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Clinical research market buoyant

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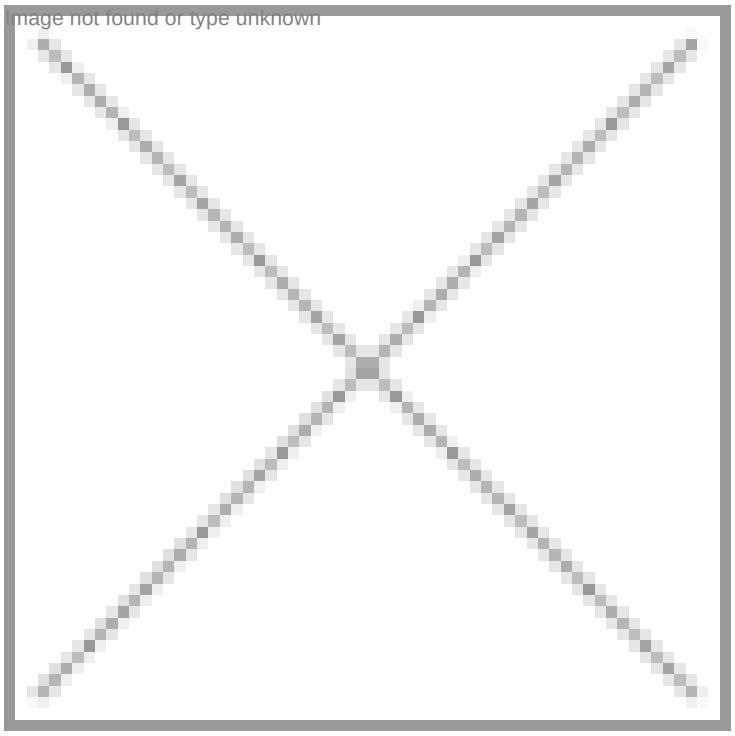

Clinical research market buoyant

The global market for clinical research is estimated to be $10 billion in 2005 and continues to grow at 12 percent per annum. India can garner up to $1.5 billion by 2010. The arrival of stronger intellectual property protection is changing the rules of the game. India has allowed product patents for drugs since January 2005 to make industry attractive and multinationals are looking towards India.

India Clinical Research Market Size

The Indian clinical research industry remains in infancy stage with 0-10 years of operation. The Phase I to IV clinical trials were started in 1995 by domestic firms such as SIRO Clinpharm and Apothecaries. Quintiles was the first international CRO to enter India in 1997. The year 1999-2005 saw a number of CROs setting base independently or through collaboration. With the global pharmaceuticals companies looking outward to reduce their ballooning research costs, India is in a good position to tap the new business opportunities. Quintiles Spectral, SiroClinpharm and Syngene are the 3 key independent CRO players in India accounting for 71 percent of the market share.

The health system in India is at the cross roads, though dramatically changed from what it was a few decades ago. India has 1 billion plus population, largest patient pool, and 50-60 percent cost advantage in the clinical trials. At a time there are around 80,000 to 1 lakh clinical trials going across the world. Cost advantage is the biggest benefit that India provides, but there are still significant issues that need attention.

Advantage India

The key concern is the regulatory structure, GCP and ethical practice and skilled manpower. The changes in the regulatory framework are happening and gradually gaining momentum. The government is planning to take a number of steps such as single regulatory authority, forum for CGP, patient registry database, clinical trials website, speeding up the clinical trials application review process and infrastructure up-gradation to foster industry growth. In order to meet the skilled manpower shortage, CROs have started in house training programs and educational tie ups.

BioSpectrum Advisory Services research indicates that a maximum number of CROs were started in 2004 and 2005. Some CROs have sufficient financial backing of the parent company. Bangalore and Mumbai are the favored destinations for starting clinical research operation with other parts of the countries also gaining attention.

The clinical trials sites are spread across length and breadth of the country with large number of small cities also offering adequate clinical research facility. Clinical data management, statistical analysis, regulatory affairs, trials supplies management, training and auditing services are expected to grow faster. The industry will see niche players, capacity expansion and collaboration to fuel the growth plan.

The introduction of the ethical guidelines for Biomedical research in human beings, acceptance of GCP guidelines, revision of Schedule Y (multi-centric Phase II and Phase III trials) and patent regime is making the industry attractive.

We see India moving from low cost destination to full service provider where CROs offer services from the earliest stage of development through clinical trials and post approval research.

Further, with life sciences and pharmaceutical companies showing a definite inclination towards electronic technologies and investing substantial amounts in transitioning from paper-based to electronic processes, revenues in the eClinical trials (eCT) market are expected to increase from approximately $210 million in 2004 to $857.4 million in 2011.

Sponsors prefer India over china because with the start of product patent regime in India, MNCs are now looking towards India. Currently, there are more than 25 well-established clinical trial organizations in India with a well-developed skill set to comply with the standards such as ICH-GCP guidelines.

India Clinical Research Industry

2004-05: $100-150 million

2010: $1000-1500 million

More than 40 CROs located

International certification achieved: CAP, ANVISA, MCC, ISO 9002