Interview: Ciro Garcia â?? CEO, Accelerium Clinical Research, Mexico

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The CEO of Accelerium Clinical Research, Ciro Garcia speaks about the trends currently impacting Mexicoâ??s clinical research space, while detailing the companyâ??s ambition to pivot from just one full-service research center to the nationâ??s leading network of clinical research facilities.

Could you please introduce yourself to our international audience as well as the main activities of Accelerium Clinical Research?

Iâ??m very proud to be part of a leading company dedicated to provide Phase I to IV clinical research services to the international pharmaceutical and biotechnology industries in Mexico. Having traditionally operated through one research center in the northern city of Monterrey, weâ??re now in the process of expanding our site network and opening more standardized research sites around the country. We recently started our second Phase II â?? IV research center south of the state of Nuevo Leon, this new research facility is co-located in one wing of Hospital La Carlota owned by the University of Montemorelos and the Seventh Day Adventist Church.

We conduct trials across all clinical phases in accordance of national and international guidelines and regulations. We also provide training on good clinical practices (ICH-GCP), both to our teams internally and externally to organizations and other companies in the industry.

Having been recently appointed CEO, Iâ??ve reshaped our strategic direction to focus on leveraging technology to enhance the productivity and efficiency of our operations, while overall helping the industry to increase the access to larger patient populations.

We recognize that in order to do so, we will need to collaborate with the CROs and pharmaceutical sponsors to increase the level of clinical research in Mexico. On one hand, we collaborate with regulatory authorities to help streamline and facilitate the authorization of clinical trials in the country, while working with the industry to integrating best practices in the development and conduction of clinical studies.

What factors warranted this directional shift?

The international requirements for conducting clinical trials are becoming increasingly stringent. Consequently, weâ??ve had to enhance our own infrastructure and organization to stay in line with these trends. Previously, clinical research could have been easily performed in a small doctorâ??s office, manually recording data, with barebones equipment. To keep up with quality and safety, regulators now require more complex infrastructure and controls. As such, weâ??re currently creating a prototype of the model weâ??re using here in Monterrey, so that we can leverage it in other locations in Mexico.

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When it comes to clinical trials, the proper selection of patients is one of the main challenges considering that approximately two thirds of the evaluated patients are rejected because of incongruity with the study criteria. How is Accelerium selecting its patients in order to minimize such risk?

That statistic is due in part to the increased level of complexity associated with the selection criteria, a trend pervasive worldwide. Where we can help then is to increase the access to patients and our presence in the south of Mexico. Essentially, the aim is to augment the volume of patients participating on clinical trials, particularly late-stage studies which require more patients.

Actually, in January 2017, President PeÃ±a Nieto and the General Director of Mexican Social Security Institute (IMSS) announced the Institution themselves would be formally engaging in clinical research, which will invariably help in these efforts.

We are also working with the media to implement education and awareness initiatives and help the community to understand the process of researching new drugs and the benefits for the population.

As a Research Group, how has the organization responded to the biotech industryâ??s push towards increasingly complex and innovative molecules?

Indeed, the new generation of drugs is inherently more complex, warranting more thorough studies and increasingly stringent procedures. The physical stability of the drugs, for example, else the molecule might be compromised. As a research organization, we have to always certify that the proper controls are put in placeâ??an on-going effort to say the least.

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Accelerium has a quite broad portfolio of services sorted out in clinical studies from Phase I to Phase IV. How has your business divided between each segment?

The majority of our business is attributed to late phase studies, mainly Phase II to Phase III. In line with the rest of the industry here in Mexico, we engage very little in phase I studies because the strategic and tactical work done in Phase-I has a greater impact on downstream Phase-II and Phase-III costs than any other factor, and has the greatest impact on drug development success. This is a very critical point in the research process. Drugs that should go forward need to move

ahead quickly and drugs that should be abandoned should be jettisoned even faster. Any oversight on this phase may represent potential loses to pharmaceutical sponsors. We are trying to attract early phase studies to our state of the art Phase I Unit and demonstrate that Mexico is now capable to deliver results comparable in quality with the top Phase I units in the world. In fact, we are pioneers in conducting international phase I trials in complex therapeutic areas such as oncology.

What would you identify as the main quality that differentiates Accelerium from your peers in the industry?

Our competitive differentiator is our unparalleled emphasis on quality and access to large pool of patients and trained investigators, an aspect highlighted by the fact that we have our SOPs in place covering all the operating elements across the board clinical operations including recruitment, study coordination, regulatory affairs, laboratory, pharmacy and administration. All these parts move together in a seamless fashion to provide one collective face for the company, and top-notch services for our clients.

Where would you like to have taken the organization in the next three to five years?

Firstly, weâ??re looking to increase the number of research sites and our overall presence in other regions of Mexico. We also have a strong interest in participating on current initiatives to conduct clinical trials in the social medicine sector in Mexico.

Secondly, we would like to enhance our collaborative partnerships with the CROs and the pharmaceutical community instead of solely operating as a standalone contractor. In order to succeed in establishing a meaningful, sustainable and strategic alliances that build real value, Accelerium is focused on integrated operational relationships built around drug development specialization, capacity, centralization of operations, technology, economy of scales, cost efficiency and most important, on the right patient recruiting strategies. This makes it possible to enhance shared risk and benefits expanding mutual capabilities through integrated partnerships. That is also why long-term relationships have been one of the main drivers behind our success.

Thirdly, our ambitions will focus on generating a larger volume of active clinical trials in Mexico to not only enhance our business, but also improve the level of clinical research in the country.

Leveraging your longstanding expertise in the industry, what is your outlook on Mexicoâ??s clinical research potential?

I believe that Mexico has strong potential to become a clinical research leader worldwide. We have all the elements such as population, disease profile, ensemble of trained investigators and the local representation of the international bio-pharmaceutical and CRO industries, as well as the supporting regulatory agency COFEPRIS on par with the even the most recognized agencies worldwide. So, Iâ??m confident that these fundamentals will eventually assimilate together in the most synergistic manner to significantly elevate the total number of the active trials in the years to follow.

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