Puerto Rico Consortium for Clinical Investigation

NEWSLETTER /046
September 2019

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

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

Upcoming Event:
YCCI Training and Education Series

Presenters:

Linda Coleman, JD, CIP, CHC, CHRC, CCIP-I

Director, Human Research Protection Program, Research Administration, Yale University

Alyssa K. Gateman, MPH, CCRP

Associate Director for Quality Assurance, Yale Center for Clinical Investigation

Tesheia H. Johnson, MBA, MHS

Deputy Director and Chief Operations Officer for the Yale Center for Clinical Investigation

Associate Director of Clinical Research for Yale School of Medicine

Kelly Anastasio, COC, CPC-H, CPC-I, CPC-P

Associate Director of Clinical Trial Resources, Yale Center for Clinical Investigation

Continuation...

The Puerto Rico Consortium for Clinical Investigation (**PRCCI**) is proud to be partnering with Yale Center for Clinical Investigation (**YCCI**) to deliver a number of clinical research workshops from **October 21 - 23, 2019** from renowned speakers.

DAY 1, Monday, October 21, 2019

The sessions of Day 1 will focus on the investigative site including recruitment and retention strategies, eConsent, reporting obligations to the IRB, monitoring and auditing processes.

Presentations include: "Out of the Box" Recruitment and Retention Strategies, Informed Consent and eConsent, Reporting Obligations to the IRB, Clinical Research Monitoring Processes (Remote Monitoring, Risk based Monitoring) and Audit/Inspection Readiness

DAY 2, Tuesday, October 22, 2019

The sessions of Day 2 will focus Investigator Initiated Research, including managing single IRBs, protocol and grant development, Sponsor Investigator responsibilities and managing risk through quality.

Presentations include: sIRB Requirements and Strategies, Investigator Initiated Trials and Grant Proposal Development, Sponsor Investigator Responsibilities, Risk Management, and Quality Systems and SOCRA Chapter Meeting

Continuation...

DAY 3, Wednesday, October 23, 2019

The sessions of Day 3 have two morning tracks. Track 1 features developing robust source documentation and SOPs. Track 2 covers topics on planned emergency research and root cause analysis and CAPA development.

Presentations include: Source Documentation Development, Planned Emergency Research, SOP Development, Root Cause Analysis & CAPA, and Investigator Site Regulatory Files- Hands-on session

REGISTER NOW!

This is an once in a year opportunity. Lunch, snacks, and coffee will be provided. Don't miss your chance to register since seats and materials are limited.

To learn more and register, please visit:
http://bit.ly/YCCIWorkshops

YALE CENTER FOR CLINICAL INVESTIGATION
TRAINING AND EDUCATION SERIES

Click the Link to Register
LAST CALL FOR TICKETS
http://bit.ly/YCCIWorkshops

October 21-23, 2019

Seats and materials limited, registration required to reserve your space.

Puerto Rico Science and Technology Trust
105 Carr. #21, Km. 0.8 Bo. Monacillo
San Juan, PR 00927

Yale Center for Clinical Investigation

Puerto Rico Consortium for Clinical Investigation

Highlights from Operations and Business Development: September 2019

An important goal in our consortium of clinical research sites is to maintain a culture of continuous improvement. When we embed continuous improvement processes in our site's operations, it will impact quality, costs, efficiencies, effectiveness, services and satisfaction for the key components of the research ecosystem: patients, sponsors, institutions, partners, vendors and research professionals.

There are several different models that are widely used for continuous process improvement which apply to many different industries. Some of the best known and widely used ones are Six Sigma and Total Quality Management.

There is, however, another simple method that is very useful, but which also requires commitment from the organization's management: The four-step quality model known as the Plan-Do-Check Act (PDCA) cycle. The four steps are:

- **Plan:** Identify an opportunity and plan for change.

- **Do:** Implement the change on a small scale.

- **Check:** Use data to analyze the results of the change and determine whether it made a difference.

- **Act:** It the change was successful, implement it on a wider scale and continuously assess the results. If the change did not work, begin the cycle again.

Continuation...

As a clinical research site, the PDCA cycle will be a successful method if the research team is committed to this process improvement. There are various elements that should be evaluated at each site to help navigate the organization towards an efficient clinical research operation. The following is a list of questions about operational areas that are routinely assessed by clinical research teams, not only to improve the operations, but also to strengthen the site's profile as a highly efficient and world-class research organization:

- How effective are your communication processes with your key stakeholders? Do you communicate frequently? Are you meeting the timelines in responding promptly and thoroughly to your partners, sponsors, colleagues?

- Do you have clear and current standard operating procedures?

- What are your objectives in developing your study pipeline?

- Which processes have you established for due diligence in the negotiation of contracts and budgets?

- Can you outline your internal processes related to the management of your site's finances and accounts receivable?

- Have you considered outsourcing certain areas to support or strengthen your operations?

- What internal processes or guidelines have you established to ensure the professional development of your staff?

As an important goal for the clinical research sites, you should read and learn about continuous process improvement as an area to complement your interests in clinical research. There are many organizations and publications in this subject. Recently, WCG and PharmaSeek presented a Complion educational webinar entitled "Achieve an efficient clinical research operation? Yes you can!" These series of educational webinars provide information about interesting and practical topics for clinical research professionals. We also encourage staff and professionals to engage with the various organizations that impact our clinical research ecosystem. Continuous learning and development is a step in the right direction.

Monthly Quality Corner

Focus on Quality

This month PRCCI's quality team focused on adhering risk based quality management system!

The idea behind risk-based quality management is to continuously identify the risks that may affect the activities performed throughout the study design, conduct, evaluation and reporting of clinical trial data.

This systemic process applied at a site level will help identify, assess, control, communicate and review the risks associated during a clinical trial lifecycle. This type of management facilitates decision making, nonetheless, the process should be documented and implemented as part of the site's existing quality system.

Risk Assessment

Consists of identifying unfavorable outcomes; their impact and their chance of re-occurrence. There are two levels to consider when performing risk assessments in clinical trials:

1. A risk assessment performed at a system level requires:
   - Identifying organization and facility capabilities
   - Verifying training and qualification of personnel
   - Revising quality systems and processes established
   - Revising performance and compliance metrics
   - Assuming regulatory knowledge

2. A risk assessment performed at a project/study level requires:
   - Investigate medicinal product risks, such as, toxicity, anticipated SAEs and drug handling
   - Complexity trial design-related risks (population, the complexity of the trial, inclusion/exclusion criteria)
   - Oversee site operational risks, that include, staff resource, budget, inadequate planning and study management

Continuation...

Risk Control

Risk control consists of the mitigation measures for identified risks and the implementation of the risk management plan. The site is responsible of identifying the risks and prioritize. These, should be reviewed regularly and adapted as deemed necessary. The mitigation actions should be put into practice to address identified risks at a system level or a project/study level. Once the priorities and assessment of the mitigation process have been established, the site can advance to identify the tolerance limits and metrics to be implemented.

Risk Review

Risk review consists of the re-assessment of the risks by evaluating new information and assessing the impact on the risk management plan and the already established tolerance limits. They can be set for a specific clinical trial, general or defined per a sponsor quality system.

The following are tolerance limits that should be reviewed:

- Clinical trial data
- Clinical trial protocol procedures and GCP compliance
- Clinical trial management procedures

Risk Management Tools

Risk management tools are resources that will facilitate the detection, identification, prediction, tracking, and analysis of metrics. The tools will help support risk management decision making. They can be paper-based or electronic, some examples are:

- Standard Operating Procedures
- Risk-based quality management software
- Flowcharts
- Process Mapping
- Fishbone diagram

Continuation...

Risk Communications

Risk communication consists of the distribution of the documents related to the risk; including the mitigation and action plan to all the decision-makers of the site

Risk-based quality management is a dynamic and continuous task. This process should be constantly reviewed to adapt new changes as they become available and routinely evaluated to test its effectiveness.
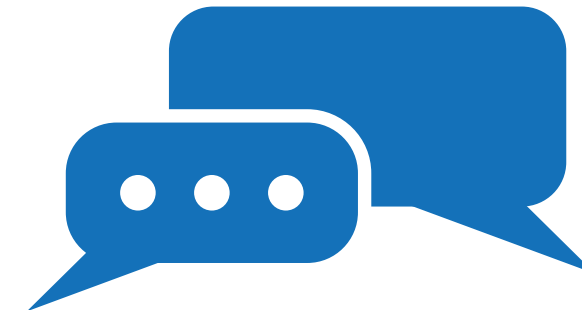
Let's Talk!

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.