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DATA BASICS

Volume 5
Number 3
Fall 1999

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

From the Editors

We hope that you had a pleasant summer in spite of the soaring temperatures, lack of rain or the opposite depending upon where you are! By the time this issue reaches you, fall will be in the air, school bells will be ringing and summer will be a quickly fading memory – happy for the most part… we hope. Have you noticed that what used to be a welcome slow down in both pace and pressure – especially during July and August – doesn't seem to happen anymore…at least not in CDM. We hope you can sit back and enjoy reading this latest issue of *Data Basics.*

The focus of this issue is the interesting survey article on electronic data capture. We want to specially thank Rebecca Kush for contributing this article. We very much appreciate and recognize the significant work and effort involved in contributing an article such as this one. Thanks, Becky!

Be sure to check out the latest on the guidance for industry recently issued by FDA on use of computerized systems in clinical trials. This final guidance is something that professional data managers should know inside and out.

We are really looking forward to the upcoming Fall Conference in the Windy City – the sessions, the vendor exhibits, and the networking opportunities. Becki Filice and Ken Carlson have done a fantastic job in the planning. Hope to see you there!

Regards,
Lana and Frannie

Electronic Data Capture: A SURVEY

Rebecca D. Kush, Ph.D.

INTRODUCTION

The typical clinical trial for biopharmaceutical product development is conducted using paper case report forms for recording the data. In fact, it is estimated that approximately 90-95% of clinical trials have a paper-based data collection process. A number of new technologies have been introduced and tested in an attempt to streamline clinical trials and the product approval cycle. Despite reports (1,2) of the benefits (decreased time for database lock, decreased error rates in data collected), these new technologies have obviously not been widely adopted in the industry; concerns remain that must be addressed, however, these are not insurmountable.

In an attempt to better understand the usage of electronic data capture (EDC) tools and the impressions of those who have been involved in their implementation in clinical trials, members of the ACRP Technology Forum conducted a survey. This survey was distributed at the Annual Meeting of the Association of Clinical Research Professionals (ACRP), April 1998, and the Annual Fall Conference of the Society for Clinical Data Management (SCDM), September 1998. For review, analysis and presentation, the objective results (Questions 1-3) were entered into a database, and subjective results (Questions 4-5) were manually categorized. The questionnaire content and results are presented herein. The findings indicate that, although there are valid concerns that must be addressed, EDC experiences have still been viewed by the overwhelming majority of those surveyed (93%) in a positive or neutral way, i.e. not negatively. When compared to the existing paper process, collecting data electronically provides clear advantages, which will only increase as the EDC solutions are improved.

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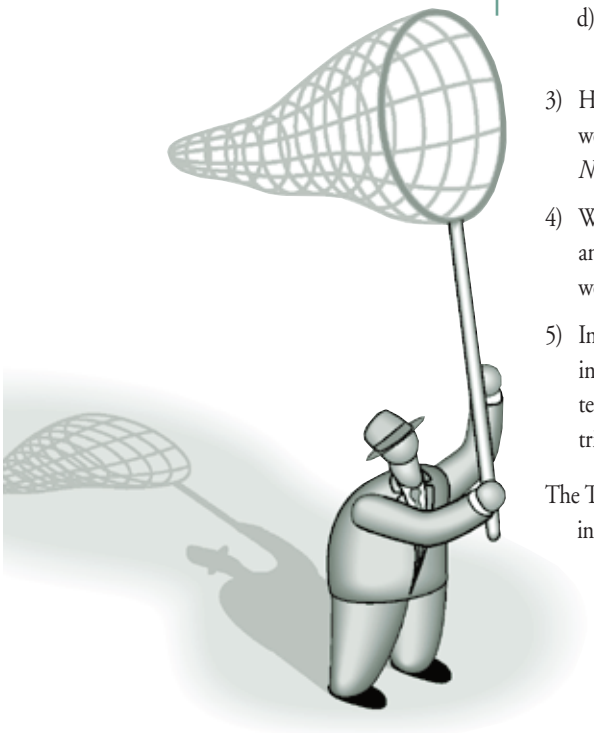
THIS ISSUE

Farewell from Frannie

This is my final issue of Data Basics *in my role as Co-editor. My term as Co-editor and Trustee concludes as of the Fall Conference. I want to take this opportunity to thank all of you for your help and support. I especially want to salute my Co-editor – thanks, Lana, for all your hard work, for making it so much fun, and for being a friend as well. I am confident that* Data Basics *will continue to be successful in your very capable hands! And to the Board of Trustees – thanks to all of you for allowing me the opportunity during the past three years – I wouldn't have missed it for the world!*

Frannie



Electronic Data Capture

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Survey Content

The questionnaire began with a definition of EDC, which was developed by the Glossary Group of CDISC (Clinical Data Interchange Standards Committee) (3,4): **Electronic Data Capture (EDC)** — *The process of collection of data into a persistent electronic form. This includes* ***data entry*** *(e.g. keyboard EDC, pen-based systems, voice recognition) and automated (or direct)* ***data acquisition*** *(e.g. bar code scanners, blood pressure cuff devices).*

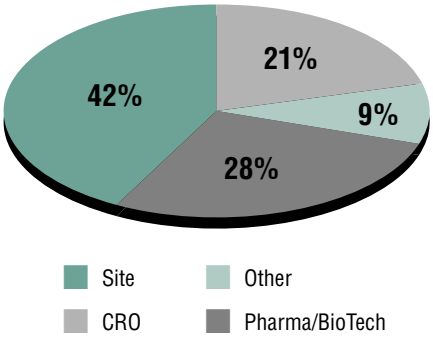
The questions on the survey were:

1) My company utilizes the following technology (mark all that apply): *Internet, Intranet, Extranet, GroupWare, Don't Know*
2) My company has used an EDC system/process to conduct a clinical trial: *Yes, No*
   a) If yes, what was the origin of the EDC methodologies used?
   b) If yes, what phase and therapeutic area was the trial (or majority of trials)?
   c) If yes, what technology supported your use of the EDC system(s)?
   d) If no, does your company have an interest in implementing an EDC system?
3) How would you rate your overall experience(s) working with EDC system(s)? *Positive, Negative, Neutral*
4) What did you like best about working with an EDC system? What did you like least about working with an EDC system?
5) In your opinion, why hasn't the pharmaceutical industry more actively embraced new technologies for collecting and managing clinical trial data?

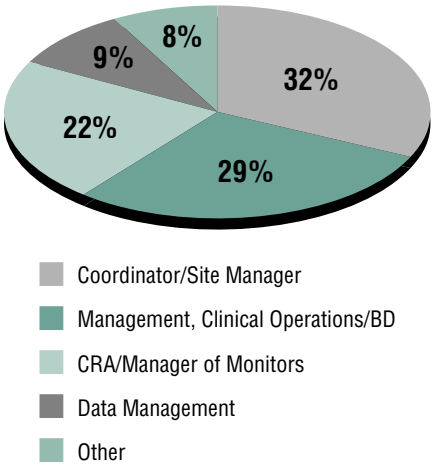
The Type of Company and Role/Title of the individual completing the survey were requested. The Company Name, Name (of individual completing the survey), and E-mail Address were optional, hence a respondent could remain anonymous if so desired.

Survey Results – Description of Respondents

There were a total of 203 completed surveys retrieved. The respondents numbered 83 from *Sites* (i.e. Investigator Sites, Academic Sites, Site Management Organizations, and Trial Management Organizations), 57 from *Pharmaceutical/Biotech Companies,* 43 from *Contract Research Organizations,* and 18 from *Other Sources* (i.e. Hospitals, Independents, Consulting, IRB).



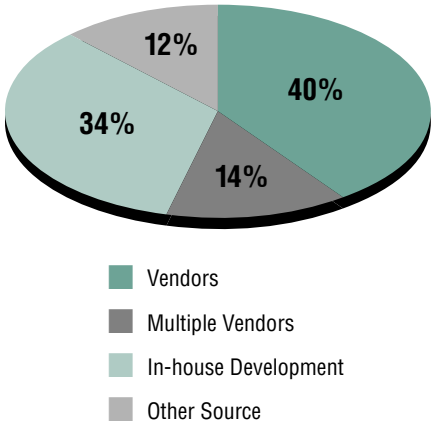
The Roles/Titles of the survey participants fell in the general categories of *Coordinator* – 64; *Management, Clinical/Operations/Business Development* – 58 (i.e. Project Manager, Program Manager, Director, Associate Director, President, VP of Business Development (BD), Marketing Director, etc.); *CRA, Manager of Monitors* – 45; *Data Management* – 19; and *Other* – 17 (i.e. Regulatory Affairs/QA, Consultant, Administrator, Process Advisor, Nursing Supervisor, Secretary, Investigator Services Manager, SOP Specialist).



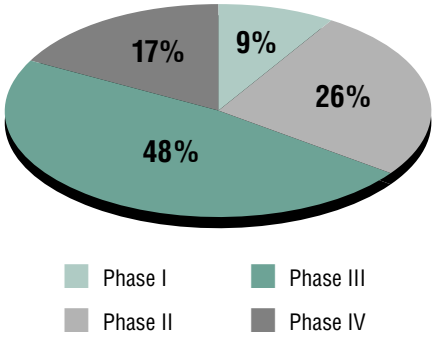
Objective Results – Survey Questions 1-3

With respect to technology utilized by the participant's companies, the *Internet* is used in 165 cases, *Intranets* in 68 cases, *GroupWare* in 66 cases, *Extranets* in 4 cases, and 3 respondents *did not know* what their respective companies use. Out of the 203 surveys received, 121 respondents indicated that their company has used an EDC system/process to conduct a clinical trial and 82 stated their company has not yet used an EDC system/process.

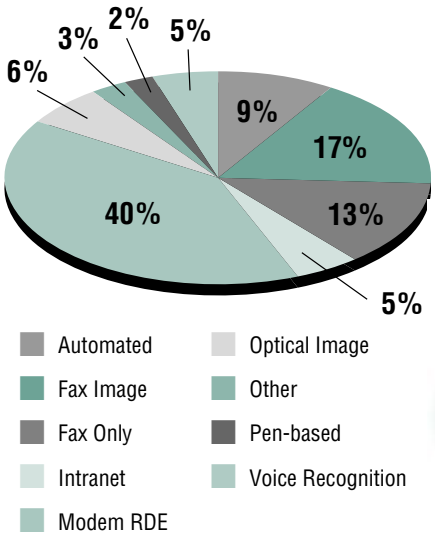
For the 121 respondents who indicated that their company has employed EDC systems/processes, 54 worked with *Vendors* on at least one of their clinical trials, while 20 worked with *Multiple Vendors.* In 47 cases, the systems/processes were developed In-house. Seventeen of the companies had *Other Sources* for their EDC methodologies (i.e. sponsor-provided system for a CRO or site). In some cases, there was experience with more than one system of differing origin.



The clinical trials conducted using EDC systems/processes were primarily *Phase III* trials (92 respondents), however, all phases of trials were included in the EDC experiences reported. There were 50 respondents who applied EDC to *Phase II* trials, 33 to *Phase IV* trials and 17 to *Phase I* trials.

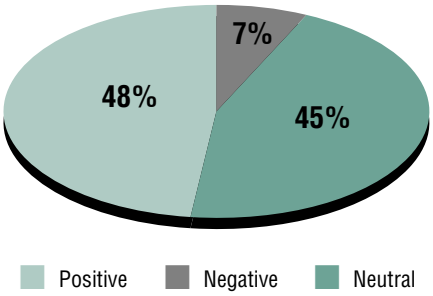


The principal EDC system employed was *Modem Remote Data Entry (RDE),* which was used in 89 cases. *Fax/Imaging* was employed in 37 cases, *Fax Only* in 28 cases, *Automated Data Acquisition* in 19 cases and *Optical Imaging* in 14 cases. *Interactive Voice Recognition* was employed in 12 cases, an *Intranet* in 11 cases, *Pen-based* in 4 cases and *Other* in 7 cases.



For the respondents who stated that their company had not used EDC systems, when asked if there is interest in implementing such a system, their responses were *Don't Know* – 28, *Yes* – 24, and *No* – 5.

The third question on the survey was "**How would you rate your overall experience(s) working with EDC system(s)?**" Experiences were rated as *Positive* by 63 respondents, while a rating of *Neutral* was a close second with 60, and the respondents with *Negative* experiences totaled 9.



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Electronic Data Capture

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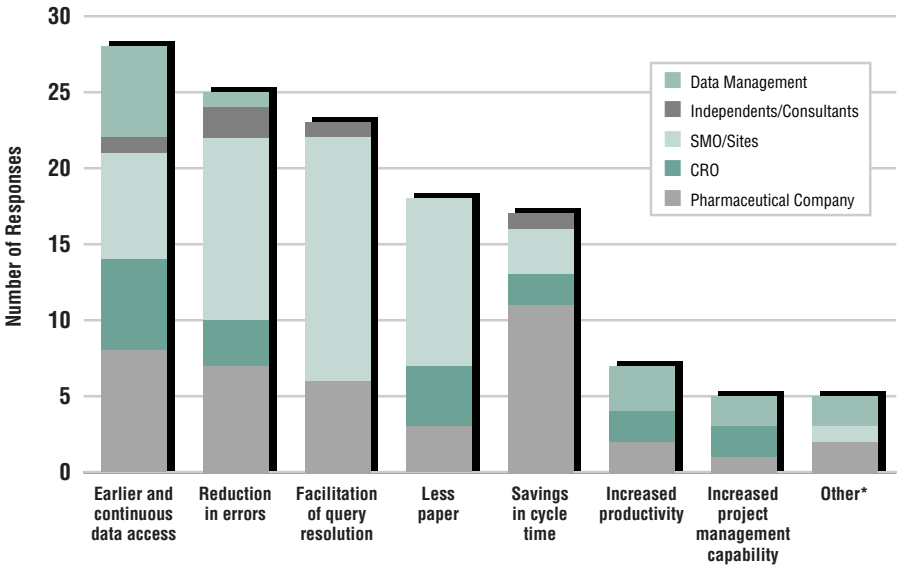
Subjective Results – Survey Questions 4-5

To better understand the issues behind the implementation of EDC systems/processes, the subjective comments were summarized from the responses to the last two survey questions regarding what was liked best and least about EDC and why EDC has not been more actively embraced in this industry. These summarized comments were categorized and tabulated, as totals and by respondent affiliations.

The fourth survey question produced the results given in the next two bar charts and corresponding text.

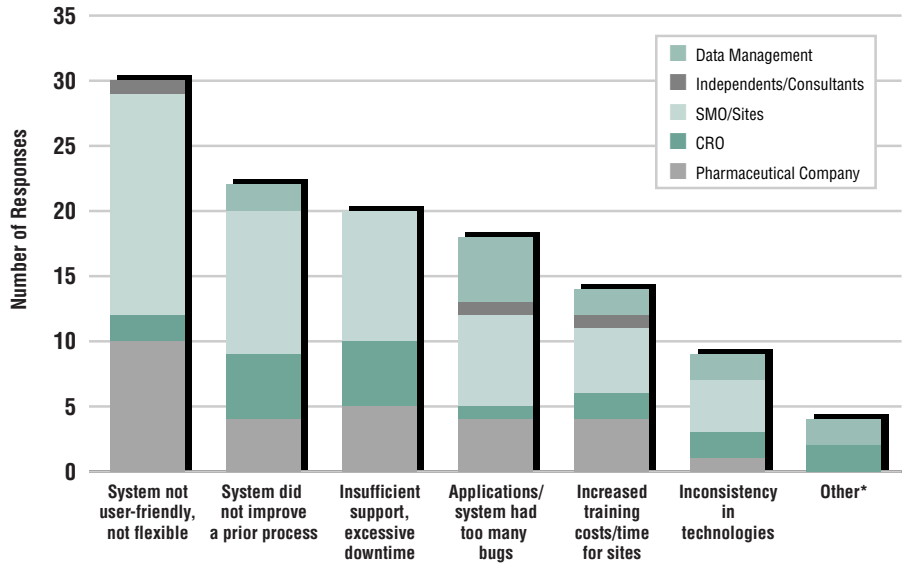
"What did you like best about working with an EDC system?"



The primary reason provided in response to this question was *earlier and continuous data access.* This response was given by 28 respondents. Two other reasons that were given almost as frequently were the *reduction in errors,* typically as a result of front-end edit checks (25 responses), and the *facilitation of query resolution* when queries did arise (23 responses). *Less paper* and *savings in cycle time,* in particular when the database is locked, were the responses in 18 and 17 cases, respectively. *Increased productivity (decreased monitoring costs, more productive site visits and reduced data entry requirements)* was the response in 7 cases, and *increased project management capability and reporting* was the reason indicated by 5 respondents. *Other** responses given (5 cases) were the *availability of images, real-time safety monitoring, standardization opportunities and a recruitment database.*

The response most frequently given by respondents from biopharmaceutical companies was the *savings in cycle time,* whereas CRO respondents most frequently responded with the *facilitated data access.* Data managers also liked the *earlier and continuous data access* the most, whereas site respondents most frequently cited *facilitation of query resolution.*

"What did you like least about working with an EDC system?"

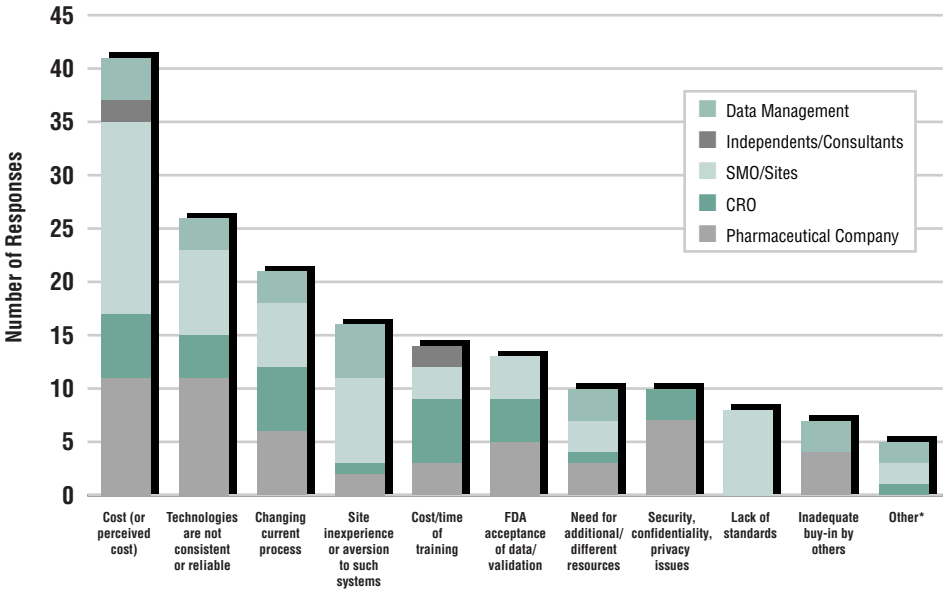


The primary reason provided in response to this question was *the system was not user-friendly, not flexible for data entry and difficult to learn* (30 responses). The reason provided by 22 respondents was *the system did not improve a prior process (e.g. paper still required, data were not clean, data were collected unmonitored or there were inadequate front-end edit checks, insufficient information on project status).* Twenty respondents cited *insufficient support and/or excessive downtime* for the system. Eighteen individuals indicated that *the applications/system had too many bugs and were unreliable or difficult to validate. Increased training costs/time for sites* was a reason given by 14 respondents, and 9 individuals stated there was *inconsistency in the technologies, multiple systems for different trials and cumbersome technology. Other** reasons, given in four cases were *coding issues, integration issues with the back-end systems and security issues.*

The respondents from biopharmaceutical companies and site representatives most frequently cited that the *system was not user-friendly or flexible* as the primary issue. From CROs, the *insufficient support* and the fact that the *system did not improve a prior process* were cited at equal frequencies.

The final question on the survey was:

"In your opinion, why hasn't the pharmaceutical industry more actively embraced new technologies for collecting and managing clinical trial data?"



The most frequent response given for this question was overwhelmingly the *cost or perceived cost of these technologies and their implementation and/or the lack of commitment or allocation of the monies required for this purpose;* this response was given in 41 cases. In 26 cases, the response was that these *technologies are not consistent or reliable or user-friendly and/or there are too many systems from which to choose. Training issues or changing current processes* was cited as a reason in 21 cases. Sixteen respondents felt that the *site inexperience or aversion to such systems* was a major factor, whereas 14 felt that the *cost/time of training* is an issue. In 13 cases, the response had to do with concern over *FDA acceptance of data/validation.* The need for *additional/different resources and personnel time required and resource management* was cited in 10 cases, and an equal number of respondents cited *security, confidentiality, and privacy issues. Lack of standards* was the reason given by 9 respondents and *inadequate buy-in by others (management, clinical, medical or data management)* was cited as an issue by 7 respondents. Five gave *Other** reasons (e.g. *pilot failures, insufficient metrics showing benefits, and space requirements for the hardware).*

Biopharmaceutical representatives most frequently cited the *cost/perceived cost and that the technologies are not consistent or reliable/excessive choices* as reasons for the slow adoption of EDC by this industry. CRO representatives gave equal weight to the *cost/perceived cost, difficulty in changing current processes or training and the cost/time of training* as their primary reasons. The issue that most concerned site representatives was the *cost/perceived costs,* with the next most important being divided equally between the *lack of standards, technologies not consistent or reliable/excessive choices* and *site inexperience with such systems.*

Conclusions

As further experience with EDC is gained, it is quite clear that metrics on the costs, cycle times, error rates and other indicators of performance need to be collected and shared. For EDC, as for the implementation of other new technologies, the maximum benefit or return on investment is achieved when the way the work is done (e.g. process) is changed and the new technology is then integrated/superimposed. (5) However, if the technology does not adequately enhance the process, if it is not user-friendly, if it is inadequately supported, if it has excessive application bugs, or if the system is not adequately validated, then process changes do not stand a chance of allowing for a successful EDC experience.

Of interest in the overall results is that, despite the fact that respondents provided a number of solid issues that can detract from a successful EDC experience, 48% of those surveyed did report a positive overall experience and the overwhelming majority (93%) were either positive or neutral about

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Election RESULTS

Congratulations to the new members of the SCDM Board of Trustees!!

Hugh Donovan
of Hoechst Marion Roussel

Brenda Hoeper of Kendle

Karen Klingler of Wyeth-Ayerst

The proposed change to the SCDM Bylaws that expanded the pool of candidates eligible to hold office on the Board of Trustees was passed by the membership. The updated Bylaws appear in the 1999 SCDM Membership Directory.

Thanks

Many, many thanks to the outgoing members of the Board of Trustees. You will be sorely missed!

Ron Copp
of Worldwide Clinical Trials (Treasurer)

Kristin O'Connor
of Boehringer-Ingelheim (Past Chair)

Frannie Rink of Wyeth-Ayerst
(Secretary, Historian,
Newsletter Co-editor)

Ken Buchholz (INC Research) will stay on the Board of Trustees for one additional year as Past Chair. Thanks to **Annette Schmit** (Pharmaceutical Research Associates) for her interim appointment as SCDM Treasurer.

Electronic Data Capture

continued from previous page

their overall experience. Only 9 of the 132 (7%) individuals who responded to this question reported a negative experience. By listening to those who are users of these systems, improvements can be forth-coming. Already, the second and third generations of the EDC tools are becoming available and improvements are noteworthy.

Through their goal of becoming paperless by the year 2002, the FDA is encouraging standardization and the move to electronic data submission. There has been a recent concentration on related guidelines (6), including 21CFR Part 11 "Electronic Signature; Electronic Records", Guidance for Industry "Computerized Systems Used in Clinical Trials" and Guidance for Industry "Providing Regulatory Submissions in Electronic Format — General Considerations". An obvious place to begin when one wants to streamline the electronic submission process is at the front end, with the collection of electronic data in a standard format that is defined in concert with standards for electronic data submissions. (CDISC is currently working with FDA in the development of these data submission standards.)

Kubick proposes, in his article "The Elegant Machine: Applying Technology to Optimize Clinical Trials"(7), seven principles for the elegant machine to "dramatically improve clinical research". These principles include advance study planning to facilitate collection of essential, clean data; standardization of data (structures, names and codes) into an integrated data repository; collecting data "as close to the point of patient contact as possible"; selecting the best data capture tool, depending upon program characteristics; providing rapid access online to useful information; and letting "technology drive the process wherever possible".

Systems that require the data to be entered only once and never on paper, and systems that truly facilitate workflow and build in efficiency and quality from the beginning should be our ultimate goal. Workshops and conferences where experiences are shared and groups such as CDISC are providing opportunities for those of us interested in becoming involved in the future of clinical trials, in particular the implementation of standards and the early capture of high quality electronic data.

Acknowledgements

Sherrie Margiotta and Edwin Ziegler are to be commended for their contributions to this manuscript, in particular with respect to the data processing, analysis and QC reviews. Their efforts are greatly appreciated.

References

1) DIA Workshop on "Electronic Data Capture: Technologies, Implications and Future Requirements", November 1998, Baltimore, MD.

2) IIR Symposia on "Automated Data Capture", February 1998, Orlando, FL and September 1998, Washington, D.C.

3) CDISC (Clinical Data Interchange Standards Committee) — A DIA Special Interest Advisory Committee; for further information, contact Rebecca Kush, Ph.D., e-mail: rkush@earthlink.net or phone: 512-750-7612.

4) Latham, D., "EDC: Establishing standards for electronic data capture", interview of K. Vaillant, *Pharmaceutical Visions,* Autumn 1998.

5) Daniels, J.L. and Daniels, N.C. *Global Vision,* 1993, McGraw Hill.

6) Chew, N., Morgan, J., Wartowski , C., "Taming the Paper Tiger at FDA", *Applied Clinical Trials,* February 1998.

7) Kubick, W. "The Elegant Machine: Applying Technology to Optimize Clinical Trials", *Drug Information Journal,* v. 32, pp. 861-869, 1998.

If you have any comments or questions related to the results of this survey, please contact Rebecca Kush via e-mail (rkush@earthlink.net) or phone (512-750-7612).

Computerized Systems Used in Clinical Trials Dated April 1999

(*www.fda.gov/cber/guidelines.htm* posted May 10, 1999)

Have you read this final (not draft) guidance that affects clinical data managers yet? Although I cited the CBER Web site above as a convenient location to find this document, the Guidance is blessed by HHS, FDA, CBER, CDRH (devices and radiology), CFSAN (food safety), CVM (veterinary medicine) and ORA (Regulatory Affairs), as well as CBER. The whole gang. It broadly covers how computerized systems should be used to create, modify, maintain, archive, retrieve or transmit clinical data intended for submission to the agency.

I won't attempt to summarize the entire document, as it is important for you to familiarize yourself with its contents. I will highlight a couple of notables.

First note is the Guidance focuses on computer systems used at clinical sites. It states that "the principles set forth ***may also***" apply to sponsors and CROs (my emphasis).

It states that each ***study protocol*** should identify where computer systems are used. Again, my emphasis. You might want to review your company's study protocol templates. Further it states that site study files need to contain information about the computer systems used for that study, and that SOPs for systems operations should be available at each site.

There are some very explicit statements requiring data entry screens to display the name of the person inputting data ***as a deterrent to another individual inadvertently entering data under the wrong user ID.*** My reaction is that if someone on your staff needs that type of prompt to realize they are working at the wrong workstation, I'd bet *mucho dinero* that person is the new hire your "friend" from a competing company recommended. My advice? Don't wait for the next annual performance review; act NOW!

FDA personnel expect access to audit trail information at the study site ***and at any other location where associated electronic study records are maintained.*** You may want to review how your "older" RDC system handles the transmission of audit trail information.

The following is simply an example of insomnia having many causes. The Guidance details the need for electronic date/time stamps to be local to the activity being documented. The Guidance recognizes that multi-center studies might use servers located in different time zones and suggests that the calculation of local date/time stamps be derived from a remote server in a different time zone. I find this curious only because my concern would be different. What would "keep me awake at night", is that date/time stamps accurately reflect the sequential changes to a database DESPITE the different time zones. In today's networked infrastructures, data entered into some Web-based application by a Baltimore investigator at 9:00 am could be modified by a CRO data manager in Paris twenty minutes later at 15:20.

CRF designers who are still fighting the battle to outlaw comment fields take note. The Guidance is clear that electronic patient diaries and e-CRFs should allow users to make annotations to capture "ad hoc", unexpected information. Annotations = data quality. You are going to have to find a new cause in life.

Ugly issues like the handling of data, audit trails, retrieval and analysis programs, etc. for legacy systems are discussed. I'll go no further. These issues are very important and always a killjoy.

The Guidance expects a cumulative record of the names, titles and access privileges of all users that is relevant for any point in time. Could you tell me who, including job title (and I would add affiliation), had access (details needed as to level of access) to the database for study XYZ on January 20th of last year?

I didn't find anything really new in the system validation sections of the new Guidance. It does note that sponsors and CROs should have documentation of the design-level validation activities performed by the commercial software vendor. Send a copy of the Guidance with a love note to your favorite software vendor; some software vendors are still pretty bad at making validation documentation available to customers.

All in all, the Guidance offers much helpful information. Please read, discuss, learn and act upon the Guidance. All part of the fun – and responsibility – of working in a regulated industry.

Pat Teden

In Memory of

Leslie Robinson
1964 – 1999

Leslie Robinson, Associate Manager of Clinical Data Management at Amgen, passed away on June 4, 1999 after a courageous battle with cancer. For those of us who had the privilege of working with Leslie, and especially for those of us for whom Leslie was a dear friend, the untimely passing of someone so young, so full of vigor, and so enthusiastic about life is grievous beyond words.

Outside the office, Leslie loved the outdoors – walking the beach with Nike, her canine companion, hiking and rafting with friends, and most of all, swimming. Leslie was an accomplished swimmer, and was most proud of the team she led to successful completion of the Long Beach to Catalina Island swim.

As a Clinical Data Manager, Leslie was first and foremost a team player and leader by example. She possessed a good understanding of clinical development, and demonstrated an appreciation for balancing good science with good business practice. Coupled with her dedication, strong work ethic, and "can-do" attitude, Leslie was a respected and valued member of the product teams she worked with over the years as well as our profession. Her sense of personal balance and her humor provided welcomed relief during stressful times, and her wide-eyed wonderment and enjoyment of people made Leslie a pleasure to be with.

To a dear friend and cherished colleague, we miss you.

Ken Buchholz
Vice President, Clinical Data Management and Biostatistics
INC Research Inc.

Clinical Data Management Task List

The tasks which occur in Data Management Organizations differ from company to company. Below you will find a comprehensive list of Clinical Data Management tasks. We hope this list is of use to you for development of SOPs, job descriptions, etc. in your organization. Please forward any comments on this CDM task list to Susan Bornstein, Director Data Management MTRA/AAI, at sbornste@mtra.com. Special thanks to Brenda Hoeper for her contributions to the development of this list.

Project Start-up

- Protocol review
- CRF design
- Maintain CRF standard library
- CRF printing
- CRF distribution and tracking
- Attend investigator meetings
- Present at investigator meetings *(i.e. CRF completion guidelines, CRF and query flow, etc.)*
- Data Management Plan development *(includes database specifications, electronic edit checks, data review guidelines, annotated CRF)*
- Timeline development and maintenance
- Generation of CRF completion guidelines
- Contract negotiations and review for vendors providing central laboratory services
- Contract negotiations and review for vendors providing clinical data management services

Database Creation and Programming

- Entry database screen design
- Entry database set-up/validation *(testing)*
- Development of data entry guidelines
- Definition of data validation guidelines
- Programming and validation of electronic edits *(checks for logic and consistency and protocol compliance)*
- Creation and validation of standard data sets
- Creation and validation of analysis data sets
- Programming and validation of ad hoc data listings
- Programming and validation of final data listings
- Programming and generation of final report tables
- Development and production of patient summaries/profiles/information displays

Data Processing

- CRF tracking and inventory
- CRF scanning/image management
- CRF data entry
- CRF data verification *(data entry discrepancy resolution)*
- CRF data validation *(i.e. scrubbing, cleaning, query generation, applying data handling conventions)*
- Manual CRF review
- Query resolution *(i.e. correspondence with investigator sites to obtain resolution to queries)*
- Query tracking
- Communication of data trends
- Identification and reporting of protocol deviations/violations
- Database updates

Database Support

- Create and maintain data dictionary
- Create and maintain code lists
- Security (user access)

Safety Data

- Safety review
- Coding adverse events/signs and symptoms
- Coding medications
- Coding Medical History/Physical Exam
- Coding procedures/indications
- SAE processing
- SAE reconciliation
- Maintenance of AE, Medication, etc., coding dictionaries

Laboratory and PK Data

- Processing local laboratory data
- Processing (loading/merging) central laboratory data
- Maintenance of laboratory normal range information
- Processing (loading/merging) PK data

Randomization

- Generation of randomization schemes
- Maintenance of randomization schemes
- Application of randomization schemes to study databases *(i.e. breaking the blind)*
- IVRS (Interactive Voice Response System) support

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Calendar of Events

September 26-29, 1999
Fall Conference
The Fairmont Hotel
Chicago, IL
Optimizing Clinical Data Management through People, Processes, and Standards

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

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

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 Atlanta
Atlanta, GA

SCDM Web Site Committee Update

The SCDM Web Site is well on its way to becoming a reality! We are planning to have www.SCDM.org up and running by the Fall Conference. In its first release, it will include information on SCDM, committee happenings and links to other organizations. Future enhancements are planned. Look for information at the Fall Conference in Chicago!

We anticipate the ability to send members information by e-mail in the near future as well. **Please make sure that your e-mail address in the SCDM Membership Directory is correct.** If it is missing or incorrect, e-mail the correction to April Pennacchio at april@profmgmt.com.

The SCDM Web Site Committee is looking for an individual interested in coordinating the maintenance of the SCDM Web site. Responsibilities include editing Web site content, acting as the Project Manager to ensure that updates are performed on a consistent basis and communicating updates and enhancements to the SCDM membership.

A commitment of 6 – 12 months is desired. Please contact Christine Tattrie (ctattrie@mtra.com) or Doug Schantz (douglas.schantz@wl.com) by October 1st if you are interested.

Clinical Data Management Task List

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Database Closure

- Database lock procedures
- Database quality control audits
- Review of final data listings
- Review of final data tables or graphs
- Review of final reports
- Archiving database and associated documentation

Miscellaneous

- Involved in selection of new technologies for evaluation
- Involved in piloting new technologies
- Electronic submission management
- CRO management
- Standards development and maintenance
- Validation of CDM systems
- Training of users
- SOP development and maintenance

Call for Co-Editor Applicants

Is anyone interested in becoming a Co-editor for *Data Basics?* We are looking for a replacement for retiring Co-editor, Frannie Rink. If you are interested in this opportunity or would like more details (e.g. job description, etc.), please contact Lana Turner via phone (616-833-0542) or e-mail (lana.f.turner@am.pnu.com). A prompt response is recommended as the Board of Trustees hopes to decide on this replacement at our next Board meeting on September 26.

SCDM Education Committee Update

The Education Committee is working on outlines for courses that range from "What is CDM?" to "Advanced Topics" such as current advances in technologies for clinical data management. The committee will complete the course outlines in September of 1999. The course outlines will be organized into Introductory, Intermediate, Advanced, and Special Topic categories to be offered in the future.

The following are members of this committee:

Susan Bornstein – *Board Liaison*	Demetria Jones	Susanne Prokscha
Paula Chambers	Kristan Gallitano	Martha Schmidt
Gregg Dearhammer	Lisa MacAskill	Jill Tufano
	Louise Murphy	Katherine Voss

Thanks to all committee members for their efforts. If you are interested in joining this committee, please contact Susan Bornstein at sbornste@mtra.com.

DATA BASICS

Call for Articles

The search continues…!

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

Editorial Board

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Publication Schedule

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

Volume 5, Issue #4 (Winter)	October 26, 1999
Volume 6, Issue #1 (Spring)	February 1, 2000
Volume 6, Issue #2 (Summer)	April 28, 2000

Publication Policy

We welcome submission of previously unpublished materials for publication in *Data Basics.* Materials should preferably be submitted in electronic form (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.

Spring Forum 2000

The next Spring Forum will be held on March 19 – 21, 2000 at the Isle of Palms, SC. The proposed overall theme is "quality" covering key topics such as

How do you build quality into the process from the management perspective?

How do you balance quality vs. timelines?

Setting DM standards – what do we standardize, why and how?

How does one lead an organization towards quality?
What are the elements of a quality system (e.g. SOPs, guidelines, standards, QC, QA, etc.)?

How do we enable quality when working across multiple sites?
How do we harmonize across sites (both US and international)?

Some individuals interested in participating have already been identified from the 1999 Spring Forum Evaluation Survey Results. Additional volunteers are encouraged to contact Kristin O'Connor, *Program Chair* (e-mail: koconnor@rdg.boehringer-ingelheim.com; phone: 203-798-4244).

Web Sites to Check Out

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

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

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

SUGGESTED CLINICAL DATA MANAGEMENT READING LIST

Read any good CDM articles or books lately?

You may want to check out "FTC's Quest For Money Damages: An Unauthorized Power Grab" by Michael S. Kelly and Bilal Sayyed in the June 11, 1999 issue of Washington Legal Foundation (WLF) *Legal Backgrounder* (Vol. 14 No. 21). WLF publications are available on Lexis/Nexis®. WLF's Web site is http://www.wlf.org.

Please submit suggested reading to the Editorial Board.

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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