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

(+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.

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

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	CA - Registration requirements for clinical trials – **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** – **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Language of Submission	**Language(s) of application** French **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** 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** – **Additional Information** English is accepted, but a French version is mandatory for summary and volunteer information and consent forms
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
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** No
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** – **Additional Information** 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	**Entitled to study submission** Sponsor **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** Application is limited to the institution **Additional Information** 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	**Standard application form available** Yes **Standard application form** http://ansm.sante.fr/
Language of Submission	**Language(s) of application** French English **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** French **English accepted** Yes Partly, not for all documents **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** – **Additional Information** English is accepted, but a French version is mandatory for summary and volunteer information and consent forms
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
Safety Reporting	**Investigator shall report SAE to** National CA Institution Sponsor 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

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

	Applicable ethical regulations National International EU directive (2001/20/EC) **Applicable legal framework / Reference (Vulnerable Population)** International and EU regulations are included in the French ones. We have no specific rules for vulnerable groups
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Adults only Time effort Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel) A certain amount **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** – **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
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** Yes

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).