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Clinical investigation of medical devices for human subjects — Good clinical practice

Investigation clinique des dispositifs médicaux pour sujets humains — Bonne pratique clinique

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 14155:2020), which has been technically revised.

The main changes are as follows:

— changed definition of clinical performance (3.12);

— clarified deviations from eligibility criteria not being permitted but subject to CIP amendment (see 5.6.4);

— clarified informed consent to be obtained where applicable from subject's legally designated representative (see 5.8.1);

— clarified subject must be given opportunity to discuss participation with others e.g. family members (see 5.8.2);

— clarified risk management by making clear distinction between risks related to the use of the device and risks related to the procedures required by the CIP which are not part of routine clinical practice (see 6.2.1);

— included required assessment of residual risks (see 6.2.2);

— corrected reference to risks related to the use of the investigational device (see 6.2.1, 7.4.4, 8.2, Annex F, Annex H and 3.2);

— added requirements (previously in Annex A) to 6.4;

— added requirement for data monitoring committee to confirm conditions for suspending or stopping the clinical investigation (see 6.11);

- clarified situations of reduced adverse events reporting requirements (see 7.4.2);
- included management of risks related to clinical procedures required by the CIP (see 7.4.5);
- clarified process of suspension or premature termination of the clinical investigation also in line with updated 7.4.4 and Figure H.1 (see 8.2);
- updated procedure section in CIP with methods and timing for assessing, recording and analysing variables and added requirement for calibration of equipment (see A.6.4);
- clarified requirements for non-inferiority margins and missing data (see Clause A.7);
- added requirement to justify absence of DMC involvement (see Clause A.14);
- added requirement for subject follow up and continued care to include those different from normal practice (see Clause A.16);
- clarified aspects of local representative for better harmonisation with national regulatory requirements (see 9.2.1);
- included requirement for implant card (see 9.2.2);
- moved general requirements to 6.4 on objective and study design (see Clause A.5);
- updated adverse events categorization clarifying terminology in Figure F.1;
- updated Annex H in line with 6.2.1 and updated Figure H.1;
- included principles of estimands and their attributes (see 6.4, Clause A.5, Clause A.6, Clause A.7 and Annex K);
- included precautions (see Clause B.5), information on training on the use of investigational device (see Clause B.2), and in-silico tests (see Clause B.3).
- added an adverse event associated with a device deficiency – both Figure F.1 and Figure F.2 now apply.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

For the purpose of this document, the use of the term compliance is applied when compliance to clinical investigation requirements and good clinical practice as per this document is required. In case of requirements outlined in regulatory documents or other standards the term ‘conformance with’ is applied.