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

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 inter-agency and team-based collaboration.

Week 1: 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 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, submit questions for speakers/office hours and mini-quiz

Week 2: 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 (ETB) Capabilities (Matt Hall)

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

Lecture 2c: Using Phenotypic-Based Drug Discovery Approaches to Discover Anti-Metastatic Drugs (Marc Ferrer)

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

Week 3: 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, submit questions for speakers/office hours, and mini-quiz

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

Assignment: Week 3 Self-Reflection Discussion Board Post. More information about this will be forthcoming closer to week 3 and included in the instructions for this post.

Week 4: Partnering for Success: Cross-agency Research Alliances and Interdisciplinary Science Teams

Lecture 4a: Partnering for Success, Part 1: Principles and Management of Intellectual Property (Krishna "Balki" Balakrishnan)

Lecture 4b: Partnering for Success, Part 2: Approaches for Effective Collaboration (Krishna "Balki" Balakrishnan)

Lecture 4c: Strategies for Effective Team Interactions: Evidence Based Practices from the Science of Team Science Field (Amanda Vogel)

Lecture 4d: Planning for Success in Team Science (Amanda Vogel)

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

Week 5: 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 c: 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)

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

Week 6: 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, submit questions for speakers/office hours, and mini-quiz

Assignment: Week 6 Self-Reflection Discussion Board Post. More information about this will be forthcoming closer to week 6 and included in the instructions for this post.

Week 7: 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)

Special feature: Discussion with Dr. Sui Huang about the discovery of perinucleolar compartments (PNC), association of PNC with cancer cells, and cancer research (Sui Huang)

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

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

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