

REAL-TIME DATA**OmniComm, IVR Clinical Partner**

The integration of electronic data capture (EDC) with interactive voice response (IVR) systems to randomize patients is a natural one, and not routinely managed in a seamless manner. Two Florida firms are trying to make that easier.

Late last year, OmniComm Systems, the small, publicly traded EDC firm, and IVR Clinical Concepts, a privately held IVR concern, announced they are trying speed the integration of their respective technologies for customers using both firms. They'll co-market their software together, hoping that customers comfortable with one firm will also choose the other.

"EDC is great, but it's only real-time when the study coordinator sits down and fills out the electronic form," notes IVR Clinical Concepts' Mary Stefanzick, director of operations. "What's wonderful about IVR and EDC together is that the IVR drives the EDC systems. The IVR is your real time data. That's very important. Everything just comes together very nicely to manage your clinical trial." Her firm also provides electronic patient reported outcomes (ePRO) and patient registration, both of which make intuitive sense to combine with EDC.

Two Tools

Perhaps five percent of all trials integrate systems for EDC and randomization, Stefanzick estimates. But she says more such projects are coming. "That marriage of IVR and EDC is going to be the future. It may take a while to get the word out."



At OmniComm, meanwhile, the EDC company says it wants to expand on the functionality available to customers, even for non-EDC

features. OmniComm does offers randomization but realizes some customers may want to use a firm specializing in IVR or one like IVR Clinical Concepts, with additional expertise. "We're constantly out there trying to make it easy for customers to have a fully integrated suite of applications," says Steven Johnson, executive VP of business development at OmniComm.

Help from Microsoft

His firm has a mapping utility, based on Microsoft's .Net platform. But in the case of IVR Clinical the connections between EDC and IVR will be especially easy to configure. "That's several hours worth of effort vs. several weeks of effort," Johnson explains.

.Net helps speed the connections between the two systems, he says. "We actually hire Microsoft experts that come in and bless our design and make sure we are doing things to optimize our performance."

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Some customers in the industry, he says, are realizing that larger trials will benefit from combining EDC and IVR. "When you try to scale that up, you can't manage that voluminous amount of data unless you have the integration capability." Johnson

believes that the industry is still trying to determine which EDC solutions can truly handle large trials, or "scale" in IT-jargon, and which cannot.

Home Rule

In comparison to the competition, Johnson says OmniComm's EDC system, TrialMaster, can be more easily administered by clients themselves. They can add users, change passwords or import data from other clinical systems. Says Johnson: "Our customers can do this themselves. You can easily use our mapping utility to pull that data that allows our own customer to map that file. We allow 100 percent of our customers, including hosted services customers, to administer their own application. They can do their own exports. Most [EDC] companies don't do that. You'd have to contact the EDC company and wait for them to do that for you."

Indeed, Johnson says the troubles of other EDC firms are creating an opportunity for surviving firms like his. It's worth

noting that OmniComm's stock is not exactly a blue chip, selling for 65 cents on a recent day. (Revenues in the quarter ending September 30, 2007, rose 6.8 percent to \$842,000.) But Johnson notes new offices in Germany and Russia and dozens of people joining the company over the past year. "We've made a good living off customers that have used other solutions and have not been happy," he says.



Patients: Enter Thyne Own Data?

Johnson says it may be difficult to forecast how EDC will change in the next few years. He says it's possible that EDC systems could morph into what are now traditionally viewed as patient diaries. "We're starting to hear customers ask us about patients being able to log into the EDC system and enter data directly, particularly in Phase IV projects," Johnson says.

OmniComm is sensitive to the perception that mid-study changes should be reasonably priced. A significant number of change orders are typically included in the basic OmniComm price for a study. "If there are minor little tweaks and changes you add a case report form here or a question here, sponsors don't want to be nickel and dimed," he says.

Capitalizing on the weakness of one of the early entrants into the EDC space, OmniComm has a special piece of software to take advantage of forms and libraries built for Oracle Clinical. There's more information about OmniComm's OC Connect Solution on the company website.

—MARK UEHLING, EDITOR