

## Indian CROs chant consolidation mantra

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*Indian CROs are now moving towards consolidation to expand the existing operations, to enter newer areas and also become global players by opting different routes like tie-ups, acquisitions and partnerships*

India's entry into the patent regime in 2005 has brought in many MNCs, both the pharmas and CROs, to set up their offices or branches in India for their outsourcing activities. At the same time, mergers and acquisitions activity too has picked up pace in the Indian clinical research space, owing to lower costs and better infrastructure.

Considering the India advantage factor and huge potential to do business from India, Amgen, the No.1 biotech company in the world, will be setting up its own CRO unit in the country to do its global studies. It is expected that Amgen will start its operations in January 2007. Other global CROs like PRA International and Parexel too have entered the Indian CRO space by using different approaches.

In the recent past, the Indian CRO sector has witnessed many merger and acquisition deals. The latest one is the acquisition of Pune-based Sterling Synergy Systems by PRA International, a leading international CRO. On the other side, the US-based Parexel International has entered into an agreement with Synchron Research Services. The two have formed a joint venture called Parexel International Synchron, into which Synchron has transferred its clinical trial business. As a part of the same deal, Parexel has also acquired a minority stake in the clinical pharmacology business of Synchron Research in Ahmedabad.

It is just not the MNCs looking at India. Indian companies too are looking at CROs outside the country to become global players. Last year, there was one such deal from Jubilant Organosys that has picked up 100 per cent stake in a US-based clinical research organisation (CRO), Target Research Associates, in a \$33.5-million (Rs 145 crore) cash deal. This is the first acquisition of a US CRO by an Indian company, making it the largest Indian CRO with operations in India and the US. It will enable Jubilant to expand its CRO services globally.

### **Moving towards consolidation**

Outsourcing will increase due to increased workload and larger studies without the internal staff to oversee the projects. As long as the trials keep getting larger and more complicated and R&D spend keeps going up, then outsourcing should climb steadily higher, according to a CRO industry update by William Blair & Company, USA. The outsourcing brings in a lot of opportunity for the Indian players.

"India's entry into the patent regime in 2005 brought in more activities in the CRO space. It has increased faith and confidence among the sponsors and also among the global CROs who are now setting up base in the country," observed Dr Kiran Marthak, director, Veeda Clinical Research.

India offers \$1 billion opportunity in clinical research, according to reports. "It's going to be a big cake. Every one can have his/her share or pie in the big cake. Hence, firms are rooting for different options like acquiring stakes, having direct presence, mergers and acquisition to have their pie in the cake," said Dr Kiran Marthak.

### **Recent trends**

- Amgen to set up its own CRO unit in India
- PRA International acquires Sterling Synergy Systems, Pune
- Parexel International signs JV with Synchron Research Services, Ahmedabad
- Jubilant Organosys picks up 100 percent stake in Target Research Associates
- Barings Private Equity Partners buys stake in Siro ClinPharm
- ICICI Venture Fund picks up equity in Metropolis (Rs 35 crore).
- IL&FS Investment Managers invests Rs 45 crore in Manipal Acunova

Sharing his views, Dr Arun Bhatt, president, ClinInvent Research, said, "Mergers and acquisitions in the CRO space would keep happening in India. This is mainly because of three main factors-manpower, speedy trials to reduce time in conducting clinical research and also the quality of service. This would be beneficial to Indian CROs as it helps to enter new areas of operations, improve the image and offer quality services to the customers."

"Inorganic growth is important for any business and a CRO is not an exception to it," noted Dr Rajesh Jain, senior manager, projects, Reliance Clinical Research Services.

On consolidation of CROs, Dr Adeep Bagati, vice president, clinical research, Reliance Clinical Research Services, said, "It's a healthy sign. Consolidation of CROs will work better for sponsors as well as for Indian companies. In the next couple of years, we see more activities in alliances/ mergers or acquisitions. Consolidation helps the CROs that are into different areas of operations. It will work wonders for the companies that are into BA/BE studies by joining hands with companies which are into Phase I & IV clinical trials."

"There are many areas that still need to be tapped like site identification, management, monitoring, training the manpower, issues related to ethic committees and identification of investigators. Opportunity exists for every one if they look at niche areas and also for consolidation to grow and to provide value added services to the customers," said Dr Anupama Ramkumar, director, Arkus Clinical Trail Support Solutions.

The India advantage has pulled down the top global CROs like PPD, Quintiles, ICON, PRA, Parexel, Kendle, PharmaNet, Omnicare, Chiltern, and Covance to have a direct or indirect presence in the country. True to this, India witnessed the entry of many of these global CROs in the last couple of years.

Commenting on the entry of global CROs, Priya Pawar, head, business development, SIRO ClinPharm, said, "They are under pressure from the sponsors to speed up the trial processes. They have no other way but to look at India as a destination for clinical research outsourcing activities. It will be beneficial for the Indian companies too to gain from their experience they had in doing trials globally."

Dr Viral Shah, medical director, Global Spectrum Clinical Research, said, "The Indian CRO market has a very huge potential. Every one has an opportunity to set up his/her enterprise. The entry of global CROs like PRA International, Kendle, Parexel and Pliva will not affect the business for Indian CROs."

Adding to this, Dr Chetan Tamhankar, chief operating officer, SIRO ClinPharm, said, "The Indian clinical research scene compares favorably with the best worldwide in terms of patient pool, cost efficiency, regulatory conditions, infrastructure and environment and relevant expertise. High quality, low cost, faster time, better local expertise, and additional expertise are actually favoring the contract clinical research activities in India."

He further said, "The entry of MNCs shows that the Indian CRO sector is at a maturing stage. To be effective in the world market, the global CROs need to have strong foothold in India for their clinical research activities instead of having a loose arrangement. Just having an office in India with a handful of people will not work well as a good CRO should have at least have 40-50 skilled and trained personnel. The consolidation will continue for a while."

Dr Kiran Marthak said, "Consolidation will increase the market size of Indian CRO segment. The entry of leading names in pharma and CROs in clinical research allows other small players to follow the giants. It is a good sign. Though the entry of global players in the CRO space will result in attrition of about 7-8 percent, it will bring in expertise and also skill sets to India. It also provides on-the-job training opportunity for local professionals. It will be a win-win for both the Indian as well as global players."

In addition to the CROs, global pharmas like Astra Zeneca, Eli Lilly, Johnson & Johnson, Pfizer, Sanofi Aventis, Novartis, Bayer, Merck and Wyeth, Novo Nordisk, Bristol Myers Squibb and Roche too have set up CRO units in India. These companies have been carrying out clinical trials as a part of global studies for data generation as well as for registration in the local market.

"Faced with increasing R&D costs and diminishing pipeline output, these pharma companies are adopting a variety of strategies in an attempt to improve R&D productivity. Key strategies that are attracting industry attention at present include: M&A; Investing in R&D enabling technologies, such as high throughput screening, proteomics, combinatorial chemistry and genomics; eR&D, including eRecruitment, electronic data capture (eDC) and management, eNDA submissions and in silico research; adjusting corporate R&D structure and internal incentive mechanisms; outsourcing," noted Dr Kiran Marthak.

### **Looking beyond India**

Indian CROs like SIRO ClinPharm, iGATE Clinical Research International, Lambda Therapeutics Research, ClinInvent are expanding their operations, increasing the headcounts and also making investments on infrastructure to make it more attractive for the sponsors. To fulfil such many other things, they do need funding. The venture capitalists, institutional bankers and the private equity partners are eager to fund these growing CROs, considering the low risks and high growth potential. There are few such investments from the VC community that have happened recently.

Barings Private Equity Partners has bought a stake in Siro ClinPharm for an undisclosed sum. The stake is estimated to be less than 30 percent. ICICI Venture Fund has picked up minority equity in diagnostics-chain Metropolis Health Services for Rs 35 crore. IL&FS Investment Managers has invested Rs 45 crore by picking up a minority stake in Manipal Acunova.

Commenting on this trend, Dr Kiran Marthak said, "In the next 2-3 years, Indian CROs might go for public issue for expansions and becoming global players. The Indian CROs are getting funds from venture capitalists/private equity."

The Indian CRO segment has been growing in the terms of number of companies. The segment will get a boost because of more outsourcing activities. India witnessed not only the new entrants from the local players but also the global pharmas and CRO giants. The India advantage factor will push for consolidation of companies to offer better services and to leverage each other's expertise on their core strengths and to deliver within the timelines, a key parameter for a good CRO.

### **Sponsors prefer CRO fragmentation**

Despite widespread views that the large drug companies are very cost conscious, cost was not among the top three attributes for defining a quality CRO. The key attributes are delivery within timelines, quality deliverables, flexibility, expertise and experience and then comes the cost. The other key factors include problem solving, responsiveness, customer service, and cooperation, efficiency, geography, consistency, intelligence, lack of staff turnover, minimal change orders, pro activeness. The CRO business is really about project management. A company that completes a study on time with clean data will usually have a happy client. This is according to the CRO industry update from William Blair & Company, USA that conducted a survey of pharma and biotech sponsors regarding their experience with the vendors in conjunction with Thomson CenterWatch.

The global companies require global capabilities and prefer working with a single vendor rather than several, as it is favorable, easier access to patients, less expensive and better turnaround time. Many studies are international and moving outside the US, need to work where local affiliates are located, need to be present globally but act locally and companies without global expertise rely on the CROs for their global knowledge.

Global CROs have an edge over the smaller, more narrowly focused peers as the trend of drug development is shifting beyond the US to better access patients and thus reduce time and cost. The CRO industry growth will come from the developing world.

However, the CRO industry update reported that the consolidation of CROs would be bad for sponsors mainly because of factors such as costs would be less competitive, availability of CRO teams could diminish, too much control in too few entities, sponsors like going to different CROs for different services, CROs would lose focus and attention to detail, smaller and mid-tier CROs play a large role in the market and their service and quality would suffer if merged with large CROs.

On the other hand, a few sponsors noted that consolidation would be good for them as CROs would spend less time and money on business development and the RFP process would be more standardized and consistent. The industry would focus more on quality and less on marketing and false promises.

The CRO industry update by William Blair & Company, USA concluded that sponsors prefer CRO fragmentation and will probably not move quickly to a prime vendor model where one CRO gets virtually all the business. Sponsors also prefer the checks and balances of many CROs to the efficiencies that could be gained by more streamlined RFP/ bid defense process with fewer vendors.

Narayan Kulkarni