Puerto Rico Consortium for Clinical Investigation

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Issue 33

PRCCI Newsletter

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

Gathering Momentum

Spotlight on Our Consortium

Puerto Rico Consortium for Clinical Investigation

Consortium Highlights:

PRCCI Joins #CoverTheProgress Movement

The initiative #CoverTheProgress was created to send a positive message of all Puerto Rico has achieved since the passing of Hurricane Maria. PRCCI is joining the initiative to include the Clinical Research Industry on the island. PRCCI encourages everyone to share their stories of success and readiness after hurricane Maria on social media platforms. Remember to use **#covertheprogress.**

YCCI Completes After Hurricane Maria Site Visits

Recently, The Puerto Rico Consortium for Clinical Investigation (PRCCI) hosted quality partner Yale Center for Clinical Investigation (YCCI) as they completed the visits to PRCCI member clinical research sites to assess research-readiness post-Hurricane Maria. Results provided by YCCI reveal continuity in research operations, both during and after the historic storm, largely due to careful planning, solid procedures, and the unifying support of PRCCI programs and initiatives.

Building Research Capabilities

As a part of PRCCI's ongoing commitment to building research capabilities in Puerto Rico, PRCCI hosted Yale Center for Clinical Investigation (YCCI) and the Food and Drug Administration (FDA) in presenting a 4 day workshops from August 6th to the 9th, 2018.

The trainings were a huge success. Over 120 certificates were given. Some of the participants who attended the event were Physicians, Investigators, Coordinators, Administrators, Monitors and individuals who were interested in learning more about clinical investigation.

The first day's session was given by YCCI and focused on **Budget Development and Regulatory Updates.**

The second day's workshops were on **Clinical Research in a Hospital Setting and Study Start Up Best Practices,** both by YCCI.

The third day's session was an **Overview of the FDA Office of Minority Health, Importance of Research Diversity, ICH and FDA Guidance by the FDA.**

The afternoon session was on **Monitoring, Inspection, and Audit Readiness** by YCCI.

The last day was directed to Patient Advocacy Group Leaders. The participants included the community representatives from PR, the FDA Office of Minority Health, YCCI, and the Yale Cultural Ambassadors for Clinical Research representatives from Junta for Progressive Action and African Methodist Episcopal Zion (AME Zion) Church.
PRCCI would like to thank YCCI and FDA for coming to Puerto Rico and offering the workshops. We look forward to having you back for more sessions.

"It was a pleasure for the Yale Center for Clinical Investigation to participate in this four day workshop series with PRCCI alongside the FDA Office of Minority Health. Each of the workshops were met with enthusiastic care providers and investigators ready to improve their clinical research practices and passionate patients advocates excited to begin the work to improve clinical trial diversity."
–Asia Brown, Operations Intern at YCCI

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Consortium Highlights: Sunshine Seminar, Ob-GYN

On August 3-5, 2018, PRCCI attended **the Sunshine Seminar, Ob-GYN** at the Sheraton Hotel & Convention Center. This seminar provided PRCCI with the opportunity to connect with existing members, physicians, and sponsors while promoting clinical research.

Attending on Friday: Magdalena Carbonell, Business Support Specialist, Jorge Martínez, Operations Support Specialist and Astrid Navarro, CPA, Director of Finance

Attending on Saturday: Dr. Amarilys Silva Pharm, D., PRCCI Executive Director and Michelle Martínez, Quality Assurance Specialist

Upcoming Events; Investigator Training Program

Puerto Rico Consortium for Clinical Investigation

Investigator Training Program
-offering GCP Training

On October 3rd, 2018, Dr. Luis Samuel Abreu, Pharm D. from Pfizer will be offering an Investigator Training Program Event at the **Puerto Rico Science, Technology and Research Trust (PRSTRT).**
The ***Investigator Training Program***, which has been approved by ***TransCelerate***, will offer **Good Clinical Prractice (GCP) tr**aining for Clinical Research Investigators (CRIs) and Clinical Research Coordinators (CRCs).
The training is aimed at staff with between 0 - 7 years of clinical research experience, however, we also welcome more experienced staff, so that they can share their knowledge and experience amongst the training cohort.
The training will cover the following modules:
- Drug development process,
- Planning and preparation,
- Recruitment and enrollment,
- In-trial procedures,
- Safety in clinical trials,
- Monitoring, audits, inspections, and publications, and
- Additional regulations (self-study module)

For tickets see link below:
https://bit.ly/2KRaZXW

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 August, we will focus on utilizing Human Centered Design (HCD) in building the right team as well as the framework for disseminating and documenting the information essential to achieving compliance.

Building the Team

Ensuring that your team covers all of the bases is the foundation for compliance. During the first steps in the HCD process, it is essential to identify every person who is involved throughout the full study lifecycle. Utilizing planning tools such as flow charts and process maps will allow you to identify every person who will be involved in the execution of a clinical trial protocol. Once you've identified the team, bringing them together promotes efficient transparency. For example, creating a working group that brings together contract and budget negotiators with clinical personnel creates a solidarity that ensures budget and contract terms that fully support clinical teams.

Framework for Teamwork

Creating an infrastructure for documenting and disseminating meeting topics is as important as bringing the team you've built together. Creating an official outlet for discussing protocol deviations, safety data, protocol amendments, and all other compliance matters is also an essential output of the HCD process. Tailoring the dissemination and documentation of training and discussion to each specific team is a recipe for true compliance.