

The India Opportunity

IndiPharm: Your Gateway to Clinical Research in India

“There is no doubt that the cost of doing clinical trials in the U.S. is absolutely prohibitive, and we can save substantially – I mean hundreds of millions of dollars of pure savings – by switching some of those trials to other, lower-cost countries.”

GlaxoSmithKline Former CEO Jean-Pierre Garnier to Business Week

The total worldwide R&D spending for pharmaceutical and biotech companies (Pharma) in 2007 was \$117 Billion, of which 70% represented development costs. This spending is expected to grow at 11% annually and will be \$218 billion in 2013. The CRO market for Phase 1 through 4 trials represented about \$7.8 Billion in 2007 and is projected to grow to \$17.2 Billion in 2013.

India provides a number of significant advantages for the outsourcing of clinical trials because it offers a large patient population that facilitates **faster recruitment, low trial cost** per patient, a **highly qualified professional medical community**, plus **global quality** hospitals and clinical research facilities. Furthermore, with a highly developed IT and data collection capability and no language barrier, India has become an important destination for clinical trials, and exponential growth is expected in the number of trials conducted there in the near future.

India Background

Until recently, there were few clinical trials conducted in India by Western pharmaceutical and biotech companies, primarily because of regulatory hurdles. In January 2005, recognizing the significant advantages that India offers to multinational companies and the potential and benefits of conducting clinical trials in India, the Government of India upgraded Schedule Y of the Drugs and Cosmetics Act of India, the equivalent of the sections of the Code of Federal Regulations applicable to the FDA, to harmonize it with U.S. and International Conference on Harmonization (ICH) standards. These changes removed a number of regulatory barriers to performing clinical trials in India. The changes formalized the definition and conduct of clinical trials; specified the responsibilities of the sponsor, the investigators, and the Ethics Committees; developed guidelines and procedures for importing drugs for clinical trials; instituted required compliance with GCP; specified the requirements for informed consent; and defined the structure, content and formats of clinical study reports. In addition, the Indian Government provided increased protection for intellectual property (IP).

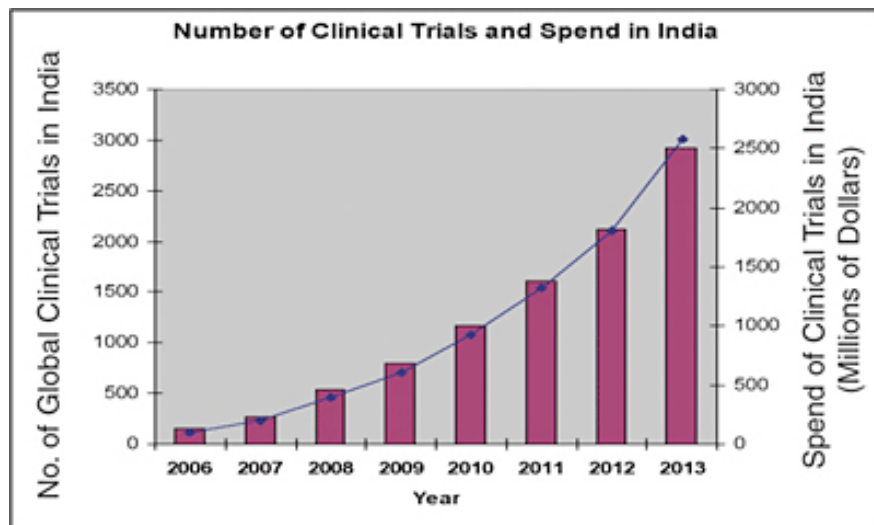
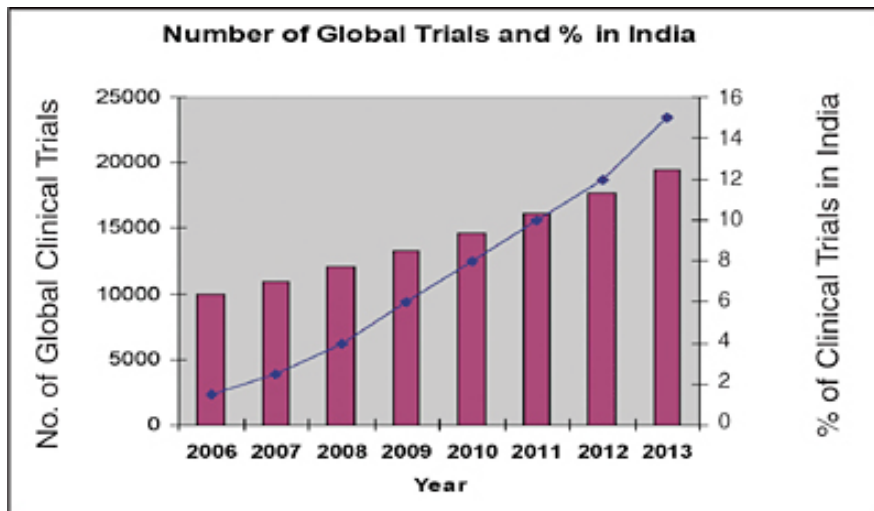


India Advantages

- “Western” disease distribution
- High patient numbers available
- Many tertiary care and specialty hospitals
- Large number of medical specialists
- Patients generally “therapy naïve”
- Low cost
- No language barriers
- IT-based advantages

India Projections

The cost per patient for trials in India is approximately 40 to 60% of the cost in Western nations. More importantly, patient recruitment can be greatly accelerated, and this provides a major advantage in terms of shortening the time to market for a new drug. Based on these advantages and those listed above, the number of clinical trials in India is expected to grow exponentially over the next five to ten years. It has been estimated that in 2005 only 1% of global clinical trials were conducted in India. This percentage is projected to grow to 15% of global trials by 2011. The charts below illustrate the effects of such rapid growth, projecting that by the year 2011 over 300,000 patients will be enrolled in clinical trials in India. McKinsey projects that 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.



Source: IndiPharm projections based on information from The Boston Consulting Group and Business Communications Co.

India's Capacity to Meet Increasing Demands

India has substantial capacity to meet the rapidly growing demand for clinical trials. India has 300 universities, over 750 graduate and post-graduate programs, and about 50 million college graduates. There are over 700,000 medical professionals and over 600 ICH/GCP compliant sites. Furthermore, the Indian Government and industry have cooperatively taken a number of major steps to strengthen the infrastructure for conducting clinical trials. New GCP standards have been established, a number of comprehensive training programs have been developed, and many new graduate and undergraduate programs have been initiated. English is the medium of transaction in higher education, business and medicine.



These measures have led to the creation of a large pool of specialist clinical investigators who are GCP-trained and compliant, and who have participated in numerous international clinical trials. Supporting these investigators is a large pool of trained clinical research professionals. In addition, the Government also streamlined the process for regulatory review of clinical trials to facilitate protocol approvals.

The Regulatory Approval Process

Clinical trials are now regulated by the Drugs Controller General of India (DCGI), who is responsible for assuring that all clinical trials comply with the requirements of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, as well as Good Clinical Practices. The DCGI approval process categorizes clinical trials into two types. If the study protocol has already been approved by a cognizant regulatory authority in one or more developed countries (such as the U.S., Canada, U.K., Switzerland, Germany, Australia, Japan, and South Africa), the study is classified as a Type A trial and can be approved using a fast-track process within two to six weeks after the required documentation has been submitted. All other studies are classified as Type B. For these, the approval process is generally 8 to 12 weeks. The Institutional Review Board (IRB) approval process can be conducted in parallel with the DCGI review and, if import licenses are needed, the applications for these can also proceed in parallel. These provisions facilitate the process of getting study protocols in place and quickly initiating the trials.

Bridging the Needs

Western Pharma companies need to increase productivity, decrease costs, and shorten the time to market for new drugs. One solution is conducting clinical trials that provide lower cost and faster recruitment without compromising the quality of the research. India clearly offers this solution. In the past, several constraints have limited the number of clinical trials conducted in India:

- Communication can be an issue because of cultural differences between Western countries and India.
- The difference in time zones creates further difficulties in communication and monitoring of work.
- There are some significant differences between Western and Indian business cultures.
- Indian researchers need to clearly understand the requirements of Western pharmaceutical companies and their regulatory requirements.
- Western companies need to overcome their perception of India as a non-traditional “developing” nation that is the “land of the generics” with limited capacity and uncertain quality of work.

These issues are not unique to clinical trials. Similar issues have been faced and successfully addressed in fields such as information technology (IT) and business process outsourcing (BPO), where India is now a leading provider of services to Western clients. IndiPharm was established to provide a “bridge” to Western clients interested in conducting clinical trials in India. IndiPharm executives have taken advantage of the lessons learned in IT, BPO and other fields to create an organization that provides a strong Western presence for client interface and client services combined with an Indian operation that can execute projects and programs efficiently and effectively.

IndiPharm maintains a full project management staff in both the U.S. and India. All of these staff members participate in a cross-training where they spend time working in the role of their counterpart in the other country. This allows them to understand and bridge the similarities and differences between the two countries.

The substantial time difference between the U.S. and India allows IndiPharm to work effectively nearly 24/7. Our teams have teleconferences daily to assure seamless transition as the India day ends and the U.S. day is just beginning.

Our scientific advisors have deep experience as investigators and researchers. They have published and presented extensively in the West and have their research organizations built on this model.