April 10, 2025

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

Course Syllabus

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 (Amanda Vogel and Jessica Faupel-Badger)
Lecture 1b: Translational Science: Maximizing the Success of Translational Research (Joni Rutter)
Lecture 1c: Translational Science Principles (Amanda Vogel)
Lecture 1d: Challenges in Development of Selective Anti-Metastasis Therapies in Today's Cancer Treatment Landscape (Udo Rudloff)
Lecture 1e: Pursuing Novelty to Accelerate Innovation in Translational Research (Juan Marugan)

Week 2: **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: The Division of Preclinical Innovation (DPI) Systems Approach to Creating and Sustaining a Team Science Environment (Ann Knebel)
Lecture 2d: Identification of a phenotypic marker for selective anti-metastasis drug development (Sui Huang)
Lecture 2e: In vitro Assays for Drug Discovery and Development: Towards Better Clinical Predictability (Marc Ferrer)
Lecture 2f: Using Phenotypic-Based Drug Discovery Approaches to Discover Anti-Metastatic Drugs (Marc Ferrer)

Week 3: **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 (Rebecca Erwin-Cohen)
Lecture 3d: Partnering for Success, Part 2: Approaches for Effective Collaboration (Rebecca Erwin-Cohen)

Week 4: **Evidence-Based Practices to Enhance Team-based Collaboration, Creativity, and Innovation in Translational Research**
Lecture 4a: Enhancing Team Based Collaboration (Amanda Vogel)
Lecture 4b: Strategies for Effective Team Interactions: Evidence Based Practices from the Science of Team Science Field (Amanda Vogel)
Lecture 4c: Planning for Success in Team Science (Amanda Vogel)
Lecture 4d: Team Science in the Metarrestin Project: Group Interview (Amanda Vogel)
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)

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)
Special Interview: Dr. Jessica Faupel-Badger Interviews Dr. Phil Sanderson about Transitioning from Discovery Research to IND Enabling Studies (Jessica Faupel-Badger and Phil Sanderson)
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)

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)
Lecture 6c: Clinical Trials Goals, Design and Implementation, Part 1 (Elizabeth Ness)
Lecture 6d: Clinical Trials Goals, Design and Implementation, Part 2 (Elizabeth Ness)

Week 7: Regulated Clinical Trials and Course Wrap-Up
Lecture 7a: 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 7b: Course Conclusion and Additional Resources (Amanda Vogel and Jessica Faupel-Badger)