Medical Device	France
Competent Authority	
Contact Details	
Contact name 1	French National Agency for the Safety of Medicines and Health Products (ANSM)
Contact name 2	medical devices and in vitro diagnostic medical devices department
Contact name 3	
Phone	(+33) 01 55 87 36 87
Fax	(+33) 01 55 87 37 17
Email General	
Email Department	EC.DM-COS@ansm.sante.fr
Address	143/147 Boulevard Anatole France
ZIP/City	93285 Saint-Denis Cedex
Country	France
Web address	http://www.ansm.sante.fr
Additional information	Only a central CA, no local CA in France.
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Competent Authority/-ies (CA) Ethics committee(s)
CA - Submission for authorisation mandatory for...	depending on the class of MD and the invasive nature of the clinical investigation- favorable opinion from ethic committee
CE-marked MD used within label are exempted from any notification obligation to CA	Yes
Guidance on submission of application available	Yes
Guidance on submission of application	Notice to sponsors: https://ansm.sante.fr/uploads/2021/05/31/2021-05-28-aap-partie-i-dispo-generales-ic-dm-v1-2-tqg.pdf Terms and conditions for submitting an application : https://ansm.sante.fr/uploads/2022/02/04/20220204-modalites-pratiques.pdf
National legal framework in place	Yes
Applicable national legal framework/reference	Articles L. 1125-1 to L.1125-31 of CSP (french public health code)
Additional information	Before the entered in force of the Medical Device Regulation (UE), the clinical trials involving medical device were submitted
Submission Format	
Online portal	Pending the availability of Eudamed, investigational applications must be sent to ANSM by e-mail to the following address: EC.DM-COS@ansm.sante.fr
Standard application form available	Yes

Medical Device	France
Standard application form	Standard application forms for clinical investigations requiring authorisation: "*Clinical investigation – application form under Medical Device Regulation for the competent authority (ANSM) and the ethics committee (CPP)*" Available on ANSM website: your steps /researcher /request authorisation for clinical investigation ANSM website https://ansm.sante.fr/uploads/2022/03/02/20220302-annexe-2-modele-faec.docx
Standard application form - additional information	Files must be submitted in Word or PDF format, signed where applicable
Use of standard application form binding	Yes
Guidance on submission format available	Yes
Guidance on submission format	Detailed information on submission format is provided in the following guidance documents : Notice to sponsors Party 1:https://ansm.sante.fr/uploads/2021/05/31/2021-05-28-aap-partie-i-dispo-generales-ic-dm-v1-2-tqg.pdf See also : Practical details: https://ansm.sante.fr/uploads/2022/02/04/20220204-modalites-pratiques.pdf
National legal framework in place	Yes
Applicable national legal framework/reference	N/A
Additional information	Submission by two channels : By Email : EC.DM-COS@ansm.sante.fr Via Eudralink (EMA)
Language of Submission	
Language(s) of application	French English
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	Documents may be submitted in English; French is nevertheless required for certain documents document
National legal framework in place	N/A
Applicable national legal framework/reference	N/A

Medical Device	France
Additional information	Documents which are submitted in French are listed in the following document: Practical details guidance_*Annex 1 : Clinical investigation dossier – List of documents required by ANSM and CPP (document in english)* https://ansm.sante.fr/uploads/2022/02/04/20220204-annexe-1-liste-recapitulative-des-documents-exiges-par-lansm-et-les-cpp.pdf For example there are : • protocol synopsis • proof of insurance • Documents to be used to obtain informed consent Related information is provided in the guidances as refers above
Submission Fees	
Fees for trial submission mandatory	No
Fees	No submission fees
Waiver for academic (non-commercial) studies possible	N/A
Payment requirements (timelines)	N/A
Official guidance on required fees available	N/A
Official guidance on required fees	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	
Additional information	
Timelines Autorisation	
General timespan (maw 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	Tacit (Silent) Explicit authorization only for research relating to MD incorporating products of human or animal origin
Clock-stop possible if complementary information requested	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A

Medical Device	France
Additional information	The processing times for requests are described in the following document: "table of classification and process of clinical investigations": https://ansm.sante.fr/uploads/2022/02/10/20220210-classification-et-process-devaluation-des-investigations-cliniques-dm-selon-le-reglement-2017-745-et-adaptations-nationales.pdf Validation deadline (validation time to allow applications to be processed) : 10 days (+ 10 days for the sponsor (option of an additional 20 days on reasoned request) and 5 days for ANSM if the dossier is incomplete) A< Assessment deadline:45 days (+ 20 days if expert consultation) + clock-stop of clock-stop of 12 days max.
Amendments/Substantial Amendments	
Standard notification form	Application for substantial modification and other modifications https://ansm.sante.fr/uploads/2021/05/25/msa-doc032-v01-ax1-fmsa-dmdmdiv-2021-05-19.docx Notice to sponsor party III https://ansm.sante.fr/uploads/2021/06/29/2021-06-29-aap-partie-iii-modalites-pratiques-msa-ic-dm-v1-0-vf.pdf
Timeline for approval of SA (max nr days)	60 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 of submission of SA available	Yes
Guidance of submission of SA	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	Articles R.1123-35 to 37 of the CSP Decree Substantial Modification
Additional information	1: Validation by ANSM / CPP / or coordinated by ANSM (depending on whether the MS is the responsibility of ANSM / CPP / both) 10 days (+ 10 days for the sponsor and 5 days for ANSM and/or CPP if the dossier is incomplete) 2: Evaluation period: Evaluation by ANSM and/or CPP 38 days (+ 7 days for ANSM) if expert consultation) + clock-stop of 12 days max Submission format: Electronically (see Application Format). In exceptional circumstances, it is possible to transmit the file of request by post or messenger.
Safety Reporting	
Sponsor must declare reportable events to	National CA Relevant EC(s)
Investogator/PI shall separately report any SAE/SADE to CA	N/A
Reportable AEs	SAE (Serious Adverse Event) - Near Incidents All suspicions of USADE (Unanticipated Serious Adverse Device Effect)
SUSAR being life-threateningor leading to death must be reported	Immediately
All other SUSARs	N/A
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

Medical Device	France
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
Online safety reporting portal	N/A
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 available	N/A
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)
National legal framework in place	Yes
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
End of trial	
End of trial declaration: who, when, what?	All clinical investigations requiring authorisation by CA
Responsible for end of trial declaration	Sponsor Legal representative
Regular termination - declaration of 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)
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	Yes
Standard declaration form	Available on the ANSM website in section end of clinical investigation : 21/05/25/fin-doc032-v01-ax1-2021-05-20.docx To be sent to ANSM by e-mail to: EC.DM-COS@ansm.sante.fr + to the CPP via SIRIPH2G

Medical Device	France
Guidance on end of trial declaration available	No
Guidance on end of trial declaration	Notice to sponsors in progress
National legal framework in place	No
Applicable national legal framework/reference	**Article L1125-20** of the CSP There are no specific provisions in national law. The sponsor shall inform the competent Data Protection Committee and the competent authority of the start and end of the clinical investigation, in accordance with the procedures laid down in Article 77 of the MDR (EU).
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Ethics Committee	
Contact Details	
Contact name 1	Comités de Protection des Personnes (CPP)
Contact name 2	N/A
Contact name 3	N/A
Phone	N/A
Fax	N/A
Email General	N/A
Email Department	N/A
Address	N/A
ZIP/City	N/A
Country	N/A
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. list of EC: https://sante.gouv.fr/IMG/pdf/repertoire_cpp_23042024.pdf
Ethical Review - General	
Submission for Ethical review mandatory for	All clinical investigations of MD
Submission to CA and EC to be performed in the following order	In parallel EC first
Procedural interaction between CA and EC during approval proccess	Yes
Procedural interaction - additional information	N/A

Medical Device	France
Additional information	Submission to EC first because in the application form submitted to the CA, the CPP selected must be indicated. However submission to EC and CA the same day.
Single-Centre Studies - Ethical Review	
Ethical approval (favourable opinion) to be obtained from	Any competent EC
Additional information	There are 39 competent regional ECs in France. The sponsor submits the application to the EC appointed at random from among the available committees and with the relevant expertise
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Regional EC (authorised to issue a single opinion)
Submission of application required to	Any accredited EC
Additional information	The sponsor submits the application to the EC appointed at random from among the available committees and with the relevant expertise
Submission of Application	
Responsible for study submission	Sponsor
Entitled to study submission	N/A
Prerequisites for submission	N/A
Guidance on submission of application available	Yes
Guidance on submission of application	The required content of the application dossier is provided in Notice to sponsors party II *_Annex 1 : Clinical investigation dossier – List of documents required by ANSM and CPP* https://ansm.sante.fr/uploads/2022/02/04/20220204-annexe-1-liste-recapitulative-des-documents-exiges-par-lansm-et-les-cpp.pdf The additional document to the request for an opinion from the EC described in the appendix to the Order of 2 December 2016 laying down the content, format and presentation procedures for the file requesting an opinion from the EC: https://www.legifrance.gouv.fr/download/pdf?id=6rHR0rznWmItf5IaRDLRPmWUgvYvfJ3GciREwkWtl3E= Available at (only in French) Applicant's guidance and FAQ: https://sante.gouv.fr/IMG/pdf/guide_deposant_siriph2g_v7_avril_2023.pdf
National legal framework in place	Yes
Applicable national legal framework/reference	**Article L1125-2** **Articles R1123-1 à R1123-26** of CSP
Additional information	N/A
Submission Format	
Format option(s)	Online portal
Preferred format	Not applicable
Online portal	
Standard application form available	N/A
Standard application form	N/A

Medical Device	France
Standard application form - additional information	N/A
Use of standard application form binding	Yes
Guidance on submission format available	Yes
Guidance on submission format	Online portal- Connexion - SI RIPH 2G (sante.gouv.fr) The required content of the application dossier is provided by cf "sublission of application" 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	
Applicable national legal framework/reference	N/A
Additional information	N/A
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 Import request form
Documents mandatory to be in local language of study site	N/A
Documents mandatory to be in language of study participant	Information material, Documents and Forms intended for study participants and patient information
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	Annex 1 : Clinical investigation dossier – List of documents required by ANSM and CPP- the mandatory langage of some documents is indicated
Submission Fees	
Fees for ethical review mandatory	No
Waiver for academic (non-commercial) studies possible	N/A
Fees for ethical review	No submission fees.

Medical Device	France
Official guidance on required fees available	N/A
Official guidance on required fees	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	
Timelines Ethical Review	
General timespan for single-centre studies (max nr days)	45 45 j + clock-stop of 12 days max.
General timespan for multi-centre studies (max nr days)	N/A
Clock-stop possible if complementary information requested	Yes
Timespan counted from	Date of receipt of valid and complete application
National legal framework in place	Yes
Applicable national legal framework/reference	Article R1123-24 CSP
Additional information	N/A
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial modifications having a significant impact on any aspect of research
Responsible for submission of SA	Sponsor
Standard notification form available	Yes
Standard notification form	The CA standard form is provided on the ANSM website : https://ansm.sante.fr/uploads/2021/05/25/msa-doc032-v01-ax1-fmsa-dmdmdiv-2021-05-19.docx Submission guidance/notice to sponsors: https://ansm.sante.fr/uploads/2021/06/29/2021-06-29-aap-partie-iii-modalites-pratiques-msa-ic-dm-v1-0-vf.pdf
Timeline for approval of SA (max nr days)	35 38 days
Guidance of submission of SA available	N/A
Guidance on submission of SA	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	Articles L1123-9 and R1123-35&36 CSP
Additional information	EC notifies the CA on its decision.
Safety Reporting	

Medical Device	France
Reportable AEs	SAE (Serious Adverse Event) SAE (Serious Adverse Event) likely to be related to the procedure of implementation of the MD SAE (Serious Adverse Event) including AE being life-threatening or leading to death or to a serious deterioration in health, prolonged hospitalisation, additional surgery or medical intervention SAE (Serious Adverse Event) arising from the testing of the MD
Investigator shall report SAE to	Sponsor
Reporting timeline	Immediately Within a max of 2 d upon first knowledge for events being fatal, life-threatening, or deteriorating health Within a max of 7d upon first knowledge
Responsible for AE reporting to relevant EC(s)	Sponsor
SUSAR being life-threatening or leading to death must be reported	N/A
All other SUSAR must be reported	N/A
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 occurence	Yes
National standard reporting form available	Use of corresponding form (for AE reporting to CA) possible
Standard reporting form	"Investigation summary safety report form » (MDCG-2020-10/2) available at the following adress : https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-10- 2_guidance_safety_report_form_en.xlsx This table will be updated and sent each time a new event to be reported or new information relating to an event already reported is to be notified. Where appropriate, more detailed information should be provided at the request of the ANSM.
Reporting format - options	Email
Preferred format	N/A
Online safety reporting portal	not yet
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	Not required
Guidance on AE reporting procedure available	Yes
Guidance on AE reporting procedure	Notice to sponsors: Provides detailed information reporting obligations including required contents and format of reports https://ansm.sante.fr/uploads/2021/11/19/2021-11-16-aap-partie-iv-vigilance-ic-dm-v2.pdf
National legal framework in place	No

Medical Device	France
Applicable national legal framework/reference	The applicable provisions are those specified in the RDM (Article 80) For the clinical investigation under article 82 of RDM- the ANSM applies provisions of article 80.5 et .6 du RDM.
Additional information	"Investigation summary safety report form » (MDCG-2020-10/2) available at the following adress : https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-10- 2_guidance_safety_report_form_en.xlsx This table will be updated and sent each time a new event to be reported or new information relating to an event already reported is to be notified. Where appropriate, more detailed information should be provided at the request of the ANSM. Details of the information to be included in this table are given in section 10 of recommendation MDCG-2020-10/1 referred to above. The concepts of new safety fact and annual safety report (ASR), for which provisions exist in the amended Jardé law, have not been introduced into the MDR and are therefore not applicable to clinical investigations submitted within the framework of the MDR. However, the sponsor may draw up an ASR or declare new facts to the ANSM.
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of 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) 2 declarations might be required, if the research does not come to an end simultaneously in France and other countries
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	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	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Article R1123-59 CSP
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	

Medical Device	France
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 the 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) But, since the entered in force of the MDR, the term of "Sponsor" is defined by the MDR- article 2 (49)
Sponsorship mandatory	Yes
Sponsorship mandatory - Additional information	
Co-Sponsor - Definition available in national law	No
Co-Sponsor - Definition (pursuant to national law)	
Co-sponsorship allowed	No
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	N/A
Investigator	
Entitled to be principal investigator	N/A
Additional Information	N/A
Study participants - informed consent	
Standard IC form (ICF) available	Not specified
Standard IC form (ICF)	N/A
Standard ICF - Additional Information	N/A
IC is regulated by law	No
Informed Consent - Definition/ Requirements	Nos specific national provisions (cf **Article L1125-17**) Informed consent is regulated by MDR. Legal representative is designated under the national law.
Applicable national legal framework/ Reference	**Article L1125-17 of CSP** **Article L1125-21 offense of conducting a clinical investigation without consent**
Additional Information	N/A
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	Legal representative of the minor is designated uner the national law

Medical Device	France
Legal framework/Reference (Minors/Children)	Civil code
Incapacitated persons - Studies allowed	Yes Special provisions apply
Specific provisions	N/A
Legal framework / Reference (Incapacitated persons)	Article L1121-6/8/9 CSP Article L1122-2 CSP
Emergency situations - Studies allowed	Yes
Specific provisions	N/A
Emergency situation without prior consent of patient or proxy - Studies allowed	Yes With limitations
Conditions allowing trial participation in emergency setting without prior consent	Provisions of article 68 of the MDR Legal representative is designated under the french law
Legal framework / Reference (Emergency Situation)	**Article L1122-1-3**
Pregnant or breastfeeding women - Studies allowed	Yes
Specific provisions	
Legal framework / Reference (Pregnant or breastfeeding women)	
National legal framework for protection of vulnerable populations in place	Yes
Applicable legal framework / Reference (Vulnerable Population)	Legal representative designated under national law- provisions of civil code
Guidelines & conventions for protection of vulnerable populations	N/A
Additional Information	N/A
Study participants - compensation & reimbursement	
Reimbursement for study participants	Mandatory
Compensation is limited to/provided for	Adults only A certain amount
Additional Information	The clinical investigation does not give rise to any direct or indirect financial compensation for the persons who take part in it, apart from the reimbursement of expenses incurred and, where applicable, compensation for constraints suffered paid by the promoter. The total amount of compensation that a person may receive in any one year is limited to a maximum set by the Order of 15 February 2023 on the maximum amount of compensation for hardship that a person may receive during one same year.
Study participants - recriutment & trial outcome >> end of study	
Mandatory to inform participant of clinical trial outcome	On Patient's request
Additional information	The participants have the right to be informed of the outcome of a clinical investigation

Medical Device	France
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	Yes
Approval/authorisation required	For some study types
Specific notification timelines before operations start	No deadline
Laguage of notification	Official National Language(s)
Notification format	Online portal
Notification fee required	No
Fee	N/A
Guidance on notification requirements available	No
Guidance on notification requirements	information on regulatory process may be found on CNIL website www.cnil.fr
Data protection authority/agency - contact details	online services: https://www.cnil.fr/fr/services-en-ligne
Contact name 2	N/A
Contact name 3	N/A
Phone	N/A
Fax	N/A
E-mail	N/A
Web address	https://www.cnil.fr/en/home
Address	8 rue vivienne
ZIP/City	75083 Paris cedex 02
Country	France
Additional information	Notification is required for interventional and observational investigations on MD (and combination studies with MP).
Archiving & data management	
Study documents must be kept at least (in years)	10 15
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes
Official website providing relevant national legislation	ANSM website (CA) provides applicable regulations and decrees in section: Your regulatory steps /medical devices/ researcher

Medical Device	France
Official governmental legal database available	Yes
Official governmental legal database	Legifrance: public legal database
Additional information	N/A
Investigations on Medical Devices	
Applicable national regulations	N/A
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).
Transposition of Directive 90/385/EEC	N/A
Transposition of Directive 93/42/EEC	N/A
Transposition of Directive 98/79/EC	N/A
Transposition of Directive 2007/47/EC	N/A
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	N/A
Additional Information	The documents shall be kept for at least ten (10)years after the end of the clinical investigation concerning the device in question or, if the device is subsequently placed on the market, for at least ten years after the last device is placed on the market. In the case of implantable devices, this period is at least fifteen years (15). (Annex XV chap III RDM).
Combination studies (IMP/MD)	
Applicable national regulations	N/A
Legal act applicable to both study types	N/A
Other applicable regulations/implementing provisions (acts, laws, decrees, ordinances, circulars, etc)	N/A
Additional information	N/A
Radiation & Radiotherapy	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Biobanking	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Data protection	

Medical Device	France
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	Personal data are collected and processed for the purpose of the clinical investigation in compliance with the GDPR and the french data protection law n° 78-17 of January 6th, 1978. This law includes provision concerning health data collecting within clinical research
Implementing decrees / ordinances	N/A
Other applicable regulations (covering DP related issues)	N/A
Additional Information	N/A
Insurance	
Specific requirements	
Applicable legal framework	**Article L1125-9** of CSP
Additional information	N/A
EC operations/ Fees	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
CA operations/ Fees	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	
MD/MD Investigation	
MD - Definition available in national law	No
MD - Definition	No specific French definition- applicable definitions are provided by the MDR. '
Investigation of MD - Definition available in national law	N/A
MD Investigation - Definition	N/A
Additional Information	N/A
Further Definitions	
Additional information	N/A
Additional Information & Specifics	

Medical Device	France
Additional Information & Specifics Additional Information & Specifics	N/A