Interview: Ricardo Uribe – Director of Country Operations, Mexico, Central America & Caribbean, Covance

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10.04.2017

Tags: Mexico, Covance, CRO, Clinical Trials, Healthcare, Research, R&D,

With an impressive achievement of growing the novel "flexible solutions" business unit by an astounding 50 percent in his first year of spearheading the region, Ricardo Uribe, Covance Mexico's Director of Country Operations, shares his insights into the attractiveness of the region for clinical research. He speaks about the impressive 10-year leadership stance of the company in the market, the suitability of the epidemiological profile of the region, as well as the crucial role that CROs play in creating a sustainable healthcare system.

Covance is the world's most comprehensive drug development company. Can you please a brief overview and history of the Mexican Covance affiliate, as well as the activities wider Central American and Caribbean region?

Covance Mexico has had an established presence in the market for the last decade and in fact is celebrating its 10-year anniversary this year. Nonetheless, my responsibilities span across Mexico, Central America and the Caribbean in this office. At its inception, the idea had always been to create a regional office in Mexico as a hub to service the wider region. I assumed this position one year ago and we have been achieving positive results thus far. In the interests of increasing our footprint in the region, we are focused not only on the provision of full service clinical research solutions, but more so on catering flexible solutions to the market. We are conscientious with

creating synergies between the gaps in the market and the capabilities of the regulatory framework, which has been attractive in Mexico due to shorter approval rates. Moreover, we are continually adapting to the local needs and capitalize on global expertise in delivering local and regional solutions.

Given the recent additions to the already comprehensive solutions in your portfolio, what do you foresee will be the key growth driver of your wide breadth of services?

The attractiveness of our services to our clients are primarily based on a quality-cost effective duo. The decision to contract the research activities to a CRO is typically driven by both the quality that the sponsor will receive and the cost-saving prospect of no longer needing to hire long-term employees in-house. This is especially attractive for temporary projects wherein the costs are not only absorbed through outsourcing, but quality is ensured in an expedited timeframe. We do not solely identify ourselves as part of a company’s clinical research arm, but as a trusted research partner that will help drive companies forward. We offer services that range from management to quality review and mentoring, either for a specific project or a set of projects. The prime benefit to our client is that we are able to absorb costs for hiring and execution of the project for its duration.

Aside from the argument of cost, the expertise that are inherent in outsourcing to CROs are incomparable. We offer an in-depth knowledge in areas such as monitoring, startup, regulatory affairs, medical writing and other pertinent areas. We also focus on creating synergies between the companies in the sense that the personnel that are provided for by our clients are also treated equally within Covance. Our agility to be able to cater both traditional and flexible solutions would allow retention of key big pharma players, but also attract new innovative players, especially in the bio-tech and start-up landscape.

The attractiveness factor of Mexico as a clinical trials destination is not only based on the size of its market, but also according to its suitable epidemiological profile and proximity to other countries. In spearheading the Central American and Caribbean region as a whole, how have these factors offered a competitive advantage to the business?

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Though Mexico is inherently diverse, the sample size and diversity of patient populations are further enhanced when the focus is expanded to other countries, such as those in Central America and the Caribbean region in particular. In having a holistic scope, we are able to cover a wider set of ethnicities and therapy areas that mirror those in Western and Eastern World. One of the

advantages of being able to cover a greater region through the Mexican office is that we have a higher sample pool of patient populations through a centralized system. In parallel with conducting sites in Mexico, we can also simultaneously conduct sites in Puerto Rico, Guatemala and Dominican Republic and therefore produce more comprehensive reports.

Moreover, we also have the capacity to study orphan diseases that are only pertinent to certain ethnicities. The prevalence of some of these diseases are mostly concentrated in areas in the Tropical Belt of Central America and the Caribbean. Ergo, our operations are not only limited to what is available in Mexico, but to the scope of the region as a whole. Mexico is a convenient hub as it is only a two-hour flight to countries like Panama, Dominican Republic or any other major destinations. The concentration of the countries within the area make the populations far more accessible than those trying to cover the entire United States. Even in looking at within Mexico City itself, the proximity of major areas such as Guadalajara, Mexico City and Monterrey enables us to open just three to five sites in order to cover the entire population of the country as a whole. The level of concentration in this area creates cost-efficiency, a controllable environment in terms of quality, as well as higher engagement of the patients and the investigators.

Despite the plethora of factors that make Mexico an ideal destination for clinical trials, the country is largely underfunded in this context, especially relative to larger economies like Brazil and Argentina. What is the reason for this paradox and what are some of the measures that can be done to drive more investments into the country?

Analogous to the reasons why larger companies are typically skeptical to work with smaller ones, the hesitation is largely anchored on factors surrounding uncertainty. Mexico has not built its reputation for clinical research yet, especially in the global sense compared to the United States and more sophisticated economies in Europe. Nonetheless, reality depicts a vastly different picture. The primary reason is precisely because some companies are simply not aware of the potential, talent and infrastructure that is available in the country. There are current uncertainties in regards to quality, timelines and performance of sites which can be easily mitigated through conveying a stronger communication message of the high-level results that delivered in the country. Our robust historical data proves that conducting clinical trials in Mexico is as good as any other country in Latin America, and to some extent in Europe and the United States.

The variety of orphan diseases present in Central America and the Caribbean is, unfortunately, very high, therefore making it an ideal region to find patients to complete studies. Furthermore, given the socio-economic stance of the majority of these countries' governments, the costs of clinical trials are comparatively very low and therefore clinical trials activities are very well-

received. Oftentimes, the only chance for some patients to receive proper high-level care in these countries are through clinical trials. Access to innovative drugs are scarce and could not realistically be provided by the government, thus clinical trials are welcomed with open arms as the only redemptive means for care. In Mexico itself, some of the measures taken to increase the propensity of clinical trials in the country is to ameliorate some of the hindrances embedded in the regulatory landscape in order to induce shorter timelines and faster entry to market.

In the context of the regulatory landscape, Mexico is currently undergoing a transformative period. Could you please describe some of the key regulatory changes in the upcoming years and how they will impact the sector at large, as well as their significance for Covance?

New pharmacovigilance programs have recently been implemented in the market that require consequent changes in the protocols. In the past, the model for pharmacovigilance was primarily through call centers wherein CROs are required to have telephone operators readily willing to take calls regarding adverse reactions or other such problematic areas with the product. The problem with this traditional model is that there are no guaranteed methods to ensure that the reporting rates accurately depict the number problems that the products face in the market. In order to counter this, the government now requires tighter reporting through implementing mandatory clinical trial programs at a post-market phase when the product has already been launched in the market for two to three years. The trials are purely observational and non-interventional, with the sole purpose of providing a more accessible platform for reporting. Therefore, pharmaceutical companies have a higher obligation to report adverse events through these programs and are able to attain explicit data for these matters. Although this is a local initiative, it is also graining traction in countries like Peru, Ecuador and Panama.

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Covance is leveraging this opportunity in the sense of being able to offer a new type of service that we did not previously have in our portfolio. As these protocols are increasingly becoming more mandatory, the demands for them are also increasing. Both big pharma and smaller biotechs and start-ups alike are required to comply to the new regulation, thus we also perceive ourselves to be as a key guiding force in helping different companies to maneuver the changing landscape, especially since this new protocol is technically out of the scope of the traditional clinical trial life cycle. Everyone understands the value of increasing the level of due diligence once the product is in the market, nonetheless, companies need to feel reassured during the period of transition.

How do you build a strong rapport with the key regulatory entities in the country?

It is imperative for a CRO to have a strong relationships with MoH authorities, COFEPRIS, all the pertinent health entities, as well as hospitals. It is integral to our success to create a formidable network amongst these governing bodies. In order to do so, we liaise with them both directly and indirectly through associations such as ACROM, CANIFARMA and AMIIF. Moreover, we also make ourselves available for pilot implementations for upcoming regulations that are planned by the MoH. In regards with public hospitals, we also strive to create preferred partnerships with some of the key institutions, especially given the fact that only 20 percent of clinical trials are conducted in the public sector. The interest to increase this rate is not only due to the fact the most profound need is in this sector, but also because conducting trials in public hospitals helps ease the entry of drugs into the “basic scheme” system, wherein cost is balanced with the regulatory framework.

Leveraging on your personal background of having worked at both in-house clinical trial roles (at Lilly and Sanofi) and outsourced clinical trials (at INICAM, Pharm-Olam and Covance), how would you describe the efficiencies captured in the latter, especially given the fact that global trends are leaning towards more CRO activities?

The CRO model will reach as high as 80 percent in the upcoming years and this is primarily due to the efficacy of the timelines. Given the level of specialization, approval rates are much faster than when trials are conducted in-house. In addition, CROs are structured in a way that there are distinct roles dedicated to each function pertaining to clinical trials, such as in regulatory, monitoring, start-up and other such roles. This stands in contrast with the typical case in in-house clinical trials wherein they only have a few designated CRAs in charge of regulatory affairs, the ethics committee, monitoring and many others. Therefore, the expertise in certain areas are diluted. CROs have a great understanding of the dynamics of the market, which translates to savings in time and money.

Given today’s big data world, how receptive has Covance been to the rise of digitalization?

We have been cognizant of the needs to digitalize throughout the span of the operations as data is crucial for our business. Consolidating live data has offered tremendous advantage to the way we conduct business. At first, investment in the proper technology has been seen as a cost but it has created greater efficiency and relevance to the highly mobile ad technological world of today. Digitalization has also facilitated remote monitoring processes, thus creating a wider presence for our operations.

When we spoke with Cristobal Thompson, he spoke about the long-term vision for the healthcare system for 2024. What role do you believe clinical trials play in improving the healthcare system as a whole?

The integral role of CROs is to help bring innovative drugs to a market, which begins at clinical trials. A study was recently conducted by the World Health Organization stating that in order for countries to have a healthy investment in research and development, six percent of the GDP must be allocated to this area. As it stands today, Mexico only currently invest 1.8 percent of its GDP on R&D. For the healthcare sector, the CROs will be one of the players driving to close this gap and indirectly, therefore, create a means to bring more advanced practices and products that contribute to the sustainability of the healthcare system.

On a personal level, what do you consider as your key achievement of your first year in spearheading Covance's Mexican and Central American affiliate?

My achievement has been clear cut: the flexible business solutions has grown by 50 percent on my first year. Moving forward, my objective is to grow the region through growing the level and expertise of CRAs that we employ. It is imperative to focus on the training and improving the quality of our services with an agile approach. At the crux of our business model is to help clients achieve their goals in the context of product development and we will continually strive to deliver the high quality clinical trial service that is commensurate to our strong reputation in the market.

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