Medical Device	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 Ministy)
Contact name 3	Health Products Directorate
Phone	+351 21 798 7235
Fax	+351 21 798 7182
Email General	daps@infarmed.pt
Email Department	clinicalstudies.devices@infarmed.pt
Address	Parque de Saúde de Lisboa, Avenida do Brasil, 53
ZIP/City	1749-004 Lisboa
Country	Portugal
Web address	http://www.infarmed.pt/
Additional information	The English web pages contain selected items from its Portuguese language site and will be continuously expanded.
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Competent Authority/-ies (CA)/ For certain types of MDs National Ethics Committee Recruiting sites: Administration Board
CA - Submission for authorisation mandatory for...	Combination studies (MD+IMP)>>ref CTR MDR IVDR Notification if MD class I, IIa, IIb (non-inv.) or IVD Art. 66, point 7a) from IVDR; Authorisation for all other MDs and IVDs
CE-marked MD used within label are exempted from any notification obligation to CA	No
Guidance on submission of application available	Yes
Guidance on submission of application	**Medical Devices (MD):** Application must be submitted on RNEC (https://www.rnec.pt/pt_PT) and it should follow the list of requirements on the National Ethics Committee p submissao). The platform does not support further communications, which will be received by e-mail from clinicalstudies.devices@infarmed.pt. **In-Vitro Diagnostics Medical Devices (IVD):** Application must be submitted via e-mail to clinicalstudies.devices@infarmed.pt. There is no national submission requiremen on MDCG guidelines should be followed (https://health.ec.europa.eu/document/download/4e1f946d-a71a-42c7-bd98-0e9977752669_en?filename=mdcg_2022-19_en.pdf). requirements for MDs in terms of language, to follow those directions for common documents. **Combined Studies:** In case of a Clinical Trial combined with a IVD performance study or MD clinical investigation, the Clinical Trial must be submitted on CTIS and the oth mentioned above.
National legal framework in place	Yes
Applicable national legal framework/reference	As a Member-State, in Portugal, European Regulations 2017/745 (MDR) and 2017/746 (IVDR) apply directly. National Laws apply only on topics not covered by the Regula than National Law. In Portugal, national laws, partially derogated by the MDR and IVDR, are the following: • Decree-Law n.º 145/2009, of 17th June; • Law n.º 21/2014, of 16th of April; • Decree-Law n.º 29/2024, of 5th of April.
Additional information	Submission to Competent Authority (INFARMED) and Ethics Committee (CEIC) to be performed in the following order: In parallel. Only one dossier is submitted, via RNEC and EC coordinate with each other to review and evaluate their respective parts.
Submission Format	
Online portal	**Medical Devices:** https://www.rnec.pt/pt_PT In Vitro Diagnostics Medical Device: by e-mail to clinicalstudies.devices@infarmed.pt.
Standard application form available	Yes
Standard application form	On the National Ethics Committee there is a page with the requirements for submission of different types of clinical studies (https://www.ceic.pt/documentos-submissao). MD application form: DOCUMENTAÇÃO PARA SUBMISSÃO - Investigações clínicas de dispositivos ao abrigo do Regulamento (UE) 2017/745 - NOVA IVD application form: there isn't one yet. Submitt acording to MDCG 2022-19.
Standard application form - additional information	The application form requires the completion of the MDCG application forms: MDs: https://health.ec.europa.eu/document/download/47a8a9aa-bcc5-4cf8-bed7-933ebe263711_en IVDs: https://health.ec.europa.eu/document/download/227ccaaf-9d3d-46ce-9f27-4d0869aaa176_en
Use of standard application form binding	Yes
Guidance on submission format available	Yes
Guidance on submission format	Included on the document of submission application for MDs: DOCUMENTAÇÃO PARA SUBMISSÃO - Investigações clínicas de dispositivos ao abrigo do Regulamento (U structured yet, but applicants are advised to submit it as close as possible to the MDs.
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Language of Submission	
Language(s) of application	Official national language Portuguese English
English accepted	Partly, not for all documents

Medical Device	Portugal
Documents mandatory to be in official national language	Protocol Summary Information material, Documents and Forms intended for study participants and patient information EC clinical trial questionnaire Information on safe use of MD Instructions for use (of CE-marked MD) Site related information Labels ICFs; Patient Materials; CRF; Financial Agreements (can be bilingual); CV; GCP; Site Suitability Declarations.
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	Fees for notification and authorization of 1) Clinical Investigation/Performance Study of MD or IVD without CE marking or with CE marking for other indication: 1000,00 € 2) Clinical Investigation/Performance Study of MD or IVD with CE marking for approved indication: 400,00 € 3) Substantial modification to a Clinical Investigation/Performance Study: 200,00 € Fees are being revised to accommodate the European Regulations. Academic Studies: No submission fees. Exemption request must be placed, either on the application submission or via e-mail beforehand.
Waiver for academic (non-commercial) studies possible	Yes
Payment requirements (timelines)	Prior to submission of application
Official guidance on required fees available	Yes
Official guidance on required fees	INFARMED (CA) has a Payment Guide online. However, this document has not been revised since the entry into force of the MDR and IVDR.
National legal framework in place	Yes
Applicable national legal framework/reference	Portaria nº63/2015 (Fee Ordinance) - Available only in Portuguese
Additional information	N/A
Timelines Autorisation	
General timespan (maw nr days)	35
Mode of approval	Explicit INFARMED (CA) may perform a tacit approval of a notification, but, so far, it has been explicit.
Clock-stop possible if complementary information requested	Yes
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	Authorization from the Administration Boards of the recruitment sites must be sought before submitting the study to the National Competent Authorities. Submission to INFARMED (CA) and CEIC (EC) are simultaneous via RNEC (MDs) or e-mail (IVDs); only 1 dossier is needed, following the above-mentioned guidelines. Favorable opinion from CEIC exempts the DPO of the recruitment sites of further assessment.
Amendments/Substantial Amendments	
Standard notification form	For non-substantial modifications to the clinical investiagation/performance study, no form is available. However, it is recommended the use of the initial application form av For Substancial Modifications of MDs the form onMDCG 2021-28 and for IVDs the form on MDCG 2022-20.
Timeline for approval of SA (max nr days)	35
Guidance of submission of SA available	No
Guidance of submission of SA	Applicants are advised to utilize the initial application form available onhttps://www.ceic.pt/documentos-submissao and submit a Dossier with the relevant documentation.
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	The online portal and e-mail for submission of the initial application is the same for substantial and non substantial modifications.
Safety Reporting	
Sponsor must declare reportable events to	Competent Authority National CA CA(s) of EU&EFTA Member States concerned National (Pharmaco)Vigilance portal Relevant EC(s) Institution Other
Investogator/PI shall separately report any SAE/SADE to CA	No

Medical Device	Portugal
Reportable AEs	SAE (Serious Adverse Event) likely to be related to the procedure of implementation of the MD SAE (Serious Adverse Event) including AE being life-threatening or leading to death or to a serious deterioration in health, prolonged hospitalisation, additional surgery or m SUSAR (Suspected Unexpected Serious Adverse Reaction) SUSAR (Suspected Unexpected Serious Adverse Reaction) occurring in the respective country SADE (Serious Adverse Device Effect) Device deficiency, potentially leading to SAE Device deficiency, that might have led to SAE if no action or intervention had been made USADE (Unanticipated Serious Adverse Device Effect)
SUSAR being life-threateningor leading to death must be reported	As soon as possible Within a max of 2d upon first knowledge Followed by additional detailed report(s) (Reportable events must be fully recorded)
All other SUSARs	As soon as possible Within a max of 2d upon first knowledge Followed by additional detailed report(s) (Reportable events must be fully recorded)
SAE/SADE must be reported	Within a max of 2 d upon first knowledge for events being fatal, life-threatening, or deteriorating health As soon as possible, within a max of 7d upon first knowledge (for other AEs or AEs related to MD deficiencies, potentially leading to a SAE)
National standard reporting form available	European standard SAE reporting form MEDDEV 2.7/3 to be used
Standard reporting form	SAE reporting form: Appendix of MEDDEV 2.7/3
Reporting format - options	Not specified
Online safety reporting portal	N/A
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	National CA Relevant EC(s)
Guidance on AE reporting procedure available	Yes
Guidance on AE reporting procedure	Available on RNEC platform (https://www.rnec.pt/notificar-sae-dd). The model of report is an Excel document from the MDCG: • MDs: Appendix to MDCG 2020-10/1 Rev 1 • IVDs: Appendix to MDCG 2024-4 Submission process: • MDs: RNEC portal • IVDs: by e-mail to clinicalstudies.devices@infarmed.pt
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	An Annual Safety report is mandatory both for Clinical Investigations and Performance Studies, under the Portuguese Law nº 21/2024 (Art. 22). No*template* is yet available PMCF/PMPF: Additionally to the reporting requirements of Clinical Investigations and Performance Studies, post-market studies must also be reported according toMEDDE System). The relevant documentation must be sent to dvps@infarmed.pt (Health Products Vigilance Unit).
End of trial	
End of trial declaration: who, when, what?	All clinical trials requiring authorisation by CA All clinical trials requiring notification to CA (without approval process) All clinical investigations and performance studies, either notified or authorised, by the CA and EC
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	15
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 declared	Yes
Standard declaration form available	No
Standard declaration form	There is no template available yet. The Sponsor, or their delegate, shall submit the report, presentations and/or publication viaRNEC.
Guidance on end of trial declaration available	No
Guidance on end of trial declaration	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Additional Information & Specifics	

Medical Device	Portugal
Additional Information & Specifics	Anticipated conclusion of the trial must be notified within 15 days via RNEC.
Ethics Committee	
Contact Details	
Contact name 1	National Ethics Committee for Clinical Research / Comissão de Ética para a Investigação Clínica (CEIC)
Contact name 2	N/A
Contact name 3	N/A
Phone	+351 21 798 53 40
Fax	+351 21 798 72 09
Email General	ceic@ceic.pt
Email Department	
Address	Parque da Saúde de Lisboa Av. do Brasil, 53 - Pav. 17-A
ZIP/City	1749-004 Lisboa
Country	Portugal
Web address	http://www.ceic.pt
Additional information	Local ECs: There are almost 100 institutional ECs (public and private, health and academic). However, Clinical Investigations and Performance studies are of CEIC's compe
Ethical Review - General	
Submission for Ethical review mandatory for	
Submission to CA and EC to be performed in the following order	Only one single submission required
Procedural interaction between CA and EC during approval proccess	Yes
Procedural interaction - additional information	CEIC and INFARMED coordinate internally to assess the Submission Dossier.
Additional information	Guidance on documents that will be evaluated by CEIC Experts might be found at CEIC Website. Submission via RNEC.
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 all MD and IVD applications, though it may delegate to a research ethics committee establishe clinical trial site.
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Central EC (authorised to issue a single opinion)
Submission of application required to	Central EC (authorised to issue a single opinion)
Additional information	Regulatory and ethics bodies involved in approval process • Competent Authority (INFARMED) • National Ethics Committee (CEIC) • Recruiting sites: Administration Board
Submission of Application	
Responsible for study submission	Sponsor
Entitled to study submission	Sponsor Principal Investigator Coordinating Investigator Manufacturer acting as sponsor Legal representative domiciled in the EU/EEA Legal representative domiciled in the respective country Contract Research Organisation
Prerequisites for submission	Proof of payment of fees Appropriate insurance
Guidance on submission of application available	Yes
Guidance on submission of application	Guidance, and applicable documents, may be found on CEIC's website.
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Submission Format	
Format option(s)	Online portal Online through RNEC portal (https://www.rnec.pt/31a)
Preferred format	Email Online portal

Medical Device	Portugal
Online portal	MDs: National Registry of Clinical Studies: RNEC. IVDs: by e-mail to clinicialstudies.devices@infarmed.pt.
Standard application form available	Yes
Standard application form	Application Form for MDs may be found on CEIC's website. Application Form for IVDs not available yet.
Standard application form - additional information	Form only available for Clinical Investigations of MDs. Other studies are advised to follow, as closely as possible, the same structure. IVDs should use the MDCG 2022-19 as
Use of standard application form binding	Yes
Guidance on submission format available	Yes
Guidance on submission format	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Language of Submission	
Language(s) of application	Portuguese English
Preferred language of application	Not specified
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	Cover letter Protocol Summary Information material, Documents and Forms intended for study participants and patient information Information on safe use of MD Instructions for use (of CE-marked MD) Site related information Labels Full title of the trial (A.3) ICFs; Patient Materials; CRF; Financial Agreements (can be bilingual); CV; GCP; Site Suitability Declarations.
Documents mandatory to be in local language of study site	Not applicable
Documents mandatory to be in language of study participant	Not applicable
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Submission Fees	
Fees for ethical review mandatory	Yes
Waiver for academic (non-commercial) studies possible	Upon request
Fees for ethical review	No fee is directly charged by CEIC. INFARMED I.P, charges sponsors the fees mentioned on the Competent Authority section, upon submission of the dossier.
Official guidance on required fees available	Yes
Official guidance on required fees	Document only in portuguese and outdated: https://www.infarmed.pt/documents/15786/17838/Nova%20GP_EnsClin_Portaria63_2015%5B1%5D.pdf/b1a2d47b-eee8-46c0- information, consult the Competent Authority section.
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Timelines Ethical Review	
General timespan for single-centre studies (max nr days)	35
General timespan for multi-centre studies (max nr days)	35
Clock-stop possible if complementary information requested	N/A
Timespan counted from	Since first submission of the dossier.
National legal framework in place	Yes

Medical Device	Portugal
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	N/A
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial amendments
Responsible for submission of SA	Sponsor The Sponsor may delegate to a third-party, preferentially national, based on the EU.
Standard notification form available	Yes
Standard notification form	Medical Devices: MDCG 2021-28 + the national initial submission form mentioned above. In Vitro Diagnostics Medical Devices: MDCG 2022-20.
Timeline for approval of SA (max nr days)	20
Guidance of submission of SA available	
Guidance on submission of SA	Applicants are advised to use the initial application form and the MDCG forms mentioned above.
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	All substantial notifications must be sent to both INFARMED and CEIC, in the same way as the initial submission, for both MDs and IVDs.
Safety Reporting	
Reportable AEs	SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction) Device deficiency, potentially leading to SAE USADE (Unanticipated Serious Adverse Device Effect)
Investigator shall report SAE to	Sponsor Other third-party delegated by the Sponsor, e.g. CRO, although the main responsibility is always of the Sponsor.
Reporting timeline	As soon as possible Within a max of 2d upon first knowledge Followed by additional detailed report(s) (Reportable events must be fully recorded)
Responsible for AE reporting to relevant EC(s)	Sponsor Other third-party delegated by the Sponsor, e.g. CRO, although the main responsibility is always of the Sponsor.
SUSAR being life-threatening or leading to death must be reported	As soon as possible Within a max of 2d upon first knowledge Followed by additional detailed report(s) (Reportable events must be fully recorded)
All other SUSAR must be reported	As soon as possible Within a max of 2d upon first knowledge Followed by additional detailed report(s) (Reportable events must be fully recorded)
SAE/SADE must be reported	As soon as possible Within a max of 2 d upon first knowledge for events being fatal, life-threatening, or deteriorating health As soon as possible, within a max of 7d upon first knowledge (for other AEs or AEs related to MD deficiencies, potentially leading to a SAE) Followed by additional detailed report(s) (Reportable events must be fully recorded)
Sponsor is obliged to notify all investigators of SAE/SADE occurence	No
National standard reporting form available	No
Standard reporting form	Portugal follows the MDCG guidelines, and as such, their templates. Medical Devices: MDCG 2020-10/2 Rev. 1 In Vitro Diagnostics Medical Devices: MDCG 2024-4
Reporting format - options	Email Online portal
Preferred format	Online portal E-mail only for IVDs
Online safety reporting portal	RNEC (https://www.rnec.pt/31a)
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	National CA Relevant EC(s)
Guidance on AE reporting procedure available	No
Guidance on AE reporting procedure	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April and Decree-Law nº 145/2009 of 17th of June if not derogated by the European Regulations on the relevant articles.

Medical Device	Portugal
Additional information	An Annual Safety is mandatory for all studies with MDs and IVDs and shall be submitted to the national EC and CA.
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	15
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 declared	Yes
Standard declaration form available	No
Standard declaration form	No standard form is available yet. National EC and CA accept report, publications and presentations.
Guidance on end of trial declaration available	No
Guidance on end of trial declaration	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Law n.º 21/2014, of 16th of April, if not derogated by the European Regulations on the relevant articles.
Additional information	The final report must be submitted to the EC and CA within 12 month after trial termination.
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	
Sponsor	
Sponsor - Definition available in national law	Yes
Sponsor - Definition (pursuant to national law)	Sponsor - person, collective or singular, entity or institute responsible for the design, performance, management or funding of a clinical study. Law n.º 21/2014, of 16th of April
Sponsorship mandatory	Yes
Sponsorship mandatory - Additional information	It is mandatory to have a sponsor in all clinical studies, including MDs and IVDs.
Co-Sponsor - Definition available in national law	Yes
Co-Sponsor - Definition (pursuant to national law)	There is no definition in the law, but, under specific circumstances, has been accepted by local ECs. No data available regarding the National Ethics Committee.
Co-sponsorship allowed	Yes
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	N/A.
Investigator	
Entitled to be principal investigator	Physician Dietitian Nutritionist Nurse Pharmacist Any investigator experienced in related domain
Additional Information	Investigator - A person who practices a profession recognized in Portugal for carrying out research activities, due to their scientific qualifications and legal authorization to p for conducting the clinical study at the study center and, if applicable, for the research team that carries out the study at that center. In this case, they may be designated as of 16th of April
Study participants - informed consent	
Standard IC form (ICF) available	No
Standard IC form (ICF)	There is no standard form. However, there are several guidance documents on the topic onCEIC's Website.
Standard ICF - Additional Information	N/A
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	Informed Consent - The expressed decision to participate in a clinical study, freely made by a person capable of giving it, or, in the absence of such capacity, by their legal r informed about the nature, scope, consequences, and risks of the study, as well as the right to withdraw from it at any time, without any consequences, in accordance with t Committee (CEC), which must include the definition of an appropriate means of providing such consent, which should be in writing, whenever applicable. Law n.º 21/2014, c

Medical Device	Portugal
Applicable national legal framework/ Reference	Law n.º 21/2014, of 16th of April and Decree-Law nº 145/2009 of 17th of June if not derogated by the European Regulations on the relevant articles.
Additional Information	Specific populations have different requirements for informed consent forms. Check European Regulations 745/2017 and 746/2017, in addition to national law.
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes With limitations Special provisions apply
Specific provision	Children from birth to 4 years-old: Both parents* Informed Consent Children from 5 to 11: Separate form (Informed Assent) and both parents* Informed Consent Children from 12 to 15: Separate form (Informed Assent) and both parents* Informed Consent Children 16 to 17: Separate form (Informed Assent) and both parents* Informed Consent In total, 4 separate models of IAF/ICF are required for minors to participate on MD and IVD studies. *In case one of the parents has full custody or one single person detains legal representativeness, only their signature is necessary. CEICs guidance (PT): https://www.ceic.pt/documents/20727/57550/Documento+Orientador+CEIC+sobre+Consentimento+Informado+%28CI%29+para+participa%C3%A7%C3%A3o+em+ensaic a792-4f2b-9a57-efc184f7951c
Legal framework/Reference (Minors/Children)	Law n.º 21/2014, of 16th of April and Decree-Law nº 145/2009 of 17th of June if not derogated by the European Regulations on the relevant articles.
Incapacitated persons - Studies allowed	Yes With limitations Special provisions apply
Specific provisions	Incapacitated persons can only be included via Legal Representative. This person, according to Portuguese Law IS NOT the next of kin. It must be a person with powers att Testament or Anticipated Directive of Will. This must be verified before signing the ICF and a copy must be archived at the recruitment site.
Legal framework / Reference (Incapacitated persons)	https://www.ceic.pt/faq?p_auth=2F0GqAZq&p_p_id=faq_WAR_PortalCEICportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column- 1&p_p_col_count=1&_faq_WAR_PortalCEICportlet_javax.portlet.action=navigateToPerguntas
Emergency situations - Studies allowed	Special provisions apply No national legal framework available
Specific provisions	Clinical investigations involving subjects in emergency situations are not explicitly mentioned in Portuguese law. As such, the provisions on European Regulations 745/2017 and 746/2017 must be respected. It is important to adhere to recommendations of CEIC on this matter:https://www.ceic.pt/documents/20727/0/parecer+conjunto/85a27a71-19c1-4a03-9368-627358375b52
Emergency situation without prior consent of patient or proxy - Studies allowed	Yes According to European Regulations 745/2017 and 746/2017
Conditions allowing trial participation in emergency setting without prior consent	Refer to the provisions on European Regulations 745/2017 and 746/2017 must be respected. It is important to adhere to recommendations of CEIC on this matter:https://www.ceic.pt/documents/20727/0/parecer+conjunto/85a27a71-19c1-4a03-9368-627358375b52
Legal framework / Reference (Emergency Situation)	European Regulations 745/2017 and 746/2017 must be respected. CEIC's recommendations:https://www.ceic.pt/documents/20727/0/parecer+conjunto/85a27a71-19c1-4a(
Pregnant or breastfeeding women - Studies allowed	Special provisions apply No national legal framework available
Specific provisions	Clinical investigations involving subjects in emergency situations are not explicitly mentioned in Portuguese law. As such, the provisions on European Regulations 745/2017 and 746/2017 must be respected.
Legal framework / Reference (Pregnant or breastfeeding women)	European Regulations 745/2017 and 746/2017.
National legal framework for protection of vulnerable populations in place	No
Applicable legal framework / Reference (Vulnerable Population)	European Regulations 745/2017 and 746/2017.
Guidelines & conventions for protection of vulnerable populations	https://www.ceic.pt/
Additional Information	N/A
Study participants - compensation & reimbursement	
Reimbursement for study participants	Permissible
Compensation is limited to/provided for	Expenses arising from study participation (e.g. Travel) Salary losses
Additional Information	N/A
Study participants - recriutment & trial outcome >> end of study	
Mandatory to inform participant of clinical trial outcome	On Patient's request
Additional information	
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	No

Medical Device	Portugal
Approval/authorisation required	No
Specific notification timelines before operations start	Not applicable
Laguage of notification	Not applicable
Notification format	Not applicable
Notification fee required	N/A
Fee	N/A
Guidance on notification requirements available	Yes
Guidance on notification requirements	Still not yet for all institutions
Data protection authority/agency - contact details	Comissão Nacional de Proteção de Dados
Contact name 2	N/A
Contact name 3	N/A
Phone	+351 213928400
Fax	+351 213976832
E-mail	geral@cnpd.pt
Web address	https://www.cnpd.pt/
Address	Av. D. Carlos I, 134, 1º
ZIP/City	1200-651 Lisboa
Country	Portugal
Additional information	With the new GPPR, national DP authority (CNPD) is only responsible for auditing when a complain on data breach is formalized. Additionally, DPOs from the local sites do favorable opinion is national.
Archiving & data management	
Study documents must be kept at least (in years)	No timeline specified in national law
National legal framework in place	No
Applicable national legal framework/reference	Portuguese Law nº21/2014 defines that INFARMED is the responsible party for defining timeperiods and procedures for storage of clinical study data.
Additional information	According to CCMO: 10 years time retention period for MDs and IVDs and 15 for implantable MDs.
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes
Official website providing relevant national legislation	A list of applicable Portuguese legislation is available on the INFARMED website.
Official governmental legal database available	Yes
Official governmental legal database	https://diariodarepublica.pt/dr/home
Additional information	N/A
Investigations on Medical Devices	
Applicable national regulations	General Act(s) on Medical/Clinical Research in Humans National Act on Medical Devices Transposition of European Regulation 745/2017
Act on Medical Devices (or comparable national legal framework)	Decree-Law nº 145/2009 of 17th of June, if not derogated by the European Regulations on the relevant articles. Decree-Law nº 29/2024 (Transposition of MDR).
Transposition of Directive 90/385/EEC	N/A
Transposition of Directive 93/42/EEC	N/A
Transposition of Directive 98/79/EC	N/A
Transposition of Directive 2007/47/EC	N/A
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	Law n.º 21/2014, of 16th of April and **Law n.º 12/2005** of 17th of June, if not derogated by the European Regulations on the relevant articles.
Additional Information	N/A

Medical Device	Portugal
Combination studies (IMP/MD)	
Applicable national regulations	One legal act for both study types available
Legal act applicable to both study types	Law nº 21/2014 of 16th of April and Decree-Law nº 145/2009 of 17th of June, if not derogated by the European Regulations on the relevant articles. Decree-Law nº 29/2024
Other applicable regulations/implementing provisions (acts, laws, decrees, ordinances, circulars, etc)	Relevant norms and circulars on the INFARMED's website.
Additional information	N/A
Radiation & Radiotherapy	
Specific framework available	No
Applicable legal framework	Law nº 21/2014 of 16th of April and Decree-Law nº 145/2009 of 17th of June, if not derogated by the European Regulations on the relevant articles. Decree-Law nº 29/2024
Additional information	Relevant European Regulations directly apply to Portugal.
Biobanking	
Specific framework available	
Applicable legal framework	https://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=1660&tabela=leis
Additional information	Relevant European Regulations directly apply to Portugal.
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	**Law n.º 58/2019, of 8th of August**
Implementing decrees / ordinances	N/A
Other applicable regulations (covering DP related issues)	European General Data Protection Regulation (679/2016)
Additional Information	N/A
Insurance	
Specific requirements	
Applicable legal framework	Portuguese Law nº 21/2014 of 16th of April.
Additional information	See provisions from European Regulations 745/2017 and 746/2017.
EC operations/ Fees	
Separate legal framework available	Yes
Applicable legal framework	Portuguese Law nº 21/2014 of 16th of April.
Additional information	Consult relevant fees: https://www.infarmed.pt/documents/15786/17838/Nova%20GP_EnsClin_Portaria63_2015%5B1%5D.pdf/b1a2d47b-eee8-46c0-a189-9f025165ca30
CA operations/ Fees	
Separate legal framework available	
Applicable legal framework	Portuguese Law nº 21/2014 of 16th of April.
Additional information	Consult relevant fees: https://www.infarmed.pt/documents/15786/17838/Nova%20GP_EnsClin_Portaria63_2015%5B1%5D.pdf/b1a2d47b-eee8-46c0-a189-9f025165ca30
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	
MD/MD Investigation	
MD - Definition available in national law	Yes
MD - Definition	National Law derrogated by the European Regulations 745/2017 and 746/2017.
Investigation of MD - Definition available in national law	Yes
MD Investigation - Definition	National Law derrogated by the European Regulations 745/2017 and 746/2017.
Additional Information	N/A
Further Definitions	

Medical Device	Portugal
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	N/A