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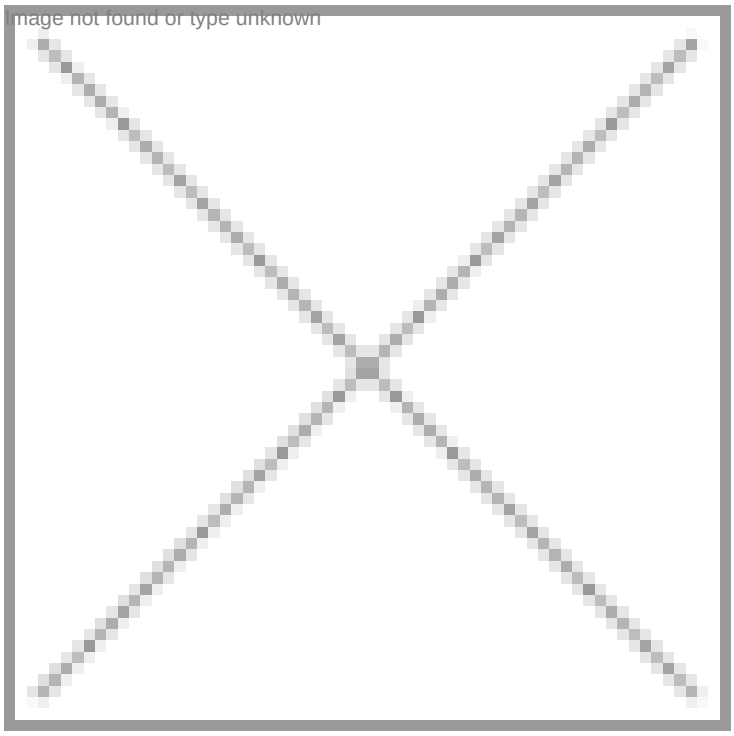
Clinical Trials can be India's Pride

12 November 2003 | News



India, having the potential to build internal capability and being a center of attraction for global pharmaceutical companies, can grow exponentially in the area of clinical trials and contract research operations.

MNCs find all the favorable conditions necessary for a knowledge-base industry and clinical trials in India. It's not a surprising fact that everyone is talking about India's knowledge base, talent and manpower. But the reality is that India has to go a long way to make a mark in the global marketplace. As of now, the high voltage regulatory conditions seem to be making clinical trials and research not a fluent and easy business option in India. It is basic to have a strong and competent drug regulatory system for the Indian pharmaceutical industry to reach global levels. Drug Controller General of India (DCGI) Dr Ashwani Kumar too acknowledges this. Citing some global facts about the good quality regulatory system, at a seminar on clinical research organized by CII in New Delhi, Dr Kumar, said, "The stature of the US Food and Drugs Administration (USFDA) is helping the US pharmaceutical industry in a big way. The stronger the regulatory authority, the better is the quality of the drugs that are manufactured in that country."

Globally, there are clinical trials involving about eight million subjects and 0.5 million clinical investigations in a year. The clinical trials situation in the country has little in common with what is taking place in other parts of the world. "India can emerge a top level destination for drug discovery and clinical research in less than a decade," believes DS Brar, CEO and MD, Ranbaxy Laboratories. This can happen only if all the stakeholders in drug research join hands to collectively enable the country to attain this status in near future. According to Brar, "For achieving this goal, we have some immediate requirements to meet like adequate infrastructure for carrying on GCP clinical trials, proper policies and systems for inspections and auditing of clinical trials, competent ethical committees and safeguards to protect the interests of the subjects, who undergo

clinical trials."

A centralized system will definitely help as there are no uniform measures yet. The experts in the industry point out that the Mashelkar committee set up for suggesting methods of improving the efficiency of drug regulation in the country had in its interim report called for a centralized system. If the centralization of drugs control would have been carried out years ago, that might have made us internationally visible. The industry believes that that even if the changes are introduced now, the industry would tremendously benefit from it.

India has untapped potential which should be tapped fully. According to JVR Prasada Rao, secretary, Ministry of Health and Family Welfare, "Clinical research in the country is bound to undergo changes in the future. Companies will not be able to survive by just being dependent on generics and will need to focus on new molecules. This will require greater financial investments as well as technological upgradations. In the area of clinical research, India would have to focus on being more open and transparent. Members of civil society acting as watchdogs would also need to be taken along."

According to CII, a large and diverse patient population, networks of academic and medical centers/hospitals, well preserved genetically distinct population groups and a pool of qualified scientists, technicians and doctors are the distinct advantages that India offers. The rapid advances in this area are set to place India on the global platform in the realm of clinical research and trials. There is an increased focus on upgradation of hospital infrastructure to meet GCP standards, regulatory guidelines and establishment of GCP complaint ethics committees. At present, a large number of bio-equivalence trials of approved products and bioavalability studies of generic products, which are under formulation development, are being conducted in India.

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