SLOVENSKI STANDARD
SIST EN ISO 14155:2026

01-junij-2026

Nadomešča:
SIST EN ISO 14155:2020
SIST EN ISO 14155:2020/A11:2025

Klinične raziskave medicinskih pripomočkov za ljudi - Dobre klinične prakse (ISO 14155:2026)

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2026)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2026)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonne pratique clinique (ISO 14155:2026)

Ta slovenski standard je istoveten z: **EN ISO 14155:2026**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14155:2026 **en,fr,de**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14155

April 2026

ICS 11.100.20

Supersedes EN ISO 14155:2020

English Version

Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2026)

Investigation clinique des dispositifs médicaux pour sujets humains - Bonne pratique clinique (ISO 14155:2026)

Klinische Prüfung von Medizinprodukten an Menschen - Gute klinische Praxis (ISO 14155:2026)

This European Standard was approved by CEN on 13 January 2026.

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European foreword

This document (EN ISO 14155:2026) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 “Biological and clinical evaluation of medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2026, and conflicting national standards shall be withdrawn at the latest by October 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14155:2020.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 14155:2026 has been approved by CEN as EN ISO 14155:2026 without any modification.

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Annex ZA
(informative)

Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to Annex XV of Regulation (EU) 2017/745 of 5 April 2017 concerning clinical investigations of medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA Regulations.

This Annex ZA covers the relationship of this European standard with Annex XV of Regulation (EU) 2017/745 (Table ZA.1). Where requirements laid down in that Annex XV refer to Article 62 of this Regulation, the related requirements laid down in the section of Article 62 cited have also been considered when establishing the relationship of the clauses of this European standard with Annex XV in Table ZA.1.

Where a definition in this harmonized standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices ((EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

For all requirements related to clinical investigations contained in Regulation (EU) 2017/745 and referred to in the following table, obligations attributed to the "sponsor" under ISO 14155 shall be incumbent under the Regulation to the Sponsor if located in the Union; When established, the Legal Representative is responsible for ensuring compliance with the sponsor's obligations pursuant to Regulation (EU) 2017/745.

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Table ZA.1 — Correspondence between this European Standard and Annex XV of Regulation (EU) 2017/745 [OJ L 117]

Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter I, 1	4 a)	Covered by a general reference to the Declaration of Helsinki; however, the latest edition of the Declaration should be used. National/regional requirements for ethics in clinical research and for protecting the safety, wellbeing, health and rights of subjects must be observed.
Annex XV, Chapter I, 2.1	6.2, 6.3, 6.4, 7.4.4, 7.4.5 and Annex A	6.2 of this document covers risk management considerations for risks related to the use of the investigational device and their disclosure, risks related to clinical procedures required by the clinical investigation plan that are outside routine clinical practice, as well as risks related to the clinical investigation process. 6.3 of this document refers to the literature review of the standard of care, as a basis to define the appropriate study design as well as the requirement to take into consideration and relevant pre-clinical data. 6.4 of this document combined with Annex A provides a detailed outline on the study design and statistical considerations required to obtain scientific valid data on safety, performance and clinical benefits. Note: This document covers the risk assessment process for potentially unacceptable risks. Aspect relating to benefit-risk of devices as referred to in Article 62(1) of Regulation (EU) 2017/745 are covered in this standard by referring to ISO 14971.
Annex XV, Chapter I, 2.2	6.3, 6.4, A.2 i), A.3, A.4, A.5, A.6 and A.7	

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Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter I, 2.3	6.3, 6.4, A.3, A.4, A.5, A.6 and A.7	
Annex XV, Chapter I, 2.4	6.3, 6.4, 6.8, 9.2.1 b) to e), 10.2, 10.3, A.2 h), A.3, A.6 and A.7	Partially covered - this document does not cover the requirements of the clinical evaluation plan as this is not part of the clinical investigation. However, 6.3 does refer to the appropriate literature review required prior to designing a clinical investigation.
Annex XV, Chapter I, 2.5	6.2, 6.3, A.2 e), f) and g), A.3, A.4, A.6, A.7 and B.2	
Annex XV, Chapter I, 2.6	6.3, A.6 and A.7	
Annex XV, Chapter I, 2.7	6.5, 9.2.1 g), 9.2.2, 10.2, A.2 h) and Annex B	
Annex XV, Chapter I, 2.8	8.4, 9.2.6, 10.6 r) and Annex D	
Annex XV, Chapter II, 2.1	B.2, B.4 a)	
Annex XV, Chapter II, 2.2	B.2 f) to h)	
Annex XV, Chapter II, 2.3	B.3	
Annex XV, Chapter II, 2.4, first indent	6.3, B.2 a), B.4	Partially covered – this document requires a prior assessment of relevant scientific literature but does not specifically require its incorporation into the Investigator's Brochure except for what is mentioned in B.2 a). Also, this document requires a prior assessment of relevant scientific literature and available data on the same or similar devices but is not specific on safety, performance and clinical benefits.
Annex XV, Chapter II, 2.4, second indent	6.3, B.2 a), B.4 a) and b)	Partially covered – this document requires a prior assessment of relevant scientific literature and available data on the same or similar devices but is not specific on safety, performance and clinical benefits.
Annex XV, Chapter II, 2.5	B.5	
Annex XV, Chapter II, 2.6	B.2 c)	Partially covered – this document does not specifically refer to a particular regulatory system. The

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Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
		document does not include the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device.
Annex XV, Chapter II, 2.7	B.6	Partially covered-this document does not specifically refer to a particular regulatory system.
Annex XV, Chapter II, 3.1.1	A.1.2 b)	
Annex XV, Chapter II, 3.1.2	9.2.1 b), A.1.3	Covered - the document outlines that a local representative shall be selected if the sponsor is not resident in the country (countries) in which the clinical investigation is to be carried out. Article 62(2) of the Regulation specifies that when the sponsor is not established in the Union, its legal representative is responsible for ensuring conformance with the sponsor's obligations pursuant to the Regulation and shall be the addressee for all communications with the sponsor provided for in the Regulation.
Annex XV, Chapter II, 3.1.3	A.1.4	
Annex XV, Chapter II, 3.1.4	A.12 f)	
Annex XV, Chapter II, 3.1.5	A.1.5	Partially covered – in the document, the language used for the synopsis is not specified as this is considered as a country specific regulatory requirement.
Annex XV, Chapter II, 3.2	6.3, A.2, A.3 a) and b), A.4 a)	Background literature review and current state of the art are not covered as part of the identification of the device but as part of the justification of the design which is derived from literature review as outlined in 6.3 of the document.
Annex XV, Chapter II, 3.3	A.4	
Annex XV, Chapter II, 3.5	A.5	
Annex XV, Chapter II, 3.6	6.3, A.6.1 a) to e), A.7	

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Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter II, 3.6.1	A.6.1 a), A.6.1 c)	
Annex XV, Chapter II, 3.6.2	A.2 a), A.6.2 a) and b)	
Annex XV, Chapter II, 3.6.3	A.5, A.6.3 j), A.15	To fully cover requirement 3.6.3, the information provided should also include immuno-compromised and elderly subjects, if applicable. However, Clause A.5 of this document does require the study design to be relevant for the target population as well as A.6.3 j) requiring clarification of the relationship of the investigation population to the target population.
Annex XV, Chapter II, 3.6.4	A.6.1 b), A.7 j), A.7 k) and A.7 l)	
Annex XV, Chapter II, 3.6.5	A.6.4	
Annex XV, Chapter II, 3.6.6	A.6.5	
Annex XV, Chapter II, 3.7	A.7	
Annex XV, Chapter II, 3.8	A.8	
Annex XV, Chapter II, 3.9	A.9	
Annex XV, Chapter II, 3.10	A.10	
Annex XV, Chapter II, 3.11	A.11	
Annex XV, Chapter II, 3.12	A.12	
Annex XV, Chapter II, 3.13	A.13	
Annex XV, Chapter II, 3.14	A.14	
Annex XV, Chapter II, 3.15	A.16, A.7 f) 6), A.7 n)	Traceability for implantable devices is not covered.
Annex XV, Chapter II, 3.16	A.6.4 h) to j), A.16 c)	To fully cover requirement 3.16, information should be provided on the additional care required that differs from that normally expected for the medical condition in question.
Annex XV, Chapter II, 3.17	A.17	
Annex XV, Chapter II, 3.18	A.2, A.5	
Annex XV, Chapter II, 3.19	A.18	
Annex XV, Chapter II, 4.2	7.1, 9.2.2 i) and j), A.12 c)	
Annex XV, Chapter II, 4.3	5.3, 9.2.2 f) and h), A.12 e)	

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Clinical Investigation Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex XV, Chapter II, 4.4	5.8	
Annex XV, Chapter II, 4.5	5.8.4 e), 7.7	
Annex XV, Chapter II, 4.5, first indent	5.8.4 e), 5.8.5 f) and g), 7.7	
Annex XV, Chapter II, 4.5, second indent	5.8.4 e), 5.8.5 f) and g), 7.7, 7.8.2 c), 7.8.3 g)	
Annex XV, Chapter III, 2	6.9, 9.2.1 a), 10.8	
Annex XV, Chapter III, 4	9.2.1 g), 9.2.3, 9.2.4	
Annex XV, Chapter III, 5	8.1, 9.2.3 f), 9.2.4.5	
Annex XV, Chapter III, 6	7.11, 9.1 c)	
Annex XV, Chapter III, 7, first indent	8.4, D.2, D.4, D.12	To fully conform to this requirement, the signature page must be part of the clinical investigation report. Note 1 of 8.4 does refer to national requirements regarding the clinical report which may be different worldwide.
Annex XV, Chapter III, 7, second indent	8.4, D.2 i) and j)	
Annex XV, Chapter III, 7, third indent	8.4, D.4	
Annex XV, Chapter III, 7, fourth indent	D.6.1	
Annex XV, Chapter III, 7, fifth indent	D.6.2, D.13	This document in addition to the clinical investigation plan summary of D.6.2 does also require the full plan to be in the Annex of the report.
Annex XV, Chapter III, 7, sixth indent	D.7 e), D.7 f), D.7 g) 1), D.7 g) 4), D.7 g) 5)	Justification and rationale for the analysis is required in Clause D.7 g) of the document.
Annex XV, Chapter III, 7, seventh indent	D.7 g) 2) and 3)	
Annex XV, Chapter III, 7, eighth indent	D.8	The discussion includes the clinical relevance and importance of the results in light of other existing data which should be understood including standard of care.

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Table ZA.2 — Normative references from clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

Table ZA.3 — Prevailing terms of Regulation (EU) 2017/745 for the use of this European standard under that Regulation

Term used in this EN	Clause(s)/subclause(s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
adverse event AE	3.2	Article 2(57)	Both definitions are substantially equivalent. The definition in this document specifies that an adverse event may be whether anticipated or unanticipated. A note specifies that the definition includes events related to the investigational medical device or the comparator. A note specifies that the definition includes events related to the use of the investigational medical device and the clinical procedure(s) required by the CIP that are outside to routine clinical practice but not related to the use of the device.
clinical investigation	3.9	Article 2(45)	Both definitions are substantially equivalent. The definition in this document specifies an investigation undertaken to assess the clinical performance, effectiveness or safety of a medical device. In the Regulation, the definition is an investigation undertaken to assess the safety or performance of a device. Effectiveness is defined in this document and introduced as the term is used in regulations outside Europe.
clinical	3.10	Article 2(47)	Both definitions are substantially

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Term used in this EN	Clause(s)/subclause(s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
investigation plan CIP			equivalent. In the Regulation, the definition includes statistical considerations. However, per Clause A.7 of Annex A of this document, a statistical design and analysis is expected in the content of the CIP. In this document, the definition includes "record-keeping".
clinical performance	3.12	Article 2(52)	Both definitions are substantially equivalent. In this document, a note specifies that not all clinical investigations have clinical benefits to subjects e.g; healthy volunteers, clinical investigations only gathering data etc..
device deficiency	3.19	Article 2(59)	Both definitions are substantially equivalent. The definition in this document includes the inadequacy of a medical device with respect to its usability. A note also specifies that the definition includes device deficiencies related to the investigational medical device or the comparator.
ethics committee EC	3.25	Article 2(56)	Both definitions are substantially equivalent. In the Regulation, the definition specifies that the EC is empowered to give opinions taking into account the views of laypersons.
informed consent	3.28	Article 2(55)	Both definitions are substantially equivalent. Per section 5.8.1 of this document informed consent is obtained in writing from the subject or where applicable, the subject's legally designated representative. In the Regulation, the definition specifies an authorization or agreement from the legally designated representative in the case of minors and of incapacitated subjects.
investigational medical device	3.30	Article 2(46)	Both definitions are substantially equivalent. The definition in this document specifies that the device

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Term used in this EN	Clause(s)/subclause (s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
			is assessed in a clinical investigation for safety, clinical performance or effectiveness. It also includes notes specifying that this includes medical devices already on the market.
investigator	3.31	Article 2(54)	The definition in this document distinguishes between the terms *principal investigator* and *investigator*, whereas the Regulation only defines the role of the investigator which corresponds to the definition of *principal investigator* in this document.
medical device	3.35	Article 2(1)	Both definitions are substantially equivalent. In the Regulation, the definition also specifies: A medical device can be used for one or more medical purposes where the standard does not specify medical Under medical purposes, the Regulation adds in the first bullet point prediction and prognosis, The Regulation second bullet point also adds disability in addition to injury, The third bullet point ads pathological process or state, The fourth bullet has additional specification including organ, blood and tissue donations The Regulation however does not include devices supporting or sustaining life as medical purpose.
serious adverse event SAE	3.46	Article 2(58)	Both definitions are substantially equivalent. The criterion v) chronic disease in the definition of the Regulation is part of the permanent impairment criterion in the definition of this document.
serious health threat	3.47	Article 2(66)	Both definitions are similar but used in a different target population. The definition in the Regulation includes the full target population of a

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Term used in this EN	Clause(s)/subclause (s) of this EN	Article in (EU) 2017/745 that defines or uses this term	Differences/Consequences
			market released product 'public' health threat, where the definition in this document has been adapted to target the clinical investigation population and is considered as a signal amongst reported serious adverse events rather than a different definition of adverse event.
sponsor	3.50	Article 2(49)	Both definitions are substantially equivalent. The definition in this document specifies that the sponsor assumes liability. A note indicates that when an investigator initiates, implements and takes full responsibility for the clinical investigation, the investigator also assumes the role of the sponsor and is identified as the sponsor-investigator.
subject	3.51	Article 2(50)	Both definitions are substantially equivalent. In this document, the definition specifies that a subject is a participant in a clinical investigation either as a recipient of the investigational medical device or a comparator. A note indicates that the definition includes healthy volunteers.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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International Standard

ISO 14155

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

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

Fourth edition
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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);

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- included new section on clinical events committee (see 3.8, 6.12 and Clause A.14);
- 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.

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Introduction

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.

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

1 Scope

This document specifies 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 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 the general requirements intended to

— protect the rights, safety and well-being of human subjects, users or other persons,

— 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.

Other standards or national requirements can also apply to the investigational device(s) under consideration or the clinical investigation(s).

NOTE For Software as a Medical Device (SaMD), where appropriate, demonstration of the analytical validity (the SaMD's output is accurate for a given input), 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 [5]). 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 can consider whether either specific sections or requirements of this document, or both, can be applicable.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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3.1
adverse device effect
ADE
adverse event (3.2) related to the use of an *investigational medical device* (3.30)

Note 1 to entry: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, operation or any *malfunction* (3.34) of the investigational medical device.

Note 2 to entry: This definition includes any event resulting from *use error* (3.53) or from intentional misuse of the investigational medical device.

Note 3 to entry: This definition applies to *'comparator'* (3.13) if the comparator is a medical device.

3.2
adverse event
AE
untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including abnormal laboratory findings) in *subjects* (3.51), users or other persons, whether or not related to the use of the *investigational medical device* (3.30) and whether anticipated or unanticipated

Note 1 to entry: This definition includes events related to the use of the investigational medical device or the *comparator* (3.13) and the clinical procedure(s) required by the *clinical investigation plan* (*CIP*) (3.10) that are outside to routine clinical practice but not related to the use of the device.

Note 2 to entry: For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators.

3.3
audit
systematic examination of activities and documents related to a *clinical investigation* (3.9) performed by (an) *independent* (3.27) person(s), to determine whether these activities were conducted, and the data recorded, analysed and accurately reported, in compliance with the *clinical investigation plan* (*CIP*) (3.10), standard operating procedures, this document and in conformance with applicable regulatory requirements

3.4
audit trail
documentation that allows reconstruction of the course of events

3.5
blinding
masking
procedure in which one or more parties to the *clinical investigation* (3.9) are kept unaware of the treatment assignment(s)

Note 1 to entry: Single blinding usually refers to the *subject(s)* (3.51) being unaware of the treatment assignment(s). Double blinding usually refers to the subject(s), *investigator(s)* (3.31), monitor and, in some cases, centralized assessors being unaware of the treatment assignment(s).

Note 2 to entry: A clinical investigation is termed 'observer blind', if at least the *primary endpoint(s)* (3.23) is/are assessed without knowledge of whether an *investigational medical device* (3.30) or *comparator* (3.13) has been used to treat a subject.

3.6
case report form
CRF
set of printed, optical or electronic documents for each *subject* (3.51) on which information to be reported to the *sponsor* (3.50) is recorded, as required by the *clinical investigation plan* (*CIP*) (3.10)

3.7
certified copy
copy (irrespective of the type of media used) of the original record that has been verified (i.e. by a dated signature or by generation through a validated process) to have the same information including data that describe the context, content and structure, as the original

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3.8
clinical events committee
CEC
central events committee
clinical adjudication committee
CAC
endpoint adjudication committee
EAC
independent (3.27) committee of clinical experts that can be established by the *sponsor* (3.50) to ensure consistent event assessment across participating centres and mitigate inadequate reporting risks

3.9
clinical investigation
clinical trial
clinical study
systematic investigation in one or more human *subjects* (3.51), undertaken to assess the *clinical performance* (3.12), *effectiveness* (3.20) or safety of a *medical device* (3.35)

3.10
clinical investigation plan
CIP
protocol
document that states the rationale, *objectives* (3.38), design and pre-specified analysis, methodology, organization, *monitoring* (3.36), conduct and record-keeping of the *clinical investigation* (3.9)

Note 1 to entry: As the term "protocol" has many different meanings, some not related to clinical investigation, and as these can differ from country to country, the term CIP is used in this document.

3.11
clinical investigation report
clinical study report
document describing the design, conduct, statistical analysis and results of a *clinical investigation* (3.9)

3.12
clinical performance
ability of a *medical device* (3.35), resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for *subject(s)* (3.51), when used as intended by the manufacturer

Note 1 to entry: Clinical performance can be defined under national regulations.

Note 2 to entry: Not all clinical investigations have clinical benefits to subjects e.g. healthy volunteers, clinical investigations only gathering data etc.

3.13
comparator
medical device (3.35), therapy (e.g. active treatment, routine clinical practice), placebo, sham or no treatment, used in the *control group* (3.15) in a *clinical investigation* (3.9)

3.14
contract research organization
CRO
person or organization contracted by the *sponsor* (3.50) to perform one or more of the sponsor's clinical investigation-related duties and functions

3.15
control group
group of *subjects* (3.51) that receives the *comparator* (3.13)

Note 1 to entry: A control group may be concurrent or historical, or subjects may serve as their own control.

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3.16
coordinating investigator
national investigator
global investigator
investigator (3.31) who is appointed by the *sponsor* (3.50) to assist in coordinating the work in a multicentre *clinical investigation* (3.9)

3.17
data monitoring committee
DMC
data and safety monitoring board
DSMB
independent data monitoring committee
IDMC
data and safety monitoring committee
DSMC
independent (3.27) committee that can be established by the *sponsor* (3.50) to assess, at intervals, the progress of the *clinical investigation* (3.9), the safety data or the critical *clinical performance* (3.12) or *effectiveness* (3.20) *endpoints* (3.23, 3.24) and to recommend to the sponsor whether to continue, suspend, modify or stop the clinical investigation

3.18
deviation
instance of failure to follow, intentionally or unintentionally, the requirements of the *clinical investigation plan* (*CIP*) (3.10)

3.19
device deficiency
inadequacy in the identity, quality, durability, reliability, usability, safety or performance of a *medical device* (3.35), including *malfunctions* (3.34), *use errors* (3.53) or inadequacy in the information supplied by the manufacturer including labelling

Note 1 to entry: This definition includes device deficiencies related to the *investigational medical device* (3.30) or the *comparator* (3.13).

3.20
effectiveness
achievement of a clinically meaningful intended result in a defined portion of the target population when the *investigational medical device* (3.30) is used within its intended uses and in compliance with its instructions for use, the *investigator's brochure* (3.32) and the *clinical investigation plan* (*CIP*) (3.10), as determined by documented scientific evidence

3.21
electronic clinical data system
hardware and software (including associated documents, such as a user manual) that creates, modifies, maintains, archives, retrieves or transmits in digital form information related to the conduct of a *clinical investigation* (3.9)

3.22
electronic record
combination of text, graphics, data, audio, imaging, or other information in digital form that is created, modified, maintained, archived, retrieved or distributed by an *electronic clinical data system* (3.21)

EXAMPLE An electronic case report form (CRF).

3.23
endpoint
<primary> principal indicator(s) used for providing the evidence for *clinical performance* (3.12), *effectiveness* (3.20) or safety in a *clinical investigation* (3.9)

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3.24
endpoint
<secondary> indicator(s) used for assessing the secondary *objectives* (3.38) of a *clinical investigation* (3.9)

3.25
ethics committee
EC
research ethics committee
independent ethics committee
institutional review board
independent (3.27) body whose responsibility it is to review *clinical investigations* (3.9) in order to protect the rights, safety, and well-being of human *subjects* (3.51) participating in a clinical investigation

Note 1 to entry: The regulatory requirements pertaining to ethics committees or similar institutions vary by country or region.

3.26
hypothesis
testable statement, derived from the *objective* (3.38) of the *clinical investigation* (3.9) to draw a conclusion about this objective, based on a pre-specified statistical test

Note 1 to entry: The primary hypothesis is formulated based on the pre-defined *primary endpoint* (3.23) and is usually used to calculate the sample size.

3.27
independent
not involved in the development of the investigational device or the conduct of a *clinical investigation* (3.9), except for their specifically assigned responsibilities, in order to avoid bias or a conflict of interest

3.28
informed consent
process by which an individual voluntarily confirms willingness to participate in a particular *clinical investigation* (3.9), after having been informed of all aspects of the investigation that are relevant to the decision to participate

3.29
investigation site
investigation centre
institution or site where the *clinical investigation* (3.9) is carried out

3.30
investigational medical device
investigational device
medical device (3.35) being assessed for safety, *clinical performance* (3.12) or *effectiveness* (3.20) in a *clinical investigation* (3.9)

Note 1 to entry: This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes.

Note 2 to entry: This includes medical devices already on the market that are being evaluated within their intended use in a post-market clinical investigation (interventional or non-interventional).

3.31
investigator
individual member of the *investigation site* (3.29) team designated and supervised by the *principal investigator* (3.40) at an investigation site to perform clinical investigation-related procedures or to make important clinical investigation-related and medical treatment decisions

Note 1 to entry: An individual member of the investigation site team can also be called “sub-investigator” or “co-investigator”.

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3.32
investigator's brochure
IB
compilation of the current clinical and non-clinical information on the *investigational medical device(s)* (3.30), relevant to the *clinical investigation* (3.9)

3.33
legally designated representative
individual, judicial, or other body authorized under applicable law to consent, on behalf of a prospective *subject* (3.51), to the subject's participation in the *clinical investigation* (3.9)

Note 1 to entry: "legally authorized representative" or "legally acceptable representative" are other terminologies used under national regulations for "legally designated representative" but not used in this document.

3.34
malfunction
failure of an *investigational medical device* (3.30) to perform according to its intended purpose when used in compliance with the instructions for use or *clinical investigation plan* (*CIP*) (3.10), or *investigator's brochure (IB)* (3.32)

3.35
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific purpose(s) of:

— diagnosis, prevention, *monitoring* (3.36), treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — "medical" has been deleted in "the specific medical purpose(s)".]

3.36
monitoring
act of overseeing the progress of a *clinical investigation* (3.9) to ensure that it is conducted, recorded and reported in compliance with the *clinical investigation plan* (*CIP*) (3.10), written procedures, this document and in conformance with the applicable regulatory requirements

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Note 1 to entry: Centralized monitoring provides additional monitoring capabilities remotely for evaluation of the accumulated data and the overall study compliance and can complement or reduce the extent and frequency of on-site monitoring.

3.37
multicentre investigation
clinical investigation (3.9) that is conducted according to a single *clinical investigation plan* (*CIP*) (3.10) and takes place at two or more *investigation sites* (3.29)

3.38
objective
main purpose for conducting the *clinical investigation* (3.9)

3.39
point of enrolment
time at which, following *recruitment* (3.44) and before any clinical investigation-related procedures are undertaken, a *subject* (3.51) signs and dates the *informed consent* (3.28) form

3.40
principal investigator
qualified person responsible for conducting the *clinical investigation* (3.9) at an *investigation site* (3.29)

Note 1 to entry: If a clinical investigation is conducted by a team of individuals at an investigation site, the principal investigator is responsible for leading the team.

Note 2 to entry: Whether this is the responsibility of an individual or an institution can depend on national regulations.

3.41
quality assurance
planned and systematic actions that are established to ensure that the *clinical investigation* (3.9) is performed, and that the data are generated, documented (recorded) and reported in compliance with this document and in conformance with the applicable regulatory requirement(s)

3.42
quality control
operational techniques and activities undertaken within the *quality assurance* (3.41) system to verify that the requirements for quality of the clinical investigation-related activities have been fulfilled

3.43
randomization
process of assigning *subjects* (3.51) to the *investigational medical device* (3.30) or *control groups* (3.15) using an established recognized statistical method based on an element of chance to determine the unforeseeable assignment in order to reduce bias

3.44
recruitment
active efforts to identify *subjects* (3.51) who can be suitable for enrolment into the *clinical investigation* (3.9)

3.45
serious adverse device effect
SADE
adverse device effect (3.1) that has resulted in any of the consequences characteristic of a *serious adverse event* (3.46)

3.46
serious adverse event
SAE
adverse event (3.2) that led to any of the following:

a) death,

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b) serious deterioration in the health of the *subject* (3.51), users, or other persons as defined by one or more of the following:

   1) a life-threatening illness or injury, or

   2) a permanent impairment of a body structure or a body function including chronic disease, or

   3) in-patient or prolonged hospitalization, or

   4) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function

c) foetal distress, foetal death, congenital abnormality or birth defect including physical or mental impairment

Note 1 to entry: Planned hospitalization for a pre-existing condition, or a procedure required by the *clinical investigation plan* (*CIP*) (3.10), without serious deterioration in health, is not considered a *serious adverse event* (3.46).

3.47
serious health threat
signal from any *adverse event* (3.2) or *device deficiency* (3.19) that indicates an imminent risk of death or a serious deterioration in the health in *subjects* (3.51), users or other persons, and that requires prompt remedial action for other subjects, users or other persons

Note 1 to entry: A serious health threat would include events that are of significant and unanticipated nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.

3.48
source data
information in original records, *certified copies* (3.7) of original records of clinical findings, observations or other activities in a *clinical investigation* (3.9), necessary for the reconstruction and evaluation of the clinical investigation

Note 1 to entry: This definition includes source data initially recorded in an electronic format.

3.49
source document
original or *certified copy* (3.7) of printed, optical or electronic document containing *source data* (3.48)

EXAMPLE Hospital records, laboratory notes, device accountability records, photographic negatives, radiographs, records kept at the *investigation site* (3.29), at the laboratories and at the medico-technical departments involved in the *clinical investigation* (3.9).

3.50
sponsor
individual, company, institution or organization taking responsibility and liability for the initiation and management of a *clinical investigation* (3.9), and arranging the financial setup

Note 1 to entry: When an *investigator* (3.31) initiates, implements and takes full responsibility for the clinical investigation, the investigator also assumes the role of the sponsor and is identified as the sponsor-investigator.

3.51
subject
individual who is or becomes a participant in a *clinical investigation* (3.9), either as a recipient of the *investigational medical device* (3.30) or a *comparator* (3.13)

Note 1 to entry: A subject can be a healthy volunteer.

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3.52
unanticipated serious adverse device effect
USADE
serious adverse device effect (3.45) which by its nature, incidence, severity or outcome has not been identified in the current risk assessment

Note 1 to entry: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, and its severity or outcome has been identified in the risk assessment.

3.53
use error
user action or lack of user action while using the *medical device* (3.35) that leads to a different result than that intended by the manufacturer or expected by the user

Note 1 to entry: Use error includes the inability of the user to complete a task.

Note 2 to entry: Use errors can result from a mismatch between the characteristics of the user, user interface, task or use environment.

Note 3 to entry: Users might be aware or unaware that a use error has occurred.

Note 4 to entry: An unexpected physiological response of the patient is not by itself considered a use error.

Note 5 to entry: A malfunction of a medical device that causes an unexpected result is not considered a use error.

[SOURCE: ISO 14971:2019, 3.30]

3.54
validation
confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled

3.55
verification
confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

3.56
vulnerable subject
individuals who are unable to fully understand all aspects of the clinical investigation that are relevant to the decision to participate, or who can be manipulated or unduly influenced as a result of a compromised position, expectation of benefits or fear of retaliatory response determined by physical, social, economic and environmental factors or processes

4 Summary of good clinical practice principles

Good clinical practice principles for clinical investigations carried out in human subjects assessing medical devices is summarized as follows:

a) Clinical investigations shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (see Reference [8]), and that are consistent with this document.

b) Before a clinical investigation is initiated, foreseeable risks and inconveniences shall be weighed against the anticipated benefit for the individual subject and society. A clinical investigation shall be initiated and continued only if the anticipated benefits justify the risk.

c) The rights, safety and well-being of human subjects are the most important considerations and shall prevail over interests of science and society.

d) The available non-clinical and clinical information on the investigational device shall be adequate to support the proposed clinical investigation.

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