Other studies	Spain
Competent Authority	
Contact Details	
Contact name 1	Spanish Agency of Medicines and Medical Devices -AEMPS - Agencia Española de Medicamentos y Productos Sanitarios
Contact name 2	N/A
Contact name 3	N/A
Phone	00 34 91 822 57 87 (International calls)
Fax	N/A
Email General	sgaem@aemps.es
Email Department	smhaem@aemps.es (Department of medicinal products for human use) and sgps@aemps.es (Department of medical device)
Address	C/ Campezo nº 1, Edificio 8, Madrid
ZIP/City	28022 Madrid
Country	Spain
Web address	http://www.aemps.gob.es
Additional information	N/A
Trial Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Competent Authority/-ies (CA) Ethics committee(s)
CA - Registration/notification without approval required for...	"Interventional research with minimal risks in IMP trials" and "Non-interventional study"
CA - Submission required to...	National CA
National trial registry - Registration mandatory	
National trial registery	The Spanish Agency of Medicines and Medical Devices shall maintain a registry of clinical studies with medicinal products for human use on its website. **The (REec) Spanish Clinical Studies Registry** shall include the following information: a) Compulsorily, clinical trials with medicinal products for human use that are authorised by the Spanish Agency of Medicines and Medical Devices, in accordance with this Royal Decree. b) Compulsorily, non-interventional post-authorisation studies that are to be conducted and have been classified by the Spanish Agency of Medicines and Medical Devices. c) Voluntarily, as with other similar databases, other types of clinical studies sponsored by national or international, public or private entities, provided they have at least one participating site located in Spain including cases, or although not including cases, that have a Spanish contribution considered as significant. There is no general national healthy volunteer registry.
National legal framework in place	
Applicable national legal framework/reference	Royal Decree (RD) 1090/2015 see article 47 and 48

Other studies	Spain
Additional information	Observational studies: All studies have to be approved by EC. Depending on the type of study, they will also have to be approved by local/national CA. Please refer to: see: Orden SAS/3470/2009) In case of doubt regarding the classification of the study, please send an email to: farmacoepi@agemed.es, requesting AEMPS to provide a classification. Registries: for further information on registries with IMPs and MD, please refer to: http://www.aemps.gob.es/informa/notasInformativas/laAEMPS/2013/NI-MUH_07-2013-reec.htm
Submission of Application	
Responsible for study submission	Sponsor Legal representative domiciled in the EU/EEA
Guidance on submission of application available	
Guidance on submission of application	The required application documentation is provided in Royal Decree (RD) 1090/2015.
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Submission Format	
Format option(s)	Online portal
Online portal	Portal ECM (Ensayos Clínicos con Medicamentos).
Standard application form available	N/A
Standard application form	N/A
Standard application form - additional information	N/A
Use of standard application form binding	N/A
Guidance on submission format available	
Guidance on submission format	The AEMPS website (Section Clinical Trials) provides practical guidance and manuals on the use of the portal ECM and the application modality. Link for submission: http://www.aemps.gob.es/ (click in “sede electrónica”, to upload the xml file with the protocol)
National legal framework in place	
Applicable national legal framework/reference	Related information to the application procedure is described in Royal Decree 1090/2015 (Chapter 5, section 2, Article 21).
Additional information	N/A
Language of Submission	
Language(s) of application	Spanish English
Preferred language of application	N/A
English accepted	Partly, not for all documents

Other studies	Spain
Documents mandatory to be in official national language	Protocol Summary Information material, Documents and Forms intended for study participants and patient information
National legal framework in place	
Applicable national legal framework/reference	Royal decree 1090/2015
Additional information	N/A
Submission Fees	
Fees for trial submission mandatory	
Fees	(1) A first clinical trial with MPs that are not authorised in a country that belongs to the International Conference on Harmonisation (ICH) with active substances or combinations of active substances that are not authorised in Spain: Fee: €4327.26 (2) a) A clinical trial with a MP that is authorised in a country other than Spain (belonging to the ICH). b) Clinical trials with medicines that are not authorised in any country belonging to the ICH, following a first clinical trial included in the category (1) c) Clinical trials with the characteristics outlined (1) in the event of resubmission when the outcome of the first application was a withdrawal of the application or was refused d) Clinical trials with a medicine that is not authorised in a country belonging to the ICH with active substances that are authorised in Spain. Fee: € 412.12 3) a) Clinical trials with MP authorised in Spain, irrespective of their specific labelling for the trial. b) Clinical trials whose sponsor is a researcher or group of researchers and in which a Pharmacy Service is responsible for preparing or blinding the medicines under investigation Fee: € 114.55 (4) Procedure for classifying a veterinary medicine that is not authorised in Spain as investigational medicinal product. Fee: € 283.76 5) Fee for the veterinary clinical trials procedure. Fee: € 114.55
Waiver for academic (non-commercial) studies possible	
Payment requirements (timelines)	N/A
Official guidance on required fees available	
Official guidance on required fees	The current fees and payment modalities are provided on theAEMPS website: Medicines for human use>Clinical research with medicines > Tasas/Fees
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Timelines Authorisation	
General timespan (max nr days)	60
Mode of approval (general)	Tacit (Silent)
Timespan counted from	Confirmation of formal completeness
National legal framework in place	

Other studies	Spain
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	The CA has 10 days to validate the application documentation and to notify the applicant on the decision. In case of any formal deficiencies communicated by the CA, the sponsor has 10 days to correct them. (Art 5. Regulation (UE) n.º 536/2014) NB! CA authorization is only possible provided that the EC's favourable opinion has been issued before the deadline. There is NO clock stop if further information or clarification is requested from sponsor (as opposed to REC assessment). Considering this, it is advisable that the CTA is submitted to the EC(s) at least 2.3 weeks prior to the date of submission to the CA!
Amendments/Substantial Amendments	
Notification mandatory for	Not specified
Responsible for submission of SA	N/A
Standard notification form available	
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: "Solicitud de autorización de una modificación relevante a un ensayo clínico con medicamentos de uso humano a la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) y de dictamen por el Comité Ético de Investigación Clínica (CEIC)." The application must be in writing, dated and signed by the sponsor and investigator.
Timeline for approval of SA (max nr days)	38
Guidance of submission of SA available	N/A
Guidance on submission of SA	N/A
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	NB: In case of amendments to clinical trials with gene therapy, somatic cell therapy, or GMO medicinal products, the time span can be extended and will be communicated to the sponsor.
End of trial	
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	15
Timespan counted from	N/A
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	
Standard declaration form available	

Other studies	Spain
Standard declaration form	
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015
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. Additionally the promotor will send to the CA a copy of the summary of the Clinical Trial results. This information will be sent (maximum timeframe) after 1 year of the anticipated trial ending.
Additional Information & Specifics	
Additional Information & Specifics	N/A
Ethics Committee	
Contact Details	
Contact name 1	Comité de evaluación ética con medicamentos (CEIM)
Contact name 2	N/A
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	http://www.msssi.gob.es/en/profesionales/farmacia/ceic/home.html
Additional information	117 Ethics Committees (EC) in Spain
Ethical Review - General	
Ethical approval (favourable opinion) to be obtained from	
Procedural interaction - additional information	N/A

Other studies	Spain
Additional information	According to thIS Decree, only the accredited ethics committees as CEIms - Committees on Ethics of Research with Medicines - are authorized to evaluate the clinical trials with medicinal or healthcare products. Submission to the EC and CA can be done in any order or simultaneously (depending on the Sponsor's preference). NB! CA authorization is only possible provided that the EC's favourable opinion has been issued before the deadline. The Sponsor can select the EC for the evaluation for the CT. There will be only one EC that will do a unique CT evaluation.
Submission of Application	
Responsible for study submission	Sponsor
Entitled to study submission	Sponsor
Guidance on submission of application available	N/A
Guidance on submission of application	N/A
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015 Circular 523/2014
Additional information	The documentation can be submitted at any time
Submission Format	
Format option(s)	Electronically
Online portal	Via AEMPS (CA) Portal
Standard application form available	N/A
Standard application form	N/A
Standard application form - additional information	N/A
Use of standard application form binding	N/A
Guidance on submission format available	
Guidance on submission format	Further practical information is provided by the AEMPS (see: AEMPS - Clinical Trials) or on the MSSSI website in section Pharmacy > Clinical Research Ethics Committee Co-ordination Centre
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015 and Circular number 07/2004
Additional information	N/A
Language of Submission	
Language(s) of application	Spanish English
English accepted	N/A

Other studies	Spain
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 ethical review mandatory	
Waiver for academic (non-commercial) studies possible	N/A
Fees for ethical review	Most of the RECs charge fees for reviewing the protocol and the assessment of the CT applications. The fees vary between the different RECs.
Official guidance on required fees available	N/A
Official guidance on required fees	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	Fees are provided on the corresponding EC website or requested by phone (contacts 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)	45
General timespan for multi-centre studies (max nr days)	45
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015 (Article 22) Circular number 07/2004
Additional information	N/A
Amendments/Substantial Amendments	
Ethical review mandatory for	Not specified
Responsible for submission of SA	Not specified
Standard notification form available	
Standard notification form	N/A
Timeline for approval of SA (max nr days)	N/A
Guidance of submission of SA available	N/A
Guidance on submission of SA	N/A
National legal framework in place	

Other studies	Spain
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	A. Submission without corrections neither clarifications: 10 days for validation + 45 days for evaluation + 5 days of final response. B. Submission with corrections: 10 days for validation + 11 days for corrections + 45 days of evaluation + 5 days of final response. C. Submission with clarifications: 10 days of validation + 45 days of evaluation + 31 days for responding of objections (clarifications) + 5 days of final response. D. Submission with corrections and clarifications: 10 days of validation + 11 days of corrections + 45 days of evaluation + 31 days for responding of objections (clarifications) + 5 days of final response. Close
End of study	
End of trial declaration mandatory	
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	15
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	
Standard declaration form available	
Standard declaration form	N/A
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015 Circular number 07/2004
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	
Sponsor	
Sponsor - Definition available in national law	N/A
Sponsor - Definition (pursuant to national law)	N/A
Sponsorship mandatory	
Sponsorship mandatory - Additional information	N/A

Other studies	Spain
Co-Sponsor - Definition available in national law	N/A
Co-Sponsor - Definition (pursuant to national law)	N/A
Co-sponsorship allowed	
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	
Additional Information	N/A
Investigator	
Entitled to be principal investigator	N/A
Additional Information	N/A
Study participants - informed consent	
Standard IC form (ICF) available	
Standard IC form (ICF)	N/A
Standard ICF - Additional Information	N/A
IC is regulated by law	
Informed Consent - Definition/ Requirements	The provisions related to the informed consent form and the patient information sheet is provided in Royal Decree 1090/2015 art 4 and Regulation (UE) n.º 536/2014.
Applicable national legal framework/ Reference	RD 1090/2015 art 4 and Regulation (UE) n.º 536/2014.
Additional Information	Informed consent obtained from vulnerable subjects (e.g. minors and incapacitated adults) who are potentially involved in the CT is specifically covered in Art 4 of Royal Decree 1090/2015.
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	N/A
Legal framework/Reference (Minors/Children)	Royal Decree 1090/2015 (Articles 4, 5, 6, 7).
Incapacitated persons - Studies allowed	Yes Special provisions apply
Specific provisions	N/A
Legal framework / Reference (Incapacitated persons)	Royal Decree 1090/2015 (Articles 4, 5, 6, 7).
Emergency situations - Studies allowed	Yes Special provisions apply
Specific provisions	N/A

Other studies	Spain
Emergency situation without prior consent of patient or proxy - Studies allowed	Special provisions apply
Conditions allowing trial participation in emergency setting without prior consent	N/A
Legal framework / Reference (Emergency Situation)	Royal Decree 1090/2015 (Articles 4, 5, 6, 7).
Pregnant or breastfeeding women - Studies allowed	Yes Special provisions apply
Specific provisions	N/A
Legal framework / Reference (Pregnant or breastfeeding women)	Royal Decree 1090/2015 (Articles 4, 5, 6, 7).
National legal framework for protection of vulnerable populations in place	
Applicable legal framework / Reference (Vulnerable Population)	Royal Decree 1090/2015 (Articles 4, 5, 6, 7).
Guidelines & conventions for protection of vulnerable populations	N/A

Other studies	Spain
Additional Information	LEGAL AGE OF CONSENT: 18 years MANDATORY / SUGGESTED AGE RANGES DEFINED FOR ASSENT: 0-11 years 12-17 years with own signature NUMBER OF REQUIRED SIGNATORIES: One parent OFFICIAL LANGUAGE OF INFORMED CONSENT: Spanish INFORMATION ON MATERIAL USED TO DESCRIBE THE CLINICAL TRIAL TO THE MINOR: The child must also receive information adapted to their age and mental maturity according to the European regulation. ADDITIONAL INFORMATION (INCLUDING REFERENCE FOR TEMPLATE): • Prior informed consent of the parents who hold custody or of the legal representative of the minor must be obtained, and the minor, if under 12 years of age, must be heard if the minor has sufficient judgment. The informed consent form of the parents shall be valid provided it is signed by one of them with the express or tacit consent of the other, which should be adequately documented, as stipulated in article 156 of the Civil Code. When the subject's condition allows, or in any case when the minor is twelve years of age or older, the subject must also give his/her consent to participate in the trial. • Reference legislation: o Royal Decree 1090/2015 (Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos) o Law 29/2006 on Medicinal Products and MD o Law 14/2007 (Ley 14/2007, de 3 de julio, de Investigación biomédica - in Title V Chapters I-IV) o Royal Decree 1716/2011 (Real Decreto 1716/2011, de 18 de noviembre) • IC template(s) / guidelines / information sources: o The Agencia Española de Medicamentos y Productos Sanitarios (AEMPS); A state agency within the Spanish Ministry of Health, Social Services and Equality - > Medicines for Human use - > Clinical Research with Medicines o The Ministry of Health, section about regulation of clinical trials: o Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for Investigation with medicinal products and the Spanish Clinical Studies Registry (English version) SOURCE(S): http://www.aemps.gob.es/en/investigacionClinica/medicamentos/home.htm http://www.aemps.gob.es/en/legislacion/espana/investigacionClinica/ensayos.htm https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf
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 and 32 of Royal Decree 1090/2015)

Other studies	Spain
Study participants - recriutment & trial outcome	
Mandatory to inform participant of clinical trial outcome	
Additional information	The sponsor is obligated to publish the study results, regardless of positive or negative outcome and to inform the patients on the outcome of the clinical trial according to Art 1 of Royal Decree 1090/2015.
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	
Approval/authorisation required	
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	
Guidance on notification requirements	N/A
Data protection authority/agency - contact details	AGPD (Agencia Española de Protección de Datos) C/Jorge Juan, 6
Contact name 2	N/A
Contact name 3	N/A
Phone	+34 901 100 099
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 1-10 of Royal Decree 1090/2015 and safeguarded by Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.
Insurance	
Liability insurance or alternative arrangements for damages mandatory for	Investigator(s) Sponsor Study participants Hospital/ trial center
Responsible for covering insurance	Sponsor

Other studies	Spain
Isurance fee: a minimum coverage sum is defined	N/A
Minimim coverage sum	The required compensation sum is: • Minimum 250000 € per patient as flat sum or 25000 € per patient/year) • Maximum 2500000 € for the whole study/ year
National legal framework/reference available	
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	N/A
Quality insurance, quality control	
Monitoring	
Audit by sponsor	
Standard operating process (SOPs)	
Additional information	Royal Decree 1090/2015
Archiving & data management	
Study documents must be kept at least (in years)	N/A
National legal framework in place	
Applicable national legal framework/reference	Royal Decree 1090/2015
Additional information	N/A
National Legislations	
Clinical trials on IMPs in Humans	
Applicable national regulations	N/A
Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)	N/A
Applicable to ATMP/ GMO trials	N/A
Transposition of (GCP) Directive 2005/28/EC	N/A
Act transposing (GCP) Directive 2005/28/EC	N/A
General legislation on Medical/ Clinical Research in Humans	N/A
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	N/A
Additional Information	N/A
ATMP/ GMO trials: Applicable regulations (if separate legal text)	N/A

Other studies	Spain
General Information	
Official governmental legal database available	
Official governmental legal database	Agencia Estatal Boletín Oficial del Estado (BOE- State Agency Official State Gazette).
Additional information	Legal framework for clinical trials with medicinal products - Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products : Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios. (BOE núm. 177, de 25 de julio de 2015). Available at (only in Spanish) : https://www.aemps.gob.es/en/legislacion/espana/laAEMPS/general.htm#leyes - Corrección de errores del Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios. (BOE núm. 306, de 23 de diciembre de 2015). Available at (only in Spanish) : https://www.aemps.gob.es/en/legislacion/espana/laAEMPS/general.htm#leyes ****** Background The Royal Decree Royal Decree 1090/2015 aims to adapt the Spanish legislation to the future application of the Clinical trials - Regulation EU No 536/2014 of 16 April 2014. Also, it aims to cover those aspects that are subject to national adaptations as well as any others aspects requiring clarification (for instance, the decree provides a definition of "non commercial trials". See definitions) This Royal Decree entered into force in January, 2016, except for a few paragraphs, which shall enter into force on the date on which the Regulation (EU) No. 536/2014 will enter into application. Pending the application of the aforementioned EU Clinical trial regulation (no sooner that 2019) and the development of a fully functional EU clinical trials portal and database, the Spanish Royal Decree has established the following transational procedure : - transitional procedure for authorization of a clinical trial before full functionality of the EU portal and the EU database - transitional arrangements relating to the functions of evaluation of the ethics committee (currently called "CEICs") (for instance, according to the Decree, only the accredited ethics committees as CEIms - Committees on Ethics of Research with Medicines - will be able to evaluate the clinical trials with medicinal or healthcare products).
Investigations on Medical Devices	
Applicable national regulations	N/A
Act on Medical Devices (or comparable national legal framework)	N/A
Transposition of Directive 90/385/EEC	N/A
Transposition of Directive 93/42/EEC	N/A

Other studies	Spain
Transposition of Directive 98/79/EC	N/A
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	N/A
Additional Information	N/A
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
Nutrition	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Radiation & Radiotherapy	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Gene Therapy	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Blood & Tissue Samples	
Specific framework available	
Applicable legal framework	Regarding clinical trials with cells tissues, considered as medicinal products, all legislation related to clinical trials with medicinal products applies. Other applicable legislation: • 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 (not considered as medicinal products) • Law 14/2007 (Ley 14/2007 de Investigación Biomédica): regulates Biomedical Research and biological samples. • Royal decree 178/2004 lays down the legal principles of the contained use, release and marketing of genetically modified organisms (GMO). • Royal decree 664/1997 deals with the exposure to biological agents (including cell cultures used to amplify the gene therapy vectors).
Additional information	N/A

Other studies	Spain
Biobanking	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Nanoparticles	
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 Other legislation covering DP related issues
National DP act	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)	Regulation (EU) 2016/679
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
Invasive Catheters	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A

Other studies	Spain
Definitions	
Clinical research	
Definition	N/A
Interventional study	
Definition	N/A
Observational study	
Definition	N/A
Combination study (IMP & DM)	
Definition	N/A
Nutrition Study	
Definition	N/A
IMP/IMP Study	
IMP - Definition available in national law	
IMP - Definition	The Spanish definition for IMP (Royal Decree 1090/2015, Chapter 1, article 2, letter I) is the literal translation of the European IMP definition provided in REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014.
Investigation of IMP - Definition available in national law	N/A
IMP Investigation - Definition	N/A
Additional Information	N/A
Further Definitions	
	N/A
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	N/A