

## Abbreviated Draft Syllabus

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

Fall 2021 Semester (7 weeks, August 30-October 15, 2021)

#### 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 of translational science 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 and agencies -- including industry, government agencies, and academia -- in advancing translational research, and how to facilitate effective inter-agency and team-based collaboration.

#### Week 1 (August 30): Overview of the Course, Translational Science, and Initiation of this Project

**Orientation Lecture:** Introduction to MEDI 501 Principles of Preclinical Translational Science: A Case Study from Cancer Drug Discovery and Development ([Lameese Akacem](#))

See email for invitation to complete pre-course survey

**Lecture 1a:** Translational Science: Maximizing the Success of Translational Research ([Joni Rutter](#))

**Lecture 1b:** Translational Science Principles ([Jessica Faupel-Badger](#))

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

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

**Assignments:** Introduction assignment, mini-quiz, assigned reading and submit questions for office hours.

#### Week 2 (September 7): Optimizing Efficiency and Effectiveness in Translational Research: Infrastructure, Teams and Partnerships, and Scientific Approaches

**Lecture 2a:** Collaborative Discovery at NCATS Early Translation Branch (ETB) Part 1 ([Matt Hall](#))

**Lecture 2b:** Collaborative Discovery at NCATS Early Translation Branch (ETB) Part 2 ([Matt Hall](#))

**Lecture 2c:** Identification of a phenotypic marker for selective anti-metastasis drug development ([Sui Huang](#))

**Lecture 2d:** *In vitro* Assays for Drug Discovery and Development: Towards Better Clinical Predictability ([Marc Ferrer](#))

**Lecture 2e:** Using Phenotypic-Based Drug Discovery Approaches to Discover Anti-Metastatic Drugs ([Marc Ferrer](#))

**Assignments:** Mini-quiz, 2-minute paper, assigned reading and submit questions for office hours.

### **Week 3 (September 13): Cross-Disciplinary Teamwork and Cross-Agency Partnerships to Advance Translation**

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

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

**Lecture 3c:** Partnering for Success, Part 1: Principles and Management of Intellectual Property ([Krishna “Balki” Balakrishnan](#))

**Lecture 3d:** Partnering for Success, Part 2: Approaches for Effective Collaboration ([Krishna “Balki” Balakrishnan](#))

**Assignments:** Mini-quiz, assigned reading and submit questions for office hours.

**LIVE office hours** TBD Lecturers will answer questions submitted in advance, and reserve time for a few live questions. More information forthcoming, including information on how to join live or view the recording.

### **Week 4 (September 20): Evidence-Based Practices to Enhance Team-based Collaboration, Creativity and Innovation in Translational Research**

**Lecture 4a:** Strategies for Effective Team Interactions: Evidence Based Practices from the Science of Team Science Field ([Amanda Vogel](#))

**Lecture 4b:** Planning for Success in Team Science ([Amanda Vogel](#))

**Lecture 4c:** Team Science in the Metarrestin Project: Group Interview ([Amanda Vogel](#))

**Lecture 4d:** The Division of Preclinical Innovation (DPI) Systems Approach to Creating and Sustaining a Team Science Environment ([Ann Knebel](#))

**Lecture 4e:** Creativity in Science Teams: What is it, and how do you achieve it? ([Roni Reiter-Palmon](#))

**Lecture 4f:** Fostering Innovation in Science Teams: Team and Organization Conditions ([Roni Reiter-Palmon](#))

**Assignments:** Mini-quiz, 2-minute paper, assigned reading, and submit questions for speakers/office hours.

### **Week 5 (September 27): 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 Discovery Research to IND Enabling Studies ([Phil Sanderson](#))

**Lecture 5d:** Application of Pharmacokinetics in Preclinical Translational Research ([Xin Xu](#))

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

**Assignments:** Mini-quiz, assigned reading and submit questions for office hours.

### **Week 6 (October 4): 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](#))  
Assigned reading and mini-quiz

**Assignments:** Mini-quiz, 2-minute paper, assigned reading and submit questions for office hours.

LIVE office hours, TBD. Lecturers will answer questions submitted in advance, and reserve time for a few live questions. More information forthcoming, including information on how to join live or view the recording.

**Week 7 (October 11): 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 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](#))

**Assignments:** Mini-quiz and assigned reading.