



GLOBAL: R&D Outsourcing

Outsourcing has always been about cutting costs and creating efficiencies, and today's pressures have made the R&D process more global than ever.

Multitude of pressures have the industry looking toward global R&D outsourcing as a life raft in a sea of change.

A U.K. report by Deloitte and Thomson Reuters surveyed a dozen pharmaceutical companies that spent the most on developing new drugs and discovered that they spent 25% more to bring a product to market in 2011 than in 2010, while the average commercial value of products remained the same as in 2010. The average cost of successfully bringing a product to market increased from \$830 million in 2010 to \$1.04 billion in 2011. The overall rate of return on R&D dropped from 11.8% in 2010 to 8.4% in 2011, according to Deloitte.

Growing trends indicate that the industry is moving toward more global R&D outsourcing, and to meet those needs, outsourcing opportunities — both development and manufacturing — are ripening in several countries.

According to Glen de Vries, president of Medidata Solutions Worldwide, adding the word “global” to R&D outsourcing has become redundant.

“The outsourcing of clinical development is a global activity, period,” he says. “It doesn't matter who is doing it — a CRO or system integrator or a huge pharma or a small biotech company. It is all about finding a geography with access to untreated patients to get the

Global Clinical Trials By Country

- » 2,860 studies in China
- » 1,856 studies in India
- » 624 studies in South Korea
- » 408 studies in Asia
- » 149 studies in Vietnam

Source: clinicaltrials.gov

data needed quickly, cost effectively, and within regulatory confinements. Whatever the incentive, R&D outsourcing is global.”

“Life-sciences organizations are looking at ways to bring innovation to the manufacturing process, cut costs, improve efficiencies, and still maintain high regulatory and quality standards,” says Nagaraja Srivatsan, senior VP and head of life sciences practice for North America at Cognizant. “To that end, they are moving toward more global contract manufacturing.”

In addition to clinical trials, several countries are rising to the top as offering the most opportunities for outsourcing manufacturing. According to Mr. Srivatsan, China, India, Vietnam, South Korea, and Bangladesh have large numbers of contract manufacturing locations. Of these, India is known for having the largest

number of FDA-approved drug manufacturing facilities outside of the United States.

Sponsors are looking to partner with CROs that possess the capabilities aligned with their needs and that can mobilize resources quickly in certain geographies. However, the defining criterion is whether the appropriate patient mix exists in those countries. Anup Kharode, a director in PwC's Global Pharma and Life Sciences industry group, says the industry has been moving R&D outsourcing toward China and India over the past several years, as well as to Japan, Eastern Europe, and Brazil.

“These are the markets experiencing an uptick in manufacturing activity and they will continue to trend in this direction as companies look to identify geographic pockets where they can identify patients,” he says.

CROs are setting up operations in these countries in increasing numbers to meet industry demand. In conjunction with this trend, some global CROs are partnering with regional or local CROs to support trial activity in particular geographies and serve as a liaison between local CROs and large multinational sponsors.

“Global pharma sponsors are more comfortable partnering with larger CROs and they are occasionally partnering with local ones,” Mr. Kharode says. “The larger CRO performs the required due diligence to ensure that the local CROs can perform the trial in accordance with their standards.”



“The reason for outsourcing cannot be driven by cost alone.”

GLEN DE VRIES

Medidata Solutions Worldwide

Partnerships Become More Strategic

As the trend toward global R&D outsourcing continues, the nature of the relationships between sponsor and CRO or CMO will

Tips for Successful R&D Outsourcing

- » Ensure the selected partner aligns to deliver on the business outcomes
- » Set up strong governance to ensure the desired outcomes are measured and delivered
- » Create a metrics-based culture to ensure all activities are measured and performed at best-in-class levels
- » Work with a partner who provides a transformational road map that is not just focused on process execution but also ensures that quality of throughput of the R&D process is increased

Source: Cognizant

develop into more strategic partnerships and away from transactional arrangements. The sponsor needs to think of the CRO as a true partner and involve them in multiple studies or therapeutic area activities.

“We will see increasing levels of trust and commitment, which include greater information sharing, joint investments, and well-established agreements around a dedicated set of resources to be deployed,” Mr. Kharode says. “These partnerships are based on cross-company, multitiered governance oversight. Instead of solely looking at study level metrics, the effectiveness of the joint operation will be assessed continuously. Companies will need to develop the appropriate vendor relationship model, including appointing the right individuals to perform relationship management roles. These emerging roles will require greater alignment with operations than traditional procurement or sourcing activities.

“This oversight model becomes more challenging as companies expand their geographic footprint,” Mr. Kharode continues. “Companies are adjusting to managing these relationships when they don’t have resources within the same regions as their CRO partners.”

At the start of forming these relationships, organizations should clearly define what is noncore to them that can be outsourced to partners, Mr. Srivatsan says. Once a company has identified key areas of the process that can be outsourced, it must create an integrated standard operating procedure to ensure the process is compliant with regulatory audits.

“In addition, the sponsor will have to identify the tangible business outcomes it desires,” he says. “This set of business outcomes will define the success of the outsourcing engagement.”

The trend toward strategic partnerships includes pharma companies such as Pfizer, Sanofi, and Lilly that have entered into partnerships with global CROs such as Parexel and ICON.

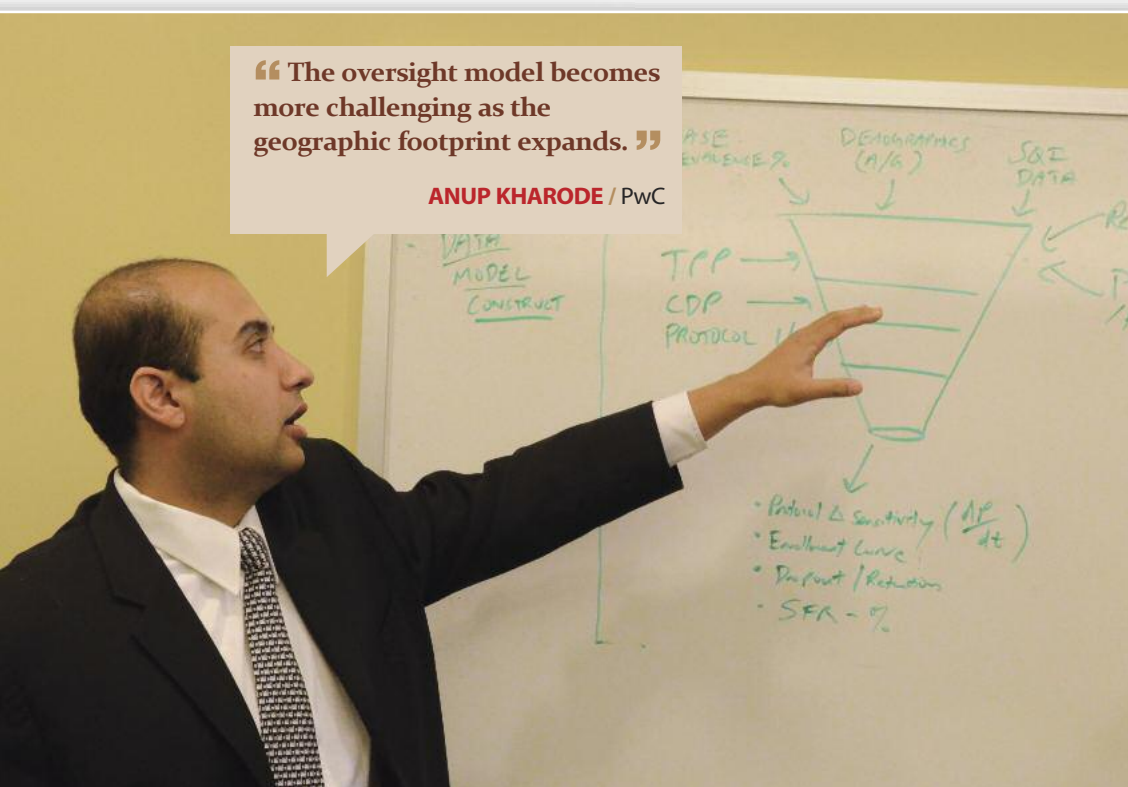
According to Mr. Kharode, it is mostly larger companies operating in multiple therapeutic areas that are using this model, and he expects smaller companies to continue using the transactional approach for the time being.

These larger contract service organizations have the capacity to address the needs of their larger clients. However, smaller companies are looking to find CRO partners of the right size and scale without compromising on quality and capabilities.

“A strong record of regulatory compliance, a focus on quality, and meeting project time-

“The oversight model becomes more challenging as the geographic footprint expands.”

ANUP KHARODE / PwC



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September - Global Product Registration

October - Global IT

lines for deliverables is essential to help meet the challenges that life-sciences organizations face,” Mr. Srivatsan says.

Once a relationship is established, it is in both partners’ best interest to maintain it, Mr. de Vries says.

“While choosing a service provider may be based on reducing costs, smart sponsors will seek out and keep an outsourcing relationship that is anchored on the metrics of ultimate delivery of data,” he says.

Global or Local, Challenges Are the Same

Outsourcing in general has its own set of challenges, and those, plus a few more, are present in a global outsourcing situation.

“Outsourcing is outsourcing and some of the challenges are consistent whether talking about local or in-country or global,” Mr. Kharode says.

Challenges specific to global R&D outsourcing include managing regulatory considerations and implementing oversight processes to manage quality and operational efficiency.

“Implementation of operations and dealing with regulatory challenges are the key differences in the global environment,” Mr. Kharode says. “Depending on any number of factors, including type of product, disease area, geographies, and local regulations can get quite complicated.”

Another key challenge of global R&D outsourcing pertains to change management.

“Organizations will have to spend time and effort to ensure that the change in the operating model is well-received and adopted to ensure success in outsourcing,” Mr. Srivatsan says.

Organizational change is always a challenge and in the case of outsourcing, while it can create an opportunity for people to do a better job, it will not fix an underlying problem, Mr. de Vries says.

“It’s a shame that some companies view

outsourcing as only a way to go from a fixed-cost to a variable-cost model, or just as a way to save money,” he says. “Unfortunately, some people think they can fix how well their organization is managing clinical development through the process of outsourcing alone, without thinking more holistically about business processes.”

The more successful life-sciences companies — in terms of reaping the benefits of outsourcing — will be those that view the outsourcing process as a time to determine the best metrics to manage the outsource provider, which elements inherent in the former processes can be challenged and changed, and ultimately what needs to be done differently when outsourced, Mr. de Vries says.

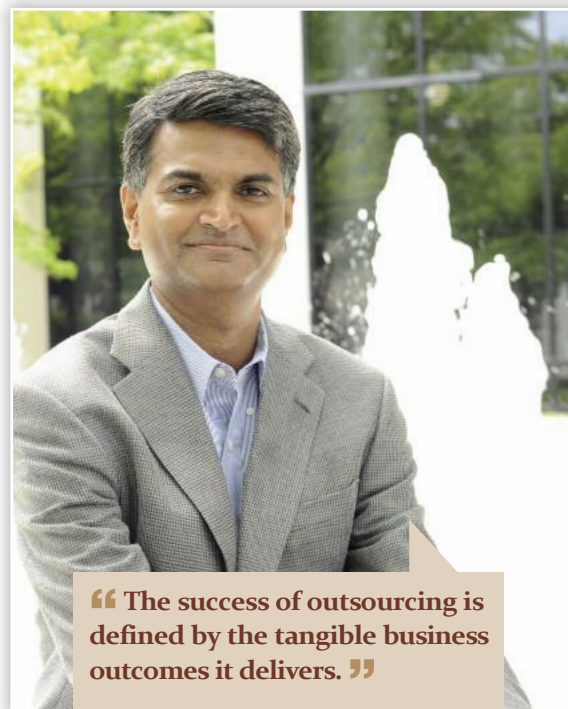
“Anytime work that has been typically done by one group of people is transferred to another group of people it creates an opportunity for change and improvement that is easier to capitalize on than if the original group was asked to do the task differently themselves,” he says.

In addition to the ever-increasing focus on cost and the business questions around choosing an outsourcing partner, quality is another concern that keeps R&D folks up at night.

“Ultimately, any success that a company has in terms of getting a product to market will depend on the data generated out of its trials in those out-of-country geographies, so quality is going to be the utmost concern,” Mr. Kharode says. “A lot depends on how those risks are being monitored.”

Mr. de Vries agrees, and cautions the industry to avoid choosing an outsourcing partner by cost alone.

“The life-sciences industry cannot be driven only by price, as it is held to the ex-



“The success of outsourcing is defined by the tangible business outcomes it delivers.”

NAGARAJA SRIVATSAN / Cognizant

tremely high standards of the regulatory agencies in the world and by ethical and moral obligations,” he adds. “The industry must always make sure it doesn’t sacrifice quality for cost.”

Focusing on efficiency, cost, and quality will create the best foundation for global R&D outsourcing, Mr. de Vries says.

“There are huge opportunities for pharma in terms of generating revenue faster by having an efficient development operation,” he says. “This is also an opportunity for outsourcing companies to more aggressively improve their own processes to make their outsourcing services more efficient.” PV

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GLEN DE VRIES. President, Medidata Solutions Worldwide, a global provider of SaaS-based clinical development solutions

that enhance the efficiency of customers’ clinical trials. For more information, visit mdsol.com.



ANUP KHARODE. Director, Global Pharma & Life Sciences, PwC, which provides assurance, tax, and advisory services to

proprietary, generic, and specialty drug

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NAGARAJA SRIVATSAN. Senior VP and Head of the Life Sciences Practices, North America, Cognizant, a global provider of

information technology, consulting, and business process outsourcing services. For more information, visit cognizant.com.