ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Regulatory and ethical requirements in medical devices studies

Spain

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

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G. Ethics Committee

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I. Healthy volunteers/Patients

J. Specific requirements

A. Type of research

A. Type of research
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F. Competent Authority
G. Ethics Committee
H. Data Ptotection
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

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

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G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

A. Type of research
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G. Ethics Committee
H. Data Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

Definitions in Spanish law

- There is no Spanish 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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

Conventions/guideline/laws to apply

- Declaration of Helsinki
- ICH Guideline of EMA
- European Directive 2001/20/EC ***(except for observational studies and registries)***
- ISO 14155:2011
- Law 29/2006 on Medicinal Products and MD
- Royal decrees 1616/2009, 1591/2009 and 1662/2000 ***(except for observational studies)***
- Royal decree 223/2004 ***(only study with DM combined with a medicinal product)***
- ORDEN SCO/3603/2003, de 18 de diciembre ***(For registries of active implantable medical devices)***
- Orden SAS/3470/2009, de 16 de diciembre, covers postauthorization (observational) studies with MP for human use.

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

Acts to apply

- Data protection act ***(Except for registries)***
- Genetical engineering act ***(Except for observational studies and registries)***
- Medical device act
- Drug act ***(Only study with MD combined with a medicinal product)***

SECTIONS

A.Type of research

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J. Specific requirements

C. Insurance

A. Type of research
B. Definitions/Legal basis
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E. Investigators
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H. Data Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

• For all the type of studies in exception of registries and observational studies, an insurance must be contracted. It has to cover:

- Patients and/or healthy volunteers
- Investigators
- Sponsor

• For observational studies, an insurance can be requested by the Ethic Committee

• It is not necessary that the insurance covers the manufacturer

• The compensation sums covered by the insurance at least of 250000 € per patient (25000 € per patient/year) and at the maximum 2500000 € for the whole study

SECTIONS

A.Type of research

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J. Specific requirements

D. Sponsor

A. Type of research
B. Definitions/Legal basis
C. Insurance
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G. Ethics Committee
H. Data Ptotection
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J. Specific requirements

It is mandatory to have a sponsor for all type of study except registries

SECTIONS

A.Type of research

B. Definitions/Legal basis

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H. Data Protection

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J. Specific requirements

E. Investigators

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

- No Spanish specific requirements/regulations for GCP training of the investigators

- In Spain the Investigator must be qualify in clinical research and in the specific field of the MD.

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

F. Competent Authority

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

Spanish Competent Authority:

AEMPS (Agencia Española de Medicamentos y Produtos Sanitarios)
c/ Campezo, 1P. Empresarial LAS MERCEDES, Edificio 8, 28022 Madrid
Tel: +34 91 822 52 70 ;
Fax +34 91 822 52 89 ;
psinvclinic@aemps.es
Website: http://www.aemps.gob.es

F. Competent Authority

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

	Approval	
	Yes	**No**
Medical device alone with CE mark use within label		x
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label	x	
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	
Observational studies with medical device		X*

*: Depending on the MP (authorization status) and MD (CE mark and use within label). See Orden SAS/3470/2009, de 16 de diciembre.

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- When a submission is required, the sponsor or an authorised representative is responsible of it
- The submission to the Spanish Competent Authority is only national, except for the observational study for which it is both local and national
- The submission must be done online on the following site: https://ecm.aemps.es/ecm/paginaPresentacion.do
- English documents are accepted
- The submission fee are 800 € for MD only and 800 + 1463.86€ for MD combined with MP

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- In general, 60 days maximum to obtain approval
- For interventional studies (except those with MD alone with CE mark use within label): Implicit approval after 60 days without questions. For Type III MD or active implantable type IIa-IIb MD it can be reduced to 15 days (except those with MD combined with MP without CE mark or used outside label
- For Observational studies: Implicit approval after 30 days without questions
- No deadlines for submission, you can submit anytime
- No need to have some kind of representative or a legal entity in Spain to submit an application to the Competent Authority if you are from the EU

F. Competant 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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

Main documents required for submission (except for observational studies) (1/2):

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Clinical Investigation Plan/Protocol summary
- CRF draft
- Inform consent form
- Subject Information leaflet
- General practitioner information letter
- Copies of advertisement materials for research participants
- Investigator's brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
- Pre-clinical and clinical evaluation
- Financial disclosure ***(only for study with MD combined with MP without CE mark or used outside label)***

F. Competant Authority – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
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E. Investigators
F. Competent Authority
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I. Healthy volunteers/Patients
J. Specific requirements

Main documents required for submission (except for observational studies) (2/2):

- Insurance certificate
- Signed and dated CV of investigators
- GCP training certificate of investigators
- Product training of investigators
- Qualification certificate of investigators
- Study approval from Ethic committee (if already got)
- Proof of payment of submission fees
- Contact details of the Sponsor and authorized representative
- Information about participating centres: list of participating centres (National and from other European countries)
- Information about study duration: dates of initiation and finalization of the study, follow-up and recruitment
- Information on the current regulatory status of the MD (CE mark, state of approval in Spain and other countries…)

F. Competant 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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

Main documents required for submission for observational studies :

- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Investigator's brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
- Pre-clinical and clinical evaluation

Depending on the CE status of the MD, requirements may change

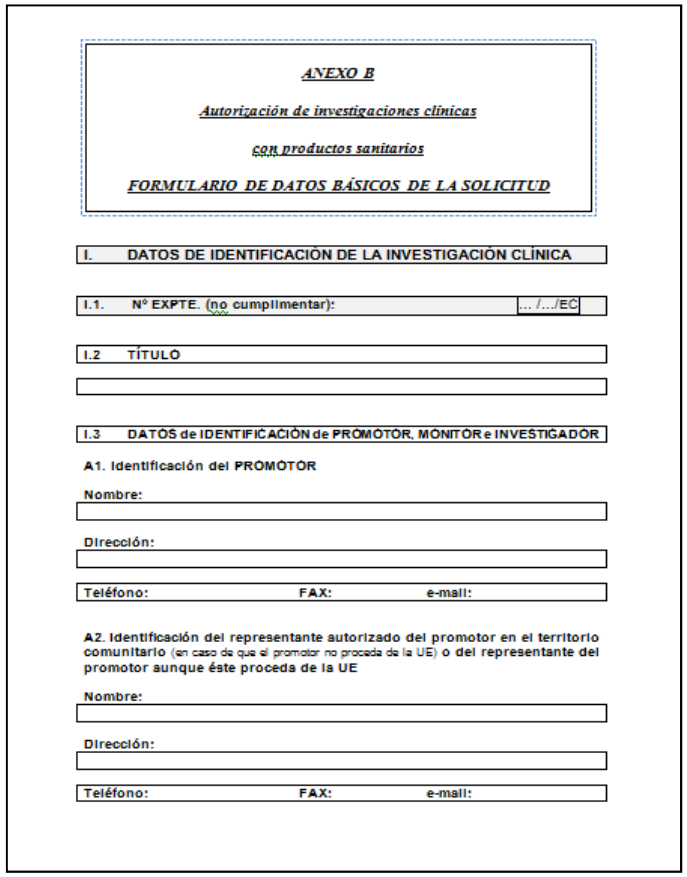
F. Competent Authority – Initial submission

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

• Standard application form available on the AEMPS's website:

• For Interventional study (except those combined with MP without CE mark or use outside label)

http://www.aemps.gob.es/investigacionClinica/productosSanitarios/home.htm



ANEXO B

Autorización de investigaciones clínicas

con productos sanitarios

FORMULARIO DE DATOS BÁSICOS DE LA SOLICITUD

I. DATOS DE IDENTIFICACIÓN DE LA INVESTIGACIÓN CLÍNICA

I.1. Nº EXPTE. (no cumplimentar): .../.../EC

I.2 TÍTULO

I.3 DATOS de IDENTIFICACIÓN de PROMOTOR, MONITOR e INVESTIGADOR

A1. Identificación del PROMOTOR

Nombre:

Dirección:

Teléfono: FAX: e-mail:

A2. Identificación del representante autorizado del promotor en el territorio comunitario (en caso de que el promotor no proceda de la UE) o del representante del promotor aunque éste proceda de la UE

Nombre:

Dirección:

Teléfono: FAX: e-mail:

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

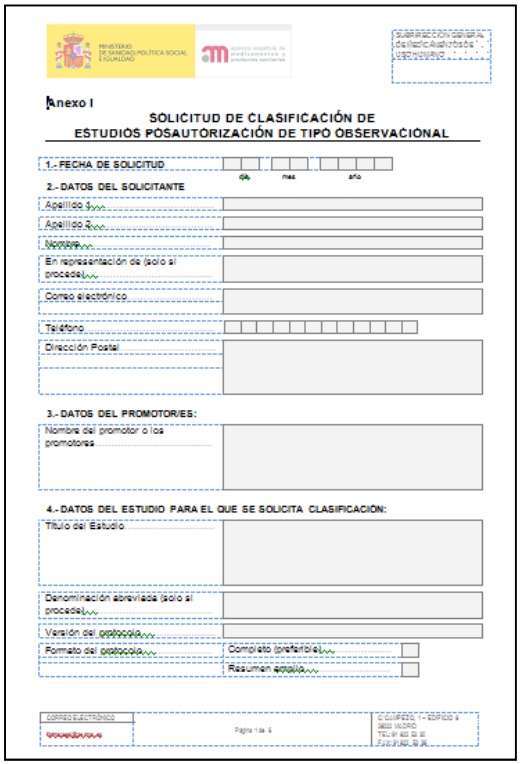
- Standard application form available on the AEMPS's website:
  - For study with MD combined with MP without CE mark or used outside label

    http://www.aemps.gob.es/ (click in "sede electrónica", to upload the xml file with the protocol

  - For Observational study

    http://www.aemps.gob.es/investigacionClinica/medicamentos/estudiosPostautorizacion.htm

    (Anexo: Solicitud de clasificación de estudios posautorización de tipo observacional)



Anexo I

SOLICITUD DE CLASIFICACIÓN DE ESTUDIOS POSAUTORIZACIÓN DE TIPO OBSERVACIONAL

1.- FECHA DE SOLICITUD

día mes año

2.- DATOS DEL SOLICITANTE

Apellido 1

Apellido 2

Nombre

En representación de (solo si procede)

Correo electrónico

Teléfono

Dirección Postal

3.- DATOS DEL PROMOTOR/ES:

Nombre del promotor o los promotores

4.- DATOS DEL ESTUDIO PARA EL QUE SE SOLICITA CLASIFICACIÓN:

Título del Estudio

Denominación abreviada (solo si procede)

Versión del protocolo

Formato del protocolo

Completo (preferible)

Resumen ampliado

CORREO ELECTRÓNICO

Página 1 de 4

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

• SAE definition:

Any event that leads to:

- Death
- A severe deterioration of patient´s health status, implying:
  - A life-threatening event or lesion
  - A permanent deficiency of a systemic function or structure.
  - Required hospital admission or extension of a concurrent hospital admission
  - Required an urgent medical or surgical intervention in order to prevent a permanent deficiency of a systemic function or structure
- Incurred in foetal distress, foetal death, birth abnormalities or a birth defect

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- SADE declaration by the sponsor:
  - If death: 7 days
  - Other case: 15 days

- The sponsor don’t have to declare events to the Competent Authorities in the specific countries

- The sponsor needs to provide to the Competent Authority an annual safety report (except for observational studies)

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

Events mandatory to declare to the Competent Authority:

	AE	ADE	SADE	SAE
Medical device alone with CE mark use within label			x	
Medical device alone with CE mark use outside label			x	
Medical device alone without CE mark			x	
Medical device combined with medicinal product with CE mark use within label			x	
Medical device combined with medicinal product with CE mark use outside label			x	
Medical device combined with medicinal product without CE mark			x	
Observational studies with medical device			x	

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 Ptotection
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:

http://ec.europa.eu/growth/sectors/medicaldevices/documents/guidelines/files/meddev/2_7_3_en.pdf

MEDDEV 2.7/3 SAE Report Table- V1															
EUDAMED - ID:															
Title of Clinical Investigation:															
CIP Number:															
Contact person (Name, Address, E-Mail, Telephone Number)										**Device type:**					
MS+NCA Reference Numbers for all participating Countries:										**Reference Member State:**					
No. of Patients enrolled to date (date of report):										**No. of Invest. Devices used to date**					
Date of Report:															
Status: a, m, u	Date Sponsor received Report of SAE	Country	Study Center	Patient ID Code	Date of Procedure/ First Use	Date of Event Onset	Event: Organ System	Description of event	action/ treatment/patient outcome	Assessment of Relationship to Procedure: Yes No Possibly	Assessment of Relationship to Investigational Device: Yes No Possibly	Unanticipated SADE yes/No	Treatment Arm: Investigational Device/ Control Group/ blinded/ n.a.	Event Status: Resolved/ Resolved with Sequelae/ Ongoing/Death	Date of Event Resolution

F. Competent Authority - Notification

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

- It is not mandatory to notify the first patient enrolled to the Competent Authority

F. Competent Authority – Substantial amendment

A. Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

• There is a specific procedure for submitting a substantial amendment to the Competent Authority

If the CA has not communicated any objections after 35 days, counted from date of notification of receipt, the amendment may be considered granted

• No substantial amendment submission for observational study

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

136 Comités Éticos de Investigación Clínica (CEIC) in Spain:

All the contact can be found at the following adress:

https://www.msssi.gob.es/profesionales/ceicsca.do

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

	Positive opinion required	
	Yes	**No**
Medical device alone with CE mark use within label	x	
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label	x	
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	
Observational studies with medical device	x	

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 Ptotection
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: **The protocol has to be submitted to and approved by all participating EC except for observational study**

• For observational study **the protocol only have to be submitted to the reference EC** but is usually sent to all EC so they can assess the study to evaluate local aspect.

• The submission have to be:

- online: https://ecm.aemps.es/ecm/inicial.do

- and by email or CD-Rom or paper (for all necessary information)

Document have to be submitted in Spanish

• The date of submission depends on the CEIC

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- Maximum 60 days to obtain approval
- Deadlines for submissions, (differents dates for each EC)
- When both Competent Authority approval and Ethics Committee positive opinion are required, it is possible to request the 2 (authorization and approval) in parallel
- No need to have some kind of representative or a legal entity in Spain to submit an application to the Ethics Committee if you are from the EU

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

Main documents required for submission:

- 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
- Financial disclosure

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- Each CEIC has it’s own specific form

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- SADE declaration by the sponsor:
  - If death: 7 days
  - Other case: 15 days

- The sponsor needs to provide to the Ethics Committee an annual safety report

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 Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

Events mandatory to declare to the Ethics Committee:

	AE	ADE	SADE	SAE
Medical device alone with CE mark use within label			x	
Medical device alone with CE mark use outside label			x	
Medical device alone without CE mark			x	
Medical device combined with medicinal product with CE mark use within label			x	
Medical device combined with medicinal product with CE mark use outside label			x	
Medical device combined with medicinal product without CE mark			x	
Observational studies with medical device			x	

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)

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

- The sponsor is responsible for the declaration to the Ethics Committee
- Same form used for the declaration to the Competent Authority:

MEDDEV 2.7/3 SAE Report Table- V1															
EUDAMED - ID:															
Title of Clinical Investigation:															
CIP Number:															
Contact person (Name, Address, E-Mail, Telephone Number)										**Device type:**					
MS+NCA Reference Numbers for all participating Countries:										**Reference Member State:**					
No. of Patients enrolled to date (date of report):										**No. of Invest. Devices used to date**					
Date of Report:															
Status: a, m, u	Date Sponsor received Report of SAE	Country	Study Center	Patient ID Code	Date of Procedure/ First Use	Date of Event Onset	Event: Organ System	Description of event	action/ treatment/patient outcome	Assessment of Relationship to Procedure: Yes No Possibly	Assessment of Relationship to Investigational Device: Yes No Possibly	Unanticipated SADE yes/No	Treatment Arm: Investigational Device/ Control Group/ blinded/ n.a.	Event Status: Resolved/ Resolved with Sequelae/ Ongoing/Death	Date of Event Resolution

G. Ethics Committee - Notification

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

- It is not mandatory to notify the first patient enrolled to the Ethics Committee

G. Ethics Committee – Substantial amendment

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

• There is a specific procedure for submitting a substantial amendment to the Ethics Committee

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

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

Spanish Data Protection:

AEPD
(Agencia Española de Protección de Datos)
C/Jorge Juan, 6 – 28001 Madrid
Tel: +34 901 100 099

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

	Notification required	
	Yes	**No**
Medical device alone with CE mark use within label		x
Medical device alone with CE mark use outside label		x
Medical device alone without CE mark		x
Medical device combined with medicinal product with CE mark use within label		x
Medical device combined with medicinal product with CE mark use outside label		x
Medical device combined with medicinal product without CE mark		x
Observational studies with medical device		x

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
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D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

• In Spain, there are specific requirements/regulations for specific population:

- Minors
- Elderly
- Pregnant women
- Lactating women
- Incapacitated persons
- Subjects in emergency situations

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 Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

• Compensations are compulsory when there is no direct benefit for the patient

• In the rest of situations, compensations are not compulsory and are only to compensate for potential inconveniences

• No national healthy volunteers registry

• 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

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J. Specific requirements

• Specific requirements to publish both positive and negative results of clinical studies in scientific journals: Mandatory to publish positive or negative results of authorized clinical studies *(Real decreto 223/2004, de 6 de febrero, Article 38)*

• Specific requirements/regulations regarding devices emitting radiation (*Real Decreto 1085/20098, regulating X-ray devices/Real Decreto 1616/2009, regulating non-implantable medical devices/Real Decreto 1591/2009, regulating active implantable medical devices)*

• Specific requirements/regulations regarding the ICF *(Real decreto 223/2004, de 6 de febrero, Article 7)*

J. Specific requirements

A. Type of research

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I. Healthy volunteers/Patients

J. Specific requirements

• Specific requirements/regulations regarding archiving of documentation:

- *Real decreto 223/2004, de 6 de febrero, Article 39: 15 years*
- *Circular Nº 07 / 2004: At least 5 years*

• Specific requirements regarding blood/tissue samples (circulation and storage)

Royal decree 65/2006, regulating the import ad export process of biological samples/Royal decree 1301/2006, regulating the donation, management and therapeutic use of human cells and tissues/Law 14/2007, that regulates Biomedical Research

J. Specific requirements

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- No specific requirements for data management

- No specific strategies for monitoring

- Mandatory to register clinical studies in a registry

- Accreditation process for research centres (Law 16/2003, regulating the cohesion and quality of the National Health System)