Nutrition/Interventional - SPAIN

Competent authority

Contact Details

Contact Name 1

The Spanish Agency of Medicines and Medical Devices/ AEMPS - Agencia Española de Medicamentos y Productos Sanitarios

Contact Name 2

Subdirección General de Medicamentos de Uso Humano (SGMUH)/ General Subdirection of Human Medicinal Products

Email General

aecaem@aemps.es

Email Department

smhaem@aemps.es

Address

C/ Campezo nº 1, Parque Empresarial Las Mercedes, Edificio 8

ZIP/City

28022 Madrid

Country

Spain (ES)

Web address

http://www.aemps.gob.es

Additional Information

AEMPS is the operating body in charge of Medicinal Products (MP) and Medical Devices (MD) within the
Ministry of Health, Social Services and Equality/ Ministerio de Sanidad, Servicios Sociales e Igualdad
Paseo del Prado, 18-20, planta baja, esquina con Lope de Vega
28014 Madrid
Tel:+34 901 400 100.
Fax: +34 915 96 44 80
Email: oiac@msssi.es
Website: http://www.msssi.gob.es/

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Institutional Competent Authority
Institutional Ethics Committee

Regulatory and ethics bodies involved in approval process for trials including patients

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Regulatory and ethics bodies involved in approval process for trials including including healthy participants

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Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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	CA - Registration/ notification without approval required for – **CA - Registration requirements for clinical trials** Registration mandatory Depends on study population **Registration requirements for clinical trials including patients** Registration mandatory **Registration requirements for clinical trials including healthy participants** Registration mandatory **Registration requirements for clinical trials including vulnerable population** Registration not mandatory **CA - Submission required to** 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** only for pharmaceuticals/drug trials (EudraCT) https://ecm.aemps.es/ecm/inicial.do (in Spanish)
Language of Submission	**Language(s) of application** Official national language Spanish English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **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** –
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Asociación Nacional deComité Ética de la Investigacion (ANCEI) **Web address** http://www.ancei.es/
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission to CA and EC to be performed in the following order** –
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** –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** – **Additional Information** Website of the Coordinator centre for CEIC Information on contact points for each independent CEIC in available in this website. (Spanish)
Submission of Application	**Entitled to study submission** Principal Investigator Investigator

	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
Language of Submission	**Language(s) of application** Official national language Spanish English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **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 study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 4 **Time in weeks from submission to positive approval (maximum)** 16 **Time in weeks from submission to positive approval (average)** 6
Safety Reporting	**Investigator shall report SAE to** National CA Institution Sponsor Trial Coordinator

Investigator shall report SAE in trials with patients to

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Investigator shall report SAE in trials with healthy participants to

–

Investigator shall report SAE in trials with volunteers to

–

Study specific Requirements

Sponsor

Sponsorship mandatory

No

Sponsorship mandatory - Additional information

only for pharmaceuticals/drug trials

Co-sponsorship allowed in trials with patients

Yes

Co-sponsorship allowed in trials with healthy participants

Yes

Co-sponsorship allowed in trials with vulnerable population

No

Set up contracts with external sponsor for trials including patients

Yes

Set up contracts with external sponsor for trials including healthy participants

Yes

Set up contracts with external sponsor for trials including vulnerable population

No

Investigator

Entitled to be principal investigator

Dietitian
Nutritionist
Nurse
Pharmacist

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

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Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Yes

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** Yes **Applicable ethical regulations** National
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional Volunteers **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Depends on study population **Compensation for patients is limited to/provided for** Adults only Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel) **Compensation for healthy participants is limited to/provided for** Adults only Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel) Phase I trials **Compensation for vulnerable population is limited to/provided for** Adults only Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel)
Funding	**Trials in patients financially supported by industry** Yes

	Trials in healthy participants financially supported by industry Yes **Trials in vulnerable population financially supported by industry** No **Name of public company/institution supporting financially** Instituto Carlos III **Name of industry company/institution supporting financially** Clinical Nutrition Companies **Funding is an issue during the approval process** Not specified **Funding is an issue during the approval process in trials including patients** Not specified **Funding is an issue during the approval process in trials including healthy participants** Not specified **Funding is an issue during the approval process in trials including vulnerable population** Not specified
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome in trials including patients** Yes **Mandatory to inform participant of clinical trial outcome in trials including healthy participants** Yes **Mandatory to inform participant of clinical trial outcome in trials including vulnerable population** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Obligation to contract a liability insurance for trials including patients for** Patients/Volunteers **Obligation to contract a liability insurance for trials including healthy participants for** Patients/Volunteers **Obligation to contract a liability insurance for trials including vulnerable population for** – **Insurance fee in € value indicated as** –

Insurance fee in € value indicated as

–

Quality Assurance/ Quality Control (QA/QC)

Regularly performed methods

Audits
Monitoring
Audit Trail

Regularly performed methods in trials including patients

–

Regularly performed methods in trials including healthy participants

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Regularly performed methods in trials including vulnerable population

–

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

–

Regularly performed audits in trials including vulnerable population

–

Regularly performed audits - Additional information

internal audits are performed in interventional studies

Archiving & Data Management

Study documents must be kept at least (in years)

–

Legal framework for data management exists

No

Additional Information

regulatory requirements for data management exist only for pharmaceuticals (Spanish)

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)
National 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 – **Applicable national laws** – **Applicable national laws for patients** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act **Applicable national laws for healthy participants** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** No
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 for trials including patients** Yes **Invasive catheters permitted for trials including healthy participants** Yes

Definition

Interventional Study	**Definition in national law** Interventional study: A study in which drugs are prescribed for experimental evaluation, and is not used in the usual manner, in accordance with the terms of the authorization. The assignment of a patient to a particular therapeutic strategy is decided in advance by a trial protocol but is determined by the practice of medicine, and the decision to prescribe a particular drug is associated with the decision to include the patient in the study.
Nutrition Study	**Definition available in national law** No