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Clinical Trials in the Asia-Pacific Region

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Abstract:

The Asia-Pacific (APAC) Region Currently represents some of the fastest growing market for Global Clinical Development activities. The sophisticated healthcare systems, strong and growing infrastructure for quality conduct of clinical research, accessible patient population also there are other numerous factors, such as shortage of trial volunteers in Europe and North America and the availability of highly trained medical professionals in the APAC region, also Asia provides significant opportunities for drug development and marketing makes the APAC region desirable destination for conduction of global clinical trials.

However the major challenges in APAC region such as timelines for clinical trials approval, complex and continually evolving regulatory environment, absence of meaningful regulatory harmonization especially with regards to process, requirements and timelines for conduction and approval of clinical trials. This complex regulatory framework can be barrier for other countries, especially those companies that don't have resource or experience to overcome the obstacles in countries such as China, Japan, Taiwan, Australia, Indonesia , Singapore, Hong Kong , India. In this study we are aiming to understand the clinical trial approval process in APAC Countries and also the reasons for such regulatory challenges

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Description:

China:

The population of china is more than a billion and it's a growing economic strength which holds immense potential as a location for conducting clinical trials for new drugs and for medical devices as well as for marketing of novel therapies for Global Pharmaceutical companies. However that potential is getting tempered by the crucial regulatory framework for clinical trials approvals in china which is continuously evolving and has begun to improve day by day. The biggest challenge in china is time taken for regulatory approval for conducting clinical Trials.

Japan:

Due to the adoption of International Conference on Harmonisation (ICH) "Guideline on Ethnic Factors in the Acceptability of Foreign Clinical Data" (E5), Japan's regulatory Agency (PMDA) Pharmaceutical and Medical Devices Agency which states about "Basic Concepts for International Joint Clinical Trials" have made it less complex for our countries as it have eased the strict restriction on accepting patients data from other countries. The regulatory environment in Japan is substantially improving which is the result of challenge facing by Japan from public health concerns about the "Drug Lag". Even if the biopharmaceutical products are approved in Europe and United States before it takes more than four years due to difficulty of conducting clinical trials in Japan.

Korea:

Until a few years ago it was very difficult to obtain approval to import a foreign investigatory new drug (IND) into Korea. In many of the cases it is mandatory that drug should have marking approval in the Europe and U.S before it could be submitted for IND application in Korea. However Korea have allowed other multinational companies to include Korean patients at the same stage of study as clinical trial being conducted elsewhere , which resulted into substantial improvement in the regulatory environment and Korean patients can receive novel therapies faster than in the past. This change in regulatory framework has provided new opportunities for global pharmaceutical companies looking to expand their multinational trials.

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Taiwan:

Like many other countries in APAC region Taiwan also in recent years has implemented number of changes to improve regulatory environment for clinical trials approval involving pharmaceutical companies in other countries. The Department of Health and its Center for Drug Evaluation are working closely with the FDA to share knowledge and opinions aimed at bringing Taiwan's regulations more closely in alignment with those of the U.S. and Europe which will help in improving the regulatory review process of IND and NDA also in getting clinical trial approvals faster.

India:

In India Clinical Trials are govern by the office of the DCGI's guidelines and the Indian Council of Medical Research (ICMR)'s. This year (2013), India amended Schedule Y of the Drugs and Cosmetics Act to create an environment conducive to conducting trials; however concrete laws and regulation are yet to be introduced with regards to time taken for clinical trial approvals. In India it is mandatory to conduct clinical trials for foreign pharmaceutical companies to launch drug, which is the potential concern for Multinational companies due to the continuously evolving regulatory guidelines and complex regulatory framework involved in the international launch of drugs. Thus there is a need of strong and precise regulatory guidelines in India. Otherwise, countries with strict regulations and supervision on adherence are likely to have an edge over the country.

According to few of the regulatory guidelines, there is a requirement for an ethical approval prior to procure the approval from health authority and vise-a-versa. This disturbs the flow of the approval and also delays the process for the initiation of the clinical trial.

The Asia-Pacific region is one of the most rapidly growing and vibrant region in the world. Within next five years China expected to become the fifth largest global pharmaceutical marketplace. Since the beginning of current century the Asia-Pacific region has shown steady improvement with significant changes over the last five years. These changes have brought greater transparency and professionalism to the regulatory arena, and increased the opportunities for the pharmaceutical industry to conduct clinical trials and introduce novel therapies. In fact, health officials in the region have made it clear that they want to play a greater role in the global

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drug development process and offer their citizens the latest therapies at the same time they are available in Europe and North America.

However, major regulatory challenges remain for pharmaceutical companies looking to expand their clinical trial programs into this region. Equally important, the challenges are different for each country. The Asia-Pacific region cannot be treated as a single market, but must be approached with an abundance of local knowledge. Success is contingent upon understanding the regulatory – as well as medical and social – nuances that characterize each country.

With the right combination of local knowledge, perseverance, and flexibility, sponsors can overcome most of the challenges and take advantage of the opportunities to expand their clinical development programs in this dynamic part of the world.

Conclusion:

There is a requirement of strong regulatory guidelines and the favorable regulatory environment for each country in Asia-Pacific Region to conduct clinical trials at the same time it should also involve the interest, safety and well-being of subjects participating in clinical trials. Instead of delaying the approval process or dismissing the trials, the implementation of the existing rules and regulation of and the identifying and fixing the loopholes in regulatory framework is highly required in Asia-Pacific Region. The Laws should be there not for “restricting” but for “regulating” the clinical trials in effective manner.

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