

India is fast emerging as one of the most strategic locations for global pharmaceutical companies to pursue their drug research and development.

Highly skilled doctors, trained paramedical personnel, and a supporting research infrastructure that is growing in sophistication are just a few of the factors that have made India one of the most sought-after destinations for clinical trial outsourcing.

India has been identified by IMS as one of several “pharmerging” countries (China, Brazil, Mexico, South Korea, Turkey, and Russia are the others) that is collectively expected to account for market growth of 12% to 13% in 2008. Additionally, among the leading 15 markets from 2008 forward, these countries are predicted to have a higher CAGR 2006 to 2011. This growth in pharmaceutical sales is being driven by a transitional disease profile, growing access to medicines, and expanding public health programs.

All in all, pharmerging markets are expected to account for 24% of the total market growth, while the top seven markets are expected to contribute just under 50% of the growth.

According to a recent report from McKinsey & Co., if the Indian economy continues on its current high-growth path, then the Indian pharmaceuticals market will undergo a major transformation in the next decade. The market will triple to \$20 billion by 2015 and move into the world’s top 10 pharmaceutical markets.

This growth in the worldwide pharmaceutical landscape will have an additive effect on the contract research landscape. In 2006, the Indian CRO market was estimated to be valued at \$265 million. The total global CRO market was \$14.3 billion in 2006. By 2010, based on a CAGR of 22.7%, the Indian market is expected to be \$600 million. The global market will experience a CAGR of 13.8% and be valued at \$24 billion.

A more aggressive estimation by analysts at McKinsey has the 2010 clinical research market in India valued at \$1 billion.

Furthermore, in 2005 an estimated 1% of global clinical trials were conducted in India, a percentage that is projected to grow to 15% by 2011. And by the year 2011,

more than 300,000 patients are expected to be enrolled in clinical trials in India. According to industry estimates, within five years, 1,500 to 2,000 GCP studies will be conducted in India per year, requiring 10,000 to 15,000 GCP-trained investigators and supported by 50,000 clinical research professionals.

According to Boston Analytics, in 2006 clinical trials accounted for 52% of the total outsourcing market of CROs in India, followed by preclinical trials, which constituted about 30%; together, research chemistry and research biology constituted 18%.

### **Driving Growth**

There are several factors as to why India is becoming a preferred region for clinical operations.

First, the Amendments made in 2005 with respect to the schedule Y of India's Drugs and Cosmetics Act, 1942, have made India more favorable as a center for new trials. The Amendment in schedule Y allows parallel trial conduct in India simultaneously with the rest of the world, eliminating the phase lag that was observed earlier.

India also is expected to become the world's most populous country by 2035, according to The McKinsey Quarterly report. The country is already the youngest: home to 20% of the world's population of people under 24 years of age.

India has a diverse patient population — genetically, culturally, and socio-economically — many of who are also treatment naive.

Diseases such as multidrug resistant pneumonia, hepatitis B, diabetes, and some cancers are far more prevalent in India than in the west. And as incidence of these and other diseases continue to increase these patients become even more important for filling recruitment quotas.

Additionally, shorter recruitment timelines are prevalent in India and patient compliance is higher. These factors are critical when global R&D costs have increased 23 fold in the past 28 years and the average development time in the

United States is approaching 15 years. Typical clinical studies in the United States take up 30% to 50% of the time allowed for R&D, a third of which is spent on patient recruitment. It is crucial to streamline the development process as much as possible. Adding to the country's viability as a clinical trial haven is the fact that many of the patent protection and intellectual property rights issues have been resolved. Since January 2005, India is now on level with developed nations by becoming compliant with the Trade Related Intellectual Property Rights Act (TRIPS).

India possesses a world-class data-processing infrastructure for biostatistics and bioinformatics. The country also possesses large generic drug manufacturing facilities, which will grow in importance as the focus on marketing generic drugs in the United States and Europe will increase radically as many name-brands and blockbusters are scheduled to lose their patent protection this decade.

While there are no language barriers for U.S.-based operations looking to establish a foot print in India, manufacturers, CROs, and patient recruitment companies will need to invest considerable resources on education as 70% of the population lives in rural areas and the poor rely on the public system for preventive and inpatient care. On the other hand, these patient populations often rely on clinical trials for their immediate healthcare needs.

### **The Challenges**

Despite the many milestones India has accomplished in the clinical research arena, there are some challenges that the estimated 120 or so CROs with operations in that country must contend with.

According to one estimation, there are only about 500 GCP-trained investigators experienced in conducting clinical trials. Moreover, with 0.6 doctors and 0.08 nurses per thousand people, India has significantly fewer physicians than the world average: 1.2 doctors and 2.6 nurses per 1,000 people, according to a recent World Health Organization report. Furthermore, the country only has 1.5 beds per 1,000 people, which is much lower than the average — three to four beds per 1,000

people — in other developing markets, such as Brazil, China, South Africa, and Thailand. In comparison, in the United States and Western Europe, where there are larger numbers of elderly populations, there are four to eight beds per 1,000 people.

But McKinsey reports that the number of hospital beds and physicians is expected to double by 2015, driven largely by private investments. The analysts report that as many as 2 million hospital beds and 400,000 physicians will be added. Furthermore, corporate hospital chains will play a leading role in transforming the quality of secondary and tertiary care. And health insurance penetration is expected to double by 2015 to cover 220 million people.

To capitalize on the many opportunities India has to offer, CROs must have a well-structured IT system and a well-supported work flow strategy in place, which will allow greater coordination between sponsor, CRO, and site.

CROs will be charged with initiating a new partnership paradigm between monitors, data managers, and sites.

For example, a CRO can best position itself and its client sponsors for success by having an in-country data management center, thereby allowing for access to information in real time. Locally, CROs should also have monitoring, clinical liaison, and business development functions available to oversee studies that are occurring in the growing number of Indian sites.

CROs may also have to hire more staff to manage sites in more rural areas, areas that tend to be less prosperous and where greater numbers of individuals may rely on studies for their primary healthcare because they do not have access to traditional medicine or health insurance.

It's also critical to have a database of Indian investigators who excel in their respective indications/therapeutic areas. Indian investigators are well-versed with laws and regulations required for the efficient conduct of clinical trials in their country. These study teams include: principal investigators who have great experience with clinical trials and are specialists in their fields; medical and nonmedical staff to ensure smooth conduct of trials; and social workers who are

appointed on certain trials as the study's needs require.

Because clinical trials in India, as in other parts of the world, undergo regulatory/sponsor audits, Indian investigators can prove to be a critical asset in meeting international regulatory standards.

Where the rubber — the technology — meets the road — the workflow — is in the collection of important real-time information necessary to manage trials.

Eliminating data silos and providing clean data back to the sites improves the efficiency of the clinical monitoring/data management process, which results in better service to sponsors, investigators, and staff.

Monitors are experienced professionals who understand that while site selection is a key to executing a successful study, timely patient enrollment and valid clinical data are also critical to the results of each study. Through the use of technology, it is possible to provide real-time data from the site to the CRO team and then back to all team members to make timely decisions.

This process is essential to assist the monitor in the field. Monitors are a precious resource and represent one of the most expensive parts of the process after the patient costs. A solid work process should include: an in-house monitor for each field monitor to reduce the amount of clerical work and corrections the field monitor must make at site visits so that he or she can concentrate on source document verification, process validation, and patient recruitment.

Monitoring in this way means more than being a field monitor. To really improve the process, monitors have to be integrated in real time with a CRO's in-house staff; these professionals get to know the sites as well or better than the field monitors do. Monitors also need to understand what technologies work best in what circumstances. The ultimate goal is reduce the barriers between monitoring and data management.

### Indian Regulation Process for of Clinical Trials

The Drug Controller General of India (DCGI) is responsible for giving regulatory permission for the conduct of clinical trials in India.

The DCGI provides approval in 12 weeks from the date of submission. After the dossier is submitted to the regulatory authorities, parallel submission is done to the respective ethics committees of the potential sites, which are usually hospitals.

There are more than 200 local ethics committees, which are constituted in line with ICH-GCP, and schedule Y of the Drugs and Cosmetic act of 1945. These local ethics committees are usually affiliated with clinical centers; occasionally they function as independent ethics committees.

The average ethics committee approval time line is four to six weeks. Many hospitals (including government and private set ups) also have scientific review committees (SRC) that first review the scientific rationale of the study for better safety and well being of trial patients.

Once the study is approved by the SRC the study is then submitted to the ethics committee for review and approval.

DCGI approval is also required to receive approval for test license to import trial supplies, which takes about two weeks.

All the above procedures in parallel processing require a total of 14 weeks on average.

After the DCGI approval is granted for a particular study, the Director General of Foreign Trade (DGFT) is contacted in the view of getting approvals for export of blood samples out of India. This usually requires an additional period of two to four weeks.

### About Criterium Inc.

Criterium is a full service, global and technology driven contract research organization that offers a unique mix of high-quality, innovative clinical research solutions for the biopharmaceutical, and pharmaceutical, medical device and CRO industries. From thought to finish, Criterium provides timely and accurate clinical trial data and support services at every phase of development allowing customers to make sound and cost effective decisions about their clinical trials. Drug development companies can benefit from Criterium's expertise, high-value services and products and high-end results.

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