原　著

国際基準からみた臨床研究法の特徴と多施設共同試験の運用

― GCPコンパリソン法による重篤な有害事象報告に関する検討 ―

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Comparing GCP requirements for serious adverse event reporting in the US, EU, and Japan

― The impact of GCP renovation on the Japanese Clinical Trials Act 2017 ―

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Abstract

Background：Medical innovation is based on research that ultimately must include studies involving human subjects. Adverse event reporting (AER) is one of the most fundamental mechanisms in clinical trials to ensure protection of human subjects and reliability of trial results.

Objective：To evaluate consistency among Good Clinical Practices (GCPs), including the Japanese Clinical Trials Act 2017 (CTA), focusing on AER in multi-center clinical trials.

Methods：GCP comparison, line-by-line evaluation, and comparison of GCPs originally developed by clinical and regulatory experts in the US-Japan Harmonization by Doing (HBD) program.

Results and conclusion：We identified relevant GCPs—guidance documents on ethical and scientific quality standards for designing, conducting, recording, and reporting trials—from the United States (US), European Union (EU), and Japan. The definitions and appropriate handling of AER presented in the GCPs were assessed with respect to four fundamental criteria: 1) protection of human subjects, 2) scientific integrity of trial methods, 3) accuracy of data, and 4) reliability as a basis for decision-making. Differences were categorized as substantive, non-substantive, or administrative. Some administrative and non-substantive differences, but no substantive differences, were identified between the CTA and the GCPs surveyed. However, the study found that the CTA guidance documents need to more clearly explain the importance of establishing an independent data monitoring committee (IDMC) and maintaining a development safety update report (DSUR) when research subjects are exposed to investigational new drugs or off-label uses.

Key words

Clinical Trials Act, GCP comparison, human subject protection, research integrity, adverse event report

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