Medical Devices - PORTUGAL

Competent authority

Contact Details

Contact Name 1

INFARMED- National Authority of Medicines and Health Products, IP/ Autoridade Nacional do Medicamento e Produtos de Saúde I.P.;

Contact Name 2

(Government agency accountable to the Health Ministy)

Contact Name 3

Health Products Directorate

Phone

+351 21 798 7235

Fax

+351 21 798 7182

Email Department

daps@infarmed.pt

Address

Parque de Saúde de Lisboa Avenida do Brasil, 53

ZIP/City

1749-004 Lisboa

Country

Portugal (PT)

Web address

http://www.infarmed.pt/

Additional Information

The English web pages contain selected items from its Portuguese language site and will be continuously expanded.

No local CAs.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
National Ethics Committee
Other
Regulatory and ethics bodies involved in approval process: Competent Authority- Infarmed; National Ethics committee (CEIC); Recruiting sites: Administration Board and Local Ethical Committee

CA - Submission for authorisation mandatory for

Active Implantable Medical Devices (AIMD)
MD without label
MD Class IIa
MD Class IIb
MD Class III
CA - Submission for authorisation mandatory for: Class IIa, IIb used for long periods of time; Class III; Invasive/ Active Implantable; Without CE label

CA - Registration/ notification without approval required for

Performance evaluations of in-vitro diagnostic MDs
MD Class I
MD Class IIa
MD Class IIb
CA - Registration/ notification without approval required for: Class I, IIa and IIb (use for short periods of time); In Vitro Diagnostic

CA - Submission required to

National CA
Other
Infarmed, CEIC (national ethical committee), recruiting sites: administration boards and local ethical committees

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 33 Law 21/2014 (pt)
Art 12 DL 145/2009 (pt))

Additional Information

Submission to CA and EC to be performed in the following order: In parallel

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

In parallel
Sequentially (in any order)

Submission of Application

Responsible for study submission

Sponsor
Other
Sponsor or other organization designated by sponsor

Entitled to study submission

–

Prerequisites for submission

–

Guidance on submission of application

Detailed guidance for the applicant on trial submission and the definite structure of documentation is provided at INFARMED website (1). There is a File to be uploaded with all documents that must be submitted " Estrutura de organização de pastas conforme Instruções ao requerente".

At RNEC website, after sponsor is registered in the platform, there is also a tutorial for on-line submission. RNEC (National Registry of Clinical Studies) http://www.rnec.pt/pt. RNEC has a private area with registered users to submit studies and manage the process approval and also a public area where it is possible to search for registered studies in Portugal since January 2017

All the information is available only in Portuguese. For further guidance an email is available: daps@infarmed.pt
Link
(1) http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/submissao_infarmed

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 25-27 Law 21/2014 (pt)
Annex VIII and Annex XV, DL 145/2009 (pt)

Submission Format	**Format option(s)** Electronically Mandatory online submission through RNEC: https://www.rnec.pt/ **Preferred format** Online portal **Standard application form available** Yes **Standard application form** Annex 1- Clinical Trial Application Form https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/application-form2009_en.pdf **Standard application form - Additional information** At Infarmed website there is a Zip File with all the files that must include documents to be submitted to CA through RNEC (on-line) as described above. http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/submissao_infarmed **Guidance on submission format available** Yes **Guidance on submission format** There is a Flowchart and Support slides describing the process and the needed documents to be submitted (Apresentação de Apoio - Ensaios Clínicos: Documentação e Boas Práticas Regulamentares - setembro 2017) Link: http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/submissao_infarmed and at https://www.rnec.pt/pt/submissao-nacional **Applicable national legal framework/ Reference** Art 25-27 Law 21/2014 (pt)
Language of Submission	**Language(s) of application** Official national language Portuguese English **Preferred language of application** – **English accepted** Partly, not for all documents For official application documents and scientific documents only **Documents mandatory to be in official national language** Cover letter Protocol Summary Information material, Documents and Forms intended for study participants and patient information Documents mandatory to be in official national language: Cover Letter; Synopsis of the Protocol; Informed consent; MD label; Patient card; Any applicable scales **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** Fees for the authorization of • MD without CE marking or with CE marking for other indication: 600,00 € • MD with CE marking: 400,00 € • Substantial amendment to protocol: 200,00 € NB! Status 2015 - Fees are being revised annually Academic Studies: No submission fees. **Waiver for academic (non-commercial) studies possible** Yes **Applicable national legal framework/ Reference** Portaria nº63/2015 (Fee Ordinance) Related information plus currently applicable Fee Ordinance (Portaria) is available on the INFARMED website in section Taxas (in Portuguese only).
Timelines Authorisation	**General timespan (max nr days)** 30 **Mode of approval (General)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 33 Law 21/2014 (pt) **Additional Information** Submission to INFARMED and CEIC are simultaneous at RNEC. Submission to Health Units and respective Ethical Committee are done at the same time. A DPO in each Health Unit is responsible for assuring the compliance of data protection procedures with GDPR.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** All clinical investigations requiring authorisation by CA Any substantial amendments to the study protocol Authorisation mandatory for: All clinical trials approved by Infarmed and CEIC (National Ethics Committee); Change in MD – Infarmed; Change in inclusion/exclusion criteria – Infarmed & CEIC

Responsible for submission of SA

Sponsor
Substantial Amendment Notification Form - Cf. Section 3.7.b of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the

Standard notification form

Standard Notification form to be used by the applicant is the same as used for IMP studies and is provided on the INFARMED website in section Medicamentos Uso Humano> Ensaios Clinicos> Formulários:
“Substantial Amendment Notification Form (pdf)”/ “Formulário de pedido de alteração (pdf)”

Timeline for approval of SA (max nr days)

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Applicable national legal framework/ Reference

Art 4, Deliberação n.º 514/2010, de 3 de Março
Art 18 Law 21/2014 (pt)

Additional Information

Substantial amendments shall be simultaneously notified to the competent EC and the national CA.

Safety Reporting

Responsible for AE reporting to CA

Sponsor
Other
Sponsor or other organization designated by sponsor

Sponsor must declare reportable events to

Competent Authority
CA(s) of EU&EFTA Member States concerned
Relevant EC(s)

Reportable AEs

SAE (Serious Adverse Event)
SADE (Serious Adverse Device Effect)
Device deficiency, potentially leading to SAE

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

–

All other SUSARs

–

SAE /SADE must be reported

Within a max of 2 d upon first knowledge for events being fatal, life-threatening, or deteriorating health
As soon as possible, within a max of 7d upon first knowledge (for other AEs or AEs related to MD deficiencies, potentially leading to a SAE)

National standard reporting form available

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

Standard Reporting Form

SAE reporting form: Appendix of MEDDEV 2.7/3

Reporting format - Options

Trials not submitted through RNEC (before January 2016): On-line: Format ICH E2B/EudraVigilance CIOMS Form to email: farmacovigilancia.ec@infarmed.pt
Trials submitted through RNEC (after January 2016): DSURs submitted through RNEC

Preferred format

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Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
Relevant EC(s)

Applicable national legal framework/ Reference

The reporting timelines are according to Art 22 Law 21/2014 (pt), Annex XVI (23) DL 145/2009 (pt) and in line with the EC's guidance document MEDDEV 2.7/3 on SAE reporting in clinical investigations under directives 90/385/EEC and 93/42/EC)
Art 22 (10) Law 21/2014 (pt) (Annual Safety Report)

Additional Information

An Annual Safety report is mandatory for clinical investigations of MD requiring authorisation by CA.
Given reporting timelines apply to all clinical investigations of MD.

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (not later than 24h)
Followed by detailed written report within 5d

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

Last patient - last visit in the respective country

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

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

Declaration of the End of Trial Form (cf. Section 4.2.1 of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial CT-1)

Applicable national legal framework/ Reference

Art 19 Law 21/2014 (pt)
Art 16 DL 145/2009 (pt)

Ethics committee

Contact Details

Contact Name 1

National Ethics Committee for Clinical Research/ Comissão de Ética para a Investigação Clínica (CEIC)

Phone

+351 21 798 53 40

Fax

+351 21 798 72 09

Address

Parque da Saúde de Lisboa Av. do Brasil, 53 - Pav. 17-A

ZIP/City

1749-004 Lisboa

Country

Portugal (PT)

E-Mail

ceic@ceic.pt

Web address

http://www.ceic.pt

Additional Information

Local ECs: There are almost 100 institutional ECs (public and private, health and academic).

Ethical Review – General

Submission for Ethical review mandatory for

All types of medical devices

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

In parallel
Sequentially (in any order)

Additional Information

Guidance on documents that will be evaluated by CEIC Experts might be found at CEIC Website: http://www.ceic.pt/documentos-submissao
and at RNEC: https://www.rnec.pt/pt/submissao-nacional

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
National Ethics Committee
Other
Regulatory and ethics bodies involved in approval process: Competent Authority- Infarmed; National Ethics committee (CEIC); Recruiting sites: Administration Board and Local Ethical Committee

Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Central EC **Additional Information** The National Research Ethics Committee (CEIC) is responsible for assessing Clinical Trial applications, though it may delegate to a research ethics committee established by a local health institution, hospital or clinical trial site.
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) **Additional Information** Central EC: the National Research Ethics Committee – CEIC Regulatory and ethics bodies involved in approval process • Competent Authority- Infarmed • National Ethics committee (CEIC) • Recruiting sites: Administration Board and Local Ethical Committee
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission** The required documentation for EC application is provided in Deliberação n.º 514/2010, de 3 de Março National Ethics Committee (CEIC) - Same as the one described above for Infarmed, but more details about the documents evaluated by CEIC experts are provided at CEIC Website: http://www.ceic.pt/documentos-submissao and at RNEC: https://www.rnec.pt/pt/submissao-nacional Local Ethics Committees have specific Forms to fill-in and the same documents evaluated by CEIC.
Submission Format	**Format option(s)** Online portal Online through RNEC **Preferred format** – **Guidance on submission format** The required documentation for EC application is provided in Deliberação n.º 514/2010, de 3 de Março National Ethics Committee (CEIC) - Same as the one described above for Infarmed, but more details about the documents evaluated by CEIC experts are provided at CEIC Website: http://www.ceic.pt/documentos-submissao and at RNEC: https://www.rnec.pt/pt/submissao-nacional

Language of Submission	**Language(s) of application** Portuguese English **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Cover letter Protocol Summary Information material, Documents and Forms intended for study participants and patient information Labels Other Documents mandatory to be in official national language: Cover Letter; Synopsis of the Protocol; Informed consent; MD label; Patient card; Any applicable scales **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Submission Fees	**Fees for Ethical review mandatory** No **Fees for Ethical review** No fee is directly charged by CEIC (INFARMED I.P, charge sponsors according to a scale of fees. CEIC are funded by INFARMED I.P.) Local institutional ECs have no funding and do not charge fees.
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 30 **General timespan for multi-centre studies (max nr days)** 30 **External expert advice required: Timespan (max nr days)** – **Timespan counted from** –
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to the study protocol Any substantial amendments (concerning investigator, trial site, informed consent) Any substantial amendments to the study protocol, the informed consent or strategy for trial advertisement **Responsible for notification of SA** Sponsor **Timeline Ethical review of SA (max nr days)** –

Applicable national legal framework/ Reference

Art 4, Deliberação n.º 514/2010, de 3 de Março (pt)
Art 18 Law 21/2014 (pt).

Additional Information

Substantial amendments to the study plan shall be simultaneously notified to the competent EC and the national CA

Safety Reporting

Adverse Events (AE) - Definitions (pursuant to national law)

SAE: Any untoward occurrence that may led to death or led to serious deterioration in the health of the subjects, according to Art 3, DL 145/2009 (pt).

Reportable AEs

SAE (Serious Adverse Event)
Device deficiency, potentially leading to SAE

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (not later than 24h)
Followed by detailed written report within 5d

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

Within a max of 2 d upon first knowledge for events being fatal, life-threatening, or deteriorating health
As soon as possible, within a max of 7d upon first knowledge (for other AEs or AEs related to MD deficiencies, potentially leading to a SAE)

National Standard Reporting form available

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

Standard Reporting Form

The standard SAE reporting form: Appendix of MEDDEV 2.7/3.

Reporting format - Options

Online portal
On-line through RNEC

Preferred reporting format

–

Provision of Annual safety report mandatory

Yes

National legal framework in place

Yes

	Applicable national legal framework/ Reference The reporting timelines are according to Art 22 Law 21/2014 (pt), Annex XVI (23) DL 145/2009 (pt) and in line with the EC's guidance document MEDDEV 2.7/3 on SAE reporting in clinical investigations under directives 90/385/EEC and 93/42/EC) **Additional Information** An Annual Safety is mandatory for clinical investigations of MD requiring authorisation by CA and Ethical approval and shall be submitted to the competent EC and the national CA.
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 90 **Timespan counted from** Last patient - last visit in the respective country **Early/premature Termination - Declaration timespan (max nr days)** 15 **Reasons for early termination shall be clearly stated** Yes **Standard Declaration form** Declaration of the End of Trial Form (cf. Section 4.2.1 of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial CT-1) **Applicable national legal framework/ Reference** Art 19 Law 21/2014 (pt) **Additional Information** The final report must be submitted to the EC within 12 month after trial termination.

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Sponsorship mandatory - Additional information** It is mandatory to have a sponsor in all clinical investigations of MD. **Co-sponsorship allowed** No
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **IC is regulated by law** Yes

Informed Consent - Definition/ Requirements

The Portuguese definition for informed consent and its related provisions (“Consentimento livre e esclarecido”) are provided in Art 3.m) and Annex XVI (15). DL 145/2009 (pt)

Applicable national legal framework/ Reference

Art 3.m) and Annex XVI (15) DL 145/2009 (pt) - Definition
Annex XVI (16) & (17) DL 145/2009 (pt) and Art 7 & 8 Law 21/2014 (pt) - Vulnerable population

Additional Information

Specific provisions apply to vulnerable persons such as minors and adults incapable of giving informed consent according to Annex XVI (16) & (17) DL 145/2009 (pt) and Art 7 & 8 Law 21/2014 (pt)

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Specific provision

Minors aged above 16 years: informed consent must be obtained from the minor and his his legal representative.
Minors aged less than 16 years: the representative is the sole responsible for grating informed consent, although it must reflect the presumed will of the minor.

(The concerned EC is given the right, under exceptional circumstances, to waive the requirements of informed consent and informing the minor patients in clinical studies without intervention. The assigned ethic committee is given the same right for adults unable to provide informed consent.)

Legal framework/Reference (Minors/Children)

Annex XVI (16) DL 145/2009 (pt) and Article 7 Law 21/2014 (pt)

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Annex XVI (17) DL 145/2009 (pt)

Emergency situations - Studies allowed

Special provisions apply
No national legal framework available

Specific provisions

Clinical investigations involving subjects in emergency situations are not explicitly mentioned in Portuguese law.
However, the same standards apply as for investigations with minors and incapacitated persons.
Any provisions on the protection of human subjects must conform to the spirit of the Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, and all phases of clinical investigations must be conducted in that spirit, from first consideration of the need and justification of the study to publication of results

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

–

Pregnant or breastfeeding women - Studies allowed

Special provisions apply
No national legal framework available

Specific provisions

Clinical trials involving pregnant or lactating women are not explicitly mentioned in Portuguese law.
However, the same standards apply as for investigations with minors and incapacitated persons.
Any provisions on the protection of human subjects must conform to the spirit of the Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, and all phases of clinical investigations must be conducted in that spirit, from first consideration of the need and justification of the study to publication of results

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

Annex XVI (16) & (17) DL 145/2009 (pt) and Art 7 & 8 Law 21/2014 (pt)

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

No

Approval/ authorisation required

No

Specific notification timelines before operations start

–

Language of notification

Official National Language(s)
English accepted

Notification format

Other
Every Health Unit has a DPO. The Notification Format depends on each institution requirements

Guidance on notification requirements

Still not yet for all institutions

Phone

+351 213928400

Fax

+351 213976832

E-Mail

geral@cnpd.pt

Address

Rua de São Bento n.º 148-3º

ZIP/City

1200-821 Lisboa

Country

Portugal (PT)

Additional Information

With the new GPPR, national DP authority (CNPD) is only responsible for auditing when a complain on data breach is formalized

	Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files) GDPR **National DP act** Under revision (information accurate as of July 2019)
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Sponsor Study participants **Responsible for covering insurance** – **Insurance fee: A minimum coverage sum is defined** No **Applicable national legal framework/ Reference** Art 15 & 16 Law 21/2014 (pt) Art 14, Annex VIII and Annex XVI (15f) DL 145/2009 (pt) **Additional Information** Insurance obligation applies to interventional investigations of MD (MD CE-marked, use within or without label, MD without label, respective combination studies with MP).
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Optional **Audit by sponsor** Optional **Standard Operating Procedures (SOPs)** Optional **Additional Information** NB: There are no specifications in the law.
Archiving & Data Management	**Study documents must be kept at least (in years)** 5 years (15 years regarding implantable medical devices) **Additional Information** All relevant information regarding the medical device, including the Statement, must be kept for inspection purposes.

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** A list of applicable Portuguese legislation is available on the INFARMED website via: Legislação> Legislação Farmacêutica Compilada> TÍTULO V - Produtos de Saúde> Cap II - Dispositivos Médicos

Investigations on Medical Devices	**Applicable national regulations** – **Act on Medical Devices (or comparable national legal framework)** Decree-Law No. 145/2009, 17 June as amended, concerning medical devices and active implantable medical devices/ Decreto-Lei n.º 145/2009, de 17 de Junho, hereafter referred to as 'DL 145/2009 (pt)'. It is the transposition of Directives 93/42/CEE, 90/385/CEE and 2007/47/CE into national law. **Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** (1) Law on clinical research Law 21/2014 (pt), published 16 April 2014 in the Official Gazette (Diário da República): repeals Law 46/2004 of 19 August 2004 (Clinical Trials on Medicinal Products for Human Use) that incorporated the principles of the Clinical Trials Directive 2001/20/EC. This law covers all clinical research with humans including not only clinical trials with IMP but also investigations with MD and all kind of observational studies. It also regulates the organization of the Comissão de Ética para a Investigação Clínica / National Ethics Committee for Clinical Research (CEIC). (2) Law 73/2015 of 27th July is an amendment to Law 21/2014 and sets the conditions in which monitors, auditors and inspectors have access to the registries of clinical studies' participants.
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** GDPR **National DP act** Under revision (information accurate as of July 2019)

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **MD - Definition** Definitions for Medical Devices (intended for clinical investigations) are given in Article 3, DL 145/2009 (pt). The classification criteria for class I, IIa, IIb, III Medical Devices are provided in Art 4 & Annex IX of DL 145/2009 (pt). **Additional Information** The related definitions and classifications are also available in EN on the INFARMED website in section: Dispositivos Médicos