Medical Devices - HUNGARY

Competent authority

Contact Details	**Contact Name 1** Health Registration and Training Center (HRTC/ENKK) **Contact Name 2** Department of Medical Devices **Phone** +36 1 235-7914, +36 1 302-5060 **Fax** +36 1 235- 7912 **Email Department** amd@enkk.hu **Address** Mail: 1380 P.O. Box 1188 (Street: Zrinyi u. 3.) **ZIP/City** 1051 Budapest **Country** Hungary (HU) **Web address** http://www.enkk.hu **Additional Information** No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) **CA - Submission for authorisation mandatory for** Interventional MD investigations Observational MD investigations **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA **National trial registry** No official national register for clinical studies or healthy volunteers is availabe. Only devices combined with IMP need to be registered in a registry. (Not needed, if the integral part of the MD is a legally marketed medicinal product) **Applicable national legal framework/ Reference** The application should be sent to the OGYÉI and it will be forwarded by them to the Scientific and Research Ethics Committee (ETT-TUKEB).

	Additional Information If the drug constituent is an IMP, opinion of NIPN/OGYÉI as a Special authority is necessary! The HRTC will call upon the NIPN/OGYÉI for its opinion. If it is a legally marketed medicinal product, NIPN/OGYÉI approval is not required, the marketing authorization of medicinal product should be attached to the applicaton Special authority for Ethical approval: Medical Research Council- ETT TUKEB (NB! there is no possibility for preliminary opinion – the HRTC will call upon the TUKEB for its opinion) **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Sponsor Legal representative **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** Documentation is specified in Annex of Executive Decree No 235/2009. Documentation for non interventional studies is specified in Annex 4 of 23/2002 Decree of the Minister of Health **Additional Information** Sponsor can assign or transfer the responsibility for trial submission to another organization like CRO. So application for the approval can be submitted by the sponsor, the CRO or even the trial site in case of single site study. In the last two cases “Declaration of Authorization” is required.
Submission Format	**Format option(s)** Paper form or electronically: 2 identical copies (one of them could be in electronic format, on CD or DVD) **Preferred format** – **Standard application form available** No
Language of Submission	**Language(s) of application** Hungarian **Preferred language of application** – **English accepted** Full protocol, product information **Documents mandatory to be in official national language** Application letter, agreements concerning the Hungarian arrangement of the investigation (Declaration of Authorization, etc.), protocol summary/synopsis, patient information brochure, informed consent, product label/packaging, IFU (Instructions for Use)

	Documents mandatory to be in local language of study site – **Documents mandatory to be in language of the study participant** –
Submission Fees	**Fees for trial submission mandatory** Yes **Fees** Application for a clinical trial: 500.000 HUF Application for a non-interventional trial: 370.000 HUF Any substantial modification or amendment that requires a new opinion of Special authorities has the same fee as a new application. **Waiver for academic (non-commercial) studies possible** Not specified **Official guidance on required fees** Fees are provided on the ENKK/HRTC website in section Eljárási díjak (Service Fees) in Hungarian only. **Additional Information** All fees payable in advance of the procedure. Fees should be sent or transferred to the account of HRTC Account No. 10032000-00285788-00000000 (MÁK/Hungarian State Treasury) IBAN number: HU28 1003 2000 0028 5788 0000 0000. Bank: Magyar Nemzeti Bank Swift code: MANEHUHB
Timelines Authorisation	**General timespan (max nr days)** 60 (21 days without involvement of special authorities; max. 50 days including process of special authorities) **Mode of approval (General)** The study can be started if the CA do not have any written objection within 60 days after official receipt of application **Timespan counted from** – **Additional Information** Applications should be sent in 2 identical copies to the CA (HRTC/ENKK) at least 20 days prior to the next TUKEB meeting (timetable of TUKEB meeting provided on website) that sends one of them to the TUKEB (acting as special authority). TUKEB has 50 days. NB: There is no possibility for preliminary opinion of TUKEB! Combination studies (MD+ IMP): A second Special authority (NIPN) is involved. It has 50 days to express its opinion. (Please note that this interval starts when NIPM receives the application and HRTC will continue its procedure when the opinions of Special authorities arrive). The general rule is one single submission to the authority that sends the relevant documents to the EC for opinion.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** Any amendments - HRTC (CA) will decide whether it is a substantial or not **Authorisation mandatory for** Any substantial amendments

Responsible for submission of SA

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Timeline for approval of SA (max nr days)

60

Applicable national legal framework/ Reference

Art 35 Executive Decree No 235/2009

Additional Information

Timeline for the acceptance of a non substantial amendment: max. 21 days (has to be reported, but no fee! the study can be continued without interruption)

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

National CA
CA(s) of EU&EFTA Member States concerned

Reportable AEs

ADE (Adverse Device Effect)
SADE (Serious Adverse Device Effect)

SUSAR being life-thereatening or leading to death must be reported

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All other SUSARs

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SAE /SADE must be reported

Immediately, not later than 3d (SADE)
Immediately, not later than15d (Any other device deficiency that might have led to SADE)

National standard reporting form available

European standard SAE reporting form MEDDEV 2.7/3 to be used

Standard Reporting Form

The Guideline MEDDEV 2.7/3 should be taken into account.

Reporting format - Options

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Preferred format

–

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA (for interventional clinical investigations on MD: CE-marked, use within or without label & non-CE-marked devices)

Applicable national legal framework/ Reference

Art 22 Decree No 33/2009

Additional Information

SADE: to be reported in all investigations on MD (interventional and observational).
ADE shall be reported in investigations on: CE-marked devices, use outside label + non-CE-marked devices + respective combination studies with IMP.

In general, the Guideline MEDDEV 2.7/3 (responsibilities, timelines and format of report) should be taken into account.

Investigator shall report SAE to

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Reporting timeline

–

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

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Regular Termination - Declaration timespan (max nr days)

30

Timespan counted from

–

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

15

Standard Declaration form available

No

Applicable national legal framework/ Reference

Art 18 Decree No 33/2009

Additional Information

Final Report (two copies) of the Study should attached to the notification!
The acceptance of the EC is also necessary for the Final Report (Final Report is submitted to the EC via HRTC).

If the study cannot be finish until the planned ending date of the study indicated in the study plan, the applicants should notify the HRTC!

Ethics committee

Contact Details

Contact Name 1

Central Ethics Committee/ Public co-authority for MD investigations:

Contact Name 2

Scientific Research Ethics Committee of the Medical Research Council - ETT TUKEB

Phone

(+36 1) 795-1197; (+36 1) 795-1198

Fax

(+36 1) 795 0167

	Country Hungary (HU) **E-Mail** tukeb@emmi.gov.hu **Web address** http://www.ett.hu/tukeb.htm
Ethical Review – General	**Submission for Ethical review mandatory for** All clinical investigations of MD **Submission to CA and EC to be performed in the following order** Only one single submission required **Procedural interaction between CA and EC during approval process** Yes **Procedural interaction - Additional information** Application for trial authorization, amendments and end of trial declaration should only be submitted to the HRTC (CA) in 2 identical copies. HRTC sends a copy or relevant documents to TUKEB (EC). **Additional Information** The central ethics committees are officially appointed by law as public co-authorities (in the meaning of the general rules of public authority procedures). This is a specific Hungarian phenomenon. The opinion of the co-authority (the ethical approval in the given case) is binding for the decision-making authority. In the case of MD trials there can be two special authorities: ETT TUKEB, NIPN/OGYÉI (for combined products: MD+IMP). Both sould be called upon excusively by the HRTC! **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s)
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Central EC (appointed as co-authority) **Additional Information** Single-site clinical investigations with medical devices fall in the nationwide competence of TUKEB (acting as co-authority for ethical approval). Every clinical investigation with medical devices (even Non-Interventional Trials) conducted within the territory of Hungary falls in the competence of HRTC, and has to be approved by CA! NB! Submission only via CA (HRTC); there is no possibility of direct submisson to the EC (TUKEB)!
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (appointed as co-authority) **Submission of application required to** Competent Authority only (no direct submission to EC)

	Additional Information Multi-site clinical investigations with medical devices fall in the nationwide competence of TUKEB (acting as co-authority for ethical approval). Every clinical investigation with medical devices (even Non-Interventional Trials) conducted within the territory of Hungary falls in the competence of HRTC, and has to be approved by CA! NB! Submission only via CA (HRTC); there is no possibility of direct submisson to the EC (TUKEB)!
Submission of Application	**Responsible for study submission** – **Entitled to study submission** – **Prerequisites for submission / approval** – **Additional Information** NB! Submission only via HRTC. There is no possibility of direct submisson to the EC! In the case of direct submisson to the EC, the TUKEB would send it back to the HRTC, which could elongate the procedure.
Submission Format	**Format option(s)** – **Preferred format** – **Additional Information** NB! Submission only via HRTC. There is no possibility of direct submisson to the EC! In the case of direct submisson to the EC, the TUKEB would send it back to the HRTC, which could elongate the procedure.
Language of Submission	**Language(s) of application** Hungarian **Preferred language of application** – **English accepted** Full protocol, product information **Documents mandatory to be in official national language** Application letter, agreements concerning the Hungarian arrangement of the investigation (Declaration of Authorization, etc.), protocol summary/synopsis, patient information brochure, informed consent, product label/packaging, IFU (Instructions for Use) **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –

	Additional Information NB! Submission only via HRTC. There is no possibility of direct submisson to the EC!
Submission Fees	**Fees for Ethical review mandatory** Yes **Fees for Ethical review** Submission fee required for all clinical investigations on MD (info identical to CA fees). Fee of TUKEB (reviewing EC) opinion is included in the submission fees provided in section CA! **Additional Information** NB! Submission only via HRTC. There is no possibility of direct submisson to the EC!
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 50 **General timespan for multi-centre studies (max nr days)** 50 **External expert advice required: Timespan (max nr days)** – **Timespan counted from** – **Additional Information** Applications should be sent in 2 identical copies to the CA (HRTC/ENKK) at least 20 days prior to the next TUKEB meeting (timetable of TUKEB meetings provided on the website). The CA sends a copy to TUKEB for Ethical review. The study can be started if the CA do not have any written objection within 60 days after official receipt of application. NB! Submission only via HRTC. There is no possibility of direct submisson to the EC! In the case of direct submisson to the EC, the TUKEB would send it back to the HRTC, which could elongate the procedure.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** – **Timeline Ethical review of SA (max nr days)** – **Additional Information** NB! Substantial amendments shall be submitted for Ethical review and authorisation via CA !

Safety Reporting	**Adverse Events (AE) - Definitions (pursuant to national law)** An adverse reaction or an adverse event is serious when the administration of any dose from the investigational medicinal product is followed by the death, danger of death, hospital treatment, prolongation of hospital treatment in progress, enduring or substantial health detriment, disability or congenial disorder or birth malfunction of the subject. **Reportable AEs** SADE (Serious Adverse Device Effect) **Investigator shall report SAE to** – **Reporting timeline** – **Responsible for AE reporting to relevant EC(s)** Sponsor **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSAR must be reported** – **SAE/SADE must be reported** Immediately, not later than 3d (SADE) Immediately, not later than15d (Any other device deficiency that might have led to SADE) **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** – **Provision of Annual safety report mandatory** Yes **Additional Information** Annual Safety report must be provided to EC for clinical investigations on: MD CE-marked use within and outside label, MD without label, respective combination studies with IMPs. Regarding the AE reporting obligations, the Guideline MEDDEV 2.7/3 (responsibilities, timelines and format of report) shall be taken into account.
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** – **Regular Termination - Declaration timespan (max nr days)** – **Timespan counted from** –

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

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Additional Information

End of trial declaration via HRTC (CA)!
Final Report (two copies) of the Study should be attached to the notification.
The acceptance of the EC is necessary for the Final Report (Final Report is submitted to the EC via HRTC).

If the study cannot be finish until the planned ending date of the study indicated in the study plan, the applicants should notify the HRTC!

Study specific Requirements

Sponsor

Sponsorship mandatory - Additional information

It is mandatory to have a sponsor in all clinical investigations of MD (CE-marked MD use outside label , non-CE-marked MD, respective combination studies with IMP).

It is not obligatory to have a sponsor for Non-Interventional Trials; they can be “unsponsored”, inicialized and conducted by the healthcare provider.

However the fee should be payed prior to the process, regardless of sponsorship, if the study results can be used for marketing purposes!

Investigator

Entitled to be principal investigator

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Additional Information

GCP Training: Mandatory for combination studies (investigations on MD including IMPs) -only Medical University-organized GCP training accepted.
Qualification of investigator in all investigations on MD: Specific board exam required.
Any personnel requirements are specified in Annex of Decree No 33/2009.

Study Participants - Informed Consent (IC)

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

Informed Consent is covered in Art 6 Decree No 35/2005 and Art 10 Decree No 33/2009 of the Minister of Health in detail.
Specific requirements for the consent form are provided in Art 10 (5) Decree No 33/2009 of the Minister of Health.

Applicable national legal framework/ Reference

Art 6 Decree No 35/2005
Art 10 Decree No 33/2009

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Specific provision

Main criteria: the investigation is directly related to the clinical condition of the child, or is nature, and can only be carried out on minors; legal representative gave consent or the child him/herself

Legal framework/Reference (Minors/Children)

Art 11 Decree No 33/2009 of the Minister of Health

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Art 12-15 Decree No 33/2009 of the Minister of Health

Emergency situations - Studies allowed

Yes
Special provisions apply

Emergency situation without prior consent of patient or proxy - Studies allowed

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Legal framework / Reference (Emergency Situation)

Art 13 & 15 Decree No 33/2009 of the Minister of Health

Pregnant or breastfeeding women - Studies allowed

Not specified

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Optional

Compensation is limited to/provided for

Expenses arising from study participation (e.g. Travel)

Additional Information

Compensation for income loss related to participation in the study, as well as costs, particularly in the context of travel or other extra costs are allowed (pursuant to Art 9(10) Decree No 33/2009).
Accordingly, travel/food reimbursement are acceptable as compensation for subjects (patients or healthy volunteers) participating in a clinical research.

Study Participants - Recruitment & Trial Outcome

Mandatory to inform participant of clinical trial outcome

No

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

No

Specific notification timelines before operations start

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Language of notification

–

Notification format

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Data Protection Authority/ Agency - Contact Details

Hungarian National Authority for Data Protection and Freedom of Information / Nemzeti Adatvédelmi és Információszabadság Hatóság

Phone

+36 -1-391-1400

Fax

36-1-391-1410

	E-Mail privacy@naih.hu **Web address** http://www.naih.hu/ **Address** Szilágyi Erzsébet fasor 22/C. **ZIP/City** 1125 Budapest **Country** Hungary (HU) **Additional Information** National Authority for Data Protection can launch an official data protection procedure if the illegal processing of personal data is presumed. **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** Study participants **Responsible for covering insurance** – **Insurance fee: A minimum coverage sum is defined** No **Additional Information** No mandatory insurance for sponsors, investigators, manufacturers for all categories of clinical investigations of MD.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Optional **Audit by sponsor** Optional **Standard Operating Procedures (SOPs)** Optional **Additional Information** ad Monitoring: HRTC (CA) has the right to inspect or monitor any clinical trials conducted with medical devices
Archiving & Data Management	**Study documents must be kept at least (in years)** 5 **Additional Information** The Clinical study documentation is a part of the Technical documentation of the Medical device! The Technical documentation has to be kept in evidence by the manufacturer at least 5 years after manufacturing the last device(s).

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation

Health Registration and Training Center (HRTC/ENKK): The website provided information on national legislation (in Hungarian)

Official governmental legal database

“Nemzeti Jogszabálytár”: the official public source of national legislation (according to the Hungarian Act CXXX. of 2010). Acts and Decrees are available only in Hungarian.

Investigations on Medical Devices

Applicable national regulations

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Act on Medical Devices (or comparable national legal framework)

Decree No 33/2009 (of 20 October 2009) of the Ministry of Health on clinical investigations with medical devices.

Transposition of Directive 93/42/EEC

Decree No 4/2009 (of 17 March 2009) of the Ministry of Health on Medical Devices (available in Hungarian only). The Hungarian law adopted the 93/42/EEC Directive

Transposition of Directive 98/79/EC

Decree No 8/2003 (of 13 march 2003) of the Ministry of Health, Social and Family Affairs on the in-vitro diagnostic medical devices.
The Hungarian law adopted the 98/79/EC Directive.

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

Authorisation Procedures:
• Executive Decree No 235/2009 (of 20 October 2009) on rules governing authorisation procedures of biomedical research, clinical trials with investigational medicinal products for human use as well as clinical investigations on medical devices intended for human use.

Combination Studies:
• Decree No 35/2005 (of 26th August 2005) EüM of the Minister of Health on the clinical trial of investigational medicinal products for human use and on the application of the good clinical practice (as amended). (This does not apply, if the integral part of the MD is a legally marketed medicinal product!)

Non-interventional clinical investigations/ trials:
• Decree 23/2002 (of 9th May 2002) of the Minister of Health on biomedical research on human individuals (as amended):
The „Decree“ is applicable to non-interventional clinical trials with IMPs and Non-Interventional Trials on Medical Devices: Art 20/A- 20/S

EC operations/ Fees

Separate legal framework available

Yes

Applicable legal framework

Medical Research Council/ Ethics Committees:
Decree 28/2014. (IV. 10.) of the Minister of Human Capacities

Definition

MD/MD Investigation

MD - Definition available in national law

Yes

MD - Definition

Definitions of MD are provided in Article 2 (1) a) of Decree No.33 of 2009

Investigation of MD - Definition

• Clinical investigations on MD:
Investigations on CE-marked MD used outside label, non-CE-marked MD, and respective combination studies with IMPs.

Combination study on CE-marked MD used within label + IMP depends on study aim and could be a Non-Interventional Trial or a Clinical Trial with IMP, that is out of the competence of HRTC.

• Non-Interventional trial on MD:
Investigations on CE-marked MD used within label; observational investigations on MD

NB! According to the Article 2 (1) a) of Decree No.33 of 2009 (October 20) of the Minister of Health Clinical Investigation cannot be performed on a device bearing CE marking, unless the aim of this investigation is to use the device for a purpose other than that referred to in the relevant assessment procedure.
If the trial to be conducted on a device bearing CE mark and the aim of the investigation is only collection and processing data originated from the application(s) that same as the intended purpose(s) referred in the related conformity assessment procedure, the study according to the Government decree 235/2009 (X.20.) Art. 16. is a Non-Interventional Trial.

Additional Information

MD Registry:
There is no obligation for registering medical devices in Hungary separately, if the device is already registered (applicable for the class I MD-s) by one of the national authorities of EU countries and/or certified (applicable for the class IIa, IIb and III MD-s, and AIMD-s) by a Notified Body (that means the devices are legally bearing CE mark). HRTC registers MD-s that their manufacturer or EC rep based within the territory of Hungary.
Registration of the IVD products already registered or certified in the EU, is possible (because of tax purposes). This is an optional process, that has a fee. (17000 Ft)