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DATA BASICS

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

From the Editors

We have an exciting issue this summer! The 2001 Spring Forum was a big success and the session chairs have created nice summaries for those of you unable to attend! You will find the next article in our series of "Other Data Management Organizations" highlighting our counterparts "down under", along with a very enlightening article on "The HHS New Data Privacy Ruling". Make sure you check out the article on "Quality Control in Data Management". We think you will find it very helpful! Finally, there is another update on the latest CDISC happenings!

Regards,
Cathie & Tam

THE 2001 SCDM SPRING FORUM

CLINICAL DATA MANAGEMENT AS A PROFESSION

The Tremont House, Galveston Island, Texas

It seems fair to say the Spring Forum this year was a success: good attendance, lively discussions, and great camaraderie. The attendees all had a genuine interest in the two significant SCDM projects discussed: the Good Clinical Data Management Practices (GCDMP) and the development of a CDM Professional Certification program.

For those of you who have never been to Galveston, the town is lovely. It has a wonderful vacation/beach atmosphere mixed with Southern charm. The Spring Forum started with a social event on Sunday night in one of the town's mansions called the Ashton Villa. The group participated in a tour of the mansion, which highlighted the history of the fairly quirky family who built the villa in the mid-1800s, as well as information about the hurricane in 1900 that did so much damage and caused huge losses of life in Galveston. Dinner at the Ashton Villa followed the stories and tour.

The Spring Forum program was similar to past forums. Each session had a facilitator who FACILITATED the discussions in which all attendees participated. This is an active and interactive conference, which might account for the great spirit of camaraderie that develops among the participants. Positive conference evaluations attest to the support by our membership of the Spring Forum format. Comments such as: "Good group size", "Limiting number of attendees is an excellent idea", "Very professional group of people", "Lots of good discussion and good integration of topics" make clear that the SCDM membership has a need for these working sessions.

Four sessions were held on Monday. Two focused on the

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THIS ISSUE

Calendar of SCDM Events

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

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

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

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

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

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

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

CLINICAL DATA MANAGEMENT AS A PROFESSION

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future development of the GCDMP and were led by Christine Little, Anthony Costello and Kaye Fendt. The other two sessions evaluated the development of the Professional Certification Program and were led by Judy Pyke and Armelde Pitre. Two sessions were held on Tuesday. The first session was led by Karen Klingler, Imogene Grimes, Meredith Nahm and Armelde Pitre and tackled whether clinical data managers needed a Code of Ethics and what might be included in a Code of Ethics. The last session, the Wrap-up, was led by three past Chairpersons and the current Chairperson for the Board of the SCDM: Ken Buchholz, Kristin O'Connor, Doug Schantz and me. Participants focused on determining the impact the two efforts might have on our profession and we highlighted implementation issues.

The articles that follow summarize the discussions that took place at March. I hope you take the time to read the articles and to think through the same issues alone or with work colleagues. The two programs discussed during Spring Forum 2001 will have significant impact on our professional lives!

I want to thank Christine, Kaye, Anthony, Judy, Armelde, Meredith, Karen, Imogene, Ken, Kristin and Doug for a job well done. All of the facilitators at this event make very significant contributions to the SCDM through the committees working on the GCDMP and Certification Programs. It is a testament to their excitement about these two programs that they also found the time to facilitate this event. Thanks also to April Pennacchio of the PMA, who, once again, treated us to a well-organized meeting.

It is not too soon to pencil the next Spring Forum in your calendars. It will be on March 10 – 12, 2002 in Fort Lauderdale, Florida. The topic is great: Successful Data Management Technology Implementation. Be there and share!

Patricia Teden, Program Chair

Participants working to identify "How much experience is needed?" during Certification session.

Opportunities for relaxation and networking with SCDM colleagues.

2002 Spring Forum

Radisson Bahia Mar Beach Resort
Fort Lauderdale, Florida

March 10 – 12, 2002

Successful Data Management Technology Implementations and How You Get There!

Dinner with Panel Discussion (EDC Vendors)

Keynote speaker:
Data Warehousing/EDM/Integration Systems/Portals

Workshop:
How to Develop a Vendor Software Selection Questionnaire

3 break out sessions

EDC Implementations

Integration Electronic Data (labs, diaries, MRI, BMD, etc.) and other technologies (data warehouses, data review tools, autoencoders)

Implementing standards — global library — roles and responsibilities of creating and maintaining standards

Call for Breakout Session Facilitators:

If you are interested in facilitating one of the three breakout sessions, contact Susan Bornstein at 781-681-2371 or susan.bornstein@serono.com.

Annual SCDM Business Meeting at Fall Conference

Call for Agenda Items

The Annual General Meeting of SCDM will be held during the 2001 Fall Conference in September. Please submit topics for discussion for the business component of this general meeting to April Pennacchio, PMA (e-mail: april@profmgmt.com).

Calendar of ACDM Events

June 27-28, 2001
Workshop on Computer System Validation in Clinical Research
Burnham Beeches Hotel
Burnham Beeches, UK

July 4, 2001
Developing and Assessing Personal Skills in Data Managers
Senior Clinical Data Managers' Forum
Commonwealth Institute, London, UK

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.

Judy Pyke, Asst. Director, CDM, Kendle International

CDM Professional Certification: Issues with Testing for CDM Competence

Facilitator:
Judy Pyke, Kendle International, Inc.

Introduction

The session started with a summary of the two main deliverables by the Certification Committee during its first year. First was the creation of the definition of certification at two experience levels of a Certified Professional CDM (see Summer 2000 issue of Data Basics). Second was the development of a matrix of competencies based on the SCDM approved list of Data Management tasks, and the survey conducted at the SCDM 2000 Fall Conference to determine which competencies were part of the job of a CDM or Senior CDM within each individual's organization.

A list of background assumptions was then presented:

1. Testing is the most widely used and generally accepted method of determining skills and technical capability.
2. A certification test's most important criteria are validity, reliability and lack of bias.
3. Changes in the field dictate that the test be reviewed and updated periodically.
4. A certification test should be offered in such a way that anyone who wants to be certified has access to it.
5. Scoring of a certification test should be objective and fair.
6. Maintenance of certification status is achieved through continuing education (per above cited definition).
7. A CDM's certification status must be readily available to certificants and hiring managers.
8. The creation and maintenance of a certification database provides the best access to certification status.

Session Questions

The participants were divided into five groups, each with questions related to one of the five following topics:

Creation and Maintenance of a Test

- How should the test be created? By whom?
- How should the test be kept up-to-date? How often should it be updated?

Administration of the Test

- What are possible ways of administering the test? Is there a best way?
- How frequently should it be administered?
- Should there be a charge?
- Should there be a limit on the number of tries to pass it?

Scoring of the Test

- How should the test be scored? What will the applicant take away?
- What should be a "passing" score? Who should determine this?
- How will "niche" data management responsibilities be fairly recognized?

Maintenance of Certification

- At what frequency should certification be renewed?
- Who should determine what constitutes continuing education? Will CEUs be required?
- How much continuing education should be required?
- Will companies support the acquisition of continuing education in their budgets?

Availability of Certification Results

- What information should be in a database related to certification?
- Who will supply the data?
- Who should be able to access the data?
- How will the data be accessed?

The groups answered these questions to present back to the rest of the participants of the session. The groups could challenge the stated assumptions if they chose.

The ideas presented by the groups, and during the ensuing discussion of the other participants in the session, are being consolidated by the Certification Committee now to guide the direction of their activities.

Armelde Pitre, Sr. Assoc. Director, Pfizer, Inc.

Issues with Assessing Qualitative Factors for CDM Competence

Facilitator:
Armelde Pitre, Pfizer Global Research and Development

Objective

To identify the key qualitative factors that will be assessed when CDMs present themselves for certification and to develop the assessment criteria. Forum attendees were asked to contribute to the certification development process by offering their experience and opinions on a number of issues being addressed by the certification committee.

Introduction

During the 2000 Spring Forum, participants contributed to the certification committee's work by helping to define the requirements for Certified CDMs and Certified Senior CDMs. These requirements included an assessment of prior relevant education and work experience, ongoing training and education, and a special requirement for Certified Senior CDMs to make industry contributions. During the 2001 Spring Forum, participants were provided with the results of job analysis and a summary of what other professional organizations are doing with respect to the requirements listed above. Participants were asked to provide their input on both these requirements and the process for applying the requirements. The specific questions debated are listed below.

Session Questions

How will we measure the quality of education and past work experience? A formal application process is required for all certification processes both within and external to the pharmaceutical industry. This process usually includes an assessment of prior work experience for relevancy as well as the requirement for certified professionals to hold a relevant education degree. These two requirements (relevant work experience, relevant education) serve a couple of purposes. First, it helps promote the image of certificants as highly trained professionals. Second, it is based on the assumption or generalization that the degree holder possesses certain critical technical skills and other skills such as: research, critical thinking and analysis, and composition/writing. Although, it is acknowledged that these skills are not always present in degree holders and that there are other ways of acquiring these skills, it is believed that these assumptions usually hold true.

CDMs enter the profession from myriad backgrounds. Additionally, formal degree programs for CDMs do not exist. Therefore, the acceptance of a degree in a related field must be considered. Yet, is a degree in public health or nursing considered relevant? Is a degree in Computer Science relevant? While these degrees might be considered relevant, the relevancy depends on the nature of the CDMs current assignment. Additionally, many CDMs do not have a degree. Does this mean that many of these highly competent professionals will never achieve certification? CRAs, study coordinators, and project managers have similar issues, and therefore developed a 'sliding scale' approach to this problem. The sliding scale approach permits substitution of work experience for a degree.

The consensus among Spring Forum participants was as follows.

- Six years of progressively responsible and related work experience in the field may be substituted for a bachelor degree (assuming no degree).
- Four years of similar work experience may be substituted for a bachelor degree for candidates with an associate degree.
- Only two years of CDM experience would be required for candidates with relevant bachelor degrees. Forum participants determined that relevant degrees include life sciences, computer science, and statistics or math.

The sliding scale approach opens certification opportunities to 'non-degreed' candidates. While the majority of the group liked the 'sliding scale' solution, a small minority proposed an approach that eliminated any degree or prior work experience requirement. This group felt that a sufficiently rigorous examination process would eliminate unqualified candidates. While this group acknowledged that degree holders might possess the soft skills listed above, they also felt that the interview process would be a better tool for assessing the skills in this area. Yet, the majority of forum participants felt that this

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approach would significantly diminish the perceived value of certification and the image of certified CDMs.

The participants extended the above discussion into the area of certified Senior CDMs. In this case, the majority of forum participants felt that candidates presenting themselves for Senior Certified CDM status must first possess certification at the CDM level and have roughly double the amount of experience.

Forum participants also discussed the logistics of applying the above criteria. The majority of participants agreed that a review board for assessing applications would need to be established. Additionally, an independent appeal process would also be needed. The process for applying would include an application, a current CV, transcripts, two letters of recommendation and two professional references. Other mechanisms such as random audits to verify work experience and school transcripts were discussed but not generally agreed upon by forum participants.

How will we assess whether or not certified CDMs are maintaining their certification status through continuing education? As above, all professional groups that either license or certify their membership acknowledge the need for continuing education to maintain currency in their profession. Additionally, while each group acknowledges that attendance at a training seminar and award of CEUs is not necessarily linked to the acquisition of knowledge, many groups base their decision on principles of trust and adherence to a code of ethics. Other groups address this problem by recognizing only those CEUs that are earned by testing. Most groups either required CEUs or recertification through testing every 2 to 3 years. A concern expressed by the participants was whether or not companies would support the CEU requirement by funding attendance at seminars or training programs. Forum participants generally favored recertification testing as an alternative to the CEU requirement.

How will we assess the quality of industry contributions that Certified Senior CDMs make? It is envisioned that Certified Senior CDMs will be an elite group of professionals. Forum participants agreed that companies must recognize, value and support Certified Senior CDMs for this assumption to hold true. Given their elite status, maintaining certification carries with it an obligation to make contributions to the profession. Examples of the various contributions deemed valuable by forum participants are:

- mentoring junior CDMs
- publishing peer reviewed articles in professional journals
- actively participating in committees such as CDISC
- presenting at conferences and tutorials

The assessment process can utilize existing methods such as conference feedback forms and peer reviews. The frequency of contributions debated by forum participants ranged from yearly to every two years.

Also discussed was a point system whereby a total of ten points would be required over a two-year period. The point system would work as follows:

- mentoring a junior CDM who subsequently gets promoted – 4 points
- beta testing software – 2 points
- presenting at a professional meeting – 2 points
- actively contributing to a technical committee – 4 points
- chairing a committee for one year – 5 points
- publishing a paper – 3 points

The types of contributions recognized and the actual number of points to be awarded would need to be reviewed and agreed upon by the Board of Trustees if this approach were adopted.

In Conclusion

SCDM membership must embark on a major education program to promote the benefits of certification to senior managers at their respective companies. To do this, it was suggested that the certification committee publish educational brochures and presentations that can be used by its membership. Many of the suggestions obtained during the forum will be effective in practice only if companies support and understand the role of CDMs and the value of certification.

While many questions were answered during the spring forum, new questions were raised. These questions can be categorized in two principles. The first principle is one of 'exclusivity'. Exclusivity implies that only highly qualified CDMs be permitted to apply for certification. This further implies that certification status will provide significant benefits to certified professionals and their companies. The second principle is one of 'inclusivity'. Inclusivity implies that anyone who wants to become professionally certified only need pass the exam. While some participants expressed concern over the inclusive approach in terms of diluting the special status of certification, many felt that by making the exam sufficiently rigorous, then only those with the proper skills would become certified. An interesting compromise was proposed by participants: Apply the inclusivity principle to those seeking professional certification at the CDM level. Apply the exclusivity principle to those seeking certification at the Sr. CDM level.

The issue of recertification through testing requires an infrastructure to support the maintenance of the examination. This infrastructure and the development of a new test could be costly.

Because these questions are questions of policy and vision, the certification committee will seek further guidance from the Board of Trustees.

Christine Little, Director, CDM, Rho, Inc.

Good Clinical Data Management Practices (GCDMP): What Other Topics Need To Be Included In The Document?

Facilitator:
Christine Little, Rho, Inc.

Session Questions

- How does your organization use GCDMP Version 1?
- How comprehensively has the document addressed the Task List? What is missing?
- What topics in Version 1 should be reworked, added to, or enhanced in Version 2?
- What new topics should be included in Version 2?

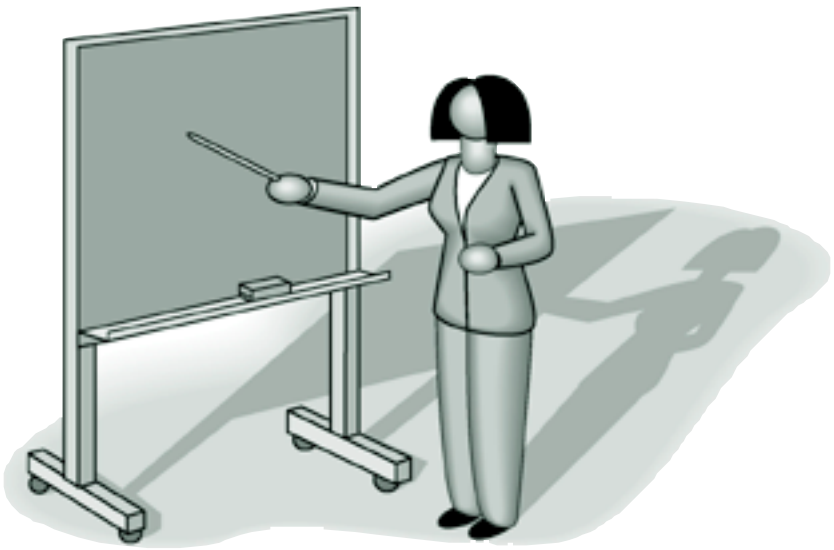
We learned that organizations using or planning to use the document include training, data management orientation, writing/reviewing SOPs and work practices review in their use of the document. It is described most often as a useful reference. Discussion about addressing the Task List quickly merged into discussion relating to reworking Version 1 of the GCDMP. These included how the current version topics might be expanded, especially in the areas of collaboration across all groups involved in clinical trials (clinical, statistics, data management), electronic data capture and coding, especially MedDRA.

Although each group had its own unique perspective and focus, there was considerable consensus among the four participating groups about what new topics should be addressed in future versions of the document. The major areas seem to be:

- **Standards:** included the use of libraries in areas other than CRF development such as standardizing reports and plans, integration of multiple studies, harmonization of global studies and, in general, standardizing ways of handling common situations.
- **Metrics:** included ways to quantify progress, quality and time performance and resource and process management, as well as information to determine how to measure the cost of gathering the numbers versus the value of the information.
- **Technologies:** included information about what new technologies are becoming available and how to evaluate them. There is interest in electronic data capture, 21 CFR Part 11, electronic submission and CDISC.
- **Management:** The area of management came up throughout all discussions. It seems that clinical data managers want to see descriptions of data management activities, flow charts, task lists with responsibilities, what requires sign-off, who signs, and at what point the audit trail begins.

In Conclusion

I believe the membership is using or planning to use the Good Clinical Data Management Practices Version 1 and would like to see it expanded and enhanced.



Anthony Costello, Founder, Nextrials, Inc.

Kaye Fendt, Independent

Good Clinical Data Management Practices (GCDMP): Electronic Data Capture

Facilitators:
Anthony Costello, Nextrials, Inc.
Kaye Fendt, Independent Consultant

Introduction

The purpose of this session was to gather information from the attendees about how the GCDMP Committee on EDC should proceed to best meet the industry needs.

Each session started with a check on agreement with the following assumptions:

- based on industry polls, conference agendas, and feedback on the GCDMP document, many companies are exploring electronic data collection
- very few companies have adopted the technology in any comprehensive way
- one reason for this tentative adoption curve may be the inability of current standards and guidance documents to give companies tools to evaluate and confidence to adopt this new technology

There were no disagreements with or questions of the validity of these assumptions.

Session Questions

Can electronic data capture enhance the clinical research process? How?

There was general agreement across all four groups that if electronic data capture could be effectively implemented it would greatly enhance the clinical trial research process. The common accord was clouded by a great divergence of opinion as to whether or not EDC could be effectively implemented.

There was evidence that many of the forum participants did not feel they had the authority, knowledge or tools to make this happen. One group was unable to productively discuss the enhancements to the clinical trial research process beyond these feelings of frustration.

The discussion of how EDC can enhance the clinical research process spanned the entire research operations spectrum from easier training to more accurate final analysis data.

The participants felt that EDC would require and enhance better site training during trial initiation. Similarly, EDC will support developing more realistic timelines because better communication between departments early in the clinical trial process will be required to implement EDC. It was also felt that this implementation of EDC would facilitate sharing of operational knowledge across the different disciplines on the research team and would generate more data management communication with the sites. Through these changes, EDC can help integrate all CDM components.

Another benefit identified is that EDC has the potential to generate cleaner data sooner by consolidating validation activities and moving the data cleaning process to the data source where the content knowledge actually exists. Discussants felt that many sites are also happy to get rid of the paper.

In summary, EDC has the potential to increase accuracy of data collected and productivity. Ultimately with EDC, researchers can have faster study start-ups, more accurate data, and greater returns on their resource investments.

What are the primary concerns preventing adoption of these new technologies?

Given the perceived potential benefits, there are concerns that are preventing adoption of the new EDC technologies. The first concern identified is that EDC forces up-front thinking about everything from data entry screens to statistical analysis plans. Thus, initial start-up can be painful with EDC today. The discussants agreed that this is not a negative factor in conducting quality clinical research. However, a paradigm change will be needed for companies to accept additional activities as required prior to study launch. Query management was identified as another concern limiting the adoption of EDC technologies. Data managers resist the workflow changes indicated above. The role of data managers will be changed by EDC and the new roles are not yet clearly defined. In addition, there is concern that the EDC systems can restrict site's response with automated data edits during the data entry

process. The current quality of technology support and a general feeling that vendor software is immature and being oversold, coupled with a perception that EDC systems need faster speed connections are also concerns limiting adoption of EDC.

Investigators and site personnel are also resisting EDC because they see it as an off-loading of data entry tasks onto the investigator sites. It can be difficult to get clinical and statistical staff to accept EDC.

While upper management in the industry is pushing for the adoption of EDC, the infrastructure changes needed for successful implementation and adoption of EDC are not yet completely understood. There is a perception that EDC is a thing, however, discussants described EDC as a "toolbox" of technical products. Also limiting the adoption of EDC is the lack of a good cost/benefit process allowing companies to choose the best tools for their needs.

Can accepted GCDMPs address the concerns that prevent companies from adopting the new technology?

Accepted GCDMPs can only address part of the concerns that prevent companies from early adoption of the new technology. More general guidance outside the GCDMP document is also needed. Incentives to bring sites on board are needed as well as IT infrastructure changes. Given the global implications of EDC adoption and the need for more interaction across the disciplines involved in clinical research, additional initiatives beyond GCDMP are needed to address the concerns that prevent companies from adopting the new technologies.

The GCDMP can help focus planning activities in clinical research. People would like additional sections or appendices in the GCDMP to address:

- examples of EDC experiences/implementation
- changing roles in the EDC world and examples
- best trial sizes for EDC
- good practices around EDC and evaluation methods

How can we best update the GCDMP document to address the most common concerns about this new technology?

To address the most common concerns about EDC, SCDM should provide a forward-looking visionary guidance in addition to updating the GCDMP guidance. SCDM should also provide a document with suggested metrics for evaluating vendors. Links to other information and organizations about EDC should be offered by the SCDM organization. SCDM can outline the procedures for process/technology changes for EDC.

In Conclusion

The general conclusion from the four sessions with senior data management personnel participating in the SCDM Spring Forum of 2001 was agreement that the end product of EDC would be great, but getting there may be difficult. This will not happen easily or overnight. There are additional issues that need to be included in the GCDMP to help industry in this transition. However, additional initiatives and cooperative agreements may also be required before the adoption of EDC technologies becomes widespread.

CDM Professional Code of Ethics

Facilitators:
Karen Klingler, Wyeth-Ayerst Research
Imogene Grimes, Yamanouchi USA, Inc.
Meredith Nahm, Duke Clinical Research Institute
Armelde Pitre, Pfizer, Inc.

Karen Klingler,
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Introduction

The SCDM Certification Committee is building a certification program for CDM professionals. In addition to creating certification definitions, requirements and testing — professional certifications normally include a code of ethics. It is this Code of Ethics that serves to bind professionals under a set of mores that is not only common to them, but that speaks to the essence of their professional character.

Codes of ethics vary substantially in length, detail, content, and readability. It is important to create a code of ethics that is appropriate to the profession yet brief enough to be readable, understandable, and memorable.

Attendees at the SCDM Spring Forum 2001 addressed the ideals, elements, and uses of a CDM professional's Code of Ethics. The purpose of this session was not to 'wordsmith' or develop a code of ethics, but to gather input around the values that will drive its development. Pre-forum reading materials included the codes of ethics from the professional organizations listed below:

- The Association of Clinical Research Professionals
- New York Association for Healthcare Quality Professionals
- The Information Systems Security Professionals
- The Hippocratic Oath
- The American Society for Quality

Session Questions

What examples of egregious behavior can be shared?
Attendees engaged in a lively warm up exercise where Mardi Gras beads were awarded to those who could expose egregious behaviors made in the past. (Disclaimer: all identities were disguised to protect the innocent).

The egregious behaviors ranged from a variety of regulatory mistakes to conscious efforts on the part of individuals to make data errors to discredit others or to personally gain from the work of others. Some egregious behaviors involved situations where confidentiality was breached, disclaimers were avoided, shortcuts were taken and bias was introduced to the data. Sloppy data retrieval and documentation were also mentioned.

While mistakes or errors in judgement governed by regulatory guidelines are fairly explicit, many of the issues shared seemed to be the result of character flaws leading to poor judgement – which clearly is the realm of a Code of Ethics.

Among the minority opinions in the four discussion groups, was a question of whether a code of ethics is necessary for a CDM professional. The presence of a wide array of regulatory guidelines and law (ICH, FDA Regulations, etc.) around this industry was cited as a reason why a code of ethics would be redundant. The presence of codes of ethics for other clinical professions that can be considered related to the CDM professional was another justification.

What elements should be included in a Code of Ethics?
Participants did a great deal of brainstorming around what elements are important for a CDM professional's code of ethics. The attendees were divided into four groups in separately facilitated sessions, yet it was interesting to see the consistency of results arising from the brainstorming. Key points identified as important to the professionalism of clinical data managers centered around conducting themselves personally and professionally at all times, with honesty, integrity, quality, objectivity, and truthfulness, and without concern for personal gain. Participants felt that clinical data managers should value the integrity of the data and guard against bias/corruption. They should respect and adhere to applicable laws, standards of industry practice and confidentiality. Safeguarding the public health