MSQM 718QH: Life Sciences Strategy
Masters in Quantitative Management: Health Analytics

Greg and David are the course faculty

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Greg Davis is an experienced medical device executive and teacher. He is CEO of MedCelerate Consulting Group which assesses international opportunities for device makers. His previous leadership roles include President and CEO of Tryton Medical and President of Guidant Japan. He holds a master's degree in business and an undergraduate degree in engineering. He has taught at Fuqua for more than a decade.

David Ridley is the Faculty Director for the Center for Health Sector Management at the Fuqua School of Business. He is an economist with a focus on the life sciences industry. His research goal is to develop innovative policy and business tools that address pressing health care problems. David was the lead author of two papers that became law. In 2006, he and his colleagues proposed the Food and Drug Administration's priority review voucher program. In 2017, he and his colleagues proposed the Environmental Protection Agency's vector expedited review voucher program.

The course focuses on strategy for devices, biotech, and pharma

We will examine business strategy in the biotech, device, and pharmaceutical industries, with a focus on product development and competition. Life science companies face new challenges and opportunities. Developed markets are experiencing changes in regulatory oversight and reimbursement, including emphasis on value-based reimbursement. Emerging markets are growing rapidly. Patient populations are shrinking as diagnostics become better able to identify which patients respond best to which medicines. Many companies are focusing on rare diseases, moving away from the old blockbuster model.

To succeed, industry professionals need to understand corporate strategy, financing options, product development, innovation management, marketing, reimbursement, and customer

needs. However, health care is different from other industries in important ways, including regulation and reimbursement.

In each virtual class, we will begin with a discussion of a case. Some people in the class will have little background in the life sciences. Please feel free to ask us to clarify unfamiliar terms. Also, for those with less background in the life sciences, the videos and readings will be helpful.

Businesses and foundations active in health care support research by our faculty. This industry interaction can provide helpful insights, but also may be a source of bias. We genuinely hope to encourage vigorous discussion about the life science industry and welcome diverse views.

By the end of the course, students should know how firms

- acquire knowledge and products
- raise capital funds
- commercialize innovative products
- evaluate product safety and efficacy
- use clinical trials to persuade regulators, payers, and providers
- manage intellectual property
- navigate opportunities and challenges of digital health
- justify the value of products
- identify healthcare inequities (race, gender, socio-economic, rural – urban)
- determine price
- market to providers and patients
- shift from blockbuster to niche product strategy
- compete following patent expiration

Grades don't matter much, but here is how they are determined

Executive students generally focus on learning rather than grades, but it is nevertheless important to outline the grading criteria.

- 30% participation
- 30% assignments
- 15% midterm exam
- 25% final exam

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

Please participate in class

Please attend class and participate. We grade on the quality, not the quantity, of class participation. Students who do not attend will not receive participation credit.

Assessments are due before each class

Each session, including the first, will have an assessment on the class web page. Ignore the questions in this case. Past students reported working 3 hours per assessment. The assessments (unlike the exams) have no time limit other than a deadline.

Please read the case and watch the videos to answer the assessment questions. Students may also use other readings and discuss the assessments with other current students. Each student should submit a unique copy in her own voice. We will penalize assignments that are copied from another publication, person, or outputted from a large language model.

Assessments are not accepted after class

Assessments are due 30 minutes before the start of class. Before the deadline, students may resubmit an assessment, but reentering an assessment will mean that all answers must be resubmitted. Before submitting the assessment, consider copying the free entry (not multiple choice) answers to a separate document to reference during class discussion.

Assessments are not accepted after class for any reason, because i) the objective of the assignment is to encourage preparation for class, ii) answers are included in the slides posted on the web page after class, iii) it is generally better to work on future assignments rather than past assignments, and iv) grades rarely matter (if the scores are high enough to pass the course).

There are two exams and each is closed

Exams are based primarily on material in the video lectures, class slides, and readings. Class materials marked “optional” will not be tested. Exams will take less than an hour to complete (adjusted for those with disabilities).

The midterm exam will be asynchronous, like the assignments. However, it will be closed, meaning you should not use external sources. The midterm exam is online and consists partially of multiple-choice questions. The midterm covers content from the first half of the class.

The final exam will be an online synchronous interview with a teaching assistant. The assistant will ask questions, take notes, and record the session. You will sign up on a Google sheet and meet on Zoom, with links provided later. Like the midterm, the final exam is closed, meaning you should not use external sources. Please maintain eye contact with the camera during the exam.

The exam will consist mainly of broad questions about regulation and reimbursement in the life sciences industry, especially biotech and pharmaceuticals. A few questions might involve calculations, such as the probability of technical success or cost effectiveness. The calculations will be simple enough to do in your head, but you may write them on paper. The exam will include 10 questions, each taking about a minute to answer, adjusted for those who require accommodations.

Unit	Theme	Videos	Live Session	Case
1	Introduction to Medical Device Industry	• Introduction to medical device industry • Industry challenges and opportunities • Regulatory pathways		Heartport, Inc.
2	Medical Device Commercialization & Clinical Adoption	• Reimbursement • Research & development • Manufacturing • Fundraising		Novasys Medical
3	Medical Device Shift to Digital Health	• Orthopedic segment • Sunshine Act • Commercialization • Digital Health		AliveCor: Changing Business Model
4	Bio-Pharma Research & Development	• R&D • Make or buy • Incentives • Priority Review Voucher		Vertex Pharma: R&D Portfolio
5	Bio-Pharma Commercialization	• Flow of funds • Medicare • Medicaid • Patient cost sharing • Global reimbursement		Merck: Pricing Gardasil
6	Bio-Pharma Competition	• Forecasting market share • Drug prices • Lifecycle management • Generics & biosimilars		Teva Pharmaceuticals

Deliverables	
Assignments	Due 15 minutes before class

Midterm exam	Due 2.5 days after class 3
Final exam	Schedule with teaching assistant

Unit 1: Introduction to Medical Device Industry

Videos:

- Introduction to medical device industry
- Industry challenges and opportunities
- Regulatory pathways

Case: Heartport, Inc.

Additional Resources:

- Optional: FDA video An Introduction to FDA's Regulation of Medical Devices

Before Class:

- Watch the videos, read the case, and answer the assignment questions. Also think about the following 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?

During 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 of the company what are your top priorities for the Q4 1999? How will your strategy help us regain positive momentum? Why is this the best course of action now?"

Unit 2: Medical Device Commercialization and Clinical Adoption

Videos:

- Reimbursement
- Research & development
- Manufacturing
- Fundraising

Case: Novasys Medical (HBS 9-180-027)

Additional Readings:

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

Before Class:

- Watch the videos, read the case, read the supplemental readings, and answer the assignment questions. Also think about the following 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 other barriers to adoption did the Renessa system face?

During Class:

Case Discussion Dynamics (be prepared to answer questions in open 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?"

Unit 3: Medical Device Shift to Digital Health

Videos:

- Orthopedic segment
- Sunshine Act
- Commercialization
- Digital Health

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

Additional readings:

- The MedTech Digital Imperative, MedTech Strategist, 11.10.21
- Optional: The Role of Physicians in Device Innovation: Critical Success Factor or Conflict of Interest? Stanford Graduate School of Business, IOT-105, 8.4.11

Before Class:

- Watch the videos, read the case, and answer the assignment questions. Also think about the following 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 it commercial effort to a Direct-to-Consumer model?
  4. What new realities did the company face operating in the consumer wearables space? What are the advantages of moving towards a business services model?

Unit 4: Pharmaceutical Research and Development

Videos:

- Research and development
- Make or buy
- Incentives for innovation
- Priority Review Voucher

Case: Vertex Pharmaceuticals: R&D Portfolio Management (A)

Additional Readings:

- Optional: DiMasi et al., "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," Journal of Health Economics, 2016

Before Class:

- Watch the videos, read the case, and answer the assignment questions.

During Class:

- Discuss Vertex strategy:
    - Which 2 candidates should Vertex develop?
    - What should Vertex do with the candidates that it does not develop? Hold or license?
- Listen to update on Vertex

Unit 5: Pharmaceutical Commercialization

Videos:

- Flow of funds
- Medicare drug reimbursement
- Medicaid drug reimbursement
- Patient cost sharing
- Global drug reimbursement
- Cost-effectiveness analysis
- Optional: Drug prices aren't based on development costs

Case: Merck: Pricing Gardasil

Before Class:

- Watch the videos, read the case, and answer the assignment questions.

During Class:

- Discuss vaccine strategy:

    - At a price of $120 per dose, what is the cost of Gardasil per quality-adjusted life year?
    - What factors should Merck consider when setting the price?
    - What launch price should Merck choose for Gardasil in the USA?
    - What launch price should Merck choose for Gardasil in emerging markets?
- Listen to update on vaccine strategy

Unit 6: Pharmaceutical Competition

Videos:

- Forecasting market share
- Drug prices
- Lifecycle management
- Generic drugs and biosimilars

Case: Teva Pharmaceutical Industries, Ltd

Additional Readings:

- Optional: Stern et al., "Biosimilars And Follow-On Products In The United States: Adoption, Prices, And Users."
- Optional: Grabowski et al., "Entry and Competition in Generic Biologics."
- Optional: ParagraphFour.com

Before Class:

- Watch the videos, read the case, and answer the assignment questions.

During Class:

- Discussion: If you were CEO of Teva, where would you focus: U.S. generic drugs, global generic drugs, innovative drugs, or biosimilars?
- Listen to updates on Teva

The following terms might be useful

Term	Abbrev.	Definition
340B		Requires drug discounts for hospitals serving low-income people.
510(k)	510(k)	FDA clearance for devices similar to existing devices.
Abbreviated New Drug Application	ANDA	Application for a generic drug approval.
Accelerated Approval		Conditional approval based on a surrogate endpoint.
Accountable Care Organization	ACO	Network of providers paid per head rather than fee for service.
Active Pharmaceutical Ingredient	API	Substance used in a finished pharmaceutical product.
Affordable Care Act	ACA	Law passed under President Obama expanding health insurance.
Average Sales Price	ASP	The average price of a drug net of most rebates.
Biologic		A medical product derived from living organisms.
Biologics License Application	BLA	Application to FDA for marketing a biologic product.
Biosimilar		Generic biologic.
Black box warning		Warning of serious or life-threatening risks.
Breakthrough status		A program that gives the developer special access to FDA staff.
Buy-and-bill reimbursement		Providers purchase products and are reimbursed by insurers.
Center for Biologics Evaluation and Research	CBER	FDA center overseeing tissues and vaccines.
Center for Devices and Radiological Health	CDRH	FDA center overseeing medical devices.
Center for Drug Evaluation and Research	CDER	FDA center overseeing drugs.
Centers for Disease Control and Prevention	CDC	US agency focused on public health.
Children's Health Insurance Program	CHIP	The government program for children in low-income families.
Class I device		Low-risk medical device.

Class II device		Moderate-risk medical device.
Class III device		High-risk medical device requiring premarket approval.
Contract Manufacturing Organization	CMO	Company that manufactures products for other companies.
Contract Research Organization	CRO	Company providing clinical trials for other companies.
Copayment		Amount paid by a patient with the remainder paid by insurance.
Corporate Integrity Agreement	CIA	Agreement as part of a civil settlement with the Inspector General.
De novo		New but low or moderate-risk device.
European Medicines Agency	EMA	European agency responsible for drug evaluation and supervision.
Fast Track		FDA process to expedite drug development.
Food and Drug Administration	FDA	US agency regulating cosmetics, devices, drugs, food, and tobacco.
Generic		A product intended to be equivalent to a branded product.
Good Manufacturing Practices	GMP	Standards for manufacturing processes.
Health Care Provider	HCP	A person providing medical services.
Health Technology Assessment	HTA	Evaluation of the cost effectiveness of a product or service.
Incremental Cost Effectiveness Ratio	ICER	Added cost per additional health outcome achieved.
Inflation Reduction Act	IRA	US law that created new Medicare price controls.
Institute for Clinical and Economic Review	ICER	Non-profit organization evaluating clinical and economic value.
Intellectual Property	IP	Legal rights protecting inventions.
ISO 13485		International standard for quality management systems.
Medicaid		US health insurance program for low-income people.
Medicare		US health insurance program for seniors and disabled people.
Monoclonal Antibody	mAb	Antibody from cloned cells which is used to neutralize antigens
National Institute for Health and Care Excellence	NICE	Agency that evaluates health technologies for the United Kingdom.
National Institutes of Health	NIH	US agency that funds medical research.
New Chemical Entity	NCE	Newly developed active ingredient in a drug.

New Drug Application	NDA	Application for approval to market a new drug.
New Molecular Entity	NME	Newly approved drug with no prior equivalents.
Orphan drug		Drug for a rare disease.
Over the Counter	OTC	Drugs available without a prescription.
Paragraph IV challenge		Legal challenge stating that a patent is infringed by a generic.
Patent		Exclusive rights granted for an invention.
Pharmacy Benefit Manager	PBM	Manages which drugs are covered and negotiates prices.
Phase I trial		Initial clinical trials assessing safety.
Phase II trial		Clinical trials assessing efficacy and side effects.
Phase III trial		Large-scale trials confirming effectiveness.
Phase IV trial		Post-marketing studies on long-term effects.
Premarket Approval	PMA	FDA clearance for devices different from existing devices.
Prescription	Rx	A doctor's authorization for medication.
Prescription Drug User Fee Act	PDUFA	Law allowing FDA to collect fees from drug manufacturers.
Priority Review		Expedited review for drugs addressing unmet needs.
Priority Review Voucher	PRV	Reward for treatments for neglected and rare diseases.
Risk Evaluation and Mitigation Strategy	REMS	Strategy to manage a drug's risks.
Substantial Equivalence	SE	FDA criterion based on similarity to an existing device.
Vaccines for Children Program	VFC	US program providing vaccines to children.
Warning Letter		FDA notice of regulatory non-compliance.
Wholesale Acquisition Cost	WAC	Manufacturer's list price for a drug.

Please feel free to suggest edits to the glossary with a 60-character limit.