BY DENISE MYSHKO

» DEVELOPMENT

# EMERGING MARKETS
# POISED FOR GROWTH

The developing world has been an attractive destination for the clinical development and marketing of new products. But **EMERGING MARKETS PRESENT BOTH OPPORTUNITIES AND CHALLENGES** for pharmaceutical companies.

Emerging markets are growing in size and in importance for drug developers. Countries outside the traditional markets of the United States, Europe, and Japan are revamping their regulatory and legal systems and reforming their healthcare systems, and they are expected to contribute more to the global pharmaceutical industry.

The seven "pharmerging" markets that IMS Health tracks — Brazil, China, India, Mexico, Russia, South Korea, and Turkey — will contribute more than half of global market growth in 2009 and sustain an average of 40% contribution through 2013.

China, which is currently the sixth-largest pharmaceutical market, will become the third-largest by 2011, according to IMS Heath.

Countries where patients directly pay a high portion of their drug costs — such as China, Brazil, and the United States — are already seeing the impact of changing consumer-spending behavior. In more publicly funded markets, including Turkey, Japan, and France, policy responses may differ, from stimulus programs that can have an indirect positive impact on pharmaceutical market growth to the imposition of price cuts in response to budgetary constraints.

In terms of clinical research, pharmaceutical companies are seeking opportunities elsewhere because of the increasing difficulty in recruiting patients for clinical trials in the United States and Europe. According to the nonprofit Center for Information & Study on Clinical Research Participation, 80% of clinical trials in the United States are delayed at least one month because of unfulfilled enrollment.

There is a great unmet need to serve patients in emerging markets with safer and more effective therapies, says Sam Azoulay, senior VP, medical and development, emerging markets business unit, Pfizer.

"We are trying to tackle this issue in a multipronged fashion by exploring new ways to provide our products to those in need with limited access and by developing new treatments and healthcare solutions specifically for diseases that afflict millions of people in the developing world," he says.

> By 2013, the global market will be between $920 billion and $940 billion.
>
> IMS HEALTH

As confidence in the management of pivotal programs grows, combined with a continued increase in access to viable patient populations, investment in staff training and healthcare facilities, well-thought-out development plans are taking these regions into consideration more frequently, says Patrick Lindsay, executive VP of United BioSource Corp.

"These markets are becoming more important to global product approvals as well as pharma's desire for global commercialization of their products," he says.

He says the number of available patients, along with quality data, continues as the primary driver of research into less-traditional markets.

"This driver becomes more powerful when one considers the fact that the increasingly Westernized way of life correlates strongly with disease etiology and need for advanced medicines," Mr. Lindsay says. "As the type of drug or biologic being developed becomes more targeted, the need for treatment-naive patients who have not been previously exposed to these products is a critical component of the safety and efficacy evaluation. With large populations of patients who have limited access to many readily available medications and in the absence of many clinical investigations in these less-traditional markets, there is a willingness to participate within the investigative and patient community, which is evidenced by a greater rate of recruitment than more saturated markets such as Western Europe and North America."

**Sam Azoulay**
*Pfizer*

*"There is a great unmet need to serve patients in emerging markets with safer and more effective therapies. We are trying to tackle this issue in a multipronged fashion."*

Previously if companies wanted 300 or 400 patients, they would go to several major centers in the United States or Europe, says Mark Weinstein, CEO of BioClinica.

"Now the average number of patients coming out of those centers is five or six per protocol," he says. "Companies have to go to far more centers than they had to in the past. That means we have to be smarter about how we do this. We can't invest a huge amount of money in every center to only get five or six subjects."

Emerging markets now contribute to 36% of global patient enrollment, compared with 20% in 2001, according to Ernst & Young and

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FICCI's recent joint report. Over the previous 15 months, countries outside the United States, Canada, and Western Europe have increased their total global study sites by 4.3%, which in absolute numbers corresponds to 6,500 sites. The rest of the world today accounts for nearly 25.9% of Phase I to Phase IV sites.

"The willingness to consider movement into these regions is characterized by the emergence of more and more CROs that have established presence in these markets," Mr. Lindsay says.

The pharmaceutical industry, stalled in part by uncertainties surrounding intellectual property, arrived late to the outsourcing party, says Michael O'Connell, director of life sciences at Tibco Spotfire.

"But pharmaceutical companies — and the emerging markets of India, China, and Eastern Europe — stand to benefit at least as much as other industries from the opportunities that offshoring presents," he says. "That's because offshoring's real value lies not just in cost savings for routine operations, but also in the faster development of new drug compounds and an expanded focus for sales and marketing organizations. For example, low costs for highly technical skill sets in emerging markets offer the prospect of more efficient clinical trial operations from IT and data management perspectives. Low patient costs allow for expanded trials in emerging market geographies, potentially speeding up late-phase development. Finally, the high technical competency in these emerging markets also provides opportunities for companies to gain better insights into clinical data and sales trends by analyzing local and global data more closely."

Terri Cooper, Ph.D., principal, Deloitte Consulting, life-sciences industry group, says there are opportunities in all the emerging markets for the pharmaceutical industry.

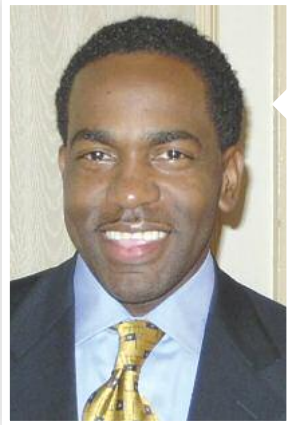
"There is the potential to leverage resources and build out a global organization that will benefit from new technologies and scientific innovations," she says. "Companies that cast a wide global net will benefit from the talents and skill sets that exist in all emerging markets. The pharmaceutical industry is always in need of innovations. China and Russia are examples of countries that are developing outstanding scientists and researchers."

The markets in China and India have registered high growth rates in terms of sales and marketing, though the growth rates in other Asian markets such as Singapore, Korea, Malaysia, Thailand, and Indonesia are equally impressive, says Umakanta Sahoo, Ph.D., executive director, Asia Pacific, Chiltern.

"Both India and China have been compared head-to-head as the future research and development hubs for the pharmaceutical industry," he says. "The key drivers for India and China to hold the most opportunity for the pharmaceutical industry are low costs, qualified staff, and extensive production and research units. Drivers of growth are the growing population in India and China, as well as the larger number of people with markedly higher demand for medicines. With economic growth and liberalization across all the sectors, there is a considerable increase in middle-class households with surplus money at their disposal, leading to improved health consciousness that contributes significantly to the growth of the pharmaceutical industry." ✦

**Mark Weinstein**
*BioClinica*

*"On the medical imaging side, we see high-quality data coming from a lot of the developing countries."*



**Patrick Lindsay**
*United BioSource*

*"Nontraditional markets are becoming more important to global product approvals as well as pharma's desire for global commercialization of their products."*

**Dr. Umakanta Sahoo**
*Chiltern*

*"India and China are characterized by a multiplicity of cultural issues; language, illiteracy, and poverty. And hence, while dealing with trial subjects, we must take utmost care to ensure that ethical and natural justice considerations are a foremost concern."*

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

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## EXPERTS ON THIS TOPIC

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BY DENISE MYSHKO

» EMERGING MARKETS

# RESEARCH & DEVELOPMENT AROUND THE WORLD

While the emerging market constitutes around 15% of global pharmaceutical sales, the **EMERGING COUNTRIES ATTRACT ONLY AROUND 1% OF GLOBAL R&D SPEND**.

According to a recent report by Business Insights, investment in R&D spending in emerging countries is rapidly growing at 20% per annum. During the last three years, pharmaceutical companies that had invested more than 60% of their R&D spend offshore offered greater shareholder return, operating margins, market capital growth, and return on assets.

Business Insights experts find that offshore investment has mainly focused on clinical and postmarketing drug development rather than preclinical drug discovery and research.

Paul Boni, chief research officer at Grail Research, says while emerging markets in general represent a great opportunity for pharmaceutical companies, he is particularly excited about the prospects for the China market.

"Like many other emerging markets, China has a large, underserved population and a fast-growing economy," he says. "What we believe makes China stand out is the government's dramatic push to increase health insurance coverage for the Chinese people. In 2002, about 8% of the Chinese population (108 million individuals) had government health insurance. That number has risen to 65% of the population (856 million individuals) in 2007 and is targeted to rise to 90% of the population in 2010 and 100% in 2020.

**Paul Boni**
*Grail Research*

*"While emerging markets in general represent a great opportunity for pharmaceutical companies, we are particularly excited about the prospects for the China market."*

"Overall, the Chinese pharmaceutical market is growing in the low to mid teens today and is expected to continue at this rate for the next several years," Mr. Boni adds.

But Mr. Boni says China is not a panacea to the industry's global woes.

"Companies will face challenges with basic issues such as establishment of strong intellectual property and regulatory rules, market access to pharmaceuticals, and the transition from out-of-pocket payments to reimbursement models will be slow to evolve," he says.

Neil Campbell, chairman and CEO of Mosaigen Corp., says Asia as a whole provides large growth opportunities, as these countries approach medicine differently from the West.

"The areas of wellness, nutraceuticals, and advanced point-of-care diagnostics are complementing the more traditional life-sciences pharmaceutical sector," he says. "The reasons are many: population growth, rise of larger middle classes, more advancement in science and technology, better care for a larger range of diseases fueled by rising middle-class wealth, and national spending are just a few."

China is among the leading R&D offshore countries, attracting 3% of total healthcare

## CRO PROVIDER OPPORTUNITIES EMERGE IN CHINA

Competition to supply CRO services is beginning to cause consolidation and attrition within China, and a small number of key preclinical service providers have emerged as strong CRO providers.

In addition, a number of state-owned labs in China, as well as private and joint-venture CROs, provide or will soon offer preclinical good laboratory practices (GLP) study services to Western clients.

A recent study by Insight Pharma Reports, Outsourcing Preclinical Studies to China: Benefits and Challenges, provides detailed analysis and cost comparison between China and U.S.-based CROs that show outsourcing preclinical studies to China can result in savings of between 35% and 50%, and that these savings are likely to continue through 2012 and beyond. The report cautions, however, that cultural, language, training, and operational issues can impact the approach Western companies take to evaluating and managing preclinical studies when using a China-based CRO.

According to the report, small- and medium-sized companies can make their preclinical studies' budget go further by using China-based CROs through appropriate due diligence and up-front project planning. U.S. and European Union regulators have accepted preclinical data generated by China-based CROs, and the FDA has begun to build a resident inspector network in China, the report observes.

Source: Insight Pharma Reports

**Neil Campbell**
*Mosaigen*

*"Asia as a whole provides large growth opportunities, as these countries approach medicine differently from the West."*

R&D spend. The BRIC economies continue to attract the greatest share of offshore investment although tertiary countries such as Australia, South Africa, and Israel are beginning to establish themselves as important sites for drug discovery, innovative technologies, and contract services.

Almost half of all offshore deals involved partnerships, codevelopment, licensing, and the supply of new products and technologies between pharma/pharma and pharma/biotech players, while a quarter of deals were associated with technology specialists.

Around 5% of deals involved contract service providers and centralized laboratory testing. These global services providers can offer a range of services from preclinical to clinical research, data analysis to regulatory filing on a national and international level to help to co-ordinate drug development programs.

While the CRO industry may be described as mature, the structure of the sector remains fragmented in terms of service offering, geography, and capabilities, says Carolyn Buck Luce, global pharmaceutical sector leader at Ernst & Young.

"As a result, CROs are forming alliances and joint ventures and undertaking acquisitions to increase their geographic coverage and expand the scope of services and capability," she says. "Regulations and the increasingly global nature of the pharmaceutical marketplace mean that the demand for international multicenter trials is growing."

Last year, Association of Clinical Research Organizations (ACRO) members conducted more than 9,000 clinical trials in 115 countries. Two factors are fueling the growth in developing world trials: fewer Americans are enrolling in trials, and global trials enable pharmaceutical companies to bring drugs to market more quickly and cost-effectively, according to a recent report by ACRO and Value of Insight Consulting.

"South Africa, China, and Brazil tend to have very slow regulatory approval procedures," says Todd Clark, president of Value of Insight Consulting. "Researchers in these countries frequently object to the fact that approval sometimes takes so long that trials are often completed in the rest of world before they are even allowed to begin. In addition to frequent price cuts, authorities in CEE countries are very reluctant to add new drugs to their already-strained reimbursement budgets. Innovative drug makers, therefore, face a significant barrier to access in these markets. Multinational pharmaceutical companies frequently complain about unethical business practices in Korea and other Asian countries. A major issue in China is that hospitals rely on drug sales for a major portion of their revenues. This creates incentives to use locally produced products on which the institution is able to negotiate much higher margins."

**Matthew Eberhart**
*Quintiles Consulting*

*"Quality is a critical issue for clinical trials around the world and especially in emerging markets such as India and China."*

He says CROs are well-established in all of the above regions.

"But there are variations," Mr. Clark says. "CROs have been present in CEE countries for 15 years and have been instrumental in bringing research capabilities in this region to a highly mature level. China, India, and Latin America have shorter histories, but the CRO model has been successfully implanted here as

## GLOBAL R&D STATS

- Global trials speed drug development: The report concludes that globalized trials can reduce development time by half while lowering costs and maintaining quality and safety. For example, Phase III cancer trials are conducted three times as fast if both U.S. and global sites are used, compared with U.S.-only sites. What takes 5.8 years to enroll takes 1.9 when a global trial is implemented.
- Research quality standards must be met worldwide: The report found that trials in emerging countries, such as China and India, are subject to the same standards as those conducted in the United States and Western Europe. CROs train research staff around the world in good clinical practice (GCP) principles, and proof of compliance is required by drug regulators in every major pharmaceutical market.
- Clinical research improves local economies: clinical research offers huge advantages for host countries, including an influx of advanced equipment, trained personnel, and high-paying jobs. The presence of CROs also results in improvements in local health systems. Clinical trial sponsors in Poland, for example, fund 30% of hospital cancer therapy.
- Emerging market equals growth market: CRO activity in Central European countries, South Korea, and Taiwan is very robust, medical infrastructures are advanced, and capabilities are just about on par with Western Europe.

Source: ACRO and VOI Consulting

**FACTORS TO CONSIDER IN EMERGING MARKETS**

- Infrastructure investment: there is a sizable cost to building local market presence. Pharma companies may choose to "build" a local market presence. Pharma companies can partner with a local company, or they can also partner with established CRO/CSO /large multinational companies that have already built a large presence in China. The cost of entry and/or the number of qualified local partners begins to limit the number of players that are able to compete in some of these markets.
- Skill set to support the industry: While many of these countries have an abundance of certain skill sets (such as qualified nurses in the Philippines), the required scientific, technical, and relevant experience may be missing to build a fully functioning infrastructure. Transfer of knowledge, training, and teaching appropriate language skills can help address these challenges.
- Intellectual property: this is still a big issue in many emerging markets, although there has been recent progress in countries such as India and China.

Source: Quintiles Consulting

well. In general, major pharmaceutical companies maintain in-house research centers in a handful of major cities in a few large developing countries, for example China and India. By contrast, CROs have a larger footprint both globally and within developing countries — more cities and institutions. This allows pharmaceutical companies to reach a much larger population base at a lower cost than would be possible by attempting to duplicate CRO infrastructure."

Ms. Buck Luce says all BRICMT (Brazil, Russia, India, China, Mexico and Turkey), Eastern Europe, and Southeast Asian countries present the biggest opportunities, depending on the portfolio and strategy of the individual global pharmaceutical companies.

"China, India, Mexico, and Russia stand out in this context because of the combination of their demographics and government-led

**Carolyn Buck Luce**
*Ernst & Young*

*"China and India are the most challenging in terms of marketing because the potential opportunity is so vast compared with the challenge to access a large, underinvested, mainly rural, and untapped part of the market."*

**Claire Wynters**
*Criterium*

*"We need to join forces with local scientists and researchers to grow both our understanding and businesses in a way that can benefit everyone."*

healthcare reform initiatives," she says. "The Chinese government passed the Healthy China 2020 healthcare reform in January 2009, which includes a $124 billion allocation to speed up the creation of a universal medical insurance system and significantly relieve the medical cost on patients. The Mexican government has also taken steps to improve healthcare for its citizens with a pledge to cover 85% of the country's population under the public sector by 2012, according to IHS Global Insight. In Russia, the public healthcare administrator is reforming the system to include coverage for prescription drugs by 2010."

Rudiger Mees, CEO of Unithink, says his company is seeing the most demand for India, and various Asian countries, plus Russia and other Eastern European countries.

"Their primary reason to conduct trials in these locations is to accelerate patient enrollment or, in many cases, to access patients not available in the Western world or Japan," he says. "These are either treatment-naive patients or patients in countries where the standard of care allows for clinical trial designs that would not be practical or possible in the United States or Europe. From a business standpoint, we do not differentiate between sites based on their geographic location; an investigational site in Mumbai is equivalent to a site in Miami."

Claire Wynters, business development associate at Criterium, says Central and South America are going to be an important challenge, more so than India, China, or even Africa.

"There is tremendous need in underserved and unrecognized populations throughout these regional areas," she says. "The ever-widening gap between the very wealthy who can afford non-regional medical expenses and technologies and the very poor who often cannot get even the most basic necessities, such as running water, is going to be a spectacular challenge for us to address."

For Pfizer, a large number of emerging market countries have been defined as key

countries for the company, says Sam Azoulay, senior VP, medical and development, emerging markets business unit, Pfizer.

"Pfizer is a global company and has the responsibility to conduct clinical trials across the globe where there are qualified pools of physician-investigators, sufficient infrastructure to support quality research, and a sufficient number of patients who are likely to be interested in participating," he says. "Increasingly, this includes countries in emerging markets. Pfizer's research is done to international standards, regardless of where the trial site is located. Our trials incorporate established international ethical standards for informed consent, independent ethics review, post-study care, and the use of placebos."

Last year, Pfizer CEO Jeff Kindler signed an agreement with the Turkish Investment and Promotion Agency (ISPAT), expressing the company's support for pharmaceutical research and development in that country. Pfizer is developing a program to enable Turkish academics working on pharmaceutical R&D projects to apply to Pfizer's international R&D office for support. In addition, Hacettepe University has been named a strategic site, with the Pfizer Clinical Department being located in its technopark. Since 2005, Pfizer has invested $14 million in research and development in Turkey.

## THE CHALLENGES

Emerging markets can present unexpected challenges, Ms. Buck Luce says.

"For example, in recent years, some governments in emerging markets have put price controls on specific drug categories, broken patents on individual drugs, or required drug makers that sell drugs in the country to have factories there," she says. "Distribution challenges related to getting medicines into emerging markets and traversing the plethora of government entities are increasing. Coordinating medical aid providers, patients, product supply, and cold storage requirements also present obstacles. Moreover, manufacturing operations are currently geared to Western consumption, where buying large quantities is economical and product costs are covered by insurance companies or governments. In emerging markets, consumers buy as little as a pill per day, and many prescriptions are never filled. This requires new thinking on packaging practices and costs."

Ms. Buck Luce says in addition to more widespread health insurance coverage and stronger intellectual property protection, governments are beginning to implement reforms aimed directly at manufacturers.

"Governments in India, China, and Russia have or are planning to implement costly safety requirements for drugmanufacturing facilities, spurring speculation that small-scale facilities may have to shut down because they are unable to comply with more costly operations," she says.

Ms. Wynters says politically unstable regions are focused on surviving, not thriving.

"In these areas, access to proper technology is difficult, and the infrastructures to support technological growth have been given short shrift," she says. "To move into these markets may require hard-dollar investment, a choice that may give pharma businesses pause. Creating an environment that invites foreign doctors and researchers to engage directly with pharma businesses worldwide may be the best interim solution toward a slowly mounting change to make inroads into these countries and populations. Companies doing this will increase their entry into markets that have wide-open potential and are not currently being tapped."

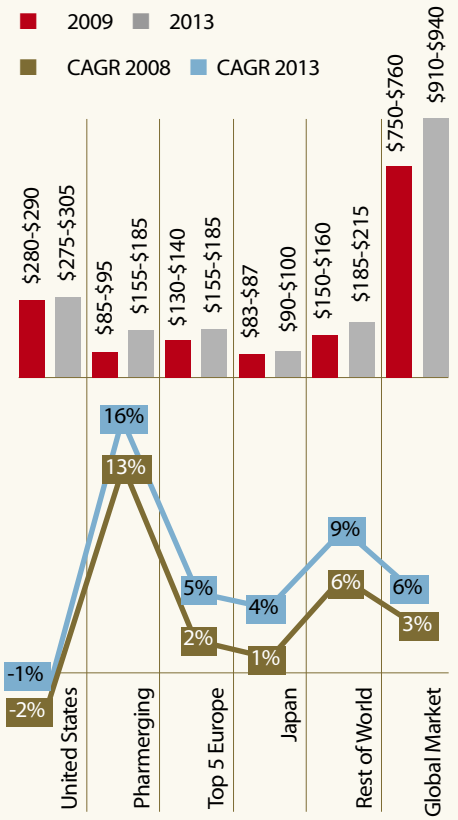
With more new players and new markets entering the value chain, there can be increased vulnerability to counterfeiting and safety lapses, as well as subsequent negative publicity and increased scrutiny from government authorities, Ms. Buck Luce says.

"Companies are expanding outsourcing strategies and are increasingly relying on global sources for active pharmaceutical ingredients, intermediates, excipients, and packaging materials," she says. "Supply chains are now traversing multiple geographic regions with multiple import and export rules, regulations, customs, and duties with fines and penalties increasing for noncompliance. Emerging markets may represent opportunities for developing manufacturing alliances and joint ventures to meet market demands at the local level. Creating such business partnerships can be a complex venture from many perspectives, including deal structuring, governance, regulatory compliance, and total quality and safety."

In terms of clinical trials, Terri Cooper, Ph.D., principal, life-sciences industry group, Deloitte Consulting, says one of the challenges pharmaceutical companies face is maintaining adherence to the regulatory controls, which are required by U.S., Canadian, and European regulatory bodies in the conduct of clinical trials.

"Pharmaceutical companies adhere to good clinical practices, but in markets that are not as developed, maintaining and sustaining this quality of performance can be challenging for clinicians who do not have experience running clinical trials," she says. "Another challenge is related to differences in the standard protocol of care in emerging markets. For example, in some markets, the first, second, and third tier of standard therapies may be very different to those in developed markets. A clinical trial designed in the United States or Europe may not transfer well in an emerging market that has a very different standard protocol of care."

**FORECASTED SALES* IN KEY MARKETS**




Note: * Dollars are in billions
Source: IMS Health

## BEST PRACTICES

Patrick Lindsay, executive VP of United BioSource, says one key attribute of selecting the right mix of countries from less-traditional markets is understanding the complex num-


ber of micro and macro social, economic, and political influences that are playing out in those regions.

"What makes one country a logical choice for one development plan may not be appropriate for the goals of another," he says. "Common hurdles that stifled growth in these markets were long regulatory timelines, complex legislation on certain human fluid and tissue samples, and availability of credentialed staff to oversee complex protocols. Harmonized legislation and centralized regulatory structures in North America and Western Europe markets have facilitated broad product adoption with relative ease. Exploring less-traditional markets, the country-by-country nuances play out to a far greater extent and can introduce greater variability into planning."

Ms. Wynters points out that it's no longer about the products or services.

"Companies have to know the culture and what is valued in the culture they are entering," she says. "They need to find a basic respect for the people and their point of worldview. If respect for them can't be conveyed, they will sense it and the open communication that is necessary to establish a successful mutual business concern will not happen. It's important to be clear that it's a partnership and the two businesses are working in conjunction. No one likes to be confronted with an entitlement sensibility, and this alone can weaken and collapse any hope of coming to a mutually beneficial relationship."

Mr. Lindsay says the move to these regions is most successful when pharmaceutical leaders have a strong working understanding of the countries' approval process — from trial design through to implementation — and healthcare infrastructure, as well as knowledge of how care is administered in those regions.

"Organizations that simply set up an office in a less-traditional market will not find rapid success," he says. "In more niche markets, there is a greater emphasis on how the research fits within the local environment."

Mr. Clark says given the rising need for clinical research participants and the fact that only 15% of the world's population lives in developed countries, pharmaceutical companies have little choice but to conduct trials in developing countries.

"Holding investigators to high standards, thoroughly protecting patient interests, and supporting industry initiatives to improve research infrastructure are all vital steps to ensuring that studies in the developing world produce reliable results in a safe and ethical environment," he says.

From a commercial perspective, he adds pharmaceutical companies need to understand how the health, regulatory, distribution, pricing, payment, marketing, and intellectual property systems work in developing markets.

"There is a great deal of variation from one country to another, and it is easy to make major mistakes by overlooking a seemingly minor detail," Mr. Clark says.

Matthew Eberhart, global business development leader at Quintiles Consulting, says it's important for companies that are pursuing these markets to consider infrastructure investment, skill sets to support the industry, and intellectual property.

### MISTAKES IN LOCATION SELECTION

- **THE HOT SPOT SYNDROME**

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

- **THE SCATTERSHOT APPROACH**

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

- **FINANCIAL MYOPIA**

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

- **GENERAL, NOT GENUINE, ANALYSIS**

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

Source: IBM Institute for Business Value analysis

**Rudiger Mees**
*Unithink*

*"We do not differentiate between sites based on their geographic location; an investigational site in Mumbai is equivalent to a site in Miami."*

Michael O'Connell, director of life sciences at Tibco Spotfire, says in these emerging, developing markets, pharmaceutical companies are building up clinical trial, informatics, and data management competency centers supported by collaborative, analytical software.

"As the competency centers grow, pharmaceutical companies will have to develop a more global approach to collaboration and data management across geographic areas," he says. "By tapping visual analytic and statistical software that is collaborative and allows for 'templating,' best practices may be developed and applied to data across global markets. This also means that eventually these emerging markets can take on more advanced, technology-focused roles, such as clinical trial data management and analysis, and target and biomarker discovery."

Mr. Mees points out that he hasn't experienced any challenges with technology.

"This area is of particular interest to us since we work with sponsors performing clinical trials to help them collect their study data from investigators and directly from patients electronically through the Web and via smart phones," he says. "We have worked with hundreds of sites in these markets and do not see any significant differences between sites in the United States or Western Europe. Sites do not require deployment of any equipment; they all have computers and Internet connectivity. Their personnel are technically proficient and generally speak English; but we do find it useful to be able to support local languages when needed for technical support. The same is true of CRO personnel in such countries. We also find that Internet connectivity is not an issue. We have worked in most of the areas noted above, and patients are easily able to transmit data and receive prompts, particularly in urban centers. It is our belief that technology makes these countries better able to support R&D."

Mark Weinstein, CEO of BioClinica, says he has seen high-quality data coming from a lot of the developing countries.

"We think it's because it's a meaningful part of their revenue stream," he says. "If we talk about medical imaging and clinical trials in the United States, most imaging centers don't make a lot of money from clinical trials. It's a very small percentage of their business. What we find internationally is that people want to get involved and they want to do a good job, and sometimes we get better quality data from those centers than we do from some of the centers in the United States." ✦

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

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