THE BOSTON CONSULTING GROUP

Looking Eastward

Tapping China and India to Reinvigorate the Global Biopharmaceutical Industry

BCG | REPORT

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AUGUST 2006

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Note to the Reader

The global biopharmaceutical industry is ailing. The main symptom is a slowdown in the output of new drugs. What's more, the number of high-earning "blockbuster" drugs going off patent could soon exceed the number of new blockbusters coming on-stream, and slowed growth and declining profits could result. This malaise is exacerbated by inexorably rising R&D costs and increasing price pressures.[1]

To the extent that the remedy is within the industry's control, the best opportunity for improvement probably lies in R&D—the activity that creates the most value for the industry in the long run. And one particularly exciting prospect for R&D lies in the East.

Biopharma executives are already pursuing some of those opportunities, but often in a piecemeal and merely tactical fashion. To get optimal value from their offshoring ventures, they need to see the big picture and build an integrated strategy on that basis.

In this report, we explore how biopharma executives can assess the potential offered by offshoring R&D to China and India, and we provide some guidance and prescriptions for integrating both countries into a global R&D strategy. The three main sections of the report address

- the current state of play in biopharma R&D in China and India and the primary benefits and risks involved in offshoring R&D
- the specific opportunities afforded by each country and across the R&D value chain
- a framework for developing an offshoring strategy for China and India

Throughout the report we highlight the relevant differences between the two countries and suggest how best to take advantage of what each one has to offer. The report reflects the level of capabilities and services available in early 2006, but the reader should bear in mind the rapid pace of change in such an energetic marketplace.

This report, one in a series from The Boston Consulting Group examining ways to improve R&D productivity, amplifies themes raised in two previous reports in the series: *A Game Plan for China: Rising to the Productivity Challenge in Biopharma R&D* (BCG Focus, December 2005) and *Harnessing the Power of India: Rising to the Productivity Challenge in Biopharma R&D* (BCG Focus, May 2006).

If you wish to explore further the R&D opportunities in China and India and how best to take advantage of them, please contact one of the authors:

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1. For a full discussion of the challenges the industry is facing, see *Rising to the Productivity Challenge: A Strategic Framework for Biopharma,* BCG Focus, July 2004.

Acknowledgments

We would like to thank BCG's India and China offshoring team—Guninder Bajwa, Gracia Gu, Tony Lau, and Kanishka Raja—for their invaluable efforts in undertaking the analysis and research supporting this report. We would also like to acknowledge our BCG colleagues Priya Chandran and Paresh Vaish for their insights and constructive criticism. And we are deeply grateful for the invaluable contributions of industry participants and experts.

Finally, we thank John Kahn and Mary DeVience for their writing and editing assistance, and Barry Adler, Gary Callahan, Kim Friedman, Gina Goldstein, and Sharon Slodki for design, editorial, and production assistance.

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Summary of Key Findings

As threats to their profitability loom, multinational pharmaceutical companies (MPCs) should take a strategic look at increasing their R&D offshoring to China and India.

- The two countries offer a vast and inexpensive talent pool, fast-growing R&D capabilities and resources, and a huge, treatment-naïve patient population
- By tapping these resources, MPCs stand to gain greater flexibility in capacity and pipeline management, in addition to considerable cost savings
- Offshoring R&D today may also be the key to unlocking rich commercial rewards, especially in China

Despite general similarities, each country offers distinct advantages.

- The best near-term opportunities in both countries are chemistry-phase activities and clinical trials, although India has more complete service offerings in these areas
- Preclinical and biology activities represent medium- and long-term opportunities, respectively, with China outpacing India in innovative biology
- Government backing for biopharma R&D, although it has been increasing impressively in India recently, remains far more committed and generous in China
- India has a more extensive vendor base, a work force fluent in English, and generally better intellectual property (IP) protection

The most significant difference between China and India as offshoring destinations lies in their overall value propositions.

- India offers MPCs a fairly fast and long-lasting payoff by turbocharging their R&D productivity quickly and sustainably
- China invites MPCs to place a strategic bet on increasing their share of the burgeoning commercial market for pharmaceuticals in both the near and the longer term

Most R&D activities currently offshored to China and India have been initiated in an ad hoc and uncoordinated way. Future efforts should be more conscientiously managed, ultimately as part of an integrated engagement strategy.

- MPCs' offshoring strategy should involve *both* countries in both the near and the longer term
- The preferred short-term option will tend to be India, where an ever-increasing selection of activities across the R&D value chain can be outsourced to local vendors
- For the longer term, China's considerable commercial promise can best be exploited through captive R&D sites rather than through piecemeal outsourcing

A three-part framework would help biopharma executives craft their R&D strategies for Asia.

- Using different scenarios of how various external variables might play out, executives should develop a vision, shared by key stakeholders, of how the company's offshoring efforts in China and India will proceed
- They should choose the optimal business model and migration path for the company's offshoring effort
- They should carefully manage the execution of the offshoring strategy to ensure rigorous implementation

Looking Eastward

China and India have become R&D hotbeds and the offshoring destinations of choice for multinational companies (MNCs) in a range of industries. Whether in automotive parts, telecommunications, or computer software, MNCs already operate some 180 R&D centers in China and more than 100 in India. Motivated by such incentives as low costs, high levels of technical skill, and shrewd government policies, they are increasing Asia's role in their global R&D networks. In a 2004 survey of senior executives at MNCs across all industries, China ranked first among the most favored offshore bases for R&D; India ranked third, just behind the United States and just ahead of the United Kingdom.[2]

In this flurry of offshoring activity, the global biopharmaceutical industry lagged, largely because the regulatory and competitive environment in China and India was not conducive to MPC investment until recently. But things are different now. Both countries are buzzing with bold and innovative biopharma R&D projects. Investment, both governmental and private, is soaring. New service providers keep springing up. Capabilities are becoming more sophisticated and more widespread—both driving and being driven by the steady increase in R&D work arriving from offshore.

Offshoring R&D Is Taking Off

Over the past three years, the major MPCs have been rapidly intensifying their offshoring activity. Each month brings reports of new R&D centers being established or new therapeutic areas being investigated in China and India. Almost all of the top 20 MPCs have outsourced chemistry work to China, and some—perhaps sensing the great commercial advantage that a captive presence might bring—have also bought or established laboratories of their own. Others have chosen to focus on collaborations with government-directed institutes, such as the Shanghai Institute of Materia Medica (SIMM). In India, MPCs are busier than ever assigning projects to local vendors, making captive investments, or entering into codevelopment alliances with Indian companies. AstraZeneca, for example, has invested in a captive R&D center in Bangalore, where its new tuberculosis candidate drug molecule is undergoing final development. In addition, the company has forged an exciting partnership with Torrent Pharmaceuticals to work on a drug for hypertension.

MPCs have also been expanding the range of activities they are prepared to move offshore, particularly in India. Already comfortable offshoring some chemistry work (such as analog preparation and compound synthesis) and some clinical development (notably clinical data management and biostatistics), they are increasingly entrusting more ambitious activities—or whole stretches of the value chain—to Indian expertise: in vitro pharmacology to GVK Biosciences, for instance, and end-to-end chemistry to Torrent Pharmaceuticals.

The Benefits of Offshoring Are Numerous and Varied

Offshoring R&D work to China and India has three main attractions for MPCs: 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 cost savings could run as high as 60 percent or even 80 percent on salaries in the discovery phases, and as high as 60 to 70 percent in cost per patient in clinical trials. Although some of these savings could be canceled out by the costs of managing activities remotely and by lower productivity in the offshore location, well-run projects should help smooth in-house work flows and relieve capacity constraints in the development pipeline.

When it comes to tapping the two countries' capabilities and resources, consider these advantages:

A Huge Talent Pool. 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

2. The Economist Intelligence Unit, *Scattering the Seeds of Invention: The Globalisation of Research and Development,* September 2004.

the master's level. Even allowing for some variable standards of training, the supply of scientists and technicians (with a few exceptions that will be discussed below) seems reassuringly abundant. And India's graduates—or the great majority of them—offer the bonus of full proficiency in English.

Considerable Government Support. In China, life sciences research, having evolved mainly in state-funded research institutes, has a tradition of government sponsorship. (See the sidebar "China's Biotech R&D Is Underwritten by the Government.") Now private and semiprivate companies, too, can receive financial backing from the state in the form of both earmarked funds and tax advantages. What's more striking, perhaps, is the impressive involvement of the Indian government in promoting India's biopharma industry. After all, the country's R&D tradition, unlike China's, is one of energetic private entrepreneurship. India's Department of Biotechnology, established in 1986, has funded more than 1,800 R&D projects, helped to develop 12 vaccines, and transferred to the biotech industry 54 technologies, of which 17 have now been commercialized.

An Increasingly Favorable Infrastructure. A network of life sciences parks has developed in both countries. As of the end of 2005, there were some 60 in China—too many, perhaps, for the current workload—and 5 were fully operational in India with 17 more in progress. These parks, while raising the efficiency of the local vendor base, are also offering MPCs the basic amenities to set up shop and are throwing in several fiscal and regulatory incentives for them to do so. In addition, private companies and institutes are investing generously in new laboratories and research centers equipped with up-to-the-minute technologies.

A Burgeoning Market. Another great attraction of offshoring R&D to China and India is the potential commercial payoff. China is expected to become the world's fifth-largest pharma market by 2010. Its spending on pharmaceuticals, which came to $12 billion in 2005, is predicted to reach $37 billion

CHINA'S BIOTECH R&D IS UNDERWRITTEN BY THE GOVERNMENT

In the 1950s the People's Republic of China set about centralizing and regimenting the country's R&D activities, assigning them to various ministries and to the Chinese Academy of Sciences instead of to the universities. Biotech R&D was strongly agricultural, rather than pharmaceutical, in emphasis. One early biotech success was a method of chemically synthesizing bovine insulin for diabetes research. But political disruptions in the 1960s made life difficult for scientists, even before the Cultural Revolution of 1966 to 1976, and it was not until the reforms of the late 1970s that R&D in the life sciences regained prominence on the country's official wish list. And R&D in pharma proper, not just agricultural biotech, began finding its way onto the agenda.

In 1983 the government set up a dedicated coordination center for biotech R&D, and in due course various biotech projects began receiving proper funding from the so-called 863 Program. Among those projects was the one that produced the antiviral and anticancer treatment Interferon alpha 1b in 1987.

In the 1990s the industry received a further boost from various government moves: administrative restructuring, investments into quasi-venture-capital funds, and, in 1993, the new policy of granting patents for medicines. Around the turn of the century, biotech R&D gained much prestige and impetus from the sequencing of the rice genome, from China's involvement in the Human Genome Project, and from the influx of capital and experienced graduates returning from abroad. Biotech companies proliferated.

Today public funding and support remain at generous levels. The 863 Program directs more than a quarter of its funding to biotech initiatives. From 2000 to 2005 an annual average of $600 million in public funds went into China's biotech sector. The government's current Five-Year Plan specifies biotechnology and innovative drug discovery on its list of key focus areas. And the government maintains incentives, such as tax perks and import-duty exemptions, to create optimal conditions for the purchase of equipment and for technology transfer.

The government's support for the industry is already bearing fruit. Recent innovations include an HIV inhibitor, an HIV vaccine, and a SARS inactivated vaccine, all of which are in Phase I clinical trials.

by 2015. (See Exhibit 1.) MPCs with an entrenched R&D presence in China can look forward to finding favorable openings to tap this market.

India is less of a draw in this respect. Its market is dominated by generics more than China's is, and the branded drugs sold there tend to be priced markedly lower than those sold in China. India's outlay on pharmaceuticals was $5.3 billion in 2005 and is predicted to reach $16 billion by 2015.

China and India Have Differing Advantages as Offshoring Destinations

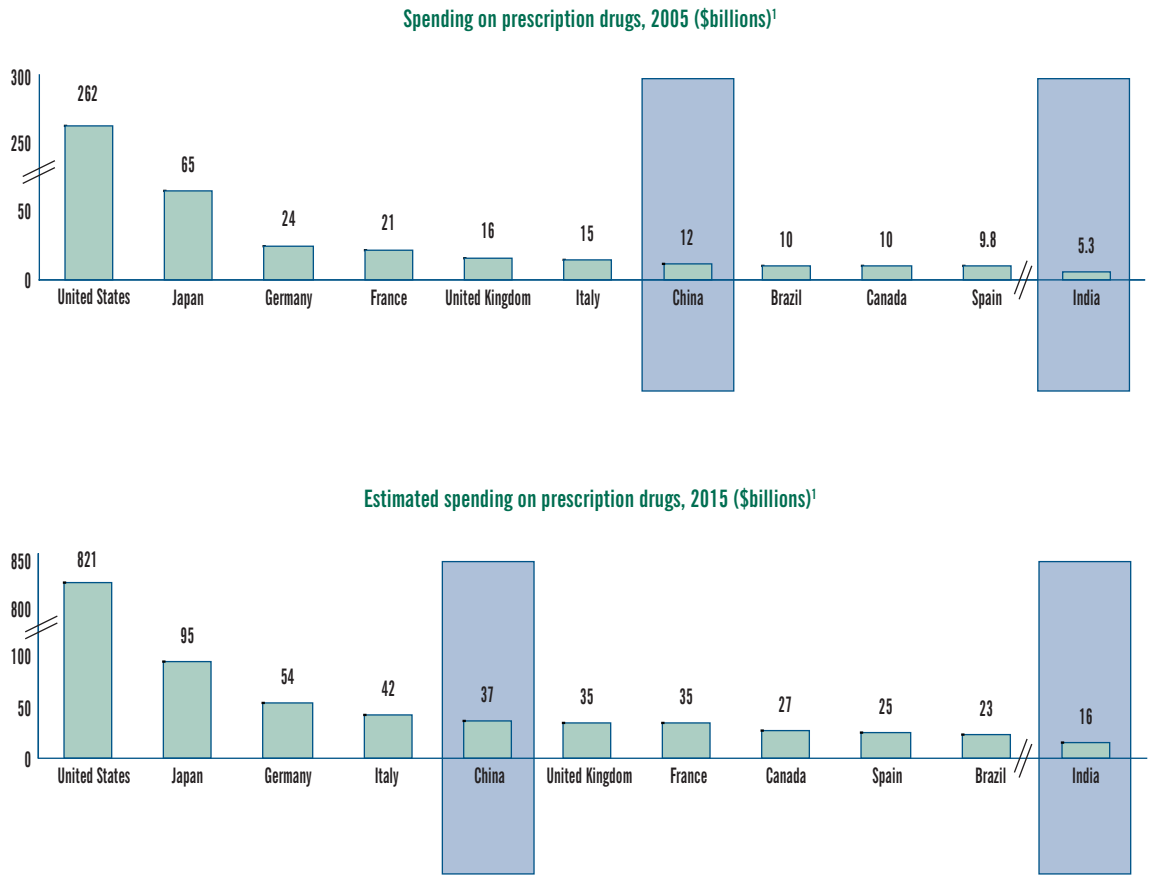
Most of the benefits of offshoring apply, in varying degrees, to both countries. But there are many differentiating factors that executives of MPCs need to consider before choosing the destination for specific R&D initiatives and developing their strategy for China and India. (See Exhibit 2, page 10.)

Viewed broadly from the perspective of strategy and investment, the attractions of the two countries can be summarized as follows: India offers a near-term and long-term productivity boost, whereas China offers lucrative near-term and long-term commercial prospects, in addition to productivity gains. India is where MPCs can turbocharge their global R&D engines, improving their cost-effectiveness and productivity levels markedly. China is where they can place their strategic bets, not just to enjoy the rewards of a vibrant R&D landscape but also to win better access to a large and evolving commercial market.

India's special advantage resides in its vendor base, which is abundant, nimble, and resourceful. It can achieve voluminous high-quality output at low cost, enabling MPCs to pursue vastly more leads, maintain a far smoother flow through the pipeline, and boost their overall efficiency and flexibility.

EXHIBIT 1

THE PHARMACEUTICAL MARKETS IN CHINA AND INDIA ARE EXPECTED TO EXPERIENCE DRAMATIC GROWTH



SOURCE: IMS Health and BCG data and analysis.

[1]Prescription drugs include patented and generic formulations.

The investment decisions of MPCs that take a more commercial view of things, however, might be swayed by the approaching bonanza of China's pharmaceutical market. By pursuing R&D in China, a company can position itself favorably in several ways:

- Ambitious R&D projects, especially on emerging-country diseases, can establish an MPC's name and image with medical officials and public alike.
- Clinical trials can bring the company into closer contact with hospital administrators and physicians who influence the sale of drugs.
- Above all, investments in R&D will impress government officials. The Chinese government is eager to raise Chinese technology to Western levels, and an MPC that brings new technology into the country can expect to receive a proportional fund of governmental goodwill in return—and should find it easier to secure approvals and get on reimbursement lists.

What's at issue here is not so much whether to choose China or India—they are by no means mutually exclusive—as how to harness the specific strengths of *each* country while managing the various risks.

EXHIBIT 2

CHINA AND INDIA PRESENT DIFFERING VARIABLES IN THE OFFSHORING EQUATION

	China	India
GDP growth per year, 1995–2005	• More than 8 percent	• 6 percent
Macroeconomic competitiveness ranking[1]	• Midrange (risks from inflation, government interference, and withdrawal penalties)	• Midrange (risks from trade unions and withdrawal penalties)
Total foreign direct investment, 2004	• About $60 billion	• About $5 billion
Growth in domestic investment in pharmaceuticals	• $550 million in domestic investment, mainly from the government, in 2004, growing at a CAGR of 33 percent since 2001	• About $380 million in public and private domestic investment in 2004, growing at a CAGR of 53 percent since 2001
Domestic market for pharmaceuticals	• About $12 billion, growing at a CAGR of approximately 13 percent (China is projected to be the fifth-largest market by 2010)	• About $5 billion, growing at a CAGR of approximately 13 percent (high penetration of generic drugs, low prices on brand-name drugs)
Current R&D offshoring model for MPCs	• Mostly captive investment or collaboration with government research institutes	• Emphasis on vendor-based outsourcing with private companies
R&D capabilities	• Capabilities in basic chemistry and clinical trials • Emerging strengths in biology and preclinical trials	• Strong capabilities in basic chemistry, data management, and clinical trials • Emerging strengths in end-to-end chemistry and preclinical trials in rodents
R&D risk factors	• Slow trial approvals (9 to 12 months) • Understaffed and unpredictable regulatory authorities • Medium vulnerability on IP rights • Limited English-language skills	• Uneven infrastructure • Regulatory hurdles for sourcing genetically modified animals and importing human tissue and other biological materials • Low to medium vulnerability on IP rights • Looming capacity constraints in clinical trials

SOURCE: BCG analysis.

[1]World Economic Forum, Growth Competitiveness Index rankings, 2005.

The Opportunities: Where to Place Your Bets

As they welcome the R&D opportunities on offer in China and India, MPCs need to keep things in proportion. Risks remain, and the countries' capabilities are by no means uniformly world-class across the R&D value chain. In light of this unevenness, R&D activities can be classified as near-term, medium-term, or long-term opportunities. Exhibit 3 summarizes the two countries' current strengths and weaknesses in each of the major phases of R&D. However, the landscape is

EXHIBIT 3

THE TWO COUNTRIES PROVIDE A DIFFERENT MIX OF CAPABILITIES ACROSS THE VALUE CHAIN

	China	India
Biology research	**Status: some capabilities, rapidly evolving** • Innovative capabilities, mainly with government institutes • Established skills in basic molecular biology and protein expression • More than 100 small companies offering MPCs some modest services • Innovative research in stem cells, biochips, and gene sequencing • Expanding biology talent pool	**Status: few capabilities, evolving** • Few innovative capabilities, mainly with government institutes • About five companies with proven skills in basic molecular biology and protein expression • Few MPCs present, mostly with captive biology investment • Innovative research focused on bioinformatics and biochips • Limited biology talent pool owing to historic focus on generics
Chemistry research	**Status: good capabilities in basic services, evolving toward more complex offerings** • Capabilities residing mostly with government institutes; only a few small private companies with a track record • Established basic-chemistry skills moving to more complex offerings (such as HTS), but no end-to-end capabilities • Large and growing pool of raw talent, but limited English-language skills still an issue	**Status: strong and proven capabilities, moving toward end-to-end offerings** • Large pool of vendors with full services and track record of strong capabilities • Extensive MPC activities with top-tier vendors • Generally better IP protection than in China • Trend toward project-based alliances and emerging build-operate-transfer (BOT) contracts • Vast pool of skilled and low-cost chemists
Preclinical trials	**Status: emerging capabilities, evolving** • Basic capabilities in preclinical trials in rodents • Capabilities residing mostly with government-sponsored institutes • Only 20 labs with good laboratory practice (GLP) certification; new regulations should boost that number	**Status: emerging capabilities, rapidly evolving** • Good capabilities for preclinical trials in rodents, limited for dogs, almost none for primates • Capabilities residing mostly with Indian pharmaceutical companies, developed through in-house R&D programs (cumulative track record of 37 new chemical entities as of the end of 2004) • Only 6 GLP-certified labs, another 12 awaiting certification • Government increasingly supportive and relaxing hurdles, though restrictions persist (for example, on exporting blood samples)
Clinical trials	**Status: fairly strong capabilities, fast growing** • Experienced contract research organizations and growing vendor pool providing full spectrum of services • High-quality FDA-approved hospitals exist • Several MPCs conducting global trials at Chinese sites • Low-cost and efficient enrollment compared with the United States and Europe • Trial approvals lengthy and complex	**Status: strong capabilities, fast growing** • Experienced contract research organizations with full service range and output of similar quality to that of developed markets • Very strong data-management capabilities and track record • Many MPCs conducting global trial activities • Greater advantage in cost and patient enrollment than in China • Shorter trial-approval times than in China • Uneven infrastructure and shortage of clinical research assistants might hamper future growth

SOURCE: BCG analysis.

changing fast, with capabilities advancing constantly, so this picture may look rather different in a year's time.

The two best bets in the near term—for both China and India—are chemistry-phase activities and clinical trials. Preclinical trials have presented some stumbling blocks and are a medium-term opportunity at best. Most biology-related activities must be classified as a long-term opportunity even though some innovative biology research is under way at Chinese research institutes.

The rest of this section provides a closer look at the two countries' current and potential capabilities—from the earliest to the final phases of biopharma R&D—together with an assessment of how those capabilities can best be exploited. The analysis is based on a detailed survey undertaken by BCG in late 2005 involving more than 90 vendors of discovery services in China and India; it also incorporates the views of officers at several prominent government research institutes in the two countries and of senior executives at more than ten MPCs operating there.

Biology Work Holds Long-Term Promise

The earliest phase of biopharma R&D—biology research—will be the last to reach its full potential in China and India. Certainly it is evolving, and some activities are already conducted with ease, but end-to-end biology research is still some way off.

The biology activities that both countries can confidently provide at the moment are the less complex ones, notably protein expression and purification, in which Chinese capabilities are moving from *E. coli* bacteria to mammalian cells. India has, in addition, growing capabilities in bioinformatics—easily understandable, given its celebrated IT skills.

In general, biology still lags relative to the other components of the R&D value chain. Part of the problem is that a culture of innovation in pharma is still not deeply ingrained in either country. India's pharma industry traditionally concentrated on process reengineering and on low-cost manufacturing techniques for generics, whereas China's focused mainly on generics, over-the-counter products, and traditional Chinese medicine (TCM) remedies. So until the 1990s, little serious pharma-related biology work was going on in China and India, and there was little incentive to build capabilities for it.[3] This legacy of neglect is not easy to shake off.

That said, some innovative research projects in pharmaceutical biology—notably in stem cell research, animal cloning, gene sequencing, gene therapy, and bioinformatics—are now being pursued in one country or the other. The work occurs mainly at government research centers, such as India's Centre for Cellular and Molecular Biology and China's Institute of Genetics and Developmental Biology. A recent report by British scientists observed that Chinese research groups are "at, or approaching, the forefront of international stem cell research."[4]

China has also won international recognition for research on transgenic animals. It was the only developing country to be a partner in the Human Genome Project, and it has made notable strides in gene therapy, too: the cancer treatment Gendicine (recombinant human Ad-p53 injection), developed by the pioneering company SiBiono GeneTech and approved for use by Chinese regulators, has excited great interest beyond China's borders.

In India, IBM has been funding substantial computer research in protein structures. In general, however, such activities are concentrated in just a few institutions, and the overall level of biology capabilities is far lower than in China. (See Exhibit 4.)

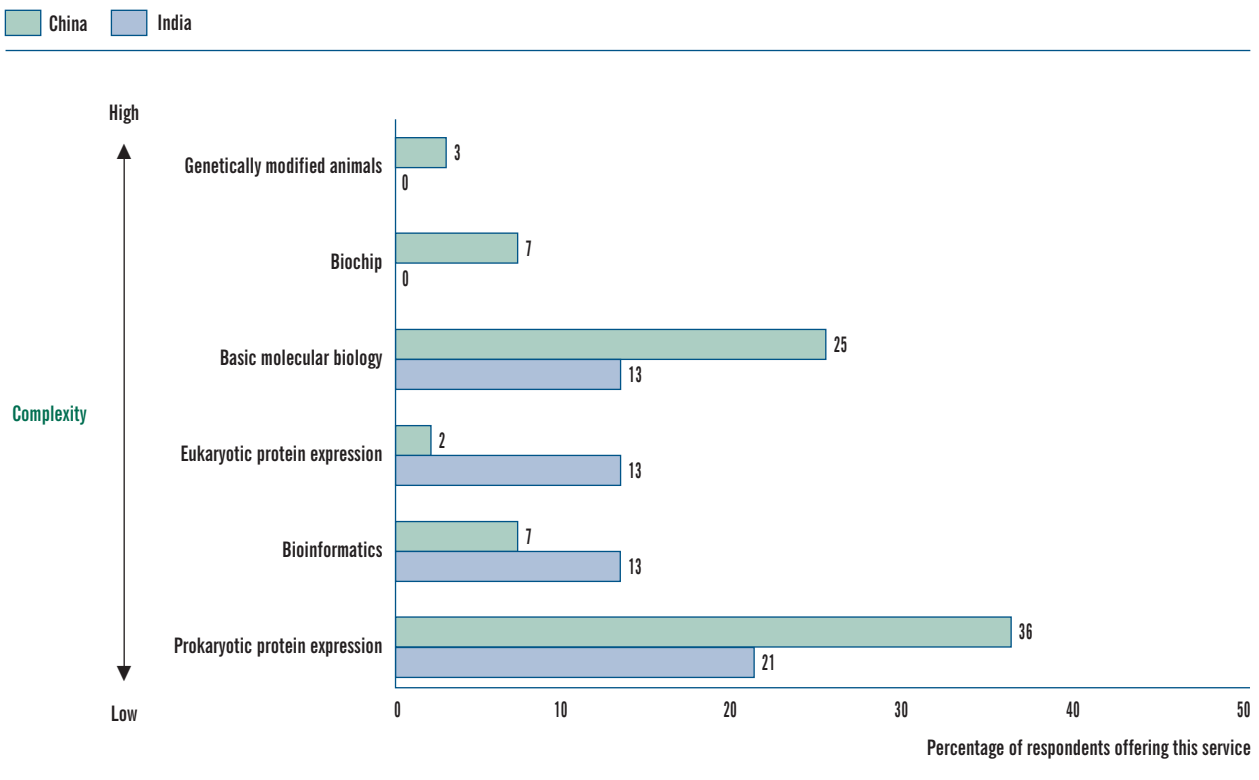
Despite their limited capabilities in biology, the two countries have attracted some interest and investment from MPCs in this phase of the innovation chain. At one end of the offshoring spectrum is Johnson & Johnson's outsourcing of basic biology work to Chinese vendors, for example; at the other is AstraZeneca's aforementioned captive R&D center in India, which is continuing the company's longstanding biology research on tubercu-

3. In other biology-driven industries, particularly agriculture, China has a well-established record of advances, such as those in transgenic plants.

4. U.K. Department of Trade and Industry, *Stem Cell Mission to China, Singapore and South Korea,* 2005.

EXHIBIT 4

CHINA HAS BETTER CAPABILITIES IN BIOLOGY AND MORE POTENTIAL PARTNERS THAN INDIA HAS



SOURCE: BCG survey of more than 90 vendors of discovery services in China and India, conducted in October 2005.

losis. AstraZeneca has invested about $15 million in this center so far and is committing another $30 million over the next five years. The center's biology capabilities include target identification using comparative genomics, target validation using knock-in and knock-out transgenic-animal-model techniques, and assay development. All have contributed to AstraZeneca's new tuberculosis candidate drug molecule, developed entirely in-house at the center.

Other advances, perhaps more modest, will no doubt continue to be made in the two countries. In China they will occur mainly at government-sponsored research centers. In India they will increasingly result from private initiatives as well, both at domestic pharma companies (working autonomously or in collaboration with an MPC) and at the captive research facilities of MPCs.

Capabilities in Chemistry Are Already Indispensable

In both China and India, chemistry is held in high regard, studied very widely, and pursued with considerable flair. Both countries offer a package of basic chemistry work—including analog preparation and combinatorial and analytical chemistry, for example—equal in quality to that of the United States, Europe, and Japan but at one-third or even one-fifth the cost. Leading MPCs have been availing themselves abundantly of this bargain service since 2000.

The rising demand has sparked a proliferation of vendors. And it has spurred some of them to expand their skills and equip themselves to pursue high-end chemistry activities. Here India has greater experience and depth, allowing it to readily provide a more complex suite of services, including assay development, for example. (See Exhibit 5, page 14.)

As vendors fill in the gaps and approach end-to-end chemistry capabilities, MPCs can consider a new type of relationship, moving from piecemeal outsourced projects to large-scale collaborations. Under this model, the MPC would hand over the active target (perhaps one that cannot be advanced in-house owing to capacity constraints), and the

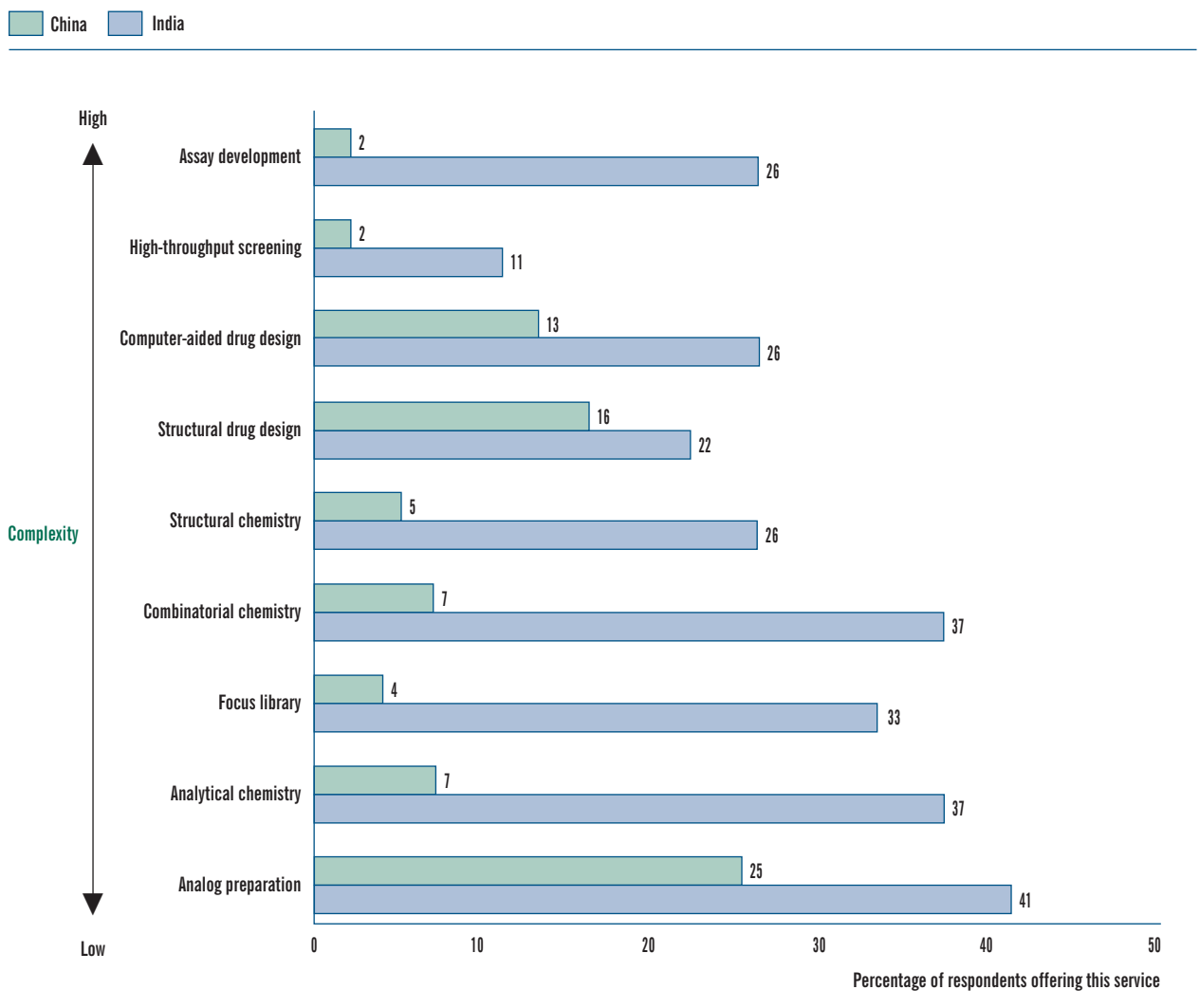
provider would carry out end-to-end chemistry followed by early-stage development before passing the baton back to the MPC.

Such codevelopment arrangements are already proceeding successfully. In China, GlaxoSmithKline has enjoyed a research partnership with SIMM since 1997, and several similar broad collaborations have been launched in India, notably the alliance of AstraZeneca with Torrent and that of GlaxoSmithKline with Ranbaxy. Whereas India currently has the edge in the range and versatility of its chemistry-service offerings, China can claim one unique advantage that is increasingly likely to interest MPCs: its pursuit of serious scientific research in traditional Chinese medicine. (See the sidebar "New Opportunities from Ancient Wisdom: Research in Traditional Chinese Medicine.")

Despite the attractions of both venues for chemistry offshoring, MPCs remain cautious, mainly owing to concerns about protecting data and IP rights. Such concerns are well founded but no longer as intense as they used to be—and certainly not grounds for staying away altogether and forfeiting the advantages of China- or India-based R&D. For one thing, vendors, especially in India, have learned to maintain strict standards of confidentiality, taking measures such as keeping an MPC project well separated from in-house R&D programs, assigning different pieces of a project to different scientists, and even making sure that the MPC client's name remains confidential.

EXHIBIT 5

INDIA HAS STRONGER CAPABILITIES AND MORE EXPERIENCE IN CHEMISTRY THAN CHINA HAS



SOURCE: BCG survey of more than 90 vendors of discovery services in China and India, conducted in October 2005.

NEW OPPORTUNITIES FROM ANCIENT WISDOM: RESEARCH IN TRADITIONAL CHINESE MEDICINE

China, in a characteristic fusion of cultural tradition and technological modernity, is increasingly subjecting traditional Chinese medicine (TCM) to proper scientific scrutiny. TCM is a form of medicine dating back thousands of years and listing a total of 12,807 medicinal materials derived from natural sources, about 5,000 of which may have some clinically proven efficacy. TCM enjoys a growing share of the global market in herbal medicines—a market that, according to the World Health Organization (WHO), stood at $60 billion per year in 2002 and will rise, according to some forecasts, to $5 trillion by 2050. No wonder MPCs are taking an interest in diversifying their pipelines.

Of that colossal herbal-medicine market, TCM now enjoys about a 5 percent share. The Chinese government's goal is to raise it to 15 percent in the next ten years. Since 1992, more than 15 labs have been set up to modernize and develop TCM studies. Several of them are dedicated to researching specific therapeutic areas, such as liver disease or diabetes.

Some of the active ingredients extracted from TCM preparations have already been proved clinically effective or are on the verge of vindication: arsenic trioxide has been approved by the U.S. Food and Drug Administration as a treatment for acute promyelocytic leukemia; and ZT-1, a novel cholinesterase inhibitor for treating Alzheimer's disease, recently underwent successful Phase II clinical trials in Europe.

MPCs have slowly been getting involved. Novartis, for example, in partnership with several Chinese research institutes and companies, helped to develop an artemisinin-based malaria drug, Coartem; it is now distributing it, with WHO backing, in malaria-endemic parts of Africa. The company is contemplating TCM as a research area for its new R&D center in China. Sanofi-Aventis is likewise keen on pursuing R&D in some areas of TCM. And Servier is teaming up with the Shanghai Institute of Materia Medica for TCM-based research in oncology, metabolism, and the central nervous system.

In addition, the legal environment has changed. Both countries in effect became bound by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement following their accession to the World Trade Organization—China in 2001 and India in 2005. In the past few years, China has thoroughly overhauled its relevant legislation and launched an awareness campaign to increase compliance. (Widespread flouting reportedly persists in other industries, however, and the biopharma industry is unlikely to be immune.) As for India, the Contract Act and various trade-secret provisions afford alternative statutory protection within the country, particularly for sensitive R&D data and know-how from the discovery phase. Although these protective measures have not yet been tested in pharma cases, precedents in the outsourcing of IT and business processes show that the laws can be enforced.

Preclinical Trials Offer a Growing Opportunity

In both countries, preclinical ability can best be described as budding rather than blossoming. What's on offer is essentially the standard safety and metabolic profiling: services in PKDM and ADME, and toxicology tests in rodents. Vendors aspire to greater scope and scale in their preclinical trials but have struggled with administrative and regulatory obstacles—whether approval hurdles or restrictions on the sourcing of biological materials—as well as with internal deficiencies, such as a shortage of specialist pharmacologists.

Like biology, preclinical work in China is conducted predominantly at government-run institutes—for example, the Institute of Pharmacology and Toxicology at the Military Academy of Medical Sciences in Beijing. In India some government institutes have preclinical capabilities, but most of this work is carried out by independent private vendors (typically through an outsourcing contract) or by larger integrated pharma companies (often through a drug development collaboration with an MPC) that have learned the necessary skills from their in-house R&D programs. (See the sidebar "Developing Preclinical Capabilities in India," page 16.)

DEVELOPING PRECLINICAL CAPABILITIES IN INDIA

In a recent BCG survey of 27 leading providers of biopharma R&D services in India, a total of 7 (26 percent) had basic capabilities in rodent ADME, and 6 (22 percent) were able to perform toxicology studies. But only 2 (7 percent) had conducted canine studies, and only 1 (4 percent) had demonstrated primate-testing capabilities.[1]

At the time of the survey, the three vendors with the most advanced preclinical capabilities—Zydus Cadila, Aurigene Discovery Technologies, and Advinus Therapeutics—offered a wide range of services, including

- *in vitro ADME tests,* such as solubility, metabolic-stability, CYP-inhibition, and protein-binding studies
- *in vivo ADME tests* (typically conducted on rodents), such as pharmacokinetic, tissue-distribution, metabolism, permeability, P-450/CYP-450 induction-and-inhibition, and selected disease-specific safety studies
- *toxicology tests* (typically conducted on rodents), such as reproductive toxicology, cytotoxicity, genotoxicity, immunotoxicology, and hypersensitivity tests

Some vendors are developing specialized preclinical services. Chembiotek's biology division, for example, designs biomarkers that track the movement of proteins inside the human body.

Despite all this activity, India's overall preclinical track record must still be regarded as limited. Facilities with good laboratory practice (GLP) certification are fairly scarce resources there, and so are capable and experienced pharmacologists. So any MPC planning to outsource preclinical work to Indian vendors must first satisfy itself that there really is adequate scientific support in the design and conduct of the study and in the analysis of results.

1. This survey of Indian companies was part of a larger survey of more than 90 vendors of discovery services in China and India, conducted by BCG in October 2005.

Vendors have a particular advantage for MPCs: with their knowledge of the "system" and local customs, they are adept at cutting through red tape, expediting approvals, and generally reducing administrative headaches.

If preclinical capabilities in China and India are to mature to global standards, some impetus will have to be given to this particular stretch of the R&D value chain. In fact, regulators are responding positively. Genetically modified animals are being made more available to laboratories; government-supervised vivariums are being established to supplement the existing private vivariums and to meet the increasing industry demand; and approvals are becoming quicker and more predictable.[5] In India an improved modus operandi for preclinical trials is now in place thanks to the June 2005 amendment to Schedule Y. This measure provides clear guidelines on the use of animals in preclinical tests and ensures that neutral scientists and experts, rather than animal rights lobbyists, predominate on the institutional animal ethics committees.

However, regulators have to keep a very firm hand. To earn international credibility for preclinical trials, they need to impose standards of laboratory practice that equal those of the United States, Europe, and Japan. As of early 2006, only six labs in India had secured good laboratory practice (GLP) certification, although another dozen were about to. China had 20 GLP-certified labs, but GLP standards might have been applied fairly loosely to reach that total. Since January 2005, China's State Food and Drug Administration has refused to grant drug registrations if the application contains data based on tests done in labs without GLP certification.

Thus, although the preclinical scene is certainly improving in China and India, it is still far from being in full flower. MPCs need to see more evidence of progress—far more GLP-certified labs, far more specialist pharmacologists, and further normalization of approval times and sourcing—before they wholeheartedly embrace preclinical opportunities in the two countries.

5. The largest vivarium in India is at the government's Central Drug Research Institute in Lucknow and is indispensable to some vendors. (Vivariums are the centers that manage and house the animals, organisms, and biological samples used for research.)

Existing Strengths in Clinical Trials Will Deepen and Broaden

In contrast to the preclinical phase, clinical trials in China and India are flourishing. Given the two countries' low cost base and huge potential patient populations, they seem tailor-made for hosting trials and are duly offering services in abundance. Almost all the top MPCs have already offshored some clinical-trial work to India, and many have offshored it to China as well.

The surge has been extraordinary. In 2002 about 40 global trials were being conducted in India; in 2005 the number was about 200. Ten years ago the vendor base in India was so meager that go-getter MPCs had to set up captive bases of their own to run clinical trials; today there are more than 20 eager contract research organizations (CROs) with established capabilities in handling Phase II through Phase IV trials, not to mention dozens of energetic smaller vendors. And in China, after a slower start, the top ten local vendors have been registering annual growth rates of 50 percent, even as 200 to 300 smaller vendors have muscled in and several international CROs have set up shop. In both countries the boom looks set to continue. Double-digit annual growth in the number of clinical trials is predicted for the next five years at least.

In offshoring a particular trial or particular aspects of a trial, an MPC will often find India and China equally appealing. The two countries' capability profiles are very similar. In some respects, however, India may have the edge. It has a long record of conducting clinical data management (CDM) and biostatistics work for MPCs and may expect to receive the lion's share of such work in the future. (See Exhibit 6, below, and the sidebar "At Home with Clinical Data Management: An Indian Specialty," page 18.)

Overall, the advantages of conducting clinical trials in the two countries are compelling. The wage bill is low. Indian and Chinese patients are often more treatment-naïve than their counterparts in the West—that is, they have not been exposed to

EXHIBIT 6

INDIA HAS AN EDGE OVER CHINA IN CLINICAL DATA MANAGEMENT

	China	India
Capability	• Most companies conduct CDM for local trials only (experience is usually limited to local bioequivalence and clinical trials) • A small proportion (about 20 percent) of science graduates speak English competently (approximately 200,000 new science graduates per year)	• Several players (local and global CROs and Indian IT companies) conduct CDM for global trials • A large pool of science graduates speak English proficiently (approximately 830,000 new science graduates per year)
Cost advantage	• Medium cost of relevant labor owing to high premium on English-speaking skills (about $9,000 per year for an IT programmer or a data entry operator)	• Low cost of relevant labor (about $5,100 per year for an IT programmer or a data entry operator)
Experience of other MPCs	• When the clinical research is conducted in China, most MPCs prefer to conduct CDM in India or Singapore	• Several MPCs (including Eli Lilly, GlaxoSmithKline, Novartis, and Pfizer) choose Indian companies to conduct CDM for global trials
Confidentiality and legal enforcement	• Legal frameworks exist to enforce data security	• Legal frameworks exist to enforce data security • CROs and IT providers ensure data security through nondisclosure agreements with liability clauses and contracts enforceable in the United States and Europe

Sources: Literature review; BCG interviews; BCG case experience.

as many treatments or medications—which arguably means that they yield more reliable results.[6] Enrollment in trials can be fast and easy because of the large number of patients with unmet medical needs. And efficiency is high, since more patients can be recruited per site. (See Exhibit 7.) Combine all these factors, and you have a unit cost per patient that is less than half, and often just one-third, that of the United States, Europe, or Japan.

Clinical trials differ from the other phases of the innovation chain in one crucial respect: by their nature they involve the public; hence, they are directly linked to future commercial activity. Most MPCs will not conduct clinical trials in countries where they do not intend to market the drug being tested. Accordingly, trials represent a major commercial commitment, giving MPCs a chance to develop relationships with physicians and patients. Since these are the people who will prescribe, request, buy, and promote the drug once it reaches the market, such relationships are crucial to enhancing the drug's sales potential.

6. Even in places where most patients are not treatment-naïve, many have been exposed only to older-generation medicines, as is the case with diabetes patients in first-tier and second-tier Indian cities, for example. Such patients are generally more willing to switch treatments and enroll in a clinical trial than are Western patients—who already receive more advanced and newer-generation medicines.

AT HOME WITH CLINICAL DATA MANAGEMENT: AN INDIAN SPECIALTY

Justifiably confident of its IT prowess, India engages in CDM with panache. Several leading MPCs draw on the country's talented work force to conduct almost the full range of CDM tasks—whether through vendors or through specialized captive facilities. These tasks range from simple data entry to interactive-voice-response-system (IVRS) programming, and from help desk support to statistics.

Two obvious concerns are data security and staff retention. MPCs and their service providers are managing these issues in established ways.

For purposes of data security, all data warehousing is carried out on servers in the United States or Europe. Each workstation in the Indian center processes only limited quantities of data, and data can be brought together only by a select set of supervisors. Workstations are secured in other ways, too, such as tightly controlled access (by means of swipe cards or intricate pass codes), restricted use of e-mail or the Internet, and external drives protected against the unauthorized downloading of data.

To retain staff, managers bring standard human-resource-management measures to bear—promoting a culture of fun, for instance, and building team spirit through regular outings and group activities. CDM centers also generally pay above-average salaries for the sector and offer productivity bonuses. And they tend to allow, or even insist on, daytime-only work—an appealing policy in an industry that often requires night shifts.

A heartening case study is the CDM center established by GlaxoSmithKline in Bangalore ten years ago with a founding staff of four and work limited to data entry. By 2003 the team had increased to 38, and its activities had expanded to cover an array of business process services for clinical trials, including protocol development, data analysis, and manuscript writing. The center recently moved into new premises to accommodate a predicted total of 300 employees.

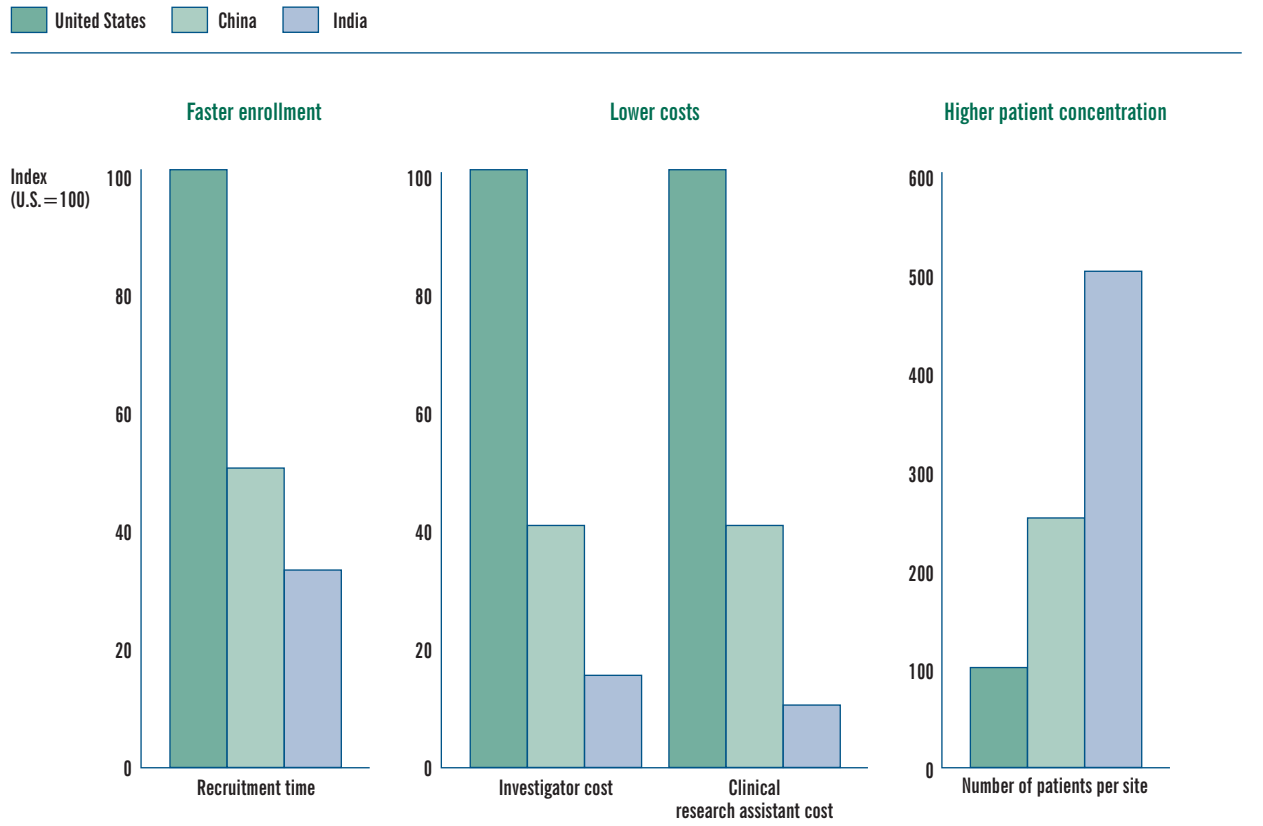
So far, the track record of GlaxoSmithKline's CDM center includes

- more than 2.2 million clinical data sheets providing support for 400 clinical trials
- clean validated data for analysis, delivered in record time, in an extraordinarily large and complex trial involving 63,000 patients worldwide
- an error rate of less than 0.01 per 100,000 pages—meeting the specified standards of regulatory authorities in the United States and Europe
- no reported breaches of data security

The center remunerates its work force at rates above the industry norm in India, yet its salary bill is barely one-third that of an equivalent center in the United States—bringing GlaxoSmithKline an annual cost saving of $30,000 per employee.

EXHIBIT 7

CHINA AND INDIA OFFER SUBSTANTIAL ADVANTAGES FOR MPCS CONDUCTING CLINICAL TRIALS



SOURCES: BCG interviews; China's State Food and Drug Administration; literature search.

From the perspective of market access, China seems the better bet, as noted above. For one thing, its government—unlike India's—plays a central role in the biopharma industry, and MPCs that earn governmental goodwill by participating in the country's R&D advancement stand to earn favorable treatment as well. For another, the Chinese market is already far larger than India's, and the difference will be vastly greater in years to come.

Of course, China and India have potential drawbacks, too. MPCs remain worried about data security and, with more reason, about timing. Drug approvals have traditionally been slow in coming through, especially in China. Another looming concern is capacity constraints. Staffing levels and infrastructure could get overstretched if clinical-trial work continues to expand at current rates. (See the sidebar "Caveat MPC: Residual Challenges to Conducting Clinical Trials in China and India," page 20.)

CAVEAT MPC: RESIDUAL CHALLENGES TO CONDUCTING CLINICAL TRIALS IN CHINA AND INDIA

Among all the attractions of China and India as clinical trial sites, certain issues persist—caveats rather than disincentives—that MPCs need to bear in mind.

First there is the issue of data security—the reputedly lax attitude of vendors toward confidentiality. This reputation is contradicted by the reality. The experience of MPCs in offshoring data management work has been extremely positive. Virtually no data breaches have been reported so far. And contract research organizations are zealous in ensuring that the situation remains that way, since nondisclosure agreements typically contain liability clauses that are enforceable abroad.

Then there is the issue of the lag for Phase I trials. The rule in India is that a new chemical entity discovered outside the country has to undergo its initial Phase I trial outside the country, and only then can a Phase I trial be conducted in India. (In practice, China labors under a similar restriction.) Exceptions are made for life-saving drugs, but the rule frequently bars MPCs from running Phase I trials in India. However, Phase II trials and beyond do not face a similar lag in India and can start concurrently with trials in other countries.

Next is the issue of slow approval times, especially in China, where approval typically takes 9 to 12 months, compared with 3 to 4 months in India. Progressive regulations and procedures are being introduced, however, and the process of securing approval is bound to ease.

Looking ahead, there is the ominous question of capacity constraints. The potential scale-up of global clinical trials in both countries is immense. Consider the estimated demand on India, for example. The country currently conducts about 1.5 percent of global clinical trials; this share could rise to 5 percent by 2008 and 15 percent by 2011—and that is the percentage of a global total that is itself increasing by 10 percent per year.

How well will China and India be able to cope with this rate of growth? First, manpower simply will not be able to keep pace with the likely demand unless there is a drastic increase in training. At current training levels, India will turn out only *one-tenth* the required number of clinical research assistants and investigators educated in good clinical practices.

Second, the public infrastructure in the two countries is going to be stretched to the limit. India is the greater concern here because its overall infrastructure development is uneven. India's metropolitan areas and the so-called tier-one cities should hold up well into the future, but the growing workload will likely mean that more and more trials will be sited in tier-two cities, and that spells trouble—inadequate road systems, unreliable connectivity, and so on. The central and state governments are mindful of the problem, and infrastructure enhancement projects are under way, but they are in danger of being outpaced by the tide of work from offshore.

Maximizing the Opportunities: Flexible Strategy and Rigorous Execution

By any standard, both China and India have made prodigious efforts in recent years to advance their expertise in biopharma R&D. Most major MPCs and many smaller ones have been actively harvesting the resulting opportunities, but they have been doing so opportunistically rather than in a properly planned way. Meanwhile, a few MPCs have remained very cautious and largely disengaged, perhaps fearing that the two countries' apparent bountifulness may yet prove to be a bubble.

The wise path, which lies somewhere between these two approaches, is one of *planned engagement*. To maximize the potential benefits of China and India, an MPC's strategists need to define a medium- to long-term R&D offshoring vision—perhaps five to seven years out—that is harmonized with the company's global R&D strategy. They can then formulate a plan to realize that vision: an integrated strategy for R&D offshoring.

This offshoring strategy will have to be flexible in order to accommodate constant shifts in the countries' R&D landscape—shifts in capabilities, availability, and risk factors, among others. It will also have to accommodate changes in the MPC's internal environment, such as budgetary constraints and the appetite for risk.

We have devised a three-part framework that MPC executives can usefully adopt as they build such a strategy and put it into practice:

1. Develop a range of *scenarios* to help define the R&D offshoring vision
2. Choose *the optimal business model and migration path* for the company
3. Ensure *rigorous implementation*

Developing Scenarios to Define the Vision

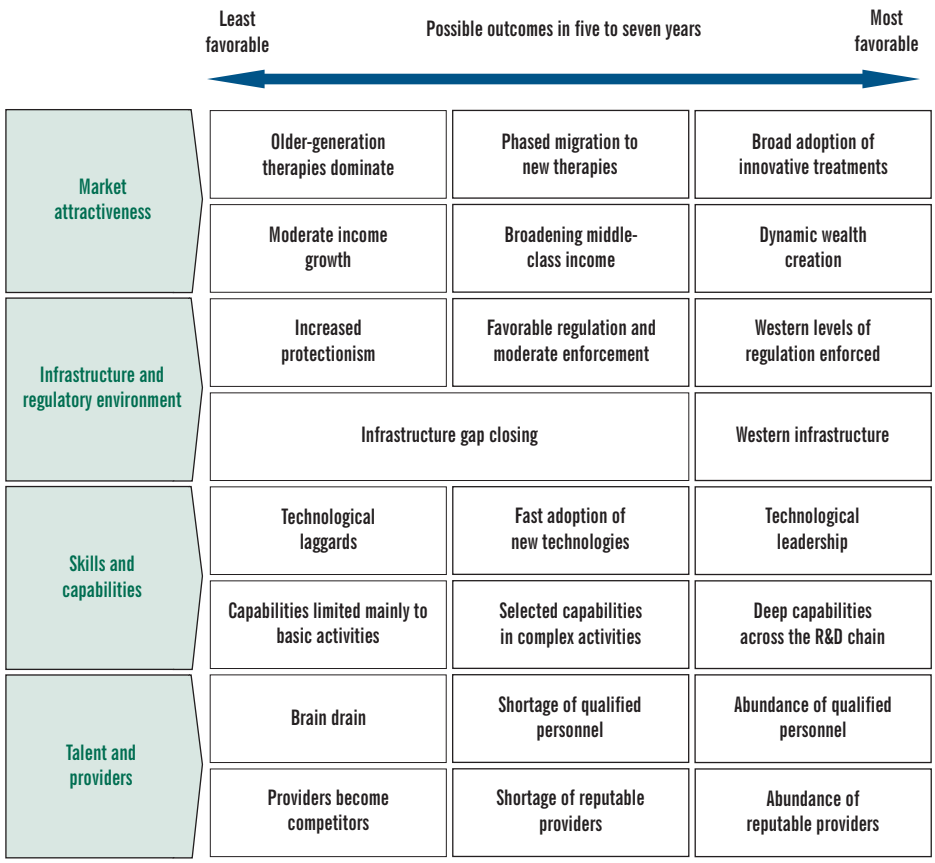
The initial vision will guide, if not determine, the reality. For example, an MPC might envision a future low-cost Chinese R&D hub, and on that basis it would methodically escalate its offshored biology work to China during the next five to seven years. Without such a vision, shared by key stakeholders, of what China and India *could* represent as part of the global R&D network, it is unlikely that a company will ever move beyond tactical bets.

The best way of defining such a vision is to develop a range of scenarios. *Scenarios,* not *scenario:* a traditional strategy, based on expectations of a single outcome, is almost sure to trip up at some point because the terrain is so uncertain. Exhibit 8, on page 22, provides one example of the range of potential outcomes to consider. The scenarios are generated by asking numerous questions about the evolution of external variables, such as market attractiveness, infrastructure and regulatory environment, available skills and capabilities, and available talent and providers.

- *Market Attractiveness.* What is the outlook for the pharmaceutical market in China and India? If the general economic boom falters in either country, how severely will that affect the growth in health care spending? To what extent will market access in China be easier for MPCs with a captive presence than for those without? Will exclusive marketing rights be more strictly enforced, and if so, will that ensure more attractive pricing options?
- *Infrastructure and Regulatory Environment.* How fast will the infrastructure improve, especially the inadequate infrastructure in some regions of India? Will China speed up the general pace of granting approvals, and if not, will there be ways of expediting approvals in specific cases? Which country will prove better at enforcing its IP-protection statutes?
- *Skills and Capabilities.* How fast will local preclinical or biology discovery skills evolve and flourish? When will vendors' capabilities consolidate across the value chain? Do late-entering MPCs risk getting locked out of attractive opportunities?
- *Talent and Providers.* When and where will the cost advantages begin to decline? Which segments are likeliest to suffer manpower shortages and thereby entail a higher wage bill?

EXHIBIT 8

DIFFERENT SCENARIOS CAN BE ENVISIONED DEPENDING ON HOW EXTERNAL VARIABLES EVOLVE



SOURCE: BCG analysis.

Choosing the Optimal Business Model and Migration Path

MPCs have five distinct business models to choose from: the captive R&D center, the partnership for end-to-end research, the build-operate-transfer (BOT) model, the vendor-based outsourcing model, and the wait-and-see approach. (See Exhibit 9, page 23, and the sidebar "The Main Business Models for Outsourcing R&D," page 24.) Each model will perform differently under different scenarios. So before choosing the most promising model and the best path toward it, an MPC's strategists should evaluate and "pressure test" each one against the various scenarios put forward.

Evaluating Different Business Models Against Different Scenarios. Exhibit 10 shows how an evaluation of models against scenarios might look—just three scenarios in this case, out of a much more numerous set. For example, the generally favorable outcomes at work in the third scenario (selected from the full gamut of outcomes laid out in Exhibit 8) could be described in a fairly upbeat way with respect to India and China jointly:

> In five to seven years' time, with both India and China having maintained their economic momentum, their populations are enjoying increased prosperity across all social classes, and the very latest medicines are in wide use. The regulatory landscape—approvals, IP protections, and so on—is reasonable, and the infrastructure is virtually at Western standards in parts of China and very much better than expected in India. In both countries, biopharma companies and institutes jointly have capabilities covering almost the entire value chain, although the adoption of the latest technologies still falls short of Western levels. And there are capacity constraints, with some favored providers overstretched and some value-chain activities suffering a shortage of specialists.

EXHIBIT 9

FIVE MAIN BUSINESS-MODEL OPTIONS EXIST

Captive R&D center	MPC develops drug candidates at a fully owned site • Large investment and limited flexibility • Full control over talent, IP, and know-how
Partnerships for end-to-end research	MPC partners with a local provider, which conducts an entire range of innovation activities and then returns the project to the MPC • Moderate investment and fairly high flexibility • Easy access to talent and limited control over IP
Build-operate-transfer for selected activities	MPC forms an alliance with a local provider, which hands over the facility and work force when the time is right • Investments spread over time, and moderate flexibility • Fast access to talent and avoidance of red tape
Vendor-based outsourcing	MPC outsources selected discrete activities to third-party vendors • Small investment and high flexibility • Moderate IP risk and little knowledge transfer
Wait and see	MPC maintains current activity (or lack of activity), holding off from further involvement until conditions improve • No investment and high flexibility • Risk of lost opportunity

SOURCE: BCG analysis.

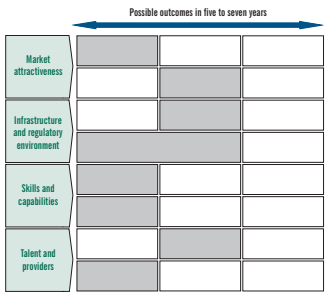
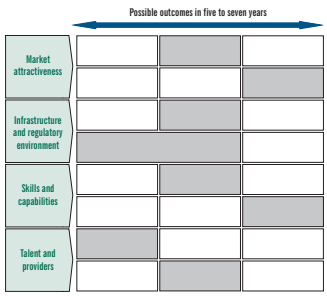
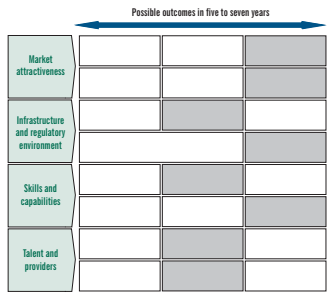
Against this scenario (and others, including the first and second scenarios in Exhibit 10), the MPC's strategists can evaluate the appropriateness of each business model for China and India jointly—or for either country separately. (For that matter, using analogous scenarios, they can do so for any other country that is an offshoring candidate.)[7] The basis for the evaluation is the importance that the MPC attaches to *internal* variables—such as the company's own predicted budgetary position, its need for access to talent, its appetite for risk, and the nature and extent of its current offshore involvement.

Although BCG's general assessment is that the model of a captive R&D center is best suited to China and the vendor-based outsourcing model (or possibly the partnership model) is best suited to India, at least initially, individual MPCs may generate different preferences. (See the sidebar "China Demands a Business Model Different from India's," page 25.)

7. China and India are under the microscope in this report, and with good reason, but obviously they are not the only possibilities. For some projects, MPCs might sensibly opt for a different offshoring destination—Singapore, for example, for historical reasons.

EXHIBIT 10

THE ATTRACTIVENESS OF THE FIVE BUSINESS MODELS VARIES SIGNIFICANTLY UNDER DIFFERENT SCENARIOS

	Scenario 1	Scenario 2	Scenario 3
			
Captive R&D center	+/–	+	+
Partnerships for end-to-end research	–	+	+/–
Build-operate-transfer for selected activities	–	+/–	+
Vendor-based outsourcing	+	–	–
Wait and see	+	–	–

SOURCE: BCG analysis.

THE MAIN BUSINESS MODELS FOR OUTSOURCING R&D

Since about 1995, when MPCs first started offshoring biopharma R&D in earnest to China and India, these companies have tried a number of different approaches. Five business models have emerged as current options:

- A *captive R&D center* represents a serious and committed presence by the MPC in the offshore country. It provides the best possible control over IP, but it is expensive to set up and maintain, especially if overseas staff are kept on. And for want of seasoned local operating know-how, it is particularly vulnerable to approval delays, problems with planning permission, and other manifestations of red tape. But these issues can be sidestepped if the MPC proceeds indirectly by undertaking a joint venture with a local partner first. The partner helps to sort out administrative problems and advises the MPC's managers on how to operate in the country. The contract eventually runs out and the relationship terminates; alternatively, the MPC buys out the local partner, and the enterprise comes under the exclusive control of the MPC (as in the BOT model, described below).

- In opting for a *partnership,* the MPC offshores activities along an entire stretch of the innovation chain to a local partner—typically a large integrated biopharma company or possibly a government-funded institute—that does end-to-end work on the candidate drug and then returns the baton to the MPC. The main advantages are the easing of pipeline bottlenecks and general capacity constraints; brisk leveraging of the vendor's specialized skills (rather than painstakingly mastering them in-house); and effective handling of red tape. The downside is the risk to IP security.

- The *build-operate-transfer (BOT) model,* successfully applied in other industries, would allow an MPC to acquire a modest captive center without having to postpone its projects. The MPC forms an alliance with a local company, drawing on its technical expertise as well as its special knowledge of local ways of doing things, with a contract to take over the partner's facility and work force when the time is right. The great value of this approach is that it allows the MPC to test the waters before taking the plunge into a full-fledged captive center.

- *Vendor-based outsourcing* provides a very flexible and inexpensive means of offshoring, and it has proved popular and successful with MPCs. It's a hands-off model, involving minimal supervisory control and knowledge sharing on the MPC's side. As a result, there is a fair degree of risk to IP, but—in part for that very reason—the projects involved tend to be less complex work, such as basic chemistry and clinical data management. A more theoretical risk is that of unsatisfactory performance by the vendor, whether through intrinsic inadequacy or erratic infrastructure and logistical support.

- The *wait-and-see approach* is the choice, or non-choice, of some lesser MPCs, whether already involved in India or China or not. Either internal conditions are unpropitious for further engagement or cautious decision makers are waiting to see which way the tiger jumps. This approach certainly has its advantages: the investment is zero and the flexibility is infinite. The risk, however, is high: the loss of lucrative opportunities.

There is one other model—arguably no more than a combination of models—that tends to develop spontaneously rather than being deliberately adopted. The *integrated offshoring model* occurs when an MPC scales up its offshoring activities and needs to integrate several projects that are running simultaneously. The company might use a small captive base to coordinate the activities of local vendors, as well as any in-house projects that are in progress. This center is modest at first, supporting the MPC's global R&D centers and leveraging established local capabilities. But as those capabilities grow, the captive center evolves into a full-fledged R&D hub in its own right.

Evaluating Business Models and Migration Paths Against the Company's Needs. Having established the value of different business models under the strategic scenarios laid out, the MPC's strategists turn to considering which model and migration path will make the most sense for the company. Matters are complicated by the shifting environment, so the best model under any particular scenario—even the likeliest one—is not necessarily the best choice overall. When it comes to predicting outcomes, strategists have to spread their bets, and the optimal choice is often the model that yields the greatest total value under all the most likely scenarios, while leaving sufficient flexibility to adjust to changing conditions (which can make a particular scenario either more realistic or less).

In the hypothetical evaluation shown in Exhibit 10, the captive model emerges as the most promising option. It scores positive or at least neutral under all three of the scenarios shown (although it lacks the flexibility of the BOT model). But the path to the optimal model may not be direct.

Let's say that the MPC currently outsources only a few low-complexity chemistry projects to local vendors, but its executives are contemplating a partnership alliance for a serious end-to-end venture. The company's strategists have concluded that this option will be suboptimal should the environment turn sour (Scenario 1 in Exhibit 10) but will provide too few advantages if the upbeat circumstances of Scenario 3 do materialize. Instead, they recom-

CHINA DEMANDS A BUSINESS MODEL DIFFERENT FROM INDIA'S

When an MPC offshores R&D to India, it gains the great strategic advantage of boosting the efficiency of its overall R&D program. By outsourcing some of its "excess" leads (to be processed at high quality, high throughput, and low cost), the company can quickly and cheaply ease its R&D bottlenecks and capacity constraints. It's an enticing short-term opportunity provided by India's broad and reliable vendor base—the handful of large, integrated domestic players and myriad smaller, high-energy vendors. It's no surprise, then, that the most propitious business model for India, in general, is the brisk, uncomplicated, arm's-length model of vendor-based outsourcing—at least initially.

In China the optimal business model, in general, is the captive R&D center. Again, this is in keeping with the country's main value proposition: the chance for an MPC to capture a greater share of the country's huge potential market. The very existence of a captive site makes a statement, signaling the company's commitment to China and its resolve to remain there for the long haul. This has more than just symbolic value: it establishes the MPC's bona fides and brand name with patients, doctors, bureaucrats, and key opinion leaders, and eventually that can mean increased sales.

A captive center contributes to China's own pharmaceutical industry—and that is how Chinese officials, eager for the country's technological advancement, will see it. It does so initially by demonstrating international best practices and standard operating procedures (or at least by inspiring local R&D providers to aim comparably high). With this infusion of know-how and encouragement, Chinese R&D institutes and vendors can move faster along the learning curve and undertake increasingly sophisticated activities. That, in turn, may help to further stanch the country's brain drain, increasing the flow, already impressively copious, of foreign-trained and foreign-based scientists returning to their homeland.

Assuming that this sequence of happy outcomes materializes, MPCs would be rewarded in two ways: individual companies might win favorable consideration when it comes to reimbursement lists and expedited approvals, and MPCs collectively would be able to ingratiate themselves more deeply with government officials and perhaps nudge government policy further along the road of smoother regulatory procedures, tighter IP protection, and even looser pricing policies.

At one level, the motivation to invest in a captive base is receding. After all, why go to the trouble and expense of establishing a captive facility when Chinese vendors are expanding their capacity and capabilities at such a pace? So if MPCs don't place their strategic stake soon, they may lose the impetus to do so—and thereby lose their market foothold and the potential goodwill of the authorities as well.

mend that the company migrate initially from its vendor-based outsourcing model to a BOT relationship with a well-staffed, street-smart provider based in a science park.

That will allow quick commencement of new projects, and it will also ease the MPC gently into a physical presence in the country with very little anxiety over setup costs, red tape, access to talent, and even day-to-day management, since the local provider will have everything in hand. In two or three years, the MPC will increasingly assume control of operations and will grow more confident and well versed in the local business and bureaucratic culture. Within five to seven years, the MPC can effect a formal takeover of the provider. Staffing and projects will continue much as before, but the BOT model will give way to the captive model, and the MPC—especially if its financial flexibility has increased in the interim—will rapidly develop its captive base into a fully rounded R&D center. (See Exhibit 11.)

Monitoring the Strategy. An offshoring strategy, like most strategies, should be dynamic rather than fixed. An MPC's executives will need to monitor the way their strategy is playing out. If they have any misgivings or if circumstances appear to be changing significantly in-house or offshore, they should revisit the various scenarios and internal variables. That may result in another round of evaluations, which, in turn, may indicate a need to adjust the planned migration path in order to realize the company's strategic vision.

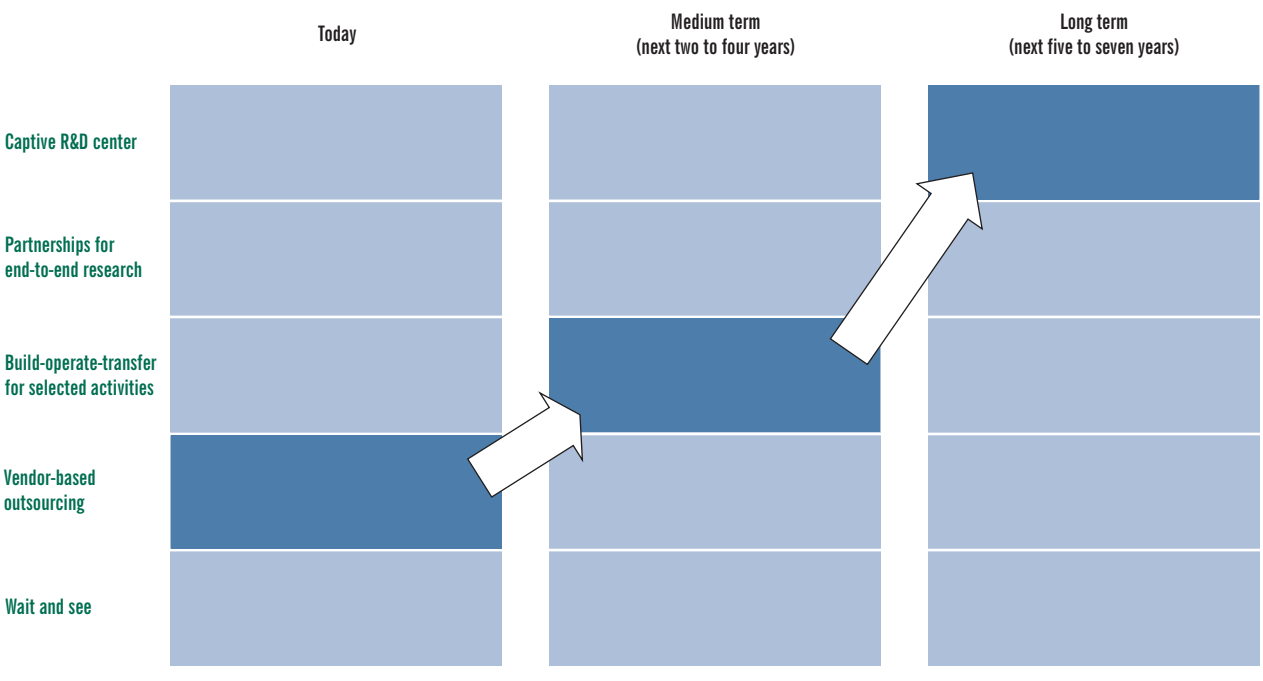
Ensuring Rigorous Implementation

Committed follow-through is crucial. Even the smartest strategy will fail if its execution falls short. To implement a new partnership model, for instance, it's not enough for a company to find a partner; it needs to find the *right* partner. And having done so, it needs to put all the required systems and processes faultlessly in place—from monitoring and evaluating to coaching and communicating, down to the most devilish details—or else a cascade of negative consequences might ensue, and the entire offshoring venture might go awry. To reduce that risk takes considerable effort and technique. MPCs can learn from the experiences of their peers.

The following dos and don'ts, which are derived from the experiences of the MPCs and providers

EXHIBIT 11

AN MPC MIGHT MIGRATE IN TWO STAGES FROM A VENDOR-BASED TO A CAPTIVE BUSINESS MODEL



SOURCE: BCG analysis.

that we questioned in the course of our recent survey, may prove useful:

Make choices methodically.

- When siting a project or base, verify the site's infrastructure and connectivity (phone, e-mail, and Internet links), as well as its accessibility if inspection or training visits are expected to be frequent
- When choosing a vendor or partner, make exhaustive due-diligence assessments to confirm its credentials: skills, capabilities, and staffing levels; track record of working with other MPCs successfully and harmoniously; and ability to attract and retain high-quality employees through incentives and performance management

Align the stakeholders.

- Clearly define all deliverables, giving timelines and quality criteria, and specify in the contract that litigation can be settled abroad
- Formulate standards of practice, introduce a training scheme to instill them into the staff, and engage in work exchanges, team-building exercises, and other means of sharing knowledge and skills

Capitalize on local know-how.

- To keep administrative headaches to a minimum, leverage to the maximum the vendor's or partner's skills at cutting through red tape
- Draw on local management expertise to prevent local working practices from becoming a stumbling block to Western managers and to prevent cultural misunderstandings from leading to high employee churn

Take appropriate precautions.

- Put in place risk management measures, such as confidentiality clauses in employment contracts to prevent data leakage
- Set up a monitoring body to track progress regularly and to anticipate problems

Obviously, the operational issues will vary from case to case and at different times in an MPC's relationship with the vendor or partner. The early stages of the relationship require much more handholding, due diligence, and monitoring. The later stages can concentrate more on sharing knowledge and enhancing capabilities for current and future projects.

* * *

With R&D capabilities and service offerings in China and India growing at such a whirlwind pace, even the best-laid strategy can occasionally get blown off course. But without a focused strategy—including a clear set of objectives, a shrewd choice of business model, and a policy for managing day-to-day relationships—MPCs will find it even harder to steer straight. They will make less headway than they otherwise would, and some of the rich opportunities offered by these two countries will be wasted.

Conclusion: Looking Forward

The decade ahead is one that economic historians may someday regard as an era of transformation in the biopharmaceutical industry. The genomics revolution that is gathering pace will come to full fruition, and the dynamic potential of China and India will be triumphantly confirmed as MPCs shift their center of gravity in R&D to these countries—and in so doing turn their fading fortunes around.

If that scenario does indeed come to pass in the next decade, it will be thanks to the dedicated efforts made over the past decade. With no serious background in innovative R&D before the 1990s, China and India have risen to modest prominence with extraordinary speed, to the point where they now hold out two separate lifelines to ailing MPCs: access to a hugely lucrative market and a turbocharged productivity boost for R&D.

It's up to MPCs to make the most of these opportunities. All it takes is the will to do it—and astute strategic vision, precise tactical choices, and scrupulous managing of ground operations. The MPCs that can meet those requirements are poised to restore their image, their productivity, and their profitability.

This report is one of a series published by The Boston Consulting Group on biopharmaceutical research-and-development productivity. The other reports in the series are:

Rising to the Productivity Challenge: A Strategic Framework for Biopharma
A Focus by The Boston Consulting Group, July 2004

Harnessing the Power of India: Rising to the Productivity Challenge in Biopharma R&D
A Focus by The Boston Consulting Group, May 2006

A Game Plan for China: Rising to the Productivity Challenge in Biopharma R&D
A Focus by The Boston Consulting Group, December 2005

The Gentle Art of Licensing: Rising to the Productivity Challenge in Biopharma R&D
A Focus by The Boston Consulting Group, July 2004

Good Governance Gives Good Value: Rising to the Productivity Challenge in Biopharma R&D
A Focus by The Boston Consulting Group, July 2004

In addition, BCG has published reports on offshoring in India and China that may be of interest to senior biopharma executives. Relevant titles include:

The New Global Challengers: How 100 Top Companies from Rapidly Developing Economies Are Changing the World
A report by The Boston Consulting Group, May 2006

Organizing for Global Advantage in China, India, and Other Rapidly Developing Economies
A report by The Boston Consulting Group, March 2006

Facing the China Challenge: Using an Intellectual Property Strategy to Capture Global Advantage
A report by The Boston Consulting Group, September 2004

BCG is also publishing, in cooperation with the Wharton School, a series of four reports that explore China's impact on business operations and strategy. Two of the reports have already been published:

Overcoming the Challenges in China Operations
March 2005
Available at http://knowledge.wharton.upenn.edu/index.cfm?fa=specialsection&specialid=32

China and the New Rules for Global Business
May 2004
Available at http://knowledge.wharton.upenn.edu/index.cfm?fa=specialsection&specialid=19

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