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## EDC and Biopharma Careers – Using Portals and Workflow to Help With Job Functional Changes

In the next issue of  
**EDC Today:**

Patient Diaries

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

*Many biopharmas are currently adopting Electronic Data Capture (EDC) and more are still supporting both EDC and paper processes. Our eighteenth issue revisits how the adoption of EDC impacts careers in the Clinical Trials arena. In particular, we will examine the pervasive influence of the Web on jobs in the clinical data area.*

*If we understand the impact of the Web, portals, and workflow, we can utilize Web tools to assist personnel in changing their job processes. Portals were described in EDC Today<sup>TM</sup> Issue 12 “Portals, and How They Can Make EDC Work Better” as “an internet Web site that provides a person with a single location and login for all the information and applications needed to perform their work over the course of a clinical trial”.<sup>1</sup> Workflow can be defined as “The automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant (human or machine resource) to another for action, according to a set of procedural rules.”<sup>2</sup>*

*The Web, portals, and workflow provide a central point of focus for individuals to perform their work. The Web can organize all of the communications and tasks associated with the job function of the person logged on the portal, and thus can be a strategically compatible and efficient vehicle for job function changes and improvements. In this issue we examine the various jobs that we discussed in EDC Today<sup>TM</sup> Issue 2 “Job Evolution or Revolution? EDC’s Impact on the Clinical Trial Team”<sup>3</sup> with a look at how the Web can help.*



## Introduction

As we have discussed in past issues, there is a general consensus that paper-based data management processes are inefficient and should be optimized. EDC transforms the process of clinical trials data collection from a paper-based Case Report Form (CRF) process (“paper process”) to an electronic-based CRF process (“EDC Process”). EDC could be viewed as the “Webification” of clinical trials data management.

EDC is an attempt to optimize the process of collecting and cleaning clinical data by moving the entry of data as well as checking the quality of the data as it is entered to the investigator sites. This change should allow data to be entered into the database faster and more accurately since the personnel performing the data entry at the site are able to make corrections to the data as it is entered and as data issues are raised.

Given the intentions of EDC to improve the efficiencies of clinical data collection, it is disappointing that the overall adoption of EDC is slower than many industry observers had hoped. Certainly one factor hindering the adoption of EDC is that clinical trial personnel must adapt their jobs to the new technology and process required by EDC. There are many reasons why change is difficult. In many instances, inertia must be overcome. People become accustomed to doing their jobs in certain ways and it takes time and effort to discontinue the previous processes and encourage the new processes. Portals with workflow show promise in assisting change.

We will examine the following jobs areas with particular emphasis on how “Webification,” portals, and workflow can help in the transition to EDC: Investigator site personnel, Clinical Research Associates (CRAs), Clinical Data Managers (CDMs) and Clinical Data Coordinators (CDCs), and Clinical Trial Project Managers (CTPMs).

## Investigator Site Personnel

Since investigator site personnel hold primary responsibility for conducting the study at a research site, their jobs will be altered by the implementation of a new data collection system. Although many of the responsibilities of the investigator site personnel will remain the same, they will have the additional responsibility of entering the clinical trial data into the EDC data entry application.

Sites may be initially resistant to adopting EDC and performing the additional task of data entry. Sponsors need to work with investigator sites to address concerns and to demonstrate how they could benefit by using EDC, since it is clearly work-saving efficiencies that will drive investigators’ increased use of the Web for entry of clinical data.

For example, Web-based portals offer more efficient tasking on a number of functions required of investigator site personnel. A portal could be used to provide housing for a central repository of trial related documentation and centralized communications with other trial personnel. The portal can assist investigator site personnel in enrolling patients and obtaining patient informed consent. Web-based patient training and consent forms could relieve the burden placed on investigator site personnel to adequately and impartially advise prospective patients. Once patient informed consent is obtained, the portal could allow integrated enrollment and randomization.

*(continued on page 3)*



Once a Web-based trial is in place, the investigator site personnel will need to be sufficiently trained on the applications to realize their potential and take advantage of its many features. Training can be incorporated as a feature of the portal and the portal may become a repository of on-line Web-based training for EDC implemented protocols.

Beyond just a center for information and communications, the trial Web portal can walk the investigator site personnel through the processes related to the protocol. Not only can the portal provide help with enrollment, but it can also alert site personnel to upcoming patient visits and protocol testing requirements.

The portal can also be the center for posting data problems and protocol issues that have been raised, so the investigator site personnel have one place to go and can immediately see what they need to work on. The portal should incorporate workflow tasks to help the investigator site deal with patient scheduling and cleaning up data problems.

In addition, the portal could be used for ancillary tasks such as AE reporting and drug dispensing and tracking. Sites could benefit from a Web entry of serious AEs, especially if this entry was tied to the clinical AE entry. Thus sites could conceivably deal with AEs in a more efficient manner. Drug inventory could likewise be more streamlined for the investigator sites. If the pharmacy has access to the portal, drug-tracking functions can be centralized with the data collection process.

A final benefit of the portal could be to assist investigator sites prepare site reports and provide information to the sites regarding patient progress and expected payments.

In short, the investigator site personnel job functions are effectively changed by the additional task of data entry. By putting a good Web tool in the hands of these people, their jobs could be more streamlined and organized. Overall, investigator site personnel should benefit from the increased efficiency that an EDC and a portal application provide. Over the course of the trial, they should spend less time handling clinical data and more time assisting and interacting with the patients.

## **CRAs**

The new functions of the CRA extend beyond the obvious one of using a computerized data entry and management system instead of handling paper forms. The EDC process offers substantial advantages to the CRA, particularly in streamlining his/her responsibilities and alleviating the repetitive tasks that take time away from productive interactions with investigator site personnel.

Under an EDC system, the actual responsibilities of CRAs do not change, but the way they fulfill those responsibilities undergoes a significant shift. For instance, CRAs will continue to make site visits and ensure that the data collected at those sites complies with required regulations. However, by using the features available through an EDC system, particularly by having access to data collected at the research site, CRAs can streamline their site visits by identifying potential problem areas before even arriving at the site.

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However, by supplementing an EDC system with a portal, the CRAs can utilize the Web not only to look at clinical data, but also to communicate efficiently with the various sites for which they are responsible. Since CRAs are the focal point of communication between the sponsor of the trial and the investigative sites, the CRAs are in a unique position to exploit the advantages offered by a portal.

CRAs, in effect, become portal content managers. They can function as the portal manager because they are the point persons when it comes to communications between the sites and the sponsor. The CRAs know what information is pertinent and relevant to each of the other people involved in the clinical data process. Certainly assistance from a technical group will be needed to address any technical concerns of the portal and perhaps even to add user accounts for the portal, but the CRAs should be able to directly manage the content of the portal.

The CRAs, with their knowledge of the clinical site personnel, may be asked to test both the portal and the EDC software developed to collect the data for the trial. The CRAs will be in a good position to verify that investigator site personnel can in fact use the EDC system.

In addition, with workflow technology, CRAs can log into the portal and see what tasks need to be done at a particular instance for a particular site. The portal can schedule the site visits for the CRAs, as well as alert CRAs to issues that need to be addressed on a day-to-day basis. For the CRA, the portal should be a major source of scheduling and task information.

If the EDC system is used properly, the CRA position will experience a major shift in focus. Rather than spend most of their time gathering information, the CRA should be able to focus more on protocol compliance, site communications, and managing the sites.

## **CDMs and CDCs**

The EDC process drastically alters data entry, and thus the traditional role of the CDCs and the CDMs as data entry managers will need to change to accommodate these differences. In particular, the focus of the personnel in these positions will shift away from overseeing data entry toward management of problems reported by CRAs and investigator site personnel. Clinical information management will form a large part of the sponsor company's knowledge information strategy, and thus the CDCs and CDMs play a significant role within the EDC process.

Although there is a distinct shift in the responsibilities of the CDCs and the CDMs under an EDC process, the job descriptions for these positions will retain many similar features of their traditional roles. The EDC process will change the way some of the responsibilities are carried out, but it will not change most of the responsibilities themselves.

CDMs and CDCs will still be involved in the development of data entry systems and edit checks. Certainly one of the more challenging aspects of the job shift will be learning any new software and system functionality offered by the EDC product as opposed to the Clinical Data Management System (CDMS) that they had been using. CDMs and CDCs may also be asked to test the EDC software and the portal, or participate with the CRAs in testing the software. These personnel can offer usability input in the testing and validation process.

*(continued on page 5)*



One strong shift in job focus not addressable by the portal or workflow is re-specifying and possibly re-writing edit checks to run at entry time as the sites are entering data, rather than in a batch process after the data has been double entered.

However, with a portal, many of the data management functions of CDMs and CDCs will be available within the portal framework. In particular, the portal will be the place that CDMs and CDCs look for data quality issues and data discrepancies. The portal, and perhaps even the EDC application itself, will be where the CDMs and CDCs send data clarification queries to the sites, and communicate data problems with the CRAs and site personnel. The portal and the EDC application can also help CDMs and CDCs keep abreast of enrollment rates, problems with patient enrollment, and problems with EDC form design.

Since CDMs and CDCs are already computer literate, their job focus will change more to managing data using the Web and its tools as opposed to the familiar client-server software. However, CDMs and CDCs will have to be savvy enough with the tools so they can help the CRAs and site personnel use both the EDC system and the portal. CDMs and the CDCs will likely be involved in defining some of the workflow set up needed by the other two groups.

Workflow technology can provide direct benefits for the CDMs and CDCs as well. In a similar manner to the alerts provided to CRAs, the CDMs and CDCs will also receive alerts for data quality problems. Instead of the paper-based routine where a hard copy came to the sponsor and triggered the work for the CDMs and CDCs, the portal will now provide the triggers in electronic format for these personnel.

## **CTPMs**

The CTPM's primary objective is to conceive, plan, coordinate, facilitate, and monitor clinical studies. This objective includes overall project management of multiple clinical studies performed in-house or by Contract Research Organizations (CROs), as well as project planning to include assessment of development team head count, resource planning, project timelines and effective utilization of budget. The CTPM is also responsible for coordinating and compiling scientific documents including protocols, clinical study reports and other regulatory documents.

In order to fulfill the responsibilities of this position, the CTPM must be able to access timely and relevant information from other clinical trial personnel, effectively communicate project-related information, and plan and host meetings and presentations.

In short, portals can help CTPMs more directly than many of the other job functions. The portal can provide a dashboard showing the status of the clinical trial. The CTPMs can look at various reports and graphs and get an instant snapshot of the current state of the trial.

With appropriate management reports built into the portal, the CTPMs can address scheduling concerns and assess site participation and determine if certain sites need more attention from CRAs and CDMs.

Please see *EDC Today*<sup>TM</sup> Issue 16 "EDC and the Clinical Trials Project Manager" for more detailed information on the impact of EDC on the CTPM.

(continued on page 6)



## Conclusions

Clearly the “Webification” of clinical trials data collection introduces new tools for personnel working in this area. Not only is there a central application for all personnel involved in a clinical trial to access as part of their jobs, but there is a central point of communication and management reports as well.

Portals can literally bring all clinical data personnel together on the same Web page. Communications can be secure and audited. Issues requiring attention of specific individuals can be raised within a portal framework and become “alerts” to those individuals when they are logged into the portal.

Incorporating workflow into the portal application can help lead individuals through the tasks they must perform. Workflow can be the one application that makes the job transitions easier for everyone involved. To the extent that processes described in the SOPs can be enforced using workflow technology, compliance with SOPs will be higher and hopefully these processes can be more efficient.

With the shift in focus of data entry, getting everyone comfortable with using the Web is a critical task for biopharma executives looking to help improve the inefficiencies of the clinical trial data collection process. Certainly the tools are available that can be used to help personnel adapt to new processes and enjoy better productivity.

## References

<sup>1</sup> EDC Today<sup>TM</sup>, Issue 12, “Portals, and How They Can Make EDC Work Better”

<sup>2</sup> <http://www.e-workflow.org/>.

<sup>3</sup> EDC Today<sup>TM</sup>, Issue 2, “Job Evolution or Revolution? EDC’s Impact on the Clinical Trial Team”

We welcome your feedback! Please send your thoughts, opinions, and comments on this or any issue to [kmousley@edcmanagement.com](mailto:kmousley@edcmanagement.com). We also welcome suggestions for future topics. Please submit requests to [kmousley@edcmanagement.com](mailto:kmousley@edcmanagement.com).



## Who's behind the research?

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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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