

Puerto Rico Consortium for Clinical Investigation



NEWSLETTER

& November
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Any questions? Please contact us via contact@prcci.org

A program of:



Puerto Rico
Science, Technology
& Research Trust

30th Annual Meeting of the Pharmaceutical Industry Association of Puerto Rico (PIA)

PRCCI participated at the 30th Annual Meeting of the Pharmaceutical Industry Association of Puerto Rico (PIA). The event was held on November 7th at the Sheraton Convention Center and Hotel in San Juan. This year's theme was "Faces of Innovation Advancing the way Science Cares for Patients". At this meeting, the latest tendencies of biopharmaceutical innovation were presented. It was a great opportunity to promote and exchange ideas and best practices among members of the pharmaceutical industry as well networking and gaining valuable contacts.



PharmaBoardroom Features PRCCI

The screenshot shows the PharmaBoardroom website interface. At the top, there is a navigation menu with categories: Country Reports, InFocus, Europe, Asia-Pacific, Americas, Middle East & Africa, and Legal & Regulatory. Below this is a secondary menu with: Contributions, China, Biotech, Biosimilars, Mid-Caps, News Releases, Directory, and Shop. The main article title is "Amarilyn Silva-Boschetti – Executive Director & Director of Operations & Miguel Vazquez-Padua – Business Development, Puerto Rico Consortium for Clinical Investigation (PRCCI)". To the right of the title is a "SAVE" button. Below the title are two portrait photos: one of Dr. Amarilyn Silva-Boschetti on the left and one of Dr. Miguel Vázquez-Padua on the right. To the right of the photos is a text block: "Dr Amarilyn 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." Below this text is a quote box: "Puerto Rico has been involved in clinical research since the 1960s, and there have been many success stories over that time".

In the link below, the Puerto Rico Consortium for Clinical Investigation (PRCCI) is featured in an article by the prestigious PharmaBoardroom. Dr. Amarilyn Silva, Executive Director and Dr. Miguel Vázquez, Operations and Business Development Director 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. In the interview, they also shared the consortium goals, the advantages and benefits of conducting clinical trials in Puerto Rico and what motivated them to switch from Pharma to Clinical Research and join PRCCI.

Interview link - <http://bit.ly/36VLuRo>

"It was an honor to participate in such a prestigious publication and to be able to portrait the clinical research landscape in Puerto Rico"

————— *Amarilyn Silva, Pharm. D.*



Highlights from Operations and Business Development: End of the Year 2019 Edition



It is amazing how quickly we have come to almost the end of this year. As you have read in other sections, this has been a year of many accomplishments for the PRCCI community and the Puerto Rico research ecosystem. Working together as a community, we have been able to meet key objectives and goals. Of course, there have been changes and challenges that we have managed and others that we continue to address. The net result is a stronger PRCCI community with new clinical trials, study opportunities, investigators and clinical research units. Our appreciation to all as a group effort!

In this last PRCCI Newsletter for 2019, the Operations and Business Development team focused on new trends and expectations in clinical research for the new year. Many thought leaders in our industry believe that 2020 will continue to be a very positive one for

- clinical research and advances in Medicine, including pharmaceuticals targeting many chronic diseases and conditions with a significant impact on our patients. New technologies continue to emerge, impacting a key objective of innovation. A great example is the new concept of chimeric antigen receptor T-cell or CAR-T cell products. Another highly promising new approach is gene editing using the CRISPR-Cas9 technique. Although still under development, scientists have already learned about this defense system in bacteria. It was discovered as a way that bacteria can manage invading bacterial viruses. Many leaders envision this area as one of the most promising ones for gene editing in cancer and other diseases. Another exciting research area is developing new mechanisms to impact several rare diseases and other conditions that have eluded major recent advancements.

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For example, and other neurologic conditions will benefit from the knowledge that new genetic tests can bring to investigators. Genetic testing will continue to increase and evolve, especially as investigators apply them to diseases in which there may be multiple genetic risk factors.

Clinical trial design and implementation will also continue to evolve. There is a high level of expectation within our industry on the potential impact of virtual clinical trials. This will bring important studies closer to patients in different types of settings. It can also improve operational efficiencies at clinical study sites and centers. Sponsors and organizations could also see a positive impact on timelines, access to diverse populations, new researchers with improvements in total costs of clinical trials. Of course, this is an expectation that remains to be proven.

- We would also like to focus on the importance of volunteering for a clinical trial. As described in the NIH website, the objective of a clinical trial is to determine how effective and safe the treatment is and how it is best delivered. In clinical trials, a wide range of new interventions can be created, including drugs or their combinations, medical devices, new surgical procedures, diagnostic tests, gene therapy, or various ways of using existing treatments. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.

Our strategic alliance partner, Yale Center for Clinical Investigation (YCCI) has also gathered some great information on their website on why to volunteer for clinical trials. Below are a couple of reasons as indicated in their website:



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1. Some people have a condition that is being treated effectively but still want to assist in developing new treatments.
2. Sometimes people have a friend or loved one with an illness or injury and they want to participate in a research study as a way of helping that person and others who may suffer from the same condition.
3. It may be that there is no effective treatment for an illness or injury or the existing treatment has harsh side effects. Participating in a clinical trial may offer potential treatment options that might otherwise be unavailable.
4. Many people choose to participate in a study even though it might not be able to help them directly. Knowing that others may be able to benefit from their efforts can be a rewarding experience.
5. Sometimes people volunteer because they are compensated for their time and effort.

- As a final recommendation to the PRCCI community, it is very important to keep pace with the new information and trends in our industry as well as your specific therapeutic area of interest. There are many ways to achieve this objective: participate in webinars, seminars, join professional societies and attend critical scientific meetings and congresses. Knowledge is power... a slogan this is true in clinical research. Our PRCCI teams look forward to addressing your questions, needs, and to support the efforts towards a stronger clinical research community for the benefit of our patients and communities.

If you would like to know more about clinical trials or how to participate, please visit us at www.prcci.org

Sources:

<https://medicine.yale.edu/ycci/clinicaltrials/volunteer/>

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/why-should-i-participate-clinical-trial>

<http://prcci.org/>

Monthly Quality Corner



This month PRCCI's quality team reviews 2019 achievements!

2019: A Spirit of Excellence!

Building a quality culture at the clinical trial site level begins with knowledge. In 2019, PRCCI focused in building a firm foundation for best practices by supporting our site members expand and optimize their quality systems.

This year PRCCI's quality team partnered with each of our site members to take quality to the next level. Our diverse roster of site members includes private practice, academic centers and specialized clinical research units. PRCCI's quality team provided quality support to sites individually based on their specific needs to assure their internal quality processes were operating optimally. Our main focus was to promote Good Clinical Practice (GCP) compliance, operational excellence and best practices.

PRCCI members are moving forward by optimizing their site capabilities and improving their quality systems for 2020. As the sites embrace these changes, they will be enhancing their quality system to improve Sponsor-Investigator relationships through the delivery of quality data, start-up timelines and risk based quality management systems.

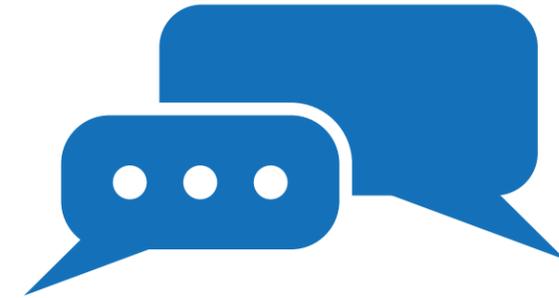
The PRCCI quality team is committed to help site members adapt to the ever-changing world of clinical research, by providing insight to current and emerging trends. We have encouraged site members the implementation of risk-based thinking to ensure risks are considered from the beginning and throughout the quality process approach. Risk-based quality management systems provide pro-active action as part of a strategic planning by helping identify opportunities of improvement.

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Through the course of the year PRCCI's quality team was able to provide site members with continuous education, such as: GCP training, Yale Center for Clinical Investigation (YCCI) quality assessment visits, Blue Cloud training and YCCI clinical research workshops. We look forward to continue helping our sites reach their full potential and continue exceeding expectations.



Let's Talk!



Taking steps towards an effective risk-based quality management system can be challenging. PRCCI is here to help! To learn more about all aspects of a supportive quality management system, reach out to PRCCI's quality team. We look forward to assisting PRCCI member sites in achieving a spirit of excellence in 2019. For quality support, please reach out to our Quality Team, Jarmary Torres and Michelle Martinez at jarmary.torres@prcci.org and/or michelle.martinez@prcci.org.



2020
**HAPPY
NEW
YEAR**

This holiday season, we are looking back with appreciation for your loyalty and looking forward to moving into the New Year together.

HAPPY NEW YEAR!