



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*

ICS 11.100

ISO/CEN PARALLEL ENQUIRY

This draft International Standard is a draft European Standard developed within the European Committee for Standardization (CEN) in accordance with subclause 5.2 of the Vienna Agreement. The document has been transmitted by CEN to ISO for circulation for ISO member body voting in parallel with CEN enquiry. Comments received from ISO member bodies, including those from non-CEN members, will be considered by the appropriate CEN technical body. **Accordingly, ISO member bodies who are not CEN members are requested to send a copy of their comments on this DIS directly to CEN/TC 258** (AFNOR, Avenue Francis de Pressensé, F-93571 Saint Denis La Plaine Cedex) **as well as returning their vote and comments in the normal way to the ISO Central Secretariat.** Should this DIS be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

Contents

Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions.....	5
4 Requirements	6
4.1 General.....	6
4.2 Clinical Investigation Plan	6
4.3 General information	6
4.3.1 Identification of the Clinical Investigation Plan	6
4.3.2 Clinical Investigators, Principal Clinical Investigator, Co-ordinating Clinical Investigator, Clinical Investigation Centres/site(s).....	6
4.3.3 Sponsor.....	6
4.3.4 Monitoring arrangements.....	6
4.3.5 Data and quality management	6
4.3.6 An overall synopsis of the clinical investigation.....	6
4.3.7 Approval and agreement to the Clinical Investigation Plan	7
4.4 Identification and description of the medical device to be investigated	7
4.5 Preliminary investigations and justification of the study.....	7
4.5.1 Literature review	7
4.5.2 Preclinical testing	7
4.5.3 Previous clinical experience.....	7
4.5.4 Device risk analysis.....	8
4.6 Objectives of the Clinical Investigation	8
4.7 Design of the Clinical Investigation	8
4.8 Statistical considerations	9
4.9 Deviations from and amendments to the Clinical Investigation Plan	10
4.10 Adverse events and adverse device effects	10
4.11 Early termination or suspension of the investigation.....	10
4.12 Publication policy	10
4.13 Case report forms	10
Annex A (informative) Case Report Forms	11
Annex ZA (normative) Normative references to international publications with their relevant European publications	12
Annex ZB (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	13
Bibliography	14

Foreword

The text of prEN ISO 14155-2:2001 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 document is currently submitted to the parallel Enquiry.

This European Standard 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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

Introduction

This standard is the second part of EN ISO 14155, Clinical Investigation of Medical Devices for Human Subjects and shall 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.

1 Scope

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

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

NOTE 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 possible improved by an independent review of the CIP.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this European Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this European Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of CEN and CENELEC maintain registers of currently valid European Standards (including amendments).

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

3 Terms and definitions

For the purposes of this part of prEN ISO 14155, the terms and definitions given in prEN ISO 14155-1:2001 and the following apply.

3.1

end point - primary

principal indicator measured to assess the primary objective of a clinical investigation

3.2

end point - secondary

indicator measured 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