

## **Clinical Trials in Asia Pacific Region : An Introduction**

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### **Abstract:**

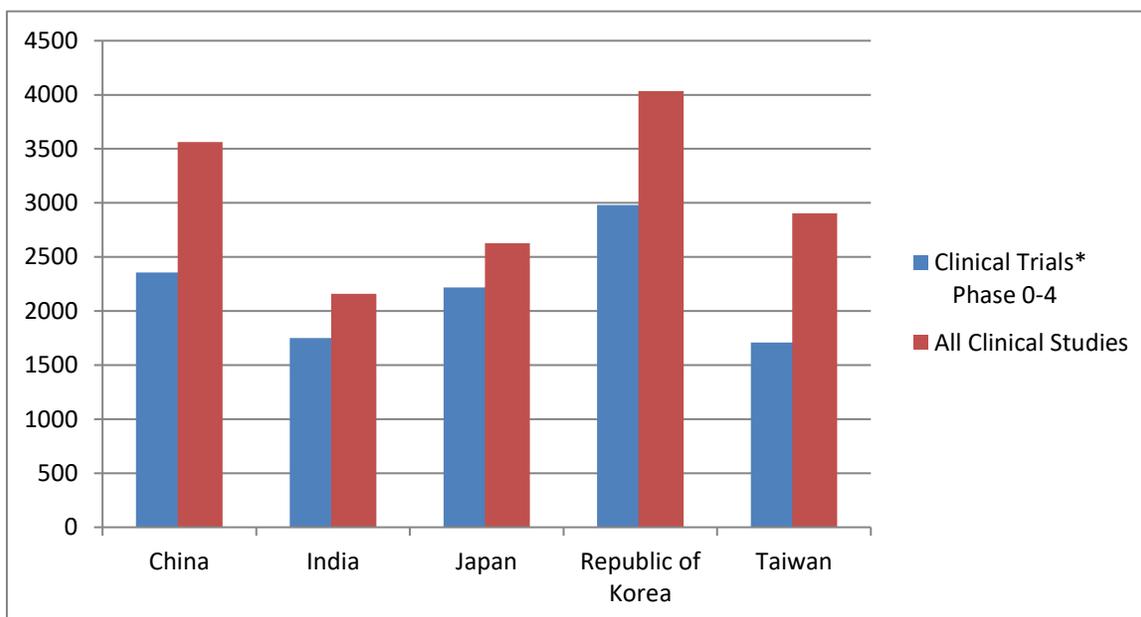
The historical approach to conduct clinical trials and have served drug companies well for the past thirty years are typically located in US, UK Canada and Western European countries

The shrinking pools of treatment populations and increasingly intense competitive environment in the traditional North American and Western European markets have led sponsors to approach APAC Region to conduct cost effective quality research and secure timely enrollment of patients. This article focusses on five the most dynamic countries in APAC region.

### **Introduction:**

As compared to Europe and North America, In these countries CRO's are less cheaper, a large pool of eligible participants, genetically diverse population, low cost per patients and various range of disease pattern and many of the patients are never treated for their medical condition, makes APAC region very attractive for sponsors. Countries like China, India, Japan, Korea, Taiwan are have become most prominent location for conducting clinical trial, especially Phase 3.

We have analyzed the clinical studies registered in the ClinicalTrials.gov from 2001-16 by Asian\* and WHO South East Asia Region Countries\*\*, and found that Asian countries had the global share of 18.2% of the clinical trials and WHO SEAR countries had only 3.6%, which is 3 and 13 times lower, respectively, than those registered by the USA (Figure 1)

**Figure 1.**

5 Leading Countries in APAC Region 2001 -2016	Clinical Trials* Phase 0-4	All Clinical Studies
China	2356	3562
India	1751	2160
Japan	2217	2626
Republic of Korea	2980	4033
Taiwan	1708	2903

According to [clinicaltrials.gov](http://clinicaltrials.gov), the number of studies conducted in Asia is increasing in comparison to other regions. A report from Research and Markets found that emerging countries will likely account for 25% of the global clinical trial market for drug development by 2020, up from 16% today. This is mainly due to some sponsors saving up to 50% on clinical trial costs in Asia. Additionally, Asian pharmaceutical sales have more than doubled from US\$97 billion in 2001 to US\$214 billion in 2010, and it is expected to hit US\$386 billion in 2016, according to the Economist Intelligence Unit in 2012.

The major reason to conduct clinical trial overseas is cost. As developing a single drug can cost more than \$200 million and take at least 10 years, Asia offers a less expensive, less time-consuming process for clinical trials.

Country	Pharmaceutical Market Size
China	\$20 billion
Japan	\$60 billion
Korea	\$6.5 billion
Taiwan	\$2.5 billion
India	\$6 billion

Aside from differences in cost, one should look at other attributes such as each country's regulatory and healthcare environment. Ease of regulatory approval can vary significantly depending on each government's regulations and laws on drugs and clinical research. Some countries may be able to provide large numbers of patients that suffer from a particular disease or illness, while other countries may not have such patient populations. Sometimes you may be willing to do the trials in a foreign language, while in other cases, English is required.

Despite the economic, demographic and epidemiologic advantages offered by Asia, biopharmaceutical companies continue to experience challenges that do not allow them to use the region to its full potential.

Despite all of the advantages of conducting clinical trials in these countries, there are also concerns and potential pitfalls that should be addressed. One concern is the lax enforcement of intellectual property laws or complete lack of intellectual property laws at all. For example, it may be difficult for a foreign pharmaceutical company doing trials in China to ensure that the formula for its new drug will be kept strictly confidential when utilized by a Chinese CRO. Confidentiality agreements, which in theory are binding in the West, may not be so "confidential" in Asia. In addition, enforcement of intellectual property is not uniform throughout the Asian region.

Measures have been taken to address such concerns. Now, with the World Trade Organization's agreement on Trade Related Aspects of Intellectual Property Rights, member countries are required to establish minimum standards concerning the scope and use of IP rights and the procedures for enforcing them. Contract research organizations (CROs) in Asia are also

enforcing stricter IP procedures. At WuXi PharmaTech in Shanghai, China, workers who fail to follow IP protection procedures are fired after two warnings. Of course, by then it may be too late.

Another concern of sponsor companies conducting clinical trial in these APAC countries is that the research and clinical trial data will be of low quality. This is certainly a legitimate issue as in some developing countries, the quality of facilities, infrastructure, and data collection may not be as high as one might expect in a typically modern, high-tech hospital in the U.S., Europe, or Japan. However, quality is constantly improving and in places like Singapore and Hong Kong, the facilities and quality control of the trials are comparable to Western standards.

There is also concern about unethical treatment of patients in countries without specific laws protecting participants. Some countries may not get the “informed consent” of the subjects in the trial beforehand. Also, many countries support to run facilities that are compliant with the International Committee on Harmonization (ICH) standards of Good Clinical Practice (GCP), but in practice they do not do so.

## **Conclusion**

It is very productive and efficient for European and U.S Pharmaceutical sponsor companies to conduct clinical trials in Asia pacific region. As per current scenario about 26% of European and US pharmaceutical sponsor companies outsource clinical trials in Asia pacific region. Although in this region there is IP protection issues exist to some extents , European and U.S Pharmaceutical sponsor companies will continue to outsource clinical trials.

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