



- **CATO, OMNICARE, CLINLOGIX AGLOW OVER EDC**
CRO Customers Praise etrials

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- One of the surprises from the **etrials** user meeting, which ClinPage **attended** earlier this month, was a handful of presentations from firms using the etrials electronic data capture (EDC) solution—and fully on board. While many contract research organizations remain skeptical or uncertain about EDC, there was no fear, uncertainty or doubt at the etrials conference.

These CROs are as impatient for the industry to move toward full usage of EDC as the software vendors tend to be.

Anne Soeder, **Cato Research**'s associate director of e-data management, described her company's role in taking over a troubled trial. The patient was saved in the end. With EDC. "In the sponsor's words," Soeder said, "it was a mess. They brought us in to turn it around. We were worried. It was so far behind."

'It Was A Mess'

As it turned out, that study database was indeed locked early, just a day after the end of the study. "We would not have been able to do that with paper," Soeder said flatly. In part, the result was an outgrowth of Cato being ... well, *attentive*, let's say, to every issue at the site *and* the sponsor. Nothing was allowed to fester, to slip, to drift.

The monitors were on top of everything. If a site was not on top of its workload, the monitor did not get on the plane for a visit. "We did not have a lot of wasted visits," Soeder notes.

That visibility, in turn, was possible thanks to technology. “Because it was real time data, we were able to identify sites having trouble,” Soeder says. “Some sites weren’t doing their work.”

Hidden Costs

It’s important to note that Cato doesn’t have a general philosophical preference for EDC. The firm simply believes it should use the technology for the sake of its own bottom line. The price of paper, Soeder suggested, should be appreciated even if it cannot be precisely quantified. And the etrials systems helped Cato refine its own processes. “By using etrials, it pointed out the areas where we can improve,” she said.

Then there was **Omnicare Clinical Research**, which has clearly invested in its own clinical trial technologies. It has a portal and other tools for viewing clinical data.

As a unit of the larger Omnicare pharmacy benefit manager for nursing homes, Omnicare’s CRO division has to accommodate sponsor requests to use specific electronic data capture solutions. But it also has its own preferences: it generally uses **ClinPhone**, to take one example, for interactive voice response.

Omnicare Presentation

When it comes to EDC, its preference is etrials. “We have pharmaceutical companies that have done tech transfer with their own EDC vendors, but the [sponsors] say, ‘use what’s good for you.’ Which is etrials,” says Casey Higgins, senior clinical data manager at Omnicare Clinical Research.

Higgins described a close and collegial relationship between the etrials programmers and Omnicare’s own 115 people in data management. Omnicare is bringing the etrials technology in-house via a technology transfer arrangement. Much of the standard work of setting up trials can be done by Omnicare, he said. But from time to time, a customer will have a request that etrials can assist with.

Just Do It

Higgins says more and more sponsors don’t care *which* EDC system Omnicare Clinical Research uses. They just want EDC. Period. “I would have thought they would want us to use theirs,” says Higgins. “That’s often not the case.”

He acknowledged that the transition to electronic can be stressful for some employees, and emphasized the importance of picking the right team to do EDC in a CRO environment. For the etrials project, he picked seasoned Omnicare programmers who had been with the company for more than five years.

Another example from the etrials meeting was **clinlogix**, which is based in North Wales outside Philadelphia, Penn. The firm bills itself as a clinical trial *management* organization that works with both sponsors and contract research organizations. Clinlogix has a network of 200 physicians in 55

different practices and 90 clinical trial sites. “Over 95% of our clinical investigators have met or exceeded patient enrollment requirements,” the company’s website notes. “We believe this provides an important competitive advantage for achieving greater efficiencies and maintaining the highest, consistent clinical trial standards.”

Prohibiting Paper

JeanMarie Markham, clinlogix’s CEO, was firm in her conviction that EDC is the future. At the trials conference, she was gently dismissive of the idea that anyone in the industry has ever really added up all the costs and delays and burdens associated with paper case report forms.

“I would not consider paper for anything that we do,” Markham said flatly. “EDC really is a competitive advantage.” She’s impatient with the torpor with which some companies are transitioning away from dead trees: “I hope we start going to conferences where we’re not discussing, ‘should I do paper or EDC.’ ”

Moving Forward

The savings from using EDC, she says, are significant: perhaps a 40 percent improvement in data cleaning, and a 50 percent boost in trial planning.

Even so, Markham does not think that all electronic data capture systems were created equal. “There are some EDC systems that require more of the data managers’ time,” she says. “I’m surprised how many sponsors will move ahead with an EDC system without moving ahead with a test. That’s always ugly.”

But the right technology generally allows greater visibility into the actual progress of a trial, she says. It can also improve communication between sponsors, sites and monitors. “Premonitoring” sites can eliminate unnecessary travel by monitors, as they see how sites are doing from their home office or the beach.

Visibility Via Technology

Notes Markham: “Everybody can look at that data concurrently,” she says. “You have a bird’s eye view of studies. You can manage enrollment better. You have a better view of investigator performance. Frankly, that wasn’t kept by many companies.”

Part of her company’s job, she believes, is to get out the message of the overall, cumulative financial savings and operational efficiencies that EDC delivers. She thinks the industry needs to move away from overly simplistic accounting that may make EDC appear to cost more. “It is a cost savings,” she says of EDC. “It’s our part to do education.”