hall
Medical & Technical Research Associates, Inc.	Educational Program Co-sponsor
Oracle Corporation	Sunday Evening Welcome Reception
Parke-Davis Pharmaceutical Research	Wednesday Continental Breakfast
	Monday Afternoon Refreshment Break
Phase Forward, Inc.	Monday Continental Breakfast
Phoenix International	Educational Program Co-sponsor
Quintiles, Inc.	Monday Evening Cocktail Reception in the Exhibit Hall
	Conference Syllabus
Smith Hanley Consulting Group, Inc.	Signage
Winnertech Corporation	Monday Speaker Breakfast

1999 SCDM Fall Conference

Evaluation Survey Results

167 Responses
(approximately 50% response rate)

Session I: The Diversity of Roles in CDM

1. Presenter(s) - *speaking ability*	21% excellent	63% good	11% fair	0% poor	5% N/R
2. Presenter(s) - *subject knowledge*	33% excellent	58% good	4% fair	0% poor	5% N/R
3. Program content	23% excellent	57% good	15% fair	0% poor	5% N/R

Session II: The Organizational Impact of New Technologies and Processes

1. Presenter(s) - *speaking ability*	36% excellent	57% good	4% fair	0% poor	3% N/R
2. Presenter(s) - *subject knowledge*	49% excellent	46% good	2% fair	2% poor	3% N/R
3. Program content	45% excellent	46% good	6% fair	0% poor	3% N/R

Session III: Panel Discussion with Speakers from Sessions I and II

1. Presenter(s) - *speaking ability*	26% excellent	51% good	5% fair	0% poor	18% N/R
2. Presenter(s) - *subject knowledge*	30% excellent	48% good	4% fair	0% poor	18% N/R
3. Program content	27% excellent	47% good	6% fair	0% poor	20% N/R

Featured Speaker: Dr. W. Leigh Thompson

1. Presenter(s) - *speaking ability*	78% excellent	10% good	0% fair	0% poor	12% N/R
2. Presenter(s) - *subject knowledge*	70% excellent	18% good	0% fair	0% poor	12% N/R
3. Program content	54% excellent	30% good	4% fair	0% poor	12% N/R

Session IV: CDM in the Product Development Team: Challenges and Opportunities

1. Presenter(s) - *speaking ability*	20% excellent	56% good	9% fair	0% poor	15% N/R
2. Presenter(s) - *subject knowledge*	29% excellent	52% good	4% fair	0% poor	15% N/R
3. Program content	22% excellent	50% good	13% fair	0% poor	15% N/R

Session V: Effective Partnering with CROs

1. Presenter(s) - *speaking ability*	36% excellent	48% good	9% fair	0% poor	7% N/R
2. Presenter(s) - *subject knowledge*	43% excellent	45% good	5% fair	0% poor	7% N/R
3. Program content	38% excellent	45% good	10% fair	0% poor	7% N/R

Session VI: Quality Management in CDM: Building and Ensuring Effective Processes

1. Presenter(s) - *speaking ability*	28% excellent	51% good	7% fair	0% poor	14% N/R
2. Presenter(s) - *subject knowledge*	34% excellent	47% good	11% fair	0% poor	8% N/R
3. Program content	26% excellent	51% good	9% fair	0% poor	14% N/R

Session VII: Standards Management in CDM

1. Presenter(s) - *speaking ability*	19% excellent	46% good	16% fair	0% poor	19% N/R
2. Presenter(s) - *subject knowledge*	25% excellent	46% good	8% fair	2% poor	19% N/R
3. Program content	19% excellent	46% good	14% fair	2% poor	19% N/R

SESSION VIII: Developing a Global Database: People, Process and Standards					
1. Presenter(s) - *speaking ability*	40% excellent	39% good	3% fair	0% poor	18% N/R
2. Presenter(s) - *subject knowledge*	46% excellent	35% good	1% fair	0% poor	18% N/R
3. Program content	35% excellent	42% good	5% fair	0% poor	18% N/R
SESSION IX: Experiences with Implementing MedDRA and Other New Standards					
1. Presenter(s) - *speaking ability*	51% excellent	21% good	0% fair	0% poor	28% N/R
2. Presenter(s) - *subject knowledge*	53% excellent	19% good	0% fair	0% poor	28% N/R
3. Program content	48% excellent	23% good	1% fair	0% poor	28% N/R
NETWORKING EVENTS					
1. Gala Welcome Reception	39% excellent	27% good	5% fair	0% poor	29% N/R
2. Luncheon in Exhibit Hall	13% excellent	38% good	24% fair	14% poor	11% N/R
3. Cocktail Reception in Exhibit Hall	20% excellent	36% good	10% fair	2% poor	32% N/R
EXHIBIT HALL					
1. Rating	22% excellent	54% good	11% fair	0% poor	13% N/R
FAIRMONT HOTEL					
1. Food	45% excellent	39% good	6% fair	0% poor	10% N/R
2. Service	56% excellent	25% good	8% fair	1% poor	10% N/R
3. Accommodations	51% excellent	23% good	6% fair	0% poor	20% N/R

SUGGESTIONS FOR TOPICS FOR FUTURE PROGRAMS

1. Session on new databases that are currently hot in the industry and company experiences with them
2. Further discussions of the skill set needed for the future CDM
3. Session on lab values
4. Session on the different perspectives of management in data management
5. Implications of MedDRA implementation on data management
6. Developments in professional certification of CDM
7. Presentation on Oracle Clinical
8. CDM and stress management
9. SAE reconciliation process/procedures
10. Market value of CDMs
11. How do we keep our people motivated
12. Data management terminology: can we develop a standard glossary
13. Differences in data management: Pharma vs CRO vs Biotech
14. Panel discussion on effective partnering with CROs

Calendar of Events

March 19-21, 2000
Spring Forum
Wild Dunes Resort
Isle of Palms, South Carolina

October 15-18, 2000
Fall Conference
Crystal Gateway Marriott
Arlington, Virginia

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

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

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

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

September 21-25, 2003
Fall Conference
Cheyenne Mountain
Conference Resort
Colorado Springs, Colorado

October 10-14, 2004
Fall Conference
Royal York Hotel
Toronto, Canada

continued from page 5

Annual SCDM Business Meeting Summary

Pat Teden congratulates Ken Buchholz upon his completion of term on the Board of Trustees. Ken served as Vice-Chair and Chair during his term.

Frannie Rink receives congratulations from Pat Teden. Frannie served as Board Secretary and Co-editor of *Data Basics*.

Technology Committee: **Ken Carlson** presented the charter of this committee, and reported that he is serving as the Chair until one can be identified. This committee is also looking for additional members.

Good Clinical Data Management Practices (GCDMP) Committee: **Meredith Nahm** presented the charter of this committee, and described several of the core processes of CDM they will be documenting and delivering.

Next, newly elected and appointed Board of Trustee members were announced. These included **Annette Schmit** (appointed, Treasurer), **Cathie Muza** (appointed, *Data Basics* Co-editor), **Brenda Hoeper**, **Karen Klingler**, and **Hugh Donovan** (all elected). New officers were announced including **Doug Schantz**, Vice Chair, and **Becki Filice**, Secretary. Special thanks were given to retiring Board of Trustee members: **Ken Buchholz**, who moves to Past-Chair, **Ron Copp**, who served as Treasurer, **Frannie Rink**, who served as Secretary and *Data Basics* Co-editor, and **Kristin O'Connor** who leaves the Board, completing her Past-Chair term. Appreciation was also given to Frannie Rink for the successful 1999 Spring Forum which she chaired, to **Ken Carlson** and **Becki Filice** as Co-chairs of the 1999 Fall Conference, and to **April Pennacchio** of Professional Management Associates for her support of these successful SCDM forums.

The meeting progressed with announcements regarding the 2000 SCDM events: the Spring Forum (by **Kristin O'Connor**) and Fall Conference (by **Ken Carlson**). Also, a raffle was held for those joining/renewing SCDM memberships for 2000. DLB Systems and DZS Software Solutions sponsored Iomega Zip Drive prizes, won by **Kristan Gallitano** and **Judy Kasperczyk**. Domain Pharma Corporation and Cost Management Incentives sponsored Palm Pilot V prizes, won by **Benjamin Cardenas** and **Juanita Garcia**.

Finally, **Christine Tattrie** and **Doug Schantz** presented the SCDM Web Site to the membership. They discussed the purposes for SCDM's presence on the web: recruiting opportunities, communication outreach to members and useful links to data management related sites. A live demonstration followed which was met with considerable approval by those present.

Good Clinical Data Management Practices (GCDMP) Committee Update

The purpose of this committee is to draft Good Clinical Data Management Practices and to monitor regulatory information regarding Clinical Data Management (CDM) and communicate the information to SCDM through *Data Basics*.

The committee has been working diligently and has established a list of regulations, guidance and reference documents related to CDM, confirmed that there is no guidance directly relating to many common CDM tasks, and produced a list of core CDM processes (see list below) not covered under current guidance documents.

The committee met at the SCDM Fall Meeting in Chicago, IL and compiled key points and quality markers for each of the core CDM processes. At the Annual Business Meeting on September 28, 1999, the committee announced an aggressive timeline to have a first draft of the Good Clinical Data Management Practices by the end of November 1999, and asked for volunteer reviewers from the Society. Over 40 people volunteered! The committee is currently working on the first draft and is looking forward to responding to the comments and representing the thoughts and ideas of the SCDM membership to promote industry wide Good Clinical Data Management Practices.

Committee Members:
Allan Burek
Debra Corak
Wendy Cuthbert
Kaye Fendt, Board Liaison
Angel Lazarou
Jennifer Manski
Meredith Nahm, Chair
Barbara Tardiff
Lisa Zimmerman

Core CDM Processes Created Using the CDM Task List

Published in Data Basics (Volume 5, Number 3, Fall 1999)

Data Acquisition

- Data Collection Tool Design (paper)
- Data Collection Tool Design (electronic)

Data Storage

- Database Structure Specification
- Forms Management
- Data Archival (paper & electronic)

Data Processing

- Forms Processing
- Data Entry
- Coding
- Cleaning (manual clinical review & programmatic checks)

Data Validation

- Design of Data Validation Strategy
- Specification of Design

Lab, Safety Reporting and Other External Data

- Data Transfers and Loads
- Database Reconciliation

Data Quality

- Auditing
- Quality Control Procedure
- Statistical Sampling
- Quantification of Database Quality

Database Closure

- Lock Criterion & Approval
- Breaking the Blind
- Handling of Post-lock Errata

Vendor Management

- Vendor Selection
- Vendor Monitoring

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.

The Society For Clinical Data Management, Inc.
c/o Professional Management Associates, LLC
203 Towne Centre Drive
Hillsborough, NJ 08876
Phone: 908-359-0623
Fax: 908-359-7619
Email: profmgmt@blast.net

1999 SCDM Fall Conference Syllabus

Attendees at the SCDM 1999 Fall Conference received a conference syllabus containing copies of speaker handouts, speaker bios, exhibitor and attendee registration list, etc.

We have a limited number of extra copies available for $25.00 (the cost of printing), plus shipping. To order your copy, contact Linda Fan at SCDM at 908-359-0623 or by email at profmgmt@blast.net.

S C D M
S C D M
S C D M
S C D M

Society for Clinical Data Management, Inc.
203 Towne Centre Drive
Hillsborough, NJ 08876

PRESORTED
FIRST-CLASS MAIL
U.S. POSTAGE PAID
DAYTON, NJ
PERMIT NO. 19