

DRAFT SYLLABUS

Course Title: MEDI 501: Principles of Preclinical Translational Science — A Case Study from Cancer Drug Discovery and Development

Summer Semester 2020 (seven weeks, June 15 – July 31, 2020)

Course learning objectives—

- Understand the definitions and goals of translational research and translational science and how they differ.
- Identify a range of scientific and operational principles that can be applied to enhance preclinical translational research projects.
- Learn about the research process necessary to enable a scientific discovery to lead to an effective compound that can be used in humans.
- Learn about the varied roles of different disciplines, as well as agencies — including industry, government agencies, and academic faculty and institutions — in advancing translational research and how to facilitate effective interagency and team-based collaboration.

Week 1 (June 15): Overview of the Course, Translational Science and Initiation of this Project

Lecture 1a: Introduction to MEDI 501: Principles of Preclinical Translational Science — A Case Study from Cancer Drug Discovery and Development ([Jessica Faupel-Badger](#))

Lecture 1b: Translational Science: Maximizing the Success of Translational Research ([Christopher P. Austin](#))

Lecture 1c: Challenges in Development of Selective Anti-Metastasis Therapies in Today's Cancer Treatment Landscape ([Udo Rudloff](#))

Lecture 1d: Pursing Novelty to Accelerate Innovation in Translational Research ([Juan Marugan](#))

Assigned reading and mini-quiz; submit questions for speakers/office hours

Week 2 (June 22): Optimizing Efficiency and Effectiveness in Translational Research: Infrastructure, Teams and Partnerships, and Scientific Approaches

Lecture 2a: Organizational Approaches to Accelerate Translational Research: NCATS Early Translation Branch Capabilities ([Matt Hall](#))

Lecture 2b: Efficiency and Effectiveness in Drug Discovery ([Marc Ferrer](#))

Lecture 2c: Rigor, Reproducibility and Scaling-up for Phenotypic Screening Approaches ([Marc Ferrer](#))

Assigned reading and mini-quiz; submit questions for speakers/office hours

Week 3 (June 29): Medicinal Chemistry to Advance Preclinical Translational Research

Lecture 3a: Medicinal Chemistry in the Preclinical Translational Research Team ([Sam Patnaik](#))

Lecture 3b: Medicinal Chemistry Approaches in the Metarrestin Project ([Sam Patnaik](#))

Assigned reading and mini-quiz; submit questions for speakers/office hours by 11:59 p.m. EDT Wednesday

Office hours at end of this week: Lecturers will answer questions submitted by students.

Assignment: Discussion board post — This week is nearing the halfway point for the course. Your assignment is to post a question or a reflection to the group. Questions should focus on the material covered so far. Reflections can address material that is applicable to your own work or something that is new or interesting to you. Also, reply to a question or a reflection from someone else in the group.

Week 4 (July 6): Partnering for Success: Cross-Agency Research Alliances and Interdisciplinary Science Teams

Lecture 4a: Cross-Agency Partnerships to Accelerate Translational Research: Overview of Goals and Approaches Used by the NCATS Office of Strategic Alliances ([Krishna "Balki" Balakrishnan](#))

Lecture 4b: Legal Approaches for Effective Cross-Agency Alliances ([Krishna "Balki" Balakrishnan](#))

Lecture 4c: Strategies for Effective Team Interactions: Evidence-Based Practices for Team Science ([Amanda Vogel](#))

Lecture 4d: Conflict Prevention and Collaboration Planning for Team Science ([Amanda Vogel](#))

Assigned reading and mini-quiz; submit questions for speakers/office hours.

Week 5 (July 13): Advancing Along the Translational Spectrum: Predictive Models in Drug Development; Pharmacology and Toxicology Testing in the Preclinical Research Project

Lecture 5a: Uses, Strengths, and Limitations of Preclinical Cancer Models, Including Animal Models, for Predicting Future Response in Humans ([Udo Rudloff](#))

Lecture 5b: Pancreatic Cancer Overview and Aligning Animal Models with Clinical Needs for the Metarrestin Project ([Udo Rudloff](#))

Lecture 5c: Transitioning from Preclinical Research to Toxicology Data Needed for Investigational New Drug (IND) Filing ([Phil Sanderson](#))

Lecture 5d: Pharmacology and Toxicology in the Preclinical Translational Research Project ([Xin Xu](#))

Lecture 5e: The Role of Toxicology Data in Filing for an IND ([Pramod Terse](#))

Assigned reading and mini-quiz; submit questions for speakers/office hours.

Week 6 (July 20): Target Identification

Lecture 6a: Principles for Target Identification in Phenotypic Drug Discovery Efforts ([Juan Marugan](#))

Lecture 6b: Principles for Target Identification in the Metarrestin Project ([Juan Marugan](#))

Office hours at end of this week: Lecturers will answer questions submitted by students. In addition, they will share reflections on lessons learned and preclinical translational science principles covered in the course.

Assigned reading and mini-quiz; submit questions for speakers/office hours by 11:59 p.m. EDT Wednesday

Week 7 (July 27): Regulated Clinical Trials and Course Wrap-Up

Lecture 7a: Clinical Trials Goals, Design and Implementation — Part 1 ([Elizabeth Ness](#))

Lecture 7b: Clinical Trials Goals, Design and Implementation — Part 2 ([Elizabeth Ness](#))

Lecture 7c: Update on the Design and Status of NCI 20-C-0023: First-in-Human Phase I Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of Metarrestin (ML-246) in Subjects with Metastatic Solid Tumors ([Udo Rudloff](#))

Lecture 7d: Course Conclusion and Additional Resources ([Jessica Faupel-Badger](#))

Assigned reading and mini-quiz.

Course Completion Certificate