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

“Regulations and EDC:  
Assuring Compliance”

## Job Evolution or Revolution? EDC’s Impact on the Clinical Trial Team

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

*Our second issue strives to identify how the implementation of EDC affects some of the jobs of those whose work is related to the conduct of clinical trials.*

Biopharma companies continuously look for ways to accelerate the prolonged process of obtaining FDA marketing approval. Toward this goal, companies are incorporating EDC to collect clinical trials data.

Traditionally, clinical trials data are collected

on paper forms called Case Report Forms (CRFs). This collection process, often mired in significant time lags, is known for its inefficiencies. EDC transforms the process of clinical trials data collection from a paper-based CRF process to an electronic one.

As a key to improved efficiency, EDC addresses the major drawbacks of the paper-based process by moving both data entry and data validation to the source of the data, the investigator site. In the clinical research setting, EDC helps to produce cleaner data faster, allows study monitoring to progress more efficiently, and permits more effective use of resources for important and timely decision-making.

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### About EDC Management:

EDC Management was founded to assist biopharma companies plan, prepare for and implement Electronic Data Capture (EDC) strategies according to their data management goals and objectives. We do not sell or endorse any specific EDC software application or vendor.

### EDC Management

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### Available **EDC In Depth** Research Reports related to this issue:

#### “The New Role of the Clinical Research Associate (CRA) in an Electronic Data Capture (EDC) Environment”

Learn how the CRAs job changes with the implementation of EDC. Specifically, learn how EDC can shift the focus of the CRA from searching for data errors to resolving site and protocol issues.

#### “The New Role of the Clinical Data Coordinator (CDC) and Clinical Data Manager (CDM) in an Electronic Data Capture (EDC) Environment”

Since data entry moves to the investigator site, CDCs and CDMs move away from directing an in-house data entry staff toward managing clinical data and improving data quality. Learn how this shift effects the job of the CDC/CDM.

#### “The New Role of Investigator Site Personnel in an Electronic Data Capture (EDC) Environment”

At first investigator site personnel may resist EDC because they are being asked to do more. Learn how a properly implemented electronic data capture system might actually save investigator sites time over the course of a trial.

#### “The New Role of the Clinical Trial Project Managers (CTPM) in an Electronic Data Capture (EDC) Environment”

Once the CTPM learns the new tasks and incorporates them into the project, EDC can provide more timely information on the progress of the clinical trial. This information may help to make management decisions that contribute to a successful trial. Learn which tasks the CTPM must adjust in order to take advantage of the EDC system.

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### Clinical Trials Personnel Affected by EDC

As with any new application incorporated into a large and complex organization, EDC requires that certain job classifications within the clinical trials process change in order to accommodate the features of the electronic application. In particular, EDC will impact four key job classifications – investigator site personnel, Clinical Research Associates (CRAs), Clinical Data Managers (CDMs)/Clinical Data Coordinators (CDCs), and Clinical Trial Project Managers (CTPMs).

Most job changes will stem from two fundamental shifts brought by EDC. First, paper CRFs will be replaced by electronic CRFs. All job functions that reviewed paper will now review electronic data using the EDC application. Second, data entry will be performed at the investigator site, which will allow data validation to be performed at entry time.

While the overarching responsibilities of these positions will remain the same, the duties that the personnel must complete to meet those responsibilities must evolve to

accommodate the features of the EDC application. Some of these duties change significantly, others change very little, and some do not change at all. In addition, some duties become obsolete and new ones emerge. (See Table 1 below.)

Though each job classification will undergo a unique evolution of duties, there are several common job trends.

### Job Impact: Increased Technical Training Requirements

EDC requires a certain level of technical expertise if it is to be utilized to its full potential. Regardless of job function, all clinical trials professionals working with the EDC system will need training for it to be successful.

Investigator site personnel will need to be proficient enough on the electronic application to correctly enter the data for the protocol and to produce potentially useful trial documentation. CRAs must also have the requisite technical knowledge to utilize the EDC system for ensuring that data collected at each research site complies with the protocol.

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**Table 1** provides an overview of how some job functions will change with the implementation of EDC.

## Effect of EDC on Significant Clinical Trial Tasks and Deliverables Under a Paper-Based System

Tasks and Deliverables	CRA	CDC/CDM	Investigator Site Personnel	Clinical Trial Project Manager
Training	Major	Major	Major	Major
Standard Operating Procedures (SOPs)	Major/minor	Major	N/A	Minor
Standards	Minor	Minor	N/A	Minor
Site Selection, Evaluation, & Start-up	Major	Minor	Major	Major/minor
CRF Design & Development	Major	Major	Major	Major
Monitoring Plan	Major	Minor	Minor	Major
Data Management Plan	Minor	Major	N/A	Major
Database Development	N/A	Major	N/A	Major
Investigator Meeting	Major	Major	Major	Major
Data Entry	N/A	Major	new	Major
Ongoing Site Visits	Major	Minor	Major	Minor
Data Corrections & Validation (DCF)	Major	Major	Major	Major
Trial Management	N/A	Major	N/A	Major
Safety Reporting	Minor	Major/minor	Major/minor	Minor
Interim Analysis	N/A	Minor	N/A	Minor
Database/CRF Quality Assurance	N/A	Obsolete	N/A	Obsolete
Final Database Lock	N/A	Major/minor	N/A	Minor
FDA Submission	N/A	Major/minor	N/A	Major/minor



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Similarly, only with thorough training, can CDC/CDMs effectively use EDC application software to implement their vision of the best screen and database designs. Clinical Trial Project Managers (CTPMs) need to understand the time and resource requirements needed to set up the data entry application as well as what management reports may be available from the EDC product.

In some cases, sponsor companies may opt to hire additional technical assistants to act as support for clinical trial personnel, or the technical aspects may be outsourced. In either scenario, the various personnel mentioned above need thorough training on the EDC system.

### **Job Impact: More Efficient Use of Time**

Once an EDC system is in place, clinical trials professionals will likely find that many of the mundane responsibilities associated with the paper-based process will be eliminated or reduced, leaving more time to focus on more fulfilling tasks.

Built-in data edit checks in EDC data entry applications should allow investigator site personnel to spend less time on data correction and more time interacting with patients. Likewise, during the site visit, CRAs can devote more time interacting with the investigator site personnel rather than in data checking activities. The EDC process allows CDC/CDMs to spend less time fixing data problems and more time helping to manage the trial and resulting data. Finally, quicker access to the data may help the CTPM make better and more timely trial-related decisions.

### **Job Impact: Improved Opportunities for Leadership**

As job duties shift to accommodate the features of EDC applications, clinical trials professionals will likely be able to assume greater leadership roles.

EDC empowers the CRA to make targeted decisions during site visits. CRAs may, therefore, take on an increased leadership role as they monitor each research site to ensure that all federal and FDA regulations are satisfied. Rather than acting as data checkers, CDC/CDMs will play a vital role in the sponsor biopharma's information management strategy. For the CTPMs, EDC provides more opportunity to react quickly and intelligently. Having timely access to current information may allow the CTPMs to help speed acceptance of drugs and/or halt costly trials that show little promise or have potential compliance issues.

### **Transitioning Personnel to an EDC System**

The effectiveness of EDC — and in turn, how efficiently clinical trials are run — depends on those who design, implement and use EDC systems. In order for EDC to succeed as a data collection and cleaning solution, clinical trial professionals need to adjust their day-to-day work lives to accommodate the differences between the electronic and the traditional paper-based collection format.

By understanding the changes that are required — including the reasoning behind those changes — clinical trials professionals will be able to evaluate how they currently fulfill their duties and how the EDC application can help them accomplish their goals.

As some clinical trials personnel may be resistant to adopting EDC and adapting to new and changing job duties, sponsor companies need to understand the changes and be ready to demonstrate the benefits of EDC.

### **Who's behind the research?**

Our lead researcher, **Kirk Mousley** 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).

**Robert Pearsall** received his BS in Electrical Engineering from MIT and his MS in Nuclear Engineering/Biomedical Instrumentation from The Ohio State University. He is Senior Consultant and Vice President for Business Development at Mousley Consulting, Inc. He has been involved with a variety of clinical data system projects for biopharma, including data management systems, electronic data capture (EDC), electronic submissions, validation compliance, and knowledge management. He was team leader and design architect for pilot projects in FDA/CBER electronic submissions.

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