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DIA Update: BioClinica, Clinical Ink and PharmaVigilant CEOs map future of electronic clinical trials

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PharmaVigilant makes strides with remote site monitoring

Electronic data capture (EDC) was a good starting point for gathering data from clinical trials, but it was just that--a starting point. PharmaVigilant has found several ways to fill gaps in the collection and monitoring of data in clinical trials with a lineup of products that involve new technology and human support, CEO James DeSanti explained to me in an interview at DIA 2012. And the company's unique approach has won over customers such as Novartis ($NVS) and Johnson & Johnson ($JNJ).

Site monitoring has traditionally been one of the most expensive aspects of conducting a clinical trial, requiring people tasked with the important job to visit clinical trial sites in person to perform a range of duties such as collecting clinical data taken from patients enrolled in studies. PharmaVigilant cuts the number of in-person site visits in clinical trials with its I-Monitor software and service, which lets clinical sites send data forms electronically to the company. This enables the company's staff to monitor sites remotely less than 5 business days after the data is sent to its specialists. DeSanti says the 5-day turnaround time beats the weeks or month it traditionally takes the data to be monitored.

DeSanti says he became aware of the shortcomings of EDC systems earlier in his career, which included a stint as vice president of sales for Phase Forward (now part of Oracle), one of the pioneers of the EDC business. In 2006, he started PharmaVigilant the old-fashioned way--without venture capital--and with the help of one of the original software architects at Phase Forward, Patty Giencke. With Giencke serving as chief architect, PharmaVigilant has built a number of software products from the ground up that are designed to fit together seamlessly. And business has been good.

"I've got our sales [figured out]," DeSanti, the veteran salesman, tells me. "Now we need to scale."

Venture investors are circling the company, he says, which has been profitable for the past 5 years and has zero debt. He didn't share nitty-gritty details about the 38-person company's finances, but the string of profitable years, appealing technology, and no tab with debtors could present a juicy bet for venture capitalists.

Novartis notices Clinical Ink's mobile clinical data capture

Clinical Ink used to be an underdog in the eClinical area. A year back, the startup was touting its technology for capturing data from patients in clinical trials with a tablet computer at study sites--without ever having completed a clinical trial with the tech. But a year later and after some early recognition (including being named in our 5 eClinical firms to watch in 2011), the company came to DIA with at least half a dozen studies under its belt and an impressed partner in Swiss drug giant Novartis.

Novartis has already done one pilot study to test the use of Clinical Ink's technology and has a second in the works, Doug Pierce, the startup's President, told me. The Winston-Salem, NC-based company impressed its partner in its first pilot study, showing that its tablet-enabled electronic source documents completed at study sites could provide data to sponsors in as little as 40 minutes rather than two weeks or more with paper source documents that need to be filled out, collected and require someone to enter data from the forms into an EDC, Pierce says.

Pierce says that he believes that his firm's technology can reduce site monitoring--which costs the industry about $9 billion annually--up to 80% because the electronic source document eliminates the need for a site monitor to visit a site and collect the data sheets in person. Beyond reducing site monitoring, he says, clinical trials will be able to know in under a day whether a drug is too toxic for a patient and whether to take the patient off the drug rather than repeating the same dose of the drug for two weeks while data from one site check-in becomes available for monitoring.

Expect to hear more from Clinical Ink this week as the company announces new accolades and hints toward future mobile product developments. Hint: The company's software is built on Microsoft ($MSFT) technology and has garnered some attention in Redmond. Look for details later this week.

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BioClinica CEO finds success with mobile, Microsoft network

A series of tablets took center stage at the BioClinica ($BIOC) booth at DIA 2012 this week, and CEO Mark Weinstein took a half hour to talk about his company's strategy for building a clinical trials software platform. "We're spending a lot more time with Microsoft [mobile tech] than the iPad," Weinstein says.

BioClinica designs its software to operate on any tablet operating system. That said, BioClinica is a proud member of the Microsoft Partner Network, which has helped the company make inroads with customers and solidify partnerships with other clinical trials software vendors in the network such as NextDocs and Paragon Solutions.

Weinstein reasons that many life sciences companies have already adopted Microsoft technologies such as Office and SharePoint, and offering clinical trial software that integrates with those platforms makes sense. For example, Newtown, PA-based BioClinica's OnPoint clinical trial management system (CTMS) is designed to work seamlessly with SharePoint reporting tools and enables users to tap Office applications such as Word, Excel and Outlook in a regulated framework, he says.

OnPoint has become the company's fastest-growing product, he says, and he attributes part of that success to the familiarity and success customers have with Microsoft products.

Meantime, BioClinica is among a bevy of eClinical players pushing to establish a unified platform of clinical trial applications that provides end-to-end support to drug and device developers. At Merge Healthcare's ($MRGE) nearby DIA booth, the company's general manager of eClinical, Zaher El-Assi, talked about his group's own ambitions to provide a unified clinical trial platform, noting the company's release of Merge eClinical OS, which brings all the company's clinical trial software together under one umbrella and a single interface.

Editor's Note: This version updates Doug Pierce's title, which has been changed from CEO to President. Ed Seguine is now CEO of Clinical Ink. We're sorry for any confusion.