Administrative Regulation 11.3.2022

Ref. no. Fimea/2021/006212

1/2022

Finnish Medicines Agency Administrative Regulation

Clinical investigations conducted with medical devices

Legal basis

Medical Devices Act (719/2021), section 16, subsection 2, and section 21, subsection 11.

Target groups

Sponsors of clinical investigations, manufacturers of medical devices (excluding in vitro diagnostic devices) and individuals conducting investigations with these devices, healthcare and social welfare units

Entry into force

This Administrative Regulation will enter into force on 15 March and will remain so until further notice.

Regulation repealed

National Supervisory Authority for Welfare and Health (Valvira) Clinical investigations conducted with medical devices and supplies. Regulation 3/2010.

This regulation implements

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (32017R0745; OJEU L 117, 5 May 2017, p. 1)

Table of contents

1 General

This Administrative Regulation of the Finnish Medicines Agency (hereinafter Fimea) lays down more detailed provisions on the documents that shall be submitted to Fimea for the evaluation of an investigation pursuant to Article 82 of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (hereinafter the MD Regulation) 82. Additionally, this Administrative Regulation lays down provisions on the notification procedures in the event of a temporary halt or early termination of the investigation, provision on the submission of a report after the end of the investigation, and a provision on the content of the report.

1.1 Scope of application

This Administrative Regulation concerns clinical investigations conducted with medical devices pursuant to Article 82 of the MD Regulation for which authorisation is applied from Fimea or which are notified to Fimea.

1.2 Definitions

For the purposes of this regulation, the following terms shall have the following meanings:

Clinical investigation means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device

Investigational device means a device that is assessed in a clinical investigation

Clinical investigation plan means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation

Sponsor means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation

Subject means an individual who participates in a clinical investigation

Investigator means an individual responsible for the conduct of a clinical investigation at a clinical investigation site

2 Notifications to Fimea

2.1 Documents to be submitted to Fimea for the evaluation of an investigation pursuant to Article 82 of the MD Regulation

Under section 21, subsection 7 of the Medical Devices Act, an application concerning a clinical investigation, or a notice of a substantial modification thereof, may not be submitted to Fimea until a competent regional committee on medical research ethics has given an opinion on the investigation or substantial modification. The application documents may be submitted in Finnish, Swedish or English. However, the investigation plan summary, the description of the informed consent process and the documents to be used to obtain informed consent shall be submitted in Finnish or Swedish. Fimea may request the sponsor to provide further clarifications or supplement the application or notice.

The application or notice shall be accompanied by the following documents:

1) Cover letter
2) Application form
3) Investigator's brochure (when the sponsor is a device company)
4) Clinical investigation plan
5) Clinical investigation plan summary
6) Declaration of conformity (if the product is CE-marked or to the extent that the product conforms to the requirements)
7) Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data
8) Written opinion of the ethics committee
9) Documents pertaining to the risk management of the investigational device (summary of the risk analysis of the investigational device)
10) Test reports of the investigational device (will be requested where applicable)
11) Information about the suitability of investigational sites and investigation site team

12) Curriculum vitae of the investigators
13) Instructions for use of the investigational device (will be requested where applicable)
14) Documents to obtain informed consent, informed consent procedure, all written information to participants, and compensation of participants
15) Certificates of notified bodies (will be requested where necessary)
16) Decisions from other countries
17) Other documents:

- Sponsor's legal representative or contact person
- The sponsor shall describe a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

Provisions on the fees chargeable for the notice/application are laid down in the Decree of the Ministry of Social Affairs and Health on fees chargeable by the Finnish Medicines Agency.

3 Reports to be submitted to Fimea

3.1 Sponsor's obligation to submit a report in the event of a temporary halt or early termination of the investigation

The sponsor shall have procedures described in the event of a temporary halt or early termination of the investigation. A report of such cases shall be prepared for Fimea. The report is of free form. The SFS-EN ISO 14155:2020:8 standard may be applied in the preparation of the report.

However, the report shall contain the following information:

1. Identification of the sponsor

2. Identification of the investigation and devices

3. Sponsor's justification for the temporary halt or early termination of the investigation (free form)

4. Notice to the ethics committee (annex to the report)

5. Post-investigation monitoring of the subjects who enrolled to the clinical investigation (description of the monitoring, including the number of subjects to be monitored and the duration of the monitoring)

6. Clinical investigation report on the data collected to date

3.2. Sponsor's obligation to submit a report upon termination of the investigation

Under section 16, subsection 2 of the Medical Devices Act, the sponsor shall draft an appropriate report on the investigation referred to in Article 82 of the MD Regulation within a year after the investigation was completed. The report shall contain the following information:

1. Identification of the devices, description of the methods and structures of the clinical investigation, any deviation from the investigation plan, analysis of the data (complete with statistics), and critical evaluation of the results of the clinical investigation in relation to the objectives

2. The sponsor and the coordinating investigator shall be requested to sign the report as proof of their acceptance of the content of the clinical investigation report. If no coordinating investigator has been designated, the report shall be signed by the principal investigator.

4 Guidance and advice

On request, Fimea will provide guidance and advice on the application of this regulation.

5 Entry into force

This Administrative Regulation will enter into force on March 15 2022 and will remain so until further notice.

Director General	Eija Pelkonen
Inspector	Minna Kymäläinen

Distribution

For information

Administrative Regulation
ISSN-L 1798-6567
ISSN 1798-6567

Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency
P.O. Box 55, 00034 FIMEA | Tel. +358 29 522 3341 | kirjaamo@fimea.fi | www.fimea.fi | Business ID 0921536-6