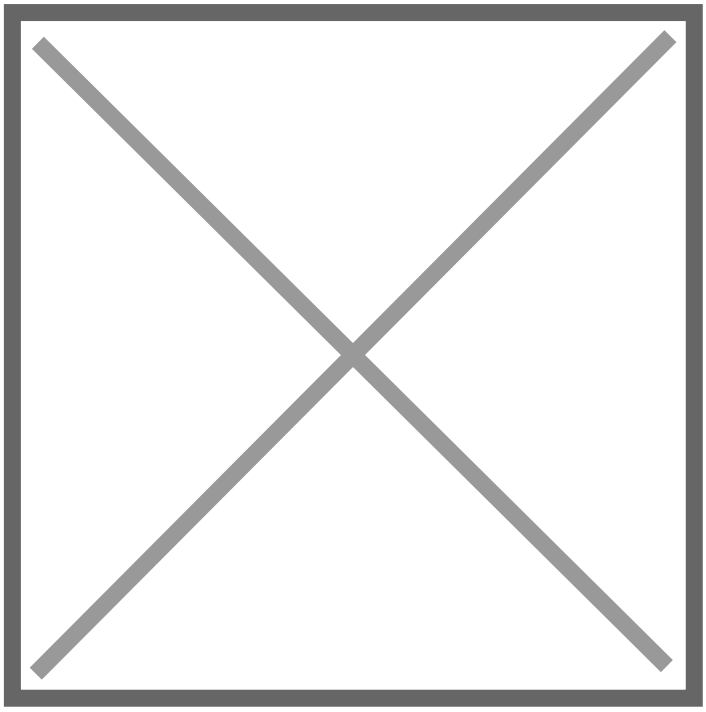
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Expert Opinion - D A Prasanna

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CLINICAL RESEARCH

Daprasannaecronacunova

Light at the end of tunnel

Despite a fine ecosystem, regulatory uncertainties have neutralized growth momentum.

Indian clinical research was projected to grow to $1 billion market by 2010 in a widely discussed McKinsey report of 2002. From these inspirational heights, the market was estimated at $250 million, in another widely discussed E&Y report in 2009. Leading CROs estimate a growth rate, since 2009, at a modest 5 percent and size the market in 2012 at $300 million. Stakeholders in clinical research are left wondering Ã¢â?¬Å?where did things derail and what is the way forward?Ã¢â?¬?

For healthy growth, fundamentals of global competitiveness should be sound and the sector should attract talent, capital and leadership. Disease burden, medical infrastructure, attractiveness as a pharma market, clinical research expertise, cost competitiveness, and regulatory environment provide sound fundamentals for the growth of the Indian clinical research sector.

It might be pertinent to note that the sector has attracted leadership and capital and capacity has been built. The ecosystem, when audited to global standards for GCP, GLP and GMP, compliance came out with very good results.

Has the return to society been good? It is difficult to answer this, but it is easy to conclude that there is an under performance to the capacity established and a gross under performance to the potential. Another indicator is the opinion of investors. There are not many liquidity events. Lotus investors' story is perhaps the best, followed by IL&FS Ventures' exit from Acunova. In most other investment cases, the funds are struggling to get a meaningful exit.

On the downside of the story, early this year, Mr Dennis Gillings, chairman, Quintiles told Economic Times 'if there is an element of doubt, you are seen as guilty and need to prove your innocence. I want to divert my investment to China'.

In our experience, sponsors from Japan, US and Germany have decided to withdraw from India citing uncertain regulatory time-line, trial injury compensation issue, patent dispute decisions and NGOs' opposition to clinical research. Clients, talent and capital have shied away from India. Headwind in the sector has neutralized the growth momentum. Regulatory uncertainty and negative public perception are the two biggest

causes.

For the environment to improve, India needs an effective regulator, mechanisms to build positive public perception and a government with political will to back the regulator for the right decisions. For the political will to return, we would probably have to wait till next election. However, we can do something about the regulatory scenario.

Meanwhile, we have to continue our focus on quality, participant safety, talent retention and align costs to revenue, to be the best in the world. Fundamentals of clinical research competitiveness of India remain robust. Let us remain motivated for the next few years and advocate a strong regulatory infrastructure.

- D A Prasanna, chairman, Ecron Acunova CRO (Views expressed by the author are not necessarily views of Ecron Acunova)