

# MDR Article 82 and Clinical Investigation

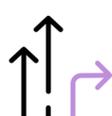
## What is meant by “other clinical investigation” under Article 82 of the MDR?

A study under Article 82 is not conducted for the CE marking of a medical device, but may include, for example:

A study that does not aim for CE marking of the device (e.g., in-house healthcare products).



A study in which the device is used contrary to the manufacturer’s intended purpose and instructions.



A study collecting additional information on the safety and performance of CE-marked devices.



Academic and investigator-initiated studies often fall under Article 82.



## What should the investigator take into consideration when planning a study under Article 82?



The regional medical research ethics committee must provide an opinion on the study before it is submitted to Fimea for review.



When drafting the study plan, it is advisable to utilize [the guidance \(health.ec.europa.eu\)](https://health.ec.europa.eu) prepared by the EU Medical Device Coordination Group and the [CIP template \(docx\)](#).



The application submitted to Fimea must include detailed information about the device under investigation and its safety. During the preparation phase, technical documentation of the investigational device should be gathered, if needed through the manufacturer of the investigational device.



It is advisable to follow the Good Clinical Practice, [GCP \(www.iso.org\)](https://www.iso.org), in the study, to ensure the rights, safety, and well-being of subjects.



The investigator must have appropriate professional and scientific competence. The medical care provided to the subjects is the responsibility of appropriately qualified medical doctor or dentist with appropriate qualifications.

## Investigator’s Checklist



### Key Legislation

- [MDR \(EU\) 2017/745, Article 82](#) (eur-lex.europa.eu)
- [Act on Medical Devices \(719/2021\)](#), Sections 12, 16, 21, 29, 30 (www.finlex.fi)
- [Fimea’s Administrative Regulation 1/2022](#) (www.finlex.fi)

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### Preparation Phase

Check the suitability of the study under Article 82.

**!** Obtain an ethics committee opinion.

Prepare the following documents:

- Study plan (CIP)
- Subject information sheet and consent form (in Finnish and Swedish)
- Cover letter and application form (signed)
- List of attachments with version information
- Other documents as required by [Fimea regulation 1/2022](#) (www.finlex.fi)

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### Application review

### Submission of the Application

Submit the application to Fimea electronically (laitetutkimus@fimea.fi) after the ethics committee has given its opinion.

Ensure all mandatory attachments are included. If any attachment is missing, justify it in the cover letter.

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### Application Supplements

Supplement the application as needed. Fimea may request additional information, which must be provided within the specified deadline.

The review and assessment of the study application at Fimea takes up to **65 days\***

- Class I devices: the study may be initiated 25 days after submitting the application or 5 days after submitting supplementary information.
- Other device classes: the study may be initiated after Fimea’s decision.

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### After Fimea Grants Permission for the Study

**!** Ensure that all necessary permits are in place before starting the study.

Ensure that the ethics committee, Fimea, and the organization have the latest and identical versions of the study plan and documentation provided to subjects.

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### While the Study is Ongoing

- Report [adverse events](#) (health.ec.europa.eu, pdf) to Fimea
- Notify Fimea of any [substantial modifications](#) (health.ec.europa.eu, pdf) to the clinical investigation.

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### After the Study Ends

- Notify Fimea about the end of the study.
- Submit the [study report](#) (www.finlex.fi) to Fimea.



### Fees and Exemption from Fees

Application process is generally subject to a fee. An exemption from the fee may be requested if:

The study does not receive external funding or the funding is from a non-profit organization.

AND

The device under investigation has not been provided for the study by an external party who has the right to use the information produced in the study for product development or clinical evaluation of the device.

More information about free services and current fees: [medical device fees](#) (fimea.fi)

\*Calendar days, including weekends and holidays. The review period is paused when Fimea requests additional information and resumes on the day Fimea receives the supplementary information.