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Puerto Rico Consortium  
for Clinical Investigation

# NEWSLETTER

Any questions? Please contact us via [contact@prcci.org](mailto:contact@prcci.org)

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

# Gathering Momentum

## Spotlight on Our Consortium



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### Spotlight on PRCCI's Newest Site Members: *Universidad Central Del Caribe (UCC)*



PRCCI is proud to announce its newest site member, Universidad Central Del Caribe (UCC), a Puerto Rican higher education institution specializing in health sciences.



The Universidad Central del Caribe (UCC) was founded in 1976. UCC was the first non-profit private medical school incorporated under the laws of the Commonwealth of Puerto Rico. During its history, UCC has evolved into a health-sciences university with fully accredited academic programs in Medicine, Medical Images Technology, Biomedical Sciences and Substance Abuse Counseling, and this year opened the first Chiropractic School in Puerto Rico. Its faculty has carried out an extensive agenda of biomedical, clinical, and psychosocial research and provides specialized health care services. What distinguishes UCC from other institutions in Puerto Rico is its continuing commitment to preparing high-quality health professionals who can offer preventive care, promote healthy lifestyles, and provide excellent services while maintaining a sense of humanism, compassion and the highest ethical values. Clinical research is at the heart of all medical advances, as it determines how effective and safe a treatment is and how it is best delivered. The need for clinical research is even more pressing in U.S.A. areas such as Puerto Rico given the chronic underrepresentation of minorities in

clinical trials. By joining PRCCI, the Universidad Central del Caribe will achieve synergies on access to research opportunities on some of the most important global health challenges of our time as well as on clinical research quality and speed of execution. Both organizations will contribute together to the growth of clinical research in Puerto Rico and will ultimately help improve medical care for future generations of Puerto Ricans.

"The agreement with the PRCCI allows the UCC to become a strategic partner to position Puerto Rico in clinical studies nationwide, particularly those focused on diseases in which the prevalence in Hispanics is higher. It is another milestone to fulfill one of the pillars of the mission of our University, which is the development of research in the biomedical, clinical and psychosocial sciences. The entrance to the consortium widens the networking and gives the space for our researchers and students to participate in new opportunities and provides the platform to contribute to new translational projects", said Dr. Waleska Crespo Rivera, President of the Universidad Central del Caribe. Dr. Amarilys Silva, Executive Director of PRCCI, added: "The Universidad Central del Caribe (UCC), is a great addition to our Consortium given its commitment to research providing an enriching environment that promotes the development of investigation in the biomedical, clinical and psychosocial sciences with an orientation toward the health needs of our immediate community in Puerto Rico. All of us at PRCCI are looking forward to working with UCC to continue expanding clinical research for the benefit of patients, clinical researchers, and the Puerto Rico economy".



### *PRCCI's Strategic Plan & Objective Meeting:*



On October 18th, 2018 PRCCI held its Strategic Plan and Key Objectives meeting. Executive Director, Dr. Amarilys Silva, Pharm.D. shared with the esteemed audience PRCCI's recent accomplishments and upcoming initiatives. Various of the topics that were discussed were PRCCI's current focus on Clinical Research Development, Quality, Clinical Operations and bringing more trials to Puerto Rico. PRCCI currently has 26 top academic and research sites in the Caribbean which include academic institutions, hospitals, clinics, specialized research centers and general research centers. The 2019 Puerto Rico Clinical Research Summit was also announced for May 9th and 10th. PRCCI's major key accomplishments were presented to the audience while also discussing new initiatives such as the patient education program and study coordinator project.



### *First Clinical Trial Agreement*

Congratulations to Manati Medical Center on signing their first Clinical Trial Agreement! We are very pleased with this milestone accomplishment. This is a historic moment that is an example of the impact that PRCCI is making in Puerto Rico.

From left to right; Sr. Idelfonso Vargas, MMC Executive Director, Martha L Villareal, PhD; Marielys Otero, MD and Aracelys Nieves, MD.

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## Forward Research & Innovation Summit 2018

On November 10th, 2018 the Puerto Rico Science, Technology & Research Trust will have its Forward Research & Innovation Summit at the Sheraton Convention Center. Puerto Rico's research, innovation, and entrepreneurship summit - the premier showcase the Caribbean of science, technology, and innovative project. They enable effective networking to enhance collaborations.

## 2018 Global Site Solutions Summit



On October 11th to the 14th, PRCCI's Executive Director, Dr. Amarilys Silva Pharm. D. attended the Global Site Solutions Summit in Boca Raton, Florida. The conference was a great success and PRCCI had to opportunity to network with professionals of the industry while also promoting Clinical Research in Puerto Rico.

## Great Progress at 9th Clinical Quality Oversight Forum

On October 10-12, PRCCI's Quality Assurance Specialist, Michelle Martinez attended the 9th Clinical Quality Oversight Forum in Philadelphia. This event focuses on ensuring trial integrity by effectively assessing, optimizing and managing the quality of clinical vendors and sites. This forum acts as the annual gathering for clinical quality, operations, management and audit professionals to engage and candidly share their experiences, struggles, obstacles, and achievements when working with varying clinical partners including CROs and investigator sites. This was a valuable experience for Michelle to learn and share her experiences in quality while bringing back lessons learned to PRCCI and Puerto Rico.

## Investigator Training Program



On October 3rd, 2018 PRCCI collaborated with Luis Samuel Abreu Pharm D., Renato Arrocho Pharm D. and Glenda Rojas DMD from Pfizer and offered the fifth Investigator Training Program Event at the Puerto Rico Science, Technology and Research Trust (PRSTRT).

The event was a huge success, more than thirty people attended and obtained the Good Clinical Practice (GCP) certificate. PRCCI will be offering this certificate again next year. Make sure to follow us on social media for upcoming dates.

## MAGI Clinical Research Convention



Operations Support Specialist, Jorge Martínez and Director of Quality and Training, Stephanie Berger attended the MAGI Clinical Research Convention in San Diego, California.

Stephanie Berger was a speaker in the "Building and Sustaining High Performance Teams" conference. The objectives were to describe and analyze various team structures, organizational composition, and dynamics. It also focused on describing how to empower employees to achieve or exceed expectations in a team setting.

## Monthly Quality Corner



## 2018 The Year of Best Practices

October has flown by in record time in 2018. PRCCI member sites have been busy on the quality front with recent sponsor and FDA audits. We are proud to recognize our member site, Emanuelli Research and Development, as they recently hosted the FDA for an audit as a top enroller with outstanding results. What's their secret? Their well developed quality management system (QMS)!

## What is QMS?

Recently the International Council for Harmonization (ICH) released the long-anticipated ICH/GCP E6 (R2) guidance. One of the important ways clinical trial sites can focus their R2 compliance efforts is by formalizing their quality efforts into an organized quality management system (QMS). The foundation of any great QMS is meaningful standard operating procedures (SOPs). Other components include identifying key risk indicators and thresholds for action. Sites can use Human Centered Design (HCD) to ensure their QMS has a meaningful impact on quality.

## Let's Talk!

If you would like to learn more about how your site can implement HCD to build a QMS, please feel free to reach out to our Director of Quality and Training, Stephanie Berger, [stephanie.berger@prcci.org](mailto:stephanie.berger@prcci.org).