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New strategies needed for integrated alliances

Inconsistent practices undermine potential for gains in efficiency, cost and speed

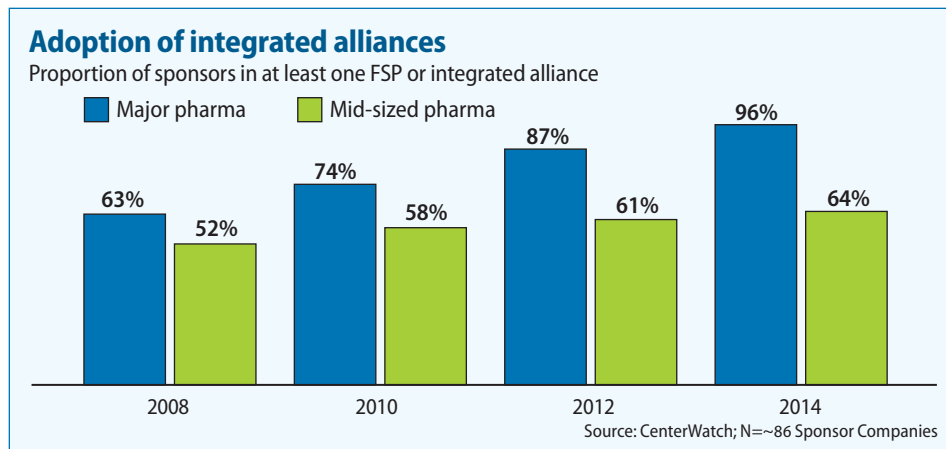
By Karyn Korieth

Strategic outsourcing relationships hold the promise of faster and more efficient R&D activity. But new research from the Tufts Center for the Study of Drug Development (CSDD) finds the goal remains elusive because sponsor companies aren't fully invested in their alliances and continue to use a variety of competing outsourcing relationship models without a clear or systematic pattern.

Despite the time and effort devoted to creating strategic partnerships, Tufts CSDD found that in no instance did study participants use a single CRO to manage all functional areas supporting an individual phase II or III study. In addition, companies fail to coordinate and enforce use of strategic partners across their portfolios in a disciplined way and sponsors vary the types of outsourcing relationship models that they use inconsistently on a study-by-study basis.

That piecemeal approach creates internal conflict and ultimately compromises the ability of integrated, multifunctional alliances to offer higher levels of efficiency at lower cost to the sponsor company.

"We are not getting the maximum value out of these partnerships and relationships," said BioClinica CEO John Hubbard, Ph.D., who led worldwide development operations at Pfizer when the company launched its groundbreaking strategic alliances with Parexel and Icon as one of several initiatives to reduce R&D spending by about \$2 billion. Hubbard previ-



ously held management positions in both the CRO and pharmaceutical industries. "We are moving toward these more efficient, strategic relationships, but I think there is still work to be done," he said.

Much of the current discussion about challenges in implementing strategic partnerships focuses on a deeply held culture of mistrust in service providers, poor communication and failure to achieve buy-in from senior staff. Yet the Tufts CSDD study, which was led by Ken Getz, director of sponsored research programs and associate professor, Tufts CSDD at Tufts University Medical School, offers new insights into why strategic outsourcing relationships may be failing and isolates specific practice factors that can be addressed to better leverage the benefits of integrated alliances.

"Closer relationships between sponsors and CROs are becoming increasingly important," said INC Research CEO Jamie Macdonald. "There are practical and tangible areas that should get a lot of attention and focus up-front. CROs have to work together with sponsors, collaborate more, plan better together and make sure we have good measurement, good communication and good governance in place."

Alliances on the rise

All of the top 30 largest sponsor companies have formed at least one strategic alliance with a CRO during the past seven years; major sponsor companies establish a mean of three strategic relationships to support their portfolios. Many companies also have introduced new internal mechanisms to oversee the strategic outsourcing partnerships and manage any problems that arise. In contrast to traditional transactional outsourcing relationships, where sponsor companies contract work with service providers on a per-project basis, the newer strategic relationships with CROs provide single functions or multifunctional support for entire programs across large portions of sponsor company portfolios.

Strategic alliances offer the promise of time savings, lower costs and increased efficiency through the use of advanced collaborative planning, shared governance and systems, transparent data, dedicated staffing and reduced sponsor oversight of CRO execution. The model gives sponsor companies the ability to leverage global scale and therapeutic expertise while also offering opportunities for risk-sharing and co-investment, which are not typically options with tactical relationships.

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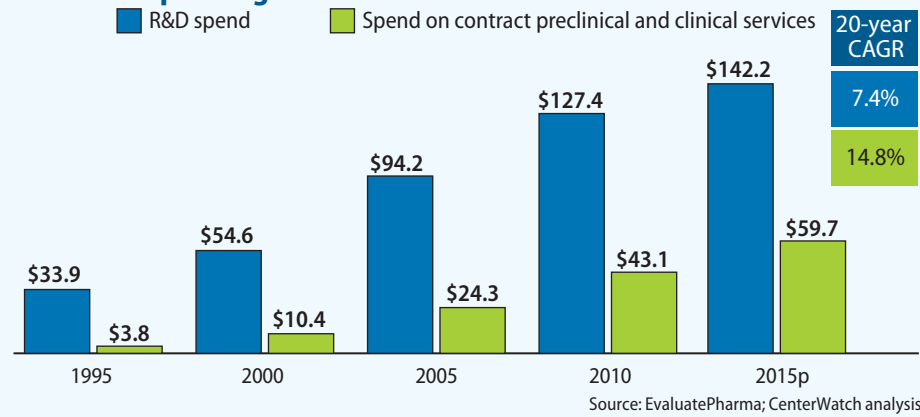
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IndustryNews

Growth in spending on contract services and overall R&D



“CROs drive efficiency through volume, planning and understanding what is coming down the pike. When we see what is coming down the pike with a partner and there is volume in it, we are able to be efficient in terms of our resourcing, pricing and our investing to make sure that innovation and creativity are brought to bear on the opportunities. If we do that, we can be very efficient. I believe we can be more efficient than typically the pharma development organization,” said Steve Cutler, Ph.D., chief operating officer at Icon.

Two of the earliest adopters of integrated alliances—Pfizer and Eli Lilly—report their strategic relationships have resulted in significant cost savings, cycle-time improvements and fewer contract delays. Eli Lilly, for example, has reported 20% cost savings for data management and monitoring, better site success rates and a 93% improvement in monthly patient-enrollment volume.

Pfizer has reported saving \$20 million annually, largely through reductions in internal management required to oversee service providers, by consolidating its number of vendors from 150 to 17. The company transitioned from using about 17 functional service providers (FSPs) for clinical development to two strategic partners—Icon and Parexel—along with a few specialized providers in targeted areas. PPD was selected as a third preferred partner earlier this year. The company also reported a 26% reduction in cycle times and an 80% decrease

in contracts delayed by more than 120 days. Meanwhile, R&D productivity increased about fourfold with improvement in data quality between 2011 and 2014 as a result of several organizational, system and process improvements. Pfizer also was able to achieve about a 12% improvement in CRO spending in 2014 versus projected costs through a combination of direct cost savings and cost avoidance, performance-based risk-sharing and CRO-Pfizer co-investments in systems and process improvements.

“I don’t believe that many of these accomplishments would have been possible with a transactional model or even the legacy FSP structure, which Pfizer had been using in prior years,” said Hubbard. “It was a fantastic period to be part of Pfizer trying to do something transformational in the industry.”

Mixed success

Several studies based on much larger numbers of sponsor companies, however, have found mixed results about the impact and satisfaction with integrated partnerships. Surveys conducted by the Avoca Group and Vantage Partners found that about one-third of sponsor organizations report their integrated alliances have not delivered expected cost savings and almost half reported difficulties in sponsor companies and CROs working collaboratively.

“The variability in the outsourcing models certainly brings mixed success. That is what the industry is experiencing now,” said Paul

Spreen, senior vice president and global head of enterprise sales at Quintiles.

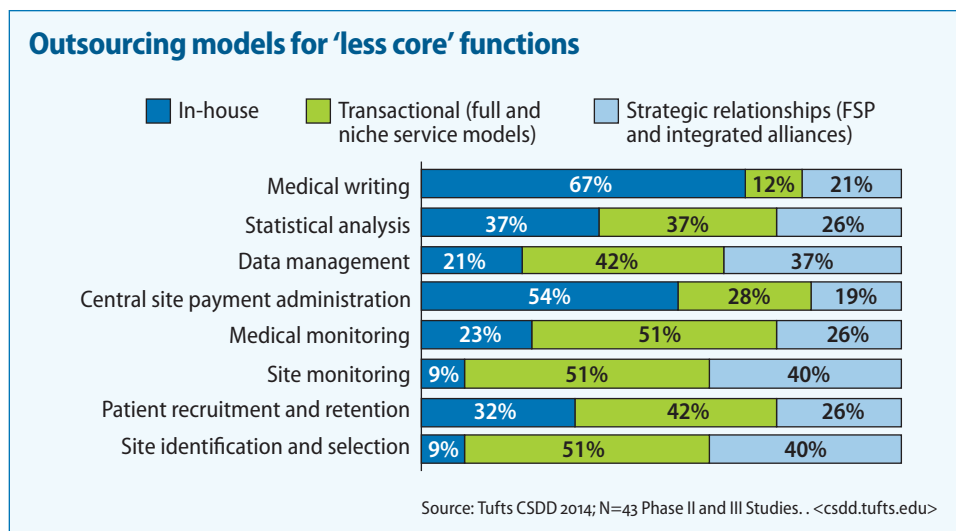
Despite an increase in the number of strategic partnerships, overall study performance across the clinical research enterprise also has not improved. In particular, Tufts CSDD found that studies managed by integrated alliances, when compared to transactional models, show no measurable improvements in performance or data quality with two exceptions: the number of screen failures was slightly higher and the rate of protocol amendments was lower in studies managed by strategic outsourcing relationships. In a separate study, Tufts CSDD found that studies managed under FSP and integrated alliances, which ideally share study planning and governance, had the same rate of written change orders to the original scope of work as those associated with transactional relationships.

“I have seen some good examples of strategic partnerships. But they don’t always get to that really embedded framework where you are actually sharing resources, sharing insight, really being transparent with each other. There are very few case studies that would demonstrate that,” said Sameer Tandon, clinical trial intelligence manager at Novartis.

Conflicting outsourcing models

The new Tufts CSDD study, which examined strategic outsourcing practices in 43 individual phase II and III clinical studies conducted by nine sponsor companies, suggests it’s not surprising that study performance and quality have not improved given the way that sponsor companies are using their alliance relationships.

Although each sponsor company had entered several strategic, integrated full-service relationships in the past three years, Tufts CSDD found that none of the CRO partners were responsible for managing all functional areas supporting an individual phase II or III study. Instead, sponsor companies used a variety of conflicting outsourcing models to support their studies, “mixing and matching” the



use of internal staff, transactional relationships, functional service providers and integrated alliances at the same time; some companies varied the types of outsourcing relationship models used on a study-by-study basis.

One company, for example, used in-house staff, non-partner CROs and strategic alliances on each study to manage site monitoring functions. Another company alternated between transactional service providers and a strategic partner to provide statistical analysis. Similar outsourcing patterns were identified for site identification and data management functions.

Site management and monitoring were the most frequently outsourced functions, according to the study, while most companies managed protocol design and regulatory affairs internally. The use of outsourced services was most variable for data management and document preparation.

The mix-and-match approach gives sponsor companies, which are working in a highly risk-adverse environment, flexibility in sourcing decisions. Yet Tufts CSDD researchers suggest that it compromises the ability of companies to leverage efficiencies or economies from a strategic alliance because of the additional cost needed to support multiple vendors. In addition, collaborative practice experience and efficiencies are isolated to individual studies and don’t carry across the development portfolio.

“I think there is a need to choose a model and then stick to it in a disciplined manner,” said Cutler. “I don’t pretend for a moment that it’s simple or easy to do. But it would bring companies some benefits if they could find a way to implement the best resourcing/outsourcing relationship for their organization in a way that really does get driven through their organization.”

Tufts CSDD identified a lack of standardization about how outsourcing strategy is defined, understood and enforced within organizations. At the moment, some strategic partners receive less work than non-partner CROs; project teams often give non-partner service providers work that already has been contractually promised through a strategic alliance. Although sometimes these decisions are made because of a quality issue with the strategic partner, they often are reactive choices made without regard to the company’s overall strategic outsourcing strategy.

“There has to be support from the top of the organization around the vision of how to work differently with CROs. The message needs to be communicated to the project teams and internal stakeholders and they need to buy into the approach and engage with CRO partners to work together and accomplish shared development goals. If it’s not embraced at the project team level, then it will not be successful and unravel,” said Hubbard.

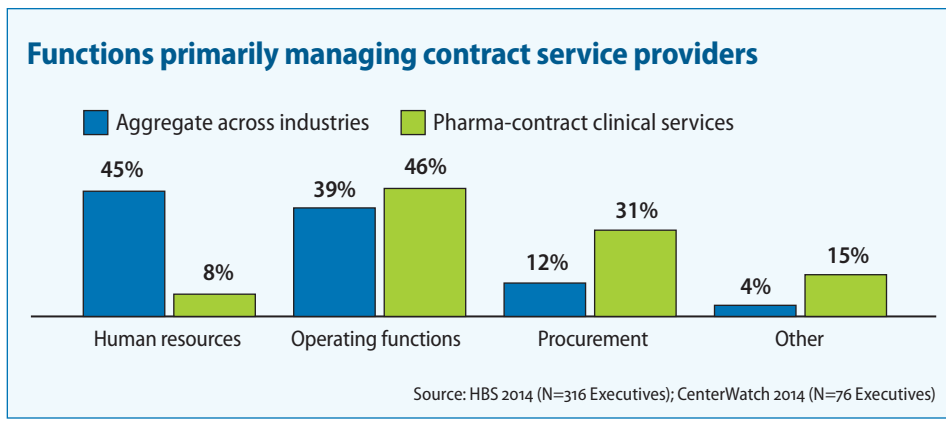
Integration difficult for many reasons

Sponsor companies have difficulties integrating their alliances for a variety of reasons. Because of their size and scale, many companies lack the internal communication and coordination needed to implement and enforce new practices. When conducting its recent study on strategic outsourcing practices, Tufts CSDD found that many clinical teams don't know which outsourcing relationships were used across multifunctional areas for their recently completed studies, suggesting a lack of cross-functional awareness and communication.

"These relationships take commitment across organizations," said INC's Macdonald. "Quite often they are conceived and hatched in smaller subsets of both organizations and then rolled out to the wider organizations. But they haven't been socialized, communication hasn't been good or change management hasn't been there and not all of the stakeholders that will then touch the relationship have bought-in at the outset. Maybe it's a lack of information, but it's certainly a lack of engagement early on with all of the stakeholders, often on both sides. There is a need on both the sponsor side and the CRO side to ensure that is in place before any of these alliances are rolled out."

Legacy activity under way when new alliances are formed also frequently contributes to integration challenges. Teams typically have established their own long-term relationships with service providers and don't want to pass existing projects to new partners. Companies going through mergers and acquisitions, in particular, often find themselves forced to allow inconsistent practices across functions to ensure legacy projects are completed as they implement new models.

"People don't like to change. They get used to working with certain providers," said Mitchell Katz, Ph.D., head of clinical research and drug safety operations at Purdue Pharma. "Or maybe they realize the quality really isn't what they want it to be or they want to use a different provider or CRO for a specific therapeutic area.



They wind up working separately as opposed to coordinating it within the organization."

When Pfizer launched its two-partner model in 2012, after two years of analysis and planning, the company put policies in place to ensure teams worked within the new partnerships. The portfolio was reviewed and about 200 studies were transitioned to the two strategic partners.

"We did it in order to transition quickly because we had to find the savings and the efficiencies. But moving that many projects from legacy organizations is really difficult and disruptive," said Hubbard. "There were definitely challenges because teams didn't like to be told they had a short list of providers. We had to work with internal stakeholders as well as the CROs to help build the relationships between the organizations."

Another dynamic that contributes to use of multiple sourcing models by sponsor companies includes turnover of key staff in the partnership, particularly when those involved in critical operating roles or ensuring consistent practices leave the organization. Partnerships can drift apart when new executives, who might have different ideas about sourcing models, take charge if the outsourcing strategy hasn't been systematically adopted across the organization. In addition, many of the large companies that have formed strategic outsourcing relationships still have significant in-house development resources, a situation that creates internal competition with alliance partners.

"There is always an element of internal sponsor development resources wanting to justify their own positions and their jobs. It's quite

natural human sort of behavior," said Cutler. "We are fairly early days in these strategic outsourcing relationships. As we mature—and this is not short-term, this is longer-term—within organizations, we are starting to get organizations that don't want to have significant in-house development resources and are very comfortable and confident with utilizing CROs and CRO development resources. They feel that their competency is not in doing the development, but in actually managing and coordinating that development resource through their CRO partner."

Frameworks for integrating alliances

Unless sponsor companies fundamentally change outsourcing practices that lead to internal friction and inefficiency, the benefits of strategic alliances will remain out of reach. Companies need to establish a clear strategic outsourcing model that meets their particular needs, and create a framework that takes the partnerships seriously at a strategic operating level and ensures alliance partners are used in a disciplined, consistent manner.

"When we have an established framework where we talk about not only projects, but also the future and how we share risk, those are the partnerships that actually do much better. We can get into more in-depth planning and maybe even the compensation is dependent on that as well. If you can delegate some of that risk—maybe there are some milestones that are built into these contracts—it allows CROs to be a little more vested into the relationship," said Tandon. "Yet often in the clinical world,

the CRO-sponsor partnerships don't go to that next step where we delegate that risk to our CRO partners."

New frameworks are emerging that could drive more consistency and collaboration in strategic partnerships and force sponsor companies to pay attention to their outsourcing practices in new ways.

Patient engagement, for example, will become an increasingly important part of outsourcing strategy for many organizations. That approach could involve CRO partners early in the process to help design protocols that take patient needs into account and provides an opportunity for CROs to innovate and share risk. In addition, patient centricity requires more integrated relationships with health systems to connect with Big Data, which is the kind of information that could help the CRO do a more effective job in managing parts of the relationships that have been delegated.

Purdue Pharma, which recently moved to a lean outsourcing model and has begun identifying new ways to work more strategically with CROs, is one company that plans to incorporate patient-centric approaches into its sourcing strategies for phase II and III studies going forward.

"To use patient engagement, you need to develop relationships with the providers who focus on patients and patient-centric approaches. You need to get them involved in the very beginning. That is the whole point. Throughout the entire study and the development of a study protocol, and even during the course of a trial, you want them fully engaged. That makes for a better-focused protocol and also better alignment with the needs of the patient population. That is going to be our approach in the future," said Katz.

Adaptive design, which involves a signifi-

cant amount of upfront scenario planning and flexibility, is another framework both parties can align themselves around in a strategic partnership. Many organizations also believe standardizing systems and sharing technologies, such as risk-based monitoring tools that collect real-time metrics from sites, can help integrate alliances.

"Both organizations should focus on the core operations initially and make sure that those work as well as possible. But if the organizations can then collaborate on important initiatives, strategies or innovation, that brings organizations closer together. It could include sites and patients, technology systems and data integration, or new methodologies of study design," said Macdonald.

Many companies also have established new, dedicated internal mechanisms to not only manage relationships with service providers and resolve problems, but also to serve as a means of moving the organization toward a more consistent and leveraged approach to strategic outsourcing.


Moving forward, sponsors and CROs committed to improving their strategic and integrated relationships need metrics to quantify the benefits of sourcing approaches throughout the development cycle and prove that CROs can deliver on those models based on volume planning and visibility of the pipelines. Many companies use a scorecard approach for large-scale, multiyear relationships to ensure objectives are aligned and met. Without a way to ensure partners are compliant with important measures of success, as well as the ability to make changes or adaptations when needed, it will be difficult for strategic alliances to mature.

"Our challenge is to not only show success, but also to determine how you measure success. We need to reduce variability, but also

quantify that value. Quantifying value has been a challenge for everyone—not only our sponsor companies, but also the CRO peers. I would say that we are well on our way and are finding ways to measure things that drive R&D productivity," said Spreen.

Looking ahead

Tufts CSDD has found that sponsors and CROs remain committed to improving their strategic outsourcing partnerships and alliances. Yet to accomplish that goal, companies need to acknowledge that inconsistent outsourcing practices undermine the potential for improvements in efficiency, development speed and cost. As they move forward, the study suggests there are many practical steps that can be taken in order to leverage the benefits these relationships can bring. Organizations need to establish a framework that drives greater partnering between sponsor companies and CROs, sets clear objectives, establishes key metrics to measure success and ensures compliance with use of alliance partners.

"When the relationships do work—and they *do* work—it's important that both sides recognize success and celebrate success," said Macdonald. "It happens more than in the past. There is an increasing respect on both sides. Our objectives are becoming more well-aligned between sponsors and CROs and the opportunities to celebrate are becoming more common." 

Karyn Korieth has been covering the clinical trials industry for CenterWatch since 2003. Her 30-year journalism career includes work in local news, the healthcare industry and national magazines. Karyn holds a Master of Science degree from the Columbia University Graduate School of Journalism. Email karyn.korieth@centerwatch.com.