Syllabus: BCMP 301qc

Translational Pharmacology—The Science of Therapeutic Discovery and Development

Harvard Medical School

January 3 – January 21, 2022

Overview

There has never been a better time in science and medicine to discover and develop effective therapies for human disease! The BCMP 301qc bootcamp course serves as an introduction to the principles of the drug discovery process and is taught by a team of academic and industry experts.

Course Directors: Dr. David Golan (david_golan@hms.harvard.edu)
Dr. Catherine Dubreuil (catherine_dubreuil@hms.harvard.edu)
Dr. Mark Namchuk (mark_namchuk@hms.harvard.edu)

Curriculum Fellow: Dr. Nuru Stracey (nuru_stracey@hms.harvard.edu) **Office hours:** Mon 2pm-3pm
Teaching Fellow: Patrick Flynn (patrick_flynn@g.harvard.edu) **Office hours:** Wed 2pm-3pm

Synchronous Meeting Times:
Required Class sessions: **Monday through Friday, 10:00 am – 12:00/1:00 pm EST**
Required Project Group meetings: **Selected days, 1:00 – 2:00 pm EST**

Suggested Textbook:
Golan DE, Armstrong EJ, Armstrong AW (eds.) *Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy*, 4th Edition. Philadelphia: Lippincott Williams & Wilkins, 2017. The book is available for purchase or rental from The COOP or online through Amazon.

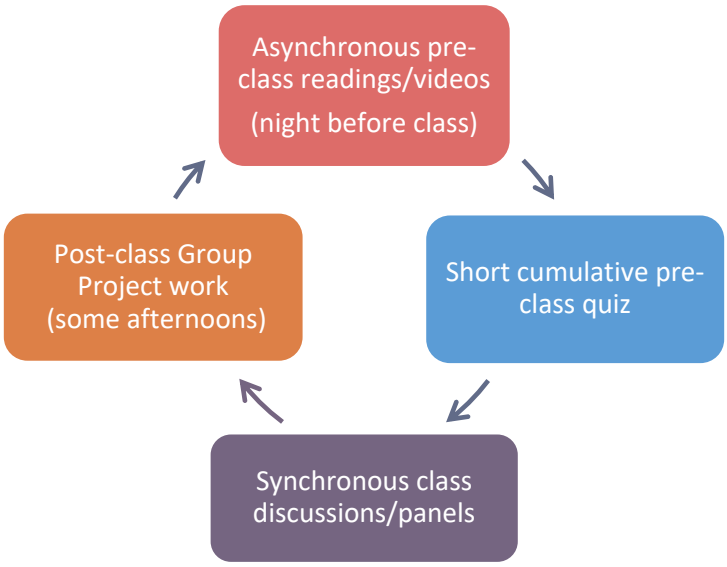
Industry Experts / Project Group Facilitators:
Meghan Flaherty (Sana Biotechnology)
Bill Forrester (Novartis)
Jochem Gokemeijer (Bristol-Meyers Squibb)
Mark Goldberg (HMS)
Camilla Graham (HMS)

Lecturers and Panel Discussants
Brian Alexander (Foundation Medicine, DFCI)
David Altshuler (Vertex)
Elliott Antman (BWH)
Barbara Bierer (BWH)
Sara Buhrlage (DFCI, HMS)
Amitabh Chandra (HBS)
Niteesh Choudhry (BWH)
Don Coen (HMS)
Natalie Franchimont (Biogen)
David Golan (HMS)
Haroon Hashmi (Ziopharm Oncology
Patricia Hurter (Lyndra Therapeutics)
Samantha Hulla (FujiFilm)
David Hutto (Boehringer Ingelheim)
Sanjat Kanjilal (BWH)
Aaron Kesselheim (BWH)
Milka Kostic (DFCI)
Christos Kyratsous (Regeneron)
Joshua Lin (BWH)
Timothy MacLachlan (Novartis)
Nicholas Marsh (Arrakis Therapeutics)
Melissa Moore (Moderna)
Samuel Moskowitz (Vertex)
Mark Namchuk (HMS)
Sebastian Schneeweiss (BWH)
Marcia Testa (HSPH)
Luk Vandenberghe (MEEI)

Course Outline:

Translational Pharmacology covers a variety of topics ranging from **Pharmacology** and **Drug Development** to **Pharmacoepidemiology** and **Pharmacoeconomics**, as applied from the identification of unmet medical needs through the development of approved drugs and their safe and effective clinical use by physicians and patients. These domains are supplemented by case studies and frontier research topics highlighting aspects of the development of actual drugs (see p. 3 for summary of weekly topics). Faculty include physicians and scientists from academia and industry, including experts who have successfully led the development of new therapeutic interventions, as well as experienced clinicians, epidemiologists, and experts in drug policy and pricing. The overarching aim is to comprehensively guide students from the discovery of drugs at the bench to their use at the bedside and then in populations of patients. Student group projects, facilitated by experts, involve developing and presenting (end-of-course) proposals for drug development strategies, from unmet need through clinical trials and pharmacovigilance. The group projects afford students the opportunity to work as teams in a collaborative environment, which reflects the manner in which drugs are designed and developed (see p. 4 for details).

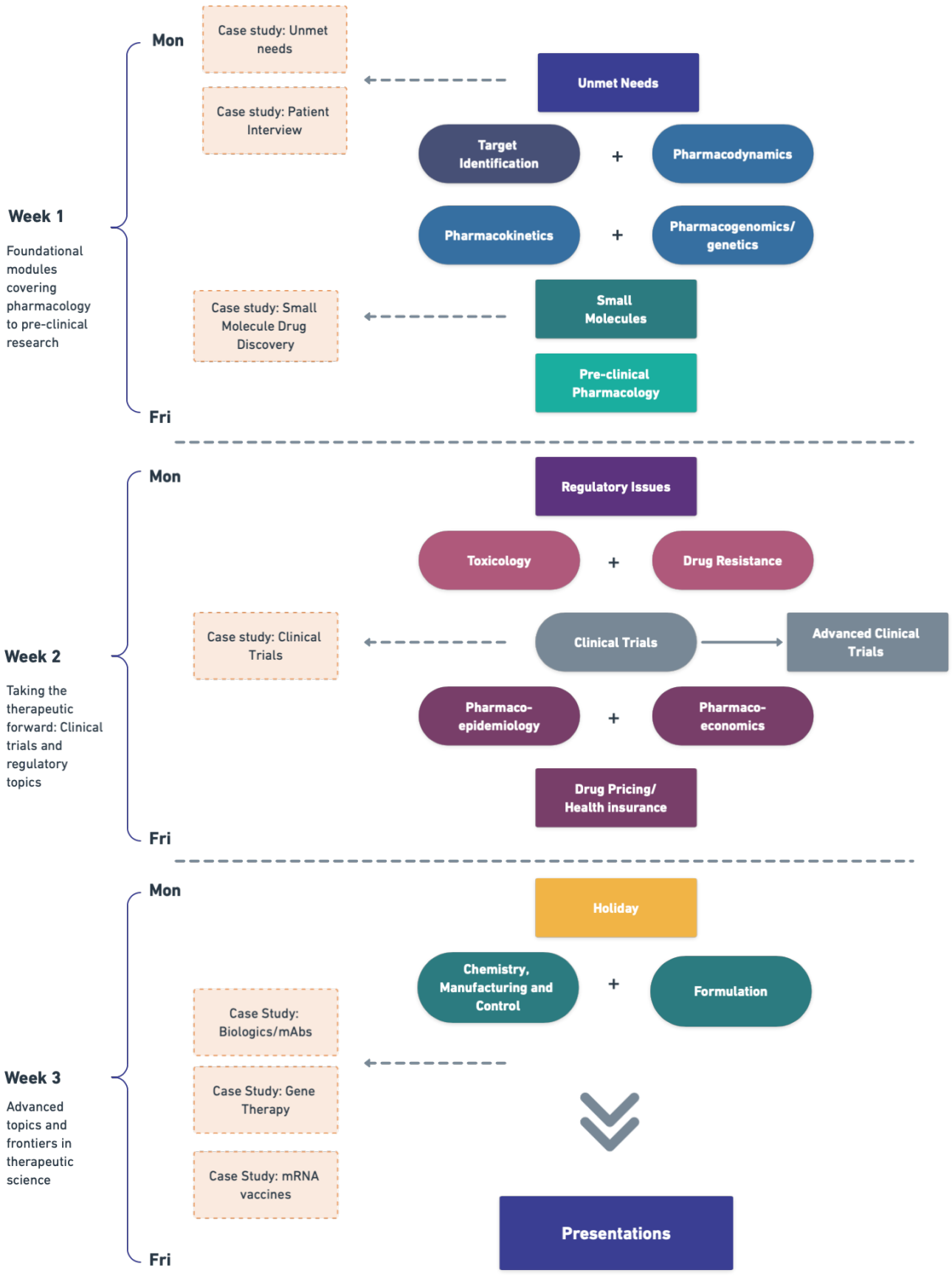
Daily Schedule:



Students are encouraged to keep up with the daily readings, videos, and quizzes, and to attend all classes, so as not to fall behind. In general, asynchronous material (30-90 min) such as videos, book chapters, publications, and/or articles will be available the day before class, with quizzes available from 2 pm the day before class to 9 am the following morning. Note that some asynchronous videos are interleaved with quizzes. This material will often be revisited in the pre-class quiz. Synchronous class activities involve highly interactive discussions and case-study lectures. Post-class work consists of bi-weekly scheduled group project sessions with experts, as well as independent work on the project. See p. 4 for more details.

Learning Objectives:

- To provide the fundamentals of pharmacodynamics, pharmacokinetics, pharmacogenomics, pharmacoepidemiology, and pharmacoeconomics in human studies.
- To communicate the methods and intellectual excitement of molecular approaches to drug action and design.
- To describe and critically assess the major issues and phases of developing a pharmaceutical or biopharmaceutical, using a multidisciplinary perspective that spans from the molecular basis of drug action to the policy implications for post-marketing surveillance, cost-effectiveness, and drug pricing.
- To apply understanding of therapeutic discovery and development to clinical settings.
- To demonstrate interpersonal and teamwork skills as an effective team member and contributor.
- To communicate the principles underlying therapeutic discovery and development to scientific and medical audiences.


Week 1
Foundational modules covering pharmacology to pre-clinical research
Mon
Case study: Unmet needs
Case study: Patient Interview
Unmet Needs
Target Identification
+
Pharmacodynamics
Pharmacokinetics
+
Pharmacogenomics/ genetics
Case study: Small Molecule Drug Discovery
Small Molecules
Pre-clinical Pharmacology
Fri
Week 2
Taking the therapeutic forward: Clinical trials and regulatory topics
Mon
Regulatory Issues
Toxicology
+
Drug Resistance
Case study: Clinical Trials
Clinical Trials
Advanced Clinical Trials
Pharmaco-epidemiology
+
Pharmaco-economics
Drug Pricing/ Health insurance
Fri
Week 3
Advanced topics and frontiers in therapeutic science
Mon
Holiday
Chemistry, Manufacturing and Control
+
Formulation
Case Study: Biologics/mAbs
Case Study: Gene Therapy
Case Study: mRNA vaccines
Presentations
Fri

Course expectations:

Evaluations and Group Projects:
All students will be evaluated on the basis of the following for a pass/fail final grade:

- Pre-class quizzes (10% of grade)
- Group Project (90% of grade)

Pre-class quizzes (**available from 2 pm the day before class to 9 am the day of class**) will heavily reflect the asynchronous course materials assigned for that day, and will also include cumulative questions on prior course concepts. Class participation includes preparedness, contributions to case studies, and contributions in all group sessions. We will provide zoom chat options in many synchronous sessions for students who feel more comfortable submitting questions and comments in that format. Additional course feedback will be provided by group facilitators. **Each student will be assigned to a group of six to seven individuals working as a team.** The team will write and present a proposal for a strategy to discover and develop a successful therapeutic agent. Final evaluations will be based on the written and oral performance of the group project; this is a unique feature of the course and should be enjoyable! Please see the detailed section on the group project assignment (pp. 7-9). Biweekly TA/CF offices hours (M/W 2 pm-3 pm) are available for additional aid. **While this is a pass/fail course, we urge students to strive for excellence in their work and devote sufficient time and effort to their education, skills development, and personal growth.**

Format of Synchronous Sessions:
Lectures and other classroom-based sessions will transmit vocabulary and key concepts. Using case studies, students will explore successes and failures in drug development with leading experts from industry and academia. To ensure that points of confusion can be reviewed and questions about the lecture can be answered before working on the relevant materials in the synchronous class sessions, a forum will be set up on Canvas and a shared document (either on Canvas or a Google Document) will be available for students to make note of any questions they may have. Course faculty will answer questions in writing in a timely manner, and post to Canvas so that all students may benefit. If multiple students have similar questions, faculty will address them in class during synchronous sessions whenever possible. There will also be opportunities to ask questions during the scheduled discussion panels.

To maximize understanding of the content, it is extremely important that students view the lecture videos, answer the lecture-embedded questions, and actively participate during the synchronous sessions. Active student participation will help reinforce understanding of the material and allow the teaching team to address any questions or misconceptions about the course content.

Requirements and Expectations:
As this is a bootcamp course, we strongly encourage all students to manage their study time wisely, so that everyone is fully prepared and on-time to all in person/virtual sessions, including scheduled group work. This is in part because we believe that education is a *shared* enterprise between instructors and students, and also because each student is expected to make a *valuable and equitable* contribution to the group project, including both the written report and preparation for the oral presentation Apart from unexpected absences (e.g., illness or family-related issues), all excused absences need to be cleared by the course directors in advance. Please ensure that you discuss with the course director ways in the missed class work will be addressed. An unexcused absence may result in a grade of Incomplete or Unsatisfactory and require remediation of missed course work. A detailed course schedule is provided at the end of the syllabus and on Canvas.

Course Website Access:
All students must be officially registered in the course in order to have full access to the course website. This is necessary for students to be assigned to a discussion section and to access all the course materials. If you are not officially enrolled in the course, please e-mail: Dr. Catherine Dubreuil (catherine_dubreuil@hms.harvard.edu) or Dr. Nuru Stracey (nuru_stracey@hms.harvard.edu) for access.

Important Course Policies:

Academic Integrity
All work in this course is governed by the academic integrity policies of GSAS (https://gsas.harvard.edu/codes-conduct/academic-integrity) and HMS (https://mastersstudenthandbook.hms.harvard.edu/409-academic-dishonesty-and-plagiarism). It is the students' responsibility to be aware of these policies and to ensure that their work adheres to them both in detail and in spirit. Unless otherwise specified by the instructor, the assumption is that all work submitted must reflect the student's own effort and understanding. Students are expected to clearly distinguish their own ideas and knowledge from information derived from other sources, including from conversations with other people. When working with others you must do so in the *spirit of collaboration*, not via a unidirectional transfer of information. Note that sharing or sending completed assignments to others will nearly always violate this collaborative standard. If you have a question about how best to complete an assignment in light of these policies, ask the instructor for clarification.

Community Standards
HMS is committed to supporting inclusive learning environments that value and affirm the diverse ideas and unique life experiences of all people. An equitable, inclusive classroom is a shared responsibility of both instructors and students, and both are encouraged to consider how their own experiences and biases may influence the learning environment. This requires an open mind and respect for differences of all kinds. Students are encouraged to contact the course director if they are experiencing bias or feel that their learning experience – including a course's content, manner of instruction, or learning environment -- is not inclusive. Curriculum Fellows, program administrators and directors, the DMS Office of Diversity, the GSAS Office of Diversity and Minority Affairs, the Title IX Office, and the Ombuds Office are also available to discuss your experiences and provide support. Additionally, students can utilize Harvard's Anonymous Reporting Hotline (https://reportinghotline.harvard.edu/) to report issues related to bias.

Reasonable Accommodations
As an institution that values diversity and inclusion, our goal is to create learning environments that are usable, equitable, inclusive, and welcoming. Harvard University complies with federal legislation for individuals with disabilities and offers reasonable accommodations to qualified students with documented disabilities and temporary impairments. To make a request for reasonable accommodations in a course, students must first connect with their local disability office. The primary point of contact for GSAS students is the Accessible Education Office (www.aeo.fas.harvard.edu). The HMS Director of Disability Services, Timothy Rogers (timothy_rogers@hms.harvard.edu), is another potential source of accommodation information for PhD students and is the primary contact for MD and master's students.

Accommodations are determined through an interactive process and are not retroactive. Therefore, students should contact their local disability office to initiate the accommodation process as soon as possible, preferably at least two weeks before accommodations are needed in a course or immediately following an injury or illness. Students are strongly encouraged to discuss their needs with their instructors; however, instructors cannot independently institute individual accommodations without prior approval from the disability office. Student privacy surrounding disability status is recognized under FERPA. Information about accommodations is shared on a need-to-know basis, and with only those individuals involved in instituting the accommodation.

Academic and Other Support Services
We value your well-being and recognize that as a graduate student you are asked to balance a variety of responsibilities and potential stressors: in class, in lab, and in life. If you are struggling with experiences either in class or outside of class, there are resources available to help. Danielle Farrell, the GSAS Director of Student

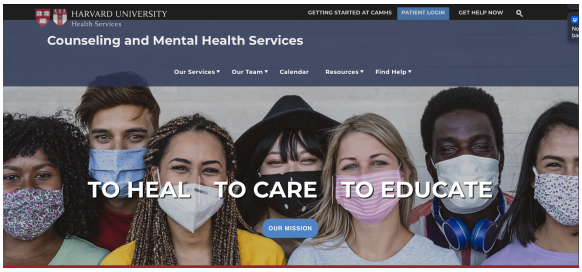
Services (617-495-5005), is available to assist students navigating academic or personal difficulties and connect them to university resources.

HILS PhD students have access to free academic tutoring, arranged through the DMS office. A variety of academic support services are also available to GSAS students through the Academic Resource Center (https://academicresourcecenter.harvard.edu) and the Center for Writing and Communicating Ideas (https://gsas.harvard.edu/center-writing-and-communicating-ideas).

Special Note for Remote Learning Sessions

If learning remotely presents specific challenges for you, it is critical that you contact the course director so appropriate actions can be taken. Potential issues include, but are not limited to, reliable access to technology or an appropriate private work space, and challenges balancing other responsibilities. In addition to the course director, your program's leadership and the Academic Resource Center are available to help.

All students have access to Counseling and Mental Health Services (CAMHS) available in Longwood, Cambridge, or remotely via webcam or phone. The use of CAMHS is included in the student health fee, regardless of insurance, at no additional cost. More information is available at https://camhs.huhs.harvard.edu or by calling the main office at 617-495-2042. Urgent care can be reached 24/7 at 617-495-5711.



Group Project:

Examples of previous group project proposals will be provided. However, even well-received proposals have flaws. Please be sure to follow the instructions in this assignment sheet rather than just using previous proposals as templates.

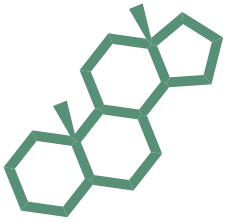
Each student will be assigned to a group of six to seven individuals working as a team. The team will write and present a proposal for a strategy to discover and develop a successful therapeutic agent. The proposed product can be of any modality; previous group projects have developed small molecules, antibodies, and even vaccines. The proposal will include the following sections:

1. **Justification of medical need.**

Why is it important to develop a new therapy or improve the current therapy for this particular disease? Essential elements of this section include a statement and assessment of the proposed indication(s), an assessment of both currently available and "in the pipeline" treatments for the disease, and a target product profile (TPP). Economic factors should also be considered. Discussion of the pathophysiology of the disease can be included in this section or the next section.

2. **Molecular target.** A molecular target protein or pathway that is well justified: a) regarding its tractability for discovering a therapeutic appropriate for the proposed indication(s) and b) relative to other possibilities for the indication(s). In other words, what are the pros and cons of the proposed target/pathway compared to other possibilities? Please note that the positive and negative features of proposed targets and pathways are discussed in the Target Identification sessions of the course. If more data are needed to help justify the target/pathway, describe appropriate experiments and what results would be needed to continue the project (go/no-go). Discussion of the pathophysiology of the disease can be included in this section or the previous section.

3. **Drug discovery strategy.**



A reasonable, feasible strategy for therapeutic discovery that will provide molecules suitable for preclinical studies. The strategy should be appropriate for the target and justified relative to alternatives. Describe and explain assays and experiments specifically (with controls). For example, don't just say "we will perform a high throughput screen;" if you propose such a screen, describe it and any counterscreen, explain why you're taking this approach, indicate the kind and size of libraries to be used, etc. Briefly mention any chemical or other support (e.g., medicinal chemistry) that may be needed for preclinical and clinical studies. Figures may be used to describe assays rather than overly wordy explanations of assay design. Don't include unnecessary details such as buffers or cell culture components, etc.; literature citations or catalog entries for kits are sufficient for these details. At the end of this section, indicate what results and properties the compounds should have in order to move to preclinical studies (go/no-go).

4. **Preclinical studies.** An outline of preclinical studies, including as essential elements: potency, efficacy, and selectivity studies beyond those in the previous section; and pharmacokinetic, toxicology, and any biomarker studies that would be particularly appropriate for the indication(s), the therapeutic being developed (and its intended route of administration), and the target. The more specific you can be, the better. Don't include unnecessary details such as buffers or cell culture components; literature citations or catalog entries for kits are sufficient for these kinds of assay conditions. At the end of this section, indicate what properties the compounds should have to be lead clinical candidates and explain decisions regarding your comparison groups, dosing, etc. (go/no-go).

5. **Clinical studies.** A plan for clinical studies designed to lead to approval of the therapeutic. The studies should be appropriate for the indication(s), the relevant patient population(s), the therapeutic, etc. It is critical to justify your important choices regarding specific clinical studies proposed relative to alternatives (e.g., placebo vs. other kinds of comparison groups, dosing regimens, length of study, numbers of subjects, etc.). The more specific you can be, the better, especially regarding outcomes (e.g., what results would be good enough, what would be aspirational, etc.). If additional indications for the therapeutic are anticipated, they can be briefly mentioned. Details (such as inclusion and exclusion criteria) and diagrams illustrating study design can be placed in tables and/or figures.

6. **Pharmacovigilance and post-marketing adverse events.** Development of a plan for pharmacovigilance and ascertainment of post-marketing adverse events, tailored for the therapeutic under investigation, the target population and condition(s), etc. The plan should define the datasets that will be created or obtained to identify rates of relevant adverse events compared to those seen with the comparable alternative treatment (if any), and the analytic plan for measuring the rates of important adverse effects, compared to existing approaches. The more specific you can be, the better.

7. **Pricing and cost effectiveness**. An analysis and *justification* for a proposed price of your new treatment/intervention, including a value proposition describing the value added for your intervention. This assessment should include a QALY analysis, as well as discussion and justification of the current drug pricing landscape, for your chosen therapeutic category and target indication. Delineate an approach to measuring the treatment's cost-effectiveness, preferably in terms of an Incremental Cost-Effectiveness Ratio (ICER).The cost analysis for your intervention should include discussion of all costs: (1) direct costs, including current standard of care for your indication if one exists, (2) considerations of healthcare/hospital/caregiver costs, and (3) ancillary costs that can be monetized (home care/loss of work or income both for the patient and family caregiver, etc.). If your drug has no comparator on the market, discussion of healthcare costs and indirect costs will be key, including emotional cost. Finally, address how payers—public or private—will respond to your proposed price, and whether your drug is likely to achieve significant market penetration.

In each section, where relevant, issues of pharmacogenetics and/or drug resistance should be addressed.

Each individual in the group should be primarily responsible for at least one of the above sections of the project, and that person should be identified. Although the group may decide to combine some of these sections in its written report, the individual contributions of each member of the group must be clearly identified.

All students should contribute to the TPP, and all students should be familiar with the content of all the sections of the project – this makes for a more integrated proposal. A major flaw in some proposals has been a lack of integration, with one section not being consistent with or even contradicting what's written in a different section. **The best proposals are those in which individual sections are well integrated with the proposal as a whole, and with the TPP.**

Both feasibility and originality are important. It is not permissible to use a previously characterized compound, although such compounds can be modified. Attention to controls and quantitative aspects is important throughout, and is absolutely expected in the pharmacoepidemiology (pharmacovigilance) and pharmacoeconomic (cost-effectiveness) sections. In the past, some groups have provided specific numbers (e.g., potencies in vitro, pharmacokinetic parameters). These values should be realistic in terms of therapeutic success and the likelihood that they can be achieved.

The relevant literature should be cited, and any direct quotation or paraphrasing should be noted (see the relevant Harvard policies and guidelines at <http://medstudenthandbook.hms.harvard.edu/409-academic-dishonesty-and-plagiarism> and <http://usingsources.fas.harvard.edu/home>).

Each group of seven is required to submit a seven-section, fourteen-page paper, excluding reference lists, figures, and tables (the TPP can be in Table format). Ordinarily, each section is expected to be approximately two pages in length. To make it easier for groups of six, the length and format is more flexible, with the paper being between twelve and fourteen pages, with either seven sections or, by combining two sections, six.

Pages should be single-spaced, the font should be 11-point, and margins in all directions must be 1/2 inch. Proposals and sections that do not follow these formatting instructions and/or are meaningfully longer than the assigned length will receive lower grades (which is better than not being reviewed at all, which can be the fate of improperly formatted or overly long NIH grant proposals).

ELEVATOR PITCH ASSIGNMENT: On Friday, January 21, each group will turn in its written proposal and give an in-person presentation as an "elevator pitch" of the project to the entire class, including course faculty. Electronic versions of the written proposal, in both Word and PDF formats, and the presentation slides should be uploaded on the course website (Canvas) no later than 9 am on Friday, January 21.

The presentation should be limited to 8-10 minutes and can be made by one presenter or by multiple presenters. Rehearsal for the presentation is highly encouraged in order to keep within the time limit. Presentations that run significantly longer than the 10 minutes allotted risk receiving lower grades. This should help provide practice for public presentations at scientific meetings, etc., where a sure way to alienate much of the audience is to go over the prescribed time. An "elevator pitch" is a useful communication tool for networking and simply communicating your research clearly to colleagues. The presentation should cover all of the key takeaways from each section of the written project and should include slides. Each group will have a 15-minute question and answer session after their presentation. All group members are expected to participate in answering questions. You may prepare a slide deck as needed to help answer questions. We expect the pitch to generate enough interest in your project for a stimulating discussion afterwards. Please sell your idea to us!

Finally, this assignment is meant to be both educational and fun! Please enjoy it.

BCMP 301 qc: Translational Pharmacology: The Science of Therapeutic Discovery and Development
January 2022: Tentative Schedule

Week 1

Day and date			Time of day	Topic	Speaker	zoom/in-person
Day 1	Monday	3-Jan	Video	Course intro	Golan, Dubreuil, Stracey, Flynn	
Day 1	Monday	3-Jan	Video	Target product profile (TPP)	Mark Namchuk	
Day 1	Monday	3-Jan	Video	DDD case 1: Unmet needs	David Altshuler	
Day 1	Monday	3-Jan	10 am-11 am	Unmet needs	Mark Namchuk	in-person
Day 1	Monday	3-Jan	11 am-12 pm	DDD case 2: Patient interview	Samuel Moskowitz, David Altshuler	in-person
Day 1	Monday	3-Jan	12 pm - 12:30 pm	Q&A	Golan, Dubreuil, Stracey, Flynn	in-person
Day 2	Tuesday	4-Jan	Video	Pharmacodynamics	David Golan	
Day 2	Tuesday	4-Jan	Video	Target identification	Don Coen	
Day 2	Tuesday	4-Jan	10 am-11 am	Target identification	Don Coen	zoom
Day 2	Tuesday	4-Jan	11 am -12 pm	Pharmacodynamics	David Golan	in-person
Day 3	Wednesday	5-Jan	Video	Pharmacokinetics	David Golan	
Day 3	Wednesday	5-Jan	Video	Pharmacogenetics/genomics	Don Coen	
Day 3	Wednesday	5-Jan	10 am -11 am	Pharmacokinetics	David Golan	in-person
Day 3	Wednesday	5-Jan	11 am-12 pm	Pharmacogenetics/genomics	Don Coen	zoom
Day 3	Wednesday	5-Jan	1 pm -2 pm	Group Project work -- required	students	in person
Day 4	Thursday	6-Jan	Video	Small molecule drug discovery and development (DDD)	Sara Buhrlage	
Day 4	Thursday	6-Jan	10 am-11 am	DDD case 3: Small molecules	Vincent Stoll	in-person
Day 4	Thursday	6-Jan	11 am-12 pm	Small Molecule Panel Discussion	Sara Buhrlage, Milka Kostic, Mark Namchuk, Vincent Stoll	in-person
Day 5	Friday	7-Jan	10 am- 12 pm	Pre-clinical pharmacology	Nicholas Marsh	in-person
Day 5	Friday	7-Jan	1 pm -2 pm	Group Project work -- required	Industry experts and students	zoom

Week 2

Day and date			Time of day	Topic	Speaker	zoom/in-person
Day 6	Monday	10-Jan	Video	Regulatory issues and hot topics	Aaron Kesselheim	
Day 6	Monday	10-Jan	Video	FDA: IND, NDA, working with the FDA, industry view	Haroon Hashmi	
Day 6	Monday	10-Jan	10 am -12 pm	Regulatory Topics Panel Discussion	Barbara Bierer, Haroon Hashmi, Aaron Kesselheim	in-person
Day 7	Tuesday	11-Jan	Video	Toxicology	Tim MacLachlan	
Day 7	Tuesday	11-Jan	10 am -11 am	Toxicology cases/panel	David Hutto, Tim MacLachlan	zoom
Day 7	Tuesday	11-Jan	11 am-12 pm	Drug Resistance Panel Discussion	Don Coen ,Sanjat Kanjilal, Dan Kuritzkes, Jessica Lin	zoom
Day 7	Tuesday	11-Jan	1 pm -2 pm	Group Project work -- required	Industry experts and students	zoom
Day 8	Wednesday	12-Jan	Video	Clinical trials basics	Elliott Antman	
Day 8	Wednesday	12-Jan	10 am -11 am	Advanced trials: adaptive trials	Brian Alexander	in-person
Day 8	Wednesday	12-Jan	11 am -12 pm	DDD Case 4: Clinical trials case	Natalie Franchimont	in-person
Day 9	Thursday	13-Jan	Video	Pharmacoepidemiology	Sebastian Schneeweiss	
Day 9	Thursday	13-Jan	Video	Pharmacoeconomics	Niteesh Choudhry	
Day 9	Thursday	13-Jan	10 am-12 pm	Pharmacoepidemiology: cases	Joshua Lin and colleagues	zoom
Day 9	Thursday	13-Jan	1 pm -2 pm	Group Project work -- required	Industry experts and students	zoom
Day 10	Friday	14-Jan	10 am -12 pm	Drug pricing and health insurance	Amitabh Chandra	in-person

Week 3

Day and date			Time of day	Topic	Speaker	zoom/in-person
Monday Jan 17th is a HOLIDAY						
Day 11	Tuesday	18-Jan	10 am- 11 am	Formulation	Patricia Hurter	zoom
Day 11	Tuesday	18-Jan	11-am-12 pm	Chemistry, Manufacturing and Control	Samantha Hulla	in-person
Day 12	Wednesday	19-Jan	10 am -11 am	DDD case 5: Biologics/mAbs	Christos Kyratsous	in-person
Day 12	Wednesday	19-Jan	11 am -12 pm	DDD case 6: Gene Therapy	Luk Vandenberghe	in-person
Day 13	Thursday	20-Jan	11 am - 12 pm	DDD Case 7: mRNA Vacccines	Melissa Moore	in-person
Day 14	Friday	21-Jan	10 am -12 pm	Presentations	Industry experts and students	in-person