Reference number
ISO 14155:2020
© ISO 2026
ISO 14155:2020
Clinical investigation of medical devices for human subjects — Good clinical practice
Edition 3
2020-07
Withdrawn

ISO 14155:2020
71690

~~ISO 14155:2020~~ Clinical investigation of medical devices for human subjects — Good clinical practice

Withdrawn (Edition 3, 2020)
New version available: ISO 14155:2026

Preview ISO 14155:2020

Abstract

This document addresses good clinical practice 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 devices.

For post-market clinical investigations, the principles set forth in this document are intended to be followed as far as relevant, considering the nature of the clinical investigation (see Annex I).

This document specifies general requirements intended to

— protect the rights, safety and well-being of human subjects,

— ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,

— define the responsibilities of the sponsor and principal investigator, and

— assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

NOTE 1 Users of this document need to consider whether other standards and/or national requirements also apply to the investigational device(s) under consideration or the clinical investigation. If differences in requirements exist, the most stringent apply.

NOTE 2 For Software as a Medical Device (SaMD) demonstration of the analytical validity (the SaMD's output is accurate for a given input), and where appropriate, the scientific validity (the SaMD's output is associated to the intended clinical condition/physiological state), and clinical performance (the SaMD's output yields a clinically meaningful association to the target use) of the SaMD, the requirements of this document apply as far as relevant (see Reference [4]). Justifications for exemptions from this document can consider the uniqueness of indirect contact between subjects and the SaMD.

This document does not apply to *in vitro* diagnostic medical devices. However, there can be situations, dependent on the device and national or regional requirements, where users of this document might consider whether specific sections and/or requirements of this document could be applicable.

General information

- Status
  : Withdrawn
  Publication date
  : 2020-07
  Stage
  : Withdrawal of International Standard [95.99]
- Edition
  : 3
  Number of pages
  : 83
- Technical Committee :
  ISO/TC 194
  ICS :
  11.100.20
- RSS updates

Life cycle

- **Previously**

  Withdrawn

  ISO 14155:2011

  Withdrawn

  ISO 14155:2011/Cor 1:2011

- **Now**

  Withdrawn

  ISO 14155:2020

  Stage: **95.99**
  - 00
    Preliminary
  - 10
    Proposal
    - 10.99 2016-06-17
      New project approved
  - 20
    Preparatory
  - 30
    Committee
    - 30.00 2017-02-03
      Committee draft (CD) registered
    - 30.20 2017-02-03
      CD consultation initiated
    - 30.60 2017-04-30
      Close of comment period
    - 30.99 2017-06-26
      CD approved for registration as DIS
  - 40
    Enquiry
    - 40.00 2018-04-17
      DIS registered
    - 40.20 2018-06-19
      DIS ballot initiated: 12 weeks
    - 40.60 2018-09-13
      Close of voting
    - 40.99 2019-08-21
      Full report circulated: DIS approved for registration as FDIS

- 50
  Approval
  - 50.00 2019-08-21
    Final text received or FDIS registered for formal approval
  - 50.20 2020-02-05
    Proof sent to secretariat or FDIS ballot initiated: 8 weeks
  - 50.60 2020-04-02
    Close of voting. Proof returned by secretariat
- 60
  Publication
  - 60.00 2020-06-18
    International Standard under publication
  - 60.60 2020-07-28
    International Standard published
- 90
  Review
  - 90.92 2022-12-12
    International Standard to be revised
- 95
  Withdrawal
  - 95.99 2026-03-23
    Withdrawal of International Standard

- **Revised by**

  Published

  ISO 14155:2026


Sustainable Development Goals

This standard contributes to the following Sustainable Development Goal

3
Good Health and Well-being

Got a question?

Check out our Help and Support

1.
2. Store
3. Store
4. ICS
5. 11
6. 11.100

7. 11.100.20
8. ISO 14155:2020

Sitemap

- Standards
  - Benefits
  - Popular standards
  - Conformity assessment
  - SDGs
- Sectors
  - Health
  - IT & related technologies
  - Management & services
  - Security, safety & risk
  - Transport
  - Energy
  - Environmental sustainability
  - Materials
- About ISO
  - What we do
  - Structure
  - Members
  - Events
  - Strategy
- Insights & news
  - Insights
    - All insights
    - Healthcare
    - Artificial intelligence
    - Climate change
    - Transport
  - News
    - Expert talk
    - Standards world
    - Media kit
  - Resources
    - ISO 9001 explained
    - ISO 14001 explained
    - Digital product passports explained
    - ISO/IEC 42001 explained
    - ISO 45001 explained
    - ISO 22000 explained
    - ISO/IEC 27090 explained
    - Biodiversity for business explained
- Taking part
  - Who develops standards

    - Deliverables
    - Get involved
    - Collaborating to accelerate effective climate action
    - Resources
        - Directives and Policies
        - Drafting standards
- Store
    - Store
    - Publications and products

- ISO name and logo
- Privacy Notice
- Copyright
- Cookie policy
- Media kit
- Jobs
- Help and support

Making lives ***easier***, ***safer*** and ***better***.

Sign up
for email updates

▶ © All Rights Reserved

Add to cart