Nutrition/Interventional - PORTUGAL

Competent authority

Contact Details	**Contact Name 1** Health Products Directorate **Phone** +351 21 798 7283 **Fax** +351 21 798 7248 **Email General** cimi@infarmed.pt **Email Department** ensaios.clinicos@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** Email: cimi@infarmed.pt (general information on clincial trials); ensaios.clinicos@infarmed.pt (information on procedures). The English web pages contain selected items from its Portuguese language site and will be continuously expanded. No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Ethics Committee Agency for data protection **Regulatory and ethics bodies involved in approval process for trials including patients** – **Regulatory and ethics bodies involved in approval process for trials including including healthy participants** – **Regulatory and ethics bodies involved in approval process for trials including vulnerable population** – **CA - Registration/ notification without approval required for** –

CA - Registration requirements for clinical trials

Not applicable

Registration requirements for clinical trials including patients

–

Registration requirements for clinical trials including healthy participants

–

Registration requirements for clinical trials including vulnerable population

–

CA - Submission required to

National CA
Institutional CA

Studies including patients - submission required to

–

Studies including healthy participants - submission required to

–

Studies including vulnerable population - submission required to

–

Submission Format

Standard application form available

No

Standard application form

INFARMED - Portuguese Authority of Medicines and Health Products, created The National Platform for Clinical Trials (PNEC), the portal contains the most important information relating to Clinical Trials in Portugal (from applicable legislation to data on approved trials). This portal is open to all interested persons who may register on it to gain access to all the data introduced by all the other registered individuals and organisations. Soon, the portal will provide access to an electronic submission tool for clinical trials authorisation applications and their amendments, for requests relating to the approval procedures for clinical trials being reviewed by the regulatory authorities, and for the selection and appropriateness of clinical trial-related information, thus avoiding duplication.

Language of Submission

Language(s) of application

Not specified

Language(s) of application for trials including patients

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Language(s) of application for trials including healthy participants

–

Language(s) of application for trials including vulnerable population

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Preferred language of application

–

English accepted

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Documents mandatory to be in official national language

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Documents mandatory to be in local language of study site

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Documents mandatory to be in language of the study participant

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Ethics committee

Contact Details

Contact Name 1

National Ethics Committee for Clinical Research (CEIC)

Web address

http://www.ceic.pt

Additional Information

There is only one EC (the CEIC) that is responsible for assessing Clinical Trials Investigational Medicine Products applications. Additionally, a research ethics committee established by the local health institution also may want to provide its authorization.

Ethical Review – General

Submission for Ethical review mandatory for

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Submission of study mandatory

Yes

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

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National declaration on Ethical requirements exists

No

National declaration

only for pharmaceuticals

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Institutional EC

Ethical approval (favourable opinion) for trials including patients to be obtained from

–

Ethical approval (favourable opinion) for trials including healthy participants to be obtained from

–

Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from

–

Submission of Application

Entitled to study submission

Sponsor
Principal Investigator
Investigator
Physician

	Entitled to submission of trials including patients – **Entitled to submission of trials including healthy participants** – **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** No **Standard application form** only for pharmaceuticals

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Co-sponsorship allowed** Yes
Investigator	**Entitled to be principal investigator** Physician **Entitled to be principal investigator for trials with patients** – **Entitled to be principal investigator for trials with healthy participants** – **Entitled to be principal investigator for trials with vulnerable population** –
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** No **Accepted format of Informed Consent (IC) form** Written consent **Accepted format of IC form for studies including patients** – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –

Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Elderly Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** No **Applicable ethical regulations** National EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Not permitted **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** – **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** – **Additional Information** By National law they mustn't be reimbursed or have any compensation, except travel expenses (Pharmaceuticals/Drug trials)
Funding	**Trials generally financially supported by industry** No **Name of public company/institution supporting financially** Foundation for Science and Technology (FCT) **Name of private company/institution supporting financially** Caloust Gulbenkian Foudation **Name of industry company/institution supporting financially** Roche, AstraZeneca **Funding is an issue during the approval process** No

	Additional Information Public / private organisations and industry: examples are indicated but not necessarily applicable for all study types and study populations such as healthy participants, patients or vulnerable population
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome in trials including patients** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory **Obligation to contract a liability insurance for trials including patients for** – **Obligation to contract a liability insurance for trials including healthy participants for** – **Obligation to contract a liability insurance for trials including vulnerable population for** – **Name and contact insurance companies insuring clinical research** Privy - Correctores de Seguros SA. **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** Fee per study participant **Additional Information** The insurance fee per individual depends on a number of different study specific factors such as type of clinical trial and the number of participants
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Inspections **Regularly performed methods in trials including patients** – **Regularly performed methods in trials including healthy participants** – **Regularly performed methods in trials including vulnerable population** – **Standards concerning quality assurance and quality control exist** No **Regularly performed audits** –

Regularly performed audits in trials including patients

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Regularly performed audits in trials including healthy participants

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Regularly performed audits in trials including vulnerable population

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Archiving & Data Management

Study documents must be kept at least (in years)

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Legal framework for data management exists

No

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)
ICH-GCP Guidelines
Other guidelines for good clinical practice (other than ICH-GCP)
International regulatory requirements
European regulatory requirements - European Directive 2001/20/EC, 2005/28/EC
National regulatory requirements
Regional regulatory requirements
Institutional regulatory requirements

Applied regulatory conventions in studies including patients

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Applied regulatory conventions in studies including healthy participants

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Applied regulatory conventions in studies including vulnerable population

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Applicable national laws

Hospital Act
Data protection Act
Genetical engineering act
Medical device act
Drug act

Applicable national laws for patients

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Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

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National regulations for volunteers exist for

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	Network providing information on regulations and ethical requirements in studies Portuguese Clinical Research Infrastructure Network - PtCRIN **Network Email** ptcrin@fcm.unl.pt **Network contact person** Ana Pais **Personal Email** ana.pais@fcm.unl.pt **Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** http://web.fcm.unl.pt/ptcrin/
Nutrition	**Nutrition considered as drug** Depends on dose Case by case
Blood & Tissue Samples	**Tissue samples permitted** Yes
Data Protection	**Specific Requirements** Yes **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Invasive Catheters	**Invasive catheters permitted** No

Definition

Interventional Study	**Definition in national law** Clinical study with intervention: any investigation which includes a change, influence or programming of health care, behavior or knowledge of the participants or caregivers, in order to discover or verify the health effects, including exposure to drugs, the use of medical devices, performing surgical techniques, exposure to radiation, the application of cosmetics and body care, physiotherapy intervention, the intervention of psychotherapy, the use of transfusion, cell therapy, participation in education sessions individually or in groups, the intervention diet, the intervention organization or access health care or therapeutic intervention designated as unconventional; Directive 2001/20/EC applies to medicinal products which are specifically addressed in the EU law on pharmaceuticals.
Nutrition Study	**Definition available in national law** Yes

Additional Information & Specifics	**Additional Information** Nutrition intervention If it applies with a medicinal product: the Directive 2001/20/EC applies to medicinal products which are specifically addressed in the EU law on pharmaceuticals. (This is an ambiguous definition because it could be a nutrition intervention with a non-medicinal product or a medicinal product)