## LECTURE SCHEDULE

**Course:** CLRE-236 – Translational Research Fundamentals  
**Instructors:** Régent Laporte, D.V.M., M.Sc., Ph.D.; Email: rlaporte@ucsd.edu; Phone/Text: (858) 729-8705  
Kanthi Athrey Kollengode, M.D., M.A.S.; Email: kaathrey@ucsd.edu  
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**Quarter:** Winter 2019  
**Class Time:** Tuesdays from 6:00 to 7:50 PM, from January 8th to March 19th, 2019  
**Class Location:** UCSD Extension, Suite 150, Room 112 - University City Center, 6256 Greenwich Dr., San Diego, CA 92122

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<th>Lesson (Date)</th>
<th>Topic</th>
<th>Learning Objectives</th>
<th>Textbook Sections</th>
<th>Evaluation (Points)</th>
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| 1 (01/08) | Introduction & Definitions  
The Changing Role of Big Pharma 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  
• Describe how Translational Medicine is changing Big Pharma Drug Discovery & Development  
• 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, 9, 10  
3.1  
3.2  
3.3  
3.4  
2.1.8  
2.1.5  
2.1.7 | 2.5 | 'Kemi Okwuegbuna  
Régent Laporte  
Kanthi A. Kollengode |
| 2 (01/15) | Intellectual Property & Innovation | • Define what is intellectual property (IP) in Translational Medicine | 7, Reviews from the literature | 2.5 | Michael K. Dunn |
| 3 (01/22) | The Omics | • Define the “Omics” and their roles in Translational Medicine | 2.1.1, 2.1.2 | 2.5 | Timothy R. Geiger |
| 4 (01/29) | Translational Imaging | • List the main translational imaging modalities and describe how they can be used in Drug Discovery & Development | 3.7.3 | 2.5 | Patrick McConville |
| 5 (02/05) | Pharmacogenomics-Driven Treatment | • Explain the role of Translational Pharmacogenetics in driving clinical decision making related to drug therapies | 2.1.4 | 2.5 | Grace M. Kuo |
| 6 (02/12) | Diagnostics | • Define a diagnostic test  
• Evaluate when it is appropriate to use a diagnostic test  
• Learn the main quantitative aspects of a diagnostic test  
• Describe the paradigm shift that led to the discovery and development of companion diagnostics and list 3 merits and demerits of the same with examples  
• What are complementary diagnostics and how do they differ from companion diagnostics  
• Describe 3 key elements that distinguish point-of-care testing from centralized laboratory testing and list 3 limitations of the same | Reviews from the literature | 2.5 | Roberta V. Alexander  
Kanthi A. Kollengode |
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| 7 (02/19)    | Drug Discovery | • Understand the place, role and purpose of Drug Discovery (i.e., Research) within Pharmaceutical 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  5 | Pierre J.-M. Rivière |
| 8 (02/26)    | Non-Clinical Development | • Describe what is regulatory non-clinical assessment in drug development | 5 | 2.5  5 | Marina S. Nelson |
| 9 (03/05)    | 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 | 4.1  4.2, 4.3  4.4  4.5, 4.6 | 2.5  7.5 | Mark S. Hixon |
| 10 (03/12)   | 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 | Reviews from the literature | 2.5  5 | Catriona Jamieson |
| Final Exam (03/19) | Online Final Exam | 20 Points |  | TOTAL  | 25  55 |

**Faculty**

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