

原著

臨床試験の信頼性確保のために

— ICH-GCP (R2) と日本における臨床研究法案をめぐる考察 —

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Ensure reliability of clinical trials: Considering ICH-GCP(R2) and the system of clinical trial in Japan

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Abstract

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH-GCP) revision 2 (R2) was agreed to at the conference on November 9 2016, and the quality management system (QMS) in clinical trial implementation was newly added. The points of this revision are for facilitating clinical trial efficiency, introducing a risk-based approach (RBA) announced as guidance by regulating authorities in each country, and clarifying reliability assurance for using records and reports through electronic data. In ISO 9001, which is the international standard of QMS, RBA has been introduced in the 2015 version. ICH-GCP specified management criteria based on ISO 9001 and would be the same as the revision and directionality of the international standard. Reliability for clinical trials is ensured by compliance with ICH-GCP. It is an international agreement. In Japan, the reliability issue for clinical trials is a current important topic, and the need/scope for legal regulations for clinical studies has been under discussion. In the progress of globalization and requirement for an international reliability assurance level at present, a system consistent with principles of ICH-GCP for all clinical trials should be developed.

Key words

ICH-GCP, quality management system (QMS), risk-based approach (RBA), corrective action and preventive action (CAPA), ISO 9001

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