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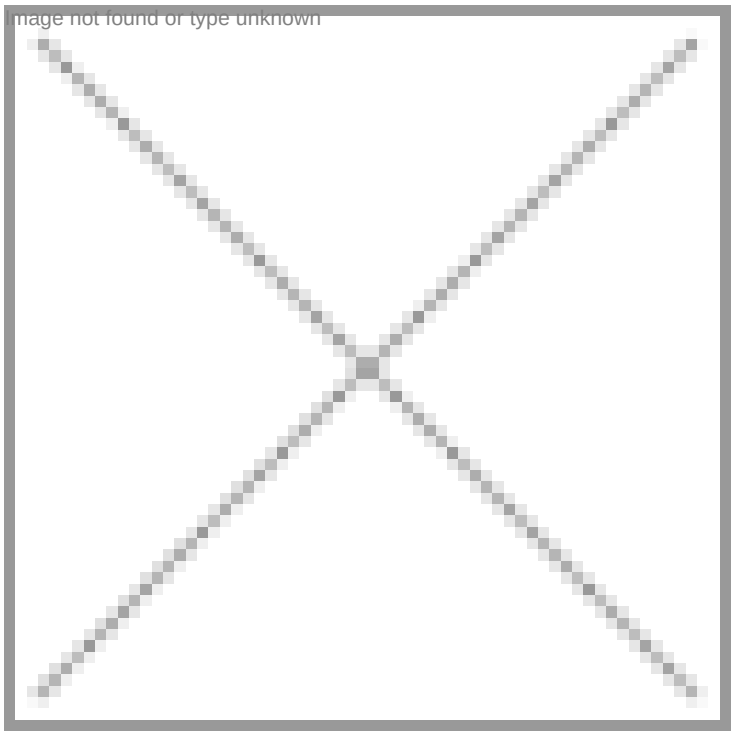
Expert Opinion - Anil Panwar

26 June 2012 | News



CLINICAL RESEARCH

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India takes a backseat

Despite having 120 CROs, the Indian clinical industry showed a downward trend last year.

Indian FDA and Clinical Trials Registry of India (CTRI) reported dramatic increase in multicenter and multinational clinical trials in India. This is in accordance with the current trend of off-shore outsourcing of clinical trials from North America to Eastern Europe, China, and India. India offers a promising solution to clinical research due to its established pharmaceutical and biotech industries environment and the ecosystem of contract research, R&D alliances, clinical trials, R&D for neglected diseases, in-licensing of pre-clinical, as well as clinical drug molecules, strong IT workforce and data management, and its herbal heritage. Low cost of innovation and development, skilled manpower, and a large patient pool are the additional advantages to clinical companies.

In 2011-12, however, the Indian clinical industry struggled slightly. India is in the state of transition. Regulatory approvals in India are taking around six to nine months, where as in US it takes around 30 days. Owing to policy paralysis, CROs such as SiroClinPharm are setting shops in other markets such as Indonesia, Malaysia, and the Philippines.

Moreover in India, only those drugs that have already passed phase I safety trials in the country of their origin

can be tested on Indians. This policy also interferes with the Indian clinical industry growth. This situation will change as soon as the government is taking these issues seriously by streamlining the processes and devising new regulations and provisions. Despite this, India still has 120 contract research organizations (CROs) focusing on clinical studies and 1,500 approved sites.

Technical trends

From the regulatory point of view, conducting clinical trials now requires lots of approvals. The situation is getting more complex. It is now more difficult for a clinical researcher to adhere to all regulations and guidelines. Same is the case with finding and enrolling the subjects in trials. Central Drug Standards Control Organization (CDSCO) has released a new draft guidlines on approval of clinical trials and new drugs on July 24, 2011. Prior to that, CDSCO had approved a guideline on clinical trials inspection.

New technologies on which research is going on include protein chips, transgenic animals, stem cells, medical devices and bioinformatics among others; impact of which is a shift in R&D view from clinical definition of disease diagnosis to molecular definition of disease diagnosis and predisposition.

Apart from scientific innovations, trends can be stated as the central lab requirements getting complex; sponsors demanding more predictability, accountability, transparency and integration from vendors; sponsors are working more closely with institutional review boards (IRBs); adoption of new software such as SAS, SPSS, STATA for data processing is increasing; studies are becoming more focused; personalized medication trials are increasing in case of oncology; biosimilar trials and observational studies showing increase; and more CROs are entering phase I trials.

- Anil Panwar, CEO, Fortis Clinical Research