

Economy & Business



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DR MANMOHAN SINGH
 Prime Minister

Its destination Karnataka for clinical research

The global pharma industry is outsourcing manufacturing and R & D in a big way. Contract Research Organisations (CROs) in India, which are helping in the discovery and development of marketable drugs, play an important role in the outsourcing process. Karnataka, more so Bangalore, is now a major hub for global clinical research, observes **Rashmi Shrikant**.

Clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations.

Most of the clinical trial business in the global market originates from the USA and Europe and directed to countries such as Eastern Europe, China and India. Thanks to the growing demand for clinical trials, the Indian clinical research market currently pegged at US \$ 600 million, is poised to grow to be a 1 billion dollar industry by the year 2010, estimated by a McKinsey study.

A huge population with a diversity of diseases, competitive costs, high enrolment rates, good patient compliance/retention, an increasingly accommodating regulatory environment are the benefits of conducting clinical research in India, as identified by Igate Clinical Research International.

The company's website states that India has 40 million asthmatic patients, 34 million diabetic patients, 8-10 million people HIV posi-

tive, 8 million epileptic patients, 3 million cancer patients, 2 million cardiac related deaths, 1.5 million patients with Alzheimer's disease, 15 per cent of population is hypertensive and 1 per cent of population suffers from schizophrenia.

The Ernst & Young Global Pharma Report notes conducting clinical trials in India results in cost savings of up to 30-50 per cent.

India advantage

One of the major reasons clinical trials are coming to India is that in the developed world it is increasingly becoming difficult to get subjects (people willing to undergo trials). This leads to delay in the drug development process. However in India, sponsors have the opportunity to recruit subjects. Subject willingness is critical in clinical trials and the compliance to undergo the full process.

In India, a large section of the population unable to afford their own treatments, opt for these trials as they are assured on treatment and healthcare, which would have not been available otherwise. Hence the subject return rates are amongst the highest in the world in India.

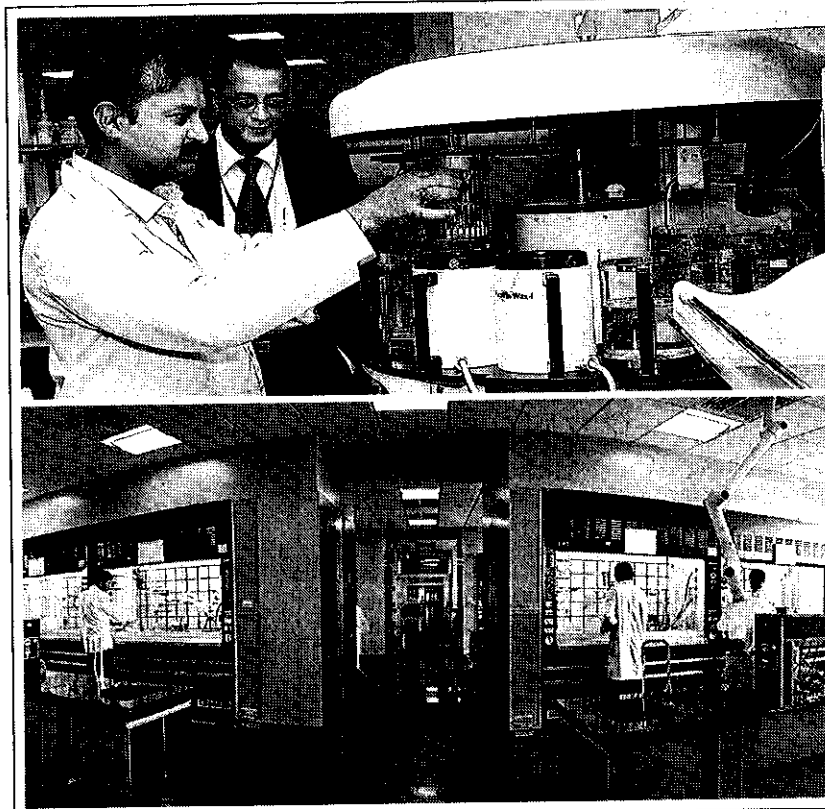
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panded their portfolios to include pre-clinical trials, Phase I-IV trials, data management and site management. Global pharma giants such as Pfizer, Novartis, Johnson and Johnson, Eli Lilly, Astra, Zeneca and Glaxo are leveraging the advantages India offers.

Trials are on-going with various CROs on drugs for diabetes, blood pressure, cancer and other diseases of interest to the international drug market.

Booming business

There are over 45 CROs and in India of which about 15-20 are in Karnataka. The leading CROs in Karnataka include Manipal AcuNova, Biocon's Clinigene and Syngene, Triesta Sciences, Quintiles, Parexel, Lotus Labs, Aurigene Discovery Technologies, part of Dr. Reddys, Clintrac International, Glaxo Smith Kline's Clinical Data Management Centre and Vaatsalya. The presence of leading re-



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(Top Left): Manipal AcuNova's Central Reference Laboratory, in Bangalore.
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CLINICAL RESEARCH MARKET

Year	Indian market (Rs in cr)	(million \$)	Global market (million \$)
2003	315	70	5000-6000
2005	810	180	10,000
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2010	4500	1,000	50,000

Estimated by McKinsey Assumption US \$ = Rs 45

search institutes like the Indian Institute of Sciences and leading hospitals like Manipal, Wockhardt, Kidwai, MS Ramaiah, NIMHANS and St. John's in Bangalore has further contributed to the growth of clinical research market in the state capital.

"It is a knowledge industry driven by doctors, patients, pharmaceutical, biotech, diagnostic and IT companies. Added to this, Karnataka has a long history of medical colleges and research institutes which helps in the growth of clinical research industry," says

D A Prasanna, Vice Chairman and Managing Director, Manipal AcuNova. Manipal AcuNova, awarded as "India's No 1 Emerging CRO", by Proximare Inc, a New Jersey based leading strategic management consulting firm, conducts Phase I - IV Clinical Research and Bio-Availability/Bio Equivalence Studies to pharma, biotech and drug companies.

The company's research facilities are located at Bangalore, Manipal and Mangalore. Manipal AcuNova's Central Reference Laboratory (CRL) at Bangalore re-

cently bagged the National Accreditation Board for Testing and Calibration Laboratories (NABL) certification for Molecular Diagnostics tests.

Manipal AcuNova has invested close to US\$6.5 million on Central Laboratory, Clinical Data Management and Clinical Research facilities. The company has mobilised a funding of \$10 million through promoters, private equity and is planning to invest further in client acquisition in Europe and America.

Drug employment

At present, 5 to 10 per cent of global trials are being held in India. According to McKinsey report, the clinical research industry will create a demand of 50,000 professionals in the next five years.

It is stated that by 2008 upto 30 percent of global clinical trials will take place outside the US and Western Europe and India would

emerge a favorable destination. However, according to some analysts, India is still lacking expertise in the field, especially in documentation.

"Documentation is very crucial to conducting clinical trials. What is not written down is not valid. But the mindset of our people, despite the huge growth in IT, is not very strong in documentation," observes Dr A S Arvind, Chief Operating Officer, Clinigene.

Clinigene and Syngene are the clinical research arms of Bangalore based biotechnology major Biocon. Established in the year 2000, Clinigene set up India's first CAP (College of American Pathologists) accredited Central Reference Laboratory. The company's value-added services include patient registries and clinical databases in diabetes, lipemia, oncology and cardiovascular diseases.

Syngene conducts high value R&D in early stage drug discovery and development for a diverse global clientele.

Life's big

Yet another company that is lining up big initiatives in the life sciences business is the Reliance Group by way of its arm, Reliance Life Sciences (RLS). RLS has R&D facilities in Bangalore and Mumbai. According to media reports, Reliance is making huge investments in FY 2007 to tap the immense potential in the clinical research market.

The promising CR business is also attracting pharmaceutical companies. For instance, Bal Pharma, a Bangalore-based pharma major, has invested Rs 4 crore in a research facility near Bangalore with an intention for contract research jobs.

"We provide clinical research services basically to some of the leading US companies. We are planning to invest another Rs 2-3 crores

in the next couple of years to expand our facility" says Shailesh Siroya, Managing Director, Bal Pharma.

Guinea Pigs for sale?

While India is now a hot destination for clinical research, the most frequently asked question is "Have Indians become Guinea Pigs for global sale?"

It has been argued that poor uneducated patients in India, who do not understand the meaning of trials, are lured into it for monetary gains. Subsequently they may become victims of the possible side effects of trials. There have also been instances of companies violating Drug Controller General of India (DCGI) norms.

While sponsors claim to take responsibility to insure the subjects involved in the trial, some of the industry observers maintain that insurance in clinical research is yet to gain grounds in India.

"All said and done, clinical research is now evolving in India and things have been changing for better. Regulations in the country are getting more and more stringent and ethical committees are playing a very significant role.

Indian regulators are careful not to permit 'First in Man' studies unless national interests warrant it," says Mr Prasanna.

The ICH-GCP guidelines, critical for reliable clinical research, have been mandated in India, unlike the rest of the world. Indian regulatory authorities including the DCGI and ICMR have issued the Indian version of Good Clinical Practices (GCP) which is in compliance with ICH-GCP.

"Early adventurism witnessed in the CR industry a few years ago is not there now. It is clear that only companies with a focused strategy, expertise and above all, good clinical practices will survive in the long run" maintains Mr Prasanna.

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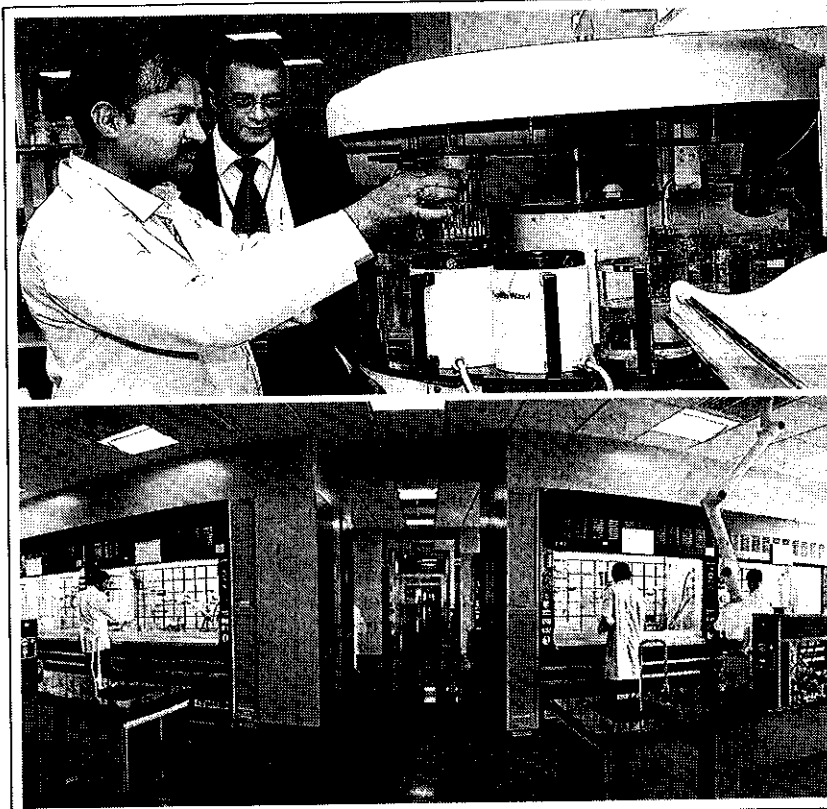
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