原　著

日本の臨床研究・治験にかかる情報提供 ― 米国，欧州との比較

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Information disclosure on clinical trials by the national registries and regulatory agencies in Japan, US, and EU

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Abstract
Objectives：To examine the current regulations, practices, and information disclosure of clinical trials, implemented by government agencies in Japan, US, and EU.
Methods：Web sites of the clinical trials registries in Japan, US and EU were examined, along with those of the regulatory agencies concerned. Information was collected on the items and contents therein disclosed. In addition, laws and regulations were summarized, which authorize, mandate and support the activities of those agencies for trial registration and regulation.
Results：In Japan, registration of clinical trials is mandated only when they are conducted for the application of drug approval. Clinical trials in general are to comply with various ethical standards, but not required to be officially registered. Disclosure of clinical trial information is not mandatory by law. In the US, clinical trials, regardless of their purposes, are to be registered by a governmental agency, and its information is publicly disclosed. Registration of clinical trials, and disclosure of their outcomes are strictly mandated by law. Also in EU, its Clinical Trials Directives mandate the registration of all the trials, whether or not their purpose is for drug approval.
Conclusions：Only in Japan, the universal registration of clinical trials, and the public disclosure of trial information is not mandated by law. To promote reliable clinical trials, and to meet the public demand for information on them, more comprehensive and authoritative systems are desirable for trial registration and information disclosure, along with laws and regulations supporting them.

Key words
clinical trials, trial registration, information disclosure, government agencies

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