

Redline version
compares Fourth edition to
Third edition



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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Reference number
ISO 14155:redline:2020(E)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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Foreword

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~~ISO 14155~~ 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 ~~second~~ ~~third~~ edition cancels and replaces the ~~first edition of~~ ~~second edition~~ (ISO 14155-1:2003:2011 and the first edition of ISO 14155-2:2003), which have been technically revised. The main changes to the previous edition are as follows:

- inclusion of a summary section of GCP principles (see [Clause 4](#));
- reference to registration of the clinical investigation in a publicly accessible database (see [5.4](#));
- inclusion of clinical quality management (see [9.1](#));
- inclusion of risk-based monitoring (see [6.7](#));
- inclusion of statistical considerations in [Annex A](#);
- inclusion of guidance for ethics committees in [Annex G](#);
- reinforcement of risk management throughout the process of a clinical investigation (planning to consideration of results) including [Annex H](#);
- clarification of applicability of the requirements of this document to the different clinical development stages (see [Annex I](#));

— inclusion of guidance on clinical investigation audits (see [Annex J](#)).

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