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From the Editors

This issue is jam packed — our biggest issue ever! The feature article, the proceedings of the Spring Forum, is filled with excellent ideas and solutions pertaining to quality and standards. We are now looking forward to our next big meeting — the Fall Conference. Do you have your calendars marked? Don't miss the update on the plans and progress on SCDM's professional certification efforts as well as the articles on ACDM, CDISC, and Pandora's Data Box. When you have finished reading this issue, perhaps you will consider some of the suggested reading ideas or visit the scdm.org web site. It is constantly being updated with the current happenings of SCDM. Use the feedback form available on the web site to let us know about any suggestions you may have pertaining to the web site, e.g. ideas for additional non-commercial web site links of interest to the membership.

Regards,
Lana and Cathie

Review of the 2000 SCDM Spring Forum

Wild Dunes Resort, Isle of Palms, South Carolina

The 2000 Spring Forum opened on Sunday evening, March 19th, with a traditional Lowcountry Oyster Roast. The weather was dripping slightly, but the oysters were great. However, Monday morning we awoke to soaking rain and almost hurricane level winds destroying our thoughts of walking on the beautiful beach. By noon the sun had returned and the promised weather continued through the rest of the conference. The 60 participants braved the weather and accepted the challenge of a daylong discussion of "Building Quality into the Process — from the Management Perspective." Congratulations to the facilitators and attendees for their endurance!!

On Tuesday Ken Getz, President and Publisher of CenterWatch, helped the group to discuss how our quality solutions of today translate into the work environment of tomorrow. The title of the workshop was "The Changing Operating Environment for Clinical Research Professions". The interactive session provided new insights for all of us. Gary Lightfoot, Secretary General of the Association of Clinical

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The exquisite beauty of Isle of Palms and the sea combined to make Wild Dunes the perfect setting for the Spring Forum.

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Review of the 2000 SCDM Spring Forum

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Research Professionals Foundation, added to the discussions. The group appreciated Ken's and Gary's enthusiasm and knowledge of the topic. The workshop demonstrated how the issues that we are facing today in Clinical Data Management are very similar to those of our peers throughout the industry.

I would like to take this opportunity to once again congratulate and thank all those who participated and particularly the session facilitators — Dee Rasmussen, Joann Masi, Jonathan Andrus and Heidi Shea. Special thanks to April Pennacchio, our Meetings Coordinator, who lead us to Wild Dunes!

Kristin O'Connor, Program Chair

Gary Lightfoot and Ken Getz presented the Tuesday Workshop.

Left to Right: K. O'Connor (Program Chair) joins Facilitators J. Andrus, J. Masi, H. Shea, D. Rasmussen and A. Pennacchio (Meetings Coordinator) for a group photo on the beautiful beach at Wild Dunes.

SESSION I

Balancing Quality Versus Time

Facilitator: Dee Rasmussen (Glaxo Wellcome Inc.)

OBJECTIVE: To examine the factors of balancing quality versus time

Introduction

Session participants were asked to share ways in which they strike a balance to bring quality to the personal time they have available. During the session, individual participants took ownership of specific questions related to balancing quality versus time. They then discussed their information with another session participant to allow expansion of ideas. Each participant presented to the whole group for further discussion. Some of the issues discussed were identification of imposed constraints, setting the acceptable quality level, how to maximize time available, identification of factors that make time a critical competitive differentiator, ways of reducing or alleviating time pressures, and how can use of metrics assist. Other questions considered were: when are diminishing returns realized on adding more resources, ways to maximize available resources, how to meet demand with current capacity, and how technology helps or hinders speed and/or quality.

Imposed Constraints

Session participants identified some of the most common constraints encountered in balancing quality versus time.

- Limited resources
- Skill and motivational levels of resources
- Training
- Timelines
- Technology
- Budgets/profits/competition
- Data structure
- Data quality
- Process complexity
- Company standards
- Management expectations
- Regulations

One participant likened the constraints to road cones. Relevant knowledge of processes is needed in order to maneuver around them with the appropriate speed and diligence.

Setting the Acceptable Quality Level

The question of "good" versus "good enough" factors into setting the appropriate quality level. A related question attempted to define minimal level of acceptable quality. It was agreed that high quality data arrives at the same conclusion as perfect data. The minimum level of quality is that level which does not put the customer at risk. The minimum acceptable level of quality may vary with the use of the data. Some of the ways to effectively set the acceptable level of quality were identified as:

- Study team collaboratively defines acceptable quality levels
- Customize quality level to specific project/study
- Agree on how good is good enough
- Build quality into process
- Clearly define data handling process
- Select appropriate tools
- Borrow from previous projects via "cut and paste"
- Apply standards where appropriate to gain efficiencies
- Schedule routine audits throughout process
- Appropriate and timely sign-off (internal/external)

Maximizing Time Available

Consensus was that the best mechanism for optimizing time available is to focus on priority setting. Time can be allocated to value added tasks that yield the most return for the time spent. It is important to agree to the minimum standard that must be met to determine how much time can be spent on particular activities. Utilizing standard processes can facilitate ability to shift resources quickly as needed. As a part of project planning activities, a contingency plan should be created which takes into account the impacts of potential delays or threats to the project.

Factors That Make Time a Critical Competitive Differentiator

Some of the factors that increase the need to become "speed demons" include the increased financial incentives and profits realized by getting to market first, patent life extensions, patent expirations, faster submissions leading to faster approvals, critical regulatory schedules, and the need to get the drugs to patients to meet unfilled needs.

Reducing or Alleviating Time Pressures

Some ideas for reducing time pressures include:

- Reduce unnecessary meetings
- Implement standards/use data conventions where appropriate
- Pre-plan and evaluate processes, adjusting where necessary on an ongoing basis (Do not crisis manage!)
- Train well
- Resource adequately
- Use resource alliances (CROs and other strategic alliances)
- Do it right the first time
- Use technology (where appropriate) to increase speed
- Manage expectations/negotiate to agree on reasonable cost/benefit of timelines
- Early project team involvement
- Focus on key objectives
- Take medication as needed

How Can Metrics Assist?

Providing metrics and tools to help with review of processes ensures consistency in quality, allows resource shifting as required, eliminates non-value added activities, and allows more adequate planning for future projects. Some examples are examination of number of SAS or internal validation hits where no data changes resulted. Such validations can be modified or eliminated. Looking at data clarification response metrics such as number of re-queries can help focus on problematic data points, which can lead to better CRF design. Examination of query turnaround response rates across sites can identify slow performers and can lead to dialogue to determine issues and increase performance rates. Collecting metrics on internal data management performance such as number of patients validated and number of patients "authorized" can help set performance standards and help manage a project more effectively by utilizing resources more efficiently.

Diminishing Returns on Adding More Resources?

One of the major considerations in whether or not to add additional resources is the phase of the project. If it is close to the end of the study, no matter how accomplished the resources are, they will not add value because there is insufficient time to train them on the particulars of the study without taking time from senior-level team members. Additionally, it can be a deterrent to add resources at any stage if the resources are not the right level/fit or if there is no time to manage the resources effectively. It is inappropriate to add more resources when it will negatively impact the decision making process.

Maximizing Resources Available

Ways identified to maximize available resources included efficient training programs, forecasting project needs to shift resources to meet priority deadlines, strong communications within project team, employing standards, job share utilization, *teamwork, teamwork, teamwork,* and examining metric tools. Other ideas were proper up-front planning, implementation of well-defined roles, good project management, minimize time spent "re-inventing the wheel", continuous process assessment, and use of technology to reduce amount of resources required.

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Meeting Demand with Capacity

Some of the ideas presented to meet demand with current capacity were cross-functional training, outsourcing or use of satellite groups, critical review of processes, thorough understanding of the demand, streamlining, multi-tasking, standardization, copy over what is possible to copy, and use of trained resources.

Technology — Help or Hindrance to Increased Speed/Quality?

Several technology benefits and costs were identified during this session as indicated below.

Technology Benefits

- More automation reduces manual input
- Allows processes to be linked (annotated imaging systems)
- Allows re-use (standardization) of established models
- Increases processing speed
- Stores large volumes of data
- Enables aggregate database to get answer that may eliminate need for a new study
- Enables global studies
- Web-based technologies allow site involvement earlier
- Forces use of standard platform that may otherwise be done in multiple ways
- Can reduce time to move data downstream
- Automates tracking of processes
- Eliminates or simplifies steps in process
- More updated information available in real time
- Reduces chance of human error
- Electronic diary more accurate/eliminates guessing
- Automated generated queries with consistent terminology for sites

Technology Costs

- Poorly designed with known defects
- Systems that don't talk to each other
- Systems that exclude access to CROs and satellite sites
- Adds task complexity rather than reducing
- Finding hybrid employees both technically savvy and data management savvy
- People resistant to change
- Inadequate support of new technology
- Consultants that bring in technology do not understand data management processes
- May decrease flexibility
- Information overload
- Individuals become too specialized
- Need for training
- Too reliant on technology
- Insufficient system validation can cause quality problems

In Conclusion...

Balancing quality and time is an ever-increasing challenge encountered each day as the race to market accelerates! Thanks to all the session participants who contributed the many excellent ideas and/or solutions summarized in this article on ways to effectively beat the clock to bring to market higher quality products.

Setting Data Management Standards

Facilitator: Joann Masi
(Wyeth-Ayerst Research)

OBJECTIVE: To share information about how data management standards are defined

Introduction

This session offered an opportunity for participants to discuss the issues and challenges surrounding standardization. In addition to sharing current practices and experiences in their own companies, participants used this forum to define the necessary requirements for setting the optimal use of data management standards.

What Does Standardization Mean?

Companies vary widely in their philosophy and approach to standards. Although there is a great deal of interest in this area, many companies are still in the development or early stages. An informal survey at the start of this session revealed that only a few companies have attempted standardizing at the company level, many only have standards at the therapeutic level, and surprisingly there were a number of organizations that have no standards at all. A large majority of the participants stated they have a standard approach to the collection and processing of safety data. There was much discussion around the desire for industry wide standards. It was noted there is currently a group of industry representatives, the Clinical Data Interchange Standards Consortium (CDISC), whose vision is to establish standards to improve the process of electronic acquisition and exchange of clinical trial information.

Which Processes and Activities are Appropriate to be Standardized?

Opportunities for standardization are listed below.

- Protocol
- CRFs
- Database structures
- Derived fields
- Data entry screens
- Edit/validation checks and guidelines
- Data listings/tabulations
- Summary tables
- Analysis plan
- Final study report
- Technology
- SOPs and IOPs (Standard and Internal Operating Procedures)
- Metric tracking and reporting
- Terminology
- Training
- SAE process
- Quality control process
- Study files
- Data management plan
- Monitoring guidelines

Do Standards Equal Quality?

The quality benefits of standardization are realized through the efficiencies gained. All participants agreed, "less standardization equals more cost". In addition to the time and cost savings of continual development and rework there is also less time spent on study-specific training and quality control of programs and processes because there is less variability from study to study.

What are the Benefits and Liabilities of Standardization?

The following are some benefits of standardization identified during this session.

- Increased efficiency
- Reduced timelines
- Consistency for all users
- Minimize new training efforts
- Improved quality
- Data pooling across protocols
- Easier to manage
- Flexibility in moving staff and work
- Better control of process
- Resource continuity/planning
- Reusability of systems and processes
- Cost effective

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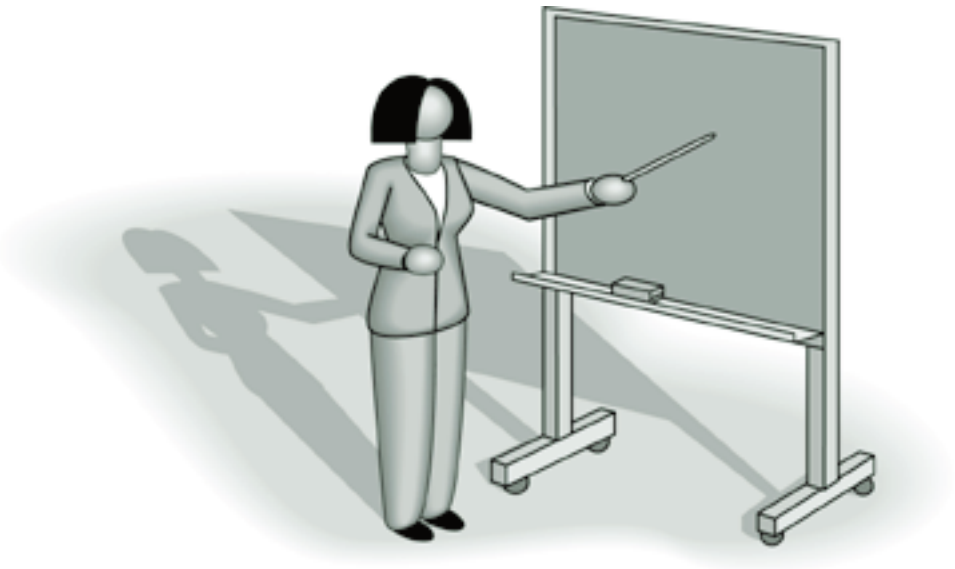
Liabilities of standardization include the following.

- Inhibitor to change
- Too restrictive
- Decreased creativity
- Differences in culture (European Union, Japan)
- Requires strong change management
- Bureaucracy

How is Standardization Implemented at an Organization?

There must be a strong desire to embrace an environment of standardization at an organization and it must be supported by a strong commitment from upper management.
In addition to recognizing the time and resources necessary to put standards into practice, management should define the goals and time frames to support it. The "Standards Team" should include representatives from the various disciplines that are primarily involved in the definition, collection, processing and statistical analysis of clinical data. This cross-functional, empowered team should have this role tied to their job description and performance objectives. The mission and objectives of this team must be communicated to the whole organization at the onset.



Who are the Partners in Standardization Efforts?

There are several partners to consider in standardization efforts.

- Upper Management
- Clinical Data Management
- Forms Design
- Clinicians/Medical Monitors
- Statisticians
- Programmers
- Field Monitors
- Medical Writers
- Site Coordinators/Investigators
- Training
- Auditors/Quality Assurance
- Regulatory Affairs
- IT System Support
- Marketing
- Safety
- CRO Partners
- Central Labs

How is Control Effectively Maintained?

In addition to supporting the development and implementation of proposed new standards, the "Standards Team" should have a formal procedure for deviation to existing standards in place. The team reviews these requests and approves or rejects as appropriate. A systematic change management process should be defined where the impact of cost and time are considered and that addresses how a change in a standard in one area affects a standard in another area. Participants felt a commitment to yearly review of all standards was necessary for effectiveness in relation to process/quality improvement.

In Conclusion...

Throughout the industry there is an emerging trend towards "better standardization". Standards today are a must due to the increasing number of drugs in development, greater number of therapeutic areas/indications and global submissions coupled with limited resources and aggressive timelines. Efficiency must be improved through effective reuse, while optimizing speed, cost and quality.

Leading an Organization Toward Quality

Facilitator: Jonathan Andrus
(Premier Research, A Division of SCP Communications)

OBJECTIVE: To discuss how to make quality a corporate value

Introduction

This session provided participants with the opportunity to discuss the methods, theories and best practices for leading an organization toward quality. Participants discussed their ideas of what quality means within the context of the pharmaceutical industry and how to get peers, employees and, most importantly, senior management to understand the importance of quality. A fictitious audit report from Karma Pharma's (maker of the most safe and efficacious drugs on the market) data management group was used to help place people in the mindset of quality.

Participant Introductions

During this phase of the session, participants introduced themselves and identified the type of organization they work in. In addition, participants were asked to identify the primary clinical data management system they use in their respective companies. This provided some interesting findings and provided a clear reason for establishing quality within an organization. Almost eighty percent of the participants indicated that they were in some form of transition/migration period with their respective systems. This helped to drive home the importance of quality within an organization.

Why is Quality so Important?

Quality inherently is important for several and varied reasons. A list of the "top ten" reasons for quality includes:

1. patient safety
2. business integrity (most important for CROs)
3. ensure successful regulatory submissions
4. decrease timelines/save time
5. increase overall quality
6. employee confidence
7. ensure valid data
8. minimize approval time
9. increase pride in work
10. no FDA 483s.

At the conclusion of this discussion, the Karma Pharma audit report was distributed for review. This audit report provided the participants with some glaring and egregious findings to reflect upon. Some time was spent discussing the findings and preparing for how, as an organization, to work toward making quality inherent in everything done.

How is an Organization Led Toward Quality?

Communication throughout the organization is critical for the successful march toward quality. All throughout the process of implementing and leading toward quality, detailed and regular communication must be undertaken to keep all concerned aware of initiatives and advancements. Commitment from the janitor to the President of the company must be established for quality to be ingrained. This will provide senior management with an understanding of why quality is important. Using the list from the above section (*Why is Quality So Important?)*, one could easily show senior management the obvious benefits, both short and long term. Obtaining this commitment at the outset is critical for its success. Session participants emphasized the critical importance of the junior members of an organization. These are the individuals for whom quality initiatives are intended to provide direction and security. This group of critical personnel must be *fully* committed for the progression toward quality.

In addition, justification of finances, resources and time must be undertaken. Do not point fingers, identify areas of inefficiency and non-compliance and work toward correcting them. Finger pointing will lead to distrust, suspicion and lack of cooperation. Feedback loops at all of the major milestones is important for effective communication and execution of quality initiatives.

Key elements of leading an organization toward quality consist of:

- Communication — appropriately focused
- Don't point fingers
- Resource allocation
- Commitment from all areas
- Quality assurance oversight
- Upper-level champion

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- Financial backing
- Continuous feedback
- Proper use of technology
- Well-thought out plan

How is the Importance of Quality Instilled in Team Members?

During this discussion, the participants talked about what they thought were effective methods for the instillation of quality in the team and the organization as a whole. First and foremost, leading by example was cited as being one of the most important methods for instilling quality. Without excellent leaders and role models, the organization and team has no compass. One can not expect their employees to embrace quality if their supervisor/boss has not. In conjunction with this thought, the concept of "pulling your weight" was discussed. In essence, a manager needs to set the example both from a quality standpoint and from a work ethic and must also be committed to seeing the quality job through to completion.

Varying methods for training and education in quality, SOPs and process were also discussed by the session participants. Ideas ranged from SOP games (SOP Jeopardy, etc) to "vision" meetings. Participants related their experiences pertaining to "boot camps" utilized as an effective initial training method. During these "boot camps," personnel are grouped in teams and provided with real-life scenarios. They are tasked with solving the problems using procedures and processes currently in place. "Drill Instructors" supervise and provide direction and training as needed. Participants indicated that, for the most part, physical training and rifle training were excluded at their respective companies. All in all, creativity is the watchword. Job standardization was also noted as being an effective way for instilling quality. Many of the participants noted that making quality a part of an employee's yearly objective is important and makes people take note of problems.

Process re-engineering and re-examination were also noted as being effective methods for obtaining the big picture of the organization and for enabling employees to understand the roles and responsibilities of both themselves and those whom their work impacts. Systems implementation and migration are often good times for this task to be completed. A thorough understanding of the requirements and processes is critical for proper vendor or systems selection. Constant re-examination of processes was also mentioned as being an integral part of quality. The concept of "low-hanging" fruit was discussed. One of the participants talked about how both management and employees should be looking for pieces of low-hanging fruit or systemic issues that are blatant and glaring. These issues should be resolved immediately. Occasionally, potentially every 12-18 months, an organization should review all processes and ensure that some of the low-hanging fruit issues have been resolved appropriately and solutions are in harmony with other processes.

For employees to embrace and understand the long-range objectives of establishing quality, they should be presented with the overall objective. Unfortunately, some individuals don't care and only want to be presented with the facts and left alone to complete those tasks. For the company, as a whole, the majority of the session participants indicated that it was important for their employees and themselves to understand and strive for the overall quality initiative and objective. It is noted here that each specific quality initiative impacts the amount of planning, information and involvement required. Each initiative must be reviewed and analyzed for its impact on the organization.

What are the Managerial Elements of a Quality System and How are They Determined?

The most important element from a managerial perspective is setting the example. For the quality system to be initiated, the manager must lead by example, roll up his/her sleeves and get to work with employees. Don't expect employees to embrace quality unless they have an example to follow. Managers must maintain an elevated level of enthusiasm and motivation to see the quality system through to fruition. In addition, integrity and honesty must be inherent in everything done.

Managers must be champions for quality and stand up for those that find areas of inefficiency. There must be open lines of communication between management and employees. Recognition of achievements with relation to quality must be noted. Participants identified thank you notes, gift certificates, and other inexpensive ideas that make employees feel appreciated for their ideas and innovations.

One of the most important managerial elements with regard to quality is balancing quality with timelines. A manager must delicately balance quality and time by assessing deliverable dates with regard to resources and time frames for intertwining quality into each of the deliverables. A manager must also stand up for the benefit of the department and not bend on quality to meet timelines.

Key managerial elements with respect to quality are as follows:

- Continuous coaching/mentoring
- Approachable
- Educate external forces (Senior Management, Business Development)
- Open lines of communication
- Set attainable goals for quality
- Encourage the team
- Honesty
- Set the example
- Recognize achievement
- Balance of quality and timelines
- Evaluate goals regularly
- "Quality" recruiting (seek out "quality" people)

Are There Levels of a Quality System?

The session participants agreed that there are definite levels of a quality system. These levels depend entirely on the scope of the quality initiative. If the scope is department wide and far-reaching (i.e. cross-department clients) there must be a more detailed and well-thought out approach. In general, an assessment of the situation is conducted. During this phase or level of the system, the team gathers information, conducts a risk assessment and reports on their findings and begins to formulate the plan of attack. An initial plan could be developed from here, but will most likely change dramatically as the assessment turns to the diagnosis level. In the diagnosis phase, the assessment is analyzed in greater detail and problem areas are identified. These problems are discussed amongst the team and the formal plan begins to be developed. The development stage is where a realistic plan is created keeping the operational group in mind. The end-users must be kept abreast of the development so that they can interject their thoughts and ideas. In addition, senior management must be aware of the development so that their approval can be obtained early on. They must be committed to the plan and the related costs and resources to complete the initiative.

From the development level, the plan is implemented. Many of the participants indicated that the best approach for implementation was the slow and steady approach. With this approach, the changes are made gradually and reassessed as often as necessary to ensure that all of the changes are occurring as expected. Again, it is noted that each and every change initiative must be assessed on its own merits and urgency. Not every change should be required to go through such an intense process. If the required change is deleterious to the company's regulatory fortitude, then change must occur immediately. In essence, a "triage" would occur to halt blatant violations of regulations and guidance.

Review must occur at each of the levels or phases of the quality system. This review is intended to provide the team, senior management, and employees the confidence that the direction of the initiative is well-balanced and focused. This is critical for the successful implementation of any quality system. Without the full embrace of those affected by these changes (i.e. employees), the quality initiative will fail miserably.

Who Controls the Levels of a Quality System?

The control of the system should be conducted by the team established to assess, diagnose, develop and implement the quality system. This team must speak a unified message when reporting and explaining developments and initiatives undertaken for the quality system. Without this unified message, derision and divisiveness will ensue and the initiative will fail. Some of the participant groups indicated that the teams should consist of a core group of individuals that meet regularly and are augmented by specialized teams that are brought in to address specific areas of quality improvement. Other ideas included using an operations group that would meet to discuss quality-related issues on a regular basis. This operations group would include managers from varying functional areas and other specialized employees. During these meetings, quality would be discussed. Comprehensive reviews of the department SOPs and guidelines would also be conducted. Establishing either the core group or the operations group would allow for the proactive identification of process and procedural inefficiencies.

Session participants identified the following points relevant for controlling the levels of a quality system.

- Team must establish the message
- Partner with quality assurance
- Provide clear documentation
- Speak a unified message
- Avoid whisper down the lane — team must firmly establish the message
- Obtain the appropriate power to implement changes

In Conclusion...

Overall, the session participants provided some insightful and ingenious methods and best practices for leading an organization toward quality. These included many and varied ideas for what were felt to be key elements for successful change. It is hoped that the information provided here will be useful in helping to initiate change. Remember: "It only takes a spark to get a fire going."

Enabling and Harmonizing Quality When Working Across Multiple Sites

Facilitator: Heidi Shea (MTRA/AAI)

OBJECTIVE: To discuss the process of implementing and managing the quality standard within a multi-site or global data management organization

Introduction

Multiple data management sites exist in several organizations in the pharmaceutical industry. These multiple sites are a result of one or multiple mergers in recent years as well as a result of growth and expansion of a single organization. Multiple sites present the challenge of harmonizing procedures and standard practices across all sites. While the initial objective of this session was to discuss how to enable quality across sites in the harmonization efforts, several other aspects of the harmonization efforts were discussed. Session participants came from larger pharmaceutical companies which are in the midst of the harmonization efforts, pharmaceutical companies which have been acquired by larger companies with no plans for harmonization, as well as companies who have multiple domestic and international sites as a result of expansion and growth. In addition to representation from several types of multi-site organizations, there was representation from all stages of the harmonization process.

Although there is not a single correct approach to enabling quality in the harmonization efforts, most companies' initial goal is to establish quality standards for all sites to attain, then harmonize the processes that are followed in achieving these quality standards.

Determination of Quality Standards

While the common determinant of quality across the industry is compliance with GCPs and FDA guidelines, there are several approaches to measuring the quality of the database. The most widespread measure of quality is the error rate as determined by a quality control audit of the final database prior to database lock. Most companies will audit 10% of all variables in a database or 100% of primary safety and critical efficacy variables plus 10% of non-critical variables. Some organizations will audit 100% of database changes, but not data points that were unchanged. Some companies perform comprehensive audits in which the interim and/or final tables and listings are compared to the CRF, data queries, and to the point of data collection. Acceptable error rates vary from 0.01% to 0.5% (or 95% to 99% accuracy rate).

In addition to performing a final quality control audit, audits are performed intermittently throughout the study. The frequency of audits is a factor of the number of patients enrolled as well as the study length. Performance audits of individual team members are also used as a tool to increase the quality of the final database.

Errors are most commonly defined as a difference between the CRF or resolved queries and the database. There was one organization represented at the forum that performs a process audit in which the documentation that team members use in processing study data are audited. If a team member is found to have used an incorrect study-related document, then each data point processed by that individual is considered to be an error.

The party responsible for performing these audits varies across organizations. Some companies will contract an external CRO to perform the audit, others will have representatives from their internal QA department and others will use representatives from the data management group.

While the acceptable error rate may be standardized across an organization, and the percentage of data to be audited may also be standardized, the process by which the audit is conducted must also be standardized. If two different audits are conducted on the same exact data, two different error rates may be calculated.

Initiatives to implement quality control measures that effect the quality of the data outside of data management are being undertaken in some organizations. These include standardized CRFs that are used across studies so that the study coordinators and CRAs do not have to use a different CRF for each study. Organizations that have implemented standard CRFs have noticed a significant increase in the quality of data collected and a reduction in the number of queries generated. Regardless of the quality control measures that are taken within data management, there is no substitute for a well-written protocol.

Parties Responsible for Harmonization Efforts

Just about all levels of staff are involved in the harmonization efforts to some extent. Because harmonization requires such a great amount of time and effort, it is imperative to have senior management's buy-in. Once a mandate to harmonize has been received from this level, it usually happens much faster than if the level of effort remains with middle managers and operational people.

The efforts to harmonize are most often the result of the implementation of a new data management system operating platform or the need to produce a quality product more efficiently. If all data management sites are utilizing a single data management system and also operating under the same SOPs, it is easier to shift work from one site to another in response to resource availability. A harmonized process also allows for de-centralized data processing of global clinical data. If the data processing occurs geographically close to the point of collection, then cultural, language and time issues are minimized more than if there is centralized data processing.

There are several models in the coordination of the harmonization process. Some organizations have a core team that is primarily responsible for ensuring that the harmonization process is carried through to execution. This core team will involve operational staff at different points of the process in order to ensure that all levels and departments are adequately represented. Other organizations have several different teams working in parallel. These teams will meet on a regular basis to discuss progress and establish upcoming milestones.

Those that have undergone a harmonization process offer these tips:

1. agree upon detailed goals
2. discuss and re-visit the benefits of harmonization
3. do it faster if possible
4. collect metrics and utilize them in the ongoing process
5. establish operating guidelines to be followed within the harmonization teams
6. ensure that all groups are involved in the harmonization efforts not just a single operations group or department
7. select members who will serve as representatives, not individuals
8. establish a sense of a democracy within teams and not sense of a hierarchy.

Allowances for Variation from Site to Site

"One technology, flexible process" is the motto of one large multi-site organization. This motto reflects the fact that the same exact processes will not be ideal for all sites despite that fact that they all must use the same technology. There should be a set of top-level processes that must be adhered to, but there should be some flexibility in the working practices that reflect the needs and organizational structure of each individual site. What works smoothly and efficiently in a large corporate site may not be the best practices for a small satellite office — however the quality of the databases produced by each site can be of the same quality.

The biggest area of variation between sites within a single organization is in the person who is responsible for each step of the process. For this reason it is common to have standard processes documented in which the tasks to be performed are emphasized and identification of the person performing them is de-emphasized. However, this does not mean that the details of the process should be overlooked in the SOPs. Standard processes should not be mandated across sites for the sole sake of standardization and harmonization in and of itself. Each process should be evaluated in light of the objectives — whether it is a single technology, increases efficiency and/or quality.

The Implementation Process

In implementing harmonized procedures, it is best to do so gradually. Some organizations start with new projects only and implement all procedures for the newer studies. Others will start with the procedures that are going to have the greatest impact on the overall process or they will pilot the new procedures for one or two studies, then follow with all studies. In general, each project is evaluated on an individual basis for the feasibility and impact of the harmonized

continued on next page

procedures. Some organizations have had up to four technology platforms and four sets of SOPs during an implementation phase, merely because it was not feasible or practical to transition all ongoing projects.

It is important to have a devoted training team and/or input from the training department regardless of the implementation strategy. In addition to ongoing training in the overall process, the specific changes should be emphasized.

The importance of senior management's commitment cannot be understated in this phase of the process. Their commitment to these efforts should be very vocal and visible to the entire organization. Their commitment should be clearly communicated through all phases of the harmonization process.

Controls to Ensure All Sites are Following the Same SOPs

The most common tool for ensuring that all sites are following the same SOPs is internal QA audits of the data management process. Metrics are also valuable tools to monitor compliance with harmonized processes across sites. These metrics can also be used for continuous process improvement, whether it be an increase in quality and/or efficiency.

In addition to internal QA audits, some organizations have a task force that is dedicated to continual improvement of the existing processes. This task force serves as the repository for suggestions for process changes for the entire organization. They will then evaluate the suggestions and if necessary assemble an additional task force, comprised of operational representatives, to implement the change.

In Conclusion...

With more and more large global clinical trials, multiple mergers, and an increased drive for efficiency and quality, harmonization is a fact of life in the pharmaceutical industry that is here to stay. Despite the many benefits to an organization, harmonization is not always well accepted across an organization and not quickly and easily implemented. Some organizations have more experience than others do in these efforts, but no one seems to have an optimal strategy for effective harmonization. Valuable lessons as well as positive and negative experiences were shared amongst the session participants.

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: profmgmt@blast.net) has a current e-mail address where you prefer to receive SCDM information.

Annual SCDM Business Meeting at Fall Conference:

Call for Agenda

The Annual General Meeting of SCDM will be held during the 2000 Fall Conference in October. Please submit topics for discussion for the business component of this general meeting to April Pennacchio, PMA (e-mail: april@profmgmt.com).

MARK YOUR CALENDARS FOR

2000 SCDM SIXTH ANNUAL FALL CONFERENCE

The State of Clinical Data Management as the Millennium Unfolds

Crystal Gateway Marriott
Arlington, Virginia
October 15 – 18, 2000

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

This conference will include a keynote speaker, panel discussions, vendor exhibits and excellent networking opportunities.

Keep an eye on your in-box for conference registration materials.

Looking forward to seeing you there!!

Calendar of Events

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

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

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

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

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

From Competencies to Professional Certification?

Overview

Over the past few months, the Certification Committee of SCDM has examined the issue of professional certification for Clinical Data Managers. We have benchmarked and surveyed various other professional groups in health care, pharmaceutical, biotechnology and other related industries. We've recently completed the definition of certification and are beginning work on the job analysis and competency assessment tools. This article is the second in a planned series of updates on the Professional CDM Certification Committee's work.

What is Certification?

At the 2000 SCDM Spring Forum, we conducted a survey to help us define certification. As a result certification is defined as the **formal assessment** and **recognition** of Clinical Data Managers' skills and knowledge. SCDM is developing a two level professional certification program. The two levels are *Certified Clinical Data Manager* and *Certified Senior Clinical Data Manager.*

What Are the Criteria for Each Level of Certification?

I. A *Certified Clinical Data Manager* has:
   a. met professional eligibility requirements
   b. demonstrated a competent level of job-related knowledge and skills
   c. subscribed and agreed to adhere to the Code of Ethics for professional CDMs
   d. agreed to fulfill ongoing continuing education requirements.

II. A *Certified Senior Clinical Data Manager* has:
   a. met professional eligibility requirements
   b. demonstrated expert level skills, proficiency and knowledge
   c. subscribed and agreed to adhere to the Code of Ethics for professional CDMs
   d. agreed to fulfill ongoing continuing education requirements
   e. made and continue to make annual industry recognized contributions to the advancement of the CDM profession.

What Are the Professional Eligibility Requirements?

Items being considered for professional eligibility requirements include:

- minimum education requirements or equivalent years in work experience
- minimum number of years of relevant work experience
- membership in SCDM or ACDM or equivalent professional organization.

Why Do We Need Certification?

As technology and businesses change at an ever-increasing rate, a gap is forming between the foundation provided by academic education, the job-related learning opportunities and the competencies that are required in today's environment. The SCDM Professional Certification Program is being established to help bridge this gap and identify the individuals who possess the skills that meet business needs.

Certification provides the means by which skilled professionals can be identified, hired and promoted. Certification contributes to professional image, profile, credibility, standards of practice, ethics and career opportunities.

How Might the Certification Process Work?

Setting up a certification process for our professionals will take careful design, establishment of standards, and meticulous execution. Additionally, the process should be a flexible one. The SCDM Certification Committee's work is enormous. However, there are many models to follow, so the task is not insurmountable. The committee is currently benchmarking certification processes from other professional organizations to capitalize on available knowledge and assure a consistent approach.

If we were to follow the model set by professions such as health care professionals and clinical research associates, certification includes a validated examination, usually after a minimum number of years of work experience that covers knowledge of general subjects.

What Are the Benefits of Being Certified to CDMs and to Industry?

The benefits are numerous. Certification brings a sense of recognition and accomplishment to the professional. It provides industry with a way to quickly assess the qualifications a CDM possesses. It also provides a framework for developing needs-based training programs. Finally, it assists CDMs and their managers with career development planning by targeting an individual's quest for increased and highly relevant practical experience.

How Will Certified CDMs Be Identified?

Candidates who successfully complete this challenging certification process would receive a formal designation of Certified CDM or Certified Senior CDM. A database of certified CDMs will be maintained.

Will Certified CDMs Be Globally Recognized?

We are currently exploring this possibility with ACDM.

When Will The Certification Program Be Available?

The SCDM Certification Committee estimates that development of this program and initial rollout will take approximately three years. Our first year's work is underway and on target. We are currently defining certification, certification requirements (education, competencies, experience), quality standards and gathering industry support. In year two, we will develop and validate individual components of Professional CDM Certification including the Code of Ethics, the CDM formal assessment tool and process. In year three, we will launch the certification program.

Watch Data Basics for updates as the Certification Committee's work unfolds.

Please contact Armelde Pitre at Armelde_Pitre@Groton.Pfizer.com if you are interested in learning more about this committee.

DATA BASICS

Call for Articles

The search continues…!

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

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(also known as Newsletter Committee)

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PUBLICATION SCHEDULE

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

Volume 6, Issue #3 (Fall)	July 31, 2000
Volume 6, Issue #4 (Winter)	October 26, 2000
Volume 7, Issue #1 (Spring)	February 1, 2001

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

Journal Articles

"A Randomized Comparison of Single and Double Data Entry in a Double-Blind Clinical Trial Conducted in the Pharmaceutical Industry", Geoff Charlwood, Damien McEntegart, and Al Merginio-Murgatroyd, *Applied Clinical Trials,* July 1999

"Ensuring Good Statistical Practice in Clinical Research: Guidelines for Standard Operating Procedures (An Update)", Philip North, *Drug Information Journal,* July-September 1998 (Volume 31, Number 3)

Books

Guide to Clinical Trials
by Bert Spilker, 1991, Raven Press

Clinical Data Management
by R. K. Rondell and S.A. Varley, 1999, Wiley

Practical Guide to Clinical Data Management
by Susanne Prokscha, 1999, Interpharm Press

Read any good CDM articles or books lately?

Please submit suggested reading to the Editorial Board.

Opening Pandora's Box of Data

Mergers, acquisitions and partnerships are common facts of life now in the pharmaceutical business. Development teams no longer have the luxury of working exclusively on their own homegrown compounds. Those who have been enriched by the experience of bringing in another organization's partially developed compound will surely have tales to tell. In some cases working with another organization's data may feel like one has opened Pandora's box. A series of Herculean challenges can be visited upon the team who opens the shipping boxes. This article will briefly summarize some of the "gotchas" encountered by one team.

Working with another organization's data challenges working assumptions and expectations. There is a tendency to think, "data is data is data" in the same way that a rose by any other name would smell just as sweet. This bias can produce errors that are devastating in impact, such as missed timelines or drawing invalid conclusions, or are simply very embarrassing. The bias often blinds us to the impact of explicit and implicit differences in data arising from differing organizational standard operating procedures (SOPs), data processing, analysis styles, and intentions for use.

A result of a recent merger involved data from several clinical trials generated by one part of an organization to be transferred to another part of the organization. The documentation accompanying the data contained lists of variables and their attributes as well as the sample protocol and case report forms, which formed the pattern for all trials. This data had been cleaned and reported upon to various health authorities prior to being passed between organizational groups. Subsequently, additional reports requiring integration of data across the various trials were needed. The integration of data across studies was not expected to be a difficult or terribly time consuming task considering the standardization apparent in the documentation.

Impact of Differing SOPs for Collection of Data and Data Processing

The first realization that assumptions did not match reality in all instances came after opening the first few data files and finding inconsistent data value (format) libraries. The existing working assumption within the receiving organization was that no mapping of data values occurred within an output table. All formatting and calculations were assumed to occur in the data set build process. This was not the same working assumption that existed within the sending organization. The first batch of results produced for the integrated analyses could not be verified against the individual trial reports previously produced. Many levels of coding values and switches to be turned on or off within each trial's data set and supporting programs and libraries were found. Early looks through the libraries and programs found the materials appeared similar and seemed to share the same structure. In practice a great deal of variation existed which was missed during the first attempts at cross trial integration.

Upon closer examination of the data files and supporting documentation, other explicit differences were found. Though different trials used the same case report form structures, the data was not encoded in the database the same way. In many cases the variable names were the same, but in one trial, variable values were stored as character, while in another, the same data and variable name was encoded as a numeric variable. It became even more complex when the team discovered that all character values were not created equally. In one trial the values were character text strings; but in another, the values were integers stored as a character code for the same character text strings as the previous trial. What was originally assumed as standard was revealed as individual trial interpretations of a standard. Again, for a single trial report these differences were not important. The differences became important only when attempting to integrate across the trials.

A particularly difficult implicit difference had the team producing negative average daily doses following integration of the data. Country-specific medical practices

countries patients received trial medication from trial personnel at the time of visit while other countries used separate pharmacies to dispense and return medication. This meant that different trials did not have the same underlying relationships between windowing variables used to calculate an average daily dose. No mention was made of these differences in the trial documentation because nothing special was done to address it for any single trial. Again, the differences only became apparent when trying to apply the same algorithm to the different trials during the process of integration.

Impact of Differing Expectations on Use

Obviously, plans for data use have an impact on how the data is handled. Clearly, the anecdotes above illustrate issues that can arise when trying to use data differently than originally planned. The end use often impacts data cleaning decisions. The origin of the negative average daily dose lay in the use of dates of dispensing and returning trial medication. The original trial reports focused on compliance not exposure. The data scrubbing verified that over the course of the trial all medication dispensed was adequately accounted for. So as long as the *patient eventually* brought back all unused medication or gave an adequate verbal explanation for any missing medication, the patient was judged to be in compliance with the trial protocol. The data was cleaned for the purpose for which it was to be used. Later use of the data required calculations on the number of pills dispensed and returned within specific time periods to relate drug exposure to a number of specific trial events. The dates of dispensing and returning were not scrubbed with respect to sequence or dosage estimates since there was no intention to use them for windowing and calculations in the original reports.

Often the regulatory environment can shift in the time between the beginning of a compound's development plan initiation and the completion of the final study reports. Many of the activities previously described were the result of changing requirements used by various agencies or strategies to meet regulatory agency requirements. As we move toward more global regulatory environments the need for data to be used and re-used, generated and transferred will increase.

Living with the Consequences of Opening the Box

While it's tempting to say it's wiser to never open the box, it's impractical. Often what's in the box is desperately needed. The following are some questions to ask and have the answers to before attempting to use the data.

- What was the original purpose of the trial?
- What are the specific current needs for the trial data?
- Was the data scrubbed for the fields crucial for the current use of the data?
- Does the data need to be integrated with other data sources?
- Is all efficacy data needed or just a portion?
- Is all safety data needed or just a portion?
- How old is the data?
- Could the standards have shifted over time?
- Did the same team conduct all related trials?
- Can original team members be contacted for help?
- Who set the rules for the trial: the pharmaceutical company, CRO, or investigator?
- To which regulatory agencies was the data sent?
- To which regulatory agencies will the data be sent?
- Is documentation of collection, coding, and processing for every individual trial accessible?
- What are/were the working assumptions/ guidelines from the data source regarding data processing and reporting? How similar are they to the receiving organization's processes?

In the time pressured and shifting environments data transfers happen within, often the answers to these questions are not fully known nor is the impact of the answers assessed until someone attempts to use the data. Issues are found and dealt with iteratively, if they are found at all. The following initiatives are recommended to help identify and solve the data headaches described above proactively rather than reactively.

1. Compare the data structures across all trials for differences, not just a sample trial.
2. Compare format libraries across all trials for differences, not just a sample trial.
3. Examine reporting programs for data-specific coding or formatting within each trial and across any integration.
4. Identify the critical variables used for previous reporting.
5. Identify the critical variables needed for current needs and compare to the list for previous uses. Differences could indicate areas where more careful handling is needed for current uses. Differences could also indicate potential algorithm or cleaning issues.

May you be prepared to face the data demons in your boxes and find the challenge exhilarating.

Tamela Blackstone, Pharmacia

Other Data Management Organizations:

The Association of Clinical Data Management: The Pioneer

Overview

Drug development is becoming more and more global. Simultaneous development in the US and Europe, often with trials utilizing investigators based in multiple continents, leading to simultaneous submissions in the US and Europe, is now commonplace. The Japanese gap is closing all the time, with Japanese submissions now typically following soon after. Also the Japanese authorities are now accepting foreign data, adding a new data management challenge. With the increase in globalization and the consequent need for increased data management expertise required for integration of data for global submissions, data management organizations have been founded all over the globe. The SCDM feels it is useful to make its membership aware of similar organizations and the services they offer. In the first of a series of articles on international data management organizations, the focus, appropriately, is on the very first, the Association of Clinical Data Management (ACDM), which was founded in early 1988, primarily to serve data management professionals in the United Kingdom. Details pertaining to the ACDM (e.g. objectives, membership, activities, etc.) are described later in this article. It is well worth visiting the ACDM web site (www.acdm.org.uk) where a comprehensive list of the association's activities, publications, training courses and scientific meetings is maintained.

The founders of the SCDM worked closely with the ACDM when drawing up the initial SCDM bylaws, and it is no coincidence that the original logos for both organizations are similar in design. The SCDM Board of Trustees has recently decided to actively seek closer cooperation with the ACDM and an initial meeting between the two organizations took place in the UK on March 10th of this year. At this meeting it was clear that there were opportunities for the two associations to benefit from sharing of information (e.g. dates of meetings and training courses), sharing of material (e.g. newsletter articles), and possible co-development of new offerings. The first such possibility is in the area of certification where the ACDM has recently begun looking into ways to supplement its successful Masters course in Clinical Data Management (CDM). The two relevant ACDM and SCDM committees are in touch at the moment to see if some sort of collaboration would be beneficial. Just like global drug development, it is clear that global co-development of data management services will be more efficient once common goals have been identified.

In addition to the Masters course, other offerings that the ACDM provides are four training courses

and relevant publications. Also it obtains financing by job postings in its newsletter and on its web site. One of its current objectives is to see how it can better serve its more experienced members. This may lead to other services that the SCDM could benefit from either directly or indirectly.

The SCDM has now become an active participant in quarterly international teleconferences held by the ACDM International Collaboration Sub-Committee. Fittingly, the current SCDM representative is Hugh Donovan, one of the co-founders of the ACDM, and its first chair. He will be reporting back to the SCDM Board of Trustees, who will ensure that the SCDM membership is kept informed of global data management activities.

It is important that the SCDM, while focusing on North America, makes use of the resources available globally to maximize the services available to its membership. Look for other data management organizations to be featured in future editions of *Data Basics.*

Introduction to the ACDM

The Association for Clinical Data Management (ACDM) is an organization that promotes the professional identity and awareness of CDM both in the pharmaceutical and related industries and regulatory authorities and academia. It is a forum for people from these backgrounds to exchange ideas and make a network of contacts and aims to establish an industry wide standard. Clinical data are important and complex which makes their collection, capture, storage, management, review, retrieval and analysis more difficult than for many other types of data. The ACDM brings together diverse groups from many disciplines to enable both the exchange and comparison of perspectives in this exciting field.

The vision of the ACDM is to lead the profession of CDM in the development and appreciation of its essential activities, promoting the development of members and enabling their participation in drug development. This is accomplished by providing key fora for the membership to develop standards within the profession and to enhance their skills and knowledge. The ACDM is an independent, non-profit making organization with an international perspective.

Objectives

ACDM's objectives are:

- To promote the professional identity of CDM
- To further technical knowledge and provide education in CDM

Membership

The ACDM is the largest organization focused on CDM, with approximately 1880 members, nearly 1600 being based in the UK, 24 in Australia, 16 in North America, 2 in Japan, and the rest being spread over 11 other European countries.

Activities

The association's activities include:

- Education
- Training
- Technical Meetings/Conferences
- Special Interest Groups
- Working Parties
- International Collaboration

Education and Training

The four currently available courses are listed below. These courses, run by CDM professionals, aim to contribute to the continual career development of the attendees and also to help move CDM forward.

- GCP in Reality
- Introduction to CDM
- Intermediate CDM
- Advanced CDM

The overall aims of these courses are to obtain an overview of the pharmaceutical industry and examine the place of data management within the clinical trial process with particular reference to European GCPs and the ICH guidelines. The courses also aim to provide an appreciation of the role of statistics in the design of clinical trials, the importance of CRF design, the aspects of handling laboratory data and also project co-ordination within clinical data management.

Furthermore, attendees can make contact with data management professionals working in many different pharmaceutical companies and contract research organizations and thus gain an industry-wide perspective of data management.

In association with Kingston University, the ACDM also offers a part-time postgraduate study in CDM. The aim of the program is to provide a formal education leading to an academic and professional qualification for CDM personnel.

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GOT A WEBSITE?

Want to support SCDM?

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

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

Web Sites to Check Out

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

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

SCDM	http://www.scdm.org

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

Other Data Management Organizations:

The Association of Clinical Data Management: The Pioneer

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Working Parties (WPs)

A Working Party is composed of a small number of ACDM members who have been identified by the ACDM Main Committee to research and discuss a particular topic or issue of value to the membership, with the aim of producing a product within a defined timeframe.

The specific Working Parties are as follows:

- ACDM/PSI Computer System Validation
- CDM Qualification
- Laboratory Data Format

Special Interest Groups (SIGs)

The Special Interest Groups are groups of ACDM members who have identified a common interest within CDM and wish to pursue this under the umbrella of the ACDM. The ACDM provides sponsorship and support for the development and maintenance of SIGs that have been initiated by members. SIGs meet on a regular basis, usually four times a year, and advertise their activities in the ACDM Newsletter.

There are six Special Interest Groups consisting of:

- Data Entry Professionals
- Electronic Data
- CRF Design
- Healthcare Economics
- System Validation
- Pharmacovigilance Data

International Collaboration

The aim of the International Collaboration Sub-Committee is to promote the exchange of information and ideas between ACDM and other CDM groups around the World. Currently this sub-committee has established a network of approximately 10 contacts from CDM groups around the world. This sub-committee will continue to strengthen these links and make new ones in order to improve communication across the various data management associations.

Clinical Data Interchange Standards Consortium (CDISC)

CDISC is an open, multi-disciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform-independent standards to improve data quality and accelerate product development in our industry.

The Case for Data Standards: An Industry Problem

Information technology advances during the last decade have been unprecedented, yet the medical and biopharmaceutical product development industry has not developed standards, procedures or software applications to effectively realize the increases in efficiency that IT advances should provide. As a result, clinical trials information management, analysis and review processes have suffered. By not fully exploiting IT, clinical trials data management remains a cumbersome, time-consuming, inefficient and painful process. Many companies have developed procedures for exporting and importing clinical trials data sets; still the transport of data from one application to another requires weeks to months of effort in manual data mapping and integration. Software systems to manage clinical trials data have improved substantially; still, individual pharmaceutical companies and individual software applications utilize fundamentally different data structures for data and metadata. Despite all of the efforts in this area, access to useful information for strategic decisions and safety assessments are still not timely.

Why have we not been able to develop standards in biopharmaceutical clinical research to date? Reasons include:

1. Our data standards requirements have not been clearly articulated or enumerated.
2. Past standards efforts have been too broad, without focusing on specific clinical data management needs and theories.
3. Most companies have limited their scope to their internal standards needs, without thinking of tackling the effort on an industry level, either for proprietary reasons or because the task is daunting at first glance.
4. Standards development in our industry may be more complicated than that in other industries, since we must accommodate the scientific complexity inherent in clinical research (thus discounting a straightforward IT solution).

Acknowledging these deterrents and difficulties, CDISC now has a growing multi-disciplinary group of experienced industry professionals, who have expressed their belief and have demonstrated with their time and expertise that, in fact, certain standards would be quite valuable and can be defined for our industry. This group believes that data standards would provide the following benefits to all industry players:

- Nearly seamless exchange of data within a company and between collaborating companies, within projects and across protocols and development programs
- Effortless archiving of data and metadata for future review or regulatory audit
- Integration of data from a wide variety of applications and systems
- Facilitated regulatory submission reviews
- Improved data quality

Composition and Organization of CDISC

During its brief existence, CDISC has grown from the grass-roots level, comprised of individuals who have personally experienced the problems associated with lack of standardization. Over time, more and more participants have joined the effort and CDISC now includes over 200 participants representing approximately 100 organizations, including global pharmaceutical and biotech companies, academia, CROs, SMOs, software and applications providers and others.

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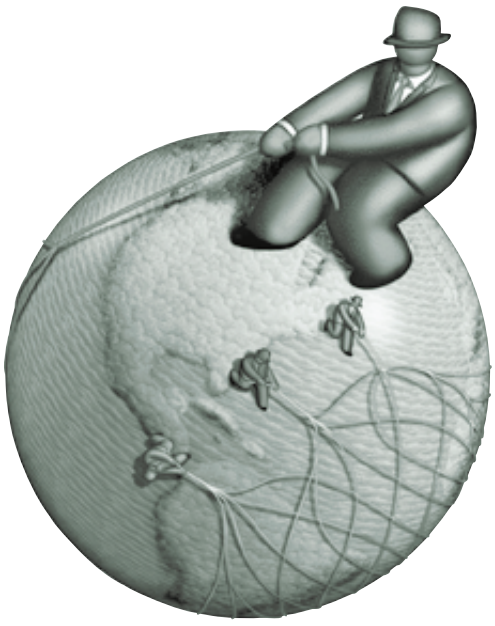

Clinical Data Interchange Standards Consortium (CDISC)

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The initial CDISC Board of Directors was formed from the pre-existing, active CDISC Steering Committee when CDISC became a non-profit organization. An Industry Advisory Board is being formed from Corporate Members, i.e. representatives of companies who are contributing seed funding to the new CDISC entity. There are plans to also initiate a Scientific Advisory Board, which would include our Agency liaisons and others who can advise on the scientific aspects of the standards development without having fiduciary responsibilities.

The diverse, multi-disciplinary experiences and talents of its participants and leaders place CDISC in a unique position to develop specific standards that can dramatically improve the current data management and review processes. This multi-disciplinary participation has benefited CDISC enormously by supplying multiple perspectives to help solve the widespread problems caused by the absence of standards. Only a multi-disciplinary approach can fully resolve the problem; no one stakeholder or functional group can solve the problem alone.

Objectives of CDISC

By focusing on the content, structure and context relevant to the electronic acquisition, use and archiving of actual clinical trials data and related information, CDISC truly has a niche of its own in the world of standards development. CDISC is focusing on the clinical data standards for the conduct of clinical trials and is positioned to work in collaboration with other standards groups, such as ICH and HL7, without duplicating their efforts. Specifically, CDISC recognizes five high-level objectives:

1. Define data interchange and information standards, without limiting the process or application implemented.
2. Ensure that the standards are open and are independent of platform and application.
3. Leverage standards to decrease cycle time and cost in drug development programs.
4. Define standard data models that meet the stipulations of the prior three objectives.
5. Define standard nomenclature related to the electronic acquisition and exchange of clinical trials information.

CDISC Concepts

Just as a set of statistical tables show results and planned labeling for a new product provide a target for protocol and CRF design, standards for the regulatory submission data content provide an obvious target for data acquisition standards. The standards can be developed independently of the mechanism and technology used for the data exchange. Regardless of the technology, clearly defined content and assumptions for data and data collection tools will provide the opportunity to build the quality in from the beginning. As more and more of the parties involved in clinical research begin to operate from a set of common assumptions with a common language and syntax, the benefits will be experienced across the complete clinical research value chain and reduce product development time overall.

That being said, the recent advances in technology can be better leveraged and will obviously provide our industry with a clear advantage when implementing the standards that are defined and agreed upon within our industry. For example, XML is receiving much attention as a simplified means of exchanging data between two different systems or databases. However, the real advantages of XML are realized only when an industry agrees upon how it will be used for their needs.

CDISC has made progress to date for a number of reasons. First, they started with clearly defined requirements for data interchange and submission standards. The scope was articulated as keeping the end in mind. They concentrated first on the metadata, staying above what most companies perceive to be their proprietary models. They took an open and multi-disciplinary approach, recognizing that no one faction in the industry can succeed without the others. And, last but certainly not least, CDISC has reaped significant benefit from the non-monetary contributions made by its participants. Numerous companies and individuals, who appreciate the potential benefits of having data standards for our industry, have devoted significant time and energy to achieving this goal.

CDISC Progress

CDISC, which became a non-profit organization in February 2000, currently has four primary working groups: Glossary Group (GG), Submission Data Standards (SDS), Data Acquisition and Interchange Standards (DAIS), and Laboratory Data (Labs). The first definitive effort was by the Glossary Group. Their goals are to compile a CDISC glossary of terms, using available definitions whenever possible and, when necessary, to develop new definitions for terms that will facilitate communication among CDISC participants.

Progress in the areas of data submission and acquisition standards was significant in 1999 due to two breakthroughs. The first breakthrough was the FDA issuance of the new industry guidance on regulatory submissions, for NDAs, BLAs and general considerations. These documents provided the focus for the Submission Data Standards Group to develop standards for the structure and content of data sets in electronic submissions. The other breakthrough was

the open sharing of two proposed XML models for electronic data interchange and archiving by three technology vendors/ consultants, which stimulated a subsequent analysis and consolidation of these models facilitated by the Data Acquisition and Interchange Standards Group.

The Submission Data Standards Group now has a metadata model that they are applying to the 12 safety domains for regulatory submissions. Subgroups are working concurrently on several data sets, but the first of the core safety domain data set examples have already been posted to the FDA Docket and the CDISC web site. The Data Acquisition and Interchange Group has developed Version 0.8 of an XML model to support data interchange; Version 1.0 is anticipated by June 2000. The next step for the latter group is to augment the model to support data archiving and other aspects of clinical trial conduct. These two groups are working together to ensure that their models are synchronized to support clinical research, from acquisition to submission of electronic data. They are also expanding their work to include reviewers from all areas of the industry and plan to delve into additional standards development, including submission standards for specific therapeutic areas, in the future.

The Laboratory Data Group has been working on the laboratory domains for the submissions standards group to date, but they plan to initiate further laboratory-related standards activities as a separate CDISC working group in the near future.

In addition, CDISC Europe had its inaugural meeting on May 9, 2000 to discuss plans for increasing European involvement and support of CDISC.

Benefits of Working with CDISC

Participants in CDISC have a direct influence on the development of standards. They are on the cutting edge of progress and thus have the ability to develop systems, applications and submissions that are in sync with the emerging standards. They will have a shorter organizational learning curve and ramp up time with respect to utilization of these standards. In addition, Corporate Members have a seat on the Industry Advisory Board, which will have input into the CDISC Governing Board with respect to the budget and operational aspects of CDISC.

How to Join CDISC

CDISC welcomes all participants interested in furthering the work towards industry data standards. We do not currently request dues from individual members, but we do look for contributions of time and support. CDISC has requested financial support from corporations involved in the drug development industry to help CDISC accomplish its standardization goals, conduct working group meetings, publish results, develop models more rapidly, and communicate progress. We do ask our CDISC participants to encourage their employers to support CDISC by becoming Corporate Members. A business plan, details on the advantages of Corporate Membership and further information are available by sending an e-mail to Rebecca Kush at rkush@nextphase.com.

Many people in the industry have begun to watch CDISC closely over the past year. We would like to encourage you not to just wait and see what happens, but to become involved and make this happen with us — to have an influence. As a mentor once said in reference to change: "The train is leaving the station. You can be on it or under it!" So come on board the standards train!

Further general information on CDISC is available at www.cdisc.org.

CDISC Governing Board Members:

David Christiansen, DrPH — Leader of the SDS Working Group; Industry Advisory Board

Kaye Fendt, MSPH — Leader of the Labs Working Group; CDISC Europe; Scientific Advisory Board; previous FDA-CDISC Liaison

Wayne Kubick, MBA — Leader of the SDS Working Group; Web site Director; DAIS-SDS Technical Liaison

Judith Sromovsky, MS — CDISC Treasurer; CDISC Europe

Rebecca Kush, PhD — CDISC President; DAIS Working Group Coordinator

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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