YEARS IN THE MAKING

CRO-sponsor partnerships require planning, time to develop

By Brian Orelli, Staff Writer

A report from Tufts Center for the Study of Drug Development (CSDD) highlights the evolving relationships between contract research organizations (CROs) and clinical trial sponsors through the adoption of strategic partnerships.

In 2008, Eli Lilly and Co., of Indianapolis, sold one of its research facilities to Covance Inc. and signed a 10-year service agreement for everything from drug discovery through phase III development with the Princeton, N.J.-based CRO.

In 2011, New York-based Pfizer Inc. signed deals with both Dublin-based Icon plc and Parexel International Corp., of Waltham, Mass. The five-year deals weren't designed to increase Pfizer's outsourcing activities but to consolidate the number of external service providers the pharma used for clinical trial execution.

Last year, Merck Serono, a division of Darmstadt, Germany-based Merck KGaA, signed a five-year clinical development agreement with Quintiles Transnational Holdings Inc., of Durham, N.C. The agreement made Quintiles the sole provider of outsourced clinical development services for Merck Serono's global clinical programs.

And the list could go on. Nearly every large pharma has signed a strategic partnership with a CRO with the goal of increasing efficiency and speed while reducing costs.

Unfortunately, despite having a few years under their belts the relationships have been slow to change, according to Tufts research derived from a forum discussion of executives from drug companies and their CRO partners.

"Highly fragmented, insular sponsor organizations with long histories of working with partners who are treated as external vendors make it very hard to form and integrate strategic relationships," Ken Getz, associate professor and director of sponsored research at Tufts CSDD, told *BioWorld Insight*.

Sponsors are still using multiple strategies – strategic partnerships, transactional relationships and in-house capabilities – to complete different aspects of clinical trials, such as site identification, patient recruitment and medical monitoring. "Risk aversion is the primary driver of this behavior, allowing sponsors to hedge their bets," the study concluded. "In no instance did a sponsor use a single source to manage all outsourced functional areas."

"Multiple simultaneous approaches give sponsor companies the ability to test new approaches without jumping in with both feet," Getz said. "The downside of this approach is that it often doesn't give a potentially compelling new approach the chance that it needs to demonstrate its impact."

In a study published by Getz et al. in this month's issue of *Clinical Therapeutics*, researchers compared studies performed under strategic partnerships with those under transactional relationships and found only one measure of increased efficiency: The number of protocol amendments in studies conducted under strategic partnerships was statistically lower than transactional relationships. The authors concluded that the lower rate may be due to "collaborative input into study design feasibility before protocol approval."

On the other hand, strategic partnerships also had higher screen failure rates, which may be associated with the use of less experienced investigative sites in emerging countries.

How do sponsors increase their confidence in the CROs' abilities allowing for the potential increases in efficiency and decreases in costs? Tufts research suggests that the solution may lie in the planning leading up to the partnership.

In one case study, Tufts pointed to a "300-page manual jointly written by both partners, which outlined responsibilities." The preparation helps align the teams at both companies, gives new employees a training document to guide their work and helps stakeholders understand the roles of each company in completing the clinical trials.

DATA TRACKING

Another way CROs and sponsors can get on the same page and improve efficiency is through adoption of technology to

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keep records straight in the trial master file (TMF).

A survey from Pleasanton, Calif.-based Veeva Systems Inc., maker of an electronic TMF (eTMF) content management system, found that 80 percent of CROs and 64 percent of sponsors were using e-mail to exchange documents between CROs and sponsors. And more than half of the CROs and sponsors still exchanged some documents through snail mail of paper.

Of the CROs and sponsors that used eTMFs, CROs consistently found more benefit in using them compared to sponsors across seven different metrics from increased SOP compliance to cost savings.

"Because the CROs are streamlining their processes, they're getting more value," Jennifer Goldsmith, vice president of Vault at Veeva Systems, told *BioWorld Insight*. "Seeing how your processes are running has a direct impact on your bottom line."

Veeva recently signed up Inventiv Health Clinical, a Princeton, N.J.-based CRO, to replace its existing eTMF with Veeva's Vault eTMF. There's a big push to integrate Drug Information Association (DIA) TMF Reference Model into eTMFs to make them uniform.

"When you're dealing with drug development and approvals, having this kind of continuity instantly applied across the board can save time and ensure standardization," Rachel Stahler, chief information officer at Inventiv Health Clinical, told *BioWorld Insight*.

TMFs are also moving from an archive of data that's used at the end of a study to create documents for regulators to something that can be inspected by regulators while the trial is ongoing.

"The system can help our clients get through a rigorous process much faster and with greater accuracy," Stahler said.

While aligning records is useful for reducing complexity it doesn't help the inability of CROs and sponsors to leverage hard metrics to ensure that the strategic partnerships are benefiting both organizations.

"I think the next generation of eTMFs are going to drive this by producing greater transparency," Goldsmith said. "CROs and sponsors are going to be able to run the same report and come to the same conclusions." //

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