

## BioServices Analysis

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According to a Confederation of Indian Industry report, the global outsourcing market in pre clinical and clinical research is over \$ 13 billion. The pharmaceutical companies are currently scouting in India for suppliers of quality ingredients, clinical development services and the painstaking chemical synthesis work for early drug development. They are also shopping for promising new treatments that may emerge from India's own drug discovery efforts.

Various studies show that the scientific talent pool of four million Indians is the second largest English-speaking group worldwide after the US. The availability of a large resource of English speaking scientists gives India an edge over other countries to reach the forefront of R&D services in biosciences. According to some estimates, 15 percent of the scientific population of pharma and biotech companies in the US is of Indian origin. Currently three million graduates, 700,000 post-graduates and 1500 PhDs qualify in the scientific stream each year in India. Presently 15,000 bio-scientists are engaged in the biotech sector. The contract research services segment has the potential to generate 50,000 jobs in the next five years with a revenue realization to the tune of \$5 billion per annum.

Due to cost advantages and competitiveness, India is being considered as a destination for contract research and manufacturing and other services like clinical research that are needed for the growth of the biopharma segment. The contract research and clinical business in India during 2003-04 was Rs 275 crore as against last year's Rs 135 crore registering a growth of 104 percent.

The contract/clinical research organizations are providing a broad range of clinical research services including bio equivalence, bioavailability, pharmacokinetic studies and phase I to phase IV clinical studies including statistical analysis,

data management and project management, clinical operations, data management, biostatistics, regulatory affairs, quality assurance, training, medical writing, pharmacovigilance, medical consultancy and laboratory services. These companies are also offering protocol designing, regulatory approvals, ethics committee approval, appointment of investigators, preparation of clinical trial study material and placebo, coding and distribution to trial centers, patient consent and recruitment, conduct of trial, laboratory investigations, monitoring, data analysis and management, interim and final reporting of results.

Most of the contract and clinical research organizations are located in Hyderabad, Bangalore, Mumbai and Ahmedabad as these places house pharmaceutical companies and have good support systems to carry out the clinical trials.

Quintiles Spectral, a subsidiary of Quintiles Transnational, Siro-Clinpharm, a group company of Bharat Serums and Vaccines, Syngene, a subsidiary of Biocon India, Vimta Labs, Pfizer Limited, Lambda Therapeutic Research, Lotus labs are the major clinical research organizations operating in India. The other players in the sector include Synchron Research Services, Clingene International, a group company of Biocon India, Reliance Clinical Research Services—a group company of Reliance Industries, Sipra Labs, Genotex International, ClinTec International, Novartis, Novo Nordisk, Vedic Lifesciences, ClinInvent Research, iGATE Clinical Research International, Wellquest, a subsidiary of Nicholas Piramal India Limited, ClinWorld Inc, among others.

Many multinational contract and clinical research organizations-Simbec, RCC, Omnicare, PharmaNet, Pharm-Olam International, ICON Clinical Research have set up their liaison/marketing offices in India. These are looking at the Indian pharmaceutical companies, which are investing in R&D. Even pathology laboratories like SRL Ranbaxy- a leading lab of Ranbaxy, Metropolis Health Services India and Dr Lal's Pathology Labs have also started conducting clinical trials using their existing infrastructure.

Companies like Indus Biotherapeutics-an arm of Intas Pharmaceuticals, Hi Tech Bio Laboratories, Chembiotek Research International-a leading company of the Chatterjee Group, Shreya Biotech and many others are active in contract research. Considering the huge opportunity in clinical research, pharmaceutical companies like Eli Lilly, Cadila Healthcare, Cadila Pharmaceuticals, Haffkine, Wockhart, Intas Pharmaceuticals, Lupin Ltd have set up their own clinical trials units. Even information technology companies like Infosys Technologies, HCL, TCS, Wipro Technologies, Essar Technologies are looking at entering clinical data management.

Although opportunities exist in the bio-services space, but the Indian companies find it difficult to convince sponsors to outsource research activities. This is mainly because many of the Indian companies do not have the multidisciplinary expertise that the sponsors look for. This can be overcome by partnering with organizations having complementary skills. Such alliances will fulfill the needs of global life sciences companies right from drug development to distribution.

Pfizer	18
Lambda Therapeutic	16
TOP 5	170.14
Others	105.00
Total BioServices Revenue	275.14
<p><i>*Note: SiroClinpharm has not confirmed its revenues. In 2003-04, its service revenues were Rs 31.20 crore and in 2003-04 it might have crossed over Rs 50 crore. Its number of projects have doubled in 2003-04.</i></p>	