SECTOR PROFILE

Clinical Research

The US$ 64 billion global clinical research industry is witnessing a transition since lifescience companies are turning toward emerging markets in Asia, Latin America and Eastern Europe, to pursue clinical research. Increasing costs, declining productivity and rising drug development timelines, combined with the strategic advantages offered by these emerging markets, is directing research-driven pharmaceutical and biotechnology companies to conduct clinical research beyond established markets.

• The share of Rest of the World (RoW) countries (countries other than the USA, Canada and Western Europe) has increased by 4.3% in total global study sites, which in absolute numbers corresponds to ~6500 sites.

• RoW countries today account for nearly 25.9% of Phase I-IV sites with the number of studies in some emerging markets growing nearly two to three times faster than the global average.

• Emerging markets now contribute to ~36% of global patient enrolment as compared to ~20% in 2001.**Promotion of the Sector by the Government**

The government is planning and executing a number of initiatives to strengthen the institutional machinery, e.g., mandatory registration of clinical trials, registration of stakeholders (CROs, ethics committees, investigator sites and investigators), enhanced monitoring and oversight (random audits, inspector training workshops by USFDA) and e-governance of the entire drug approval process. These are the government's commitments towards creating a regulatory environment in line with the highest global standards.

The government is also looking towards a major multi billion dollar initiative with 50% public funding through a public private partnership (PPP) model to harness India's innovation capability. The vision is to catapult India into one of the top-five Pharma innovation hubs by 2020 with one out of every 5 to 10 drugs discovered worldwide, coming from India by 2020.

The Private and Foreign Investment

- Big Pharma and international CROs have offshored their allied service operations to India
- Service providers operating from India have entered into multi-year contracts with Big Pharma
- Indian service providers are looking at acquisitions/ ties- ups to strengthen their capability

Regulations

Fiscal and other incentives have been churned out to the clinical research industry over the past few years:

- No import duty on clinical trial supplies (2003)
- Exemption from registration requirements for clinical trial supplies (2003)
- Export of clinical trial-related human blood specimens allowed based on the earlier practice of seeking DCGI-NOC-Approval from the Director General Foreign Trade being no longer required
- Exemption from service tax on new drug testing (2007)

MNCs already present are further consolidating their presence in India while new entrants are expanding their toehold. MNCs are increasingly restructuring their operations with global parents increasing their equity stakes in their Indian affiliates.In India, the central government, via the Central Drugs Standard Control Organization under the Ministry of Health and Family Welfare, largely works on developing standards and regulatory measures for drugs, diagnostics and devices; laying down regulatory measures by amending acts and rules; and regulating the market authorisation of new drugs – all in an effort to standardize clinical research in India and bring safer drugs to the market.

With the number of clinical trials being conducted in India increasing rapidly, the regulatory bodies are recognizing the need to frame guidelines and regulatory approval processes in line with international standards.Drivers for Growth of the Clinical Research Sector in India

Scientific Feasibility: Strong availability of study subjects across major therapeutic segments

Medical Infrastructure: The urban healthcare infrastructure in terms of beds/ physicians/ nurses per 1000 is comparable with the global average

Cost Competitiveness: India offers a significant cost advantage as compared to developed and emerging economies, 40- 60% lower than in developed countries and around 10- 20% lower than emerging economies

Clinical Research Expertise: India offers an abundant and growing pool of skilled, talented and experienced medical professional, second largest English speaking country in the world after the US

Favourable Regulatory Environment: that allows the conduct of global trials, duty-free imports of drugs intended for use in trials, bioequivalence studies for export of data, etc;

Compliance with high levels of ICH-GCP and US Food and Drug Administration standards

Key Challenges Faced by Sector

- Multiplicity of Authorities and Lack of Harmonization with Global Regulatory Pathway
- Ambiguities and Lack of Harmonization Across Regulations
- Lack of Regulation Against Fraud

Some of the Leading Clinical Research Organization:

Multinational

- Quintiles Research India Pvt Ltd
- Parexel International
- ICON
- Bristol Myer Squib
- Clinigene International
- Eli Lilly & Company
- INC Research
- Pfizer
- Glaxo Smith Kline
- Sanofi Aventis
- Novartis
- Novo Nordisk

Indian

- Manipal Acunova Ltd
- Clininvent Research Pvt Ltd
- Veeda Clinical Research
- Clinirx Research
- Dr. Reddys laboratories
- Jubilant Clinsys

Future prospects

Clinical trial and research is now a major business in India. Over 100 companies are currently conducting the clinical trials in India. Top multinational pharmaceutical companies like Pfizer, Glaxo Smith Kline, Aventis, Novartis, Novo Nordisk, Astra Zeneca, Eli Lilly are conducting clinical trials in India apart from the Indian companies like Dr. Reddys, Nicholas Piramal, Cipla and Lupin.

The following factors make India a critical destination to conduct clinical research and pave the way for it to emerge as a clinical research hub in future:

- There are numerous government-funded medical and pharmaceutical institutions with state-of-the-art facilities, which can serve as ideal centres for multi-centred clinical trials.
- India boasts of well-trained and qualified manpower, well versed in English. In terms of the cost efficiency, India is better as the cost to conduct a trial here is lower by 50 to 75% than in the United States or the European Union.
- R&D costs in India are substantially less than those in the developed world and it is possible to conduct both new drug discovery research and novel drug delivery system programmes at competitive rates.
- Clinical trials cost approximately US$ 300 to US$ 350 million abroad, they cost about INR 100 crore in India.

India being a land of diversity where Ayurveda, Unani, Siddha, and Homeopathy are practiced, clinical studies for evaluation of various alternate systems of medicine can also be conducted. India has been increasingly attracting collaborative contract proposals for conducting clinical trials and many entrepreneurs have already come forward to set up their Clinical Research Organisations (CROs). The country is projected to conduct nearly 5% of the global clinical trials by 2012. However, to achieve its goal of becoming a global centre of clinical trials, the country has to overcome few challenges.