University of Medicine and Dentistry of New Jersey  
School of Public Health

Course Syllabus

Pharmacoepidemiology & Therapeutic Risk Management (3 credits)  
Spring Session, 2009

I. General Information  
Time: Tue: 6:10pm-9:00pm  
Location: SPH

Instructor:

Zdravko Vassilev, MD, MPH  
Medical Director, Epidemiology  
Covance Inc., Princeton, NJ, 08540  
Phone: (609) 452-4442  
Fax: (609) 520-0597  
E-mail: zdravko.vassilev@covance.com

Textbooks (Recommended):
Textbook of Pharmacoepidemiology, Strom BL and Kimmel S (edited),  
2007 Wiley Publisher.  
Manual of Drug Safety and Pharmacovigilance, Colbert BL, 2007 Jones  
and Bartlett Publishers

II. Course Objectives

This course is designed to introduce students to the basic concepts and methods  
of pharmacoepidemiology and drug safety. At the conclusion of the course,  
students should be able to:

- Define the scope of pharmacoepidemiology, pharmacovigilance and their  
  role in drug safety research

- Describe and explain the main pharmacoepidemiological study designs  
  and their major strengths and weaknesses

- Explain the foregoing epidemiology methods and concepts in analyzing,  
determining, and preventing drug-related problems. Describe Risk  
  Minimization Action Plans (RiskMAPs) and drug post-marketing  
  surveillance

- Critically review and interpret the medical and epidemiological literature  
  related to studies on adverse drug reactions, drug safety, and  
  pharmacovigilance
III. Teaching Format

New material will be presented in informal lectures. The main emphasis will be put on students' hands-on experience through discussions and in-class assignments, case studies, and critical reading of relevant literature. Participation in class discussions is mandatory. Students will be expected to read the assigned material prior to the lecture or the class discussion.

IV. Student Evaluation

Grades will be based on the following:

- Mid-term exam 30%
- Final exam 30%
- Written critique of articles 20%
- Class participation 20%

Examinations

Two exams will be given during this course. The exams may consist of multiple choice, True-False, short answer questions, and statistical computations, and will be administered at the scheduled times. Students should bring a calculator for exams.

Written critique

In the second half of the course, students will complete 1 critique of a recent paper published in one of the pharmacoepidemiologic journals. Students will receive a handout with guidelines how to evaluate an epidemiologic paper. Full credit will be awarded if the critiques are completed and turned in on time. No credit will be given if the critiques are turned in 24 hours past the due date. The critiques will be discussed in class in one of the following sessions.
## V. Course Schedule

<table>
<thead>
<tr>
<th>DATE</th>
<th>TOPIC</th>
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<tbody>
<tr>
<td>Thu, Week 1</td>
<td>Introduction to Course: What is Pharmacoepidemiology, Drug safety, and Pharmacovigilance</td>
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<tr>
<td>Thu, Week 2</td>
<td>Study Designs in Pharmacoepidemiology Sample Size Considerations</td>
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<tr>
<td>Thu, Week 3</td>
<td>Basic Principles of Clinical Pharmacology used in Pharmacoepidemiology</td>
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<td>Thu, Week 4</td>
<td>Bias and Confounding in Pharmacoepidemiology. Causality</td>
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<td>Thu, Week 5</td>
<td>Drug Safety, Spontaneous Adverse Event Reporting</td>
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<td>Thu, Week 6</td>
<td>Sources of Pharmacoepidemiology Data Risk Evaluation and Mitigation Strategy</td>
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<td>Thu, Week 7</td>
<td>MID-TERM EXAM</td>
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<td>Thu, Week 8</td>
<td>Randomized Clinical Trials. Utilization of Observational and Interventional Studies in Pharmacoepidemiology</td>
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<td>Thu, Week 9</td>
<td>Bioethical Issues in Pharmacoepidemiology</td>
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<td>Thu, Week 10</td>
<td>Molecular Pharmacoepidemiology</td>
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<td>Thu, Week 11</td>
<td>Pharmacoeconomic Studies</td>
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<td>Thu, Week 12</td>
<td>Quality-of-Life Measurements in Pharmacoepidemiology. Registries of Patient Outcomes</td>
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<tr>
<td>Thu, Week 13</td>
<td>FINAL EXAM: Covers entire course</td>
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V. Grading

Letter grades are awarded in this course as follows below, and will appear on the student's official transcript.

A  Represents achievement that is outstanding relative to the level necessary to meet course requirements. (90-100 points)

B+  (86-89 points)
B  Represents achievement that is significantly above the level necessary to meet course requirements. (80-85 points)

C+  (76-79 points)
C  Represents achievement that meets the course requirements in every respect. (70-75 points)

F  Represents failure and signifies that the work was completed but not at a level of achievement worthy of credit (<70 points)

I  An incomplete grade ("I") is permitted only in cases of exceptional circumstances and following consultation with the instructor.