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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



Puerto Rico Consortium  
for Clinical Investigation

### PRCCI's Newest Site Member: *Advanced Medical Concepts*



PRCCI is proud to announce its newest site member, **Advanced Medical Concepts**. This site is a family practice medical center dedicated to direct patient care and clinical trials, lead by **Dr. Amaury Roman Miranda**. It is located in the suburban area of Cidra, it has a great floating population that works with various industries nearby. The site has been in practice in the area for over 28 years and has a data base of over 19,000 patients. The center is already well known for its outstanding patient care and clinical research. In 2007, clinical trials activities initiated by Dr. Amaury Roman as principal Investigator, and since then it has been active with multiple studies.

### *Congratulations!*



PRCCI congratulates the **HIMA San Pablo Hospitals' Office of Clinical Research** as well as its clinical trial staff for being recognized by the Cerus Corporation as the top enrolling site in the RedeS Study. This is a significant achievement and a demonstration of the focus, hard work and dedication of the study personnel at HIMA San Pablo Hospitals. RedeS is a randomized, double-blind, controlled, parallel group study with the INTERCEPT blood system for red blood cells in regions at potential risk for Zika Virus transfusion-transmitted infections.

### *29th Annual Meeting of the Pharmaceutical Industry Association of Puerto Rico (PIA)*



The Puerto Rico Consortium for Clinical Investigation (PRCCI) participated at the **29th Annual Meeting of the Pharmaceutical Industry Association of Puerto Rico (PIA)**. The event was held on November 1st 2018 at La Concha Hotel, San Juan, PR. The theme of this year's meeting was "Innovation Takes Action. We learned about new trends in the Healthcare Industry, connected with key stakeholders. We had the opportunity to educate others about PRCCI.

### *Forward Summit 2018*



On November 10th, 2018 the Puerto Rico Science, Technology & Research Trust had its **Forward Research & Innovation Summit** at the Sheraton Convention Center. The premier event showcased the latest innovations in science, technology, and research. Mr. Gualberto (Gil) Medina, PRST Trustee and PRCCI Board of Directors gave the opening reemarks at the Summit.



Our Director of Quality and Training, Stephanie Berger, lead a session on **Building & Sustaining HighPerformance Teams: HumanCentered Design in Clinical Trial Operations**.



At the event one of PRCCI's members, Dr. Carmen Zorrilla got the Bajarí Award. Bajarí, a word from the Taíno dialect, means high distinction and represents the path that researchers follow to innovate and achieve high distinctions in their fields. The award was designed by a student from the Escuela de Artes Plásticas y Diseño de Puerto Rico. The Bajarí Award was manufactured in México by the sculptor Luz Badillo.



Manu Prakash, PhD was the key note speaker at the Summit. Dr. Prakash is the creator of an ultra-low-cost, "print-and-fold" paper microscope. He captivated the audience with this innovative technology. He has been inventing and distributing low-cost, low-tech tools that are accessible to everyone. He makes affordable scientific tools that are accessible to everyone, to bring the joy and discovery of science, not just for the traditional scientist, but every single kid in the world. This year they set a goal to release a million foldscopes to kids around the world, and they will not stop until every single kid carries a tool like that in their pocket. Dr. Daniel Colón-Ramos, PRST Trustee was also in attendance.

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### Puerto Rico Chapter of the American College of Physicians



Magdalena Carbonell, Michelle Martínez, MPH and Miguel Vázquez Pharm. D. participated at the **Convention of the Puerto Rico Chapter of the American College of Physicians**, held Saturday November 17th 2018 at La Concha Hotel (San Juan, PR). It was a great opportunity to meet Key Opinion Leaders and emerging medical investigators in one event. More than 50 participants attended our booth and learned about PRCCI.

### Site Visit at the Dominican Republic



This month Michelle Martinez, MPH and Miguel A. Vazquez Padua, Ph.D., visited the Dominican Republic, one of our newest site members, "Instituto Dominicano de Estudios Viroológicos". Dr. Koenig is the principal investigator at this site where she conducts high quality clinical trials, specialized in HIV, Hepatitis B, and other sexually transmitted diseases.

### PRCCI's Visit to Yale Center For Clinical Investigation:

During the week of November 26th, PRCCI's Finance and Operations team visited the Yale Center for Clinical Investigation at New Haven, Connecticut to participate in specialized training sessions. It was a great opportunity for both organizations to share best practices and the newest updates in the clinical research industry.



### Save the Date!



**The 2019 Clinical Research Summit: Connecting the World**, will be a two day event that will bring together Puerto Rico leaders from all the groups involved in clinical research: patients, FDA, investigators, sponsors, clinical units/sites and clinical research organizations, and academic researchers. It will provide a unique opportunity to connect, do networking and explore new advances in clinical research locally and internationally. We will learn from opinion leaders about industry pipeline and patient engagement in clinical trials as well as best practices on quality and compliance with the FDA. For more information contact: [info@bigthinkgroup.com](mailto:info@bigthinkgroup.com)

## Monthly Quality Corner



### 2018 The Year of Best Practices

The 2018 Holiday Season is well under way. Holidays can be especially challenging in clinical research where strict adherence to timelines is vital for success. PRCCI would like to share some best practices during for this time of year.

### Recruiting During the Holidays

Recruitment during the holidays can be difficult. It is important for sites to proactively plan recruitment efforts that account for subject travel plans and other holiday related challenges.

### Holiday Staffing

During the holidays, research staff members may take extra days off to travel and celebrate. Advanced coordination to ensure appropriate staffing for all protocol specified activities is necessary for compliance with all applicable regulations and guidelines.

### Sponsors and Vendors

Sponsors and vendors will alert you of their holiday schedules in advance. Aligning subject visit windows and closure schedules is critical. Plan ahead to avoid protocol deviations. For example, central laboratories may be closed for Christmas. If you draw and ship blood samples December 24th, the samples will not be received on December 25th and a protocol deviation is likely. Plan ahead today!

### Let's Talk!

If you need quality support, contact our Director of Quality and Training, Stephanie Berger, [stephanie.berger@prcci.org](mailto:stephanie.berger@prcci.org).

### Happy Holidays!

All of us at Puerto Rico Consortium for Clinical Investigation wish you Happy Holidays!