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Ã¢â?¬Å?Staring at a bleak futureÃ¢â?¬?

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Choked by hyper activism on one side and uncertain regulations on the other, the clinical research industry in India is no longer an attraction. Despite its strengths of offering low cost English speaking workers, sites, and volunteers, it has lost its sheen as a potential ground for conducting clinical trials. While reasons are multifold, the immediate one is the significant decline in approvals to new trials. The litigations by activists too have stalled activities to great extent. The allegations of irregularities made the Supreme Court of India issue a ban on clinical trials but subject to changed norms. As per sources, out of close to 162 trials that were cleared by the health ministry in July-August, 2014, there were only 4 of them that were actually conducted. There has been a drop rate of 60 percent in the clinical trials conducted by Indian CROs. The average loss of business revenues stood anywhere between 30 to 40 percent.

"Over a period of time, there has been a decrease in the number of trials. From 2010 onwards, there has been a five-fold downturn in trials owing to the negative environment prevailing in the country", said Dr Shoibal Mukherjee, an experienced clinical research expert. In 2012, about 272 trials were approved, followed by 107 in 2013 and the year, 2014 has witnessed a slight increase in number but the success rate cannot be determined by approvals but the actual trials that take place. The slowdown in clearance is also evident in the case of new drug approvals. While 35 new drugs were approved by the regulator in 2013, only seven new medicines have received a go-ahead so far this year.

There used to be a time when India was looked at as the best destination to do trials but now, in order to compete with other Asian nations, the country has to improve its quality standards and clear the regulatory uncertainty. In case India streamlines its regulatory scenario, it can still be counted among one of the favourable destinations owing to trial costs, which can be 70 percent lesser than the west. Also, the R&D costs in India are substantially low than those in the developed countries making it possible to conduct both new drug discovery research and novel drug delivery system programs at competitive rates. Besides, here in India, clinical studies for the evaluation of various alternate systems of medicine can also be conducted. There are numerous government-funded medical and pharmaceutical institutions with state-of-the-art facilities, which can serve as ideal centers for multi-centered clinical trials.

"Clinical research in India should be reflective of the country's ever increasing healthcare needs," said Ms Suneela Thatte, president, Indian Society for Clinical Research (ISCR) at a panel discussion held in Delhi to discuss the clinical research environment in the country. "The growth in the industry, which peaked from 2005 to 2010, has seen a massive decline in the last few years, due to widespread misconceptions and the uncertain and unpredictable regulatory environment. We need to ensure that enough research is being done in India to address our triple burden of diseases which include communicable diseases, non-communicable diseases related to lifestyle, and infectious diseases."

In India, the CRO sector is highly fragmented and varies from hundreds of small, specialised service providers to several large full service businesses with global operations. Among the strategies employed by CROs, one is either to become a complete service provider or cater to niche services. There are also only a few companies that have their own investigative sites but more and more companies own their research bases. The acquisition of smaller firms by large full-service companies has of late been a reason behind consolidation.

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The industry body representing leading pharma companies, the Indian Pharmaceutical Alliance (IPA) in a letter to the health minister, Dr Harsh Vardhan, stressed on the need for an out-of-court settlement with health activists, fighting for the rights of clinical trial participants. "The government's job should be to create enough safeguards and provisions to ensure that the rights and safety of subjects in a clinical trial are not compromised but this does not mean stopping business or development work," the IPA said, adding "what is happening now is hindering access to affordable medicines and this is not in favour of patients either.

Among the top multinational pharmaceutical companies Pfizer, Glaxo Smith Kline, Aventis, Novartis, Novo Nordisk, Astra Zeneca, and Eli Lilly have been conducting clinical trials in India, apart from the Indian companies like Dr Reddys, Nicholas Piramal, Cipla, and Lupin. Full time clinical research companies such as Quintiles, Max Neeman International, Syngene, and Fortis Clinical Research are among few others. However, gradually there have been trends of shifting trial locations outside India due to prevailing uncertainty.

Dr Renu Razdan, vice chairman, Association of Contract Research Organization (ACRO) believes that there can be no alternative for clinical research and there have to be corrective measures before it is too late. "Shifting of trial sites out of India is going to harm patients, science, and human resources equally. In medical science, the sharing of knowledge on cutting edge technologies and new research data is important. When we do not do that, we lag behind in innovation. As a result of the current situation, countries such as Korea, Malaysia, Bangladesh etc are on the hot list of the companies who are looking

for alternatives to do trials. Certainly, a harmonious regulatory environment is important for them to have the confidence to go ahead with trials," says Dr Razdan, who is also the chief operating officer at Max Neeman International.

To gain an upper hand in the global market, this sector requires regulatory clarity and fast approvals on case to case basis. This is the only way the investors of pharma companies, who have been disappointed due to existing scenario, can gain confidence in India again. The country that was projected to conduct 5 percent of the global clinical trials last year, currently is not even conducting 2 percent of it. The situation can be salvaged only by a strong voice and awareness campaign about its importance sans commercial interests by the industry among common masses.