Arturo Rodriguez Jacob – Founder and CEO, Infinite Clinical Research

Clinical research is an opportunity for many patients to benefit from new treatments, reducing the social burden and improving lives

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Arturo Rodriguez, CEO of Infinite Clinical Research, discusses the current state of clinical trials in Mexico and highlights the country's unique advantages, such as a diverse population with experienced medical professionals and top-notch medical facilities. He addresses the challenges of streamlining regulatory processes and the need for improvements to attract more international studies. Rodriguez also shares his insights on the evolution of his company from a regulatory services provider to a global CRO and emphasizes the importance of collaboration between academia and industry to change the view of clinical research as an important support to the community in healthcare through clinical trials.

What do you consider to be Mexico’s strongest fundamentals for clinical research, especially in comparison to regions like Europe, Asia or the U.S.?

Mexico’s geographic proximity to the United States facilitates more efficient coordination and oversight for companies seeking to conduct multi-centre clinical trials while remaining less attractive to multinational European or Asian countries. With a population of 123 million people, Mexico offers a diversity of medical necessities, resulting from its genetic variability and health conditions. This creates a fertile environment for researching different therapeutic areas and improving the applicability of results.

In addition, the country has many experienced researchers and well-equipped medical facilities, which support the conduct of high-quality research. Clinical trials in Mexico tend to be more cost-effective, which, coupled with globalization processes, makes the logistics of studies even easier.

Another important aspect is the training of many researchers and health professionals in the United States and Europe, which generates a cultural affinity and a deeper understanding of international research standards. Since 2021, COFEPRIS has aligned itself with these standards by joining the ICH group, further strengthening confidence in the Mexican regulatory system and its ability to conduct clinical studies effectively and safely.

What specific steps do you believe should be taken to expedite the approval process for clinical trials in Mexico?

The first step for an expedited review is for the authority to have a diagnosis of what the international competitive times are, where we are and what is needed to be a first-choice country for doing clinical research, and thus aim for the best regulatory times. This implies establishing the responsibilities of each of the participants in the process and avoiding the duplication of reviews or procedures that have already been carried out. Improving the response capacity of regulatory personnel would allow for greater efficiency. It is important to differentiate the protocols that have already been approved by other regulatory agencies and give them an expedited process that helps reduce the authority’s workload.

One of the most important factors I have observed is that transparency and institutional consistency accelerate results. In addition, they strengthen open communication between regulatory agencies and pharmaceutical companies, which allows potential problems to be identified and resolved from the early stages of the process, thus reducing delays. It is essential that industry, CROs and the authorities involved optimize processes to be competitive and for Mexico to become a first-choice country for the development of clinical studies.

Do you think the authorities fully understand the importance of establishing Mexico as a clinical trial hub in enhancing innovation and investment in the country?

In my opinion, I believe that the authorities have not measured the advantages of supporting clinical research in all the benefits that this implies and have only seen it from the point of view of an economic profit that only benefits a few, while it is much more than that. There is indeed an

important economic spillover from doing clinical research, but sometimes we stop seeing that it is an opportunity for many patients to benefit from new treatments, which indirectly reduces the social burden of these patients and can lead them to join their working life, bringing a benefit to their families and the community. Another benefit is the approach of Mexican doctors to new technologies and new treatments that put them at the forefront of medicine in their respective specialties. On the other hand, clinical research has a “pull effect”, meaning that it indirectly benefits other companies such as clinical laboratories, transporters, lawyers, accountants and others.

In Mexico, and in fact, throughout Latin America, there is often a tendency to compare our performance with the countries of the region, while the opportunity is to compare ourselves with the best and create long-term continuous improvement strategies.

Historically Mexico has always participated with 1% of the research studies that are developed in the world, representing an economic outflow of around 200 million dollars to the country.

Mexico already has facilities, doctors, personnel specialized in clinical research, and universities to generate new resources, but even so, we are not competitive due to the administrative and regulatory times that are reported in Mexico. If a commitment to growth were established by the government and we could implement a program to attract clinical studies that guaranteed to bring 0.5% of global studies to Mexico in a sustained manner, in 5 years we would be receiving an economic outflow of around one billion dollars annually. This could help cover the medical needs of the health sector and all the secondary benefits that we already mentioned.

Other stakeholders have mentioned the potential for significant growth in the Mexican clinical trial space, suggesting it could increase to as much as USD 4 billion. Could you elaborate on this?

We must start from the fact that the figure of 200 million dollars has been around for more than 5 years, and I think that today could be higher, but we would have to verify the current environment.

To evaluate growth, we must take into account that we participate in 1% of the studies that are conducted in the world and when we talk about participation, it is that the studies are not only for Mexico; we participate as a multinational unit that may or may not have more than one research site.

In other words, if we increase participation in these multinational studies to 20%, we could talk about the number that you mention. In the previous answer, I spoke very conservatively of a sustained annual growth in participation of 0.5%, to not saturate the regulatory processes, and in 10 years we would be talking about an annual income of more than one billion dollars.

This would involve greater systematization of the processes making the regulatory processes more efficient (when we talk about making the processes more efficient, we are not talking about reducing quality, but about finding new formulas that make us more competitive).

With the pandemic, several CROs and research sites have shown that we can work with very high patient densities while maintaining GCP and quality standards.

Given the new government and its continuity with the previous administration, what do you think will happen in terms of regulatory changes? Is it too early to tell, or do you have any expectations?

It is certainly too early to make definitive predictions. However, the new authorities appointed by the president are younger and have significant experience. If they manage to foster an enabling environment that will close the gap that exists between countries that consider clinical research as part of the national health plan and us, this will give us greater growth and the opportunity to benefit a greater number of members of the community who nowadays do not have access to first-class treatments.

We know that the Health Minister is a research physician who knows very well the benefits of doing clinical research.

Ultimately, much will depend on the political agenda of the new government and its commitment to move forward in clinical research and innovation for the promotion of health in the community.

In terms of clinical trials being conducted in Mexico, are they primarily led by private hospitals and entities, or are institutions like IMSS and various research hospitals involved as well? How does this landscape look?

Currently, most clinical trials are carried out in private hospitals. This changes largely due to the need to streamline processes and reduce authorization times. The IMSS and public hospitals continue to be very valuable places for clinical trials, but they face challenges in the

implementation of the protocol. One of the main obstacles in public hospitals is the legal part, which is long and with complex processes, besides in some cases the legal framework does not allow receiving payments for services provided in the protocol if they come from private parties. Unlike private hospitals, where in many cases they have specialized areas for the implementation of research protocols.

It is not very clear to me why the clinical research is being, because it is no written in any document, but we see that it is becoming more and more difficult for us to bring studies to public hospitals. These hospitals are the ones with the population with fewest resources and requiring much more support to be more efficient in the treatments they offer.

As you mentioned earlier, in one study during the pandemic, you managed to enrol 8,000 patients in just three months. How difficult is it for Mexicans to participate in clinical trials, and what factors contribute to this success?

Mexicans in general do not have a culture of participating in clinical trials, but they trust their doctors, who are responsible for explaining them the treatments, and if the doctor is convinced that the study has more benefits than risks, it is easier to invite patients to participate in clinical studies. For the trials of vaccines, we had a favourable opportunity, because COFEPRIS introduced expedited processes to make the revision of the protocols and make an expedited process, which allowed us to obtain approvals in just 30 days. In most cases, the regulatory process was very fast, which allowed for rapid development of the studies, no matter what region of the world they came from.

During the pandemic, Mexico assumed the responsibility and collaborated with laboratories and CROs to successfully carry out vaccine trials. This allowed us to receive international recognition and an upgrade in technology. However, we have returned to long approval times of 90 days or more, so the main challenge we now face is regulatory delays. Despite this drawback, Mexico continues to have strong regulatory bodies, well-structured committees, excellent hospital facilities and experienced personnel, creating the infrastructure necessary to develop successful trials.

Now that we have a clearer understanding of clinical research in Mexico, let’s shift our focus to your company. It has been quite some time since we last met, in 2017. How has the company changed since then?

It has been an important period. Prior to 2017, Infinite was primarily a service company, focusing mainly on regulatory affairs and import/export processes, with monitoring being a secondary activity.

Since then, Infinite has transformed into a global CRO with a greater emphasis on clinical operations. While we continue to excel in regulatory affairs, thanks to our experienced team with over 20 years of experience in the industry, we have now built up a strong clinical operations group. This allows us to offer comprehensive services to our clients, including regulatory processes, clinical operations, foreign trade and pharmacovigilance, while always maintaining the flexibility of services to meet the needs of our clients, ensuring that they receive full support throughout the operational process.

What prompted this change in the company’s image and focus?

Change was essential to our evolution. Initially, leadership in the clinical research field was comprised of older professionals. We identified a young and vibrant population that is taking over decision-making positions in the industry, and we recognized the need to modernize and redefine our objectives. Our goal extends beyond meeting the demands of the industry; we are committed to taking responsibility to benefit society. This perspective marks a significant change in the way we approach our work and reinforces our commitment to generating a positive impact in the community.

Last time we spoke, you mentioned anticipating significant growth in the biotech sector. Has that growth materialized?

I think biotechnology has become increasingly important, especially as we see a shift toward understanding diseases through a biotechnology lens. The integration of medical devices with the development of new drugs has been the key. Biotechnology is now at the forefront of research, particularly in personalized medicine, which focuses on therapies targeted at specific diseases such as different types of cancer. Years ago, treatments were generalized, but biotechnology allows for personalized solutions that minimize the stress caused by treatment.

With the pandemic highlighting the value of remote and hybrid trials, how far has Mexico advanced in terms of digital tools for clinical research?

Now that the pandemic has highlighted the value of using technology in remote and hybrid clinical trials, technology can easily be implemented in Mexico due to globalized processes. We have also seen rapid adoption of remote monitoring and other digital tools. Previously, many believed that remote processes would undermine control and oversight. However, we have found that technology improves our ability to manage trials, ensuring proper compliance with protocols and facilitating remote work.

Looking ahead, what are your new priorities for Infinite Clinical Research?

Our primary focus remains on supporting improved health and benefiting society through our clinical trials, as this is core to our mission. In addition, we are focusing on networking with other companies in Latin America. A major barrier to growth is the demand from laboratories for comprehensive regional coverage. By forging collaborative agreements with CROs in Latin American countries such as Argentina, Brazil, Chile, Colombia, Ecuador and Peru, we can offer clients, comprehensive access to the region.

The drug commercialization landscape has evolved dramatically over the past 20 years. While the United States was once the focal point of the markets, today the markets are globalized. For example, Latin America is increasingly requiring the use of medications based on demographic factors. For example, the older and pediatric populations of our countries may require increasingly specific treatments compared to the standard populations in Latin America. This generates and demands a very broad spectrum of needs for medications and treatments that can help solve health problems in the region. Hence the need to support clinical research so the population can have access to these new treatments.

You have been in this business for 22 years. How did you initially become involved in this field? What is your story?

My journey began with a vision that was not solely focused on establishing a CRO. The foundation of this company was rooted in education. I was a director at a private university for many years and several of my partners had experience as teachers at universities in the United States and UNAM. Our goal was to support the industry by teaching best practices in clinical research,

including the development of standard operating procedures (SOPs) and other necessary guidelines.

As the demand for clinical studies in Mexico grew, we began receiving requests from several international CROs looking for local legal representation, as they did not have a local presence. We started with regulatory services and expanded into import and export activities. Within five years, we had become accredited as a leading reference company in regulatory affairs for Mexico. To date, we have submitted more than 300 studies to COFEPRIS.

Now, we are among the oldest independent CRO firms in Mexico, most companies that started at the same time were acquired by international corporations or have closed their activities. Despite having received offers to buy the company, for the moment I prefer to maintain its status.

What message would you like to share with our global readers as we conclude?

If we can all collaborate effectively and efficiently on clear and reliable processes and make Mexico a competitive country for clinical research developments – as they do in developed countries – this would represent an important opportunity for our families and society to improve their health and quality of life.

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