MSP 220 Signal Detection and Risk Assessment

COURSE DESCRIPTION:

Prerequisites: MSP 130
Corequisites: None

This course provides a basic understanding of how data are analyzed in order to identify safety signals and determine a product's risk profile. The course also emphasizes the overarching reason for the evaluation of medical product safety and pharmacovigilance, i.e., to ensure a medical product has a favorable benefit-risk balance throughout its lifecycle. Topics include the rationale and methods used in analyzing single cases vs. aggregate data. Upon completion of this course students will have a better understanding of the relevance of the material learned in the previous courses e.g., case processing, safety systems, safety reporting and regulations as it relates to benefit-risk, as well as the importance and need for ongoing benefit-risk assessments. Students will also have a basic understanding of how signaling and risk assessments are done. Course Hours Per Week: Class, 3. Lab, 3. Credits: 4.

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 benefit-risk concepts
2. Discuss approach to signal detection and management in clinical development as well as post-marketing settings
3. Understand signal management
4. Understand the format and contents of Risk Management Plans (RMPs) and Risk Evaluation and Mitigation Strategies (REMS)
5. Management of Safety during Clinical Development

OUTLINE OF INSTRUCTION:

I. Understand benefit-risk concepts
   - A. Limitations in clinical trials (the "rule of 3")
   - B. Limitations of post-marketing data
   - C. Key terminology (e.g., signal, risk, benefit)
   - D. Safety documents used for benefit-risk evaluations

II. Discuss approach to signal detection and management in clinical development as well as post-marketing settings
   - A. Individual Case Safety Report (ICSR), case series, aggregate data analysis
   - B. Data mining
   - C. Literature reviews
   - D. Pharmacoepidemiology
   - E. Strategy for signal detection and management

III. Understand signal management
   - A. Process

B. Implementation of a signal management strategy
C. Safety governance

IV. Understand the format and contents of Risk Management Plans (RMPs) and Risk Evaluation and Mitigation Strategies (REMS)
    A. The Medical Dictionary for Regulatory Activities (MedDRA) for coding medical history and adverse events
    B. WHO Drug dictionary for coding drugs
    C. EudraVigilance Medicinal Product Dictionary (EVMPD)

V. Management of Safety during Clinical Development
    A. Process to identify, evaluate and minimize potential safety risks
    B. Tools and resources required
    C. Governance
    D. Collection of safety data
    E. Identification and evaluation of risk from clinical trial data

REQUIRED TEXTBOOK AND MATERIAL:

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