

## ***Population Pharmacokinetics and Pharmacodynamics***

PHA 6122 Section: 30965

***Class Periods:*** Thursdays 9:00 – 10:30 AM (Active Learning Sessions)

***Location:*** LN 234 & GNV P4-20

***Academic Term:*** Spring 2024

***Credits:*** 3

### ***Instructors:***

**Sarah Kim, PhD (Course Coordinator)**

Email: [sarahkim@cop.ufl.edu](mailto:sarahkim@cop.ufl.edu)

Office Phone Number: (407) 313-7044

Office Hours: TBD

**Natalia V. De Moraes, PhD**

Email: [nataliademoraes@ufl.edu](mailto:nataliademoraes@ufl.edu)

Office Hours: TBD

**Valvanera Vozmediano Esteban, PhD**

Email: [valva@ufl.edu](mailto:valva@ufl.edu)

Office Hours: TBD

**Serge Guzy, PhD**

Email: [sergeguzy@ufl.edu](mailto:sergeguzy@ufl.edu), [poppfarm2@gmail.com](mailto:poppfarm2@gmail.com)

Office Hours: TBD

### ***Program Coordinator:***

**Nasser Nassiri Koopaei, PhD**

Email: [koopaei@ufl.edu](mailto:koopaei@ufl.edu)

### ***Teaching Assistant:***

**Shyam Ramesh, PharmD, MS**

Email: [shyamramesh@ufl.edu](mailto:shyamramesh@ufl.edu)

### ***Course Description***

This 3-credit course offers a comprehensive exploration of theoretical concepts in population pharmacokinetics/ pharmacodynamics (PK/PD) modeling, along with practical applications using continuous and non-continuous data. Each week, students will have access to two assigned lectures, which will be available online. Half of the lecture series will consist of live, hands-on active learning sessions, and recordings will be posted afterward. To reinforce the learning experience, assignments related to the active learning sessions will be provided. Students have the flexibility to watch the lectures at their convenience.

### ***Course Pre-Requisites / Co-Requisites***

PHA6125 Introduction to Quantitative Pharmacology

### ***Course Objectives***

By the end of this course, students will have acquired the skills to effectively articulate the theory and implementation of nonlinear mixed-effect modeling and simulation. They will also be proficient in data formatting, developing population PK/PD models, evaluating model performance, and conducting simulations. Moreover, students will have hands-on experience in utilizing various population PK/PD software platforms, such as MonolixSuite, Pumas, Phoenix, and R.

## **Materials and Supply Fees**

N/A

## **Required Textbooks and Software**

There are no required textbooks.

### Software

- **Phoenix:**  
License keys and installation guide will be distributed at the beginning of the course.
- **Monolix Suite:**  
Installation can be done through the website: <https://lixoft.com/downloads/>  
License keys will be distributed at the beginning of the course.
- **Pumas:**  
Students will need to follow the instructions and fill out the form in the link below to request desktop access to Pumas for Academia after ensuring their device meets the minimum required specifications (8-core processor, 16GB RAM, Windows or Mac Operating System). License keys are sent on Thursdays from [pfa@pumas.ai](mailto:pfa@pumas.ai). Students who have not received their key should check their junk/spam folders. \*Please note: Installation on Virtual Machines is not possible under the current licensing agreement.  
<https://form.jotform.com/230606204012134>
- **R & R Studio:**  
<https://cran.r-project.org/bin/windows/base/>  
<https://www.rstudio.com/products/rstudio/download/#download>

## **Recommended Materials**

- Title: Introduction to Population Pharmacokinetic/Pharmacodynamic Analysis with Nonlinear Mixed Effects Models  
Authors: Joel S. Owen, Jill Fiedler-Kelly  
Publisher: Wiley; 1st edition (July 8, 2014)  
ISBN-13: 978-0470582299 | ISBN-10: 9780470582299
- Title: Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications  
Authors: Hartmut Derendorf, Stephan Schmidt  
Publisher: Wolters Kluwer Health; 5th edition (July 11, 2019)  
ISBN-13: 978-1496385048 | ISBN-10: 1496385047
- Title: Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications  
Authors: Johan Gabrielsson, Daniel Weiner  
Publisher: Swedish Pharmaceutical Press; 4th edition (July 4, 2007)  
ISBN-13: 978-9197651004 | ISBN-10: 9197651001
- Title: Pharmacokinetic-Pharmacodynamic Modeling and Simulation  
Author: Peter L. Bonate  
Publisher: Springer; 2nd ed. 2011 edition (July 1, 2011)  
ISBN-13: 978-1441994844 | ISBN-10: 144199484X

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

## Course Schedule

Week #	Pre-recorded Lectures	Active Learning Sessions (Software) Thursdays, 9:00-10:30 AM	Assignments
<b>Week 0</b>	<b>Module 0</b> Course Overview (SK)		
<b>Week 1</b> Jan 8-12	<b>Module 1a</b> Compartmental Models, Model Evaluation (NM)	No ALS	
<b>Week 2</b> Jan 15-19	<b>Module 1b</b> Covariate Analysis, Simulation (NM)	<b>ALS Module 1 (Monolix)</b> Intro to Monolix, Modeling Building, and Covariate Analysis (NM)	<b>Assignment #1</b> (NM)
<b>Week 3</b> Jan 22-26	<b>Module 2</b> Separating Sources of Variability (SK)	No ALS	
<b>Week 4</b> Jan 29-Feb 2	<b>Module 3a</b> Nonlinear PK (VV)	<b>ALS Module 2 (Monolix &amp; R)</b> Simulation, Sources of Variability (SK)	
<b>Week 5</b> Feb 5-9	<b>Module 3b</b> Parent-Metabolite (VV)	<b>ALS Module 3a (Pumas)</b> Intro to Pumas (VV)	
<b>Week 6</b> Feb 12-16	<b>Module 3c</b> Special Populations (VV)	<b>ALS Module 3b (Pumas)</b> Parent-Metabolite (VV)	<b>Assignment #2</b> (VV)
<b>Week 7</b> Feb 19-23	<b>Module 4</b> Dose Selection (SG)	<b>ALS Module 3c (Pumas)</b> Special Population (VV)	
<b>Week 8</b> Feb 26-Mar 1	<b>Exam #1</b> Modules 1-4 (SK, NM, VV)		
<b>Week 9</b> Mar 4-8	<b>Module 5a</b> Population PK/PD: Continuous (SK)	<b>ALS Module 5a (Monolix)</b> Population PK/PD: Continuous (SK)	
<b>Week 10</b> Mar 11-15	<i>Spring Break</i>		
<b>Week 11</b> Mar 18-22	<b>Module 5b</b> Population PK/PD: Case Examples (Guest Speaker, SK)	<b>ALS Module 5b (Monolix &amp; R)</b> Population PK/PD: Continuous (SK)	<b>Assignment #3</b> (SK)
<b>Week 12</b> Mar 25-29	<b>Module 6</b> Disease Progression Models (SK)	No ALS	
<b>Week 13</b> Apr 1-5	<b>Module 7a</b> Population PK/PD: Categorical Response (SG)	<b>ALS Module 7a (Phoenix)</b> Population PK/PD: Categorical Response (SG)	
<b>Week 14</b> Apr 8-12	<b>Module 7b</b> Population PK/PD: Count Data (SG)	<b>ALS Module 7b (Phoenix)</b> Population PK/PD: Count Data (SG)	<b>Assignment #4</b> (SG)
<b>Week 15</b> Apr 15-19	<b>Module 7c</b> Population PK/PD: Time-to-Event (SG)	<b>ALS Module 7c (Phoenix)</b> Population PK/PD: Time-to-Event (SG)	
<b>Week 16</b> Apr 22-26	<b>Exam #2</b> Modules 5-7 (SK, SG)		

SK: Dr. Sarah Kim, NM: Dr. Natalia V. De Moraes, VV: Dr. Valvanera Vozmediano, SG: Dr. Serge Guzy

### Attendance Policy, Class Expectations, and Make-Up Policy

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. Active Learning Session (ALS) attendance is required. TAs will collect students' signatures on an attendance sheet in each ALS class in person for registered UF graduate students and check login information for students enrolled in the online certificate program.

Makeup assignments will be made for any excused absence and tardiness and must be submitted within two-week of the missed sessions. 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.

Four hands-on assignments will be provided to assess the students' understanding of the concepts covered in the active learning sessions. These assignments will require students to either develop their own models or replicate an analysis using a provided dataset. Students will be expected to present their modeling/analysis results in their submission reports, including key graphs and tables as specified in each assignment's description. The evaluation criteria for these assignments will focus on the quality of the models developed and the logical, comprehensible, and concise nature of the descriptions provided.

Students must finish the assignments within the two-week window and exams within the one-week window indicated in the syllabus. Students who missed the window will get a zero for that assessment item 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 is resolved. The student will either take a make-up problem set or choose other options determined by the coordinator.

Excused absences must be consistent with university policies in the [Graduate Catalog](#) and require appropriate documentation. Additional information can be found in [Attendance Policies](#).

### ***Evaluation of Grades***

<b><i>Assignment</i></b>	<b><i>Total Points</i></b>	<b><i>Percentage of Final Grade</i></b>
ALS Attendance	11	5%
Hands-on assignments (4)	20 each	75%
Exams (2)	10 each	20%
		100%

### ***Grading Policy***

The following is given as an example only.

<b><i>Percent</i></b>	<b><i>Grade</i></b>	<b><i>Grade Points</i></b>
90.0 - 100.0	A	4.00
87.0 - 89.9	A-	3.67
84.0 - 86.9	B+	3.33
81.0 - 83.9	B	3.00
78.0 - 80.9	B-	2.67
75.0 - 79.9	C+	2.33
72.0 - 74.9	C	2.00
69.0 - 71.9	C-	1.67
66.0 - 68.9	D+	1.33
63.0 - 65.9	D	1.00
60.0 - 62.9	D-	0.67
0 - 59.9	E	0.00

More information on UF grading policy may be found at:

[UF Graduate Catalog](#)  
[Grades and Grading Policies](#)

### ***Students Requiring Accommodations***

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the [Disability Resource Center](#). It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

### ***Course Evaluation***

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. [Click here for guidance on how to give feedback in a](#)

[professional and respectful manner](#). Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via [ufl.bluera.com/ufl/](http://ufl.bluera.com/ufl/). [Summaries of course evaluation results are available to students here](#).

### **University Honesty Policy**

UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor 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." [The Honor Code](#) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

### **Software Use**

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

### **Student Privacy**

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see the [Notification to Students of FERPA Rights](#).

### **Campus Resources:**

#### **Health and Wellness**

##### **U Matter, We Care:**

If you or a friend is in distress, please contact [umatter@ufl.edu](mailto:umatter@ufl.edu) or 352 392-1575 so that a team member can reach out to the student.

**Counseling and Wellness Center:** [counseling.ufl.edu/cwc](http://counseling.ufl.edu/cwc), and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

##### **Sexual Assault Recovery Services (SARS)**

Student Health Care Center, 392-1161.

**University Police Department** at 392-1111 (or 9-1-1 for emergencies), or [police.ufl.edu](http://police.ufl.edu).

#### **Academic Resources**

**E-learning technical support**, 352-392-4357 (select option 2) or e-mail to [Learning-support@ufl.edu](mailto:Learning-support@ufl.edu).

**Career Resource Center**, Reitz Union, 392-1601. Career assistance and counseling.

**Library Support**, Various ways to receive assistance with respect to using the libraries or finding resources.

**Teaching Center**, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.

**Writing Studio**, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.

**Student Complaints Campus**

**On-Line Students Complaints**