



HCAK 975-5 - Digital Health for the Entrepreneur

*Kellogg School of Management
Northwestern University*

Syllabus: Winter 2024

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1. Course Overview

Summary:

The Digital Medicine Society defines digital medicine as “a field, concerned with the use of technologies as tools for measurement, and intervention in the service of human health.” Digital health broadens that definition to look at the intersection of healthcare and technology, not solely in medicine, but across healthcare, including wellness and administration. It is a large and fast-growing field that intersects almost every area of health care. This class will examine digital health from the perspective of the entrepreneur, focusing on successful business models for startup companies and where and why venture capital investors are placing their bets.

If you ask 10 people to define digital health, you’ll likely get 10 different answers. In this class we will include regulated health technologies spanning from HIPAA regulations at one end of the spectrum to class II devices and digital therapeutics at the other. We will include companies that build and sell technologies, sometimes paired with a service, but only when the technology is, in and of itself, the service. We exclude companies selling a service. That means Omada is in – it began by selling a technology solution for managing pre-diabetes. But Oscar and One Medical are out – the former sells insurance plans, the later primary care. While both may be using technology to improve those experiences, their product is a service. Fitbit and Oura are in, Care/Of and Freshly are out.

The goal of this class is to examine what contributed to the successes and challenges for early-stage digital health companies over the last decade+ and use those learnings as a vehicle for examining existing opportunities on the horizon for the entrepreneur.

We will look at the trends in venture investment dollars and how the subsectors of digital health receiving those dollars has changed over time. 2021 was the biggest year yet for both digital health investment and M&A deals in healthcare. More than half of the digital health venture deals over the last five years have been early-stage companies. \$36B of venture capital was invested in over 1100 early-stage digital health companies in 2021, up from only \$4.5B and 332 companies in 2016. This is the first time ever that this exceeds venture investments in biopharma companies.

The class will review customer needs (desirability), business models (viability), legal/regulatory requirements for digital health in the US and abroad (feasibility). Specifically, the course goals are to:

- Evaluate the early stages of company formation and how companies achieve product market fit, not growth and scale.
- Understand the evolution of digital health business models both in a company's growth and as markets change
- Understand how legal and regulatory requirements shape digital health products and business models
- Provide you with a framework to assess digital health opportunities.
- Introduce you to digital health entrepreneurs, investors and stakeholders who can provide perspective on early-stage companies and market opportunities.
- Apply your learnings to a real digital health company.

A Note:

Our focus will be on entrepreneurship and what is required to be successful in digital health entrepreneurship. We cover topics like the role of HIPAA or the role that the self-insured employer plays in health care spending, but these will be viewed through the lens of the entrepreneur or early-stage investor. Customer problems, business model execution and policy/regulatory compliance shape the allocation of extremely limited resources in early-stage companies. The more effectively and efficiently an entrepreneur can understand those needs, the greater their chance of success. As we will see when examining both successes and failures, digital health entrepreneurs have made bets (good and bad) on what matters most and what matters when. We will also see that the answer on what the problem is and who the customer is has changed for many digital health entrepreneurs and early-stage companies and we will unpack why and the implications for the product, business model and regulatory landscape.

2. Course Format & Expectations

Format:

The course consists of five 3-hour long sessions. Classes will include lectures, group discussions, student presentations and guest speakers.

Expectations:

You are expected to attend every class, be on time and stay for the entire session. If you have an unavoidable conflict and cannot attend class, please email me **at least 24 hours in advance** (but letting me know before the course begins or during our first session is optimal). *Please note, however, that absences will result in zero-credit for your contribution in class on days that you miss which will likely have a negative impact your grade. I will only accept 1 missed class session per quarter.*

This course adheres to the guidelines established in the Kellogg Honor Code and the Kellogg Code of Classroom Etiquette. Use of technology is permitted for in class exercises only. Flat-screens are permitted for note taking. *You are allowed to use generative AI for assignment only for the purpose of creating insight prompts. Any use of generative AI should be accompanied by a disclosure at the end of an assignment explaining (1) what you used AI for; (2) the specific tool you used; and (3) what prompts you used to get the results. Any use of generative AI beyond where permitted will be viewed as a potential violation of the honor code.*

Students can find useful resources for safety and security, academic support, and mental and physical health and well-being on the NU help [website](#).

3. Course Requirements and Assignments

Your final grade is comprised of:

Class Contribution	30%
Weekly Analysis	35%
Final Project	35%

Class Contribution - 30% (individual)

All class sessions will thrive based on your active discussion of the readings, lectures and any guest. You must come prepared to show and share your ideas and listen to and interpret the concepts presented by others.

Most weeks, you will receive an assignment. *These are to be completed before the class begins.*

Weekly Analysis - 35% (individual)

Students will select one of four digital health companies from different sectors of digital health (care delivery/enablement, DTx, operation or services enablement) to examine for the duration of the term. Each week you will examine a specific aspect of that company's product and business model development. Before class each week you will submit a one-page document that summarizes your thoughts on how the company addressed one element of the value creation and your reflection on how you might think differently about your answer to the previous week's topic based on the class discussion. For example, in week two prior to our discussion of customer need, you will submit a one pager on how your company identifies and addresses its customers' needs. In your submission the following week, you will reflect on any changes you have considered as well as a discussion of the company's business model.

- Before the first class, please read up on the four companies and submit your preference for which company you will use as your case study for these assignments

Final Project/Presentation - 35% (group)

Your final deliverable will ask you to break into teams of 4-5 and select an early-stage digital health company from the provided list and apply the course framework on customer, business model and regulatory/legal landscape and make a recommendation on the path forward. Your analysis should focus on how the company has achieved product-market fit around the customer need (desirability), the business model (viability) and the regulatory landscape (feasibility).

Your group will present your analysis on the last day of class.

If you are currently working on digital health start up idea and your team would like to focus your project on that, please submit a one-page overview of the problem statement to me by **February 10**.

4. Class Schedule

	Theme	Deliverable
Session 1 - February 5	<i>What is digital health entrepreneurship?</i>	
Session 2 – February 12	<i>Understanding The Customer</i>	Analysis of company need. Submit proposed company for your final project
Session 3 – February 19	<i>Digital Health Business Models</i>	Analysis of company business model
Session 4 - February 26	<i>Regulatory and Legal; Digital Medicine & Therapeutics</i>	Analysis of regulatory and legal requirements
Session 5 – March 4	<i>Global Digital Health</i>	Final project

SESSION 1: What is Digital Health Entrepreneurship?

In the first class, we'll cover the basics of the course structure and talk about what is digital health in the context of entrepreneurship, and equally important, what it isn't. We'll look at this through the lens of trends in venture investments across digital medicine and therapeutics, but also for the wellness and wellbeing space. We will introduce the companies that will serve as our guides during the course to understand where digital health entrepreneurship has been as a field and how to evaluate where it might be going. This will include a look at successes in digital health, how business models have evolved, the parallel trends in early-stage company focus and investment dollars, some companies that didn't meet investor / regulator expectations and a look at where investment dollars have focused over time. This discussion will frame up our focus for the term – that the greatest risks in digital health entrepreneurship are not technical or clinical, but the business model, whose success depends on knowing the customer(s) needs and the regulatory requirements.

Pivoting is a common topic in entrepreneurship, where products and business models evolve (and as result, the corresponding regulatory requirements may change). Distinct from other healthcare classes, we will discuss how the landscape of entrepreneurship (the way we fund, build and execute) can fuel success or enormous liability.

Reading (Required before class):

- *Abernathy et al 2022. The Promise of Digital Health: Then, Now and the Future.* <https://nam.edu/the-promise-of-digital-health-then-now-and-the-future>
- <https://www.fiercehealthcare.com/tech/outcome-health-co-founder-former-executives-charged-1b-fraud-scheme>
- <https://www.fiercehealthcare.com/health-tech/cerebrals-ex-ceo-may-be-gearing-lawsuit-claims-investors-pushed-company-prescribe>

Reading (Optional):

- *Goldsack, Coder, Fitzgerald, et al 2019. Digital Health, Digital Medicine, Digital Therapeutics (DTx): What's the difference?* <https://www.dimesociety.org/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference/>
- *Safavi et al. 2019. Top-funded digital health companies and their impact on high-burden, high-cost conditions. Health Affairs 38(1)* <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05081>

Assignment for next week:

- Submit your final project company proposal
- One page reflection of who your Case company's customer(s) is, their need and how the company solves it. If the customer changed from the company's founding to early revenue phase, please comment on the changing customer needs that supported the change.

SESSION 2: Understanding the Customer

This week, we'll discuss who the customers are for digital health and how entrepreneurs need to understand customer needs. We will focus on the unique challenges digital health entrepreneurs face as they often have to serve multiple customers including patients/consumers, providers, health systems, payors, self-insured employers, pharma and life sciences companies. Success in reaching the digital health customer includes customer (patient and enterprise) adoption and engagement. This poses unique challenges to the digital health entrepreneur, particularly in the early stages of a company.

Unique to entrepreneurship, we will talk about how the target customer, and corresponding business model, can change or grow over time.

Reading (required before class):

- *Digital Health Consumer Adoption Report 2020. Stanford Center for Digital Health 2021.*
- *Hope & Grit: How Human Centered Product Design Enhanced Student Mental Health. Berkeley Haas Case Series 2022*

Reading (optional before class):

- Wang et al 2022. Digital patient experience: Umbrella systematic review. JMIR <https://www.jmir.org/2022/8/e37952>
- Baldwin JL, Singh H, Sittig DF, Giardina TD. Patient portals and health apps: Pitfalls, promises and what one might learn from the other symptoms. *Healthcare* 5 (2017) 81-85
- Singer N. Sleep therapy for the masses may be coming soon to you. NYT 24 Sep 2019
<https://www.nytimes.com/2019/09/24/technology/cvs-health-insomnia-app.html>

Assignment for next week:

- One page reflection on Case company's business model and how they validated willingness to pay in their pre-revenue and early revenue phases. Please also comment on any new or reconsidered perspective you have on the Case company's customer and customer needs following our class discussion this week.

SESSION 3: Digital Health Business Models

In this class we'll focus on how digital health companies make money. We will look at companies that make money by selling a technology, those that make money by enabling other health businesses/business models, those that make money by monetizing data. We'll look at the metrics companies use to evaluate success depending on their business model.

Reading (Required before class):

- Kelley et al. 2020. Barriers to creating scalable business models for digital health innovation in public systems: qualitative case study. JMIR <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7759439/>
- Fitbit. Harvard Business Case

Reading (Optional):

- Evans and Shapiro 2017. Streamlining enterprise sales in digital health. Rock Health. <https://rockhealth.com/insights/streamlining-enterprise-sales-in-digital-health/>
- Gordon et al 2020. Beyond validation: getting health apps into clinical practice. *NPJ Digital Medicine* 3 (14) <https://www.nature.com/articles/s41746-019-0212-z>
- DTx Podcast: <https://digitalhealthtoday.com/episodes/digital-therapeutics-podcast/the-winding-commercial-path-for-dtx-mike-pace-shares-the-work-done-on-commercialisation-models-where-we-go-next>

Assignment for next week:

- One page reflection on the Case company's regulatory and ethical hurdles and how they navigated those in their pre-revenue and early revenue phases. Please also comment on any new or reconsidered perspective you have on the Case company's business model and validation of the business model following our class discussion this week.

SESSION 4: Digital Medicine, Digital Therapeutics

In this class we will look at the regulatory, payment and tech hurdles that digital health companies face in their path to scale and financial success.

Reading (Required before class):

- Espie, Torous and Brennan. 2022. Digital Therapeutics should be regulated with gold-standard Evidence. *Health Affairs*. <https://www.healthaffairs.org/doi/10.1377/forefront.20220223.739329>
- Day et al. Assessing the Clinical Robustness of Digital Health Start-ups. 2022 *JMIR* 24(6). <https://www.jmir.org/2022/6/e37677>

Reading (Optional):

- Digital Health Checklist <https://recode.health/tools/>
- Schueller and Torous. Scaling evidence-based treatments in mental health. 2020 *Am Psychol* <https://pubmed.ncbi.nlm.nih.gov/33252947/>
- Downing & Perakslis. 2022. Health advertising on Facebook: Privacy and policy considerations. *Patterns* 3. [https://www.cell.com/patterns/pdf/S2666-3899\(22\)00172-6.pdf](https://www.cell.com/patterns/pdf/S2666-3899(22)00172-6.pdf)
- Dorsey & Topol. Telemedicine 2020 and the next decade. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30424-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30424-4/fulltext)

Assignment for next week:

- Final project
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SESSION 5: Global Digital Health

In this class we will turn our attention to what unique opportunities and challenges exist outside of the US. In 2019 Germany passed the Digital Healthcare Act, which formalized “prescribable applications.”

Reading (Required)

- *Digital Healthcare Act*
<https://www.bundesgesundheitsministerium.de/en/digital-healthcare-act.html>