

CTR210 Introduction to Clinical Data

COURSE DESCRIPTION:

Prerequisites: CTR 110

Corequisites: None

This course covers the collection, organization, and management of study data. Topics include database structures, data management systems, quality assurance, data collection and capture, and data confidentiality and security. Upon completion, students should be able to describe the data management team and effectively organize, enter, and review data. Course Hours Per Week: Class, 3. Semester Hours Credit, 3.

LEARNING OUTCOMES:

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

1. Describe the coordination and organization of subject data for a clinical research project
2. Describe various data collection and data capture procedures
3. Assist in the design of data collection forms
4. Review research data for subject safety
5. Review data collection forms for completeness and accuracy
6. Assist in the collection of pertinent data for a specified research publication
7. Describe means of data presentation in listings, tables and graphs

OUTLINE OF INSTRUCTION:

- I. Describe the coordination and organization of subject data for a clinical research project
 - A. Identify the key regulations and guidance that impact clinical data management
 - B. Compare Clinical Data Management and Clinical Data Science
 - C. Outline the purpose and function of Clinical Data Management Systems (CDMS)
 - D. Recall the essential data management documents
 - E.

