Efforts by JPMA to Implement the Exploratory Clinical Trials in Japan

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There have been some actions taken in the West involving exploratory clinical trials in recent years. It was reported that a position paper regarding micro-dosing examinations was produced in the EU in 2003 and that a draft guidance for exploratory clinical trials was released by the FDA in April 2005. On the other hand, the implementation of exploratory clinical trials is still a difficult situation in JAPAN. In order to prevent the deterioration of domestic clinical trials in Japan, it is thought that certain measures are required. In the task force of the Drug Evaluation Committee of the Japan Pharmaceutical Manufacturers Association (JPMA), various activities are performed for the purpose of facilitating the implementation of domestic exploratory clinical trials. Last year, the comments of each affiliated company regarding draft guidance were collected by questionnaire and the results were submitted to the FDA as a public comment from JPMA. Moreover, each affiliated company was simultaneously asked for their opinion about domestic exploratory clinical trial implementation. In addition, information on the European and American situation is being gathered, and a lecture meeting by a specialist involved will be held.

In this lecture, the activities undertaken by JPMA will be introduced and the subject of advancing domestic exploratory clinical trials will be discussed, based on the results of the questionnaire to each affiliated company.