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

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



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Contents

| | Page |
|---|-----------|
| Foreword | v |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 1 |
| 4 Summary of good clinical practice (GCP) principles | 9 |
| 5 Ethical considerations | 10 |
| 5.1 General..... | 10 |
| 5.2 Improper influence or inducement..... | 10 |
| 5.3 Compensation and additional health care..... | 10 |
| 5.4 Registration in publicly accessible database..... | 11 |
| 5.5 Responsibilities..... | 11 |
| 5.6 Communication with the ethics committee (EC)..... | 11 |
| 5.6.1 General..... | 11 |
| 5.6.2 Initial EC submission..... | 11 |
| 5.6.3 Information to be obtained from the EC..... | 12 |
| 5.6.4 Continuing communication with the EC..... | 12 |
| 5.6.5 Continuing information to be obtained from the EC..... | 12 |
| 5.7 Vulnerable populations..... | 12 |
| 5.8 Informed consent..... | 13 |
| 5.8.1 General..... | 13 |
| 5.8.2 Process of obtaining informed consent..... | 13 |
| 5.8.3 Special circumstances for informed consent..... | 14 |
| 5.8.4 Information to be provided to the subject..... | 15 |
| 5.8.5 Informed consent signature..... | 17 |
| 5.8.6 New information..... | 17 |
| 6 Clinical investigation planning | 17 |
| 6.1 General..... | 17 |
| 6.2 Risk management..... | 18 |
| 6.2.1 General..... | 18 |
| 6.2.2 Investigational device including clinical procedure risks and their disclosure..... | 18 |
| 6.2.3 Clinical investigation process..... | 18 |
| 6.3 Justification for the design of the clinical investigation..... | 19 |
| 6.4 Clinical investigation plan (CIP)..... | 19 |
| 6.5 Investigator's brochure (IB)..... | 19 |
| 6.6 Case report forms (CRFs)..... | 20 |
| 6.7 Monitoring plan..... | 20 |
| 6.8 Investigation site selection..... | 21 |
| 6.9 Agreement(s)..... | 21 |
| 6.10 Labelling..... | 21 |
| 6.11 Data monitoring committee (DMC)..... | 21 |
| 7 Clinical investigation conduct | 22 |
| 7.1 General..... | 22 |
| 7.2 Investigation site initiation..... | 22 |
| 7.3 Investigation site monitoring..... | 22 |
| 7.4 Adverse events and device deficiencies..... | 22 |
| 7.4.1 Signals requiring immediate action..... | 22 |
| 7.4.2 Adverse events..... | 23 |
| 7.4.3 Device deficiencies..... | 23 |
| 7.4.4 Risk assessment process for potentially unacceptable risks..... | 23 |
| 7.5 Clinical investigation documents and documentation..... | 24 |
| 7.5.1 Amendments..... | 24 |
| 7.5.2 Subject identification log..... | 24 |

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| | | |
|-----------|--|-----------|
| 7.5.3 | Source documents | 25 |
| 7.6 | Additional members of the investigation site team | 25 |
| 7.7 | Subject privacy and confidentiality of data | 25 |
| 7.8 | Document and data control | 25 |
| 7.8.1 | Traceability of documents and data | 25 |
| 7.8.2 | Recording of data | 25 |
| 7.8.3 | Electronic clinical data systems | 26 |
| 7.9 | Investigational device accountability | 27 |
| 7.10 | Accounting for subjects | 27 |
| 7.11 | Auditing | 27 |
| 8 | Suspension, termination, and close-out of the clinical investigation | 28 |
| 8.1 | Completion of the clinical investigation | 28 |
| 8.2 | Suspension or premature termination of the clinical investigation | 28 |
| 8.2.1 | Procedure for suspension or premature termination | 28 |
| 8.2.2 | Procedure for resuming the clinical investigation after temporary suspension | 29 |
| 8.3 | Routine close-out | 29 |
| 8.4 | Clinical investigation report | 30 |
| 8.5 | Risk assessment and conclusions | 30 |
| 8.6 | Document retention | 31 |
| 9 | Responsibilities of the sponsor | 31 |
| 9.1 | Clinical quality management | 31 |
| 9.2 | Clinical investigation planning and conduct | 31 |
| 9.2.1 | Selection and training of clinical personnel | 31 |
| 9.2.2 | Preparation of documents and materials | 32 |
| 9.2.3 | Conduct of clinical investigation | 33 |
| 9.2.4 | Monitoring | 33 |
| 9.2.5 | Safety evaluation and reporting | 36 |
| 9.2.6 | Clinical investigation close-out | 37 |
| 9.3 | Outsourcing of duties and functions | 37 |
| 9.4 | Communication with regulatory authorities | 37 |
| 10 | Responsibilities of the principal investigator | 38 |
| 10.1 | General | 38 |
| 10.2 | Qualification of the principal investigator | 38 |
| 10.3 | Qualification of investigation site | 38 |
| 10.4 | Communication with the EC | 38 |
| 10.5 | Informed consent process | 39 |
| 10.6 | Compliance with the CIP | 39 |
| 10.7 | Medical care of subjects | 40 |
| 10.8 | Safety reporting | 41 |
| | Annex A (normative) Clinical investigation plan (CIP) | 42 |
| | Annex B (normative) Investigator's brochure (IB) | 51 |
| | Annex C (informative) Case report forms (CRFs) | 54 |
| | Annex D (normative) Clinical investigation report | 56 |
| | Annex E (informative) Essential clinical investigation documents | 61 |
| | Annex F (informative) Adverse event categorization | 68 |
| | Annex G (informative) EC responsibilities | 70 |
| | Annex H (informative) Application of ISO 14971 to clinical investigations | 74 |
| | Annex I (informative) Clinical development stages | 75 |
| | Annex J (informative) Clinical investigation audits | 80 |
| | Bibliography | 83 |

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Foreword

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This third edition cancels and replaces the second edition (ISO 14155:2011), which has been technically revised. The main changes to the previous edition are as follows:

- inclusion of a summary section of GCP principles (see [Clause 4](#));
- reference to registration of the clinical investigation in a publicly accessible database (see [5.4](#));
- inclusion of clinical quality management (see [9.1](#));
- inclusion of risk-based monitoring (see [6.7](#));
- inclusion of statistical considerations in [Annex A](#);
- inclusion of guidance for ethics committees in [Annex G](#);
- reinforcement of risk management throughout the process of a clinical investigation (planning to consideration of results) including [Annex H](#);
- clarification of applicability of the requirements of this document to the different clinical development stages (see [Annex I](#));
- inclusion of guidance on clinical investigation audits (see [Annex J](#)).

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