

April
2018
Issue 29



Puerto Rico Consortium
for Clinical Investigation

PRCCI Newsletter

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

Gathering Momentum

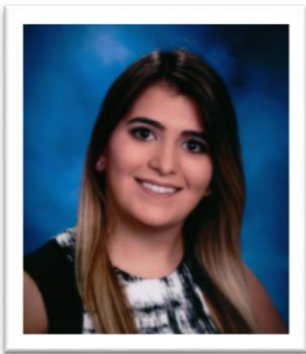
Spotlight on Our Consortium



Puerto Rico Consortium
for Clinical Investigation

Spotlight on Magdalena Carbonell, PRCCI's most recent employee

We are pleased to introduce our newest PRCCI employee, Ms. Magdalena Carbonell as our Business Support Specialist.



Ms. Magdalena Carbonell

Magdalena completed her Bachelor's Degree in Business Entrepreneurship at **Johnson & Wales University in Rhode Island**.

During her time in college she had various job experiences, one of them being a Summer Intern at First Bank where she put into practice Accounting Basics such as preparing corporate tax returns and assisting with audits.

After graduating, Magdalena worked temporarily at an Accounting Firm as an Office Manager, where she got Management and Human Resources experience, in addition to working alongside partners to meet company's goals and objectives. At PRCCI she will be assisting the Director of Finance overseeing PRCCI's accounting tasks, governance and studies finances. Magdalena has always expressed her interest in working for a non-profit organization and is excited to join PRCCI's team and continue helping

them achieve their goal of bringing clinical trials to Puerto Rico.

Consortium Highlights *PRCCI's Newest Members: Manatí Medical Center and Centro Reumatológico de Caguas*



We are excited to announce that **Manatí Medical Center** has become one of PRCCI's newest members. The Manatí Medical Center is known for their excellent medical hospital services, working professionals, advanced technology, strategic location and continuous innovation. All of these combined with their wide patient reach makes them a potentially excellent clinical research organization.

Mr. José L. Quirós Jorge, President of Manatí Medical Center: "We are very pleased to be joining PRCCI! It is a unique opportunity for us to make all our resources available to developing new knowledge in medicine. We are an institution that is also focused on the education of health professionals, so the contribution we can make to clinical research is of great value to us".



Dr. Kosmas Kretsos and the
Manatí Medical Center Team



Also joining PRCCI, we have **Centro Reumatológico de Caguas**. Dr. Amarilis Pérez De Jesús is the owner and principal investigator. She has been in practice for thirty-one years and has ten years of clinical research experience. The site has experience in different therapeutic areas, including, Rheumatology and Musculoskeletal/Orthopedics. In 2010 she published a book called "A New Life with Rheumatoid Arthritis" aimed at patients suffering from this condition.

Upcoming Event *The 2018 Puerto Rico Clinical Research Summit*



The 2018 Puerto Rico Clinical Research Summit, will take place on May 9th in San Juan, Puerto Rico at the **Sheraton Puerto Rico Hotel & Casino**.

Introducing the Summit will be **Dr. Rafael Rodríguez Mercado**, Puerto Rico Secretary of Health, **Dr. Daniel A. Colón Ramos**, Professor at Yale University and Member of the Board of Trustees of PRST, **CAPT Richard A. Arojo**, FDA Associate Commissioner for Minority Health and **Dr. Lester Martínez**, MG (R), U.S. Army, Chairman PRCCI Board, President, Martínez Medical Consulting.

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During the morning there will be a Patient-centric Panel Discussion where the panelists will discuss the roles of patients in a clinical research study. The afternoon sessions will be divided in three tracks; Quality & Compliance, Diversity in Clinical Trials and Emergency Preparedness/Lessons from Hurricane Maria.

At the Summit we will have the confirmed participation of many pharmaceutical companies such as Merck, Pfizer, Bristol-Myers Squibb, Eli Lilly, Astra Zeneca, Sanofi, Novo Nordisk, Boehringer Ingelheim, GlaxoSmithKline and our strategic partner, PAREXEL. Several companies will be visiting several PRCCI member/sites the day before and after the Summit, to see first-hand their capabilities and operational readiness.

This event will let you explore the new advances in clinical research locally and internationally, learn from opinion leaders about diversity in clinical trials, why it is important and how to achieve it, dive into emergency preparedness and response under the light of Hurricane Maria, and discuss best practices on quality and compliance with the FDA.

We at PRCCI look forward to meeting you at the 2018 Puerto Rico Clinical Research Summit! Link below to register and to get more details on the agenda.

<https://www.eventbrite.es/e/2018-clinical-research-summit-tickets-43440926982?aff=es2>

Investigator Training Program

On April 6, 2018, PRCCI collaborated with Pfizer and offered the fourth Transclerate-certified Investigator Training Program event at the Innovation Center at Puerto Rico's Science, Technology and Research Trust. The program offered GCP

(Good Clinical Practice) training for Clinical Research Investigators (CRIs) and Clinical Research Coordinators (CRCs). The event was a great success, given the outcome of participants. We at PRCCI would like to thank all who attended.



Academy of Medical Directors of Puerto Rico: "Sustaining Puerto Rico's Health System"

On April 19, 2018 our *Director of Business Development, Dr. Roberto Torres* and *Quality Assurance Specialist, Michelle Martínez*, participated in the Academy of Medical Directors of Puerto Rico Conference. The educational activity focused on "Sustaining Puerto Rico's Health System". Dr. Torres addressed the audience on the importance of clinical research and diversity in clinical trials.



Thank you, PharmaSeek

Effective July 1, 2018 PharmaSeek will no longer be a partner of PRCCI. We would like to thank PharmaSeek for a great partnership over the past two years and for helping PRCCI in its first steps. We wish you great success on your future endeavors.



Monthly Quality Corner

2018: The Year of Best Practices

Each month in 2018, we will spotlight the best practices that support the highest level of quality in conducting clinical trials. For the month of April, our **focus on Standard Operating Procedures (SOP)** best practices continues.

Testing, Iteration, Feedback

Thanks to all who attended PRCCI's first best practices webinar, Creating Next-Level SOPs using Human Centered Design (HCD). One of the most important features of the HCD process is the loop of incorporating feedback after testing your SOPs. Once your team has settled the details based on their expertise, pressure test the process by applying various real-world scenarios. For example, a site recently updated their study drug transport SOP. In order to pressure test the new procedure, personnel staged a mock transport. The team applied feedback and lessons learned from the exercise to ensure success.

Let's Talk!

To learn more about how you can apply HCD to improve your SOPs, please click on the webinar link: <http://www.prci.org/quality-webinars/>

If you have any quality questions or would like to talk more about how your site can optimize your SOPs, please feel free to reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org.