提　言

臨床研究の成果を国民のために活かすには

津田　重城　　土井　　脩
（一財）医薬品医療機器レギュラトリーサイエンス財団

How can we make the best use of clinical research results?

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Abstract

At last, the Clinical Research Act, which was drafted following the Diovan® case, passed the Diet, was promulgated on April 14th, 2017 and is to be enforced within a year from the promulgation.

"Specified Clinical Research" defined in the Act as "that involving non-approved drugs or funded by pharmaceutical companies etc." must be conducted based on the "Clinical Research Conduct Standard". Therefore, how the Standard is stipulated is critically important. If the Standard is based on ICH-GCP, the results of clinical research can be utilized as a part of the application package for regulatory approval in the PMD Act (Pharmaceutical and Medical Device Act, formerly PAL: Pharmaceutical Affairs Law). If not, the results can only be used for academic articles and the research (study) must be repeated based on J-GCP for approval.

Another issue is if and how the "Authorized Clinical Research Review Board" works to ensure the ethical and scientific integrity of a Specified Clinical Research. Its responsibility is larger even compared with IRB in GCP. The board must give an opinion about the submitted implementation plan, and then, the opinion is to be submitted to the Minister. The Minister has the authority to suspend or improve the research. This article also introduces the PMRJ's opinion on the "Clinical Research Conduct Standard" and the ICH Reflection on the "GCP Renovation" of January 2017.

Now Japan is in a pivotal situation where the future direction of clinical research will be decided, that is, whether it follows the global standard of ICH-GCP or strays in a co-called "Galapagos" situation, which is not found in other developed countries.

Key words
clinical research, Clinical Research Act, GCP (Good Clinical Practice), GCP Renovation

Rinsho Hyoka（*Clinical Evaluation*）. 2017；45：617-28.