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Conduct of Clinical Trials: Asia Pacific Region Versus Global

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Abstract:

Conducting clinical trials , this process is time-consuming and complicated, which required substantial investment. Pharmaceutical and biotechnology companies and in the Europe and United States (US) face escalating clinical trial challenges and cost in both retaining and recruiting patients. Additionally, sponsor pharmaceutical companies have to face complex regulation and continuously evolving regulatory processes. Due to these complication and, US and European biotechnology and pharmaceutical companies outsource their clinical studies to Asia pacific region. This article draw a special attention to the research on increasing trend in conducting clinical trials in Asia pacific region and worldwide.

Introduction:

An “Asian study” was defined as a clinical trial conducted in Asia (Japan, South Korea, China, Taiwan, Hong Kong, Indonesia, Malaysia, Philippines, Singapore, Thailand, and India). A “worldwide study” was defined as a clinical trial conducted globally across multiple regions including countries other than Asia. The clinical trials process is complicated and time-consuming, requiring substantial investment. Biotechnology and pharmaceutical companies in the United States (US) and Europe face escalating clinical trial costs and challenges in both recruiting and retaining patients. Additionally, companies have to navigate through complex regulatory processes.

To overcome, these challenges, US and European biotechnology and pharmaceutical companies outsource their clinical studies to contract research organizations (CROs). Clinical trials are becoming increasingly globalized to reduce costs, to shorten development timelines and to expand markets in developing countries. An increasing number of drugs submitted to the European regulatory authority, the European Medicines Agency (EMA), were developed using trials

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performed outside of the EU. A reflection paper was recently published to help extrapolate the results of clinical studies conducted outside the EU to the EU population.Furthermore, Khin et al.6 described regulatory and scientific issues regarding the use of foreign data in support of new drug applications (NDAs) to the US Food and Drug Administration (FDA).
Since ICH-E5, Asian clinical development strategies have been incorporated into global strategies due to the growing size of the Asian market. Non-Asian clinical data is increasingly being used for Asian NDAs

Asia is well positioned to become a preferred destination for clinical trials, due to a number of attractive traits.

Availability of treatment-naive patients for speedy recruitment: A pool of approximately 4.0 billion people, with more than 2.0 billion in easily accessible urban areas.

Worldwide accepted data quality: The percentage of EMA critical findings and US FDA official actions taken during inspections are lower in Asia than North America, reflecting high quality of international compliance.

Attractiveness of trials to patients: Per capita government spending on healthcare in Asian countries is lower than in the US and Western Europe. This creates opportunity for clinical trials to be an effective way for Asian patients to get access to innovative therapies.

Western disease patterns: Asian countries show similar disease patterns for major diseases to Western nations, providing a comparable environment to conduct clinical trials. Some pockets of high incidence may provide advantages in certain therapeutic areas.

The pharmaceutical environment in Asia has changed dramatically in the last decade. Recent revisions to the industry's regulatory laws, as well as improved patent laws in countries such as Japan, China, and India, have led to the burgeoning of the clinical trial market in Asia. The global pharmaceutical market has grown by 7% to US$600 billion, while sales in Asia have grown by about 9% to 10%. Indeed, an annual growth rate of up to 12% is on the Asian horizon for the next

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five years. Correspondingly, a 20% growth in the clinical trial market can also be expected. Therefore, there is an increased need for businesses involved in clinical trials to take heed of the rapidly changing environment in order to capitalize on its growth.

The intense pressure on pharmaceutical product pricing and regulations in the United States, the failure of the blockbuster model, and the introduction of new product types (such as biologics, regenerative medicines, and orphan drugs) are driving innovations in the biopharmaceutical industry. Challenges related to rapidly recruiting the right patients; working with the mostpursued investigators; and navigating federal, state, and institutional policies are putting immense pressure on small and midsize biopharma companies in the United States and Europe to look for better and faster ways to commercialize their products. Ongoing US healthcare reforms under the Trump administration are sending waves of uncertainty around the world. In an attempt to accelerate the path to market, the industry is seeing a shift to Asian countries for their clinical trials

Conclusion

Governments in APAC are embracing these opportunities and are offering incentives and infrastructure to attract companies to undertake R&D, leading to an increase in the number of pharmaceutical R&D centers in Asia Pacific. As more companies begin to concentrate in China, Japan, India, and Singapore, we will likely see a more balanced industry rather than a US/EU-dominated one. Asia Pacific continues to be an important region for the conduct of clinical trials. With multiple initiatives underway at both local and regional levels aimed at improving the conduct of studies, it is expected that this trend will continue.

The Asian market for clinical trials presents numerous comparative advantages to industry players vis-à-vis the US and Europe, where the market is very well developed and efficient, but still encounters a litany of challenges. One such key challenge for clinical trials in Europe and the US is the increasing difficulty in recruiting patients to participate in clinical trials. In contrast, where the market in Asia is only just emerging, the large populations of Asian countries like India and China facilitate patient recruitment for clinical trials, while simultaneously offering the advantage of genetic diversity. The number of well-trained researchers willing to be involved in global clinical trials is also an added bonus. Another benefit pertaining to Asia is the lower cost of conducting clinical trials in the region compared to Europe or the US. In fact, low cost is a key determinant for companies choosing to carry out their clinical trials in Asian countries. The cost

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of conducting a clinical trial in Korea, for instance, is approximately two thirds that in the US. In addition, many major global players who recognized the potential of Asia early already have a presence in Asia. This drives the extent to which global standards of conducting clinical trials are met and maintained in the region.

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