PH290: Diagnostics in Infectious Diseases: Development and Regulatory Challenges

Course Syllabus (Spring 2022)

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Course Information

Course Meeting Dates and Times: Wednesdays 6:30 – 8:30 PM; Jan 19 through May 6

Course Location: TBD

Instructors: Veronica Miller PhD, Peter J Dailey PhD, John Sninsky PhD

Course Unit Value: 2

Course Description

Diagnostics represent 3% of health care expenditure, yet direct 65% of health care spending. Diagnostics are indispensable for clinical management and if appropriate tests are available and used, can reduce late-stage health care spending. Accurate diagnostic tests are the cornerstone of global health programs, but tests need to be approved by regulatory authorities before they can be used. In this course we review domestic and global regulatory oversight and explore how tests are marketed around the world. Students will learn about the challenges to innovation generalizability and best practices to develop and translate a diagnostic test into clinical practice. Focused on diagnostics in infectious diseases, the course features ongoing epidemics and pandemics such as HIV, TB and COVID-19. Topics range from the role of diagnostics in global health, to the basics of regulatory approval and oversight, innovation in analytics, to best practices for bringing a test from the lab bench to domestic and global markets.

This highly interactive seminar course is based on discussions of assigned readings, short presentations by course instructors and/or guests from diagnostic industry in the Bay Area, online discussion forums, and written "peer-review" style critiques of published articles.

Prerequisites

This course is open to graduate level students. There are no prior course requirements.

Course Learning Objectives

After successfully completing this course, you will be able to:

- Identify the role of diagnostics in health care, including domestic, global health, with specific application to pandemics of international concern
- Describe the regulatory pathways for diagnostics
- Interpret key test parameters, such as analytic validity, clinical validity, and clinical utility.
- Evaluate and interpret data on diagnostic tests in peer-reviewed publications and technical reports
- Recognize the challenges of bringing a research test to market

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Instructor Information

Veronica Miller, PhD
Adjunct Professor IDV
Instructor Availability: TBD
Email: veronicam@berkeley.edu

Bio: Veronica Miller is a leading expert in the process of engaging stakeholders from both sides of the Atlantic to resolve significant health policy and public health issues. She has extensive experience in addressing regulatory issues in six disease areas, working closely with the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as partners in these projects.

Dr. Miller is the Director of the Forum for Collaborative Research (The Forum), a public and private partnership addressing cutting edge science and policy issues through a process of stakeholder engagement and deliberation. Dr. Miller is also Professor (Adjunct) at the UC Berkeley School of Public Health. She developed and teaches two courses on Drug Development - PH236 and PHW236A -- based on case studies from the Forum's rich history in facilitating drug development.

Dr. Miller joined The Forum in 2001 after having directed the interdisciplinary HIV Research Group at the HIV Outpatient Clinic of the JW Goethe University in Frankfurt, Germany. Together with Dr. Joep Lange, she co-founded and chaired the Euro-Guidelines Group on HIV Drug Resistance, the first pan-European group established for the purpose of assuring a common standard-of-care for patients in all European states. She has also served on numerous industry and government advisory boards.

Dr. Miller mentors interns and fellows pursuing regulatory, biotech, and translational medicine careers and she has published over 100 peer-reviewed publications on HIV treatment strategies and regulatory strategies for various disease areas.

Peter J. Dailey PhD
Adjunct Assist Professor IDV
Instructor Availability: TBD
Email: pjdailey@berkeley.edu;

Bio: Dr. Peter J. Dailey is a microbiologist who serves as a Senior Technical Officer for the Foundation for Innovative Diagnostics (FIND). Dr. Dailey received his PhD in Microbiology and MPH at UC Berkeley and his bachelor's degree in Bacteriology at UC Davis. He has 35 years of experience in infectious disease, primarily in the research and development of infectious disease molecular diagnostics. He has worked for the California Public Health Department (Viral & Rickettsial Disease Laboratory), hospital and medical center clinical laboratories, and in the molecular diagnostics biotechnology industry. Previously he was the senior vice president of

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Research & Development at Cepheid, a molecular diagnostics biotechnology company in Sunnyvale, California, and he has also held R&D leadership positions at Roche Molecular Systems and Chiron Diagnostics. He has led the research and development of over 20 diagnostic and blood-screening assays for infectious diseases including TB, MRSA, West Nile Virus, viral meningitis, HPV, HIV, SIV and HCV.

John Sninsky PhD,
Consultant:
Instructor Availability: TBD
Email: john.sninsky@gmail.com

Bio: John J. Sninsky, Ph.D. is a Translational Science and Medicine consultant with a comprehensive and deep understanding of the development and application of pioneering molecular procedures to the translation of research-grade biomarker assays into clinical-grade clinically adopted diagnostic tests. Following a faculty appointment at Albert Einstein College of Medicine, John joined the team at Cetus that developed polymerase chain reaction (PCR) and applied the powerful technology to clinical virology diagnostics, notably HIV. He has held senior management positions at Roche, Celera, Quest Diagnostics and CareDx.

He is the author of more than 110 scientific papers including advanced methods in molecular biology, application of the polymerase chain reaction (PCR) to virology and cancer, and genome-wide genetic association studies for multiple common, complex diseases. John advises commercial translation efforts at Stanford University (SPARK) and University of California, San Francisco (CATALYST) and lectures in Diagnostic Regulatory Science at University of California, Berkeley. He is a member of Coronavirus Standards Working Group, an organization focused on developing molecular standards for SARS-CoV-2 (COVID-19).

John serves as a technical advisor for Stop the Spread, with a focus on diagnostics.

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Course Format

Course Schedule (schedule is subject to change)

Session	Topic	Learning Objectives Discuss:
1	Role of diagnostics in health care (domestic and global)	- how diagnostics direct health care spending - the role of diagnostics in epidemic/pandemic monitoring and control - individual health and public health
2	Overview of regulatory path for approval (US)	- CLIA - FDA
3	Overview of regional and global infrastructure for diagnostic development and regulation; challenges in implementation	- EU system - WHO pre-qualification program - importance of TPP
4	Journal Club 1 How do we know a test "works"?	- concepts of analytic validity, clinical validity, clinical utility - false positive, false negatives and risk - PPV, NPV vs ROC
5	Case Study 1: SARS-CoV2	- challenges in new outbreaks - direct pathogen vs. exposure diagnoses - role of EUA and lessons learned - need for international collaboration, communication and standard setting
6	Case Study 2: TB, MDR/XDR TB	- need for global consortia/collaboration - integrated implementation: the whole package - ensuring impact on global health programs
7	Journal Club 2 Beyond initial diagnosis: Biomarkers and context of use/qualification Intended use	- drug approval (surrogate endpoints) - treatment monitoring - drug resistance - companion/complementary diagnostics - population screening vs diagnosis
8	Key statistical considerations in diagnostic development	
9	Biomedical informatics/AI	- synthetic data - research vs. clinical grade databases
10	Journal Club 3 Case Study 3: CARB-X	
11	From lab bench to market	- exploratory vs. directed paths - clinical utility – health economics – reimbursement - integrated approach

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12	Case Study 4: Roche MS	- evolution of PCR technology - from HIV to SARS-CoV2
13	Case Study 5: Roche MS	- Antimicrobial resistance - diagnostics for global health
14	Journal Club 4 Case Study 5: Abbott (zoom or pre-recorded)	- viral hepatitis (HCV and HBV) diagnostics and role in elimination programs - COVID-19 – getting to home testing
15	Recap/review	

Course Grading

Grading is based on the following:

Weekly in-class attendance/engagement	30 points
Weekly on-line discussion forum	30 points
"Journal club" paper review	30 points
Course evaluation/feedback	10 points

Course Materials

Bcourses website

To access the course website, go to bCourses at bcourses.berkeley.edu. Here you will find links to readings including current papers in peer-reviewed literature, technical reports, and guidances. Any changes will be reflected in the assignment section of the site.

Required Materials

No textbook required

Course Requirements

Customize this section. All evaluated and graded material will be returned to students by e.g., the next class meeting, within 7 days, etc.

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Participation

Students are expected to attend each weekly 2-hour session, having read the assigned material for that week to be prepared to participate in class discussion, divided into small groups if class size allows. Assigned readings will be available on the bCourse website.

Assignments

1) Students will contribute to an online discussion forum on the bCourse site each week, following specific prompts set by instructors. These will be reviewed and commented on weekly.
2) Students will write a peer-review journal style critique for an assigned paper and present to class at the beginning of Sessions 4, 7, 10 and 14. This is a small group assignment. Completion includes a written review and short class discussion (no formal presentation required for this assignment)

Reasonable accommodation will be made for unavoidable scheduling conflicts or for illness.

Final Exam

There is no final exam.

Course Communication

As we move through the course materials, we want to hear how the course is going for you, your questions as well as how your personal and professional experiences add to our conversation. You can learn a lot from discussing the material in this course with each other and we encourage you to take advantage of the interactive components of the course to learn from each other.

Announcements

Announcements will be posted on the home page of the bCourse site. Please check regularly for updates.

Course mail

Course announcements will also be sent out through Canvas' notification system. The default is to receive announcements via the Course Mail system, so make sure to check your Course Mailbox for message or wherever you receive notifications.

Office hours

To be determined

Policies

Due Dates

Please communicate with instructors using Canvas Course Mail if you will not be able to meet course deadlines ahead of the deadlines.

Late Assignments

Any request for extension on assignment or exams should be made in advance of the posted due date. If an emergency event prevents submitting an assignment by the deadline, please contact your instructor as soon as reasonably possible, including documentation with your request for extension.

Attendance

Students are expected to attend all 15 class sessions of this interactive course to receive the full 30 points for attendance and participation. "Participation" entails engaging in discussion, demonstrating that they have read the assigned material. Participation can include questions, comments on other students questions, debate on a position taken in one of the papers, or relating the subject matter to their own professional experience. In case of unavoidable conflict

We realize that students may face unavoidable scheduling conflicts, such as job interviews, and personal or family health issues. Please let the instructors know as far ahead in advance as possible to make arrangements for alternate work to complete that week's participation requirements.

Technology

You may use laptops in class for note-taking. However, once class is convened, it is respectful to the instructor, guest lecturers, and your colleagues to cease use of electronics for non-class purposes. This includes internet surfing, texting, e-mailing, and doing other work which should be completed outside of class. Additionally, out of respect for our presenters, no electronics should be used during student presentations.

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Correspondence

For all email correspondence please put PH 290 in the subject heading. We will try to answer your query within 48 hours during the week. If you send an email on Friday after 5:00 you will get a reply the following Monday.

SPH Course Policies

Descriptions of and relevant campus links to SPH school wide course policies on Disability Support Services, Accommodation of Religions Creed, Course Evaluations, Academic Integrity can be found at: https://berkeley.box.com/s/knh3rbk9ikgvmca4ymy93msgj9bkebq5