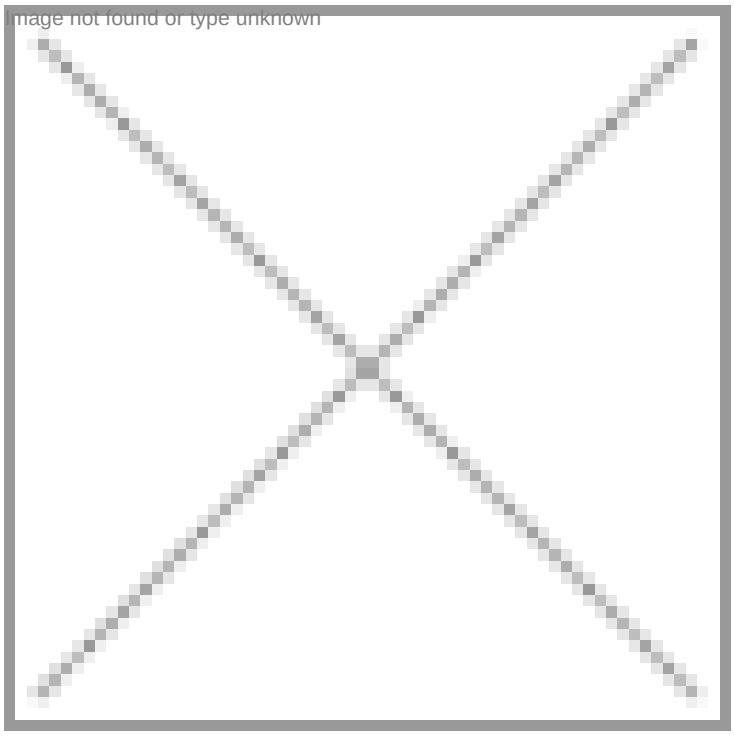
BioSpectrum the business of Bio & Health Sciences

Contract research in India: Cost factors and regulatory issues

05 May 2010 | News



Contract research came to India in the 1990s. A number of key developments came together around the turn of the centuryto make it all possible. First, there was the Indian Patents (Amendment) Act of 2005 that forced Indian pharmaceutical companies to invest in innovation. This created the initial staffing pool and generated a local market for research personnel. Then there were the implications of the process of harmonization of research regulations led by the International Conference on Harmonization (ICH) since 1990 that spelt out common regulatory requirements for countries covering 85 percent of the world's pharmaceutical markets, making it mandatory for regulatory authorities in these countries to accept research results from anywhere in the world fulfilled its requirements. And finally there was the communications revolution that swept the world making real-time collaboration across geographies a reality.

All this led to significant growth in research activity in the country, and contract research as an off-shoot. Contract research took on a life of its own after the year 2000. Companies were set up to provide services in the drug discovery space with collaborative research models. Large and small drug development service companies sprung up all over the place with clinical pharmacology beds, bioanalytical services, compound scale-up and clinical supplies units, clinical trial management teams, and data management, biostatistics and medical writing offerings.

The growth seemed rapid and remarkable, yet its impact on worldwide pharmaceutical research remained marginal. The world contract research market is estimated to be worth Rs 1.15 lakh crore ($26 bn) in 2010 while estimates of India's share do not exceed two percent at this time. Clearly, the potential for India is much greater.

Competition from China

India competes closely with China, and while in the initial years of globalization of pharmaceutical research it seemed that India had the advantages such as booming generic formulations industry, English-speaking workforce and western-style medicine. In recent years, China has pulled ahead with better infrastructure, more supportive regulations and incentives, and

a much faster growing pharmaceutical market that demands and gets investments from overseas. The big pharmaceutical companies have, over the last 10 years, invested much more heavily in R&D in China than in India. In 2009, we have seen some large CROs
following suit.

India seems to be losing to China on cost and pricing. With a reputation for low prices, international sponsors seem to expect services to cost less in India than in China. On the other hand, costs are continuously going up, with inflation now into the double digits while the Rupee seems to be strengthening in contrast to the artificially weak exchange rate for the Yuan. And payroll costs are growing at double digits too, with salary increase being higher here than anywhere else in Asia. Tax and other incentives for contract research in India fall far short of compensating to these disadvantages, leave alone matching what other countries in the region have on offer to attract contract research spending by global sponsors.

Regulatory issues
When one thinks of the state of drug development regulation in India, it seems almost as if the government is deliberate in throwing the match away. Animal rights bureaucracy has made it almost impossible for the country to grow in the area of animal testing despite some easing in recent years. Yet the length and types of animal studies that need to be completed to get permission for human trials are much more demanding in India than anywhere else in the world.

Consequently, if you have discovered a promising new medicine you would be forced to go abroad to do the first-in-human studies. And it would be a good thing too, since there is no expertise in bench-to-bedside translational medicine in the country as a result of a long-existing ban on phase I studies. When it comes to phase II and III studies, many innovative biotechs and small entrepreneurs in Europe and the US are interested in contracting to Indian CROs, since India has an advantages of patient availability and cost reduction. But our regulators will not permit it unless at least half the patients are to be recruited abroad. This beats the very purpose of coming to India.

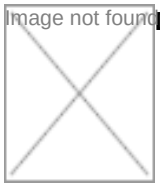
Yet one cannot blame the regulators for this â€“ the government support provided to the office of the Drugs Controller General is so poor that the regulator is heavily dependent on regulatory assessments done by foreign regulatory bodies and is diffident in approving anything that has not been reviewed abroad.
Fortunately, Indian entrepreneurship manages to survive. Government regulation has a much smaller impact on areas such as discovery research, informatics, and allied services in clinical trials such as data management, biostatistics, pharmacovigilance and medical writing.

Constraints in these areas mainly relate to the cost, quality and availability of a qualified workforce.

The future
Institutions in the country that can provide quality education at the cutting edge of scientific research are very few-but the news that education will be opened up to international investment provides a glimmer of hope. The key to a long-term future in these areas depends on the availability of a large pool of scientific manpower trained in various disciplines that contribute to the science of drug discovery and development.

The future of contract pharmaceutical research in India, is related to other infrastructure facilities available in the country. General developments such as infrastructure, education, and the economy will play a key role, as much as more specific issues like the development of regulation and incentives for medicinal research. We may have to rejoice in patchy successes in some areas of the domain and reconcile to mediocrity in others.

Getting to a leading position in drug discovery and development will require much more than that-a focused national approach and clear policy directives from the administration. Unfortunately, there are no positive signals in that direction.



Dr Shoibal Mukherjee is senior vice president and heads clinical development, GVK Bio, Hyderabad.