Interview: Alejandro Arias â?? CEO, iLS Clinical Research, Mexico

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Positioning itself as a flexible local CRO with an in-depth knowledge of the Mexican market, iLS Clinical Research CEO, Alejandro Arias, shares his insights on how to be the ideal partner for international expansion. He speaks about the companyâ??s milestones and background, navigating through the challenges of the Mexican CRO environment, as well as leveraging their corporate culture of agility and flexibility to garner clinical trial success in the international milieu.

Mr. Arias, you have quite an impressive profile working in management positions in leading clinical research companies such as Covance, PPD, and Quintiles. What are the factors that triggered you to found your own clinical research organization, iLS Clinical Research in 2015?

My educational background was in biomedical engineering, leading me to my first professional role in Siemens, which was primarily focused on engineering and clinical devices. My main responsibility included the installation project in Mexico for the first Cyclotron and PET Scan at UNAM. Thereafter, I pursued other opportunities at Quintiles in 2000 as a Clinical Research Associate. Two years later, I saw another opportunity at PPD at a time when there were only seven employees. Today, the organization has built an impressive network and I have held several positions during my tenure, including Project Manager, Line Manager of project managers, as well as Associate Director of Operations. Afterwards, I was presented with another opportunity again to work at Covance. At that time, the presence of Covance Mexicoâ??s organization was only three employees and my main task was to help establish its presence in Mexico and drive growth. For the first half of my seven

years in the company, I held the position of Operations Director for Mexico and Central America, where I supported the Mexican branch to grow to 85 people, and the Central American operations to 20 people. For the latter half, I was then assigned as the regional leader as the Executive Director for the operations in Latin America. My responsibilities included growth management, P&Ls, and provide senior leadership to each one of the countries in Latin America.

Having had such a multifaceted background with a diverse set of roles and responsibilities has been conducive towards my entrepreneurial venture, having gained a greater knowledge depth about the market. Nonetheless, my previous experience in working at multinational companies and necessitating to answer to headquarter stand in stark contrast in founding a business and taking responsibility in a variety of different aspects, from the financial to operational aspects. Having had a multitude of experiences in the sector, it was a natural step for me to open a local CRO business and apply the wealth of industry-experience that I have gained towards the business in conjunction with other professionals that we have worked together for the past 11 years.

Could you please introduce the main activities and latest accomplishments of iLS Clinical Research to our global executive readers?

We are proud to say that we have executed clinical trials from scratch into final outcome reporting to Regulatory Agencies. Clinical trials are a critical step in the development of new molecules because in many cases it is the prerequisite before any product can be marketed. Although having this necessity is universal, the processes, requirements and protocols differ in various countries. One of the points of pride of our company is being able to service novel companies who are in need of guidance in maneuvering the clinical trials environment. Through our services portfolio, we have been successful in providing them with guidance and support to complete their clinical development strategies that would allow them to register new products for commercialization.

We have also created models, databases and local processes in several aspects of the clinical trials development and thanks to our planning tools, we have successful end-to-end projects that have proven to streamline the clinical trial processes reducing cycle times with equal worldwide quality standards and within budget, and the outcomes are the evidence of the valuable work produced.

Many of our partners are top pharma companies who already have an alliance with global CROs, however we have been able to provide them a variety of services in a local basis or even more tailored solutions achieving day by day, more penetration into the industry market.

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, even taking over Argentinaâ??s position. What has been your strategy to take advantage of such a positive transition?

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Our current strategy today is to keep a primary focus on national clients and industry. In addition, we have always seen Mexico as a gateway to other Latin American countries for clinical trials. Therefore, we are now supporting Mexican clients looking to register their products in other Latin American countries such as Brazil, Colombia and Argentina. Also, in congresses and international meetings, we keep highlighting the advantages of running clinical trials in Mexico and other Latin American countries. And overall, we should always consider that the Latin American pharmaceutical market continues growing year over year.

Mexico already has a strong stance for Phase I to Phase IV studies, thus our objective is to keep pushing the attractiveness of any clinical trial phase in the country for the most important therapeutic

areas.

A second element is our customer retention policy; 2017 is showing to be a prospective year for us because we are now entering a phase of repeat businesses.

We believe in the value of persistence and we are confident in the way that our reputation is building.

Lastly, flexibility, adaptability and staying agile within the market is a key priority for us in order to establish and maintain a rapport with different industry stakeholders and most importantly in a constant evolving industry.

The CRO industry is quite challenging and dynamic. Millions of dollars are invested in developing molecules that may seem to be apparently safe and effective in early stages but ultimately turn out to be unsafe and ineffective later before being cancelled; indeed, only one of every 5,000 to 10,000 compounds becomes an approved drug. Could you expand on how is iLS Clinical Research approaching such a challenge in order to maximize the success of its operations?

In addition to our national market strategy, we started different initiatives to enter the international market. We have built a rapport with different consultants in the US to partner us with small and medium-sized biotech companies in order to increase the level of investments and clinical trials in Mexico. And as mentioned already, we aim to capitalize on Mexicoâ??s positioning as the gateway to other Latin American countries where we want to increase our presence. In this vein, the first two countries that we are looking at are Colombia and Brazil, for which we are already developing strategies.

iLS Clinical Research has quite a broad portfolio of services that are designed for pharmaceutical, clinical sites, and CROs. Could you expand on the added value that the company is bringing to each one of the segments and what are your most demanded services?

As mentioned already, our services portfolio has been designed to support the complete drug development process. Start a clinical trial from scratch and successfully close it into final reporting for a defined objective is our passion.

One of our biggest appeals and where we will specialize is to be able to design and conduct clinical trials studies for our clients and go through all clinical trial phases. The drug development industry keeps evolving and changing over time, so we have clarity that our services will also need to evolve to meet our clientÂ´s demands and requirements in the future.

As a new company in the market and as mentioned before, flexibility is a key element so we are always in a position to customize any part of the process if needed. For example, if a client simply wants remote monitoring services or the review of database, we can solely provide that service on its own. We want to provide the most tailored form of service that directly addresses the clientsâ?? needs. The time will define what will be our most demanded services.

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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. However there is still a lot to be done in the public arena since only 20 percent of the clinical trials are carried out in public hospitals, which are the ones which have access to larger amount of patients. How is iLS Clinical Research collaborating with public institutions to continue enhancing the

openness of the public hospitals to the clinical development arena?

We have successfully worked with public institutions for with we have proven that we can work quickly and efficiently as a team. It is important to consider that companies and institutions will always have an administrative infrastructure in place and at some point bureaucracy will add time to an already complex development such as a clinical trial. Understanding each party requirements and the start up process along with being flexible helps remove barriers and reducing cycle times. Continue working together as an industry will be key to enhance the clinical development arena.

It is important to mention that one of the major drivers for extending the timelines is the lack of adaptability to the challenges that any clinical trial will present, or having waste time/added work or repeated cycles to any step in the process.

When we had the pleasure to meet with Arturo Rodriguez, the president of the Mexican association of CROs (ACROM), he explained how is technology creating important breakthroughs within the clinical development industry. Could you tell our international audience how iLS Clinical Research has embraced such technological developments in its operations?

Every CRO has several IT needs, ranging from the company servers to the central imaging reading in a clinical trial. At this stage in our business, we have decided to outsource our IT requirements to US vendors as they are always developing new products and solutions while adapting to client/industry needs and most importantly they are compliant with international specifications and/or FDA regulations such as CFR part 11. We decided to take this approach because it allows us to focus on our core business as a CRO while having access to the most recent technological solutions.

However, it is really important to always continue connecting and validating new vendors in the IT environment and always being aware of all new developments in the industry for clinical trials. This has always been one of our objectives and successfully we have connected with numerous companies that can offer from eDC (electronic Data Capture) to electronic medical charts and/or PRO tools.

Human capital is one of the most important assets in your operations since your employees are the ones that are certainly bringing high quality and reliable results to your clients. Indeed, iLS Clinical Research has less than five percent of employeesâ?? turnover as well as 80 percent of employeesâ?? engagement. How is iLS Clinical Research attracting, retaining and developing its professionals to maintain such quality in its operations?

This is not an easy task and this competency is built through experience over time. Staff retention and retention are always key performance indicators of a CRO. In addition, at iLS Clinical Research we agree on an individual development plan for each team member as it is routinely done.

However, we invest a lot of time on identifying professional challenges for all the team. And while it is really important to offer competitive salaries/benefits, measurable objectives and individual plans, our corporate culture is based on the fact that our staff should always feel well nurtured in many aspects and with a focus on the work-life balance.

One of your main objectives as CEO of iLS Clinical Research is to contribute to clinical research development in Latin America; indeed, it is in your mission statement. Could you expand on your internationalization strategy within the region in order to meet such goal?

As mentioned, our key target for this year is to have a presence in Colombia and Brazil and we have enforced people on the ground in these countries who are developing strategies in order to enter these markets. Because of the close-knit relationships we have built with some clients, we are able to be transparent about our circumstances and how we would approach any requirement or need they would have.

What are the key competitive advantages that truly differentiate iLS Clinical Research from any of its competitors in Mexico and within the region?

The understanding of the local processes at cost-effective price is at the core of our value proposition. Agility and flexibility of our services does not only cater to the gap in the market, but offer means to have more of an international presence. Lastly, the global experience from all our management team applied into local solutions will always provide an innovative approach to any of our clientsâ?? needs.

Mr. Arias, you have quite impressive track within the clinical development arena leading the clinical development of pharmaceutical companies and CROs. As an expert in the field, what is your vision about the clinical eco-system in Mexico and the region?

The Mexican landscape is very promising as many key players, especially at COFEPRIS, are making great and positive changes for the industry. Though the advantages of running clinical trials in Mexico are plenty, we need to continue working together as an industry so challenges causing variability and affecting regional credibility can be countered in the very near future in this fast-paced, dynamic market that is constantly transforming.

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