Syllabus: PHM 487: Pharmacovigilance Capstone

Course Title: PHM 487: Pharmacovigilance Capstone

Semester: Fall 2024

Instructor: Dr. Megan Lewis

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Office Hours: Fridays 2:00-4:30 PM OR by appointment

Class Time & Place: Wednesday or Friday 3:00-4:15 PM in SANCA 485

Course Description:

This capstone course focuses on the development and implementation of pharmacovigilance plans for newly approved drugs. Students will design a pharmacovigilance system, collect and analyze safety data, and implement risk mitigation strategies, culminating in a presentation of their findings at the Innovation Showcase. The course includes the development of a project proposal, risk assessment, data collection, and a final report.

Course Objectives:

Develop and implement a pharmacovigilance plan for a newly approved drug.

Monitor and analyze safety data from clinical trials and post-marketing surveillance.

Identify safety signals and implement risk mitigation strategies.

Effectively present the project at the Innovation Showcase.

Learning Outcomes:

Gain expertise in pharmacovigilance and drug safety monitoring.

Develop practical skills in risk assessment and management.

Improve communication skills through written reports and presentations.

Enhance the ability to manage pharmacovigilance projects from conception to completion.

Group Project and Required Subtasks:

The group project for this course will involve the development of a pharmacovigilance plan for a newly approved drug. The project will be broken down into the following subtasks:

1. **Project Proposal (Week 3):**
   - Create a proposal detailing the drug, the pharmacovigilance plan, and the anticipated outcomes. Include a timeline and assign roles to team members.

2. **Literature Review and Risk Assessment (Weeks 4-6):**
   - Conduct a thorough literature review to identify potential risks and adverse effects associated with the drug. Develop a risk assessment and management plan.

3. **Data Collection and Monitoring (Weeks 7-10):**
   - Design a pharmacovigilance system for monitoring adverse events. Collect and analyze data from clinical trials and post-marketing surveillance.

4. **Signal Detection and Risk Mitigation (Weeks 11-12):**
   - Identify safety signals and implement risk mitigation strategies. Update the pharmacovigilance plan based on the findings.

5. **Final Report and Presentation (Weeks 13-15):**
   - Document the entire pharmacovigilance process, including challenges, solutions, and outcomes in a final report.
   - Prepare a presentation and poster for the Innovation Showcase that highlights the key aspects of the project.

Groups are expected to collaborate closely, meeting regularly to discuss progress and resolve any

issues. Instructor check-ins will be scheduled to provide guidance and feedback.

Evaluation:

Class meetings (5): 20 points

Individual meetings (3): 12 points

Project Proposal: 10 points

Literature Review and Risk Assessment: 15 points

Data Collection and Monitoring: 18 points

Signal Detection and Risk Mitigation: 10 points

Final Report: 10 points

Presentation: 5 points

Poster: 10 points

Total: 100 points

Course Policies:

Attendance and Participation: Regular attendance and active participation are crucial for success in this course. Students are expected to attend all scheduled class meetings and individual sessions. If a student is unable to attend a class, they should inform the instructor in advance and arrange to complete any missed work.

Academic Integrity: All students must adhere to ASU's academic integrity policy. Any form of academic dishonesty, including plagiarism, will be reported and may result in severe penalties, including a failing grade for the course.

Accommodations: Students with disabilities or special needs should contact the ASU Disability Resource Center to arrange appropriate accommodations and notify the instructor as soon as possible.

Important Dates:

Class Week 1: Introductions & Project Brainstorming (Aug 26)

Individual Meeting #1: Discuss Ideas and Readings (Sep 4)

Class Week 2: Proposal Presentation & Group Feedback (Sep 18)

Individual Meeting #2: Proposal Feedback & Methods Discussion (Oct 2)

Class Week 3: Revised Proposal Presentation & CERTT Tour (Oct 23)

Individual Meeting #3: Data Analysis & Progress Review (Nov 13)

Class Week 4: Professional Development & Project Discussion (Nov 27)

Innovation Showcase: Final Presentations & Poster Display (Dec 6)