Medical Device	Spain
Competent Authority	
Contact Details	
Contact name 1	Spanish Agency of Medicines and Medical Devices/ Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Contact name 2	
Contact name 3	
Phone	00 34 918 22 52 61
Fax	N/A
Email General	sgps@aemps.es
Email Department	Department of medical device: sgps@aemps.es
Address	C/ Campezo nº 1, Parque Empresarial Las Mercedes, Edificio 8
ZIP/City	28022 Madrid
Country	Spain
Web address	http://www.aemps.gob.es
Additional information	For research involving medical devices, the contact email address is psinvclinic@aemps.es .The head of this area is Mª Concepción Rodríguez Mateos.
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s)
CA - Submission for authorisation mandatory for...	Medical devices without CE marking and those with or without CE marking that are used for a purpose other than the original.
CE-marked MD used within label are exempted from any notification obligation to CA	Yes
Guidance on submission of application available	Yes
Guidance on submission of application	To follow the instructions from the AEMPS for conducting clinical investigations with medical devices review them here.
National legal framework in place	Yes
Applicable national legal framework/reference	To review the Spanish national law, this is thewebsite where the AEMPS updates everything related to it. Law in effect: Royal Decree 192/2023, Art 30-34 Royal Decree 1591/2009, Art 30 Royal Decree 1090/2015

Medical Device	Spain
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 Format	
Online portal	Documentation related to the application for authorization of a clinical investigation with a medical device, as well as any subsequent communications during its processing, should be submitted through the General Electronic Register of the General State Administrationaddressed to the AEMPS until the Eudamed electronic system is available. This applies when the applicant is required to interact electronically with the Administration (Article 14 of Law 39/2015 of October 1).
Standard application form available	Yes
Standard application form	Everything related to how to apply is providedhere, including the annex with important documentation. Authorization for the clinical investigation must be requested through a written application from the sponsor addressed to the Director of the AEMPS, accompanied by the documentation described in Chapter II of Annex XV of Regulation 2017/745 on medical devices, as listed in Annex A of the below website, along with proof of payment of the corresponding fee (code 8.19).
Standard application form - additional information	N/A
Use of standard application form binding	N/A
Guidance on submission format available	N/A
Guidance on submission format	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A

Medical Device	Spain
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 English
English accepted	Yes
Documents mandatory to be in official national language	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
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
Payment requirements (timelines)	Not specified
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
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Timelines Autorisation	
General timespan (maw nr days)	60
Mode of approval	Tacit (Silent)
Clock-stop possible if complementary information requested	Yes
National legal framework in place	Yes

Medical Device	Spain
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	
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 automatic confirmation of receipt By silent (implicit) approval
Guidance of submission of SA available	N/A
Guidance of submission of SA	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	N/A
Safety Reporting	
Sponsor must declare reportable events to	National CA Competent Bodies of the Autonomous Communities
Investogator/PI shall separately report any SAE/SADE to CA	Yes
Reportable AEs	SUSAR (Suspected Unexpected Serious Adverse Reaction) in combination studies only SADE (Serious Adverse Device Effect)
SUSAR being life-threateningor 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	N/A
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	N/A
Online safety reporting portal	N/A

Medical Device	Spain
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	N/A
Guidance on AE reporting procedure available	Yes
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.
National legal framework in place	Yes
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	N/A
End of trial	
End of trial declaration: who, when, what?	All clinical trials requiring authorisation by CA
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	90
Timespan counted from	N/A
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	Yes
Standard declaration form	The standard reporting form to be used is provided on theAEMPS website in section “Aclaraciones sobre la aplicación de la normativa de ensayos clínicos”: Anexo 1D: Notificación del fin del ensayo.
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	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 & Specifics	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)

Medical Device	Spain
Contact name 2	About 136 CEICs/ RECs in Spain.
Contact name 3	N/A
Phone	N/A
Fax	N/A
Email General	N/A
Email Department	N/A
Address	N/A
ZIP/City	N/A
Country	N/A
Web address	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)
Procedural interaction between CA and EC during approval proccess	N/A
Procedural interaction - additional information	N/A
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!
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 option) required form	All local ECs of participating sites
Submission of application required to	All local ECs of participating sites

Medical Device	Spain
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	N/A
Prerequisites for submission	N/A
Guidance on submission of application available	N/A
Guidance on submission of application	N/A
National legal framework in place	Yes
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
Preferred format	N/A
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).
Standard application form - additional information	N/A
Use of standard application form binding	N/A
Guidance on submission format available	Yes
Guidance on submission format	The application must include the documentation according toArt 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"
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Language of Submission	

Medical Device	Spain
Language(s) of application	Spanish English
Preferred language of application	N/A
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	N/A
Documents mandatory to be in local language of study site	N/A
Documents mandatory to be in language of study participant	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Submission Fees	
Fees for ethical review mandatory	Yes
Waiver for academic (non-commercial) studies possible	N/A
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.
Official guidance on required fees available	N/A
Official guidance on required fees	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	Contacts of ECs are provided on theMSSSI 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
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

Medical Device	Spain
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	
Ethical review mandatory for	SA relating to aspects and documents that have been assessed by concerned EC(s)
Responsible for submission of SA	N/A
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 for approval of SA (max nr days)	35
Guidance of submission of SA available	N/A
Guidance on submission of SA	N/A
National legal framework in place	Yes
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	
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
Responsible for AE reporting to relevant EC(s)	Sponsor
SUSAR being life-threatening or leading to death must be reported	N/A
All other SUSAR must be reported	N/A
SAE/SADE must be reported	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
Sponsor is obliged to notify all investigators of SAE/SADE occurence	N/A
National standard reporting form available	Not specified
Standard reporting form	N/A

Medical Device	Spain
Reporting format - options	N/A
Preferred format	N/A
Online safety reporting portal	N/A
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	N/A
Guidance on AE reporting procedure available	N/A
Guidance on AE reporting procedure	N/A
National legal framework in place	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 of timespan (max nr days)	90
Timespan counted from	N/A
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	No
Standard declaration form	There is no standard form available for investigations of MD
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	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,
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	
Sponsor	

Medical Device	Spain
Sponsor - Definition available in national law	Yes
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-Sponsor - Definition (pursuant to national law)	N/A
Co-sponsorship allowed	No
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	N/A
Investigator	
Entitled to be principal investigator	N/A
Additional Information	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	
Standard IC form (ICF) available	N/A
Standard IC form (ICF)	N/A
Standard ICF - Additional Information	N/A
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
Specific provision	N/A

Medical Device	Spain
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
Specific provisions	N/A
Legal framework / Reference (Incapacitated persons)	Art 3, 5, 6.2 and 7.3 Circular 7/2004
Emergency situations - Studies allowed	Not specified
Specific provisions	N/A
Emergency situation without prior consent of patient or proxy - Studies allowed	Yes Special provisions apply
Conditions allowing trial participation in emergency setting without prior consent	N/A
Legal framework / Reference (Emergency Situation)	Art 7.4 Circular 7/2004
Pregnant or breastfeeding women - Studies allowed	Yes Special provisions apply
Specific provisions	N/A
Legal framework / Reference (Pregnant or breastfeeding women)	Art 3, 6.3 Circular 7/2004
National legal framework for protection of vulnerable populations in place	N/A
Applicable legal framework / Reference (Vulnerable Population)	N/A
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.
Additional Information	N/A
Study participants - compensation & reimbursement	
Reimbursement for study participants	Depends on clinical benefit
Compensation is limited to/provided for	N/A
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 - recriutment & trial outcome >> end of study	
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	

Medical Device	Spain
Notification to DP Authority/ Ombudsmann is mandatory	No
Approval/authorisation required	No
Specific notification timelines before operations start	N/A
Laguage of notification	N/A
Notification format	N/A
Notification fee required	N/A
Fee	N/A
Guidance on notification requirements available	N/A
Guidance on notification requirements	N/A
Data protection authority/agency - contact details	AGPD (Agencia Española de Protección de Datos)
Contact name 2	N/A
Contact name 3	N/A
Phone	N/A
Fax	N/A
E-mail	N/A
Web address	N/A
Address	C/Jorge Juan, 6
ZIP/City	28001 Madrid
Country	Spain
Additional information	The protection of the data of study subjects is mentioned inArt 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.
Archiving & data management	
Study documents must be kept at least (in years)	5
National legal framework in place	Yes
Applicable national legal framework/reference	Royal Decree 1090/2015 Art 39 Circular 7/2004
Additional information	N/A
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes

Medical Device	Spain
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
Transposition of Directive 90/385/EEC	N/A
Transposition of Directive 93/42/EEC	N/A
Transposition of Directive 98/79/EC	N/A
Transposition of Directive 2007/47/EC	N/A
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	(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.
Combination studies (IMP/MD)	
Applicable national regulations	N/A
Legal act applicable to both study types	N/A
Other applicable regulations/implementing provisions (acts, laws, decrees, ordinances, circulars, etc)	N/A
Additional information	N/A
Radiation & Radiotherapy	

Medical Device	Spain
Specific framework available	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
Additional information	N/A
Biobanking	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
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)
Implementing decrees / ordinances	N/A
Other applicable regulations (covering DP related issues)	N/A
Additional Information	N/A
Insurance	
Specific requirements	N/A
Applicable legal framework	N/A
Additional information	N/A
EC operations/ Fees	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
CA operations/ Fees	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	
MD/MD Investigation	
MD - Definition available in national law	Yes

Medical Device	Spain
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
Investigation of MD - Definition available in national law	N/A
MD Investigation - Definition	N/A
Additional Information	N/A
Further Definitions	
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	N/A