

**CTR 230**  
**DATA TRENDS AND REPORTING**

**COURSE DESCRIPTION:**

Prerequisites: CTR 210, 215, 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.

**STATEMENT FOR STUDENTS WITH DISABILITIES:**

Students who require academic accommodations due to any physical, psychological, or learning disability are encouraged to request assistance from a disability services counselor within the first two weeks of class. Likewise, students who potentially require emergency medical attention due to any chronic health condition are encouraged to disclose this information to a disability services counselor within the first two weeks of class. Counselors can be contacted by calling 686-3652 or by visiting the Student Development Office in the Phail Wynn Jr. Student Services Center, room 1309.