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Clinical research expanding

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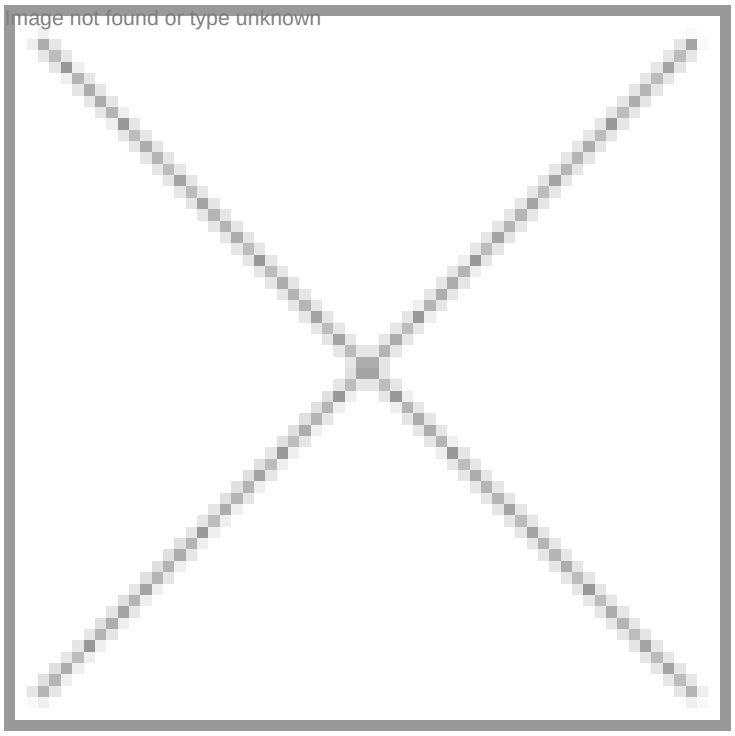
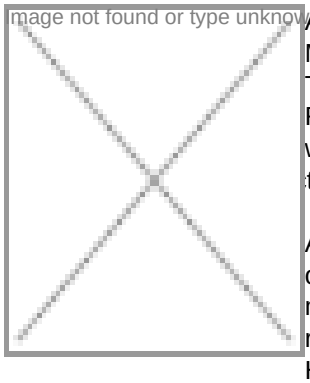


Image not found or type unknown, vice president of business development, SIRO Clinpharm, Maharashtra
Dr Anand Bidarkar is the vice president of business development with SIRO Clinpharm. He completed the senior management program from the Indian Institute of Management, Ahmedabad; MBA from SP Jain Institute of Management and Research, Mumbai; and BDS from AME's Dental College and Hospital, Raichur

The growth pace of clinical research in India has been steady, however, it has not attained the rapid expansion that was predicted. There are more than 300 different entities, that have conducted clinical trials in India. These include multinational and Indian biopharmaceutical companies, NGOs and academic medical centers.

As per publicly available reliable data sources, the largest number of clinical trials in India were conducted by Pfizer, followed by GSK, Novartis, Eli Lilly and Sanofi-Aventis. Pfizer has conducted nearly a 100 clinical trials in India, and among them, the top five companies account for more than 25 percent of the total clinical studies conducted in India.

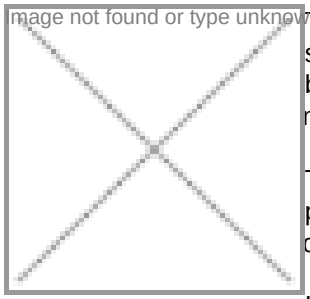
Reports from publicly available sources of data and information shared at industry forums reveal that the top five companies have internal teams that conduct clinical trials, or in-source clinical research staff from CROs that provide staffing solutions. Many of the trials being conducted by these companies through international CROs in India, might be outsourced at a global level from their head office; hence, while they do a large percentage of clinical research activity in India, their contribution to the growth of the Indian CRO sector is quite limited.



Among the academic medical centers conducting clinical research in India, All India Institute of Medical Sciences (AIIMS), New Delhi, tops the list, with around 46 clinical trials; followed by the Tata Memorial Hospital, Mumbai, with 30; and Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, with about 20. These figures include only trials listed on the website, clinicaltrials.gov registry, with the institutes as the sponsor. It is quite possible that these ting a number of local trials and also for other companies.

Accurate data on the trials conducted by various CROs is not available, even from public sources, or from the Clinical Trial Registry – India (CTRI), as in many instances, the sponsor companies might apply to the Drug Controller General of India (DCGI) for regulatory permission and also register with CTRI. In such cases, the name of the CRO conducting the trial might not be available. However, from the trend of regulatory approvals from DCGI, it appears that Quintiles, SIRO and ICON conduct the most number of clinical trials in India. While Quintiles and ICON are large global CROs with their headquarters in the West, SIRO is an
Indian multinational with operations across Europe and Asia Pacific. It is estimated that the top three CROs are currently running around 200 clinical studies in India.
The diverse set of organizations conducting clinical trials in India has also meant a large diversity in the therapeutic areas in which clinical trials are being performed.

The top five therapeutic areas in which trials are being conducted in India are:
• oncology
• metabolic disorders including diabetes
• infectious diseases including partly respiratory diseases
• cardiovascular disorders, and
• central nervous system/psychiatric conditions



There has been no perceptible change in the phase of trials being conducted in India over the last several years. The continuing regulatory challenges for phase I trials and first-in-man trials in India by non-Indian companies, have meant little or no growth in phase I trials. The majority of phase I nducted by Indian companies with new drug discovery programs.

The majority of the trials being conducted continue to be phase II and phase III. As per data presented at the Clinical Trial Forum Thailand, on July 22-23, 2010; of the more than 1,200 studies over 50 percent of studies are phase III.

In fact, India leads China in the number of phase III studies, and is almost at par in the number of cases of phase II studies. The large number of phase IV studies being conducted in China need to be viewed at, from the overall market attractiveness perspective, which is higher in the case of China. It is estimated that the number of phase IV trials in India would also rise, given the entry of new companies and new pharmaceutical compounds into the country.

The biopharmaceutical companies conducting clinical trials in India are working on different business models. Most of the large MNC pharmaceutical and biotechnology companies have their offices in India. There is also a large chunk of companies that do not have their presence in India, but their clinical operations are managed either through CROs with an India presence, or in partnership with Indian academic centers or research institutes.

The two most common models used in India to carry out clinical research are: setting up in-house clinical research teams or using the services of a CRO.

The advantages of setting up in-house clinical research teams are: greater control over the clinical trial conduct, and focused effort on the company's priorities. On the face of it, this model seems to work well for companies that conduct a large number of clinical trials in India, and are assured of a steady flow of clinical trials from their global offices.

Globally, however, the trend of setting up clinical research teams, is being increasingly replaced by partnership withspecialist preferred provider CROs. The main reason driving this shift, is that clinical development activity is seldom predictable, and it is a significant burden on the finances of a company, to maintain large teams without activity. The recent mass layoffs in the clinical research teams of several large companies in the US and Europe are indicative of the liabilities of maintaining large teams. As companies focus on cost-rationalization and operational efficiencies, working with efficient CROs can provide significant value.

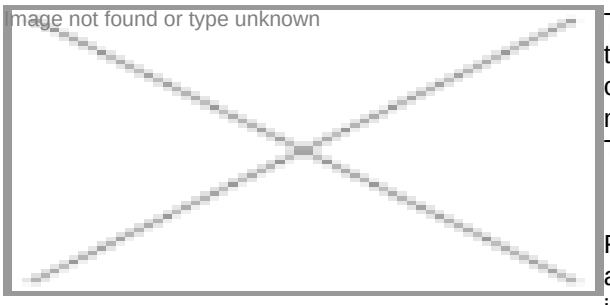
The trend in India among many of the major companies is to have large in-house clinical research teams. This was a good

option initially, as there were not many Indian CROs, and multinational CROs did not have presence in India. The global principals of many MNCs did not find the high headcount a challenge, because of the significantly lower salaries, and the low costs of conducting trials in India.

This is, however, changing as the clinical research costs in India continue to increase, and Indian offices of global companies are being asked to bring in greater efficiencies in trial conduct. The other factor that has changed significantly is the CRO presence in India. The major national and international CROs have a large operational presence in the country, and unlike before, it is possible to outsource trials.

As per industry intelligence gathered from various sources, recently many companies have had limits expansion of in-house teams, and a mid-sized European MNC actually disbanded its entire clinical research team.

Smaller and mid-sized companies usually do not venture out to set up in-house clinical research teams, as they are unableto achieve a critical mass of personnel required for conducting studies independently in India. The large, diverse nature of India presents several challenges for the regulatory Institutional Review Board (IRB) and investigator selection. A strong feasibility, regulatory and operational team is essential. The other complicating factor is the high attrition in this sector. Several small companies have failed in their attempt to leverage India's strengths in clinical research due to this reason.



The CRO model in India is emerging rapidly as the preferred alternative to in-house teams. This is as per the global trends and is likely to continue to grow. The main benefits of working with a CRO for small and mid-sized companies include: better investigator reach and follow up. This model also provides access to therapeutic area expertise, which the

For larger companies, the CRO model provides greater cost-efficiencies as well as the flexibility to scale up when required. The other advantage is the CROs might transfer their learning from previous studies and other clients, to ensure successful study execution.

Whatever be the model, the fact remains that the clinical research scenario in India is at an inflection point, and all stakeholders including the regulators, need to reassess their current strategy in terms of the latest global developments.

The number of companies that include India in their clinical development plans is increasing rapidly, for the obvious benefits and to tap the growing market. The growing clinical research industry has brought a significant change for the betterment in medical practice, patient access and patient care at centers taking part in clinical trials. It would be interesting to see if the country evolves as other mature markets have evolved in the past, or charts an altogether new path.