

Outsourcing Relationships MATURE

The sponsor-CRO partnership continues to evolve toward an integrated approach to clinical development that decreases fixed costs and provides sponsors with access to capabilities not found internally.

R&D outsourcing will continue to increase in the coming years. CRO relationships are maturing, industry experts say. Many partnerships are being structured on an outcomes-based model, helping to ensure that goals are well aligned with the delivery required by the CROs.

Innovative partnerships and alliances are critical to the health and success of the industry and, in turn, to bringing new therapies to patients, says Paula Brown Stafford, president, clinical development at Quintiles.

"We see these partnerships growing in importance as biopharmaceutical companies grapple with rising costs, increasing complexity, and reduced return on investment now that the 'age of the blockbuster' is gone," she says. "We're focused on collaborations that leverage the core competencies of both sponsor and provider so that we can drive efficiencies."

She says one example is Quintiles' integrated, end-to-end product development collaboration with Merck Serono. Announced in May 2013, this collaboration creates a process that integrates the expertise and experience from both organizations into a single, well-aligned clinical development engine. Merck Serono will shape and lead the strategy of its clinical development programs, with Quintiles directing clinical trial planning and execution. Quintiles also will be a key contributor to Merck Serono's future clinical trial design activities.

"Quintiles was selected as the sole primary provider of Merck Serono's outsourced clinical development services, leading clinical trial planning and execution for Merck's global programs," Ms. Brown Stafford says. "Merck Serono will be responsible for shaping and leading the strategy of its clinical development programs and trials. By combining the best of Merck Serono and Quintiles, and not only working, but also making decisions together, we believe we will be able to create a stream-

FAST FACT

THE TOTAL COMBINED REVENUE FOR CROS INCREASED BY 10.2% YEAR-TO-YEAR, FROM \$12.4 BILLION IN 2011 TO \$13.6 BILLION IN 2012.

Source: GlobalData

lined and more efficient approach to developing new therapies. The ultimate goal for both companies is to help bring new therapies to patients in need faster and more efficiently while remaining steadfast in our commitment to quality and safety."

The majority of biopharma executives believe strategic partnerships positively impact their engagement with CROs. In fact, 85% of biopharmaceutical industry executives interviewed by Parexel and who were engaged in strategic partnerships believe that the relationship between their companies and CROs were positively impacted.

The Parexel study finds that strategic partnerships will continue to evolve away from the traditional transactional model toward more integrated relationships that drive value through increased alignment and efficiencies. The next-generation of strategic partnerships must involve a greater alignment of commercial terms and a true collaboration of the best talent from the CRO and sponsor, according to biopharmaceutical executives. Among the biopharmaceutical executives interviewed, 65% expect their companies will increase their level of clinical trial outsourcing over the next five years. There are a number of factors driving the executives' decisions to increase their investment in outsourcing. Two of the leading factors include an ability to access capabilities not found internally and to reduce fixed costs and minimize utilization of internal resources.

"Biopharma companies collaborate with service providers to help them maximize efficiency, improve clinical success rates, and turn fixed costs into variable costs," Ms. Brown Stafford says. "As sponsors develop more personalized medicines and in-license drugs outside of their therapeutic expertise, they partner with us to leverage our deep and broad therapeutic and scientific expertise, and our data analytics platforms that provide more sophisticated approaches to trial management."

Given that the pharmaceutical industry is under great pressure to counter rising costs, diminishing pipelines, and looming patent expirations, strategic partnerships are becoming increasingly important because they can help overcome these challenges by minimizing the inefficiencies that drive up R&D costs, says Neil Ferguson, executive VP, business development at INC Research.

"The industry spends more and more each year on research and development, and yet the number of compounds gaining approval has declined or remained flat," he says. "The rising costs are compounded by a slow drug development process and a challenging regulatory environment. Sponsors are increasingly looking to their CRO partners to help in these areas by improving R&D efficiency and performance."

Abraham Gutman, CEO of AG Mednet,

Factors Driving Outsourcing

- » Access to capabilities not found internally
- » Reducing fixed costs/internal resource utilization
- » Improved global reach
- » Quality of/greater efficiencies in execution
- » Reducing the level of required sponsor oversight
- » Risk mitigation
- » Accelerating time to market
- » Access to innovation not found internally

Source: Parexel

says internal resource availability and costs are key drivers for the partnering.

“Large sponsors have a hard time being nimble, and the process of discovery and testing requires flexibility that is often found in smaller or specialized organizations,” he says. “Fully integrated CROs are key to lowering the cost and the risk of clinical trials, as long as sponsors are not penny-wise and pound foolish.”

Graham Reynolds, VP, marketing and innovation, pharmaceutical delivery systems, at West Pharmaceutical Services, says there will be an increasing need for effective partnerships and collaborations within the industry, with the recognition that creative relationships with industry leaders may be the best way to achieve success.

“Many pharmaceutical and biotech companies continue to develop strategies for outsourcing and will look to their industry partners to provide increasing levels of support in this area,” he says.

For small companies, however, these strategic partnerships are not the preferred approach, says Mark Joing, VP of clinical operations, at Nora Therapeutics.

“Most of the larger, established CROs have placed a priority on large pharma partnership, to the detriment of smaller drug developers,” he says. “This has allowed smaller, more nimble CROs to gain a foothold in the market for CRO services from smaller sponsors. I believe this trend will continue.”

Partnering with one or two large CROs can be an advantage in that the development strategy of the companies can be aligned over the long term and the CRO effectively acts as the clinical development department for large pharma, Mr. Joing says.

“Thus, the pharma company reaps the benefit of a highly effective clinical trial operations group that can be increased or decreased in size to fit the current development pipeline more readily than an in-house staff,” he says. “What is lost in these partnerships is the ability to fit each specific trial to the best CRO available, which often is not the preferred/partner CRO.”

Challenges to Creating Partnerships

Mr. Ferguson says the biggest challenge is ensuring alignment to the goals of the partnership between the sponsor company and the CRO.

“If both sides have clear expectations and an aligned focus on what the partnership is to achieve, it ensures a more solid foundation from which to develop and build the partnership,” he says. “Strategic partnerships require a collaborative effort where both the CRO and



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NEIL FERGUSON / INC Research

the sponsor invest up front to ensure the right people are in place to manage the relationship and ideally, measured against the same goals for the partnership.”

Establishing realistic expectations around the partnership also is important.

It is easier to evolve a preexisting relationship over time than to force a partnership transformation overnight, Mr. Ferguson says.

“While not all sponsor-CRO relationships are suitable to evolve into a strategic partnership, those that do can serve as a source of differentiation if both sides are able to establish a solid foundation and find common objectives,” he says. “Additionally these partnerships allow both parties to focus on their core competencies, accelerating the speed and streamlining the efficiency with which better medicines are brought to patients.”

Charmaine Gittleton, VP, clinical R&D, global, at CSL Behring, says trust can be a difficult hurdle in partnerships.

“It’s often daunting for the people in R&D who have worked so closely on a project, and are committed to and passionate about it’s development, to simply hand over the reins to an outsider, no matter how expert the CRO,” she says. “And, once the decision is made to work with a CRO, a different set of skills is needed. Instead of doing the work internally, there is the need to manage the work being done; and in my experience this is very different. People and talent are an important part of this transformation of the ecosystem and if it’s not done right, the partnership won’t be successful.”

Ms. Brown Stafford says one of the biggest challenges is keeping the momentum alive

throughout the entire lifecycle of a partnership.

“I describe year one of any partnership as the honeymoon where everyone is enthusiastic about the relationship and getting ready for implementation,” she says. “Year two is where momentum can begin to fade, especially if a key executive sponsor has left the company or shifted responsibilities away from the partnership. This is quite common in biopharma since we’re an industry of movers and shakers. Management changes can cause big problems if not managed for success. My advice is to stay diligent, focused, and aligned — and alignment begins at the very top. Communication is especially critical during times of transition so that everyone understands the goals and objectives of the partnership, and is pulling in the same direction.”

Keys to Successful Partnerships

Time will tell just how valuable strategic partnerships will be moving forward, Ms. Gittleton says.

“The key to success is to choose a partner that is an expert in all areas, and that’s tough,” she says. “So while there are advantages such as a reduction in fixed costs, I think that there will continue to be a role for the functional service provider model.”

While drug sponsor use of strategic relationships with contract service providers has increased dramatically during the past five years, improvements in clinical trial efficiency has fallen short, suggesting that both parties need to better align practices, processes, and systems, according to leaders from the re-



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ABRAHAM GUTMAN / AG Mednet

search-based drug industry recently convened by the Tufts Center for the Study of Drug Development.

The study also found that sponsors that take a more proactive approach to relationship quality management, compared with those who are more reactive, attain greater levels of satisfaction with the work of their CRO partners. Additionally, both parties are recognizing the need to move from a risk-averse to a value-creation orientation, but industry experts acknowledge that it requires a mindset that says, “we are all colleagues and collaborators.” Further, productivity gains will flow from sponsors engaging CROs in protocol design to reduce the need for amendments and greater use of big-data capabilities to manage and assess clinical trial data in real-time.

Mr. Ferguson says a priority for building a successful relationship is a collaborative dialogue on needs, expectations, and capabilities.

“Pharma partners must be clear with their CROs about what they want from the relationship,” he says. “In turn, CROs must be open and up front about their capabilities. With a commitment from management teams on both sides, a shared plan and the resources to evolve the relationship into a productive long-term engagement, both sides can benefit from the many advantages these types of partnerships offer.”

In addition to a more traditional operational governance approach to manage day-to-



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PAULA BROWN STAFFORD / Quintiles

day delivery of assigned projects, success also requires an additional governance structure that looks at the overall strategic partnership, focusing on the strategic goals and relationship between two organizations.

“By planning for upcoming work together, implementing processes to work together more efficiently and having a clear charter for next steps, a governance structure can pave the way for continuous improvement, ultimately improving the partnership,” Mr. Ferguson says. “We’re also seeing more movement toward risk-sharing arrangements, where a series of milestone-based bonuses and penalties are agreed upon jointly by the CRO and sponsor. Partnership models that allow risks and milestones to be shared between sponsor and CRO and encourage programs that ensure mutual development and performance improvement can offer a number of benefits to both parties. This is an area that will continue to evolve in 2014 and we expect to see more partnership arrangements that align the success of the CRO more directly with the success of the sponsor.”

Mr. Joing says a clear understanding of the objectives of the project and the roles of responsibilities of each party is a key to any new outsourcing relationship.

“In addition, frequent communication through both routine meetings and less frequent project check-in team meetings — often face-to-face — is an important tool in



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PHIL BIRCH / Aptiv Solutions

identifying any weak links or deficiencies in the project or the relationship,” he says. “Finally, a commitment from senior management of both companies for the relationship to succeed is imperative to the CRO/sponsor relationship.”

Phil Birch, senior VP, global strategic marketing, at Aptiv Solutions, says a sponsor must be comfortable that the interests of outside parties are in sync with a sponsor’s own bottom line.

“Sponsor companies are not always confident they are being supported by the standard CRO business model, in which profits flow from greater utilization of resources involved in a project rather than from the quality of data generated or its usefulness as a guide to the sponsor’s decision making,” he says. “Sponsors should insist that the partnered organization is aligned with their goals and that organizational inertia has been addressed. Changing a multinational organization from the top down with one contract isn’t always simple.”

Brian Bollwage, VP of global regulatory affairs at Theorem Clinical Research, says technology can be a key for successful partnerships.

“Electronic data capture technology has been available since the 1990s, but only recently did the FDA signal its willingness to support risk-based monitoring in clinical trials,” he says. “With a very defined approach to data visualization, quality, and risk mitigation, it is possible for CROs that have a readiness for change at their investigator sites to use risk-based monitoring while still meeting the demands of the regulatory landscape and still have unquestioned data integrity. Sponsors, of course, benefit from more efficient trials and potential improvements in data quality.” **PV**

Attributes of Future Strategic Partnerships

- » More risk-sharing on development timelines
- » Greater alignment between sponsor and CRO, a true collaboration
- » Faster time-to-market through improved cycle times
- » Support emerging geographies
- » Ability to move compounds from first in humans to NDA/MAA
- » More risk-sharing in general

Source: Parexel



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