Denise Myshko

Strategic Outsourcing

CROs and pharmaceutical companies continue to finetune their strategic partnerships to gain a competitive edge.

> "Companies are looking at outsourcing models that allow for sharper research focus, enhanced quality, improved efficiency, and offer a lower and more flexible cost base."
>
> **ALAN MORGAN** / ICON Clinical Research

> "Going forward, we will see an increase in true collaboration and joint IP development as companies respond to industry challenges and opportunities."
>
> **DR. FRANK BROWN** / Accelrys

Leading pharmaceutical manufacturers are increasingly seeking to outsource all stages of the drug development process. A desire to decrease clinical trial costs remains a major driver, but increasingly company leaders are also seeking partnerships for strategic reasons, such as accessing knowledge, talent, technologies, and solutions.

Outsourcing helps companies reduce costs, but that's only half the story, says Nagaraja Srivatsan, senior VP and head of life-sciences, North America, for Cognizant.

"The savings can then be applied toward innovation and business transformation," he says. "Outsourcing helps companies quickly leverage the vast pool of global talent that supports not only expansion in major markets, but to new geographies with emerging economies. Outsourcing brings consistency of processes across all business areas."

He says outsourcing also helps bring the right technology infrastructure to consistently deliver business outcomes. External partners can make the technological leap, which the pharma companies may not be prepared to do on their own, and this opens the door to disruptive transformation.

For Francois Nader, M.D., president and CEO of NPS Pharmaceuticals, the desire to lower overhead and fixed costs and increase flexibility are key drivers of outsourcing.

"Specialization of R&D outsourcing gives companies access to specific expertise that they might not have internally," he says. "Outsourcing provides geographic flexibility, especially when R&D has to be conducted in areas where a company lacks an operational presence. Given that the CRO sector is increasingly competitive, outsourcing clinical trials has gradually become more cost-effective and services have become competitively priced in recent years."

Michael O'Gorman, president and general manager, Sentrx, says everyone is looking for faster and greater returns on their investments, and therefore drug companies are looking for less-expensive ways to conduct trials and pave

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>
> **VINCE AURENTZ** / Quintiles

the path for more expedient product commercialization.

“Outsourcing has proven to be an immediate way for companies to realize substantial cost savings,” he says. “Outsourcing has also proven to be an effective way to procure resources and expertise needed without adding headcount and at price points not typically achieved through hiring full-time employees. Additionally, most effective outsourcing firms can leverage technologies built specifically for their offering and spread the costs of such technologies over their customer population. Typically these technologies operate faster, are far less expensive, and can be more easily serviced than building and maintaining such technologies in-house.”

According to Deloitte Consulting analysts, life-science companies that have established outsourcing partnerships benefit from their partner’s ability to provide operating agility and flexible capacity to support unexpected changes in demand due to scientific, regulatory, or market shifts. Most companies are increasingly outsourcing capabilities that surround clinical trial execution, including patient recruitment, site monitoring, and data management, as well as other critical activities across the development process, such as data analysis (biostatistics) and reporting in preparation for regulatory submissions and publications.

Sanjeev Wadhwa, principal, life-sciences advisory services, at Ernst & Young, says as big pharma companies continue to look for ways to carve billions of dollars from the R&D budget, they are relying on strategic partners to do the clinical trial work they no longer want to do in-house.

“As a result, strategic outsourcing will continue to ramp up, and it is anticipated that the collective market share of larger CROs will be around 50% over the next five years,” he says.

The CRO Market

World pharma clinical trial services revenue totaled $21.69 billion in 2010 and will reach $32.73 billion in 2015, according to a recent report from Visiongain. The main drivers for CRO revenue growth are the cost advantages of outsourcing and the regional and therapeutic expertise of research service providers. Offshoring clinical trials to emerging markets, particularly India and China, will create revenue growth for global CROs.

In the United States, according to Frost & Sullivan, the CRO market generated revenue of $11.43 billion in 2010 and is expected to reach $20.09 billion in 2017.

Vince Aurentz, executive VP, customer solutions business, at Quintiles, says multiple factors are contributing to increased outsourcing: unproductive and unmanageable R&D costs and declining approvals; greater emphasis on safety; patients and payers demanding more evidence of value; and the many top-selling drugs going off patent.

“All of these factors have created a perfect storm,” he says. “The old way of doing business is over. Sponsors are outsourcing more and forming strategic co-development and co-commercialization relationships with solutions providers — with outsourcing companies willing to put skin in the game and take on shared risk in return for shared reward. Outsourcing and strategic alliances reduce infrastructure costs and transform fixed costs into variable costs, enabling companies to be more nimble in adapting to the new health environment.”

As recruitment in Western nations has become more difficult and emerging markets grow in importance to sales, sponsors of R&D are looking globally to recruit the sites and patients necessary to satisfy regulatory requirements for statistically significant data on efficacy and safety, says Joseph Bedford, Ph.D., director of marketing, Almac Group.

“Rather than take on the cost and other burdens of global expansion, sponsors have turned to large, global CROs, CMOs, and other suppliers to manage R&D,” he says. “This allows sponsor organizations to convert fixed costs into variable costs by reducing infrastructure and associated personnel, while also being able to manage global trials through outsourcing.”

Jamie Macdonald, chief operating officer, INC Research, says there are both push and pull components fueling the trend toward outsourcing.

“The push comes from the well-documented trend of financial pressures on large pharma companies and the near-term patent expirations,” he says. “Internal cost reductions and midsized pharma and biotech companies holding onto compounds longer to increase their value — and the company’s enterprise value — at a later clinical stage are other push factors.”

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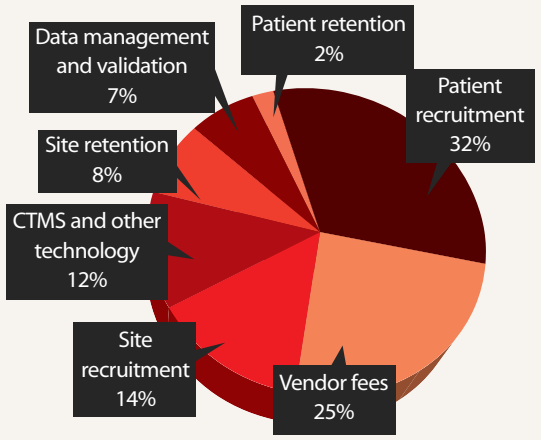
> **NAGARAJA SRIVATSAN** / Cognizant

Clinical Cost Drivers



Source: Cutting Edge Information.
For more information, visit cuttingedgeinfo.com.

Building Partnerships

- Commitment at the top levels of the organization: Engage senior leadership to avoid the pursuit of tactical objectives at the expense of the broader portfolio. Articulate a clear vision that links to broader business goals and is promoted throughout the organization.
- Know your core needs and objectives: Establish explicit objectives, requirements, and incentives; build arrangements that reward targeted outcomes and minimize transactional incentives. Consider how a partner may enable, or potentially hinder, long-term objectives.
- Identify the right partners: Take a holistic approach to partner selection, looking beyond price as the single criterion. Partnerships evolve; some partners may not be ready to deliver on day one.
- Build a mutually beneficial relationship: Invest time and resources upfront to jointly build the capabilities that will be the foundation of a long-term partnership. Foster a culture of continuous improvement, and focus on measuring performance and sharing leading practices throughout both organizations.
- Manage partnerships to achieve outcomes: Make alliance management an operational line unit, outside of procurement, with full management support and governance structures. Create a dedicated and centralized team of resources initially to build the competency, with the goal of diffusing responsibility over time.

Source: Dr. Terri Cooper, Deloitte Consulting LLP.
For more information, visit deloitte.com.

Mr. Macdonald says the pull component really comes from the maturing of the CRO industry.

"CROs have amassed an incredible talent pool and track record, have developed sophisticated systems, and have built the required scope and scale to handle a wide range of outsourcing needs," he says. "The healthy competitive landscape has driven CROs to refine their positioning and differentiation within the industry."

Alan Morgan, president of ICON Clinical Research, says the pharmaceutical industry is at a crossroads and to ensure sustainable innovation, pharmaceutical companies are implementing comprehensive programs of change in R&D.

"Companies are looking at outsourcing models that allow for sharper research focus, enhanced quality, improved efficiency, and offer a lower and more flexible cost base," he says.

Services Outsourced

Industry experts say all clinical development activities across all phases of a trial are being outsourced. Most frequently these services include: study building and data management, clinical monitoring, medical writing, statistical and biostatistics services, submission management, and pharmacovigilance services.

A recent Visiongain report finds the demand for late-stage development services has outgrown that for early-stage services in recent years. Pharma and biotech companies are increasingly focusing on near-registration projects to combat the impending patent cliff. Continued late-stage service demand will drive market growth from 2011 to 2015. Strategic alliances across full development programs will secure long-term revenue for CROs.

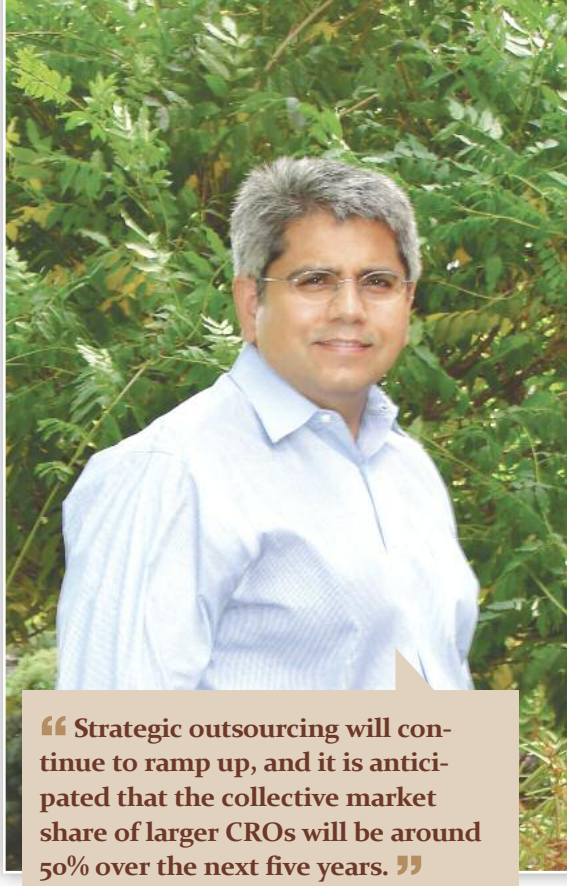
Another study, by Cutting Edge Information, found that Phase II outsourcing has grown at a faster rate than any other phase. Patient recruitment, complex setup requirements, and the need for global coordination point to a continuation of outsourcing trends. On average, companies outsourced 63% of their Phase II clinical budgets in 2011, up from 36% in 2008. Phase I outsourcing rose from 35% to 58% and Phase III outsourcing rose from 46% to 55% of total investment over the same time period.

Elliott Berger, VP, global marketing and strategy for Catalent, says there are two types of activities that are currently being bundled in the outsourcing definition.

"The first type is the outsourcing of activities previously done in-house and the other is partnering for expertise and technologies rarely present in-house to begin with," he says. "We believe the latter type of activities are going to be really important as reduced R&D budgets and increased development complexity will drive the industry to a step-change in the level of cooperation for highly specialized activities and technologies not present in-house. When the activities are not core to the drug development process and can be performed with more expertise, excellence, and efficiency at higher scale by outside partners, outsourcing will grow. This will apply to CMC and analytical services, clinical trial supply and logistics management, and manufacturing."

Mr. Berger says one area in which outsourcing partnerships are on the rise is in clinical trial supplies and logistics.

"Following on the heels of consolidation in the CRO arena, larger customers are looking to consolidate comprehensive supply services, including global logistics, packaging/labeling/kitting, storage, cold chain management and more," he says. "Smaller customers are also looking for a one-stop provider with capabilities and expertise to deliver a total solution with reduced risk to market."



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SANJEEV WADHWA / Ernst & Young

Industry experts also say outsourcing of earlier phase and discovery programs will grow in the future.

Frank Brown, Ph.D., senior VP and chief science officer, Accelrys, says there has been a trend for some time now to outsource basic research elements, but going forward, there will be an increase in true collaboration and joint IP development as companies respond to industry challenges and opportunities.

"There is a growing trend to outsource some of the operational aspects of discovery programs — chemistry and screening as discrete units," Mr. Srivatsan says. "Pharma companies that can allow their scientists to manage these activities virtually can reduce costs and increase throughput."

Deloitte analysts agree, saying companies are recognizing the need to reinvigorate their drug discovery engines, and they are seeking external collaborations with academia to access new technologies.

According to Deloitte, since 2008 pharma companies have engaged in more the 25 major R&D collaborations with academia. These collaborations provide access to new and leading-edge platform technologies; access to external talent and a wider knowledge base including less-traditional disease areas; and cost and efficiency gains in structured discovery

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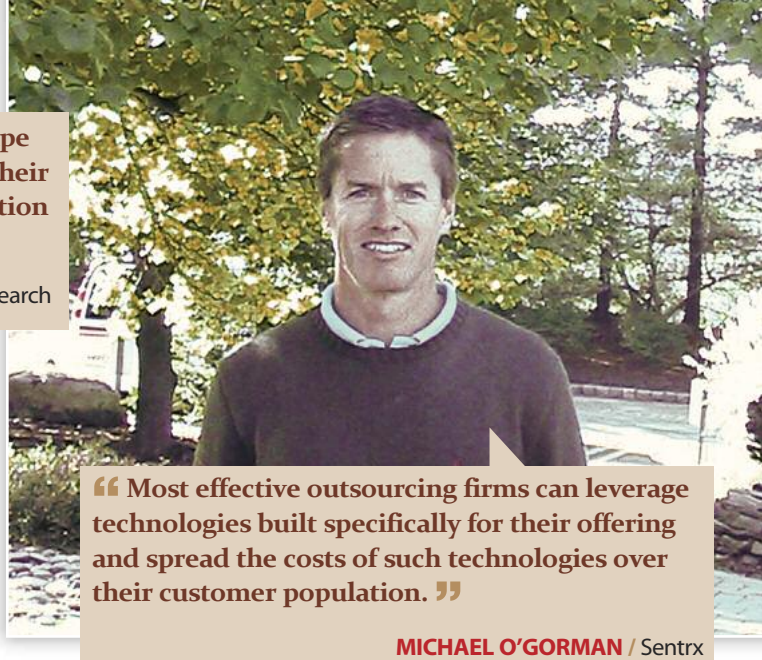

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> **MICHAEL O'GORMAN** / Sentrx

processes such as screening existing databases for drug repositioning.

INC Research's Mr. Macdonald says his company also is engaging with more customers for Phase I activities, as the outcomes and decisions from early-development activities are becoming increasingly critical for the remaining development stages.

The consulting team at Thomson Reuters expects the outsourcing of discovery services to become much more common. They anticipate that the outsourced discovery market will be the fastest-growing segment of the CRO market, expanding with a CAGR of 11% to $4.8 billion in 2015. This is a direct result of an increasing demand for specialized support including toxicology studies, protein structure analysis, and chemical library screening.

Because the pharmaceutical industry continues to suffer from depleted pipelines and a low rate of delivery of new medicines into the marketplace, a majority of pharmaceutical companies are expanding their discovery efforts in the hopes of filling their late-stage clinical pipelines.

As a consequence, Thomson Reuters says the majority of pharmaceutical companies have stated their intent to outsource the bulk of their discovery work to reduce overheads and streamline the discovery process. Additionally, the streamlining of the pharmaceutical workforce has resulted in a potential talent pool for CROs growing enormously. PV

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EXPERTS

VINCE AURENTZ. Executive VP, Customer Solutions Business, Quintiles, a fully integrated biopharmaceutical services company offering clinical, commercial, consulting, and capital solutions worldwide. For more information, visit quintiles.com.

JOSEPH BEDFORD, PH.D. Director of Marketing, Almac Group, which provides a range of services extending from research through pharmaceutical and clinical development to commercialization of product. For more information, visit almacgroup.com.

ELLIOTT BERGER. VP, Global Marketing and Strategy for Catalent Pharma Solutions, which provides development services to advanced delivery technologies to supply solutions for drugs and biologics. For more information, visit catalent.com.

FRANK BROWN, PH.D. Senior VP and Chief Science Officer, Accelrys, a scientific enterprise R&D software and services company. For more information, visit accelyrs.com.

JAMIE MACDONALD. Chief Operating Officer, INC Research, a therapeutically focused clinical research organization conducting global clinical development programs of the highest integrity. For more information, visit incresearch.com.

ALAN MORGAN. President, ICON Clinical Research, a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical device industries. For more information, visit iconplc.com.

FRANCOIS NADER, M.D. President and CEO, NPS Pharmaceuticals Inc., a specialty pharmaceutical company developing innovative therapeutics for rare gastrointestinal and endocrine disorders. For more information, visit npsp.com.

MICHAEL O'GORMAN. President and General Manager, Sentrx, a provider of drug safety services to the life-sciences industry. For more information, visit sentrx.com.

NAGARAJA SRIVATSAN. Senior VP and Head of Life-Sciences, North America, for Cognizant, a provider of information technology, consulting, and business process outsourcing services. For more information, visit cognizant.com.

SANJEEV WADHWA. Principal, Life Sciences Advisory Services, Ernst & Young, a global provider of assurance, tax, transaction, and advisory services. For more information, visit ey.com.

Denise Myshko

Outsourcing *Best* PRACTICES

Trust, collaboration, and communications are three of the key factors to ensuring a successful outsourcing partnership — easy to say, harder to operationalize.

Over the years, PharmaVOICE has covered the necessity for best practices to ensure that CRO/sponsorship partnerships operate at an optimal level, yet most agree there is still a great deal of work to be done to ensure all parties' goals and expectations are met.

Alan Morgan, president of ICON Clinical Research, says the success of an outsourcing relationship depends on a number of factors.

"First, communication is key," he says. "There must be full transparency and an open flow of communication between both companies. Both parties should work in a close, collaborative manner that is based on honesty and trust and openly engage in joint short- and long-term planning so that the needs of the sponsor are fully understood by the CRO. And finally, delivering quality work to agreed milestones is fundamental to a successful relationship."

Joseph Bedford, Ph.D., director of marketing at the Almac Group, agrees that establishing strong communications and governance are two of the most important best practices.

"When both parties in an outsourcing relationship communicate effectively, they are better able to scope and define project goals and objectives, assign joint ownership and accountability of key responsibilities, keep to timeliness, and achieve high levels of quality," he says. "Similarly, when sponsors and suppliers create effective governance structures they often find that study-related goals are met. Ideally, governance structures should involve various levels of both sponsor and supplier firms, including the highest levels inside both organizations. When such conditions exist, joint strategic planning and investments are made in the relationship to assure its success."

Darlene Panzitta, president and founder of DSP Clinical Research, believes trust is key to the partnership.

"Pharma companies have to trust their CROs to make the decisions and use their expertise instead of trying to run the study themselves," she says. "Working to develop an atmosphere of mutual trust and respect is the best way to ensure good communications and

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a collaboration strategy, to stay within budget, and to have a successful study. Pharma clients should also engage their CRO partner before the protocol is developed."

Vince Aurentz, executive VP, customer solutions business, at Quintiles, says outsourcing works best when there is a clear understanding of the goals of the relationship; robust planning at the outset; and strong communications at all times.

"Companies are increasingly taking advantage of the vast expertise some CROs have acquired in conducting many trials in similar indications and patient populations," he says. "A strong alliance relationship allows for an exchange of ideas and recommendations at the beginning of the process and alignment of expectations. This can dramatically reduce change orders and complications that can slow down the trial. But moving successfully from a transactional to an alliance relationship requires a new collaborative skill set that employs and encourages open communication."

Andrew Grygiel, chief marketing officer at ClearTrial, says it's easy to define best practices but much harder to operationalize them.

"There is always a lot of talk about transparency and better communications being keys to better sponsor/CRO relationships," he says. "But how are companies making these goals a reality? The approach can be summed up in a phrase that was made famous during the Cold War: 'Trust, but verify.' The right way to implement this approach is a delicate balance of the two. Most life-sciences companies are leaning heavily toward the verification side, heaping on the oversight and control and maintaining internal operations redundant to those provided by the CRO. While this is somewhat understandable given that sponsors are ultimately held responsible for a clinical study by regulatory bodies, it does little to build a truly sustainable business model."

Francois Nader, M.D., president and CEO of NPS Pharmaceuticals, says successful partnerships are always based on a win-win equation.

"Both parties need to make sure that the terms of the equation are well-defined before embarking on the journey," he says. "Both partners have to ensure that a philosophical strategic and cultural alignment are present at the top of each organization and that this alignment is communicated and practiced as often as needed throughout the course of the relationship. It is of utmost importance to define the roles and accountabilities as clearly as possible and as early as possible during the relationship, as well as putting in place a graded conflict resolution process that identifies the tiebreakers at every stage of the escalation. Consensus, at times, can lead to the lowest common denominator rather than the best outcome for the project. The interface process should identify clear leadership and decision-making roles."

Mr. Grygiel says forward-looking organizations are using cloud-based technologies to collaborate closely with their CRO partners, building trust by developing clinical study project plans together from an early stage.

"For example, many companies are using cloud technology to share real-time information regarding project status, trends, and costs tracked against the project plan," he says. "This approach gives sponsors instant visibility without having to replicate resources. Lastly, the more innovative companies are creating business models that reward outsourcing partners that work collaboratively with the sponsor to increase efficiencies in the work effort that is outsourced. This has resulted in greater adoption of enabling platforms." PV

FAST FACT

WORLD PHARMA CLINICAL TRIAL SERVICES REVENUE WILL REACH $32.73 BILLION IN 2015. REVENUE FOR THOSE COMPANIES (CROS) TOTALLED $21.69 BILLION IN 2010.

Source: Visiongain

EXPERTS

VINCE AURENTZ. Executive VP, Customer Solutions Business, Quintiles, a fully integrated biopharmaceutical services company offering clinical, commercial, consulting, and capital solutions worldwide. For more information, visit quintiles.com.

JOSEPH BEDFORD, PH.D. Director of Marketing, Almac Group, which provides a range of services extending from research through pharmaceutical and clinical development to commercialization of product. For more information, visit almacgroup.com.

ANDREW GRYGIEL. Chief Marketing Officer, ClearTrial, a provider of clinical trial operations software. For more information, visit cleartrial.com.

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FRANCOIS NADER, M.D. President and CEO, NPS Pharmaceuticals Inc., a specialty pharmaceutical company developing innovative therapeutics for rare gastrointestinal and endocrine disorders. For more information, visit npsp.com.

DARLENE PANZITTA. President and Founder, DSP Clinical Research, a full-service CRO that manages Phase I through IV clinical studies for small to midsized pharmaceutical, biotech, and device companies. For more information, visit dspclinical.com.