

# Medicinal Products for Human Use - FRANCE

## Competent authority

### Contact Details

#### Contact Name 1

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

#### Phone

+33 (0)1 55 87 36 58

#### Fax

+33 (0)1 55 87 32 82

#### Email General

dajr@ansm.sante.fr

#### Email Department

aec-essaiscliniques@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

PLEASE NOTE THAT WE ARE CURRENTLY UPDATING OUR DATABASE

### Trial Authorisation / Registration / Notification

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

Competent Authority/-ies (CA)  
Ethics committee(s)  
Agency for data protection  
Other

#### CA - Submission for authorisation mandatory for

All clinical trials on Medicinal Products (MP)

#### CA - Registration/ notification without approval required for

Non-interventional IMP trials

#### CA - Submission required to

National CA

#### National trial registry - Registration mandatory

Yes

**National legal framework in place**

Yes

**Applicable national legal framework/ Reference**

All interventional research on medicinal products, regardless of the potential risk level, require authorization by the ANSM. ( Cf. "Jardé law", see also Articles L. 1121-1, 1°, L1123-8, L1123-12, etc of the Public Health Code)

Non-interventional research must be notified to the ANSM but doesn't require authorization. ( Cf. "Jardé law", see also Article L. 1121-1, 3° of the Public Health Code)

Submission of Application

**Responsible for study submission**

Sponsor  
Legal representative domiciled in the EU/EEA

**Entitled to study submission**

—

**Prerequisites for submission**

—

**Guidance on submission of application available**

Yes

**Guidance on submission of application**

Avis aux promoteurs d'essais cliniques de médicaments, y compris les essais cliniques portant sur les médicaments de thérapie innovante (MTI) - Tome 1 (31/05/2018) (855 ko)

Available at : [www.ansm.sante.fr/Activites/Medicaments-et-produits-biologiques/Avis-aux-promoteurs-Formulaires/](http://www.ansm.sante.fr/Activites/Medicaments-et-produits-biologiques/Avis-aux-promoteurs-Formulaires/)

It covers in detail the legal framework, the submission procedure and all other relevant requirements on amendments, safety reporting and trial termination

**National legal framework in place**

Yes

**Additional Information**

PLEASE NOTE THAT WE ARE CURRENTLY UPDATING OUR DATABASE

Submission Format

**Format option(s)**

Email

**Preferred format**

—

**Standard application form**

CAEC Form (Formulaire - Courrier de demande d'autorisation d'essai clinique)

Document available in French at:  
<http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Essais-cliniques>

Title in French:  
Annexe 2-Liste récapitulative des pièces constitutives du dossier de demande d'autorisation d'essai clinique de médicament (01/06/2015) (127 ko)

### **Standard application form - Additional information**

Standard application form is available on the website in section: Activités > Médicaments et produits biologiques > Avis aux promoteurs - Formulaires.

### **Guidance on submission format available**

Yes

### **Guidance on submission format**

The required content of the application dossier is provided in Annex II, available on the ANSM website

Document available in French at:  
<http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Essais-cliniques>

Title in French:  
Annexe 2-Liste récapitulative des pièces constitutives du dossier de demande d'autorisation d'essai clinique de médicament (01/06/2015) (127 ko)

### **Applicable national legal framework/ Reference**

### **Additional Information**

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Language of Submission

### **Language(s) of application**

French  
English

### **Preferred language of application**

—

### **English accepted**

Partly, not for all documents

### **Documents mandatory to be in official national language**

Protocol Summary + Import request form + “Répertoire public des essais cliniques autorisés - Informations sur l’essai”

### **Additional Information**

PLEASE NOTE THAT WE ARE CURRENTLY UPDATING OUR DATABASE

Submission Fees

### **Fees for trial submission mandatory**

No

### **Fees**

No submission fees required.

Timelines Authorisation

### **General timespan (max nr days)**

60

### **Mode of approval (General)**

Tacit (Silent)

### **ATMP/GMO trials (max nr days)**

90

### **Mode of approval (ATMP/GMO trials)**

Explicit

Amendments/  
Substantial  
Amendments (SA)

**External expert advice required (max nr days)**

–

**Xenogeneic cell therapy (max nr days)**

–

**Mode of approval (Xenogeneic cell therapy)**

Explicit approval possible before expiration of time period

**Timespan counted from**

–

**Notification mandatory for**

–

**Authorisation mandatory for**

Substantial amendments (as determined by CA)

**Responsible for submission of SA**

Sponsor  
Legal representative domiciled in the EU/EEA

**Standard notification form**

1) Substantial Amendment Notification Form (en) of EudraLex - Volume 10  
Clinical trials guidelines  
2) Formulaire FAMS - Médicaments (fr)  
Both forms are available on the ANSM website in section: Activités >  
Médicaments et produits biologiques > Avis aux promoteurs - Formulaires

**Timeline for approval of SA (max nr days)**

45/ extension to 60 possible (if further questions; for trials with cell therapy,  
gene therapy, or GMOs)

**Guidance on submission of SA available**

Yes

**Guidance on submission of SA**

A guidance for sponsors regarding the definition and examples of substantial  
and non-substantial amendments to be notified to ANSM is available on the  
website in section:  
Activités > Médicaments et produits biologiques > Avis aux promoteurs -  
Formulaires

Documents available in French at:  
[http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-  
Essais-cliniques](http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Essais-cliniques)

Titles in French:  
Annexe 14 : Exemples de modifications substantielles et non substantielles  
pour l'ANSM (01/06/2015) (266 ko)  
Annexe 15 : Exemples de tableau comparatif mettant en évidence les  
modifications substantielles apportées à un document par rapport à la  
version précédemment soumise (01/06/2015) (86 ko)

**Applicable national legal framework/ Reference**

Articles L1123-42 and L1123-44 of the French Public Health Code (Code de la  
santé publique).

**Additional Information**

NB! Non-substantial amendments and substantial amendments on trial -  
related aspects falling within the EC's competence only (e.g. additional  
investigators) need not be notified to the CA any longer.

**Responsible for AE reporting to CA**

Sponsor  
Legal representative domiciled in the EU/EEA

**Sponsor must declare reportable events to**

Competent Authority

**Investigator/PI shall separately report any SAE /SADE to CA**

Yes

**Reportable AEs**

SUSAR (Suspected Unexpected Serious Adverse Reaction)  
Other  
New event (see definition below)

**SUSAR being life-threatening or leading to death must be reported**

Immediately (without delay)  
Other  
Without delay if Healthy Volunteers (whatever the clinical trial phase)

**All other SUSARs**

Within a max of 15d upon first knowledge  
Other  
Without delay if Healthy Volunteers (whatever the clinical trial phase)

**SAE /SADE must be reported**

Other  
Without delay if Healthy Volunteers

**National standard reporting form available**

Yes

**Reporting format - Options**

Email  
Email: [declarationsusars\(at\)ansm.sante.fr](mailto:declarationsusars@ansm.sante.fr)

**Preferred format**

Email

**Annual safety report shall be provided by sponsor to**

National CA

**Guidance on AE reporting procedure available**

Yes

**Guidance on AE reporting procedure**

Detailed guidance on safety reporting procedure and format is available in English and French on the ANSM website in section Déclaration des effets indésirables (SUSARs):  
"Explanatory note : Clinical Trial Vigilance Data Reporting (SUSARs) (en)"/  
"Fiche explicative : Déclaration des données de vigilance des essais cliniques (fr)"

**National legal framework in place**

Yes

**Applicable national legal framework/ Reference**

Articles R1123-45 - R1123-61 of the Public Health Code  
Decree n° 2016-1537 of November 16th, 2016 concerning research involving human beings  
Decree n° 2017-884 of May 9th, 2017 modifying certain regulatory provisions concerning research involving human beings

**Additional Information**

According to Article R1123-46, 12° of the Public Health Code, a NEW EVENT is defined as :  
All new data that may lead to :

- the reassessment of the risk-benefit balance of the research or of the product being evaluated,
- the modification of the product utilization,
- the modification of the conduct of research or of the research related documents, or
- the suspension, interruption or modification of the research protocol or similar research protocols.

For studies on the first administration or utilization of a health product on a healthy person: all serious adverse events.

**Investigator shall report SAE to**

—

**Reporting timeline**

—

End of Trial

**End of trial declaration mandatory for**

All clinical trials requiring authorisation by CA

**Responsible for End of trial declaration**

Sponsor  
Legal representative domiciled in the EU/EEA

**Regular Termination - Declaration timespan (max nr days)**

90

**Timespan counted from**

—

**Early/premature Termination - Declaration timespan (max nr days)**

15

**Reasons for early termination shall be clearly stated**

Yes

**Standard Declaration form**

- 1) Declaration of the End of Trial Form (en) of EudraLex Volume 10 Guidelines OR
  - 2) Formulaire FFE - Déclaration de fin de recherche biomédicale (fr).
- The templates for both forms (+ final report) are available for download on ANSM website in section: Activités > Médicaments et produits biologiques > Avis aux promoteurs - Formulaires.

## Guidance on End of trial declaration

"Avis aux promoteurs-Tome 1":

A comprehensive guidance for sponsors is published on the ANSM website in section: Activités > Médicaments et produits biologiques > Avis aux promoteurs - Formulaires.

It covers in detail the legal framework, the submission procedure and all other relevant requirements on amendments, safety reporting and trial termination (applicable for studies submitted after august 2006).

### Applicable national legal framework/ Reference

R1123-59 CSP

### Additional Information

In case of multinational clinical trials, the sponsor has to declare when the trial ends in France and when the trial ends in all countries.

The participants have the right to be informed of the outcome of a clinical trial.

Additional Information & Specifics

### Additional Information

PLEASE NOTE THAT WE ARE CURRENTLY UPDATING OUR DATABASE

## Ethics committee

Contact Details

### Contact Name 1

Comités de Protection des Personnes (CPP)

### Additional Information

39 competent regional (lead) ECs in France (no local ECs).  
The ECs that will review the protocole is randomly selected.

Ethical Review - General

### Submission for Ethical review mandatory for

Clinical IMP trials  
Clinical ATMP trials

### Submission to CA and EC to be performed in the following order

In parallel  
Sequentially (in any order)

### Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)  
Ethics committee(s)  
Agency for data protection  
Other

Single-Centre Studies - Ethical Review

### Ethical approval (favourable opinion) to be obtained from

Any competent EC of the region where PI is located

### Additional Information

There are 40 lead ECs in France (no local ECs).  
The trial application can be submitted to any Comité de Protection des Personnes (CPP) in the region where the principal investigator is located.

Multi-Centre Studies - Ethical Review

### Ethical approval (favourable opinion) required from

Lead EC (authorised to issue a single opinion)

### Submission of application required to

Any competent EC where PI or coordinator is located

	<p><b>Additional Information</b></p> <p>40 Lead ECs in France, no local ECs. France has been divided in seven regional areas and the clinical trial application authorisation can be submitted by the sponsor to any Comité de Protection des Personnes (CPP) in the region where the principal investigator (or coordinator in multicentre Clinical trials) is located. This CPP is responsible for the single opinion and has to evaluate i.a. the participant's protection, the adequacy between objectives of the research and means used and the qualification of the investigators.</p>
Submission of Application	<p><b>Responsible for study submission</b></p> <p>Sponsor Legal representative domiciled in the EU/EEA</p> <p><b>Entitled to study submission</b></p> <p>—</p> <p><b>Prerequisites for submission / approval</b></p> <p>—</p> <p><b>Guidance on study submission available</b></p> <p>Yes</p> <p><b>Guidance on study submission</b></p> <p>The required content of the application dossier is provided in :</p> <p>Arrêté du 2 décembre 2016 fixant le contenu, le format et les modalités de présentation du dossier de demande d'avis au comité de protection des personnes sur un projet de recherche mentionnée au 1° de l'article L. 1121-1 du code de la santé publique portant sur un médicament à usage humain.</p> <p>Available at ( only in French) : <a href="https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033546922&amp;dateTexte=20180626">https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033546922&amp;dateTexte=20180626</a></p>
Submission Format	<p><b>Format option(s)</b></p> <p>Email Paper hardcopy Data carrier (CD-rom/DVD)</p> <p><b>Preferred format</b></p> <p>—</p> <p><b>Guidance on submission format</b></p> <p>The required content of the application dossier is provided in :</p> <p>Arrêté du 2 décembre 2016 fixant le contenu, le format et les modalités de présentation du dossier de demande d'avis au comité de protection des personnes sur un projet de recherche mentionnée au 1° de l'article L. 1121-1 du code de la santé publique portant sur un médicament à usage humain.</p> <p>Available at ( only in French) : <a href="https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033546922&amp;dateTexte=20180626">https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033546922&amp;dateTexte=20180626</a></p>
Language of Submission	<p><b>Language(s) of application</b></p> <p>French English</p> <p><b>Preferred language of application</b></p> <p>—</p> <p><b>English accepted</b></p> <p>Partly, not for all documents</p>



	<p><b>Documents mandatory to be in official national language</b></p> <p>Protocol Summary Information material, Documents and Forms intended for study participants and patient information</p>
Submission Fees	<p><b>Fees for Ethical review mandatory</b></p> <p>No</p> <p><b>Fees for Ethical review</b></p> <p>No submission fees applicable.</p>
Timelines Ethical Review	<p><b>General timespan for single-centre studies (max nr days)</b></p> <p>45 Extension to 60 days if questions to applicant</p> <p><b>General timespan for multi-centre studies (max nr days)</b></p> <p>45 Extension to 60 days if questions to applicant</p> <p><b>ATMP/GMO trials (max nr days)</b></p> <p>—</p> <p><b>External expert advice required: Timespan (max nr days)</b></p> <p>—</p> <p><b>Xenogeneic cell therapy: Timespan (max nr days)</b></p> <p>—</p> <p><b>Clock-stop possible if complementary information requested</b></p> <p>Yes</p> <p><b>Timespan counted from</b></p> <p>—</p> <p><b>Applicable national legal framework/ Reference</b></p> <p>Article R1123-24 CSP</p> <p><b>Additional Information</b></p> <p>The absence of a reply within 45 days implies rejection.</p>
Amendments/ Substantial Amendments (SA)	<p><b>Ethical review mandatory for</b></p> <p>Any substantial amendments</p> <p><b>Responsible for notification of SA</b></p> <p>Sponsor Legal representative domiciled in the EU/EEA</p> <p><b>Timeline Ethical review of SA (max nr days)</b></p> <p>35</p> <p><b>Applicable national legal framework/ Reference</b></p> <p>L1123-9 Chapter 3 CSP</p> <p><b>Additional Information</b></p> <p>EC notifies the CA on its decision.</p>

**Adverse Events (AE) - Definitions (pursuant to national law)**

New event ( "fait nouveau" in French) (see Definition below)

" 12° Pour les recherches impliquant la personne humaine, fait nouveau : toute nouvelle donnée pouvant conduire à une réévaluation du rapport des bénéfices et des risques de la recherche ou du produit objet de la recherche, à des modifications dans l'utilisation de ce produit, dans la conduite de la recherche, ou des documents relatifs à la recherche, ou à suspendre ou interrompre ou modifier le protocole de la recherche ou des recherches similaires. Pour les essais portant sur la première administration ou utilisation d'un produit de santé chez des personnes qui ne présentent aucune affection : tout effet indésirable grave" (Article R1123-46, °12 of the French Public Health Code).

! Definition available in French only.

**Reportable AEs**

Any new event which could have an unfavourable impact on participants' safety or on the method of trial  
See complete definition above

**Investigator shall report SAE to**

—

**Reporting timeline**

—

**Responsible for AE reporting to relevant EC(s)**

Sponsor  
Article R1123-62 of the French Public Health Code

**SUSAR being life-threatening or leading to death must be reported**

Immediately

**All other SUSAR must be reported**

—

**SAE/SADE must be reported**

—

**National Standard Reporting form available**

—

**Reporting format - Options**

—

**Preferred reporting format**

—

**Provision of Annual safety report mandatory**

Yes

**Applicable national legal framework/ Reference**

Article R1123-62 of the French Public Health Code  
Article R1123-46, °12 of the French Public Health Code

**End of trial Declaration mandatory**

Yes

**Responsible for End of trial Declaration**

Sponsor  
Legal representative domiciled in the EU/EEA

**Regular Termination - Declaration timespan (max nr days)**

90

**Timespan counted from**

—

**Early/premature Termination - Declaration timespan (max nr days)**

15

**Reasons for early termination shall be clearly stated**

Yes

**Standard Declaration form**

Available on ANSM website in section: Activités > Médicaments et produits biologiques > Avis aux promoteurs - Formulaires

**Applicable national legal framework/ Reference**

R1123-59 CSP

**Additional Information**

In case of multinational clinical trial, the sponsor has to declare when the trial ends in France and when the trial ends in all countries.  
The sending of a summary of the final report and of the results to the EC by one year after the end of the trial is not mandatory but can be appreciated.

**Additional Information & Specifics****Additional Information**

The Comité Consultatif National d'Ethique - CCNE gives opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine and health.

**Study specific Requirements****Sponsor****Sponsor - Definition available in national law**

Yes

**Sponsor - Definition (pursuant to national law)**

Definition "Promoteur" (Sponsor) pursuant to Article L1121-1 CSP:  
La personne physique ou la personne morale qui prend l'initiative d'une recherche biomédicale sur l'être humain, qui en assure la gestion et qui vérifie que son financement est prévu, est dénommée le promoteur.

**Sponsorship mandatory**

Yes

**Co-Sponsor - Definition available in national law**

No

**Co-sponsorship allowed**

No

**Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:**

Yes

Study Participants -  
Informed Consent (IC)

### **IC is regulated by law**

Yes

### **Informed Consent - Definition/ Requirements**

Informed consent needs to be obtained in writing before the commencement of a clinical trial. Definition according to Article L1122-1 Chapter 2 CSP.

### **Applicable national legal framework/ Reference**

Art L1122-1 Chapter 2 CSP  
Art L1121-5 to 9 (Chapter 1 CSP), L1122-1 & 2

### **Additional Information**

Special conditions apply for the inclusion of vulnerable persons (e.g. children, pregnant and lactating women and adult protected by the law.

Study Participants -  
Vulnerable Population

### **Minors / Children - Studies allowed**

Yes  
Special provisions apply

### **Specific provision**

Studies with minors (i.e. under 18 years old) are possible under special provisions.

### **Legal framework/Reference (Minors/Children)**

Article L1121-7 Chapter 1 CSP  
Article L1122-2 CSP covers specific requirements for the informed consent of minors.

### **Incapacitated persons - Studies allowed**

Yes  
Special provisions apply

### **Legal framework / Reference (Incapacitated persons)**

L1121-6/8/9 CSP ; L1122-2 CSP

### **Emergency situations - Studies allowed**

Yes  
Special provisions apply

### **Emergency situation without prior consent of patient or proxy - Studies allowed**

No

### **Conditions allowing trial participation in emergency setting without prior consent**

Under current legislation, it is not possible to start the study in acute emergency settings without the informed consent of the legal representative if the latter is "present" (pursuant to L1122-1-2 Chapter 2 CSP).

However, the current legislation (Jardé law) allows research in emergency situations to start without informed consent of the legal representative in immediately life-threatening situations. (in French: "recherches en situation d'urgence vitale immédiate") (pursuant to L1122-1-3 Chapter 2 CSP)

### **Legal framework / Reference (Emergency Situation)**

L1122-1-2 Chapter 2 CSP

### **Pregnant or breastfeeding women - Studies allowed**

Yes  
Special provisions apply

	<p><b>Legal framework / Reference (Pregnant or breastfeeding women)</b></p> <p>L1121-5 Chapter 1 CSP</p> <p><b>National legal framework for protection of vulnerable populations in place</b></p> <p>Yes</p> <p><b>Applicable legal framework / Reference (Vulnerable Population)</b></p> <p>Special conditions apply for the inclusion of vulnerable persons (e.g. children, pregnant and lactating women and adult protected by the law) pursuant to L1121-5 to 9 (Chapter 1 CSP), L1122-1 &amp; 2.</p>
<p>Study Participants - Compensation &amp; Reimbursement</p>	<p><b>Reimbursement for study participants</b></p> <p>Depends on study population (healthy subjects or patients)</p> <p><b>Compensation is limited to/provided for</b></p> <p>—</p> <p><b>Additional Information</b></p> <p>Healthy volunteers participating in clinical research have to be compensated (not mandatory for patients, but possible)</p>
<p>Study Participants - Recruitment &amp; Trial Outcome</p>	<p><b>Mandatory to inform participant of clinical trial outcome</b></p> <p>Yes</p> <p><b>Additional Information</b></p> <p>The participants have the right to be informed of the outcome of a clinical trial.</p>
<p>Data Protection</p>	<p><b>Notification to DP Authority/ Ombudsmann is mandatory</b></p> <p>Yes</p> <p><b>Approval/ authorisation required</b></p> <p>Yes</p> <p><b>Specific notification timelines before operations start</b></p> <p>—</p> <p><b>Language of notification</b></p> <p>French</p> <p><b>Notification format</b></p> <p>Online portal</p> <p><b>Notification fee required</b></p> <p>No</p> <p><b>Data Protection Authority/ Agency - Contact Details</b></p> <p>Commission Nationale de l'Informatique et des Libertés - CNIL / National Committee for Data Protection</p> <p><b>Phone</b></p> <p>+33 153 73 22 22</p> <p><b>Fax</b></p> <p>+33 153 73 22 00</p>

**Address**

8 rue vivienne

**ZIP/City**

75083 Paris cedex 02

**Country**

France (FR)

**Additional Information**

The trial must be submitted to the committee for data protection (Commission Nationale de l'Informatique et des Libertés - CNIL) assessing the storage and to the CEREES assessing the content of information collected.  
A simplified process is possible if a reference methodology is used.

**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)**

-

Insurance

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

Investigator(s)  
Sponsor  
Study participants

**Responsible for covering insurance**

Sponsor

**Applicable national legal framework/ Reference**

L1121-10 Chapter 1 CSP

**National legislation**

General Information:  
Applicable Legislation &  
Conventions

**Official website providing relevant national legislation available**

Yes

**Official website providing relevant national legislation**LEGIFRANCE: [www.legifrance.gouv.fr](http://www.legifrance.gouv.fr)**Official governmental legal database available**

Yes

**Official governmental legal database**LEGIFRANCE : [www.legifrance.gouv.fr](http://www.legifrance.gouv.fr)**Additional Information**

Legal and regulatory framework for research involving human beings

LOI n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine (JO n°0056 du 6 mars 2012) ( Commonly called the "Jardé law").

Available at : [www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00002544158](http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00002544158)

Ordonnance n° 2016-800 du 16 juin 2016 relative aux recherches impliquant la personne humaine (JO du 8 décembre 2017).

Available at : [www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFT](http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFT)

Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés. Version consolidée au 08 décembre 2017.

Available at: [www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT](http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT)

Décret n° 2017-884 du 9 mai 2017 modifiant certaines dispositions réglementaires relatives aux recherches impliquant la personne humaine (JO n°0109 du 10 mai 2017)

Available at : [www.legifrance.gouv.fr/eli/decret/2017](http://www.legifrance.gouv.fr/eli/decret/2017)

Décret n° 2016-1537 du 16 novembre 2016 relatif aux recherches impliquant la personne humaine ( JO n°0267 du 17 novembre 2016)

Available at: [www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033394083](http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033394083)

Data protection legislation

LOI n° 2018-493 du 20 juin 2018 relative à la protection des données personnelles (JORF n°0141 du 21 juin 2018)

Available at: <https://www.legifrance.gouv.fr>

### \*\*\* BACKGROUND

The scope of the new French law ( "Jardé Law", No. 2012-300, 2012) is very broad. It applies to all research involving human beings, with a view to developing biological or medical knowledge. Potentially, the law could apply to studies in social sciences designed to develop biological or medical knowledge.

The "Jardé Law", No. 2012-300, 2012 introduced a risk-based classification for research involving human beings.

The law divides research into three categories :

1. Interventional research [with risk or burden above minimal risk/burden] ( Article L. 1121-1, 1° of the Public Health Code)

This category concerns research studies involving interventions “not justified by the person’s usual care”.

e.g. research on medicinal products, evaluation of medical devices, but also other types of research such as surgical research, etc.

This category of research can only be implemented after authorization by the ANSM and with a favorable opinion of an Ethics Committee (CPP in French).

(Articles L. 1121-1, 1°, L1123-8, L1123-12, etc of the Public Health Code)

2. Interventional research with minimal risk or burden ( Article L. 1121-1, 2° of the Public Health Code)

A list of interventions that present no more than minimal risk was laid down by the Ministry of Health.

The list of 2° can be find at : <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000036805796>

(Arrêté du 12 avril 2018 fixant la liste des recherches mentionnées au 2° de l'article L. 1121-1 du code de la santé publique)

This category excludes research on medicinal products but may include the use of medicinal products under the usual conditions of use.

The research must be declared to the ANSM but doesn't require authorization.

Such research requires a favorable opinion of an Ethics Committee (CPP in French).

3. Non-interventional research (Article L. 1121-1, 3° of the Public Health Code)

This category concerns research that does not involve any risk or burden. The acts are practiced, and the products used in the usual way.

The list of 3° can be find at :

<https://www.legifrance.gouv.fr/eli/arrete/2018/4/12/SSAP1810240A/jo/texte/fr>  
(Arrêté du 12 avril 2018 fixant la liste des recherches mentionnées au 3° de l'article L. 1121-1 du code de la santé publique)

The research must be declared to the ANSM but doesn't require

	<p>authorization. Such research requires a favorable opinion of an Ethics Committee (CPP in French).</p>
<p>Clinical Trials on IMPs in Humans</p>	<p><b>Applicable national regulations</b></p> <p>Transposition of (CT) Directive 2001/20/EC</p> <p><b>Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)</b></p> <p>LOI no 2004-806 du 9 août 2004 relative à la politique de santé publique (complétée par le décret 2006-477 du 26 avril 2006).</p> <p><b>Applicable to ATMP/ GMO trials</b></p> <p>Yes</p> <p><b>Transposition of (GCP) Directive 2005/28/EC</b></p> <p>—</p> <p><b>General legislation on Medical/ Clinical Research in Humans</b></p> <p>LOI n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine (JO n°0056 du 6 mars 2012) ( Commonly called the "Jardé law"). Available at : <a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00002544158">www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT00002544158</a></p> <p>Ordonnance n° 2016-800 du 16 juin 2016 relative aux recherches impliquant la personne humaine (JO du 8 décembre 2017). Available at : <a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFT">www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFT</a></p> <p><b>Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)</b></p> <p>Décret n° 2017-884 du 9 mai 2017 modifiant certaines dispositions réglementaires relatives aux recherches impliquant la personne humaine (JO n°0109 du 10 mai 2017) Available at : <a href="http://www.legifrance.gouv.fr/eli/decret/2017">www.legifrance.gouv.fr/eli/decret/2017</a></p> <p>Décret n° 2016-1537 du 16 novembre 2016 relatif aux recherches impliquant la personne humaine ( JO n°0267 du 17 novembre 2016) Available at: <a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033394083">www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033394083</a></p> <p><b>Additional Information</b></p> <p>Jardé Law is part of the Code de la Santé Publique/CSP and has to be regarded for all research involving human beings.</p>
<p>Radiation &amp; Radiotherapy</p>	<p><b>Use of radiation or radioactive compounds - Specific requirements</b></p> <p>Yes</p> <p><b>Applicable legal framework</b></p> <p>Chapter 3 (section 5, Article R1333-56) CSP: specific requirements apply in case that study participants are exposed to ionising radiation or radioactive substances in the clinical trial.</p> <p><b>Additional Information</b></p> <p>Further information can be found on the website of IRSN (Institute de Radioprotection et de sûreté nucléaire)</p>
<p>Gene Therapy</p>	<p><b>Specific requirements</b></p> <p>Yes</p>



## Applicable legal framework

(1) Due to the fact that gene transfer medicinal products are covered by LOI no 2004-806 du 9 août 2004 relative à la politique de santé publique the legal procedure is generally the same as for medicinal products for human use.

Any specific requirements are indicated in the applicable sections.

(2) Bioethics Law 2004: Genetic studies are covered by the bioethics law of August 2004, with an important role of the newly created "Agence de biomédecine".

## Data Protection

### **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)**

National Data Protection Act

#### **National DP act**

Loi 2004-801 (fr)/ French Data Protection Law (en)

### **Other applicable regulations (covering DP related issues)**

In France, the privacy of participants is protected by the French Data Protection Law relating to the protection of individuals with regard to the processing of personal data that modifies Act 78-17 of 6 January 1978 on Data Processing, Data Files and Individual Liberties. This law includes provision concerning health data collecting within clinical research.

## Definition

### IMP/IMP Study

#### **IMP - Definition**

The investigational medicinal product is the study drug and the comparator including the placebo or active drug. The background treatment is also considered an investigational medicinal product if collecting information on it is one of the objectives of the study.

#### **IMP Study - Definition**

The definition of a clinical trial on Medicinal Products ("essai clinique d'un ou plusieurs médicaments") is provided in Article R. 1121-1 du CSP (according to Art2 of Directive 2001/20/CE)

#### **Additional Information**

Further definitions (e.g. Biomedical research, Interventional Studies, Observational Studies) are provided in "Annexe 1- Définitions", provided on the ANSM website in section: Activités > Médicaments et produits biologiques > Avis aux promoteurs - Formulaires.