Course Title: Principles of Pharmacotherapy in Clinical and Translational Cancer Research
Course Number: M390
Credits: 0.5
Course Directors:

- Lane Nguyen, PharmD, BCCPS
  Pediatric Critical Care Medicine
  Memorial Sloan Kettering Cancer Center, MSK Kids

Course Lecturers & Lectures:

- Raymond G. DeMatteo, PharmD, BCOP
  Clinical Pharmacy Specialist, Early Drug Development
  - "*Pharmacokinetics & Drug Transporters*"
- Issam Hamadeh, PharmD, BCOP
  Clinical Pharmacy Specialist, Multiple Myeloma
  - *"Pharmacodynamic Considerations"*
  - *"Pharmacogenomics & Drug Interactions"*
- Lane Nguyen, PharmD, BCPPS
  Clinical Pharmacy Specialist, Pediatric Critical Care
  - *"Pharmacotherapy Principles in Special Populations"*

Grading Policy: Pass/Fail
Course Location: This course will be held on Teams.
https://teams.microsoft.com/meet/26173299266683?p=tVvlfDVhojbXv1dwqU
Meeting ID: 261 732 992 666 83
Passcode: 7XR9RZ9K

Course Description
Conducting safe, high-quality clinical research warrants considerations for on- and off-target drug effects and how drugs reach those targets across a diverse cohort. Principal investigators must apply foundational pharmacotherapeutic concepts when designing clinical cancer research to ensure protocols direct efforts to manage intra- and inter-patient differences in drug exposure and maximize safety.

This course explores principles of pharmacotherapy as they relate to clinical cancer research, including pharmacokinetics, pharmacodynamics, pharmacogenomics, drug interactions, and considerations in special populations. The course's intent is to provide investigators with a practical foundation for rational incorporation of these principles into research protocols.

Course Goals and Learning Objectives
Upon completion, course participants should be able to:

- Review pharmacokinetic principles including absorption/bioavailability, distribution, metabolism, and excretion, including the role of drug transporters
- Contrast pharmacodynamic principles of classical oncologic agents, targeted agents, and immunotherapy agents
- Describe principles of pharmacogenomics

- Compare pharmacotherapy principles in special populations (geriatrics, pediatrics, obesity, organ dysfunction)
- Provide an in-depth look at drug-drug interactions relative to clinical research

Course Structure and Schedule

Participants are required to attend four live one-hour sessions with time for questions/answers over two days, followed by completion of an approximately 30-minute assignment incorporating the principles discussed.

September 15h, 2026 | 8:00 AM to 11:00 AM

Session 1: Pharmacodynamic Considerations in Oncology Drug Development

Session 2: Pharmacotherapy Principles in Special Populations

September 29th, 2026 | 8:00 AM to 11:00 AM

Session 3: Pharmacokinetics & Drug Transporters

Session 4: Pharmacogenomics and Drug Interactions

Assignments and Methods for Assessing Student Achievement

Participants are required to complete a case study-style assignment. The assignment will incorporate principles taken from each lecture in mock preclinical and early clinical data for an investigative agent for which a study protocol is being written – candidates will answer multiple choice questions about the study design based on the information provided. Passing is a score of at least 80%.

Assignments are due by October 13th, 2026 by 5:00 PM and should be submitted on the course Moodle platform.

Basis for Grade Determination

Students will receive a pass/fail grade for this course based on attendance of the live sessions and receiving a score of at least 80% on the assignment.

Course Bibliography and Resources

- https://ocr.od.nih.gov/courses/pcpRegistration.html
- Banerji U, Workman P. Critical parameters in targeted drug development: the pharmacological audit trail. Semin Oncol. 2016 Aug;43(4):436-45.
- Bonate PL, Howard DR, editors. Pharmacokinetics in Drug Development: Problems and Challenges in Oncology, vol 4. Switzerland: Springer International Publishing; 2016.Fan J, de Lannoy IAM. Pharmacokinetics. Biochem Pharmacol. 2014;87(1):93-120.
- Figg WD, McLeod HL, Editors. Handbook of Anticancer Pharmacokinetics and Pharmacodynamics, 2e. New York, NY, United States: Springer Science+Business Media; 2014.
- Parchment RE, Doroshow JH. Pharmacodynamic endpoints as clinical trial objectives to answer important questions in oncology drug development. Semin Oncol. 2016;43(4):514-525.

- Parchment RE, Voth AR, Doroshow JH, Berzofsky JA. Immuno-pharmacodynamics for evaluating mechanism of action and developing immunotherapy combinations. Semin Oncol. 2016;43(4):501-513.
- Tomlin M, editor. Pharmacology & Pharmacokinetics: A Basic Reader. London, United Kingdom: Springer-Verlag London Limited; 2010.
- Watanabe H, Nagano N, Tsuji Y, Noto N, Ayusawa M, Morioka I. Challenges of pediatric pharmacotherapy: A narrative review of pharmacokinetics, pharmacodynamics, and pharmacogenetics. *Eur J Clin Pharmacol*. 2024;80(2):203-221. doi:10.1007/s00228-023-03598-x

Academic Integrity Policy

Each student in this course is expected to abide by the Gerstner Sloan Kettering Policy of Academic Integrity and Plagiarism.

Students are expected to understand all standard rules associated with plagiarism. Resources available to further inform the student of what constitutes plagiarism can be found in the MSK Code of Conduct, the content of the Responsible Conduct of Research course as well as in many guides offered to explain the seriousness of any breach of not submitting one's own work for credit. A guidebook "Writing with Sources – a Guide for Students", is offered to each student upon matriculation; an additional copy is available in the student library.

Any instance of suspected plagiarism by a student will be brought to the attention of the Dean for further inquiry and action. Proven instances of plagiarism can result in dismissal from GSK.

Course Evaluation

Students will be encouraged to complete an anonymous survey that will evaluate the effectiveness of the course. This survey is used to improve future course offerings.