Medical Devices - 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

Competent Authority/-ies (CA)
Ethics committee(s)

CA - Submission for authorisation mandatory for

MD CE-marked, use outside label
MD CE-marked, use outside label + IMP
MD without label
MD without label + IMP
MD CE- marked, use within label (+IMP) with extra burden and invasive examination for the patients

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA

CE-marked MD used within label are exempted from any notification obligation to CA

Yes

Additional Information

Clinical investigations of CE-marked MD used within label are exempt from authorisation requirement

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

In parallel
Sequentially (in any order)

Submission of Application

Responsible for study submission

Sponsor
Legal representative

Entitled to study submission

–

Prerequisites for submission

The sponsor must connect to the ANSM website to obtain a registration number for research (ID RCB).

Guidance on submission of application available

Yes

Guidance on submission of application

(1) A comprehensive guidance for sponsors is available for download on the ANSM website in French !

Recherches impliquant la personne humaine portant sur des dispositifs médicaux ou sur des dispositifs médicaux de diagnostic in vitro - Avis aux promoteurs (14/06/2017)

Available at : http://ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Essais-cliniques-portant-sur-les-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/(offset)/0#dm

See also :
(2) Decree of 16 August 2006 ('Decree AEC') fixing the contents, the format and the methods of presentation to the French Agency for Medical Safety of products of health of the dossier for request for authorisation of biomedical research relating to a medical device or in vitro diagnostic medical device

Additional Information

Radiopharmaceutical drugs:
The use and the detention of radionuclides, for their use in biomedical research, and products or devices containing them, are subject to authorisation by the minister in charge of health. A copy of this authorisation, delivered by the Directorate-General of nuclear safety and protection against radiation (DGSNR), must be added to the application dossier of request for AEC.

Blood/ tissue samples (circulation and storage): additional forms have to be submitted to the CA.

Submission Format

Format option(s)

Data carrier (CD-rom/DVD)
Registered post with proof of delivery or by messenger
Email (up to 5 MB): EC.DM-COS@ansm.sante.fr

Preferred format

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Standard application form

Standard application form for clinical investigations requiring authorisation: 'Formulaire 1' & 'Formulaire 2'.
Available on ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Formulaires et modèles à télécharger (Forms & Downloads)

Guidance on submission format

Detailed information on submission format is provided in the following guidance documents :

"Avis au promoteurs/ Notice to sponsors" available in French : Recherches impliquant la personne humaine portant sur des dispositifs médicaux ou sur des dispositifs médicaux de diagnostic in vitro - Avis aux promoteurs (14/06/2017) application/pdf (1794 ko)

Available at : http://ansm.sante.fr/Activites/Dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/Essais-cliniques-portant-sur-les-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro/(offset)/0

See also :
Application forms on the CA website under the Section : RIPH- Recherche impliquant la personne humaine - Formulaires et modèles à télécharger

Available at: http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Essais-cliniques

Additional Information

Submission by post :

Agence nationale de sécurité du médicament et des produits de santé (ANSM) Direction des dispositifs médicaux thérapeutiques et des cosmétiques
Essais cliniques
143-147 Boulevard Anatole France
93285 Saint-Denis cedex

By Email :

EC.DM-COS@ansm.sante.fr

Also possible via Eudralink

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

e.g. Protocol summary, “Répertoire public des essais cliniques autorisés – Informations sur l’essai”)

Documents mandatory to be in local language of study site

–

Documents mandatory to be in language of the study participant

–

	Additional Information Related information is provided in the guidance document "Avis au promoters/ Notice to sponsors" available on ANMS website.
Submission Fees	**Fees for trial submission mandatory** No **Fees** No submission fees
Timelines Authorisation	**General timespan (max nr days)** 60 30 (for class I or IIa MD, other than MD of long term invasive IIa class + MD or IVD MD, having already been the subject of authorisation in France) **Mode of approval (General)** Tacit (Silent) Explicit authorization only for research relating to MD incorporating products of human or animal origin **Timespan counted from** Date of submission of valid application **Additional Information** ANSM has to the option of notifying the applicant of its decision before the expiry of the 30 or 60 days deadline (e.g. in case of no objection and no request for additional information, the final decision of ANSM could be formulated within 15 resp. 30 days and would then be notified by letter to the applicant). Related details are provided in the guidance "Avis au promoters/ Notice to sponsor" available on ANMS website.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Any substantial modifications having a significant impact on any aspect of research **Responsible for submission of SA** Sponsor Legal representative **Standard notification form** The standard form 'Form of request for substantial modification' (Formulaire 3) is provided on the ANMS website in section: Formulaires et modèles à télécharger (Forms and Downloads). **Timeline for approval of SA (max nr days)** 35 From date of receipt of valid application By silent (implicit) approval By explicit authorization only for research relating to MD incorporating products of human or animal origin

	Guidance on submission of SA (1) The contents of the dossier of request for authorisation of substantial modification are detailed in section 2.2.2.1 of the comprehensive guidance 'Avis au promoteurs/ Notice to sponsors'. (2) 'Tome 3- Fiche pratiques' provides examples for substantial and non-substantial amendments as defined by ANSM Both documents available on ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Avis aux promoteurs / fiches (Notice to sponsors/ guidelines) **Applicable national legal framework/ Reference** Articles R.1123-35 to 37 of the CSP Decree Substantial Modification **Additional Information** ANSM may notify the applicant of its decision before the expiry of this 35 day deadline. Submission format: Electronically (see Application Format). In exceptional circumstances, it is possible to transmit the file of request by post or messenger.
Safety Reporting	**Responsible for AE reporting to CA** Sponsor **Sponsor must declare reportable events to** National CA Relevant EC(s) **Reportable AEs** SAE (Serious Adverse Event) likely to be related to the procedure of implementation of the MD All suspicions of USADE (Unanticipated Serious Adverse Device Effect) **SUSAR being life-thereatening or leading to death must be reported** Immediately **All other SUSARs** – **SAE /SADE must be reported** Immediately, within a max of 15d for other reportable events (Suspicions of USADE + SAE likely to be related to the procedure of implementation of MD) Immediately, for events bieng life-threatening or leading to death **National standard reporting form available** Yes **Standard Reporting Form** A standard reporting form ('Formulaire 5' & 'Formulaire 6') is available on the ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Formulaires et modèles à télécharger (Forms and Downloads) Available at : http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Essais-cliniques **Reporting format - Options** Electronically Exceptionally by post

Preferred format

Electronically

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
Relevant EC(s)

Guidance on AE reporting procedure

"Avis au promoters/ Notice to sponsors': Provides detailed information reporting obligations including required contents and format of reports

Document available on ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Avis aux promoteurs / fiches (Notice to sponsors/ guidelines)

Applicable national legal framework/ Reference

Article R. 1123-48 of the CSP
Decree EI (articles 4 and 8)
Article R. 1123-53 of the CSP (Annual Safety Report)
Decree : Décret n°2017-884 du 9 mai 2017 modifiant certaines dispositions réglementaires relatives aux recherches impliquant la personne humaine

Additional Information

These provisions apply to interventional clinical trials carried out on MD and IVD MD

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Sponsor
Legal representative

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

Last participant - last visit in the respective country
Last participant - last visit in all involved countries (multinational trials)
NB: Two declarations might be required, if the research does not come to an end simultaneously in France and in all the other countries concerned

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

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

"Form of declaration of end of trial" (Formulaire 10)
Available on the ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Formulaires et modèles à télécharger (Forms and Downloads)

Guidance on End of trial declaration available

Yes

Guidance on End of trial declaration

'Avis au promoters/ Notice to sponsors':
Contents of the dossier and required format of the end of trial declaration is specified in section 4.3.1 of the comprehensive guidance (available on the ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Avis aux promoteurs / fiches (Notice to sponsors/ guidelines)

Applicable national legal framework/ Reference

Article L 1123-11 of the CSP
Article R. 1123-59 of the CSP
End of Trial Decree: Order of 25 August 2006 relating to the contents and the methods of presentation of information relating at the end of research, the final report and the summary of the final report of a biomedical research relating to a DM or DM-DIV

Ethics committee

Contact Details

Contact Name 1

Comités de Protection des Personnes (CPP)

Web address

http://www.cpp-sudmed2.fr/IMG/pdf/Coordonnes-CPP-A3-180607.pdf

Additional Information

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

Ethical Review – General

Submission for Ethical review mandatory for

Interventional MD investigations
Observational MD investigations
All combination studies (MD+IMP)

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)

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Regional EC (competent for the area where investigator is located)

Additional Information

There are 39 competent regional ECs in France.

Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Regional EC (authorised to issue a single opinion) **Submission of application required to** Regional EC (authorised to issue a single opinion) **Additional Information** There are 39 Lead ECs in France, no local ECs. Multi-centre studies require only one approval (single opinion).
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **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° et au 2° de l'article L. 1121-1 du code de la santé publique portant sur un dispositif médical ou sur un dispositif médical de diagnostic in vitro (JORF n°0284 du 7 décembre 2016) Available at (only in French): https://www.legifrance.gouv.fr/eli/arrete/2016/12/2/AFSP1635568A/jo/texte **National legal framework in place** Yes
Submission Format	**Format option(s)** – **Preferred format** – **Guidance on submission format available** Yes **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° et au 2° de l'article L. 1121-1 du code de la santé publique portant sur un dispositif médical ou sur un dispositif médical de diagnostic in vitro (JORF n°0284 du 7 décembre 2016) Available at (only in French): https://www.legifrance.gouv.fr/eli/arrete/2016/12/2/AFSP1635568A/jo/texte
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 **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Submission Fees	**Fees for Ethical review mandatory** No **Fees for Ethical review** No submission fees.
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 **External expert advice required: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **Applicable national legal framework/ Reference** Article R1123-24 CSP
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial modifications having a significant impact on any aspect of research **Responsible for notification of SA** Sponsor **Standard notification form** The CA standard form 'Form of request for substantial modification' (Formulaire 3) can also be used for application to EC and is provided on the ANMS website in section: Formulaires et modèles à télécharger (Forms and Downloads) **Timeline Ethical review of SA (max nr days)** 35

Applicable national legal framework/ Reference

Articles L1123-9 and R1123-35&36 CSP

Additional Information

EC notifies the CA on its decision.

Safety Reporting

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

The definitions of Article R.1123-39 of the CSP apply.

Reportable AEs

SAE (Serious Adverse Event)
SAE (Serious Adverse Event) likely to be related to the procedure of implementation of the MD
All suspicions of USADE (Unanticipated Serious Adverse Device Effect)
Any new event which could have an unfavourable impact on participants' safety or on the method of trial

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately

Responsible for AE reporting to relevant EC(s)

Sponsor

SUSAR being life-thereatening or leading to death must be reported

–

All other SUSAR must be reported

–

SAE/SADE must be reported

Immediately, within a max of 7 d upon first knowledge (+8d for additional information) for reportable events being life-threatening or leading to death
Immediately, within a max of 15d for other reportable events (Suspicions of USADE + SAE likely to be related to the procedure of implementation of MD)

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

National Standard Reporting form available

Use of corresponding form (for AE reporting to CA) possible

Standard Reporting Form

A standard reporting form ('Formulaire 5' & 'Formulaire 6') is available on the ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Formulaires et modèles à télécharger (Forms and Downloads)

Reporting format - Options

–

Preferred reporting format

–

Provision of Annual safety report mandatory

Yes

	Guidance on AE reporting procedure (1) Fiche: "Schéma de déclaration des données de sécurité à l'ANSM et au CPP": A summary table of the safety data to be declared to ANSM and the CPP concerned, (2) "Avis au promoters/ Notice to sponsors': Provides detailed information reporting obligations including required contents and format of reports Both documents available on ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Avis aux promoteurs / fiches (Notice to sponsors/ guidelines) **Applicable national legal framework/ Reference** Article L1123-10 CSP Article R1123-48 CSP **Additional Information** Semi-annually report: a list of suspicions of USADE and adverse events likely to be related to the procedure of implementation of the MD which have occurred outside national territory in the trial concerned. All these provisions apply to interventional clinical trials carried out on MD and IVD MD
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 90 **Timespan counted from** Last participant - last visit in the respective country Last participant - last visit in all involved countries (multinational trials) NB: Two declarations might be required, if the research does not come to an end simultaneously in France and in all the other countries concerned **Early/premature Termination - Declaration timespan (max nr days)** 15 **Reasons for early termination shall be clearly stated** Yes **Standard Declaration form** 'Form of declaration of end of trial' ('Formulaire 10'): Available on the ANSM website in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Formulaires et modèles à télécharger (Forms and Downloads) **Applicable national legal framework/ Reference** Article R1123-59 CSP **Additional Information** 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.

Study specific Requirements

Sponsor	**Sponsor - Definition available in national law** Yes **Sponsor - Definition (pursuant to national law)** The sponsor is the person or entity who takes the initiative of biomedical research on human beings, which ensures the management of this research, and which verifies that its financing is planned. When several persons or entities take the initiative of undertaking the same research, a single sponsor must be designated to assume the responsibility for the course of the research on national territory. (Article L. 1121-1 of the CSP) **Sponsorship mandatory - Additional information** There is no need to have some kind of representative or a legal entity if sponsor is from EU
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **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 according to Article L1122-1 Chapter 2 CSP. 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. **Applicable national legal framework/ Reference** Articles L1122-1&2, L1121-5 to 9
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply **Legal framework/Reference (Minors/Children)** Article L1121-7 Article L1122-2 CSP **Incapacitated persons - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Incapacitated persons)** Article L1121-6/8/9 CSP Article 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 intensive care patients in acute emergency settings without the informed consent of the legal representative if the latter is "present" (see L1122-1-2 Chapter 2 CSP) However, the future legislation (Jardé law) will allow 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") **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
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	**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 **Specific notification timelines before operations start** – **Language of notification** French only **Notification format** Online **Notification fee required** No **Data Protection Authority/ Agency - Contact Details** Commission Nationale de l'Informatique et des Libertés (CNIL) **Phone** +33 153 73 22 22 **Fax** +33 153 73 22 00

	Web address https://www.cnil.fr/en/home **Address** 8 rue vivienne **ZIP/City** 75083 Paris cedex 02 **Country** France (FR) **Additional Information** Notification is required for interventional and observational investigations on MD (and combination studies with MP). **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** – **National DP act** The privacy of participants is protected by the French Data Protection Law (Loi 2004-801) 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 (also available in English: French Data Protection Law).
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Sponsor Study participants **Responsible for covering insurance** – **Minimum coverage sum** The compensation sum covered by the insurance depends on the protocol. **Additional Information** Insurance is mandatory in interventional investigations on MD. Insurance is not mandatory for manufacturers.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Not specified **Audit by sponsor** Not specified **Standard Operating Procedures (SOPs)** Not specified
Archiving & Data Management	**Study documents must be kept at least (in years)** 15

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** ANSM website (CA) provides applicable regulations and decrees in section: Activités > Dispositifs médicaux > Essais cliniques portant sur les dispositifs médicaux et dispositifs médicaux de diagnostic in vitro > Réglementation **Official governmental legal database available** Yes **Official governmental legal database** Legifrance: public legal database
Investigations on Medical Devices	**Applicable national regulations** – **Act on Medical Devices (or comparable national legal framework)** Clinical trials on MD in France are covered by: 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). This law (following the “Huriet - Sérusclat” Law) has to be regarded for all biomedical research involving human beings. It is part of the Code de la Santé Publique/CSP (see: Code de la santé publique - Titre II Recherches biomédicales). **Additional Information** NB: The “Jardé” Law, regulating research on human beings and promulgated on March 5th, 2012, is still not applicable as decrees are not yet implemented.
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** – **National DP act** The privacy of participants is protected by the French Data Protection Law (Loi 2004-801) 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 (also available in English: French Data Protection Law).

Definition

MD/MD Investigation	**Investigation of MD - Definition** No specific French definition for studies with MD, only for observational studies with MD (Article R1121-2 CSP). A definition for "Interventional clinical trials on a medical device (MD)" is provided in guidance document "Avis au promoters/ Notice to sponsors" available on ANSM website as follows: 'any clinical trial or clinical investigation of one or more medical devices aiming at determining or confirming their performances or highlighting their adverse effects and at evaluating if these constitute risks taking into consideration the performances imputed to the device.'