José F. Rodríguez Orengo – CEO, FDI Clinical Research, Puerto Rico



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José F Rodríguez Orengo is the CEO and Chief Scientific Officer at the Fundación de Investigación (FDI) Clinical Trials, Puerto Rico's main clinical research centre. In this interview, Rodríguez Orengo highlights his priorities of extending the capabilities and also becoming active in the space of public health. He also discusses opportunities to strengthen the local R&D sector on the island.

Can you introduce the FDI to our international readers?

The FDI is a research site with state-of-the-art facilities and medical care clinics with access to a viable patient population for research trials. We have successfully completed hundreds of FDA-regulated clinical trials sponsored by numerous pharmaceutical companies. At FDI, patients receive their primary medical care, and many of them participate in our clinical trials. This active medical care clinic model provides us with a robust pool of potential subjects for our clinical trials and has been instrumental in our enrolment successes.

As we last met the FDI in 2015, could you update our international readers on FDI's capabilities and goals?

Since 2015, we have increased our capabilities to perform phase 1 clinical trials, as we are now able to do fresh-in-human studies, that helped in the development of different products. These include drugs that will be produced here on the island, for instance by Romark. Our data has been forwarded to the FDA, so our sponsor is now able to move forward with the commercialization process.

Another big achievement of the FDI has been its pioneering role in the successful treatment of around 1000 patients with Hepatitis C prior to the approval of the medications; a disease, which today can be cured easily with Sofosbuvir and other compounds. We are now getting more involved with liver diseases, in particular, the hidden epidemic that is fatty liver. We are successfully collaborating with multiple companies doing research and conducting clinical trials, while also providing treatments for hundreds of patients, to avoid the need for liver transplantations. The FDI covers the whole spectrum from phase 1 to phase 3 studies for this disease, which has become a huge health issue in the US in recent years.

We have also grown tremendously in the area of oncology, where we are specialized in immunotherapy, so we offer patients the option to receive treatment in this field in Puerto Rico, which has not been possible a few years ago.

Apart from these activities, there has been a focus on increased branding activities by changing our name from Fundación de Investigación to FDI Clinical Research, as the previous name created a lot of confusion for non-Spanish speakers.

What have been your main priorities since being appointed the president of the FDI?

Our ambition is to be the prime site for clinical research not only in Puerto Rico but also in the Southern part of the US, with the goal to have sponsors from the US to look beyond Florida, when searching for high-quality clinical trials facilities. We also want to incorporate more business features into our operations and to drive forward this process, I took part in the SPS Emerging Leaders program, which essential is a six months MBA program. The final project was to create a three-year business plan, which we applied to the FDI since I have become president in 2016.

We are in the process of expanding our capacities, now offering research activities in nephrology, immunology, gastroenterology beyond liver diseases and even to rheumatology in the near future.

In addition to our core business of clinical research, we are also aiming to become an academic site. A collaboration with Harvard University has been established, in which we have received three

different research project grants from the NIH, one of them being RO1, the most competitive grant of the institute, as well as R21 and a foundation grant. With this help, we conduct public health studies across the island to positively impact Puerto Rico's population. Through the project, we expect to receive data on chronic diseases, environmental issues and nutritional aspects of more than 2000 Puerto Ricans. In July, we will start interventional studies to see if we can modify the nutritional aspects of 100 families, with the goal of preventing diabetes. The majority source of funding remains the clinical research, but we are in the process of diversifying our operations.

Last year we have seen Puerto Rico's first biotech MBQ Pharma being launched. With this development in mind, what is your assessment of the state of R&D in Puerto Rico today?

The Puerto Rico Science, Technology & Research Trust, led by Eng. Lucy Crespo, literally came to the rescue of our researchers, as they created the needed R&D infrastructure on the island, by providing expertise on intellectual property rights and licensing issues. This particularly helps small start-ups in the medical field, like MBQ Pharma, Puerto Rico's first biotech company, as the Trust gave us guidance and helped us to avoid bureaucratic obstacles. In two months, we will also start a new company for anti-cancer agents, so there is definitely movement in the island's R&D ecosystem with more new initiatives being born.

What is needed to see more success stories like MBQ Pharma?

We need to encourage more researchers to take the leap and start their businesses, as people, which mainly worked in academia, might be a bit more cautious and conservative. Today, there is some progress as we have people like Dr José R. Rodríguez Medina leading the department of biochemistry at the University Puerto Rico, who encourages and supports students and researchers to become active in the entrepreneurial environment. This mindset will help to build the right ecosystem necessary for start-ups. I believe we have all the right pieces here on the island, with angel investor ready to devote capital to local R&D projects from Puerto Rico, as they are eager and passionate about supporting us. However, more investment is needed at the academic and industry level to create more success stories. I think we are on the right track, as there are more start-ups in the life sciences field, which are currently using the P18 accelerator program of the Puerto Rico Science, Technology & Research Trust.

How will Puerto Rico’s life sciences industry look like when we will come back for our next report in 2024?

We need a long-term plan for the island’s research ecosystem

Today, the manufacturing industry contributes to around 45 percent of Puerto Rico’s GDP, while research only accounting for 0.8 percent. We would like to see this number grow by four or five times within the next five years, positioning R&D as a significant contributor to the Puerto Rican economy. We see the cuts to public university budgets as a great challenge, as it will most likely impact the research activities. The world’s leading universities have built their reputation due to their research capabilities, so prioritizing research is also crucial to position Puerto Rican universities amongst this group. We need a long-term plan for the island’s research ecosystem.

What are your plans for the FDI?

We want to increase our capacity in other areas of interest, that currently are underserved on the island. Our aim is to be a venue for research initiated on the island, by providing the right environment. We want to be a hub for putting together the motion of research in Puerto Rico.

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