Nutrition - 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 Ministry)

Contact Name 3

Health Products Directorate

Phone

+351 21 798 7283

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+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

Emai: 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

CA - Registration requirements for clinical trials

Registration mandatory

CA - Submission required to

National CA
Institutional CA

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** Portuguese **Preferred language of application** – **English accepted** No **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** –
Safety Reporting	**Sponsor must declare reportable events to** –

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** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** –

	National declaration on Ethical requirements exists No
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Institutional EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Single Opinion
Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Physician Dietitian Nutritionist PhD Industry **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Portuguese **Preferred language of application** – **English accepted** No **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Safety Reporting	**Investigator shall report SAE to** National CA

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Co-sponsorship allowed** Yes
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist Nurse Pharmacist PhD Each investigator

	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 **Compensation 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** Yes **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
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory **Name and contact insurance companies insuring clinical research** Privy - Correctores de Seguros SA. **Insurance fee in € value indicated as** Fee per study participant **Insurance fee in € value indicated as** – **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 **Standards concerning quality assurance and quality control exist** No **Regularly performed audits** – **Regularly performed audits - Additional information** Internal and External
Archiving & Data Management	**Study documents must be kept at least (in years)** – **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 **Applicable national laws** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act **National regulations for volunteers exist for** – **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** No
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

Observational Study	**Definition in national law** An observational study is a clinical study without intervention Conditions: i) are prescribed medications or medical devices are used in accordance with the terms specified in the marketing authorization; ii) the inclusion of the participant in a particular therapeutic strategy is not decided in advance by a trial protocol but depends on the current practice; iii) the decision to prescribe medicine or use a medical device is clearly separated from the decision to include the participant in the study or not;