

**Harvard Medical School, Institute
Medical Engineering and Science (MIT),
and Ragon Institute
BCMP 311qc: Unmet Medical Needs and
Translational Solutions
Summer 2016 Course Syllabus**



Course Description

In this course, students will investigate how unmet medical needs are identified, follow the discovery process that uncovers the causes of disease, and examine the practice of effective disease detection, diagnosis, and treatment. The course will feature assessments of unmet medical needs, case studies of successes and failures in translation, seminars from translational experts, and discussions of current topics in therapeutics development. The deep understanding of translational medicine imparted by the HMS TransMed course will endow students with the requisite lens through which to identify the unmet medical needs of patients and engage in the creation of novel interventions.

Course Website: <http://hms.harvard.edu/transmed>

Course Details and Information

Class Days and Times: M-F 9:00 am – 5:00 pm, Monday June 13th – Friday June 24th

Meeting Spaces: Armenise 108 [June 13th – 17th]
TMEC-008 [June 20th, 21st]
Modell 100A [June 22nd]
TMEC-007 [June 23rd, 24th]

Course Binder URL: Google Drive to which instructors will provide access

Course Director: Jagesh V. Shah, Ph.D. (jagesh@hms.harvard.edu)

Co-Director of Global Component: Filippos Porichis, Ph.D. (fporichis@mgh.harvard.edu)

Faculty Lecturers: *see attached schedule*

Curriculum Fellows: Catherine Dubreuil, Ph.D. (catherine_dubreuil@hms.harvard.edu)
Megan Mittelstadt, Ph.D. (megan_mittelstadt@hms.harvard.edu)

Course Administrator: Gail Rock Townsend (trans_med@hms.harvard.edu)

Course Topics

- Turning unmet medical needs into therapies
- Preclinical testing: choosing the right models for the appropriate discovery modalities
- Clinical testing: design and evaluation of human clinical trials
- Biomarkers and diagnostics
- Regulatory approval and pharmacovigilance
- New frontiers in therapeutics

Course Objectives

- Identify unmet medical needs
- Understand the drug discovery/development pipeline
- Identify discovery-based science methods for therapeutic development
- Evaluate unmet medical needs in the context of development and approval pipeline
- Understand different clinical testing paradigms and current issues in regulatory approval

Course Schedule

Class will be held Monday through Friday, from 9 am-5 pm for the entire two weeks of the course. Students are expected to attend **all** classes and actively participate in class discussions. Students should prepare for each session by reading the assigned material prior to each class meeting. Lecture slides will be provided electronically the night before each session. Session leaders will expect that students will have read the introductory materials. A full schedule of class meetings and topics covered are in the class schedule (in the class binder). Please see the individual session learning objectives for required readings.

Lecture and Session Format

For each of the main course topics, classes will consist of a mixture of lectures, structured discussions and case discussions. **Please always arrive at approximately five minutes before the scheduled start time of each session so that we can start class promptly.** For every session, we expect students to complete the suggested reading and review the case documents **before** attending each class. This will ensure that you can most effectively participate in the class discussions with our expert faculty.

Lectures: In these presentations, basic information will be covered along with several examples to highlight each topic. Students are strongly encouraged to review the posted lecture notes and recommended readings before each lecture.

Structured discussions: In these sessions, faculty will present short cases/examples on the listed topic. Students are expected to read the materials prior to each session and consider the thought questions and learning objectives given for each topic. During each session, faculty will guide in depth discussion of the issues using the thought questions as a foundation.

Case studies: This course will include three mini cases (Statins, PKD and Vioxx) and two major cases (Gleevec and Alzheimer's Disease). For each major case, students will be assigned one of four perspectives: that of a basic scientist, clinician, industry scientist/executive or regulatory scientist/official, and will approach each case from the lens of this specific perspective. Students will rotate between perspectives for each case. Written cases and thought questions will be provided and should be read and considered prior to each case discussion. During the major case discussion, faculty experts will be present to participate and help guide the discussion. For the two major cases, students will be expected to present their ideas (using the thought questions as a guide) at the case wrap up and present their specific perspective to the other members of the class.

For each mini case, faculty experts will lead the discussion but students will be expected to ask questions and drive the direction towards their interests.

Course materials

The materials for this course will be available online via Google Drive. All students will have access to the shared course drive and all course documents and recommended reading list will be available. Please bring a laptop or other mobile device with you so that you may access the course drive during class sessions. Please access any papers that cannot be posted to the course drive due to copyright laws through your own institution. Please see the teaching staff if you require access to a specific document.

Lunch and Coffee Breaks

Lunch will be provided for students each day. If you have any dietary restrictions, please let us know immediately at trans_med@hms.harvard.edu. In addition, coffee and tea will be provided during the morning and afternoon breaks.

Global Component

An optional week-long curriculum component will be available to a subset of students. This component will consist of fieldwork in Durban, South Africa to study therapeutics in the context of tuberculosis and HIV. Students will observe how therapeutics are deployed in resource poor conditions and identify opportunities for basic science and clinical studies in high disease burden regions.

Special Support and Services

Students with Disabilities: Be assured that services for persons with health conditions or disabilities who require accommodation are available to all Harvard students who need them, by way of the Accessible Education Office (www.aeo.fas.harvard.edu). With information from you, along with proper confidential clinical documentation, they are able to plan with you to provide reasonable accommodation of course materials, classrooms and other aspects of student life, as appropriate. For more information, please contact aeo@fas.harvard.edu or call (617) 496-8707.