Clinical trials in Korea : Experiences with Alzheimer’s drug studies at Asan Medical Center

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Clinical trials in Korea have been on the rapid rise in the past decade. Korea used to be new to modern day clinical trials. The Korea Food and Drug Administration (KFDA), which was established in 1998, approved for the first time 5 INDs for multinational sponsors in 2000. As of 2012, the number jumped to 367. Currently, Korea is more active in conducting global clinical trials than Japan and China. The reasons for Korea’s attracting global trials are many fold: high class medical infrastructure, cost-effectiveness, high literacy, well-trained investigators, and a trial-friendly regulatory system.

Institutional Review Board (IRB) is another important factor for facilitation of clinical trials. There is no central IRB in Korea, which could cause some nuisances such as different protocol amendments and various application procedures. But IRBs are generally cooperative and their actions rarely delay the study initiation. Patients are recruited from investigator’s own pool of patients rather than referral. Korean investigators generally are good at meeting the recruitment timeline. In terms of compliance, Korea has a high compliance rate and a low drop-out rate. Korea is a small densely populated country. Entire Korea can be covered in one day. Forty percent of its population lives and around Seoul. Most major hospitals are located in Seoul and are reachable in one hour. For any clinical trials, the participation of ‘big 5 hospitals’ in Seoul will suffice. The streamlined regulatory process has substantially shortened the time to initiation of clinical trials, creating a trial-friendly environment and facilitating participation in global clinical trials. The Korea National Enterprise for Clinical Trials (KoNECT), which was established in 2007, is working actively to meet the increasing demands for clinical trials and raise national competitiveness by fostering necessary human resources and building a solid infrastructure to become a global clinical trial hub under government support. A number of challenges remain to be overcome before we further grow into a global clinical trial powerhouse. We need to switch from the current permit system over to the clinical notification system at least for less risky clinical trials. Also, we could use a central IRB for common use.

At Asan Medical Center, the largest hospital in Korea, we have conducted 12 global clinical trials for Alzheimer’s therapy in the past 5 years. Among those are insulin sensitizer, serotonin receptor agonist, rivastigmine patch, high dose donepezil, monoclonal antibodies to Abeta, and so forth. Half of them are phase I or II clinical studies. We are now a regular customer of multinational sponsors.

With the growing commercial importance of China, Korea, Taiwan and other Asian markets, this region is of central importance in the global drug development strategies. Organizing the clinical trial involving Japan, Korea, China/Taiwan would provide the great potential opportunity. When properly planned and implemented, Asian regional studies have the potential to deliver significant efficacies in terms of time and cost, and their data applications in different target countries.