INVESTIGAÇÃO CLÍNICA E ESTUDOS DE DESEMPENHO DE DISPOSITIVOS

DA TEORIA À PRÁTICA

SESSÕES DE FORMAÇÃO

Uma iniciativa AICIB

Em parceria com

NOVA MEDICAL SCHOOL · Infarmed · ceic · apormed

Webinar

Introduction to Monitoring and Audits within the scope of Clinical Research and Performance Studies

INVESTIGAÇÃO CLÍNICA E ESTUDOS DE DESEMPENHO DE DISPOSITIVOS

DA TEORIA À PRÁTICA

SESSÕES DE FORMAÇÃO

Uma iniciativa AICIB

Em parceria com NOVA MEDICAL SCHOOL, Infarmed, ceic, apormed

Audit of Clinical Studies with Medical Devices

Michael Minzer, Clinical QA Manager

BIOTRONIK

Audit of Clinical Studies with Medical Devices

Agenda

1. **Definition**
2. **Objectives and Aims**
3. **Guidelines**
4. **Responsibilities** of sponsor, auditor and auditee

Question

Do you have experience with audits?

Yes – I know audits quite well
Somewhat – I have heard about audits but I don't know exactly
No – I don't really know much about audits

1. Definition of audits

ISO 14155, 3.3 audit

systematic examination of activities and documents related to a *clinical investigation* (3.8) performed by (an) *independent* (3.26) person(s), to determine whether these activities were conducted, and the data recorded, analysed and accurately reported, according to the CIP, standard operating procedures, this document and applicable regulatory requirements

ISO 14155, 7.11 Auditing

(…)These audits may cover all involved parties, systems, processes, and facilities, and are independent of, and separate from quality control functions or routine monitoring.

Nice to know: Audit ≠ Inspection

2. Objectives and Aims

ISO 14155, 7.11 Auditing

Audits of the clinical investigation may be conducted to evaluate compliance with the CIP, written procedures, this document and the applicable regulatory requirements (see Annex J).

(…).

2. Objectives and Aims

ISO 14155, Annex J (Clinical investigation audits)
The (site) audit should include an evaluation of:

- EC and regulatory approvals
- Delegation of tasks, appropriate qualifications and experience of site staff
- Training records
- Agreements
- Suitability of facilities and equipment
- Financial disclosure
- Document storage and retention
- Use of the approved CIP
- CIP deviations
- Informed consent
- Source documents (e.g. organization, condition, completeness, and legibility)
- CRFs
- Monitoring
- Investigational device handling
- Safety reporting

Also important for the sponsor:

- Any critical or systematic problems
- Internal improvement potential
- Feedback and suggestions

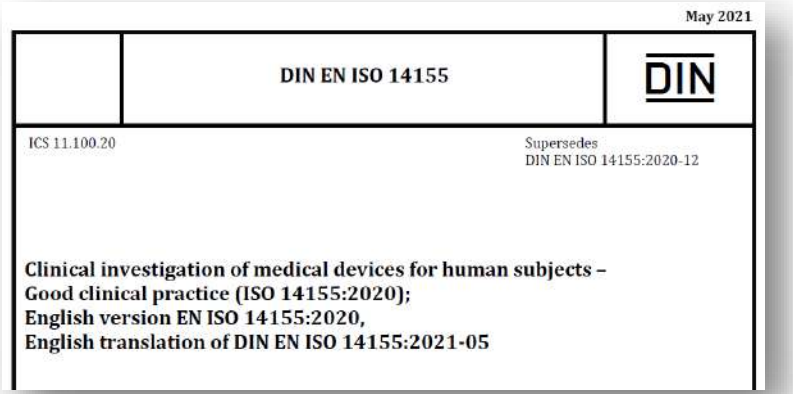
3. Guidelines: clinical audits for medical device studies

GCP (good clinical practice) for **medical device** studies in EU:

➡ **ISO 14155**

Guidance for audits (device studies)**:**

Annex J: Clinical investigation audits



May 2021

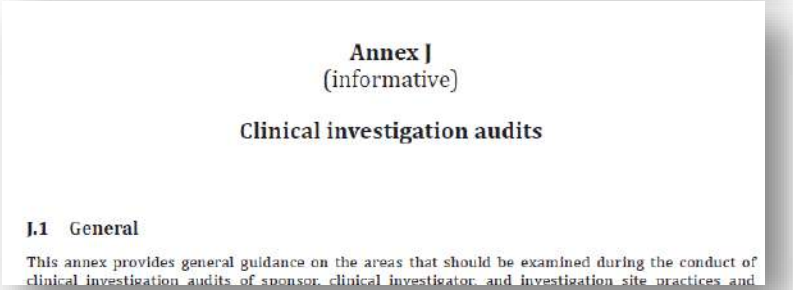
DIN EN ISO 14155

DIN

ICS 11.100.20

Supersedes
DIN EN ISO 14155:2020-12

Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2020); English version EN ISO 14155:2020, English translation of DIN EN ISO 14155:2021-05



Annex J
(informative)

Clinical investigation audits

J.1 General

This annex provides general guidance on the areas that should be examined during the conduct of clinical investigation audits of sponsor, clinical investigator, and investigation site practices and

4. Responsibilities of the sponsor and auditor

Sponsor

- Maintain audit program

Auditor

- Be qualified
- Planning
- Announcement
- Conduct
- Reporting
- Follow-up of audit findings

4. Responsibilities of the auditee

Auditee

- Allow and support audits
- Prepare (review files)
- Participate in interviews
- Follow-up of audit findings
  - Corrective actions
  - Preventive actions (avoid recurrence)

ISO 14155, 10) Responsibilities of the principal investigator: **"allow and support the sponsor to perform monitoring and auditing activities"**

Main take aways

1. Audits are a mandatory quality assurance measure
2. Audits may cover all aspects of clinical studies
3. Audits help to identify problems and improve study conduct
4. ISO 14155 provides guidance for audit planning and conduct