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#### **HS** Home Study article

##### **LEARNING OBJECTIVE**

At the conclusion of this course, participants should be able to identify informational needs for their organization and plan for selection and implementation of CTMS to meet those needs.

##### **DISCLOSURES**

Lorraine D. Ellis, MS, MBA, and Maria A. Durkin, MBA, disclose that they have no actual or potential conflict of interest in relation to this article.

## Meeting the Real-Time Informational Needs of a Successful Clinical Trial **HS**

**C**linical trials entail complex workflow. With that, there is a need for interaction and for quick, efficient communication and exchange of information among organizations sponsoring, coordinating, and executing trials.

An entity-specific system, like a clinical trial management system (CTMS) for investigative sites, improves clinical trial efficiency and productivity, but only at the site level. Additionally, there are many other information technology (IT) systems that address only specific functional needs, such as electronic data capture (EDC), subject recruitment, and project management. However, a multifunctional clinical trial team needs an enterprise CTMS that provides study-wide workflow management and enables quick, real-time exchange of needed information to all team members for successful trial completion and optimum results.

This article describes the benefits achieved during one contract research organization's (CRO's) implementation of an enterprise CTMS, focusing on real-time exchange of information among the CRO, sponsors, and sites.

### **The Challenge**

A CRO working with a variety of sponsors over the years has learned that sponsors have different operational needs, as well as specific informational needs. CROs need to have the flexibility of managing projects and providing up-to-date project information in a variety of formats and details, and in the most cost-efficient manner. Whatever the precise means of getting there may be, a successfully completed trial is the result of the collaboration of many different experts and companies working as an integrated team.

Because of the need to share large amounts of information among team members, most companies opt for the relative convenience, flexibility, and speed of spreadsheets to report and e-mails to exchange rapidly changing information and documents while a trial is under way. However, within the industry, it is recognized that this is not the optimal possible situation. For instance, the limitations of individual spreadsheets and documents sometimes override their usefulness, and they definitely are not the most efficient or cost-effective way to share constantly changing information.

Since the data are not integrated or shared among the spreadsheets, the updating of information in one spreadsheet can cause information in one or

more documents to be out-of-date and incorrect; in any project, at least one person, and perhaps several, must keep track of this issue on a more or less constant basis. Additionally, all team members must be assured of having the same updated information at the same time to have productive team discussions.

## Case Study

Several years ago, the lead author's CRO vowed to find a better way to exchange information with sponsors and investigator sites. Although the organization had used a CTMS for years, it continued to use spreadsheets because of the system's inflexibility; it was difficult to use, impossible to customize for the dissemination of information as needed among team members, and sponsors and sites were reluctant to learn its complexities.

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The CRO hit the proverbial "wall" when it had to provide 25 spreadsheets to one sponsor, at the sponsor's request, and most had to be updated weekly. This constant updating required some serious resources, with no gain in efficiency or improved timeliness of information exchange relative to the resources spent. A new CTMS, with the functionality and flexibility to address information exchange among the clinical trial team, was the key requirement of any solution to this dilemma.

In order to find the best fit for a new CTMS, the organization had to

answer the following questions as specifically as possible:

- How would the system be used, and by whom, on a daily basis?
- What role would sites, sponsors, and other vendors play in the CTMS?
- What hardware and software and Internet connection would be needed to use the system?
- What are the most and least critical data elements in the CTMS?
- Which is more important: ease of use or extensive data?
- What amount of training is required to use the system?
- How intuitive is the menu system and the user interface?
- Would this system meet the organization's informational needs and make information exchange more efficient?

Also, the system needed to work with the trial workflow, so that the people using it did not feel it was just another information source to keep up-to-date, but a flexible, customizable tool for each project and for all team members. It had to have a document exchange function and an easy "virtual filing cabinet" for sharing and viewing all regulatory and other trial documents. It had to have clear and easy-to-understand project management metrics for details such as enrollment, institutional review board status, projected and real start/finish dates for each site and the project, case report form completion, document status, budgets, cost tracking, and more.

It was also important for the CTMS to have definable roles and responsibilities, so that each site and sponsor saw only its own information and only the information the CRO wanted to share with each member.

All things considered, the CRO's intended use of the new CTMS product's functionality spanned business development, study protocol setup and changes, partner selection, budgeting, project management, milestone schedules, dashboards, document sharing, monitor visit plans and actions, other study execution functionality, financial tracking and management, reporting, and metrics. Additional functionality for patient recruitment, material management, and finances should also be available if needed.

## The Solution

The organization's search for the right CTMS ended with its choice to use a system designed for the entire enterprise of clinical research, ranging from sites to sponsors and from CROs to other vendors. Two years of experience with the system show that it meets the needs described above. In addition, the company's philosophy of working with beta sites in the industry has enabled a collaborative approach to developing additional functionality and flexibility for meeting specific needs associated with the diversity of its sponsors, and the need to work with sites that have limited resources.

Implementation of the system involved the following key activities:

- Training all users at their level of use
- Defining roles and responsibilities for proper information exchange while retaining key security elements, since many other stakeholders or clinical research team members would be using the system
- Redesigning workflow with all team members so the CTMS is used for reporting and information exchange instead of other

tasks, such as creating spreadsheets and weekly reports

- Setting up the parameters and libraries of the system to match the CRO's workflow and process details
- Setting up an administrator and the administrative function
- Setting up portals for sites and sponsors to use the system

With the new CTMS in full use, there are no more spreadsheets to update; when someone wants a report, he or she goes into the system and gets the information without having to wait for someone else to compile it. There is no more waiting for project metrics reports or a list of documents that are in the files or needed from the sites.

Furthermore, training the users was easy, since the system has a simple menu system and intuitive user interface that allows them to retrieve information in formats they can use quickly. All team members know that the faster they put the information into the system, the more accurate the reports will be that they pull out of the system. The system requires no troubleshooting from an IT perspective, and any questions on system use are addressed by customer support.

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For ease of use, the CRO's sites, sponsors, and other stakeholders access the system through a web-based portal that is configured to their security characteristics. The system is a third-party hosted

**Table 1** Comparison of Project Work Before and After Implementing the New System

BEFORE the CTMS	AFTER the CTMS
Documents were exchanged by e-mail and regular mail and filed as hard copy.	Documents can be requested and delivered through a portal; they are stored in the system and are accessible to all through a virtual filing cabinet. (Note: Hard copy originals are still kept as needed.)
Project milestone information was updated to team members on a weekly or monthly basis, so the milestone status was not up-to-date. These milestones include patient entry and status, site startup and completion, budget status, etc. There were no real-time alerts to ensure critical items were addressed on a timely basis, so milestones or urgent issues may have been missed.	Milestone status is available to all team members in real-time for more productive team discussions.  A color alert system provides priority notice for key issue resolution.
Monitoring status and reports were shared via spreadsheets and e-mail.	Monitoring status and reports are in the CTMS for sponsors to view at any time.
Budget status was kept in accounting in a separate system.	Budget information is available only to those authorized, but in real-time.

software solution with full security, data backup, and uptime capability.

## Results

The CRO's sponsors have experienced project team meetings that are completed faster because everyone has the same information in real-time and can make decisions and plans based on the shared information (see Table 1). Meanwhile, sites like the ease of document collection and sharing through the portals. The integration of the CTMS into the CRO's daily workflow has provided faster and less costly information sharing, a shared communication system for all team members, and a central location for all trial documents and information for all to access.

This CRO's use of a CTMS with the right functionality has helped the clinical research team save money even as it becomes more efficient and effective. Importantly, the system is driving improved accountability.

The next steps in using the CTMS include an increased emphasis on study-

wide workflow management, which will take the organization to the next level of proactive, automated project management. **ACRP**

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