PARTNERSHIPS FOR SUCCESS

Strategic alliances — between pharmaceutical companies, contract research organizations, and other outsourcing providers — are expected to impact the future of drug development.

Pharmaceutical companies are under pressure from the public, analysts, Wall Street, and their shareholders to bring more drugs to market, safely and efficiently. Thus, most pharmaceutical companies are examining ways to refine their processes and challenge the status quo. Some analysts and industry insiders believe outsourcing is a business model that bears careful consideration.

OUTSOURCING FOR MAXIMUM EFFICIENCY

"R&D outsourcing is increasingly seen as a crucial component of any long-term solution to the expedited-drug-development-at-a-lower-cost imperative," says Joseph Herring, chairman and CEO of Covance Inc. "This evolution, however, begs a strategic question relating to how pharmaceutical companies work with contract research providers."

Currently, pharmaceutical and biotechnology companies outsource 57% of their spending on Phase III clinical trials, according to a new benchmarking report, Clinical Operations: Accelerating Trials, Allocating Resources and Measuring Performance, published by Cutting Edge Information.

The company surveyed dozens of leading pharmaceutical and biotech firms about their clinical-development spending, staffing, and performance measurement practices. The surveyed companies follow a similar outsourcing pattern for Phase I, Phase II, and Phase IV studies, as well. On average, outsourcing ranges from 54% to 64% for trials in these development phases.

In the biopharmaceutical arena alone there are more than 250 clinical projects underway in the United States this year — a jump of 29% over last year — with 75% of the projects being in the Phase III and Phase II stages of development, according to Anne Anscomb, author of the second edition of Pharmaceutical Outsourcing Opportunities Post-Launch, published by Kalorama Information.

"It's easy to see why the sheer number of biologics in the pipeline is creating this enormous market for outsourcing," Ms. Anscomb says.

According to Mr. Herring, historically most pharmaceutical companies consider the decision to engage a CRO to be a transactional, siloed decision with little consideration for the strategic impact a partner can provide. This transactional paradigm, where decisions are made on a serial, project-by-project basis, can actually impede the delivery of new drugs to market. In particular, transactional outsourcing makes it difficult to build trust-based working relationships between project teams or continued learnings that occur when two companies partner effectively.

"I believe the key to expediting drug development is for CROs and sponsors to develop long-term alliances as true partners," Mr. Herring says. "Although the concept of strategic partnerships is still in its infancy, it is inevitable that this new paradigm will become the norm. For the future growth and economic viability of both sponsor and CRO, it is an absolute imperative. We must recognize that traditional, transactional working relationships have not and will not produce expedited drug development or drive long-term cost-effectiveness."

When the relationship between sponsor and CRO is that of a strategic alliance, there is a well-defined governance structure, established

The wise path to outsourcing is one of planned engagement, defining a medium- to long-term R&D offshoring vision that harmonizes with the company's global research and development strategy.

John Wong
Boston Consulting

Thought Leaders

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Covance

metrics, escalation processes, collaborative planning and resource sharing, and more candid feedback that assure both sponsor and CRO live up to expectations and share accountability for the success of their projects, Mr. Herring says.

Furthermore, internal benchmarks provide a reliable means to measure CRO performance over time, especially regarding the crucial question of driving down costs and speeding up development.

Because of the ongoing trend toward outsourcing, drug companies are focusing on the most critical problems in their own labs and outsourcing other specialties, says Isy Goldwasser, president of Symyx Technologies Inc.

"To fully realize the benefit of such arrangements, large pharmaceutical companies and contract research organizations will be forced to find better ways of collaborating and sharing information across distributed research centers," he says. "The current generation of electronic lab notebook software not only allows scientists to store and retrieve information but also enables scientific collaboration, knowledge sharing, improved adherence to SOPs, and better IP protection."

GLOBAL CONSIDERATIONS

Multinational pharmaceutical companies are increasingly looking at outsourcing R&D to China and India to help them increase productivity and reduce costs. While historically the biopharma industry has lagged in this area, it is catching up as the regulatory and competitive environments in both countries improve, according to a report by The Boston Consulting Group.

"Both countries hold great opportunity to meet the R&D productivity challenge," says John Wong, senior VP at The Boston Consulting Group. "But to most effectively create value through offshoring in both the short and the long term, companies must see the big picture and build an integrated strategy that balances the advantages and the risks."

OFFSHORING OPTIONS: CHINA AND INDIA

OFFSHORING R&D WORK TO CHINA AND INDIA HAS THREE MAIN ATTRACTIONS: THE POTENTIAL TO REDUCE COSTS AND EASE BOTTLENECKS AND OTHER INEFFICIENCIES; THE OPPORTUNITY TO TAP THE TWO COUNTRIES' BURGEONING BIOPHARMA R&D CAPABILITIES AND RESOURCES; AND THE PROSPECTIVE COMMERCIAL PAYOFF FROM ESTABLISHING A FOOTHOLD IN THESE RAPIDLY GROWING MARKETS.

- **Direct savings could run as high as 60%** or even **80%** on salaries in the discovery phases and as high as **60%** or **70%** in cost per patient in clinical trials, predicts The Boston Consulting Group.
- **In both China and India**, annual graduates in chemistry, for example, outnumber their U.S. counterparts more than fivefold at the bachelor's level and more than threefold at the master's level.
- **In China, life-sciences research has a tradition** of government sponsorship, and private and semi-private firms can receive both earmarked funds and tax advantages. In India, the government is involved in promoting the country's biopharma industry.
- **Additionally, a network of life-sciences parks** has developed in both countries. As of the end of 2005, there were about **60** in China and five were fully operational in India with **17** more in progress.
- **China is expected to become the world's fifth-largest pharma market by 2010**. Its spending on pharmaceuticals, which was **$12 billion** in **2005**, is predicted to reach **$37 billion** by **2015**. India's market is dominated by generics. Still, by **2015**, its outlay on branded pharmaceuticals is predicted to reach **$16 billion**.

Source: The Boston Consulting Group, Boston. For more information, visit bcg.com.

JOHN M. HUDAK. President and Founder, Criterium Inc., Saratoga Springs, N.Y.; Criterium is a full-service, global CRO offering a unique mix of high-quality clinical research services, real-time data acquisition, and personalized communication processes to manage a clinical trial from initial planning to approval, on time and on budget. For more information, visit criteriuminc.com.

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OUTLOOK: STRATEGIC PARTNERSHIP TRENDS AND OPPORTUNITIES

PHARMAVOICE ASKED EXPERTS INVOLVED IN THE CLINICAL OUTSOURCING ARENA TO DISCUSS THEIR EXPERIENCES WITH OUTSOURCING PARTNERS AND WHAT THEY EXPECT IN THE FUTURE.

Isy Goldwasser
Symyx Technologies

Companies are seeking ways to be more productive, innovative, and efficient with their assets. In 2007, development groups increasingly will use automation that encompasses all lab processes to extend the productivity of individual scientists. Emerging high-throughput research technologies are having a significant impact on productivity in the pharmaceutical industry. Linking information from scientists and data from instruments will require robust software that provides benefits across the enterprise.

Joseph Herring
Covance

My company's experience with strategic alliances has been a revelation on a number of levels. Our alliances have allowed us to help sponsors consistently beat timelines. In one particularly complicated study on the therapeutic impact of a cancer compound, we enrolled hundreds of study participants nine months ahead of schedule. This result accelerated the sponsor's go-to-market strategy and, by definition, lowered the cost of development.

We attribute this performance to a collaborative governance structure that, from the very beginning, aligned this program for success. The executive oversight and support facilitated access to the best processes of each company without the distraction of one-upmanship or finger pointing.

John Hudak
Criterium

We should see a continued trend for big pharma consolidation as companies look for economies of scale and greater ability to compete globally; this is no surprise as many other industries have already gone through this.

Also, because big pharma companies have the financial resources, they will develop more partnerships with small discovery firms, and the trend will extend to them buying many of these smaller, more successful innovators. The line between drugs and devices will blur as more devices incorporate drugs into their systems for better effect.

There will continue to be new small pharma companies developing and conducting studies on better formulations or delivery of older drugs, either under license or when the drugs become generic; the financial resources will come from venture companies while others will come from generic companies that wish to develop their own 'brands,' as well as some of the more difficult to evaluate generics — intranasal, transdermal, inhalation products — and biosimilars — biotech products coming off patent.

Overall, there will be increased concentration on, and sophistication of, generic drug development.

John Wong
Boston Consulting

An effective offshoring strategy will have to be flexible to accommodate constant shifts in both countries' R&D landscape, including shifts in capabilities, availability, and risk factors.

At the same time, multinational companies will need to accommodate changes in their own internal environment, including budgetary constraints and the corporate appetite for risk.

As the globalization of the pharma industry continues through the incorporation of more sites from around the world into clinical trials it will become even more of a challenge to stay on top of each country's often unique regulatory requirements and related cultural norms.

John Hudak
Criterium

According to John Hudak, president and founder of Criterium Inc., as the globalization of the pharmaceutical industry continues through the incorporation of more sites from around the world into clinical trials, combined with the fact that this remains one of the world's most regulated industries, it will become even more of a challenge to stay on top of each country's often unique regulatory requirements and related cultural norms.

"We would consider it progress if there were more standardized policies, such as what is occurring in the European Union for drug and device regulations," he says. "But the current state of the world market is that most nations continue to hold onto their own guidelines and procedures. This is both the biggest challenge and opportunity. Those companies that can navigate the nuances of regulation will succeed in 2007 and beyond. Clinical executives must be knowledgeable on each country to execute strategies on a local level. But it's not easy: often just getting basic market information for some countries that is accurate and up to date is extremely difficult." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

To access a FREE Podcast on this topic, featuring John Hudak, go to pharmavoice.com/podcasts.