

**PSCI 662: Advanced  
Pharmacokinetics/Pharmacodynamics  
2 units  
Fall 2023—Mon—10:00 AM-12:00 PM  
Location: PSC B13**

**Course Coordinator(s):**

J. Andrew MacKay: jamackay@usc.edu  
Office: PSC 306A Phone: (323) 442-4118

**Office Hours:**

MacKay: Thursdays at 1

Office hours may be held in an office, in a classroom, or on Zoom.

**Instructors:**

Paul Beringer: beringer@usc.edu  
Michael Bolger: bolger@usc.edu

**IT Help:**

**Blackboard is the Learning Management System (LMS) used at the USC Mann School of Pharmacy and Pharmaceutical Sciences. For 24/7 help with Blackboard:**

- Call (213) 740-5555 and choose Option 2.
- Send an e-mail to [blackboard@usc.edu](mailto:blackboard@usc.edu).
- Visit USC's Blackboard Online Help site for how-to videos and guides.
- Access additional Blackboard training videos on LinkedIn Learning at <https://itservices.usc.edu/linkedin-learning/>.
- **Zoom and Panopto may be used for lecture capture and delivery, Zoom and Poll Everywhere may be used as an audience response system, and Blackboard and ExamSoft may be used to administer quizzes and examinations.**
- For help with Zoom, visit <https://itservices.usc.edu/zoom/>.
- For help with Panopto, call the 24/7 Panopto support team at (855) 765-2341 or e-mail [support@panopto.com](mailto:support@panopto.com)
- For help with ExamSoft, call the 24/7 ExamSoft support team at (866) 429-8889, e-mail [support@examsoft.com](mailto:support@examsoft.com) , or visit <https://help.examsoft.com/>.
- You may also visit our Technical Support Specialists in PSC 302B, M-F from 8:00 AM-5:00 PM, call (323) 442-0002, or e-mail [mannit@usc.edu](mailto:mannit@usc.edu).
- **For all other technology-related questions, call USC Information Technology Services at (213) 740-5555.**

## Course Description

Advanced Pharmacokinetics/Pharmacodynamics (PSCI 662) will present concepts, standard terminology, and mathematical models of the drug disposition process. Students will focus on understanding and practicing common methods for the collection, analysis, interpretation, and comparison of pharmacokinetic data. In addition to the derivation of analytical solutions for common pharmacokinetic profiles, students will be introduced to several software packages capable of solving and fitting more complex models. In addition, the course will introduce students to advanced approaches to parameter estimates, including allometric scaling, Bayesian Statistics and Physiologically-Based Pharmacokinetic modeling.

## Course Learning Objectives

By the end of this course on Pharmacokinetics, learners will master:

- OBJECTIVE 1: Model Derivation. Use mass balances to derive analytical solutions for common PK profiles following a single dose. These include one and two compartment models of an intravenous bolus, during and after short and long intravenous infusions, and absorption of an extravascular/oral dose. Differentiate between compartmental and model-independent PK.
- OBJECTIVE 2: Understanding Parameters. Describe, calculate, and interpret common parameters and outputs involved with PK, which include volume of distribution, clearance, half-life, area under the curve, bioavailability, protein-binding, loading dose, and maintenance dose.
- Objective 3: Analyze, compare, write, and communicate regarding experimental PK data using available data and tools.

## Course Notes

BLACKBOARD: Blackboard is utilized as the learning management system for this course. Lecture slides, lecture videos, assignments, solutions, and grades will be posted on blackboard. Assignments will be submitted for grading through blackboard. Instructions related to examinations and discussion activities will be provided through blackboard.

ZOOM: Accessed via Blackboard, Zoom may be used on computers for office hours and possibly other content as needed. In general, zoom office hours will not be recorded for this course.

SAAM2: A software program (Simulation, Analysis, and Modeling 2, SAAM2) may be used to fit and model pharmacokinetic data. Instructions for accessing this software and using it to solve HW and cases for your term paper will be made throughout the course.

## Required Readings and Supplementary Materials

- Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications (Rowland and Tozer, available through the Norris Medical Library (NML) E-resources)

## Description and Assessment of Assignments

Homework will be assigned via blackboard. Completed assignments should be uploaded into blackboard before the posted deadline. Assignment solutions will be posted within one week of the due date. There will be between 5 and 11 homework scores; however, the two lowest scores will be automatically dropped from the calculation of your grade. You do not need to email to request this.

Assessment methods used in this course:

Multiple guess questions

Fill-in-the-blank/Short answer questions

Hand-written essay questions

Homework assignments

Written Term project with Oral presentation

## Methods

### Teaching Methods

#### Before Event

- Online lecture

#### During Event

- Classroom lecture
- Student presentation
- Team based learning

### Assessment Methods

#### Examination

- Short answer
- Essay

#### In Class

- Oral presentation
- Attendance and Participation

#### Longer term

- Term paper

### Grading Breakdown

Assignment	Percent
Homework	25
Midterm	25
Term Project	25
Final Exam	25

### Grading Scale

A	95-100.00
A-	90-94.99
B+	87-89.99
B	83-86.99
B-	80-82.99
C+	77-79.99
C	73-76.99
C-	70-72.99
D+	67-69.99
D	63-66.99
D-	60-62.99
F	59.99 and below

## Additional Policies

### Policy Regarding Class Recordings

All class recordings (Zoom, Panopto, etc.) are accessible only to students currently enrolled in the class, instructors, and TAs. These recordings may not be shared or used for purposes outside of this course. Students are also not permitted to record or distribute any course materials or activities on their own without the instructor's permission.

## Policy Regarding Assignments and Examinations

The following actions are all violations of academic integrity and subject to disciplinary action:

- a. Any use or attempted use of external assistance in the completion of an academic assignment and/or during an examination, or any behavior that defeats the intent of an examination or other classwork or assignment, unless expressly permitted by the instructor.
- b. The following are examples of unacceptable behaviors: communicating with fellow students during an exam, copying or attempting to copy material from another student's exam; allowing another student to copy from an exam or assignment; possession or use of unauthorized notes, calculator, or other materials during exams and/or unauthorized removal of exam materials.
- c. Other examples of academic misconduct have been and will be considered.

For more information about academic integrity see [the student handbook](#) or the [Office of Academic Integrity's website](#).

## Policy Regarding Missed Examinations

The policy for this course will follow the policy contained within the Academic Policies and Procedures section of the Student Handbook located on the [USC Mann School of Pharmacy and Pharmaceutical Sciences Intranet](#).

Students who miss an examination are referred to this policy.

## Technological Requirements and Software Updates

Students may be required to bring an internet-enabled device with browser capabilities, such as a cell phone, tablet, or laptop to class. During class time, it is expected that students will use their devices only to participate in activities guided by the instructor. Use of devices for other purposes is not permitted during class time.

The USC Mann School of Pharmacy and Pharmaceutical Sciences recommends that students purchase a computer that meets, at minimum, the "medium" level hardware requirements that are also recommended for faculty and staff: <https://itservices.usc.edu/recommendations/>.

Students who use Zoom should be running the latest version of Zoom available at <https://zoom.us/download>.

Students who use ExamSoft will also be required to have the latest version of Examplify installed on their laptops at all times compatible with their operating system. Occasional updates to the software may be asked of you throughout the year. It is your responsibility to read your USC e-mails regarding Examplify and follow the instructions as listed.

## Policy on Learning & Assessment Feedback (LAF)

Feedback on examinations/assessments will be provided using the following methods.

- Complete examination will be returned and a key will be made available

## Learning Experience Evaluation Notes:

Extra credit may be provided for completion of the online course evaluation during the last week of classes.

## University Policy on Absences

University policy grants students excused absences from class for observance of religious holy days. Faculty are asked to be responsive to requests when students contact them IN ADVANCE to request such an excused absence. The student should be given an opportunity to make up missed work because of religious observance. Students are advised to scan their syllabi at the beginning of each course to detect potential conflicts with their religious observances. Please note that this applies only to the sort of holy day that necessitates absence from class and/or whose religious requirements clearly conflict with aspects of academic performance. For additional program-

specific absence policies, please refer to the Student Handbook on the [USC Mann School of Pharmacy and Pharmaceutical Sciences Intranet](#).

### **USC Mann School Policy for Written Assignments Regarding Citation Style**

All written assignments in the course should use the uniform style of the USC Mann School of Pharmacy and Pharmaceutical Sciences for formatting in-text citations and reference lists. This style corresponds to the AMA (American Medical Association) format and can be found through this following guide <https://libguides.usc.edu/ama11> and handout [https://libguides.usc.edu/ld.php?content\\_id=54130825](https://libguides.usc.edu/ld.php?content_id=54130825). The complete AMA Manual of Style is also available as an e-book at [tinyurl.com/bdh8amka](http://tinyurl.com/bdh8amka).

## **Statement on Academic Conduct and Support Systems**

### **Academic Integrity:**

The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, comprises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

Other violations of academic integrity include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), collusion, knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see [the student handbook](#) or the [Office of Academic Integrity's website](#), and university policies on [Research and Scholarship Misconduct](#).

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment, or what information requires citation and/or attribution.

### **Student Accessibility Services:**

USC welcomes students with disabilities into all of the University's educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, an OSAS letter will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at [osas.usc.edu](http://osas.usc.edu). You may contact OSAS at (213) 740-0776 or via email at [osasfrontdesk@usc.edu](mailto:osasfrontdesk@usc.edu).

## **Support Systems:**

[Counseling and Mental Health](#) - (213) 740-9355 – 24/7 on call

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

At USC Mann, we acknowledge being a student can be difficult at times while managing all personal life matters. Having an accessible mental health and wellness staff member on campus is intended to provide direct supportive services for our students.

Veronica Acosta, LCSW, Wellness Counselor, offers coping tools to reduce stress and anxiety and offers insight from a wellness perspective on how to adjust accordingly to life while being a student. Email: [vaacosta@usc.edu](mailto:vaacosta@usc.edu); Office: Seaver Residence Hall (SRH) room 307; Appointments: <https://engage.usc.edu/meetings/2569802/wellnessmeet>

[988 Suicide and Crisis Lifeline](#) - 988 for both calls and text messages – 24/7 on call

The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

[Relationship and Sexual Violence Prevention Services \(RSVP\)](#) - (213) 740-9355(WELL) – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

[Office for Equity, Equal Opportunity, and Title IX \(EEO-TIX\)](#) - (213) 740-5086

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

[Reporting Incidents of Bias or Harassment](#) - (213) 740-5086 or (213) 821-8298

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

[The Office of Student Accessibility Services \(OSAS\)](#) - (213) 740-0776

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

[USC Campus Support and Intervention](#) - (213) 740-0411

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

[Diversity, Equity and Inclusion](#) - (213) 740-2101

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

[USC Emergency](#) - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

[USC Department of Public Safety](#) - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call

Non-emergency assistance or information.

[Office of the Ombuds](#) - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

[Occupational Therapy Faculty Practice](#) - (323) 442-2850 or [otfp@med.usc.edu](mailto:otfp@med.usc.edu)

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.

## About Your Instructor(s)

J. Andrew MacKay, Ph.D.

Office: 306A

Contact Info: [jamackay@usc.edu](mailto:jamackay@usc.edu)

Attempts will be made to respond to emails within one week; however, students are urged to make use of scheduled office hours, recorded lectures, solutions to assignments, and in-class discussion sessions.

## Summary of Course Schedule

Date	Lecturer	Event
Mon 08/21/23 10:00a - 12:00p	J. Andrew MacKay	Module 1: Course Overview, Topics in PK, ADME, graphing
Mon 08/28/23 10:00a - 12:00p	J. Andrew MacKay	Module 2: rate constants, compartmental models, Clearance, Volume of Distribution, Half-life
Thu 09/07/23 01:00p - 03:00p	J. Andrew MacKay	Module 3: AUC, Bioavailability, IV Infusion Model, IV Short Infusion vs. Bolus model, Protein Binding
Mon 09/11/23 10:00a - 12:00p	J. Andrew MacKay	Module 4: Extravascular (Oral) Model, Time Maximum Concentration, Method of Residuals
Mon 09/18/23 10:00a - 12:00p	J. Andrew MacKay	Module 5: Two-compartment IV Bolus Model, Macroconstants, Microconstants, Volume at Steady State
Mon 09/25/23 10:00a - 12:00p	J. Andrew MacKay	Module 6: Hepatic Physiological Clearance Equation, Intrinsic Clearance
Mon 10/02/23 09:00a - 12:00p		Exam 1
Mon 10/09/23 10:00a - 12:00p	J. Andrew MacKay	Module 7: Modeling Data in Term Paper using SAAM
Mon 10/16/23 10:00a - 12:00p	Paul Beringer	Module 8: Multiple Dose: IV Bolus, IV Short Infusion, Oral Rapid and Controlled Release, Time to Steady-State, Loading Doses
Mon 10/23/23 10:00a - 12:00p	Paul Beringer	Module 9: Renal Clearance, Assessment of Renal Function, Drug Dosing in Renal Disease
Mon 10/30/23 10:00a - 12:00p	Michael Bolger	Module 10: Allometric scaling, Physiologically-based Pharmacokinetic models (PBPK)
Mon 11/06/23 10:00a - 12:00p	J. Andrew MacKay	Module 11: SAAM Modeling Monoclonal Antibody PK, Bayesian Estimation

Date	Lecturer	Event
Mon 11/13/23 09:00a - 12:00p	J. Andrew MacKay	Exam 2
Mon 11/27/23 10:00a - 12:00p	J. Andrew MacKay	Module 12: Term-paper presentations and due date

### Expanded Course Schedule

Date	Lecturer	Event
Mon 08/21/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 1: Course Overview, Topics in PK, ADME, graphing</p> <p>MODULE DESCRIPTION: In this module, you will be introduced to common pharmacokinetic parameters required to solve and interpret pharmacokinetics.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Compare and contrast pharmacokinetics and pharmacodynamics</li> <li>- List processes involved with ADME</li> <li>- Explain differences between blood, serum, plasma</li> <li>- List applications of PK from drug development to therapeutic dose monitoring</li> <li>- Use graphing paper to plot PK data</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read chapters 1,2,3 (Rowland &amp; Tozer)</li> <li>- Prior to class review HW1 (need not complete)</li> <li>- During class be prepared to discuss asynchronous content, participate in small group discussions, solve problems.</li> <li>- After class HW1 will not be due until week 2</li> </ul>
Mon 08/28/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 2: rate constants, compartmental models, Clearance, Volume of Distribution, Half-life</p> <p>MODULE DESCRIPTION: In this module, you will be introduced to additional pharmacokinetic parameters, as well as methods to use graphing to quantify pharmacokinetics.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Explain variables important to the solution of PK models</li> <li>- Use mass balances to setup equations for compartmental models</li> <li>- Describe how changes in clearance and volume of distribution influence the observed half-life of the drug</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read Chapter 4 (Rowland &amp; Tozer)</li> <li>- Prior to class complete homework (HW1)</li> <li>- During class be prepared to discuss homework</li> <li>- After class HW is due by 11:59pm</li> </ul>
Thu 09/07/23	J. Andrew MacKay	Module 3: AUC, Bioavailability, IV Infusion Model, IV Short Infusion



01:00p - 03:00p		<p>vs. Bolus model, Protein Binding</p> <p>MODULE DESCRIPTION: In this module, you will learn how to solve and calculate drug concentration after IV administration.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Calculate AUC after a single IV bolus dose using the trapezoid method</li> <li>- Calculate bioavailability following single dose IV and PO</li> <li>- Solve the plasma concentration-time profile after a single bolus iv</li> <li>- Identify factors that affect the plasma concentration-time profile after a single bolus iv administration</li> <li>- Use IV infusion model to solve for the concentration after: <ul style="list-style-type: none"> <li>-a long infusion, which reached steady state</li> <li>-a short infusion, which did not reach steady state</li> </ul> </li> <li>- Calculate loading doses by infusion using <ul style="list-style-type: none"> <li>-bolus model</li> <li>-short infusion model</li> </ul> </li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read chapters 5,10, Appendix A,C,D (Rowland &amp; Tozer)</li> <li>- Prior to class complete homework (HW2)</li> <li>- After class HW is due by 11:59pm</li> </ul>
Mon 09/11/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 4: Extravascular (Oral) Model, Time Maximum Concentration, Method of Residuals</p> <p>MODULE DESCRIPTION: In this module, you will be introduced to additional pharmacokinetic parameters, as well as methods to use graphing and model independent methods to quantify pharmacokinetics.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Use mass balance to model concentration after absorption of an extravascular dose</li> <li>- Explain and calculate parameters related to absorption</li> <li>- Explain and use method of residuals</li> <li>- Explain how bioavailability affects the estimation of clearance and volume of distribution</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read Chapter 6,7 Appendix F (Rowland &amp; Tozer)</li> <li>- Prior to class complete homework (HW3)</li> <li>- During class be prepared to discuss homework</li> <li>- After class HW is due by 11:59pm</li> </ul>
Mon 09/18/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 5: Two-compartment IV Bolus Model, Macroconstants, Microconstants, Volume at Steady State</p> <p>MODULE DESCRIPTION: In this module, you will learn how to solve and interpret data for drugs that follow a 'two-compartment'</p>

		<p>model after IV administration.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Compare and contrast the 1-and 2-compartment PK models</li> <li>- Use method of residuals to determine distinct exponential terms relevant to PO, IV-infusion, 2-compartment drugs</li> <li>- Calculate the plasma concentration following a iv bolus that follows 2-compartment PK model</li> <li>- Explain/estimate the the difference between microconstants and macroconstants in the 2 compartment model</li> <li>- Describe volume of distribution and clearance as it relates to 2 compartment drugs</li> <li>- Analyze the effect of changing pk parameters on the plasma concentration-time profile after iv bolus of drugs that follow 2-compartment pk model</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read Chapter 19, Appendix E (Rowland &amp; Tozer)</li> <li>- Prior to class complete homework (HW4)</li> <li>- During class be prepared to discuss homework</li> <li>- After class HW is due by 11:59pm</li> </ul>
<p>Mon 09/25/23 10:00a - 12:00p</p>	<p>J. Andrew MacKay</p>	<p>Module 6: Hepatic Physiological Clearance Equation, Intrinsic Clearance</p> <p>MODULE DESCRIPTION: In this module, you will learn how to apply models of physiological clearance in the context of the liver and their implications in drug interactions.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Describe the physiological meaning of total body clearance in terms of organ blood flow, intrinsic clearance, fracon of unbound drug, and extraction ratio</li> <li>- Describe the effect of changing the hepatic intrinsic clearance and blood flow on the hepatic extraction ratio</li> <li>- Analyze the effect of changing either intrinsic clearance or liver blood flow on the plasma concentration-time profile after IV and oral administration</li> <li>- Describe the relationship between hepatic clearance and liver blood flow, enzyme activity and protein binding</li> <li>- Discuss biliary excretion and enterohepatic recycling</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides (1 hr)</li> <li>- During class participate in small group discussions</li> <li>- During class be prepared to discuss homework</li> </ul>
<p>Mon 10/02/23 09:00a - 12:00p</p>		<p>Exam 1</p> <p>This exam tests the content covered on Modules 1 through 6.</p>

Date	Lecturer	Event
Mon 10/09/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 7: Modeling Data in Term Paper using SAAM</p> <p>MODULE DESCRIPTION: In this module, you will learn to use SAAM to model your PK data for your term paper.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Identify a compartmental model that can be used to characterize your data.</li> <li>- Determine if there is a testable hypothesis that you can answer using available data and models</li> <li>- Tabulate fit parameters</li> <li>- Create prediction curves for a regimen</li> <li>- Hands on help using SAAM software</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class complete homework</li> <li>- During class be prepared to work on your data fitting</li> <li>- After class HW is due by 11:59pm</li> </ul>
Mon 10/16/23 10:00a - 12:00p	Paul Beringer	<p>Module 8: Multiple Dose: IV Bolus, IV Short Infusion, Oral Rapid and Controlled Release, Time to Steady-State, Loading Doses</p> <p>MODULE DESCRIPTION: In this module, you will learn how to apply multiple dosing models to estimate plasma concentrations after doses when a patient has been taking a regimen for some duration.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Define steady state during multiple dose administration.</li> <li>- Determine whether a loading dose is needed given a multiple dose regimen and pharmacokinetic parameters.</li> <li>- Calculate an appropriate loading dose to rapidly achieve target concentrations.</li> <li>- Choose the appropriate dosing model to predict steady-state concentrations following multiple dose administration.</li> <li>- Determine the steady state drug concentrations and patient pk parameters during multiple dose administration.</li> <li>- Analyze the effect of changing one or more of the pk parameters on the steady state plasma concentration during multiple dose administration.</li> <li>- Recommend a maintenance dosing regimen to achieve specific plasma concentrations in patients.</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read Chapter 2 (Beringer &amp; Winter)</li> <li>- Prior to class complete homework</li> <li>- During class be prepared to discuss homework</li> <li>- After class HW is due by 11:59pm</li> </ul>
Mon 10/23/23 10:00a - 12:00p	Paul Beringer	<p>Module 9: Renal Clearance, Assessment of Renal Function, Drug Dosing in Renal Disease</p>

		<p>MODULE DESCRIPTION: In this module, you will learn how to apply models of physiological clearance in the context of the kidneys and their implications in dose adjustment and drug interaction.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Identify some causes of variability in drug pharmacokinetics in different individuals.</li> <li>- Determine the factors that affect the change in drug pharmacokinetics in patients with kidney dysfunction during multiple drug administration.</li> <li>- Analyze the effect of changing the kidney function and the fraction of dose excreted unchanged in urine on drug pharmacokinetics.</li> <li>- Recommend an appropriate dosing regimen in patients with kidney failure.</li> <li>- Evaluate the appropriateness of dosing regimens in patients with kidney dysfunction.</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class read Chapter 3 (Beringer &amp; Winter)</li> <li>- Prior to class complete homework</li> <li>- After class HW is due by 11:59pm</li> </ul>
<p>Mon 10/30/23 10:00a - 12:00p</p>	<p>Michael Bolger</p>	<p>Module 10: Allometric scaling, Physiologically-based Pharmacokinetic models (PBPK)</p> <p>MODULE DESCRIPTION: In this module, you will be introduced to PBPK modeling and allometric scaling, two methods useful for predicting PK in humans.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Review examples of how PK parameters can be estimated across species.</li> <li>- Understand what parameters can be used in PBPK models</li> <li>- Explain and understand relative strengths of PBPK vs compartmental modeling.</li> <li>- Introduction to Simulations Plus PBPK software</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class complete homework</li> <li>- During class be prepared to discuss HW</li> <li>- After class HW is due by 11:59pm</li> </ul>

Date	Lecturer	Event
Mon 11/06/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 11: SAAM Modeling Monoclonal Antibody PK, Bayesian Estimation</p> <p>MODULE DESCRIPTION: In this module, you will be introduced to population pharmacokinetic modeling, using examples of monoclonal antibody therapies. SAAM will be used to analyze data.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Introduce concept of Bayesian Parameter Estimation</li> <li>- Connect this with the concept of using population PK parameter fits to make estimates of individual PK parameters using sparse data</li> <li>- Be able to describe examples of monoclonal antibody therapeutics.</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review asynchronous lectures and slides</li> <li>- Prior to class complete homework</li> <li>- During class be prepared to discuss HW</li> <li>- After class HW is due by 11:59pm</li> </ul>
Mon 11/13/23 09:00a - 12:00p	J. Andrew MacKay	<p>Exam 2</p> <p>This exam tests the content covered on Modules 7 through 11.</p>
Mon 11/27/23 10:00a - 12:00p	J. Andrew MacKay	<p>Module 12: Term-paper presentations and due date</p> <p>MODULE DESCRIPTION: In this session, we will hear from each group a short presentation on their term paper.</p> <p>LEARNING OBJECTIVES:</p> <ul style="list-style-type: none"> <li>- Demonstrate competence discussing PK data and parameters</li> <li>- Identify strengths and weaknesses of your own PK data</li> <li>- Identify possible connections between PK parameter issues and evidence for toxicity/efficacy</li> </ul> <p>TASKS:</p> <ul style="list-style-type: none"> <li>- Prior to class review powerpoint slides of entire class</li> <li>- During class be prepared to present your topic and provide comments</li> <li>- Take time to complete Learning Experience Evaluation</li> <li>- NOTE: The HW for this week is the term project and powerpoint presentation, Due Dec 2nd, 2022, 11:59 pm</li> </ul>