7/10/2020

DRAFT SYLLABUS (SUBJECT TO CHANGE)

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

Fall Semester 2020 (7 weeks, September 8- October 23, 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 inter-agency and team-based collaboration.

Week 1: 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 (Jessica Faupel-Badger)

Lecture 1a: Translational Science: Maximizing the Success of Translational Research (Christopher Austin)

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

Lecture 1c: Pursuing 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 by 11:59pm EDT Wednesday, and mini-quiz

LIVE office hours, date and time 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.

Assignments: 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 5c: Application of Pharmacokinetics in Preclinical Translational Research (Xin Xu)

Lecture 5d: The Role of Toxicology Data in Filing for an Investigational New Drug (IND) (Pramod Terse)

Special feature: Discussion with Dr. Phil Sanderson about transitioning from discovery research to IND enabling studies (Phil Sanderson)

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

LIVE office hours, date and time TBD. Theme: Reflections on evaluating projects, lessons learned, and preclinical translational science principles covered in course. More information forthcoming, including date, time, and information on how to join live or view the recording.

Assignments: 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 and mini-quiz