

Statistics in Pharmaceutical Research

A Seminar Series

Fall 2009

Indiana University-Purdue University Indianapolis

INSTRUCTORS

Zachary Skrivanek, Ph.D.

Dr. Skrivanek is a Principal Research Scientist in Global Statistical Sciences at Eli Lilly. He is the chair of the course and will coordinate the seminar series and provide the initial overview of the course.

Aranuva Chakravartty, Ph.D.

Dr Chakravartty is a Research Scientist in Genomics Informatics. He will lecture on statistical analyses of data from technologies related to early drug development, such as microarray analysis and high throughput screening.

Alan Chiang, Ph.D.

Dr. Chiang is a Project Statistician in Toxicology & Drug Disposition. He will lecture on statistical issues related to toxicology.

Parag Garhyan, Ph.D.

Dr Garhyan is a Research Scientist in Pharmacokinetics/Pharmacodynamics. He will lecture on fundamental concepts in pharmacokinetics and pharmacodynamics.

Kristi Griffiths, Ph.D.

Dr. Griffiths is a Research Adviser in Product R&D. She will lecture on the development process for creating and evaluating a drug from the non-clinical point of view, specifically, product development.

Mike Heathman, M.S.

Mr. Heathman is a Research Advisor in population pharmacokinetics. He is an expert in modeling in simulation. He will lecture on the principles of population pharmacokinetics.

Quan Hong, Ph.D.

Dr. Hong is a Research Scientist in Program Phase Statistics. He will lecture on statistical issues in early drug development, including analyses of pharmacokinetics data.

Julie Satterwhite, Ph.D.

Dr Satterwhite is a Research Fellow and an expert in pharmacodynamics. She will lecture on the concepts and approaches behind pharmacodynamic modeling.

Mary Seger, M.S.

Ms. Seger is a Research Scientist in early drug development. She will lecture on the requirements and issues involved in biopharm packages.

Roy Tamura, Ph.D.

Dr. Tamura is a Senior Research Adviser in Global Brand Development. He will lecture on subjects related to large Phase III clinical trials and interim analyses.

Eshetu Wondmagegnehu, Ph.D.

Dr Wondmagegnehu is a Research Scientist in early drug development. He will lecture on materials from late phase biopharmaceutical (biopharm) studies, such as special renal population studies or bioequivalence studies.

Luping Zhao, Ph.D.

Dr Zhao is a Research Scientist in Global Statistical Sciences. She will lecture on Bayesian statistics applied to design and analyses of clinical studies.

OVERVIEW

Statistics in Pharmaceutical Research is a lecture series developed by experts in pharmaceutical research. The goal of the series is to further strengthen the ties between industry and academia by introducing participants to the broad spectrum of issues surrounding the drug development process in the pharmaceutical industry.

SCHEDULE*

The course will meet Tuesdays and Thursdays on the IUPUI campus from 6:00 p.m. to 7:15 p.m., in room 1110 of the HITS (Health Information & Translational Sciences) building. Students may register for this 3-credit hour course as BIOS S627, section 27959.

Date	Speaker	Topic
August 27	Zachary Skrivanek	Introduction-Drug Development History
September 1 September 3	Kristi Griffiths Kristi Griffiths	Clinical Material & Manufacturing Part 1 Clinical Material & Manufacturing Part 2
September 8 September 10	Kristi Griffiths Kristi Griffiths	Clinical Material & Manufacturing Part 3 Clinical Material & Manufacturing Part 4
September 15 September 17	Aranuva Chakravartty Aranuva Chakravartty	Drug Discovery - Part 1 Drug Discovery - Part 2
September 22 September 24	Aranuva Chakravartty Aranuva Chakravartty	Drug Discovery - Part 3 Drug Discovery - Part 4
September 29 October 1	Alan Chiang Alan Chiang	Toxicology - Part 1 Toxicology - Part 2
October 6 October 8	Alan Chiang Parag Garhyan	Toxicology - Part 3 Introduction to PK/PD
October 13 October 15	Quan Hong Quan Hong	Early Phase Clinical Trials - Part 1 Early Phase Clinical Trials - Part 2
October 20 October 22	Quan Hong Midterm Exam	Early Phase Clinical Trials - Part 3 No Lecture (midterm exam)
October 27 October 29	Roy Tamura Roy Tamura	Design Issues in Phase III Trials Part 1 Design Issues in Phase III Trials Part 2
November 3 November 5	Roy Tamura Roy Tamura	Design Issues in Phase III Trials Part 3 Design Issues in Phase III Trials Part 4
November 10 November 12	Luping Zhao Luping Zhao	Bayesian Methods & Bayesian Adaptive Designs Bayesian Methods & Bayesian Adaptive Designs
November 17 November 19	Luping Zhao Luping Zhao	Bayesian Methods & Bayesian Adaptive Designs Bayesian Methods & Bayesian Adaptive Designs
November 24 December 1	Satterwhite & Heathman Satterwhite & Heathman	Population Pharmacokinetics/dynamics - Part 1 Population Pharmacokinetics/dynamics - Part 2
December 3 December 8	Mary Seger Eshetu Wondmagegnehu	Introduction to Biopharm Packages Bioequivalence Studies
December 10 December 15	Eshetu Wondmagegnehu FINAL EXAM	QT No Lecture (final exam)

* Schedule subject to change.

For More Information

Kelly Houser, Graduate Programs Coordinator

Department of Mathematical Sciences
Indiana University-Purdue University Indianapolis

317-278-4127

khouser@math.iupui.edu