ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK
IA-Integrating Activity

Regulatory and ethical requirements in medical devices studies

Iceland

SECTIONS

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

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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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B. Definitions/Legal basis

- For clinical research on medical device combined with medicinal products, same ethical and regulatory requirements apply as for research on medicinal products

- Requirements for clinical research on medical device are stated in Regulation on medical device 934//2010.

B. Definitions/Legal basis

Conventions/guideline/laws to apply

- Declaration of Helsinki
- ICH Guideline of EMA
- European Directive 2011/20/EC

B. Definitions/Legal basis

Acts to apply

- Act on Medical Devices No 6/2001

- Regulation on Medical Devices No 934/2010

- Health Sector Research Act No 44/2014

- Data Protection Act No 77/2000.

- Regulation-on-clinical-trials-of-medicinal-products-in-humans-no-443-2004 (for medical device combined with medicinal prodocts)

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C. Insurance

• For all interventional studies an insurance must be contracted for Patients/Subjects. The compensation sums covered by the insurance depends on the impact of interventoin

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D. Sponsor

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

- 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

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E. Investigators

- Investigator has to be a specialist in his field of research

- No GCP training is mandatory for investigator

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F. Competent Authority

Icelandic Medicines Agency (IMA)
Vínlandsleið 14
113 Reykjavík
Iceland

Phone 520 2100 - Fax 561 2170
ima@ima.is

F. Competent Authority

	Approval	
	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

F. Competent Authority – Initial submission

- Submission to Competent Authorities is the responsibiliy of Sponsor
- The submission to the Icelandic Medicines Agency is national: you only have to submit one dossier to the national competent authority
- The submission has to be on paper
- Application in English is accepted except documents aimed at the patient/subject
- Submission fees range from 2800-4200 Eur

F. Competent Authority – Initial submission

- In general, 60 days maximum to obtain approval

- No deadlines for submission, you can submit anytime

F. Competant Authority – Initial submission

Main documents required for submission:

- Submission letter
- Clinical Investigation Plan/Protocol
- Investigator's brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
- Insurance certificate
- List of the Competent Authority where protocol was submitted with their decision if available
- Study approval from administration department

F. Competent Authority – Initial submission

- No standard application form

F. Competent Authority - Vigilance

According to regulation 443/2004 on medicinal products in humans SAE is defined as:
“A damaging or unexpected reaction or effect where any dosage is fatal, life-threatening, disabling or incapacitating, results in a congenital defect or results in or prolongs hospitalisation.” The term SAE is used in regulation on medical devices without further definition.

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			x	x
Medical device alone with CE mark use outside label			x	x
Medical device alone without CE mark			x	x
Medical device combined with medicinal product with CE mark use within label			x	x
Medical device combined with medicinal product with CE mark use outside label			x	x
Medical device combined with medicinal product without CE mark			x	x
Observational studies with medical device			x	x

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

- The sponsor is responsible for the declaration to the Competent Authority
- No special forms are avalible for the declaration of AE
- It is not mandatory to notify the first patient enrolled to the Competent Authority

F. Competent Authority – Substantial amendment

- There is a specific procedure for submitting a substantial amendment to the Competent Authority

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G. Ethics Committee

1) The National Biotehics Committee (NBC)
Borgartun 21
105 Reykjavik
Iceland
Website: http://www.vsn.is/en
Phone: +354 5517100

2) 2 Local Institutional review boards:

- Institutional review board of Landspitali University Hospital
- Institutional reveiw board of Akureyri Hospital

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	
Observational studies with medical device	x	

G. Ethics Committee – Initial submission

- Sponsor is responsible of submission
- Depending on the study type the submission is sent to The National Bioethics Committee or one of two local institutional review boards.
- The submission has to be sent elcetronically
- Certain parts of the submission has to be in Icelandic (art. 3) also all documents aimed at patients/subjects. Other parts of submission can be in English.
- No submission fee
- In general, 35-60 days to obtain approval

G. Ethics Committee – Initial submission

Main documents required for submission:

Submission letter

- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Inform Consent Form and subject Information leaflet
- CV of PIs
- Copie of advertisement materials for research participant
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Insurance certificate
- Study approval from administration department

G. Ethics committee – Initial submission

Application forms available on NBC website. Different forms depending on study type. For studies on medical device form for general studies should be used. http://vsn.is/en/content/general-studies

For studies on medical device combined with medicinal product form for clinical trials should be used. http://vsn.is/en/content/application-form-and-checklist-clinical-trials

G. Ethics Committee - Vigilance

- SAE declaration by the sponsor:
  - If life in danger: 7 days
  - Other case: 15 days

- The sponsor needs to provide to the Ethics Committee an annual safety report

G. Ethics Committee - Vigilance

Events mandatory to declare to the competent authority:

	AE	ADE	SADE	SAE
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	x	x
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			x	x

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)

G. Ethics Committee - Vigilance

- The sponsor is responsible for the declaration of SAE's and SUSAR's to the Ethics Committee
- All SUSARS resulting in death or life threatning condition should be declared to EC within 7 days
- All other SUSAR's and SAE's should be declared to EC within 15 days

G. Ethics Committee - Notification

- It is not mandatory to notify the first patient enrolled to the Ethics Committee

G. Ethics Committee – Substantial amendment

• There is a specific procedure for submitting a substantial amendment to the Ethics Committee

(Submission of a dossier and waiting for approval)

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I. Healthy volunteers/Patients

J. Specific requirements

H. Data Protection

Data Protection Authority
Raudararstig 10
105 Reykjavik
Iceland

Tel: +354 5109600

postur@personuvernd.is

personuvernd.is

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	

H. Data Protection

Submissions to Ethics Committee are sent to Data Protection Authorities for review. DPA has 10 days to comment on the submission. DPA then sends the application back to EC who concludes the review process.

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J. Specific requirements

I. Healthy volunteers/Patients

• Special requirements are for children and individuals with limited ability to consent to participation.

• No special requirements are for healthy volounteers/patients except the right to be provided information before consenting to participation.

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J. Specific requirements

- No specific requirements to publish both positive and negative results of clinical studies in scientific journals

- Specific requirements/regulations regarding the ICF: needs to be given in writing

- No specific strategies for monitoring