



December
2018

Issue #37



Puerto Rico Consortium
for Clinical Investigation

NEWSLETTER

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

A program of:



Puerto Rico
Science, Technology
& Research Trust

Gathering Momentum

Spotlight on Our Consortium

*Message from PRCCI's
Executive Director*

Dr. Amarilyn Silva-Boschetti, Pharm. D.

As the end of 2018 draws near, we would like to take this opportunity to thank all of you for an amazing year. The success of PRCCI is based on the relationships we have built, and we really wouldn't be where we are without you. Over this past year we have added new sites, new sponsors and new staff. We are grateful for the opportunity to work with, and for you. Our passion for enhancing and expanding clinical investigation remains strong.

Working together this past year has been a pleasure and we are grateful for all your support. Best wishes and happiness to you and your families over the festive season. We look forward to a successful 2019 working together!.

PRCCI's Newest Site Member:

SCB Research Center Corp.



PRCCI's new site member is SCB Research Center Corp. located in Bayamón, PR. This research center has extensive experience and specializes in Psychiatry and Neurology. The principal investigator is Dr. William Julio, MD, DFAPA. Dr. Julio is a very experienced clinical research investigator. Dr. Julio completed his medical degree at the Central University of the Caribbean School of Medicine. Dr. Julio is a diplomate of the American Academy of Disability Analyst and of the American Academy of Psychiatry and Neurology. He is certified in Psychiatry and Geriatric Psychiatry. Currently, he is the elected president of the Psychiatric Society of Puerto Rico, Rama District of the APA. His research experience in alzheimers has helped great amount of patients with this condition. Dr. Julio's coordinator is Ivelisse Rojas. We are very honored to have Dr. Julio's site join PRCCI.



Puerto Rico Consortium
for Clinical Investigation

*Puerto Rico Clinical Research
Summit 2019*



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

Main focus in the upcoming Summit is "Connecting the World", as a way to bring the best of Clinical Research to address our audience. 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, UPR- RCM, Universidad Central del Caribe, the FDA, YCCI, and our Summit planner, The Big Think Group.

There is opportunity 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, commencing on May 6. This activity will be ACCME accredited for physicians, and also for nurses and pharmacists.

Early Bird ticket sales will start in February on Eventbrite.

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PRCCI's Newest Employees:

We are pleased to introduce our newest PRCCI employees



Jarmary Torres

Jarmary Torres obtained her BS in Health Sciences from the University Of South Florida and an MPH from Walden University. Ms. Torres has over 18 years of experience in clinical research settings. Her professional strengths are in the guidance of pharmaceutical related protocol compliance and GCPs. Ms. Torres has extensive experience in administration, management, regulatory guidelines, standard operating procedures, quality, monitoring, customer service, leadership, white glove service, planning and coordination. Ms. Torres started her career as a Study Coordinator where she leveraged her clinical research background to excel at monitoring. As a monitor she worked in various therapeutic areas and with different Pharma/CROs such as Quintiles, Sanofi Pasteur, Merck, Research Pharmaceutical Services, Inventive Health and most recently AbbVie. Her passion for clinical research had propelled her to pursue a new role as **Clinical Research Quality Manager** with the Puerto Rico Consortium for Clinical Investigation (PRCCI) team. Ms. Torres is looking forward to enhance the quality outcome and research goals of all the research site members of PRCCI.



Jorge Claudio

Jorge Claudio obtained a Bachelor's Degree in Accounting from the University of Puerto Rico and completed an internship program in International Finance and Economics at the University of Salamanca. After completing his studies, he worked as an Auditor for a Certified Public Accounting Firm. His passion for auditing led him to start working for the federal government auditing contracts, regulations and management controls. After hurricane Maria hit Puerto Rico, he decided to return home and help rebuild his country while maintaining as a goal to provide essential service for the people of Puerto Rico. Jorge is excited to be part of a team whose mission is to promote and enhance clinical research and development for the benefit of patients, the Puerto Rican economy and global scientific innovation.

Puerto Rican Society of Endocrinology and Diabetes Meeting (SPED)



The Puerto Rico Consortium for Clinical Investigation (PRCCI) participated at the Puerto Rican Society of Endocrinology and Diabetes Meeting at the San Juan Hotel. The event was held on December 8, 2018 at the San Juan Hotel. We had the opportunity to engage with various physicians and investigators in our efforts to promote and create awareness of PRCCI.

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Highlights from Operations and Business Development

Starting this month, our Operations and Business Development team will provide important highlights about both Operations of Clinical Trials and Business Development for the members of our Consortium. This section will include updates, news and other practical information relevant to clinical research. Clinical Conductor (Clinical Trials Management System):

- Bio-optronics recently announced the availability of a new release. This update will include new payment category colors, new cost allocation justification and other improvements to existing features.

- Reminder about Clinical Conductor functionalities: Whenever there is a change in budget, it is important that each site goes to their version of Clinical Conductor and accept the changes which will update the budget information in your version of the portal.

Current trends in this industry:

- The current and upcoming patent expirations continue to stimulate significant research into generic drug trials. You should keep in mind that each clinical trials unit must self-report to the FDA to run generic drug trials which will comply with the Generic Drug User Fees Amendment of 2012.

- There is significant activity on CRO and Sponsor consolidations. This is expected to continue in 2019 due to patent expirations, tax reforms and the need for cost containment and efficiencies.

- Key areas that have been forecasted as top indications for 2019: Oncology, Atopic Dermatitis (small molecules and biological agents), Psoriasis, Inflammatory Bowel Diseases (Crohn's and Ulcerative Colitis), Alzheimer's Diseases, Non Alcoholic Fatty Liver Disease, especially NASH (non-alcoholic Steatohepatitis). These areas of research will need involvement of specialists with active practices and/or a trusted referral network as well as more robust databases. Also, there is a greater emphasis on specialized pediatric studies.

- **Tip #1:** Growing your access to patients is key to get studies. We should build relationships with potential participants and key stakeholders (meetings, newsletters, advertising, referrals, websites, etc.).

- **Tip #2:** It is important to be strategic to maximize our chances of being awarded competitive studies. Things to consider are: which potential investigator has appropriate access to patients, understand the expectations of the sponsor/CRO and be aware of who will be performing study procedures and their facilities.

- **Tip#3:** It is important to make a strong impression by highlighting why your site is a great fit, including access to patients, facilities, past performance, metrics and/or dashboards that will showcase your success in recruiting and retaining subjects as well as effective and efficient processes leading to short turnaround times for study initiation.

Monthly Quality Corner



2018 The Year of Best Practices

As we prepare to welcome a brand new year, PRCCI's Office of Quality and Training would like to take a moment to thank each and every stakeholder that made 2018 truly The Year of Best Practices. For the month of December, PRCCI's quality team would like to take a moment to express our gratitude and best wishes for 2019.

From Stephanie Berger, Director of Quality

To our amazing research sites, partners, trial sponsors, CROs, and everyone who has supported PRCCI's mission to improve the clinical trial landscape in Puerto Rico, cheers to a year well spent! Together, we have brought forward the best practices that are the foundation of our commitment to quality. Our light burns brighter than ever as we move forward together into 2019 with a spirit of excellence! Love and light to all! –Stephanie

From Michelle Martínez, Quality Assurance Specialist

Happy Holidays to our friends and site members from PRCCI's quality team. Your support and enthusiasm is what keeps us going. Here's to an even more productive and successful new year!

From Jarmary Torres, Quality Manager

As the newest member of PRCCI's quality team, I'm looking forward to getting to know each of you and learning more about how we can work together to promote a spirit of excellence in 2019. I'm grateful to be a part of the PRCCI family as we continue to grow and prosper.

Happy Holidays! --Jarmary

Stay tuned to this space in January for the launch of PRCCI's 2019 Quality Program.

A Spirit of Excellence in 2019

Our theme for the new year, A Spirit of Excellence in 2019, will guide us as we collectively rise. For quality support, please reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org



Happy New Year

Dear All,

As we look back upon the past year, we would like to acknowledge those who have helped us shape our business. Thanks for a great year, and we look forward to a New Year filled with opportunities. PRCCI wishes you all the best in 2019!!!

— Amarilyn Silva-Boschetti, PharmD

Executive Director

Puerto Rico Consortium
for Clinical Investigation (PRCCI)