Medical Devices - ICELAND

Competent authority

Contact Details

Contact Name 1

Icelandic Medicines Agency (IMA)

Phone

520 2100

Fax

561 2170

Email Department

clinical.trials@ima.is

Address

Vínlandsleið 14

ZIP/City

113 Reykjavík

Country

Iceland (IS)

Web address

http://www.ima.is

Additional Information

No local CA.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)
Agency for data protection

CA - Submission for authorisation mandatory for

Observational MD investigations
MD CE-marked, use within label + IMP
MD CE-marked, use outside label
MD CE-marked, use outside label + IMP
MD without label
MD without label + IMP

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA

CE-marked MD used within label are exempted from any notification obligation to CA

Yes

National legal framework in place

Yes

	Applicable national legal framework/ Reference Art 21 Regulation no. 934/2010 **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Manufacturer acting as sponsor Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 9 Act on MD no 16/2001 Art 21 Regulation no 934/2010
Submission Format	**Format option(s)** Letter **Preferred format** – **Standard application form available** No **Standard application form** No standard application form, application by letter.
Language of Submission	**Language(s) of application** Icelandic English **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –

Submission Fees	**Fees** Fee depends on categories regarding implantable vs non implantable, intervention vs non- intervention and long term vs short term use. Range: 400.000.-600.000 ISK (approx. 2800 EUR – 4200 EUR) Major changes in clinical testing of medical devices: 150.000 ISK (approx. 1053 EUR) Minor changes in clinical testing of medical devices: 25.000 ISK (approx. 175 EUR) **Waiver for academic (non-commercial) studies possible** Yes **Official guidance on required fees available** Yes **Official guidance on required fees** Tariff for evaluation of applications on clinical tests on medical devices nr. 1295/2013, available in Icelandic only. (Gjaldskrá vegna mats á umsóknum um klíníska prófanir á lækningatækjum nr. 1295/2013)
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Tacit (Silent) Explicit approval possible before expiration of time period **Timespan counted from** Date of submission of valid application **Applicable national legal framework/ Reference** Art 21 Regulation no. 934/2010 **Additional Information** 60-d period applies to Class IIa,b and III MD. Class I: Authorisation may be granted immediately after the date of notification, given that the relevant EC has issued its favourable opinion. NB! During summer holidays no clinical trial applications will be confirmed. The holidays are published on the IMA website in section Home > Licences > Clinical Trials > Application.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** All clinical investigations requiring authorisation by CA **Responsible for submission of SA** Sponsor Manufacturer acting as sponsor **Standard notification form available** No **Standard notification form** No special application forms, application is sent by letter. **Timeline for approval of SA (max nr days)** Not specified

Safety Reporting	**Responsible for AE reporting to CA** Manufacturer acting as sponsor **Sponsor must declare reportable events to** National CA CA(s) of EU&EFTA Member States concerned **Reportable AEs** SAE (Serious Adverse Event) **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSARs** – **SAE /SADE must be reported** Immediately (without delay) **National standard reporting form available** – **Reporting format - Options** – **Preferred format** – **Annual safety report shall be provided by sponsor to** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** Annex X, Art 2 Regulation no. 934/2010) **Additional Information** All SAEs must be fully recorded. **Investigator shall report SAE to** – **Reporting timeline** –
End of Trial	**End of trial declaration mandatory for** All clinical investigations requiring authorisation by CA **Responsible for End of trial declaration** Sponsor Manufacturer acting as sponsor **Regular Termination - Declaration timespan (max nr days)** No timeline specified in national law **Timespan counted from** –

Early/premature Termination - Declaration timespan (max nr days)

No timeline specified in national law

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

No

Standard Declaration form

No special form; should be announced by letter.

Applicable national legal framework/ Reference

Art 21 Regulation no. 934/2010

Additional Information

CAs of Member states of the EEA shall be also notified of the conclusion of a clinical investigation on MD.

Ethics committee

Contact Details

Contact Name 1

The National Bioethics Committee - NBC (Vísindasiðanefnd)

Phone

+354 5517100

Address

Borgartún 21

ZIP/City

101 Reykjavík

Country

Iceland (IS)

E-Mail

vsn@vsn.is

Web address

http://www.vsn.is/en

Ethical Review – General

Submission for Ethical review mandatory for

All scientific health research projects
All clinical investigations of MD

Submission to CA and EC to be performed in the following order

In parallel
Sequentially (in any order)

Regulatory and ethics bodies involved in approval process

–

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Central EC
Institutional EC

	Additional Information All scientific health research projects as well as applications concerning clinical trials shall be approved by the NBC or the local Institutional Review Boards local Institutional review board for ethical review pursuant to Art 12 Scientific Research Act 2014
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion) **Submission of application required to** Central EC (authorised to issue a single opinion)
Submission of Application	**Responsible for study submission** Not specified **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission** Guidance is provided on the webpage of the National Biotethics Committee regarding general studies.
Submission Format	**Format option(s)** – **Preferred format** – **Standard application form available** Yes **Standard application form** Application form to the NBC, Iceland: General study with active participation or a registry based study The form is available on the NBC website in section: General studies » Application form **Guidance on submission format available** Yes **Guidance on submission format** Guidance for application available on NBC website in section: General studies » Guidelines for applicants.
Language of Submission	**Language(s) of application** Icelandic English **Preferred language of application** – **English accepted** Yes

	Documents mandatory to be in official national language Information material, Documents and Forms intended for study participants and patient information Item A3 of application form (summary of study objective) + title of study **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** – **Additional Information** Related information available on NBC website in section: General studies » Application form + General studies » Guidelines for applicants.
Submission Fees	**Fees for Ethical review mandatory** No **Additional Information** The service of the committees is free of charge.
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** No timeline specified in national law **General timespan for multi-centre studies (max nr days)** No timeline specified in national law **External expert advice required: Timespan (max nr days)** – **Timespan counted from** – **Additional Information** Average processing time in 2015: 32 days
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** SA relating to aspects and documents that have been assessed by concerned EC(s) **Responsible for notification of SA** – **Timeline Ethical review of SA (max nr days)** – **Additional Information** No alterations to the nature or scope of a scientific study, nor any other major alteration, may be made unless previously approved by the NBC or HREC which approved the original research protocol. The NBC may determine that minor changes to a general scientific study are subject only to notification to the NBC or HREC, under rules to be issued by the NBC.
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) **Investigator shall report SAE to** –

	Reporting timeline – **Responsible for AE reporting to relevant EC(s)** – **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSAR must be reported** – **SAE/SADE must be reported** – **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** – **Additional Information** All SAEs must be fully recorded and immediately notified to all CAs of the Member States in which the clinical investigation is being performed. (Annex X, Art 2 Regulation no. 934/2010)
End of Trial	**End of trial Declaration mandatory** Not specified **Responsible for End of trial Declaration** – **Regular Termination - Declaration timespan (max nr days)** – **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** – **Additional Information** No special requirements or time limits.

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:** Yes
Investigator	**Entitled to be principal investigator** –

	Additional Information The investigation must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment (pursuant to Annex X, Regulation no. 934/2010)
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **IC is regulated by law** Yes **Informed Consent - Definition/ Requirements** "Consent shall be in writing and freely granted after the participant has been provided with adequate information on the study, risks it may entail, potential benefits, and the nature of the participation. The participant shall be informed that he/she may decline to take part in a scientific study, or withdraw from participation at any time after it commences, without stating any reason“ **Applicable national legal framework/ Reference** Art 18 Scientific Research Act 2014 **Additional Information** Related details including provisions applicable to vulnerable groups are set out in Section V (Art 18-24 Scientific Research Act 2014)
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply **Legal framework/Reference (Minors/Children)** Art 23 Scientific Research Act 2014 Detailed information is also provided on the NBC website in sections Home » Criteria » Vulnerable groups including Children. **Incapacitated persons - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Incapacitated persons)** Art 23 Scientific Research Act 2014 **Emergency situations - Studies allowed** – **Emergency situation without prior consent of patient or proxy - Studies allowed** Yes Special provisions apply

Conditions allowing trial participation in emergency setting without prior consent

In case that prior consent of the patient or of the next of kin can not be obtained, the study can be commenced if specific criteria are met:
a) patient's risk and burden are minor
b) patient is not opposed to participation
c) similar results cannot be achieved by research on individuals able to grant consent
d) the study is justified with regard to the potential for its findings being beneficial for the individual in question or individuals with the same disease, or promoting important preventive measure, diagnoses or cures
e) prior approval by the National Bioethics Committee or Institutional Review Board

Consent shall be obtained as soon as possible for continuation of the study.

Legal framework / Reference (Emergency Situation)

Art 24 Scientific Research Act 2014

Pregnant or breastfeeding women - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Pregnant or breastfeeding women)

Specific requirements for vulnerable groups (as described on the NBC website in sections Home » Criteria » Vulnerable groups including Children) also apply to pregnant women (Art 15 Scientific Research Act 2014)

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

Section V (Art 18-24) Scientific Research Act 2014

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

No specific provisions

Compensation is limited to/provided for

–

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

Yes

Approval/ authorisation required

Yes

Specific notification timelines before operations start

–

Language of notification

–

Notification format

–

Data Protection Authority/ Agency - Contact Details

Icelandic Data Protection Authority (Persónuvernd)

Phone

510 9600

	Fax 510 9606 **E-Mail** postur@personuvernd.is **Web address** http://www.personuvernd.is/information-in-english/ **ZIP/City** 105 Reykjavík **Country** Iceland (IS) **Additional Information** Pursuant to Art 13 Scientific Research Act 2014, the National Bioethics Committee (NBC) shall as soon as possible submit a summary of each application to the Data Protection Authority for approval. Data Protection Authority: shall issue an opinion and notify the NBE within 10 working days after receipt of the summary from the National Bioethics Committee. Processing of personal data is subject to the provisions of the Data Protection Act 2000. **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Sponsor Study participants **Responsible for covering insurance** Sponsor Principal Investigator (if no sponsor related to study) **Additional Information** Subjects participating in a clinical trial of a medicinal product must be sufficiently insured against conceivable damage to their health resulting from the trial. The principal investigator or, as the case may be, the investigator shall be responsible for ensuring satisfactory insurance coverage.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Optional **Audit by sponsor** Optional **Standard Operating Procedures (SOPs)** Optional
Archiving & Data Management	**Study documents must be kept at least (in years)** No timeline specified in national law

Additional Information

No specific provisions

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation

A list on the applicable legislation in English is provided on the websites of:
• IMA in section Home » IMA » Laws and Legislation AND
• NBC in section Home » The Bioethics Committee System » Legal Framework

Investigations on Medical Devices

Applicable national regulations

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Act on Medical Devices (or comparable national legal framework)

(1) Act on Medical Devices, No. 16/2001 as amended by Act No. 76/2002, Act No. 88/2008 and Act No. 28/2011.
This act includes provisions on safety requirements, labelling, instructions for use, treatment, clinical investigation and surveillance with medical devices. With Icelands participation in the EEA, the three EU directives (90/385/EEC, 93/42/EEC, 98/79/EC) came into effect.
(2) Regulation on Medical Devices No. 934/2010

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

(1) Act on Scientific Research in the Health Sector No. 44/2014 („Scientific Research Act 2014“).
It applies to scietific studies carried out, in whole or in part, in Iceland.

(2) Act on Patient Insurance, No. 111/2000, as amended:
Patients who suffer physical or mental damage in connection with examination or medical treatment in a hospital, health-care centre or other health institution are covered by this act.

Radiation & Radiotherapy

Use of radiation or radioactive compounds - Specific requirements

Yes

Applicable legal framework

Clinical trials on medical device involving radiaton are covered by:
Act on radiation protection No. 44/2002 and further described in Regulation No 640/2003 on radioactive protection regarding use of x-ray device, other than dental x-ray device, for medical radiaton.

Data Protection

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

National Data Protection Act

National DP act

Act on the Protection of Privacy as regards the Processing of Personal Data No. 77/2000 (The Data Protection Act 2000)
This act regulates the handling and processing of personal data in the context of scientific research clinical trials. It shall apply insofar as specific provisions of the Reg. 433/2004 do not take precedence.

Definition

MD/MD Investigation

MD - Definition available in national law

Yes

MD - Definition

Definition of MD is provided in Art 3 Act on MD no. 16/2001 and Art 2(1) Regulation no. 934/2010.
Definition of a 'Device intended for clinical investigation' is provided in Art 2(5) Regulation no. 934/2010.

Investigation of MD - Definition available in national law

Yes

Investigation of MD - Definition

Definition pursuant to Art 3 Act on MD no. 16/2001:
'Clinical investigation: means research on humans for the purpose of obtaining information and/or verifying that medical devices, in normal use, conform to basic requirements on characteristics and performance, as provided for in the EU Directives which form a part of the Agreement on the European Economic Area and the Convention establishing the European Free Trade Association. Clinical investigations include assessment of undesired side-effects of medical devices.

Additional Information

A device which forms part of a medical device, or which is in any other way connected with the use of a medical device shall also constitute a medical device.
A device which primarily has an effect on or in the human body by pharmacological, immunological or metabolic means does not constitute a medical device, although it may form a part of a medical device.
IMA will make the final decision on the classification, if it is unclear.