

## Indian CROs eyeing a lion's share

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*With increasing outsourcing activities, opening up of the market and government initiatives, Indian Clinical Research Organizations (CROs) are making efforts to strengthen their base and to have a bigger share of the pie in the big and growing CRO market.*

Over a period of 14 years, as many as 70 independent players including healthcare, information technology and pharma companies started offering services and solutions in clinical research and trials space to MNCs. The top Indian CROs have the backing of the leading pharma companies that supported them during the initial period. And those who are offering data management services include Indian IT giants like HCL, Cognizant, TCS, Satyam and Infosys.

The competition has increased with too many players in the space. To have an edge over the others and to meet the requirements of the sponsors, the CROs have been applying for certifications and accreditations. There are many agencies that audit the organizations and provide them with accreditations/certifications. Most the leading names in the CRO space already had many certifications and accreditations from agencies like UK-MHRA, Brazil-Anvisa and Israel-MOH.

In the recent past, many other CROs too received certification. Manipal AcuNova, the first Indian CRO to be ISO 9001 certified, has received NABL accreditation to its central reference laboratory at Bangalore. The ISO 15189:2003 accreditation has been given by the department of science and technology (DST) for diagnostic testing. In one year, Manipal AcuNova has completed the certification process for two of its laboratories. Manipal AcuNova's central reference laboratory specializes in

patient testing, advanced molecular diagnostics and clinical trial testing.

Similarly Glenmark Pharmaceuticals, a leading pharma company that has a clinical research division, has got regulatory approval from the Brazilian authorities ANVISA (Agência Nacional de Vigilância Sanitária) to conduct bioavailability and bioequivalence studies in human volunteers. Its clinical research unit is located at Turbhe, Navi Mumbai and accommodates about 72 volunteers. It also has developed a phase I unit equipped with eight beds to conduct phase I human volunteer studies. Regulatory submissions have also been made to the US and the European Union from this facility.

Another CRO, Lambda Therapeutic, with 160-bed phase-I units (increasing it to 260 beds) and own central reference lab for clinical and bioanalytical evaluations, has become the country's first level National Glycosylation Standardisation Program (NGSP) certified lab for glycosylated hemoglobin (HbA1C). NGSP standardizes HbA1C test results so that lab results are comparable to those reported in Diabetes Control and Complications Trial (DCCT) where relationships to mean blood glucose and risk for vascular complications have been established.

About five Indian organizations (three CROs-Clinigene, Lambda and IGate Clinical Research and two pathology labs-Dr Lal Pathlabs and SRL Ranbaxy) have received the CAP (College of American Pathologists) accreditation. Clinigene is the first to get this in the CRO space while SRL Ranbaxy became the first pathology laboratory to be accredited by the College of American Pathologists.

### **New initiatives**

Considering the growing market in CRO space the healthcare companies are making inroads into CRO business. Fortis Healthcare group, a flagship firm from Ranbaxy has started its own clinical research services company under the banner Fortis Clinical Research Ltd (FCRL). It has a state-of-the-art facility located within the Sunflag Hospital & Research Centre in Faridabad near Delhi. The infrastructure consists of a 78-bed ward and sophisticated bioanalytical labs with LC/MS machines spread over 19,000 sq ft area and manned by 50 professionals. The current services include bioequivalence studies, clinical pharmacokinetics, bioanalytics, and CAP-accredited central laboratory support for Phase I-III clinical trials. The facility is GCP compliant and approved by DCGI (India) and ANVISA (Brazil).

Dr Lal PathLabs, a leading medical diagnostics company with turnover of Rs 100 crore, too has launched its clinical research services by opening a dedicated state-of-the-art clinical trial laboratory (central lab). It has set up the 4,000-sft facility at Gurgaon exclusively for clinical trial operations. And it is also setting up a mega 65,000 sft laboratory at Rohini in North Delhi, which is expected to be in place by 2008.

On the other side, Synchron Research Services has expanded its operation in India by acquiring Innovance, a local start-up CRO having a world-class clinical research facility in Ahmedabad. This acquisition provides Synchron an additional facility which offers internationally accepted clinical research services. The new clinical facility has totally 200 beds across Asia. This makes Synchron one of the largest Asian CROs. In addition to this, Synchron is building a 32,000 sft facility exclusively for bio-analytics and data management, which would be ready by August. It has also entered into a tie-up with HCL Technologies for clinical trial solutions. This initiative from HCL will become end-to-end solution provider to clinical trials and data management companies. It also partnered with Parexel, a leading International CRO in 2006.

ICRI Research (P) Ltd (IRL), an associate company of the Institute of Clinical Research India (ICRI) the clinical research institute offering courses in clinical research, has entered into a collaboration with UK-based Synexus Clinical Research plc, a patient recruitment SMO (Site Management Organization) 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 II-Phase IV clinical trials.

Looking at the potential and opportunity in the CRO space, WellQuest, a division of Nicholas Piramal India Ltd (NPIL), is doubling its present capacities and expanding its activities to Hyderabad. Similarly, Mumbai-based ClinWorld, the clinical research arm of the Sami Labs, will be investing Rs 30 crore in the next three years to strengthen the existing facilities in Mumbai and Bangalore.

Even Reliance Clinical Research Services, a subsidiary of Reliance Life Sciences that has set up its US entity, will be adding more staff. By end of 2007, it is expected to touch 500 personnel in Mumbai and Bangalore in addition to the functional leaders located in the US and EU.

### **Investments from VCs**

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 has witnessed new entrants from local players to global CRO giants. To offer better services and to deliver within timelines, which is a key parameter for a good CRO, the organizations have to expand their operations in all parameters like headcount, services and infrastructure.

To fulfil such many other requirements, the CROs need funding. Venture capitalists, institutional bankers and the private equity partners are eager to fund these growing CROs considering the low risks and high growth potential. A few such investments from the VC community have happened in the recent past.

According to an US-IVCA/Venture Intelligence study, VCs have made four investments worth \$16 million in the healthcare and life sciences industry during 2006 of which three are in the CRO space.

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.

Aureos India has invested about Rs 18 crore in Accutest Research.

### **Government support**

According to the BCG report, the CRO market growth is expected to be double digit in the next five years. India has a record of conducting clinical data management and biostatistics work for MNCs. It is expected to get major share of such work in near the future too. At present India conducts about 1.5 percent of the global clinical trials. This could rise to five percent by 2008 and 15 percent by 2011. And that is the percentage of a global total that itself is increasing by 10 percent every year.

To support this growing service sector, in its recent Budget, the Central government announced exemption of service tax for CROs. The industry welcoming the initiative, noted that it will bring more customers to India and also more companies would start operations in this area.

The government has also committed \$1 million fund to upscale the capacities and competence of the country's clinical research organizations. The DBT and the Indian Council of Medical Research are supporting this fund.

Besides the financial support, the ministry of health and family welfare has constituted the National Council for Clinical Establishments under the directorate of health services with a view to determine minimum standards for clinical establishments and to maintain and update a national register of clinical establishments in the country. The director general of health service, ministry of health and family welfare, will head the council as chairman.

The functions of the National Council for Clinical Establishments shall be to determine the standards for clinical establishments; classify the clinical establishment into different categories; develop the minimum standards and their periodic review; compile, maintain and update a national register of clinical establishments; perform any other function determined by the Central government from time to time.

### **Future ahead**

The Indian CRO market is expected to undergo a composition change in the coming few years. Bioavailability and bioequivalence studies that occupied a major share in the clinical research market pie, are likely to lose to other areas such as clinical trials (phase I-IV) and data management. The cost advantage will no longer be the prime-attracting factor for the Indian players. The importance would shift to factors such as quality, timeliness, and value added services that are being offered by the Indian CROs.

However, data security, manpower and public infrastructure still act as roadblock or a potential drawback for the growth of the industry. And also the issue of the lag for phase I trials in India. But Frost & Sullivan noted that the nascent markets like phase I and pre-clinical toxicology will see growth due to the pressure from the industry on government and the industry's need to become a one-stop solution for its clients. Once that is in place, Indian CROs can increase their share in the global CRO market.

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## Investments in CROs

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- Aureos India invests in Accutest Research

## Trends in CROs

- The full services CROs are seeing a downward shift in preference by the big players who are now focusing on functional experts to leverage the cost advantage further.
- The growth rate of this market is on an upward trend
- BA/BE studies occupy a major chunk of the market. However, it is forecasted that this segment of clinical research would slowly decrease in terms of total contribution to the market pie over the forecast period (2006-13), as consequence of growth in other segments of clinical research.
- Most of the participants in these segments offer a gamut of services and are moving towards becoming a one-stop solution for their sponsors
- China, India, Vietnam and Thailand are emerging as preferred destinations

*Source: Frost & Sullivan CRAMS report 2007*

## CROs having strong support of parent group

- IGATE Clinical Research International is backed by IGATE Solutions
- Integrated Clinical Research Sciences is backed by Wadia Group
- Reliance Clinical Research Services is backed by Reliance Industries
- Jubilant Clinsys is backed by Jubilant Organosys
- Lambda Therapeutic Research is backed by Intas Pharma
- Manipal Acunova is backed by Manipal Group
- SIRO ClinPharm is backed by Bharat Serums and Vaccines
- Fortis Clinical Research is backed by Ranbaxy and Fortis Healthcare

