

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

A Solution for CROs

A description of clinical trial management systems
for clinical research organizations

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Introduction

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. That it is necessary for sponsors to implement controls that demonstrate their trial results cannot be questioned. If a sponsor contracts with a clinical research organization (CRO) to run a trial on the sponsor's behalf, the sponsor will most likely be looking for those controls from the CRO. The CRO's use of a CTMS to enforce adherence to the sponsor's rules will go a long way towards providing the needed reassurances.

A CRO needs a tool that increases efficiency, productivity, capability, performance, and internal communication, as well as communication with the sponsor. A tool that helps decrease manpower, and administrative overhead also helps decrease associated costs. These benefits, in turn, can be passed on to a sponsor, giving the CRO a competitive edge. This paper helps to outline some of these key benefits.

What is a CTMS?

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 CRO 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, and deviation tracking
- Inventory management
- Financial management
- Contact management

How can a CTMS benefit a CRO and clinical operations?

REAL-TIME SHARING AND COLLABORATION

One of the overriding problems with using file shares and paper document copies is the lack of efficient access to the data. Directory structures are often very complex or randomly created. It is not unusual for one user to check out a document for edit, which another user from editing the same document or even a completely different document. Users are prevented from using their time effectively as wait for the file to be available. Or worse, data slips through.

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 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.

Another common example would be the embarrassment caused when the sponsor suddenly calls for a report on the status of something. The person who deals with that area isn't in the office and the sponsor is desperate for the report. Or worse yet, that person is busy with other tasks and taking the time to create the report can have an adverse effect on the other work. By having a CTMS system, a CRO can allow the sponsor to retrieve their own reports without involving anyone else. The sponsor gets what it wants instantly, and the CRO does not need to tie up valuable resources.

**FEWER RESOURCES
REQUIRED**

ClinOps teams are notoriously overworked. Use of a CTMS can streamline processes and functions. By simplifying tasks that are traditionally very time and resource consuming, a CTMS can lead to fewer people being required. The cost savings this brings to you can be passed on to a sponsor. As a result, a CRO is more economical to sponsors and becomes more sought-after in the marketplace.

**INSTANT STATUS AND
TRACKING**

In addition to the collaboration issues mentioned previously, using a CTMS can give a CRO 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) and even the sponsor without needing to generate reports or give the users access to raw data. They can see or order scheduled snapshots of relevant areas.

**FORCES STANDARD
OPERATING PROCEDURES
TO BE ADHERED TO**

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 that 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.

**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 above 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.

How do these benefits help a CRO?

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. As a result, a CRO can have 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.

COMPETITIVE EDGE

A decrease in the time and cost of performing duties can result in an increase in profits and a decrease in costs quoted to sponsors. This can make a CRO more competitive in the marketplace. The CRO can advertise its use of a CTMS system as a bonus in addition to its services. This demonstrates the CRO's investment in the success of a sponsor's trial, as well as the regulatory and communication benefits for them.

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 and the sponsor.

CONTROL

With the ability to bring functions back in-house, a CTMS enables a CRO 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.

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.

MANPOWER SAVINGS

Perform more study tasks with fewer people.

INTANGIBLE COST SAVINGS

CROs 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.

- Benefits to marketing

A CRO can market its company as using a CTMS in order to highlight its mature, state-of-the-art clinical trial management infrastructure. By providing cutting-edge capabilities to sponsors, the CRO obtains a competitive advantage.

Conclusion

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 CRO would be wise to consider implementing CTMS software to assist it in delivering successful outcomes with its clinical trials. The CRO just may wonder how it ever managed without it.