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"There exists a big training gap between demand and supply" - Dr Arun Bhatt, president, ClinInvent Research Pvt Ltd

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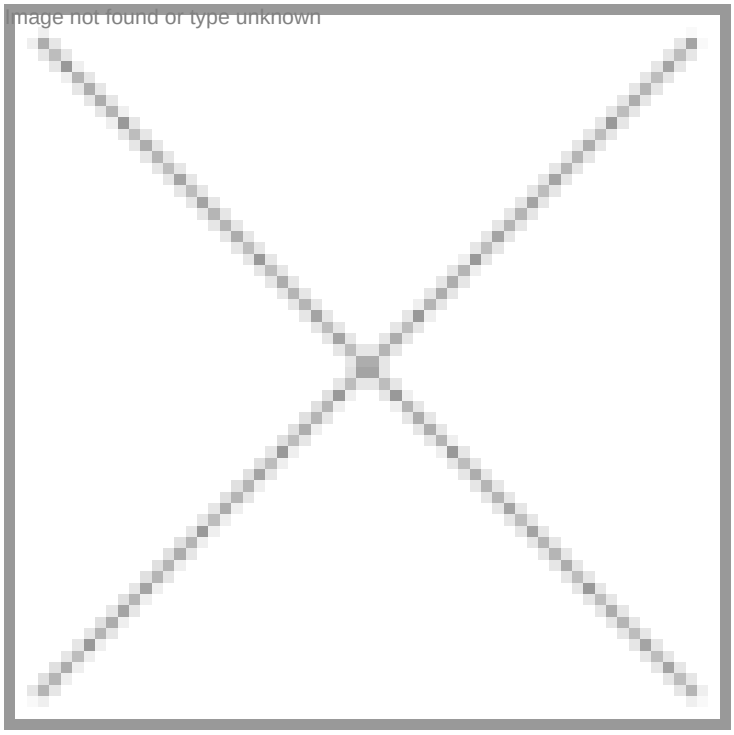

Why do CROs prefer Bangalore, Hyderabad, Mumbai and Ahmedabad?
The main reasons seem to be the support of local pharmaceutical industry, availability of manpower and infrastructure and early establishment of bioequivalence CROs at these locations.

Why are several Indian sponsors outsourcing clinical trial (Phase I) to MNCs outside India?
The strategy of local companies is to license out the new molecule to an international company. The international company would expect the Phase I to be compliant with global regulations, GCP guidelines and scientific requirements. Besides, Phase I studies require excellent technical infrastructure for monitoring safety e.g., advanced cardiac/CNS instruments and bioanalytical support for estimation of new chemical entities. At present, India does not have adequate expertise and infrastructure for Phase I studies of global standards. In addition, compared to the West, our regulatory approval is slow for Phase I trials.

Which are the key disease areas that Indian CROs are focusing on?
Oncology, CVS, diabetes, CNS and psychiatry

Is there a shortage of trained people in India to carry out clinical trials and research?
Clinical trial management requires diverse skills â€“ project management, communication, presentation, writing, interpersonal, time management, finance management etc and good knowledge of clinical research therapeutic areas,

statistics, pharmaco-vigilance, regulatory and ethical guidelines, GCP etc. These are not covered in the curriculum. Hence, there is a big training gap between demand and supply.

What are the issues that confront a sponsor outsourcing its work to Indian CROs?
The sponsor-CRO relationship requires the commitment of the top management of both sides. Besides, most Indian sponsors consider CRO activities as an additional expense and not an expert support. In addition, the sponsors are concerned that many Indian CROs lack trained and experienced manpower.

At ClinInvent, we have focused on quality and training and hence, we have a large team of trained and experienced clinical trial professionals. We have already gained the confidence of sponsors and are currently running several global clinical trial projects.

What is your expectation from the institutes offering courses on clinical research and data management?
The institutes need to have experienced faculty, which can provide uniform education and requisite skills to students. Students should be made to realize the critical importance of their role in clinical trials and also should be prepared to face the interviews.

Narayan Kulkarni