Medicinal Products for Human Use - SPAIN

Competent authority

Contact Details

Contact Name 1

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

Contact Name 2

Department of Human Medicine Products

Email General

aecaem@aemps.es

Email Department

smhaem@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

AEMPS is the operating body in charge of Medicinal Products (MP) and Medical Devices (MD) within the
Ministry of Health, Social Services and Equality/ Ministerio de Sanidad, Servicios Sociales e Igualdad
Paseo del Prado, 18-20, planta baja, esquina con Lope de Vega
28014 Madrid
Tel:+34 901 400 100.
Fax: +34 915 96 44 80
Email: oiac@msssi.es
Website: http://www.msssi.gob.es/

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)

CA - Submission for authorisation mandatory for

Clinical IMP trials
Clinical ATMP trials

CA - Registration/ notification without approval required for

–

CA - Submission required to

National CA

National trial registry - Registration mandatory

Yes

National trial registry

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 in a registry according to Art 62 (on transparency) of Law 29/2006 on Medicinal Products and Medical Devices.

There is no general national healthy volunteer registry.

Applicable national legal framework/ Reference

Royal Decree (RD) 1090/2015

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

Entitled to study submission

–

Prerequisites for submission

–

Guidance on submission of application

The required application documentation is provided in Royal Decree (RD) 1090/2015

Submission Format

Format option(s)

Online portal

Preferred format

–

Online portal

Portal ECM (Ensayos Clínicos con Medicamentos).

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)

Applicable national legal framework/ Reference

Related information to the application procedure is described in Royal Decree 1090/2015 (Chapter 5, section 2, Article 21).

Language of Submission	**Language(s) of application** Spanish English **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** Protocol Summary Information material, Documents and Forms intended for study participants and patient information **Applicable national legal framework/ Reference** Royal decree 1090/2015
Submission Fees	**Fees for trial submission mandatory** Yes **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** Reduced fees are charged **Official guidance on required fees** The current fees and payment modalities are provided on the AEMPS website: Medicines for human use>Clinical research with medicines > Tasas/Fees
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Tacit (Silent)

ATMP/GMO trials (max nr days)

Other

Mode of approval (ATMP/GMO trials)

–

External expert advice required (max nr days)

–

Xenogeneic cell therapy (max nr days)

No time limit

Mode of approval (Xenogeneic cell therapy)

Explicit

Clock-stop possible if complementary information requested

No

Timespan counted from

Confirmation of formal completeness

National legal framework in place

Yes

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 (SA)

Notification mandatory for

–

Authorisation mandatory for

All clinical investigations previously authorised by CA (NB: If the amendment relates to a specific document that has been evaluated exclusively by either the CA or the EC, it only has to be submitted to the respective institution)

Responsible for submission of SA

–

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: "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)

Other
38

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.

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

National CA

Reportable AEs

SAE (Serious Adverse Event)
SUSAR (Suspected Unexpected Serious Adverse Reaction)

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

–

National standard reporting form available

Only for reportable events occurring in the respective country

Standard Reporting Form

(1) Notification form in paper for SUSARs occurring in Spain:
Use of the standard reporting form provided on the AEMPS website in section “Aclaraciones sobre la aplicación de la normativa de ensayos clínicos”: Anexo D: Formulario de notificación de reacción adversa grave e inesperada ocurrida en España
Notifications on any SUSARs occurring in Spain shall be in Spanish.
(2) International standard form for SUSARs occurring outside Spain.

Reporting format - Options

Paper hardcopy
Electronically

Preferred format

Electronically

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA + the competent bodies of the concerned Autonomous Communities

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Detailed guidance and practical instructions are given in the document ""“Transmisión electrónica de sospechas de reacciones adversas de medicamentos de uso humano / Electronic transmission on suspected adverse reactions with human use medicines"

Applicable national legal framework/ Reference

Royal Decree 1090/2015 (Article 49)

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)

15

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

National legal framework in place

Yes

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.

Ethics committee

Contact Details	**Contact Name 1** Comité de evaluación ética con medicamentos (CEIM) **Web address** http://www.msssi.gob.es/en/profesionales/farmacia/ceic/home.htm **Additional Information** 117 Ethics Committees (EC) in Spain
Ethical Review – General	**Submission for Ethical review mandatory for** Clinical IMP trials Clinical ATMP trials **Submission to CA and EC to be performed in the following order** In parallel Sequentially (in any order) **Additional Information** Royal Decree 1090/2015 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. **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) 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** Any accredited EC Single Opinion **Submission of application required to** – **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.

Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** Sponsor **Prerequisites for submission / approval** – **National legal framework in place** Yes **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 **Preferred format** – **Online portal** Via AEMPS (CA) Portal **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 **Applicable national legal framework/ Reference** Royal Decree 1090/2015 and Circular number 07/2004
Language of Submission	**Language(s) of application** Spanish **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** –
Submission Fees	**Fees for Ethical review mandatory** Yes **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. **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 **ATMP/GMO trials (max nr days)** – **External expert advice required: Timespan (max nr days)** – **Xenogeneic cell therapy: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** Royal Decree 1090/2015 (Article 22) Circular number 07/2004
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** – **Responsible for notification of SA** – **Standard notification form available** Yes **Timeline Ethical review of SA (max nr days)** – **National legal framework in place** Yes **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.
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction)

	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** Within a max of 7d upon first knowledge (+ 8d for additional information) **All other SUSAR must be reported** Within a max of 15d upon first knowledge **SAE/SADE must be reported** – **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** – **Provision of Annual safety report mandatory** Yes **Applicable national legal framework/ Reference** Royal Decree 1090/2015
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 15 **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 **National legal framework in place** Yes

Applicable national legal framework/ Reference

Royal Decree 1090/2015
Circular number 07/2004

Study specific Requirements

Sponsor

Sponsorship mandatory

Yes

Co-sponsorship allowed

No

Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:

Yes

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Not specified

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 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

Legal framework/Reference (Minors/Children)

Royal Decree 1090/2015 (Articles 4, 5, 6, 7)

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Royal Decree 1090/2015 (Articles 4, 5, 6, 7)

Emergency situations - Studies allowed

Yes
Special provisions apply

Emergency situation without prior consent of patient or proxy - Studies allowed

Special provisions apply

Legal framework / Reference (Emergency Situation)

Royal Decree 1090/2015 (Articles 4, 5, 6, 7)

Pregnant or breastfeeding women - Studies allowed

Yes
Special provisions apply

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

Yes

Applicable legal framework / Reference (Vulnerable Population)

Royal Decree 1090/2015 (Articles 4, 5, 6, 7)

Additional Information

ADDITIONAL PAEDIATRIC 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 for study participant **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 and 32 of Royal Decree 1090/2015)
Study Participants - Recruitment & Trial Outcome	**Mandatory to inform participant of clinical trial outcome** Yes **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** 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) C/Jorge Juan, 6 **Phone** +34 901 100 099 **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 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. Royal Decree 1090/2015 (Article 3d)

	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 **Other applicable regulations (covering DP related issues)** Regulation (EU) 2016/679
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Investigator(s) Sponsor Study participants Hospital/ trial center **Responsible for covering insurance** Sponsor **Minimum 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 **Applicable national legal framework/ Reference** Royal Decree 1090/2015
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
Archiving & Data Management	**Study documents must be kept at least (in years)** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** Royal Decree 1090/2015

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes

Official website providing relevant national legislation

A list of the International standards as well as European and Spanish legislation regarding medical research is provided on the AEMPS website: Inicio >Legislación>España>Investigación (in Spanish only)

Official governmental legal database available

Yes

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)

Clinical Trials on IMPs in Humans

Applicable national regulations

General Act(s) on Medical/Clinical Research in Humans
Transposition of (CT) Directive 2001/20/EC
Transposition of (GCP) Directive 2005/28/EC
Other

Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)

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): regulating clinical trials with medicinal products.

It supersedes Royal Decree 223/2004 (Real Decreto 223/2004, de 6 de febrero) on interventional clinical trials with medicinal products (no longer applicable).

Transposition of (GCP) Directive 2005/28/EC

Available as separate legal text

Act transposing (GCP) Directive 2005/28/EC

Ordinance SCO/256/2007 (Orden SCO/256/2007, de 5 de febrero) is the implementation of Directive 2005/28/EC (GCP Directive) into Spanish law.

General legislation on Medical/ Clinical Research in Humans

Law 29/2006 on Medicinal Products and MD (Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios):
It regulates aspects related to medicinal products and medical devices such as clinical research, assessment and authorisation, registry, manufacturing, quality control, storage, shipment and distribution, etc.

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

(1) Law 14/2007 (Ley 14/2007, de 3 de julio, de Investigación biomédica - in Title V Chapters I-IV): It deals with biomedical research in general, focusing on interventional studies (except for clinical trials on medicinal products, on medical devices, on cells/Tissues/ organ transplants), non interventional studies, data protection and ethical aspects. It also covers genetic analyses, management and storage of biological samples and biobank regulation.
(2) Royal Decree 1716/2011 (Real Decreto 1716/2011, de 18 de noviembre): This Decree refers to Ley 14/2007 and provides detailed information on the basic requirements of authorization and functioning of biobanks for biomedical research and the management of human biological samples, and regulating the functioning and organization of the National Registry of Biobanks for biomedical research
(3) Observational studies:
Orden SAS/3470/2009, de 16 de diciembre, covers postauthorization (observational) studies with MP for human use.

Data protection: Data Protection. Orden SAS 3470/2009, Law 15/1999 and RD 1720/2007

Blood & Tissue Samples

Specific requirements

Yes

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).

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 **Other applicable regulations (covering DP related issues)** Regulation (EU) 2016/679

Definition

IMP/IMP Study	**IMP - Definition available in national law** Yes **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.