



SIRO Clinpharm

# Asia—A New Frontier for Clinical Research and Development



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## Executive Summary

As the pharmaceutical market experiences rapid growth in Asia, more clinical trials are being conducted in the region, offering new opportunities for the biopharma. Offshore clinical trial development offers several advantages to both U.S. and European firms—larger patient populations than the West resulting in faster recruitment rates, regional expertise, overcoming local regulatory hurdles, meeting global regulatory requirements etc. Studies conducted in Asia have also been shown to be more cost-effective, particularly in the area of patient enrollment.

For companies interested in expanding clinical trial development activities into Asia, several key points should be considered such as each target country's demographics. Key considerations will include new and different population segments, disease patterns, literacy rates, and mortality rates—which can impact a study in several ways. In addition, health care staff to patient ratios, insurance practices, and health care practices to treat common diseases will vary between countries.

Regulations also differ and approvals may take longer, depending upon the country. Firms interested in conducting Asian clinical trials must make sure that the requisite infrastructure and technology is in place for consistent, high quality results that coincide with U.S. or European operations. Experienced investigators, skilled study teams, and qualified clinical research professionals exist throughout Asia, delivering the same quality of experience as more developed markets. Although cultural differences can impact study results if not mitigated up front, biopharma companies interested in conducting trials in Asia must ensure that native staff are aware and knowledgeable about a patient population's cultures and customs to ensure successful trial outcomes.

## Introduction

As clinical research and development expands internationally, several up-and-coming pharmaceutical markets are ripe for expansion. One of the greatest opportunities lies in Asia. An article on 2010 market trends, predicts that the Asia-Pacific region will emerge as the fastest growing global pharma market in years to come, creating a paradigm shift from the industry's long emphasis on marketing drugs to Western patients only. As populations increase and more Asian customers can afford to buy Western medicines, more pharmaceutical firms are exploring this new market. For example, the Chinese drug market is growing by 25 percent per year, compared to U.S. and European markets which grow only about two to five percent per year.<sup>1</sup>



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Increased research and development in the region has helped the Asia-Pacific pharmaceutical industry to achieve an estimated market size of U.S.\$187 billion in 2009 and the pharma industry and market are expected to grow at a CAGR of 12.6 percent during 2010-2012.<sup>2</sup> In addition to being one of the fastest growing regions for pharmaceutical sales, more and more clinical trials have been conducted in India, China, South Korea, Malaysia, Taiwan and the Philippines in the past five to ten years. Underscoring this trend, Asia contributed 9.7 percent of all industry-sponsored study sites in 2011—up from only 5.9 percent in 2005/2007.<sup>3</sup>

Offshore clinical trial development in Asia offers several advantages. By 2050, Asia is expected to account for 60 percent of the world's population.<sup>4</sup> The region's huge population offers tremendous opportunities for recruiting patients—both from the perspective of faster recruitment and expanding research of new tropical and lifestyle diseases. By collecting data from such a large population and from different diseases that occur more frequently in Asia, biopharma can develop a deeper regional knowledge base. Conducting studies is also generally more cost-effective in Asia, compared to Western countries.

For example, cost of conducting clinical research in Asian countries like India, China, Indonesia, Malaysia, Philippines and Thailand is 2/3 lower than the west.<sup>5</sup> This is largely due to cost efficiencies in patient enrollment, which can be accomplished more quickly than other developed markets. Despite the reduced costs, however, Asia offers the same quality of research and development as clinical trials conducted in the U.S. and in Europe. This white paper offers several key considerations for global pharma companies interested in Asia as a new frontier for clinical trial development.

## **Key Considerations for Conducting Clinical Trials in Asia**

### **Demographics**

Demographics play a key role when expanding clinical research and development efforts into Asia. Pharmaceutical companies must consider new and different population segments, disease patterns, literacy rates and treatment mortality rates—which can impact a study in different ways. In addition, the health care staff to patient ratio, insurance policies and available health care practices to treat common diseases all vary between countries and must be accounted for.

Asia offers a large population of accessible patient participants, which is attracting large, Western pharma firms. Many of these patients in developing countries in Asia have lesser healthcare options so they are more keen to participate in new treatment studies. For example, last year Pfizer began work at a research facility in Shanghai on an anti-inflammatory compound to treat liver disease, following a hepatitis B infection—a condition more prevalent in Asia than in the U.S.<sup>6</sup>



Also, since 2008, Johnson & Johnson has partnered with Tianjin Medical University in Beijing to improve the treatment of head, neck, and other cancers prevalent in Asia.<sup>7</sup> In cases like these; clinical trials must be modified from a design, implementation and endpoint perspective to match each country or region's demographics. For example, in the Johnson & Johnson study, clinical trial materials needed to be localized into Chinese and researchers undoubtedly had to understand Chinese health insurance practices.

### **Regulatory Scenario**

Institutional reviews and government regulations governing clinical trials vary and most countries create their own guidelines, which pharmaceutical companies and clinical research organizations (CROs) must adhere to. Regulatory timeframes also differ according to region. For example, approvals typically take longer in China compared to India or Singapore. The regulations process in Asia is growing more streamlined and U.S. and European countries are beginning to take notice as faster approvals generally translate to improved speed to market.

### **Infrastructure and Health Care Quality**

Infrastructure and health care quality are important considerations when conducting clinical trials. Modern health care facilities exist in Asia that offer the same technology, operational expertise, infrastructure and standards as Western hospitals. Although considered an emerging market, Asian CROs employ skilled investigators with knowledge gained from performing clinical trials in other global locations. In this way, drug manufacturers interested in conducting clinical trials in Asia can rest assured that drugs will be tested according to the highest standards.

To ensure quality, global clinical trials require that the same equipment be located in all trial locations. So, for example, if a pharma company wants to expand a tumor study to incorporate Asian populations, investigators would need to verify that the same MRI scanning equipment, skilled technicians, and qualified radiologists found at the U.S. and European trial sites would also be available in Asian facilities. Asian hospitals provide the modern equipment, technologies and staff needed to diagnose and treat diseases. In addition, high quality clinical laboratories exist for safety assessments and other health care practices.

### **Clinical Research Talent Pool**

To ensure success, Asian countries rely on a large pool of talented research and clinical development professionals to conduct drug trials. Talented investigators with similar education and qualifications as U.S. and European physicians are currently managing clinical trials in Asia. India, for



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example, features an excellent tertiary education system and produces about 115,000 scientists with Master's degrees and 12,000 with PhDs every year.<sup>8</sup> In addition to experienced investigators, pharma companies also require qualified clinical research professionals. Research staff in many countries in Asia such as study nurses to administer medications or record blood pressures and study monitors are well-educated and speak English fluently—an advantage for global studies. Asia also features many well-qualified study coordinators to document studies, deliver reports and conduct patient follow-ups and individual assessments.

## **Cultural Differences**

Differences between Eastern and Western cultures can dramatically impact study results and must be accounted for up front to ensure success. Approximately 62 percent of the world's Muslims live in Asia<sup>9</sup>, so sensitivity to Muslim traditions is a prerequisite for conducting studies in this region. For example, some drugs are formulated in capsules made from a gelatin containing pork products which Muslims will not consume. Also, study teams need to be aware of Asian holidays and customs. For example, Ramadan's fasting requirement can impact study results because some medications need to be taken one hour after food is ingested.

## **Conclusion**

Asia offers several unique advantages for clinical trial research and development due to the growing pharma market and large population. Global firms interested in exploring this new market can enhance drug discovery, reduce time to market and cut costs especially if they choose to partner with CROs that possess experience in the region. In this way drug companies can conduct studies in Asia that will streamline the clinical trial process and bring new drugs to market faster and more cost-effectively.

## **About SIRO Clinpharm**

SIRO Clinpharm is among one of the leading global Clinical Research Organizations (CROs), offering a full scope of services, conducting clinical trials in the pharma, biotechnology and medical devices sectors in compliance with international standards. The company has offices in the U.S., Israel and in Asia at India and Malaysia. European offices include Germany, the Czech Republic, Greece, Estonia, Romania, Spain, and France.



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**Dr. Ajit Nair**

**President, SIRO Asia**

Dr. Ajit Nair is the President for SIRO Clinpharm's Asia Business. He provides leadership, vision and direction to the growth of SIRO's operations in Asia and is focused on creating an efficient and responsive organization to service the growing client pool at SIRO. He also supports the Chief Executive Officer in strategic issues concerning integration across various operational geographies and global delivery mechanisms.



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Rajendra Talele is Vice President – Clinical Operations Asia and is responsible for overseeing the execution and operational excellence of Clinical Research, including Clinical Project Management, Clinical Monitoring and Clinical Documentation departments.

He has over 16 years of experiences serving Pharmaceutical and CROs based out of India.