CTR 210 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 practical 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. Outline the elements of the data management plan and the case report form
   F. Summarize the JTF core competency expectations for data managers
   G. Explain the importance of team science and methods to work effectively in a cross-functional team

II. Describe various data collection and data capture procedures
   A. Outline the origin, flow and management of data through a clinical study
   B. Summarize methods of data collection including digital and decentralized approaches
   C. Identify the different types of case report forms
   D. 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

III. Assist in the design of data collection forms

A. Relate principles of patient focused research and diversity in clinical trials to data collection strategies
B. Relate Quality by Design (QBD) and Quality Risk Management (QRM) to database design
C. Identify study objectives, endpoints and Critical to Quality (CTQ) factors
D. Summarize common types of data collected for safety and efficacy analysis
E. Identify common data standards and data standards organizations

IV. Review research data for subject safety
A. Relate Quality by Design (QBD) and Quality Risk Management (QRM) to subject safety
B. Summarize safety monitoring methods
C. Compare adverse events (AE) with serious adverse events (SAE)
D. Explain the purpose of AE to SAE reconciliation
E. Identify additional (non-AE) sources of safety data such as vital signs, lab results and symptoms
F. Recall the purpose and process of medical coding
G. Identify common coding dictionaries including MedDRA, ICD and WHODrug

V. Review data collection forms for completeness and accuracy
A. Relate Quality by Design (QBD) and Quality Risk Management (QRM) to data validation activities
B. Summarize the elements of the data validation plan
C. Recall examples of common data validation methods including programmatic and manual reviews
D. Explain how data analytic and data visualization tools support data validation
E. Define data quality and data integrity
F. Relate data quality and data integrity to ALCOA principles

VI. Assist in the collection of pertinent data for a specified research publication
A. Summarize the basic purpose of statistics and informatics as applied in clinical studies (e.g., randomization, sample size, adverse events, analysis, results)
B. Compare expectations for academic and regulatory reporting
C. Summarize means of data presentation in listings, tables and graphs
D. Identify common study conduct reporting activities including quality risk management, safety monitoring and interim analysis

VII. Describe means of data presentation in listings, tables and graphs
A. Recall regulatory requirements for Clinical Study Reports (CSR)
B. Recall required elements of a CSR
C. Relate data collection and validation tasks to the production of the CSR
D. Relate the concept of "fit for purpose" to data quality and decision making

REQUIRED TEXTBOOK AND MATERIAL:

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