GLOBAL PHARMA COMPANIES LOOKING TO INDIA ADVANTAGE FOR CLINICAL RESEARCH SERVICES: FICCI - E&Y PAPER

India ranks third in overall attractiveness as clinical trial destination

NEW DELHI, August 8, 2009. As global pharma companies re-visit their strategies by dovetailing speed, cost of drug development and tapping high-growth pharma markets in their business models, India is emerging as the preferred choice for clinical research services.

This prognosis is held out by a FICCI-Ernst & Young (E&Y) paper on the compelling reasons for doing clinical research in India.

The Indian market is growing by leaps and bounds and is gearing itself to becoming one of the fastest growing clinical research destinations with a growth rate that is two and a half times the overall market growth. India participates in 7% of global Phase III and 3.2% of Phase II trials with industry-sponsored trials having grown at a spectacular 39% CAGR between 2004-2008.

The FICCI-E&Y paper notes that the number of industry-sponsored Phase II-III sites in India has grown by 116% over the last 15 months and India has moved from rank 18 to 12 across the 60 most active countries. India ranks second in Asia after Japan in its number of industry-sponsored Phase II-III clinical trial study sites and accounts for nearly 20% of all Asian study sites.

Says Dr. Surinder Kher, Senior Vice President, Vanthys Pharmaceutical Development Pvt. Ltd and Chairman, FICCI Clinical Research Task Force: “The drug development scenario in India has transformed in the last ten years. This transformation has not only brought India to the attention of the pharmaceutical world for clinical research but many big pharma and biotechs have developed the so called "India Strategy" as a part of their growth strategies. This is the beginning of the road towards scientific innovation including clinical research and the vision of India being the drug development hub. India is probably in the best situation than ever before to achieve this vision with the complete commitment and partnerships between the government, industry and the academia that we have been witnessing especially in the last few years. This certainly is an exciting time.”

As the world’s third-largest producer of drugs by volume, with the third-largest drug research and development workforce, India is a major player in the pharmaceutical industry. The most active 25 pharmaceutical companies worldwide, based on the number of study sites registered, are also active sponsors of clinical studies in the country

The number of investigators in India has also grown the fastest among Asian, Latin American and Eastern European countries with a 42% CAGR between 2002–2008.

India has one of the fastest subject recruitment rates globally (nearly three to five times the global average), with screen failure and drop out rates lower by nearly 40–50%, as compared to global averages. As a result, India contributes 15–30% of global enrolment in multi-centric studies where it is a participant.

Data submissions from India in the recent past have been part of at least 13 successful NDA approvals.

Not surprisingly, therefore, India is ranked third across all countries after the USA and China in terms of its overall attractiveness as a clinical trial destination, according to a recent AT Kearney global survey.
Among the emerging markets such as BRIC nations (Brazil, Russia, India, China), Eastern Europe and South East Asian Countries, the FICCI-E&Y paper notes that India enjoys an unmatched position by virtue of the following uniquely differentiating capabilities:

- Large, genetically diverse and treatment naïve population

- Patient profile aligned with the key research focus of global pharma industry such as cardiology, oncology, central nervous system, anti-infective and asthma
- Transforming provider-care environment characterized by rapidly growing number of world-class medical and diagnostic facilities, investigators and abundant availability of scientific talent
- Well-established presence of most of the global pharma companies and global clinical research organizations
- Ability to offer end-to-end services in clinical research covering trials, data management, medical writing, biostatistics, pharmacovigilance and central laboratory services
- A booming domestic pharma market growing at a rate of 12%-14% annually.

India's clinical research landscape is undergoing a glorious metamorphosis, aided as it is by a rapidly transforming healthcare market and an enabling environment that is rapidly adapting itself to global standards.

Scientific feasibility:

- India constitutes 16% of the global population with 20% of the global disease burden. With 32 million patients in urban areas and ~72 million patients in rural areas at any given point of time, India has a diverse mix of subjects, who are relatively treatment naïve as well as subjects with a high standard of care to meet diverse study protocols.
- The country's disease burden is also well aligned with the new drug development therapy focus of global pharma and biotech, with a shift toward non-communicable diseases. India has 65 million patients with CNS disorders, 31 million diabetics, 29 million cardiac patients, 41 million COPD and asthma patients, 0.8 million cancer patients, with most of these ailments expected to increase by over 50% in the number of cases by 2015.

- All the five major racial types -- Australoid, Mongoloid, Europoid, Caucasian and Negroid — find representation among the people of India, with Caucasian being the most prevalent.

Medical infrastructure:

- The urban healthcare infrastructure, in terms of the number of beds/physicians/nurses per 1000, is comparable with the global average. India has 8,40,000 urban beds. There are over 6,00,000 English-speaking physicians and nearly 1,00,000 specialists, with many of them having been trained in the best global institutes.
- There are 41 hospitals accredited under International Society for Quality in Healthcare (ISQua) by National Accreditation Board for Hospital and Healthcare Providers (NABH) and Joint Commission International (JCI), while 84 hospitals are currently in the process of applying for NABH.
- The Clinical Establishment (Registration and Regulation) Act, which is being promulgated by the government to regulate private hospitals and laboratories across the country, will play a significant role in devising and implementing uniform standards of facilities/services and further enhance the quality of care provided by the Indian healthcare delivery system.

Clinical research expertise:

- There are 350 clinical trials that are ongoing in the country with 64% of the studies being in the five key therapies for oncology, cardio-vascular, neuro-psychiatry, diabetes and infectious diseases.
- India has more than 2299 industry-sponsored Phase II-III clinical trial study sites that are carrying out clinical trial activity across the top 15 cities in the country. All medical records at the sites are maintained in English.
- There are 1500 investigators with the investigator base growing at >40% per year, faster than in other emerging markets. The government is laying significant emphasis on training and capacity building, with the Department of Biotechnology (DBT) setting up six Clinical Research Training Centres (CRTCs) to provide specialized training to clinical investigators (MBBS and MD).
- Nine of the top 15 global pharmaceutical and biotech companies have set up captive clinical research centers in the country.
- Seven of the top 10 global CROs have an established India presence.
- There are more than 20 CAP-certified central laboratories with a significant number of international laboratories providing a suite of esoteric testing services.

According to Dr. Urmila Thatte, MD, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, “Compared to five years ago, the capacity building in ethics review has been very encouraging with ICMR-NIH program and even sponsors contributing actively to training of Ethics Committee members. FERCI (Forum for Ethics Review Committee in India) has

developed a module for training community members who are the backbone of the Ethics Committee."

Policy, regulations and public investment:

- The policies and regulations governing clinical trial conduct in the country, e.g., Revised Schedule Y (of the Drugs and Cosmetics IInd Amendment Rules, 2005), Good Clinical Practice Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services and the Ethical Guidelines for Biomedical Research on Human Participants issued by Indian Council of Medical Research, 2006 are consistent with the principles enshrined in the Declaration of Helsinki, which ensures the credibility of clinical trial data emanating from India.
- The government is planning and executing a number of initiatives to strengthen the institutional machinery, e.g., mandatory registration of clinical trials (w.e.f.15 June 2009), mandatory registration of stakeholders (viz. CROs, ethics committees, investigator sites and investigators), enhanced monitoring and oversight (random audits, inspector training workshops by USFDA, imposition of penal provisions such as 10-year imprisonment for misconduct and fraud in trials) and "e-governance" of the entire drug approval process. These are a testimony of the government's commitment to create a regulatory environment in line with the highest global standards.
- The government is also embarking on a major multi-billion dollar initiative with 50% public funding through a public private partnership model to harness India's innovation capability. The vision is to catapult India into one of the top five pharma Innovation hubs by 2020 with one out of every 5 to 10 drugs discovered worldwide coming from India by 2020.

Commercial attractiveness of India as a pharmaceutical market:

- The Indian pharmaceutical market — the third-largest globally by volume is expected to treble in value to USD20b by 2015, to be counted in the top 10 markets of the world.
- The advent of the product patent regime in 2005 has instilled confidence in the intellectual property regime with many patented drug launches over the last two to three years.
- While, pharmaceutical MNCs already present in India are further consolidating their presence through acquisitions, many MNCs have staged a re-entry post 2005. It is estimated that the share of pharmaceutical MNCs in the domestic pharmaceutical market will rise to 35% by 2015 from the current 25%.

Cost competitiveness:

- In addition to the above advantages, clinical trial conduct in India comes at 50–60% of the cost as compared to developed markets.

- India's value proposition extends beyond Phase I-IV trials with other allied services such as data management, medical writing, pharmacovigilance and biostatistics services gaining the attention of sponsors and CROs.
- Delivery of allied services requires an appropriate blend of system and domain skills, and India's proven IT/ITES track record, domain expertise and cost advantage has made it a destination of choice for these services. The Indian industry for these allied services is growing at 21%, which is almost thrice the global average.
- India has consistently been ranked as the most preferred destination for the provision of outsourcing services in the IT/ITES segment. India accounts for 65% of the global offshore IT services with KPO exports growing at 51% p.a. (2004-08).
- There are more than 45 companies with six to seven years experience spanning CROs, IT/ITES companies, specialized providers and the captive centers of global sponsors that are offering the complete spectrum of allied services. At least 8 of the top 10 pharma companies are providing one or more of these services from India, either by setting up captive centers or through tie-ups with CROs and IT/ITES companies.

Paradoxically, however, the FICCI-E&Y paper notes, despite its inherent advantages, India still contributes only 1.5% of global patient enrolment and sites and 2% of clinical trial volume. The global community not set to harvest the full potential of its patient pool, medical infrastructure, clinical trial expertise, IT capabilities and regulatory reform to the fullest extent.

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