

The emerging CROs

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The Indian CRO sector registered 70 percent growth in 2006-07 over the previous year's revenues of Rs 425 crore with exports dominating the sector.

Datamonitor's R&D Strategies 2007 report points out that the drug developers have become increasingly dependent on CROs, which themselves have become increasingly globalized. This is being driven by both the rise in the number of CROs in emerging markets and the increasing internationalization of western CROs. Most global CROs are present in India or have formed alliances there: seven out of the top 10 CROs have local offices in India with leading companies such as Quintiles, Chiltern, ICON Clinical Research building up a significant India presence. Meanwhile, local CROs are picking up pace, and there is likely to be a period of consolidation in this sector. The Indian CRO sector is growing at nearly 70 percent over the previous year's revenues of Rs 425 crore with exports dominating the sector. There are over 40 companies active in this space. Most of these are actively involved in doing bioavailability/bioequivalence (BA/BE) studies with a handful of them into clinical trials (Phase I–IV). Considering the potential of doing business in India, many leading CROs of the world who are looking at both India and China as potential markets of investments, are entering India. Given the two countries' low cost base and huge potential patient populations, both the countries are offering services in abundance.

Considering the advantages India has and its offerings to the sponsors, McKinsey has estimated that the size of the clinical research market in India will be close to \$1.5 billion by 2010. At present the market is just \$160 million. As of today, India has witnessed different types of players venturing into the clinical trial data management business, some of them are full fledged

CROs starting separate data management units, some of them are IT and ITES companies diversifying to data management business and some are pharmaceutical companies setting up biometrics and data management operations solely on their own or through partnership.

Dr Chetan Tamhankar, chief operating officer, SIRO Clinpharm

In India there are two aspects -- companies are on the move to develop new molecules and they have been needing services from CRO providers for helping them deliver both within India as well as other geographies. Moreover, there is a lot of pressure now on the supply side of aspects like getting enough CRAs, doctors and putting data management systems in place will be a challenge for the industry for at least the next 3-4 years.

India's story is very credible. It may not support on a shorter term a really larger growth - like globalization for instance, if we need to become global players, it is imperative that when we go to a customer, we do our studies in India and other countries and that is also one reason why Indian CROs are expanding to other geographies. To have this global delivery, we at SIRO are trying to emerge as a multinational CRO by extending to non-traditional countries like Central and Eastern Europe and other parts of Asia like Philippine, Singapore, China, Korea, Thailand and Malaysia. To have this global desirability, we need to have seamless operations

In fact the main demand for Indian CRO industry is that that it should not be foreign CROs coming to India but Indians on the basis of their credibility going to other countries as a global MNC. That will happen in the near future and SIRO at the moment is targeting countries with Europe from that perspective and in the domestic market we are going to tier 2 and tier 3 cities and tying up with Centers of Excellence (CoEs) for clinical research

Nilesh Nayak, senior executive, business and development, Rubicon Research, Mumbai

CROs have been the backbone of the Indian biotech industry. The biotech industry is resource-intensive and has a high gestation period for any biotech product to come out. CROs in India have augmented their progress because they have taken off or shared the burden of innovation by providing the requisite infrastructure and with increasing cost, they have also shared the cost with these companies for these trials.

CROs in India

Cintec International, the global CRO have been successful in entering into a co-development with Dr. Reddy's Laboratories some time back and is also looking in the area of biotechnology particularly developing new cancer drugs. Quintiles in Bangalore is expanding the data management team by moving work to India and has hired 187 people in data management. SIRO Clinpharm has a full fledged data management unit and is also working with Pfizer on a retained FTE model providing contract staffing operations. ICON Clinical Research has acquired a Chennai-based data management company, Biomin Research Solutions which will focus on data management and biometrics services. Mumbai-based Wellquest CRO, the clinical outsourcing division of India pharmaceutical company Nicholas Piramal, opened a 30,000 square foot research facility in Hyderabad and has conducted about 100 pivotal trials and 40 pilot studies. Bangalore based Acunova, an offshoot of Manipal group of hospitals has expertise in bioinformatics and medical software and offers clinical data management and biostatistics services to Pharma companies, besides the site management and contract research capabilities. Synchron, a local CRO offers complete clinical data management services for data processing, analysis and management from their Bangalore facilities. Besides these many clinical trial CROs including Covance, Parexel, Chiltern, PRA International, MDS, Lambda, etc. are exploring the possibility of setting up clinical trial data management and biostatistics in India.

IT-biopharma ventures

There has also been the involvement of IT companies like Wipro, Intel, Satyam, Cognizant, IBM, Oracle and TCS in their bio-IT initiatives in India. While some of them have actively started the clinical data management initiatives, others are planning to

venture into IT solutions. Satyam Computers has recently launched the Satyam LifeSciences Center of Excellence. The LS CoE is a hub for knowledge proliferation, cross leverage of customer experience, domain competence and virtually demonstrable solutions. In-house IT solutions have been developed in the area of drug accountability, drug counterfeiting, cell line management systems, high throughput analyzers, clinical development, bioinformatics, and sales and marketing solutions in CRM, Key Opinion Leader portals etc.

Although there has been a number of local and multinational players in this segment but the ones meeting the industry expectations, with high global standards, regulatory compliances and the pressures of cost and cycle time reductions in drug development, with an efficient data management system will survive.