Nutrition/Interventional - 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 **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** 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** Yes
Language of Submission	**Language(s) of application** Italian **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** 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 **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** 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 –
Submission of Application	**Entitled to study submission** 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** Yes
Language of Submission	**Language(s) of application** Italian **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** 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 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 **Investigator shall report SAE in trials with patients to** – **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 **Co-sponsorship allowed** Yes
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** 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

	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** –
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process in trials including patients** Yes
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor **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** – **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)

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

Yes

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

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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

Applied regulatory conventions in studies including patients

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Applied regulatory conventions in studies including healthy participants

–

Applied regulatory conventions in studies including vulnerable population

–

Applicable national laws

Hospital Act

Applicable national laws for patients

–

	Applicable national laws for healthy participants – **Applicable national laws for vulnerable population** – **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** 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** Yes

Definition

Interventional Study	**Definition in national law** Study in which a new treatment/procedure, which is not part of routine approach, is tested. This means that studies testing already acknowledged and validated therapies/procedures in a new clinical setting should be considered as intervention studies.