ISO 14155 Ed.3

Clinical investigation of medical devices for human subjects

— Good clinical practice

＜Overview＞

ISO 14155 Ed.3 addresses Good Clinical Practice (GCP) for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical device.

＜Technical Committee＞

ISO/TC 194/WG 4

＜Main Points＞

- This standard outlines the requirements for the protection of human subjects' rights, safety, and well-being; ensuring the scientific quality of clinical trials and the reliability of clinical data; investigator responsibilities; and the support of organizations involved in conformity assessment of medical devices.
- Statistical considerations in Clause 7 of Annex A, revised in Ed.3, are mandatory. However, for parts not aligned with Japan’s specific circumstances, the phrase “if applicable” has been added.
- Major revisions from Ed.2 to Ed.3 include:
  - Clause 4: Summary of GCP principles was added.
  - Clause 5.4: Requirement for registration of clinical investigations in publicly accessible databases was incorporated.
  - Clause 6.7: Risk-based monitoring was introduced.
  - Clause 9.1: Guidelines for clinical investigation quality management were added.
  - Annex G: Ethical committee guidelines were included.
  - Annex H: Reinforcement of risk management throughout the clinical investigation was added.
  - Annex I: Explanation of the applicability of the requirements at each stage of the clinical investigation was included.
  - Annex J: Guidelines for auditing clinical investigations were added.

＜Publication History＞

- During the five-year review of Ed.2 (published in 2011), requests for revision were made by

various countries. A new proposal for revision was approved in June 2016.

- The DIS (Draft International Standard) ballot was conducted from June to September 2018 and was approved; however, an ad-hoc group teleconference was held in October 2018 to resolve the numerous comments that were submitted.
- At the ISO/TC 194 general meeting in December 2018, comments that could not be resolved during the October 2018 teleconference were discussed, including parts that did not align with the actual situation in Japan. Regarding those parts, Japan presented a revised proposal for discussion, which was largely adopted.

＜PMDA Involvement＞

- Attendance at international conferences, teleconferences, and domestic committee meetings.