

The CTMS Story: Focusing on Need

By Timothy Pratt, PhD

So you've decided you need a clinical trial management system (CTMS). You're in the process of sourcing bids from companies that profess to offer such things. You may well have started your search by asking peers and colleagues "Who do you know that makes a good CTMS? Or searched online for CTMS and came up with a list of names. You're not alone. A recent survey of 839 key pharma decision makers indicated that 57% of those surveyed who are involved in clinical trials saw CTMS as the most important technology initiative in their area.¹ But before you bask in the warm fuzzy glow of affirmation, STOP. Begin with the end in mind. You don't necessarily need a CTMS. In fact, you may actually want a 1/2-inch hole.

Beyond Drill Bits

How are a CTMS and a 1/2-inch hole the same? They both relate to what you actually need, rather than what you use to achieve it. It's an old marketing adage that "Customers don't buy 1/2-inch drill bits, they buy 1/2-inch holes." This sage wisdom is used to remind marketers (and by them to remind companies) that the focus should be on what customers actually need- in this example, a hole-rather than the product itself, which merely helps them achieve that end. Focusing on the product runs the risk of ignoring a needs-satisfying solution that may be cheaper/faster/more convenient because a product focus is inherently narrowed in on that thing to the exclusion of all else. It's an easy trap to fall into, presupposing the answer to a need is to be found in a known product.

Try going into a store and asking for sunscreen. You'll probably get exactly what you asked for. Now, go to the same store and talk about your need: facial freckle avoidance. You may well walk out with a broad-brimmed hat that will do a better job of meeting your need.

So, why don't more people take the time to talk about their need rather than a product that they think will meet their need? Two primary reasons:

- They want to appear to be informed consumers (so they don't get taken for a ride, are respected by their peers as knowledgeable, and can succinctly explain to their manager why they need an increased budget).
- They don't know what they don't know, but they do know (or presume to know) item X will probably work.

Problem Posing Needs

How does this relate to a CTMS? Let's start with what

is actually needed from a CTMS. Basically, visibility into operational metrics and strategic management of clinical trials, with the goal of getting studies up and running quickly and smoothly and increasing the likelihood of success. The components that make up those broad topics of metrics and management include: site documentation, recruitment rates, overall data quality, IRB status and renewal, clinical product distribution and tracking, resource allocation and utilization, budgets and payments, visit and outcomes monitoring, and more.

These are laudable goals. But standalone CTMS products suffer greatly for the fact that they are inherently overlays onto a variety of disparate systems. That means that someone from your clinical staff has to take time to enter summary information into the CTMS, which necessarily takes time away from their core function of running the study.² Some systems can draw data from the underlying programs, but as one large pharma company discovered, making that work effectively is a lengthy, time-consuming, and at best ROI-neutral process.³

It has historically been problematic to get software to "talk" to other software. And the simple act of changing the version of one of the underlying software elements in a CTMS may throw everything into chaos when it no longer communicates. The solution to that problem is to stick with the original version of the underlying element, which may condemn large segments of the organization to use obsolescent, bug-ridden early versions for which support may no longer be available. Technology integration or lack thereof is thus a major problem.

Some industry analysts predict that an inability to exchange data with underlying applications will actually cause some established CTMS market players to fail in the relatively near term.⁴ So, if we concede that standalone CTMS products are not without their problems, what to do? The future, available now from a few leading companies, is actually very bright indeed if we focus on the 1/2-inch hole (AKA the need). And it comes in the form of liquid soap.



Liquid Soap & EDC

SOAP is an old sales acronym for “Sell Only Available Product” used to focus salespeople on what the company has to offer rather than what they don’t have, or may possibly get in the future. The trouble with soap, especially as regards a CTMS, is that you could end up with a product that doesn’t fit anyone’s needs particularly well, except the salesperson’s need to bring home the bacon that month.

What is needed is liquid soap that penetrates into all the nooks and crevices to do its job, rather than a hard scratchy bar that rubs the hands raw trying to achieve the same end. All of that is an obtuse way of saying the product you select to meet your need should be flexible enough to adapt to your specific circumstances, rather than be an “out-of-the-box” standard offering that necessarily descends to the lowest common denominator. And that product may not bear the label “CTMS.”

Does such a product exist with respect to meeting the need for a CTMS? Yes, it’s called EDC. Not your common or garden variety EDC mind you, but highly advanced state-of-the-art EDC that in fact forms a functional CTMS by its very nature—in short, EDC systems that produce operational metrics as a by-product of their operation² and either integrate other systems into their overarching schema or replace those systems entirely. The most advanced EDC systems perform like liquid soap, gently adapting to your specific needs and processes, and they do a far better job of achieving your goals than older, inflexible EDC systems that force sponsors to adapt to them – that’s the hard, scratchy, and somewhat painful experience most people would rather avoid.

According to Hanover and Julian in *Life Sciences Insights*⁴:

“These systems leverage EDC within the setting of an automated, integrated, clinical trial workflow...[such] Clinical trial management systems provide more efficient and cost-effective functionality than their component technologies, increasingly driving pharmaceutical and biotech companies toward adoption.”

A state-of-the-art advanced EDC will obviate the need for staff to enter summary data. The real-time availability of data in a Web-based system can roll up the information, across multiple initiatives, without the need for human intervention. Instances have occurred where development of specific modules within the EDC offering actually obsoleted the sponsor’s existing system, such as control of clinical product inventory and distribution. The EDC CDMS/CTMS controls shipments, receipts, returns, and which patients get allocated what product, and it articulates seamlessly with the distribution company.⁵ Of course, the sponsor can view where any product is at any given point in time through a by-product drug/ device accountability log.

But even advanced EDC must be able to integrate with, or at least talk seamlessly to, other systems within the sponsor corporation. Simply obsoleting other systems won’t work in some instances. Such an instance might be the generation of investigator payments via the corporate accounting system – it’s highly unlikely a corporation will use the advanced EDC system to pay its bills! A good example is my own experience at Guidant Corporation (2003-2004) in clinical applications research studies.

We used advanced EDC to track investigator honoraria due (which the system could feed into a single report that described which forms were complete, which were unsigned, which required deviations, etc), which we then had the vendor turn into an electronic file that could feed directly into the corporate SAP financial system. What happened then was many hundreds of checks poured out the other end each quarter, replete with a cover letter letting the physician know what they were getting paid for. The reduction in staff burden amounted to some 3.0 FTE headcount. We had similar experiences with monitoring, contact tracking, data quality, and other key elements.

The Real Deal

Some authors contend that advanced EDC will never replace standalone CTMS products because they can’t handle budgeting and contract management or monitor visit scheduling.² A quick scan of the industry, however, indicates otherwise. Various companies are now offering an advanced EDC CDMS/CTMS that does in fact cover these bases, as my own experience from two years ago bears out - and those companies may not be the ones you’re thinking of. As one pundit put it in late 2004, “It’s Oracle and Phase Forward’s market to lose.”⁶

So, in Covey’s immortal words, “Begin with the end in mind.”⁷ When you’ve decided that you need a CTMS, step back and ask yourself the 1/2-inch hole question. Look for a system, regardless of what it’s called, that offers you real-time visibility into operational metrics and strategic management capabilities, as well as the flexibility (or liquid nature) to adapt to your specific needs - including the ability to produce such operational efficiencies as obsolescence of existing systems and leverage of broader extant corporate systems. Remember, you don’t need a CTMS, you need a 1/2-inch hole.

¹ E. Julian, “What Pharma Wants from IT Today” *Pharmaceutical Executive*, www.pharmexec.com (July 2005).

² D. Fishbach, “Does EDC Herald the End of CTMS?” *Bio-IT WORLD*, www.bioitworld.com (July 2005).

³ R. Case, “In Search of the Holy Grail,” *Pharmaceutical Executive*, www.pharmaexec.com (July 2005).

⁴ J. Hanover and E. Julian, “U.S. Clinical Trial Management System 2004-2008 Forecast and Analysis,” *Life Sciences Insights*, www.lifescience-insights.com (October 2004).

⁵ P. Fadden, Director of Project Management & Customer Service, MedNet Solutions, personal communication, August 2005.

⁶ J. Hanover, *LSI Report on CTMS*, *Bio-IT WORLD*, www.bio-itworld.com (November 2004).

⁷ S. Covey, *The 7 Habits of Highly Effective People* (Free Press, November 2004)