

The Graduate College of RUSH University

PVM 552: Introduction to Clinical Research (27 hours in the Graduate College's Summer Quarter)

The course objective for PVM 552 is: "To introduce young clinical investigators to important concepts in epidemiology that form the basis for commonly-executed clinical research studies."

The Specific Aims for PVM 552 can be summarized as follows:

At the conclusion of this course, the successful student should be able to:

- 1) Define risk (in the context of medicine and epidemiology) and contrast three (3) types of risk that are commonly used in this discipline.
- 2) Calculate sensitivity and specificity, given a standard 2 x 2 table of results (or the data from which such a table can be generated).
- 3) Name three (3) common "confounders" in medical and epidemiological studies, and two (2) ways that can be used to examine the effects of such confounders on an independent primary outcome.
- 4) Calculate a "5-year number needed to treat," given the results of a long-term comparative trial of a therapy against placebo (or no treatment).
- 5) Compare and contrast: descriptive studies, case-control studies, cohort studies, and clinical trials, regarding their place in the hierarchy of medical evidence, and their propensity for providing correct and unbiased answers to clinical questions.
- 6) Calculate and explain the differences between: attack rate, odds ratio, rate ratio, relative risk, and hazard ratio.
- 7) Name four (4) challenges in data collection and management in clinical research studies, and a common "solution" for each one.

PVM 546: Biostatistics I (27 hours in the Graduate College's Fall Quarter)

PVM 547: Biostatistics II (30 hours in the Graduate College's Winter Quarter)

PVM 553: Observational Epidemiology I (11 hours in the Graduate College's Winter Quarter)

PVM 557: Clinical Trials I* (27 hours in the Graduate College's Winter Quarter)

The course objective for PVM 557 is: "To introduce young clinical investigators to important concepts in clinical trial design, execution, and reporting (and controversies related to these issues)."

The Specific Aims for PVM 557 can be summarized as follows:

At the conclusion of this course, the successful student should be able to:

- 1) Define and give three (3) examples of an appropriate primary outcome measure, and an appropriate set of inclusion and exclusion criteria for a clinical trial that the student would like to see performed.
- 2) Define and give two (2) examples of methods of randomization, and three different types of blinding (“masking”) commonly used in clinical trials.
- 3) Use three (3) methods of determining the sample size for three different types of clinical trials.
- 4) Provide a rationale and an example for why measurement of baseline characteristics, adherence to the protocol, concomitant treatments after randomization, and adverse effects are important in clinical trials.
- 5) Name three different ways of performing survival (“time-to-event”) analyses, the advantages and disadvantages of each, and one widely-accepted method for adapting at least one of these for use by a Data and Safety Monitoring Board.
- 6) Name three serious responsibilities of any person or group of persons who wish to organize and execute a clinical trial.

PVM 554: Observational Epidemiology II (13 hours in the Graduate College’s Spring Quarter)

PVM 558: Management, Evaluation, and Statistical Interpretation of Clinical Trials (28.5 hours in the Graduate College’s Spring Quarter)

The course objective for PVM 558 is: “To examine, in depth, the planning, execution, and reporting of a large, NIH-sponsored clinical trial that has changed medical practice forever. This case study may illustrate how well-designed and properly-executed clinical research studies are best done now in the USA.”