

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.

