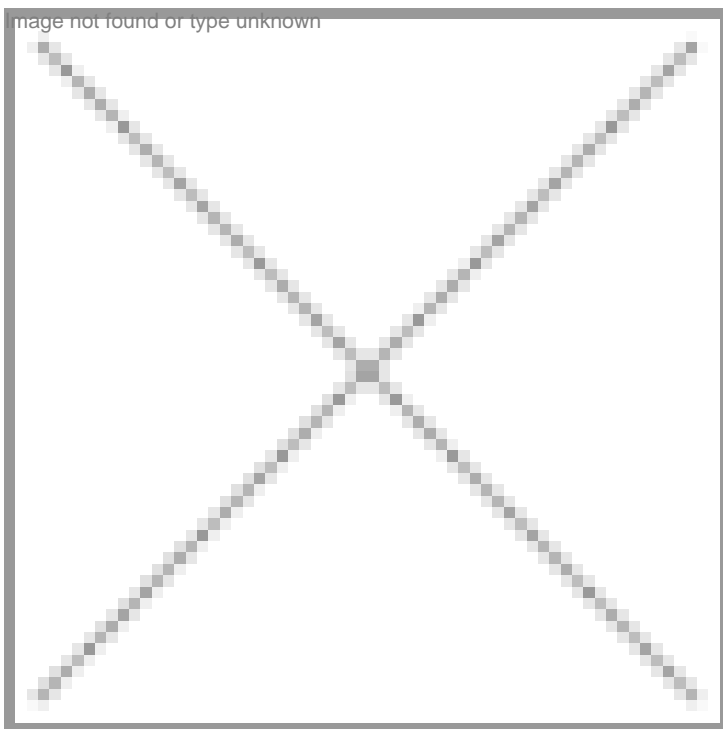


'India is trailing behind China in many aspects'

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The clinical trials industry, which was once riding on the growth wave and dubbed as the 'sunshine sector' by market observers, now lacks a meticulous regulatory structure and is stung by delays in approvals of clinical trials. In an interaction with BioSpectrum, Ashish K Dasgupta, vice-chairman, Association of Contract Research Organizations (ACRO), India gets candid about the current predicaments prevailing in the Indian CRO industry and hides no bones about the need for a transparency in the system. He envisions ACRO India to be the apex body representing the clinical research industry in India. Excerpts of the interview:

Q Globally, many biopharmaceutical companies are focusing on cutting down the cost of research and development (R&D) while bringing drugs to market faster. How should Indian CROs gear up towards this development?

Dasgupta: To take a significant share of the global market as a result of biopharmaceutical companies cutting down budgets, the regulatory environment needs to change. The R&D productivity, which is key to the growth and success of the industry, has declined dramatically in the last few years in the US. The cost of developing and bringing a molecule to market is now estimated at \$1.3 billion. However, company revenues are not growing fast enough to sustain such spending levels. The good news is that despite all negative reports, all Indian CROs have gone through international regulatory audits successfully.

Q The fall in clinical trials in the US has resulted in increase of clinical trials in the emerging nations of the world. What has been the progress in India, especially compared with China?

India is still trailing behind China in many aspects. While India has a market share of 2.20 percent, China has 2.83 percent of it. As of 2009, India is lagging behind China in terms of number of clinical trials too, with the total being 246 as compared to 316 in China. Between 2008 and 2009, the Indian clinical research market registered 9.60 percent decline in revenues while China's grew by 15.30 percent.

Q 2011 saw a drop in the number of clinical trials approvals. Any particular reason for the decline?

The numbers have decreased because we have become reactionary to various issues raised by the media and have not been able to defend our stand in the right manner. As a consequence, the approval process has become extremely slow.

Q What are some of ACRO's current initiatives in dealing with the negative reports about the industry?

ACRO is proactively conducting regional meetings with print media and sharing with them the reality of the situation in the country. In 2012-13, we intend to make ACRO a more robust body by implementing a code of ethics among the members and initiating a high level advisory board.

Nayantara Som Banerjee in Mumbai