CTR 230 Data Trends and Reporting

COURSE DESCRIPTION:

Prerequisites: CTR 225
Corequisites: None

This course covers the reporting of clinical trial data including identification of safety and efficacy trends in the data. Topics include generation of tables, listing and graphs, the identification and reporting of data trends, and the generation of various types of study reports. Upon completion, students should be able to understand the process for review and reporting of clinical trial data results.
Course Hours Per Week: Class, 1, Lab, 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. Understand the statistical analysis plan with respect to how data will be presented
2. Identify and communicate data trends in data, including safety trends
3. Understand the management of pharmacovigilance data
4. Understand the management of laboratory data
5. Understand the content of a clinical study report (CSR), including Integrated Summary of Effectiveness, Integrated Safety Summary

OUTLINE OF INSTRUCTION:

I. Understand the statistical analysis plan with respect to how data will be presented
   A. Describe the role and importance of statistic and informatics in clinical studies
   B. Summarize the purpose of the statistical analysis plan (SAP)
   C. Recall basic statistical terms related to clinical research studies
   D. Recall common listing, table and graph formats
   E. Identify study objectives, endpoints and Critical to Quality (CTQ) factors when reviewing mock protocol and statistical analysis plan (SAP)
   F. Identify data reporting requirements based on regulatory requirements and protocol design

II. Identify and communicate data trends in data, including safety trends
   A. Relate the concept of "fit for purpose" to preparation of data utilized for review and reporting
   B. Identify the cross-functional stakeholders who participate in trend review and reporting
   C. Identify and understand data outliers and inconsistencies
   D. Identify significant trends in mock safety and laboratory data
   E. Model appropriate safety and laboratory data status and trend communications

III. Understand the management of pharmacovigilance data
   A. Describe the pre and post approval safety reporting requirements of regulatory agencies
   B. Contrast symptoms, adverse events and serious adverse events
   C. Summarize adverse event management process including collection, validation, reconciliation and reporting

IV. Understand the management of laboratory data.
    A. Summarize regulatory requirements for collecting and reporting laboratory data
    B. Summarize the laboratory data management process including collection, validation and reporting
    C. Identify significant trends in mock safety data

V. Understand the content of a clinical study report (CSR), including Integrated Summary of Effectiveness, Integrated Safety Summary
    A. Recall regulatory requirements for Clinical Study Reports (CSR)
    B. Contrast CSR with traditional academic publications
    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.