

治験推進のためのインフラストラクチャー整備

—東大病院及び大学病院臨床試験アライアンスの取り組み—***

荒川 義弘*, UHCT アライアンス推進室**

**Improvement of Clinical Trial Environment
—Activities of University of Tokyo Hospital and
University Hospital Clinical Trial Alliance—**

Yoshihiro ARAKAWA* and UHCT Alliance members**

Summary

To overcome the drug-lag issue, it is mandatory to improve our clinical trial environment and to join multi-national trials. We have been trying to improve our environment, considering what we can do by ourselves or in collaboration with other hospitals. In Tokyo University, the implementation ratio of industry-sponsored clinical trials has improved to 75~78% in recent years. The period from the submission of documents for preliminary hearing to the institutional review board (IRB) has been shortened to 35 days. We provide the Q&A obtained in the hearing to the IRB for efficient review. A research database for clinical studies has been established and is used for participant screening for secure implementation of trials. Attendance of investigators at a research ethics seminar every two years is mandatory to join clinical trials in Tokyo University Hospital. Although these in-house improvements are important, further effort is necessary to overcome issues related to 'few subjects per site and many sites'. The University Hospital Clinical Trial Alliance (UHCT Alliance) was established in February 2006 to solve these issues and to join multi-national trials. At present, it consists of seven national universities around the Kanto area. The Alliance possesses a large pool of patients —5,860 beds and 13,300 out-patients per day. We have specialists in various diseases. All the members have excellent performance in clinical trials. Some of the features of the Alliance activities are quick answers from the Alliance office to initial inquiries about the eligibility of patients, cooperative hearings using a video-conference system and standardized documents and forms. Since October 2006, the Alliance has been implementing 15 clinical trials, six of which were multi-national trials (as of June 2007). We are continuing to improve our environment to ensure more efficient and safer clinical trials.

Key words

Clinical trial environment, Alliance, Multi-national study, Clinical trial
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