わが国における今後の臨床研究等のあるべき姿について
― 疫学・臨床研究倫理指針の見直しに関する中間取りまとめを受けて ―

津田　重城　　野口　隆志*　　土井　脩
一般財団法人医薬品医療機器レギュラトリーサイエンス財団

How clinical research in Japan must be done in the future
― In response to the interim summary of issues on the review of Ethical Guidelines for Epidemiological Research and Clinical Research ―

Shigeki Tsuda　Takashi Noguchi *　Osamu Doi
General Incorporated Foundation Pharmaceutical and Medical Device Regulatory Science Society of Japan

Abstract

Research misconduct events involving Diovan and several university hospitals in Japan which led to the retraction of articles in leading international journals discredited clinical research conducted in Japan. Its gravity is apparent from the fact that the Ministry of Health, Labour and Welfare formed an investigation committee and it issued an interim report on its handling and preventive measures within 2 months, which is a surprisingly quick action.

At roughly the same time, integration of Ethical Guidelines for Epidemiological and Clinical Research has been discussed by a governmental committee. However, it seems that a fundamental review on the legally non-binding guidelines has not yet been initiated, while clinical research is regulated by law in US and EU.

We, therefore, submitted an opinion in response to the solicitation on the interim summary of issues on the integration that clinical research must be conducted according to ICH-GCP. Only by doing so, we believe that the rights, safety and well being of subjects can be protected, and that the clinical research data are credible.

Also, by applying ICH-GCP, the results of clinical research can be used as application material for new drugs, etc. after necessary audit and/or inspection by the regulatory authority. Until now, such results cannot be used and that leads to repetition of similar studies.

We must learn from the introduction of ICH-GCP in 1997. It was criticized that the introduction had brought about the decrease of clinical trials. However, without that, clinical trials in Japan would not have been accepted by FDA and EMA even now.

Key words
clinical research, ethical guideline, ICH-GCP(Good Clinical Practice), Diovan®, research misconduct

Rinsho Hyoka（*Clinical Evaluation*）2014；41：551-8.

＊ 昭和大学薬学部 (School of Pharmacy, Showa University)