Questra clinical research

GOOD CLINICAL PRACTICE WORKSHOP for CLINICAL RESEARCH SUPPORT TEAM

"Build Your Team For Research Success"

WHAT IS A GOOD CLINICAL PRACTICE (GCP)?

- An international ethical and scientific quality standard for design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials with its origin from the **Declaration of Helsinki**.
- Provides assurance that the data and reported results are credible and accurate.
- Serves to protect and respect the rights, safety, integrity and confidentiality of human subjects.
- Describes the responsibilities of the sponsors, monitors, investigators and Institutional Review Board (IRB) both in the laws governing clinical research and ideals of research ethics and good science

WHY YOU NEED A GCP?

- The primary responsibility of **a Study Coordinator** (SC) **or Clinical Research Coordinator** is to ensure the smooth progress of the study from start-up to close-out through the day-to-day coordination of study operations.
- Therefore, GCP knowledge is **a major requirement for SC and a knowledgeable SC serves as a second check to the Principal Investigator (PI) to ensure protocol requirements are met.**

OBJECTIVE

- To ensure each participant understand the purpose of Good Clinical Practice (GCP) dictated by International Conference on Harmonization (ICH).
- To ensure each participant realize the importance of GCP guidelines in conducting safe, ethical and sound clinical trials requested by ICH.
- To ensure each participant understand the role and responsibility of a support staff in clinical trials.

TARGET AUDIENCE

- Nurses and Assistant Medical Officers
- Medical Laboratory Technologists
- Experienced research personnel who are interested in updating their knowledge regarding GCP
- Physiotherapist / Occupational therapist
- Dietitian and anyone in health science who needs a grounding in clinical research

METHODOLOGY

- Interactive learning and participants will learn through several case studies which will be guided by instructors on common GCP topics in clinical trial.

TOPICS

- Conducting a Clinical Trial According to GCP
- Getting a Clinical Trial Approved: Roles & Responsibilities of IRB/IEC
- Role of an Investigator
- Regulatory Role and Responsibility
- Working with Sponsor
- The Clinical Trial Protocol
- Inform Consent Process
- Develop & Improve The Effective Communication Skills
- A day in the life of a Clinical Research Coordinator
- Site Monitoring / CRA Roles
- Study Drug Management
- Site preparation for Audit & Inspection
- Handling of Biological Sample/ Clinical Trial Logistics
- Management of Adverse Experiences
- Good Documentation, Data Monitoring & Query Resolution
- Archiving

"This workshop has been certified and recognized by National Committee for Clinical Research (NCCR) since 2013"