

# Nutrition/Interventional - 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

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(+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.

### Trial Authorisation / Registration / Notification

#### Regulatory and ethics bodies involved in approval process

—

#### 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

—

	<b>CA - Registration requirements for clinical trials</b>
	–
	<b>Registration requirements for clinical trials including patients</b>
	–
	<b>Registration requirements for clinical trials including healthy participants</b>
	–
	<b>Registration requirements for clinical trials including vulnerable population</b>
	–
	<b>CA - Submission required to</b>
	–
Language of Submission	<b>Studies including patients - submission required to</b>
	–
	<b>Studies including healthy participants - submission required to</b>
	–
	<b>Studies including vulnerable population - submission required to</b>
	–
	<b>Language(s) of application</b>
	French
	<b>Language(s) of application for trials including patients</b>
	–
	<b>Language(s) of application for trials including healthy participants</b>
	–
	<b>Language(s) of application for trials including vulnerable population</b>
	–
	<b>Preferred language of application</b>
	–
	<b>English accepted</b>
	Yes
	<b>Documents mandatory to be in official national language</b>
	–
	<b>Documents mandatory to be in local language of study site</b>
	–
	<b>Documents mandatory to be in language of the study participant</b>
	–
	<b>Additional Information</b>
	English is accepted, but a French version is mandatory for summary and volunteer information and consent forms
Timelines Authorisation	<b>Time to approval of CA in weeks (minimum)</b>
	2

	<b>Time to approval of CA in weeks (maximum)</b> 4 <b>Time to approval CA in weeks (average)</b> 3
Safety Reporting	<b>Sponsor must declare reportable events to</b> —
<b>Ethics committee</b>	
Ethical Review – General	<b>Submission for Ethical review mandatory for</b> — <b>Submission to CA and EC to be performed in the following order</b> — <b>National declaration on Ethical requirements exists</b> No
Multi-Centre Studies - Ethical Review	<b>Ethical approval (favourable opinion) required from</b> Single Opinion <b>Ethical approval in trials including patients obtained from</b> — <b>Ethical approval in trials including healthy participants obtained from</b> — <b>Ethical approval in trials including vulnerable population obtained from</b> — <b>Additional Information</b> A single ethical committee is required for French multicenter projects. If the institution responsible for the study is not located in France, the project should also be submitted to a French ethical committee
Submission of Application	<b>Entitled to study submission</b> Sponsor <b>Entitled to submission of trials including patients</b> — <b>Entitled to submission of trials including healthy participants</b> — <b>Responsible for submission of trials including vulnerable population</b> — <b>Prerequisites for submission / approval</b> Application is limited to the institution <b>Additional Information</b> Application is done by the institution which is legally responsible for the study, called “promoteur” promotor. It can be a public institution (Hospitals, Inserm, Inra..) or industry. The submission is done by a sponsor only when this sponsor is the promotor Of course the project is prepared by investigators. The main investigator must be MD.

Submission Format	<p><b>Standard application form available</b></p> <p>Yes</p> <p><b>Standard application form</b></p> <p><a href="http://ansm.sante.fr/">http://ansm.sante.fr/</a></p>
Language of Submission	<p><b>Language(s) of application</b></p> <p>French English</p> <p><b>Language(s) of application for trials including patients</b></p> <p>—</p> <p><b>Language(s) of application for trials including healthy participants</b></p> <p>—</p> <p><b>Language(s) of application for trials including vulnerable population</b></p> <p>—</p> <p><b>Preferred language of application</b></p> <p>French</p> <p><b>English accepted</b></p> <p>Yes Partly, not for all documents</p> <p><b>Documents mandatory to be in official national language</b></p> <p>—</p> <p><b>Documents mandatory to be in local language of study site</b></p> <p>—</p> <p><b>Documents mandatory to be in language of study participant</b></p> <p>—</p> <p><b>Additional Information</b></p> <p>English is accepted, but a French version is mandatory for summary and volunteer information and consent forms</p>
Timelines Ethical Review	<p><b>Time in weeks from submission to positive approval (minimum)</b></p> <p>4</p> <p><b>Time in weeks from submission to positive approval (maximum)</b></p> <p>12</p> <p><b>Time in weeks from submission to positive approval (average)</b></p> <p>8</p>
Safety Reporting	<p><b>Investigator shall report SAE to</b></p> <p>National CA Institution Sponsor Trial Coordinator</p> <p><b>Investigator shall report SAE in trials with patients to</b></p> <p>—</p> <p><b>Investigator shall report SAE in trials with healthy participants to</b></p> <p>—</p>

Investigator shall report SAE in trials with volunteers to

—

## Study specific Requirements

Sponsor

**Sponsorship mandatory**

Yes

**Co-sponsorship allowed**

Yes

**Contracts with external sponsor**

Yes

Investigator

**Entitled to be principal investigator**

Physician

**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**

No

**Accepted format of Informed Consent (IC) form**

Oral consent

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

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**

Yes

	<p><b>Applicable ethical regulations</b></p> <p>National International EU directive (2001/20/EC)</p> <p><b>Applicable legal framework / Reference (Vulnerable Population)</b></p> <p>International and EU regulations are included in the French ones. We have no specific rules for vulnerable groups</p>
Study Participants - Compensation & Reimbursement	<p><b>Reimbursement for study participants</b></p> <p>Optional</p> <p><b>Reimbursement for patients</b></p> <p>—</p> <p><b>Reimbursement for healthy participants</b></p> <p>—</p> <p><b>Reimbursement for vulnerable population</b></p> <p>—</p> <p><b>Compensation is limited to/provided for</b></p> <p>Adults only Time effort Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel) A certain amount</p> <p><b>Compensation for patients is limited to/provided for</b></p> <p>—</p> <p><b>Compensation for healthy participants is limited to/provided for</b></p> <p>—</p> <p><b>Compensation for vulnerable population is limited to/provided for</b></p> <p>—</p> <p><b>Additional Information</b></p> <p>Reimbursement is limited to 4500€/year</p>
Funding	<p><b>Trials generally financially supported by industry</b></p> <p>Yes</p> <p><b>Name of public company/institution supporting financially</b></p> <p>French Research Agency; Clinical Research Hospital programs</p> <p><b>Name of private company/institution supporting financially</b></p> <p>Patient associations</p> <p><b>Name of industry company/institution supporting financially</b></p> <p>Nutrition or Pharmaceutical Companies</p> <p><b>Funding is an issue during the approval process</b></p> <p>Yes</p>
Study Participants - Recruitment & Trial Outcome	<p><b>Regulations on recruitment process exist</b></p> <p>Yes</p>

**Mandatory to inform participant of clinical trial outcome**

Yes

**Insurance****Liability insurance or alternative arrangements for damages mandatory for**

Patients/Volunteers  
Researchers  
Sponsor  
Institution  
Sponsor/Institution = Promoteur

**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**

—

**Name and contact insurance companies insuring clinical research**

Société Hospitalière d'Assurances Mutuelles

**Insurance fee in € for lowest risk research (minimum)**

500

**Insurance fee in € for lowest risk research (maximum)**

2000

**Insurance fee in € for lowest risk research (average)**

1500

**Insurance fee in € value indicated as**

Fee per study participant

**Insurance fee in € for highest risk research (minimum)**

1500

**Insurance fee in € for highest risk research (maximum)**

4000

**Insurance fee in € for highest risk research (average)**

3000

**Insurance fee in € value indicated as**

Fee per study participant

**Additional Information**

Promoteur/Promotor= Institution which is legally responsible for the study. It can be a public institution (Hospitals, Inserm, Inra..) or industry, (it may or may not be the sponsor)

Quality Assurance/  
Quality Control (QA/QC)

#### **Regularly performed methods**

Audits  
Inspections  
Monitoring  
Standard Operating Procedures (SOP)  
Audit Trail  
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**

—

#### **Regularly performed audits - Additional information**

Internal and external audits are performed

## **National legislation**

General Information:  
Applicable Legislation &  
Conventions

#### **Applied regulatory conventions**

—

#### **Applied regulatory conventions in studies including patients**

—

#### **Applied regulatory conventions in studies including healthy participants**

—

#### **Applied regulatory conventions in studies including vulnerable population**

—

#### **Applicable national laws**

—

#### **Applicable national laws for patients**

—

#### **Applicable national laws for healthy participants**

—



**Applicable national laws for vulnerable population**

—

**National regulations for volunteers exist for**

Nutrition intervention in healthy people  
Pharmaceuticals/drug trials  
Invasive procedures  
Catheters  
Isotopes  
Tissue samples

**Network providing information on regulations and ethical requirements in studies**

Agence nationale de sécurité du médicament et des produits de santé (ANSM)

**Network Email**

EC.DM-COS@ansm.sante.fr

**Official website providing relevant national legislation available**

Yes

**Official website providing relevant national legislation**

<http://ansm.sante.fr/>

Blood & Tissue Samples

**Tissue samples permitted**

Yes

**Definition**

Interventional Study

**Definition in national law**

Provided is not an official definition of interventional trials in France 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).