

## **Challenges for Implementation of Global Clinical Trials: Sponsor's Perspectives**

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What we provide patients suffered by diseases with new products as soon as possible is important mission for pharmaceutical companies. However, “Drug lag has been recently highlighted as serious issues. “Drug-lag” occurs when a new drug which is approved in the EU and US is not approved in Japan. One of the reasons for “Drug lag” is delay in the initiation of the development of new products in Japan. This issue could be addressed if Japan is involved to global development at an early stage and participates in global clinical trials. It was proposed that the infrastructure of clinical trials should be improved in a five-year implementation plan for clinical trial activation, issued in March 2007. A guidance “Basic principles on Global Clinical Trials” was also issued in September 2007 in order to promote participation in the global clinical trials.

I will present strategic views from Pharmaceutical Companies on global clinical trials, taking into consideration the guidance and current environment of clinical trails in Japan. I will also propose resolutions to operational issues based on the results of a questionnaire on global clinical trails to members of the Japan Pharmaceutical Manufacturers Association in October 2006. I will also outline some recent approaches to effective implementation of clinical trials.