Sections
- Market
- Management
- CPhI Worldwide Spl.
- Pharma Life
- Pharma Ally

Specials
- Pharma Bio Career Guide 2009
- Express Biotech

Services
- Editorial Advisory Board
- Open Forum
- Subscribe/Renew
- Archives
- Search
- Media Kit
- Contact Us

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- Express Channel Business
- Express Hospitality
- Express TravelWorld
- Express Healthcare

Group Sites
- ExpressIndia
- Indian Express
- Financial Express

Home - CPhI Worldwide Special - Article Printer Friendly Version

Strategic partners in prosperity

Playing BIG with CROs

Slowly and steadily, the growing Indian CRO industry is expected to show positive growth in the coming future as well. ***Sachin Jagdale*** *analyses the possible trends and challenges that the Indian CRO industry has to sail through*

Contract research is today a multi-billion dollar industry. Steadily inflating production costs with not much increase in the productivity have made pharma companies outsource their functions to CRO's. This is also an effort toward cost reduction and time saving. According to market analysts, next three years would see an approximate 16 percent growth in the CRO industry. The growing CRO industry has brought in many changes in the business models.

Tracing the trend

Chetan Tamhankar
CEO
Siro Clinpharm

Chetan Tamhankar, CEO, Siro Clinpharm, forecasts some of the noted happenings in the coming future in the CRO industry, "As per recent market reports, the world wide R&D spend for pharma industry is estimated at about $100 billion for 2010. Though the period from the year 2000 up to 2008 witnessed a double digit CAGR, the same is estimated to be around just three percent for the period 2009 to 2014. This will naturally have an adverse impact on outsourcing clinical R&D. There will however be high demand impact on some therapeutic categories like oncology, anti rheumatics, anti diabetics and vaccines."

He adds, "Apart from cost, there are few issues influencing outsourcing of clinical R&D to emerging markets. Primarily they are data security; lack of stringent, predictable, speedy regulatory processes and inadequate infrastructure. However, the Government of India has in recent past taken lot of steps to address these issues upfront."

According to Jayesh Chaudhary, MD and CEO, Vedic Life Sciences, some trends are risk-sharing by CROs on select projects, greater willingness by CROs (and sponsors) for site development activities, greater appetite for translational research, strategic partnerships, simpler and shorter CRFs. Even though business is slower, outsourcing of pharma services is here to stay as we become a more networked place. "Even large firms like Lilly are exploring the fully integrated pharma network (FIPNET) model instead of the traditional fully integrated pharma company (FIPCO) model," Chaudhary points out.

Even Arun Bhatt, President, Clininvent Research, feels that sponsors do look for a CRO who can become a partner and share their risk in drug development. According to him trends and issues in outsourcing clinical R&D varies. At one end the sponsors look for CROs who can provide functional services eg monitoring, report writing etc. "Another trend is to outsource the trial to a US/European CRO but ask them to work with a local CRO in each country. The major issues are, regulatory/ethical challenges, and compliance to quality," informs Bhatt.

Newer therapeutic areas and biosimilars are making an increased foray into Indian bio pharmaceutical market leading to greater focus in these areas. Mahesh Malneedi, President, Makrocare, feels that first in human studies still continues to be a challenge for Indian CROs.

The right choice

Pharma companies have two options--either to perform trials in the company itself or give this responsibility to an external source ie to a CRO. Looking at the current trend, it is clearly evident

that pharma companies are more confident about CROs and the services offered by them. Therefore, the number of pharma companies that are transferring their jobs to CROs will only rise.


Arun Bhatt, President, Clininvent Research

"Apart from reduced costs, outsourcing helps pharma companies free up resources for higher value activities, gain access to capabilities and expertise that is not available internally, thus helps achieve higher levels of performance. Good competent CROs have a scientific, regulatory and information management expertise which pharma companies gain access to due to outsourcing. Pharma companies' pipelines are always oscillating and thus the cost of upfront and huge clinical infrastructure has to be borne by them if projects are done in house thus increasing financial risk," explains Tamhankar.

Tamhankar highlights the fact that not just the technical expertise but also familiarity with the local culture and beliefs is important. This is where local CROs come handy. He adds, "CROs provide standardisation of operating procedures and at the same time, are more likely to have a deeper understanding of local language, culture and regulatory norms. These qualities lead to better relations with investigators and improved trial execution."

Chaudhary's view is synonymous with Tamhankar. He says, "Pharma companies rightly outsource their individual projects to clinical development specialists so that the in-house team of the drug company can focus on their core competencies of medico-marketing and the larger issues of the whole drug development pipeline."

According to Chaudhary, there are just too many reasons to outsource to CROs, hence it is an established model worldwide. There are many other activities/methods that too get outsourced many times. "Several other critical steps in chemistry, screening and preclinical development are also routinely outsourced by drug companies who want to fast-track their molecules without building inhouse capacities outside their core areas," Chaudhary mentions.

Financial feasibility is yet another factor that should propel pharma companies outsource their activities. As informed by Bhatt, many a times a small/medium size biotech has one to two compounds in pipeline. For such a small effort, the company cannot invest in a full fledged clinical operation team. If the company does not have internal team for managing trials, then a CRO provides a useful alternative. If the team is busy with several projects, the CRO can support the team in managing extra workload for additional projects.

Besides the cost and the dearth of specific skills there are other factors as well that are on the 'list of worries' of the pharma company. Though Malneedi endorses some of the issues raised by his counterparts, he adds to the discussion that for pharma other departments are equally important like R&D, sales and manufacturing. "CROs can offer specialists in certain therapeutic areas that pharma may not have if that product portfolio is new to the company. With the growing competition and pressure to expand product portfolio, pharma companies need to run multiple products through clinical and this will put a burden on headcount overhead. CROs can alleviate these burdens by partnering well with pharma," asserts Malneedi.

Impact of regulation


Jayesh Chaudhary, MD and CEO, Vedic Life Sciences

Regulation is always an issue for any company when their operations are not confined to one country. Variations in regulatory requirements do make the job tougher for entrepreneurs. Though their motive is to find out safe and effective remedies for various health ailments during the trials the possibility of things going wrong always exists. Abiding to the regulators norms would indeed add to the overall expenses of the CRO firm.


Prahlad Tayade, DGM, Contract

Bhatt opines, "The regulations in countries like ours will become more stringent in line with global expectations. This is likely to lead to increase in the requirements of regulatory documentation and regulatory review time, and potential delays in approval process. The process of CRO registration and trial inspection are additional challenges. All these factors will affect the cost of regulatory process for clinical trials. "

Research Raptakos Brett and Co

Mahesh Malneedi, President, Makrocare

Prahlad Tayade, DGM, Contract Research, Raptakos Brett and Co, echoes Bhatt's concerns. He says, "Regulatory requirements is the biggest hurdle faced by CRO industries in India. To maintain different approvals/certifications is like taking care of white elephant without any value addition. Investment is required to maintain all the approvals and at the same time generation of business to recover the cost involved in certifications."

According to Malneedi, regulation is always good for industry, if that ensures safe and effective medicines to patients. Like any other regulated industry, in pharma industry also there is cost of maintaining regulations and it is a part of doing business in this industry. "This will remain in future too and players in this industry factor that effect anyways," he asserts.

Among the worries about possible rise in the cost of regulation in the coming future there are some initiatives that would perhaps minimise the cost of regulation. Tamhankar feels that in this scenario government can play crucial role. The world's biggest CRO nexus lies in US which is quite obvious as they already have the biggest pharma market. However, in the emerging markets like India government have had to upgrade the regulatory infrastructure rapidly. "Once the regulations are standardised, the cost of compliance will actually decrease," says an optimistic Tamhankar.

India, being an emerging market for the CRO industry, its regulation policies for the overseas companies will affect the future growth of the industry. However, Chaudhary does not think so. Malneedi narrates the contrary view, "As trials are becoming tougher day-by-day and mere expensive, companies are looking for other countries and the primary determinant factor is the regulation coupled with quality services/coming in from that country. As regulatory bodies like FDA, EMA focus on high quality data, countries where there's GCP depth and breadth are capturing this market, provided regulatory path is clear and fair."

Future growth opportunities

According to Bhatt, clinical trial project management and monitoring, electronic data capture and new sample technologies for trial management are the areas where future growth opportunities lie. Chaudhary adds to the list, "Large, simple trials, mapping disease patterns in India using public-private initiatives, site training activities and tapping the pool of non-practicing doctors, traditional medicine doctors and para-medics for site coordination work and contributing immensely to quality of site data and subject compliance will be the future growth areas."

Tamhankar sees more complex trials heading to India. "We also expect data management, statistics and medical writing to show rapid growth in the coming years. These segments can generate revenue quickly since they have shorter turn-around time," he says. Besides this, biosimilars and trials in medical devices are an area of growth. Very few CROs have the necessary experience although the infrastructure and capabilities required are similar to those required by drugs.

Issues raised by industry experts like Chaudhary, Bhatt, Tayade, Tamhankar and Malneedi are the ones that will decide the future of the CRO industry. On the other hand old issues like disputes between private business and public interest will keep on flaring up now and then as it has been the case in the past. However, the growth and sustenance of the Indian CRO industry should be a trend setter and not a trend follower.

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