DEMAREST

A BRIEF OUTLOOK ON THE NEW CLINICAL TRIALS LAW

LAW NO. 14,874/24

JUNE, 2025

OVERVIEW

After years of discussion in the Brazilian Congress, the new Clinical Research Law (Law No. 14,874/2024) came into effect on August 28, 2024, establishing the new regulatory framework for conducting clinical research with human subjects in Brazil.

The law's main innovations include:

- Streamlining and harmonization of the ethical and regulatory approval process;
- Clear deadlines for activities performed by the competent authorities;
- Expanded use of the informed consent; and
- Legal basis for continuing or interrupting post-study drug supply.

PRESIDENTIAL VETO

On May 28, 2024, the Brazilian President vetoed a section of the law that established a maximum 5-year term for post-study supply (which begins when the experimental medicine becomes available in Brazil). Since June 28, 2024, this veto had pending review before the Brazilian Congress.

On June 17, 2025, the Brazilian Congress decided to reject the veto.

The presidential veto imposed an indefinite obligation on sponsors of experimental drug research to continue supplying the medication, significantly reducing Brazil's attractiveness for conducting innovative drug studies. With the veto overturned, study sponsors may discontinue post-trial supply five years after the drug becomes available in Brazil.

The veto's rejection reinforces the commitment to fostering the advancement of clinical research in Brazil, establishing a necessary balance to attract investment in the research and development of innovative medicines in the country.

UPCOMING REGULATION

In addition, more than 30 provisions in the new law state the need for further regulation by the Ministry of Health, which include the topics below:

- Good Clinical Practices (GCP) criteria.
- Criteria for qualification and disqualification of the Research Ethics Committee (CEP).
- Fast-track procedure for the ethical review of research of strategic interest to SUS.
- Procedure applicable in case of non-compliance with the deadlines established for ANVISA's review of preliminary applications.
- Post-study supply conditions.

On May 29, 2025, during the latest executive meeting of the Ministry of Health's Health Economic-Industrial Complex (CEIS), Minister Alexandre Padilha stated that the draft decree of the Clinical Research Law has been discussed with the National Health Council and the pharmaceutical industry.

Padilha also stated that the draft decree is at an advanced stage and is expected to be published before the CEIS' next executive meeting, which is held every six months.

MAIN TOPICS

The new legal framework governs topics such as:

- Protection of the research subject.
- Ethics review conditions.
- Post-study supply conditions.
- Responsibilities of the sponsor, investigator, and sponsor-investigator.
- Conditions for manufacturing, using, importing, and exporting goods or products for scientific purposes.
- **It also waives the dual instance of approval for clinical research**, given that INEP should not conduct the ethics review. The Research Ethics Committee (CEP) should be the sole body responsible for the ethics review, approval, non-approval, or suspension of the research.

DEADLINES

A primary concern for the legislator was the slow pace of activities carried out by regulatory authorities. As a result, the new law establishes clear deadlines that each competent authority must observe:

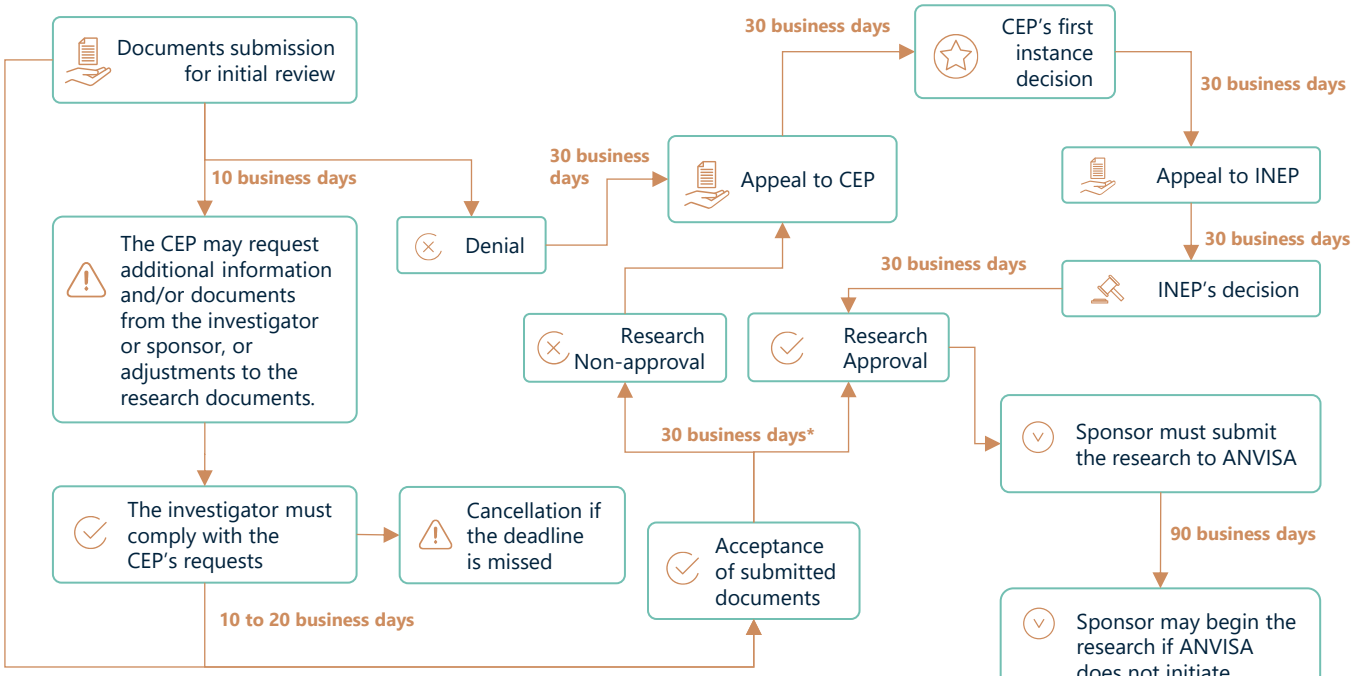
CEP (Research Ethics Committees)

- The CEP must conduct the ethics review and issue an opinion within 30 business days from the acceptance of the research documents. This deadline reduces to 15 days in case of strategic research for the Brazilian Unified Health System (SUS).
- The CEP must accept or reject the research documents within 10 business days from the submission date.
- The investigator must address the CEP's requests within 20 business days.
- Appeals against the CEP's decision must be filed within 30 business days, in first instance to the CEP, and ultimately to the INEP.

ANVISA

- ANVISA must analyze primary applications within 90 business days.
- If there is no response, the sponsor can only start the research with the CEP's approval.

DEADLINES FLOWCHART



*Research projects of strategic interest to the SUS and public health emergencies will be prioritized with a 15-business day deadline for the ethic review to ensure timely responses.

POST-STUDY SUPPLY DISCONTINUATION

According to the new law, post-study supply may only be discontinued upon evaluation by the CEP if:

- The subject or their legal representative decide to withdraw from the medicine.
- The subject will not benefit from the continued use of the experimental medicine, considering the risk-benefit ratio outside the context of the clinical trial or new evidence of risks related to the safety profile of the experimental medicine.
- The disease is cured, the health condition worsens, or a satisfactory therapeutic alternative is introduced.
- Continued supply becomes unfeasible due to an adverse event, at the investigator's discretion.
- The experimental medicine can no longer be obtained or manufactured due to technical or safety issues. This requires the sponsor to provide a rationale for such issue and supply an equivalent or superior alternative treatment available on the market.
- The experimental medicine is available in the public healthcare system.

In addition, the sponsor may discontinue post-trial access to the investigational drug after a period of five (5) years has passed from the date the drug became commercially available in the country.

LIFE SCIENCES AND HEALTHCARE KEY CONTACTS

ELYSANGELA RABELO
PARTNER
erabelo@demarest.com.br
+55 11 3356 1252

GIULIO GATTI
ASSOCIATE
ggatti@demarest.com.br
+55 11 3356 1304