Medicinal Products for Human use	France
Competent Authority	
Submission Fees	
Fees for trial submission mandatory	No
Fees	No submission fees required.
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	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	
Ethics Committee	
Submission Fees	
Fees for ethical review mandatory	Not applicable
Waiver for academic (non-commercial) studies possible	Not applicable
Fees for ethical review	No submission fees applicable.
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	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirements	
Study participants - informed consent	
Standard IC form (ICF) available	No

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Standard IC form (ICF)	No standard IC form available. However, the french national commission for research (CNRIPH) which mission is to coordinate, harmonize and evaluate the practices of national ethic committee, has published a guide for drafting the inform consent form (general outline) applicable to the studies on humain being before the entered in force of the Regulation on clinical trials on medicinal products for human use (the guide is now applicable to the others studies in France).The sponsors can always use it as a basis for drafting their IC form
Standard ICF - Additional Information	N/A
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	Informed consent is mainly regulated in France by the CTR. However, France has enacted some specific rules relative to the research on deceased person. No clinical trial may be carried out on a deceased person, in a state of brain death, without his or her consent expressed during his or her lifetime or through the testimony of his or her family. However, if the deceased person is a minor, this consent must be expressed by each of the holders of parental authority. If it is not possible to consult one of the holders of parental authority, the research may be carried out provided that the other holder consents. It is an offence in France to carry out a clinical trial or to have such a trial carried out on a person, without having obtained the free, informed and, where appropriate, written consent of the person concerned, of the legal representative or of any other person, authority or body designated to give consent to the research or to authorise it. A clarification can also be given about the e-consent, but it is not specific to the clinical trials on medicinal products. E-consent with an electronic signature is possible in France within the compliance with the rules on the processing of personal data.(guidelines in progress in France on the more general matter of decentralized clinical trials)
National legal framework in place	Yes
Applicable national legal framework/ Reference	We cant' say there is a specific national legal framework for the inform consent- but there are some particular rules. Clinical trial on deceased person: L. 1121-14 of french public health code. Legal provisions relative to the offence "conduct of a clinical trial without consent": L.1128-1 of french public health code. French legal framework for electronic signature : 1366 and 1367 of french civil code.
Additional Information	
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	The legally designated representative of the minor is designated by the national rules according to the CTR provisions
Legal framework/Reference (Minors/Children)	The applicable rules are those set forth in the CTR (Art. 29 and Art. 32). The rules relative to the legally designated representative of the minor or to any person or body/authority who is able to authorise the clinical trial are set forth in the french civil code (articles 372 et seq.).
Incapacitated persons - Studies allowed	Special provisions apply
Specific provisions	The legally designated representative of the incapacitated person is designated by the national rules according to the CTR provisions

Medicinal Products for Human use	France
Legal framework / Reference (Incapacitated persons)	The applicable rules in France are those set forth in the CTR(Art. 29 and Art. 31). The rules relative to the legally representative of the incapacitated person or to any person or body/authority who is able to authorise the clinical trial are set forth in the french civil code (Articles 425 and seq)
Emergency situations - Studies allowed	Yes
Specific provisions	The applicable rules in France are those set forth in the CTR (Art. 35). The rules relative to the legally representative designated for person that cannot express his consent to pursuit his participation to the clinical trial (other than minor or incapacitated person) are set forth in the french public health code (Article L1122-1-3) In any case, the protocol must cover the emergency situation and specify the persons who may receive the information from the investigator and give their consent if the subject cannot consent to continue the research. As soon as its condition permits, participant must give its consent to the clinical trail.
Emergency situation without prior consent of patient or proxy - Studies allowed	Yes
Conditions allowing trial participation in emergency setting without prior consent	cf above The applicable rules are those set fort in the CTR (prerequisites of article 35) The applicable rules in France don't explicitly refers to the article L. 1122-1-3 of french health public code but the competent authorities applies the rules set forth in this article. If the person is not legally protected, the persons in a position to give consent are members of the family, or the trusted support person (french concept). In any case, the protocol must cover the emergency situation and specify the persons who may receive the information from the investigator and give their consent if the subject cannot consent to continue the research. As soon as its condition permits, participant must give its consent to the clinical trail.
Legal framework / Reference (Emergency Situation)	L1122-1-3 CSP
Pregnant or breastfeeding women - Studies allowed	Yes
Specific provisions	No specific provisions In France. The applicable rules are those set forth in the CTR (Article 33).
Legal framework / Reference (Pregnant or breastfeeding women)	general provisions of CTR (Art. 33).
Study participants - compensation & reimbursement	
Reimbursement for study participants	Not applicable
Compensation is limited to/provided for	A certain amount

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Additional Information	L1121-11 CSP A Ministerial Order of 15 February 2023 sets the maximum amount of compensation for constraints suffered that a person may receive in any one year for taking part in a clinical trial. The order sets the total amount of compensation that a person may receive over a period of twelve consecutive months for their participation in a clinical trial at 6,000 euros. The payment of compensation to healthy participant may be made by means of benefits in kind, when the following two conditions are met: the sponsor has carried out a financial evaluation of these benefits in kind and checked that the amount of €6,000 is not exceeded; the sponsor has justified the use of these benefits in terms of the specific nature of the research or the target population. The national ethical committee must accept it. https://www.legifrance.gouv.fr/eli/arrete/2023/2/15/SPRP2305216A/jo/texte
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	N/A
Guidance on notification requirements	N/A
Data protection authority/agency - contact details	Commission Nationale de l'Informatique et des Libertés - CNIL / National Committee for Data Protection
Contact name 2	N/A
Contact name 3	N/A
Phone	+33 153 73 22 22 / health desk , monday 9h30-12h
Fax	+33 153 73 22 00
E-mail	N/A
Web address	https://www.cnil.fr/fr/professionnel
Address	3 Place de Fontenoy
ZIP/City	75334 PARIS CEDEX 07
Country	France

Medicinal Products for Human use	France
Additional information	In accordance to articles 66 and 73 of the french data protection law, Where the processing complies with a reference methodology, in this case MR-001, it may be implemented without authorisation from the CNIL. The data controller must first submit a declaration of compliance to the CNIL. It is a fast track and simplified process because the declaration is made on line on the CNIL website. If the data processing cannot comply with MR-001, the data controller must submit an application for to obtain the authorisation to implement the data processing. The application is the application is examined by a committee the CEREES assessing the scientific and ethical aspect and after by the CNIL;
Insurance	
Liability insurance or alternative arrangements for damages mandatory for	Investigator(s) Sponsor Study participants Hospital/ trial center
Responsible for covering insurance	Sponsor
Isurance fee: a minimum coverage sum is defined	Yes
Minimim coverage sum	The insurance contracts referred to in article R. 1121-4 of french public health code may not provide cover for less than : 1° 1,000,000 euros per victim ; 2° 6,000,000 euros per protocol; 3° 10,000,000 euros for all claims made during one insurance year in respect of several research protocols.
National legal framework/reference	Yes
Applicable national legal framework/reference	a specific legal framework applies in France set forth in the french public health code L1121-10 Chapter 1 CSP **Article R1121-4 and seq**
Additional information	Certain clauses excluding insurance cover are prohibited. Contracts may provide for an excess per victim.
National legislations	
General Information	
Official governmental legal database available	Yes
Official governmental legal database	LEGIFRANCE: https://www.legifrance.gouv.fr/

Medicinal Products for Human use	France
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") Ordonnance n° 2016-800 du 16 juin 2016 relative aux recherches impliquant la personne humaine (JO du 8 décembre 2017). 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) Décret n° 2016-1537 du 16 novembre 2016 relatif aux recherches impliquant la personne humaine (JO n°0267 du 17 novembre 2016) Data protection legislation Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés. in its latest amended version *** **BACKGROUND** Since the entered in force of the Clinical Trial Regulation (536/2014), the jardé law no longer applies in principle to clinical drug trials (principle of direct effect of european regulations). However, of all of the law doesn't apply to clinical trials of medicinal products, some articles remain applicable, those are specified in article L. 1124-1 of french public health code.
Clinical trials on IMPs in Humans	
Applicable national regulations	Transposition of (CT) Directive 2001/20/EC
Radiation & Radiotherapy	
Specific framework available	Yes
Applicable legal framework	Chapter 3 (section 5, Article R1333-56) CSP: specific requirements apply in case that study participants are exposed to ionizing 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 nucléaire)
Biobanking	
Specific framework available	N/A
Applicable legal framework	There is a specific framework in France for storing and using biological samples obtained either as part of clinical research or as part of healthcare (secondary ude of the humain biological sample). The subject must be informed of the secondary use and do not oppose to it (.**Article L1211-2**- and other ethical principles L. 1211-3 and seq of french health public code) Some regulatory procedures with the ministry of research are required in order to use the human biological samples for internal research purposes or to sell, import or export them.
Additional information	
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	
Observational study	
Observational study - Definition available in national law	Yes

Medicinal Products for Human use	France
Observational study - Definition	(Article L. 1121-1, 3° of the Public Health Code) Non-interventional research involving no risk or constraint, in which all procedures are carried out and products are used in the usual way. these studies are called "non-interventional studies" - this is a French particularity because they are considered to be carried out on human beings with interventions considered to be without risks and without constraints. The list of procedures is set by a ministerial decree of April 12, 2018 https://www.legifrance.gouv.fr/loda/id/JORFTEXT000036805820 Jardé law provisions apply to these studies.
Academic sponsors	
Academic Sponsors - Definition available in national law	No
Academic Sponsors - Definition	No definition. However, jardé law defines the "Non-commercial research" as esearch whose results are not exploited for profit, which pursues a public health objective and whose promoter or investigator(s) are independent of the companies which manufacture or which market the products that are the subject of the research. **Article L1121-16-1 of french public health code**