Regulatory and ethical requirements in medical devices studies

France
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
We have differentiated 8 types of research:

- Medical device alone with CE mark use within label
- Medical device alone with CE mark use outside label
- Medical device alone without CE mark
- Medical device combined with medicinal product with CE mark use within label
- Medical device combined with medicinal product with CE mark use outside label
- Medical device combined with medicinal product without CE mark
- Observational studies with medical device
- Registries
A. Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements
• Except for « Observational studies with medical device », there is no French definition for studies with medical devices.
**B. Definitions/Legal basis**

A. Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

**Conventions/guideline/laws to apply**

- Declaration of Helsinki
- ICH Guideline of EMA
- European Directive 2011/20/EC *(Only for studies with MD alone and observational studies)*
- ISO 14155:2011
- European Directive 90/385/EC and 93/42/EC
B. Definitions/Legal basis

Acts to apply

• Data protection act (*Except for registries*)
• Genetical engineering act (*Except for observational studies and registries*)
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
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H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
• For all the type of studies in exception of registries, an insurance must be contracted. It has to cover:
  - Patients and /or healthy volunteers
  - Investigators
  - Sponsor

• It is not necessary that the insurance covers the manufacturer

• The compensation sums covered by the insurance depends of the protocol
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
### D. Sponsor

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>It is mandatory to have a sponsor in all the interventional studies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Medical device alone with CE mark use within label</td>
</tr>
<tr>
<td>C. Insurance</td>
<td>• Medical device alone with CE mark use outside label</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>• Medical device alone without CE mark</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>• Medical device combined with medicinal product with CE mark use within label</td>
</tr>
<tr>
<td>F. Competent Authority</td>
<td>• Medical device combined with medicinal product with CE mark use outside label</td>
</tr>
<tr>
<td>G. Ethics Committee</td>
<td>• Medical device combined with medicinal product without CE mark</td>
</tr>
<tr>
<td>H. Data Protection</td>
<td></td>
</tr>
<tr>
<td>I. Healthy volunteers/Patients</td>
<td></td>
</tr>
<tr>
<td>J. Specific requirements</td>
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</table>
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• No French specific requirements/regulations for GCP training of the investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td></td>
</tr>
<tr>
<td>C. Insurance</td>
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<tr>
<td>D. Sponsor</td>
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<tr>
<td>E. Investigators</td>
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<tr>
<td>F. Competent Authority</td>
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<td>G. Ethics Committee</td>
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<td>H. Data Protection</td>
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<td></td>
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<tr>
<td>J. Specific requirements</td>
<td></td>
</tr>
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SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
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E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
French Competent Authority:

ANSM
Agence national de sécurité du médicament et des produits de santé
143/147 Boulevard Anatole France
93285 Saint-Denis Cedex
+33 155 87 30 00

dedim.dm@ansm.sante.fr or EC.DM-COS@ansm.sante.fr
## F. Competent Authority

<table>
<thead>
<tr>
<th>Type of research</th>
<th>Definitions/Legal basis</th>
<th>Insurance</th>
<th>Sponsor</th>
<th>Investigators</th>
<th>Ethics Committee</th>
<th>Data Protection</th>
<th>Healthy volunteers/Patients</th>
<th>Specific requirements</th>
</tr>
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</table>

<table>
<thead>
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<th>Medical device alone with CE mark use outside label</th>
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<th>Medical device combined with medicinal product with CE mark use within label</th>
<th>Medical device combined with medicinal product with CE mark use outside label</th>
<th>Medical device combined with medicinal product without CE mark</th>
<th>Observational studies with medical device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>x (if no risky exam)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>No</td>
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</tbody>
</table>

- **A. Type of research**
- **B. Definitions/Legal basis**
- **C. Insurance**
- **D. Sponsor**
- **E. Investigators**
- **F. Competent Authority**
- **G. Ethics Committee**
- **H. Data Protection**
- **I. Healthy volunteers/Patients**
- **J. Specific requirements**
F. Competent Authority – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- When a submission is required, the sponsor is responsible of it
- The submission to the French Competent Authority is national: you only have to submit one dossier to the national competent authority
- The submission have to be:
  - by paper
  - or by email or CD-Rom
- English documents are accepted, at the exception of the protocol summary, the inform consent form and the information document for patient
- No submission fee
**F. Competent Authority – Initial submission**

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td></td>
</tr>
<tr>
<td>C. Insurance</td>
<td></td>
</tr>
<tr>
<td>D. Sponsor</td>
<td></td>
</tr>
<tr>
<td>E. Investigators</td>
<td></td>
</tr>
<tr>
<td><strong>F. Competent Authority</strong></td>
<td></td>
</tr>
<tr>
<td>G. Ethics Committee</td>
<td></td>
</tr>
<tr>
<td>H. Data Protection</td>
<td></td>
</tr>
<tr>
<td>I. Healthy volunteers/Patients</td>
<td></td>
</tr>
<tr>
<td>J. Specific requirements</td>
<td></td>
</tr>
</tbody>
</table>

- In general, 60 days maximum to obtain approval
- Implicit approval after 60 days without questions
- No deadlines for submission, you can submit anytime
- No need to have some kind of representative or a legal entity in France to submit an application to the Competent Authority if you are from the EU
Main documents required for submission:

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Clinical Investigation Plan/Protocol summary
- Copies of advertisement materials for research participants
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
- Pre-clinical evaluation
- Insurance certificate
- List of the Competent Authority where protocol was submitted with their decision if available
- Copy of the required authorization (“authorisation de lieu de recherche”)
F. Competent Authority – Initial submission

- Standard application form available on the ANSM’s website:
### F. Competent Authority - Vigilance

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• SAE definition:</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>Any untoward medical occurrence or effect that at any dose:</td>
</tr>
<tr>
<td>C. Insurance</td>
<td>- Result in death</td>
</tr>
<tr>
<td>D. Sponsor</td>
<td>- Is life threatening</td>
</tr>
<tr>
<td>E. Investigators</td>
<td>- Requires hospitalisation or prolongation of existing hospitalisation</td>
</tr>
<tr>
<td>F. Competent Authority</td>
<td>- Results in persistent or significant disability or incapacity</td>
</tr>
<tr>
<td>G. Ethics Committee</td>
<td>- Or is a congenital anomaly or birth defect</td>
</tr>
<tr>
<td>H. Data Protection</td>
<td>• SAE declaration by the sponsor:</td>
</tr>
<tr>
<td>I. Healthy volunteers/Patients</td>
<td>- If life in danger: 7 days</td>
</tr>
<tr>
<td>J. Specific requirements</td>
<td>- Other case: 15 days</td>
</tr>
</tbody>
</table>

• The sponsor has to declare events to the Competent Authorities in the specific countries

• The sponsor needs to provide to the Competent Authority an annual safety report
F. Competent Authority - Vigilance

Events mandatory to declare to the Competent Authority:

<table>
<thead>
<tr>
<th>Event Description</th>
<th>AE</th>
<th>ADE</th>
<th>SADE</th>
<th>SAE</th>
</tr>
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<tbody>
<tr>
<td>Medical device alone with CE mark use within label</td>
<td></td>
<td></td>
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<tr>
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<td>x</td>
</tr>
<tr>
<td>Medical device combined with medicinal product without CE mark</td>
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<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Observational studies with medical device</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

AE: Adverse Event (Non device related)  
ADE: Adverse Device Effect (Device or procedure related)  
SADE: Serious adverse Device Effect (Device or procedure related)  
SAE: Serious Adverse Event (Non device related)
F. Competent Authority - Vigilance

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- The sponsor is responsible for the declaration to the Competent Authority
- Special form for the declaration of AE:
## F. Competent Authority - Notification

- **A. Type of research**
- **B. Definitions/Legal basis**
- **C. Insurance**
- **D. Sponsor**
- **E. Investigators**
- **F. Competent Authority**
  - It is not mandatory to notify the first patient enrolled to the Competent Authority
- **G. Ethics Committee**
- **H. Data Protection**
- **I. Healthy volunteers/Patients**
- **J. Specific requirements**
F. Competent Authority – Substantial amendment

• There is a specific procedure for submitting a substantial amendment to the Competent Authority (Submission of a dossier and waiting for approval)
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
G. Ethics Committee

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

40 Comités de Protection des Personnes (CPP) in France:

1 - ÎLE-DE-FRANCE
Région Île-de-France : 11 CPP

2 - NORD-OUEST
Inter-régions Nord-Ouest : 4 CPP (Régions : Nord Pas de Calais, Basse Normandie, Haute Normandie, Picardie)

3 - OUEST
Inter-régions Ouest : 6 CPP (Régions : Bretagne, Centre, Pays de la Loire, Poitou Charentes)
G. Ethics Committee

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
### G. Ethics Committee

<table>
<thead>
<tr>
<th>Type of research</th>
<th>Positive opinion required</th>
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</thead>
<tbody>
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<td>No</td>
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<td>Medical device alone without CE mark</td>
<td>Yes</td>
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<tr>
<td>Medical device combined with medicinal product with CE mark use within label</td>
<td>Yes</td>
</tr>
<tr>
<td>Medical device combined with medicinal product with CE mark use outside label</td>
<td>No</td>
</tr>
<tr>
<td>Medical device combined with medicinal product without CE mark</td>
<td>Yes</td>
</tr>
<tr>
<td>Observational studies with medical device</td>
<td>Yes</td>
</tr>
</tbody>
</table>
G. Ethics Committee – Initial submission

A. Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

• When a submission is required, the sponsor is responsible of it

• The submission to the Ethics Committee is local: you only have to submit one dossier to one of the regional Ethics Committee in the region of the Principal Investigator

• The submission have to be:
  - by paper (usually many copies)
  - and/or by email or CD-Rom

• English documents are accepted, at the exception of the protocol summary, the inform consent form, the information document for patient and additional document

• No submission fee
G. Ethics Committee – Initial submission

| A. Type of research | • In general, 35-60 days to obtain approval |
| B. Definitions/Legal basis | • No implicit approval |
| C. Insurance | • Deadlines for submissions, once per month in each EC (different dates for each EC) |
| D. Sponsor | • When both Competent Authority approval and Ethics Committee positive opinion are required, it is possible to request the 2 (authorization and approval) in parallel |
| E. Investigators | • No need to have some kind of representative or a legal entity in France to submit an application to the Competent Authority or Ethics Committee if you are from the EU |
| F. Competent Authority | |
| G. Ethics Committee | |
| H. Data Protection | |
| I. Healthy volunteers/Patients | |
| J. Specific requirements | |
### G. Ethics Committee – Initial submission

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>Main documents required for submission:</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
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</tr>
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<td>C. Insurance</td>
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<tr>
<td>D. Sponsor</td>
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<tr>
<td>E. Investigators</td>
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<td>F. Competent Authority</td>
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<td>H. Data Protection</td>
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</tr>
<tr>
<td>I. Healthy volunteers/Patients</td>
<td></td>
</tr>
<tr>
<td>J. Specific requirements</td>
<td></td>
</tr>
</tbody>
</table>

 Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Clinical Investigation Plan/Protocol summary
- Inform Consent Form and subject Information leaflet
- CV of PIs
- Copie of advertisement materials for research participant
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Insurance certificate
- List of the CA where protocol was submitted with their decision if available
- Copy of the required authorization (“authorisation de lieu de recherche”)
- Additional document
G. Ethics committee – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority

G. Ethics Committee

H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- Use the same standard application form that for the Competent Authority
- Standard application form available on the ANSM’s website:
G. Ethics Committee - Vigilance

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority

G. Ethics Committee

H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- SAE declaration by the sponsor:
  - If life in danger: 7 days
  - Other case: 15 days

- The sponsor also has to declare events to the Ethics Committee in the specific countries

- The sponsor needs to provide to the Ethics Committee an annual safety report
**G. Ethics Committee - Vigilance**

Events mandatory to declare to the competent authority:

<table>
<thead>
<tr>
<th>Medical device alone with CE mark use within label</th>
<th>AE</th>
<th>ADE</th>
<th>SADE</th>
<th>SAE</th>
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<td>x</td>
<td></td>
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<tr>
<td>Observational studies with medical device</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

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ADE: Adverse Device Effect (Device or procedure related)
SADE: Serious adverse Device Effect (Device or procedure related)
SAE: Serious Adverse Event (Non device related)
G. Ethics Committee - Vigilance

- The sponsor is responsible for the declaration to the Ethics Committee
- No special form for the declaration of AE, possible to use the Competent Authority’s form:
G. Ethics Committee - Notification

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee - Notification
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- It is not mandatory to notify the first patient enrolled to the Ethics Committee
• There is a specific procedure for submitting a substantial amendment to the Ethics Committee (Submission of a dossier and waiting for approval)
A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
French Data Protection:

CNIL
(Commission Nationale de l’Informatique et des Liberté)
8 rue vivienne
75083 Paris cedex 02
Tel : +33 153 73 22 22 / Fax : +33 153 73 22 00
### H. Data Protection

<table>
<thead>
<tr>
<th>Notification required</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
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<td>Medical device alone with CE mark use within label</td>
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<tr>
<td>Observational studies with medical device</td>
<td>x</td>
<td></td>
</tr>
</tbody>
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- **A. Type of research**
- **B. Definitions/Legal basis**
- **C. Insurance**
- **D. Sponsor**
- **E. Investigators**
- **F. Competent Authority**
- **G. Ethics Committee**
- **H. Data Protection**
- **I. Healthy volunteers/Patients**
- **J. Specific requirements**
H. Data Protection

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements

- Submission in French only
- No submission fee
- Online submission
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients
J. Specific requirements
I. Healthy volunteers/Patients

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. **Healthy volunteers/Patients**
J. Specific requirements

- In France, there are specific requirements/regulations for specific population:
  - Children
  - Pregnant women
  - Lactating women
  - Adults protected by the law
## I. Healthy volunteers/Patients

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td>Type of research</td>
</tr>
<tr>
<td>B.</td>
<td>Definitions/Legal basis</td>
</tr>
<tr>
<td>C.</td>
<td>Insurance</td>
</tr>
<tr>
<td>D.</td>
<td>Sponsor</td>
</tr>
<tr>
<td>E.</td>
<td>Investigators</td>
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<td>F.</td>
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<td>H.</td>
<td>Data Protection</td>
</tr>
<tr>
<td>I.</td>
<td>Healthy volunteers/Patients</td>
</tr>
<tr>
<td>J.</td>
<td>Specific requirements</td>
</tr>
</tbody>
</table>

- Healthy volunteers participating in clinical research have to be compensated (not mandatory for patients, but possible)

- National healthy volunteers registry: VRB

- Obligation to inform the healthy volunteers/patients on the outcomes of the study if she/he asks
SECTIONS

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Protection
I. Healthy volunteers/Patients

J. Specific requirements
J. Specific requirements

- No specific requirements to publish both positive and negative results of clinical studies in scientific journals

- Specific requirements/regulations regarding the ICF: **needs to be given in writing**

- Specific requirements/regulations regarding archiving of documentation: **15 years**

- Specific requirements regarding blood/tissue samples (circulation and storage) – Additional forms to submit to the Competent Authority
<table>
<thead>
<tr>
<th>J. Specific requirements</th>
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<tbody>
<tr>
<td><strong>A. Type of research</strong></td>
<td>• No specific requirements for data management</td>
</tr>
<tr>
<td><strong>B. Definitions/Legal basis</strong></td>
<td>• No specific strategies for monitoring</td>
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<tr>
<td><strong>C. Insurance</strong></td>
<td>• Mandatory to register clinical studies which include medicinal product in a registry managed by the Competent Authority</td>
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<tr>
<td><strong>D. Sponsor</strong></td>
<td>• Accreditation process for research centres (“Code de santé publique” article R1121-11 to article R1121-16)</td>
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