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CLINICAL TRIALS LOSING THE PLOT IN INDIA

MNCs increasingly turning to emerging destinations in Southeast Asia due to clearer set of procedures, approval

P B JAYAKUMAR
Mumbai, 26 December

In 2000, it was projected as the next big thing to happen in healthcare, for its potential to replicate the outsourcing success stories in information technology (IT) and business process outsourcing (BPO).

Listing various 'Advantage India' factors, experts had predicted the country would bag 15 per cent of the global clinical trial industry by 2011, from less than one per cent at the time.

The projections have remained largely on paper. Data show the growth rate is dipping. And, many multinational companies (MNCs) are preferring other emerging destinations in Southeast Asia such as China, Korea and Singapore.

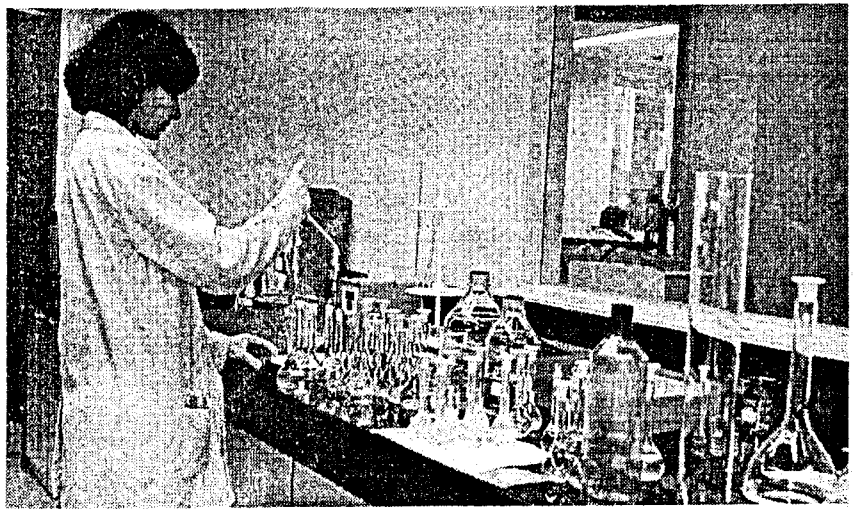
Data from the US government's global trials registry, clinicaltrial.gov, show only 246 clinical trials were held in India in 2009. That was 9.6 per cent lower than the number of trials a year before. On the other hand, the number in China (316) and Korea (397) grew 15.3 per cent and 20.7 per cent, respectively, in 2009 as against the previous year.

"India's industry is still evolving and many Indian companies have gained capabilities in Phase-II and Phase-III trials and to some extent in pre-clinical development, at comparatively cheaper costs. But cost is not the criteria; it is quality and speed," said Aaron Schacht, executive director and chief operating officer of global external research and development (R&D) at Lilly Research Laboratories, the R&D division of US-based multinational drug major, Eli Lilly, in a recent interaction with *Business Standard*.

McKinsey had earlier projected that by 2011, over 3,00,000 patients would be enrolled for clinical trials in India and 1,500 to 2,000 studies conducted here each year. Various industry estimates also projected the industry to grow to over Rs 5,000 crore by 2011.

As against this, the Indian clinical trial industry did only 240-260 trials from MNCs and another 180-200 trials of domestic companies last year. The exact business is not known, since almost all the 120-plus Clinical Research Organisations (CRO)s operating in India are privately held.

Industry experts believe the business in 2009 was not more than $250-300 million (Rs 1,100 crore to Rs 1,500 crore). A study by Hyderabad-based Cygnus Business Consulting & Research said the clinical research industry in India had touched $258 mn in 2008, up from $140 mn in 2006, with a growth rate of 85 per cent in those two years.



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Hurdles

Recession, regulatory issues, lack of laws, concerns on data protection, skill sets, infrastructure and delay in approvals are among the many reasons given by sector experts for the decline.

If a trial is approved in the US within a month, it takes six to eight weeks for the apex drug regulator, Drug Controller General of India, to respond. Normally 12-16 weeks are needed to get approval for a trial, they said.

"Countries like China, Korea or Singapore have plenty of government-certified and trained trial sites. In India, the government is yet to start certifying trial sites. Quality assurance and training at site are major areas of concern for companies wanting to do trials in India, though we have about 1,500 sites," says Arun Bhatt, president of Clininvent Research, one of the top CROs operating in India.

Not only the trial sites: quality and infrastructure of CROs are another area of concern. Of the 120-plus CROs, only about 20 comply with the global benchmark ICH- GCP (International Conference on Harmonisation/ WHO Good Clinical Practice) standards, said an industry expert.

DCGI had, a few days earlier, come out with a comprehensive clinical trial inspection programme, with specific guidelines and checklists to make trial regulations more stringent and uniform. At present, trials are based on guidelines brought out by the Indian Council of Medical Research and the office of DCGI. India had amended Schedule Y of the Drugs and Cosmetics Act in 2005 to create a conducive environment for doing trials in India, but specific laws are yet to be in place to effectively regulate trials in the country.

MNCs account for almost 70 per cent of the trials in India. Most of them have their own CROs. Indian CROs mainly do the work of domestic companies and small and medium drug companies from the US and Europe.

The leading players in India include Clinigene International, Vimta Labs, Lotus labs, Veeda and multinationals like Quintiles Spectral, Pharmanet, Clintec, Quintiles, ICON, GVK Bio, Siro Clinpharm, Parexel, PRA International, PPD, Covance, Omnicare and Kendle, among others.

"Now the regulator dema
that a drug has to be launch
in India if trials of that drug
done in India. It will be diffic
for multinational companies
give such a commitment, si
international launch of a d
involves various factors, ti
lines and priorities," said an
ecutive of a CRO associated w
an MNC, who wished not to
named.

"The number of trials h
pening globally has come do
due to the dwindling pipel
of multinationals. Further,
dia's skills in this field are li
ited to oncology, cardio-v
cular and metabolic disease
said Krathish Bopanna, pr
ident and executive direc
of Semler Research Cent
a CRO.

At present, India does
allow Phase-I of clinical
als, in which a drug is first
perimented on a human be
This is another reason for l
of growth for the sector, say
dustry experts. They agree
dia is yet to have a favoura
regulatory environment and
frastructure to allow the ri
Phase-1 trials.

"For Phase-1, Singapore,
rea and China are the most p
ferred destinations in Sou
east Asia," said Schacht.