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Life Sciences and
Pharmaceuticals

Pharma's new worldview

Transforming R&D through
emerging markets



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Pharma's new worldview

Transforming R&D through emerging markets

To date, research and development (R&D) within the pharmaceutical industry has been dominated by a developed markets perspective. But as emerging markets change Pharma's worldview, it's time for drugmakers to fundamentally rethink how R&D is done.

Over US\$150 billion worth of products will lose patent protection over the next decade.¹ And late stage failures and safety withdrawals have wiped out tens of billions more in forecasted sales revenue. Even though Pharma handily outperformed the Standard and Poor's (S&P) 500 during the high-flying 1990s, the story has been the opposite for most of this decade. In 2005, the S&P 500 Pharma *lost* 3.4 percent of its value, while the overall S&P 500 gained nearly 5 percent.²

This steep financial challenge is forcing multinational pharmaceutical companies to consider a range of alternatives, including outsourcing and offshore opportunities. Like other industries, big Pharma has grown comfortable with certain offshore capabilities, such as manufacturing. But because they consider R&D such a defining capability, pharma companies have generally been hesitant to move R&D activities outside the firm – much less offshore.

Squeezed by shareholder and payer demands, these companies are now reevaluating that position and considering the possibility of performing selected R&D activities offshore. From our review of the pharmaceutical sector, however, it appears that offshore R&D remains a relatively untapped opportunity – one that big Pharma may not be prepared to exploit fully.

For the most part, Pharma's R&D business models are still skewed toward a developed markets perspective – witness how often research priorities are focused on the needs of developed nations and in-licensing opportunities from developed markets take precedence. To capture the full potential associated with emerging markets, our research suggests that pharmaceutical companies need to rethink some fundamental tenets of their R&D approach.

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The combination of pressure in home markets and promise in emerging markets is prompting Pharma to move R&D activities offshore.

What is pushing (and pulling) R&D offshore?

While pharma companies struggle to compensate for expiring patents, they face unprecedented pricing pressure and intensifying competition. Worldwide, the size of the elderly demographic group is growing, and government health organizations and insurance companies are desperate to reduce drug spend. In the United States, for instance, 10 states have banded together under the National Medicaid Pooling Initiative to negotiate significant bulk discounts.³

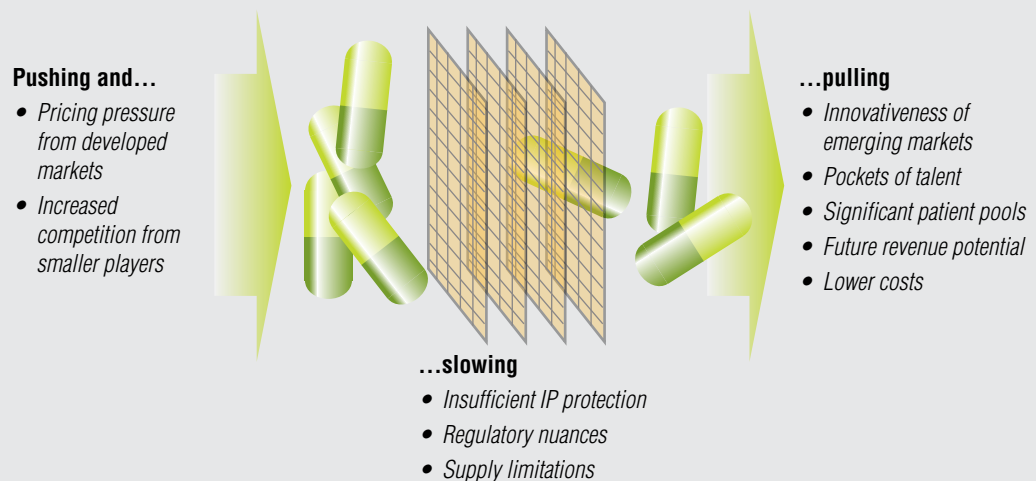
On the competitive front, an increase in available funding has opened the door for smaller players. Public funding, private philanthropic donations and venture capital are on the rise – and often are either specifically earmarked for small businesses or directed toward their prime research areas.

For example, the Taiwanese government invested US\$1.6 billion in biotechnology venture capital firms between 2002 and 2006.⁴ Along with its funding, the US government provides an additional perk, allowing small businesses to retain intellectual property (IP) rights.⁵

Affordable technology is breaking down market-entry barriers as well. Grid technology now allows fledgling companies access to the kind of computing and data storage capacity that was previously available only to major players.

As they become better funded and equipped, smaller biotech companies and contract research organizations (CROs) are emerging as competitors, not just research partners. Between 2000 and 2004, the global biotechnology market grew by 11.5 percent to reach a value of US\$114.1 billion.⁶

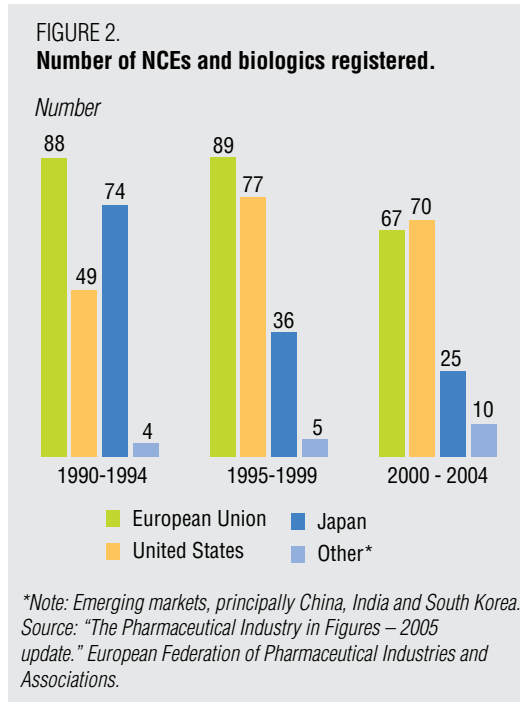
FIGURE 1.
Pharma is being shoved and tugged in the same direction.



Source: IBM Institute for Business Value analysis.

In addition to the forces pushing R&D offshore, emerging markets have several characteristics that are attracting pharmaceutical companies:

Innovation investment – Emerging countries are beginning to invest more significantly in R&D. For example, six of India's top pharma companies increased R&D expenditure by more than 20 percent between 2003 and 2005.⁷ Not surprisingly, innovation is following, as measured by registration of new chemical entities (NCEs) and biologics (see Figure 2). In addition, recent improvements in patent protection in emerging nations like China and India could encourage even more R&D investment in the future.



Talent – Though suitable talent in emerging markets is generally limited, specific skills are plentiful in certain countries. For example, as of 2005, India had over 115,000 scientists with Masters degrees in Chemistry, and 12,000 more with Chemistry Doctorate degrees.⁸

Such numbers will also likely grow as Western-trained Indian and Chinese scientists, who are now working in developed nations, decide to move back to their home countries.

Clinical trial participants – Emerging countries can offer huge pools of naïve patients (by naïve, we mean individuals not previously exposed to other drugs that might interfere with testing). This can prove especially beneficial when working in therapeutic areas like oncology and anti-infectives where the cost of clinical trials is high (see Figure 3). Possibilities are particularly high in China and India, given population size and the presence of multiple ethnicities.

Consumers – Even though drug spend per capita is still low in emerging nations (US\$10 in China versus US\$623 in the United States), population size and growing economies make them attractive markets long term.⁹ By 2035, the emerging nations of Brazil, Russia, India and China (the BRICs) are expected to represent a full quarter of the global pharma market.¹⁰

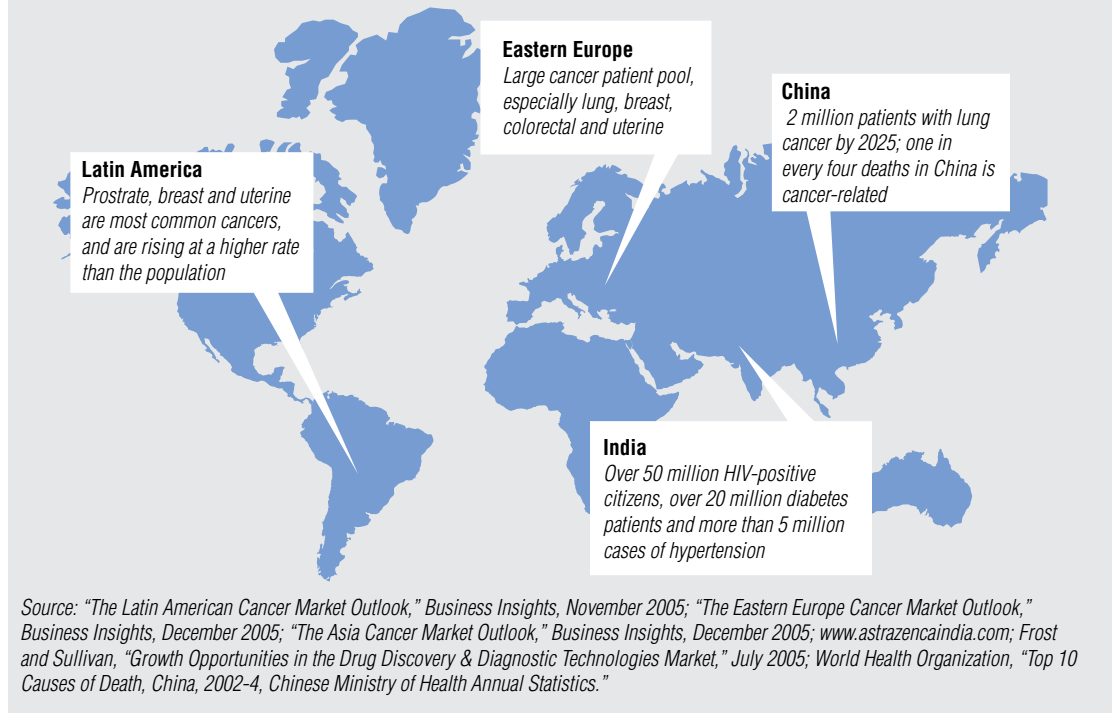
Cost – Obviously, lower costs in emerging countries are a major benefit. Research in India costs 40 percent less than in the United States – and developing a new drug in India can cost a tenth of what it does in the West.¹¹

What is slowing it down?

Given all of these reasons for moving some portion of R&D offshore, why have companies hesitated?

Perhaps the most publicized concern has been intellectual property protection. For example, in July 2004, the Chinese patent review board overturned Pfizer's Viagra patent, allowing more than a dozen domestic drugmakers to use Viagra's main ingredient. Nearly two years later, Pfizer won its appeal with the country's State Intellectual Property

FIGURE 3.
Significant patient pools exist in emerging markets.



Before big Pharma can operate comfortably in emerging markets, it must believe patents are safe, regulatory environments are suitable, and resources are accessible.

Office. However, this may not be the final chapter, since one of the Chinese generic drug firms is considering an appeal of the June 2006 ruling.¹²

Despite China's adoption of a stronger patent protection structure, many pharma companies remain skeptical about enforcement. In India, the story is similar. The Director General of the Organization of Pharmaceutical Producers of India estimates that there are 10,000 small domestic companies creating copycat drugs for the local market.¹³ Even with newly enacted laws, it will take time for India to establish a proven track record. But as emerging markets create more of their own IP – and seek to protect it – we anticipate a commensurate increase in patent enforcement.

Each emerging region also presents its own challenges in terms of regulation. For example, China has laws restricting the export of genetic material such as blood and biopsy specimens, while India has special regulatory guidelines related to animal experimentation.

Early movers have found that high absolute numbers of skilled labor in major emerging markets do not necessarily guarantee the presence of specific skills. And even where an acceptable number of skilled individuals exists, the talent is not always accessible because of barriers such as language or insufficient connectivity in rural settings. Other resources besides people are often in short supply as well – like raw materials for chemistry services.

Working in emerging markets involves refocusing on neglected diseases that are devastating those nations.

Rethinking the R&D business model

Despite the hurdles, the promise of near-term cost relief and long-term growth make offshore R&D an attractive proposition for large pharmaceutical firms. But based on our analysis, we believe companies need to rethink four key aspects of their R&D approach before they can fully exploit this opportunity:

- Research focus areas
- R&D activities to perform offshore
- Optimal locations
- Business model alternatives

Research focus areas

With its old worldview, Pharma could rationalize abandoning research in certain therapeutic areas because those diseases were largely contained in developed nations. However, rising social consciousness has drawn attention to these so-called *neglected diseases*.

Poorer countries faced with life-threatening diseases are demanding the ability to produce their own generic drugs without permission from patent holders or to buy unauthorized generics from manufacturers in other countries. Based on what we see happening in the marketplace, it seems pharma companies face an important choice: find a way to collaborate with emerging countries, or expect them to rise up as fierce competitors.

Some smaller competitors have already targeted this Pharma portfolio gap and are focusing primarily on neglected diseases – and the accompanying public funds – to fuel their growth. For example, US drugmaker Immtech is pursuing an area “long ignored” by large pharmaceutical companies: oral drugs for the treatment of infectious diseases in developing nations.¹⁴ The company receives approximately half of its funding from public

sources, including the Medicines for Malaria Venture (MMV) and the Gates Foundation. Also through its relationship with the MMV, the company has obtained discounted rates from the CRO, Quintiles, (for assistance with clinical trials) and from the Swiss Tropical Institute (for parasitology services).¹⁵

In response to these types of competitive threats, pharma firms are revisiting abandoned research areas and trying to find more profitable approaches. For instance, some companies are concentrating on early discovery and relying on public partners for clinical development. In 2005, half of big Pharma’s research on neglected diseases involved public-private partnerships (PPPs) and philanthropic donations.¹⁶

As companies seek to serve emerging markets, there will likely be other shifts in their research portfolios. They may choose to tackle medical challenges that are particularly acute in specific regions, such as hepatitis in China. Pharma companies also have the opportunity to combine conventional medicine with natural medicines indigenous to certain locations.

Collaborating internationally to save lives

Novartis’ anti-malarial drug Coartem was codeveloped with the two Chinese partners that supply its active ingredients: Kunming Pharmaceutical Corporation and Zhejiang Medicine Company. Interestingly, one of its core ingredients is derived from China’s sweet wormwood plant, which has been used for centuries in traditional Chinese medicine.

With a 95 percent cure rate, the drug is proving critical in the battle against malaria, which claims more than one million lives each year – the majority of which are African children. As part of its philanthropic efforts, Novartis is providing Coartem at cost (US\$2.40 for adult treatment and US\$0.90 for children) to developing countries where the disease is endemic.¹⁷

**Emerging markets R&D
should include the R,
not just the D.**

PPPs' impact on research

GlaxoSmithKline (GSK) participates in several PPPs, such as the MMV, the Malaria Vaccine Initiative, the International AIDS Vaccine Initiative (IAVI), the Global Alliance for TB Drug Development and the Aeras Global TB Vaccine Foundation. These collaborations provide funding to do research of utmost importance to developing nations, including diseases such as malaria, HIV/AIDS and tuberculosis.

For example, in the HIV/AIDS area, GSK launched a PPP with the IAVI to develop an AIDS vaccine; IAVI is providing technical expertise and funding, while GSK and IAVI will establish a joint research team. In November 2005, the company announced it would also be working with the Institut Pasteur on AIDS vaccine research. This project is enabled by a €5.5 million grant from the European Union. GSK is also supporting clinical trials sponsored by organizations, such as the World Health Organization, the UK's Medical Research Council and the US National Institutes of Health.¹⁸

One valuable exercise pharma companies can undertake is evaluating their existing portfolios against the special needs of emerging markets. Existing drugs, diagnostic tools and treatments often require adaptation before they can be considered viable solutions. For instance, observation-based practices – such as the common tuberculosis treatment regimen known as “directly-observed therapy, short-course” – are simply impractical for developing nations: patients cannot afford the cost of direct supervision (in this case, daily drug administration for six to eight months) and may not live near treatment facilities.¹⁹

R&D activities to perform offshore

Compared to Research, the Development stage of R&D is more labor intensive, and spending on Development constitutes about 70 percent of the total cost of R&D.²⁰ In fact, more than half the cost of bringing a new drug to market is tied to clinical trials.²¹ As a result, shifting Development activities to countries where labor costs are lower can make a substantial financial impact. Not surprisingly, this is where many pharma firms initially focus. Clinical trials and related data management are frequently the first R&D activities moved offshore.

But based on our industry assessment, we believe pharmaceutical companies are only beginning to explore offshore possibilities in the *Research* stage. Driven primarily by a shortage of chemists in the West, most of the Research activity performed offshore to date has been focused on chemistry. For example, Eli Lilly is outsourcing about 20 percent of its early-stage R&D – mainly chemistry – to China, and Wyeth has announced a US\$40 million outsourcing agreement with GVK of India for synthetic chemistry services.²²

And yet other discrete discovery activities, such as bioinformatics and absorption, distribution, metabolization and excretion (ADME), are attractive targets for offshore work too. ADME is a historical bottleneck in the discovery process – but specialized outsourcing centers can often accelerate the normal turnaround. Currently, just over 50 percent of large pharma companies have outsourced some portion of their ADME activity. That percentage is expected to grow to 94 percent by 2008, creating an enormous market opportunity for potential outsourcers in both developed and emerging markets.²³ Another boon for research, emerging nations often provide a more flexible regulatory environment that allows some controversial types of research, such as stem cell research.

Perhaps one of most underexploited Research opportunities is in-licensing. In the US pharma sector, 73 percent of big Pharma R&D spend still goes toward developing self-originated compounds.²⁴ The fraction that is spent on in-licensing has predominantly been in developed markets. Companies have barely scratched the surface of in-licensing possibilities worldwide.

Tapping India's innovativeness

Cipro XR was the first India-developed drug launched in a global market. Bayer licensed the compound from Ranbaxy in 1999 and subsequently introduced it in the United States in 2003.²⁵ Others are expected soon.

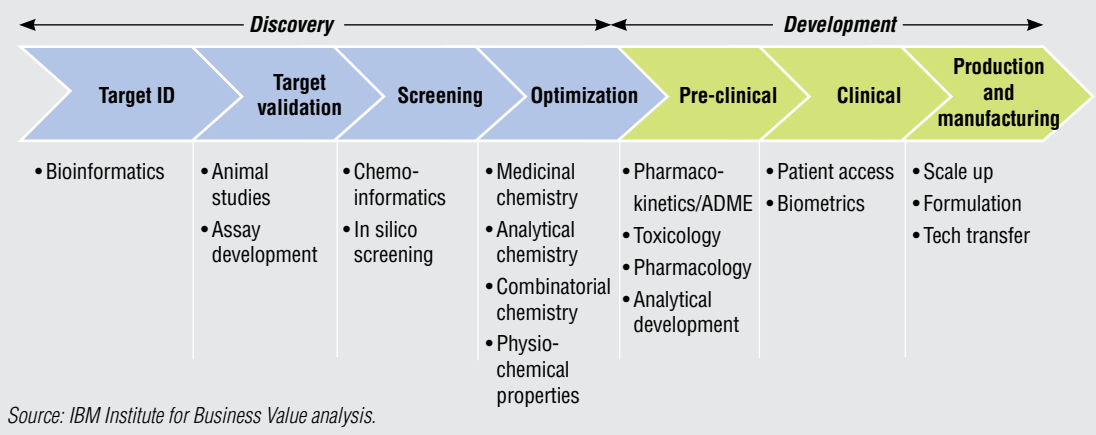
Ranbaxy licensed a uroselective beta blocker to German drugmaker Schwarz Pharma AG in 2002, and Torrent sold first right of refusal for a hypertension treatment molecule to Swiss-based Novartis in 2004.²⁶ More recently, Glenmark licensed a PDE-4 inhibitor for asthma and chronic obstructive pulmonary disease to Forest Laboratories for the North American market and to Teijin Pharma for the Japanese market. Together the two deals totaled US\$243 million.²⁷

Looking across the R&D lifecycle, we believe certain activities are better suited for offshore work than others. For us, the candidates in Figure 4 stood out because they:

- Currently cause bottlenecks in the process (primarily due to skill shortages)
- Offer opportunities to reduce cost without compromising quality
- Rely heavily on patient pools, which are often larger or more effective in emerging markets
- Take advantage of skills and technologies that may have already been acquired through drug manufacturing experiences.

When making decisions about which activities to transfer offshore, it is important to consider the impact a particular move may have on other activities. For instance, some companies that opted to perform "commodity" services like clinical data management offshore subsequently encountered knowledge management challenges. It became more difficult for in-house data management staff and statisticians to learn from the data on an ongoing basis.

FIGURE 4.
Top candidates for offshore work



Candidate countries should be evaluated against a full set of business, scientific, political and economic criteria – not just cost benefits.

Considering potential consequences upfront allows companies to avoid pitfalls or at least mitigate negative outcomes.

In addition, as companies begin to sell into emerging markets, their choices of what to do in which location will likely change. For instance, it is easier to manage the regulatory approval process when performing those activities within the target market.

Optimal locations

Historically, it seemed simpler for large pharma companies to conduct the majority of R&D in their home markets. After all, new drug approval typically hinges on at least 60 percent of the trials being conducted in the main demand market, and the efficacy of 30 percent of all drugs is impacted by ethnicity. Simply from an efficiency standpoint, it made sense for certain functions to be performed in close proximity.

But the old decision-making rules are changing as companies target emerging market consumers and financial dilemmas force companies to break apart tightly coupled processes. The maze of location options can seem overwhelming, but huge patient pools, underexploited talent and flexible regulatory environments are waiting to be found.

Certain combinations of research area and R&D activity will naturally point toward particular countries, for instance, because of their patient pools or skills. However, companies should consider a cross-section of factors, such as:

- CRO industry maturity
- IP protection status and an adequate legal system (including enforcement) to protect confidentiality of data and processes
- Relevant cost and time benefits (e.g., trial start-up time in India is five months, as compared to nine months in China)²⁸
- Test population potential
- Skills and experience of available professionals
- Workforce productivity, flexibility, motivation and loyalty
- Labor regulation flexibility
- Accreditation process and prevalence of accredited labs (for example, adherence to Good Laboratory Practice)
- IT and infrastructure availability (e.g., property, communications, transportation, adequate quality of life to attract necessary expatriates)
- Local tax breaks, grants and other incentives
- Impact on corporate tax.

Each of these factors needs to be evaluated in depth. For example, the skills assessment should not only include scientific skills, but also language abilities and technical expertise. In fact, engineering and IT skills will become more critical as pharma's view of therapy expands from just drugs to targeted treatment solutions – solutions that typically include diagnostic tests, monitoring devices and more technologically advanced delivery systems.²⁹

Because of the number of interrelated elements to be evaluated across a rather extensive list of countries, pharma firms are turning to sophisticated evaluation tools. Pfizer, for example, is using a program based on a multidimensional model that evaluates 30 different countries.³⁰

Business model alternatives

As discussed earlier, clinical trials and the associated data management have been pioneering offshore activities. Pharma companies now conduct up to 20 to 30 percent of

Simultaneously tapping talent and patient data

Although emerging countries produce sizable numbers of pre-med undergraduates, these students have limited abilities to engage in research in their home countries and often head West for a graduate degree and residency opportunities.

For example, India has more than 200 medical colleges, but less than 5 percent of those schools have research programs.³¹ Through academic alliances, pharma companies could establish on-campus research facilities and gain access to talented minds and the patient pools available in the university's teaching hospitals.

Imagine the value hidden away in the data produced in an Indian teaching hospital that treats 50,000 in-patients and more than 1 million out-patients each year. With India's data management experience in managing IT and other back-office business processes, it is well positioned to manage this kind of research data challenge.

FIGURE 5.
Avoiding typical mistakes in location selection.



The hot spot syndrome

Rather than select locations based on the best match to their needs, companies follow others' lead. Moving in mass only tightens the labor market in popular countries. It may be better to avoid "hot spots" than join them.



The scattershot approach

Some companies make the mistake of spreading their efforts across too many locations. Focusing on specific countries offers some key advantages, such as easier integration of onshore and offshore activities and a greater capacity to attract talent (especially after establishing local operations).



Financial myopia

Making location decisions based primarily on cost and tax advantages can leave companies exposed to other disadvantages, like insufficient talent. Almost always, there is a tradeoff between cost and quality of location.



General, not genuine, analysis

If companies rely solely on generally available statistics, they may overlook important risks and opportunities. A preferable approach is to assess risk through field verification. The analysis does not necessarily have to be intensive, but it should logically explain why specific locations are – and are not – selected.

Source: IBM Institute for Business Value analysis.

The strategic choice of business model will vary based on whether the activity is related to Research or Development, and where in the world the work is done.

their global clinical trial in emerging countries.³² And they are primarily doing so through outsourcing arrangements.

Many CROs are expanding their presence in Eastern Europe and Asia through alliances and acquisitions. Local CRO organizations are also emerging to serve multinational pharma companies. Since 2001, the growth in spending on contract research outsourcing (15 percent) has outpaced that of R&D (11 percent).³³

But a number of major players have decided to go direct. For instance, Eli Lilly, Sanofi, Novartis, GSK and Pfizer have all set up development operations in India.³⁴ In fact, pharma firms are using a full spectrum of business models from CROs to codevelopment to captive subsidiaries (see Figure 6).

The following factors will likely influence companies' decisions about which type of business model alternative is most appropriate for each venture:

- Their own mid- to long-term plans
- Internal management resources and experience in outsourcing/offshoring
- Whether they have other local operations in the country (e.g., Sales and Marketing, Manufacturing)
- The presence, size, and reliability of local external service providers (in terms of reliability, companies need to assess quality, speed and ability to protect confidential information)

FIGURE 6. Pharma companies are using a full spectrum of business models from CROs to codevelopment to captive subsidiaries.

CRO	Exclusive CRO	Codevelopment	Build/operate/transfer	Captive subsidiary
<i>Employing the services and expertise of multiple partners to execute discrete tasks or maintain redundancy in operations</i>	<i>Maintaining a strategic, sole-source relationship (vs. project by project), which often involves dedicated personnel</i>	<i>Collaborating jointly with another enterprise on the development and management of a globally sourced component</i>	<i>Using a third-party service provider to oversee the development, launch and short-term management of operations, which it then transfers back to the company</i>	<i>Funding the development of a company-owned and managed operation beyond the company's existing geographic footprint</i>
Novartis seeks collaboration worldwide, including CRO agreements with Syngene to support new drug discovery and development and with Jubilant Biosys for bioinformatics services	Pfizer strategically outsources its chemistry services to ChemBridge, using Russian resources to design and develop custom compound libraries to supplement Pfizer's existing libraries	GSK has tightened an alliance with Ranbaxy, under which Ranbaxy identifies new promising drugs and performs preclinical trials, while GSK performs later stage developments and retains the right to market the drugs in all countries except India	Shanghai ChemPartner provides a turn-key model for Eli Lilly. It set up and now operates the joint venture chemistry lab, ChemExplorer. Eli Lilly has the option to buy the entire operation over time	Eisai has made a strategic decision to set up its fourth global drug discovery site in India and will concentrate on drugs for unmet needs across Asia and Africa
Fully external	Ownership			Fully internal

Source: IBM Institute for Business Value analysis of company Web sites; "Outsourcing in Drug Discovery, 2nd Edition." Kalorama Information, January 1, 2006; Miller, Jim. "First Impressions." Pharmaceutical Technology, July 2006.

- The risk-adjusted cost of the various options (i.e., costs adjusted for risk of delays due to insufficient local expertise or relationships and likely labor rate increases required to retain resources over time).

As companies move Development activities offshore, we suggest a staged approach to increase flexibility. For instance, firms can use international CROs that have offshore operations to test the waters before making major financial commitments. CRO agreements can be structured so that operations can be transferred back in-house at some point. Then, periodically, companies should evaluate which markets and locations warrant a more significant presence. Setting up their own operations in key strategic markets can help companies capture more of the cost-saving potential and retain know-how. Over time, this approach allows firms to adopt a hybrid position with a direct presence in a few critical markets and an indirect (CRO) presence in minor or unproven markets.

For offshore Research, we believe companies should selectively pursue risk- and profit-sharing ventures in countries that enable special avenues of research, such as stem cell or traditional medicine.

What's your view?

As competition and opportunity continue to reshape how you view the rest of the world outside your main demand markets, here are some questions worth thinking through:

- Are we approaching offshore options strategically or primarily to cut costs?
- How far down the research agenda do we have to go to find a research area focused on emerging markets' priorities?

- How can we collaborate with emerging countries to find affordable, practical treatments for neglected diseases?
- Do we know which of our existing treatments are impractical for emerging markets and why?
- What percentage of our clinical trials and associated data management are performed outside the main demand market? What is a reasonable upper limit?
- Thinking beyond Development, which Research activities are we planning to send offshore?
- Are we equipped to collaborate interactively on a worldwide scale?
- How much innovation are we buying from emerging markets? What percentage of our pipeline is still based on self-originated compounds?
- Are we using a structured method for evaluating and selecting offshore activities and locations?

Don't be surprised if your answers expose a developed markets bias. Though some early movers have shifted selected activities to emerging markets, our analysis suggests that offshore R&D remains an underexploited opportunity for Pharma – particularly in the area of Research. But by rethinking their fundamental approach to R&D, we believe pharmaceutical companies can expose phenomenal opportunities for innovation and financial gain.

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Acknowledgments

The authors would like to thank our IBM Life Sciences and Pharma colleagues from China, India and Japan and the IBM Research staff in Russia, who all provided valuable insights for this paper.

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