Interview: Maribel Rodríguez-Torres – Founder, President and Chief Medical Officer, Fundación de Investigación, Puerto Rico



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Maribel Rodríguez-Torres of Fundación de Investigación assesses the current R&D situation in Puerto Rico, explains the activities of the center as well as some of their most important success stories. The Fundación is Puerto Rico's largest research center and the only Phase 1 research clinical trials unit in Latin America and the Caribbean.

What is your assessment of the state of R&D in Puerto Rico today?

Fundación de Investigación is the largest research center in Puerto Rico and the only Phase 1 research unit in Latin America and the Caribbean. For this reason alone, we should be conducting more clinical studies; however, R&D in Puerto Rico is still limited. At Fundación de Investigacion we are trying to increase the number of trials that are conducted in Puerto Rico. We have reached the conclusion that to increase local R&D and incentivize drug manufacturers to keep investing in Puerto Rico; we have to actively participate in the early development of new molecules, by becoming a partner of the sponsors.

We are currently in negotiations with companies interested in growing cannabis on the island, and to pursue the development of pharmaceutical drugs including oncology drugs. We are also talking with big pharma companies such as Merck and Pfizer that have local operations to collaborate for

the development of new indications, especially for generics. Unfortunately, we have not achieved much so far. Currently we are working with the Mexican manufacturer Neolpharma, which acquired a former Pfizer facility on the island, to conduct studies for biosimilar drugs. The project has been delayed, but we hope it is going to happen by the end of this year or early next year

Are the right incentives in place to attract investment in the sector?

The government offers incentives to businesses operating in the life sciences sector mainly in the form of tax credits for R&D investments, and operational costs. Unfortunately, recently, obtaining these incentives has been challenging. Local authorities appear to treat local companies and big pharma differently; providing incentives to the big pharmaceutical companies much more quickly. For example, we submitted a request in February of this year and it was approved; however, to date (5 months later); we have not received the funds. These delays have hurt our opportunities to invest in participation with other companies, to develop molecules in Puerto Rico.

What have been some of the success stories that have come out of the Fundación?

We have had many. Fundación de Investigacion has been critical in the development of therapies for HCV infection. In particular, we worked with sofosbuvir (Sovaldi) now Gilead’s blockbuster drug to treat hepatitis C. I have personally been an adviser to the drug company (Pharmasset) since the beginning, and participated in the design of the development plan from A to Z, choosing the studies to be conducted and the population to be used. Our site was the first place where the drug was tested in combination with Pegylated IFN and RBV, and five out of the six enrolled patients were cured.

Although our success in the drug development of Sovaldi is probably our most important accomplishment, we have worked with several other companies as well. We have conducted multiple Phase 1 studies for Pharmasset, later Gilead, and for multiple other sponsors like Merck, Bristol, AbbVie, Johnson and Johnson and many others.

We are also very proud of our contribution to cure patients while their participation in clinical research. We cannot forget the real life outcomes of many patients cured. We cannot forget the money the government saved in health care costs because improved patient management, a fact that sometimes gets lost when talking about research, manufacturing and costs. We have cured and saved more than 3,000 patients with hepatitis C infection with our clinical research program and this is a tremendous achievement!

It is very surprising to hear that Fundación de Investigación is the only Phase 1 research center in Latin America and the Caribbean. Why do you think this is the case?

The main reason is that Puerto Rico is FDA regulated. That is a fantastic advantage, and a main reason for many foraneous companies to contract us. We are the only territory where you can engage in both US-regulated and Global research. Latin America sites are very limited in this sense. Still, I often complain that many pharmaceutical companies that already own Phase 1 facilities elsewhere in the world prefer to do the early trials in-house, and then conduct the early studies in countries such as the Netherlands, Australia or New Zealand, because the requirements are less strict than to conduct those trials under FDA.

In terms of patient recruitment, is it easy to find the right people to enroll?

We do not have any problems. It is interesting because the population of Puerto Rico is very open to medical research. In Puerto Rico, the population has a cultural preference for a dedicated relationship with physicians, and to participate in clinical trials provides a robust and intense relationship with a physician. Hence, it is uncommon for patients to refuse to enroll in a trial, and our study trial attrition is very low. For example, two years ago we announced in public media that we needed normal volunteers for a Phase 1 study, and within 24 hours, we received more than 300 contact requests. We ended conducting clinical evaluation and running tests for 250 people, and now have a database of 200 normal volunteers. Our population is different from the population that you can find at Phase 1 centers in the US. Those centers have many “professional volunteers” who do that for a living and even fly from one state to the other to enroll and are mostly males. Our normal volunteer database is 50% female, and this is preferred by sponsors. Compliance and adherence are excellent and the follow-up is personalized.

What are your plans for the Fundación?

First, we expanded into other therapeutic areas. We have now a strong program in Oncology, Infectious Diseases and Inflammatory and Neurological diseases.

Nevertheless, most importantly, we want to develop molecules. I think this is the next big opportunity for Fundacion de Investigacion; to grow and conduct research that starts and ends here. During the past year, we have implemented a different approach: we have started suggesting new research developments to companies. We have been exploring ways to become a partner of the sponsors, by investing in the companies. We have been working aggressively and are surprised about how productive this approach has been. We expect that by 2016, we will be conducting research with molecules where we have part ownership. We are convinced that this approach will

increase the opportunity for drugs to end being manufactured in Puerto Rico and creating more jobs.

I expect R&D to continue to receive incentives, and those incentives to be available to local companies as well as to foraneous companies. With the population of 3.5 million, Puerto Rico should have more robust clinical research sites and more R&D initiatives at universities. Unfortunately, clinical research is minimal at academic centers, and only of importance at private organizations like Fundacion de Investigacion and CDI Laboratories, the best proteomics lab in the world. Clinical Research should be actively included in the medical education, as we have incredibly talented people in the island. Probably this is the best we have to offer to the world, our gifted human resources that are willing to stay in Puerto Rico and work hard to make any project a success.

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