

Puerto Rico Consortium for Clinical Investigation



NEWSLETTER
February 2019 / 039



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

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

Puerto Rico Clinical Research Summit 2019



May 9 & 10, 2019
Sheraton Puerto Rico
Hotel Convention Center

**SAVE
THE
DATE**



Please save the date for our upcoming continuing medical educational activity:
Clinical Research Summit May 9th and 10th 2019.

This event has been submitted for continuing education for the following professionals:

- | | |
|----------------------------------|---------------------------------|
| ✓ Physicians | ✓ Pharmacists |
| ✓ Nurses | ✓ Medical Technologists |
| ✓ Dentists | ✓ Social Workers |
| ✓ Nutritionists | ✓ Respiratory Care Technologist |
| ✓ Psychologist | ✓ Neuropathic Doctors |
| ✓ Pharmacy Techonologist | ✓ Health Educators |
| ✓ Health Services Administrators | |

The 2019 PRCCI Summit will be held during the Puerto Rico Clinical Research Week from May 6th to 10th. There will be several activities about clinical and translational research, as a joint effort among various institutions. If interested in sponsoring this outstanding educational and networking opportunity, please contact:

Menchu Agueros - The Big Think Group
Phone: **787-478-5282**
Email: info@bigthinkgroup.com

The Clinical Research Summit will be held on May 9th & 10th, 2019 at the Sheraton Hotel Convention Center.

Stay tuned for tickets and registration information on Eventbrite.

PRCCI's New Support Staff

We are pleased to introduce our new PRCCI support staff



Obed Pérez *Business Intern*

Obed Pérez obtained a Bachelor's degree in Business Administration with a focus on Management from the University of Puerto Rico. He completed an internship program in the pharmaceutical industry where he obtained hands on experience on project management, process improvements, cost reductions, operational excellence, as well as GMP regulations. Obed has gained knowledge in all the components of supply chain management on warehouse & logistics, sourcing & procurement and planning functions. His major focus was on plant capacity production planning and performance metrics.

He's excited and very grateful to be part of the PRCCI team, where he will support current and new projects, coordinate special events and activities, as well as assist in business operations. He will support all administrative areas to help the organization in its vision of enhancing clinical research and development for the benefit of patients, the Puerto Rican economy and global scientific innovation.

Investigator Training (Good Clinical Practices) Certification Program for Staff Engaged in Clinical Investigations

On March 21st, 2019, Dr. Luis Samuel Abreu García 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 Practice (GCP) training for Clinical Research Investigators (CRIs) and Clinical Research Coordinators (CRCs). The training is aimed at staff with 0-7 years of clinical research experience; however, we also welcome more experienced staff, so that they can share their knowledge and experience with 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
- Additional regulations (self-study module)

Follow us on Social Media (LinkedIn, Twitter) for upcoming details on purchasing tickets for the event.

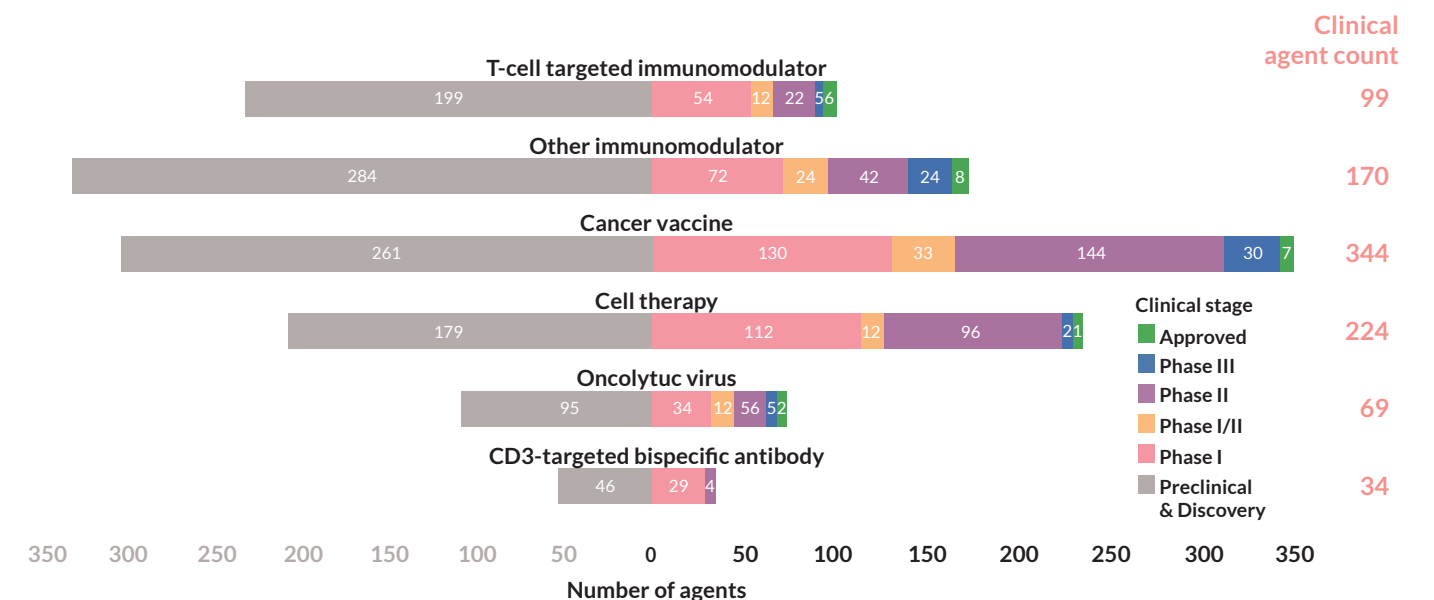
Highlights from Operations and Business Development: February 2019

Our team continues to search for study opportunities for our Consortium members. We will use this section in this and upcoming Newsletters to provide information about current trends in several therapeutic areas. In this month's section, we focus on the Immuno-Oncology landscape.

The Immuno-Oncology area is very active in the number of companies and institutions involved in clinical research and clinical trials. Similarly, the volume of publications in this field can be overwhelming. There have been many advances in new molecular entities, strategies, and novel approaches targeting several tumor types. These could well represent opportunities to continue the evolution of the standard of care of many cancer types and of drug development. One interesting reference in this field is the Anna-Maria Kellen Clinical Accelerator, a novel partnership model which involves nonprofit organizations, academia and industry (www.cancerresearch.org/scientists/clinical-accelerator), which has already published several articles on their partnerships and data analyses.

In an editorial published in Annals of Oncology (Volume 29 (1): 84-91, 2018), the authors J Tang, A Shalabi and VM Hubbard-Lucey analyzed data from various sources and databases. This article entitled “Comprehensive analysis of the clinical immune-oncology landscape,” reported the development of two databases. In one of these, there are 2004 immuno-oncology agents (940 in clinical stages) involving 303 targets from 864 companies; meanwhile, the other database tracks 3042 active clinical trials of these agents with a target enrollment of 577,076 patients. As evident in this article, there are several areas of opportunities to maximize these efforts. Nonetheless, they conclude that this is “probably the best time for progress in oncology in the past decades.” The following graph from this article is reproduced as per an open access license (<https://creativecommons.org/licenses/by-nc/3.0/>). Figure 1 of this article in Annals of Oncology (Oxford University Press) provides an overview of 2004 immuno-oncology agents and it represents six classes of agents identified on the basis of different mechanisms of actions.

Figure 1.



For additional information, you can also follow other reports from this group in the journal Nature Reviews Drug Discovery: May 2018 (Vol. 17: 465-466), October 2018 (Vol. 17: 783-784) and November 2018 (Vol. 17: 854-855). The Cancer Research Institute’s analyses are derived from public data sources.

Spotlight on this month's events

Puerto Rico Consortium for Clinical Investigation (PRCCI) attended the 3rd Interdisciplinary Research Symposium at the San Juan Bautista School of Medicine on February 28th, 2019. One of our Consortium members, Dr. Carmen Zorrilla, delivered the Plenary Conference entitled “The impact of biomedical research in public policy and public health.”



Puerto Rico Consortium for Clinical Investigation (PRCCI) attended Puerto Rico Science, Technology & Research Trust's first resilience summit "Caribbean Strong." Pictured below is PRCCI's Executive Director Amarilys Silva, PharmD, and PRCCI's Director of Operations and Business Development Miguel A. Vazquez Padua, Ph.D. with John Englander, who delivered the thought-provoking presentation “Rebuilding Higher for Storms, Tides, and Sea Level Rise.”



For the first time in history, The Puerto Rico Manufacturers Association (PRMA) brought together the life sciences manufacturing sector and the health care industry in an innovative two-day forum. It featured high-caliber international speakers and leaders of the industry. PRCCI participated in this important forum.



PRCCI's Executive Director, Amarilys Silva, PharmD., participated in a panel entitled "Training the Future Workforce of Cancer Researchers: Panel Discussion" at the FLASCO (Florida Society of Clinical Oncology) 9th Annual Puerto Rico Oncology Symposium. Dr. Silva presented PRCCI's mission and how it supports clinical research in Puerto Rico.



Monthly Quality Corner



2019: A Spirit of Excellence

Each month in 2019, this space will be dedicated to exploring how clinical trial sites can optimize to conduct clinical trials with a spirit of excellence. In the spirit of celebrating American Heart Month along with the American Heart Association, we dedicate our focus in February to the heart of any great quality management system: Training

Training: an attribute of strong data

Training is one of the 12 core quality indicators that PRCCI seeks to optimize with our member sites. Qualified Principal Investigators delegate authority to complete protocol specified tasks based on the training and credentials of individual research team members. The reliability of any data point reported in the CRF is directly relatable to the training of the originator.

For example:

Data Point	Data Attribute	Documentation Method
Subject Blood Pressure	Measurement performed by site staff qualified by training	CV, License, Training Certificate, Protocol Training

Without proper training the data generated by measuring a subject's blood pressure is unreliable. Documentation of training that qualifies a study team member to perform delegated tasks is essential. PRCCI works closely with member sites to ensure a robust understanding of how to leverage training to provide clinical trial sponsors with the bold assurance that their assets and data are protected and supported by site-level quality systems.

Onboard for excellence

Among the various types of training that create a culture of quality, strong onboarding training for new site staff sets the stage for success.

In addition to explicit training to familiarize new team members with organizational expectations, operations, procedures, and policies, strong sites leverage their staff to the top of their scope and capabilities. Evaluating the training that each individual brings to the table when they join the team is vital to understanding how they can best contribute. Identifying the unique strengths, interests, and areas where they can progress creates synergy within the site team. This is the space where optimization begins to unfold. Assisting member sites in augmenting their onboarding training practices is a top priority for PRCCI's quality team in 2019.

Onward and upward

Once the foundation is set, developing a culture of quality through continuing training further supports sites in becoming high quality data producers. Policy and process changes occur naturally as clinical research sites grow. Deviations and deficiencies also present in real-time for correction and prevention. Building in checkpoints and training opportunities as part of an overall quality management strategy ensures that your research staff is prepared to manage data in meaningful and proactive ways. Mapping training back to the original trigger to evaluate effectiveness is an often neglected activity. Testing the impact of training is as important as the training itself in ensuring quality. An important aspect of PRCCI's 2019 quality program, we support each of our unique sites to assess, enrich, and optimize their internal methods of providing effective ongoing training.

Let's Talk!

We look forward to assisting PRCCI member sites in achieving a spirit of excellence in 2019. For quality support, please reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org.