CTR 215 Data Management Concepts

COURSE DESCRIPTION:

Prerequisites: CTR 210
Corequisites: None

This course is designed to discuss the elements involved in implementing and managing a clinical study from the perspective of the Data Manager. Topics include development of the data management plan, coordination of data collection and capture, plan the closure and archival of study materials and participate in project management activities. Upon completion, students should be able to design, prepare and execute a complete data management plan for the implementation and management of a sample clinical research project. Course Hours Per Week: Class: 2. Semester Hours Credit: 2.

LEARNING OUTCOMES:

Upon completion of this course, the student will demonstrate basic cognitive and practical knowledge and skills in each of the following areas:

1. Develop and coordinate a data management plan for a clinical research project
2. Understand and coordinate the relationship between the contract research organization and Sponsor
3. Understand appropriate communication between the CRO, Sponsor and clinical research site
4. Assist in the planning and implementation of a clinical research project
5. Understand procedures for database lock and data archival

OUTLINE OF INSTRUCTION:

I. Develop and coordinate a data management plan for a clinical research project
   A. Develop data management plan in compliance with industry, federal and GCP accepted standards and best practices
   B. Identify documents and resources related standards and best practices associated with the collection, data capture, data management, data analysis, and data reporting in clinical research
   C. Summarize data management activities across clinical studies from creation of protocol specific source documents, collection and entry of data and performing quality management activities

II. Understand and coordinate the relationship between the contract research organization and Sponsor
   A. Relate regulatory requirements for Transfer of Regulatory Obligation (TORO) to conduct of data management activities
   B. Summarize roles of site, sponsor and CRO in regard to study conduct
   C. Identify and recognize each member of the team and their respective roles and responsibilities and understand that communications within a clinical study team is vital to the success of the study
   D. Summarize requirements and best practices for vendor selection and qualification

E. Relate Quality by Design (QBD) and Quality Risk Management (QRM) to regulatory requirements for vendor oversight

III. Assist in the planning, implementation and conduct of a clinical research project
   A. Make use of project documentation to identify scope of work, project timelines and deliverables
   B. Outline key data management activities at each stage of study conduct including study planning, startup, conduct, close and archival
   C. Develop a data flow diagram, and study timeline
   D. Take part in discussions to assist others with various aspects of study management using effective communication methods and documentation

IV. Understand procedures for database lock and data archival
   A. Compare interim and final database lock procedures
   B. Develop database locking timelines and checklist
   C. Summarize the purpose and process of study archival
   D. Relate Quality by Design (QBD) and Quality Risk Management (QRM) to inspection readiness

REQUIRED TEXTBOOK AND MATERIAL:

The textbook and other instructional material will be determined by the instructor.