News
Current Issue
Archives
SourceBook
Op-Ed/Newsletters
Free Subscriptions
Product Coverage
Health-IT World
Resource Centers
Career Center
Events Calendar
Awards Programs
White Papers
About Us
Editorial Calendar
Marketing / Media Services
Privacy Policy
Contact Us
Featured Webcasts

eCLINIQUA

DIA 2004: Who Needs a CDM System Now?

By Mark D. Uehling
Senior Science Editor
Jun 17, 2004

Who Needs a CDMS Now?

Assumptions shape everything. One assumes a person to be unfriendly – only to learn otherwise. One assumes that bacon cheeseburgers are fattening, not a central component of a nutritionally sound weight-loss regimen. One assumes that a clinical trial needs an expensive clinical data management (CDM) system, and then . . .

And then one arrives at the 2004 Drug Information Association's annual meeting. A full report about this year's big Washington, D.C., conference will appear in *Bio-IT World's* July issue.

For now, one of the most intriguing aspects of this year's meeting was the idea that a major piece of machinery on the metaphorical "factory floor" of the clinical trial – applications to track and clean clinical data – might not be as indispensable as some believe.

I'm not saying CDMS implementations were mistaken. Especially with prior generations of electronic data capture (EDC) systems, which gathered data that needed to be laboriously cleaned and handled, the CDM applications filled a need for many organizations and will continue to do so for the largest sponsors of clinical trials.

But what about everybody else? What about companies that have tight budgets? Going forward, leaner companies sponsoring clinical trials may be able to avoid the expense, the migraine, and the delay that accompany connecting a CDMS to other analytical and managerial tools for clinical data.

This was hardly my own epiphany. Far from it. But it seems more plausible today than even a year or two ago.

I've been hearing versions of this notion from a number of vendors at DIA – and prior to the meeting. I won't put words in the mouths of these companies – I'll just write about them over the coming months. But small, thriving EDC companies have rapid growth rates and the ability to do most of what CDM systems offer through bigger, better, more mature EDC

demands.

systems.

At the same time, the conventional wisdom at the two old-line CDM leaders seems to be fading. In brief, their argument is that a CDM and an EDC system from the same company can "work seamlessly" together. But their customers don't say that very convincingly. Instead, their customers say, more or less, "It was tough, but we got it to work eventually."

In some ways, the leaders' pitch could be flipped, with a little marketing jujitsu, into a backhanded, upside-down argument that may also serve sponsors deciding not to bother with CDM systems. Here's the logic. If someone tells you two widgets work perfectly together, doesn't a warning bell go off? Aren't they really saying you might want to consider one widget that does the work of both? Which is more or less what many next-generation EDC vendors offer. These companies can clean data and provide SAS datasets with one application. The data never languish in an intermediate digestive step, basically a separate, additional stomach called a CDMS.

Today, statisticians and the FDA prefer to analyze their clinical data in SAS files. But with a nudge from the FDA, it's reasonable to think the final resting state for clinical data might be an XML file using the CDISC (Clinical Data Interchange Standards Consortium) data models. In such a world, parking data in a conventional CDMS could be an unnecessary detour prior to a statistician receiving the data at last. New tools from SAS and other companies like Lincoln Technologies will be able to work with the data in CDISC formats, making CDM obsolete for the most forward-looking companies.

At DIA, I heard a somewhat unexpected endorsement of CDISC from another company that, to be fair, expressed no opinions whatsoever on my main topic here, CDM systems.

Steve Shihadeh, general manager, healthcare and life sciences, joined Microsoft from Siemens Medical Solutions. I am somewhat relieved to report that Mr. Shihadeh has no plans to start a publication about technology in the life sciences: He would be a formidable competitor in any industry. Shihadeh well remembers a period of hesitation and resistance that accompanied the HL-7 standard for hospital and physician IT.

Shihadeh thinks CDISC adoption will follow a similar trajectory, and prove as important to the life sciences as a standard railway gauge was to the U.S. economy in the 1800s. "That will happen in this business," he says of CDISC's gradual acceptance. "As CDISC becomes more ubiquitous, it will become the norm in how people communicate in pharma. CDISC will, we think, really light a fire." Microsoft made its first appearance at DIA this year. Its booth was deluged. The company also became a dues-paying member of CDISC.

One tricky call is whether the lower prices and easier implementations of younger, smaller, single-widget EDC companies will displace the older, double-widget EDC and CDM systems at big companies.

Will large sponsors ever elect to unplug their massive investments in CDMS? Is it possible that painful costs might lead them to slowly mothball such systems? Or are there long-term reasons to keep them? Set me straight at: mark_uehling@bio-itworld.com.

A Good Outcome

Outcome Sciences, based in Cambridge, Mass. continues to impress. The company is growing quite rapidly, as its president, Richard Gliklich explained recently, ticking off impressive metrics like five million electronic case report forms collected and 350,000 patients recruited annually. That's a result of what Gliklich says are relationships of one sort or another with every major medical center in the U.S. The privately held company does mostly Phase IV work. "Occasionally a late Phase III trial slips in," Gliklich notes.

But fundamentally, he says, Phase IV should be considered on its own terms. "We're really talking about a new segment of the market," he says. "It's a new space. It's driven by medical affairs or marketing" fiefdoms within pharma.

The demands of those customers – and the larger numbers of patients enrolled once a drug has been approved – have dictated demanding specs for the technology. Says Gliklich: "The platform has to be more scalable. It has to be easy to train people. It has to be flexible. These are research-naïve sites you are trying to reach." Like any number of companies, Gliklich is rolling together voice-response, diary, and safety systems into his core application. "I think voice is going to be more and more important," says Gliklich.

In some ways, he sounds like a heretic on the topic of customization, which is simply a fact of life with sponsors of clinical trials that have homegrown or more aged applications, which his system must connect. "If you take the approach of customizing," he says, "it is a nightmare." He prefers to have one system, which allows his trainers (there are just four of them) to routinely get 200 sites a week comfortable with the Outcome Sciences tools. "That tells you it's working in their workflow," Gliklich says.

He's as hamstrung by nondisclosure agreements as any other vendor, and unable to name customers he says are quite satisfied. But he does note that he began work as one of four vendors helping one state as part of a four-state, 20,000-patient registry project in cystic fibrosis. At the end of the first year, he reports, the other three states switched to his stuff. "The thing that has been most critical," he says, "is building site loyalty. That part is critical. The customer is different than the user. In the end, we will be judged by how well we serve the user."

Another Way To Use PDFs

The Adobe Acrobat form is an unheralded workhorse in the clinical realm. Sure, it requires some mousing around a screen. But clinical staff like it. It's familiar. It feels like paper. And Oracle Clinical and Pfizer are not the only companies exploring it, as I learned after a quick stop at the booth of Document Solutions Group (DSG) at DIA.

The Oaks, Pennsylvania, company was founded by Tony Varano, president and CEO, who remains the sole owner. "We're different than everybody else," he maintains. "We haven't spent $400 million on marketing." He has managed to take care of McNeil Consumer Healthcare well enough to do all of that company's trials since the first study five years ago.

There are other customers (Bausch & Lomb, Wyeth, the National Institutes of Health), but the crux of the matter is that what the sites think matters. Greatly. They can't always articulate what they like about his software, but they express their satisfaction wholeheartedly. Says Varano: "We don't have the same issues of site acceptance. How long do you have to wait for the [CRF] page to turn? That issue doesn't exist. There is nothing to be downloaded to the client." The data only go back to the server when the

whole form is filled out with in-range data.

Varano doesn't want competitors borrowing any of his ideas, and so cannot divulge all of the programming tricks. In a demo, however, the case report form (CRF) is a live PDF viewed in a Web browser. The edit checks for the clinical data are built into either Internet Explorer or Adobe's software – I can only guess which. But the key point for the user is that every out-of-range piece of demographic data (ex: age=204) is instantly flagged in his EDC application, called eCaseLink EDC, with a pop-up message. That happens _before_ the data are sent to the server, which makes the system exceedingly responsive. It also requires the clinical research associate entering the data to fix the problem immediately.

The traditional approach in the industry, of course, is to process the clinical data in batches after the clinical staff have entered it. It's not uncommon for several days (or longer) to pass before someone who entered the data is advised of a discrepancy or potential error. With the DSG approach, Varano says, there is no need to scratch one's head and remember whether Mrs. Smith was 68 or 88.

Like Outcome Sciences, DSG has its own diary and can export the data directly into SAS. It's not that the functionality of the CDM system has been neglected; rather it has been incorporated into the EDC system from the start. "This is the cleanest data we've ever seen," says Varano. "This data is very, very clean."

Subscribe to the free eCliniqua e-newsletter at this link:
http://www.bio-itworld.com/newsletters/newsletters.cfm

Featured Events: