Clinical Trials : Know What the KFDA Wants

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Recently, the circumstance surroundings pharmaceutical products has been greatly changed due to the international globalization : ICH regulatory harmonization, the innovation of pharmaceutical sciences, advanced technologies and different medical system. Such changes have significantly affected our regulations that resulted in a recent great revision of our pharmaceutical regulations. The major regulatory changes in Korea which are affected on the environment for clinical studies are enforcing KGCP, the adoption of the bridging concept and the separation of investigational new drug applications(INDs) from new drug applications(NDAs). Especially, IND was established to accelerate new drug development and harmonize with international standards in 2002. These changes has been affected by the global drug development strategy and made it possible to participate in multinational studies. Clinical trial is the most important step in new drug development for only through which the efficacy and safety of a new drug can be explored and confirmed.

Due to these dramatic regulatory changes, the number of multinational trial increased from 17 in year 2002 to 62 in 2004. At this point of time, we have realized we can't continue with business as usual to develop new drugs and review them. We are working on several initiatives for scientific and appropriate INDs and NDAs reviewing. There are many scientific issues embedded in new drug approval process from non-clinical studies to phase 3 clinical trials ; sample size, application of endpoint, statistical method, and etc. However the overall relationship between protocols/reports of clinical trials and the characteristics of domestic pharmaceutical conditions should be considered in drug approval process.

Now, knowing the regulations for clinical trials is just beginning. We tried to help understand the new drug development process and clinical trials by reviewing them and to investigate the condition in Korea. It is more useful to understand what the KFDA's thinking on the clinical trials is. At this time I would like to explain the essential elements in clinical trials, requirements for clinical trial approvals(CTA's) application and the key points on reviewing the protocols and reports of clinical trials on KFDA's perspectives, especially, showing some cases.