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China: Emerging drug discovery destination

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China's growing economic strength and population of 1.3 billion people holds tremendous potential for global pharma and biotech companies as a location for clinical trials, as well as a market for novel therapies. With low costs of labor and infrastructure and cost per patient, it is also the second largest CRO market and a hotbed of mergers and acquisitions, deals and partnerships, many of which are between multinationals and local CROs. Recent pharmaceutical mergers and acquisitions in the market by foreign companies have also increased the number of pharmaceutical manufacturers in China. With growing R&D capabilities and resources and increasing number of sites for clinical trials, it has attracted many. However, along with this tremendous potential, there are a number of important challenges that should be considered.

One of the major challenges is the time it takes to receive regulatory approval for a clinical trial. On an average, it currently takes nine-to-ten months and another one-to-two months for ethics approval. In Hong Kong, the review process takes around two months and a parallel IRB/regulatory application can also be made. Despite this lengthy regulatory approval, attempts are being made by the Chinese government to streamline its regulations and align the country with international standards of practice but this aspect will remain a constraining factor for many sponsors for some time.

The growing importance of centralized laboratories for patient sample analysis will present as another challenge for sponsors of clinical trials as the export of whole blood and tissue samples requires that a sponsor must apply for an export permit for each shipment a process that can take weeks. Although these restrictions have been eased in recent months, the process still remains difficult. This burdensome export process poses a substantial but not insurmountable drawback for clinical trial programs, but could be overcome if sponsors are prepared to work with established, accredited central laboratories based in China.

China has an international reputation for patent and intellectual property rights violations across all industries. Counterfeiting of almost every product is still a major problem, despite attempts by the Chinese government to tackle the problem. A not

uncommon scenario is that an overseas company could find that it is competing for sites and patients with one or more local Chinese companies who are developing a generic version of the overseas company? own patent-protected drug! Therefore, the importance of taking out as much local patent protection as possible before embarking on trials in China cannot be stressed enough.

Etiquette is vitally important in China. Therefore, for small companies without resources in China, it is important to work with an organization that is based in China and understands both ICH GCP and China SFDA GCP requirements is very important for ensuring clinical trial integrity and success. 'Guanxiis the concept of contacts and networks and as such it is considered to be very important to establish close contacts with people in government or quasi-government bodies.

In China, most people are not fluent nor proficient in English. Currently, all documentation must be submitted in Mandarin Chinese, the official language of China (850 million speakers). Other main languages spoken in China include Wu (90 million speakers), Min (70 million speakers), and Cantonese (70 million speakers). The extent and complexity of these secondary languages are important factors for getting accurate results from clinical trials. Medical practices such as acupuncture and herbal medicine, as well as cultural differences that affect medical practice are also paramount factors in China.

With rapid growth in the research arena there is currently a shortage of qualified staff and the number of trained staff to conduct the increasing number of trials compared to the amount of work coming to China is increasing. This aspect is probably going to be the biggest challenge in coming years and more efforts and better ways of training people involved in clinical trials in China is urgently required.

China offers tremendous opportunities such as low cost, increase in potential revenue and the availability of large pool of patients, many of which are treatment nave, but the hurdles for conducting research in China are more daunting, but the benefits can be large. Even smaller companies with very limited resources can benefit from conducting their trials in China provided it is borne in mind that strategies and regulatory procedures employed in other countries will not always work when doing business in China. There are also significant challenges within the Chinese pharmaceutical market, including hospital sector problems, procurement policies and intellectual property infringement. Any company looking to conduct clinical research in China is strongly advised to work with an established partner or a contract research organization that has knowledge of the local regulations, testing facilities, etiquette and culture. This will not only smooth things and help absorb some of the frustrations, but will also make research work in China more interesting and rewarding.

The author Mr James Thorburn, director, Clinical Trial Concepts Limited, Hong Kong, has experience in both early and late stage pharmaceutical studies. He has worked on clinical trials in Europe, the UK and Hong Kong, where he managed all aspects of clinical research. He was responsible for the recruitment and training of investigators, preparation of ethics committee submissions, writing study protocols, designing case report forms and informed consent documentation, study monitoring, and training of in-house clinical research associates.