## SCHEDULE

**Course:** CLRE-236 – Translational Research Fundamentals (Translational Medicine - From Bench to Bedside and Back)  
**Course Director:** Régent Laporte, D.V.M., M.Sc., Ph.D.  
**Quarter:** Winter 2018  
**Class Time:** Tuesdays from 2:00 to 3:50 PM, from January 9th to March 20th, 2018  
**Class Location:** UCSD Extension, Suite 150, Room 112 - University City Center, 6256 Greenwich Dr., San Diego, CA 92122

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<tr>
<th>Lesson (Date)</th>
<th>Topic</th>
<th>Learning Objectives</th>
<th>Textbook Sections</th>
<th>Evaluation (Points)</th>
<th>Faculty</th>
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| 1 (01/09)     | Introduction & Definitions Biomarkers | • Define Translational Medicine, explain why it is needed, what are its main remits, what is its current challenge, and what is the NIH Roadmap  
• Define biomarkers and describe their impact and remits in Drug Development  
• Describe how biomarkers could be used for decision making in Drug Development  
• Describe how biomarkers could be developed  
• Describe the predictivity classification of biomarkers and scores  
• Describe the use and value of biomarkers for health authorities and consortia  
• Describe the principles and types of tissue biobanks and the current challenges that they are facing  
• Describe the main biomarker localization technologies and immunoassays and their values for molecular medicine | 1 3.1 3.2 3.3 3.4 2.1.8 2.1.5 2.1.7 | Class Participation: 2.5  | Régent Laporte |
| 2 (01/16)     | Intellectual Property & Innovation | • Define what is intellectual property (IP) in Translational Medicine | 7 | 2.5  | Michael K. Dunn |
| 3 (01/23)     | The Omics | • Define the "Omics" and their roles in Translational Medicine | 2.1.1, 2.1.2 | 2.5  | 7.5  | Timothy R. Geiger |
| 4 (01/30)     | Translational Imaging | • List the main translational imaging modalities and describe how they can be used in Drug Discovery & Development | 3.7.3 | 2.5  | 7.5  | Patrick McConville |
| 5 (02/06)     | Pharmacogenomics-Driven Treatment | • Explain the role of Translational Pharmacogenetics in driving clinical decision making related to drug therapies | 2.1.4 | 2.5  | 5    | Grace M. Kuo |
| 6 (02/13)     | Drug Discovery | • Understand the place, role and purpose of Drug Discovery (i.e., Research) within Biopharmaceutical Research & Development (R&D)  
• Integrate the business and economic considerations impacting drug discovery programs  
• Recognize and appreciate the diversity of therapeutic modalities and their respective strengths and limitations  
• Map the drug discovery processes, from conception to execution | Reviews from the literature | 2.5  | 7.5  | Pierre J.-M. Rivière |
<p>| 7 (02/20)     | Non-Clinical Development | • Describe what is regulatory non-clinical assessment in drug development | 5 4.1 | 2.5  | 5    | Marina S. Nelson |</p>
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| 8 (02/27)    | Clinical Development | • Describe the methodological principles of Phase I clinical trials  
• Define what are Phase 0 clinical trials (a.k.a. exploratory clinical trials/studies) and how they can be used in drug development  
• Describe what is adaptive trial design  
• Describe what are basket or umbrella trial designs  
• Describe how regulatory and exploratory clinical trials could be combined and accelerate the generation of a clinical proof of concept | 4.2, 4.3  
4.4  
4.5, 4.6 | 2.5  
7.5 | Beverly Knight |
| 9 (03/06)    | Translational Stem Cell Research | • Explain the challenges associated with Translational Stem Cell Research  
• Explain how Stem-Cell-Derived Therapies Discovery & Development differs from Drug Discovery & Development  
• List the Stem-Cell-Derived Therapies and illustrate their applications | Review from the literature | 2.5  
5 | Catriona Jamieson |
| 10 (03/13)   | The Changing Role of Big Pharma Translational Science in Medicine: Putting the Pieces Together | • Describe how Translational Medicine is changing Big Pharma Drug Discovery & Development  
• Describe how to use the toolbox developed in the course to practice Translational Medicine | 9, 10 | 2.5  
No Homework Assignment | Régent Laporte |
| Final Exam (03/20) | Final Exam | 20 Points | | | |

TOTAL 25  
55

Faculty

Michael K. Dunn, Ph.D., M.B.A.  
Senior Director, Scientific Information & Intelligence  
Ferring Pharmaceuticals

Timothy R. Geiger, Ph.D.  
Field Applications Manager - North America West  
ProteinSimple

Catriona Jamieson, M.D., Ph.D.  
Assistant Professor of Medicine, Division of Hematology-Oncology  
Chief, Division of Regenerative Medicine  
Deputy Director, Sanford Stem Cell Clinical Center  
Co-Leader, Hematologic Malignancies Program  
Director, Stem Cell Research Program, Moores Cancer Center  
University of California, San Diego

Beverly Knight, Ph.D.  
Associate Director, Clinical Pharmacology  
Oncology Business Unit, Pfizer Inc.

Grace M. Kuo, Pharm.D., Ph.D., M.P.H., F.C.C.P.  
Professor of Clinical Pharmacy  
Associate Dean for Strategic Planning and Program Development

Skaggs School of Pharmacy and Pharmaceutical Sciences  
Adjunct Professor of Family and Preventive Medicine  
Director of SDPharmNet™ & PharmGenEd™  
University of California, San Diego

Régent Laporte, D.V.M., M.Sc., Ph.D.  
Principal Consultant, Laporte & Associates LLC  
Senior Director, Translational Pharmacology, Peptide Logic, LLC  
Research Fellow, Bio Nova Institute

Patrick McConville, Ph.D.  
Vice-President, Non-Clinical Research Services, inviCRO, LLC  
Adjunct Professor, Department of Radiology, School of Medicine  
University of California, San Diego

Marina S. Nelson, Ph.D.  
Drug Development Leader, Early Phase Development Solutions  
Covance Laboratories

Pierre J.-M. Rivière, Ph.D.  
CEO, Peptide Logic, LLC  
Research Fellow, Bio Nova Institute