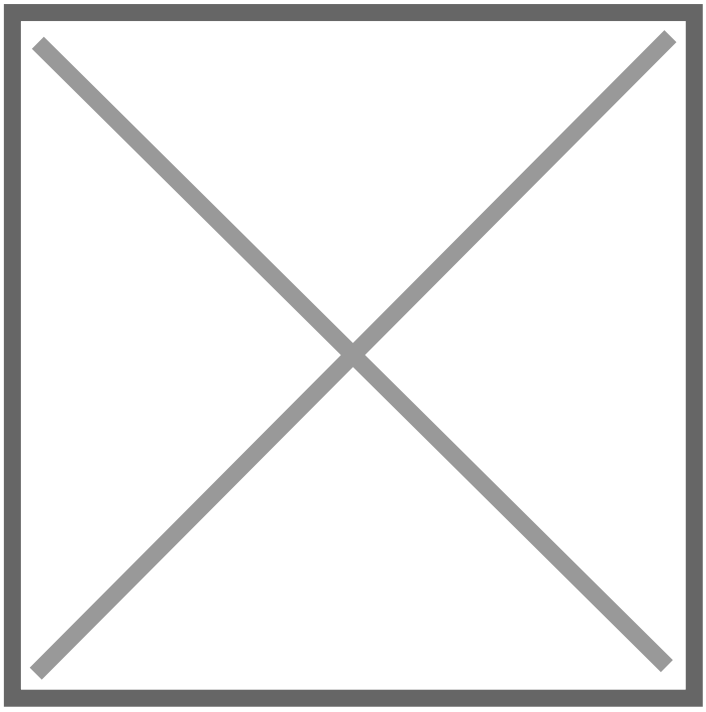
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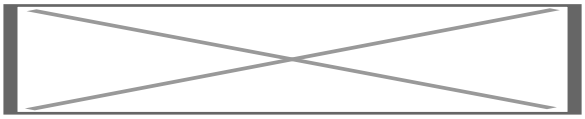
Rocky road to newer heights

08 September 2010 | News



India provides a number of advantages for the outsourcing of clinical trials because it offers a large patient population that facilitates faster recruitment, low trial cost per patient, a highly qualified professional medical community, plus global quality hospitals and clinical research facilities. Also, there is a highly developed IT and data collection capability with no language barrier. This has opened up many opportunities for CROs in India. At the same time they are facing challenges due to overcrowding of the industry.

The challenges that India faces for expansion of its clinical research market, are non-availability of sufficient number of hospital sites, trained personnel matching the International Conference on Harmonisation of Technical Requirements for Human Use-Good Clinical Practice (ICH-GCP) norms; equipments at hospitals/sites for conducting trials not always on par with trial sites in Western countries, besides bureaucratic hurdles for regulatory approvals for global clinical trials.



Chairman of the Institute of Clinical Research India (ICRI), Mr Shiv Raman Duggal says, “Approval time in India for phase I studies which is restricted to Indian molecules, is around 90 days, whereas for the same in Western countries, it is about 30 days. Also, lack of protection for the data generated in these trials is a matter of concern. There have also been concerns over ethical issues in patient recruitment and conduct of trial, along with lack of sufficient infrastructure for central laboratory services.”

The key issues of CRO market, Mr Duggal says, are consistent high quality, credibility, reliability, offering a range of services, broad and focused therapeutic expertise, timeliness, GLOCAL approach (Global Reach Local Expertise) and expertise in developing Novel Drug Delivery System (NDDS) packages.
Dr Anand Bidarkar, vice president, Business Development, Siro Clinpharm, points out that it is the image of India that is portrayed to the global community. We have been portrayed as a country which uses patients as guinea pigs and that is not so, because some patients need those medicines and clinical trials become very useful. In cancer, for instance, altogether, there are 5000 trials being conducted in the world, out of which only 92 trials are taking place in India. Instead, we should compare the number of clinical trial deaths against the total number of trials that are conducted in all.

According to Mr Murali Mohan, business development manager, Ecron Acunova, the Indian CROs are facing two distinct challenges today, one is immediate and the second is strategic. The immediate challenge: Operational Delivery. Until the CRO’s “potential” revenue is converted into “kinetic” profit, it is still at risk, and can be pulled at any time. Therefore, finding enough patients, sites and staff to operationally deliver on their growing backlog is a major challenge. The strategic challenge: Service Differentiation. In a growing, crowded, and competitive market, companies have to differentiate themselves or face commoditization. CROs are close to painting themselves into the commodity corner.

The challenge for CROs, Mr Murali Mohan, says, in this market is to differentiate at a speed faster than commoditization is

gaining on them.

To overcome many of the challenges, the CROs need to adopt both short and long term strategies to beat the competition and look for a strong growth.

Clinical trial deaths on rise

The number of death occurrences in clinical trials in India has increased with each passing year. According to the official sources in Ministry of Health, Government of India, there were 132 deaths in 2007, 288 deaths in 2008, 637 deaths in 2009 and 462 deaths up to June, 2010. The report says death may occur during clinical trials for various reasons. These could be terminal disease-related deaths like cancer, or administration to critical or terminally ill patients or side effects of unrelated cause. Such deaths are investigated for causal relationship by investigator and by medical experts of sponsor.

Challenges

Regulatory challenges: Uncertainty of regulatory processes and time lines, quality of documentation at Indian sites, lack of sites for early phase trials, increasing requirements from ethics committees, shortage of GCP trained investigators and sites.
Difficulties in identifying sponsors due to alliances/ mergers, increased costs due to inflation, acceptance of potential new sites/hospitals by sponsors/ CROs, small start up CROs and mushrooming of Site Management Organizations (SMOs).
Human resources: Shortage of managerial manpower, retention of personnel, lack of stable and qualified CRAs, training.
Commoditization: Competition between big CROs and big IT companies, lack of having global capabilities, price reduction due to short sighted policies of competitors, offering services in niche areas instead of offering basket full of services.
Patient recruitment: Lack of patient pool in some therapeutic area, Patient consent.