Interview with Diana Valencia, Executive Director, LatAm Clinical Trials

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Tags: Latam Clinical Trials

While LatAm originally emerged from the SIPLAS organization, how was it evolved since then to be where it is today?

LatAm was born in 2000 as a business unit of SIPLAS labs and was known at the time as SIPLAS Research Organization. We decided to change our name to LatAm we wanted to establish ourselves as an independent Contract Research Organization (CRO) that provides services to pharmaceutical, medical device, biological, and vaccine companies in the areas of project management and monitoring of clinical trials, quality assessment and regulatory submmissions. LatAm is a private organization with approximately eighteen investors from various countries who wanted to establish an original CRO that serves as a geographic niche provider in this emerging area. We want to develop the business of clinical trials and bring more of them to the Andean Region, Central America, and the Caribbean. So far we have been very successful in doing just that. Our American brand company was launched in 2005 and since then we have brought a lot of clinical trials to the region in different therapeutical areas such as infectious diseases, medical devices, and vaccines.

While our main clients are pharmaceutical companies, over the last few years we have focused on vaccines. We certainly want to be a major player in the vaccines area. We have been monitoring around seven vaccine programs in Colombia, Panama, Costa Rica, and the Dominican Republic, amongst others. We have also helped with different H1N1 vaccine projects in the Dominican

Republic and Costa Rica and over time we have worked alongside companies such as Gilead, GlaxoSmithKline, and Novartis. Additionally, we also support CROs who do not have operations in Latin America and are in need of contract work from a company such as LatAm with a regional presence.

What are the advantages that LatAm enjoys being a niche player in this industry as opposed to a multinational, global company?

We have a tremendous knowledge of the cultural diversity of this region which makes us completely different from the global players. We also don't compete with the global players because they are just that – global – and will not be interested in the small studies that are allocated regionally. Our group has a specific knowledge in the cultural diversity of this area which we consider to be an emerging market and untapped region. Argentina and Brazil are a little bit crowded right now with a high volume of clinical research projects and so cannot offer many subjects. We in Colombia have an opportunity through new, untested subjects and because of our geographic proximity to the US. A three hour flight to Miami or a five hour trip to New York certainly decreases the logistical costs of any studies on Latin American subjects.
Also, the therapeutical profiles of our subjects overlap with the same areas that are associated with the ten major causes of mortality in the US. This country, epidemiologically, behaves very similar to developed countries. We can also offer treatment and services in infectious diseases that are typically found in under-developed countries but are now starting to appear in the developed world. Dengue fever, for example, was not previously common in the US but because of changing weather patterns is now becoming more prevalent. Pharmaceutical companies are growing more interested in clinical trials in emerging diseases and we can therefore offer more of those subjects because of the endemic situation that has always existed here.

Our geographic niche role is focused on Latin America, Central America, and the Caribbean but in therapeutic areas we are slowly expanding our niche because of the variety in emerging diseases that we cover. Ultimately, however, we want to keep our focus limited in order to give us more efficiencies. Obviously there is more market to explore – oncology, cardiology, etc. – but I really want to be a recognized niche CRO specialized in infectious diseases and vaccines. We are always open to new opportunities as they come along, but at this moment we want to be focused on our areas of expertise.

In these areas we are a "one-stop shop" for services. We conduct Phase 1-4 studies as and all the start-up and pre-start up activities and feasibility studies.

What types of approvals and certifications are required being a CRO that works in so many countries on behalf of multinational companies?

All global studies are looking for different subjects with a variety of clinical profiles. Any good study will need a large sample size to have the necessary diversification – for example subjects from Latin America, Asia, and the US. Clinical trials used to be focused mainly in the US because they could provide the required diversity. But now the market is being increasingly crowded with trials and there are fewer subjects to choose from. This country will obviously provide the necessary Latin American subjects and we follow all the respective regulations in Colombia. To manage any study here we need the institutional approval of the protocol, the internal approval of each institution, and INVIMA approval. Last year INVIMA released a new, stricter regulation for Good Clinical Practice certification to ensure that each institution will follow international requirements for clinical trials. Since our domestic regulations are aligned with international regulations we essentially meet all global standards. A global study that we conduct will be aligned with those international regulations and the final approval for the home country sponsoring the study will be accepted. We do not need FDA approval but because our standards are aligned with those of the FDA we can participate in any of their studies to provide subjects.

Colombia is an untapped market and untapped markets typically attract a wave of business. There is a steady stream of investment that is flowing in for clinical trials in Colombia. What is LatAm's piece of that pie?

We work regionally and are focused on vaccines. At the moment we are participating in twelve clinical trials which are not exclusively in Colombia; Regarding mega vaccines trials we are running four vaccine clinical trials one is in Panama, another in Costa Rica, and additionally in the Dominican Republic and Peru. It is a small part of that overall clinical trials pie in terms of the number of studies, but in terms of the number of subjects we reach, our engagement is massive. In the studies that we are participating in vaccines we have 12,000 subjects enrolled at the moment, compared to a clinical trial in oncology that may only enroll five to ten subjects per site. Vaccines are different, megatrial studies with healthy subjects who will be followed-up with over a long period of time. The vaccine studies focus on healthy people to prevent an outcome. The main purpose is to conduct a surveillance of healthy people to detect if an intervention will prevent an outcome in the future; this is completely different than a regular clinical trial to test the optimal treatment. Our participation in terms of the number of studies may be small, but it is huge in terms of sites and subjects. This requires more work effort, resources and infrastructure.

How do you go about seeking the proper contracts and partnerships for LatAm?

The past five years have been a learning process. I realize that I am not able to make a partnership with anyone at anytime and have been very selective with our partnerships. We want to forge a relationship with a partner that allows both companies to grow together. As we are a small company, sometimes the relationship with a large company is not necessarily fair. We are small CRO who pays our taxes and compensates our people correctly according to industry standards. It is sometimes that case that big CROs come here virtually and do not base themselves like a real company. They form contracts without legal representation; they do not pay taxes; sometimes do not pay their employees adequately; and they have even recruited some LatAm employees while under contract with us. There is an unfairness about those situations which we, as a small company, need to protect ourselves from.

Because we have been through unsettling business relationships we are very selective with the CROs that we subcontract with and are looking for partnerships with an entity that wants to grow alongside LatAm in the long-run.

We currently do business directly with big pharmaceuticals such as GSK and Novartis and are looking for new clients such as Sanofi- Pasteur. I am confident that we will contract with the big companies in vaccines in a mutually beneficial relationship and avoid being subcontracted.
What is your opinion on the potential of Colombia becoming the next major hub for clinical trials similar to how Mexico and Argentina are now?
I think this country offers a tremendous opportunity to serve as a hub for clinical trials. Because of that, LatAm's window of opportunity will shrink a little more everyday. Once the big companies establish themselves here the competition will be very different for a small, regional company such as LatAm. It poses a threat to us in the near future. However, one possible outcome is to be acquired by a larger company who wants to grow faster than the others. That possibility always exists.

Do you think the growth potential of CROs in Colombia comes from vaccines or another therapeutical area?

Quite frankly, perhaps from another therapeutical area. I am in this field of vaccines because I saw an opportunity, but fully realize that other opportunities indeed exist. At this point I do not want to explore other areas. We have enjoyed success in this area of opportunity and want to gain more expertise in it day-by-day. Any CRO that comes here will have different opportunities in different therapeutical areas. But we are comfortable and steadily growing in our field of expertise.

From an objective opinion, considering that the CRO industry is not directly affected by the current Social Emergency Crisis, what is your evaluation of the state of healthcare in this country today?

There are two sides to look at when evaluating the crisis: the customer who receives the service and the medical service provider. An ideal situation would be for a country to provide all necessary health services to anyone who needs it. That, of course, requires a significant amount of money and investment. For example, it would be tremendously difficult for a country to provide HIV or oncology subjects with all the necessary medications for a complete treatment. That is essentially what happened with the crisis – everyone, based on their constitutional right, asked to receive the best and equal treatment for different diseases. I think it is fair and the ideal situation. But for a country like Colombia, it is difficult to achieve as we are seeing with the health system that is on the verge of collapse because it does not have sufficient money to pay the providers.

We need to look at the situation from a balanced perspective. It is honorable to provide people with the best services but we need to assess the most cost-effective solution to reach that objective. We cannot take a polarized position because the government has to enforce some solutions which may not be the most popular, but are done in order to preserve the system. The fact that the government did exactly that – take a polarized stance to provide everything for everyone – is the reason why the system is breaking right now.

However, I believe that clinical trials activities will not be affected y the health crisis.

What types of background do leaders in your position typically come from?

I am a physician with a masters in clinical epidemiology and an expertise in health administration and medical education.

The president of a CRO typically comes from the health profession with administrative and management skills; but also teaching skills are desired for this type of position.

By 2013 LatAm’s goal is to be recognized as a high quality clinical trials provider in the region. What is your standard for high quality by which you measure yourself?

We have implemented a quality management system and follow ISO 9001 standards. We want all of our subsidiaries to be accredited with ISO 9001 as well. But the most important bar that we set for ourselves is to ensure that our research subjects are protected and that the objectives of any investigation will not compromise their rights as a patient or a person. We want to ensure that the data that we oversee is accurate and reliable enough to be published and we strive to guarantee that any medication that will participate in the registration will be one that helps the worldwide

public. For that reason we provide our employees a continues education program that assures those statements.

How would you assess LatAm’s recognition right now amongst the CROs in Latin America?

I look at the number of vaccine trials that there are in Latin America and how many of them LatAm is participating in. I believe that over the last three years we have had a 100% participation rate.

What would be your final message to the readers of Pharmaceutical Executive about the skills and strengths of LatAm?

LatAm is a regional CRO that offers high quality service and high responsiveness to our clients. We are an adaptable CRO that knows the regional culture and can provide customized services for pharmaceutical companies, vaccine companies, and medical device companies.

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