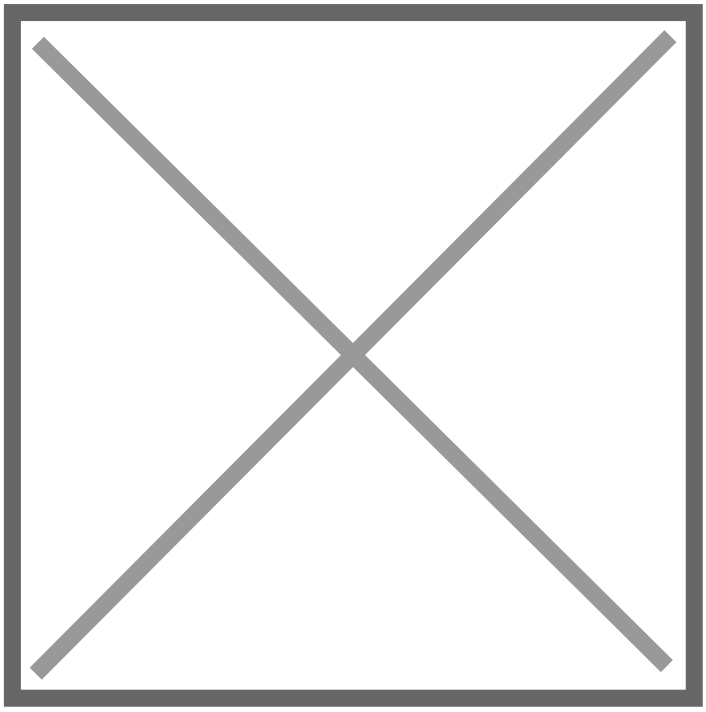
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Expert Opinion - Apurva Shah

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CLINICAL RESEARCH

Apurvashahveeda

Buoyant, but not booming

India's clinical research sector has seen a negative tide since 2008

After witnessing a single digit growth for a couple of years, the global growth of outsourced drug development and clinical research has been steadily rising and it is expected to average between 12-14 percent over the next few years. The increase in the valuations of the global contract research organizations (CROs) is the reflection of the optimism about its growth prospects again. This is perhaps due to the fact that the world needs continuous investments in research and development (R&D) and a larger portion of the R&D is being outsourced every year. There is a trend to conduct increasing amount of R&D in new geographies where the right quality of data can be generated by optimizing cost and speed so that the new medicines can be brought to the market faster.

During 2005-2009, India's clinical research industry grew by 17.7 percent, which is well above the world's average of 2.6 percent. But since 2008, we have been having a negative growth due to the non-industry friendly environment in India. Countries such as China have been growing consistently and the more shocking numbers are from South Korea which, in spite of having a tiny population in comparison to India, is doing more clinical trials in absolute terms and are growing at a faster pace. India must learn from countries such as Korea, which has invested in infrastructure to ensure that clinical research happens in an organized manner and which has established a robust regulatory framework that allows good clinical practice (GCP) compliant trials across the country.

The Indian government will need to take a number of steps to eliminate the issues and regulatory hurdles that slow down the growth of the Indian clinical trial market. CROs are both optimistic and slightly skeptical about whether the predicted 20-25 percent growth figure will be achieved.

Indian pharmaceutical companies are currently developing drugs for diseases including cancer, malaria and tuberculosis. These are green shoots of promise in the future which need to be nurtured, so that we develop the required expertise in the country to develop new drugs. This isn't a quick learning experience and will take years but the end result will be that, we will have the capability of developing drugs in India in an economical way and have a treatment for our local illnesses which does not exist in the western world either.

To conclude, the Indian clinical research market is buoyant and many of the world's major pharmaceutical

companies are looking at India for outsourcing partners thanks to its large patient population, disease demographics and significantly lower operational costs. In order to achieve aggressive growth targets, CROs and pharmaceutical companies must work with the Indian government to streamline regulatory framework, address ethical issues and establish new mechanisms for private-public partnership (PPP), enabling India to offer scientifically driven, value-added research. This way, India can lead the way in drug discovery and research innovation, while also addressing domestic healthcare challenges.

- Apurva Shah, founder and group managing director, Veeda Clinical Research; chairman ACRO India.