Interview: Arturo RodrÃguez Jacob â?? CEO, Infinite Clinical Research; President, ACROM, Mexico

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Arturo RodrÃguez Jacob, CEO at Infinite Clinical Research (ICR) and president of the national association of CROs (ACROM), explains what make Mexico the regional clinical research hub and showcases how ICR is developing clinical studies

for allopathic, biotech, medtech, and herbal medicine companies.

Only 15 years ago, the Mexican clinical trials industry was barely existent. However, Mexico is now one of the strongest clinical research hubs in Latin America taking over Argentinaâ??s position. As president of the national association of CROs (ACROM), what are the main drivers that triggered such a transition?

There has been a drastic change in Mexico during the last 15 years: in 2000 the CRO eco-system in Mexico was just started to arise. Concreting on this transition, the quality of the clinical studies developed in Mexico has certainly improved in comparison to a decade ago; as president of ACROM, I am proud to confirm that the Mexican CRO industry now fully complies with the highest international quality standards.

In addition, the clinical development process has been professionalized with a clearer role for each stakeholder, such as coordinators and medical professionals that take part in the process. Finally, the evolution of the mindset in academia and public institutions has played an important role in positioning Mexico as an important hub for clinical trials within the region; such institutions are

increasingly supporting the development of the Mexican clinical research arena, which was not the case in the past.

ACROM is the voice of 16 multinational and local companies that represent around 80 percent of the total CROs in the Mexican market. In addition, it collaborates with the development of more than 7,000 drugs for key therapeutic areas such as oncology, cardiovascular, and others. Could you tell our international audience what role the association has played in such a transition since its creation in 2010?

ACROM has been actively involved in such transition since its foundation in 2010; indeed, the association has gained a lot of weight within the industry and now it includes most of the clinical trials carried out in Mexico. In this sense, we are working directly with the national authorities and the industry stakeholders to consolidate the Mexican clinical research based in that will continue driving such performance. It is important to mention that ACROM gathers the expertise from different CROs and use it to implement the best practices within the clinical development processes.

What is the role of technology within CROsâ?? operations?

New technologies, such as digital monitoring, are creating efficiency and efficacy breakthroughs within the clinical research operations. Indeed, technology is one of the most important investments of any CRO since it ensures better quality of the data and, consequently, it enhances the outcomes. I would like to highlight that the healthcare and life sciences industry knows that the clinical expertise highly remains within the CROs, as we are able to conduct clinical studies 30 percent quicker than those conducted in-house; such impact is also supported by the latest technologies.

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Could you expand on the current challenges and opportunities of the Mexican CRO eco-system?

The main challenges came up when the Mexican clinical research arena is compared to other regions such as Europe and the US. Even though Mexico is the clinical research hub within Latin America, we are not attracting as many clinical projects as we would like to, therefore our challenge as well as opportunity is to attract those studies that are conducted in other leading clinical markets. ACROM is strongly working on promoting the clinical benefits of Mexico and on enhancing the national credibility outdoors.

The whole industry recognizes the outstanding work done by Cofepris to reduce the timeframe to approve new protocols in Mexico from 360 to 60 days. How is ACROM collaborating with the national regulator and other public institutions to continue enhancing the national CRO eco-system?

ACROM is actively working with Mexican authorities, public and private hospitals, and other industry stakeholders to continue improving the national clinical landscape. Nevertheless, it is important to mention that there is a huge bureaucracy such as ethical committees before starting the clinical trials that is negatively affecting the clinical operations lead times; such lead times can sometimes take more than 300 days. Hence, if you compare such times with the ones in Europe and the US, where you can find 70 percent fewer time than the one existing in Mexico, the country is not that competitive. Expanding on that point, ACROM is playing a highly important role to reduce lead times to enhance the CROsâ?? eco-system: diminishing translating times for the study documents, standardizing the different process for submitting to the Investigation and Ethics Committees, in such way that the submissions to the MoH authorities would be standardized, permitting the easiest way to make the review and approvals in less time, in this way we are trying to impact at both times: out

of COFEPRIS and in COFEPRIS.

How is ACROM partnering with other CRO associations within Latin America in order to homogenize the processes and consolidate the presence of CROs within the region?

There is a sizeable challenge when trying to homogenize the heterogenic clinical research landscape in Latin America because each country has its own clinical regulation. Nonetheless, we have several initiatives to consolidate the clinical arena within the region but the results are pretty slow and complicated.

Letâ??s focus on Infinite Clinical Research (ICR). Could you please introduce the main operations and latest accomplishments of the company?

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ICR is a Mexican Full Service CRO, dedicated to enhance the quality and development of Clinical Research in Mexico and Latin America. At ICR we strive for a high responsible performance in our operations based on our clientâ??s requirements, maintaining a strong ethical profile within our processes.

Since I founded the company in 2002, ICRâ??s operations have evolved from clinical training to a more complete solution; indeed, ICR offers clinical development, regulatory and post-approval services, bio-statistics and logistics. During the last three years, we have also been developing our pharmacovigilance business line as we have perceived a growing unmet need in such area. In terms of our clientsâ?? portfolio, we serve a vast array of customers sorted out in four main segments: pharma, biotech, medtech and herbal medicine.

In which therapeutic areas is ICR most involved?

The therapeutic areas in which we are most involved vary depending on the client segment. Hence, ICR carry out a lot of gynecology clinical studies for medical devices and diabetes, oncology and neurology clinical trials for medicines.

ICR is positioned as the clinical development partner of choice for allopathic, biotech, medtech, and herbal medicine companies. What is your footprint in each of these segments?

Pharmaceutical companies, both biotech and allopathic, represent around 60 percent of our business. Medtech contributes to 30 percent of our sales and herbal medicine, which is a new segment, represents around 10 percent.

Nonetheless, it is very clear that the future lies in biotech and we have perceived such trend in our clientsâ?? portfolio; indeed, biotech business within our pharmaceutical segment is certainly gaining more and more weight in our business.

ICR partners with several private and public institutions such as IMSS and Blanchard y Asociados to enlarge the reach of its operations. What is your partnership strategy with public and private organizations?

In terms of private partnerships, we collaborate with local CROs from other countries within Latin America such as Blanchard y Asociados to leverage on their infrastructure and local knowledge to run regional clinical studies. Such partnerships certainly reinforce our commercial strategy helping us to offer a more complete solution to our clients.

In terms of public partnerships, we are already working with public health institutions such as IMSS and ISSSTE to develop clinical trials in their hospitals and enhance the openness of such public institutions to clinical studies. Indeed, it is important to consider that 80 percent of the clinical research activities are carried out in private institutes since public institutions have recently started to receive such type of clinical trials.

What are the key objectives that you would like to achieve in the upcoming three years?

The main priority on my agenda is to train both my employees and the industry stakeholders implementing the best clinical research practices. Secondly, one of my objectives is to help the government reduce the high existing bureaucracy to carry out clinical studies within the public institutions. Finally, I want to develop my team of high quality professionals to support the accomplishment of the aforementioned objectives.

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