

わが国アカデミア発臨床試験の 国際的な信用回復の条件

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Prerequisites to reclaim global reliance on academic clinical trials in Japan

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Abstract

Credibility of clinical trials from the Japanese academia was completely lost, due to the series of misconduct revealed for the valsartan trials. Although futile efforts are being devoted to pursue the responsibility of relevant researchers and pharmaceutical company, the essential cause for such misconduct is the lack of rules to ensure the quality and reliability of academic trials, as well as the shortage of fundamental knowledge on clinical science and its methodology. Particularly, credibility of data is not stipulated in the current clinical study guideline, allowing for the spread of studies with poor quality and/or malpractice. Under such conditions, we must be aware that the global standard for conducting clinical trials is ICH-GCP, the compliance with which provides public assurance that the clinical trial data are credible. If so, the global reliance will never be restored, unless ICH-GCP is applied to all clinical trials even for academic purposes. Moreover, quality control and assurance of data are the basic requirements of clinical science, which are applied to all types of clinical studies. To meet the requirements, the study data should be strictly managed at independent data centers, and analyzed by dedicated experienced biostatisticians. Also, to increase transparency, information of the studies must be open to the public, and the relationship with the industry should be held accountable. In addition, for the proper execution of academic trials, a mechanism to avoid inappropriate interference by industry needs to be in place, as well as an education system for researchers. These issues need to be promptly addressed, as the prerequisites for reclaiming global reliance on clinical trials in the nation, in order to remain in the intense competition of clinical science and medical technology development.

Key words

clinical trials, clinical studies, ICH-GCP, quality control, regulatory science

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