

Clinical investigation of medical devices for human subjects —

Part 2: Clinical investigation plans

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British Standard

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological Evaluation of Medical Devices, which has the responsibility to:

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Klinische Prüfung von Medizinprodukten an Menschen -
Teil 2: Klinische Prüfpläne (ISO 14155-2:2003)

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Contents

	page
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 (CIP).....	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, 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.....	7
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.....	8
4.5.4 Device risk analysis and risk assessment	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 the clinical investigation plan	10
4.10 Amendments to the clinical investigation plan	10
4.11 Adverse events and adverse device effects	10
4.12 Early termination or suspension of the investigation.....	10
4.13 Publication policy	10
4.14 Case Report Forms	11
Annex A (informative) Case Report Forms	12
Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	13
Bibliography	14

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).

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

Annex A is informative.

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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.