

**Medical Device Strategy**  
**HLTHMGMT 712**  
**Fall 2 2023**

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## **HLTHMGMT 712 - Medical Device Strategy**

### **Fall 2 2023 Term**

Greg Davis

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Office Hours: W216E (by appointment)

Class Sessions: Tuesday & Friday, 8:00 – 10:15 AM

Classroom: Sauer Classroom

Teaching Assistants:

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- [Sarah.gillman@duke.edu](mailto:Sarah.gillman@duke.edu)

### **Course Description**

This course is for students aspiring to work in the medical device industry, either in an incumbent firm or entrepreneurial start-up. The course is also relevant for students interested in pursuing careers in management consulting within the healthcare sector. We will discuss numerous case studies on medical device companies throughout the term and gain insights into what drives superior performance in this dynamic and fast-changing industry.

### **Educational Objectives**

Medical device companies face significant challenges and opportunities in a business environment characterized by rapid growth in emerging markets but plateauing growth, increasing regulatory oversight and reimbursement challenges in the developed markets. Our objective is to help you acquire the skill set you need to work and thrive within this industry. To succeed in an increasingly dynamic and complex world, industry professionals need a deep understanding of corporate strategy, regulatory and reimbursement frameworks, new company formation and financing, product development, manufacturing supply chain, customer needs, and other related issues.

### **Selected Topics**

- Product Development, Supply Chain Management
- Navigating Regulatory and Reimbursement Processes
- Intellectual Property Management
- Entrepreneurial Strategies and Financing
- Digital Health/Cloud-Based Medical Devices/Remote Patient Monitoring
- Disruptive Technologies/Robotics/Artificial Intelligence & Machine Learning
- FemTech & Women's Health
- Healthcare Inequities (race, gender, socio-economic, rural - urban)
- Commercialization Strategies
- Emerging Market Strategies

## **Classroom Structure**

Many classes start with a case study discussion. The general setup for the case study discussion is to look at the challenges from the perspective of investors, the board of directors or the executive management team. Each discussion will begin with one student being asked to share their recommendations to the specific questions provided under the ***Case Discussion Dynamics*** in Attachment (1) for each case. Following the opening recommendations, the class will debate what is the best course of action for the company, management team or CEO. The instructor will facilitate this discussion.

The second half of the class will be an interactive lecture addressing important industry topics and reinforcing key learning points of the case study. The instructor will also share real-world experiences from his 30+ year career in the industry as an executive in a major multi-national corporation, start-up CEO, and industry consultant.

Lecture presentation slides will be made available prior to the start of most classes.

## Class Schedule Fall 2 2023

Class	Date	Topics	Case
1	10/31	Introduction to Medical Device Industry, Market Size and Segments, Industry Trends	Pre-Reading: Heartport, Inc
2	11/3	FDA/CE Mark Basics, Reimbursement Overview, Introduction to Digital Health	No case
3	11/7	Research & Development Process, Design Controls, Supply Chain Management	Tryton (A) case handed out in class
4	11/10	Tryton (A) Case Debrief, Entrepreneurship, Funding, Commercialization Hurdles	Fred Khosravi & AccessClosure
5	11/14	Orthopedic Sector, Bundled Payments, Value Based Healthcare, Sunshine Act, Race into Robotics	Zimmer
6	11/17	Reimbursement, Healthcare Economics, Inequalities in HC, FemTech, Women's Health,	Novasys Medical
7	11/21	Commercialization, Corporate War Games, Innovation  <i>**Team Project, Part 1 due by 8:00 AM**</i>	Conor Medsystems, Tryton (B) case handed out in class
8	11/28	<b>Guest Speaker:</b> Carrie Strozinsky  Approach to Customers, Industry Opportunities/Challenges  <i>**Mid-Term Exam**</i>	No case
9	12/1	<b>Guest Speaker:</b> John Tushar, CEO, Plasma Surgical Inc.  Tryton (B) Case Debrief, Remote Patient Monitoring, Direct to Consumer, Digital Health Opportunities/ Challenges	AliveCor
10	12/5	Diagnostic Accuracy, Machine Learning & AI, Cloud-Based Medical Devices, Software as a Medical Device, Rural vs. Urban Access, Point-of-Care diagnostics	CorVista Health case handed out in class
11	12/8	Global Commercialization, Strategies for Emerging Markets	Medtronic: Navigating Shifting HC Landscape
12	12/12	<b>Guest Speaker:</b> Perry Genova, Senior VP R&D, EndoQuest Robotics  Course Summary  <i>**Team Project, Part 2 due by 8:00 AM**</i>	
	12/14	<i>**Peer Evaluation Surveys due by 5 PM**</i>	

## Grading

Final grades will be comprised of the following elements:

Individual Participation		60%
1. Class participation	35%	
2. Mid-term exam	25%	
Team Project		40%
1. Team project, Part 1	Not graded	
2. Team project, Part 2	30%	
3. Team peer evaluation	10%	

## Assignment Due Dates

Team project, part 1	November 21 by 8 AM
Team project, part 2	December 12 by 8 AM
Team peer evaluations	December 14 by 5 PM

No late assignments will be accepted

The Fuqua School of Business Honor Code applies to all aspects of the course.

## Class Participation & Attendance

Your individual class participation grade will be evaluated on your punctuality, attendance, and engagement in class discussions. A significant portion of learning in this course comes from participation in the case discussions and because of this, class attendance is required. Multiple unexcused absences will reduce your class participation grade.

## Mid-Term Exam

During class 8, **November 28th**, there will be a 45-minute, closed book, closed note exam given in class. The exam will cover the materials presented in the first seven classes. The exam questions will be generated from the readings, podcasts, YouTube videos, lecture notes and class discussion.

## Teams

Students are responsible for forming their own project teams, utilizing *Team Builder* in Canvas. Each team must have no less than five students and no more than six students. You should start to look for your teammates as soon as possible. All teams must be formed, and team member names provided to the professor and TAs, by the end of Class

2 (November 3rd). The professor reserves the right to reassign students to another team if a team has less than 5 students or more than 6 students.

## Team Project

Your team is pitching a **digital health** technology to a venture capitalist or Angel investor or to the corporate venture capital arm of a large multi-national corporation for an equity investment. You choose the digital health technology and the indication (either novel or already developed). Funding of digital health technologies is highly competitive so your investor pitch paper should be pervasive and engaging.

### Team Project Deliverables, Part 1

Part 1 (partial investor pitch written report) is due on **November 21** at 8 AM (uploaded to Canvas) and should be no longer than 1,200 words (4 pages) and contain the following elements:

- Cover page (excluded from page count). On page 1 include paper title, authors, acknowledgments, whether the material was submitted in other contexts (work or class), who helped you with the paper, and whether the paper may be shared with others.
- Explain how the technology meets the definition of digital health (discussed in class 2)
  - Note: Technology must require FDA 510(k) clearance or PMA approval for U.S. launch
- How would you describe the key technical features of your technology? (use pictures)
- What is the unmet medical need and how will your technology address this need?
- How will new technology change the current care pathway for the patient? (use diagram)
- What is the size of the potential market?
- Using Porter's Five Forces how would you assess the power of supplier and buyers, the threat of new entrants and substitute products and the rivalry of competitors?
- Competition: What is the current standard of care and what does the competitive landscape look like?
- References: Include a list of paper citations to credit other authors and to help the reader identify further reading.

### Team Project Deliverables, Part 2

Part 2 (final investor pitch written report) is due **December 12** at 8 AM (uploaded to Canvas) and should be no longer than 3,600 words (12 pages). Materials presented in appendices are not counted towards the 12 pages.

- Cover page (excluded from page count). On page 1 include paper title, authors, acknowledgments, whether the material was submitted in other contexts (work or class), who helped you with the paper, and whether the paper may be shared with others.
- Executive summary (i.e., paper abstract). On page 2 summarize the paper in 300 words or less. Remember, the funder may receive hundreds of these business plans each year, so engage your audience quickly! **Clearly state how much money you are raising and how you will use the funds.**

- Integrate Part I project deliverables into the final paper
- Technology development: What technology development remains? How will you assure your final design is robust and ready for clinical use?
- What is your strategy for producing clinical data required for regulatory approvals?
- How will you commercialize the technology in the U.S. market?
- How does the technology benefit patients, clinicians/doctors, payers and providers?
- Reimbursement: What does the reimbursement landscape look like today? Who will pay for the new digital health technology and why?
- Address the following strategic questions (as applicable) based on your technologies' characteristics:
  - If your technology is Software as a Medical Device (SaMD), how will you protect sensitive patient health information (HIPPA) and address Cybersecurity threats?
  - If applicable, explain how your technology leverages machine learning (ML) and artificial intelligence (AI) to improve patient outcomes
  - How will your technology help address current inequality of care (gender, race, rural vs. urban, socioeconomic)?
  - If you are using a direct-to-consumer sales approach what are the expected opportunities and challenges in driving adoption with consumers?
- What are possible exit strategies for investors and what path do you think is most likely?
- References: Remember to include a list of paper citations to credit other authors and to help the reader identify further reading.

## **Paper Grading Criteria**

The paper will be graded using the following criteria:

### **Content:**

- Is the digital health technology selected compelling for investment?
  - (market size, unmet medical need, competition, technology advantages)
- Does the technology benefit patients, clinicians/doctors, payers and providers?
- Is Porter's Five Forces analysis logical and reasonable?
- Are product development, clinical and regulatory strategies sound?
- Have the right major milestones been identified for the investment?
- Is it clear how the company will generate revenue and make money?
- Are strategic questions answered thoughtfully?
- Can investors see a clear path to a profitable exit?

### **Organization:**

- Does the executive summary grab the reader's interest quickly?
- Is the pitch organized in a way that is easy for the investors to understand and follow?
- Is the layout of the paper logical and clear?

### **Writing:**

- Is writing understandable, succinct, and clear?
- Is the writing free of grammatical and spelling errors?

## Online Resources You May Find Helpful

<https://rockhealth.com/>

<http://femtechfocus.org>

<http://www.mddionline.com/>

<https://digitalhealth.modernhealthcare.com/>

<http://www.fiercemedicaldevices.com/>

<http://www.smartbrief.com/industry/health-care/health-it-news>

<http://medcitynews.com/>

<http://www.advamed.org/>

<http://www.medicaldevices.org/>

[www.fdanews.com/](http://www.fdanews.com/)

<https://www.fda.gov/training-and-continuing-education/cdrh-learn>

<https://www.medicaldevicesgroup.net>



**Guest Speakers**  
- LinkedIn Profiles



November 28<sup>th</sup>  
[Carrie Strozinsky](#)



December 1<sup>st</sup>  
[John Tushar](#)



December 12<sup>th</sup>  
[Perry Genova](#)

Attachment (1)

## **Class-By-Class Detail**

### **Class 1**

Topics:

- Introduction to medical device industry, market size and segments, industry trends

Readings:

- none

Case:

- Heartport, Inc. (HBS 9-600-020)

Study Questions:

1. What do you think of the underlying innovation?
2. What has Heartport done to date? Why?
3. What does the adoption process look like?
4. How should Heartport define success?

### **Case Discussion Dynamics (be prepared to answer questions in class)**

**We are in Heartport's board of directors meeting at the end of September 1999. You have been the new CEO for four weeks. The chairman of the board turns to you and asks the following questions: "As the new CEO what are your top priorities for the next six months? How will your strategy help us regain positive momentum? Why is this the best course of action now?"**

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### **Class 2**

Topics:

- FDA/CE Mark basics
- Reimbursement overview
- Introduction to Digital Health

Readings:

- Can Innovative Value-Based Pricing Models Relieve Pricing Pressure in MedTech Industry, MedTech Strategist, 4.3.19
- Disruption in MedTech: Is the Model Changing? MedTech Strategist, 10.3.16

FDA Video Presentation Links:

- [An Introduction to FDA's Regulation of Medical Devices](#)

Case: none

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### **Class 3**

#### Topics:

- Medical device research and development process, design controls, supply chain management

#### Readings:

- none

#### Case:

- Tryton Medical (A), handed out in class

#### Study Questions:

- none in advance of class
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### **Class 4**

#### Topics:

- Tryton (A) case debrief, entrepreneurship, funding, commercialization hurdles

#### Readings:

- none

#### Case:

- Fred Khosravi and AccessClosure (HBS 9-806-044)

#### Study Questions:

1. What is your assessment of Fred's Khosravi's career and his record as a medical device entrepreneur?
2. What rules or generalizations, if any, about medical device start-ups can you draw from Khosravi's experiences?
3. What is your assessment of the AccessClosure venture? Do you have any criticisms of how the venture has been managed to date?

#### **Case Discussion Dynamics (be prepared to answer questions in class)**

**You are holding a conference call with the partners of your largest venture capital investor wanting an update on the strategic direction of the company. During the conversation the senior partner asks: "What decision have you made regarding the future direction of the company? Will you recommend to sell now, wait one year then sell or build a stand-alone company?" What are the pros and cons of the strategic option you have selected? Why are you confident this is the best course of action?"**

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## **Class 5**

### Topics:

- Orthopedic sector, bundled payments, value-based healthcare, sunshine act, race into robotics

### Readings:

- Surgery 4.0: The Future of Healthcare in a Robotics World: An Interview with Scott Huennekens, MedTech Strategist, 6.13.19
- The Role of Physicians in Device Innovation: Critical Success Factor or Conflict of Interest? Stanford Graduate School of Business, IOT-105, 8.4.11

### Case:

- Zimmer: The Gender-Specific Knee (Kellogg KEL276)

### Study Questions:

1. Is this a good business?
2. How significant are the threats to the industry?
3. How will the gender-specific knee build profits?
4. How will the competitors respond?

### **Case Discussion Dynamics (be prepared to answer questions in class)**

**You are in a senior executive team meeting to discuss the gender-specific knee. The president of the division turns to you and asks: "Should we launch the gender-specific knee? What is your rationale for this recommendation? What are the potential risks with this launch and what steps would you take to minimize the risks?"**

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## **Class 6**

### Topics:

- Reimbursement, healthcare economics, inequalities in HC, FemTech, Women's Health

### Readings:

- FemTech Landscape 2021 Annual Report, FemTechFocus.org & Coyote Ventures, 2021
- The Dawn of the FemTech Revolution, McKinsey & Company, February 2022

### Case:

- Novasys Medical (HBS 9-810-027)

### Study Questions:

1. What are the reasons that female SUI do not undergo surgery for this condition?
2. Why did Novasys have difficulties with their FDA clinical trial submission?
3. Beside reimbursement, what have been other barriers to adoption did the Renessa system face?

### **Case Discussion Dynamics (be prepared to answer questions in class)**

**It is Sunday evening, and you receive a call from the chairman of the board. She said the board and investors are very concerned about your ability to create commercial traction with Renessa. Clearly reimbursement for the procedure has been a challenge. She asks you: “What specific actions are you taking to drive stronger adoption of the product? Why should the board continue to back this strategy?”**

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### **Class 7**

Topics:

- Commercialization, Corporate War Games, Innovation

Readings:

- None

Case:

- Conor Medsystems (HBS 9-804-180)
- Tryton Medical (B), handed out in class

Study Questions:

1. How attractive is the opportunity that Conor MedSystems is pursuing?
2. How well have Litvak and his team done to date in managing the uncertainty inherent in pursuing the coronary stent opportunity?

**Case Discussion Dynamics (be prepared to answer questions in open class)**

**You pick up the phone and its Bob Higgins, a board director and general partner of your largest investor, Highland Capital Partners. He is interested in how the company is going to move forward and what decisions you have been made about funding. He asks: “Frank how much will you raise in this upcoming round and what types of investors are at the top of your list? Besides valuation, what intangible factors are important in your decision-making?”**

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### **Class 8**

Topics:

- **Guest Speaker:** Carrie Strozinsky
- Approach to customers
- Industry opportunities/challenges
- Mid-term exam (9:30 – 10:15 AM)

Readings:

- Distribution of guest speaker pre-read materials will be done before this class starts

Case:

- None

### **Class 9**

Topics:

- **Guest Speaker:** John Tushar, Plasma Surgical Inc.
- Tryton (B) case debrief
- Remote patient monitoring
- Direct to consumer
- Digital health opportunities/challenges

Readings:

- AI Adoption in U.S. Healthcare Won't Come Easy, HBP H07SKX-PDR-ENG
- The MedTech Digital Imperative, MedTech Strategist, 11.10.21
- Distribution of guest speaker pre-read materials will be done before this class starts

Case:

- Iterating The Business Model in a Nascent Market: AliveCor, Stanford Biodesign, 10.21.21

Study Questions:

1. Why were early adopters of medical technologies so excited about the AliveCor product concept when first introduced?
2. How did the company get feedback from the clinical community?
3. Why did the company shift its commercial effort to a Direct-to-Consumer model?
4. What new realities did the company face operating in the consumer wearables space?
5. What are the advantages of moving towards a business services model?

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**Class 10**

Topics:

- Diagnostic accuracy
- Machine learning and AI
- Cloud-based medical devices
- Software as a Medical Device
- Rural vs. Urban Access
- Point-of-Care diagnostics

Readings: None

Case: Corvista Health case handed out in class

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**Class 11**

Topics:

- Global Commercialization
- Strategies for Winning in Emerging Markets

Readings: None

Case:

- Medtronic: Navigating a Shifting Healthcare Landscape (HBS 9-718-471, June 28, 2018)

Study Questions:

1. What did Medtronic management use as broad categories for VBHC projects?
  2. Why was the TYRX Envelope chosen as the initial therapy Optimization project?
  3. Why did Medtronic make an equity investment in NOK?
  4. What are a few barriers to the further expansion of the VBHC strategy?
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## **Class 12**

### Topics:

- Guest Speaker: Perry Genova
- Course summary

### Readings:

- Distribution of guest speaker pre-read materials will be done before this class starts

Case: None