

Enrique Muñoz Guizar, Ana Gabriela Suárez López

COFEPRIS Simplifies Authorization of Clinical Trials in Mexico – Opportunity for International Investment

The Federal Commission for the Protection against Health Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS) has issued a new Resolution, which was published in the Official Gazette of the Federation on March 24, 2025. The Resolution in question simplifies and streamlines the authorization of clinical research protocols in humans, particularly clinical research protocols that have already received prior approval from recognized foreign regulatory agencies.

This Resolution represents a significant advance in the simplification and streamlining of authorization processes for clinical research protocols in Mexico by establishing mechanisms for recognizing decisions issued by reputable foreign regulatory authorities.

The measure will come into effect on June 17, 2025, and represents a decisive step in positioning Mexico as a strategic destination for investment in clinical research by transnational companies.

Under a Trusted Regulatory Practices (Reliance) approach, the Resolution provides that COFEPRIS may recognize authorizations of research protocols or clinical trials approved by at least one of the four most reputable international regulatory agencies:

- The Food and Drug Administration (FDA), the United States.
- The European Medicines Agency (EMA), the European Union, through a centralized process.
- The Medicines and Healthcare products Regulatory Agency (MHRA), the United Kingdom.
- Health Canada, Canada.

This means that Phase III clinical trials approved by any of these agencies can be evaluated more rapidly by COFEPRIS, significantly reducing response times and preventing the duplication of processes during technical reviews.

The Resolution applies specifically to requests for research protocols in humans for biological and biotechnological products, with the following characteristics:

- Phase III research protocols (excluding Phases I, II, IV, and pilot studies).
- For active investigational products with no history of health alerts or safety withdrawals.

- In specific areas of research, such as oncology, endocrinology, cardiology, rheumatology, allergology, dermatology, gastroenterology, hematology, ophthalmology, nephrology, or those which address pathologies with a high epidemiological impact in Mexico.

The Resolution's implementation will offer multiple benefits for clinical research in Mexico, including:

- Expediting the evaluation of research protocols and allowing faster access to innovative medical therapies without sacrificing compliance with international Good Clinical Practice standards.
- Strengthening international collaboration, thus avoiding the duplication of processes, and recognizing reliable evaluations carried out by other health authorities with aligned regulatory frameworks.
- Promoting an efficient regulatory environment, which increases confidence for companies that develop medicines, biotechnological therapies, and cutting-edge treatments.
- Expanding access to innovative therapies, new medical technologies, and research opportunities for the Mexican population.
- Creating a more predictable and efficient regulatory environment that makes Mexico more attractive to global pharmaceutical companies, thereby increasing investment by international pharmaceutical and biotechnology enterprises.

The new Reliance regulatory framework represents a significant step towards consolidating Mexico as a clinical development hub in Latin America and attracting direct investment from global pharmaceutical companies. The ability to integrate reliable international processes within a robust national framework creates both legal and operational certainty for clinical trial sponsors.

Contacts



Enrique Muñoz Guizar

Life Sciences and Healthcare Counsel

enrique.munoz@perezllorca.com

T. +52 55 5202 7622

Offices

Europe [↗](#)

Barcelona
Lisbon
Madrid

Brussels
London

America [↗](#)

New York
Mexico City
Monterrey

Asia-Pacific [↗](#)

Singapore

The information contained in this Legal Briefing is of a general nature and does not constitute legal advice.

This document was prepared on May 30th, 2025 and Pérez-Llorca does not assume any commitment to update or revise its contents.

©2025 Pérez-Llorca. All rights reserved.

perezllorca.com [↗](#)

Pérez-Llorca