The New Face of Outsourcing

The pressing need to control costs and reduce development timelines has led many biopharmaceutical manufacturers to increasingly outsource components of their clinical research programs. By Lisa Zamosky

THE DRUG INDUSTRY TODAY is part of a rapidly changing market and one under increasing pressure to produce innovative new medicines to keep pace with its own expectations based on past performance. The rapid and often double-digit growth the industry once enjoyed appears to be a thing of the past, at least in mature markets. In fact, the pharmaceutical industry's drug pipeline produces roughly half the number of new medicines it did a decade ago, and the expectation is that this trend will continue. At the same time, the industry is seeing fewer drugs making their way to market, and it watches anxiously as patents expire and drug development costs continue to rise.

Smaller pharmaceutical and biotechnology companies often lack the financing necessary to create internal organizations for drug pipeline development. The large, consolidated business model that big pharmaceutical companies generally supported in the past is no longer flexible enough for today's global market. As a result, outsourcing pieces of clinical research to contract research organizations (CROs) as an integral part of pipeline development strategy has evolved over the past decade, with the biopharmaceutical industry increasingly recognizing the CRO as a critical business partner in its effort to develop and commercialize compounds.

"There's no question about pipeline volatility," says Derek Winstanly, executive vice president of strategic partnerships for Quintiles in Durham, N.C., USA, "and pharmaceutical companies seem to carry a lot of overhead for what they are generating today and what's coming down the pipeline for tomorrow. It's really forcing the hand of many chief executives to trim back."

As cause for belt tightening increases, many biopharmaceutical manufacturers see an opportunity—and sound business justification—for the role of CROs in the development of drug pipelines to expand and deepen.

The relationship between the biopharmaceutical industry and CROs is not new, but the level of commitment between these two parties continues to grow. Since 2001, the amount of money drug sponsors spend on clinical research services has grown 15 percent annually, with approximately US$15 billion spent each year on outsourcing. As the industry's reliance on CROs grows, so does its recognition that these organizations have the ability to bring efficiencies—and therefore, significant savings—to the drug development process.

The acknowledgement from the biopharmaceutical industry of the CRO's ability to achieve results and bring complimentary strengths to the table has not been easy to obtain. The tide, however, seems to be shifting.

"We are all transforming as an industry," Winstanly says. "I think it's been very difficult for pharma until recently to say there may be folks out there who can do this as well as ourselves."

Getting to the Core of the Issue

Cost-cutting for the biopharmaceutical industry is as much about accurate self-assessment as it is about strategic business planning: the two practices go hand-in-hand. As the industry continues to face fears about its bottom line, companies are starting to evaluate which in-house functions they can and should relinquish to vendors and where their energies are best focused internally.

"Here we're looking for flexibility, we're looking for speed, and the ability to focus resources on core clinical competencies," explains Dr. Lynn Kramer, executive vice president and chief operating officer of Eisai Global Clinical Development, in Ridgefield Park, N.J., USA. "The core competencies for a company like ours are those skill sets that generate and convey information. These are related to the science of trial design and interpretation. That is how I look at clinical research," Kramer says. "The supportive functions—like data management and data monitoring aspects—are important, but those are not our core needs. Certainly for CROs, that is their core competence."

Patrick Jordan, global vice president of alliance management for Quintiles, agrees that the skills of the biopharmaceutical company versus those of a CRO are distinct, but highly complementary. "After years of building up global infrastructures to research, develop and commercialize drugs, pharmaceutical companies are now examining themselves for their core and non-core activities, and that's yielding some interesting partnership models."

Increasingly the industry is realizing that its core competence may not be managing data, identifying and selecting investigator sites, reviewing case report forms, or improving processes around these components, Jordan says. Most companies will focus their efforts instead on the key functions associated with advancing molecules that have commercial potential. "It's in that separation of core and non-core that they start to see ways to reduce their fixed infrastructure costs and focus instead on their core competence of developing products to meet patient needs, which drives enterprise value," he says.

According to Lulu Pickering, Ph.D., an analyst with Decision Resources, a research and consulting firm located in Waltham, Mass., USA, companies that can expect success are the ones that can truly look at what they're good at, what they are not good at, and where they want to be 10 years from now and try to map out the tasks to get there. "Outsourcing might be a piece of that," Pickering says. "It might be a small piece for some companies, it might be a big piece for other companies, but it's certainly not the answer for everybody all of the time."

A trend that Kramer has observed and anticipates will continue is the specialization of CROs, with some companies focusing exclusively in the strategy of trial design, imaging or electronic data capture, for example. "So it's increasingly specialized, but it's a specialization in your own core competence," Kramer says. "To me, that makes more sense. As the world gets more complicated, it gets harder and harder to be an expert in everything. So you better pick what you're an expert in and be an expert in it."

Industry and CROs: A Deepening Relationship

As the biopharmaceutical market becomes increasingly global and complex, costs continue to rise and resources become difficult to manage, the relationship between the biopharmaceutical industry and CROs will continue to strengthen. Exactly how these relationships will evolve depends on the needs of each company, but indications are that a move toward a partnership model, rather than one-off job assignments, is increasingly perceived as a move toward greater efficiency.

As is the case with many other companies, at this point, Eisai predominantly outsources one study at a time, a practice Kramer says he imagines the company will begin to alter. "I see us outsourcing more than one project at a time or a group of projects with more selective, but fewer, vendors so that we both gain in scale. That gives us advantages in scale for cost."

Winstanly also observes the industry increasingly recognizing the need for a flexible resourcing model as a critical component to their future. "If you really believe a pipeline is going to deliver every time, which we know it doesn't, then sure, you could carry the overhead and do everything in-house," he says. "It's the pipeline volatility that actually makes it a compelling story to do more and more outsourcing. Companies have to manage costs and look at different business models to get the best return on investment."