

DrugDev acquires SecureConsent

By Karyn Korieth

DrugDev has acquired **SecureConsent**, an electronic informed consent (eConsent) provider, in a move that expands the company's suite of technology offerings designed to improve the efficiency of clinical operations at investigative sites. No financial terms of the deal were disclosed.

SecureConsent, formerly a division of Enforme Interactive, will be fully integrated into DrugDev as a new patient solutions business unit led by SecureConsent President and Co-Founder Eric Delente. The new division will also offer a patient engagement and communication tool, which includes study appointment reminders, and plans to add a system for paying patient stipends next year.

Brett Kleger, chief commercial officer at DrugDev, said that strategically, the SecureConsent acquisition supports the company's overall mission of making it easier for investigators to conduct clinical trials and create a single, integrated suite of technologies to support site operations. Through acquisitions of CFS Clinical in 2013 and TrialNetworks in 2014, the company formed a unified platform that can improve communication between investigative sites and sponsors or CROs by optimizing site selection and start up, investigator payments and clinical operations. Kleger said DrugDev can use its eConsent offering to facilitate better interactions between investigators and patients.



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“The premise is trying to make trials easier for all stakeholders, but we have always had a primary filter on the investigator. The investigator is such a crucial part of the process, and frankly, that is where the inefficiencies are,” said Kleger. “We are trying to create one suite of solutions to make the investigator's life easier. eConsent is a key part of that. There is value in having better patient comprehension [of study requirements] and fewer patients falling out. We want to help investigators interact with patients and we see eConsent as the start of that relationship.”

With the acquisition of SecureConsent, DrugDev plans to rebrand its technologies across the company into one platform that includes eConsent, payments and activation modules. The products will be offered as both integrated and standalone solutions.

Neal McCarthy, a founding partner and managing director of **Fairmount Partners**, where he focuses primarily on healthcare and pharmaceutical outsourced services, said the deal provides another special software tool that the DrugDev team can provide to improve trial efficiency and safety.

“DrugDev is trying to organize the relationship between sponsors and sites,” said McCarthy. “This latest acquisition is a continuation of the strategy to improve performance of sites. The sponsor has a duty to inform and educate the patient about the trial and its risks and rewards and then get the patient's written consent. SecureConsent can do this electronically. The ability to use eLearning, video and interactive technology to provide the patient with all of the details they need to be informed could avoid misunderstandings by the patient.”

The SecureConsent system, which has evolved since 2003 from a desktop application to a browser-based system that works with any device, including tablets and other mobile devices, features multimedia education, real-time reporting and end-to-end document management to create better-informed patients, eliminate paperwork, simplify remote monitoring and ensure complete transparency for regulatory audits.

“The common thinking used to be that paper is cheap and works well enough because that's what the industry had used for years,” said Hugo Stephenson, M.D., DrugDev executive chairman. “Thankfully, times have changed. Today, we have a much better understanding of the staggering potential cost of resolving paper-based errors and we have access to smart technology that enables us to fix these clearly broken practices.”

Wider industry adoption of eConsent technology is poised to grow following the recent release of an **FDA** draft guidance with recommendations on the use of eConsent to help improve human subject protection and reduce regulatory burden in clinical trials.

“We realized early on how much pent-up demand there was in the industry for a solu-

tion like ours and that scalability would be a primary challenge to solve sooner rather than later," said Delente. "Although we had several financing options, the moment we met DrugDev, we were inspired by the similarities in our vision to help the world bring more drugs to market by easing the site and patient experience. By joining DrugDev, our solution will be a key part of a unified platform, rather than yet another standalone system, and frees us from worrying about company growth logistics so we can spend

all of our time focused exclusively on creating the best eConsent solution possible."

Following the acquisition, the integration process is expected to go smoothly since the two companies have worked together as strategic partners since 2014 through the DrugDev Innovation Lab, which was designed to accelerate emerging solutions in clinical trial automation. Lead by Stephenson, the Innovation Lab provides expert guidance, capital resources and the ecosystem needed for smaller companies to improve their products and achieve their vision

faster than would be possible alone.

"It made a lot of sense for us to join a team of people who we were learning a lot from as opposed to going out and getting venture capital and trying to do it ourselves," said Delente.

The eConsent team at SecureConsent will continue to operate out of its headquarters in the Washington, D.C., area. The division currently has 22 employees and Delente said that number will grow as it assumes responsibilities for DrugDev's entire portfolio of patient solutions. 