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The Puerto Rico Consortium for Clinical Investigation (PRCCI) is a non-profit organisation offering specialised clinical trials services. Executive director Dr Amarilys Silva-Boschetti shares key developments since she last spoke with PharmaBoardroom in 2020, including the creation of a new clinical research centre with trials set to begin in 2024 and the implementation of an economic study that revealed the USD 50-million impact of clinical research on the local economy. She also explains the PRCCI's ongoing efforts to enhance workforce development and onboard physicians, and weighs in on the new FDA diversity rules, and the potential of new tax incentives to boost Puerto Rico's role in clinical research.

To begin, could you provide an update on what has been happening at the PRCCI since our last interview in 2020?

A great deal has transpired here since then. Surprisingly, we found the pandemic period to be a time of opportunity. While it was challenging for many, we were able to collaborate with various sponsors in the pharmaceutical industry, facilitating several trials in Puerto Rico, including vaccine studies.

During this time, we also focused on developing new talent, which is a key aspect of our mission. We launched a remote version of our clinical research coordinator training programme, allowing us to expand our reach. Additionally, we began engaging with various partners across different industries, which led to the establishment of a new clinical research centre. This initiative aimed to support investigators in Puerto Rico who wished to pursue clinical research but were hesitant to invest in establishing their own sites.

We completed our assessment process by the end of 2022 and received approval at the start of 2023 to establish a research site at the Innovation Centre of the Puerto Rico Science, Technology and Research Trust. Our vision was to create a supportive environment for both seasoned mentors and interested newcomers to clinical research.

We were able to complete the site in record time by August 2023. This state-of-the-art facility is now equipped to start hosting trials from January 2024. Our collaboration with external partners helped shift our focus from merely supporting existing sites to developing a central location that fosters growth and collaboration with the pharmaceutical, medical device, and biotech industries.

We committed to conducting an economic study to evaluate the impact of clinical research in Puerto Rico, led by Dr. Mario Marazzi, a respected economist. The study sought to quantify the economic activity generated by our efforts, revealing that in the 2020-21 fiscal year, the clinical research industry contributed around USD 50 million to the local economy, with USD 27 million from direct impact and the remainder from indirect effects. â?? figures we previously had no means to measure.

PRCCI is at the forefront of developing clinical research centres on the island. It is essential to have trained clinical research coordinators, as they play a pivotal role in conducting trials. Our efforts not only aim to expand clinical research but also support facilities across Puerto Rico, ensuring they have the resources they need to thrive.

How many clinical research professionals have you trained, and what initiatives do you have in place to enhance workforce development in this field?

We have trained over 220 clinical research professionals in Puerto Rico, and I am proud to say that all of them are currently employed. This success underscores the growing demand for trained individuals in clinical research. To further enhance our workforce, we have established partnerships with nursing schools across the island, recognising that many nursing professionals are well-suited to transition into roles as clinical research coordinators. For instance, we will be welcoming a group from Universidad Sagrado CorazÃ³n to discuss these opportunities with students in scientific disciplines.

The last time we spoke, you mentioned developing partnerships with universities to integrate clinical research into the curriculum. Is this the type of initiative you are currently working on?

We are developing a certificate programme that offers credits for professionals seeking to obtain credentials in clinical research, ensuring they remain competitive in the job market. Puerto Rico boasts several accredited institutions, including two schools of pharmacy and four schools of medicine, providing a solid foundation for cultivating talent in this area. We are also aiming to attract retiring doctors who wish to continue contributing to the field, as their experience can greatly benefit clinical research.

Importantly, our training programmes are accredited by TransCelerate, a non-profit organization focused on improving the efficiency of clinical trials and the drug development process which recognises the quality of our clinical research coordinator and investigator training. This accreditation means that our programmes are acknowledged by all pharmaceutical companies associated with TransCelerate, making us the only institution in Puerto Rico with such recognition. This ensures that our graduates are well-prepared to meet the demands of the industry.

What level of opportunity do the new FDA clinical trial diversity rules represent for Puerto Rico, particularly given its primarily Hispanic population?

The new FDA clinical trial diversity draft guidance represents a significant opportunity for Puerto Rico. Historically, the representation of Hispanics in clinical research has been quite low, often comprising only 1-2 percent of total participants in trials. With the implementation of this new draft guidance, we can expect greater visibility and involvement of our unique population in clinical trials. Puerto Rico is renowned for its rich genetic diversity, which is crucial for understanding how different genetic combinations may respond to various drugs. This unique aspect positions Puerto Rico as an attractive site for increasing Hispanic participation in clinical research before drugs are approved.

What tax incentives are available for R&D that make it a cost-effective destination for clinical trials compared to other Latin American countries?

Puerto Rico offers exceptionally appealing tax incentives for pharmaceutical companies engaging in research and development. Currently, companies can receive a tax credit of up to 50 percent on their investments in Puerto Rico, contingent upon presenting data that supports the impact of R&D investments. While this is a common practice in manufacturing, it is more challenging to demonstrate in clinical research. Nonetheless, a 50 percent tax credit is extraordinarily attractive and not something typically found in other Latin American countries.

Specifically, the Puerto Rico Tax Act 60, also known as the Puerto Rico Incentives Code, consolidates various tax incentives, including those for businesses engaged in clinical research. Some key aspects of Act 60 for clinical research are tax credits for R&D and exemption from income taxes. To qualify, companies need to demonstrate that their activities meet the definition of qualified research, which often includes a focus on innovation and development of new products or processes. Companies must ensure compliance with all local regulations and filing requirements to take full advantage of these incentives. Benefits under Act 60 can vary in duration and may require periodic renewal or demonstration of ongoing compliance with programme criteria.

You raised an important point regarding human resources, particularly the shortage of healthcare workers globally. This often results in heavy workloads for physicians, making it difficult for them to engage in clinical trials. How is the situation in Puerto Rico, and how is PRCCI addressing this challenge?

Many physicians in Puerto Rico are deeply committed to their practices, dedicating long hours to patient care. Introducing opportunities for them to participate in clinical research can enhance the diversity of their professional activities and may encourage them to remain on the island rather than relocating to the mainland United States.

PRCCI is dedicated to providing the necessary infrastructure to support physicians in this endeavour. We assist them by managing the clinical trial protocols and ensuring they have a clinical research coordinator, research nurse, and lab technician on-site to facilitate the process. Our approach allows physicians to remain engaged in patient care while contributing to clinical trials without overwhelming their schedules.

Participating in clinical research not only enriches their professional lives but also allows them to offer innovative therapies to their patients. In fields like oncology, for example, clinical trials often represent the only treatment options available to patients. By conducting these trials in Puerto Rico, physicians can provide their patients with new therapeutic opportunities, thereby enhancing their practice and professional recognition.

Regarding the economic impact of clinical research, we have previously estimated it to be around USD 50 million based on a study conducted in 2021. While we plan to update this data soon, we believe that the current impact has grown significantly, likely exceeding USD 15 million. We are continuously looking for ways to measure and report this growth, reinforcing the value of clinical research in our community.

Given all the initiatives you are currently implementing, do you have any projections for the future impact of clinical research in Puerto Rico?

To be honest, we do not have a precise projection at this time. While we are making significant efforts, it is important to be responsible with the data we present. Each time we bring a new trial to Puerto Rico, we impact various sectors—imaging centres, laboratories, and the recruitment of new physician-scientists. The infrastructure we establish also plays a crucial role in this growth.

However, I can say that the opening of our centre has generated considerable local activity and media attention, setting a positive tone for how clinical studies are conducted in Puerto Rico. We aim to ensure that these studies adhere to rigorous standards and transparency. Historically, there has been scepticism surrounding clinical trials here, partly due to past instances where patients were not treated ethically or transparently.

Our goal at PRCCI is to establish trust and ensure compliance with Good Clinical Practice (GCP) guidelines. We have a dedicated team, including regulatory professionals, to oversee this process. Recently, we underwent our first review by a pharmaceutical company for trials already running at our site, and I am pleased to report that there were no observations noted during that review. This reflects the hard work and commitment of our staff since PRCCI's inception in 2016, as we strive to maintain high-quality standards and support our clinical sites throughout Puerto Rico.

How many clinical trials are currently being conducted at PRCCI?

Currently, we are engaged in several trials. We have a significant programme with the National Institutes of Health (NIH) that began in March of last year. This initiative aims to collect one million samples from diverse patients across the US and Puerto Rico. Our goal for this year is to enrol 790 participants in this programme. This is a crucial effort, as it allows us to request access to the data collected and analyse it to develop potential cures or new treatments for various diseases.

In addition to the NIH programme, we have signed contracts for four clinical trials—two focused on obesity and two on migraine treatment. These initiatives reflect our commitment to advancing clinical

research in Puerto Rico and providing valuable opportunities for both participants and researchers.

If I were to return in four years, what changes might I see here at PRCCI?

In four years, we envision having our own dedicated building for PRCCI. This facility would enable us to consolidate our efforts, with distinct floors designated for various functions— one for regulatory and training, and another for clinical trials across different therapeutic areas. Our aim is to create a comprehensive hub for clinical research in Puerto Rico.

I believe that, over this period, Puerto Rico could become a significant player in the drug development value chain, integrating research, manufacturing, and clinical trials. Clinical research is central to this process, sitting between discovery and market approval. Unfortunately, many people are unaware of the robust activities happening here. Our goal is to increase visibility and showcase our capabilities to the global market.

The turning point for us came right after the pandemic, when we recognised the need to elevate our presence in the US market. With support from partners like Latin2Latin, we have begun to emerge in the US market. Additionally, we are actively exploring opportunities with companies from other countries that are interested in conducting trials in Puerto Rico. This momentum is promising for the future of clinical research and development on the island.

You have been with PRCCI for nearly seven years now. What continues to interest you about your role?

It has been almost seven years, and I came here with a very specific mission: to develop PRCCI and enhance clinical research in Puerto Rico. This was no easy task initially, but I embraced the challenge. It has driven me to expand our initiatives, leading to the establishment of our Clinical Research Center and various other projects.

What truly motivates me is the knowledge that there is still so much work to be done. I am passionate about helping our professionals and patients in Puerto Rico access innovative treatments and ensuring that our island is recognised globally as a preferred location for clinical research.

Is there any final message you would you like to convey to our global readers?

I want to encourage the global community to view Puerto Rico as a viable opportunity for the development of their products and projects. Our island has a wealth of resources to offer, and we are seeking the same opportunities in clinical research that we have successfully pursued in manufacturing.

Additionally, it is important to highlight that Puerto Rico boasts a highly educated population. We are actively working on initiatives to develop programmes that will prepare talent in health and science fields. With four accredited medical schools and numerous universities offering health professions, we are well-equipped to meet the needs of the industry. The opportunities here are real, and the success we have seen in manufacturing serves as a testament to what can be achieved in other sectors, including clinical research.

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