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**It is well known that mergers and acquisitions are rampant in the pharmaceutical industry this year. Why do you think this is happening? Can you give us an overview of what impact M&A has had in Latin America?**

**Diego:** Sure. The main reason why mergers and acquisitions are ramping up in Latin America is because Latin America is becoming a very important pharma market now. Countries like Brazil and Mexico, for example, are among the top 12 countries in terms of pharma product sales. So, it makes the market very attractive for international pharma and for multinational pharma. Also, the fact that the generic market in Latin America is also very strong. Global pharmas are very interested in acquiring local generic companies in order to penetrate this market.

**Are you seeing a lot of growth with biosimilars in Latin America given the generic market landscape in the region?**

**Diego:** Yes, I am seeing a lot of potential for biosimilars. In fact, the regulators (particularly in Brazil, but also in Mexico, again the two most important pharma markets in the region) are discussing changing the legislation for biosimilars for them to be very much in line with global regulation. They will heavily promote the expansion of biosimilar products in the region, in this case Brazil and Mexico.

**What are some of the notable mergers and acquisitions that you've seen that have taken place in Brazil since the beginning of the year?**

**Diego:** I don't know about since the beginning of the year, but lately the most notable one was the acquisition of Medley by Sanofi-aventis. I think that was probably the most notable in Brazil. But also the most recent one was in Argentina and it was done GSK – GlaxoSmithKline to Phoenix. Phoenix was the fourth largest local pharma in Argentina. So, I guess those are the latest and the most important ones. They also created an impact in the local markets.

**So, you are seeing some of the global pharmaceutical companies buy some of the local or regional pharmaceutical companies that are strong in their respective markets?**

**Diego:** Yes. Correct. I am seeing that the multinational companies are very interested in these companies. The main reason why is the one I explained before. They really are very strong in their generic market, but also they have a very large and strong sales force and a market presence, which is critical for the success of these multinational companies in the local market. So, that's what I see.

**Are you seeing any negative impacts in terms of regional drug developments that are occurring as a result of some of the mergers and acquisitions?**

**Diego:** Not really because historically the local companies have not been investing heavily in drug development. The impact will be more on the, I would say, commercial side because they are interested in the local knowledge of these companies. So, basically they improve the way they sell products and they are more effective in the way they sell products in this country.

**There are still many countries in Latin America that are considered emerging regions. Do you think mergers and acquisitions will be more rampant in some of those regions or are you seeing it more established in mature markets like Brazil?**

**Diego:** I think the mergers and acquisitions will continue ramping up, particularly in Brazil and Mexico because of the market size. Those are, again, the largest markets. Maybe in other markets we will see some acquisitions. But again, multinational companies are very interested in increasing their sales in these markets because they are growing at a higher rate than traditional pharma markets. And because innovation – we are seeing less innovation and the more generic markets want to strengthen the acquisitioning in the marketplace by acquiring local companies.

**Now, one of the things at the upcoming Partnerships in Clinical Trials Latin America meeting that you'll be presenting on is some of the strategic partnerships and some of the tips that sponsors and CROs can use for building an effective outsourcing relationship. Let's talk a little bit about what that entails. In your opinion or in your own definition, what makes an outsourcing partnership strategic?**

**Diego:** Partnerships make it strategic basically when the vendor or the third party vendor integrates with the client or the sponsor, in this case. So, when you integrate your processes you create a governance committee to strategically discuss the directions of your pipeline and how you are going to develop your products. When you discuss this with your partner the partnership becomes strategic. This is, I think, a big shift in the industry because the outsourcing in the past was more tactical than strategic. Now the discussions between CROs and sponsors is on how they will develop the products and how they can be more efficient in developing the products than outsourcing a particular study or project. So, that's the way I see it.

**At what point do those discussions happen?**

**Diego:** That's a good question. It is a very good question related to Latin America because I think Latin America has very little input in this discussion. Basically, Latin America is one more region and that is the result – basically it is more in implementation phase than in the discussion of the strategy. This is typically happening at a high level or at the headquarters level and not at the lower level like in Latin America.

**So, for working in Latin America you feel the challenge is more in the implementation because the region isn't necessarily part of the initial strategic discussions?**

**Diego:** No, I think this is the same for all – the same concept applies to all regions, not only to Latin America. I think when a sponsor makes a strategic decision to outsource their operations to one or two CROs because that's what the strategic partnership is all about – I mean basically to concentrate the number of vendors you use and integrate with your vendor. This is a discussion that you have at a higher level and not at the regional level. So, the region is more an executor of the global strategy than participating in the discussion of the strategy.

**What do you think are the biggest mistakes that sponsors make when outsourcing in Latin America?**

**Diego:** Probably the biggest mistake is to believe that the local market operates the same way as – I mean the Latin America market operates the same way as other regions where headquarters are located. Each country is different. You have to be respectful of the culture, also about the way their regulatory outsourcing thinks regarding clinical trials and what the most effective way to recruit patients and provide data quality would be for this region. So, I think understanding the local culture is critical for the success of any clinical trial.

**Are you seeing any specific type of strategic relationship proving to be most effective in the Latin America marketplace?**

**Diego:** Yes, I think it is very important to establish very close communication, particularly when – I mean the strategic partnerships are happening, typically, between large global pharmas and CROs. Some other pharmas, as well. It is not something that we see often with small biotech pharma. So, typically those multinational companies, multinational pharmas have affiliates – I mean at the local operating companies in Latin America and the communication between the CRO local affiliates and the sponsor local affiliates are critical for the success of any project and to have

a common interpretation of the strategy that these two companies are trying to put in place in order to be successful executing clinical trials.

**For people from biotech pharma, medical device companies or CROs who have never worked in Brazil (in particular) and are looking to do clinical research in that country, do you have any crucial tips or considerations that they should be thinking about?**

**Diego:** Yes. I think it is very critical for them to rely on a local partner or local partners. Local partners are not only the CROs. They are also the investigators or other providers and drug supply companies. Basically the vendors in general. It is very important for these people to come to the region, to come to the countries where they plan to run the studies to meet with the investigators, to understand how they think, how they work, what the local culture is and understand the market before they make the decision to come and work in Latin America. It is not very complicated. It is just a matter of understanding the market and to rely on the investigators who are extremely good in the region. Typically the quality coming from Latin America is very high, very good. But, they need to know the market, they need to understand the environment.

**For more information on Diego's presentation and the rest of the partnerships in Clinical Trials Latin America agenda, please visit our webpage at [www.pctla.com](http://www.pctla.com)**