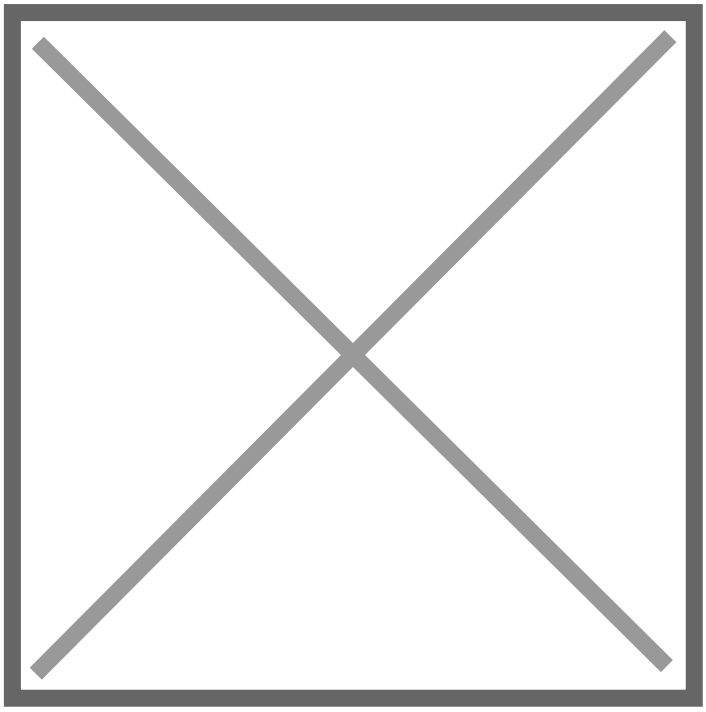
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Overcoming challenges ...

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Clinical research is losing its attractiveness in the US due to the shortage of investigators. By 2005, there will not be enough clinical investigators to handle the number of drugs in clinical development. CenterWatch estimates that against a 2005 demand for 56,000 investigators, only 48,000 will be available, a shortfall of 15 percent.

On the other hand, India is moving closer to sponsors. It is mainly due to advantages it has. In contrast to this India too faces the dearth of investigators. According to industry sources, the country has about 500 investigators. If we go by the statistics, India has over 572,000 doctors, 43,322 hospitals and dispensaries and about 8.7 lakh beds including both private and public (2000). Majority of the doctors are graduates with little or no knowledge about clinical trials and hence would not qualify as investigators for complex international clinical trials. The issue here is that most of the medical professionals/specialists are not looking at investigation as a career option. They have their own reasons like time pressure, ethical and scientific complexity of GCP trials and lack of interest to take part in clinical trials.

The situation requires tremendous efforts to attract the medical professionals/specialists to clinical research. Identifying and attracting potential investigators is the biggest challenge, requiring innovative approaches. The current efforts at training are fragmented. The training focus of sponsors and CROs is on the investigators involved in their trials and their own monitors and other professionals. As a result, a small number of trained investigators are retrained and large numbers of untrained physicians remain unexposed to research training.

The enormous challenge of large number of quality professionals in medical and clinical research can only be met by cooperative and collaborative efforts between industry, academia and government. Besides the manpower efforts, the training activity will need financial support. In the US, the industry spends over $300 million on training. The funding has to come from all stakeholders, with majority share coming from the major beneficiary, the pharma industry.

The National Institute of Health has established more than 80 General Clinical Research Centers (GCRCs) across the US. In 2002, these centers supported 11,000 clinical scientists who pursued more than 7,400 studies. In India we don't have such centers.

At present there are two institutes offering courses related to clinical research and data management. One is the Academia of Clinical Excellence (ACE) and the other one is the Institute of Clinical Research India (ICRI). ACE was set up in October 2002 at the Bombay College of Pharmacy through the initiative and financial contribution of Pfizer India Ltd. It is expected that Pfizer will be contributing to the tune of $100,000 for a period of five years for the development of the academy. Subsequently, the academy was opened up for industry collaboration and Suven Life Sciences Ltd of Hyderabad has become a partner of ACE by making a financial contribution. The academy is conceived, as a one-stop-shop for all training needs of all clinical research professionals in the country. The ICRI commenced its operation in 2004 with its campuses located at Dehradun in Uttaranchal and in Mumbai.

At present, training programs in clinical research are an occasional one-day or a two-day workshop planned by CROs and academia. To overcome the dearth of skilled people, Dr Arun Bhatt, President, ClinInvent Research Pvt Ltd suggested a new model that will generate 10,000 professional in a year.

"We need to develop a new model along the lines of training provided for industry sales persons. We have the experience of conducting successfully a one-day basic GCP training module for 50 participants. Based on this experience, we feel that such a module can be expanded to a five-day (50 hours) orientation course covering core knowledge of clinical research and relevant management skills. A team of 10 full time trainers, with expertise in diverse disciplines, can manage such a course for 50 participants. Such a course, if run every week, will cover over 2,500 professionals in one year. By preparing five such teams located in different cities, we can train over 10,000 professionals in just one year. Of course, the faculty should be full time, drawn from senior retired professionals from industry/academia, many of whom are willing to devote their time to such activities. Besides, there are professionals in industry/CRO, who are keen to have a full time career in training," said Dr Arun Bhatt.

If this model works out well with funding from public and private sector then crossing $1 billion mark will soon become a reality.

Narayan Kulkarni