PHA6418 Introduction to Model-Informed Drug Development (MIDD)
Fall 2021
3 Credit Hours – A-E Grading

Course Description
Introduction to Model-Informed Drug Development (MIDD) is a 3-credit course that serves as a broad overview of applying modeling and simulation strategies to improve drug development decision-making and trial designs. Examples of applications include translational approaches from preclinical to clinical research, translation from biomarker to clinical endpoint, dose finding during Phase 1 and 2, clinical confirmation during Phase 3, avoiding the need for certain clinical trials, characterizing sources of variability in drug response, regulatory interactions and post-marketing assessment. Upon completion of the course, students will have a basic understanding of how model-based drug development can be applied to help bring new drugs to market more efficiently.

Course Coordinator
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Participating Faculty
Richard Lalonde, PharmD
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Teaching Assistant
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Course Faculty
Lectures will be provided by numerous adjunct faculty members from the pharmaceutical industry with vast experience in model-based drug development. Details and biographical sketches of the faculty can be found on the Canvas course site.

Course-Level Objectives
Upon completion of this course, the student will be able to:

1. Discuss and appreciate the role of model-informed drug development during the following stages: discovery, preclinical, clinical, regulatory review and post-approval.
2. Identify specific drug development questions or issues that can be addressed using MIDD.
3. Select and apply pharmacometric method(s) used in MIDD: population PK or PK-PD, clinical trial simulation, meta-analysis, systems pharmacology, PBPK, etc.
4. Contrast MIDD applications to support regulatory agency decisions versus drug development decisions within pharmaceutical industry.
5. Understand the development strategies for various therapeutic areas and identify the question that needed to be answered using MIDD
6. Describe MIDD approaches used to answer the above question: e.g. modeling, simulation, results, key assumptions and uncertainties.
7. Explain the impact of MIDD on specific drug development examples and regulatory decisions or interactions.
8. Apply MIDD concepts to all Phase(s) of drug development: preclinical, Phase 1, 2, 3, regulatory agency interactions, and post-regulatory approval.
9. Explain the critical aspects of conducting clinical trials including human subject protections, Phase 1, 2, and 3 trials, regulatory requirements, and clinical data management.

10. Answer specific drug development questions or issues that can be addressed by MIDD: dose selection, trial design for Phase 1, 2, or 3, go/no go, labeling, development strategy, avoiding the need to conduct a clinical trial, selecting between compounds in development, etc.
11. Apply MIDD to various therapeutic areas: cardiovascular, neuroscience, metabolic diseases, oncology, rare diseases, etc.

Course Pre-Requisites: none
Course Co-Requisites: none
Course Contact Hours: 45

Course Outline
Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule and deadlines.

Every week, two lectures will be assigned and made available online. In addition, reading assignment will be provided related to the recorded lectures. These lectures can be watched by the students at any time. Furthermore, a discussion session will be held that will allow interactive participation by the students. The time of the discussion session will be set in the first course meeting in order to find a suitable time slot that will work well for everybody.

Date *Dates for Independent Study*	**Module #**	**Unit Topic**	**Learning Objectives Covered**
	1	Introduction Model-Informed Drug Development	1-3
8/20-9/13		Introduction to the Course Review of Pharmacometric Methods Strategies of MIDD	
9/13	Assignment #1	Participate in Discussion Board	
9/11-9/13	Quiz 1	20 min, covers Module 1	
	2	Translation from Preclinical Development	4-7
9/16-9/27		In-Vitro Data Animal Data Prediction for Humans	
9/27	Assignment #2	Participate in Discussion Board	
9/25-9/27	Quiz 2	20 min, covers Module 2	
	3	Early in Human Studies (Phase 1)	4-7
9/30-10/11		Dose-Ascending Studies PK Characterization Safety Assessment	
10/11	Assignment #3	Participate in Discussion Board	
10/9-10/11	Quiz 3	20 min, covers Module 3	
	4	Dose Optimization (Phase 2) and Clinical Trials (Phase 3)	4-7

Date *Dates for Independent Study*	**Module #**	**Unit Topic**	**Learning Objectives Covered**
10/14-10/25		Dose Optimization and Finding Risk-Benefit Assessment Phase 3 Confirmation	
10/25	Assignment #4	Participate in Discussion Board	
10/23-10/25	Quiz 4	20 min, covers Module 4	
	5	Regulatory Requirements	8-9
10/28-11/8		Investigational New Drug (IND) Filing New Drug Application (NDA) Filing Interaction with Regulatory Agencies	
11/8	Assignment #5	Participate in Discussion Board	
11/6-11/8	Quiz 5	20 min, covers Module 5	
	6	Post-Marketing Assessment	10
11/11-11/22		MIDD approaches in Post-Marketing Surveillance Pharmacovigilance	
11/22	Assignment #6	Participate in Discussion Board	
11/20-11/22	Quiz 6	20 min, covers Module 6	
Due 12/3	**Final paper**	**Minimum 5 pages, double-spaced, 1-inch margins, 11- point font, Arial**	

Recommended Textbooks

- Title: Applied Pharmacometrics
- Authors: S. Schmidt, H. Derendorf
- AAPS Press/Springer
- 2014
- ISBN number: 978-1493913039

- Title: Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications
- Authors:. H. Derendorf, S. Schmidt
- Wolters & Kluwer
- 2020
- ISBN number: 978-1496385048

Additional reading assignments will be made available on the Canvas course site.

Quizzes, Problem Sets and Exams
All problem sets and exams have a one-week window for completion. There will be a 10-question multiple choice quiz following each module.

Discussion Boards
See affiliated course materials for instructions.

Materials & Supplies Fees
None

Student Evaluation & Grading
Evaluation Methods and How Grades are calculated.

Assessment Item	Grade Percentage
Exams (2x25%)	50%
Problem Sets (4x5%)	20%
Quizzes (6X5%)	30%
Total	100%

Percentage Range	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Class Attendance Policy
Pease refer to UF attendance policy: https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/

Students are required to watch lectures within the period that is indicated in the syllabus. Conflict with work schedules is not an excused absence for not watching the lectures.

Makeup assignment(s) will be made for any excused absence(s) and must be submitted ***within one-week of the missed session(s)***. If the situation leads to missing multiple class sessions and makeup becomes difficult, the student and course coordinator will discuss with the administration to explore options such as a remediation plan or course withdrawal. Class attendance requires full engagement of activities including problem sets, assignments and course reflection.

Additional Policy Specific to This Course: Problem Set and Exam Policy
Students must finish the problem sets and exams within the one-week window indicated in the syllabus. Students who missed the quiz window will get a zero for that quiz without an excused reason. Students need to contact the course coordinator through email for any emergency situation that prevents the student from taking the problem set and explain the situation immediately when the situation resolved. The student will either take a make-up problem set or choose other options determined by the coordinator.

Academic Integrity Policy
Students are expected to act in accordance with the University of Florida policy on academic integrity (http://www.dso.ufl.edu/sccr/honorcodes/honorcode.php). This Honor Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obliged to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult the course's Teaching Partnership Leader. Students are also expected to abide by the UF Honor Code.

The following is the UF Honor Pledge: We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty and integrity by abiding by the Honor Code.
On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment."