# LECTURE SCHEDULE

**Course:** CLRE-236 – Translational Research Fundamentals  
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**Teaching Assistant:** Oluwakemi “Kemi” Okwuegbuna, M.D., F.M.C.Path., M.Sc., M.A.S.; Email: ookwuegb@ad.ucsd.edu  
**Quarter:** Summer 2018  
**Class Time:** Fridays from 2:00 to 3:50 PM, from July 6th to September 14th, 2018  
**Class Location:** UCSD Extension, Suite 150, Room 111 - 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>Speaker</th>
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</thead>
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| 1 (07/06)     | 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  
5 | Régent Laporte  
Kanthi A. Kollengode |
| 2 (07/13)     | 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  
5 | Roberta V. Alexander  
Kanthi A. Kollengode |
| 3 (07/20)     | Intellectual Property & Innovation | • Define what is intellectual property (IP) in Translational Medicine | 7, Reviews from the literature | 2.5  
5 | Michael K. Dunn |
| 4 (07/27)     | The Omics | • Define the “Omics” and their roles in Translational Medicine | 2.1.1, 2.1.2 | 2.5  
7.5 | Timothy R. Geiger |
| 5 (08/03)     | Translational Imaging | • List the main translational imaging modalities and describe how they can be used in Drug Discovery & Development | 3.7.3 | 2.5  
5 | Patrick McConville |
| 6 (08/10)     | 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 |
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| 7 (08/17)   | 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 (08/24)   | Non-Clinical Development   | • Describe what is regulatory non-clinical assessment in drug development           | 5                 | 2.5 5               | Marina S. Nelson         |
| 9 (08/31)   | 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 (09/07)  | 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  | Final Exam | 20 Points |  |  |  |

**TOTAL** | 25 55

**Faculty**

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