

# CTMS — Once You Have One, You'll Wonder How You Managed Without It

## A Solution for Sponsors

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A description of clinical trial management systems  
for sponsor organizations

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## Introduction

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Clinical trials are an expensive but essential part of a sponsor's existence. Unless the articles are being tested in the most efficient (yet still safe and complete) way possible, costs of development can rapidly become excessive and needlessly increased. Because testing must include multiple phases and comply with many strict regulations (which also vary between countries), it is essential that companies efficiently organize and manage their trials. With the recent disclosures about problems with drugs on the market (such as Vioxx) and calls for investigation into others, sponsors now, more than ever, must be extremely vigilant in the eyes of both the regulatory bodies and the general public.

A clinical trial management system (CTMS) is software specifically designed to assist in the management of a clinical trial. It is a tool that a sponsor can use to increase efficiency, productivity, capability, communication and performance, while helping to decrease manpower, administrative overhead and, by extension, associated costs. At the same time, it is a tool that can help verify the efficiency and effectiveness of processes and methods used to run a trial, and help determine whether procedures need to be refined. This paper helps to outline some of these key benefits.

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## What is a CTMS?

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A CTMS is software specifically designed to track, structure, guide, conform, prompt, notify, and report on trial progress and information. Consider it a “mission control” for clinical studies.

Note that a CTMS is not designed to store or capture actual clinical trial data that is used to determine the efficacy of the item or items being studied. That is the job of Electronic Data Capture (EDC) software. A CTMS, in contrast, tracks the status of the people, events, data, finances and documentation involved in, and required for, the trial. It tracks planned activities and events to ensure that they occur, and notifies users about upcoming activities and events. A CTMS enables a sponsor to be proactive rather than reactive where possible. It enables control of clinical trials in ways not possible when only spreadsheets or other manual processes are used.

Key features of a comprehensive CTMS include:

- Site management
- Patient screening status tracking
- Patient enrollment status tracking
- Site monitoring
- Regulatory document tracking
- CRF, visit & deviation tracking
- Inventory management
- Financial management
- Contact management

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## How can a CTMS benefit a sponsor and clinical operations?

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### REAL-TIME SHARING AND COLLABORATION

Just how can teams keep current in such a dynamic environment as clinical operations? One of the overriding problems with using file shares and paper document copies is the lack of efficient access to the data. A CTMS helps reduce the dependency on point-sources of data, and allows people to collate and share information in real-time.

#### Example

*Friday morning...* User A opens and begins editing the file that tracks regulatory document status. User B is handed the final regulatory documents for a site that allow the site to receive its initial drug shipment. User B needs to add this information to the file being edited by User A. Because User B is unable to update the file, he leaves the assessed documents on his desk to update later. Going forward, the scenario path can branch in a number of ways.

*Path 1:* User B remembers to enter the information later in the day:

- This is done in time for User C, who is responsible for handling shipments, to view the file with the updated information. In this case, luckily, everything works out.

-Or -

- User C, who was told by the project manager that the paperwork is available, now has to waste time tracking down the project manager to find out who has the documents. User C then needs to track down that user to verify that documents are okay, confirm it's an oversight and the system isn't up-to-date. There are two possible outcomes:

- User C manages to find User B and verify the documents.

-Or -

- User C fails to find User B and consequently can't verify the documents. The ramifications:

- User C delays the shipment.

-Or -

- User C risks making the shipment because it's urgent, only to find out later that the paperwork wasn't approved by ClinOps. Now reconciliation has to be done on various fronts (such as Compliance, Shipping, and Regulatory), wasting yet more time and money.

*Path 2:* As the day continues, User B has many priorities that require attention and forgets to enter the information before leaving that evening. All the items in Path 1 still apply, but now others also have to waste a considerable amount of

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time to track down the documents and to verify them (something which has already been done, but as it's not recorded, has to be done again) and then enter them into the system... assuming the file is not still locked.

These are simple, all too common examples of avoidable and unnecessary wasted time and effort that may even result in needing to alter patient schedules. If the above was to happen with a financial matter such as site payments there are even further complications. Reconciliation is also more complex and makes it potentially costly.

By using a CTMS, these scenarios would never have happened. The record required would not have locked in the first place. Each user would have been able to enter the information when needed and all subsequent users would see the current data in realtime.

**BRING MORE FUNCTIONS  
IN-HOUSE WITHOUT  
REQUIRING MORE  
INTERNAL RESOURCES**

ClinOps teams are notoriously overworked and often have no choice but to out-source functions to CROs and other contract staff. Use of a CTMS can streamline processes and functions so that tasks traditionally very time and resource consuming come well within the capabilities of the current in-house staff. This inherently brings not only costs savings, but greater transparency, efficiency, and control over the trial.

**INSTANT STATUS AND  
TRACKING**

In addition to the collaboration issues mentioned previously, using a CTMS can give a sponsor real-time access not only for its administrators and project managers who require data to be readily available and clear, but also for other users (such as management or executives) without needing to generate reports or give the users access to raw data. They can see or order scheduled snapshots of relevant areas.

**FORCES ADHERENCE TO  
STANDARD OPERATING  
PROCEDURES**

Because the CTMS system would be configured at the start of a trial with the rules and requirements for that trial, it can enforce adherence to procedures. This might appear to be cumbersome and inflexible. The advantage is that it enables the trial to be more easily conducted according to the trial protocol and company rules. This in turn helps to prevent any hint of impropriety or making a trial invalid over small but repeated procedural irregularities which could have been easily avoided

**QUICKLY HIGHLIGHTS  
DEFICIENCIES AND PRE-  
EMPTS POTENTIAL  
PROBLEMS**

The ability to clearly define and report on each functional area according to the rules of the trial make it possible both to be quickly reactive to problems that arise, and often to be proactive in dealing with problems before they can happen. There is no need to sift through huge spreadsheets or go to multiple locations looking for potential problems. A CTMS can help to identify out of variance visits, deficient regulatory documents, and unresolved monitoring issues, as well as to help renew documents before they expire.

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**STOPS “TO-BE-DONE”  
ITEMS SLIPPING THROUGH  
– BOTH INTERNAL AND  
MONITORING**

The system never forgets! Even the most organized people sometimes make mistakes and forget to make a note of something, or do so in haste and not in the “usual place,” which can lead to forgetting or misplacing the item or task. The system will not! It keeps track of every task, either according to the protocol, company SOPs, or individual rules for the clinical trial. The system tracks tirelessly and will continue to remind users that resolution is required until a task is completed.

**FEWER ERRORS IN BOTH  
DATA AND PROCEDURES**

The culmination of all the previous points is that fewer errors occur due to the CTMS.

- Stopping items from slipping through the cracks.
- Enforcing procedures.
- Only adding the data once, always in the same place and in real-time.
- Prompting for issue resolution.

Decisions are made based on more accurate and up-to-date data, without having to hunt for and then piece together the complete picture. Complex and in-depth reconciliation is therefore needed less and less.

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## How do these benefits help a sponsor?

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### TIME SAVINGS

End the frustration of constantly creating and chasing down reports, reconciliation, duplicating tasks, finding data, analyzing data to see if it is in compliance with the rules, and looking for problems. These issues can all be easily and seamlessly addressed within a CTMS. This results in a decreased workload and a smaller, more focused team. Not only does *Time equal Money*, but *Workload is directly proportional to Stress* and hence productivity.

### COMPLIANCE

Regulations cover an increasingly broad spectrum of clinical research operations, resulting in heightened concerns regarding full accountability and compliance. To avoid the risks involved with altering or substituting a page that a hard-copy report affords, a CTMS makes it possible to capture every alteration of data in audit trails and often with a comment as to why the data was amended. This provides greater transparency into a situation that might have occurred years before and maybe even made by employees who have since left the company. This makes the results of the trial more credible to the regulatory bodies.

### CONTROL

With the ability to bring functions back in-house, a CTMS enables you to more easily control operations and adherence to procedures. By having the data readily available and clearly presented, managers can make better decisions regarding the running of a trial. This in turn leads to a more favorable and efficient outcome and a lower administration cost for the trial.

### INTERNAL COMMUNICATIONS AND ALERTS

A CTMS provides easy and automated notification when key tasks need to be performed. Users can make approvals but don't have to constantly police the whole study system for such important tasks or issues. The system alerts them instead.

All users see the same real-time information. It doesn't matter who's in the office or not, or who's got a document buried on their desk.

A CTMS provides direct access to reports for management and executives. It is no longer necessary to customize data for a specific request; all information is available on-demand.

### INTERNAL MANPOWER SAVINGS

Perform more study tasks with fewer people.

### OUTSOURCING SAVINGS

A CTMS provides two opportunities for outsourcing savings.

- If a sponsor still chooses to outsource some or all of the trial functions to a CRO or to contract monitors and administrators, it can have these contractors enter data directly into its system. The sponsor can then avoid the costs

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of having contractors collate information and reports every time something is required, or avoid additional expense in interfacing with the contractors' systems.

- While outsourcing provides a sponsor with more resources without increasing direct headcount, and is cost effective from a share price standpoint, it would be even better not to have any additional outgoing costs. For many trials, the in-house team required to track and administer the CRO and report to management would be virtually identical as it would be for a sponsor to administer the trial itself with a CTMS. In addition, the outgoing cost would only be incurred once rather than for each trial. Using a CTMS to run your trial rather than a hiring CRO for each trial means you are not repeatedly paying for a CRO. Your outlay for help is only once.

## **INTANGIBLE COST SAVINGS**

Sponsors can also realize some less tangible but nonetheless very real cost savings.

- Decreased errors

It is very hard to put a price on how much errors cost, as there are so many factors involved in their reconciliation. It is however, considerable.

- Less stressful work environment

By smoothing out the extremes in the burden of task spectrum (mindless at one end and very complex at the other), a CTMS can improve employee productivity and reduce staff turnover, with downstream effects of reduced training costs and improved continuity in trial management and practices.

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## Conclusion

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As described in this document, there are many substantial savings to be made, both directly and indirectly, from the use of a CTMS. Direct savings in administration costs alone could pay for the CTMS within one trial. By improving overall efficiency, a CTMS can help reduce product timelines and meet trial deadlines. With the pressures that characterize the current state of the drug development industry, a sponsor would be wise to consider implementing CTMS software to assist it in delivering successful outcomes with its clinical trials. The sponsor just may wonder how it ever managed without it.