New system and a role of Pharmacist in the core Clinical Research Center and the Major Trial Institutions—from a clinical research coordinator's (a pharmacist's) point of view—

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There is remarkable progress in environment surrounding the clinical trial, and each country of not only Europe and America but also Africa and Asia participates in many international multi-centered trials, and the approval of medical supplies is enabled in a short-term and low-cost.

In Japan, the prolongation of the clinical trial period and a remarkable rise of the clinical trial cost become the serious problem for delays of the maintenance of the clinical trial enforcement system.

In addition, so-called "drug rag" which we cannot use medical supplies approved in other countries in Japan is brought into question.

"New five yearly clinical trial activation plan" that Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labour and Welfare devised on March 30, 2007 was announced for the purpose of solving such problem.

In this plan, five action plans are shown as main subjects.

- (1) Clinical Study infrastructure Building
- (2) Human Resource Development for Clinical Research
- (3) Public Promotion of Clinical Trial and Encouraging Participation
- (4) Efficient Clinical Research Management and Sponsors' ease
- (5) Others

Nihon University Itabashi Hospital was adopted in 2007 as the Major Trial Institutions, and started the maintenance of the clinical trial enforcement system in October, 2007. In this Symposium, I hope to have an opportunity to think about a role of the pharmacist in the medical supplies development and an ideal method of the pharmacy education.