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The variety of gene pool, large number of diseases, English speaking physicians and support staff and therapy-naïve patients — together these factors make India an irresistible destination for conducting clinical trials. India is ranked third — after the US and China — in terms of attractiveness as a clinical trial destination. After the call centre boom, it is now the clinical trial outsourcing business that is all set to redefine the market rules.

But does India have the regulatory framework to ensure that poor and illiterate patients are not exploited? Will this industry bring in allied services, generate more employment? Are studies being conducted in India so that unsafe drugs can be ruled out?

As a part of the efforts to regulate the market, in the past few months, new laws have come into force, amendments have been made to the existing ones and the authorities are keeping a hawk-eyed watch on the industry. *The Indian Express* takes a look at the booming business of clinical trials as the government takes steps to further its boost.

WHY INDIA IS IRRESISTIBLE FOR GLOBAL COMPANIES

WHY has India suddenly become the favoured destination for Contract Research Organisations (CROs)? In North America or Europe, many clinical trials are caught in litigation as the patients are very aware of their rights to healthcare. However, compared to time-consuming, expensive and painstakingly regulated trials conducted in North America or Europe, clinical trials in India are executed in a system that is known for its inconsistencies. The lack of access to information, especially for the poor and illiterate patients, is the biggest challenge facing the regulators.

"What India offers is quite the opposite of what companies working in the US or UK will be used to," admits Dr Surinder Singh, Drugs Controller General of India (DCGI). "We have been trying to generate awareness among patients regarding their rights. The regulatory landscape has undergone a dramatic change in the past 18 months with the passing of several amendments and Bills in the Drugs and Cosmetics Act. Recent reforms include mandatory Registry of Clinical Trials, Review of Ethical Committees, Registration of CROs, transparency in the regulatory system and pharmacovigilance activity across medical colleges in India," said Dr Singh speaking at a symposium in New Delhi on clinical trials in India.

The two most important factors making India a dream destination for clinical research organisations are English speaking physicians and the presence of six out of seven genetic variations. "The Government of India has traditionally been over cautious and conservative as far as the clinical trial industry is concerned. This was to ensure that our people are not exploited. The changes brought in the past few years will ensure that our indigenous industry survives while we open our markets to match international standards," said Dr V M Katoch, the Director General of Indian Council of Medical Research (ICMR).

THE GOLDEN GOOSE: INDUSTRY TO TOUCH $1.5 BILLION

THE clinical trial industry is valued to go up to $1 to 1.5 billion in the next five years. The offshoring of clinical trials brings with it allied services, and hence, more opportunity in clinical data management (CDM), biostatistics, pharmacovigilance and medical welfare.

Given the potential, the Health Ministry and Drugs Controller General of India are bringing in measures to regulate the market. "The government is planning and executing a number of initiatives to strengthen the clinical trial sector. These are testimonials to the government's commitment to create regulatory environment in line with the highest global standards. In keeping with that, our institute aims to educate clinical research professionals and enhance the culture to international standards," said Dr S K Gupta, Dean and Director General, Institute of Clinical Research.

Currently, seven of the top 10 global CROs have an established presence in India. Trials for a standard drug in the US can cost about $150 million. A similar drug could be tested in India for 60 per cent less.

Since India stands to benefit from these trials by much-needed investment into healthcare and access to beneficial drugs, there is an urgent need to create an agreeable environment by raising awareness and ensuring ethical clinical practice. "Our long-term goals are to create an environment conducive to trials in India. The mandatory registrations of trial sites and ethics committee will help regulate the industry better. In the next five years, we want to ensure penal provisions for fraud and misconduct in clinical research," added Dr Singh.

TACKLING ISSUES: FROM REGULATION TO ETHICS

EVER since the registration of clinical trial was made mandatory by the DCGI from June 15, 2009, there has been an added momentum in the number of registrations of clinical trials in the country. Extensive regulatory reforms of the booming clinical trial industry will be in place within six months, he said while ad-

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dressing a symposium on 'India — An Emerging Destination for Clinical Trials' organised by Institute of Clinical Research.

According to ASSOCHAM, 15 per cent of the global clinical trials will be conducted in India by 2011, grabbing business worth $1 billion.

"We will completely change the regulatory landscape for clinical trials in 2010. This will be a historic year in that regard. We are putting in place a system brick-by-brick by the next one year or 18 months," said Singh. "To make this a global hub of trials, a host of issues ranging from regulatory to ethics and patient safety need to be addressed urgently," said Dr Gupta.

According to Central Drugs Standard Control Organisation (CDSCO), within the next six months, regular, random, on-the-spot inspections of trial sites will be underway. "Inspectors will visit trial sites with updated checklist. This will ensure protection of volunteers, reliability of data and proper checks and balances," Dr Gupta said speaking at the symposium.

Since October 2009, India has taken steps to centralise licensing for pharmaceutical products as part of its ongoing programme to streamline the regulatory process with respect to pharmaceutical manufacturing. In the past three months, the DCGI's office has worked on reviving the pharmacovigilance programme that was introduced in 2004. "The plan is to involve 40 of the 294 medical colleges in the country as of now to record adverse drug reactions. There are a lot of drugs which have been in the markets for years, but there is no record to show their impact on patients," said Dr Singh.

PHARMACOGENOMICS: NEW SCIENCE, FRESH TALENT

THE science of tailor-made medicines — suiting each patient's genetic make-up — is the next frontier. And doctors like Uma Tekur will ensure we get there faster. Dr Tekur has been studying pharmacogenomics for the past two decades at Maulana Azad Medical College. But it is only in the past four to five years that this branch of science has started attracting the attention of regulators, doctors, industry and, most importantly, fresh talent. "Pharmacogenomics has to be studied at a macro level. Sitting in this hospital, collecting data of the few thousand patients coming here, I cannot tell you what is the genetic structure of patients from the Northeast or South India. We are still not collating data as efficiently as the West to deduct conclusions about genomics," said Dr Tekur, Professor at the Department of Pharmacology, Maulana Azad Medical College.

Pharmacogenomics is the use of genetic analysis in the drug development process to understand the interaction between a given drug therapy and an individual genetic make-up; by using this information it is possible to design drugs based on individual needs to reduce side effects and avoid adverse drug reaction. Globally, several pharmaceutical industries are working in this area.

"Every drug has different effect on patients. It is now recognised that this effect may wholly or partially be different due to difference in the genetic make-up of patients. The government's mandate is that each medical college generates its own data, which can be collected at a higher level. In the next four to five years, when all this data falls in place, we will have evidence-based medicines and that will be the start," she added.

Pharmacogenomics is thus the study of identification and analysis of genomic variations that affect the efficacy of a drug. Pharmacogenomic studies can potentially be predictive of an individual's drug-response or adverse reactions or susceptibility to iatrogenic disorders, and may reveal new targets that can help in the design of new drugs.

PHARMACOVIGILANCE: FINAL KEY TO THE BOOM

ACCORDING to experts, 2010 is going to be historic as far as health research in India is concerned. The government's ambitious plan to use the patient data generated by all 300 medical colleges in India by imbibing Pharmacovigilance (PV) will revolutionise health care in India. "It is just a matter of recording every adverse drug event. Our doctors are amongst the smartest and we can be the fastest when it comes to adapting to new methods like PV," says Dr Katoch.

To sustain the booming clinical trial industry, the government is focusing on strengthening infrastructure in medical colleges, setting up rural units and virology network across medical colleges. "What we are witnessing is a revolution and India had been preparing for it for the last three to four years. Our health infrastructure is now up for the challenge this growing industry presents. This is a historic time in the health research industry," added Dr Katoch.

Pharmacovigilance or PV is the study of adverse drug reactions (ADRs) while introducing a new line of treatment.

PV is the science of collecting, monitoring, researching and assessing information from medical colleges and patients on the adverse effects of medications, biological products, herbs and traditional medicines with a view to identifying new information about hazards associated with medicines and preventing harm to patients.

This year is going to be historic as far as health research in India is concerned. The government's ambitious plan to use the patient data generated by all 300 medical colleges in the country by imbibing Pharmacovigilance, or the study of adverse drug reactions, will revolutionise health care in India

FACT FILE

Process

The pharmaceutical company appoints a Contract Research Organisation (CRO) to plan and execute the clinical trial. The CRO identifies doctors, health institutions and demographics of patients to be involved in the trial. The Independent Ethics Committee (IEC) studies and approves this and is supposed to review regular reports once the trial is launched.

Benefits

Clinical trials are conducted to help companies find out ways to give a new treatment safely and effectively. All patients participating in a clinical trial provide information on the effectiveness and risks of the new treatment. New therapies are designed to take advantage of what has worked in the past and to improve on this base. There are certain steps and protocols which need to be followed while carrying out actual clinical trials.

Resources

Medical colleges: 300 (143 government and 157 private)
MBBS seats: 35,202
Hospitals: 15,622
Beds: 9,03,952
Diagnostic Labs: 14,000
Manpower: Over 7,00,000 scientists and engineering graduates annually
(Source: Central Drugs Standard Control Organisation)

Figures

- As per Ernst & Young Survey Report, 2008, India can attract up to 10 per cent of the global contract research outsourced market in the next five years.
- The industry is valued to go up to $1-1.5 billion (Rs 4,800-Rs 7,200 crore) from the current $300 million (Rs 1,440 crore) (Source: Mckinsey & Co)
- In 2005, only 100 clinical trials were being conducted in India. At present, the figure stands at 350.
- In the first 18 days of 2010, 21 clinical trials were registered at CDSCO; 546 clinical trials were registered in 2009.
- There has been a 116% growth in the industry-sponsored research in the past 15 months.