

Leveraging the India advantage

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The India advantage has brought in leading global CROs to leverage its strengths and to serve the global customers in a better way and in a cost effective manner.

Quintiles Transnational, a leading global CRO with revenues touching \$2 billion, has completed 10 years in India in 2007. Quintiles India contributes about three percent to its total global sales. And it is growing at a rate of 25 percent over the global growth rate of 20 percent. In 1997, Quintiles Transnational took a strategic decision to enter India and opened an office in Ahmedabad, though it was not a demand from its customers. In 10 years, it has emerged as the leading CRO in India with revenues touching in Rs 136 crore in 2006, registering over 100 percent growth over the previous year.

Quintiles India opened its new central lab in Mumbai to mark its 10th anniversary in April. With this offering added to its list of services, Quintiles India now offers all the services to that are on offerings at the parent organization. Besides its central lab and clinical research businesses, it offers electrocardiogram (ECG), interactive voice response (IVR) and data management services.

Global CROs in India

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| CROs | Presence |
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| Chiltern International | 2005 |
| ClinTec International | 2002 |
| Kendle | 2004 |
| Omnicare Clinical Research | 1990 |
| PPD | 2004 |
| PharmaNet | 1996 |
| Pharmacia and its division Quintiles | 2005 |
| Quintiles | 1997 |
| RCC | 2002 |

During the course of the time, Quintiles India added offices in Mumbai and Bangalore. With a full complement of services, it expanded its clinical research staff to 750 and has conducted more than 700 global trials across business lines. It is also involved in the training of hundreds of investigators on GCP guidelines and helped put India on the world map for clinical research.

Considering the growth and success of Quintiles India, the other global CROs like PPD, ICON, PRA, Parexel, Kendle, PharmaNet, Omnicare, Chiltern, ClinTec and Covance too felt the urge to start their operations in a country where economy is booming and has plenty of resources to do business in the CRO space. Most of these have set up shop only in last couple of years, thanks to the Central government for its initiatives in the implementation of the patent regime in 2005, promoting medical tourism and announcing incentives to the CROs sector.

Depending on the risk and confidence level, these CROs opted different routes such as acquisition, alliance and direct to enter the Indian market. CROs like PPD, Kendle, PharmaNet, Omnicare, Chiltern, ClinTec, RCC and Simbec opted for direct entry route while others such as PRA International and ICON decided to adopt the acquisition model. Some others like Parexel, Covance and INC Research to be on safer side, took the alliance partnership approach.

PPD, a leading global CRO, set up its office in India in 2004 to provide patient recruitment and clinical monitoring for phase II-IV studies in key therapeutic areas. The Mumbai office expands its geographic footprint in Asia and enhances its ability to conduct global studies in industry-targeted therapeutics. Extending its drug development expertise to India allows PPD to assist clients in offering cost-effective clinical research opportunities to treatment-naïve patients for a number of therapies, including oncology and metabolic disease, such as diabetes.

With the goal of providing high-quality, cost-effective data management and biometrics services to its clients, ICON Clinical Research (a division of ICON plc), again another leading global CROs, has established an office in Chennai. This move will give ICON access to a large talent pool that includes many highly educated and experienced data management professionals. It also acknowledges the increasing importance of India as a center for technological expertise and clinical research. It also acquired a Chennai-based data management company, Biomines Research Solutions. In addition to providing data management and biometrics services, ICON has recruited several clinical research associates to support its growing clinical research activities in India.

PRA International, a leading global CRO, entered India in 2006 by acquiring Sterling Synergy Systems Pvt Ltd, a CRO based in Mumbai and Pune. This acquisition establishes a solid foundation for PRA in India and greatly increases its access to clinical sites, investigators and patients. PRA's clinical operations are based out of Mumbai while it has a data management center in Pune. With the Pune center, PRA will be able to provide integrated around-the-clock data management capability, augmenting its existing facilities in Lenexa, Kansas; Victoria, British Columbia; and Swansea, Wales.

However, Covance, a leading and most comprehensive drug development solution provider, entered into an alliance with SIRO ClinPharm in 2003 to offer drug development services in India to support domestic and international customers. It has the people, global resources and problem-solving culture to respond to even the most demanding challenges of drug development services.

Similarly Spacelabs Medical Data, a leading US-based global cardiac safety monitoring service provider, formed a strategic alliance with SIRO in December 2004. The alliance aims at providing companies conducting trials in India with centralized cardiac safety monitoring services (i.e. 12 lead ECG, Holter monitoring, Ambulatory Blood Pressure monitoring etc.).

GCPSiro, a US-based CRO has entered into a partnership with SIRO in 2006 to offer immediate clinical development solutions to pharmaceutical and biotechnology companies operating in that country. The partnership seeks to offer clients the necessary project management and other drug development support services in real time as well as in their respective time zones. inVentiv Clinical Solutions, a leading US-based pharmaceutical commercialization services provider offering solutions in clinical staffing, biostatistics and data management, has entered into a joint venture with SIRO. inVentiv-SIRO (India) will provide pharmaceutical and biotech companies access to a broad pool of offshore talent who will design databases, conduct data and statistical analysis. This joint venture is also capable of providing large-scale off-shore services to fulfil clinical data management and biometrics requirements in a cost-effective manner.

Symbiotic global partnership

Biocon group company, Syngene International, recently entered into a research partnership with Bristol-Myers Squibb to provide R&D services for discovery and early drug development.

"The new Bristol-Myers Squibb and Syngene research facility is underway. Spread over approximately 150,000 sft, the facility is planned to ultimately house more than 400 scientists to help advance Bristol-Myers Squibb's discovery and early drug development in India. This is expected to significantly increase the scope of Bristol Myers Squibb's existing relationship with Syngene to further develop integrated capabilities in medicinal chemistry, biology, drug metabolism and pharmaceutical development. Through this symbiotic global partnership, Biocon's Syngene will provide research and development services for discovery and early drug development," said Arun Chandavarkar, COO, Biocon.

INC Research and GVK Biosciences entered into a 50:50 joint venture to form INC GVK BIO Pvt Ltd in 2006. The JV will establish a dedicated resource capability to offer phase I-IV clinical development programs in India for INC's global clients. The joint venture will enable INC research to conduct its global clinical trials in the areas of oncology, CNS, infectious diseases and pediatrics involving phase I-IV studies.

UK-based Synexus Clinical Research plc, a patient recruitment site management organization, has entered into a collaboration with ICRI Research (P) Ltd (IRL), an associate company of Institute of Clinical Research India (ICRI), the clinical research institute offering courses in clinical research, to establish a chain of dedicated, GCP-compliant clinical research centers in India. IRL-Synexus will offer dedicated investigator sites (clinical research centers) for phase IIâ€“ phase IV clinical trials.

Parexel International Corporation, a leading global CRO, entered into a joint venture arrangement with Synchron Research Services in 2006, pursuant to which it purchased a majority stake in a newly formed entity, Parexel International Synchron into which Synchron moved its clinical trial business operations to Bangalore. Parexel also acquired a minority equity interest in the clinical pharmacology business of Synchron Research in Ahmedabad. However, Parexel entered into an exclusive strategic collaboration with Synchron in 2004.

The presence of leading global CROs including the top 10, will encourage the others to look at India as a global market for CRO services, which is growing rapidly with a focus on India and other emerging economies. India will witness more activities in the near future with the entry of more global CROs.