Legislation

International regulations

- Good clinical practices (GCP) and ICH Standards (International Harmonisation Conference).
- Commission Directive 2005/28/EC, dated 8 April, 2005, establishing the principles and guidelines for good clinical practices regarding research on drugs for human use, as well as the requirements to authorise the manufacture or importation of these products.
- European Parliament and Council Directive 2001/20/EC, dated 4 April, 2001, regarding the approach of the legal, regulatory and administrative provisions of the member states on the application of good clinical practices when performing clinical trials with drugs for human use.
- Pan-American Health Organization and Council of International Organizations of Medical Sciences. International ethical guidelines for health-related research with human beings, Fourth Edition. Geneva: Council for International Organizations of Medical Sciences (CIOM); 2016.
- Detailed guide regarding the request to the competent authorities to authorise a clinical trial of a drug for use in humans, the notification of relevant modifications and the communication of completion of the test. (CT-1) - (2010/C 82/01) - Official Journal of the European Union 30-03-2010.

Clarifications on the application of the standard:

- European Regulations for clinical trials with drugs for human use. ER no. 536/2014.
- Auxiliary drugs. Volume 10 Eudralex.

National regulations

- Royal Decree 957/2020, dated 3 November, regulating observational studies with drugs for human use.
- Question and answer document on the entry into force of RD 957/2020.
- Royal Decree 1090/2015, dated 4 December, regulating clinical trials with drugs, ethics committees for drug research and the Spanish registry of clinical trials.
- AEMPS Instructions Document in RD 1090/2015.
- AEMPS-CEIM collaboration memoranda in RD 1090/2015.

- Detailed guidelines on presenting to the competent authorities the request for authorisation of a clinical trial of a drug for human use, the notification of relevant modifications, and communicating test completion ("CT-1").
- Law 14/2007, dated 3 July, regarding Biomedical Research..
- Royal Decree 1716/2011, dated 18 November, establishing the basic requirements for the authorisation and operation of biobanks for the purposes of biomedical research and the treatment of biological samples of human origin, and regulating the operation and organisation of the national biobank registry for biomedical research.
- Questions and answers about RD 1716/2011 regarding biobanks.
- Law 29/2006, dated 26 July,, regarding guarantees and the rational use of drugs and medical devices.
- Memo 7/2004. Clinical research with medical devices.
- Royal Decree 1591/2009, dated 16 October, through which medical devices are regulated.
- Royal Decree 1616/2009, dated 26 October, through which active implantable medical devices are regulated.
- Royal Decree 577/2013, dated 26 November, regulating observational studies with drugs for human use.
- Order SCO/256/2007, dated 5 February, establishing the principles and detailed guidelines for good clinical practice and the requirements to authorise the manufacture or importation of drugs in research for human use.
- Royal Decree 1015/2009, dated 19 June, which regulates the availability of drugs in special situations.
- Data Protection Law: Organic Law 3/2018, dated 5 December, personal data protection and guarantee of digital rights.
- European Parliament and Council Regulation (EU) 2016/679, dated 27 April, 2016 regarding the Protection of Physical Persons with regard to the treatment of personal data and the free circulation of these data and by which Directive 95/46/EC (General Regulation of Data Protection) is repealed.
- Law 9/2003, dated 25 April, by which the legal regime of the confined use, voluntary release and commercialisation of genetically modified organisms is established.
- Law 41/2002, dated 14 November, as the basic regulator of the autonomy of the patient and their rights and obligations in the terms of information and clinical documentation.