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**W**e thought we were done. We thought the controversy about electronic data capture (EDC) was resolved. Once again, we were wrong.

We'd thought we had pondered EDC for about as long as it is healthy for a journalist to ponder anything. The only thing we've pondered longer, to be honest, is why Steve Jobs hasn't been crucified by the news media for ruining Apple's formerly world-class operating system at a time when wholly competent senior managers at Dell or HP get publicly disemboweled just for spying on a few board members or missing a few earnings estimates. Clearly, we had not thought hard enough about EDC.

Michael Rosenberg at [Health Decisions](#) was nice enough to provide us with a few thoughts. He's president and CEO; the firm has 125 employees. Don't get us wrong -- Rosenberg is excited about technology. He's not a Luddite. He confesses much frustration for years at the slow rate of adoption of EDC. "I was always frustrated by the fact that nothing happened. Now a lot of stuff is happening."

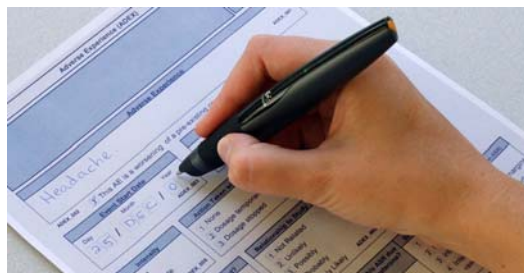
But many of the world's perhaps 1,500 contract research organizations (CROs), Rosenberg says, are starting to get into trouble without appropriate technology. "They are going to have to get technology and make a substantial investment before they go much farther. We develop technology. We're also a CRO. But most people will end up licensing technology. That will be the CRO model."

The rationale for some EDC investments, he says, is just as murky. He recently explored

the topic in the *Journal of Clinical Research Best Practices*; you can find the article on the company's website. "An important limitation of web-based eCRF systems is that somebody has to sit down in front of a keyboard, remember how to use the system, and enter the data," he writes. Yes, he says, that should work well in theory. His article goes on to say: "As Yogi Berra may have said, 'In theory, practice and theory are the same thing; in practice, they aren't.'"

What is less appreciated, Rosenberg says, is whether most EDC solutions are obligatory and perfunctory -- or as transformative as they were promised to be in the infancy of the technology. In trials that rely on EDC, he says, "the timelines for studies really have not changed that much. Sites say there are a lot of problems. For the vast majority of people, web-based EDC doesn't do much to speed up their processes. There has been this myopic focus on the data rather than what the data say." Those are fighting words.

Rosenberg has a different approach, and he believes it could bring transformative effects for customers. The Health Decisions technology uses a special pen, the SmartPen, which scans and records what a user writes directly into a database. Users must be trained to write numbers in the proper way so that handwriting recognition software can convert your hand's squiggles into a 4.



"The idea of having to have someone enter data at a keyboard -- those days are numbered," says Rosenberg. "This has the benefit of being absolutely intuitive. I've handed it to people and said, 'Just fill this out.' The software reads it into values, but also flags things it is uncertain of. You immediately have data that is pretty clean."

Artificial intelligence, he says, helps the Health Decisions system adapt over time. "The system tends to learn," Rosenberg notes. The savings in time from using his system, he says, may mean project lengths half as long as are typically standard. Monitoring visits have been transformed into a virtual, electronic mode, with productivity increases in excess of 200 percent.

With more data in the system sooner after a patient visit, the sponsor or the CRO running the trial can immediately identify problems. That is not necessarily possible with web-based EDC systems, with which some nuances of a trial may only be apparent once the data is locked. Can you see the failure rates for screened patients? It's a piece of cake in the Health Decisions system.

In general, Rosenberg says, having data in the system more quickly will allow the trial to be managed in ways that traditional web-based EDC still does not allow. "In order to manage something well," says Rosenberg, "you have to know what is going on all the way down the line. The issue with web-based EDC is that everybody focuses on getting data into the system -- and that's it."

In any factory, of course, getting the spare parts is only part of the story; the final assembly of clinical data may be no different.

Rosenberg is especially excited about adaptive designs. The phrase has been added to his company marketing. "This is the most interesting development over the last 20-30 years," he says. "This is what is going to take this industry to the next step." In one oncology trial that his company recently worked on, an adaptive design coupled with the SmartPen allowed the necessary number of patients to be cut in half. "We saved one client nine months getting to market," he adds.

Rosenberg concedes his pricing is a bit higher, but he's not apologetic. Recent growth in his client base has left him able to have some discretion in taking on new business, he says: "Our value proposition is being able to get a study through a whole program faster. People who have vision and perspective will recognize that."

*Michael Rosenberg, M.D., MPH, is President and CEO of Health Decisions Inc., Chapel Hill, N.C., a full-service, globally capable CRO that leverages technology to simplify and improve processes for rapid, effective clinical evaluation of pharmaceutical products. Web site: [www.healthdec.com](http://www.healthdec.com)*