Puerto Rico Consortium for Clinical Investigation

NEWSLETTER

January 2019

038

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

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

PRCCI's New support staff

We are pleased to introduce our new PRCCI support staff

Javier Rivera

Graphic Designer

Javier Rivera obtained a Bachelor's degree in Digital Graphic Design at Atlantic University College in Guaynabo, PR. During his time in college, Javier did his practice at "RED Comunicaciones Integradas" where he worked as a Jr. Art Designer. He gained experience and developed new skills by creating logos, business cards, flyers, web banners and social media content.

After graduating, Javier worked as a freelancer on different projects and continued expanding his works by making posters, t-shirts, banners, restaurant menus, recital posters and digital art work for clients.
Javier's goal is to gain experience in the field specializing as a graphic designer to provide service within Puerto Rico's needs for publicity and design assessment for the customer; all in order to successfully develop as a graphic designer. Javier believes joining PRCCI serves as a great opportunity to gain experience and a great leap towards bigger projects.

Zuleika Bonilla, M.D.

Program Associate

Dr. Zuleika Bonilla holds a Bachelor of Science from the University of Puerto Rico, Rio Piedras campus. She earned her medical degree at Ben Gurion University and Columbia University Medical Center in a joint program focusing on International Health. Prior to joining PRCCI, Dr. Bonilla completed a fellowship in Autoimmune Diseases at the University of Pennsylvania while supporting an expert team in serving patients and people in need. In addition, she enhanced her clinical research experience while developing and implementing research plans at the University of Miami School of Medicine.

Zuleika will manage PRCCI's leading-edge sample storage facility that will protect the viability of clinical research samples and investigational products on the island. She is also collaborating in the development and implementation of the Clinical Research Coordinator Course intended to train new coordinators that will enhance the research workforce in Puerto Rico. Zuleika is pleased to join PRCCI's team in the mission of taking clinical research to the next level for the benefit of patients and the research community in Puerto Rico.

Puerto Rico Clinical Research Summit 2019

The agenda Committee for the 2019 Clinical Research Summit: Connecting the World has drafted a first-class agenda and confirmed over 15 distinguished speakers for the May 2019 event.

The theme for the upcoming Summit is "Connecting the World", as a way to bring the best of Clinical Research to address our audience. Topics such as: it will include topics such as disparity, team science, pipeline of trials and trends in the development of sites, among others.

The agenda committee was composed by representatives from our Consortium sites, Ponce School of Medicine, Medical Sciences Campus, Universidad Central del Caribe School of Medicine, the FDA, YCCI Yale Center for Clinical Investigation, and our Summit planner, The Big Think Group.

There are opportunities for sponsorship. We have created numerous alternatives to sponsor the Summit. We will have a spacious exhibition hall for sponsors. We expect over 350 people each day. For more information please contact Menchu Agüeros at 787-478-5282 or **info@bigthinkgroup.com.**

The Summit will take place at the Sheraton-Convention Center on May 9 & 10, and is part of a full week dedicated to Clinical Investigation in Puerto Rico, which will begin on May 6th. This activity will be ACCME accredited for physicians, and also for nurses and pharmacists.

Early Bird ticket sales will start in February 8th on Eventbrite.

Upcoming Investigator Training Program

On March 21, 2018, Dr. Luis Abreu Pharm D. from Pfizer will be offering an Investigator Training Program Event at the Puerto Rico Science, Technology and Research Trust (PRSTRT).

The Investigator Training Program, which has been approved by Transcelerate, will offer Good Clinical Practice (GCP) training for Clinical Research Investigators (CRIs) and Clinical Research Coordinators (CRCs). The training is aimed at staff with between 0-7 years of clinical research experience; however, we also welcome more experienced staff, so that they can share their knowledge and experience with the training cohort.

The training will cover the following modules:

- Drug development process
- Planning and preparation
- Recruitment and enrollment
- In-trial procedures
- Safety in clinical trials
- Monitoring, audits, inspections and publications
- Additional regulations (self-study module)

Follow us on Social Media (LinkedIn, Twitter) for upcoming details on purchasing tickets to the event.

Highlights from Operations and Business Development: January 2019

We have started 2019 with significant activity in the Operations and Business Development areas at PRCCI. The following sections highlight some of our most recent activities and, in addition, we have included a brief section about the Generic Drug User Fee Amendments, also known as GDUFA II.

PRCCI meets with the Novartis Senior Leadership Team (SLT)

On Monday, January 14th, members of the PRCCI met with the Novartis SLT during their visit to Puerto Rico. In two different meetings, Dr. Amarilys Silva, Mrs. Astrid Navarro, Dr. Miguel A. Vázquez Padua as well as investigators members of the Consortium (Dr. Gregorio Cortés, Dr. Oscar Soto Raíces, Mrs. Michelle Echeandía and Dr. Griselle Ortiz) shared information with Novartis SLT about PRCCI, the clinical research environment in Puerto Rico and the various factors that strengthen the proposition and advantages of why bring clinical trials to Puerto Rico. The SLT included: Dr. Marcia Kayath (Head, US Clinical Development and Medical Affairs), Eugene Patin (VP, Clinical Operations), Dhaval Desai (VP, Ophthalmology), Stephanie Visioli (VP, Medical Service Operations), Robert Stevens (VP, Digital Transformation), Amy Rudolph (VP, Health Economics and Research Outcomes), David Briff (VP, Human Resouces-Medical), Norman Putzki (VP, Neuroscience), Anthony Yadao (VP, Immunology, Dermatology and Rheumatology), Jack Scannelli (VP, Regulatory), Maria Figliomeni (VP, Early Development), and Mrs. Mary Louis (Administration). We had the great collaboration of members of the Novartis Medical team who operate in Puerto Rico (Drs. Eileen Pabón, Elsa Gibson and Michael Nash). Great teamwork!

PAREXEL visit to PRCCI member sites

On January 23-24, 2019, Mrs. Felicia Vandrey, Associate Site Alliance Director at PAREXEL, visited several of our member sites in Puerto Rico as part of our strategic partnership and collaboration. The meetings served as a great opportunity to demonstrate the facilities of our member sites and introduce their clinical research teams. The Operations and Business Development team were able to have a conversation about the interests, experiences and capabilities of our sites, while Mrs. Vandrey provided information about our Site Alliance Program and current market trends. PRCCI is confident that these types of visits to our member sites will further our efforts to bring relevant and interesting clinical trials for the benefit of our patient population. There will be additional site visits during the next quarters in 2019. This time, we were able to visit the following research sites: UPR Clinical and Translational Research Center (Dr. Clemente Díaz and team), Mindful Medical Research (Dr. Oscar Soto Raíces), FDI Clinical Research (Dr. José Rodríguez Orengo and Mrs. Michelle Echeandía), SanaCoop (Dr. Ismael Toro Grajales) and ERD (Dr. Andrés Emanuelli).

PAREXEL visit to PRCCI member sites

PRCCI meets with the Novartis Senior Leadership Team (SLT)

The Generic Drug User Fee Amendments (GDUFA II):

According to the Federal Drug Administration (FDA), the generic drug user fees make it possible for the agency and the pharmaceutical industry to ensure access to safe and high quality generic drugs and generic drug products. GDUFA was reauthorized on August 28, 2017 (GDUFA II) with provisions that are effective through September 30th 2022. It is important for clinical investigation units interested in participating in clinical trials in which generic drugs are used to be familiar with these activities. For additional information, please access **www.fda.gov/forindustry/userfees/genericdruguserfees.**

Monthly Quality Corner

2019: A Spirit of Excellence

January 2019 has flown by. Now 27 sites strong, PRCCI is moving forward into the New Year with a spirit of excellence, which is our 2019 Quality Program theme. Each month in 2019, this space will be dedicated to exploring how clinical trial sites can optimize and rise to support clinical trial sponsors and CROs in their endeavors to implement risk-based, centralized, and remote monitoring. Building from the best practices we shared in 2018, PRCCI's Quality Department will be working with each of our sites to implement a quality management system tailored to their needs and goals for 2019.

Partners in Quality, PRCCI and YCCI

PRCCI's continues our strong relationship with our quality partners at Yale Center for Clinical Investigation (YCCI) in 2019. YCCI's role in facilitating PRCCI site quality has evolved from auditing to clinical trial site optimization. On a quarterly basis, the YCCI team will conduct visits to assist member sites in implementing and perfecting the quality systems that make sites attractive to clinical trial sponsors.

Excellence through Quality Systems

In 2019, the PRCCI Quality Department is committed to taking member sites to the next level of quality. By providing sites with the tools, training, and resources needed to build strong quality systems, the team at PRCCI is devoted to elevating Puerto Rican sites as top contenders in global clinical trial markets. Stay tuned to this space for more on the enhancements to PRCCI's quality program for the coming year.

Site Facilities Check by YCCI

Next month our third-party quality partners, Yale Center for Clinical Investigation will conduct five site facility check visits. They will validate quality at each site with research readiness.

Let's Talk!

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**