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.

COURSE OBJECTIVES:

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

A. Understand the statistical analysis plan with respect to how data will be presented.
B. Identify and communicate data trends in data, including safety trends.
C. Understand the management of pharmacovigilance data.
D. Understand the management of laboratory data.
E. Understand the content of a clinical study report (CSR), including Integrated Summary of Effectiveness, Integrated Safety Summary.

OUTLINE OF INSTRUCTION:

A. Understand the statistical analysis plan with respect to how data will be presented.
   1. Describe presentation of raw data versus summary data.
   2. Generate and understand tables, listings and graphs.
   3. Review final tables, listing and graphs.

B. Identify and communicate data trends in data, including safety trends.
   1. Define guidelines for identifying and communicating safety data and trends.
   2. Identify and understand data outliers and inconsistencies.

C. Understand the management of pharmacovigilance data.
   1. Describe what pharmacovigilance data will be collected during a trial.
   2. Describe the SAE reconciliation process.
   3. Reconcile safety information using similar medical terminology.
D. Understand the management of laboratory data.
   1. Understand what types of laboratory data should be collected.
   2. Understand the process for handling and review of lab data.
   3. Describe what is required for reconciliation of laboratory data.

E. Understand the content of a clinical study report (CSR), including Integrated Summary of Effectiveness, Integrated Safety Summary.
   1. Generate a clinical study report.
   2. Perform final quality assurance audit on the CSR.

REQUIRED TEXTBOOKS AND MATERIALS:

To be announced by Instructor.