

ISO 20916:2019 (E)

In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

Contents

| | |
|----------|--|
| | Foreword |
| | Introduction |
| 1 | Scope |
| 2 | Normative references |
| 3 | Terms and definitions |
| 4 | Ethical considerations |
| 4.1 | General |
| 4.2 | Improper influence or inducement |
| 4.3 | Responsibilities |
| 4.4 | Ethics committee involvement |
| 4.5 | Informed consent |
| 5 | Clinical performance study planning |
| 5.1 | General |
| 5.2 | Risk evaluation |
| 5.3 | Design of the clinical performance study |
| 5.4 | Investigator brochure |
| 5.5 | Clinical Performance Study Protocol (CPSP) |
| 5.5.1 | General |
| 5.5.2 | Principal investigator responsibilities |
| 5.5.3 | Contents of the CPSP |
| 5.5.3.1 | General |
| 5.5.3.2 | Identification of the clinical performance study protocol |
| 5.5.3.3 | Identification and description of the IVD medical device under investigation |
| 5.5.3.4 | Sponsor |
| 5.5.3.5 | Study site(s) |
| 5.5.3.6 | Overall synopsis of the clinical performance study |
| 5.5.3.7 | Objectives of the clinical performance study |
| 5.5.3.8 | IVD medical device under investigation and comparator(s) |
| 5.5.3.9 | Specimens and when applicable, subjects providing specimens |
| 5.5.3.10 | Procedures |
| 5.5.3.11 | Monitoring plan |
| 5.5.3.12 | Data management |
| 5.5.3.13 | Statistical considerations |
| 5.5.3.14 | Amendments to the CPSP |
| 5.5.3.15 | Deviations from clinical performance study protocol |
| 5.5.3.16 | Accountability of IVD medical devices under investigation |
| 5.5.3.17 | Statements of conformity |
| 5.5.3.18 | Informed consent process |
| 5.5.3.19 | Adverse events, adverse device effects and device deficiencies |
| 5.5.3.20 | Bibliography |
| 5.6 | Case report forms |
| 5.7 | Recording of specimen information |
| 5.8 | Specimen accountability and integrity |
| 5.9 | Study site selection |
| 5.9.1 | Site qualification |
| 5.9.2 | Site assessment |
| 5.9.3 | Site selection |

| | |
|----------------|---|
| 5.10 | Monitoring plan |
| 5.11 | Agreements |
| 5.12 | Labelling |
| 6 | Study site initiation |
| 6.1 | General |
| 6.2 | Prerequisites |
| 6.3 | Training |
| 6.4 | Initiation of the study site |
| 7 | Clinical performance study conduct |
| 7.1 | General |
| 7.2 | Responsibilities of the sponsor |
| 7.3 | Study site monitoring |
| 7.3.1 | General |
| 7.3.2 | Routine monitoring |
| 7.3.3 | Monitoring reports |
| 7.4 | Security and confidentiality of data |
| 8 | Close-out of the clinical performance study |
| 8.1 | Close-out activities |
| 8.2 | Clinical performance study report |
| 8.3 | Document retention |
| 8.4 | Suspension or premature termination of the clinical performance study |
| 9 | Auditing |
| Annex A | (normative) Additional general requirements for certain studies |
| A.1 | Introduction |
| A.2 | Ethics committee approval |
| A.3 | Informed consent |
| A.4 | Accounting for subjects |
| A.5 | Case report forms |
| A.6 | Suspension or termination of a clinical performance study |
| A.6.1 | Procedure for suspension/termination |
| A.6.2 | Procedure for resuming the clinical performance study after temporary suspension |
| A.7 | Medical care of subjects |
| A.8 | Compensation |
| A.9 | Vulnerable populations |
| Annex B | (normative) Clinical performance study protocol (CPSP) |
| B.1 | General |
| B.2 | Identification and description of the IVD medical device under investigation |
| B.3 | Identification of the clinical performance study protocol |
| B.4 | Sponsor |
| B.5 | Principal investigator and study site(s) |
| B.6 | Overall synopsis of the clinical performance study |
| B.7 | Risks and benefits of the IVD medical device under investigation and clinical performance study |
| B.8 | Design of the clinical performance study |
| B.8.1 | General |
| B.8.2 | IVD medical device under investigation and comparator(s) |
| B.8.3 | Specimens and when applicable, subjects providing specimens |
| B.8.4 | Procedures |
| B.8.5 | Monitoring plan |
| B.8.6 | Data management |
| B.8.7 | Statistical considerations |
| B.8.8 | Deviations from clinical performance study protocol |
| B.8.9 | Accountability of IVD medical devices under investigation |
| B.8.10 | Insurance |
| B.8.11 | Adverse events, adverse device effects and device deficiencies |
| B.8.12 | Vulnerable population |
| B.8.13 | Suspension or premature termination of the clinical performance study |
| B.8.14 | Publication and Communication policy |

B.8.15 Bibliography

Annex C (normative) Investigator brochure

- C.1 Introduction**
- C.1.1 General**
- C.1.2 Identification of the investigator brochure**
- C.1.3 Sponsor**
- C.2 Information on IVD medical device under investigation**
- C.3 Analytical testing**
- C.4 Existing clinical performance data**
- C.5 Risk management**
- C.6 Regulatory and other references**

Annex D (normative) Clinical performance study report

- D.1 General**
- D.2 Signature page**
- D.3 Cover page**
- D.4 Table of contents**
- D.5 Summary**
- D.6 Introduction**
- D.7 IVD medical device under investigation and methods**
- D.7.1 Description of the IVD medical device under investigation**
- D.7.2 Clinical performance study protocol (CPSP)**
- D.8 Results**
- D.9 Discussion and overall conclusions**
- D.10 Abbreviated terms and definitions**
- D.11 Ethics**
- D.12 Investigators and administrative structure of clinical performance study**
- D.13 Annexes to the report**

Annex E (normative) Communication with the ethics committee

- E.1 Introduction**
- E.2 Initial ethics committee submission**
- E.3 Information to be obtained from the ethics committee**
- E.4 Continuing communication with the ethics committee**
- E.5 Continuing information to be obtained from the ethics committee**

Annex F (normative) Informed consent

- F.1 General**
- F.2 Process of obtaining informed consent**
- F.3 Special circumstances for informed consent**
- F.3.1 General**
- F.3.2 Subject needing legally authorized representatives**
- F.3.3 Subject unable to read or write**
- F.4 Information to be provided to the subject**
- F.5 Informed consent signature**
- F.6 New information**

Annex G (normative) Adverse event categorization

- G.1 Direct and indirect harms**
- G.2 Categories of adverse events**
- G.3 Safety evaluation and monitoring**
- G.4 Safety recording and reporting**

Annex H (informative) Good clinical performance study documentation

Annex I (informative) Auditing