

# Puerto Rico Consortium for Clinical Investigation



**NEWSLETTER**  
October 2019 / 047



Any questions? Please contact us via [contact@prcci.org](mailto:contact@prcci.org)

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

# Successful Clinical Research Training

The Puerto Rico Consortium for Clinical Investigation (PRCCI) is proud to share that the Clinical Research Workshops delivered by **Yale Center for Clinical Investigation (YCCI)** held on October 21 - 23, 2019 was a complete success.

Attendees participated in unique three (3) days training event developed by top experts from the YCCI team. These trainings and workshops were carefully designed to expand the foundation for strong strategic planning, practical decision-making and focus on quality during the conduct of clinical research activities at research sites in 2019 and beyond.





## Continuation...



PRCCI is committed to continuing expanding people's knowledge in clinical research education and facilitating all the processes necessary for the success of clinical research sites. Aligned with our objective to continue offering education to those interested in clinical research, we will be providing a Professional Certification in Clinical Research soon. Also, we encourage our readers to email [contact@prcci.org](mailto:contact@prcci.org) with suggestions on topics we should include in future trainings.



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## Highlights from Operations and Business Development: October 2019

PRCCI is the largest network of high-quality clinical trial units in Puerto Rico. One of our key objectives is to strengthen our capabilities, quality and efficiencies in the processes that impact the planning, approval, implementation, and execution of clinical trials at the site and network level. An early step in this process is the in-depth review of the logistical elements of a clinical study before we initiate the study activation process. The study or protocol feasibility evaluation is a critical step. It is such an important aspect of a successful clinical trial that many organizations have published articles, white papers and webinars on this subject. A few examples are: Institute of Medicine, SOCRA, SCRS, ACRP, Forte Research, WCG, and others. Some academic organizations have also published clinical trial feasibility checklists (for example, see UCLA clinical study feasibility tool at [www.researchgo.ucla.edu](http://www.researchgo.ucla.edu)).

- The main objective at the study feasibility step is to answer: Can the site really do the study? A thorough evaluation of this step will ensure a successful clinical trial experience in which patients, investigators and sponsors will benefit and can even save time, money and resources. Evidence of the critical nature of this step is that there are various publications reporting that even up to 20 to 50% of clinical trials close at the site-level with zero accrual (access webinar on this subject in [www.forteresearch.com](http://www.forteresearch.com)). The key areas to evaluate are:
  1. Access to patient population (internal, referrals, advertisements, etc.)
  2. Availability of appropriately trained staff
  3. Equipment and resources required for the study
  4. Time or staff limitations at the site
  5. Financial resources to manage expenses and costs

## Continuation...

It is recommended that each investigation center put a process in place for the appropriate evaluation of the feasibility of the clinical study opportunity. This is in addition to the IRB review. A well-planned approach will have a small team of knowledgeable professionals who can assess the scientific/ethical elements of the study but also examine the study design and requirements. This team, which should be very familiar with the research center and the organization, can then critically examine whether the clinical research center can:

1. Meet the expectations on patients/subject accrual for the study.
2. Provide the staff, facilities, resources and equipment required for study execution.
3. Manage expectations on staff expertise and training tailored to the study complexities.
4. Provide the financial evaluation to responsibly initiate the study with the negotiated budget.

The strategies described above are very straight-forward but will require the dedication and commitment of a small team or

- committee with a focused and efficient leader to ensure
- thoroughness in the evaluation, a sense of urgency for fast
- turn-around times and excellent communication skills to engage all
- members of the team, including the sponsor. When you put together
- all these basic elements together, you are in a path towards a
- successful clinical trial experience that will benefit your patients,
- staff, organization and the sponsor. It is equally important to know
- and communicate if your site will not be able to meet the study's
- expectations.

This will strengthen your reputation as a high-quality, compliant and reliable site- an excellent partner for future collaborations. Operational efficiencies along with excellent trial metrics are critical success factors for a highly competitive site that can become a preferred partner for many sponsors and new opportunities. For the last few years, PRCCI teams have worked in synergy with our consortium clinical sites to become the best clinical investigation alternative for current and potentially new sponsors and partners.

## 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 ensure clinical data accuracy and integrity. For the month of November, PRCCI's Quality Team is sharing information on quality control and assurance.

### *Quality Control and Assurance*

- Quality assurance (QA): the systematic and independent examination of all trial-related activities and documents. These audits determine whether the evaluated activities were appropriately conducted and that the data were generated, recorded, analyzed, and accurately reported according to protocol, standard operating procedures (SOPs), and good clinical practices (GCPs).<sup>1</sup>

- Quality control (QC): periodic operational checks within each functional department to verify that clinical data are generated, collected, handled, analyzed, and reported according to protocol, SOPs, and GCPs.<sup>1</sup>

- All research studies on human subjects should have a level of quality and ethical standard assurance built into their operations to ensure that the rights and well-being of human subjects are protected and that the data is reliable. Maintaining accuracy and quality throughout a clinical study is a persistent and active process. This ongoing process requires revising mechanisms and communicating these revisions clearly to all investigators and support staff. It is very important for a site and for the team to have a quality plan in check.

1. ICH/GCP Consolidated Guidelines, E6



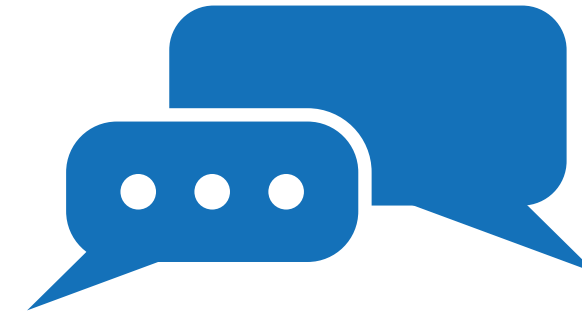
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## Quality Plan

A quality plan describes how the quality control and quality assurance processes will be applied throughout the clinical trial. It defines the various quality-related tasks in the study. A quality plan documents specific quality practices, resources, and activities relevant to a specific project. This includes both operational quality control and quality assurance activities. These plans should include conducting internal (self) audits, actively implementing and revising SOPs, recording protocol deviations, and initiating procedures to correct any shortcomings and prevent their recurrence.

One of the benefits of developing and implementing a quality plan includes developing proactive communication among clinical trial team members. This benefits clinical trial teams by encouraging early identification and resolution of clinical trial problems and concerns. Implementing a quality plan can also encourage conformity with SOP's, Good Clinical Practice (GCP), Good Laboratory Practice, and the site's policies and procedures. This leads to an overall reduction in external (Sponsor, FDA) and internal data queries, and helps reduce clinical trial closeout time.

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](mailto:jarmary.torres@prcci.org) and/or [michelle.martinez@prcci.org](mailto:michelle.martinez@prcci.org).