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Clinical research in India

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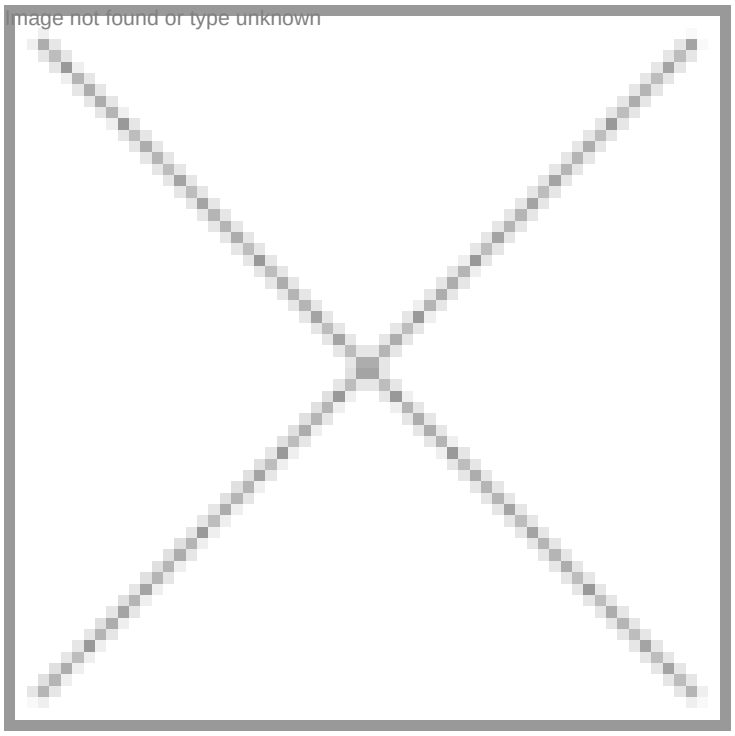

Clinical research in India

The unique position of India in clinical research is no accident, but a result of many compounding factors

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Suneela

In India, the clinical research industry has enjoyed a sharp growth like few other industrial sectors. The potential of clinical research in India is not only recognized by the stakeholders and the government; but now, every company must have an 'India strategy' regardless of whether it is a pharmaceutical company or contract research organization (CRO).

The unique position of India in clinical research is no accident, but a result of many compounding factors. It is an undeniable fact that the spiraling cost of new drug development and declining R&D outputs are driving the pharmaceutical companies to explore emerging markets, giving a boost to clinical research in these regions, including India. However, the industry has evolved from its initial focus on the bio-availability and bio-equivalence (BA/BE) services, and the local pharmaceutical industry to a full service provider to the global pharmaceutical and biotechnology community, including phase I–IV trials and associated services.

Transforming factors

Several factors have played vital roles in the transformation of the industry. The most prominent factor is perhaps the access to patients across a variety of disease areas, including treatment naive patients, coupled with medical expertise and infrastructure, and a standard of care that is comparable to developed countries. With a prominent socio-economic

transformation and urban-to-rural migration, the disease profile of the country has changed considerably in the past two decades.
With increased urbanization, industrialization, and adoption to western lifestyle and diet patterns, there has been a surge in the lifestyle-related disorders. Today, in India, we can see the diseases of both the developing and the developed world. This scenario coupled with a high number of English speaking and well-qualified allopathic physicians provide a unique advantage. The advantage that language offers in India makes the country unique among emerging nations. In addition to all of the above, the cost competitiveness that India offers cannot be ignored.

Regulatory environment

Another important point is the regulatory environment, which is stable and conducive for the growth of clinical research. The requirements laid down in the revised Schedule Y of the Drugs and Cosmetic Act 1940, which governs conduct of clinical research in India; the GCP guidelines published by Directorate General of Health Services; and ethical guidelines for biomedical research on human participants by Indian Council of Medical Research are in line with the principles laid down by ICH GCP guidelines and Declaration of Helsinki.
Over the past few years, regulators have taken definitive steps to enhance acceptability and attractiveness of India as a clinical research destination. The most significant step was allowing the conduct of concurrent phases of drug development with the roll-out of revised Schedule Y in 2005. Some of the recent initiatives such as mandatory registration of clinical trials, and planned ones such as registration of organizations involved in clinical research and enhanced monitoring by inspections, indicate the commitment of the regulators to ensure that regulatory environment is of highest global standards.

Areas of attention

Even though there has been an increase in the number of competent clinical research professionals, this is not comparable with the increase in trial numbers. While most pharmaceutical companies and CROs have machinery to train their own staff, training of investigational site staff remains an area that requires attention.
Each player in the clinical research arena must remember that clinical trials are experiments, while these experiments are an essential step in new drug development, as they deal with human life. This passion must be felt by each member of the clinical research fraternity in India.