

Puerto Rico Consortium for Clinical Investigation



NEWSLETTER
June 2019

043



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

A program of:  Puerto Rico
Science, Technology
& Research Trust

PRCCI Team at BIO 2019

Our team continues to search for study opportunities for our Consortium members in several types of forums. PRCCI took active participation at BIO (Biotechnology Innovation Organization) International Convention 2019, which was held at Philadelphia from June 3-6th. The BIO organization represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the USA and more than 30 other countries. Along with members of INDUNIV, PIA, Academic Institutions, Government and Private Sector, the delegation from Puerto Rico proudly represented our island and the many opportunities for business and partnerships at the great Puerto Rico Pavilion.

This Convention gave us an unique opportunity to identify potential sponsors and partners, to network and bring innovative research to Puerto Rico, and the members of our Consortium. This year, the BIO 2019 theme was “It Starts with One.” It is aligned to who we are as it highlights the potential for game-changing impact of small and consistent efforts that can have a global effect. We know that this effort will be well invested for our community of clinical researchers.



Executive Director, Amarilys Silva, PharmD being interviewed by Fabian Sandoval, MD for his show "Tu Salud, Tu Familia" at BIO Convention in Philadelphia.

The topic discussed at this interview was about the vision of PRCCI expanding clinical research in Puerto Rico.



Leader's Summit-Puerto Rico- Free of Cancer Associated with HPV

.....

Amarilys Silva, PharmD, PRCCI's Executive Director appreciates the opportunity to moderate a panel focused on creating a clinical research agenda at "Cumbre de Lideres-Puerto Rico-Libre de Canceres Asociados a VPH". Distinguished investigators: Dr. Josefina Romaguera, Dr. Ana Patricia Ortiz and Dr. Shayanne Lajud shared relevant data as well as their perspectives around this subject.





GK Pharmaceuticals CMO

PRCCI was present at the inauguration of the first biopharmaceutical funded by four Puerto Rican women. GK Pharmaceuticals CMO is dedicated to the production of biosimilars, antibody monoclonal, vaccines, genetic therapies - which are a permanent alteration of the sequence of deoxyribonucleic acid (DNA) which consists of a gene - and protein therapeutics, among other products. This pharmaceutical aims to provide the highest quality of products and develop services, through the combination of experience, resources, and solutions for the life sciences. Amarilys Silva, PharmD, PRCCI's Executive Director was present at the event.

"I appreciate the opportunity to share such a special and emotional moment, as it was the inauguration of GK Pharmaceuticals CMO, with its management, employees, family members, government personalities and others. This organization has made history as the first biotechnology company founded in the United States and Puerto Rico by Puerto Rican women. We admire the commitment of its founders to improve the lives of patients by integrating innovation with the academy, creating jobs and strengthening the economy of Puerto Rico. At PRCCI, we wish you the greatest success!"

- Amarilys Silva, PharmD

Click below for more information.
<http://bit.ly/3259PBZ>

Drug Information Association Global Annual Meeting

PRCCI's Director of Operations and Business Development, Dr. Miguel A. Vázquez Padua, attended the 2019 Global Annual Meeting of the Drug Information Association (DIA) held at San Diego, California from June 23-27, 2019. DIA is a global association of life science professionals from many areas of expertise to engage patients, peers, and thought leaders. The DIA Global Annual Meeting provides educational sessions and various types of venues to foster discussions, exchanges of best practices and meaningful networking opportunities among stakeholders that will lead to actionable insights towards the improvement in global health through the advancement of lifesaving medicines and technologies. This special event gathered participants who are key stakeholders from different countries, therapeutic areas, types of institutions, and disciplines. It was an excellent opportunity to meet and connect with leaders from different organizations and companies whose services and products can contribute to further PRCCI's mission and vision as well as strengthen our Consortium. This event also provided an opportunity to learn about recent trends in our industry and new initiatives from the USA and other global regulators. We will see a positive outcome of our participation within the next few months.



Highlights from Operations and Business Development: June 2019

In this issue, we want to focus on a new collaborative effort of PRCCI to continue to enhance our capabilities, tools and more effective ways to support our clinical trial sites. On June 25th, a press release was published to announce a new partnership between PRCCI and BlueCloud, a strategic alliance that will have immediate positive effects on our Consortium sites. Below are key excerpts from the press release:

BlueCloud by Healthcare Point

BlueCloud by Healthcare Point (HCP), a Texas-based healthcare and clinical research networking technology company founded by patient survivors began the collaborative effort to bring BlueCloud technologies to investigative sites for the purposes of clinical research readiness and economic opportunity for Puerto Rico and the Dominican Republic. With the support of the local Puerto Rican government, the cooperative of top academic and private research sites known as PRCCI, will act as distributor for BlueCloud Quality Management Systems and its DDIT mechanisms. The site network strategy will include the implementation of BlueCloud technologies which will enhance the educational opportunities, market visibility and quality of life for patients and clinical practitioners.

Continuation...

Dr. Amarilys Silva, PharmD, PRCCI’s Executive Director, indicated that “BlueCloud Quality Management Systems are essential for PRCCI to bring additional capabilities such as standards of care to clinical practice and research. The BlueCloud technology will help us to maximize our options to connect with the global research ecosystem, enhance our local clinical research capabilities for the benefit of patients, the Puerto Rican economy and to support global innovation.

Moving forward:

At PRCCI we are working with BlueCloud and our Consortium members to promptly configure their information in this platform. Our teams are aligned on a fast and smooth transition to enhance further access to global clinical trials, an important element for our patient community, and addressing one of our key objectives on bringing innovative alternatives to patients and our healthcare community.

To view the full press release, click below:
<http://bit.ly/2Npgm7l>

Monthly Quality Corner



2019: A Spirit of Excellence

Each month in 2019, this space will be dedicated to exploring how clinical trial sites can optimize to conduct clinical trials with a spirit of excellence. As PRCCI acknowledges Men's Health Month, we dedicate our focus for the month of June to applying preventative care measures at the clinical trial site level to manage quality.

Small Steps, Big Results

Implementing a quality management system at the clinical trial site level can seem like an overwhelming process. Even small, resource limited sites can identify areas of improvement and implement components of an overall quality management system. Sites that take ownership of their data quality are attractive to clinical trial sponsors and CROs. Regardless of size or resources, clinical trial sites can take three basic steps towards implementing a quality management system without delay:

Step 1: Look for ways to integrate quality control components into existing processes. For example, sites can review existing data collection worksheets and include quality control checkpoints to be evaluated prior to the close of a protocol-specified subject visit. This supports the collection of any missed data prior to the clinical trial subject's departure from the site.

Step 2: Integrate quality and training components into regular or existing meetings. For example, an existing regularly scheduled staff meeting can be optimized to include agenda items that support quality. Sites can formalize discussions regarding protocol deviations, the root causes, and preventative actions by adding an ongoing agenda item to the staff meeting agenda.

Continuation...

Step 3: Strive to connect the dots. For any quality issue that occurs, determine all associated processes and review them for process improvement. For example, was a protocol deviation or finding the result of an SOP that needs updates? Does the existing process work well but more training is necessary to ensure that the research staff is managing procedures properly? The FDA wants to see sites applying lessons learned from errors and deviations at a system level, across all studies. Building in a quality component that connects the dots supports holistic site quality and protects the rights, safety, and welfare of clinical trial subjects.

Let's Talk!

Taking steps towards an overall quality management system acts as supportive, preventative care at the point of clinical trial data collection. We look forward to assisting PRCCI member sites in achieving a spirit of excellence in 2019. For quality support, please reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org