INTERNATIONAL STANDARD

ISO 14155-2

First edition
2003-05-15

Clinical investigation of medical devices for human subjects —

Part 2: Clinical investigation plans

Investigation clinique des dispositifs médicaux pour sujets humains —

Partie 2: Plans d'investigation clinique

Reference number
ISO 14155-2:2003(E)

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 14155-2 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 194, *Biological evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

This first edition, together with the first edition of ISO 14155-1, cancels and replaces ISO 14155:1996, which has been technically revised.

ISO 14155 consists of the following parts, under the general title *Clinical investigation of medical devices for human subjects*:

— *Part 1: General requirements*

— *Part 2: Clinical investigation plans*

For the purposes of this part of ISO 14155, the CEN annex regarding fulfilment of European Council Directives has been removed.

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Foreword

This document (EN ISO 14155-2:2003) has been prepared by Technical Committee CEN /TC 258 "Clinical investigation of medical devices", the secretariat of which is held by AFNOR, in collaboration with Technical Committee ISO/TC 194 "Biological evaluation of medical devices".

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of an identical text or by endorsement, at the latest by November 2003, and conflicting national standards shall be withdrawn at the latest by November 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Annex A is informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This standard is the second part of EN ISO 14155 "Clinical investigation of medical devices for human subjects", and should be read in conjunction with that standard.

The standard is intended to assist manufacturers, sponsors, monitors and clinical investigators in the design and conduct of clinical investigations. It is also intended to assist regulatory bodies and ethics committees in their roles of reviewing Clinical Investigation Plans (CIP). The CIP is a framework within which appropriate experience, insight, judgement, qualification and education need to be applied. The scientific rigour of a CIP can be verified and possibly improved by an independent review of the CIP.

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1 Scope

This part of EN ISO 14155 provides requirements for the preparation of a Clinical Investigation Plan (CIP) for the clinical investigation of medical devices. The compilation of a CIP in accordance with the requirements of this standard and adherence to it will help in optimising the scientific validity and reproducibility of the results of a clinical investigation.

This Standard does not apply to in vitro diagnostic medical devices.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements. (ISO 14155-1:2001)*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN ISO 14155-1:2003 and the following apply.

3.1
end point - primary
principal indicator measured or determined to assess the primary objective of a clinical investigation

3.2
end point - secondary
indicator measured or determined in addition to the primary end-point to assess some other objective of a clinical investigation

3.3
point of enrolment
time at which, following recruitment, a subject has signed the informed consent form and is regarded as part of the study population

3.4
follow-up period
period of the clinical investigation after the application of the device under investigation in each subject during which the effects of the device are observed

3.5
recruitment
process of identifying subjects who may be suitable for enrolment into the clinical investigation

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