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The Newest EDC  
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## Knowledge is Power: EDC Training in Your Organization

*EDC Today is an independent publication on current information and issues in Electronic Data Capture (EDC) strategies and technologies for the Biotechnology and Pharmaceutical (biopharma) industry. Each month we examine topics related to EDC theory, technology, practice, or implementation.*

*To assist organizations making the transition from paper-based clinical trials to EDC-facilitated trials, our fourteenth issue takes a closer look at the impact of implementing an EDC system on your company's training program. As with any new software system, training is essential in order to receive the maximum benefits of EDC.*

### Introduction

EDC Management conducted a survey of attendees at the Society of Clinical Data Managers (SCDM) Annual meeting in Atlanta, GA in November 2002. One of the more compelling conclusions from this survey was "training is important." In particular, companies that have already started using EDC were twice as likely to indicate that training was highly important than those that have not started using EDC.

There are several factors that elevate the importance of training when using EDC. First, there are many more users to train in an EDC environment than in a traditional Clinical Data Management System (CDMS) environment. Second, there are many more users for whom the computer is not a major component of their primary job. Lastly, the user population is geographically dispersed.

This issue first discusses why there are more users and identifies different types of users. After describing the user types and what sort of training they need, the issue then discusses different styles of training, including web-based training, that could help with the issue of geographic dispersion.

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## Larger User Population

To begin with, many biopharmas use traditional CDMS applications such as Oracle Clinical™, Phase Forward's Clintrial™, eResearch Technologies eData Management™, or DZS ClinPlus™. Let's consider the typical population of employees that would use such a system. There will be data entry people, clinical data assistants, clinical data managers (CDMs), clinical dictionary people, system developers, and IT people who would be involved in a day-to-day manner with the system. Clinical research associates (CRAs), statisticians and project managers may also have a limited use of the CDMS if they access trial related data reports, but likely they will be using another software tool such as a Clinical Trial Management System (CTMS) or a data browser tool such as Brio. All told, for a typical company there may be 20 to 30 users of the software.

EDC also encompasses the people who previously (and possibly currently) handle paper Case Report Forms (CRFs). This includes investigator site personnel and CRAs. In addition, there are positions inside the biopharmas that handled the paper CRFs (such as Central Document Control) which may need to use the EDC system.

For the first EDC trial, there may be 20 sites. That may mean an additional 30 users just between the site personnel and the CRAs. The first EDC trial therefore could double the number of computer system users. Each additional trial potentially adds that many new users again. Thus the number of users will continue to grow over time.

## Different User Population

In addition to there being many more users, the new users are probably not everyday computer users. While technology and computer use has increased over time, there are some areas that still do not use computers as a normal course of operations. Patient care is one of these areas. More investigator sites are starting to use electronic medical records (EMRs), but the percentage of users is still fairly small, and thus training at the investigator site is an important consideration in planning for EDC implementation.

Contrast these people to those that biopharmas hire to work in clinical data management. Most clinical data management related positions require computer skills, and data entry people are expected to have several years of computer experience and the ability to enter data quickly. Likewise, data managers also are often required to have computer experience.

Still, task specific skills and material may need to be presented in training sessions. Certainly the competency level of the audiences needs to be ascertained before and during training, and perhaps more attention would need to be given to testing for understanding of the training concepts.

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## Types of Training

Training is traditionally broken up into different types based on how the system will be used. Table 1 shows a breakdown of training by types of EDC use.

**Table 1. Types of Training Based on Classification of Usage**

<p><b>Application Use Training</b></p> <ul style="list-style-type: none"> <li>- Training on “How to use the EDC system.” There are several aspects:               <ul style="list-style-type: none"> <li>a) Data Capture – for Investigator site personnel and CRAs</li> <li>b) Data Management – for CRAs and CDMs</li> <li>c) Project Management and Reporting – for ad hoc and other managerial users</li> <li>d) Recurring introductory and refresher training</li> </ul> </li> <li>- Training on “Protocol-specific aspects of the EDC system”               <ul style="list-style-type: none"> <li>a) Investigator site personnel</li> <li>b) CRAs</li> <li>c) CDM</li> <li>d) Ad hoc and other managerial users</li> </ul> </li> </ul> <p>Planning for training and training materials should recognized different user knowledge levels (introductory, refresher) and usage levels (full-time, part-time)</p>
<p><b>EDC System Training</b></p> <ul style="list-style-type: none"> <li>- Training on “How to install and maintain the EDC System”               <ul style="list-style-type: none"> <li>a) Day to day support (IT Support, Application Developers)</li> <li>b) System installation and maintenance OQ, patches, change control</li> </ul> </li> </ul>
<p><b>EDC Developer Training</b></p> <ul style="list-style-type: none"> <li>- Training on “How to create protocol-specific EDC systems”               <ul style="list-style-type: none"> <li>a) Day to day protocol development (Project Managers, Application Developers)</li> </ul> </li> </ul> <p>This training includes Integrated Development Environment (IDE) tools and EDC System Internals.</p>
<p><b>Other Systems Development Training</b></p> <ul style="list-style-type: none"> <li>a) EDC and Legacy system integration</li> <li>b) Auxiliary system integration</li> </ul>

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Breaking down training according to how the software system is to be used not only makes sense, but also allows the training to follow the workflow of the users, thus reinforcing what the users need to know. Denise DeRenzo Lacey of Waife and Associates states the following:

“CRAs will benefit from a workflow that arranges the conventions into a guide to the EDC steps of a monitoring visit. Unfamiliar tasks may include monitoring randomization numbers in the system; setting flags to indicate different levels of source data verification; reviewing and accepting automatically-generated discrepancies and their responses; generating discrepancies manually; reviewing the audit trail to trace back the history of a response; filtering data to look for missing items and other trends; and running ad hoc queries on data...The instructional designer who creates this training must be familiar with the protocol and with typical monitoring scenarios. He or she must coordinate availability of a study-specific test system with the vendor...It is not sufficient to have CRAs enter random practice data of their own invention, and then pretend to monitor that data; the training, like the study itself, must be ‘well-controlled.’”<sup>1</sup>

Lacey goes on to say that these CRAs should then train their site personnel. It is likely, however, that the site personnel will receive initial training at an investigator meeting. If that is the case, then CRAs may provide follow-up training for site personnel, or perhaps additional training for sites that undergo personnel changes.

Keep in mind, some users may overlap classifications and need more than one type of training, and some training should be recurring.

## **Geographic Dispersion**

The next training hurdle to overcome is that the users are no longer centrally located within the walls of the biopharma. This dispersion makes face-to-face training expensive and logistically difficult. Certainly, as mentioned above, site personnel can be trained at investigator meetings. In this case the personnel that will actually enter the data in the EDC application, as well as all investigators, must attend the meeting. In addition, a separate training program must be designed for new personnel who join during the course of the EDC study.

While CRAs will still be visiting sites and are a natural selection for a site trainer, they may or may not be the best trainers. In addition, a biopharma may decide that it is not a good use of the CRAs time. As a result, many biopharmas are investigating distance training using the Internet. While distance training cannot completely replace the interactivity of face-to-face training, it might nonetheless be a viable option.

## **Advances In Training**

According to a Press Release from Centra Software:

“This year alone, pharmaceutical companies will spend hundreds of millions of dollars hosting face-to-face meetings to manage the geographically dispersed internal and external study staff responsible for conducting their clinical development programs. This has become an expensive and timely process that pulls the physician investigators and study staff away from daily patient care, and the internal team away from project responsibilities.”<sup>2</sup>

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ePharmaLearning and Centra have teamed together to provide webcasting of pharmaceutical meetings. The press release further states:

“By customizing a Web-based platform and content library specifically for the pharmaceutical industry, we make the design and delivery of clinically focused online meetings and eLearning sessions faster and more effective than ever,” said Lance Converse, CEO for ePharmaLearning. ‘After a careful analysis of vendors, we found Centra to have the most appropriate collaborative platform for our highly regulated industry. Many sessions we deliver such as online Investigators’ meetings and project update meetings are highly interactive and need to be fully documented, recorded and archived. Centra was willing to work with us to develop solutions that meet the strict needs of our pharmaceutical clients.’”<sup>2</sup>

Another company that provides online meeting and conferencing facilities is WebEx. WebEx’s Web site states:

“With WebEx Training Center you can train employees, customers, and partners via Internet conferencing using only a browser...effectively, efficiently, and affordably. All it takes is the push of a single online button and a complete set of powerful training capabilities is at your fingertips.”<sup>3</sup>

Many companies are trying web-based training. A number of EDC vendors offer Web-based training for their products. One of those vendors is DataTrak. According to their Web site:

“DATATRAK offers a state-of-the-art, web-based training program for the DATATRAK Entry™ module. It is self-paced, offers proof of training, and has an assessment at the end of the course.”<sup>4</sup>

In his Drug Information Journal article, “Leveraging The Internet To Deliver Dramatic Cost Efficiencies: Webcasting In Clinical Research,” Astra Zeneca’s Ellis Wilson, Jr. provides a good overview on how to use webcasting. He states:

“Our experience with Webcasting investigators’ meetings has been largely but not exclusively positive; it has afforded an opportunity to validate many potential advantages while acknowledging important shortcomings. Our conclusion, consistent with that of our Webcast participants, is that Webcasting is a viable option in clinical research.”<sup>5</sup>

## **Conclusions**

Training is important because the EDC system is one of the few crucial tools that will move a study agent toward becoming a marketable drug. Training becomes much more important because of the larger number of users and a larger number of users that do not traditionally use the computer as a major component of their job.

By basing the different training needs on classification of usage, training materials can be developed that follow the workflow of the users, thereby helping to maximize the benefits of the training.

*(continued on page 6)*



References:

- <sup>1</sup> Lacey, Denise Derenzo, "To Train is Holy; To Teach Fully Divine" <http://www.waife.com/Pages/articles.html>
- <sup>2</sup> Centra Software Press Release, <http://www.epharmalearning.com/news/01312002.htm>
- <sup>3</sup> WebEx, [http://www.webex.com/services\\_training.html?Track=hometext](http://www.webex.com/services_training.html?Track=hometext)
- <sup>4</sup> DataTrak, [http://www.datatraknet.com/master.cfm?site\\_id=228](http://www.datatraknet.com/master.cfm?site_id=228)
- <sup>5</sup> Wilson, Ellis Jr., "Leveraging The Internet To Deliver Dramatic Cost Efficiencies: Webcasting In Clinical Research," *Drug Information Journal*, Vol. 36, pp. 707-715, 2002

Who's behind the research?

Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).



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