MTR 632: Drug Development Decision Criteria
Fall 2014
Mondays and Wednesdays, 3:00-4:30pm
Location: 8030 Maloney, HUP

Course Director:
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Global Head, Pediatric Clinical Pharmacology
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Course Coordinator:
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Course Description:
Drug development is a highly regulated process with a great deal of oversight provided by both the global regulatory community and the internal management of the companies themselves. In addition to the regulatory milestones that designate a target molecule's status, there are scientific hurdles that a drug candidate must traverse in order to gain passage to the next development phase. The pharmaceutical industry over time has systematically outlined critical junctures at which data, assumptions, models and experience are collated and reviewed by decision makers within the company, and many times in view of external experts, to decide if a compound should progress and also define the best course of action.

This course reviews the critical junctures over which innovative and generic drugs are evaluated and the decision criteria used to judge performance and plan next steps. The nature of the collective data under review, the decision paths and the decision makers themselves often change depending on the stage of development. This course covers decision criteria from drug discovery through post marketing and even entertains decision points for generic drugs (pharmaceutical- and bio- equivalence). Metrics for evaluation, company and regulatory expectations and the tools used to facilitate decision (e.g., modeling and simulation techniques to generate "what-if" scenarios) making are all discussed in detail. A key feature of the course is 7 "labs" which involve instructor-led decision analysis role playing. The class will be divided into small teams that review data generated at different stages to examine the thought processes and decision criteria evaluable at different stages of drug development. Labs are constructed from actual case study examples and team performance will be evaluated at the conclusion of the lab session.

Attendance:
Students are expected to attend all classes. If for any reason a student will not be in class, they should contact the Course Coordinator prior to class to alert them of the absence and make arrangements to make up course content. Lecture recordings will be made available on Canvas.

Evaluation Methods:
Students will be graded based on class attendance, participation, and exams.
20% – Lab Participation & Class Attendance
40% – Mid-term
40% – Final

Academic Policies:
For information on academic policies please refer to the MTR Student Handbook on the web:
http://www.itmat.upenn.edu/mtr-studentresources.shtml

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barrettj@email.chop.edu; jeffrey.barrett@sanofi.com
Class Time: 3:00-4:30pm Mondays & Wednesdays
Location: 8030 Maloney Building
Hospital of the University of Pennsylvania

Date	Topic	Lecturer
Wed Aug 27	Landscape for decsion making in the pharmaceutical industry: historical perpsective and current practice	Jeff Barrett
Mon Sept 1	No Class - Labor Day	
Wed Sept 3	Decision Theory and its application (or not) in drug development	Jeff Barrett
Mon Sept 8	Drug Screening, developing ranking drug discovery criteria	Jeff Ming
Wed Sept 10	Lab: Drug screening	Jeff Ming
Mon Sept 15	Toxicology signals, margin of safety	Jane Bai
Wed Sept 17	Lab: Toxicology signals	Jane Bai
Mon Sept 22	FTIM: The therapeutic window; phase I criteria	Jeff Barrett
Wed Sept 24	Lab: FTIM	Jeff Barrett
Mon Sept 29	In Vivo pharmacology, predictability of animal disease models	Manish Gupta
Wed Oct 1	Biomarkers and surrogate markers	Shashank Rohatagi
Mon Oct 6	Proof-of-concept, proof-of-mechanism, proof-of-principal	Marc Gastonguay
Wed Oct 8	Lab: PoC, PoM, and PoP	Marc Gastonguay
Mon Oct 13	Statistical vs clinical basis for approval	Jay Mei
Wed Oct 15	Bioequivalence criteria	Jeff Barrett
Mon Oct 20	Lab: Bioequivalence	Jeff Barrett
Wed Oct 22	MIDTERM Exam	
Mon Oct 27	Bridging criteria for special populations	Jeff Barrett
Wed Oct 29	Lab: Bridging Criteria	Jeff Barrett

Mon Nov 3	Competitive surveillance	Jay Mei
Wed Nov 5	Market performance	TBD
Mon Nov 10	Formulation development	Ram Agarkar
Wed Nov 12	Lab: Formulation development	Ram Agarkar
Mon Nov 17	Manufacturability	Ram Agarkar
Wed Nov 19	Commercialization	Donna Humski
Mon Nov 24	Taking product off the market and other legal considerations	Jeffrey Skolink
Wed Nov 26	Advanced topics in Bioavailability and Bioequivalence: Lifestyle effects (food, DDI, etc)	Jeff Barrett
Mon Dec 1	Make-up date	
Wed Dec 3	Make-up date	
Mon Dec 8	Make-up date	
Wed Dec 10	FINAL	