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Nextrials Sees Latest Trial as the Future of EDC

Electronic data capture (EDC) company Nextrials is conducting a multisite trial that CEO James Rogers views as the future of clinical trials and possibly of his company.

The six-site trial, conducted with electronic health record (EHR) vendor Greenway Medical Technologies, is the first trial to collect data from the EHR systems of multiple sites and integrate them into one database using EDC software, according to Rogers.

The trial uses a standard backed by the Clinical Data Interchange Standards Consortium (CDISC) and Integrating the Healthcare Enterprise that enables EHR vendors who've adopted the standard to exchange data with EDC vendors who've adopted the same standard.

"What's nice about it is that it integrates data that's already in the medical record, but it also collects new information. It's pre-populating with existing data and collecting new data. It's not just data-mining," Rogers said. "Some of the studies that have been done before are just data-mining where they mine the database and there's no new information entered. This study that we're working on has that component of new information entered."

The advantage of EDC-EHR interoperability, Rogers said, is that it saves clinicians at inves-

tigative sites from having to learn a new EDC software for every clinical trial, enabling them to focus on patient care.

"It's just like using the EHR system that they use every day but it pulls up unique forms that collect data for that clinical trial. Everything looks the same. There's nothing new to learn and it's all within the same workflow that they normally have," he said.

Nextrials is one of three EDC vendors in this space, according to Rogers, and Greenway is one of only a handful of EHR providers to have adopted the standard. Several big pharma companies support the adoption of the standard and have launched their own efforts to support it. Some of the big EDC companies, however, are not yet on board.

"The big EDC vendors are not participating. I think that's because they want to maintain the status quo," Rogers said. "If you're already number one and number two in the industry, you don't want things to change; you want them to stay the same. I think that's why they're cool to this effort."

Although Rogers enjoys being among the first companies to embrace this standard and use it in clinical trials, he hopes to see the number of participating vendors grow. The more sites that adopt the standard, he said, the more clinical studies that will be able to

use this technology.

"The collective manpower being put on this is more than any one company could. Having multiple points of view helps us develop a standard that is truly an independent standard that is not skewed toward one company or another," Rogers said. "Yes, we are competitors, but there's a pretty good cooperative spirit on this effort. I think everyone is saving their competitive juices for the marketplace."

Ultimately, however, Rogers does see Nextrials' adoption of the standard as a strategic move for his company.

"We feel that by being one of the first movers it's going to give us a competitive advantage. Down the road, as this movement grows, I think [the big EDC companies] are going to have to join the effort, and they'll be playing catch-up. We see this as a way to gain an early competitive advantage."

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