Regulatory and ethical requirements in medical device studies

Finland

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

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A. Type of research

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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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:

- o Medical Device alone with CE mark use within label
- o Observational studies
- o Registries

B. Definitions/Legal basis

Conventions/guideline/laws to apply

- Declaration of Helsinki
- National legislation.
- Standard SFS-EN ISO14155-1
- Standard SFS-EN-ISO 14155-2
- Order- Medical Device Clinical Trials 3/2010
- *European Directive 2011/20/EC (*Combined device and medicinal product studies only)

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.

B. Definitions/Legal basis

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

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C. Insurance

• **Patients:** In Finland all health and medical care providers must be coverd 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

It is mandatory to have a sponsor in all the interventional studies listed below:

- 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

D. Sponsor

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- Co sponsorship is allowed.

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E. Investigators

- There are no specific requirements/regulations for GCP training of the investigators in Finland for any of the study types.
- National legislation and standards SFS-EN-ISO14155-1 and SFS-EN-ISO14155-2 apply.
- There are no specific requirements/regulations for specific qualifications of the investigators in Finland for any of the study types.

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F. Competent Authority

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

F. Competent Authority

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	Approval	
	Yes	**No**
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label		
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	
Observational studies with medical device		x
Registries		X

F. Competent Authority – Initial submission

- The sponsor is responsible for the submission
- The submission to the Finnish Competent Authority is national: you only have to submit one dossier to the national Competent Authority
- The submission has to be paper, via mail
- Both Swedish and Finnish documents are accepted.
- Submission fee is 335 Euro for Category A (non risk) products and 840 Euro for Category B (risk products)

F. Competent Authority – Initial submission

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- There is a standard application form ‘ Notification of a Clinical Investigation of Medical Devices’
- Application form is available on:

www.valvira.fi/en/licensing/medical_devices/clinical_investigation

- 60 days maximum to obtain approval
- No deadlines for submission.
- 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

F. Competant Authority – Initial submission

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

F. Competent Authority - Vigilance

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Events mandatory to declare to the Competent Authority:

	AE	ADE	SADE	SAE
Medical device alone with CE mark use within label				
Medical device alone with CE mark use outside label		x	x	x
Medical device alone without CE mark		x	x	x
Medical device combined with medicinal product with CE mark use within label				
Medical device combined with medicinal product with CE mark use outside label		x	x	x
Medical device combined with medicinal product without CE mark		x	x	x
Observational studies with medical device + registry studies				

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

- 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

• 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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G. Ethics Committee

- 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.

G. Ethics Committee

	Positive opinion required	
	Yes	**No**
Medical device alone with CE mark use within label	x	
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label	x	
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	

G. Ethics Committee – Initial submission

- The PI is resonsible 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

Main documents required for submission-

Refer to regional ECs for requirements.

G. Ethics Committee - Vigilance

- 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.

G. Ethics Committee - Notification

- It is not mandatory to notify the EC re first patient enrolled.
- No specific procedure for submitting amendment to EC – refer to regional EC for requirements.

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H. Data Protection

Offfice 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

	Notification required	
	Yes	No
Medical device alone with CE mark use within label	x	
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label	x	
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	
Observational studies with medical device	x	
Registries	x	

H. Data Protection

- No submission fee

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I. Healthy volunteers/Patients

- 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

• 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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J. Specific requirements

• 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.

• Specific requirements regarding devices emitting radiation. Radiation Act 592/1991, Radiation Decree 1512/1991 and Decree on Medical use of Radiation 423/2000

• No Specific requirements re ICF

J. Specific requirements

• 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

- 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.