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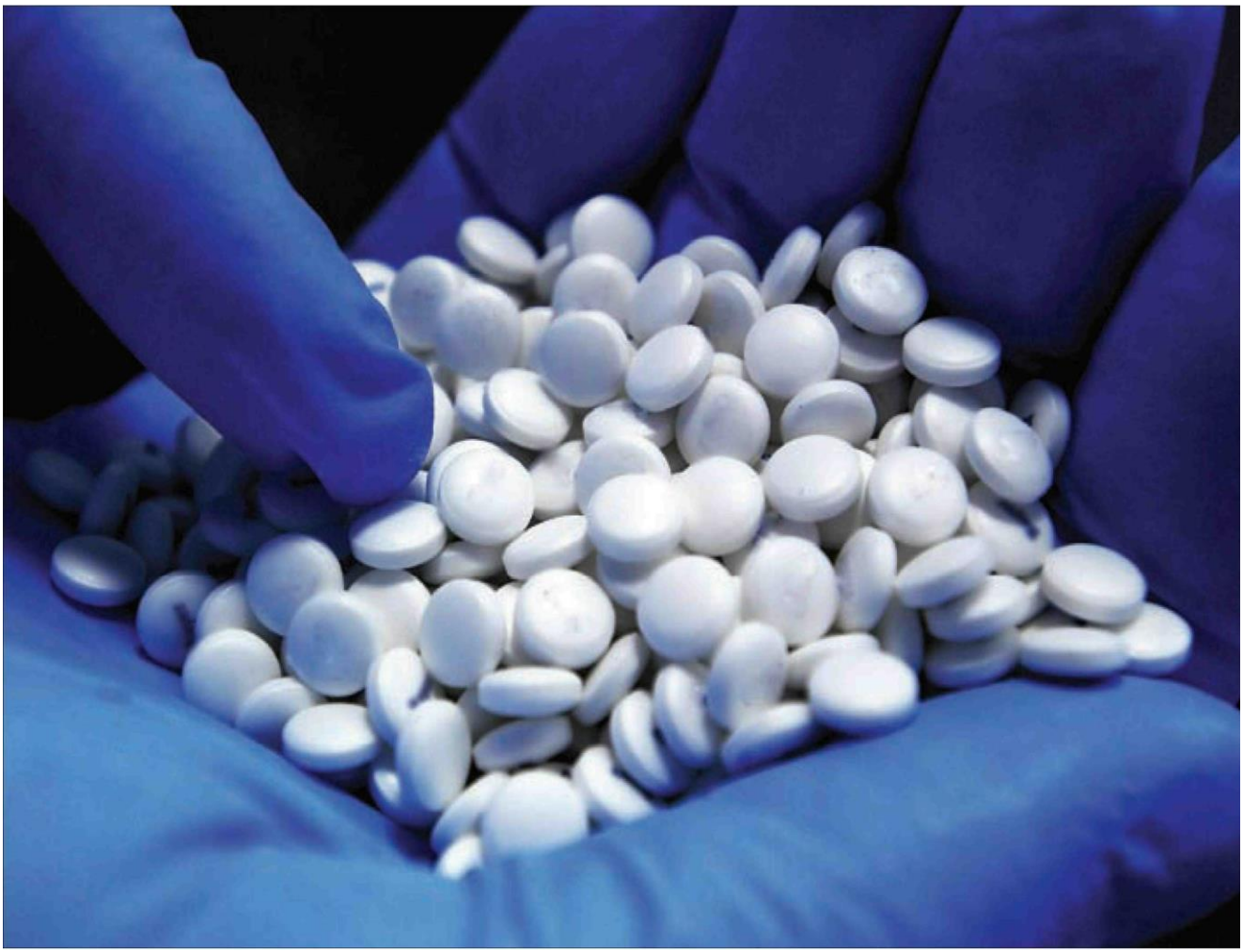
an Economist Intelligence Unit business healthcare

Asia's Fast Evolving Clinical Research Landscape | Spotlight India:

The New Frontier of Growth



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Rapidly increasing demand augmented with steadily improving expertise

Asia's growing significance as a key destination for clinical trials

Globalization of clinical research has been evident with the shift of clinical activities into Asia Pacific (APAC). Asia is not just a market and manufacturing powerhouse for the pharmaceutical industry, but is also evolving to become a major destination for drug development and clinical research. Emerging markets especially Asia, are increasingly becoming the choice off-shore destination for biopharmaceutical companies conducting clinical research. Of the markets, Asia is the leading location selected by biopharmaceutical companies to offshore clinical trials (Exhibit 1)[1].

"Asia looks to be a promising destination for upcoming shift of clinical activities from Western countries"

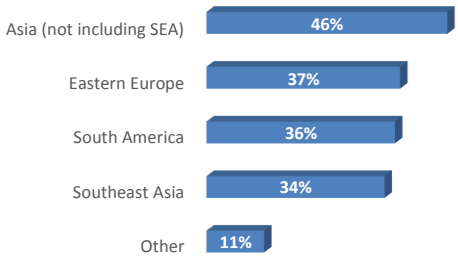

Exhibit 1. Off-shore locations selected by 116 biopharmaceutical companies. Source: UBM Tech Web and Wipro research (2011)

There are various push factors contributing to the rise of Asia Pacific as a clinical research hub:

- **Huge and fast growing pharmaceutical market in Asia.** Asia houses approximately half of the world's population and represents a huge addressable market for the pharmaceutical industry. Furthermore, the Economist Intelligence Unit reported a healthy growth of pharmaceutical sales in Asia, forecasted to reach USD $386 billion by 2016.

- **Conducive clinical environment.** Asia inherently possesses a large treatment-naive population ideal for recruitment of trial subjects. Government bodies are pushing out incentives and tax exemption to promote R&D activities in the region, and streamlining regulatory procedures ease the initiation of trials in these countries. Quality of Clinical research Associates (CRAs) and quality of trials conducted in the Asia are continuously improving with the adoption of GCP guidelines integrated with international standards, offering a favourable environment for clinical trials to be conducted in Asia.

- **Cost advantage.** Budget constraints and limited patent period also compel pharmaceuticals to explore more profit-driven strategy to increase productivity and maximize profit margins, by reducing the time taken to market drug and

[1] UBM TechWeb and Wipro Research, The state of Global Clinical Research Trials (2011).

by controlling headcount costs. Asia offers cost competiveness, where cost of R&D can be 30-45% cheaper than in developed markets such as US and Europe.

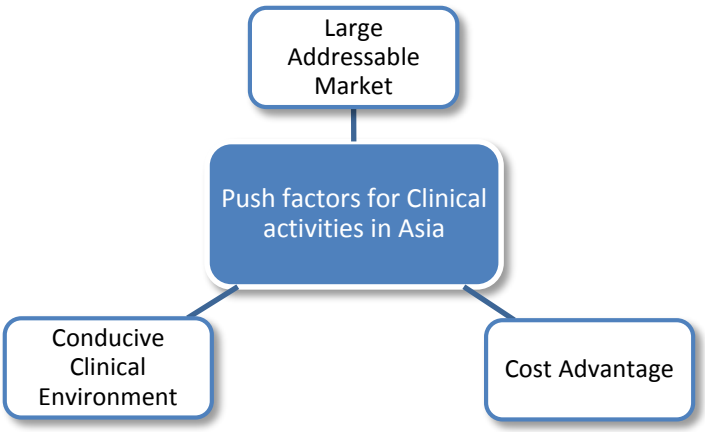

Exhibit 2. Factors contributing to the rise of Asia as a destination for conducting clinical trials.

Clinical Research Outsourcing under-penetrated in Asia

APAC clinical research organization (CRO) market remains an industry mainly driven by global pharmaceutical companies. Approximately 30% of total APAC clinical spend is outsourced in 2012. This presents an opportunity for CROs looking to penetrate the APAC outsource market and significant headroom for growth is expected in emerging markets within APAC, especially in China, India and South East Asia.

"APAC outsourced market estimated to grow at a CAGR of 12% for the next 5 years"

A study conducted by Clearstate in 2013 observed that among the listed attributes in the Industry Standard Research (ISR), low cost, therapeutic expertise, project manager quality, staff quality, local market/regulatory knowledge and data quality metrics were important attributes for pharmaceutical companies when outsourcing clinical trial services. APAC is constantly improving in its clinical trial capabilities, with the increasing quality of sites and staff, and the rise of local knowledge among the domestic CROs, hence contributing to the future growth of the CRO industry.

Growing adoption of clinical outsourcing services in Asia

The clinical outsourcing industry in APAC is projected to grow at a CAGR of 12% over the next 5 years. APAC represents significant opportunities for CRO businesses as clinical activities continue to thrive in the region. External factors including rising cost of drug development and the impending patent cliff also compel pharmaceutical companies to look for alternative cost-effective and risk-diversified business approaches. The aspiration to build capabilities and expand geographical reach in the region also contributes to the surge in outsourcing decisions, where companies lacking in resources and local expertise outsource to external parties.

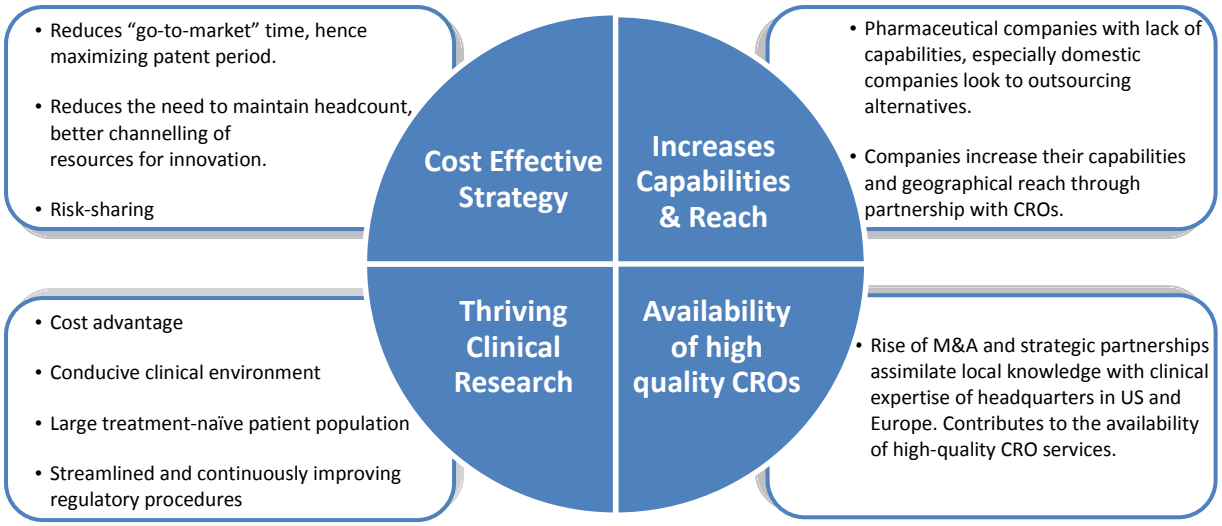

Exhibit 3. Factors for high growth potential of APAC CRO industry.

A networked business model is evolving in Asia, with rising trend of partnerships and mergers in the clinical research space

A trend towards mergers and acquisitions (M&A), and forging of strategic partnership is observed across various fields in bioscience, including the clinical trial service industry. The lack of local market knowledge and the lack of resources in Asia have contributed to the rising trend of M&A and partnerships among companies, especially global CROs, looking to expand geographical coverage in Asia. M&A and strategic partnerships with local players set a platform for CROs and pharmaceutical companies to enhance their capabilities and resources within APAC. CROs were

"M&A and strategic partnerships are commonplace in APAC clinical research space"

mainly engaged for specific services in the past, but more recently, CROs are increasingly engaged for a whole range of clinical services, a partnership that allows for risk sharing.

Global pharmaceutical companies conducting multi-country trials largely engage the services of international CROs, while the domestic pharmaceutical companies generally prefer domestic CROs. M&A and strategic alliances might be a platform to penetrate the domestic market, especially in China since the biotechnology and pharmaceutical industry is poised for growth in the coming years. China has ambitions to strengthen its CRO industry, and the existence of strong domestic players like Wuxi AppTech (largely in pre-clinical services) and Tigermed (largely in clinical services) provide the opportunity for strategic alliances to be forged. The table below details some of the recent partnerships and M&A amongst CROs.

Strategic Partnerships		Year
Quintiles	Biocore	2013
PRA International	WuXi AppTec	2013
Cliantha Research Partners	Acceliant	2013
Quintiles	Prodia	2011
WuXi AppTec	BMS	2011
ICON	Tigermed	2010

Merger & Acquisitions		Year
BioClinica	CoreLab Partners	2013
ICON	BeijingWits	2012
INC Research	Trident Clinical Research	2011
InVentiv	Pharmanet	2011

Exhibit 4. Recent M&A and strategic alliances forged in CRO industry.

Dynamic CRO Landscape in Asia

In Asia, the CRO landscape varies between countries and these markets can be broadly segmented. Assessing the capabilities and opportunities within the region may be important for pharmaceutical companies when deciding to outsource or offshore clinical services.

Mature markets

Developed countries such as Australia and Singapore, have an effective regulatory system and well-equipped infrastructure. These markets represent an attractive clinical research environment for pharmaceutical sponsors, especially for conducting complex trials that require greater capabilities and skilled work force. Healthy growth is still expected even in mature markets like Australia, driven by the globalization of clinical trials and the continual shift of clinical research activities from the West to the East.

Emerging markets

Emerging markets serve as cost-effective alternatives for outsourcing and offshoring work with low labour and operation costs. China and India, for example, offer highly competitive cost of services, and it is estimated that the cost of conducting clinical trials in China is 30-50% lower than developed Western countries. Growth in China and India is projected to be approximately 20% and 13% respectively, as regulatory procedures are streamlined and as infrastructure continues to improve. Emerging markets can be seen as feasible entrance option with significant savings in drug development cost, possibly an increasingly preferred choice of destination for outsourcing services.

Fragmented markets

China is a relatively fragmented market. The top few international CROs such as Quintiles and Covance, and the largest domestic player, Tigermed, each occupy 5-10% of the outsourced market, along with more than 100 other small, medium-sized domestic players also providing clinical trial services. A fragmented market like China poses the opportunity for positioning and gaining foothold in the market leader position in the CRO space.

India in Focus: A promising outlook for the CRO industry

India's future growth potential in the clinical research space has been a much debated topic, though the appeal of India as an off-shoring destination is undeniable.

India's CRO industry encompasses inherent opportunities

India's large patient population, diverse pool of medical conditions including communicable and lifestyle diseases and the rising disease burden, set the stage for the ease of conducting clinical trials in India. Cost advantage, coupled with the availability of medical and technical expertise and talents, also contribute to the opportunity for a growing CRO industry. India's unique position with its developed IT expertise and capabilities enhances its value proposition as an ideal off-shore destination for clinical IT services like data management. With a healthy clinical research environment, the potential of India being a clinical research hub in the APAC region should be promising.

Regulatory concerns is a main barrier to the growth of clinical research industry in India

The obstacle hindering the progress of the CRO industry in India, however, has always been the regulatory issues that have also placed India in the limelight in recent times. The lack of transparency in clinical trial processes and unethical issues resulting in trial-related deaths, are some of the issues facing the clinical research space in India. This inevitably raises concern in terms of data integrity and data quality when selecting India as an off-shore destination, which ultimately slows down clinical activity, affecting existing businesses.

India's commitment to change represents opportunities and challenges

Reforms in the Indian regulations have been on-going since 2005, and have led to a continuously evolving regulatory landscape. In recent times, there seems to be a firmer commitment and affirmation by the Indian regulators to resolve the issues that have since plagued the clinical research space. Mandatory trial registration of clinical trials and inspection of trials sites were implemented, though still with limitations in curbing the ethical irregularities, due to inadequacy of the drug regulators in India. Stricter laws and punishments were also laid down to hold investigators and sponsors responsible for trial subjects.

In February this year, the regulators have made reforms to tighten control over integrity of trials conducted in India, placing liability on sponsors to compensate for injuries or deaths that occur in the process of a clinical trial, and the authorization of local licensing authority and the Central Drugs Standard Control Organization (CDSCO) to conduct

inspections on clinical trials sites. This regulatory hurdle, a supposed positive change to protect the well-being of citizens in India, has however caused a plummet in the clinical trial volumes, as number of drugs approved drastically decreased. Pharmaceuticals are also less likely to apply for trials in India with the increasingly stringent regulations. This is expected to be temporary, as regulatory procedures are still being streamlined. Confidence in India's clinical trial market will be elevated as a more robust regulatory landscape is implemented.

Recent decision from the Indian Supreme Court to deny a patent for Novartis medicine Glivec, an anticancer drug that has patents granted in nearly 40 countries has also raised a debate on the future of clinical research innovation in India. India's Supreme Court dismisses the patent on the issue that only minor alterations were made to the formulation of the drug, a term known as "evergreening" in the industry. The failure to recognize the importance of patent protection might be seen as a drawback for other innovative investment in India, a hit on the R&D industry. The flip-side, though may not be as obviously verbalized, is that the Indian Supreme Court has shown insights and judgement in tightening the control of patent protection, not frivolously approving patents. This shows the seriousness of the government to tighten laws and rules, much advocated by humanitarian organizations that recognize the effort in law designed to prevent "evergreening", where millions of impoverished patients in developing countries depending on affordable medicines will be impacted. India, though applauded for their efforts, should at the same time thread cautiously to prevent an overly hostile environment for pharmaceutical companies.

Outlook of India's future

With a favorable clinical environment, and the government's commitment to create a more conducive clinical research and regulatory environment in line with global standards, India looks to be a promising market especially in the technical IT services. The government also focuses on building the innovative capacity of the country by initiating a multi-billion dollar public-private partnership model. In the present situation, India's clinical landscape may seem to be facing challenges, but a recent global study still finds India 3rd in ranking among all countries in terms of overall attractiveness as a clinical trial destination. India does have the capacity and potential to thrive amidst the challenges.

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About Clearstate

Clearstate (www.clearstate.com), a business of the Economist Intelligence Unit, is a highly specialized healthcare research consulting firm that offers in-market insights and business intelligence complimented by strategic advisory to help clients to implement pragmatic and innovative growth strategies to tap into opportunities in the emerging economies.

Clearstate's expertise extends across key healthcare and life sciences domain namely pharmaceuticals, medical devices, hospital services and applied sciences.
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Strategic Advisory Services

Whether it is a market entry country scan, competitor benchmarking, channel optimization or customer insight problem, we can tailor a solution that is driven by primary research and credibly synthesized through healthcare centric analysis frameworks.

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