Outsourcing: The Time *is* RIGHT

Most of our experts agree that one of the industry's greatest paradigm shifts in the last 10 years has been the transition from internal to external development; they also agree that it's about time.

The recent world economic events have set the stage for the shape of the industry going forward.

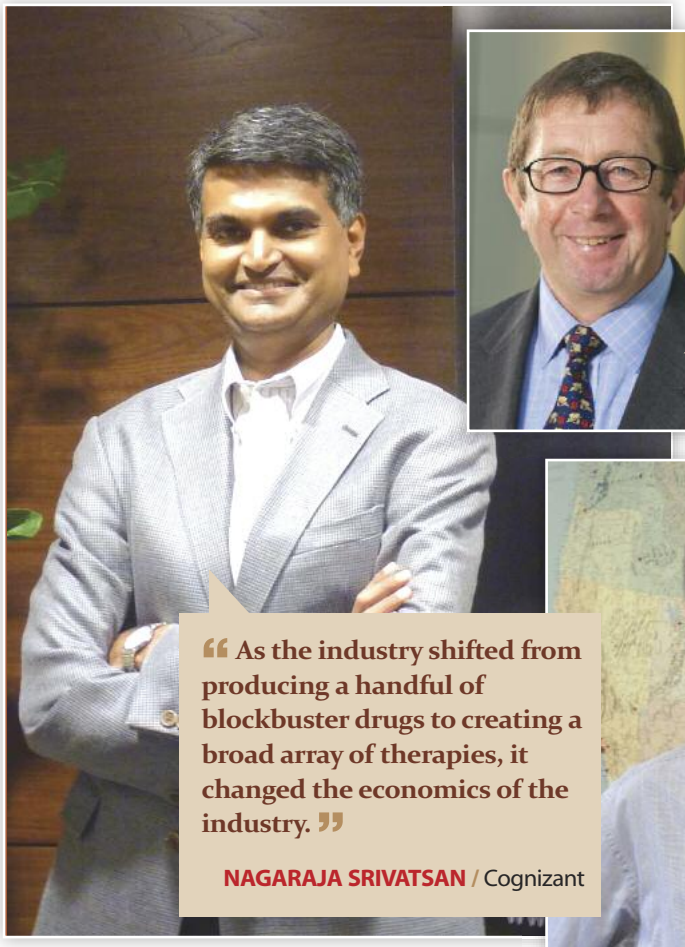
"As market conditions evolve, pharma companies are reducing their infrastructures and costs, resulting in a stronger reliance on vendors to meet trial objectives, timelines, and budgets," says Jim DeSanti, CEO of PharmaVigilant, a clinical trial service provider. "Even oversight has been reduced. R&D budgets continued to shrink to align with reduced revenue associated with the industry's current patent cliff. As such, vendor management started to take a leading role, with clinical at the forefront. The focus is now shifting to quality and accuracy as the industry continues to align with the demands of the regulatory agencies. In the end, depending on which side of the fence you are on, the reliance on vendors is viewed as both a benefit and detriment to clinical development programs."

Partners for Real

There has been a shift from tactical outsourcing to strategic long-term relationships.

"Most would agree that this has been a necessary and beneficial trend for both sponsors and CROs as these strategic alliances have helped reduce the costs and have helped to improve quality and time to completion of clinical trials," says Bill Taaffe, president of corporate development, Icon Clinical Research, a global provider of outsourced development services. "There will be more consolidation in both the pharma and CRO industries. Large CROs should continue to prosper and benefit from the expansion and globalization of multi-center studies. But there will still be a significant market for specialty/niche CROs particularly for the smaller proof-of-concept studies. The focus of the regulatory agencies on requirements for large postapproval studies will increase, and this is also good news for the outsourcing industry. The Asia-Pacific region will grow in importance for drug sales and drug development. It is noteworthy that two of the last three outsourcing companies to go public are based in China. As always, there are challenges ahead but R&D is the lifeblood of the drug industry and will continue, albeit in different form."

There has been a movement toward functional outsourcing and away from the all-inclu-



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>
> **JOHN VANN** / Chiltern

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BACK TO THE FUTURE

CRO PARTNERSHIPS

BILL TAAFFE
President, Corporate Development, Icon Clinical Research

» **THEN (2001):** Relationships between sponsors and CROs have changed considerably over the past few years. In an effort to formalize the process, most sponsors now require CROs to conduct all business aspects of a study or program with an outsourcing/procurement department. This new initiative has introduced CROs to a formal RFP process with detailed bid grids and elaborative bid-defense meetings.

» **NOW:** In 2002, someone made the comment: 'At this time CROs are regarded as a necessary evil and some argued over the word necessary.' Or to paraphrase Romeo and Juliet, go hence to have more talk of these sad things, some shall be pardoned and some punished, for never was a story of more woe, than this of the sponsor and the CRO. Thankfully those days are long gone. The CRO industry has seen significant growth because of pressures on drug companies to reduce fixed costs and speed up development time. Also the refinement of the development process by CROs makes them valuable assets and important partners in the drug development process.

> **"The industry has hoped for the elusive paperless clinical trial for years. That myth can now become a reality as the momentum and speed of innovation in this space gathers pace."**
>
> **ALISON SHURELL** / IntraLinks

Outsourcing Tips

Executives who recently met as part of the Tufts CSDD Executive Forum Roundtable agreed that good governance — critical to the success of alliances and partnerships — is supported by:

» **Sharing definitions of the relationship, goals, and processes** to assure a standard and consistent approach to oversight.

» **Instituting an audit plan** that lets sponsors adopt a "trust-but-verify" approach to CROs, enabling sponsors to evaluate CRO methods and systems without co-monitoring trials.

» **Keeping the joint executive committee focused** on learning how problems get solved, not how to solve them.

Source: Tufts Center for the Study of Drug Development. For more information, visit csdd.tufts.edu.

sive approach of CROs, but it will be the next 10 years when the functional service provider (FSP) model will come to a tipping point and big pharma companies narrow their outsourcing relationships to preferred specialist partners.

"We'll see greater collaboration between sponsors and outsourcing partners and the growing utilization of capacity planning and forecasting tools," says Brett Barber, director clinical solutions at Kforce Clinical Research, a provider of clinical trial resourcing solutions. "This will lessen risks and give greater assurance to the sponsor that specialized functions are being performed by quality partners. Outsourcing may even narrow to just one contractor-like partner that has total oversight of assumed, and subcontracted, responsibilities."

As companies are now being challenged to find newer and better ways to develop drugs at lower costs to appease a smaller market segment/patient population, Michael Harte, founder and president of The Harte Group, a functional services management organization, says the solution will be the use of FSPs, which will allow for greater flexibility in terms of trial execution and overall development strategy.

"The all-in-one solution, full-service CRO model will find it challenging in the new era, when sponsors' newer product assets will need to be developed with limited budgets by smaller virtual companies that are more nimble and experienced," he adds.

The integral role of strategic outsourcing partners as key drivers of the development of drug candidates will be the biggest market shaper over the next 10 years, particularly as pharmaceutical companies focus resources on the "bookends" of drug development — discovery and commercialization, says Tim Tyson, CEO of Aptuit, a provider of drug development solutions.

"The outsourcing vendor role has already begun to become a notion of the past," Mr. Tyson says. "Integrated, strategic outsourcing partners will increasingly be relied upon in new capacities, such as risk-sharing alliances, preferred provider relationships, and strategic scientific and program advisers. This market shift is essential for the industry to efficiently and sustainably develop and market new therapies."

Focus on the Core

According to John Vann, executive VP of global corporate development at Chiltern, a global CRO, as pharma companies continue to drive to reduce costs, making their organizations more virtual to better manage both cost and risk, there will be an increased reliance on structured and strategic outsourcing deals, which will continue to change how CROs relate to sponsors and other service providers.

"The delineation of the roles of CRO and sponsor will become even more fluid to capitalize on all organizations' strengths, support each other's needs, drive synergy, and achieve success," he says.

Nagaraja Srivatsan, senior VP and head of life sciences, North America, at Cognizant, a global services partner for the life-sciences industry, says as the industry shifted from producing a handful of blockbuster drugs to creating a broad array of therapies, it changed the economics of the industry.

"Companies started to evaluate what was core vs. non-core for their businesses, and this led them to explore outsourcing of operational functions," Mr. Srivatsan says. "The trend began with IT outsourcing, then evolved to include business processes such as clinical operations, finance, and commercial operations. Outsourcing non-core functions provided life-sciences organizations with cost savings they could apply toward R&D or newer markets. This model enabled companies to be more agile and flexible to meet the economic demands of the post-blockbuster era."

According to Stephen Cutler, Ph.D., senior VP and chief operating officer at Kendle, a global CRO, 10 years ago sponsors were just beginning to accept CROs as a partner in the clinical development process, rather than simply as a vendor to cover gaps in capacity.

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>
> **BRETT BARBER** / Kforce Clinical Research

"Today, CROs are intimately involved in every facet of clinical development, driving efficiency and quality across the development process," he says. "The relationships between sponsors and CROs have evolved and are much more complex ranging from specialty/niche provider to FSP to strategic partner. The pharma industry of 2011 has a much better understanding of the advantages of CROs and many sponsors now accept that CROs can do clinical development faster, better, and cheaper."

Mr. Taaffe says historically procurement departments managed the purchasing of commodity services, but the management of clinical development is about the science and data collection; it is not an assembly-line production of a widget over and over.

"Clinical development is far too complicated, complex, and unpredictable to be commoditized," he adds. "The efforts to commoditize the clinical development service have in some cases led to the creation of inefficient processes. In the late 1990s, there was an attempt to standardize the units of activity in a clinical trial. It failed because the task was impossible. Every monitoring trip is unique, every adverse event is unique, and similarly almost every activity in a clinical trial is unique. Now more sponsors are embracing the true concept of partnering with CROs — strategic partnerships and alliances — but there is still a reluctance to move to true outsourcing, which is well-defined by Peter Bendor Samuel: 'Outsourcing is the transfer of ownership of a process to a supplier.' Progress is being made, we are not there yet. But as Shakespeare said 'I do desire we be better strangers.' "

E-Clinical: An Imperative

The continued growth of outsourcing and use of e-clinical technologies has allowed drug companies to prioritize their spend of time and money on research and to effectively resource their operations without the up and down flux that comes with intermittent trials, but this hasn't always been the case.

"E-clinical suites of products have allowed small pharma and biotech development companies to remain competitive and operate within their bandwidth of capabilities, says John Cline, CEO of Unithink, an electronic clinical research organization. "This trend drives innovation and has resulted in advances from adaptive trials to fast-tracked drugs."

The ideal technology platform has gotten considerably closer, Mr. Cline says, but there are still too many companies taking a propri-

> "EDC and the acquisition of data using technology tools make for a more agile trial, in real time, with accurate reporting."
>
> **JOHN HUDAK** / Criterium

BACK TO THE FUTURE

OUTSOURCING FOR SPEED

DR. MARK A. GOLDBERG
Chief Operating Officer,
Parexel International

» **THEN (2001):** It's a challenge to integrate technology into the way we do business because some sponsors are not prepared, or their culture isn't at the place that allows them to readily take advantage of technology. The pharmaceutical industry has invested relatively less in IT than most other industries.

» **NOW:** Standalone systems to facilitate trials are not well integrated, and therefore the opportunity to maximally leverage these systems is limited. Although individual e-clinical technologies have delivered dramatic improvements in trial productivity and data accuracy in recent years, the biopharmaceutical industry must move beyond the gains provided by these individual systems if they are to achieve the cost and time savings that are essential for their future success. The next level of efficiency requires widespread use of integrated technology throughout the clinical enterprise combined with innovative clinical expertise and capabilities.

BACK TO THE FUTURE

EDC AND BEYOND

JOHN CLINE
CEO, unithink

» **THEN (2001):** The pharmaceutical company of the future that's going to win is the company that can put together a technology platform that can go from the molecule to the money. People concentrate, in my view, way too much just on the electronic data capture piece. To me, that misses the excitement. The future is having a fully integrated electronic environment for the development of drugs.

» **NOW:** Technology for the most part is no longer the barrier. The barrier exists primarily with people and industry. There is still a silo mentality where even inside the same company there appears to be a lack of standards.

> "Depending on which side of the fence you are on, the reliance on vendors is viewed as both a benefit and detriment to clinical development programs."
>
> **JIM DESANTI** / PharmaVigilant

etary approach for the industry to have a unified molecule-to-market platform.

"We've seen much progress toward industry standards, but there is still work to be done before diverse technologies can easily communicate and share data," he explains.

"With EDC breaking the seal and being widely adopted by the industry over the past 10 years, it has opened the door for the introduction of other innovations and solutions that are changing the face of clinical research," says Alison Shurell, VP of life-sciences product marketing at IntraLinks, a provider of critical information exchange solutions. "The biggest paradigm shift is the movement of the industry away from paper to electronic systems for clinical data capture and process management. The industry has hoped for the elusive paperless clinical trial for years. That myth can now become a reality as the momentum and speed of innovation in this space gathers pace."

Mr. Harte agrees that the biggest game changer has been the increased use of technology across all aspects of the clinical research and development spectrum.

"These tools have created opportunities to locate potential assets to develop, fostered better communication across silos, enabled trials to extend beyond local shores to include many

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>
> **MICHAEL HARTE** / The Harte Group

countries, and allowed companies to access their data more quickly and readily than ever before," he says.

According to Mr. Barber, EDC has not only enabled remote monitoring but has had huge implications on drug safety.

"Pharmaceutical companies can, comparatively speaking, look at real-time data and not wait several weeks or months to review safety data," he says. "Additionally, interactive voice response (IVR) systems have changed the way the clinical drug supply chain is managed. The systems have reduced costs by efficiently shipping only drugs that are to be dispensed. This minimizes storage of excessive stock and helps prevent expiration of drugs at sites."

Ms. Shurell also believes e-solutions that bring the clinical research community together in a meaningful way to accelerate trials and efficiently bring safe drugs to market will be the biggest market shaper.

"Clinical trials will continue to be global but the ecosystem of people involved will become even more complex, she says. "Members of the global community — sponsors, sites, CROs, IRBs/ECs, regulators, patients, etc. — are trying to connect with each other and work together in a richer and more efficient way. For this reason, secure cloud-based solutions that are globally available 24/7/365 in multiple languages to support clinical processes, workflows, and communities are going to have the biggest impact over the next 10 years."

John Hudak, founder and president of Criterium, a global CRO, has been watching the migration from paper to paperless processes for 20 years.

"We started the first application of IVR in 1991," he says. "The biggest impact has been the move to EDC and the acquisition of data using technology tools. This makes for a more agile trial, in real time, with accurate reporting."

The exponential increase in acceptance and use of electronic data tools, especially EDC, was anticipated for many years, but it has only been recently that we've seen a tremendous yet subtle, transformation of the industry, Mr. Vann says.

"Crossing the line from being predominately paper-based, the industry — sites, sponsors, and CROs alike — is now not only embracing technology but driving it forward," he adds. "Processes have moved to a higher level of maturity, changing workflow and driving greater efficiency in collecting, monitoring, and managing this critically important information, while at the same time enhancing quality and opportunity for collaborative success."

Jennifer Price, senior director of clinical solutions at BioClinica, a global provider of clinical trial management services, says the biggest innovation is absolutely the use of the Internet, but more specifically, the use of the Internet by people who were previously non-computer users.

"The lack of access to a computer was the excuse sites would use to not enter data electronically," she says. "As clinical sites acquired the technology needed to access clinical research EDC systems, the same sites were notoriously staffed with medical personnel who didn't have a strong interest, desire, or the skills necessary to interact with their newly acquired technology.

"Today, the majority of staff at clinical sites have grown up with computers and are demanding the efficiencies gained by using the technology available," Ms. Price says. PV

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