The Georgia Clinical & Translational Science Alliance (Georgia CTSA) and Southern California Clinical and Translational Science Institute (SC-CTSI) have collaborated to provide free, high quality educational programs for clinical research professionals at novice to expert levels of experience. At the completion of each course or program, participants earn contact hours recognized by a certificate and/or badge.

The newest program, "Quality by Design in Clinical Trial", is comprised of five (5) courses. Individual courses in all programs receive a certificate, and completing the program earns a badge.

Program title:

"Quality by Design in Clinical Trial"

Program Picture:

Program Overview:

This five (5) course program, presents concept of QbD, the QbD framework and tools for implementation, and strategies for adaptation of principles to real-life cases.

Clinical trial data is critical to evaluating a medical product's efficacy and safety, and must be of sufficient quality and reliability to ensure valid analyses. The clinical trials enterprise has historically linked the gathering of more data with trial quality, 'more is better". Not only was it considered essential to gather detailed data on every aspect of a clinical trial, but also that data must be entered, reviewed, scrutinized, queried, and validated multiple times during the life cycle of a trial. This concept of over-collection and analysis is so entrenched, it is considered risky by investigators not to collect ever-increasing volumes of data and metadata. Growing evidence suggests a myopic focus on the accuracy of each data point, regardless of its criticality, adds little value (if anything) to trial quality and safety and, in fact adds to a trials significant expense and effort. This has prompted interest in more tailored approaches that are informed by trial design and how trial conduct influences quality.

This program introduces Quality by Design (QbD) as a systematic approach to medical product development to ensure trial quality by applying analytical and risk-management methodologies to the design, development, and manufacturing of products.

Program Outcome:

At the end of the Quality by Design (QbD) program, participants will understand the principles of QbD and how quality issues encountered from clinical research sites/ contract research organizations/ pharmaceutical companies can be prevented by designing for quality at each critical junction. Participants will be prepared to use the Plan-Do-Check-Act cycle for risk-based monitoring to improve clinical trial quality.

Program Topics:

- Course 1: What do we mean by Quality by Design (QbD)?
- Course 2: Clinical Trials Transformative Initiative (CITTI) Approach to QbD
- Course 3: Developing QbD Tools for Clinical Researchers
- Course 4: Integrating QbD into Team Science and Project Management for Research Success
- Course 5: Applying Design for Six Sigma

Learner Level: Intermediate/ Advanced

Audience:

This program is designed for Clinical Research Coordinators, Project Managers, Monitors, Regulatory, Medical and Clinical Affairs Professionals or junior faculty with 3+ years of experience seeking to further develop clinical research conduct skills and principles. Clinical research professionals should have responsibilities that include clinical trial start up planning, mentoring and complex issues involving site management, study management, and sponsor/ CRO challenges.

View the Online Course Catalog to get started.
https://twd.ce.emorynursingexperience.com/

COMING SOON – Next Program: "**Patient-Centered Drug Development and Real-World Evidence/Data"**