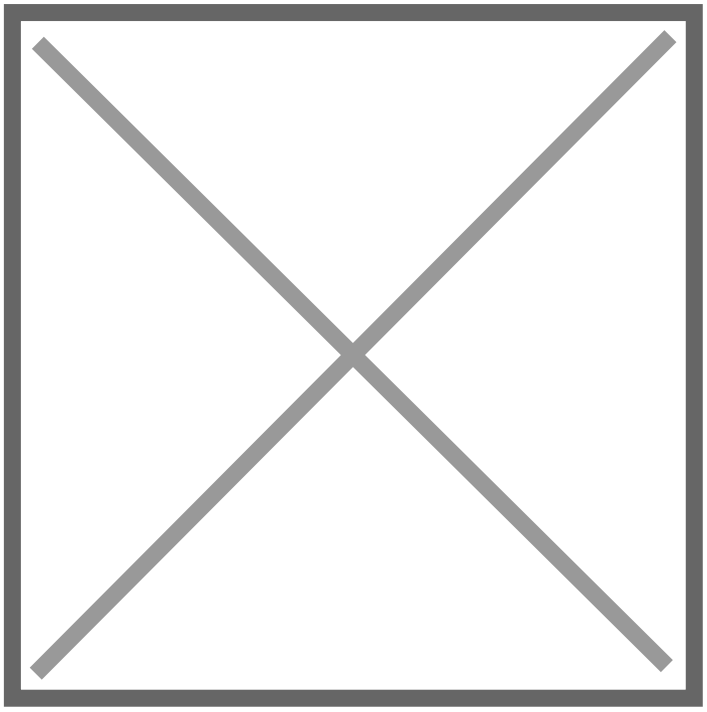
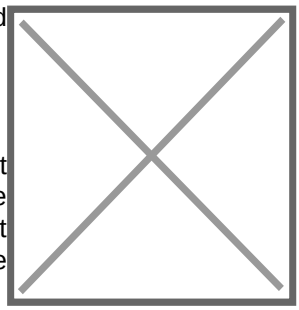
BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Overcoming challenges facing clinical trials in India

13 June 2005 | News





Regulatory uncertainties, involvement of multiple agencies for approval of biotech products and several other factors are hurdles in planning a clinical trial in the country.

India is attracting a lot of attention as a new region for conducting global clinical trials.

The 2010 projections for the Indian clinical market of $1.5-2 billion are based on the likelihood that Indian trial sites can contribute almost 20 percent patients to global clinical trials Ã¢â?¬â?? the current acceptable FDA limit for data from developing country population. However, the current contribution of Indian affiliates of global CROs is around one percent of the global turnover. The journey from one percent to 20 percent is fraught with several challenges.

From the global pharma industry view point, the attractiveness of a country for clinical trial depends on speed and quality of data. The speed is affected by the following factors: regulatory permission time, Ethics Committee (EC) approval, patient recruitment and retention. The quality of data is largely influenced by GCP culture, ethics, documentation and record keeping.

Global pharma companies are concerned about India's potential for meeting these challenges. The regulatory uncertainties about time to approval, involvement of multiple agencies for approval of biotech products and for processing import/export licenses are a major stumbling block in planning a trial. In addition, the lack of uniformity of EC functioning and absence of a central EC delay the trial initiation.

As most institutions lack organized patient databases, the patient recruitment rates are either underestimates or overestimates. Besides, it is difficult to obtain real estimates for diseases of global interest, for example refractory depression. Retention of patients in today's long and complex trial process depends on the investigator team's communication skills and relationship with the subject. There is also a major impact of patient literacy, society's attitude and bad media publicity on the recruitment and retention of patients in trials.

The factors influencing quality of data depend a lot on the GCP culture and training of the investigator site staff and in the sponsor / CRO team.

In a country which boasts of a large medical fraternity, only 400-500 investigator sites have taken part in global GCP trials. A large majority of potential investigators lack knowledge of regulations, ethics and GCP, and skills for clinical trial management. The quality of global trials and academic clinical research is not uniform. There are also issues of inadequate permanent research staff and lack of adequate infrastructure for communication, drug / sample storage, archival. The situation is worse in non-metro cities which have tremendous potential for participation in global trials. In addition, the institutional policies are not yet geared up to support the investigator in managing clinical trials efficiently.

The regulatory authorities and ECs have a major role to play in the quality of data generated. The EC's efforts to continuous review and regulatory system for inspection are a must to ensure that the subject's rights and safety are protected and data generated meet GCP standards.

We have significant opportunities of participation in global clinical trials. However, if we want India's contribution to rise from one percent to 20 percent, it would require tremendous efforts from all stakeholders Ã¢â?¬â?? regulators, investigators, sponsor/CRO and ethics committee Ã¢â?¬â?? to cooperate in overcoming the challenges.

Dr Arun Bhatt
President, ClinInvent Research India Pvt Ltd,
Mumbai
arunbhatt@clininvent.com

Â