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

The Newest Regulations  
Affecting EDC

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## EDC and the Clinical Trials Project Manager

*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.*

*To assist organizations making the transition from paper-based clinical trials to Electronic Data Capture (EDC) facilitated trials, our sixteenth issue takes a look at how the adoption of EDC impacts jobs in the Clinical Trials arena. In particular, this issue is an excerpt from our EDC In Depth Research Report Issue 2.4, where we examine the job of the Clinical Trials Project Manager (CTPM). If we understand the impact of the change in process from paper-based clinical trial data collection to EDC, we can appreciate the impact on jobs in the organization.*

*The CTPM is responsible for planning the protocols and processes that are involved with a clinical trial. With an EDC system this responsibility continues to be vital; the duties that must be completed to fulfill this responsibility will change to take into account the differences between a paper-based and an electronic collection format.*

### Introduction

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, as well as communicate project-related information effectively, and coordinate project-specific activities such as the planning and hosting of meetings and presentations.

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## The Major Process Changes for EDC

Before we consider the job changes for the CTPM, let’s first consider the major changes in the process between paper-based data collection and EDC. There are five major changes as follows:

1. The paper CRF is eliminated
2. Data Entry is performed at Investigator sites
3. The EDC database may be external to Sponsor
4. Data correction is performed at Investigator sites
5. New process of locking and closing the database

With these major changes in mind, let’s look at what happens to the CTPM’s job.

## The CTPM Under EDC: Changes To The Job Description

The responsibilities of the CTPM are tied to milestones and deliverables. The following pages delineate some of the related job responsibilities under the traditional paper-based data collection process and how they change under the EDC process. Table 1 shows the areas we will discuss, and assesses the impact of EDC on these areas.

Responsibilities Under The Paper-Based System	Impact of EDC?
Write, distribute, and update standard operating procedures (SOPs)	Minor
Site selection, evaluation and start-up	Major
Design, review, and approve CRF	Major
Write, review, and approve monitoring plan	Major
Write, review and approve data management plan	Minor
Design and implement database structure	Minor
Design, implement and validate data entry system	Major
Specify, implement, and validate edit checks	Major
Investigator meeting	Major
Investigator training	Major
Develop and implement CRF tracking system	Minor
Monitor site visits	Major
Monitor the progress of the trial through CRF receipt and data entry, verification, and edit checks	Major
Generate, deliver and receive Data Clarification Forms (DCFs)	Major
Schedule and monitor interim analysis	Minor
CDM data quality assurance	Major
Final database lock	Minor
NDA submission	Minor
Personnel management	Major
Develop and establish standards	Minor
Develop new tools	Minor

Table 1. List of tasks and milestones. This list is by no means meant to be exhaustive—it merely represents significant areas that fall within the responsibility of the CTPM.

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Now let's examine these tasks and milestones in more details.

### ***Standard Operating Procedures (SOPs)***

With the implementation of an EDC process, the SOPs will change during the first few trials. Once the process is formulated and improvements are made based on lessons learned during the first few trials, the SOPs will become relatively static.

The biggest task in rewriting the SOPs will be identifying all the processes that change under an EDC system. Some examples of changes to SOPs include the processing of Data Clarification Forms (DCFs) and defining edit checks. Data Clarifications Forms will likely be sent to the investigator through the EDC software and not via fax or mail. The completion of the DCF by the Investigator will likely be the data update. Likewise, the definition of the edit checks will now be split into a large proportion of checks that run at data entry time, and a much smaller proportion of checks that continue to be run after the data is saved in the database. The following pages will detail more of the ways to update SOPs, but each company will need to decide how to update their own procedures.

### ***Sites***

In order to accomplish the tasks that are inherent to the EDC process at the sites, the CTPM will have to allocate more time to site related activities. The CTPM may also need to consider assigning technically oriented personnel to some tasks (e.g., supplying broadband internet access) in order to ease the burden on other clinical trials personnel.

### ***Case Report Form (CRF)***

The incorporation of an electronic means of collecting data will require the CTPM to redefine each step of the CRF creation process. For instance, rather than graphic artists helping the Clinical Data Managers design the paper form, application programmers will aid in the design and implementation of EDC data entry screens. The design stage of the CRF process will likely take more time than was required in the paper-based system, and the CTPM must account for this change and ensure that the additional time is available.

The CTPM must also be aware that the CRF in an EDC system will have different features than were available on a paper form, and these features will require new skills for implementation. For example, the data entry screens need to be much more user friendly in EDC trials than in paper-based CRF trials, because a much larger and more diverse user community will be using the electronic forms.

In order to ensure that the requirements for the EDC system are met, the CTPM will need to allocate time and resources for design, development, testing and rollout.

### ***Monitoring Plan***

The Monitoring Plan will change considerably under an EDC process, in large part because the data from each site will be available to the CRA before a site visit. The Monitoring Plan will need to incorporate the fact that access to the data will allow CRAs to plan their site visits and prepare lists of issues to address before arriving at the site.

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## ***Data Management Plan***

The Data Management Plan will change under an EDC process since it outlines the way data management will be performed. In particular, two types of edit checks now need to be developed: one of those types will be the traditional edit checks that run against the CDMS database and the second of those will be a new type of edit check, those used on the entry form. The Data Management Plan will need to have scheduled time for EDC edit check programming, running the program(s) and resolving discrepancies.

## ***Database Structure***

Under an EDC system, the database setup task moves to the beginning of the clinical trial process—in fact, the database must be in place before the EDC data entry screens can be developed. The CTPM must be aware of this change and adjust the timelines of project management accordingly.

## ***Data Entry System***

Under the EDC process, the data entry system becomes the CRF. Three separate milestones – CRF creation, Data Entry System design and development, and Edit-checks – are thus combined into one step in the EDC process: the development of the EDC data entry screens. Again, CTPMs need to adjust their plan so that this step is completed in the beginning of the clinical trials process.

## ***Edit Checks***

Since most edit checks will be built directly into the EDC data entry application, the CTPM will need to schedule less time for this process and more time to the data entry design and development phase. However, a few edit checks may remain outside of the EDC data entry system. The CTPM should keep track of those edits as a separate milestone and schedule time appropriately.

## ***Investigator Meeting***

Under an EDC process, investigator site personnel are no longer trained on how to fill in the CRF but instead are trained on how to use the EDC entry system. CTPMs need to be aware that the EDC data entry application will need to be completed prior to the Investigator Meeting if EDC system training is to be performed at the meeting.

## ***Investigator Training***

Under an EDC system, CTPMs need to be aware that it will be harder to add sites to a trial, since the entire process of performing site evaluations, setting up the user accounts, and scheduling site user training is more involved with the electronic system. If new sites are added, CTPMs must account for the increased time necessary to bring the new sites to a functional capability.

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## ***CRF Tracking System***

In an EDC system, CRF tracking will be replaced by a completely different tracking system, that is, one that tracks the site's progress with data entry. The first few EDC trials will concentrate on what information will be tracked and where the information will come from. CTPMs will continue to receive ongoing management information. The time allowance for setting up the tracking system will depend upon the reporting information provided by the EDC application and its internal design considerations.

## ***Monitor Site Visits***

Under the EDC process, CTPMs need to be aware that the monitoring schedule will change, and they will have to make suitable adjustments in their plans. CTPMs will also be able to monitor much of the trial's progress continuously, due to the accessibility of the data through the EDC database. CTPMs should understand the application well enough to be able to take advantage of this accessibility and incorporate changes into their timelines and plans based on such monitoring.

## ***Monitor the Progress of the Trial Through CRF Receipt and Data Entry, Verification, and Edit Checks***

### **CRFs received in house**

Under the EDC process, this milestone is removed since the paper CRF no longer exists. Instead, data will be entered at the sites and will be largely monitored by the CRAs.

### **CRF entered into tracking system**

This milestone will change under an EDC process based on the specifics of the tracking information provided by the EDC application.

### **CRF data entered**

Under the EDC process, data are entered at the research site in one pass. This milestone will change under an EDC process based on the specifics of the tracking information provided by the EDC application.

### **CRF data verification**

Under the EDC process, verification of data (i.e., second pass entry) is no longer necessary. As a result, monitoring data verification will no longer be one of the CTPM's responsibilities.

### **Edit checks run on sponsor's Clinical Data Management System database**

In an EDC process, most edit checks are part of the data entry system, and thus no longer need to be monitored by the CTPM. There may still be a small number of edit checks that are run by sponsor company personnel on the database as a batch process.

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## ***Data Clarification Forms (DCFs)***

In an EDC process, there will be fewer DCFs because most errors will be caught at data entry time. The process for handling the remaining DCFs will depend upon how it is set up within the EDC application. It is likely that data can be flagged as potential errors, and messages or emails can be sent to the sites to let them know about potential errors. Investigator site personnel could then log into the EDC application to apply the necessary corrections directly into the database. Once the CTPM knows how this process is defined, they will develop new milestones or activities related to this process under the EDC system.

## ***Interim Analysis***

Under an EDC system, the analysis process may change based on where the EDC application stores the CRF data. Some EDC applications store data at the EDC vendor company site, and thus transferring data for interim analysis may need to be worked out with the EDC vendor—a responsibility that falls within the purview of the CTPM. Other than this scenario, the CTPM responsibilities toward interim analysis will not differ significantly from those in the traditional paper-based data collection system.

## ***CDM Data Quality Assurance***

Under an EDC process, this step is no longer needed since the EDC system replaces the CRF, and there is no CRF to compare with the database. Instead, source document verification, which takes place during monitor site visits, compares source documents with the database.

## ***Final Database Lock***

As in the interim analysis section above, the only change to this area of responsibility under an EDC process may be the additional step of coordinating the transfer of data from an EDC vendor site to the sponsor's analysis group.

## ***NDA Submissions Material***

EDC will change the submissions material related to the CRF. A new process will have to be developed to decide how to present the CRF data as part of the submission. Once that process is developed, the CTPM's responsibilities toward NDA submissions milestones should be roughly the same as those under the traditional paper-based system.

## ***Personnel Management***

The CTPM is responsible for managing the various personnel who participate in reaching milestones such as the ones described above. The following paragraphs describe the ways an EDC process will impact these personnel, in turn impacting the management responsibilities of the CTPM.

Safety personnel participate in Serious Adverse Experience (SAE) reporting and periodic safety updates. Under the EDC process, Safety personnel may be able to obtain part or most of their AE information directly from the EDC application. CTPMs may help schedule time to define and develop the data transfer software needed.

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Clinical research personnel (i.e., medical personnel employed by the sponsor) are involved with the trial design and the development of the protocol. This group of personnel will remain largely unaffected under the EDC process.

Investigator site personnel enroll patients, perform dosing and all protocol required testing, and fill out the CRF for the sponsor company. Investigator site personnel also review DCFs and make corrections as needed. The EDC process significantly impacts investigator site personnel as they will perform data entry using the EDC application. CTPMs need to be aware that more time may be needed to train Investigator site personnel to use the new application.

CRA's perform site monitoring. Again, the role of the monitor is significantly impacted by the EDC system. CTPMs need to keep in mind the new technical aspect of the CRA position. CTPMs will also need to help CRA's as they change their site visits to adapt to the EDC application.

Clinical data managers perform data management functions from the design of the CRF to the Quality Assurance (QA) of the database as described above. The EDC process significantly impacts the responsibilities of the CDM, as they no longer supervise data entry personnel. CTPMs will need to account for the extra time the CDM will need interacting with EDC application developers and validating and using the EDC application. In addition, the CTPM should be aware that the CDM should need to spend less time finding and correcting data errors and should alter the data management plan accordingly.

EDC application developers design and implement the database, the data entry system, and the edit checks specified in the Data Management Plan. Under the EDC process, these application developers will become critical to the success of the clinical trial. The ability to properly develop usable EDC data entry systems will count heavily towards the acceptance and use of the EDC application by investigator site personnel. CTPMs will need to schedule the application developers' time early in the clinical trial process.

## **Ongoing Project Management Tasks**

The CTPM has certain responsibilities that fall outside the milestone timeline discussed above. These ongoing project management tasks will also change in response to the implementation of an EDC system.

### **Standards**

Under an EDC system, some existing standards should be altered for use in the EDC application environment (e.g., edit-checks). Once these standard elements have been converted to the new environment, continuing development of standards will progress in the same way as in the traditional paper-based system. Thus, the CTPM should continue to encourage and, if necessary, argue for the establishment of standards.

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## **New Tools**

CTPMs should always be looking for ways to obtain management information about trial progress. Such information will help them assess project status, assess task completion times, and task interdependencies. Under an EDC system, a number of existing management tools such as CRF tracking may be replaced by a tracking system that will require design and implementation. Once these tools are rewritten, the continuing development of new tools will be very similar to that conducted under the traditional paper-based system.

## **Conclusions**

One of the most significant benefits of the EDC application to the CTPM is the accessibility of “near real-time” trial data. This accessibility allows the CTPM to monitor the trial’s progress without having to wait for CRA site visits and reports from investigator site personnel.

The CTPM may find that the task of managing the trial receives substantial assistance from various features of the EDC application. With a thorough understanding of the electronic application and the changes that the EDC process brings, the CTPM may find that his/her job progresses with greater efficiency.

With the overview of the tasks and milestones that are impacted, other workers in the Clinical Trials data collection field can see what changes for them as well. Certainly their jobs will be impacted by the changes to the SOPs, the shift of the data entry to the site, and the changing focus of edit checks. Clearly all jobs at biopharmas are going to become more Investigator site involved.



## 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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