

Case studies in Translational Research Fall 2021

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Introduction

CSTR is a course about translational research, the process of “translating” great ideas into new therapies, diagnostic tests and cures. Because we intend to build upon what you already learned in college, medical school and graduate school, CSTR is limited to 2nd year MD/PhD students and to VMD/PhD students at the analogous point in their program. Our intent is to have as much of the course be in person rather virtual as Penn policies permit.

CSTR goals

To help you learn about:

- 1) How physician-scientists may pursue translational research.
- 2) Steps needed to translate ideas into new products and approaches.
- 3) Impact of new therapy, protection of intellectual property, potential markets, disparities, and the inclusion or exclusion of vulnerable populations.

What CSTR is and what CSTR is not:

CSTR should focus on topics far outside of the usual medical school curriculum. We want you to learn about careers in industry, working with regulatory agencies, patenting, licensing, clinical trials and other topics listed on the CSTR website: <https://www.med.upenn.edu/cstr/>.

CSTR is not a course in medicine or science, although both are important as background. Any presentation explicitly about the underlying science and medicine should therefore be limited to what is needed to understand the goals of the project. If more is needed beyond MS1 and MS2 courses, assign a brief review to read before the class. Assume everyone will do their homework before coming to class.

Time commitment and format

- There will be 10 classes (90 minutes/class session) plus an introductory session to discuss course structure and goals.
- Each class is a “case study” of a translational research project led by 3-4 students and a preceptor. Each student will help lead only one session. Discussion and active participation are encouraged in all sessions.

- Students leading a class session will meet with the preceptor in advance to plan the session. Typical class preparation takes 2-3 hours for the lead group and less than an hour for other weeks for background reading (if any).
- We suggest the following time allocation and content for each class.
 - 1) Part 1: Introduction of the preceptor by the student discussion leaders. (< 5 minutes)
 - 2) Part 2: Prepared presentation by student class leaders (25-30 minutes) covering:
 - a. What is the primary goal or problem that will be addressed?
 - b. What would be considered to be a success?
 - c. What is the potential impact of the project if it is successful?
 - d. Who is in the target audience? This might be thought of as the potential market or the potential patient population who could benefit.
 - e. How are existing racial and socioeconomic disparities taken into account in the planning of this project? For some projects this might include considerations of device or therapeutic costs, and how they will be borne by patients (think about the high costs of gene or CAR T-cell therapy). For other projects, it might include willingness to accept therapies or devices (think vaccines).
 - f. How do vulnerable populations impact or how are they impacted by this work? For example, does this project include children? If so, how will that affect the design, testing and implementation of a new therapy or device?
 - 3) Part 3 (1 hour): Should be led by the preceptor and be planned in advance with student discussion leaders. There is no set format. One goal is to convey the experience of the preceptor as a physician-scientist within the context of the project or company. Topics could include:
 - a. How was the project originally conceived?
 - b. What role(s) does the preceptor have in advancing the project?
 - c. How did the preceptor come to their present position?
 - d. What obstacles to success have already be overcome?
 - e. What obstacles remain to be encountered and/or overcome?
 - f. How will this project be funded (or how has it been funded)?
 - g. How will the safety and efficacy of a new therapeutic or device be tested and established?
 - h. What are the challenges and benefits of development of a new therapy or device in industry versus academia?
 - i. What IP (intellectual property) is essential for this project to be carried out?
 - j. How will that IP be protected?
 - k. What is the role of the FDA and other regulatory agencies in bringing this device or therapy to market? What do you need to know about working with these agencies?
 - 4) At the end of each 90 minute class, the discussion leaders should remain behind for 10 minutes to meet with the course director and (if available) the preceptor. We will discuss perspectives on how the class went and consider whether important course goals were omitted.

The preceptor's main roles are:

- 1) To meet with the student discussion leaders several weeks in advance of the class to decide what to present.
- 2) To meet a second time before the class to review the student preparations.
- 3) To share with the entire class their experience with the selected project, their perspectives on their role in translational research, and their career path. Preceptors should feel free to share "what I wish I knew when I was a student" advice.
- 4) It would be ideal if the preceptor's presentation provided in depth insight into one CSTR topic. See the CSTR website: <https://www.med.upenn.edu/cstr/>.

Grades

CSTR is a graduate course. All students will receive a letter grade. Since there is no test, grades will be based on group presentations and class participation. In past years, everyone received an A.

Course checks

At the end of the 2nd case, we (the course directors) will meet with the entire class to make sure that the course is meeting CSTR goals and adjust as needed. Everyone should plan to remain for that discussion, lasting no more than 15 minutes.

At the end of the final case, we will meet with the entire class to review the course and discuss ways to improve it for next year. Everyone should plan to remain for that discussion, lasting no more than 20 minutes.

After the final class meeting there will also be an online anonymous survey to evaluate how well CSTR met its learning goals.