

Business Times - 08 Dec 2005

Life sciences taking off in Asia

Region's market is enjoying healthy growth and proving to be a fertile test-bed for clinical trials of new products

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THE global life sciences market is currently valued at approximately US\$600 billion, enjoying a healthy year-on-year growth rate of 10-12 per cent. It includes products and services related to pharmaceuticals, medical devices, and biotechnology.

Treatments for life-threatening diseases, chronic diseases which substantially affect the quality of life, and conditions where prevention can significantly reduce the risk of long-term impairment, have become major drivers of growth.

In Asia, however, the life sciences market has picked up pace only recently. For several years, Japan had been the sole focal point within Asia for global firms. But increasing competition and rising costs of research & development (R&D), marketing, and manufacturing have led many companies to pursue the potential of other emerging markets in Asia.

And why not? After all, annual growth rates of the Asian market are much higher in comparison with those in the United States of America and Europe, and the population that can afford new and innovative products is growing rapidly - thanks to rising disposable incomes and emerging health insurance schemes.

So in the last 10 years, several multinational companies have invested in Asia. And many are expanding their facilities for R&D, manufacturing, as well as clinical trials, particularly in high-potential markets such as China, India, Singapore, South Korea, and Taiwan. Clinical trials, until recently, had been conducted exclusively in the US and Europe. However, as more and more firms are waking up to the benefits and advantages of carrying out trials in Asia, this trend is changing.

Asia is home to more than four billion ethnically diverse people, comprising a large pool of patients. Many of these patients are untouched by any prior treatment or medication for their conditions, and therefore well suited for clinical trials. Higher availability of such patients significantly cuts down recruitment time of subjects, making trials faster, easier, more efficient and, in turn, cheaper compared to the US and Europe.

Some Asian countries offer monetary incentives, while others provide free medication and, often, better medical attention to clinical trial patients. Processes have also been established to ensure that proper patient consent is obtained before a trial and patients' rights are protected. Such measures further boost patient involvement in studies.

Asian countries also have well-qualified engineers, scientists, and technicians, many of them trained in the US or Europe. Some are even familiar with the US Food and Drug Administration (FDA) regulations on clinical research.

In the past, a significant concern for western companies conducting trials in Asia was intellectual property (IP) protection. But with the World Trade Organization's agreement on Trade Related Aspects of Intellectual Property Rights, member countries are now required to establish minimum standards concerning the scope and use of IP rights and the procedures for enforcing them.

Governments in Asia are actively driving clinical research in their countries. Singapore, for one, has

become a much talked-of centre for Asian clinical trials. The government has placed considerable emphasis on biomedical sciences, attracting a number of major pharmaceutical firms like Pfizer, GlaxoSmithKline, Eli Lilly, AstraZeneca, Novartis, Merck & Co, Sanofi-Aventis and Roche. The Biopolis has become a landmark for life-sciences and pharmaceutical-related research in Asia. Singapore's Economic Development Board (EDB) has also launched the Biomedical Sciences Investment Fund scheme to encourage local researchers to develop ideas and commercialise them for the market.

Clinical research

Moreover, Contract Research Organisations (CROs), which are proliferating across the region, have put clinical research on a fast growth track. Now, life sciences firms that do not have a presence here, or whose Asian bases lack resources to conduct trials in-house, can easily engage CROs to execute the task for them.

CROs specialise in clinical research and are therefore able to accomplish these tasks faster, getting products to market earlier.

This time saving, in the context of a pharmaceutical firm for example, translates directly into revenue. The earlier a drug reaches the market, the longer is its window to generate revenue before the drug loses patent protection and returns begin to be absorbed by generic producers.

As life science firms globally are under constant pressure to contain their research and development expenses, outsourcing trials to CROs in Asia can mean significant cost savings. Hence, multinational firms can reduce their product development expenses.

At the same time, they can garner a foothold in the lucrative Asian market. Therefore all parties stand to gain - life sciences firms benefit from reduced costs, Asian consumers benefit from early introduction of new medical products, and CROs benefit from the revenue streams.

The CRO market in Asia stood at an estimated US\$1 billion in 2004 having grown at a compounded average growth rate of 9 per cent.

The chart in the accompanying graphic gives a snapshot of the major markets.

The Asian market is dominated by large multinationals like Quintiles, Covance, PPD, MDS and ICON. They typically provide the entire breadth of services from the pre-clinical phase to the post-approval phase.

Other regional players like Gleneagles CRC (Singapore), APEX (Taiwan), SiroClinpharm (India), EPS (Japan), and Novotech (Australia) bring with them an abundance of local experience and know-how. Foreign CROs often partner with such research organisations to leverage on their local expertise.

As in other regions, a reputation for research quality and thoroughness is the key determinant of success for CROs. Patient recruitment skills also figure high on the list of requisite competencies. However, two other capabilities are uniquely important in the Asian context:

- Relationship with key client decision makers - due to the relative insularity of the market, and the tendency of companies to award business to firms with whom they have long-standing relationships;
- Knowledge of local regulatory environment, language, and culture - especially for CROs wishing to expand into China, India, Japan, South Korea, and Thailand.

Quality, communication and timeliness have long been matters of concern for multinational firms when dealing with Asian CROs. But today, many Asian CROs can claim business efficiency levels equivalent to that of US-based CROs.

Successful FDA approvals of drugs which were trialed by local CROs also testify to their quality and reliability. Even the logistical challenges of moving samples between laboratories, investigation sites, and drug companies, have been resolved through partnerships of CROs with distribution & logistics firms that specialise in this field. Thus, samples and supplies can be transported without difficulty or delay.

Global practices

However, some long-standing challenges persist. Standardisation of clinical trial procedures in Asia has long been a bone of contention. Not all procedures are consistent with global practices. Methods for documenting medical procedures also vary. Implementing the required frameworks throughout Asia will continue to be a challenge for a few years to come.

Even the clinical trial regulations in countries within Asia are different. For example, the Indian government does not allow companies to conduct Phase I clinical studies, in which drugs are tested for safety, on patients in India. On the other hand, companies have no obligation to conduct Phase III trials in Singapore in order to register a product here. Varying regulatory frameworks across the region require firms to diversify their goals, risks, and resources accordingly, thus adding to the complexity.

Another major consideration is the time taken by the regulatory boards and ethics committees to provide approval for Investigational New Drug (IND) and New Drug Approval. These are required for companies to kick-start clinical trials and register products in a country, respectively. While an IND approval in the US can be obtained within a month, in China the process can take longer than a year, resulting in significant loss of time. Governments are aware and are taking measures to make these processes more efficient. However, increasing number of submissions every year may counter their efforts in coming years.

Lastly, many firms in the West still perceive Asia as lacking in infrastructure and capabilities, and still others are yet to realise its full potential. This disparity between perception and reality exists mainly due to the chasms in available information.

The author is programme manager in the Asia-Pacific Healthcare practice division of Frost & Sullivan, a global consulting company. Frost and Sullivan recently published a report on clinical development and outsourcing in Asia. It will also host the inaugural Asia Clinical Development and Outsourcing Summit 2006 in Singapore in May 2006.

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