Interview: Marco Cid – Director General, Investigacion Biomedica, Mexico

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Marco Cid, Director General of Investigacion Biomedica, shares how he successfully launched an innovative clinical research center (CRC) despite a challenging regulatory environment. He speaks about the inspiration behind his business model, the necessity of building a strong rapport with authoritative entities in the market, as well as fostering a spirit of collaboration in cultivating the growth of the landscape to entice further investment in this sphere.

Mr. Cid, what was your primary inspiration for founding Investigacion Biomedica and what were the key gaps in the market that needed to be catered to with this business model?

Current research sites display a clear lack of quality, especially when put in contrast with the international standards held by large pharmaceutical companies. Catering to improving this status quo is the gap that we identified in the market. The landscape was very minimally regulated with several private players incoherently conducting studies. Identifying this issue prompted us to create research sites through leveraging the experience that I previously had in the pharmaceutical industry and understanding the standards to which we need to elevate the market.

At the onset of the company, we conducted a pilot study in order to track the behavior of the market and understand how to grow. When we saw traction, we understood the viability of the

business and began scaling up to three to four projects. We wanted to be inherently different from Big Pharma companies in the way we operated as they typically tend to have a managerial perspective. Corporate mindsets have a tendency to be focused on providing directions and setting milestones, whereas the research environment affix to a more collaborative model. Understanding the polarities of the corporate and clinical mindsets has been key to our business.

Investigacion Biomedica's business model is anchored on implementing a corporate structure within a clinical research facility. Embedded in our company roles are HR, Finance, Marketing and other such functionalities that a typical business structure contains. Though we are a small company at the moment, we plan on working with large companies and therefore we need to have the capabilities prepared to leverage our network to propel growth and expansion.

The process of clinical research is capital and time intensive. The process first begins with the site selection. A month thereafter, once selected, the necessary paperwork needs to be submitted which will be reviewed by the ethics committee thereafter, which requires another month. Afterwards, everything needs to be submitted to Cofepris for approval, which is a process that takes about three months. Therefore, CRCs require six months' worth of capital to be able to support themselves while undergoing all the approval processes.

iBiomedica is a new entrant in the market, but despite the company only being five years old, it is already starting to gain traction, having established three locations in Guadalajara, Aguacalientes and Mexico City. What was the rationale for targeting these locations first?

We began in Guadalajara as it is the cultural center of Mexico. It is the second largest city of the country with a plethora of dynamic activities. There are currently 20 projects running in Guadalajara on 12 therapeutic areas. Moreover, there are 16 projects in 10 therapeutic areas in Aguascalientes, which is the fourth largest city in Mexico. The location of the Mexico City branch stands outside of Mexico City in an area where there are only two CRCs and we have identified a strong need. One of our key rationales for entering a location is the plausibility of partnering with a large hospital in order to have a strong patient population to conduct trials.

iBiomedica's portfolio is essentially divided into two segments: research protocols and the comprehensive healthcare program. Nonetheless, the business is primarily known for your research services which encompass several therapeutic areas. In the context of research, what are the key growth drivers of your portfolio?

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Our portfolio is driven by our mandate to conduct clinical research for the top eight pharmaceutical companies. The key areas of focus are rheumatology and nephrology and we have an average of five protocols for each therapeutic area. We are also starting to be active in gynecology, endocrinology and cardiovascular diseases. Oncology is also represented here as it is an area that is prominent across the industry. However, it is slightly difficult to run certain types of cancer research in Mexico and we are conscious of mitigating against these difficulties.

In the context of the comprehensive healthcare, can you please elaborate on the concept of the PIAM program?

Anchored on the philosophy that clinical research has enormous benefits to our people, it was only logical to indirectly provide them with free healthcare. Thus, we developed the PIAM program, which stands for Program Integral A function Medica. The aim was to provide new patients with quality healthcare at a very low charge of approximately 300 pesos (USD 15.7) for each medical review. Once their medical history is analyzed, we then recommend certain specialists for the patients in order for them to receive more targeted care. At times, some of the patients become candidates for our clinical trials. Nevertheless, the key objective for the program is to segue into the creation of an NGO for healthcare. As a non-profit, we will also be able to look for more funds from big pharmaceutical companies. Our overarching objective is to create universal healthcare for the economically marginalized population while sustaining a viable business for clinical research.

What has been the key challenge of clinical trials in Mexico?

The bureaucracy in Mexico is exhaustive. It is a false assumption that once a product is approved by the FDA, it will automatically breeze through Cofepris. The latter is an entity of its own accord with its own sets of criteria and requirements. The length of the processes is by no mean indicative of their respective quality; it is simply indicative of the number of steps in place that the organization has to take in order to get to market. Exacerbating the lengthy bureaucracy of Cofepris, is the process for the acquisition of patients that also requires a certain time investment and utilization of certain media channels.

The lack of regulation in the private sector also brings a lack of coherence to the market as a whole. Many new entrants in the market are unsure as to which step to pursue because of the lack of guidelines and the novelty of the landscape as a whole. This is partly due to the lack of formal education that exist for professionals entering this sector, which should be one of the primary changes done for this sector. Everyone involved in this sector should also be cognizant of the fact that the administrative tasks far outweighs the clinical tasks and therefore procedures should

reflect this accordingly.

Lastly, there is also an inherent challenge of the necessity to change the image associated with clinical research. Part of the resistance met is due to the fact that it is understood under false pretenses of experimentation. In truth, it is a paradise for patients to receive the necessary care. Especially given the fact that most trials in Mexico are in the Phase III stage, this means that products have already met approval and are entering last rounds of trials for due diligence before entering the market. Clinical trials need to be understood as a haven for underprivileged patients and a means to alleviate the financial burden of the public sector.

As a fairly new entrant in the market, how do you build a rapport with key regulators, academic institutions and medical groups?

The majority of my responsibilities as a director are about building and fostering a strong relationship with key players in the market. My primary targets to liaise with were the directors of CROs and pharmaceutical companies. At the initial contact, I have met with plenty of skepticism as a new entrant but persistence carried me through. Eventually one trial become three and gained traction to carry the momentum we have today. We are fortunate to be able to partner with companies such as Sanofi and Novartis. It is important for us to build a rapport with strong and reputable players as 70 percent of our business come from CROs, while 30 percent comes from pharmaceutical companies directly. We are conscious of the fact that the trend is moving towards more outsourcing to CROs and therefore there is a growing importance for elevating the standards of the research landscape as a whole.

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I have also expanded beyond the Mexican borders and reached out to start-up companies from Texas and California, as they are a hotbed for innovation. We have been successful in acquiring US clients who have entrusted us with different parts of their clinical trial life cycle. Having a repertoire of foreign clients in our portfolio is a strong testament of confidence of our competencies as a novel Mexican clinical research firm. We have also expanded in working with nutraceuticals and consulting groups.

In the grander context of the research landscape, how would you evaluate the trend of the CRC market in Mexico and its trajectory for growth?

There are five to seven new entrants in the CRC market in recent times. Although we are essentially competing with each other, we perceive each other as allies in helping the landscape

grow and attracting business to Mexico. The market is growing as reported by PwC and other such reputable consulting firms. It is our collective task to ignite change in some of the regulatory inefficiencies and improve on the current shortcomings of the system. Our key focus today is to reduce the timelines for research in order to attract an influx of trials into the country and gain heightened recognition for the quality that we deliver.

What differentiates iBiomedica from other players in the CRC landscape in Mexico?

In being very cognizant of the shortcomings of the system, we have established the best protocols for mitigating challenges. Although the average timeframe for initiating clinical trials is six months, we can do it in four. We have delegated a select team especially focused on expediting the timeframes that cause many clinical trials to stagnate. Moreover, we have established key point indicators to gain a better understanding of our performance in the market. Additionally, we also have medical promoters which carefully build relationships with physicians in both the public and private sectors in order to communicate the value of the trials to their patients. We are currently the only ones in the landscape utilizing an approach that is similar to the “door-to-door” sales method, as relationship-building is the key to success in a country like Mexico. Our long-term goal is not to remain as a traditional CRC, but to become a research hub for clinical trials.

What are some of your key strategic priorities in the next two to three years and what geographies in Latin America would you like to expand into?

Firstly, expanding our presence within Mexico is a priority. In the next few years, we plan to open a research hospital in Yucatan which will largely be equipped with biotech combability tools as this is a growing trend in generics. Yucatan is strategically positioned as it is a short flight from different US cities, as well as being a short distance from strong Latin American countries such as Venezuela and Colombia. We are also keenly focused on Puerto Rico as it is a country with strong Latin ties, but is fully American in its regulatory requirements. This is an ideal country for us on many fronts and we are prioritizing becoming established in Puerto Rico before anywhere else. Cuba is also another country in our radar, as it is an economy that is opening, but it is further down the priority list.

On a more personal level, what advice would you have given yourself five years ago when you decided to found this company?

Persistence is key. It is important to keep going under any circumstances and be firm-headed in achieving your goals. Despite the challenges, solutions can be found when you believe in your business model. iBiomedica has been the fruit of my hard labour and I believe it is on the right path

for stronger growth ahead.

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