Nutrition - ITALY

Competent authority

Contact Details	**Contact Name 1** Italian Medicines (Drug) Agency/ Agenzia Italiana del Farmaco (AIFA) **Contact Name 2** Clinical Trial Office/ Ufficio Sperimentazione Clinica of AIFA **Phone** +39 06 5978401 **Fax** +39 06 59944142 **Email Department** sperimentazione.clinica@aifa.gov.it **Address** Via del Tritone 181 **ZIP/City** 00187 Rome **Country** Italy (IT) **Web address** http://www.agenziafarmaco.gov.it/en/content/clinical-trials **Additional Information** AIFA is operating on behalf of the: Ministry of Health/ Ministero della salute Dipartimento del l'innovazione Direzione Generale dei Farmaci e Dispositivi Medici Piazzale dell'Industria 20 00144 Roma Phone + 39 06 59943809 E-mail: Segr.DGFDM@sanita.it Websites: http://www.salute.gov.it/ (English version: under construction)
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Ethics Committee **CA - Registration requirements for clinical trials** Not applicable **CA - Submission required to** Institutional CA
Submission Format	**Standard application form available** Yes
Language of Submission	**Language(s) of application** Italian

	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** –
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 5 **Time to approval of CA in weeks (maximum)** 8 **Time to approval CA in weeks (average)** 6
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Local Ethics Committees (there are 84 certified ECs in Italy) **Web address** https://www.agenziafarmaco.gov.it/ricclin/en/node/26 **Additional Information** The complete list of certified ECs available via AIFA website.
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** Not specified
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** Investigator

	Prerequisites for submission / approval –
Submission Format	**Standard application form available** Yes
Language of Submission	**Language(s) of application** Italian **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** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 4 **Time in weeks from submission to positive approval (maximum)** 6 **Time in weeks from submission to positive approval (average)** 5
Safety Reporting	**Investigator shall report SAE to** Institution Trial Coordinator

Study specific Requirements

Sponsor	**Sponsorship mandatory** No **Co-sponsorship allowed** Yes
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** No **Accepted format of Informed Consent (IC) form** Written consent Consent by proxy **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** Not specified **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC) EU directive (2005/28/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Are not reimbursed **Compensation is limited to/provided for** –
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process** No
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** No
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** Inspections Monitoring Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** – **Regularly performed audits - Additional information** Regularly performed audits: External

Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Not specified

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki European regulatory requirements - European Directive 2001/20/EC, 2005/28/EC **Applicable national laws** Hospital Act **National regulations for volunteers exist for** Not specified **Network providing information on regulations and ethical requirements in studies** Istituto Mario Negri, Milano **Official website providing relevant national legislation** http://www.marionegri.it/
Nutrition	**Nutrition considered as drug** No
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