CTMS: Promise versus Reality

Before we start to talk about CTMS, we should first make sure we are in agreement as to what is meant by CTMS. I can imagine some of you reading and wondering why I am bothering to waste your time defining what CTMS is. We all know, don’t we? CTMS has been around for years, we know what it is. Well, I thought I knew, but I recognize that sometimes my view gets too biased by the firm and systems I work with on a daily basis. So I went to my favorite search engine and typed in CTMS. Obviously, CTMS is just a four letter acronym and can mean many different things, so I narrowed down my search by entering clinical trial management system. The very first article I found had a definition of CTMS that included everything from protocol development to data collection to analysis to safety monitoring. This sounds more like the definition of an e-clinical solution suite to me.

Okay, so maybe this is just one extreme view. The very next link I followed brought me to the caBIG site of NCI. Here they refer to a CTMS workspace that sounds very similar to the first definition. Needless to say I started to get a bit anxious. I’m beginning to wonder if I’ve been living in my own private little bubble so long I don’t even know the definition of CTMS.

The next link I follow brings me to Wikipedia. Here I find a definition that agrees with my own understanding of the term, and as far as I know the most common interpretation of what CTMS means. Whew, what a relief! So this is the definition I’m using. Basically it boils down to a project management system that relies heavily on tracking details to support the management of clinical trials. So let’s take a look at this at this definition.

“A **Clinical Trial Management System**, also known as **CTMS**, is a customizable software solution used by the biotechnology and pharmaceutical industries to manage the large amounts of data involved with the operation of a clinical trial. It maintains and manages the planning, preparation, performance, and reporting of clinical trials, with emphasis on keeping up-to-date contact information for participants and tracking deadlines and milestones such as those for regulatory approval or the issue of progress reports. Often, a clinical trial management system provides data to a business intelligence system, which acts as a digital dashboard for trial managers.

In the early phases of clinical trials, when the number of patients and tests are small, most managers use an in-house or home-grown program to handle their data. As the amount of data grows, though, organizations increasingly look to replace their systems with more stable, feature-rich software provided by specialized vendors. Each manager has different requirements that a system must satisfy. Some popular requirements include: budgeting, patient
management, compliance with government regulations, and compatibility with other data management systems.

Each sponsor has different requirements that their CTMS must satisfy; it would be impossible to create a complete list of CTMS requirements. Despite differences, several requirements are pervasive, including: project management, budgeting and financials, patient management, investigator management, EC/IRB approvals, compliance with FDA regulations, and compatibility with other systems such as data management systems, electronic data capture, and adverse event reporting systems.”


First it is customizable software to manage the large amounts of data involved in the operation of a clinical trial. Let’s face it, in comparison to other industries such as insurance and banking, we are not really working with LARGE amounts of data, but are we are dealing with diverse data. But an important point here is that we are already talking about customizable – so the expectation is set from the very beginning here that this is not a completely standardized area. Each client has some nuances that they want to be able to uniquely customize the system as they see fit. Next it deals with maintaining and managing the planning, preparation, performance and reporting of clinical trials. How does it do this, by keeping up to date contact information and tracking milestones. This data is then made available to the end users through the use of business intelligence systems via dashboards.

The need for customization is reiterated by the statements that each sponsor and manager have different requirements that a CTMS must try to satisfy. But common requirements include project management, budgeting, financials, patient management, investigator management, ethical approvals, compliance, and integration with other clinical systems. Patient and investigator management might be a bit overstated – in reality these systems track items such as enrollment and achievement of specific milestones.

The promise of clinical trial management systems are several fold. There are the straightforward items such as central recording of pertinent details about the investigator sites and support of financial aspects. Based on these details, the intention is to be able to have better oversight of the trial and therefore have the ability to intervene earlier, keep things on track, reduce total costs, etc.

Let’s just take a look at a sampling of some claims for CTM systems from a variety of vendors:

- Efficient planning and tracking of clinical studies
- Earlier problem detection for earlier corrective actions
- Improve relationships with investigators
- More effective use of resources
- Site/investigator profiling
• Facilitate investigator and subject recruitment
• Cost savings
• Manage communications with sites
• Manage investigator payments
• Forecast enrollment and costs
• Project planning and resource management
• Schedule site visits
• Electronic trip report templates customized to your SOPs
• Alert triggers
• Integration with EDC, IVRS, data management system, etc
• Scorecards
• Dashboards
• Track everything: subject visits, trial progress, project progress, documentation, you name it
• Reports, reports, reports for everyone and anyone
• Multiple views: Aggregated project level down to individual trial site
• Etc etc etc

Fantastic. We select, license, and install one of these systems and all our problems are solved. Or are they? In my experience, and also from talking to colleagues in the industry, many users are not satisfied with their CTMS implementations. During an e-Clinical presentation I gave at a recent conference, I mentioned that CTMS systems are data hungry beasts. The nods and smiles of agreement from the audience were nearly unanimous. I went on to describe that in my experience, the CTMS systems suffer from poor data compliance and data quality. As a result, users create their own side solutions in spreadsheets or in simple databases. Again the response of agreement was near unanimous. Why is this so? Clinical Trial Management Systems (CTMS) offer the promise of better clinical trial management. They accomplish this by tracking details of the trial process and reporting performance metrics. Valuable and useful to be sure.

At this same conference we were fortunate to have an investigator present in the audience. He described his general surprise at how often sponsor companies act as though they do not have information that they clearly should have. Examples cited included cases of sponsor companies contacting physicians who no longer participate in clinical trials, also of contacting physicians who did not have the appropriate patient population for the trial, late payments, and the list goes on. So why is it that investigators still lament about late payments and internal users bypass systems designed to address such problems? In my opinion the reasons come down to a few key root causes. First, is that historically clinical trials have been seen as an extension of research. Run as a scientific endeavor rather than as a business process. Given this focus, attention is paid to the scientific merits of the trial, the accuracy of the data, and the regulatory compliance to assure that results hold up to the rigor of scrutiny. This model may have been perfectly acceptable
ten years ago, but the current environment requires a stronger business focus and better management practices.

Second is that the nature of CTMS design is that the value derives from tracking and reporting metrics. As such, the first line user has to enter a lot of data into the system but they themselves get limited value from it, hence my reference to these systems as data hungry beasts. The first line users, who are typically the trial monitors, have the responsibility of feeding and caring for this hungry beast. However they get very little value from doing so, therefore the timeliness and quality of the data entry suffers. Not only do they get limited value from entering the data, but all too often this entry is a transcription from other records. Nobody likes to transcribe information from one place to another. Because of the resultant poor data quality, second and third line users start to distrust the information they obtain from the system. It is common for pressure to be applied to the first line users to get them to enter the data and improve the quality. This stick based approach works for awhile and then users start to slack off and the problems re-emerge. The stick is then typically supplemented with a carrot in the form of training to highlight the value to the organization of having reliable data in the CTMS. Compliance improves for awhile but then human nature reasserts itself and monitors again start to slack off on the data entry. At this point it is common to find second and third line users developing side solutions to meet their needs. Most common are spreadsheets initially loaded with an extract from the CTMS then manually updated with personal information obtained from discussions with various project team members. A highly inefficient process ensues with multiple users keeping overlapping copies of relevant data supplemented by manual periodic updates taken from the CTMS with varying levels of sophistication. Other user groups who find that the CTMS does not fully meet their needs develop their own custom solutions using simple database systems. All of which leads to less and less data being fed into the CTMS which leads to a self-fulfilling prophecy. Users feel that the system doesn’t meet their needs and then their actions guarantee that the system cannot meet their needs.

To the vendors’ credit, many of them have recognized this problem and begun addressing it by providing interfaces to other systems as data sources, such as EDC, IVRS, CDMS, etc. Additionally, support is provided to define workflows and have monitoring visit reports created through the system to capture some of the data. Yet users still complain. Is this because users just like to complain and haven’t yet recognized the improvements already realized? Or is it that there is still more improvement needed? As with most things in life, the answer often lies in the grey zone. It my impression that the truth here lies in the middle ground, in the grey zone. Yes features continue to be added to CTMS that improve the data quality, and yes there is still room for additional improvements.

So how can CTMS regain their promise? It appears as though current products available have been designed with the end product in mind, but without enough attention given to the actual trial process itself. What is required is a new type of trial facilitation tool, a system that is designed with the first line users in mind. In my view the answer to this problem lies in a two pronged approach. At the beginning of this article, I mentioned the first definition that I came
across that included everything and the kitchen sink. While this is not the common definition of CTMS within the industry, it is the more appropriate definition. Whether you want to call it CTMS, or e-Clinical, or something else really doesn’t matter. The crux of the matter is that we need to see all the activities as feeding into one large assembly line that is used for manufacturing our end product – namely the regulatory submission (you could even take a broader view, but this will suffice for the purposes of this article). To support this view, all the systems supporting the clinical trial process need to be designed at the outset to work with each other. This requires defining one central set of meta-data standards that all the systems use. Another key component is a common approach to exchanging data, so that all the systems can exchange data. To couch this in terms of the latest IT craze, this requires the development of an SOA (service oriented architecture) framework. So the first prong is based on a robust IT architecture that can assure common definition of data elements and the ability to exchange data between individual components.

The second prong is to carefully examine the work processes of the first line users. These are users who end up being responsible for feeding all the data into the hungry beast. Tools need to be developed to allow the users to go about their jobs in an unencumbered manner that captures relevant data in a format that can easily be fed into the CTMS without creating redundant effort or mere transcription tasks. Technologies that hold some promise here include tablet PCs, digital pens, PDAs, etc.

By following these two prongs we can see the true value of CTMS, which is not really CTMS but of an integrated suite of products that support the entire clinical trial process. You can call that CTMS, or e-Clinical, or anything else you like.

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