Medicinal Products for Human Use - PORTUGAL

Competent authority

Contact Details	**Contact Name 1** INFARMED- National Authority of Medicines and Health Products, IP/ Autoridade Nacional do Medicamento e Produtos de Saúde I.P. **Contact Name 2** (Government agency accountable to the Health Ministry) **Contact Name 3** Health Products Directorate **Phone** +351 21 798 7283 **Fax** +351 21 798 7248 **Email General** cimi@infarmed.pt **Email Department** ensaios.clinicos@infarmed.pt **Address** Parque de Saúde de Lisboa; Avenida do Brasil 53 **ZIP/City** 1749-004 Lisboa **Country** Portugal (PT) **Web address** http://www.infarmed.pt/ **Additional Information** Emai: cimi@infarmed.pt (general information on clincial trials); ensaios.clinicos@infarmed.pt (information on procedures). The English web pages contain selected items from its Portuguese language site and will be continuously expanded. No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) • Recruiting sites: Administration Board and Local Ethical Committee **CA - Submission for authorisation mandatory for** Clinical IMP trials Clinical ATMP trials Drugs; Biologicals including ATMPs; Xenogenic products; GMO

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA
Infarmed

National trial registry

RNEC (National Registry of Clinical Studies) http://www.rnec.pt/pt
RNEC has a private area with registered users to submit studies and manage the process approval and also a public area where it is possible to search for registered studies in Portugal since January 2017
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Additional Information

Detailed guidance for the applicant on trial submission and the definite structure of documentation is provided at INFARMED website. There is a File to be uploaded with all documents that must be submitted " Estrutura de organização de pastas conforme Instruções ao requerente".

There is also a Flowchart and Support slides describing the process and the needed documents to be submitted.
All the information is available only in Portuguese.

For further guidance an email is available: ensaios.clinicos@infarmed.pt

Submission of Application

Responsible for study submission

Sponsor
Other
Sponsor or other organization designated by sponsor

Entitled to study submission

–

Prerequisites for submission

–

Guidance on submission of application available

Yes

Guidance on submission of application

Detailed guidance for the applicant on trial submission and the definite structure of documentation is provided at INFARMED website (1). There is a File to be uploaded with all documents that must be submitted "Estrutura de organização de pastas conforme Instruções ao requerente".

At RNEC website, after sponsor is registered in the platform, there is also a tutorial for on-line submission.

All the information is available only in Portuguese. For further guidance an email is available: ensaios.clinicos@infarmed.pt

Link
(1) http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/submissao_infarmed

Applicable national legal framework/ Reference

Art 25-27 Law 21/2014 (pt), amended by Law 73/2015 (pt)

Submission Format	**Format option(s)** Online portal Mandatory On-line Submission through RNEC: https://www.rnec.pt/ **Preferred format** Online portal **Standard application form** Annex 1: Clinical trial Application Form https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/application-form2009_en.pdf **Standard application form - Additional information** At INFARMED website there is a Zip File with all the files that must include documents to be submitted to CA through RNEC (on-line) as described above. http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/submissao_infarmed **Guidance on submission format available** Yes **Guidance on submission format** Yes, but only in Portuguese There is a Flowchart and Support slides describing the process and the needed documents to be submitted (Apresentação de Apoio - Ensaios Clínicos: Documentação e Boas Práticas Regulamentares - setembro 2017) Links: http://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/ensaios-clinicos/submissao_infarmed and at https://www.rnec.pt/pt/submissao-nacional **National legal framework in place** Yes **Applicable national legal framework/ Reference** Art 26 (1) Law 21/2014 (pt)
Language of Submission	**Language(s) of application** Portuguese English **Preferred language of application** – **English accepted** Partly (for official application documents and scientific documents only) **Documents mandatory to be in official national language** Cover letter Information material, Documents and Forms intended for study participants and patient information Cover Letter; Synopsis of the Protocol; Informed consent; IMP label; Patient card; Scales
Submission Fees	**Fees for trial submission mandatory** Yes

Fees

Authorisation fees according to Ordinance 63/2015 (Portaria n° 63/215):
• Clinical trial Phase I-III: 1000 €
• Clinical trial Phase IV: 600 €
• Studies on Bioavailability and Bioequivalence: 350 €
• Substantial amendment to protocol: 200 €

INFARMED may grant exemption of fees when sponsors of clinical studies are non-profit institutions or in the case of clinical studies of non-commercial nature (Art 3, Portaria n.º 63/2015)

NB: Fees are being revised annually!

Waiver for academic (non-commercial) studies possible

Yes

Official guidance on required fees

Portaria nº63/2015 (Fee Ordinance)
Related information plus currently applicable Fee Ordinance (Portaria) is available on the INFARMED website in section Taxas (in Portuguese only).

Timelines Authorisation

General timespan (max nr days)

30

Mode of approval (General)

INFARMED usually sends an email confirmation and a letter.

ATMP/GMO trials (max nr days)

50

Mode of approval (ATMP/GMO trials)

Explicit

External expert advice required (max nr days)

100

Xenogeneic cell therapy (max nr days)

No time limit

Mode of approval (Xenogeneic cell therapy)

Explicit

Clock-stop possible if complementary information requested

Yes

Timespan counted from

–

Applicable national legal framework/ Reference

Art 26 & 77 of Law 21/2014 (pt)

Additional Information

Submission to INFARMED and CEIC are simultaneous at RNEC.
Submission to Health Units and respective Ethical Committee are done at the same time.
A DPO in each Health Unit is responsible for assuring the compliance of data protection procedures with GDPR.

NB! Hospital administrations may delay the approval even after receiving authorization from INFARMED/ CEIC/ CNPD because of several internal requirements.

Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** All clinical trials requiring authorisation by CA All clinical trials approved by INFARMED and CEIC (National Ethics Committee); Change in IMP – INFARMED; Change in inclusion/exclusion criteria – INFARMED & CEIC; Change in Recruiting sites, Informed consent - CEIC **Responsible for submission of SA** Sponsor Substantial Amendment Notification Form - Cf. Sec. 3.7.b of Detailed guidance on request to competent authorities for authorisation of clinical trial on a medicinal product for human use, notification of substantial amendments & declaration of trial end **Standard notification form** European “Substantial Amendment Notification Form”/"Formulário de pedido de alteração": provided on the INFARMED website in section Medicamentos Uso Humano> Ensaios Clinicos> Formulários: **Timeline for approval of SA (max nr days)** – **Guidance on submission of SA available** Yes **Guidance on submission of SA** Substantial Amendment Notification Form - Cf. Section 3.7.b of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1) **Applicable national legal framework/ Reference** Art 18 Law 21/2014 (pt), amended by Law 73/2015 **Additional Information** Submission to INFARMED and CEIC are simultaneous at RNEC.
Safety Reporting	**Responsible for AE reporting to CA** Sponsor Other Sponsor or other organization designated by sponsor **Sponsor must declare reportable events to** Competent Authority CA(s) of EU&EFTA Member States concerned Relevant EC(s) **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** – **Reporting format - Options** Online portal **Preferred format** – **Provision of Annual safety report mandatory** Yes **Annual safety report shall be provided by sponsor to** National CA Relevant EC(s) **Applicable national legal framework/ Reference** Art 22 Law 21/2014 (pt) **Investigator shall report SAE to** Sponsor **Reporting timeline** Immediately (not later than 24h) Followed by detailed written report within 5d
End of Trial	**End of trial declaration mandatory for** All clinical trials requiring authorisation by CA **Responsible for End of trial declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 90 **Timespan counted from** Last patient - last visit in the respective country **Early/premature Termination - Declaration timespan (max nr days)** 15 **Reasons for early termination shall be clearly stated** Yes **Standard Declaration form available** Yes **Standard Declaration form** European "Declaration of the End of Trial Form" (Formulário de declaração de fim de EC): to be used for declaration to the CA and the EC, provided on the INFARMED website in section Medicamentos Uso Humano> Ensaios Clinicos> Formulários

Guidance on End of trial declaration

Declaration of the End of Trial Form (cf. Section 4.2.1 of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial CT-1)

Applicable national legal framework/ Reference

Art 19 Law 21/2014 (pt), amended by Law 73/2015

Ethics committee

Contact Details

Contact Name 1

National Ethics Committee for Clinical Research/ Comissão de Ética para a Investigação Clínica (CEIC)

Phone

+351 21 798 53 40

Fax

+351 21 798 72 09

Address

Parque da Saúde de Lisboa; Av. do Brasil, 53 - Pav. 17-A

ZIP/City

1749-004 Lisboa

Country

Portugal (PT)

E-Mail

ceic@ceic.pt

Additional Information

In addition, there are almost 100 institutional ECs (public and private, health and academic) in Portugal.

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)

Procedural interaction - Additional information

National Ethics Committee (CEIC) - Same as the one described above for Infarmed, but more details about the documents evaluated by CEIC experts are provided at CEIC website

Additional Information

NB! For performing clinical trials in Portugal, sponsors have to get authorization from the Competent Authority and ethical approval from the Ethics Committee (CEIC) plus approval from the National Data Protection Authority (CNPD – “Comissão Nacional de Proteção de Dados”) according Art 16 & 25 Law 21/2014 (pt).

	Regulatory and ethics bodies involved in approval process Competent Authority/-ies (CA) Ethics committee(s) • Recruiting sites: Administration Board and Local Ethical Committee
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Central EC **Additional Information** The National Research Ethics Committee (CEIC) is responsible for assessing Clinical Trial applications, though it may delegate to a research ethics committee established by a local health institution, hospital or clinical trial site.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion) **Submission of application required to** Central EC (authorised to issue a single opinion) **Additional Information** Central EC in PortugaL: National Research Ethics Committee – CEIC
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission available** Yes **Guidance on study submission** "Note on Procedures for issuing CEIC s single opinion to carrying out Clinical Trials with medicinal products for human use" (also available in English on the CEIC website in section: Utilities/Information (Utilidades/Informação) > Notices (Notas Informativas). The request for approval includes the application form, proof of payment of fees to INFARMED and the required documentation.
Submission Format	**Format option(s)** Mandatory On-line Submission through RNEC **Preferred format** – **Standard application form available** Yes **Standard application form** European "Clinical trial Application Form"/ "Formulário de pedido de AEC" provided on the CEIC website in section Medicamentos Uso Humano> Ensaios Clinicos> Formulários.
Language of Submission	**Language(s) of application** Portuguese English

	Preferred language of application – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Protocol Summary Information material, Documents and Forms intended for study participants and patient information
Submission Fees	**Fees for Ethical review mandatory** No **Fees for Ethical review** No fee is directly charged by CEIC (INFARMED I.P, charge sponsors according to a scale of fees. CEIC are funded by INFARMED I.P.)
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 30 **General timespan for multi-centre studies (max nr days)** 30 **ATMP/GMO trials (max nr days)** 50 **External expert advice required: Timespan (max nr days)** 100 **Xenogeneic cell therapy: Timespan (max nr days)** No time limit **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **National legal framework in place** Yes **Applicable national legal framework/ Reference** 16 & 17 of Law 21/2014 **Additional Information** The given timelines also apply to any designated ECs. In most cases, requests for permission to conduct clinical trials are answered by INFARMED, CEIC, and CNPD within 60 days, if the applications are submitted concurrently. NB! Hospital administrations may delay the approval even after receiving authorization from INFARMED/ CEIC/ CNPD because of several internal requirements.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to the study protocol

	Responsible for notification of SA Sponsor **Timeline Ethical review of SA (max nr days)** 20 **Applicable national legal framework/ Reference** Art 18 Law 21/2014 (pt)
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction) **Investigator shall report SAE to** Sponsor **Reporting timeline** Immediately (not later than 24h) Followed by detailed written report within 5d **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** Art 22 Law 21/2014 (pt), as amended by law 73/2015 **Additional Information** Trials not submitted through RNEC (before January 2016): On-line: Format ICH E2B/EudraVigilance CIOMS Form to email: farmacovigilancia.ec@infarmed.pt Trials submitted through RNEC (after January 2016): DSURs submitted through RNEC
End of Trial	**End of trial Declaration mandatory** Yes

Responsible for End of trial Declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

Last patient - last visit in the respective country

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

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

European "Declaration of the End of Trial Form")/ "Formulário de declaração de fim de EC": provided on the INFARMED website in section Medicamentos Uso Humano> Ensaios Clinicos> Formulários

Applicable national legal framework/ Reference

Art 19 Law 21/2014 (pt)

Additional Information

The final report must be submitted to the EC within 12 month after trial termination.

Additional Information & Specifics

Additional Information

Guidance on documents that will be evaluated by CEIC Experts might be found at CEIC website

Study specific Requirements

Sponsor

Sponsorship mandatory

Yes

Co-sponsorship allowed

No

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Not specified

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

English translation for Portuguese definition for informed consent ("Consentimento informado"):
'Permission obtained voluntarily from a study participant or his/ her legal representative after being informed in detail about the nature, the consequences and risks as well as the right to withdraw participation at any time without any consequences.'

Applicable national legal framework/ Reference

Chapter 1, Art 2(j) Law 21/2014 - Definition
Art 7 & 8 Law 21/2014 (pt)- Vulnerable persons

Additional Information

Specific provisions apply to vulnerable persons such as minors and adults incapable of giving informed consent.

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Specific provision

Minors aged above 16 years: Informed consent must be obtained from the minor and his his legal representative.
Minors aged less than 16 years: the representative is the sole responsible for grating informed consent, although it must reflect the presumed will of the minor.

(The concerned EC is given the right, under exceptional circumstances, to waive the requirements of informed consent and informing the minor patients in clinical studies without intervention. The assigned ethic committee is given the same right for adults unable to provide informed consent).

Legal framework/Reference (Minors/Children)

Article 7 Law 21/2014 (pt).

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Art 8 Law 21/2014 (pt)

Emergency situations - Studies allowed

Special provisions apply
No national legal framework available

Specific provisions

Clinical trials involving subjects in emergency situations are not explicitly mentioned in Portuguese law.
However, the same standards apply as for investigations with minors and incapacitated persons.
Any provisions on the protection of human subjects must conform to the spirit of the Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, and all phases of clinical investigations must be conducted in that spirit, from first consideration of the need and justification of the study to publication of results.

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

No national legal framework available

Pregnant or breastfeeding women - Studies allowed

Special provisions apply
No national legal framework available

Specific provisions

Clinical trials involving pregnant or lactating women are not explicitly mentioned in Portuguese law.
However, the same standards apply as for investigations with minors and incapacitated persons.
Any provisions on the protection of human subjects must conform to the spirit of the Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, and all phases of clinical investigations must be conducted in that spirit, from first consideration of the need and justification of the study to publication of results.

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

Art 7 & 8 Law 21/2014 (pt)

Additional Information

ADDITIONAL PAEDIATRIC INFORMATION

LEGAL AGE OF CONSENT:
18 years

MANDATORY / SUGGESTED AGE RANGES DEFINED FOR ASSENT:
Case 1: <5 years; Case 2: 16< years>=5; Case 3: >=16 years
Specifications regarding assent: >12, but the investigator decides about the maturity of the child

NUMBER OF REQUIRED SIGNATORIES:
Case 1: both parents/legal tutor (1 document); Case 2: assent from child and consent from both parents/legal tutor (2 documents); Case 3: consent from child and both parents/legal tutor (1 document)

OFFICIAL LANGUAGE OF INFORMED CONSENT:
Portuguese and adapted to the age of the child

INFORMATION ON MATERIAL USED TO DESCRIBE THE CLINICAL TRIAL TO THE MINOR:
Different models should be used for child assent in the different age groups: 5-11 and 12-15.

ADDITIONAL INFORMATION (INCLUDING REFERENCE FOR TEMPLATE):
• From 12-15 years: when the assent from the child is required and the investigator decides about their maturity, a signed declaration from the investigator should be added assuring that clear and adapted information was provided and understood by the child about the clinical trial and all the procedures and risks.
• Reference legislation:
Recommendation from National Ethical Committee (CEIC) entitled: "Documento Orientador CEIC sobre Consentimento Informado (CI) para participação em ensaios clínicos em pediatria ", written in Portuguese and accessible on CEIC website
• IC template(s) / guidelines / information sources
Recommendations by National Ethical Committee for Clinical research (CEIC); Clinical research national Law 21/2014, 14 April 2014; Ethical considerations for clinical trials on medicinal products conducted with minors (18 September 2017); ICH E11(R1) guideline on clinical investigation of medicinal products in the paediatric population (28 Feb 2018); Regulation (EC) No 1901/2006 of the European Parliament and of the Council (12 December 2006)

SOURCE(S):
https://www.ceic.pt/documentos-orientadores
https://www.ceic.pt/web/ceic/legislacao-especifica

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Mandatory

Compensation is limited to/provided for

Expenses (e.g. transportation, meals, and others such as salary lost)

Additional Information

Compensation for expenses is mandatory according to Art 13 Law 21/2014 (pt).
The EC verifies and evaluates the compensation arrangements for study subjects, pursuant to Art 16 (6) Law 21/2014 (pt).

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

Yes

Approval/ authorisation required

Yes

Specific notification timelines before operations start

–

Language of notification

Official National Language(s)
English accepted

Notification format

e-notification via electronic system on the CNPD website

Notification fee required

Yes

Fee

150 € for prior authorization (75 € for simple registration)

Guidance on notification requirements available

Yes

Guidance on notification requirements

Further guidance on the e-notificatoin procedure is provided on the CNPD website in section 'Notification'.

Data Protection Authority/ Agency - Contact Details

National Data Protection Authority/ Comissão Nacional de Protecção de Dados (CNPD)

Phone

+351 213928400

Fax

+351 213976832

E-Mail

geral@cnpd.pt

Web address

https://www.cnpd.pt

Address

Rua de São Bento n.º 148-3º

ZIP/City

1200-821 Lisboa

Country

Portugal (PT)

Additional Information

All personal data processing must be notified to the CNPD (Art 27 of the Data Protection Act.). The processing of personal data obtained from study subjects requires prior authorization according to Art 28 Data Protection Act.

Timelines for authorization: 30 days according to Art 16 (9) Law 21/2014 (pt).

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

–

Insurance

Liability insurance or alternative arrangements for damages mandatory for

Investigator(s)
Sponsor
Study participants

Responsible for covering insurance

–

Applicable national legal framework/ Reference

Art 15 & 16 Law 21/2014 (pt)
General Liability Insurance Law, DL 72/2008 (pt): Art 137-148 provides the legal requirements of the insurance contract.
Further legislation:
The Norma Regulamentar n.º14/2008-R (de 27 de Novembro)
is a liability law for mandatory insurance

Additional Information

The insurance covers all cases of liability for property damage and injuries suffered by the patient during the study and the year following its completion (if the damage to health it is imputable to the trial).

Quality Assurance/ Quality Control (QA/QC)

Monitoring

Optional

Audit by sponsor

Optional

Standard Operating Procedures (SOPs)

Optional

Additional Information

There are no specifications in the law.

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

Art 25-27 Law 21/2014 (pt), amended by Law 73/2015 (pt)

A list of applicable Portuguese legislation is available on the
• INFARMED website via: Medicamentos Uso Humano> Ensaios Clinicos> Normativos de referência – Nacional: Legislação nacional aplicável) of
• CEIC website via: Utilidades/Informação - Legislação - Nacional

Clinical Trials on IMPs in Humans	**Applicable national regulations** – **Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)** Law 21/2014 on clinical research (pt) published 16 April 2014 in Diário da República/ Lei n.º 21/2014, of 16th of April. This law repeals Law 46/2004 of 19 August 2004 (Clinical Trials on Medicinal Products for Human Use) that incorporated the principles Amendment Lei n.º 73/2015 (auditors, monitors, inspectors – access to clinical trial registries) **Transposition of (GCP) Directive 2005/28/EC** – **Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** ad Law 21/2014: This law repeals Law 46/2004 of 19 August 2004 (Clinical Trials on Medicinal Products for Human Use) that incorporated the principles of the Clinical Trials Directive 2001/20/EC. This law covers all clinical research with humans including not only clinical trials with IMP but also investigations with MD and all kind of observational studies. It also regulates the organization of the Comissão de Ética para a Investigação Clínica / National Ethics Committee for Clinical Research (CEIC). Law 73/2015 of 27th July is an amendment to Law 21/2014 and sets the conditions in which monitors, auditors and inspectors have access to the registries of clinical studies' participants. Insurance: - General Liability Insurance Law, DL 72/2008 (pt): Art 137-148 provides the legal requirements of the insurance contract. - Norma Regulamentar n.º14/2008-R (de 27 de Novembro) is a liability law for mandatory insurance (applicable to many cases including clinical trials). **Additional Information** Orphan diseases: There is no specific Portuguese law for orphan diseases. We follow the European regulation for orphan Diseases and their human medicines (e.g. EC 141/2000). There are however specific Portuguese ministry of health lists of orphan drugs not for investigational purposes, but for reimbursement. NB! Up until April 2014, the procedure for submitting and requesting an approval of a clinical trial in Portugal was governed by Law 46/2004 of 19 August 2004. This law was revoked by Law 21/2014, of 16 April 2014, which introduced some new considerations that sponsors have to be aware when seeking to conduct clinical trials in Portugal. Both laws incorporate the principles of the Clinical Trials Directive 2001/20/EC. It is worth noting that while Law 21/2014 introduced new procedures for submitting a clinical trial authorization request, some of the procedures are still not fully operational. Thus, some of the principles of previous law are still in use.
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** Data Protection Act – Act 67/98 of 26 October (en) / Lei n.o 67/98- Lei da Protecção de Dados Pessoais (pt)

Definition

IMP/IMP Study	**IMP - Definition available in national law** Yes **IMP - Definition** An “investigational medicinal product” (IMP) is a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form. Medicinal products with a marketing authorisation (MA) are classified as IMPs when they are to be used as the test substance or reference substance in a clinical trial, provided they are used or assembled (formulated or packaged) in a way different from the authorised form, or used for an unauthorised indication, or used to gain further information about the authorised form. On this basis, provided that the requirement(s) are met, reference products used as comparators should be considered as IMPs.