

Medical Entrepreneurship: Commercializing Translational Science

(MTR 6200 / BE 6080)

Course Director: Nalaka Gooneratne, MD, MSc.

Course Director: Adam Dakin, MBA

When: Tuesday and Thursday 3:30 - 5:00 PM

**Location: 3711 Market Street, Quorum Conference Room
(in person sessions)**

Start date: Jan 12, 2023 End date: April 25, 2023

(Final Exam due by May 4 at 5:30 pm)

Course objective: This course provides in depth insight into the process by which health technology platforms are transformed into viable commercial entities. This includes methods to evaluate market opportunities and derisk critical assumptions within the rapidly changing academic medical and commercial healthcare environments. Topics include intellectual property creation and licensing, technology transfer, regulatory pathways, raising capital/NIH SBIR/STTR grant funding, go to market strategy, market sizing, formation equity, and raising capital. The major project involves the formation of teams that create defensible business plans and consummate in a presentation (investor pitch deck) intended to raise capital. The course will be especially valuable for students who may be considering entrepreneurial career paths including starting a company, working for an early stage venture, healthcare consulting, or innovation leadership. Note, the course focus is on commercialization rather than product development.

Organization: The course contents fall into four broad categories:

- 1) Lectures by the course professors and outside subject matter experts covering fundamental elements of entrepreneurship and business plan creation.
- 2) Presentations from senior executives and health system stakeholders including hospital systems and payers/insurers/health plans.
- 3) Presentations by successful healthtech entrepreneurs describing their journeys and offering unique insights on specific challenges.

- 4) Creation of an investor pitch deck addressing essential elements needed to raise capital. The course offers both academic subject matter regarding the commercialization process combined with practical insights from outside health technology and innovation stakeholders and entrepreneurs.

Dr. Nalaka Gooneratne is an Associate Professor of Medicine at the University of Pennsylvania. He is also Associate Director of the Master of Science in Translational Research program and directs the Entrepreneurial Science Track. Dr. Gooneratne is Course Director for MTR 620/BE 608 Translational Therapeutics and MTR 640 Entrepreneurial Science Seminar.

Adam Dakin is a Partner at Dreamit Ventures, a healthtech focused venture fund. He co-founded five startups, and served as the Chief Executive Officer of PhotoSonix Medical, Bioconnect Systems, and X-SITE Medical. He has over 25 years of experience building early stage and venture-backed health technology companies and has led numerous M&A transactions. He is a named inventor on eight US patents, an active angel investor, and received the Philadelphia Alliance and Capital Medtech Leadership Award. He has served on the board of directors for 15 startups. He holds an MBA from The Anderson Graduate School of Management at UCLA and a BSE from Wharton. Adam started his first company while an undergraduate at Penn.

Attendance:

Attendance will be taken within the first 5 minutes of every class. If you arrived late or are marked absent incorrectly, please email the course coordinator to confirm your attendance.

Canvas:

All course materials are posted here. Log in with Pennkey and Password at <https://canvas.upenn.edu>

Course Evaluations:

Course & Lecture evaluations are completed via BLUE at the end of each semester. These are a required part of course participation for MTR/BE students. Students can access evaluation forms with their Pennkey and Password and will also receive emails when forms are available.

Schedule:

2023 Dates	Tues/Thurs	Speaker(s)	Subject
Jan 12	Thurs	Nalaka Goonerate & Adam Dakin	Course Introduction and Case Study
Jan 17	Tues	Adam Dakin	Derisking your start-up idea
Jan 19	Thurs	Nalaka Gooneratne	Hackathon Workshop - initial project ideas

Jan 24	Tues	Adam Dakin	IP 101: What founders need to know
Jan 26	Thurs	Nalaka Gooneratne	University Licensing & Tech Transfer
Jan 31	Tues	Adam Dakin	Market Sizing & Go To Market Strategy
Feb 2	Thurs	Blake Wilson at Hogan Lovells	FDA regulatory process for devices
Feb 7	Tues	Roy Rosin, Chief Innovation Officer, Penn Medicine	Changing delivery models: Perspective on Innovation from the C-Suite
Feb 9	Thurs	Pitou Devgon, MD, Cofounder, Velano Vascular	From MD to Exit: The Velano Vascular Story
Feb 14	Tues	Eric Sugalski, CEO, Archimedics	Product Development & Initial Design Considerations
Feb 16	Thurs	Nalaka Gooneratne/Tom Schaer	FDA regulatory process for biologics/Pre-Clinical Testing
Feb 21	Tues	Nalaka Gooneratne	FDA regulatory process for drugs
Feb 23	Thurs	Brian Halak	Seed funding/Exits and IPOs
Feb 28	Tues	Subha Airan-Javia, MD, CEO & CO-founder, CareAlign	Leaving Academic Medicine for Entrepreneurship: The Founding of CareAlign
Mar 2		Course Directors	Mid Term
Mar 7 and Mar 9		Spring Break	Spring Break
Mar 14	Tues	Darren Sandberg	How VC's Evaluate Investment Opportunities
Mar 16	Thurs	Nalaka Gooneratne	SBIR Grant Writing
Mar 21	Tues	Chris Molaro, CEO & Founder & Adam Pardes, COO & Founder, Neuroflow	Opposites Attract: The Co-founding of Neuroflow

Mar 23	Thurs	Dave Eichler	From Volume to Value: Healthcare Innovation from the Payer's Perspective
Mar 28	Tues	Adam Dakin	The Art of Pitching Investors
Mar 30	Thurs	Nalaka Gooneratne & Adam Dakin	Workshop Part I: Group Presentations to the class
Apr 4	Tues	Adam Dakin	VC Finance 101: What Founders Need to Know
Apr 6	Thurs	Nalaka Gooneratne & Adam Dakin	Workshop Part II: Presentations continued
Apr 11	Tues	Matt Grennan	HeartPort Case Study: Read Case Study
Apr 13	Thurs	Nalaka Gooneratne	Academic Conflict of Interest
Apr 18	Tues	Course Directors	Final Presentations I
Apr 20	Thurs	Course Directors	Final Presentations II
Apr 25	Tues	Adam Dakin	Working for a Startup: What you need to know

MTR 6200/BE 6080 Grade composition:

(each item described in more detail below)

Table 2: Grade composition

30%	1. Class Participation
30%	2. Team Project
20%	3. Mid-Term
20%	4. Final

Table 3: Timeline

1/12	First day of class—the course instructors will explain objectives and the class project. To enhance the experiential component, students can select projects from active startups (this will allow them to engage with the startup team during the class). Students can also develop their own ideas (self-proposed) based on work they or others are currently doing
1/18	(Optional) Students who wish to work on a self-proposed project are asked to submit one 100-200 word post explaining their concept by midnight. “Candidate Concept” should be emailed to Dr. Gooneratne at ngooneera@pennteamcare.upenn.edu and include a title, IP description, and goals/market.
1/19	Students will learn about the active startups or self-proposed projects
1/24	Students will review all candidate projects by 1/24 at noon, and rank them In cases where a team has more than four members, the members will be randomly assigned to their first or second choice teams. Teams can then begin delegating duties.
2/2	Upload the Team Project Plan (which lists the team members, title) to Canvas by midnight; update equity documents on Google Drive.
3/2	Mid-Term Exam
3/30 and 4/6	Class workshops where course instructors can look over the current status of presentations and give feedback.
4/18	Final presentations due. A draft of the presentation should be uploaded to Canvas <u>before the start of class</u> . Presentation to be held 4/18 and 4/20
Due 5/4/2023	Final Exam to be due by 5/4 at 5:30 pm

1. CLASS PARTICIPATION

In Class Participation Grade: This consists of in-class questions

2. TEAM PROJECT

The goal of the project is to put together the various aspects of commercialization covered in class. To that effect, students will work on teams on simulating a commercial technology development in the form of a startup.

The project revolves around the commercialization of a technology. Each team will pick a technology (a patent, a technology from an academic technology transfer office, or similar) and address the eight points. Candidate IP can be found here: <http://upenn.technologypublisher.com/> or from their research lab if the lab PI allows or they may propose their own ideas.

The culmination of the project is an in-class presentation in the form of a pitch to investors or development partners.

Team Composition

Only matriculated students are required to complete the project. If they so desire, non-matriculated class participants may do the project as well, but must obtain permission from the course directors and must commit to completing the project.

Teams consist of four members, but in some cases exceptions may be made to allow for three or five members. One or two members of the team must either be enrolled in the MTR program or the MRA program (that is, a team cannot consist of all MTR students or all bioengineering students, but must represent a mixture of backgrounds in order to enhance the diversity of the skill set of the team).

Each team will have a name and a designated “liaison” who will be the point person for the course directors to communicate with if needed.

Team Formation

Students may choose to work with an active startup from a list of companies that are currently active on the UPenn campus.

Alternatively, they may also propose a concept from their lab or based on personal interest. In this case, they should prepare a 200 word post that contains the following elements (“Candidate Concept”):

Filename: Last name of student first name_5-9 word title. Example: Smith_John_Knee arthroscopy assistive device

The document should contain (200 words): Title, IP description (3-7 sentences) and Overall goals/plans (this should include a description of your planned market/disease target, and the product you plan to develop from the IP). The actual project presented at the end of the class by the team (if your candidate concept is selected) can differ substantially from the candidate concept.

This document should be sent to Dr. Gooneratne at ngoонера@penmedicine.upenn.edu

From 1/19-1/24 at noon: Students will briefly review the “Candidate Concepts”, rank them (from 1 to 3, with 1 being “highly interested” and 3 being “low interest”--this will be done using a Google Spreadsheet link, and the top seven will then be available for team formation.

Enter your rankings in Canvas by noon on 2/2.

In cases where a team has more than four members, the members will be randomly assigned to their first or second choice teams. Teams can then begin delegating duties to prepare the pitch presentation. Teams may change their focus later; they will not be tied to the initial ideas presented.

By 2/3: Teams should complete the “Team Project Plan” assignment by 2/3 at midnight. Documents should be saved to your team’s Google Drive folder which Dr. Gooneratne will assign to each of you. This

is being done via Google Drive because the Grunt Equity item (#3 below) requires weekly updates that are not easy to do using Canvas currently.

1. Team Composition: One page that indicates the title of the project, project description (50-100 words—the project can change as you are working on it, so this does not need to be set in stone), the team members, and their titles. This should be uploaded to Canvas. Also please save a copy on your team's Google Drive folder.
2. Founders Pie: Complete the Founders Pie worksheet (in your team's Google Drive folder). This will be a static document--You will not update/edit this after the 2/3 submission. You do not need to upload this to Canvas.
3. Grunt Equity: Complete the Grunt Equity worksheet (in your team's Google Drive folder). This will be a living document--You will continue to update and edit this weekly (ideally by 5 PM on Mondays) as your team works on the project, with the final version at the end of April when you do your pitch; this will be reviewed in class after your pitch presentation. You do not need to upload this to Canvas.

Presentation Guidelines

- Each group should make presentation that is a maximum of **10 minutes** that addresses each topic below. There will then be 10 minutes for Q&A. **The 10 minute time limit will be rigorously enforced and will be a grading factor.**
- You will be graded on how well all the topics are covered and your ability to stay on time and on topic, i.e. you lose points for saying too little or too much. The “pitch” goal is to capture a potential investor or collaborator’s interest.
- Each member of the team is responsible for presenting 2-3 of the points below (assuming four members per team). Teams should coordinate hand-offs and where members will stand during the presentation to maximize impact (i.e., the entire team should not cluster around the podium and just move the mic from one to the other).
- Presentations should be uploaded to Canvas. A draft presentation should be uploaded before the Workshop class, and a final presentation should be uploaded before the Final Presentation class.
- To harmonize presentations, company should assume they are at the Seed A round. The specific needs may depend on the device—for a drug, this may cover first Phase 1 trial, for an app, this may be for a Phase 3 trial. The presentation should explain percent shares that are up for discussion based on the investment (i.e., we are looking to raise 10 million and would allocate 20% ownership, etc.).

The final team presentation must address the following:

(each point must have at least one dedicated presentation slide, with a maximum of two presented slides, and additional slides may be included in the presentation appendix in case the audience has questions).

1. **Problem:** Describe the unmet clinical need. What specific problem are you solving and for who? How is this being solved today and what are the gaps or challenges for the current solutions?
2. **Solution:** Describe your product or service and how it addresses the problem. Include the overall economic impact of your solution. Describe the value proposition at a high level.

3. **Use Case:** Give a real-world example that shows how the product is used by and impacts the relevant stakeholders (doctors, patients, family, caregivers, administrators, etc.). For example, “Meet Aunt Mary and her oncologist, Dr. Smith. Mary has been diagnosed with cancer.....”
4. **Market & Market Size:** Identify the users and buyers (often different). Quantify the total number of potential customers and unit sales, proposed pricing, and total potential sales revenue.
5. **Go to Market Strategy:** Who are your target customers and stakeholders (institutions? individuals within these institutions?) and how will you reach them? How will you price the product and how did you determine this price? What is your value proposition (lowers cost, improves outcomes and workflow, improves patient satisfaction, etc.) to the different stakeholders?
6. **Competition:** Describe existing products and how your proposed solution is clearly different and better. Should include a table that compares features between existing products/your solution.
7. **Disclosure and IP:** Who owns the IP? Will a license be required? If the IP is from within the University, has it been disclosed to the University?
8. **Regulatory process:** If FDA approval or clearance is required, describe the pathway (PMA, 510(k) IND, etc.) and requirements. If a clinical trial is needed, outline the design of the trial.
9. **Capitalization:** How much capital will be raised initially and what milestones will be achieved with this funding?

Presentation Appendix: Presentations should have 5-7 appendix slides that go deeper into specific challenges or issues unique to the team’s product.

Dress Code/Coordination: During the final presentation, students are asked to wear business casual clothing (i.e., no shorts, sandals).

Resources: Office Hours: Dr. Gooneratne is available for office hours upon request. Please email him to set up a time to meet.

Presentation Evaluation:

Presentations will be graded by the course directors based on effectively addressing the eight key points outlined earlier. A student’s grade will recognize both their individual work (70%) and group work (30%). Specifically, 70% will be based on the quality of the two to three topics the individual student presented, and 30% will be based on the overall quality of the group’s presentation.

We will also review the original Founders’ Pie equity allocation (prepared in early February) and the weekly updated Grunt Equity spreadsheet as well.

Venture Capital Student Groups: In addition to the presentation evaluation by the course instructors, presenters will receive feedback from impromptu Venture Capital (VC) groups formed by the students. These will be identical in membership to the project teams to facilitate organization. They will act as “Partners” of the VC firm and will be given a funding portfolio of 10 million dollars. They will be asked to allocate their funds after hearing the presentation pitches from the various presentation teams throughout the course of the semester; one individual will record their funding allocations, as well as

strengths/weaknesses of the presentation pitch that influenced their funding decisions. A template will be provided in Canvas.

Members may come up with a name for their impromptu Venture Capital group, and are encouraged to pose questions during the team presentations in order to decide how they wish to judiciously allocate their portfolio for maximum profit.

3. MID-TERM EXAM

The mid-term exam will be conducted via Canvas. It will cover material from the first half of the class (up until the lecture immediately prior to the mid-term). It will primarily be based on the book chapters assigned for each class, and will include some content from the presentation slides also.

4. FINAL EXAM

The final exam will be conducted via Canvas. It will cover material from the second half of the class (it will exclude lectures before the mid-term and will cover new lectures up until the lecture immediately prior to the final). It will primarily be based on the book chapters assigned for each class, and will include some content from the presentation slides also. The exam will be due by Tuesday, May 5 at 5:30 pm. Once a student begins the exam, they will only have 90 minutes to complete.

5. MAKE-UP WORK FOR MISSED CLASSES

Students who miss a class will be asked to prepare a post drawn from the assigned reading material for that missed class. Specifically, students will be asked to:

1. Query: Pick an item from the chapter that is of interest to you and about which you would like to learn more. Describe it as a question or gap in the chapter that you would like to explore more deeply than is presented in the chapter. Please remember to mention the chapter number.
 - a. For example: "Query: Chapter 6. How do you identify the correct FDA institute for pre-IND review?"
2. Answer: Answer this in a 700-1000 word post
3. References: Provide at least two references in MLA format.

Your post should clearly describe these three steps. Thus, your post should have a "Query:" and an "Answer:" and "References:". Please post your findings to Canvas within 3 business days of the class you missed (so if class is on Jan 24 from 3:30-5:00, your post should be uploaded to Canvas by Jan 25 at 5:30 PM).

OPTIONAL: EXTRA CREDIT

Students may elect after the final presentation to write an additional review paper or interview case (approximately 6-8 pages, including 5-10 references). The option for extra credit is only available for students earning a grade of C+ or below after the final exam due by May 20. Please contact Dr. Gooneratne for instructions.