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BioServices Grows over 20 percent

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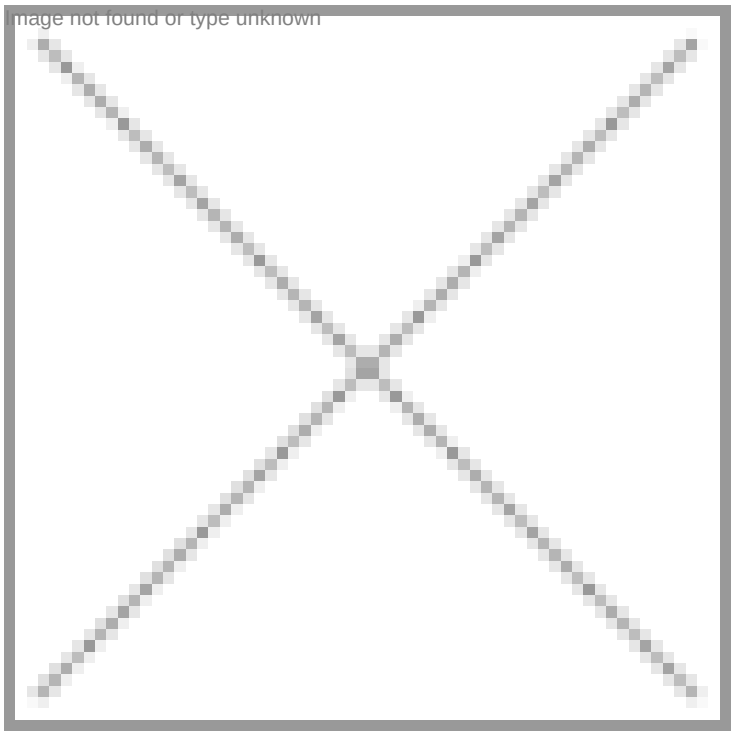

- BioServices segment clocked sales of ₹ 3,245.97 crore registering a growth of 23 percent for FY 2010-11
- MNCs continue to dominate the market
- Total number of clinical trials stood at 1,584 in 2011
- Indian CROs aggressively looking at expansion to South East Asian markets
- Sector to grow at 20-30 percent over the next three years

The bioServices sector clocked total revenues of ₹ 3,245.97 crore in 2010-11, registering a growth of 23 percent over last year's (2009-10) total segment revenue of ₹ 2,639 crore. This constitutes about 19 percent of the total biotech industry revenue for the fiscal.

Compared to the previous two fiscals, where the CRO industry was hard hit by the global downturn in particular, fiscal 2010-11 saw some positive developments in this segment. Companies as well as the Indian government (the DCGI in particular) authorities were proactive in creating a favorable environment for clinical trials. Consolidation in the global landscape, in the form of mergers and acquisitions, had its cascade effect on the Indian CRO industry. However, in spite of the fall in the number of global clinical trials, the clinical research sector witnessed a growth of 23 percent over last year as the country saw a rise in the number of local clinical trials.

A good number of global companies are now looking at India to conduct large scale global trials. While low costs and large patient pool still remain the crucial deciding factors for attracting these companies, skilled investigators and emphasis on quality are some of the rising factors contributing to the segment's growth. Above all, India is gradually emerging as a drug discovery destination rather than a mere drug development destination, as more companies are looking at innovative and novel products. In terms of key therapeutic areas, the CROs are focusing on oncology, neurology, respiratory, diabetes, anti-

infective, psychiatry, endocrinology, central nervous system, cardiovascular system. Diabetes takes the top spot due to the large population suffering from diabetes.

Players operating in the Indian segment include multinational CROs, Indian CROs, multinational pharmaceutical companies and Indian pharmaceutical companies. While the first three categories of companies are into global trials, Indian pharma companies usually look at conducting primarily local trials. The Indian market is still dominated by multinational CROs. Major global players include Quintiles, PPD, Parexel, ICON, Pharmanet, Kendle, i3 InVentiv, Omnicare Clinical Research, Inveresk Research, MDS and SCIREX Corporation.

Major Indian players include Siro Clinpharm, GVK Bio, Clininvent, Ecron Acunova, CliniRx, Asian Clinical Trials, Jubilant Clinsys, Vimta Labs, Lotus, Lambda Therapeutics, Clinigene, Max Neeman Medical and International, Synchron Research, iGate (now Diagnosearch Life Sciences), Veeda Clinical Research and Actimus Biosciences.

According to estimates, there are around 30 CROs conducting BA/BE trials, 50 CROs looking at phase I-IV trials. Major companies looking at BA/BE studies include Lambda Synchron, BA Research, Veeda Clinical Research, Vimta, Bioserve, Accutest, Accunova and Lotus Labs. In India, there are only a few companies into phase I trials (due to issues of large scale investments in infrastructure).

The much favored business model followed by most of the homegrown CROs is to commence their business with a focus on BA/BE studies and then gradually move up the value chain, once they develop their competency. This model is an emerging trend and will stay so for some years.

Since June 2009, the DCGI made it mandatory that all clinical trials have to be registered with the Clinical Trials Registry of India (CTRI) before a single subject is recruited for the study. As of January 2011, according to the CTRI, the total number of trials stood at 1,584 as against 806 trials between January-December 2010. Quintiles India conducts the largest number of trials in the country.

There are a total of 2,000 investigators overseeing clinical trials across various sites in India. India still faces the challenge of a dire paucity of investigators as well as lack of sites. Estimates point out that India requires an additional 25-30 percent more investigators. Industry experts opine that this shortage can be overcome by by tapping tier II and III cities and towns and by constant training on GCP and GLP to these investigators.

Homegrown CROs are also aggressively looking at expanding to other markets of the world, the South East Asian marketsin particular. A direct presence in these countries will give Indian CROs the advantage of close proximity to their clients. Other upcoming destinations include Eastern Europe and Africa. East Europe offers advantages like large patient pool, low cost and proximity to multinational companies present in West and Central Europe.

About two-three CROs are doing phase I trial, 15-20 CROs are involved in phase II trials, 12-15 CROs are involved in phase III and 20-25 CROs are doing Bio Avaibility /Bio Equivalence (BA/BE) studies. In India, most clinical CROs carry out phase II-IV studies. Very few CROs carry out phase I studies. The number of BA/BE CROs would be around 100.

Siro Clinpharm, in early 2011, announced the start of their operations in Malaysia thus expanding reach in the Asian continent. They already have consolidated their position in Western as well as Eastern Europe. Veeda Clinical Research again, towards May 2011, announced from its Ahmedabad headquarters, that the final steps had been put in place for the commissioning of its CRC Veeda (Malaysia) phase I unit in the Ampang Hospital in Kuala Lumpur in Malaysia, most likely to be called ‘CVM’. Having established a presence in Thailand, Synchron Research is looking at tapping the growing South East Asian market, with Vietnam being the favoured destination.This is due to the rise of the pharmaceutical sector in this region, coupled with the influx of a large number of multinational companies into this region.
Looking into the future, the CRO industry will continue to grow at a rate of 20-30 percent in the next three years. Thesegment will also see the entry of a number of small-sized homegrown CROs into the market looking at BA/BE studies. Also, being on the growth mode, Indian CROs will look at outbound acquisitions both big and small. Mandatory resgistration of all clincial trials in India has brought about the much-needed transparency into the system and this in turn will lead to a rise in the number of global companies outsourcing clinical trials to India.