

DATA BASICS

Volume 6
Number 1
Spring 2000

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



From the Editors

Well, we all survived Y2K! This looks to be another great year for SCDM as you will see in this issue of

Data Basics. Check out the article on “Clinical Data Management – The ‘Other’ Clinical Profession or SCDM: Why Bother?” to find out the Board of Trustees’ view. Don’t miss the calls for Board of Trustees nominations and session chairs, presenters,

sponsors, and exhibitors for the 2000 Fall Conference, which looks to be another exciting meeting. Reports from the Membership Committee show continued growth with 1245 members and growing! The Certification Committee’s efforts are also highlighted in this issue. Don’t miss the update on our new web site and the invitation to set up links in support of SCDM.

Enjoy!
Cathie and Lana

Clinical Data Management – The “Other” Clinical Profession — or — SCDM: Why Bother?

Did you ever wonder why the SCDM exists or what the SCDM Board of Trustees does? Let’s address the latter question first. The BOT (an annoying acronym we’ve gotten in the habit of using) just concluded a two-day strategy meeting so it is a good time to tell you a little about how the BOT operates. With luck this might inspire you to respond to the call for nominations for this year’s election of new BOT members (see page 6 of this issue). At a minimum, we hope you will send comments and suggestions to the BOT via the SCDM web site.

The SCDM is young, growing, and dare-I-say dynamic organization dedicated to clinical data management. Its Board has twelve members serving rotating terms of various lengths (typically three

years). The heart of the SCDM is the committee structure comprised of scores of members who define and execute the various SCDM initiatives. The SCDM Bylaws state that the BOT will meet four times a year – an expectation exceeded by the occasional additional teleconference. Most meetings are one day in length, and two of the four meetings are held in conjunction with SCDM conferences. For the past three years, BOT members

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found the time to start the year’s work in a two-day strategy session.

The two-day meeting allows new BOT members the time to get comfortable with the scope of SCDM activities (there are at least 3 new members each year due to the rotating term scheme of the BOT). It allows all BOT members to get to know each other (teamwork, teamwork). The BOT uses this meeting as an opportunity to try out locations for future SCDM conferences (nobody said being on the BOT was

hardship duty!). And it allows the BOT to ask existential questions such as “SCDM: Why bother?” and “How are we doing?” to paraphrase former NYC mayor Ed Koch.

In early February, BOT members met for two days within the splendor of a conference center built on the site of a tobacco baron’s mansion in North Carolina. And we did the following:

- Conducted the requisite BOT business meeting. Business items range from the mundane, such as reviewing the year 2000 contract for services from the PMA, to the far more interesting, such as reviewing the work accomplished by the CDM Professional Certification Committee and the committee defining Good Clinical Data Management Practices. If you read *Data Basics* cover-to-cover (which we all do!), you know the ever-increasing number of initiatives sponsored by our professional organization.
- Discussed those pesky existential questions.

So why does the SCDM exist? Why do twelve members of the pharmaceutical industry spend their time supporting the SCDM Board of Trustees, and scores of SCDM members spend time, talent, and energy participating at a variety of levels?

The current BOT members felt the SCDM was important because the profession of clinical data management needs an organization that recognizes our profession in ways that the broader industry groups do not. It serves as a focal point for data managers to get to know other CDM professionals outside of their own corporation, and for data managers to signal the importance of the function to colleagues, especially “upper” management. The SCDM is a vehicle for data managers and the FDA to interact. Opportunities for career development by **contributing** to the industry are plentiful. The SCDM has been successful in clearly defining data management, and continues to design programs that advance the profession.

How is that for a *raison d’être*? Worth the mere \$45 annually to support and to participate in the SCDM? Worth your own time and talents spent as a member of the Board of Trustees? The BOT would love to know your views.

On behalf of the current SCDM Board of Trustees,

*Patricia Teden,
Chair of the SCDM
Board of Trustees, 2000*

SCDM: Why bother? How are we doing?

Let the BOT know what you think by responding to this article on the www.scdm.org site. Responses will be summarized and posted on the web site in the future.



Membership Committee Update

The membership committee has been in existence for about 2 years. Members include:

- Pam Adkins (*Clinical Trials Support Services*)
- Catherine Celingant, Chair (*Genetics Institute*)
- Bonnie Featherstone (*Independent*)
- Carol Nelson (*Merck & Co.*)
- Marianne Plaunt (*STATPROBE*)
- Lynn Searles (*Pharmacia & Upjohn*).

Pat Teden was the committee's liaison to the SCDM Board of Trustees until her recent election as Board Chair and has now been replaced in this capacity by Hugh Donovan (Aventis). We wish to take this opportunity to thank Pat for her continuous support, unfailing energy, and good ideas during the committee's start up phase! Linda Fan from PMA, SCDM's administrative support organization, assists the committee with logistics.

The objective of the committee is to recruit and retain CDM professionals as active members of the Society. To this end, the committee has set two goals:

- 1) To identify the needs of the membership and ensure that the Board of Trustees is responsive to them.
- 2) To increase the Society's membership by 20% annually over the next three years by aggressive and innovative recruitment campaigns and by reducing membership turnover.

The committee went to work on its first goal in the summer of last year by sending a survey to all members. The purpose of the survey was twofold: to gain a better understanding of our members and to identify their needs and expectations with respect to the Society. The results of this survey (published in the Summer 1999 issue of *Data Basics*) are being used to plan

conferences and future services. Main areas of interest emerged as noted in the *Data Basics* article, namely:

- Training, in particular certification of Data Management Professionals
- Creation of an SCDM web site.

We are pleased to report progress in each of these areas.

An active and enthusiastic Certification Committee has recently been established. One of their deliverables is to set quality standards for training programs. Arnelde Pitre (*Pfizer*) chairs this group and its work will be described in detail in a future edition of *Data Basics*.

The SCDM web site (www.scdm.org) came on line in September of 1999 thanks to the diligence of the Web Site Committee (Christine Tattrie, Chair, Nick Stamos and Doug Schantz). The purpose of the site is to provide the SCDM membership with access to the organization through contacts, program information and publications. The site also provides data management-specific links to web sites. Dave Fielding has joined the committee recently and

Sandy Ricciardi joined late last year to serve as the Web Master. Plans being considered for 2000 include job postings, announcements and advertising. We are looking forward to making the SCDM web site a place that the membership will want to visit frequently.

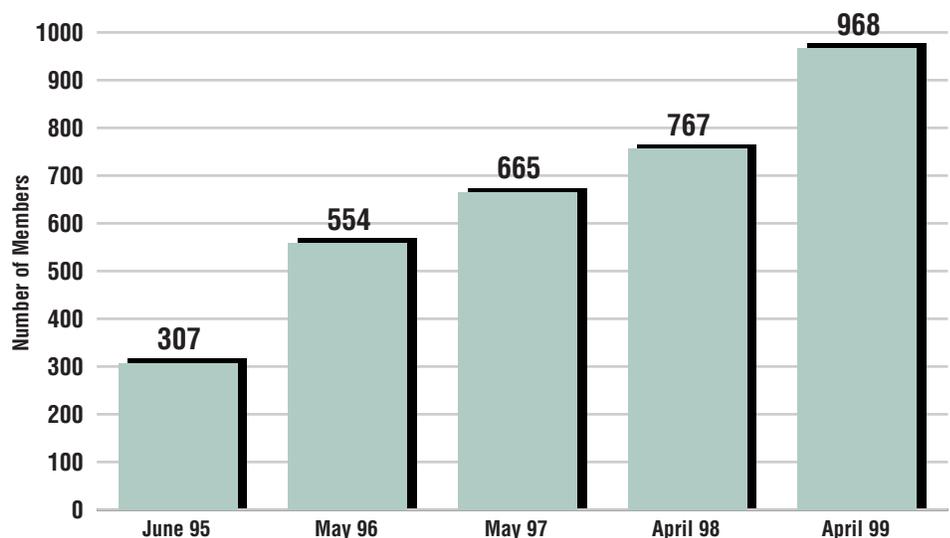
So, as you can see, your voice is being heard.

The committee has also been very active with various recruiting campaigns (free-standing or in conjunction with membership renewal mailings) to increase the visibility of the Society, especially in under-represented segments of our industry, such as contract research organizations and the vendor community.

The committee also worked with the web site development taskforce to give input on desirable features and suggest links. Reciprocal links have now been established with some key organizations and others are in the works.

To reduce turnover the committee issues regular renewal reminders to the existing membership and this year will be using e-mail for this purpose for the first time. If all else fails, we will

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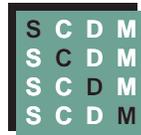
Membership Committee Update continued from previous page

attempt to make direct contact by phone with individuals.

We are currently in the midst of the 2000 membership renewal period. The committee is happy to report a 26% increase in membership between April 1998 and April 1999 (close of the renewal period). The figure on previous

page shows growth in membership since the Society was founded. As of January 24, 2000, the Society had 1,245 members.

If you have ideas about how SCDM could better serve its members or could increase membership, please contact Catherine Celingant at 617-876-1170 or ccelinga@genetics.com.



SCDM Membership by Country

(as of January 24, 2000)

United States	1206	Pennsylvania	209
Arizona	1	Rhode Island	1
California	131	Tennessee	6
Colorado	6	Texas	45
Connecticut	52	Utah	2
Delaware	39	Virginia	12
District of Columbia	1	Washington	15
Florida	13	Wisconsin	2
Georgia	5	Canada	29
Illinois	63	England	10
Indiana	10	TOTAL	1245
Kansas	26		
Kentucky	2		
Massachusetts	106		
Maryland	23		
Michigan	74		
Minnesota	3		
Mississippi	2		
Missouri	24		
North Carolina	83		
Nebraska	1		
Nevada	2		
New Jersey	184		
New York	41		
Ohio	22		



Call for Advertising Business Manager

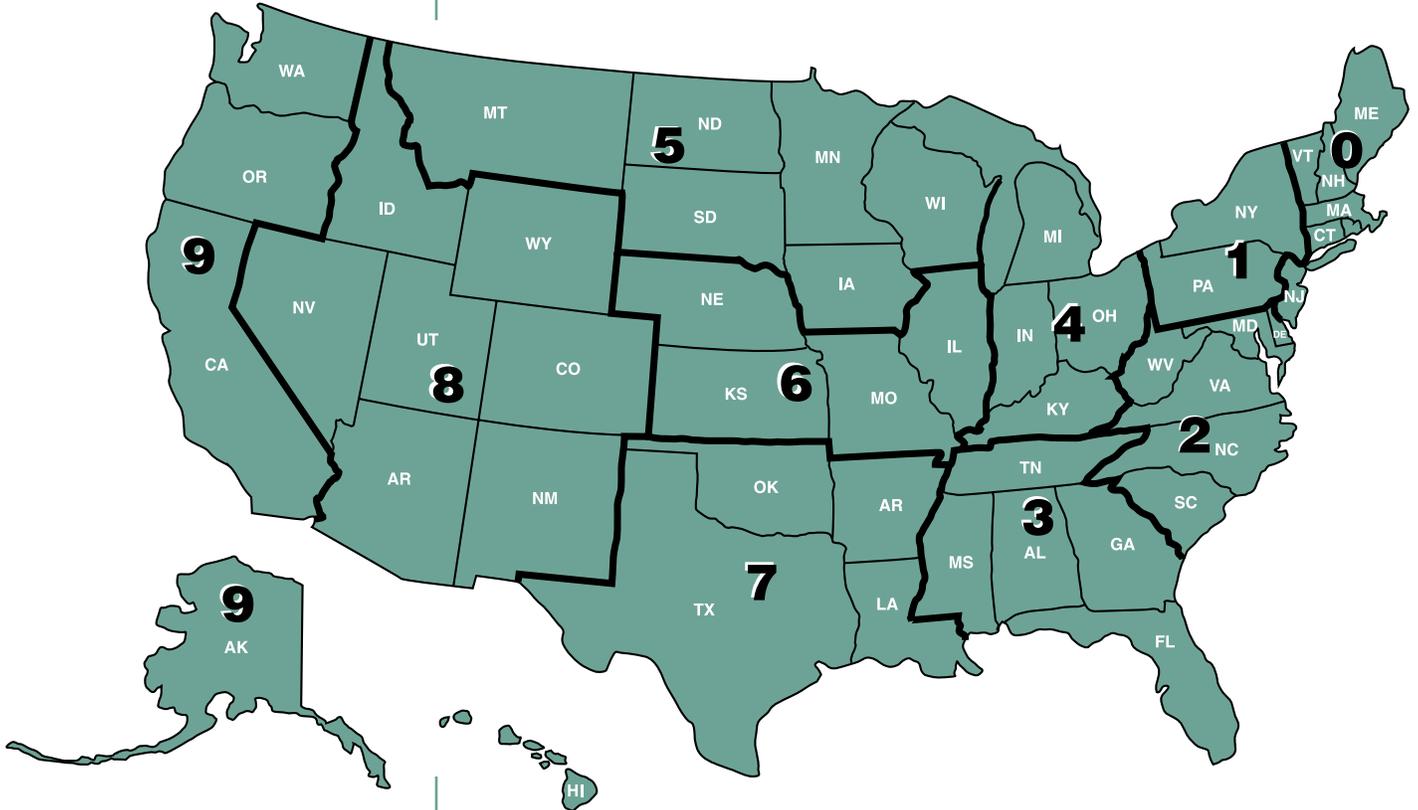
Is anyone interested in becoming a member of the Editorial Board as the Advertising Business Manager for *Data Basics*? We are looking for a volunteer to coordinate the advertising requests and submissions soon to be coming to *Data Basics*. If you are interested in this opportunity or would like more details please contact Cathie Muza via phone 508-416-2629 or e-mail (cmuza@bostonbio.com).



United States SCDM Membership

(as of January 24, 2000)

Total Members: 1206



Note: Numbers on map represent first digit of zip code

Zone 0:	343	Zone 5:	5
Zone 1:	289	Zone 6:	114
Zone 2:	119	Zone 7:	45
Zone 3:	26	Zone 8:	11
Zone 4:	108	Zone 9:	146



Call for Nominations – SCDM Board of Trustees

Volunteers from the SCDM membership are being sought who are interested in lending their time and expertise by becoming a Board member. Three Board members are completing their terms in the fall of this year.

As defined in the Society's Bylaws, the Fall Conference marks the terms of service of Board members and officers. Board members begin and conclude their tenure as of this meeting. The current Board creates a slate of candidates and considers geographic, corporate and membership representation when creating the slate of nominees to assure that the SCDM membership has a large cross-section from which to elect Board members. The SCDM membership vote on the nominees via mail-in ballot.

The Board would like the general membership's involvement in identifying candidates to fill the three vacancies. Interested individuals may nominate themselves or others by letter, fax (908-359-7619) or e-mail (april@profmgmt.com) to SCDM by April 14, 2000.

It is important for Board members to have their employer's commitment in terms of time and money. The responsibilities of a Board member include attendance at four meetings each year (two of which coincide with the Spring Forum and the Fall Conference) plus a variable amount of time to conduct SCDM work. Board members or their employers pay for travel and lodging costs associated with attending Board meetings.

Questions regarding this process should be directed to Doug Schantz, SCDM Vice Chair (douglas.schantz@wl.com).



Update your e-mail address!

It is important to update your e-mail address with PMA because you wouldn't want to miss the timely information that is periodically sent. Just drop them a note at profmgmt@blast.net.

Call for Session Chairs, Papers, Sponsors, and Exhibitors for the Fall Conference



The State of Clinical Data Management as the Millennium Unfolds

As we look back to the success of the 1999 Fall Conference, we can only look forward to the upcoming 2000 Fall Conference with great anticipation. 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 either as Session Chairs or as Presenters. We are also seeking Companies who want to sponsor events or exhibit at the conference.

Session Chairs play a key role in shaping the conference, as they select the speakers who will present in their session. Presenters are equally key to a successful conference, as the attendees walk away with the information from their talks.

SESSIONS ARE PLANNED IN THE FOLLOWING AREAS:

- Measuring Timeliness, Quality and Productivity in CDM
- New Technology in Support of CDM
- Innovative Approaches to Capturing Data without CRFs
- Developing, Training, and Motivating People to Excel in CDM
- Novel Processes in Support of CDM
- Working with CROs and Vendors
- Regulatory Considerations in CDM
- Collecting and Processing Laboratory Data
- State of the Art in Coding of Clinical Data

Individuals who are interested in the role of Session Chair should contact one of the conference Co-chairs, as outlined below. Individuals who would like to present should

send a brief 2-3 paragraph abstract summarizing their proposed paper to one of the conference Co-chairs.

Conference Co-chairs:

Ken Carlson, Pfizer

Phone: 212-573-7985

e-mail: carlks@pfizer.com

Jean Mazalewski, Novartis

Phone: 973-781-8475

e-mail: jean.mazalewski@pharma.novartis.com

Companies who are interested in sponsoring events at the Fall Conference or exhibiting should contact April Pennacchio at SCDM's administrative offices:

203 Towne Centre Drive

Hillsborough, NJ 08876

Phone: 908-359-0623

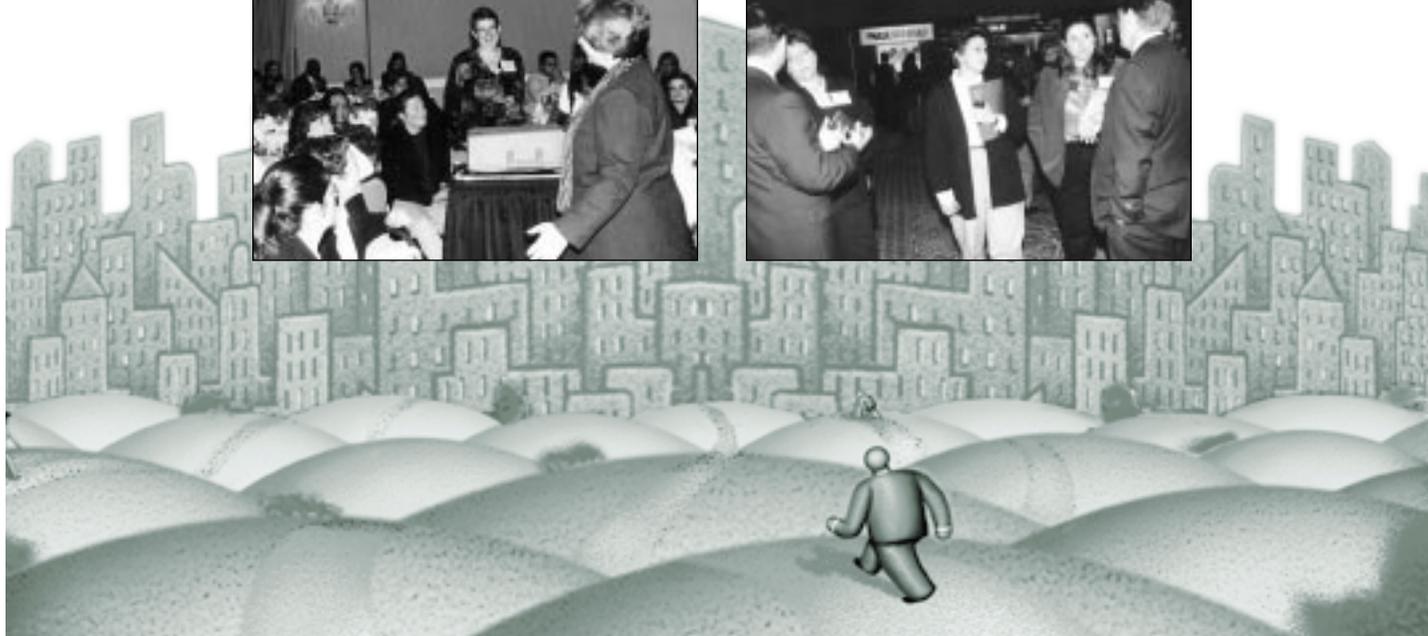
e-mail: april@profmgmt.com



The 1999 Fall Conference

A Photo Essay

The following are some photographs taken during the Fall Conference sessions, break periods, business meeting and vendor exhibits.



DATA BASICS

Call for Articles

The search continues...!

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



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PUBLICATION SCHEDULE

*Our quarterly publication schedule for the next 3 issues
requires the following input deadlines:*

Volume 6, Issue #2 (Summer)	April 26, 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.

SUGGESTED CLINICAL DATA MANAGEMENT READING LIST

*If you want to make God really laugh,
show him your business plan:
the 101 universal laws of business*

by Barry J. Gibbons,
former Chairman and CEO of Burger King.
Read any good CDM articles or books lately?

Please submit suggested reading to
the Editorial Board.

Web Sites to Check Out

ACDM
<http://www.acdm.org.uk>

CDISC
<http://www.diahome.org/cdisc>

FDA guidance
<http://www.fda.gov/cder/guidance>

ICH guidance
<http://www.ifpma.org/ich1.html>

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.

Calendar of Events

March 19-21, 2000

Spring Forum
Wild Dunes Resort
Isle of Palms, SC
*Building Quality Into the
Process – From the
Management Perspective*

October 15-18, 2000

Fall Conference
Crystal Gateway Marriott
Arlington, VA
*The State of Clinical Data
Management as
the Millennium Unfolds*

March 18-20, 2001

Spring Forum
The Tremont House Hotel
Galveston, TX

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

September 21-25, 2003

Fall Conference
Cheyenne Mountain
Conference Resort
Colorado Springs, CO

October 10-14, 2004

Fall Conference
Royal York Hotel
Toronto, Canada



The SCDM Web Site:

www.scdm.org

Our web site displays a range of data management-specific information including general details about SCDM, upcoming events, links to web sites and the latest version of *Data Basics*. We hope the web site proves to be a key source of interest for SCDM members and that you'll bookmark it as one of your "favorites" on your web browser. Please visit the web site frequently and keep up with the latest events and information on SCDM. We welcome input and suggestions for enhancements. There is a feedback form available on the web site so please feel free to send us your comments. You can also use the web page for e-mail links to the various SCDM Board of Trustee members and committees. If you have a web site and would like to support SCDM you are invited to place a link on your web site to SCDM. Contact Doug Schantz (douglas.schantz@wl.com) for more information. Check it out!



Professional CDM Certification Committee Update

GCP requirements, sections 5.4.1 and 5.4.2, specify that the “sponsor should utilize qualified individuals...throughout all stages of the trial process...” How does the pharmaceutical industry demonstrate the qualification of clinical data managers? This question poses a challenge for many in the industry.

Take a look at clinical data manager’s starting point. Many clinical data managers enter the workforce through various career and education avenues. They achieve their training and education via numerous and diverse routes. While there are numerous training and education programs available, none of these programs are officially recognized by SCDM. SCDM has recognized and embraced the challenge by forming a new committee to investigate and implement a single standard measure of excellence in clinical data managers. This new committee has held some interesting teleconferences on the topic of certification.

Regulatory requirements notwithstanding, in today’s world, where competition is a fact of life and the need for a work force proficient in the principles and practices of clinical data management is a central concern of many pharmaceutical companies and contract research organizations, certification is a mark of excellence. It demonstrates that the individual has the knowledge to assure quality of products and services. Certification is an investment in your career and in the future of your employer.

Certification will provide formal recognition by SCDM that an individual has demonstrated proficiency and possesses comprehension of a specified body of knowledge. SCDM certification is a mark of career excellence that affirms an individual’s commitment to quality and demonstrates expertise and knowledge of state of the practice. Equally important, it is formal acceptance and recognition from an individual’s peers.

Watch *Data Basics* for updates on SCDM’s work in professional certification. Please contact Armelde Pitre at armelde_pitre@groton.pfizer.com if you are interested in learning more about this new committee.





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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