Validating the Problem
A critical first step in the innovation process is to validate that you are addressing a real problem that demands a solution. After this session, teams will be able to clearly articulate what problem they are trying to solve, how the problem is currently being addressed (or the current standard of care process/patient journey), and develop a clear statement on the unmet clinical need. Teams will also begin to identify relevant stakeholders and learn how to test, through interviews, their specific assumptions about the problem being solved.

Envisioned Product, Your Value Proposition
Once you have validated your problem and identified relevant stakeholders, an important next step is to understand how your envisioned product will fit into the existing clinical workflow and who would be positively and negatively impacted if your solution is implemented. Teams will also learn how to develop and test specific value proposition(s) for your envisioned product. A value proposition explains what benefit your product provides for each stakeholder, and why it is distinctly better than alternatives. Teams will also continue to test, through interviews, their specific assumptions about their envisioned product and associated value proposition(s).

Validating the Business Case
Once you have validated the value proposition(s) for your solution, the next step is to determine the business opportunity for your solution. Understanding your customer’s needs and the market potential for your technology is a critical step on the path to market and will help attract partners and investors.

After validating the problem and the business case for a new medical device, the next focus should be understanding what it takes to bring the product to market, including understanding the key risks that you will encounter along the way and developing strategies to mitigate those risks. The next three sessions will focus on the most common risks in your path to commercialization, from intellectual property to regulatory requirements and reimbursement issues. The first session will cover the basics of intellectual property (IP) for medical devices and key considerations for IP developed in a University setting.

**Guest Speaker Cynthia Dahl, Esq., Practice Professor of Law, Director of the Detkin Intellectual Property and Technology Legal Clinic**

The next session will review regulatory requirements for medical devices, including resources on how to determine your device classification and regulatory pathway and the importance of predicate devices. We will also describe resources available within Penn’s Office of Clinical Research for early clinical evaluation of new technologies.

**Guest Speaker Monica Ferrante, DPA, VP of Regulatory, Quality, and Clinical, Vitara**

This session will address another important risk for new medical devices under development, reimbursement, and will highlight the importance of developing a reimbursement strategy. We will review the basics of reimbursement (i.e., coverage, coding, and payment) and learn how to assess the existing reimbursement landscape and whether it will accommodate your new solution.

**Guest Speaker Michael Finch, PhD, Adjunct Associate Professor, Carlson School of Management, University of Minnesota**

Path to Market, Milestones

During this session, we will introduce and review major technical and business milestones on the path to market for a medical device. By the end of this session, teams will be equipped to propose commercialization milestones for their project and identify the associated timeline and funding requirements and sources. We will also share techniques and tips on telling your story and giving an effective pitch.

By Invite Only

Health-Tech Innovator Spotlight: Idea to Commercialization

We will hear from a seasoned med-tech inventor and entrepreneur about his journey from the bench to the bedside in a "Health-Tech Innovator Spotlight".

Guest Speaker Pitou Devgon, MD, Advisor, Becton Dickinson

Penn Health-Tech Alumni Panel

We will hear from select Penn Health-Tech alumni teams about their journey, lessons learned, and future plans.
Commercializing Intellectual Property

In this session, we will discuss the process for university "exit" and commercialization for innovations developed in an academic setting as well as resources within Penn to support innovation. This session will overview business and legal terms that are found in most licensing agreements and discuss negotiations involved.

Guest Speaker Cynthia Dahl, Esq., Practice Professor of Law, Director of the Detkin Intellectual Property and Technology Legal Clinic

Understanding Investment and Financing

Formation of a start-up company is often a logical next step for your team on the path from the lab to the clinic. The next two sessions will cover key considerations for start-ups, including financing, company formation, and building your start-up team and advisory board. The first session will start with understanding investment and financing for early-stage medical device start-ups.

Guest Speaker Craig Kenesky, PhD, JD, Associate, Wilson Sonsini Goodrich & Rosati (WSGR)

Start-Ups 101

The final session will focus on key considerations for start-ups. By the end of this session, teams will be familiar with the steps involved in forming a company and key considerations for how to build a team and advisory board.

Guest Speaker Michael Dishowitz, PhD, Director of UPStart, Penn Center for Innovation Ventures (PCIV)