Nutrition - 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 **CA - Registration requirements for clinical trials** Not mandatory **CA - Submission required to** Institutional CA
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language Spanish English

	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) **Phone** info@ancei.es **Country** Spain (ES) **Web address** http://www.ancei.es/
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** –
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** Lead EC (authorised to issue a single opinion) **Ethical approval - Additional information** Clinical Research Ethics Committees (Comités de Ética en Investigación Clínica, CEIC)
Submission of Application	**Entitled to study submission** Principal Investigator Investigator **Prerequisites for submission / approval** –

Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language Spanish **Preferred language of application** – **English accepted** Yes **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

Study specific Requirements

Sponsor	**Sponsorship mandatory** No **Co-sponsorship allowed** No **Co-sponsorship allowed - Additional information** Only in interventional trials **Contracts with external sponsor** No **Additional Information** Contracts with external sponsors are usually set up only in interventional trials
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** –
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** No **Regulations concerning the inclusion or exclusion** only in interventional trials **Applicable ethical regulations** National
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional Volunteers **Compensation is limited to/provided for** Adults only Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel)
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process** Not specified

	Additional Information only in case of interventional trials
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No **Additional Information** only in case of interventional trials
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory **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 audits** – **Regularly performed audits - Additional information** only internal audits (not external) are regularly performed in observational trials
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) National regulatory requirements Institutional regulatory requirements **Applicable national laws** Data protection Act **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** 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)

–

Definition

Observational Study	**Definition in national law** Observational study: (Law 29/2006, of July 26): A study in which drugs/nutrients are prescribed in the usual manner, in accordance with the terms of the authorization. The assignment of a patient to a particular therapeutic strategy is not decided in advance by a trial protocol but is determined by the practice of medicine, and the decision to prescribe a particular drug will be clearly dissociated from the decision to include the patient in the study. It does not apply to patients nor intervention, whether diagnostic or monitoring, other than the usual clinical practice and epidemiological methods shall be used to analyze the data collected.
Nutrition Study	**Definition available in national law** No