

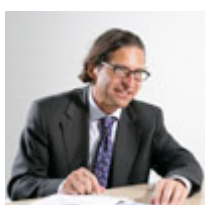
EDC Co-Development a Win-Win for Ferring, Target Health

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By Deb Borfitz

May 26, 2009 | Common wisdom holds that drug makers should stay out of the business of developing information technology (IT) software and instead buy one of the many proven, off-the-shelf solutions. But that's not necessarily the best and cheapest way to collect data or manage clinical trials.



Per Cantor

Just ask Per Cantor, senior VP of clinical and non-clinical R&D at Swiss-based Ferring. Here, electronic data capture (EDC) happens via a web-based system co-developed with New York-based Target Health, a clinical research organization (CRO). The system has all the bells and whistles that Ferring desires, including easy-to-build electronic case report forms with embedded guidance and intelligence, dashboard views of study progress, and automated coding of adverse events—not to mention rapid turnaround on virtually every service request, says Cantor.

Target Health president Jules Mitchel says that the CRO began its EDC work with Ferring ten years and four New Drug Application (NDA) approvals ago. The relationship gives Ferring the technical features it asks for—nothing more and nothing less—as well as a lot of attention, faster study builds, and a more user-friendly end product. But the companies are not financial partners and Ferring has no exclusive rights to the software, so the relationship also serves as a development platform for Target Health's commercially available EDC system.

Ferring is a mid-sized pharmaceutical company specializing in treating diseases mainly through peptide/protein pathways and initiates about 15 new phase I-III studies annually. All of the phase II-IV trials use EDC and the technology is now migrating into the phase I arena.



The latest NDA for Ferring's prostate cancer treatment degarelix (Firmagon) was based primarily on results of a global 600-patient study, which achieved data lock ten days after last patient visit, says Cantor. Three months later, the full regulatory dossier of 24 clinical studies was submitted to U.S. and European regulatory authorities and approval came less than ten months thereafter, in December 2008. Cantor credits the EDC system, coupled with electronic submission, for the compressed timeframe and swift approval.

Small but determined Target Health was “pushed” by Ferring to “continually develop and improve the software,” says Cantor, based on major upgrades being made to commercial EDC systems.

Over the past six months, Target Health has co-developed a clinical trial management system (CTMS) with an international CRO and recently began co-developing both an EDC and CTMS system for Hill Top Research, a full-service CRO which operates a handful of research sites.

Target Health's advantage over a straight technology vendor is that it's in the trenches of clinical research and therefore knows what does and doesn't work at the site level. "We don't partner passively with [other companies]," says Mitchel. "If we don't think something's a good idea, we tell them."

Having outgrown its homemade CTMS, Ferring is now evaluating several early-stage providers—including Target Health—that can help it build a suitable replacement utilizing the popular Microsoft SharePoint platform. Says Cantor: "This is now being debated intensely by clinical functions and our own IT group, but I think we'll end up taking the risk and not buying off the shelf."

As the contenders are all small companies, financial stability is one chief concern. The other is that none of them has yet to develop a full-fledged CTMS for a global pharmaceutical company. They primarily serve small biotechnology firms.

So why not just use Oracle's Siebel or Perceptive Informatics' IMPACT? "Those systems require a lot of resources, not just to implement but also to maintain," says Cantor. "Plus, we want something [simpler]. What's important to us is that it be user friendly and interface with our EDC system."

Safety management and electronic submission systems currently on the market "work pretty well," adds Cantor, so Ferring isn't looking to tread on those IT grounds.

To co-develop rather than acquire technology, it helps to be a small and nimble company. "The cost and impact of changing our systems is less for us than GSK or Pfizer," says Cantor. Most large pharmaceutical companies have already invested in a leading-brand CTMS and EDC systems and trained thousands of users.

The way Cantor sees it, Ferring has shaved 20-40% off its EDC costs by working with Target Health in lieu of an out-of-the-box solution. "But it's the flexibility that's important. We're treated as their primary customer." And that fits well with Ferring's golden rule when acquiring and implementing new technology: "Do it as intensely and in as short of time as possible."

Editor's note: Borfitz will discuss how big pharma is eyeing "clinical cloud" solutions for its trial technology needs in a future edition of eCliniqua.