Interview with Arturo Rodriguez Jacob, Director, Infinite Clinical Research

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Tags: Infinite Clinical Research

We understand that Mexico has a lot of advantages for holding clinical trials, including the large population, access to specialized patient populations, higher patient retention rates and cheaper costs by up to 30% when compared to the United States and Europe. In your opinion, what is the most common reason for foreign companies to be performing clinical trials in Mexico in terms of it being an advantageous country?

The main advantage of developing clinical studies here in Mexico, aside from the significantly lower costs, is the type of population that we have- from children and adolescents, to adults and seniors, and from a variety of different climates that enables us to re-create different situations and setups for the clinical trials. We believe that cost is not the most important point for doing trials here in Mexico, but the quality we have seen develop over the last ten years in the industry. All of the CROs together with the pharmaceutical industry have worked together on projecting the quality of our trials in Mexico, and above all it is quality that determines how well the effect of a drug can be reproduced on the population.

We are currently working on harmonizing Mexico’s guidelines on clinical trials with those of the international community.

So you say that population diversity and quality are more attractive qualities than cost for doing clinical trials in Mexico, especially now that Mexico is aligning itself with international guidelines.

On the other side of the coin, Mexico is renowned for having the lengthiest and slowest moving regulatory approval system in the world with average approval times reaching 14 to 16 weeks… why do you think this is? And how have you seen these regulations evolve over the last two to three years?

The lengthy process in the area of regulation is historically due to the authorities when they were in the process of modifying their procedures; the bio-equivalence processes were changed and bio-equivalence submissions increased at the same time which meant the length of the process increased by about 200% in comparison to the previous year.

Today, the regulation process length can be attributed to the audit from the Pan American Health Organization, which spurred the harmonization with international guidelines that I mentioned earlier, in turn making Mexico competitive on an international level. When this is achieved, the government has promised to reduce regulatory process timeframes, and to also increase the number of reviewers, at the same time implementing a specialized section in COFEPRIS made up of experts who will work on setting up a faster approval structure depending on the type of submissions.

What do you think PAHO approval of COFEPRIS would mean for the clinical trial industry in Mexico?

At the moment the clinical trial industry is a little worried because it now takes almost triple the time to get approvals, which sometimes means that if we wait weeks for an answer, we lose out on clinical trials because customers move them to other countries, predominantly in Asia. International companies place a high value on time alongside quality when deciding where to place their clinical trials, and as we already have the quality we are only limiting ourselves with the timings.

So yes, we are waiting keenly for PAHO approval and then our authorities will support us in reducing the element of time which is currently holding us back from foreign investment in clinical trials.

So you said that time is now the biggest issue, but what do you think of the infrastructure that is now in place in Mexico in terms of hospitals and quality of researchers and research centers?

When we started about ten years ago, there were only three or four CROs in Mexico, and the quality of researchers was not great. This lack of quality infrastructure was exactly what caused Argentina and Brazil to move ahead of Mexico. We saw the opportunity to improve this situation in Mexico and create a company dedicated to training groups of researchers; we started to train

researchers from local clinical companies, before moving on to doing the same for international laboratories. Then came the ‘boom’ of CROs in Mexico, and due to the complex legislation surrounding clinical trials and research, we were also able to guide companies in that sense.

We became a CRO that offered the whole range of services, including training and consulting. Training is extremely important in this industry, and in ACROM (Association of CROs in Mexico), it is one of our main focuses alongside the development of new research centers- due to current saturation. For this reason, we created a workshop specifically for new researchers where we mimic trials that have been done five or six years ago, whilst bringing in more experienced researchers to talk about their learning experiences, for example on the topics of informed consent, and the administrative side of clinical trials. These workshops have been very interactive and worked very well, and in this way we are continuing to contribute and train people in the industry.

In ACROM we are also working on a project that is called the “Grupo Unificado”, where we work with members of each pharmaceutical association to improve communication with COFEPRIS. These work groups have been going on for about two years now.

We have also had round-table discussions with multi-national companies and training on key issues such as Good Clinical Practices (GCPs), the International Conference of Harmonization (ICH), managing the electronic Case Report Form (e-CRF), and informed consent. We do this because the quality of our research here in Mexico will bring more business for everyone. If one person tarnishes the reputation with low quality; it affects all of us. We are all direct competitors, but we all have a common goal; to search and aim for higher quality each day.

You mentioned earlier that informed consent was one of the key training issues for the industry…

Informed consent is something on which we have worked on various occasions, and I believe that today great care is taken over it; both the way in which we get informed consent, and the informed consent itself. Why? Because there is risk surrounding it- it is a legal document that contains the consent of both patient and doctor, and there needs to be a high level of security.

I believe that the situation has really improved over the years in both hospitals and research centers.

What actual steps were taken to prevent sensitive situations like this?

The main step taken was the audits, both from those inside the same clinical research companies, or externally. Our business culture does not allow a mistake to happen more than once, and this can be attributed to the amount of feedback with which we work. For example if a doctor did not

register a piece of information or did not safe-keep paperwork for the patient, the solution we find to prevent it from happening a second time is almost always through better training for those involved, and for those who were not, but who can learn from the situation.

Moving onto the company for a moment, we have not been able to get too much information, but please can you tell us a little bit more about ICR's customers; core business areas, and major achievements and challenges over the last few years?

ICR is a company formed around ten years ago with the idea of training and regulation guidance for CROs. Since then we have converted to a full-service company, whilst retaining our core business: now we also do pharmaco-vigilance, storage for medical research tools, and the registration of new molecules with COFEPRIS.

Three years ago there were just three people in the company, and in order to diversify we had to grow. Since then we have implemented the area of training, registration, and storage, and now there are 25 people in the company. We have had to modernize ourselves, change equipment and use new systems with servers; something that goes hand in hand with growth.

Our vision of growth through quality is exactly what enables us to compete with international CROs, and be the only Mexican company in the ACROM organization. As I am President of the association, we are also taking leadership one step further as the Latin American CRO Congress will be held here in Mexico this year, and ACROM is also taking part in the Latin American Committee for the Latin American Research Congress of the Drug Information Association (DIA) which enables us to contribute to the direction of clinical research in Latin America.

In the last five years, Infinite Clinical Research has gone through a radical change: from the quality systems we have implemented, to the way that we interact with our clients. We have gone from being just a regular company, to a group that works closely with their customers, forming a strategy with them that permits us to grow together; a symbiosis that allows results and ensures that we stick to what is actually needed.

We consider ourselves a malleable company- we are managed through procedures but we always look to adapt ourselves to the needs of the client.

To sum up your previous answer: if I was an international pharmaceutical company, tell me why should I work with you, and not somebody else?

Firstly, our responsiveness: we can cover everything from regulatory aspects, to the delivery of the final report. Secondly, we know Mexico. The idiosyncrasies of Mexico and its researchers cannot

just be learnt, so we provide that communication edge. Thirdly, because we are a fairly flat organization, we do not have to push through many layers in order to get a final decision which makes us fast, and lowers our costs.

Where will we find Infinite Clinical Research in ten years' from now?

In the next ten years, we hope to open offices in other Latin American countries. We have already started this process by opening some studies in Argentina, Brazil and Colombia with the idea of getting a more regional vision, which is what the industry is now increasingly focused on.

Do you have a final message for our readers?

Mexico is a country that has all the opportunities to develop clinical research, and I think that between everyone in the industry, we have formed a team focused on quality and training which has, and will continue to provide us, with a good reputation amongst big pharma in Mexico.

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