



Puerto Rico Consortium
for Clinical Investigation

PRCCI Newsletter

March
2018
Issue 28

Gathering Momentum

Spotlight on Our Consortium



Puerto Rico Consortium
for Clinical Investigation

Spotlight on The 2018 Puerto Rico Clinical Research Summit

In this month's issue we highlight *The 2018 Puerto Rico Clinical Research Summit*, which will take place on May 9th in San Juan, Puerto Rico at the **Sheraton Puerto Rico Hotel & Casino by the Convention Center**.



The Summit is a full day event that will bring together leaders from three continents and from all the groups involved in clinical research: patients, FDA, investigators, sponsors, clinical units/sites and contract research organizations. An opportunity to connect and network within the global clinical research ecosystem while getting continuing education credits.

PRCCI is co-organizing this event with great institutions: *the FDA, the Yale Center for Clinical Investigation (YCCI), patient advocates, Universidad de Puerto Rico- Medical Sciences Campus, Ponce Health Sciences University, Universidad Central del Caribe and the Puerto Rico Science, Technology and Research Trust*. Together, we have prepared a strong agenda covering timely and important themes. The event will commence with keynote presentations followed by a patient-centered discussion panel. Speakers/experts from the US FDA, academia, the pharmaceutical industry and the Puerto Rican

community of patients and researchers will carry out three parallel sessions in the afternoon with continuous education accreditation. The themes are Quality/Compliance, Emergency Preparedness and Recovery, and Diversity in Clinical Trials.

Confirmed speakers for the event include:

FDA Speakers:

- **Annette Melendez** - Consumer Safety Officer, Puerto Rico Office
- **Dr. Cynthia Kleppinger** - Senior Medical Officer, Center for Drug Evaluation and Research
- **Jovonni Spinner**, Senior Public Health Advisor, Office of Minority Health
- **Anne E. Johnson** - District Director, Philadelphia District Office
- **CAPT Brenda Stodart** - Small Business & Industry Assistance Program, Center for Drugs Evaluation and Research

Guest Speakers:

- **Dr. Lester Martínez López** - Major General (Retired), U.S. Army, Chairman of PRCCI Board
- **Dr. Gabriela Dávila Loaiza** - Director of Clinical Site Management, Pfizer
- **Dr. Oscar Soto-Raíces** - Medical Director, Mindful Clinical Research, Puerto Rico
- **Tesheia Johnson**, Deputy Director and Chief Operations Officer, Yale Center for Clinical Investigation
- **Dr. Amarilys Silva**, Director Medical Affairs, Eli Lilly Puerto Rico
- **Dr. Helen Kellar Wood**, Lead, Diversity and Patient Engagement, Bristol Myers-Squibb
- **Dr. James A. Borowiec**, Director, Research Emergency Management and Enterprise Resilience, New York University School of Medicine
- **Stephanie Berger** - Director of Quality and Training, PRCCI

- **Dr. Gregorio Cortes Maisonet** - President and Research Director, GCM Medical Group, Puerto Rico
- **Dr. Andrés Emanuelli Anzalotta** - President and Research Director, Emanuelli Research and Development Center, Puerto Rico
- **Dr. José F. Rodríguez Orengo** - Professor, University of Puerto Rico - School of Medicine, CEO & CSO, FDI Clinical Research, Puerto Rico
- **Dr. Barbara Segarra Vázquez** - Dean of School of Health Professions, University of Puerto Rico, Medical Sciences Campus
- **Dr. Kenira Thompson**, Dean of Research, Ponce Health Sciences University
- **Dr. Francesca Carvajal** - Regional Head of Clinical Operations for GCTO, Merck
- **Heidi Rodriguez** - Esq., Executive Vice-president, HIMA-San Pablo Hospitals

To register please visit our page by clicking the link below:

www.prcrs.org

We at PRCCI look forward to meeting you at the 2018 Puerto Rico Clinical Research Summit!

Consortium Highlights

PRCCI's Newest Research Site: San Miguel Medical

PRCCI is pleased to welcome its newest member of the Consortium, **San Miguel Medical**.

Dr. Elba Antoinette Pérez is the Principal Investigator and has 11 years of experience conducting clinical trials.



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The site has experience in different therapeutic areas including Endocrinology, Cardiology, Gastroenterology, Orthopedics and Nephrology. PRCCI is very excited to have Dr. Pérez and her research staff as part of the Consortium.

PRCCI Video Launch

In *April 2018* it will be two years since the **Puerto Rico Consortium for Clinical Investigation** started operations. Many successes, challenges and tremendous people power have built what PRCCI is today. We put together a short video about PRCCI with key stakeholders explaining what we do and why it is important. To watch the video please see link below:

<https://www.youtube.com/watch?v=6EzWC0ScILE&>

SAI 20th Annual Conference 2018: Advancing the Research Enterprise to Brighten Puerto Rico's Future

On March 9, 2018 our *Director of Business Development, Dr. Roberto Torres* and our *Director of Operations, Ms. Vanessa Soto*, attended the **SAI 20th Annual Conference 2018: Advancing the Research Enterprise to Brighten Puerto Rico's Future** at *Interamerican University of Puerto Rico, Ponce campus*. Dr. Torres addressed the audience on "How Puerto Rico can help increase Diversity in Clinical Trials"



H-IDEAS: Applied Statistics for Patient Advocates

On March 11, 2018 **Puerto Rico Consortium for Clinical Investigation** is proud to have facilitated at the *Puerto Rico Science, Technology, and Research Trust H-IDEAS'* (breast cancer patient advocacy group) training on applied statistics for patient advocates. We are glad we could help!



Thank you, United For Puerto Rico

We would like to thank **United for Puerto Rico** for their donation to PRCCI. With the donation we will develop a resilient clinical samples backup storage facility available to all of our Consortium members for any future emergencies. We will be stronger after Hurricane Maria!



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 March, our **focus on Standard Operating Procedures (SOP)** best practices continues.

Striving for Next-Level SOPs
Standard Operating Procedures are often designed to ensure that site processes align with regulatory obligations. PRCCI seeks to empower sites to progress beyond compliance to create SOPs that align with the natural way that site personnel engage their workflow. This can be achieved through applying Human Centered Design (HCD) principles to the SOP design process. IDEO.org, a not-for-profit design organization, describes Human Centered Design as a "process that starts with the people you're designing for and ends with new solutions that are tailor made to suit their needs."

How to learn more

To learn more about how you can apply HCD to create next-level SOPs, please click on the link below to view PRCCI's latest quality webinar on our website and YouTube channel:
<http://www.prci.org/quality-webinars/>

If you have any quality questions or concerns, please feel free to reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org.