Puerto Rico Consortium for Clinical Investigation

NEWSLETTER

July 2019

044

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

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

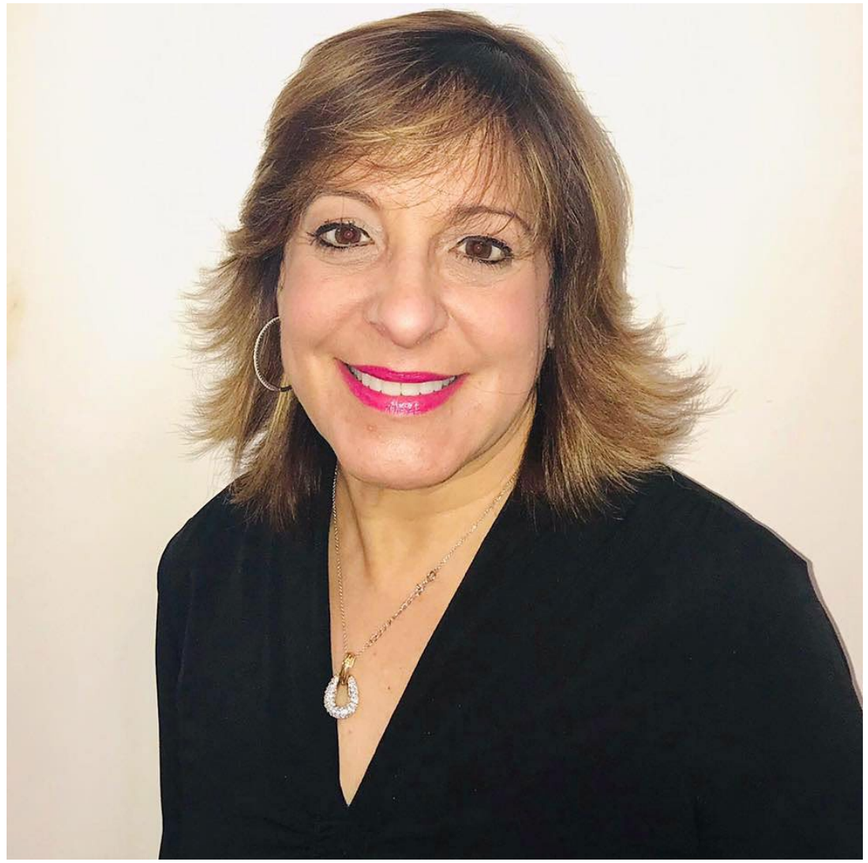
July 2019 Spotlight: BDH Research

Barbara Díaz Hernández, MD Research Inc. (BDH Research) is a clinical research site based in San Juan, Puerto Rico. Investigators to this site are Ileana M. Fumero-Pérez, MD and Mario R. Lopez-Cabrera, MD.

This research site has conducted multiple clinical trials for psychiatric, neurological, and infectious diseases as well as other medical conditions in child, adolescent, and adult populations.

BDH Research has built a strong reputation over the years within the research community as being a diligent and insightful research facility. It has been recognized with certifications and awards on excellence.

With more than 50 clinical trials experience, BDH Research ensures top quality services, excellent patient care, and thorough involvement in the research process. This site's team has been able to manage multiple trials simultaneously, from inception to completion, as well following patients even after the research trial has been completed successfully. These strengths have been key to ensure their success. At BDH Research, they are certain that they will comply and achieve the established goals.



Virtual Clinical Trials

In this brief overview, we will focus on the value of virtual clinical trials and how PRCCI is positioning itself to join this novel modality. Virtual clinical trials represent an alternative modality that can positively impact patient recruitment and retention while increasing operational efficiencies. It provides a way for patients who are not within close proximity of clinical research centers to access clinical trials. The value-proposition of virtual clinical trials is that they will deliver faster, patient-centric clinical trials compared to the traditional ones.

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The concept of virtual clinical trials revolves around the proposition that it puts the patient at the center of the activities. **IQVIA** has worked with various partners and sponsors in this industry to advance virtual clinical trials. From their perspective, virtual clinical trials have several advantages: Streamlined, faster site start-up, expanded access to patients, faster recruitment, low patient burden, lower study drop out, data transparency and automation, high data quality and performance consistency as well as no CRA site travel costs. These are significant factors that will continue to shape our industry and open new trends. In this model, there is a virtual PI study team composed of a Principal Investigator, a Patient Guide, a Study Concierge, and a Recruitment Expert who will work with local care of a health care practitioner, a home health nurse, and a phlebotomist. This team will work with the patient in the clinical trial using mobile health devices such as blood pressure monitors, glucose monitors, electrocardiography and spirometry devices, among others.

The tools that are now available to research centers and patients, a benefit from the evolution of the Internet of Things, enable virtual clinical trials for the following therapeutic areas: **Endocrinology, CNS, Dermatology, Immunology, Cardiovascular, Rare Diseases, Respiratory, GI, and observational studies, among others.** PRCCI has initiated collaborations with IQVIA to identify opportunities for virtual clinical trials for our Consortium members. This is a very exciting opportunity since these will broaden our capabilities, streamline our operational processes, and provide access to a more diverse patient population with a significant improvement in patient convenience and visit compliance. Overall, these trials will result in increased efficiencies and operational excellence across our sites.

We will continue to work with our sponsors and clinical trial units to bring these new alternatives to PRCCI and our patient community.

Highlights from Operations and Business Development: July 2019

PRCCI will implement a Clinical Research Coordinator Certification Program

The Puerto Rico Department of Economic Development and Commerce (DDEC, as its acronym in Spanish) recently approved a grant to PRCCI for the implementation of a **Clinical Research Coordinator Certification Program**. This grant by DDEC will be funded under the Workforce Innovation and Opportunity Act program. The Puerto Rico Science, Technology and Research Trust will provide matching funds as part of the requirements of this initiative.

GOBIERNO DE PUERTO RICO
Departamento de Desarrollo Económico y Comercio

The Clinical Research Coordinator (CRC) role is critical to the successful implementation and execution of clinical trials. These professionals are key personnel at a clinical research unit. They also may contribute not only at the clinical trial unit but can be part of clinical research personnel for sponsors and CROs in this industry. In Puerto Rico, there is a significant need to train CRCs to fill current and future positions in our industry. This will make it viable for local clinical trial units to obtain new clinical studies, which will benefit patients, our communities and contribute to the knowledge economy of Puerto Rico.

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As per the approved grant, the **CRC Certification Program** will benefit up to 25 participants. The program includes classroom interactions, assignments and online certification courses, all focused on the key areas and requirements to be able to immediately start working at a clinical site or employer. As part of this program, the participants will also complete the following certifications: HIPAA Compliance, Good Clinical Practices (GCP) and the International Air Transport Association (IATA) training/certification for the shipment of hazardous and dangerous goods.

The following are the minimum requirements for candidates who are interested in participating in this program:

- Communication skills: bilingual with strong communication skills in English and Spanish (oral and written).
- Computer literacy: Computer literate with knowledge in using the internet as well as experienced (intermediate to advanced) user of Microsoft Outlook, Excel, and Powerpoint.
- Education: Completion of at least an Associate Degree in Sciences or Health-related field from an accredited institution.
- Work experience: At least 2 years of work experience in science or health-related field.
- Evidence of USA citizenship.
- Evidence of registration in the selective service system of the US Military (for those male US citizens born after January 1st, 1960).

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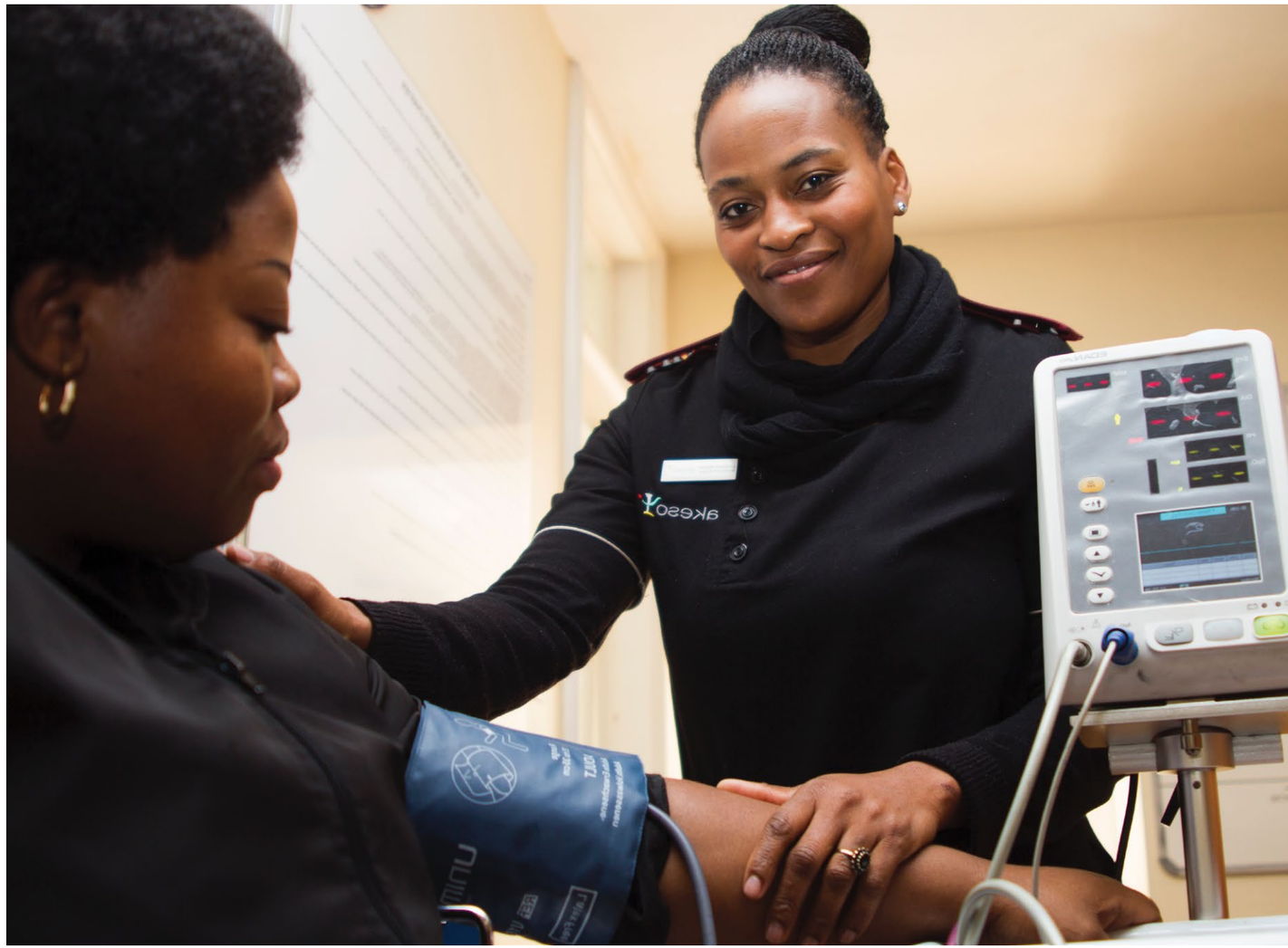
Those interested in this program, who meet the minimum requirements mentioned above, can contact PRCCI by sending an email to ***contact@prcci.org***. The email should include an updated version of the candidate's curriculum vitae. PRCCI will publish a call for applications in PRCCI's social media outlets (Facebook, Instagram, and LinkedIn) and PRCCI's webpage (www.prcci.org).

We expect to begin this program during the third quarter of 2019. With this initiative, PRCCI will further contribute to its mission to help strengthen Puerto Rico's clinical research ecosystem, provide patients with access to innovative clinical trials and impact the economy of 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. For the month of July, PRCCI's Quality Support Specialist, Michelle Martinez, joins us to share more on an important component of a solid Quality Management System: Risk assessment.

What is Risk Management?

Risk management is a core component of a robust Quality Management System (QMS). Risk management is considered an industry best practice for preventing human subject protection issues and guarding the integrity of clinical trial data collected at investigative sites. Risks can lead to costly disruptions that consume essential resources in the form of repeat work and corrective actions. Ensuring that the essential components of a risk management process are in place can accelerate clinical trial timelines.

Components of a Risk Management Process

At the clinical trial site level, risk management can be easily integrated into daily routines across the organization. Immediate implementation of a QMS system component to identify, assess, mitigate, and respond to risks can be both simple and effective.

Once a risk is identified, a risk management process generally consists of the following fundamental components:

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Gathering data and information to understand the context of a risk is an important first step. After carefully assessing the risk, data-driven decisions can be made to neutralize and mitigate the risk, both immediately and moving forward. An ongoing review and monitoring aspect allows for adjustment and alignment. It is also critical to consult subject matter experts and communicate clearly throughout the risk management process.

Let's Talk!

Taking steps towards implementing risk management at the clinical trial site level can seem overwhelming. PRCCI is here to help! To learn more about all aspects of a supportive quality management system, reach out to PRCCI's quality team. We look forward to assisting PRCCI member sites in achieving a spirit of excellence in 2019. For quality support, please reach out to our Quality Assurance Specialist, Michelle Martinez, ***michelle.martinez@prcci.org***