Medical Devices - SPAIN

Competent authority

Contact Details

Contact Name 1

The Spanish Agency of Medicines and Medical Devices/ Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Contact Name 2

Subdirección General de Productos Sanitarios (SGPS)/ General Subdirection of Medical Devices

Phone

+34 91 822 52 70

Fax

+34 91 822 52 89

Email Department

psinvclinic@aemps.es

Address

C/ Campezo nº 1, Parque Empresarial Las Mercedes, Edificio 8

ZIP/City

28022 Madrid

Country

Spain (ES)

Web address

http://www.aemps.gob.es

Additional Information

"Department of Human Medicine Products" applicable to some combination studies (MP+MD)
Email: aecaem@aemps.es; smhaem@aemps.es

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)/ For certain types of MDs
Ethics committee(s)

CA - Submission for authorisation mandatory for

Observational MD investigations
MD CE-marked, use outside label
MD CE-marked, use outside label + IMP
MD without label
MD without label + IMP

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA (AEMPS - SGPS)

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

Yes

National trial registry - Registration mandatory

Yes

National trial registry

There is an official national registry in Spain:
REec - Registro Español de Estudios Clínicos (Spanish National General Registry of Clinical Studies)
It is mandatory to register the clinical trial according to Art 62 (on transparency) of Law 29/2006 on Medicinal Products and Medical Devices.

There is no general national healthy volunteer registry.

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 30 Royal Decree 1591/2009
Royal Decree 1090/2015
Royal Decree 1616/2009
Circular No. 7 of 2004

Additional Information

• CE-marked MD used within label only require approval from EC!

• Combination studies:
(1) MD with CE-marked used outside label or without label + MP: Submission to SGMUH (General Subdirection of Human Medicinal Products') in 2 copies. Evaluation by SGMUH and SGPS (General Subdirection of Medical Devices). Single unified opinion after evaluation process.
(2) MP (not authorized in any EU country) integrated in a MD (e.g. insulin pre-filled pens): Submission to SGMUH (evaluation process like IMP trial)
(3) Comparing MP vs MD with CE mark used within label: Submission to SGMUH (evaluation process like IMP trial)
(4) Comparing MP vs MD without CE mark and/or with CE- mark used outside label: 2 applications (to SGMUH and SGPS). Sponsor notifies the Subdirections of application dates. Evaluation by both the Subdirections. Single unified opinion after evaluation process.

• Observational studies: Submission obligation depends on authorisation status of the IMP and the MD (CE mark and use within or outside label). In case of required authorisation, the trial has to be submitted to both local + national CA. For any other types of clinical research only submission to national CA is required. (see: Orden SAS/3470/2009)

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

–

Submission of Application

Responsible for study submission

Sponsor

Entitled to study submission

–

Prerequisites for submission

–

Additional Information

(1) Clinical studies on MD with CE-marked used outside label or without label + MP: Submission to SGMUH (General Subdirection of Human Medicinal Products') in 2 copies. Evaluation by SGMUH and SGPS (General Subdirection of Medical Devices). Single unified opinion after evaluation process.

(2) Clinical studies on MP (not authorized in any EU country) integrated in a MD (e.g. insulin pre-filled pens): Submission to SGMUH (evaluation process like IMP trial)

(3) Comparing MP vs MD with CE mark used within label: Submission to SGMUH (evaluation process like IMP trial)

(4) Comparing MP vs MD without CE mark and/or with CE- mark used outside label: 2 applications (to SGMUH and SGPS). Sponsor notifies the Subdirections of application dates. Evaluation by both the Subdirections. Single unified opinion after evaluation process.

Submission Format

Format option(s)

Depends on type of MD (CE-marked, non-CE-marked, use within or outside label) and study (investigation of MD alone or Combination study with MP)

Preferred format

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Standard application form available

Yes

Standard application form

(1) Submission to AEMPS/ Dept. Medical Devices- SGPS: (MDs non-CE marked and/or CE-marked used outside label): The protocol has to be submitted by use of the standard application form “Formulario de datos básicos de la solicitud de autorización de investigaciones clínicas con productos sanitarios”, available for download on the AEMPS website.

(2) Submission to AEMPS/ Dpt. for Medicinal Products for Human Use - SGMUH (MP+MD Combination studies): The protocol has to be submitted via the online portal “Sede Electrónica” (upload the xml file with the protocol).

Additional Information

1) Submission to AEMPS/ Dept. Medical Devices- SGPS:
• email to psinvclinic@aemps.es,
• CD-ROM with the information dissected into separate files and a paper version of the form B (by ordinary mail)

2) Submission to AEMPS/ Dpt. for Medicinal Products for Human Use - SGMUH:
Online submission via Portal ECM (Ensayos Clínicos con Medicamentos)
The AEMPS website (Section Clinical Trials) provides practical guidance and manuals on the use of the portal ECM and the application modality.
The submission portal is also accessible via "sede electrónica” to upload the xml file with the protocol.

Language of Submission

Language(s) of application

Spanish

Preferred language of application

–

English accepted

Yes

Documents mandatory to be in official national language

–

	Documents mandatory to be in local language of study site – **Documents mandatory to be in language of the study participant** –
Submission Fees	**Fees for trial submission mandatory** Yes **Fees** • Authorization of MD studies: € 824.24 - (Cat II-III) • Authorization of combined (MD+MP) studies: € 824.24 + €1508.22 for the evaluation of the active substance incorporated into the MD (Cat IV-VI) **Waiver for academic (non-commercial) studies possible** No **Official guidance on required fees available** Yes **Official guidance on required fees** The current fees (Tasas del Grupo VIII) and payment modalities (Instrucciones para el pago de las tasks por residentes/ no residentes en España) are provided on the AEMPS website in section Clinical research with Medical Devices>Tasas/Fees
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Tacit (Silent) **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Confirmation of formal completeness **Applicable national legal framework/ Reference** Art 30.2-4 of Royal Decree 1591/2009 Art 127.2-4 of Royal Decree 1616/2009 **Additional Information** The CA validates the correctness and completeness of the application and notifies the applicant on the decision. In case of any deficiencies the sponsor has a maximum time span of 10 days to correct them. For Type III MD or active implantable type IIa-IIb MD the period for approval (by affirmative administrative silence) is reduced to 15 days. If clarifications are requested by the AEMPS, the Sponsor will have to submit a reply within 15 days. Refer to Royal Decree 1090/2015.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Substantial amendments relating to a specific document that has been exclusively evaluated by either CA or EC: only submission to respective institution required

Responsible for submission of SA

Sponsor

Standard notification form available

Yes

Standard notification form

The standard application form to be used for the submission of substantial amendments is provided on the AEMPS website in section “Aclaraciones sobre la aplicación de la normativa de ensayos clínicos”: Anexo 1C.
The application must be in writing, dated and signed by the sponsor and investigator.

Timeline for approval of SA (max nr days)

35
From date of notification of receipt
By silent (implicit) approval

Applicable national legal framework/ Reference

Royal Decree 1090/2015

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

National CA
Competent Bodies of the Autonomous Communities

Reportable AEs

SUSAR (Suspected Unexpected Serious Adverse Reaction) in combination studies only
SADE (Serious Adverse Device Effect)

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

Within a max of 7d upon first knowledge (+ 8d for additional information)

All other SUSARs

Within a max of 15d upon first knowledge

SAE /SADE must be reported

Within a max of 7 d upon first knowledge (+8d for additional information) for events being life-threatening or leading to death
Within a max of 15d upon first knowledge

National standard reporting form available

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Standard Reporting Form

(1) SAE reporting form MEDDEV 2.7/3
(2) For combination studies: SUSAR reporting form CIOMS-I (provided on the AEMPS website in section “Aclaraciones sobre la aplicación de la normativa de ensayos clínicos”)

Reporting format - Options

–

Preferred format

–

	Provision of Annual safety report mandatory Yes **Annual safety report shall be provided by sponsor to** – **Guidance on AE reporting procedure** Combination studies: Detailed guidance and practical instructions are given in the document "Aclaraciones sobre la aplicación de la normativa de ensayos clínicos", published on the AEMPS website **Applicable national legal framework/ Reference** Royal Decree 1090/2015 **Investigator shall report SAE to** Sponsor **Reporting timeline** Immediately (without delay)
End of Trial	**End of trial declaration mandatory for** All clinical investigations requiring authorisation by CA **Responsible for End of trial declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 90 **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** 15 **Reasons for early termination shall be clearly stated** Yes **Standard Declaration form available** Yes **Standard Declaration form** The standard reporting form to be used is provided on the AEMPS website in section “Aclaraciones sobre la aplicación de la normativa de ensayos clínicos”: Anexo 1D: Notificación del fin del ensayo. **Applicable national legal framework/ Reference** Royal decree 1090/2015 Art 30 Royal Decree 1591/2009 **Additional Information** In case of premature trial termination, the notification must include the study data obtained until the study termination as well as the reasons for this and the measures taken relating to the study participants
Additional Information & Specifics	**Additional Information** The accreditation process for research centres is covered by Law 16/2003, regulating the cohesion and quality of the National Health System.

Ethics committee

Contact Details	**Contact Name 1** Comités Éticos de Investigación Clínica (CEIC) - Competent Research Ethics Committees (RECs) **Contact Name 2** About 136 CEICs/ RECs in Spain. **Web address** https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/listado-comites-investigacion-clinica.pdf **Additional Information** On the Health Ministry website MSSSI (Ministerio de Sanidad, Servicios Sociales e Igualdad) there is a register of the accredited RECs with functional and organizational aspects (Home>Professionals >Pharmacy>Directory of the accredited CIECs in Spain) . There is no central Ethics Committee in Spain. The Coordinator Centre for CEICs (Centro Coordinador de CEIC) is the contact point of the CEIC network and collaborates with the Health Authorities in the Autonomous Regions in Spain (17 all over the country).
Ethical Review – General	**Submission for Ethical review mandatory for** Interventional MD investigations Observational MD investigations **Submission to CA and EC to be performed in the following order** In parallel Sequentially (in any order) **Additional Information** According to the law, submission to the EC and CA can be done in any order or simultaneously, depending on the sponsor’s preference (pursuant to Art 15 Circular 7/2004) NB! Approval by the EC is a necessary requirement for CA authorization! **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s)
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Any competent EC **Additional Information** The competent REC (Research Ethics Committee), selected by the sponsor, evaluates the clinical trial as well as any modifications/ amendments of authorized clinical trials and issues its reasonable opinion.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** All local ECs of participating sites **Submission of application required to** All local ECs of participating sites

	Additional Information The application of MD studies (with randomization) has to be submitted to and approved by all local RECs of the participating sites (Art 18 & 19 Circular 7/2004). For observational studies with no randomization, the protocol has to be submitted to all participating EC (for the evaluation of local issues), but it is only required the approval from one EC.
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **Applicable national legal framework/ Reference** Art 18 & 19 Circular 7/2004 **Additional Information** The sponsor is responsible for the submission to the concerned Research ECs of all sites involved in the trial
Submission Format	**Format option(s)** Online portal Other **Preferred format** – **Online portal** (1) Portal ECM (Ensayos Clínicos con Medicamentos) It also provides further guidance on the use of the portal and the application procedure. (2) CD-ROM, e-mail or paper by attaching the specific documentation required by the EC. Online submission is compulsory for all ECs. Additionally, there are specific requirements for each EC the Sponsor has to fulfil. **Standard application form available** No **Standard application form** There is no standard application form for all RECs (each EC has its own specific forms). **Guidance on submission format** The application must include the documentation according to Art 16 of Circular 7/2004. A list of required documents (including practical examples) is available on the MSSSI website in section "Documentación del ensayo clínico para presentar a los CEIC"
Language of Submission	**Language(s) of application** Spanish **Preferred language of application** – **English accepted** Partly, not for all documents

	Documents mandatory to be in official national language – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Submission Fees	**Fees for Ethical review mandatory** Yes **Fees for Ethical review** Fees are mandatory for all clinical investigation of MD (interventional and observational) and vary according to the EC concerned. Fees are provided on the corresponding EC website or requested by phone. **Applicable national legal framework/ Reference** Royal Decree 1090/2015 **Additional Information** Contacts of ECs are provided on the MSSSI website in section Directorios de los CEIC's acreditados en España.
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 **General timespan for multi-centre studies (max nr days)** 60 **External expert advice required: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Confirmation of formal completeness **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 18 Circular 7/2004 Royal Decree 1090/2015 **Additional Information** Formal evaluation of application dossier for both mono-centre and multicentre trials: The REC(s) has/have 10 days to validate the application documentation and to notify the sponsor on the decision. There are different submission deadlines for each of the RECs. The corresponding meeting schedules are provided on the MSSSI website in section "Calendario de los CEIC's".
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** SA relating to aspects and documents that have been assessed by concerned EC(s)

Responsible for notification of SA

–

Standard notification form available

Yes

Standard notification form

There is no standard form, unlike CT with IMPs. Only required information and documents have to be sent.
The application must be in writing, dated and signed by the sponsor and investigator.

Timeline Ethical review of SA (max nr days)

35

Applicable national legal framework/ Reference

Royal Decree 1090/2015 (Article 22)
Art 25 Circular 7/2004

Additional Information

Formal validation of application dossier: The EC has 10 days to validate the application of the substantial amendment.
A reasonable opinion is communicated to the sponsor and the national CA within the given timeline.

Safety Reporting

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

The definitions for AD, SAE, SADE are provided in Art 2 Circular 7/2004/ Royal Decree 1090/2015

Reportable AEs

SUSAR (Suspected Unexpected Serious Adverse Reaction) in combination studies only
SADE (Serious Adverse Device Effect)

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (without delay)

Responsible for AE reporting to relevant EC(s)

Sponsor

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

–

All other SUSAR must be reported

–

SAE/SADE must be reported

Within a max of 7 d upon first knowledge (+8d for additional information) for events being life-threatening or leading to death
Within a max of 15d upon first knowledge

National Standard Reporting form available

Not specified

Reporting format - Options

–

Preferred reporting format

–

Provision of Annual safety report mandatory

Yes

Applicable national legal framework/ Reference

Royal Decree 1090/2015

Additional Information

For Combination studies (MD+MP) when the AE is associated to the MP, only SUSARs (Suspected Unexpected Adverse Reaction) are reported (in compliance with the reporting timelines).

End of Trial

End of trial Declaration mandatory

Yes

Responsible for End of trial Declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

–

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

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

No

Standard Declaration form

There is no standard form available for investigations of MD

Applicable national legal framework/ Reference

Art 27 Circular 7/2004 & Royal Decree 1090/2015

Additional Information

In case of premature trial termination, the notification must include the study data obtained so far as well as the reasons for early study termination and the measures taken relating to the study participants,

Study specific Requirements

Sponsor

Sponsor - Definition (pursuant to national law)

Promotor (pursuant to Art 2e) Circular 07/2004)
Individuo u organización que asume la responsabilidad de la iniciación y/o puesta en práctica de una investigación clínica.
NOTA: Cuando un investigador clínico de forma independiente inicia, pone y práctica y asume la total responsabilidad de una investigación clínica, el investigador clínico asume también el papel de promotor.

Sponsorship mandatory

Yes

	Sponsorship mandatory - Additional information It is mandatory to have a sponsor in clinical investigations of MD (interventional and observational). **Co-Sponsor - Definition available in national law** No **Co-sponsorship allowed** No **Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:** Yes
Investigator	**Entitled to be principal investigator** – **Additional Information** There are no specific requirements/regulations for GCP training of the investigators Qualification and Adequacy of IPs: they must be qualified in clinical research and in the specific field of the MD.
Study Participants - Informed Consent (IC)	**IC is regulated by law** Yes **Informed Consent - Definition/ Requirements** The provisions related to the informed consent form and the patient information sheet is provided in Article 7 Circular 7/2004 & Royal Decree 1090/2015 (articles,4 ,5, 6) **Applicable national legal framework/ Reference** The aspects on ethical principles, methodologies and protection of trial subjects are also applicable to clinical investigations with MD (pursuant to Art 30.1. RD 1591/2009) (refer to Royal Decree 1090/2015). **Additional Information** Informed consent obtained from vulnerable subjects (e.g. minors and incapacitated adults) who are potentially involved in the clinical investigation is specifically covered in Royal Decree 1090/2015.
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply **Legal framework/Reference (Minors/Children)** Law 29/2006 Royal Decree 1090/2015 (Articles 4, 5, 6, 7) Art 3, 4, 6.2 and 7.3 of Circular 7/2004 **Incapacitated persons - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Incapacitated persons)** Art 3, 5, 6.2 and 7.3 Circular 7/2004 **Emergency situations - Studies allowed** –

	Emergency situation without prior consent of patient or proxy - Studies allowed Yes Special provisions apply **Legal framework / Reference (Emergency Situation)** Art 7.4 Circular 7/2004 **Pregnant or breastfeeding women - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Pregnant or breastfeeding women)** Art 3, 6.3 Circular 7/2004 **Guidelines & conventions for protection of vulnerable populations** The European Guideline "Ethical considerations for clinical trials on medicinal products conducted with the paediatric population" contains further helpful recommendations concerning minors.
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Depends on clinical benefit **Compensation is limited to/provided for** – **Additional Information** Compensations are compulsory when there is no direct clinical benefit for the patient. Otherwise, compensations are not mandatory and are only paid to compensate for expenses (e.g. transport tickets) or potential inconveniences (like extra visits) (see Art 3 Circular 7/2004/ Royal Decree 1090/2015).
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** Yes **Additional Information** The sponsor is obliged to inform the patients on the outcome of the clinical trial and to publish the results of the investigation (pursuant to Art 38 Circular 7/2004)
Data Protection	**Notification to DP Authority/ Ombudsmann is mandatory** No **Approval/ authorisation required** No **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Data Protection Authority/ Agency - Contact Details** AGPD (Agencia Española de Protección de Datos) **Address** C/Jorge Juan, 6

ZIP/City

28001 Madrid

Country

Spain (ES)

Additional Information

The protection of the data of study subjects is mentioned in Art 3.2, 3.6, 38.3 of Circular 7/2004) and safeguarded by Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

–

Insurance

Liability insurance or alternative arrangements for damages mandatory for

Investigator(s)
Sponsor
Manufacturer
Study participants

Responsible for covering insurance

Sponsor

Insurance fee: A minimum coverage sum is defined

Yes

Minimum coverage sum

Required compensation sum coverage: • Minimum 250000 € per patient as flat sum or 25000 € per patient/year) • Maximum 2500000 € for the whole study

National legal framework in place

Yes

Applicable national legal framework/ Reference

Art 8 of Circular 7/2004

Additional Information

Insurance mandatory for participants (patients and healthy volunteers) in all clinical investigations of MD (interventional and observational) and for investigators, sponsors and manufacturers in clinical investigations with MD CE-marked use outside label, MD without label, respective combination studies and observational studies.

Quality Assurance/ Quality Control (QA/QC)

Monitoring

Compulsory

Audit by sponsor

Not specified

Standard Operating Procedures (SOPs)

Not specified

Additional Information

Royal Decree 1090/2015
Ordinance SCO/256/2007 contains information regarding GCP and, therefore, compliance with a Quality Assurance system.
Quality Assurance aspects (e.g. Monitoring and Audits) are also listed in chapter 5 ICH-GCP.

Archiving & Data Management

Study documents must be kept at least (in years)

5

Applicable national legal framework/ Reference

Royal Decree 1090/2015
Art 39 Circular 7/2004

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

A list of International standards as well as European and Spanish legislation applicable to clinical trials with MDs is also available on the AEMPS website in section Investigaciones clínicas con productos sanitarios (in Spanish only).

Official governmental legal database available

Yes

Official governmental legal database

The Spanish regulations and ordinances can be found on the official website of the State Agency Official Gazette within the Ministry of the Presidency BOE (Boletín Oficial del Estado).

Additional Information

Note: Currently, the Spanish Law regarding medical devices is not as fully characterized as it is regarding medicinal products.
In the event of doubts concerning the classification of the study, required documents or on the submission process itself, the Subdivision of Medical Devices at the Spanish Agency may be contacted for further clarifications:
Email: psinvclinic@agemed.es
FAX: +34 91 822 52 89

Investigations on Medical Devices

Applicable national regulations

National Act on Medicinal Products and Medical Devices
Transposition of EU Directives on MD
Other

Act on Medical Devices (or comparable national legal framework)

(1) Law 29/2006 on Medicinal Products and MD
(2) Royal Decree 1090/2015
(2) Royal Decree 1591/2009, on Medical Devices (Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios)
(3) Royal Decree 1616/2009 on Active Implantable Medical Devices

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

(1) Royal Decree 1090/2015

(2) Circular 7/2004 on Clinical Investigations with MD (Circular Nº 07 / 2004, investigaciones clínicas con productos sanitarios) incorporates Royal Decree 223/2204 and other applicable regulations.

3) Registry: Ordinance SCO/3603/2003 (Orden SCO/3603/2003, de 18 de diciembre) regulates Registries of active implantable medical devices

	Additional Information Observational studies: Orden SAS/3470/2009, de 16 de diciembre, covers postauthorization (observational) studies with MP for human use.
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Applicable legal framework** Royal decree 1085/2009, regulating X-ray devices has to be considered in addition to • Royal Decree 1591/2009 and • Royal Decree 1616/2009
Blood & Tissue Samples	**Specific requirements** Yes **Applicable legal framework** • 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 (Ley 14/2007 de Investigación Biomédica): regulates Biomedical Research and biological samples.
Data Protection	**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** The data protection of the participants is safeguarded by the Law 15/1999 (Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal)

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **MD - Definition** Definition for MDs and its classification (I,IIa,IIb,III) is provided in Spanish legislation in Art 2 and Annex IX of Royal Decree 1591/2009 and Art 2 of Royal Decree 1616/2009. Circular number 07/2007