

CLINICAL RESEARCH? TAKE A LOOK AT MEXICO

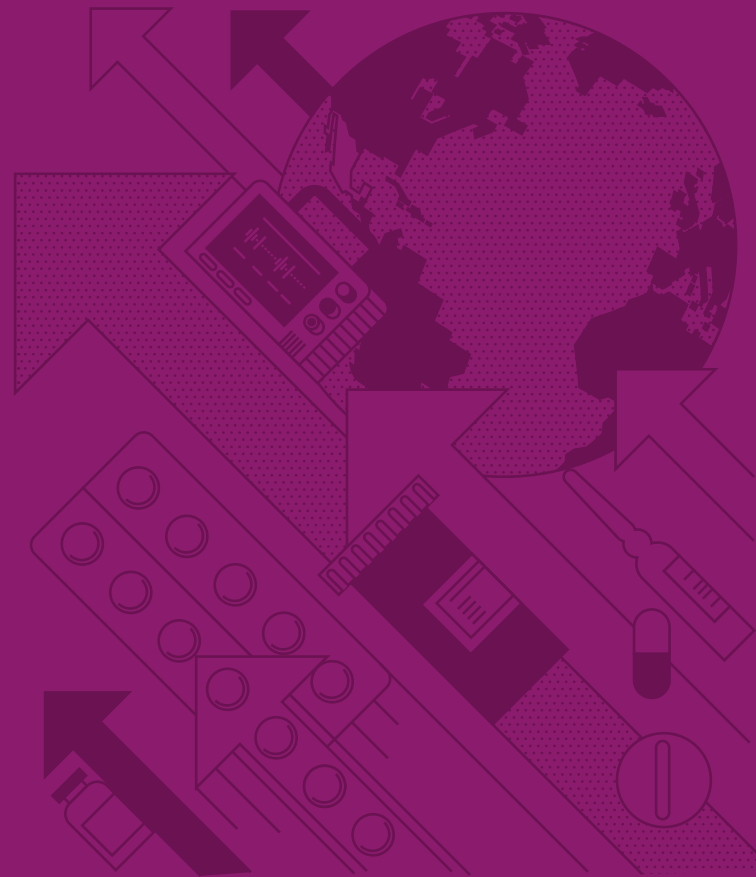


MEXICO AT A GLANCE

- According to PwC, Mexico is the **8th most attractive investment destination** in the world.
- The country is the **2nd largest destination** for foreign direct investment in **Latin America**.
- Mexico's network of free trade agreements grants **preferential access** to markets in **46 countries**.
- Additionally, the country has signed **32 agreements for the promotion and reciprocal protection of investments**.
- Mexico is the **largest exporter of medium- and high-tech goods** (as a percentage of GDP) in **Latin America** and the **3rd largest** among the **G20 countries**.
- Medium- and high-tech products account for 61% of Mexican exports.

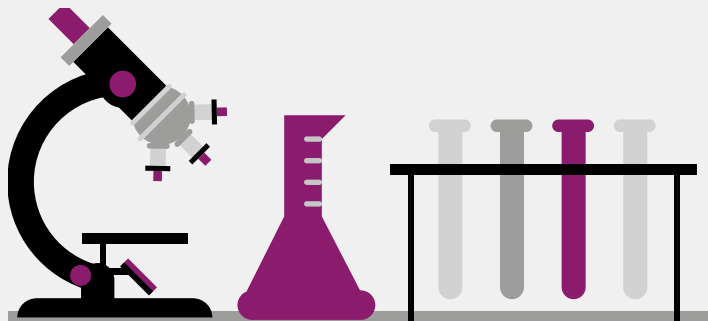
A BIG LEAGUE PLAYER IN THE PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRIES, MEXICO IS THE...

- **Number one** exporter of medical devices in Latin America and the **8th** globally.
- **Leading exporter** of pharmaceutical products in Latin America.
- **2nd largest market** for the pharmaceutical industry in Latin America.



WHY CHOOSE MEXICO AS A CLINICAL RESEARCH PARTNER?

MEXICO HAS TALENT AND EXPERIENCE



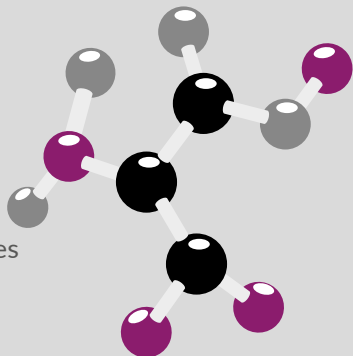
- Researchers trained in the most stringent regulatory standards and with **experience in all therapeutic areas** and population groups (children, adults and senior citizens).
- More than **four decades** of experience in clinical research.
- Experience implementing protocols in multiple therapeutic areas and a **diverse epidemiological profile** that includes transmissible, non-transmissible, chronic-degenerative and rare diseases.

AN INDUSTRIAL SECTOR FULLY COMMITTED TO CLINICAL RESEARCH

The **Clinical Research Organizations Alliance of Mexico (ACROM)**

represents 16 companies that conduct contract clinical research (14 multinationals and two Mexican companies). Together, these companies account for:

- 2,000 researchers.
- 1,400 employees.
- 400 monitors.



THE COUNTRY IS A LEADING PHARMACEUTICAL MARKET IN THE REGION AND A SETTER OF REGULATORY TRENDS

- Mexico's regulatory framework sets out criteria for the conducting of clinical trials on **human subjects**.
- These are comprehensive regulations that allow for the conducting of **all research phases** and the use of innovative models and designs.
- In January 2017, the Federal Commission for the Prevention of Health Risks (COFEPRIS), the Tax Administration Service (SAT), the Mexican Social Security Institute (IMSS) and industry representatives entered into a framework agreement to promote clinical research.
- Under the Mexico-European Union Competitiveness and Innovation Program (PROCEI), 31 Clinical Research Units (UIC) were integrated and obtained certification in the ISO 9000-2008 standard by virtue of their quality management model.

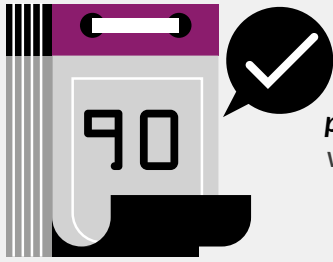


Official Mexican Standard 257-SSA1-2014, which stipulates requirements for the evaluation, registration and authorization of clinical trials and specifications for biotech medicines, is one of a kind in Latin America.

A KEY ACTOR

In 2012, **COFEPRIS** obtained **level IV certification as a national regulatory authority** with the capacity to perform duties recommended by the PHO/WHO to guarantee drug efficacy, safety and quality standards.

In 2014, COFEPRIS was acknowledged as **a benchmark health agency** authorized to issue equivalence registration certificates valid in other countries.



COFEPRIS is required to **authorize clinical research protocols in just 90 days** – a very competitive time frame compared to other Latin American countries.

MEXICO OFFERS TANGIBLE COMPETITIVE ADVANTAGES

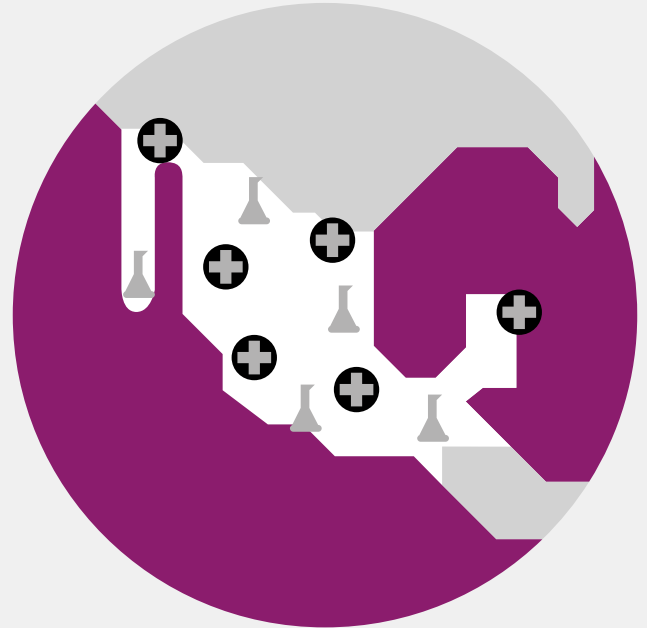
- The Mexican health system offers a range of clinical research alternatives in both the **private and public sectors**, where health care services are extremely diversified.
- **Competitive costs** and a high level of specialization at all clinical research phases.
- **237 Research Ethics Committees (REC)** for the approval of research protocols throughout the country, all of them **registered by** the National Commission of Bioethics (**CONBIOETICA**), institution that offers information, services, and training on bioethics.
- Approved clinical research sites, hospital **infrastructure** and systems for the monitoring of patients' medical care.
- Pursuant to regulations currently in force, if a clinical research trial includes Mexican patients, Mexico has the option of being the first country in the world to authorize the registration of a molecule.
- **Mexico's time zone** is aligned with key research centers worldwide and the region's major cities.



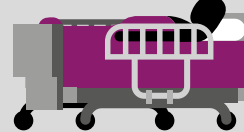
A DIVERSE DEMOGRAPHIC PROFILE

Mexico has enormous potential for the **recruitment of patients** on a large scale and an extremely diverse epidemiological profile:

- The country has a population of over **120 million**.
- Its ten most densely populated cities provide a **large pool of potential volunteers** for research in all population groups.



70%



As third parties or support units authorized to issue preliminary opinions on the approval of clinical research protocols, the **IMSS and other national health institutions** potentially have **access to over 70% of the country's patient population** and offer a wide range of therapeutic areas for the implementation of clinical research protocols.

PRO MÉXICO

Trade and Investment

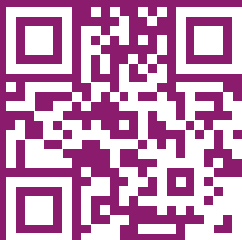


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