editorial

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Clinical research in China and India: a paradigm shift in drug development

The global business consulting firm Bain and Co. has estimated the cost of developing new drugs to be as high as US$1.7 billion, and they have attributed these rising costs largely to an increasing failure rate for prospective drugs in clinical trials. However, researchers from the Tufts Center for the Study of Drug Development published a more widely accepted estimate of US$800 million for drug development in 2003. From this sum, US$467 million – ~60% of the cost – is associated with clinical trials, and this rate is about four times higher than those estimated during previous surveys.

As western pharmaceutical companies feel pressure to produce innovative, well-differentiated drugs at reduced costs, there has been an increasing trend toward focusing on speeding up the clinical study process. The drive to speed up clinical studies in the USA and the European Union, in conjunction with fierce competition over decreasing numbers of patients, has prompted western companies to look to the East for solutions. Estimates predict that nearly 30% of clinical trials will be conducted in developing countries in the near future. This has resulted in increased investment in conducting clinical trials in non-ICH (International Committee on Harmonisation) regions of the world such as Central and Eastern Europe (CEE) and Asia, including India and China. In these developing nations, pharmaceutical companies have the added benefit of launching clinical trials more rapidly and with less financial investment than is the case in the USA.

India and China, strikingly similar yet also vastly different, together account for ~40% of the world's population. It is no coincidence then that, over the past decade of economic liberalization and years of unprecedented growth, these countries, which have been considered as difficult markets to enter, have taken significant strides forward as emerging markets in drug development, becoming a preferred clinical research destination for multinational pharmaceutical corporations.

Rapidly growing pharmaceutical markets and buying power, coupled with the current pharmaceutical annual growth rate of 10–15%, provide further incentive. Recognizing the economic potential has inspired strong government support across the drug development spectrum, with a focus on clinical trials. Currently, the value of clinical trials conducted both in India and China is estimated to be ~US$100 million, from the US$7.8 billion total worldwide, but the target value is US$1 billion each (>20% of worldwide market share) by 2010. In addition, both of these countries have diversity and prevalence of disease; and many of the patients are treatment naïve, in other words they have not received any treatment medications – a fact that simplifies patient recruitment and the interpretation of results. Other positives are a strong hospital infrastructure and a highly trained and educated medical resource pool.

Despite all the advantages, however, both India and China face their share of challenges. Both countries have a good medical education system in place to produce physicians, but very few of them are actually trained to be clinical investigators. Strides are

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being made to adhere strictly to good clinical practice (GCP) ICH guidelines, because clinical research is an emerging field in India and China. Certainly, the various contract research organizations (CROs) and companies conducting clinical research in India and China are cognizant of the expectations of the sophisticated regulatory agencies, and the need for high-quality clinical data that are in accordance with ICH guidelines.

Furthermore and historically, the Indian and Chinese regulatory agencies have been focused on chemistry and manufacturing in their clinical trial review and approval processes; and only recently have they become equipped to review and approve the clinical trial applications (CSAs). However, forming the right infrastructure for regulatory agencies to monitor clinical research activities successfully has proved to be a challenge. Although there has been substantial activity at the government level, and an alliance has been formed with the WHO Collaborating Center for International Drug Monitoring, the areas of pharmacovigilance and adverse event monitoring could still be improved in both countries.

Finally, according to a new study published in November 2005 by Ernst and Young (http://www.ey.com/global/download.nsf/US/China_and_India_-_Risk_and_Returns/$file/NM_Pharma_Report_Asia_Blockbuster_Markets.pdf), pharmaceutical companies are unable to take advantage of the opportunities posed by India and China because of concerns over a lack of intellectual property (IP) rights protection. As a result, the multinational pharmaceutical companies are not investing in China and India at the same pace as other industries. In this study >70% of pharmaceutical executives said that threats to IP pose a significant business risk in China, and 62% said the same thing about India. With the recent signing of the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, both China and India have agreed to adhere to minimum international standards of IP protection, but significant challenges remain in the implementation and enforcement of this.

By all accounts, it appears that most of the major pharmaceutical companies are already conducting clinical studies in these two countries, and there are ambitious plans of expanding such activities over the next few years. Whether these efforts will continue to grow, plateau or diminish, it is too soon to know. Still, the ultimate question remains: will clinical research be the next IT or manufacturing wonder for India and China? With billions already invested, and with positive returns being realized, the question is not if, but how much? – Only time will tell.

To address some of the complex issues associated with conducting clinical research and drug registrations in China and India, the Drug Information Association (DIA) will hold the first conference of its kind in Princeton, NJ, USA: Clinical Research and Drug Registration in China and India (September 18–19, 2006; http://www.diahome.org/product/11302/06034.pdf). Formed in 1964, the DIA is a neutral, global, volunteer-driven association of professionals involved in the lifecycle management of pharmaceuticals and medical products, committed to improving the world's health through the dissemination of information and scientific interchange. The conference aims to provide a detailed analysis of what it takes to conduct clinical trials in China and India, and it will address such topics as risk–benefit balance, anecdotal experiences of the multinational pharmaceutical industry in China and India, selection and role of CROs, logistics of operations, clinical trial management, government policies (including IP issues) and pharmacovigilance. There will also be sessions on regulatory requirements for clinical study conduct and the process of drug registrations. Speakers from various regulatory bodies [including FDA, China's State Food and Drug Administration (SFDA) and the Central Drugs Standard Control Organization (CDSCO)], industry experts with hands-on experience of conducting studies in India and China, legal experts, high-ranking government officials from India and China and other highly qualified speakers will be present at this conference.

Dr Romi Singh of Global Strategic Regulatory Development at Merck is the program chair of the DIA conference. Because the DIA is a neutral non-lobbying organization, which provides a forum for industry professionals, researchers, academics and regulators to discuss diverse perspectives and, therefore, does not advance any one position, Dr Singh wrote this editorial based on his personal and professional experience.

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