

Puerto Rico Consortium for Clinical Investigation



NEWSLETTER

August 2019

045



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

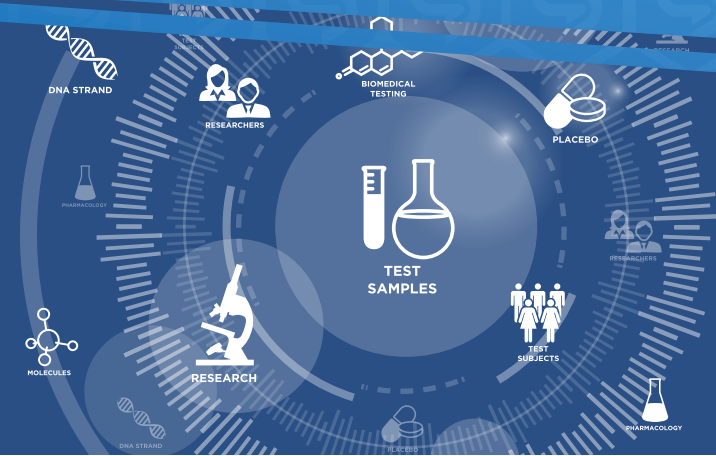
A program of:



Puerto Rico
Science, Technology
& Research Trust

Clinical Research Coordinator Certification Program

August 2019 Spotlight:



A **Clinical Research Coordinator (CRC)** is a specialized research professional working alongside the Principal Investigator. The CRC supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study. By performing these duties, the clinical research coordinator works directly with the study subjects, auditors and industry representatives. A CRC is responsible for maintaining the records of all study activities, including case report forms, handling of study products or medical devices, and regulatory affairs forms according to the study protocol. Also, are involved in the process of recruiting patients by evaluating eligibility of subjects or patients through interviews, reviews of medical records or contacts with doctors and nurses. This person is part of the clinical trial from beginning to end and is key to a successful study.

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.

Continuation...

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.

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. Entire program totals 102 hours of training.

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

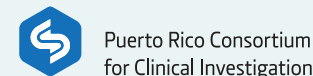
Clinical Research Coordinator Certification Program



Requirements:

- 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).**

Those interested in this program, who meet the minimum requirements mentioned above, can apply by sending an email along with their curriculum vitae to contact@prcci.org.



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We expect to begin this program during the next months. 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.



SWIA's "Women Business Talk"

On August 16, 2019, PRCCI's Executive Director, **Amarilys Silva, Pharm.D** was invited to participate in SWIA's (Southwestern Industrial Association) "**Women Business Talk**" joining other female leaders of Puerto Rico. The topic of the panel in which PRCCI's Executive Director participated was titled "**How Women Overcome Obstacles in the Business Environment**". SWIA provides leadership in the development of competitiveness and the integration of manufacturing and service companies in the Southwest of Puerto Rico.

Pictured are Amarilys Silva, Pharm.D. and Frances Rios, international speaker and President of The Women Who Lead Summit™ the largest summit in Latin America exclusively for high-level executives.

8th Clinical Trials Inspection Readiness Summit

Puerto Rico Consortium for Clinical Investigation's Quality Assurance Specialist, **Michelle Martínez, MPH** attended ExL Events "8th Clinical Trials Inspection Readiness Summit" in Philadelphia in August. The event featured 17+ expert speakers from various backgrounds featuring case studies presented by clinical inspection experts. Some of the learning objectives of the event were how to use different perspectives of inspection readiness to improve clinical operations and guarantee success, ensure trials are organized with improved oversight and communication to protect study participant's rights, safety, and welfare, assure quality and compliance is paramount and convert inspection readiness from a singular activity to an organizational culture for successful clinical trials, among others. This was a very valuable opportunity for PRCCI to bring the latest trends in quality/inspection readiness back to Puerto Rico and our sites.





Highlights from Operations and Business Development: August 2019

In this issue, we want to focus on the various initiatives at PRCCI to continue bringing clinical trials to our consortium members. PRCCI has continued to engage with various organizations in the clinical research industry. We continue to strengthen our relationship with our alliance partner PAREXEL. In August, we completed a very detailed, site-specific questionnaire with the objective of sharing knowledge about the consortium members. The document helps simplify access to data and reduce the burden during the study startup phase. Our team has also been connecting with new potential sponsors including Lundbeck, Milestone Pharma, Enzo Life Sciences and Nexeon Medsystems, among others. Enzo and Nexeon have a focus in the area of medical devices which have ongoing trials. We are excited to continue learning about these new devices and technologies.

As an outcome of our participation at DIA, IQVIA and PRCCI are planning for the opportunity to participate in virtual clinical trials. Virtual clinical trials focus on lowering the patient burden and increasing study participation. This modality allows investigators to conduct remote visits while the patients participate from their home or preferred locations using currently available technology. This is a perfect opportunity to bring these trials to the consortium and provide an alternative to patients that can't visit one of our centers but would like to benefit from our trials.

Please, stay tuned for our next update about new partnerships and opportunities in various therapeutic areas from pharmaceuticals to medical devices and emerging technologies. We are working on new business opportunities that will be shared in our next publication.

Monthly Quality Corner



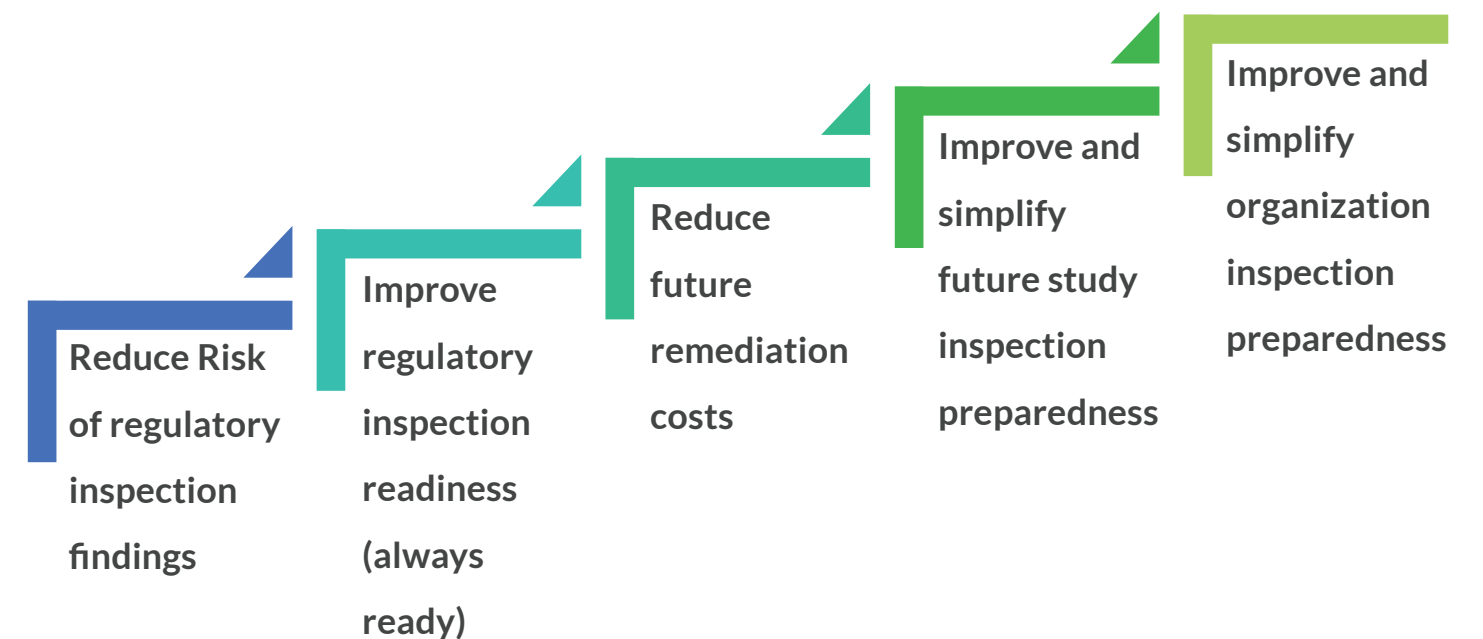
2019: A Spirit of Excellence

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. It is vital for every site to always be prepared for an inspection visit, especially from the FDA. For the month of August, PRCCI's Quality Support Specialist, Michelle Martinez, joins us to share more on an important component of a solid Quality Management System: Inspection Readiness.

What is Inspection Readiness?

FDA investigators call and announce they will be visiting your site soon for an inspection. Are you ready? PRCCI's Quality program ensures that sites are audit ready. Inspection readiness is a quality objective - the objective being to function at a level that is always ready for inspection, without requiring much preparation in the days or hours leading up to the inspection.

Benefits of Inspection Readiness

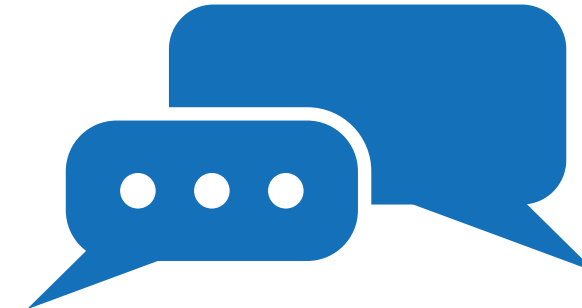


Continuation...

Inspection Preparedness

Inspection Readiness is a culture in which there is a strong commitment to quality and proactive risk management. Inspection Preparedness becomes part of an organization as they leverage prospective actions like Quality-By-Design to ensure an Inspection Readiness state throughout the execution of the clinical program. Elements of this mindset are embedded into SOPs and working documents.

By adhering to these while performing daily activities, an organization will operate in a mindset of “Inspection Preparedness” and be in a state of “Inspection Readiness”.



Let's Talk!

Taking steps towards being inspection ready 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 Team, Jarmary Torres and Michelle Martinez at jarmary.torres@prcci.org and/or michelle.martinez@prcci.org.



Hurricane Season

Dear PRCCI Sponsors and Partners

As all of you may know, hurricane season is upon us, Tropical Storm conditions are expected and Hurricane conditions are possible in Puerto Rico. The PRCCI team and its Consortium members would like to share with you our emergency preparation, business continuity and disaster plans:

- A PRCCI staff member is monitoring hourly weather updates, flight cancellations, and other logistics.
- As part of PRCCI's risk mitigation efforts, we have asked our sites to watch for communications and reach out for instructions if the vendors serving them are within the affected area.

The following PRCCI personnel will be available to assist with the implementation of disaster plans:

- Dr. Amarilys Silva, Executive Director – (787) 232-6175
- Dr. Miguel Vázquez, Director of Operations and Business Development – (787) 239-4083
- Ricardo García, Finance Manager – (787) 671-5617
- Jarmary Torres, Clinical Research Quality Manager - (787) 529-5347