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/

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** PLEASE NOTE THAT WE ARE CURRENTLY UPDATING OUR DATABASE
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

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

–

Amendments/ Substantial Amendments (SA)

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

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.

Safety Reporting

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-thereatening 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)

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

	Additional Information 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.
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission available** Yes **Guidance on study submission** The required content of the application dossier is provided in : 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. Available at (only in French) : https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033546922&dateTexte=20180626
Submission Format	**Format option(s)** Email Paper hardcopy Data carrier (CD-rom/DVD) **Preferred format** – **Guidance on submission format** The required content of the application dossier is provided in : 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. Available at (only in French) : https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000033546922&dateTexte=20180626
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 Information material, Documents and Forms intended for study participants and patient information
Submission Fees	**Fees for Ethical review mandatory** No **Fees for Ethical review** No submission fees applicable.
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 45 Extension to 60 days if questions to applicant **General timespan for multi-centre studies (max nr days)** 45 Extension to 60 days if questions to applicant **ATMP/GMO trials (max nr days)** – **External expert advice required: Timespan (max nr days)** – **Xenogeneic cell therapy: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **Applicable national legal framework/ Reference** Article R1123-24 CSP **Additional Information** The absence of a reply within 45 days implies rejection.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Sponsor Legal representative domiciled in the EU/EEA **Timeline Ethical review of SA (max nr days)** 35 **Applicable national legal framework/ Reference** L1123-9 Chapter 3 CSP **Additional Information** EC notifies the CA on its decision.

Safety Reporting	**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-thereatening 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	**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" (Sponosr) 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

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

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

Official governmental legal database available

Yes

Official governmental legal database

LEGIFRANCE : 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

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

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

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

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

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

	authorization. Such research requires a favorable opinion of an Ethics Committee (CPP in French).
Clinical Trials on IMPs in Humans	**Applicable national regulations** Transposition of (CT) Directive 2001/20/EC **Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)** 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). **Applicable to ATMP/ GMO trials** Yes **Transposition of (GCP) Directive 2005/28/EC** – **General legislation on Medical/ Clinical Research in Humans** 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 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 **Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** 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 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 **Additional Information** Jardé Law is part of the Code de la Santé Publique/CSP and has to be regarded for all research involving human beings.
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Applicable legal framework** 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. **Additional Information** Further information can be found on the website of IRSN (Institute de Radioprotection et de sûreté nucléair)
Gene Therapy	**Specific requirements** Yes

	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- Définitons", provided on the ANSM website in section: Activités > Médicaments et produits biologiques > Avis aux promoteurs - Formulaires.