Regulatory and ethical requirements in medical device studies

Finland
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
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H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
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J. Specific requirements
## We have differentiated 8 types of research:

- Medical device alone with CE mark use within label
- Medical device alone with CE mark use outside label
- Medical device alone without CE mark
- Medical device combined with medicinal product with CE mark use within label
- Medical device combined with medicinal product with CE mark use outside label
- Medical device combined with medicinal product without CE mark
- Observational studies with medical device
- Registries
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J. Specific requirements
B. Definitions/Legal basis

Definitions in Finnish law

- The following are sources for the definition for clinical research in medical device studies in Finland:
  - Medical Devices Act 629/2010
  - Clinical Investigations of Medical Devices –Valvira 3/2010

These are applicable to medical device studies other than:
  - Medical Device alone with CE mark use within label
  - Observational studies
  - Registries
## B. Definitions/Legal basis

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th><strong>Conventions/guideline/laws to apply</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Declaration of Helsinki</td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• National legislation.</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• Standard SFS-EN ISO14155-1</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>• Standard SFS-EN-ISO 14155-2</td>
</tr>
<tr>
<td>F. Competent Authority</td>
<td>• Order- Medical Device Clinical Trials 3/2010</td>
</tr>
<tr>
<td>G. Ethics Committee</td>
<td>•*European Directive 2011/20/EC ( *Combined device and medicinal product studies only)</td>
</tr>
<tr>
<td>H. Data Protection</td>
<td>These apply to all medical device studies other than medical device with CE mark use within label (device alone or combined with medicinal product), observational, registry studies.</td>
</tr>
<tr>
<td>I. Healthy volunteers/Patients</td>
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<td>J. Specific requirements</td>
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</tbody>
</table>
B. Definitions/Legal basis

A. Type of research
B. Definitions/Legal basis
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Acts to apply

- Hospital Act
- Data Protection Act
- Medical Device Act
- Medical Research Act 488/1999

*Drug Act (*Only applies to Medical Device combined with medicinal product with CE mark use outside label)

These apply to all studies except:
- Medical device combined with medicinal product without CE mark
- Observational studies
- Registries
C. Insurance
• **Patients:** In Finland all health and medical care providers must be covered by Patient Injuries Insurance against liabilities arising as provided under the Patient Injuries Act.

• **Investigators and study personnel:** All legally operating health care units in Finland are obliged to have insurance for all employees working with patients. For a valid insurance cover all employees must have valid, signed employment contracts with the unit/hospital where they are working.
C. Insurance

- For medical device studies it is necessary to cover insurance for:
  - Patients or healthy volunteers
  - Investigators
  - Sponsor

- It is mandatory to have a compensation sum per trial for all studies aside from observational and registry studies.
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D. Sponsor

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I. Healthy volunteers/Patients
J. Specific requirements
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<tbody>
<tr>
<td><strong>D. Sponsor</strong></td>
<td>It is mandatory to have a sponsor in all the interventional studies listed below:</td>
</tr>
<tr>
<td>A. Type of research</td>
<td>• Medical device alone with CE mark use within label</td>
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<tr>
<td>B. Definitions/Legal basis</td>
<td>• Medical device alone with CE mark use outside label</td>
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<tr>
<td>C. Insurance</td>
<td>• Medical device alone without CE mark</td>
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<tr>
<td>D. Sponsor</td>
<td>• Medical device combined with medicinal product with CE mark use within label</td>
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<tr>
<td>E. Investigators</td>
<td>• Medical device combined with medicinal product with CE mark use outside label</td>
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<tr>
<td>F. Competent Authority</td>
<td>• Medical device combined with medicinal product without CE mark</td>
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<td>G. Ethics Committee</td>
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<td>H. Data Protection</td>
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<td>I. Healthy volunteers/Patients</td>
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<tr>
<td>J. Specific requirements</td>
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</tbody>
</table>
D. Sponsor

- Co sponsorship is allowed.
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J. Specific requirements
E. Investigators

- There are no specific requirements/regulations for GCP training of the investigators in Finland for any of the study types.
- There are no specific requirements/regulations for specific qualifications of the investigators in Finland for any of the study types.
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B. Definitions/Legal basis
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Finnish Competent Authority:

Valvira – Supervising Authority for Welfare and Health
PO Box 210
FI-00531 HELSINKI

Telephone: +358 295 209 216
Fax: +358 295 209 700

Website: [http://www.valvira.fi](http://www.valvira.fi)
## F. Competent Authority

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<thead>
<tr>
<th></th>
<th>Approval</th>
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<tr>
<td><strong>Yes</strong></td>
<td><strong>No</strong></td>
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<tr>
<td>Medical device combined with medicinal product without CE mark</td>
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</tr>
<tr>
<td>Observational studies with medical device</td>
<td>x</td>
</tr>
<tr>
<td>Registries</td>
<td>X</td>
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</tbody>
</table>
### F. Competent Authority – Initial submission

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• The sponsor is responsible for the submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• The submission to the Finnish Competent Authority is national: you only have to submit one dossier to the national Competent Authority</td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• The submission has to be paper, via mail</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• Both Swedish and Finnish documents are accepted.</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>• Submission fee is 335 Euro for Category A (non risk) products and 840 Euro for Category B (risk products)</td>
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<tr>
<td>F. Competent Authority</td>
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<td>G. Ethics Committee</td>
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<tr>
<td>J. Specific requirements</td>
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</tbody>
</table>
### F. Competent Authority – Initial submission

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• There is a standard application form ‘Notification of a Clinical Investigation of Medical Devices’</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Application form is available on: <a href="http://www.valvira.fi/en/licensing/medical_devices/clinical_investigation">www.valvira.fi/en/licensing/medical_devices/clinical_investigation</a></td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• 60 days maximum to obtain approval</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• No deadlines for submission.</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>• If sponsor is outside the EU it is necessary to have some kind of representative or a legal entity in Finland to submit an application to the Competent Authority</td>
</tr>
</tbody>
</table>
Main documents required for submission:

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Informed Consent from
- Subject Information leaflet
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Performance Evaluation
- Pre Clinical Evaluation
- Signed and dated CV of investigators
### Events mandatory to declare to the Competent Authority:

<table>
<thead>
<tr>
<th>Event Description</th>
<th>AE</th>
<th>ADE</th>
<th>SADE</th>
<th>SAE</th>
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<tbody>
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<tr>
<td>Observational studies with medical device + registry studies</td>
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</table>

**AE:** Adverse Event (Non device related)

**ADE:** Adverse Device Effect (Device or procedure related)

**SADE:** Serious adverse Device Effect (Device or procedure related)

**SAE:** Serious Adverse Event (Non device related)
F. Competent Authority - Vigilance

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- Necessary to comply with Meddev 2.7/3 'Clinical Investigations: SAE Reporting'.
- SAE definition corresponds to Meddev 2.7/3.
- Declare SAE to the Competent Authority as soon as possible and no later than 10 days after Sponsor has been made aware of the event. SAE declaration by the sponsor:
  - The sponsor is responsible for declaring Adverse Events to the Competent Authorities in the specific countries
  - Use Meddev 2.7/3 form for SAE reporting.
  - Follow 93/42 EEC for annual safety reporting
### F. Competent Authority - Notification

<table>
<thead>
<tr>
<th>A. Type of research</th>
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<td>B. Definitions/Legal basis</td>
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<td><strong>F. Competent Authority</strong></td>
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<tr>
<td>I. Healthy volunteers/Patients</td>
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<tr>
<td>J. Specific requirements</td>
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</tbody>
</table>

- There are no specific requirements/regulations for notification to the Competent Authority of first patient enrolled.

- There is a specific procedure for submitting a substantial amendment to the Finnish Competent Authority for medical device alone with CE mark use outside label and for medical device alone without CE mark.
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J. Specific requirements

- 21 Regional Ethics Committees – use the regional EC located in the hospital district where the National coordinator of the study is located.
- Varying requirements for the regional Ethics Committees.
- Contact the regional Ethics Committee re requirements and fees.
<table>
<thead>
<tr>
<th>Positive opinion required</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical device alone with CE mark use within label</td>
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<tr>
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<tr>
<td>Medical device combined with medicinal product without CE mark</td>
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</tbody>
</table>
G. Ethics Committee – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
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E. Investigators
F. Competent Authority

G. Ethics Committee

H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- The PI is responsible for submission.
- The submission has to be paper.
- English documents are accepted as well as Finnish and Swedish.
G. Ethics Committee – Initial submission

- In general, 1 Month to obtain approval
- Deadlines for submissions.
- When both Competent Authority approval and Ethics Committee positive opinion are required, it is possible to request the 2 in parallel.
- If sponsor outside EU needs to have some kind of representative or a legal entity in Finland to submit an application to the Competent Authority or Ethics Committee.
### G. Ethics Committee – Initial submission

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>B. Definitions/Legal basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Insurance</td>
<td>D. Sponsor</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>F. Competent Authority</td>
</tr>
<tr>
<td>G. <strong>Ethics Committee</strong></td>
<td>H. Data Protection</td>
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<tr>
<td>I. Healthy volunteers/Patients</td>
<td>J. Specific requirements</td>
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</tbody>
</table>

Main documents required for submission-

Refer to regional ECs for requirements.
G. Ethics Committee - Vigilance

A. Type of research
B. Definitions/Legal basis
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G. Ethics Committee

H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- PI is responsible for SAE declaration to Ethics Committee.

- No standard form for declaring AE to EC - refer to regional EC for requirements.

- Timelines for reporting AEs to EC - refer to the regional EC + follow 93/42 EEC.

- No requirement to declare events to the Ethics Committee in the specific countries.

- Annual safety report must be provided to the Ethics Committee.
<table>
<thead>
<tr>
<th>Section</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>G. Ethics Committee - Notification</td>
<td>• It is not mandatory to notify the EC re first patient enrolled.</td>
</tr>
<tr>
<td></td>
<td>• No specific procedure for submitting amendment to EC – refer to regional EC for requirements.</td>
</tr>
</tbody>
</table>
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H. Data Protection

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Office of the Data Protection Ombudsman
PO box 800
FIN-00521 Helsinki
Finland
Telephone: +358 29 5666 700
Website: http://www.tietosuoja.fi
Email: tietosuoja@om.fi
### H. Data Protection

<table>
<thead>
<tr>
<th>Notification required</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Medical device alone with CE mark use within label</td>
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<tr>
<td>Observational studies with medical device</td>
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<tr>
<td>Registries</td>
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</tbody>
</table>
H. Data Protection

- No submission fee
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### I. Healthy volunteers/Patients

<table>
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<tr>
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<td>J. Specific requirements</td>
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</table>

- In Finland there are specific requirements/regulations for the following specific populations:
  - Children – Medical research Act 488/1999
  - Pregnant and lactating women – Medical Research Act 488/1999

- Other situations are also covered under Medical Research Act 488/1999
I. Healthy volunteers/Patients

A. Type of research

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G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

- In Finland no fees for subjects are allowed, but costs can be compensated e.g. travel, daily allowance.

- No national healthy volunteers registry in Finland.

- No obligation to inform patients on the outcome of the trial.
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- No specific requirements to publish both positive and negative results of clinical studies in scientific journals.

- No specific requirements to provide devices without CE mark, or used outside intended use for free.


- No Specific requirements re ICF
<table>
<thead>
<tr>
<th>J. Specific requirements</th>
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<tbody>
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</table>

- Specific requirements/regulations regarding archiving of documentation Order 3/2010 – stipulates 15 years after close of study.

- No specific requirements for data management of clinical investigations.

- No specific strategies for monitoring of medical device studies. ISO 13155 gives guidance.
### J. Specific requirements

- **A. Type of research**

- **B. Definitions/Legal basis**

- **C. Insurance**

- **D. Sponsor**

- **E. Investigators**

- **F. Competent Authority**

- **G. Ethics Committee**

- **H. Data Protection**

- **I. Healthy volunteers/Patients**

- **J. Specific requirements**

  - It is not mandatory to register clinical studies in a registry.

  - There is no official national register for clinical studies in Finland.

  - There is no official accreditation process for research centres.