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The genomic revolution represents a before and after in the field of medicine. Sistemas Genómicos has understood this back in 1998 and today is the largest private organization offering DNA and RNA sequencing in Spain. The director for Latin America and country manager for Mexico discuss the unmet needs they have identified on the Mexican market and how the company is interested in creating a local as well as regional knowledge network with the objective of increasingly incorporate genomics into medicine.

Could you please briefly introduce Sistemas Genómicos to our readers?

Dr Mayte Gil Borja (MGB): Sistemas Genómicos was founded in 1998. It is a biotechnology company specializing in the research, development and application of genomic and genetic technologies in biomedicine and for the agri-food sector. Over the years, the company has contributed deciphering keys large genomes model using Next-Generation Sequencing, as well as participated in numerous national and international research projects in personalized medicine. It has built a strong R&D internal culture providing solid grounds for the development of its products and services. In the medical field, Sistemas Genómicos offers an integral array of genetic diagnosis applications ranging from before the conception of a human being, with its mutation carrier screening services, to after its death, studying the genome of dead relatives to identify causes of

sudden death and allow early-diagnosis of family members.

This specialist knowledge of human genetics and medical diagnosis is the one that Sistemas Genómicos is now bringing to the pharmaceutical industry. Its fifteen years of experience diagnosing diseases ranging from heart diseases to cancer, neurologic disorders, osteopathies, collagenopathies, intellectual disability and numerous rare diseases and syndromes, allow it to help selecting patients with specific genetic markers in order to develop pharmacogenetics and precision medicine solutions. Another example of the capacity of the company is the European Union-funded project Venomics, where the company has been key in creating a peptide bank for drug discovery and identification of leads, by using an innovative process reducing discovery times to four years instead of the usual ten to fifteen years.

Mexico is Sistemas Genómicos's first subsidiary outside of Spain. Why Mexico? What opportunities did the company identify in the market?

MGB: After consolidating the company on the Spanish and European markets, the management decided to start an internationalization process to seek for new business opportunities abroad. We already had sales representatives in the UK, France, Italy and in Saudi Arabia, but started evaluating further regions the company could grow into. We thought Latin America could be a natural market for expansion, mainly because – starting from the language – we have so much in common. Even though, with time, you realize there are many aspects, which divide us. Our network of contacts made us understand Mexico could be an interesting option for the first adventure of the company abroad, as the country relies on a very diverse population in terms of genetics and highly qualified human capital.

Christian Sweeney (CS): In Mexico, besides the increasing need for genomic research and services, we have also identified great opportunities in the area of diagnostics for physicians, who need genetic answers to diagnose patients' conditions, especially in case of rare diseases, oncology and cardiology. The company was established two years ago and I have been in Mexico for the last six months. Currently we are mainly a sales-oriented subsidiary, but in 2015 plan to establish ourselves as a Mexican-based laboratory, as the country, as well as the whole American continent, represents a great bet for Sistemas Genómicos.

So, how does Sistemas Genómicos's presence look like in the Americas today?

MGB: Today we have the subsidiary in Mexico, from which we hope to expand the business to the rest of Latin America, as well as sales reps in Colombia, Argentina and Costa Rica, from where we are expanding our business in Central America. Recently we have also opened a subsidiary in

Toronto, Canada, and we are interested in entering the US market. However, to operate in the segment of diagnostics, the US Food and Drug Administration requires us to comply with the Clinical Laboratory Improvement Amendments (CLIA), which require clinical laboratories to be certified by the Center for Medicare and Medicaid Services before they can accept human samples for diagnostic testing. Sistemas Genómicos got the authorization in 2014, so we plan to enter the US market soon.

How would you assess the commitment of the Mexican government with prevention and what bottlenecks do you see compared to Spain and other countries?

MGB: When the city of Madrid, in Spain, started a massive screening for breast cancer, Dr Javier Benitez, our scientific director and soul of many of our developments, approached the prevention councilor of the municipality to make her understand that prevention is key to save lives, but also money in the long term. This is the philosophy behind our product portfolio – we save lives, but also money. I think the Mexican government is moving in the right direction. If we focus on prevention, we can avoid future deaths and save money, which can be reinvested in the health system. Unfortunately we cannot do much for patients, who are already ill, but can for their families and relatives. For this reason, in Spain the company also relies on a Foundation, which has agreements with local patients' associations. The objective is to spread the knowledge and support patients and their families.

CS: One of the main challenges the Mexican health system poses is the fragmentation among different institutions. We overcame this in Spain a long time ago, however here it's still a reality. Also, the percentage of GDP allocated to health is still very low compared to European countries or even other countries in the region, especially considering the growing population and the burden of diseases, which currently affects the country.

How would you assess the status of genomics and its application to medicine in Mexico compared to other countries?

MGB: In Europe we have become opinion leaders in massive genomic sequencing and pioneers in launching GeneProfile®, a study which simultaneously analyzes different genes using massive genomic sequencing and allows medical professionals to provide a very personalized solution to their patients. Personalized medicine for us is not a word, it's a reality – and doctors in Europe have understood very well the value-added of this product. As a matter of fact, in 2014 the company was awarded the 2nd Prize for "European Life Science Awards" as well as the Spanish prize for innovation.

CS: In Mexico applying genomics to medicine still lags behind, but it's improving significantly. We have seen a dramatic change over the past two years and the medical community is increasingly understanding that genetic sequencing services open up a variety of treatment options. Today our objective – and probably biggest challenge – is making the physicians incorporate our products and services into their everyday medical practice.

How are you making sure the medical community in Mexico gets to know the products and services Sistemas Genómicos offers?

MGB: We are creating networks of know-how with KOLs. We just signed an alliance with the Interamerican Society of Cardiology, which is very interested in increasingly incorporating genomic technology to better understand sudden infant death syndrome. Here in Mexico we are working with the National Oncology Institute INCan on an R&D project for Mexican women, who do not react to specific medical treatment. We want to create medical know-how in Latin America, offer something useful to society, share experiences, know-how and best practices. Everyone needs to offer what they are best at, as we share a common concern: patients. This is our philosophy.

What about the pharmaceutical industry?

MGB: We have been partnering up with the pharmaceutical industry for a long time, mainly for R&D and product development purposes. This because having a team focused on genomics is very expensive. We integrate ourselves into the company's product development and value chain as an outsourced department to develop solutions to their needs. Today we are actively offering our services to pharmaceutical companies in Mexico and our letter of presentation is our experience and our accreditations. We do not consider companies we work with clients, but technological partners, because we create synergies from the very beginning.

What further initiatives are you promoting in Mexico and the region to create and share knowledge in the fields you operate in?

MGB: We are creating a high-specialty Master of Science in clinical bioinformatics for Latin America, which is going to start at the end of 2015 and be co-hosted by the University of Costa Rica and the University of Valencia in Spain. We are interested in education and in creating know-how, and for this we need professionals. We already have people applying from Chile and Argentina and are interested in having Mexico's Inmegen (the National Institute for Genomic Medicine) and the UNAM (the National Autonomous University of Mexico) as partners for the master.

Where would you like to see Sistemas Genómicos in five years in Mexico and Latin America?

MGB: I personally believe Mexico is going to explode in genomics! The country relies on highly skilled professionals, state-of-the-art technology and public and private industry work very well together. Furthermore, the needs are there: a large population in need of being diagnosed correctly and current large economic resources lost. If the government includes genomic tools in treatment and prevention, it can save money, which can, in turn, be reinvested into R&D. We see lots of opportunities in Mexico because genomics is crucial for medicine. In Europe we have experienced the industrial revolution, now we are experiencing the genomic revolution. After the learning curve we have accumulated over the past ten years, the genomic revolution is now happening. It's a before and after.

CS: Our objective is to be useful. The company will disappear when this is not the case anymore. We want our services to enrich the country where they are provided, whether it's Mexico or anywhere else. In five years we see us well positioned in the market, known as a company which helps generate and share knowledge in the field of genomics, not only in the medical but also in the agri-food field.

What attracted you to the company?

MGB: I am a biologist, specialized in molecular and cellular biology. I started in the lab and, after having worked in R&D in different companies, I joined Sistemas Genómicos at its very beginning, almost fourteen years ago, to head an R&D project, which eventually turned into an R&D department, which I am still heading besides my activities in business development for Latin America, where we build networks of knowledge and scientific relationships with national as well as international experts with the objective of creating value-added for the sector. We collaborate in large R&D projects at national as well as international level, such as the breast cancer project 'Life'. We raised a fund for EUR 25 million and are developing services and products – even patented products – for breast cancer. The project so far has been mainly focusing on Caucasian women, but our plan is to also expand it to Latin American women.

CS: I have been with the company only for six months, though come from the healthcare sector, where I have been mainly focusing on the implementation of public-private partnerships and hospital management projects, which are currently being promoted as alternative models for Latin America. What attracted me to Sistemas Genómicos was its technological capacity, its terrific human capital and the expansion plans they had for Latin America, a region I have always been

interested in.

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