Nutrition - FRANCE

Competent authority

Contact Details	**Contact Name 1** Agence nationale de sécurité du médicament et des produits de santé (ANSM) **Contact Name 2** Direction des dispositifs médicaux thérapeutiques et des cosmétiques **Contact Name 3** Essais cliniques **Phone** (+33) 01 55 87 36 87 **Fax** (+33) 01 55 87 37 17 **Email Department** EC.DM-COS@ansm.sante.fr **Address** 143/147 Boulevard Anatole France **ZIP/City** 93285 Saint-Denis Cedex **Country** France (FR) **Web address** http://www.ansm.sante.fr **Additional Information** Only a central CA, no local CA in France.
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 2 **Time to approval of CA in weeks (maximum)** 4 **Time to approval CA in weeks (average)** 3

Ethics committee

Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** EC review not required
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 4

Time in weeks from submission to positive approval (maximum)

12

Time in weeks from submission to positive approval (average)

8

Study specific Requirements

Sponsor

Sponsorship mandatory

Yes

Co-sponsorship allowed

Yes

Contracts with external sponsor

Yes

Study Participants - Informed Consent (IC)

Accepted format of Informed Consent (IC) form

Oral consent
Written consent
Consent by proxy

Accepted format of IC form for studies including patients

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Accepted format of IC form for studies including healthy participants

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Accepted format of IC form for studies including vulnerable population

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Study Participants - Vulnerable Population

Considered as vulnerable population

Children
Pregnant women (Pregnancy)
Lactating women
Unconscious Persons
Incapacitated adults
People with psychiatric disorder
People with dementia

Vulnerable population - Additional information

By legal definition vulnerability can be caused by age, diseases, disability, physical or psychological deficiency and pregnancy

Regulations concerning the inclusion or exclusion available

No

Applicable ethical regulations

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Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Not specified

Compensation is limited to/provided for

Adults only
Time effort
Inconvenience, Pain, Discomfort
Expenses arising from study participation (e.g. Travel)
A certain amount

	Additional Information Reimbursement is limited to 4500€/year
Funding	**Trials generally financially supported by industry** Yes **Name of public company/institution supporting financially** French Research Agency; Clinical Research Hospital programs **Name of private company/institution supporting financially** Patient associations **Name of industry company/institution supporting financially** Nutrition or Pharmaceutical Companies **Funding is an issue during the approval process** Yes

Definition

Observational Study	**Definition in national law** Provided is not the official definition in national law but an explanation: Regulatory rules are similar for all categories of studies, excepted for observational studies. Studies are considered as observational only when participants are just observed. If there is any exam performed, such as blood or urine sampling, body composition or energy expenditure measurement, which is not included in the usual management, the study is considered as interventional (even without any nutritional or pharmaceutical intervention).