Make Your Move: Taking Clinical Trials to the Best Location

Should pharmaceutical companies augment their offshore strategies by performing some clinical trials in lower-cost locations? The short answer is yes. Emerging markets offer faster time to market, reduced costs and the same high quality that companies demand. But which countries present the best opportunities? China, India and Russia top the list according to A.T. Kearney’s Country Attractiveness Index for Clinical Trials.

Healthy margins and little appetite for risk have kept most pharmaceutical companies close to home, for all but their manufacturing activities. But as financial pressures increase, pharmaceutical executives are finding that going offshore is not only less risky than it once was but also too attractive to ignore. This is especially true for conducting clinical trials, which can account for two-thirds of the cost of developing a new drug.
The leading global pharmaceutical companies conduct the majority of their clinical trials in familiar territory, with most trials taking place in the United States and Western Europe. Those highly touted, low-cost countries that other industries favor are still on the outer-edges of the pharmaceutical industry’s radar screen. In August 2005, the top 12 pharmaceutical companies reported performing 175 ongoing trials in Germany and 161 in the United Kingdom, but only 26 in India, 24 in China, and five in Russia.¹

Of course, there are many factors that go into determining where to conduct clinical trials. Decisions are based on the location of key partners, internal facilities and future product launches. Increasingly, emerging markets are becoming a factor in the decision-making process as well. These markets offer significant potential without compromising the quality of the trials. For example, depending on the choice of location, cost savings can range from 30 to 65 percent compared with sites in the United States or Western Europe. The revenue implications are equally attractive. In low-cost countries, pharmaceutical companies can complete Phase Three clinical trials up to six to seven months sooner than in domestic markets (see sidebar: The Three Phases of Clinical Trials). This translates into getting the drug to market faster—thus providing earlier relief to patients, a faster return on investment, a potential edge over competitors and a longer patent protection.

Certainly, sending all clinical trials offshore will never be practical, but as developing countries become big markets for drug sales, companies should consider tapping into them for clinical trials.

Country Attractiveness Index For Clinical Trials

In devising their offshore strategies, many pharmaceutical companies do not use the same scientific rigor that defines their industry, and instead make decisions based on existing relationships and anecdotal evidence. This is partly because executives do not have the hard data necessary to make such decisions.

The Three Phases of Clinical Trials

In developing a new drug, researchers generally follow three phases:

Phase one establishes the drug’s safety in humans. Researchers give the drug to a small group of healthy volunteers to gain a better understanding of how they metabolize the drug and determine if there are any side effects as the dosage increases.

Phase two determines the drug’s efficacy on actual patients. Researchers study the drug’s efficacy on a larger group of volunteers over a period of up to two years. Most of these studies are random trials in which certain groups receive a placebo while others take the drug. In most cases, neither the researchers nor the patients know which group they are in.

Phase three expands testing to include hundreds or thousands of patients to ensure they understand the full range of side effects and efficacy. Again, these are generally double-blind trials. At the end of this phase, researchers submit the drug to the FDA for market approval.

Once a drug is on the market, pharmaceutical companies continue to study its comparative effectiveness against other drugs on the market and monitor its long-term effects.

Source: www.centerwatch.com

¹ www.clinicaltrials.gov.
With this in mind, A.T. Kearney developed the Country Attractiveness Index for Clinical Trials. The Index provides a fact-based ranking of low-cost countries, highlights the evolving clinical trials landscape and, perhaps most important, provides pharmaceutical executives with a stronger foundation from which to make more informed clinical offshore decisions.

In the Country Attractiveness Index for Clinical Trials, we rank the attractiveness of 15 offshore locations by evaluating five key areas: patient availability, cost efficiency, relevant expertise, regulatory conditions and national infrastructure (see sidebar, “About the Study,” on page 60). The countries were selected based on either their popularity for current trials, such as the United States and the United Kingdom, or their potential attractiveness as an offshore location, such as China and India.

Using the data to compare the relative attractiveness of low-cost countries, China, India and Russia emerge as the most favorable destinations (see figure). A snapshot of each explains why.

**China takes the top spot.** China is unquestionably among the most attractive markets...
for performing clinical trials. With the largest urban population in the world, the country provides a vast patient pool and a large infrastructure of hospitals. China also has close to 1.4 million doctors and more than a million nurses and technicians. Their low salaries, in part, mean that conducting a trial in China could cost about half of what it would cost in the United States.

China is attractive to pharmaceutical companies—with some estimates suggesting that the country could overtake the United States as the world’s largest market by 2020. AstraZeneca opened its East Asia Clinical Trial Center in Shanghai in 2003, but others have been slow to follow.

To encourage more foreign companies to conduct clinical trials in China, the government has passed new regulations and is establishing clinical practice centers to train investigators and staff. Although only hospitals designated by the Chinese State Food and Drug Administration (SFDA) can conduct trials, principal investigators from these institutions often have extensive experience with Western companies, making for a smoother process.

Still, China has its drawbacks. Bureaucracy and strict government regulations pose ongoing risks for companies. For example, gaining approval from the SFDA to conduct a trial can take nine to 12 months, and companies must acquire a drug import license for every shipment that enters the country, rather than one for each type of drug. The country continues to suffer from a weak national infrastructure and sporadic enforcement of intellectual property rights. Cultural and language differences are costly and can slow the process. For example, researchers continue to record data in Chinese, which increases costs for translation and causes further delays.

India is a growing, sophisticated market. Much like China, India offers a vast population and a growing market. The capabilities and expertise of the country’s scientists are on par with the highest international standards. Clinical trial data from India is accepted at major conferences and by refereed journals, and English is the primary language for education and research. Also, strong overall economic growth is bound to lead to improvements in the health-care infrastructure.

The Indian government is offering incentives to promote local pharmaceutical companies and attract foreign firms. For example, there is a tax exemption on all profits for companies that conduct in-house R&D. India plans to create an independent drug regulatory authority that will emulate the U.S. Food and Drug Administration within the next two years. This central group should lead to more rigorous and consistent drug regulations and higher overall standards. Eventually, India hopes to establish a reciprocal agreement with the United States.
so when one country approves a drug, the other will clear it at the same time.

The incentives have coaxed more than one company to India. GlaxoSmithKline conducted several trials in 2004. Pfizer doubled its clinical research investment in India to roughly $13 million and plans to invest another $30 million there over the next five years. Of course, this is a tiny fraction of Pfizer’s total global R&D spend of $8 billion, but the growing optimism for this market is clear.

On the downside, IP protection in India has been weak and currently the country does not permit foreign companies to conduct phase one clinical trials, though both are likely to change in the near future. There are some bureaucratic headaches as well. For example, it is mandatory for pharmaceutical companies to coordinate their efforts with local physicians and hospitals and to perform toxicology tests between phases two and three, which can cause delays.

**Russia dominates Eastern Europe.** Leading companies report performing fewer than 10 trials in Russia, although this number is likely to go up as more companies recognize the benefits. In addition to lower costs, Russia

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**About the Study**

A.T. Kearney’s Country Attractiveness Index for Clinical Trials provides pharmaceutical companies with a systematic way of assessing offshore locations for performing clinical trials. The countries in this year’s study were selected based on a subset of countries that represent regions as well as their overall level of interest as offshore locations—participating countries are from each major global region. We used the developed markets of the United States, Germany and the United Kingdom to establish the baseline countries for comparison. The list of countries is not intended to be comprehensive, but rather a snapshot of country attractiveness across a range of global regions.

Data was derived from both primary and secondary research. Primary research included interviews with pharmaceutical executives and findings from A.T. Kearney’s Global Services Location Index, particularly the examination of country infrastructures and environments.* Secondary research included data from the United Nations, the World Bank, the World Health Organization, the U.S. Food and Drug Administration, and the U.S. National Institutes of Health.

For the analysis, categories were weighted according to the relative importance each plays in making location decisions (see figure). Relative weights could adjust the results of a country’s attractiveness, however, sensitivity analysis highlighted that the positions of the top three countries—China, India and Russia—remained unchanged.

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* A.T. Kearney’s Global Services Location Index white paper is at www.atkearney.com.
offers an appealing patient pool. Under the centralized medical system, patients with similar symptoms receive treatment in the same ward, which facilitates patient recruitment. Many of these patients are also treatment naïve, meaning they haven’t been on prior drug therapies. Such factors allow companies to recruit patients up to 10 times faster than in the United States—slashing the time and money required for a clinical trial.

The problems in Russia are similar to those in India and China. Weak IP protection and various forms of government intervention, such as a tax on clinical trials, are significant hurdles. Ethics in patient recruitment is also a concern. Because doctors can make 10 times their salary by performing clinical trials, there is an underlying fear that some may neglect to inform patients of important risk factors. Companies performing trials in Russia should establish clear procedures and keep a close watch on patient recruitment to ensure compliance with international ethical standards.

Managing Risk

The first few steps into a low-cost country can be the most turbulent. It’s best to begin slowly by conducting a small trial or one component of a trial. This will help create a safe environment and allow executives time to find out what works and what doesn’t. In general, it will take conducting two or three trials in a new location to develop a solid base. To further mitigate risk, many companies decide to collaborate with a multinational clinical research organization (CRO) with hands-on in-country experience.

Over the longer term, companies should develop a comprehensive strategy that pinpoints and manages ongoing risk. The following are key issues to consider:

**Protect intellectual property.** Legislation to protect intellectual property varies widely from country to country, as does enforcement. Until 2005, for example, IP rights in India focused only on process, leaving the door open for local companies to reverse engineer generic drugs in a way that would infringe on U.S. patent laws. Today, many developing countries—including India—are strengthening their legislation, partly because they want to continue to attract western companies. Although the shift is encouraging, skepticism will no doubt linger until new legislation is fully tested and enforced. In the meantime, companies must not underestimate the importance of due diligence and tight contracts.

**Know the regulatory requirements.** From the National Institute for Clinical Excellence in England and Wales to China’s State Food and Drug Administration, drug approval processes vary significantly from country to country. And in many cases, exact guidelines are
not always clear. Because clinical trials vary from one treatment to another, for example, the FDA has not established blanket rules governing them, including those conducted offshore. The FDA largely relies on companies to conduct clinical trials that adhere to their own highest standards and periodically requires companies to open up their international sites for spot inspections. In 2004, the FDA found that researchers did not follow protocol in 30 percent of the inspected sites.

However, an increasing number of countries are improving their standards for trials. In addition to national regulatory guidelines, international guidelines known as the Good Clinical Practice provide a common platform that all pharmaceutical companies, local professionals and CROs should follow.

Learn the ethnicity and understand cultural differences. Ethnicity may affect a trial’s results due to different metabolic rates and genetic variations. Companies should design clinical trials to recognize ethnic diversity and ensure they conduct a sufficient percentage of trials in other countries. Knowledge of ethnic diversity will be an asset if long-term plans include selling within clinical trial countries.

In terms of culture, differences in how professionals practice medicine may skew trial results or affect trial execution. Local customs may also undermine results. In China, for example, herbal medicines account for up to one-third of the nation’s pharmaceutical sales. Researchers may not report the use of traditional herbal medicines, but this could affect the results.

Also, most regulatory agencies require patient diversity within a clinical trial, which means that as companies expand their offshore trials, they must spread the trials out among different regions.

Accelerating Results

A low-cost country approach should not replace current strategies, but rather should integrate into a company’s existing strategy for clinical trials. In line with this, a company should not explore its low-cost country options without first reviewing its decision-making processes and metrics. Is there a process for assessing the supply market? Are the evaluation criteria comprehensive and objective? All supply chain implications and other company-specific goals should be addressed early in the process, and all aspects of the deal, especially those that might affect location attractiveness, should be monitored. With this level of rigor, companies are more likely to realize all the potential benefits from offshoring clinical trials to lower-cost countries.

Consulting Authors

Wynn Bailey is a vice president and leads the firm’s pharmaceutical practice for North America. Based in Chicago, he can be reached at wynn.bailey@atkearney.com.

Carol Cruickshank is a vice president in the firm’s pharmaceutical practice. Based in Toronto, she can be reached at carol.cruickshank@atkearney.com.

Nikhil Sharma is a consultant in the firm’s Chicago office. He can be reached at nikhil.sharma@atkearney.com.
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A.T. Kearney, Inc.
Marketing & Communications
222 West Adams Street
Chicago, Illinois 60606 U.S.A.
1 312 648 0111
fax: 1 312 223 6759
e-mail: insight@atkearney.com
www.atkearney.com

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