

# Business and Legal Tools for Digital Health Entrepreneurship

**3 Credit Graduate Online Course**  
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## COURSE DESCRIPTION

Transformative innovators in digital health are challenged to enhance the delivery and management of health care services while improving patient care, access and affordability.

To successfully develop and implement the next generation of digital health innovations, clinician intra/entrepreneurs require a number of foundational skill sets.

This course introduces students to the key business and legal tools required for establishing a digital health program, product and/or service and examines the critical issues confronting innovating clinicians.

We will explore different business models in digital health and outline the legal/business tools required to establish a start-up through the lens of emerging case studies.

Key legal steps include creating a robust intellectual property (IP) portfolio with licensing and IP centered contracts, raising capital, hiring talent, obtaining FDA and CMS approval, and navigating HIPAA and privacy for data streams.

The course is geared for health care professionals interested in broadening their knowledge in this rapidly changing and exciting field, particularly those preparing to launch a start-up or in-house program.

## INTERACTIVE COURSE STRUCTURE

The course features 8 Modules that include a myriad of asynchronous learning tools, video lectures with live Q&A, peer to peer Discussion Boards, Ask the Professor modalities, visual and audio presentations and readings from key thought leaders.

Hands-on practical assignments will enable students to acquire key business and legal drafting skills, with the final pitch presentation to guest lecturers preparing them for next steps.

Virtual synchronous networking opportunities with key players will further enable engagement and forging of future relationships within the digital health ecosystem.

## COURSE FACULTY

### **Carolyn Hochstadter, Esquire**

*Lead Course Instructor*

*Managing Attorney, E. Carolyn Hochstadter Dicker LLC*

Professor Hochstadter runs a boutique law firm, specializing in business law with a niche in the digital health space. She takes a passionate interest in her clients, guiding them to be self-sustaining entrepreneurs. Prior to launching this course, Professor Hochstadter taught The Legal Aspects of Entrepreneurship at The Wharton School, University of Pennsylvania. She also serves as an Arbitrator for the Philadelphia Court of Common Pleas and has authored numerous publications. She hosts weekly Office Hours with Venture Cafe Philly and is a Coach for Tribe 12.

### **Adam P. Dicker, MD, PhD**

*Course Instructor*

*Enterprise Senior VP*

*Professor & Chair, Dept of Radiation Oncology at Thomas Jefferson University – Jefferson Health, Sidney Kimmel Medical College & Cancer Center*

Dr. Dicker leads a University-wide effort in Digital Health and Data Science and founded the Jefferson Center for Digital Health & Data Science using the convergence of mobile technology, platforms, networks, and machine learning to improve the lives of patients.

## GUEST SPEAKERS

The course will feature a variety of speakers reflecting a multi-disciplinary cross-section of stakeholders, including entrepreneurs, funders, clinicians, pharma and payers.

Highlights include the founding principals of Livongo, Click Therapeutics, Mymee and Viz.ai and funder-accelerators from Rock Health, 7wireVentures, StartUp Health, Osage Venture Partners, Anthem and Highmark.

We will also introduce Philadelphia based incubators and accelerators hosted by Dreamit Ventures and The University City Science Center.

## ADDITIONAL JEFFERSON FACULTY

Jefferson Clinicians, Innovation, Tech Transfer and Venture experts will be contributing to the Course.

<p><b>Module 1</b></p> <p><b>Introducing Business Models &amp; the Regulatory Environment</b></p> <p>What is Digital Health?</p> <p>Why Innovate Now?</p> <p>Current Trends</p> <p>Who are the Players?</p> <ul style="list-style-type: none"> <li>• Patient</li> <li>• Clinician</li> <li>• Healthcare system</li> <li>• Pharma</li> <li>• Insurance</li> <li>• Start-up</li> </ul> <p>How do you get Paid?</p> <ul style="list-style-type: none"> <li>• Billing Codes</li> <li>• Case by Case Deals</li> </ul> <p>Intrapreneurship vs. Entrepreneurship</p> <p>How to Build an App</p>	<p><b>Module 2</b></p> <p><b>Exploring Use Cases in Telehealth and Connected Care</b></p> <p>Let's discuss Jefferson</p> <ul style="list-style-type: none"> <li>• JeffConnect</li> <li>• Nursing Innovation</li> <li>• Ecofibre</li> </ul> <p>Use Cases: Exit Modes</p> <ul style="list-style-type: none"> <li>• "Lifestyle"</li> <li>• M&amp;A</li> <li>• IPO</li> </ul> <p>Blended Models &amp; Implementation Tips</p> <ul style="list-style-type: none"> <li>• Highmark use case</li> </ul> <p>Customer-users differ</p> <ul style="list-style-type: none"> <li>• Digital therapeutic</li> <li>• Chronic care</li> <li>• Behavioral health</li> </ul> <p>Start-up Nation</p>	<p><b>Module 3</b></p> <p><b>Monetizing Intellectual Capital via Your Intellectual Property Portfolio</b></p> <p>How to create IP</p> <ul style="list-style-type: none"> <li>• Trade Secrets</li> <li>• Trademarks</li> <li>• Copyrights</li> <li>• Design Patents</li> <li>• Utility Patents</li> </ul> <p>IP is a core asset that must be protected from day 1</p> <p>Consult your lawyer &amp; financial advisor from day 1</p> <p>Funders will want the start-up to own its IP</p> <p>Founders Roundtable</p> <ul style="list-style-type: none"> <li>• Academic faculty explore IP start-up challenges</li> <li>• University leveraging</li> <li>• Spinning out a start-up</li> </ul>	<p><b>Module 4</b></p> <p><b>Securing &amp; Expanding Intellectual Property with Contracts &amp; Licenses</b></p> <p>Learn to Protect, Expand &amp; Use IP via Contracts</p> <p>Protect &amp; Expand IP</p> <ul style="list-style-type: none"> <li>• Confidentiality (NDA)</li> <li>• Invention Assignment</li> <li>• Non-compete</li> <li>• Non-solicitation</li> <li>• Anti-piracy</li> </ul> <p>Use or Share IP; Mitigate Risk</p> <ul style="list-style-type: none"> <li>• Licenses</li> <li>• Insurance</li> <li>• Indemnification</li> <li>• Warranties</li> </ul> <p>Navigating Tech Transfer</p> <ul style="list-style-type: none"> <li>• Risk Prevention</li> <li>• Licensing</li> </ul> <p>Funder-University ventures</p>
<p><b>Module 5</b></p> <p><b>Building the Start-up, Founder Issues, Funding, Compliance, Exit &amp; Talent</b></p> <p>Why create a company?</p> <p>What type of company should you create?</p> <p>How do you handle co-founder equity, control, management &amp; profits?</p> <p>What do you do to avoid being squeezed out?</p> <p>How do you fund your company?</p> <ul style="list-style-type: none"> <li>• SBIR grant</li> <li>• Incubator/Accelerator</li> <li>• Angel</li> <li>• Growth Equity</li> <li>• Venture Capital</li> <li>• Entrepreneur stories</li> <li>• Funder perspective</li> </ul>	<p><b>Module 6</b></p> <p><b>Planning a Trajectory for FDA Regulation, Marketing &amp; CMS Reimbursement</b></p> <p>How to plan FDA &amp; CMS trajectories from day 1</p> <p>Is FDA approval a must?</p> <p>Is your start-up exempt?</p> <p>What are the various modes of approval &amp; how can a start-up plan ahead?</p> <p>New digital health pre-certification pathway</p> <p>Does CMS reimburse your payer? This is key</p> <p>Navigating the CMS pathway; new models</p> <p>Digital health codes</p> <ul style="list-style-type: none"> <li>• Hear from Viz.ai</li> <li>• Funders want a plan</li> </ul>	<p><b>Module 7</b></p> <p><b>Navigating &amp; Complying with HIPAA and Data Privacy Regulations</b></p> <p>What HIPAA &amp; Data Privacy issues are at stake?</p> <p>Does digital health data require more precaution?</p> <ul style="list-style-type: none"> <li>• Personalized medicine</li> <li>• Artificial Intelligence</li> <li>• Platform sharing</li> <li>• EHR integration</li> <li>• Blockchain solutions</li> </ul> <p>HIPAA covers PHI – Protected Health Information</p> <p>Data Privacy covers any personal data</p> <ul style="list-style-type: none"> <li>• EU's GDPR &amp; U.S. certification</li> <li>• CCPA – California law</li> <li>• Use cases explored</li> </ul>	<p><b>Module 8</b></p> <p><b>Takeaways – The Patient as Winner</b></p> <p>Can we attain this goal?</p> <p>Let's talk about a futuristic vision for digital health</p> <p>How can our community of stakeholders collaborate to pave the way for the clinician innovator?</p> <p>How can you contribute your ideation, expertise &amp; effort to this endeavor?</p> <p>What are your next steps?</p> <p>How can we help?</p> <p>Closing remarks from</p> <ul style="list-style-type: none"> <li>• Patient entrepreneurs &amp; advocates</li> <li>• Key thought leaders</li> <li>• DiMe collaborations</li> </ul>

## PRACTICAL SKILLS THAT YOU WILL ACQUIRE

- Draft a sketch of your business idea
- Implement a risk management policy
- Craft a business plan legal structure
- Draft an FDA trajectory and/or reimbursement plan

## PITCH YOUR REAL OR HYPOTHETICAL START-UP

Virtual meet-up with faculty and entrepreneur judges

## MEET THE PLAYERS IN THE FIELD

- Virtual networking opportunity with leaders of the Philadelphia based Science Center & Venture Café – learn about its myriad offerings:
  - ~ ic@3401 incubator
  - ~ Launch Lane accelerator for digital health start-ups
  - ~ OnRamp pre-accelerator program
  - ~ Grant openings
  - ~ Funding
- Virtual exposure to case studies of lessons learned and visionary tips, just a “click” away

## EXPLORE READINGS OF KEY OPINION LEADERS

- Wulfovich and Meyers, *Digital Health Entrepreneurship* (2020)
- Bagley & Dauchy, *The Entrepreneur’s Guide to Law and Strategy* (5th ed. 2018)
- Grant, Adam, *Originals, How Non-Conformists Move the World* (2016)

