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DATA BASICS

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Promoting Clinical Data Management Excellence

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

Letter from the Editors

We hope everyone enjoyed the summer. Inside this issue you'll find session summaries from the Spring Forum, *"Successful Data Management Technology Implementations and How You Get There"* and updates from the web committee and the GCDMP committee. It's amazing that version 3 of the document is nearing completion. It's even more amazing that this is the only document of its kind for our profession. Our featured article this issue describes HIPPA from a newcomer to the field's perspective. The article provides an important overview of some of the implications the legislation has on our tasks.

Regards, *Tam & Cherie*

2002 SCDM Spring Forum Meeting Summary

Successful Data Management Technology Implementations and How Your Get There!

Susan Bornstein Spring Forum 2002 Chair

The Eighth Annual SCDM Spring Forum brought together leaders in Clinical Data Management for two days of intensive interactive discussions. The Forum, unlike the Fall Conference, is limited to 60 attendees. This years' focus was on *Successful Data Management Technology Implementations And How You Get There!* **Susan Bornstein**, Director, Data Management, Serono, Inc., was the 2002 Spring Forum Chairperson. The forum took place Sunday, March 10, through Tuesday, March 12, 2002 at the Radisson Bahia Mar Beach Resort in Fort Lauderdale, Florida.

"The new learning doesn't come from the traditional sources of knowledge. It comes from the conversations among smart people in shared spaces."

— Thornton May, Corporate Futurist and Chief Awareness Officer, Guardent

The 2002 Spring Forum opened on Sunday evening, March 10, with a 90-minute narrated scenic Water Taxi cruise past the millionaires' mansions and marinas along the Intracoastal Waterway, followed by a Seaside Buffet Networking Event in the Radisson Bahia Mar's Waterfront Gardens.

What does it mean when consultants observe that traditional clinical data management is obsolete? Why does the idea of electronic clinical trials challenge traditional CDM so strongly? Day One of the Spring Forum began with *"Transitioning From Clinical Data Management To Electronic Clinical Trials: Possibilities, Pitfalls, Pathways,"* presented by **Ronald S. Waife**, President, Waife & Associates, Inc. This presentation outlined some of the possibilities, pitfalls and pathways for transitioning from clinical data management to

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THIS ISSUE

Comments from the Membership

This section will appear from time to time as comments are forwarded to *Data Basics.*

Unfortunately no comments/questions/thoughts/concerns were submitted for this issue. Remember, this is a forum for you to speak up, stir thoughts, or begin discussion topics. Does anybody have an opinion or question they'd like to pose to the rest of the membership on MedDRA, HIPPA, CDM Certification, or other topic? If you are shy, we can withhold names to give contributors anonymity.

Call for Letters TO the Editors

Do you have an opinion or concern about some activity of one of SCDM's various committees?

Do you have a question you feel needs more discussion or a more in-depth answer?

Have you been wishing for a way to express yourself to both the society membership and those serving on a specific committee?

Well the wait is OVER! Your opportunity to express yourself is here, and "no," you don't have to publish your comments with your name.

Data Basics has created the "**Comments from the Membership**" column in order to give you that opportunity. We want to hear from you, the membership, on any data management or society-related topic that interests you.

All letters should be submitted for publication to *Data Basics* co-editors Tam Blackstone (tblackstone@allos.com) or Cherie Stabell (stabell@gene.com). Materials are requested to be submitted in electronic form (MS Word) but may be submitted via e-mail, fax, or by mail. Acceptance for publication will be at the sole discretion of the Editorial Board. The decision to publish 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 (principally for formatting and grammar/spelling).

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2002 SCDM Spring Forum Meeting Summary

Successful Data Management Technology Implementations and How Your Get There!

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electronic clinical trials. The presentation also described steps to prepare the organization tactically after the strategy is selected, and the tasks required for implementing new technologies and processes successfully. Some suggestions for preparing the organization were to create awareness, set expectations correctly, develop meaningful metrics and follow through, access roles and skills, map your processes (current and future), assess IT infrastructure, perform a structured and informed vendor evaluation based on your needs, and manage the implementation.

Day One explored four aspects of the Spring Forum theme. Breakout discussion groups of 15 attendees explored all four themes by rotating through the sessions held throughout the day. Each session included a "randomized" group of participants so that the attendees had optimal opportunity to meet and collaborate with colleagues. The unique format of this meeting fostered the exchange of information while giving the opportunity for thought-provoking debate as well. Facilitators presented a summary of the breakout sessions the following morning in the form of a game. The attendees were divided into four teams. The facilitators asked summary questions from their sessions and the teams had to be the first to complete writing down the answer on the flip chart then ring a bell. We found there to be a very competitive spirit in many of the attendees. The four sessions were:

- EDC Implementation
- EDC Integration
- Other Technology
- Implementing Standards

Day Two featured an interactive discussion on EDC Implementation Experiences with industry and vendor representatives. Panelists: **Paul F. Clarkson,** Senior Manager, Clinical Data Management, Genentech, Inc.; **Jeffrey Green,** PharmD, CEO, DATATRAK International; **Jeffrey Klofft,** Vice President, Products and Technology, Phase Forward Inc.; **David Ng, PhD,** Vice President, Biostats & DM Consultative Services, PPD Development; **Andrew Silverman, PhD,** Senior Director, Clinical Operations, Data Spectrum; and **Stephen Young,** Assistant Director, CDM, Centocor, Inc. "Ask the Experts" forms were completed by some attendees with questions for the panelists including:

- "Would EDC be better utilized in Phase I, II, III, or IV trials?" Responses in opinion varied from recommending Phase I or IV trials to pilot to the approach of choosing a pivotal Phase III trial to ensure support from senior management.
- There were several questions on FDA requirements for live data kept at the site and definitions of electronic source documentation.
- "If the focus changed from EDC to ECT, would organizational support and recognition likely be greater and therefore likely to be successfully implemented?" This discussion started with the panelists defining what ECT's mean to them then continued with a discussion on how to gain upper management support and sell technology implementations successfully in different organizations.

The Spring Forum concluded with a Workshop on *"How To Develop A Vendor Software Selection Questionnaire."* **Susan Bornstein,** Director, Data Management, and **Marie Payton,** Manager Database Development, Serono, Inc., shared Serono's approach and experience on selecting a new CDMS system and facilitated the workshop. The workshop included an interactive working session on how to develop a vendor RFI (Request for Information). An RFI should include sections such as:

- Scope, Objective and Timeline of sponsor project
- Request for General Vendor Information
- Request for Product Information
- Request for Contractual Information
- Pricing options descriptions
- Functional Requirements as defined by sponsor
- Product Technical Architecture and Operational Environment
- Product Integration with Other Applications

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2002 SCDM Spring Forum Meeting Summary

Successful Data Management Technology Implementations and How Your Get There!

Susan Bornstein Spring Forum 2002 Chair

- Vendor Technical Support and Training
- Vendor User Support
- Security and 21 CFR Part 11 Compliance
- Requirements for Vendor Demonstration (including sample CRF Pages and associated edit checks)
- Sponsor Company Acronym List

The workshop focused the attendees on defining functionality requirements for an EDC/CDMS system. The functional requirements included:

- CRF and Database Design
- Data Object
- End-user Interface
- Database Reports
- Data Monitoring
- Data Entry
- Data Validation and Protocol Violation
- Database lock/unlock
- SAE Reconciliation
- Event Tracking and Trial Status
- External Electronic Data
- Dictionary Coding
- User Profile Administration

The Serono RFI had Criteria Scoring for each Functionality Grid defined as follows:

3 = currently has functionalities as specified by CTOP Sub team 4

2 = next version will include functionality within 6 months – specify date

1 = functionality expected 6 – 12 months – specify date

0 = not available or not available within the next 12 months or not available as part of the core system

The Process

- Serono developed a long list of vendors (17) and asked each to submit RFIs. Serono received 13 responses.
- Vendors were rated according to process matrixes and questionnaires and 7 vendors were selected to present.
- 5 vendors were selected for a second presentation and demonstration. Both build vs. buy scenarios were discussed.
- The list was then narrowed down to three vendors. At this point a two-day visit was scheduled at each vendor to do a detailed gap analysis of functionality required by Serono vs. functionality of the vendor offering.
- The final analysis included a cost benefit analysis and timeline estimates of when missing functionality would be available.

This was a long process which began with defining "as is" process maps then "to be" process maps. Serono's approach was to define the processes then select a technology to match how they wanted to work. Serono decided to take the EDC/CDMS technologies in house via a vendor technology transfer partnership. It is important to set realistic expectations and develop a true partnership with your vendor

Thank you to all the facilitators, panelists, keynote speaker, attendees, and **April Pennacchio** for a very productive and successful Spring Forum 2002.

Website Committee News

It's been a busy year for the members of the Website Committee. Much has been accomplished, but there is still work to be done.

There are 8 members on the committee. ***Jeffrey Sadik*** is currently serving as committee Chairperson. ***Greg Dziem,*** the past committee Chairperson, is now a member of the Board of Trustees. He now acts as the committee's Board Liaison. We would like to thank ***Jonathan Kfoury*** for his time and contributions. Due to work commitments, he is no longer on the Website committee.

New members are always welcome. If you would like to contribute, please contact ***Jeffrey Sadik*** at sadikj@immunex.com or ***Greg Dziem*** at greg@amgen.com.

The members of the committee hold regular monthly teleconferences to discuss issues related to the SCDM website. The committee is empowered to make decisions regarding the content of the page, but we also look to the Board of Trustees for guidance and approval. Professional Management Associates (PMA) performs the actual website maintenance and upgrades, and works with the Website Committee when decisions are to be made.

Recent additions to the web page include:

- Code of Ethics added. (Click on the "About SCDM" link.)
- Renewing membership online. (Click on the "For Members" link first, you will then be able to review your info and enter a credit card for billing.)
- Papers from the February conference in Seattle are available. (Click on "For Members", then select "Recently Held Events".)

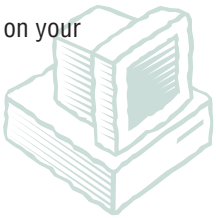
Ongoing committee topics include:

- Adding Message boards/discussion forums. PMA and the committee are currently reviewing different packages and expect to make a decision in the next two months.
- Online voting for the Board of Trustees is in process.
- The site will also have a hit counter in the near future. PMA will be putting this into production shortly.
- New job postings appear each month. The committee reviews these before being posted.

So, please browse the SCDM web pages and let us know how we're doing. We'd love to hear from you!

Got A Website?

Want to support SCDM?



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

Contact Jeff Sadik

(sadikj@immunex.com)

if you need more information.

SESSION

EDC Implementations

*Facilitated by **Gary Drucker,** Deputy Director, Clinical Data Management, Bayer Corporation*

Objective:

Characterizing EDC in the context of the Clinical Data Management profession.

Overall this session provided a forum for CDM professionals to offer their perspective on the state of Electronic Data Capture (EDC) in the Pharmaceutical industry. The overall session consensus is that EDC defined as data entry at the sites with electronic edits at point of entry, is really a combination technology/process (techno-process) that has taken hold within the industry. Although there is still significant resistance to its full implementation mostly due to fear of change, enthusiasm for EDC from CDM professionals is significant and is becoming a driving force towards increasing EDC implementations. It is recognized that this techno-process must be carefully managed and implemented with the support of nearly all functions within clinical development. The future of EDC will be defined by increasing EDC implementations and it's integration into the full complement of techno-processes that do and will continue to support Pharmaceutical product development in the coming decades.

Session Specifics:

QUESTION #1

Do Data Management personnel support EDC? If so, why? If not, why not? It might be stated that EDC is a technology that has been thrust upon the CDM profession. Where do CDM personnel stand on its implementation?

CDM professionals support EDC for the following reasons:

- Decrease in paper handling
- Improved data clarification process, electronic edits built into EDC system for sites to address at point of entry which in turn improves data quality
- Access to data faster for study management decision making
- Improved communication between CDM and study monitoring personnel, although responsibility lines may be blurred
- Increased clinical data throughput to regulatory agency submissions
- CDM involvement with site and CRA training of EDC functionality
- Requires less CDM resources to process data

CDM professionals have the following reservations about implementing EDC:

- Fear or resistance to change, job security concerns
- Technical training may be required for CDM professionals to support EDC which may offer personal growth
- Concerns about integrating EDC with other CDM process outputs (labs data, IVRS, safety data)
- Uncertain about appropriateness of EDC for all studies, may need to be selective
- Compliance with FDA regulations
- Data confidentiality, may be legal issues
- Increased set-up time at start of study. Will this be accepted?

QUESTION #2

Roadblocks to implementing EDC: It has taken a long time for EDC to begin to gather acceptance in the Pharmaceutical Industry. Why has it taken so long?

Roadblocks to successful implementation:

- Fear of the unknown
- Costs for implementation and support
- IT infrastructure and support requirements
- Telecommunications uncertainties
- Site acceptance issues
- Setting and managing expectations
- EDC does not cover all CDM functions (coding, lab data handling, etc.)
- Meeting CFR Part 11 and any other government regulations

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SCDM Officers and Committee Chairs

Chair of the Society	**Hugh Donovan** Aventis (hugh.Donovan@aventis.com) / 908-231-3938
Vice-Chair of the Society	**Sally Cassells** Lexington Clinical Data Systems (sally44@rcn.com) / 781-863-9918
Treasurer of the Society	**Judy Kasperczyk** TAP Pharmaceuticals (judy.kasperczyk@tap.com) / 847-236-2474
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EDC Implementations

Facilitated by ***Gary Drucker,*** *Deputy Director, Clinical Data Management, Bayer Corporation*

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QUESTION #3

Key factors leading to successful EDC implementation: Itemize the factors that CDM personnel believe are key to a successful EDC implementation.

Key Factors:

1. Self Evaluation

- Define and plan to manage expectations of upper management, CDM, sites, study monitoring, regulatory, etc.

2. Planning/Processes

- Define work flow
- Define roles and responsibilities
- Carefully budget human resources and dollars
- Consider data integration
- Commit to standardization (screens, edits, reports)

3. Building Support/User Acceptance

- Consider CDM, Clinical Operations, Regulatory, IT, Sites, Safety, Finance, Stats, etc. needs
- Celebrate successes, identify problems with plans to fix them
- Keep stakeholders informed and involved

4. Selecting Technology Partner

- Pick the right vendor for your organization's "fit"
- Be open with partner
- Cultivate the relationship and keep at it
- Do not expect perfection, expect evolution which means changes will occur

QUESTION #4

Is EDC the optimal process for Clinical Data Management? Do CDM personnel see EDC as the end-all in clinical data capture? What would CDM personnel like to see as the next steps?

- EDC is not the be-all-and-end-all; considerable CDM resources still needed to process data
- But EDC does have significant advantages over paper
  - Data availability for decision making and assessment of study compliance
  - Edits for cleaning data at site, closer to source of data
- EDC goes beyond CDM, affects other parts of product development
- EDC may not be appropriate for all studies, need to do assessment
- EDC integration with other CDM processes is a key for it's long-term success, EDC is not standalone

SESSION

EDC Integration

Facilitated by ***Sally Cassells,*** *Lexington Clinical Data Systems*

Objective:

Share and discuss strategies for Integrating Electronic Data within a study, within a clinical program and across the enterprise.

The topic for this session was Integration of EDC. Two themes were explored:

1. ***How to Integrate EDC with other Clinical Research systems to meet the needs of Data Managers***
2. ***How processes for working with EDC would be integrated into the Data Management workflow***

BASIC INTEGRATION TECHNOLOGIES

For most participants, a key EDC issue is integration with back end CDM systems. Companies with extensive EDC experience have set up agreements with EDC vendors to provide ASCII data transfers periodically through the course of a study. They use the data loading features in their CDM systems to pull data into their back end systems.

Once data are loaded into the CDM system, AutoCoding and QC checking procedures are run on the data much as if it had been hand entered.

In companies where Data Management is mostly out-sourced to CROs, integration of EDC data is more typically accomplished by loading of SAS datasets or transport files into a Data Repository that becomes the source for study analysis and reporting.

SYSTEMS TO BE INTEGRATED

EDC systems also need to be integrated with Interactive Voice Response (IVR) systems, Electronic Patient Diaries, Labs, EKGs and Serious Adverse Events. Each of these systems has some unique challenges. Few if any companies had yet assembled a fully integrated, EDC based environment.

LAB INTEGRATION

Many participants indicated that integration of lab data was a significant challenge – whether or not EDC was used. Developing clearly defined requirements for lab data, and frequent checking that the transfer files met the agreed upon requirements were some of the strategies suggested. When the CDISC Lab Standard is published, it will provide a basis for standardizing transfers across central lab vendors and studies.

The EDC vendors present indicated that they are asked to load in central lab data for most studies. However, in some sessions, participants indicated that for some studies it was sufficient to load lab data into the back-end data management system. As EDC systems become easier to use, Investigators may be more interested in looking at lab data on-line.

EDC PROCESS INTEGRATION

Study Setup

Integration of EDC technology means significant changes to the Study Setup process. More specifically, participants indicated that:

- Study Setup needs to begin earlier
- Data management needs to be involved in defining the eCRF, the study database and edit checks in consultation with other departments
- Signoff on all aspects of the study configuration requirements should be obtained before beginning the configuration work
- Well defined standards help in expediting the setup process

In most companies Data Managers are finding they need to educate their Clinical Operations colleagues about the need for the up front design work. As the study teams gain experience, Data Management's role in assuring that the study is properly setup in the EDC system becomes recognized.

Queries and DCFs

Participants who had more extensive EDC experience indicated that they had gone through a trial and error process in determining how to use edit checks with EDC. Adding too many 'low value' checks led to annoyance by users at sites. Adding too few checks means giving up a good deal of the benefit of EDC. Many 'traditional' edit checks such as checks for data type, conditional missing values and out of range checks are done implicitly by the data capture software. Checks involving multiple values on a single data entry page provide the best 'return' on the programming effort involved. In most cases, checks involving multiple values on different data entry pages are difficult to program correctly.

There was also good agreement that Data Management could still add significant value by running 'back end' QC checks prior to the EDC database lock. A substantial number, if not a majority, of participants indicated that these back end edit checks could be run in SAS. For longer-term efficiencies, automated means of loading queries from a back end system into an EDC system would be needed.

The Query Resolution process for EDC may require review and change of both the Data Management and CRA work processes. In general, much less of Data Managements time will be spent reviewing and managing queries which will enable groups to increase study capacity without adding headcount. A few participants indicated that CRA processes would also change significantly. Data Managers and their management should establish an open dialogue between CRAs and Data Managers so that they can work together to refine roles and responsibilities and realize efficiency gains.

eSOURCE AND BEYOND

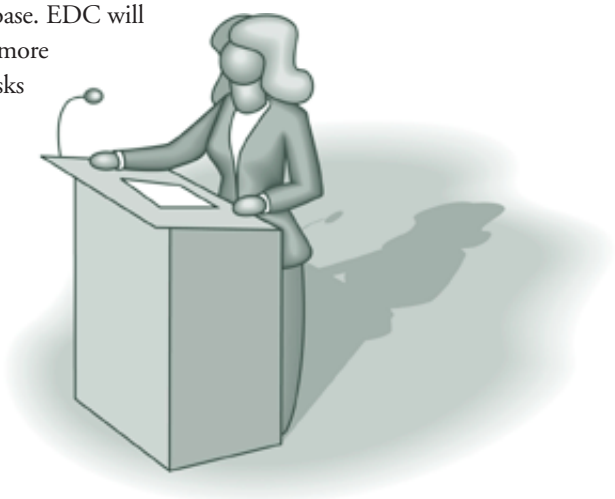
Integration techniques deployed today are based on transfer of a point in time state of the EDC system to the sponsor or CRO. Most sponsors are relying on EDC vendors to maintain 21 CFR Part 11 compliant audit trails both during the trial and through the records retention period.

Archival CDs containing PDF images of the data capture screens are usually made and sent to the Investigative Sites to meet site ownership requirements in the predicate rules.

Some participants are looking ahead to providing full electronic submissions including part 11 compliant transfers of the audit trail and metadata. A few companies are already building this capability into the CDM environment.

CONCLUSION

As most companies are still in the piloting or very early implementation phase of their EDC based Data Management systems, integration strategies are still being developed. Data Managers should be reassured that they will have an important role in driving the study setup process, integrating back-end data management processes and assuring quality in the resulting study data base. EDC will help to reduce some of the more repetitive and frustrating tasks and enable development of better-integrated Data Management systems environments.



SESSION

Other Technologies

*Facilitated by **Linda A. DeNardo,** Director, Global CDM Compliance, Wyeth-Ayerst Research*

Objective:

Share experiences and look to the future of new emerging technologies, including their development, the benefits and the risks.

Participants shared thoughts and experiences using various data collection devices, new technology for data transfers, types of data most adaptable and most cost effective for utilizing new technologies, and areas of concern.

e-DATA COLLECTION DEVICES

Some participants have experience using PDAs (hand-held devices, Palm Pilots, etc.) and find it a very efficient way of capturing data from subjects. In this case, the medical staff entered the data, not the subject.

- Many vendors offer metrics or tracking programs to monitor patient schedules and compliance.
- One large company has successfully used hand-held devices for pain measurement. The device displays a diagram of the human body.
- Some participants expressed concerns as to whether the computer aptitude of the subjects and the size of the display could be limiting factors when study subjects use PDAs to record responses.
- Downloading of data was identified as a potential problem. Security and encryption must be addressed. Sponsor firewalls may be an issue for remote sites.
- Pilot study using these devices should be done on either a Phase I or Phase IV trial, not on a pivotal study.
- Lead-time for set-up of PDAs is longer than set-up for EDC.
- May need input from ethics committees in some countries prior to using PDAs.
- Must define the source-data monitoring plan for the study to assure regulatory compliance.

e-DATA TRANSFERS

Discussions included security of transfers, use of telephone lines, preserving confidentiality of subjects, and the need for regular transfers.

- In one group, use of a single central repository for the data is the norm. Use of Citrix is improving response for remote users.
- One experience shared is the use of hybrid technology. The local site keeps a copy of CRFs synchronized with the vendor's database at a central location.
- Users must determine how the data will be loaded into the sponsor database. Will the vendor assure data transfer, or will the sponsor grab the data from the site?

e-DATA TYPES

- Optical Character Recognition used with a fax-in system is "not that good, but it's a step-up from straight paper and manual data entry." Subjects fill out forms at home. Need to address "electronic signature" requirement of 21 CFR Part 11 with this approach.
- VRS systems track entry date/time, and subjects can enter responses via telephone. Poor hearing over the telephone can limit quality of responses. Security measures can include using patient number and pin number for identification of subject and secure access to only that subjects own data.
- e-Patient diaries can support data collection as well as administrative study information (event reminders and alarms) and assist with monitoring patient compliance.
- Participants stated that the vendor must understand the patient population in the trial.

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GCDMP Committee Update

What has the GCDMP committee been doing over the summer?

The GCDMP committee has been meeting weekly in anticipation of the release of version 3 of the document at the Fall Conference in October.

Version 3 will contain several new chapters:

- Archiving
- Electronic Data Capture (EDC)
- Data Privacy
- Dictionary Management

Each of these new chapters has gone through a rigorous development process. Research and initial drafts are developed by the authors and distributed to the Committee for review. The initial draft and comments are then discussed at a weekly conference call with the Committee. The author and/or editor then integrate the feedback and post the document for a secondary review. Once the secondary review is completed, the chapter is forwarded to the BOT for review. Comments from the BOT are incorporated and the chapter is then ready to become part of the GCDMP.

In addition, we have been incorporating comments from both domestic and international sources into the existing sections of the document.

It is your input that make this document a great resource, keep the comments coming!

Other Technologies

*Facilitated by **Linda A. DeNardo,** Director, Global CDM Compliance, Wyeth-Ayerst Research*

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e-DATA ISSUES AND CONCERNS

Just as the data must be validated, the process of collection and transfer must be validated as well. Authenticity from the source to submission must be insured. What defines "source" for regulatory authorities – is it when the data hits the sponsor's server or when it is entered into a PDA? The data collection device may be 21 CFR Part 11 compliant, but companies must also ensure that the processes surrounding the data collection are compliant as well.

Security & Confidentiality

- HIPAA and European patient confidentiality restrictions must be heeded.
- Interpretation of regulations is a universal issue of concern and great anxiety.
- The environment for electronic data is changing rapidly. One company successfully completed an RDE trial, in which they dialed into the site's computer system at night to extract the study data. Current security concerns would not permit this today.

Process

- Many participants voiced concern that process re-engineering is not occurring with the introduction of new technology.
- Electronic data phobias can make people overly romantic or nostalgic about paper capture.
- Multi-media models of data collection can work well with integrated technology, but process challenges and finding appropriately experienced personnel are difficult.
- Electronic systems promote "freshness" of data. Alarms can be set to remind subjects to record data in hand-held devices.
- Some sponsors have successfully integrated the use of paper, thin client, and hybrid systems within the same study.

Changes in Results

- Introducing technology into a study can affect the way that patients perceive outcomes. An example was given, in which the electronic diaries were not available at the time the study started. There was a very obvious shift in responses by the patients when paper was used versus electronic diaries.
- Studies have been done which show many subjects are non-compliant with paper diaries. e-Data capture devices help by documenting the date/time of the entry.
- Electronic collection of specific data, such as AEs, may actually increase the number reported.

System Considerations

- Connectivity and data loading can be problematic in remote regions.
- Need to explore risks with software viruses to Palm Pilots and wireless transfers.
- One site, using IVRS system, downloaded data provided by the vendor. It was corrupt and contained duplicate data.
- One Phase IV study, using RDC, switched to paper due to data corruption.
- Some sponsors are requiring sites collecting e-data to have DSL or ISDN connections in order to participate in studies.
- Must have sites which buy into the use of electronic data capture. Two to three times the usual amount of training time will be required. Determine who will be responsible for "Help Desk" functionality (site or vendor).
- Re-usable hardware may help to defray costs. An incentive of offering PDAs to the subjects may be used, but some IRBs do not permit this. Cost of PDAs can be justified by recycling them to other subjects on short studies.
- More complex and comprehensive patient data collection devices are being developed (e.g. LifeVest, which collects many patient parameters concurrently).

SESSION

Implementing Standards

*Facilitated by **Marie Payton,** Manager Database Development, Serono, Inc.*

Objective:

Share and discuss benefits of data standards, how they are developed and maintained.

DEVELOPING DATA STANDARDS

According to participants, a cross-functional team should develop data standards. This helps to ensure ultimate buy in and use of standards. Data management representatives, biostatistics representatives, CRAs, project managers/leads from therapeutic areas, and medical directors can be members of the cross-functional team. Most companies represented at the forum had an established data standards team. Teams should be kept as small as possible in order to move the development process ahead quickly.

Keeping the standards team focused on the big picture rather than spending lots of time on minor details is important. There is a need for an ultimate decision maker for issues where the team cannot agree. For many companies, this person was often a VP or an MD. In order for the organization to develop and use data standards, upper management needs to be committed to enforcing the use of these standards.

Companies should be able to calculate the expected and actual benefits of using standards. Cost (FTE) and timesavings are the most valuable metrics to show. Some areas where the cost and time savings can be measured are CRF/screen design, database setup, and edit check programming as well as study reports, and continuing into statistical analysis, the tables and listings.

When data standards are developed, they should be released into use rather than piloting them. A review of the standards and any issues can be performed on a yearly basis. There was discussion regarding the review of these standards: reviewing them too often doesn't give them a chance to really be used and can lead to frustration if the standards change too often.

When standards are released, they can be released with a history and rationale, so that users can understand the changes and the reasons for changes. This will also help create buy-in of the standards.

Most companies had effectively removed administrative data from the CRF, by concentrating on collecting only clinical data. One way to convince others to remove this information from the CRF is to associate a cost with collecting and querying this data. Most companies had dedicated the CRF for recording clinical data only and not for extraneous information or prompts to assist the site or the CRA.

Phase I studies – some participants expressed experiences regarding the difficulty of getting their Phase I units to use standards. Most participants had used standards for Phase I studies, and suggested making standards for different types of Phase I studies (food effect, interaction).

ADHERENCE TO DATA STANDARDS

Participants felt that there needed to be oversight of use of standards. Some companies make it very difficult to deviate from the standards by putting up bureaucratic barriers, making it such a long and tough process that people will really think hard and need a very motivating reason to want to go through the process. Other companies try to allow flexibility in their standards by trying to make a quick review of any requests for deviation. There was some concern shared over having too quick of a review because you might not have enough time to fully evaluate the full effects of a deviation (looking through to analysis and data pooling, reports that are used, etc.).

DATA STANDARDS (WHAT'S INCLUDED)
Most participants included the following in their data standards:

- Data structure (variable names, variable types, and labels)
- Screen layout / paper CRF module
- Completion Instructions
- Monitoring Guidelines
- Standard Reports, Tables, Listings

The more items that are standardized, the quicker study startup can be. In addition, the data collection will be consistent across studies and data can then be more easily pooled across studies for ISS or ISEs.

CDISC
Most participants were familiar with CDISC, while some others had never heard of it. There are currently over 50 companies that are members of CDISC, and many companies are starting to adopt the CDISC SDM models, even down to the variable name. CDISC recently sent out a survey asking companies their plans to be involved with CDISC and how they are planning to implement it, but the results are not yet available.

Some participants were eager to start sharing standards across organizations, and were hoping to start seeing a trend of openness across companies.

Questions arose regarding how to handle evolving CDISC standards. Suggestions were made that just as you do not implement every new version of software, when a new version of CDISC comes out, you can evaluate the impact of the changes to your organization and decide which versions you will choose to implement.

Here is some information from the CDISC website (www.cdisc.org):

> *CDISC is an open, multidisciplinary, 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 CDISC data models will ultimately support the end-to end data flow of clinical trials, from the source(s) into an operational database, through analysis to regulatory submission. Operational Data Modeling (ODM) refers to the standard data interchange models that are being developed to support the data acquisition, interchange and archiving of operational data. Submission Data Modeling (SDM) refers to the standard metadata models being developed to support the data flow from the operational database to regulatory submission.*

CDISC is open to all who want to participate. One can participate by attending CDISC meetings, providing feedback on CDISC models through the Website Discussion facility, attending presentations at conferences, joining as a CDISC Corporate Sponsor or Corporate Member, working with support groups such as the Glossary Group, and/or participating in the working teams.

LEGACY DATA
Many companies expressed concern over how to handle legacy data when new standards were released. When this happens, thought needs to go into where in the clinical development project plan each legacy study fits in. If it is the first in an anticipated series of

continues on next page

Calendar of Events

October 6-9, 2002
EDC: Making It Real
Fall Conference
Grand Hyatt Buckhead
Atlanta, GA

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

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

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

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

SESSION continued

Implementing Standards

Facilitated by ***Marie Payton,*** *Manager Database Development, Serono, Inc.*

continued from page 17

studies, then it makes sense to convert that database to the new standards for future data pooling. If you have a new study that is the last in a large series of studies, then you might want to use the old standards to complete that project. A lot depends on what the existing data is going to be used for – will any part of it be combined with future data? Perhaps only the adverse events will need to be pooled for safety reporting.

LAB STANDARDS

Lab standards are always very difficult to establish and get correct. Some participants referred to CDISC, as the CDISC SDS and ODM GROUP have expended a lot of effort in developing standards for central labs. Looking at what is really necessary for the analysis of labs will help to focus on what should be collected. Most central labs can comply with standard requests.

GLOBAL LIBRARY

Some participants felt that data standards live in the global library within data management, while some other participants felt that the standards should live outside of data management so that the entire organization owns them. Most organizations had a global librarian as a role or a full time position, depending on the size of the company and the amount of trials running.

EDC AND DATA STANDARDS

Questions were brought up about whether or not data standards could be shared on both paper and EDC trials.

- Data Structure: Participants felt that the underlying data structure could be shared on both types of trials.
- Edit Checks: In EDC there are edit checks that are inherent within the system, so not all the paper edit checks need to be programmed with an EDC study. An example of this is using radio groups in EDC – by using a radio group, no edit check is necessary to ensure that only one option is checked.
- Layout: A different layout is required for EDC than for paper. In paper trials, we often try to squeeze as many items into a module and as many modules onto a page as possible. There are other considerations with EDC screens such as minimizing number of data points on a screen in order to prevent scrolling, and simplifying screens to ensure all data points are entered.
- Some companies had 2 libraries of screen/CRF layouts and edit checks – one for paper and one for EDC.

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Submission Deadlines (Articles and Advertising Art Work)

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

Volume 8, Issue #4 (Winter)	October 25, 2002
Volume 9, Issue #1 (Spring)	February 3, 2003
Volume 9, Issue #2 (Summer)	April 28, 2003
Volume 9, Issue #3 (Fall)	July 15, 2003

Each issue is mailed to the membership approximately 6 – 7 weeks after the corresponding submission deadline and posted on the SCDM web page (www.SCDM.org).

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.

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The Effect of HIPAA Regulations on Clinical Data Management

The Perspective of A Newcomer to The Field

By Francine Gumkowski

In the spring of 2001, I enrolled in the Clinical Data Management Certificate Program (CDMCP) offered by the University of Connecticut. My goal was to train for a new career, incorporating the three R's of education, with emphasis on the 'rithmetic'. By the spring of 2002, however, I had learned of three important new R's that affect the field of Clinical Data Management – Review, Respond and Report. Those buzz words are the mantra offered by the U.S. Department of Health and Human Services (HHS) to ensure health care industry compliance with HIPAA regulations. HIPAA? If you have not heard about it yet, get ready, you will.

BACKGROUND

Since 1974, there has been a Privacy Act for Federal Agencies, and there are state laws that protect the confidentiality of medical data. Due to rapid advances in information technology and data sharing capabilities, however, Congress saw fit to enact The Health Insurance Portability and Accountability Act of 1996 (HIPAA). This responded to the American people's expectation that they are entitled to confidential, fair, and respectful treatment of health information about themselves. While the primary intent of HIPAA is to provide better access to health insurance and limit fraud, it also contains data privacy restrictions applicable to clinical trial implementation. Specifically, it required HHS to issue certain Administrative Standards and a Privacy Rule. To date, HHS has finalized an Electronic Transactions and Code Sets Standard and a Privacy Rule.

The HIPAA Privacy Rule restricts the uses and disclosure of Protected Health Information (PHI) and requires implementation of administrative, technical, and physical means to safeguard PHI. These must be in place by April 14, 2003. The Privacy Rule is applicable to health care providers that engage in standard electronic transactions. As a general rule, if an institution submits electronic claims, then it is a HIPAA covered entity in which case the Privacy Rule applies to all PHI, including oral communications and paper records. Sponsors of clinical trials must be familiar with the HIPAA Privacy Rule as they share health information with institutions that are HIPAA covered entities.

HHS also has developed, but not yet issued, a Security Standard. This standard is intended to guard data integrity, confidentiality, and availability and also to guard against unauthorized access to data transmitted over a communication network.

HIPAA AND YOU

A cornerstone of the HIPAA Privacy Rule is the concept of Protected Health Information. When individually identifiable information - as common as names and SSNs or as esoteric as biometric identifiers - are combined with health information (medical records, treatment codes etc.) they become PHI and are subject to privacy regulation. Under the HIPAA Privacy Rule CDMs must adopt reasonable standards to safeguard PHI in whatever form it may be transmitted or stored, adopt certain administrative requirements, including workforce training, and allow patients certain individual rights. What's more, your institution also must comply with more stringent state laws. While project databases don't store identifiable information as blatant as names or SSNs, in this age of pharmacogenomic research, CDMs must be aware that DNA/genomic information is an absolute patient identifier and must be handled carefully. It is recommended that this data not even be kept in the same database as the Case Report Form data, with all databases having secure access. In addition, CDMs must ensure that external vendors associated with a clinical trial adhere to HIPAA standards, keeping in mind that the sponsor of the trial is ultimately responsible for all of the data in their possession.

To address security concerns, CDMs must assure that adequate plans are in place to protect PHI from improper use and disclosure. Care should be taken when designing data collection instruments to collect only the minimum amount of patient identifiers to ensure proper assignment of data and to resolve any discrepancies that might arise from transcription errors. Encryption methods for data transmission must be fail-safe. HIPAA requires a plan to be in place to protect PHI from improper use and disclosure. Identifiers must be destroyed at the earliest opportunity consistent with the conduct of the research unless there is a

research justification for retaining the identifiers, or retention is required by law. In addition, a research subject is entitled to remove permission to use data acquired from them. The impact these requirements may have on the movement toward data warehousing is worth considering within each company.

HIPAA's Standards for Electronic Transactions are meant to encourage and protect electronic transmission of data. I have learned through the CDMCP that the conduct of clinical trials over the internet and other forms of telemedicine are fast becoming a reality. HIPAA's impact on the growing use of novel forms of data acquisition and transmission must be considered.

HIPAA legislation includes significant punishment for those who misuse PHI. There are criminal penalties for knowingly disclosing or using medical information in violation of the privacy law. These penalties will be higher when violations are for monetary gain. In addition, the Secretary of HHS may impose civil monetary penalties on covered entities that violate the privacy rule

THE FUTURE

HIPAA is challenging the way clinical trial processes and information technology are structured. These privacy, security and transaction rules are comprehensive and complex, and require dedicated effort by CDMs to implement and maintain. It is left up to each individual healthcare organization to assess their own privacy and security risks and determine an appropriate plan of action to achieve compliance. The plan must include developing written policies and procedures compliant with the HHS rules.

Obtaining information about these laws and their impact on your own niche field within CDM (Review) would not only ensure your ability to comply, (Respond) it could keep you out of jail (Report)!

To review the HIPAA administrative standards, and to sign up for e-mail updates about HIPAA go to the HHS Administrative Simplification web site at **http://aspe.hhs.gov/admnsimp/.**

A Handy HIPAA Primer

Protected Health Information - Individually identifiable health information that is transmitted or maintained in any form, including electronic.

The HIPPA Privacy Rule is intended to implement the following five key principles:

Boundaries: Individually identifiable health care information, including demographic data, should be confidential and used for health purposes only.

Security: Organizations to which we entrust health information ought to protect it against deliberate or inadvertent misuse or disclosure

Consumer Control: Patients should be able to see what is in their records, get a copy, correct errors, and find out who else has seen them.

Accountability: Those who misuse personal health information should be punished, and those who are harmed by its misuse should have legal recourse.

Public Responsibility: Individuals' claims to privacy must be balanced by their public responsibility to contribute to the common good, through use of their information for important, socially useful purposes, with the understanding that their information will be used with respect and care and will be legally protected.

The Security Standard guidelines for confidentiality and security are organized into five major areas:

- Administrative Procedures
- Physical Safeguards
- Technical Security Services
- Technical Security Mechanisms
- Electronic Signature

If the Security Standard is finalized this year, covered entities will be allowed two years to achieve compliance.

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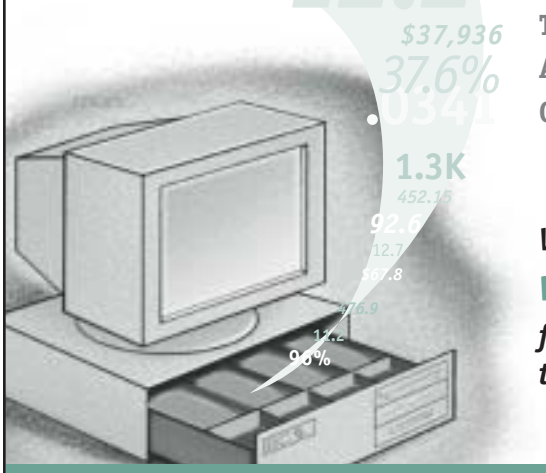

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