

SAFE-BioPharma Signing up Sites, CROs

Wednesday, June 23, 2010 08:48 AM

Contract research organizations (CROs) and investigative sites have begun to adopt [SAFE-BioPharma](#) digital identities, which are already widely used by biopharmaceutical companies, in order to sign contracts and other clinical trial documents electronically.

Among these early adopters are McDougall Scientific, a Toronto-based data management CRO, and IPS Research Company, a major Southwest clinical research site. The two organizations recently joined the SAFE-BioPharma Association, a non-profit consortium that manages a digital identity and signature standard for the pharmaceutical industry. The system has been recognized by both the FDA and EMEA.

Now that the association has begun to expand beyond its traditional biopharmaceutical-company base, Mollie Shields-Uehling, president and CEO of the SAFE-BioPharma Association, anticipates a steady increase in new members, especially among CROs, as the industry continues to move towards a paperless clinical trial process.

“Everyone is fully aware that we have to move to a fully electronic process. It’s a step-by-step approach.

You can’t do everything at once. It’s gaining experience, understanding what sponsors want and certainly moving in that direction,” she said.

Shields-Uehling added that drug sponsors have begun to encourage their partners to adopt digital identities as the industry focuses on projects that can reduce costs and improve business processes. Digital signatures have been shown to cut costs associated with printing, copying, storing and routing paper-based documents. They also can eliminate the time-lags associated with paper-based approvals and submissions. “If you have a digital identity and a digital signature, you can sign any place in the world that you have Internet access at any time,” said Shields-Uehling. “There is a huge savings in terms of personnel time and the green aspects of shipping, faxing, copying, archiving, storing and retrieving documents.”

In addition, an increasing number of CROs and investigative sites are using digital signatures through systems offered by SAFE-BioPharma vendor partners. The association has certified more than 20 vendor partners that make software and hardware supporting digital signatures.