Abreu advogados

New framework for clinical trials of medicinal products for human use

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1. Introduction

On March 6th, Law No. 9/2026 was published, establishing the legal framework applicable to clinical trials of medicinal products for human use in Portugal and ensuring the implementation, in the national legal system, of Regulation (EU) No. 536/2014 of the European Parliament and of the Council.

2. Competent Entities

INFARMED, I.P., assumes the central role as the entity responsible for the application of the Regulation and as a national contact point. The Ethics Committee for Clinical Research ("CEIC") will be, in turn, responsible for the evaluation of ethical aspects in clinical trial contexts.

3. Validation and Evaluation Procedures

Clinical trials of medicines for human use depend on prior authorisation issued by INFARMED, IP, preceded by technical-scientific and ethical assessment.
The applications for clinical trials must be submitted through the European Union Clinical Trials Information System ("CTIS"), as provided for in Regulation (EU) No 536/2014. The authorisation decision is incumbent on INFARMED, I.P., based on:

- the results of the technical-scientific and ethical evaluation;
- the binding opinion of CEIC.

Administrative appeals may be lodged against decisions, by guardianship appeal, to the member of the Government responsible for the health area, as well as court challenges.

4. Protection of Participants and Informed Consent

The law lays down specific rules on the protection of participants, including:

(i) Emergency situations: when the subject is at serious or immediate risk to life and it is not possible to obtain his/her consent in a timely manner, he/she may be included in a clinical trial without prior consent, provided that the research is directly related to the clinical situation and the protocol has been previously approved by the competent ethics committee.

(ii) Participation of minors: for minors aged 16 or over, it is necessary to obtain their consent, in addition to the consent of the legal representative.

5. Civil Liability and Mandatory Insurance

The sponsor and the investigator are jointly and severally liable and regardless of fault for the property and non-property damage caused by the clinical trial. Thus, it is mandatory to take out civil liability insurance.

Damage to the participants' health during the trial and in the year following the end of participation is presumed to be caused by the clinical trial.

6. Free of charge provision for participants

Experimental medicines, auxiliaries and medical devices, as well as consultations and complementary exams, will be mandatorily provided free of charge to the participant. After the conclusion of the trial, these should continue to be made available free of charge to the participant for as long as the researcher considers it indispensable and there are no comparable therapeutic alternatives, until the introduction of the medicine into the NHS.

7. Administrative Offence Regime

The conduction of a trial without authorization, non-compliance with the standards of good clinical practice, failure to comply with notification obligations and the conduction of trials without civil liability insurance are considered administrative offences punishable with a fine between EUR 500 to EUR 50,000 for individuals or EUR 5,000 to EUR 750,000 for legal persons.

8. Next Steps

Law No. 9/2026 will enter into force 30 days after its publication, on April 5, 2026.

Sponsors, research centres, and professionals involved in clinical trials should:

- Assess the compliance of internal procedures;
- Ensure the adaptation of the submission and authorisation processes to the system provided for in Regulation (EU) No. 536/2014 and to the articulation with INFARMED, IP and CEIC;
- Verify the suitability of the liability insurance coverage applicable to clinical trials;
- Review the procedures for obtaining informed consent, in particular for minors and incapacitated participants.

Ordinance No. 63/2015, of 5 March 2015 remains in force until the new ordinance that will define the fees applicable to the evaluation procedures is published.

Thinking about tomorrow? Let's talk today.

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