Clinical Trials in Asia Pacific

MANAGING CLINICAL TRIALS IN ASIA

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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 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.

Asia vs. Europe & USA

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 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.
Challenges on the Road Ahead

Even as the pharmaceutical and clinical trial market continues to expand, the Asian market is not devoid of challenges. While some countries in the region are already showing promising signs with respect to regulatory changes, it will take some time before they keep pace with the industry's global standards of, for example, good laboratory practices. There is also a need to look into providing the necessary support for the creation of a larger pool of local, well-trained researchers and technologists in order to cope with the industry's rapid growth and to ensure that this growth is sustained in the long term.

When test samples are transported overseas via air freight, their movement is subject to regulation by the International Air Transport Association (IATA), which has stringent requirements for packaging, documentation, and regulatory declarations. Yet, many medical doctors in the region, who are getting involved in clinical trials for the first time, may not be trained or certified by IATA. Inadequate knowledge, which leads to inaccurate labeling or packaging, can result in customs delays for days and thus render the test samples invalid.

Specialist Expertise Is the Answer

Besides strict adherence to regulations and the right skill sets, the full execution of a successful clinical trial is dependent on one essential component: logistics. The complexities of managing clinical trial logistics in Asia have spawned the entry of global, full-service logistics providers, such as TNT, into the pharmaceutical logistics industry.

In clinical trials, diagnostic specimens such as blood samples are both time- and temperature-sensitive. To maintain the accuracy of the test results from such patient specimens, they need to be kept within specific temperature ranges and tested within 72 hours of collection. The typical temperature ranges required for such samples include ambient (room temperature), refrigerated (2°C–80°C), and frozen (below –20°C) temperatures. As the lack of a homogeneous and well-connected transportation network in Asia to facilitate the movement of samples to remote places remains a challenge, many pharmaceutical companies and central laboratories have turned to specialist logistics providers to help ensure the integrity of test kits and samples throughout the clinical trial process.

To this end, TNT offers an immediate, integrated, and reliable solution that meets the needs of the clinical trial business and that enables pharmaceutical companies to focus on their core competencies. As one such viable solution, TNT launched “Clinical Express” — a suite of expert services for the clinical trial logistics market — in April 2004. Targeted at pharmaceutical companies, central laboratories, and contract research organizations engaged in clinical research and drug development, Clinical Express offers two distinct levels of services: “Clinical Express Exclusive,” the global door-to-door service for diagnostic specimens under frozen conditions; and “Clinical Express Network” for ambient diagnostic specimens. In 2004, TNT also set up its Life Sciences Excellence Center (LSEC) in Singapore to provide expertise in handling specialized and time-critical goods primarily for clinical research. TNT’s LSEC serves as a regional coordination and knowledge management center, functioning as a resource hub in the biomedical sector for the region.
At TNT, not only are the needs of clinical trial logistics recognized, but the company is also well positioned to meet the growth and challenges presented by the sector through its innovative solutions and the ability to sustain and develop the services it provides. Apart from providing customers with a full suite of customized services, TNT also seeks to ensure that its dedicated team constantly upgrades its skill sets and is always kept up to date with the most current knowledge of health, safety, and customs regulations.

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