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The India challenge for clinical research

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by **Prabhu Ram**

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Once upon a time, not so long ago, India's clinical research industry was one of the most highly sought after destinations for conducting studies. The clinical research market in India was growing at a rapid pace and was estimated to be worth $500 million. The key pull factors for the India market was the large diverse patient population, faster patient recruitment and a significant cost advantage compared to other markets. Some other pull factors were the availability of skilled medical professionals, a good infrastructure, and sites compliant with the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

But now, the uncertain times are upon the industry in the country. With the Supreme Court's interventions, the regulatory authorities are now gearing-up for stricter laws for patient compensation and penalties. According to the new regulations, the patients have to be compensated in case of lack of therapeutic effect of a drug. When it comes to a new drug, it is difficult to know about its efficacy. Compensation for clinical trials patients for those who got injured or died from adverse reactions has always been rare. The issue of compensation has led to debates between sponsors and human right activists. Sponsors are not prepared to expose themselves to unlimited and unspecified levels of compensation in an ecosystem that is relatively new and where clinical trials are, in some instances, done unscientifically. This has led to sponsors moving phase I trials away from India, causing loss in business for local clinical research organizations (CROs).

The draft compensation guidelines need to be re-looked at and reworded to ensure that they are balanced, just and protect the interest of all stakeholders in the drug development process. New conditions for clinical trials have been laid down by the

Government of India. In addition, it has been proposed to empower officers to inspect premises of sponsors without prior notice. The officer's purview covers the employees, subsidiaries, agents, contractors, sub-contractors and trial sites of the sponsors. When it comes to ethical committees, all the ethical committees must be registered with the authorities before conducting drug trials.

The regulatory uncertainties in a nascent industry have meant many errant fly-by-night firms continue to operate in India, while the local CROs are looking at pre-clinical services, or establishing presence in new markets, and sponsors are looking at newer markets.

Adding to the regulatory issues mentioned above, intellectual property protection and compulsory licensing continue to pose significant challenges for sponsors looking at India. All the uncertainties and delays have translated into very few clinical trials in 2013. India currently presents a very challenging environment for clinical research. Sponsors and CROs are on a wait-and-watch mode, and awaiting clarity in the regulatory process.