

TECH, SERVICE CRO

Paperless Push At Target Health

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Jules Mitchel might be a good source to consult if you doubt the continents of services and technology are tectonically colliding. With his wife, Joyce, Mitchel runs Target Health, a small New York contract research organization (CRO) that has always been keenly interested in building its own technology—both for the sake of internal efficiency and for what customers can do with it. Business sounds good.

“We see an enormous amount of outsourcing going on,” says Mitchel. “The CRO industry is growing. People are very comfortable having 1-2 knowledgeable people in house—and farming everything else out.”

Mitchel also sees appropriate trepidation around picking the *right* CRO. “The biggest danger for small companies is to pick the wrong CRO,” he says. “The implications of something you do early on can destroy you later.” The list of companies that have chosen his firm can be found [here](#).

Seasoned Skipper

Mitchel goes on to say that the business development people at a CRO, however charming and persuasive, will not actually gather your data. Do your medical writing. Or sit down with the FDA. Target Health can help on all three fronts.

Despite an irrepressible exuberance, Mitchel is no longer a young person. We don't know his age. Let's just say the man has been around the industry. Perhaps as a result of that, he is not shy about sharing his views in the appropriate time and forum. That extends to customers who may be about to undertake something that is ill-advised.

Speaking Plainly

Says Mitchel: “If you don't know how to negotiate with FDA, you're dead in the water. You have to know how to talk to FDA and occasionally challenge them. Most of the time, they're right.”

Some CROs, perhaps out of inexperience or deference to a client, may allow a sponsor to blunder forward in a manner that is unlikely to be satisfactory over the long haul. Target Health's approach is to speak up *before* a project goes off-track.

“We have two customers,” Mitchel says. “One is the FDA. The other is the client—the sponsor. When we feel the sponsor is wrong, we tell them. At times, the sponsor is wrong. When we feel FDA is wrong, we challenge them or at least negotiate.” Not long ago, Mitchel told a client: “I can’t present that argument to FDA. They’ll throw us out.”

But the dynamic also works the other way. On one occasion recently, Target Health went to bat for a client and was able to defer an additional trial until after the submission of the new drug application.

Like many in the CRO industry, Mitchel thinks the industry has overemphasized mere database creation and software with superficial, eye-candy glitz. He holds there has been a parallel under-appreciation of the procedural differences between paper-based studies and electronic data capture (EDC) projects. Says Mitchel: “The key is to have extremely knowledgeable people in the EDC company that know data management and clinical research.”

Audit Success

Inordinately demanding clients in the life sciences, he says, make personal accountability and company accountability intertwined for Target Health. He knows his clients will call him personally to complain. Mitchel’s staff knows that, too. “Service is key,” says Mitchel. “It may take 2-3 years to get a client. It takes a second to lose them. Bad news travels a lot faster than good news.”

He’s had good news lately. CytoDyn chose Target Health for a more end-to-end solution than is typically seen in the industry, involving both EDC and FDA submissions. Prometheus Laboratories uses the document management system at Target Health. And back in February, Regeneron used Target’s EDC system, Target e*CRF, to generate data that became an approved BLA, as this release telegraphs.

The Target Health software is clearly creating data and documents that pass muster at the agency. In one recent FDA inspection of Target Health, the formal letter had no findings. No Form 483 was issued. Notes Mitchel: “We did all the toxicology, regulatory, clinical (Phase I, II and III), data management, statistics, medical writing and NDA submission. There were two pivotal trials and a rescue protocol for treatment failures. The audit also included a detailed review of Target e*CRF and data management.”

Paperless Push

Aside from Octagon Research, Target Health is as far as we know unique in being one company with systems that can both gather clinical data and marshal it into regulatory documents. Mitchel’s company has always been interested in

the management of documents, as its Target Document application demonstrates.

Target Health does accept a bit of paper from sites, but is taking a harder line on accepting dried, pressed tree cellulose from other sources. "I will not accept paper reports from monitors," says Mitchel. "Clinical research associates cannot send us paper. None of our clients will want it. Everything is on the web. Nobody in Target Health can ask me to sign things by hand any more. It's not allowed."

The firm has also been trying to banish the fax machine in favor of using Target Document. "If I see faxes coming in," says Mitchel, "people get reminded that we're a green company."

Looking ahead, Mitchel is confident the industry will be seeking ways to populate clinical trial systems from computers used in patient care. Electronic health records, or EHRs, are much in vogue, with another batch of politicians seeking to build on President Bush's early enthusiasm for them. Mitchel is keeping his cards close to his chest. But he hints Target Health may be able to pioneer technology that others could license to link research- and hospital-oriented systems. "There is no question we have to integrate with the electronic health record," he says of the clinical trial technology community.