

LECTURE SCHEDULE

Course: CLRE-236 – Translational Research Fundamentals

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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

Lesson (Date)	Topic	Learning Objectives	Textbook Sections	Evaluation (Points)		Speaker
				Class Participation	Homework	
1 (01/08)	Introduction & Definitions The Changing Role of Big Pharma Biomarkers	<ul style="list-style-type: none"> • 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	'Kemi Okwuegbuna Régent Laporte Kanthi A. Kollengode
2 (01/15)	Intellectual Property & Innovation	<ul style="list-style-type: none"> • Define what is intellectual property (IP) in Translational Medicine 	7, Reviews from the literature	2.5	5	Michael K. Dunn
3 (01/22)	The Omics	<ul style="list-style-type: none"> • Define the "Omics" and their roles in Translational Medicine 	2.1.1, 2.1.2	2.5	7.5	Timothy R. Geiger
4 (01/29)	Translational Imaging	<ul style="list-style-type: none"> • 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
5 (02/05)	Pharmacogenomics-Driven Treatment	<ul style="list-style-type: none"> • 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 (02/12)	Diagnostics	<ul style="list-style-type: none"> • 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

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7 (02/19)	Drug Discovery	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Describe what is regulatory non-clinical assessment in drug development 	5	2.5	5	Marina S. Nelson
9 (03/05)	Clinical Development	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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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