

Indian CROs Going Global

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Clinical Research in India - Background

The history of international clinical research dates back to 1747 with James Lind proving the effectiveness of lemon juice in preventing scurvy in a controlled comparative clinical trial. International clinical trials day is thus celebrated every year on 21st May in memory of James Lind.

Although clinical trials in India being conducted to global standards had started around 1996, the landmark year for the industry was in 2005. The volume of international clinical studies pre 2005 in India gets dwarfed compared to the volume in just last 5 years primarily due to Government of India adopting product patent regime. This move gave a huge impetus to clinical research in India attracting more and more MNC sponsored global studies. In addition there were many other initiatives on part of the Government like formation of the Indian GCP guidelines, amendment to the schedule Y for multi-centric concurrent clinical trials to be conducted in India, launch of Clinical trials Registry website for mandatory registration of clinical trials being the major ones.

Indian Clinical Research Industry - Potential, capabilities and drivers for growth

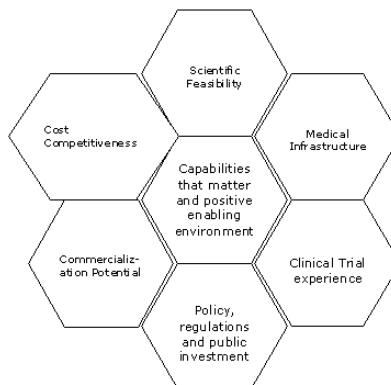
Global drug companies have in the past decade found India's clinical research space and opportunity very attractive. India in comparison to the western world offers a vast and varied patient population with lifestyle and endemic diseases of the tropical world, trained man-power, significant cost arbitrage, world class medical facilities & trained physicians to run clinical trials. Having seen this opportunity close to a decade ago, a few multi-national CROs began operations in India and the number grew slowly but surely in the subsequent few years with now almost every global CRO

having operations in India. Having seen the opportunity early, some entrepreneurs in India also decided to seriously enter the fray. While setting up operations, Indian CROs did face challenges of not having the support to get operations going full steam which MNC CROs enjoyed from their parent companies, but the early Indian CROs put in their best to reach a level which is now no less than MNC CROs in the country.

India born CROs were able to offer the advantages of understanding the Indian scenario better, provide services at more competitive costs, and having better knowledge of Investigator sites in the country compared to the newer entrants in the market.

India's clinical research landscape is being aided by many uniquely differentiated capabilities, a rapidly transforming healthcare market and an enabling environment that is rapidly adapting itself to global standards. As per a recent report from FICCI scientific feasibility, medical infrastructure, clinical trial experience, regulations, commercialization potential and cost competitiveness are some of the growth drivers responsible for the metamorphosis of Indian Clinical Research in the recent past.

Indian Clinical Research - Capabilities and enabling environment

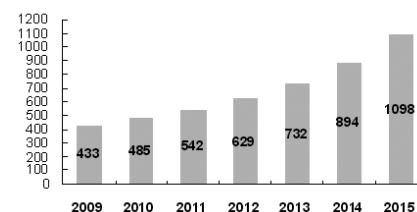


Source: FICCI report - The Glorious Metamorphosis - Compelling reasons for doing clinical research in India

Clinical Research in India: The Market Perspective

The global CRO market is pegged at around \$20 billion with India's share being about \$485 million. The later is projected to cross the \$1 billion mark by 2015.

CRO Market revenue Forecast (India), 2009-2015



Source: Frost & Sullivan Industry reports

Total number of trials 2009-2015



Source: Frost & Sullivan Industry reports

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Landscape of CROs in India

CROs in India essentially fall into two broad categories—those which were founded in India like SIRO Clinpharm, Diagnosearch and the others being global CROs which established office in India such as Quintiles, PPD, Parexel.

Post 2005, Indian CROs experienced sudden increase in workload due to many MNC pharmaceutical companies adding India to their clinical trial destination map. Many of these CROs had to ramp up their capacities in terms of workforce, technology and other required infrastructure. The growing market also attracted attention of the financial sector and few VCs (venture capitalists) and PE (private equity) players also jumped into the fray with significant upfront investments.

While the Indian market was experiencing a boom in terms of rapidly expanding clinical trial numbers three things were simultaneously happening. Firstly, increasing market attractiveness drew attention of a lot of global CROs which setup operations, secondly regulatory authorities became increasingly demanding asking companies to recruit more patients to be convinced on safety of compounds under development and thirdly late 2008 when global economic recession set in, it meant that cost effectiveness of drug development was even more imperative than before. This obviously meant that cost effective and high recruiting potential countries like India, countries in Central Eastern Europe, China could not be ignored.

Indian CROs: Strategic imperatives

The global environment opportunity, investment potential from the financial sector, increasing market attractiveness and the ascent on the clinical research learning curve led a few Indian CROs to spread wings and transcend Indian boundaries. There were primarily three strategic choices available with Indian CROs - one, grow organically by starting own operations and setting up teams in the countries they intend to be present in, two, form an alliance with an international CRO and thereby gain access to countries in which the international CRO had presence in and three, grow inorganically by acquiring a CRO with international presence. Any of these three approaches would increase manifold, the probability of winning multicountry studies thus justifying the increased investments and capacities.

The first option of growing organically, though had advantages of being able to choose and strategize the right services and people to run the organization in countries of choice, the approach was also fraught with challenges like longer gestation periods for being operationally ready to deliver on projects, cultural differences of working in a country with no prior knowledge of having worked in and knowledge of local regulatory practices. The second option of forming alliances with international CROs had limitations since management control was not with the Indian CRO and customers would have had to be convinced about the relationship within an alliance model before they chose to work with the CRO.

Hence most Indian CROs chose the inorganic route of expansion through acquisitions & mergers. Inorganic growth ensured faster penetration into new territories, ready access to local talent and expertise and building-in newer strengths.

Indian CROs going global: Challenges and responsibilities

Though the 'Going global' tag appears exciting and attractive, from a business perspective, it also brings along with it its own set of challenges. The biggest challenge post the acquisition is the integration piece of bringing together people, systems and processes.

The first and foremost challenge is understanding culture of the people from new geography. It assumes much more importance during cross border post acquisition integration process especially when cultures are divergent and bear little or no similarities. Though India is known for its cultural diversity and people in general are more attuned to be adaptable and sensitive to other cultures, the challenge still manifests itself in terms of different languages, accent, personal characteristics.

At the ground level, localization of operations becomes very important instead of exporting the home culture and organization structure. At the same time, implementation of best practices from the acquiring company is also important.

With the industry being highly process oriented, SOP (Standard Operating Procedures) harmonization also assumes a very important challenge which needs to be addressed and can be quite protracted and time consuming if not articulated and planned well.

Other integration challenges include understanding and respecting the existing investigator and vendor relationships and taking it forward in the new entity is crucial. Integration of sales and support teams post acquisition is also of great significance since eventually the new organization would be cross selling services across multiple locations in different countries.

A very critical aspect of integration post acquisition is the communication to customers. It is important to realize that the company being acquired has a certain brand value and equity with its customers which cannot be disregarded and ignored. A proper communication strategy and plan is essential to inform customers about the newly formed organization and generally a staggered approach in renaming the new organization in a phased manner generally works well.

Integration of technology poses another challenge. With multiple systems and applications being used by CROs, it is important to assess the best fit application while can meet global customer requirements and weed off redundancy and duplication. Also it is critical to have appropriate technology put in place so that cross geography teams can work seamlessly in an integrated way across time zones on a single application and thereby leverage the advantage of time zones and more cost effective manpower.

The recent challenge of the global recession and its financial implications on the clinical research industry cannot be ignored. Besides the fact that the US market recovery is taking time, the recent news from Europe is also not encouraging. From the clinical market research perspective however, this recessionary trend will put further pressure on global pharma companies thus compelling them to outsource more to emerging markets and countries like India. Thus Indian headquartered international CROs are likely to gain in terms of incremental work which needs to be managed well with the right distribution of work to be spread across geographies in which they operate. Indian CROs have been able to read through not just the present but also future needs of their clients. With competition building in, some will emerge much stronger than before by enriching their learning curve. The challenge is to manage people and operations in the most productive and profitable way in the geographies which India based CROs operate in.