

CTMS Procurement: The Seven Deadly Sins

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Keywords: Clinical Trial Management System (CTMS)

Clinical trials are becoming larger, more expensive and increasingly complex. Numerous factors conspire to drive this increase in size, cost and complexity including increased regulatory scrutiny; submissions in greater numbers of markets; a greater proportion of investigational drugs targeted at chronic diseases; and, in some therapeutic areas at least, competition for patients and investigators. Effective management of clinical trials is, therefore, critical for pharmaceutical and biotechnology companies worldwide. In response, vendors have produced a number of IT solutions allowing sponsors, Clinical Research Organisations (CROs) and investigators to run clinical trials more effectively and efficiently. Many clinical trials now employ clinical data management systems (CDMS), clinical trial management systems (CTMS), electronic data capture (EDC), drug supply management (DSM), and interactive voice response systems (IVRS).

CTMS, for example, helps improve trial management processes and better manage costs. Cost management is a particular priority for pharmaceutical and biotechnology companies aiming to maximise their return on investment or minimise the financial burn. It is estimated that keeping a trial running costs around US\$40,000 per day. The impact on lost sales revenue is even more marked: every extra day that a drug remains in clinical studies costs the sponsor at least US\$600,000 in lost sales. Apart from making it easier for sponsors to attain key clinical trial milestones and helping to control costs, CTMS also offers intangible benefits, such as improved regulatory compliance, reduced complexity, superior information flow and enhanced relationships with clinical investigators.

Several CTMS solutions are available commercially, and the most appropriate choice depends on numerous internal and external factors, many of which are company-specific. However, the author has identified seven 'deadly procurement sins' surrounding CTMS. Executives that fail to consider these issues could find that the CTMS does not meet their needs and does not optimise the benefits that the technology could offer their organisation. This article will begin, however, by briefly considering the benefits of CTMS.

The benefits of CTMS

CTMS offers the opportunity to track, measure and report on virtually every aspect of a clinical trial or study program. The relational database at the heart of the CTMS groups, analyses and filters information at various levels including, among others, trial, country, site, investigator, product, clinical research associate (CRA) etc. As a result, a CTMS provides a view of trial management data suited to a variety of individuals within the organisation, including high-level, consolidated metrics for senior managers. The CTMS allows managers to view the progress of several studies and compare approaches in order to optimise future studies. Financial managers can view the total costs and expenditures across clinical programs. The CTMS can also provide detailed reports allowing, for example, a project manager to view enrolment figures for a specific site or investigator and assess the performance of the study recruitment strategy to respond in a timely manner by opening new study sites or taking other actions to ensure target timelines can be met.

Against this background, the CTMS offers five main benefits:

- Companies can track and obtain reports on every aspect of day-to-day trial management. This enhances operational and project management control. Moreover, the CTMS allows managers to deploy monitoring resources in the most appropriate manner to address a particular issue.
- The CTMS delivers relevant information to study stakeholders as rapidly as possible. This helps to manage the relationship between CRO and sponsor as well as enhancing operational control of individual studies and the entire program.
- The CTMS helps sponsors promote operational and workflow standards. CTMS standardises processes across all project teams and increases efficiency, by sharing common data across clinical studies.
- The CTMS can ensure timely investigator payments and allow accurate financial reporting. Timely payments help maintain investigators' interest in and commitment to the study.
- The CTMS should import data from and

export data to other key technologies, such as IVR, EDC and CDMS solutions. Once again, this helps reduce the risk of data entry errors and facilitates the timely completion of the clinical study.

Most vendors offer configuration and customisation options to allow a company to configure a CTMS to meet its specific needs. Beyond these common attributes, the various CTMS differ in several ways. As a result, to ensure that investment in a CTMS is maximised, executives with procurement responsibilities should avoid these seven 'deadly sins'.

Deadly sin #1: Using old technology

It's a truism that technology dates rapidly. Therefore, to make the most of the functionality and utility offered by a CTMS (as well as to future-proof the system) the interface and relational databases need to be up-to-date and employ new technologies. Despite this, some CTMS still use technology introduced some 15 years ago. This use of older technology can lead to several problems:

- Installing CTMS based on older technology can be protracted. It can take three days just to load the program from CD-ROMs to the database server.
- Relatively few people have the experience to program and trouble-shoot older software systems. This may be a particular issue in smaller companies.
- Many Windows-based techniques that we use almost instinctively, such as the right mouse click, are not available with the older systems. Using newer systems, users can navigate rapidly, promoting consistent and efficient work processes.

An increasing number of studies are performed in non-traditional countries, such as Central and Eastern Europe, Asia and Latin America. Web-based systems, such as TrialWorks® by ClinPhone, IMPACT™, and globalTRIALS™ have a distinct advantage in these studies. The program does not need installation on the user's PC, which can give substantial savings in terms of PC support. Moreover, web-based systems allow the instant implementation of software updates.

Deadly sin #2: Protracted implementation

Some CTMS applications can be slow to implement. As mentioned above, systems based on older software can take three days to load the program from CD-ROM to the database server. For

newer solutions, installation typically takes place in a matter of days. Further, the easy-to-use user interface of modern CTMS, means that clients can begin using these solutions within a few days of installation. With trials often costing tens of thousands of dollars a day, getting the system up and running rapidly is a commercial priority.

Deadly sin #3: Insufficient reporting capability

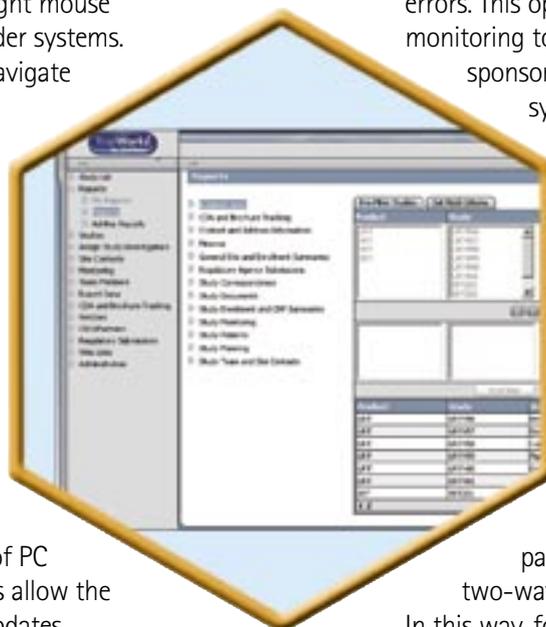
The ability to access a diverse range of reports tailored to the specific needs of multiple users is the *raison d'être* for a CTMS. Therefore, the CTMS should offer a vast suite of standard reports, as well as *ad hoc* reporting, enabling users to quickly access the consolidated information they require. Using systems based on older technology, writing a report can take a day, compared to minutes with newer systems.

Deadly sin #4: No remote monitoring module

Remote monitoring modules offer a valuable tool for mobile CRAs. Before a site visit, the CRA downloads the relevant data they need onto their laptops. During the site visit, the CRA updates the data in the remote monitoring module; this data is then used to create monitoring visit reports and other documentation, and is uploaded to the central database where it is available to other CTMS users. Using a remote monitoring tool is more efficient than employing paper-based systems and, in particular, reduces the risk of errors. This optimises the use of CRA time. Remote monitoring tools are especially valuable when the sponsor uses multiple CROs. The standardised system avoids complications that can arise from different CROs using different management software.

Deadly sin #5: Not working with other key technologies

The CTMS should work with the other IT solutions that are now commonplace in clinical trials. For example, IVR is widely used for randomisation, management of trial supplies and collection of patient diaries. The CTMS should offer two-way, real-time integration with IVR. In this way, for example, the IVRS automatically enters patient enrollment and visit information into the CTMS, providing an accurate and continually updated picture of patient recruitment and progress within the CTMS. Indeed, the CTMS should be able to import relevant information from virtually any IVR, EDC or data management system. This increases the currency of essential



tracking and performance data contained within the CTMS, facilitating timely management reports and decisions.

Procurement executives should consider the benefits of being able to export data to Microsoft Word, Outlook, Project, Excel and email/calendaring software, as well as other productivity tools, such as FedEx shipping software. They should also consider including the abilities to hyperlink to study templates, documents and folders; to create XML files for upload to www.clinicaltrials.gov; and to automatically generate check requests. Finally, integrating patient visits with payment data to ensure investigator payment is generated quickly. Rapid payments help establish a good relationships with investigators and their sites.

Deadly sin #6: No hosted solution

Many CTMS companies do not offer a hosted solution. Unfortunately, many smaller clients cannot call on the large IT infrastructure common in larger companies. In other cases, larger companies prefer to outsource IT support in order to focus on their core competencies. As a result, procurement executives need to consider the benefits of licensing and installing the CTMS on-site compared to implementing a hosted solution. In hosted solutions, third-party companies act as

an IT department and provide unlimited technical support. The software resides at the host's facilities, which users access over the internet. The hosting environments are secure and include 24/7 network engineering support, redundant power supplies, redundant internet connectivity and scheduled backups.

Deadly sin #7: Hidden costs

In some ways, the system's price is the least important of the seven deadly sins. The cost itself is probably less important than the value it represents. Prices for a CTMS can vary from \$50,000 to several million dollars. There is often the perception that the higher the price, the better the product. However, in the case of modern CTMS solutions, the very features that make them easy to use and rapid to implement, also lend themselves to rapid development lifecycles, and hence lower license costs.

Executives also need to consider the license structure. Many solutions only offer licenses based on named users, which is inflexible in the current model of clinical research, where companies frequently redeploy resources to maximise efficiency and the use of CROs is prevalent. By comparison, the concurrent user licence model gives companies complete flexibility in how to deploy internal resources and use external ones.

Moreover, using a system with an intuitive and user-friendly interface minimises user training, increases user efficiency and requires less user support. Intuitive systems also facilitate use by third parties or infrequent users with minimal training. These factors all contribute to reducing the overall cost of implementation and ongoing support for the lifetime of the product.

In conclusion, a CTMS makes managing clinical trials easier, faster and more efficient. The choice of vendor and system depends on balancing various and sometimes competing factors. Nevertheless, considering the seven potentially deadly sins outlined above allows companies to procure the most cost-effective and efficient CTMS to meet their needs, maximises the return on investment and helps get the company's drugs to market as rapidly as possible.

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