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Mexico is well-positioned to contribute meaningfully to global healthcare advancements

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Cecilia Moreno, from the PPD™ clinical research business of Thermo Fisher Scientific, highlights Mexico's growing role in clinical research, supported by regulatory advancements and a skilled workforce. Moreno emphasizes the potential for expanding clinical trials in Mexico, enhancing patient access to innovative therapies, and leveraging the country's strategic advantages in supporting global studies. She also reflects on the PPD business's evolution, its commitment to excellence, and the importance of nurturing local talent.

What is the potential for clinical trials in Latin America, particularly in terms of leveraging the region's diversity and inclusivity?

Latin America holds immense potential for clinical trials, driven by its large and diverse population, as well as the high prevalence of various diseases across its countries. Historically, clinical research was limited in scope, often focusing on a narrow demographic—focusing on a less diverse population. However, biopharmaceutical companies and regulatory bodies are now prioritizing the inclusion of diverse populations in studies, incorporating participants from various ethnic, genetic and demographic backgrounds. This shift is particularly advantageous for Latin America, where there is a rich blend of cultural and genetic diversity. Ensuring broader representation in clinical trials not only enhances the relevance of research within the region, but it also helps produce

treatments and therapies that are more globally applicable. Ultimately, this inclusivity strengthens the development of drugs that can effectively serve diverse populations worldwide.

What makes Mexico a competitive destination for clinical research, and how do its regulatory environment, patient willingness, and hospital infrastructure support this potential?

Mexico stands out as a promising hub for clinical research due to several strategic advantages. First, its regulatory framework has reached global standards since COFEPRIS, the Mexican health authority, became a member of the International Council for Harmonization (ICH) in 2017. This alignment ensures that clinical trials in Mexico meet the rigorous requirements of international regulatory bodies, positioning the country as a credible player in the field.

Mexico's large and diverse population is another crucial asset, allowing for efficient patient recruitment. In major cities such as Mexico City, Monterrey and Guadalajara, clinical sites can enrol significantly higher numbers of patients compared to clinical trial-saturated countries, where individual sites may only recruit a few participants. This concentration of patients enables researchers to conduct large-scale studies with fewer sites, increasing efficiency and reducing timeframes.

Furthermore, Mexican patients are generally receptive to participating in clinical trials, particularly when they trust their physicians, who play a pivotal role in presenting clinical studies as beneficial opportunities. Although there is a need for broader public awareness regarding the value and process of clinical trials, participation rates remain strong. Clinical trials in Mexico are conducted across both private and public hospitals, with private institutions sometimes taking a larger share of the workload. This balance further strengthens Mexico's capacity to support diverse and expansive clinical research initiatives.

What steps are necessary for Mexico to become a leading hub for clinical trials, and how does patient retention contribute to the success of these studies?

For Mexico to emerge as a premier destination for clinical trials, one area of opportunity lies in the approval timelines. Although Mexico's regulatory environment, led by COFEPRIS, is well-aligned with international standards, the overall process—including regulatory approvals and internal procedures within hospitals, pharmaceutical companies, and contract research organizations

(CROs)—could be more competitive. Shorter approval timelines are crucial, especially as Mexico competes with countries that can implement studies more rapidly. Streamlining both regulatory and internal processes would significantly enhance Mexico's competitiveness in attracting more clinical trials.

Once studies are underway, Mexico's real strength lies in the ability to recruit and retain patients. Patient retention is particularly important, as many clinical trials span multiple years, and maintaining participant involvement is critical to the success of these studies. In Mexico, patient retention rates are notably high, thanks to the strong relationships patients have with their physicians and clinical sites. This trust leads to a greater likelihood of patients remaining engaged throughout the trial, which is vital for the integrity and continuity of the research.

Patients in clinical trials often receive exceptional care, far beyond the standard level of medical attention, which encourages them to stay enrolled. This heightened level of monitoring and treatment makes participation in clinical trials an attractive option for many, particularly for those with serious conditions. While retention rates can vary depending on the nature of the study—healthy participants in vaccine trials, for instance, may drop out more easily—patients facing more severe health challenges, such as oncology patients, tend to remain engaged due to the potential long-term benefits. Although I don't have specific global benchmarks on retention rates, based on my experience, the majority of Mexican patients continue to participate throughout the trial, which is a key advantage for the country's clinical research landscape.

How has the PPD clinical research business of Thermo Fisher evolved in Mexico over the past few years, and what makes the business stand out in today's competitive market?

Our business's evolution in Mexico has mirrored the broader transformation of clinical research. Sixteen years ago, when I first joined the company, the concept of CROs was still relatively new, and their role in the pharmaceutical industry was not fully established. Today, CROs are integral to the clinical development process, and we have matured into a well-respected and trusted partner in this space. In Mexico, we are recognized for our ethical standards and positive work environment—earning recognition as one of the best places to work in August 2021.

PPD has matured into a well-respected and trusted partner in this space, committed to our Thermo Fisher Scientific's mission to enable our customer to make the world healthier, cleaner and safer"

One of the key strengths of our company in Mexico is the exceptional talent we have here. The company focuses on investment in talent development, and the younger generation is highly skilled, with excellent proficiency in English, which enables us to operate on a global scale. Thanks to technological advancements, we can now support clinical trials around the world remotely. Mexico's favourable time zone, especially in relation to the United States (a major market for clinical research), also gives us a strategic advantage by allowing us to collaborate seamlessly across borders.

In terms of clinical trials, we cover a wide range of therapeutic areas and phases, from early-phase trials (Phase I and II) to late-phase (Phase III IV and peri/post approval, non-interventional studies and expanded access studies that gather the necessary data for product approvals. Our work spans cardiovascular diseases, oncology, infectious diseases and immunology, and vaccines among others, adjusting to market demands over time.

Currently, we are a strong, growing company in Mexico. With the trust and confidence of our global company, and the talented professionals we have in Mexico, we are well-positioned for continued growth and success in the clinical research landscape.

How has Mexico advanced in digitalization within clinical research, particularly in critical care, and what impact has technology had on patient monitoring and healthcare accessibility?

Mexico has made notable progress in digitalizing clinical research processes, particularly with the introduction of COFEPRIS's digital platform last December. This is a significant leap forward, as it aligns Mexico with other regulatory agencies that have long embraced digitalization. The new system is expected to reduce approval timelines and simplify procedures, making the overall process more efficient and competitive.

In terms of clinical trials, PPD is committed to an increased patient-centric approach, ultimately reducing the burden on patients and sites. Technology has dramatically, transformed the way we monitor and engage with patients. We now use wearable devices, such as smartwatches and electronic monitors to track patients' data in real-time. This allows researchers to review data from anywhere in the world, giving a global perspective on patient outcomes. Compared to the manual, paper-based systems we used decades ago, this shift is revolutionary. Today, remote monitoring and real-time data access enable us to oversee clinical trials with greater precision and efficiency, reducing the need for frequent onsite visits. Technologies like risk-based monitoring allow us to

manage patient data from a distance, further streamlining the process.

Telemedicine has also become a key tool in expanding access to healthcare. It allows physicians to stay connected with patients in remote or underserved areas, offering them the opportunity to participate in clinical trials. This is particularly valuable for patients living in distant regions, as it removes geographical barriers and brings healthcare services directly to them. As a result, we are able to involve a more diverse range of patients in clinical trials, contributing to more comprehensive and inclusive research. Looking ahead, these technological advancements will continue to broaden the reach of clinical trials and improve patient care across Mexico.

What are PPD's key priorities for the coming years, and how do you see the company's role evolving in Mexico?

Our foremost priority is, and will continue to be, the patients. Over the next few years, our focus is on expanding the number of clinical trials we bring to Mexico, thereby offering patients increased access to innovative therapies and groundbreaking treatments. This is a tremendous opportunity for patients to engage in cutting-edge medical advancements. Mexico is particularly well-positioned for this, given the expertise of our investigators and the presence of world-class institutions such as the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ) and the Instituto Nacional de Cancerología (INCAN). These institutions have both the patient populations and the infrastructure necessary to conduct high-quality clinical trials. It's a mutually beneficial situation, as patients gain access to new treatments while the medical community enhances its research capabilities.

We will continue to focus on helping our clients deliver safe and innovative therapies, and we aim to further expand clinical research in Mexico. Our commitment to excellence and professionalism will ensure that we continue to contribute meaningfully to healthcare advancements both in Mexico and globally.

What inspired your journey into clinical research, and what continues to drive your passion after more than 20 years in the field?

As a nurse, my initial inspiration has always been the desire to help patients and witness firsthand the transformative impact of new medical treatments. The ability to contribute, even in a small way, to the development of innovative therapies is deeply fulfilling. I am incredibly proud to have

played a role in the development of life-changing vaccines, such as those for COVID-19 and HPV, as well as treatments for HIV. Seeing how these advancements can truly change lives has been a continuous source of motivation for me.

Additionally, I'm driven by the opportunity to foster talent in Mexico. It's rewarding to create high-quality employment opportunities for young professionals and to see them flourish in the field of clinical research. Their passion for making a difference in healthcare is inspiring, and it's exciting to watch them grow. We never know when we or our loved ones may need access to these groundbreaking therapies and knowing that my work contributes to this keeps me motivated every single day, even after nearly 30 years in this field.

What final message would you like to share with our global readers?

I would encourage everyone to have confidence in Mexico. We have highly skilled professionals, and our clinical research capabilities are world-class. Mexico is not only contributing to global medical advancements but also poised for continued growth. We are committed to delivering high-quality clinical research that supports the global healthcare landscape and look forward to furthering our impact on a global scale.

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