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Dr Amarilys Silva-Boschetti and Dr Miguel Vázquez-Padua of the Puerto Rico Consortium for Clinical Investigation (PRCCI) underline the various benefits for pharmaceutical, biotechnology and medtech companies to conduct clinical trials in Puerto Rico. They also highlight further steps of how the Consortium, which is part of the Puerto Rico Science, Technology & Research Trust, will aim to transform the island into a global hub for clinical research and investigation.

The PRCCI was founded as part of the Puerto Rico Science, Technology & Research Trust in 2016. What is the goal of the consortium?

Amarilys Silva-Boschetti (AS): The objective of the consortium is to expand and enhance clinical research in Puerto Rico, as the island has many capabilities, which can attract sponsors. We are part of the Puerto Rico Science, Research and Technology Trust, which has prioritized driving forward clinical trial development on the island. PRCCI is a not-for-profit cooperative of top academic and private research sites. Our world-class research sites are our key assets and they are investing in this initiative for sustainable and tangible benefits for their businesses. Our vision is to

position Puerto Rico a global hub for clinical research and investigation.

Which stages of clinical trials can be conducted in Puerto Rico?

AS: Our institutions have the capability to conduct clinical trials from phase 1 to phase 4, the most frequent ones are phase 2 and phase 3 trials. Puerto Rico has been involved in clinical research since the 1960s, and there have been many success stories over that time, for example in relation to HIV treatment. For our trials, we are looking to attract a mix of companies from big pharmaceutical and medical device companies to small and medium-sized biotechs from the US, Europe and across the globe.

Miguel Vázquez-Padua (MV): We also have been involved in observational and real-world experience studies both in pharma and medical devices as well. In the 1960s, the Medical Sciences Campus of the University of Puerto Rico was called Tropical Diseases School of Medicine, as its main focus was on tropical medicine and infectious diseases. While we have significant expertise in these treatment areas, we have developed a broad, diversified portfolio in various medical areas.

What are some the advantages and benefits of conducting clinical trials on the island?

AS: We have a long history of success, implementing clinical research from the standpoint of pharma and medical devices as Many of our investigators have been trained in the US and have a wealth of clinical and research experience. Our island is a territory of the US and hence has processes and operations that fall under FDA regulations. Additionally, we have a strategic location, being situated between the Americas. We are a primarily Hispanic population which is an opportunity for sponsors to recruit a population that will contribute to diversity in clinical research. Puerto Rico has four accredited schools of medicine. There is also a training initiative at PRCCI, where we provide education to clinical research centers on the island, to keep them up to date in terms of clinical research activities.

MV: There is a high population density on the island, so access to clinical trial sites for patients is rather easy. The patient-doctor relationship is also unique. Puerto Rican patients are treated by Puerto Rican doctors, different from the mainland US, where Hispanic patients may be treated by doctors from a different ethnicity and language, which may affect the nature of the relationship. In Puerto Rico, there is not a significant cultural gap. There is a special relationship between investigators and patients and, hence, excellent recruitment and retention rates. The performance

of our clinical trials also speaks for itself, as our sponsors expect the exact same standards when conducting trials here as on the mainland US. This includes the same academic and professional preparations, certifications and the credentials of the investigators

Is it hard to find patients that are willing to sign up for trials?

MV: An important difference compared with other places is that, Puerto Ricans are generally open and willing to participate in clinical trials, as they see it as an opportunity to receive the best and most innovative medicines. PRCCI works closely with patient advocacy groups, as it is important for us that patients are aware of what clinical trials are about and how they contribute to medical progress.

How do the costs for clinical research and investigation in Puerto Rico compare to other countries in the region?

MV: It really depends on the types of clinical trials conducted, but in general some may have a similar budget to US sites, while others may be cheaper here than conducting them on the mainland US or in Latin America. One advantage is our flexibility and ability to start clinical trials very quickly. Clinical trials in Puerto Rico do not have to go through a customs process like it is the case in other countries, as we are already covered by the FDA.

AS: Speed of execution is a crucial advantage of clinical trials in Puerto Rico and we have examples of pharmaceutical companies approaching our investigators to learn how we manage recruitment in Puerto Rico. In an experience with a particular sponsor, study team members visited the site and they were amazed by the rapid pace of recruitment, as it was the fastest and top recruiter globally.

What are the next steps for PRCCI to further promote the clinical research landscape of Puerto Rico?

MV: We will continue to share our capabilities, expertise and history to educate companies in the US and the world on the current situation of Puerto Rico. We have faced some companies that have a perception about our infrastructure in Puerto Rico as being limited or suboptimal poor. While this may be true in certain rural or remote areas, the island has been back to business in clinical research within days after Hurricane Maria. Today, Puerto Rico’s sites have contingency plans that

significantly minimize any potential disruption of operations due to natural disasters or other unplanned situations. It is time for us to strongly communicate this message to the world.

We are also committed to strengthening our pipeline of investigators, as we work with people even before they become pharmacists, physicians or other health professionals. In May, we hosted our Clinical Research Summit, which was attended by over 360 people, amongst them many students from the medical and science field, presenting their studies on posters. We are also encouraging student exchanges between the mainland US and Puerto Rico, to develop the next generation of clinical investigators, which will have a positive impact on global healthcare.

AS: PRCCI has a responsibility for Puerto Rico to ensure the sustainability of clinical trials, medical education and research, nourish the ecosystem in the early stages, and attract more young people to this field. We are developing partnerships with universities to integrate the clinical research component into the curriculums. At the same time, we are working with Puerto Rico's Department of Economic Development and Commerce (DDEC) to implement a program to train people who are changing their profession or job role or position. One key target are those professionals who have been displaced from their jobs and want to enter the clinical research industry. We do this by offering training courses, so they can be part of the clinical research workforce.

Both of you have had a long career at global heavyweights in the pharma industry. What has been your motivation to switch sides and join PRCCI?

AS: After working 20 years in several areas of the pharmaceutical industry including manufacturing, positions in corporate offices in the area of clinical affairs, regulatory compliance and global pharmacovigilance in the US, I decided to come back to Puerto Rico to bring the knowledge and experience obtained over the years back to my country. Upon my return, I continued to work for 12 more years in big pharma in the area of clinical and medical affairs and started contributing to clinical research projects, until I was approached to participate in a clinical trials initiative in Puerto Rico about five years before the PRCCI was created. When I had the chance to lead the PRCCI, which I worked for as an advisor, I felt the need to seize this chance, in order to provide continuity for the PRCCI, with the goal to grow its activities and footprint. To me, PRCCI is a country initiative and I embraced the responsibility to drive this project forward to continue enhancing the quality of clinical research and development for the benefit of patients, the Puerto Rico economy and global scientific innovation.

MV: My background is in science and research, so this is part of who I am. My experience in the industry showed me how medicines are developed and used, and the life-changing effect they can have on patients and communities. To me it was shocking to see Puerto Rican families taking out personal loans and using their life’s savings to be able to go to the US and participate in clinical trials. In some cases this was their last hope for improving a health condition or even continuing to live. Hence, I am strongly committed to bring these possibilities to Puerto Ricans on the island to improve their health, lives, and contribute to Science and Medicine. My position at PRCCI is a great way to do this.

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