

Introduction to Biomedical Innovation (ENRH 116) – Course Description

Course Directors:

Ann Majewicz Fey, PhD

Student Facilitators:

Galen Gao
Nita Tunga
Brad Bradshaw

Requirements:

Minimum of 10 students
Maximum of 40 students

Mission:

Through the Biomedical Innovation Program, students will acquire the skills and mindset required to accurately assess clinical needs and develop feasible solutions in a team-based environment. Using these skills and the aid of course facilitators, students will tackle real world healthcare challenges.



Course Objectives:

- Think holistically about the current standard of care and how that standard could be improved.
- Identify unmet clinical needs via effective communication with members of the healthcare team and keen understanding of the context of care delivery.
- Use a structured process to evaluate the practical impact of a problem, adverse contributing factors, stakeholders, competing solutions, and economic implications.
- Understand the lifecycle of products in the healthcare industry, including the strategic and operational events from conception through commercialization.
- Lead multidisciplinary teams that bridge the gap between the clinic, research, and business to deliver high quality patient care.

Course Text:

All required reading will be provided to students in class. The following text may be useful as a supplement to course material.

Biodesign: The Process of Innovating Medical Technologies.

Zenios, Makower, Yock. Edition 1. ISBN-10: 0521517427

Free Website: ebiodesign.org

Schedule Summary

BI 2019 Schedule

Class	Instructor	Week Of	Location
Introduction to Biomedical Innovation	Majewicz / facilitators	8/12	D1.102
The Entrepreneurial Perspective	Paul Nichols	8/19	D1.102
Clinical Needs Finding	Gilberto Salazar	8/30	D1.102
Developing Successful Business Ideas & Needs Statements	Paul Nichols	9/3	D1.102
Teams, Teamwork, and Communication	Keith Argenbright	9/9	D1.102
Case Study: Trocar Insertion	Kimberly Kho	9/16	D1.102
Evaluating the Opportunity	Jackie Kimzey	9/23	D1.102
Crucial Conversations and Conflict Management	Keith Argenbright	9/30	D1.102
Competitive Analysis: Implementing Entrepreneurial Product Strategies & Developing a Business Model	Jackie Kimzey	10/7	D1.106
TBD	TBD	10/14	E2.305
Marketing Is Strategy & Essentials of Selling	Paul Nichols	10/21	E2.305
Financial Planning for Fun and Profit	Paul Nichols	10/28	E2.305
Intellectual Property Considerations	Claire Aldridge	11/4	E2.305
Regulatory Considerations for Medical Products	Darold Tippey	11/12	D1.102
Attracting Stakeholders: Financing and Valuing the New Venture & Introduction to Venture Capital & Deal Structure, Deal Terms	Jackie Kimzey	11/18	D1.100

Final Presentation Outline & Pitching Tips	Paul Nichols	11/25	D1.106
Quick Pitch Day	Majewicz / facilitators	12/2	D1.102
Intro to Spring BI & Makerspace 101	Majewicz / facilitators	12/9	D1.102

Schedule and Specific Objectives

Introduction to Biomedical Innovation

Monday, August 12 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Innovation as part of a medical career
- Provide a brief overview of the course goals and expectations
- Describe and define innovation and the common traits of innovators
- Use examples of past projects to explain how needs are discovered and addressed
- Explain the mentor-mentee relationship and shadowing experiences
- Introduce available clinical needs and survey student interest in each

Speakers

- Ann Majewicz Fey, PhD (Course Director & UTD/UTSW Engineering)

Assignments: Students will complete the clinical needs survey online to be placed into teams and receive mentor assignments. Students should also register for the course on D2L.

The Entrepreneurial Perspective

Monday, August 19 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Foundations of entrepreneurship
- The nature and importance of entrepreneurs
- Can entrepreneurship be learned? Myths, Self-Assessment, the entrepreneurial mindset
- Readings: Bhidé, A. 1996. The Questions Every Entrepreneur Must Answer. Harvard Business Review Nov-Dec 1996 (HBR 96603)

Speaker

- Paul Nichols (UT Dallas Institute for Innovation and Entrepreneurship)

Assignments:

- N/A

Clinical Needs Finding

Friday, August 30 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Introduce the fundamentals of needs-finding
- Understand the relationship between an observation, a problem, and a need
- Know the three parts of a need statement: problem, population, and outcome
- Understand that need statements are solution-independent
- Appreciate the importance of unbiased observation and thick descriptions
- Understand the importance of background research before problem-solving

Speaker

- Gilberto Salazar, MD (Emergency Physician and Serial Inventor)

Assignments:

- Student teams will contact their assigned mentor to establish a meeting time within the next two weeks. At this meeting, students should seek additional context to understand the clinical need and gain an appreciation for the currently utilized approaches used by physicians or patients to solve the problem. Students are also encouraged to request shadowing opportunities that help demonstrate and clarify the clinical need.

Developing Successful Business Ideas & Need Statements

Tuesday, September 3 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Creativity and the business idea
- Business models
- Case discussion: FHPWireless (HBS E-222)
- Learn how to write and refine need statements from the problems identified while shadowing
- Confirm that need statements are solution independent
- Practice 'up-scoping and down-scoping' to obtain a need statement that is neither too narrow nor too broad
- Learn research strategies and how to use databases for the purpose of understanding the terminology, technology, physiology, and economics of the need

Speaker

- Paul Nichols (UT Dallas Institute for Innovation and Entrepreneurship)

Assignments:

- Teams should meet to discuss observations from shadowing and develop a needs statement that appropriately describes their assigned clinical need. Each team's need statement must be submitted via email to stanley.bradshaw@utsouthwestern.edu before midnight on October 6th, 2019.

Teams, Teamwork, and Communication

Monday, September 9 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Team Dynamics
- Effective team communication
- DISC assessment: how is it relevant?

Speaker

- Keith Argenbright (Simmons Comprehensive Cancer Center)

Assignments:

- Herzlinger, Regina E. "Why Innovation in Healthcare is So Hard" Harvard Business Review, May 2006.
- Teams should meet to discuss observations from shadowing and develop a needs statement that appropriately describes their assigned clinical need. Each team's need statement must be submitted via email to stanley.bradshaw@utsouthwestern.edu before midnight on October 6th, 2019.

Case Example: Trocar Insertion

Monday, September 16 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Case Study

Speaker

- Kimberly Kho (Obstetrics and Gynecology)

Assignments:

- Teams should meet to discuss observations from shadowing and develop a needs statement that appropriately describes their assigned clinical need. Each team's need statement must be submitted via email to stanley.bradshaw@utsouthwestern.edu before midnight on October 6th, 2019.

Evaluating the Opportunity

Monday, September 23 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Evaluating opportunities
- Conducting feasibility analysis
- Innovation and market acceptance

Speaker

- Jackie Kimzey (UT Dallas Naveen Jindal School of Management)

Assignments:

- The Deep Dive-- IDEO & creativity discussion
- Teams should meet to discuss observations from shadowing and develop a needs statement that appropriately describes their assigned clinical need. Each team's need statement must be submitted via email to stanley.bradshaw@utsouthwestern.edu before midnight on October 6th, 2019.

Teams, Teamwork, and Communication

Monday, September 30, 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Creativity and the business idea

Speaker

- Keith Argenbright (Simmons Comprehensive Cancer Center)

Assignments:

- Teams should meet to discuss observations from shadowing and develop a needs statement that appropriately describes their assigned clinical need. Each team's need statement must be submitted via email to stanley.bradshaw@utsouthwestern.edu before midnight on October 6th, 2019.

Competitive Analysis: Implementing Entrepreneurial Product Strategies & Developing a Business Model

Monday, October 7 2019: 12:00-1:00 PM; D1.106

Learning Objectives

- Competitive forces
- Collecting competitive intelligence
- New entry strategy
- Growth strategies
- Creating a resource bundle

Speaker

- Jackie Kimzey (UT Dallas Naveen Jindal School of Management)

Assignments:

- Case discussion: ZipCar: Refining the Business Model (HBS 9-803-096)

TBD

Monday, October 14 2019: 12:00-1:00 PM; E2.305

Learning Objectives

- TBD

Speaker

- TBD

Marketing Is Strategy & Essentials of Selling

Monday, October 21 2019: 12:00-1:00 PM; E2.305

Learning Objectives

- Great moments in marketing
- Market analysis & competition
- Segmenting the market
- Product positioning
- Sales channels
- Closed Loop Marketing and Sales Process
- Sales Learning Curve in the new Enterprise
- Format and content of presentations
- Psychology of the presentation
- Essential elements

Speaker

- Paul Nichols (UT Dallas Institute for Innovation and Entrepreneurship)

Assignments:

- Readings: Roberts, Michael and Lauren Bartley, How Venture Capitalists Evaluate Potential Venture Opportunities
- Case Discussion: Walnut Venture Associates (A & D) (HBS 9-899-097)

Financial Planning for Fun and Profit

Monday, October 28 2019: 12:00-1:00 PM; E2.305

Learning Objectives

- Sales forecasting
- Budgeting
- Revenue planning
- Income statements
- Burn rates
- Defining the business model
- Integrating the plan into the organization
- Relationship between strategic and operating plans
- Tying performance to plan

Speaker

- Paul Nichols (UT Dallas Institute for Innovation and Entrepreneurship)

Assignments:

- Readings: Roberts, Michael and Lauren Bartley, How Venture Capitalists Evaluate Potential Venture Opportunities
- Case Discussion: Walnut Venture Associates (A & D) (HBS 9-899-097)

Intellectual Property Considerations

Monday, November 4 2019: 12:00-1:00 PM; E2.305

Learning Objectives

- Learn how to protect your ideas at UT Southwestern and at the national level
- Know the definitions of intellectual property and patents
- Become familiar with the different types patents
 - o Utility, design, plant, etc.
- Understand the importance of patenting your ideas
- Understand the requirements of patentability
 - o Utility, novelty, obviousness
- Learn how to conduct a patent search
- Learn the process of filing a patent (with examples)

Speaker

- Claire Aldridge (AVP, Commercialization and Business Development, UTSW)

Assignments

- Teams should conduct a prior art search to explore pre-existing solutions for their clinical need. Assemble a list of the most relevant and informative prior art for your team's solutions so that these resources may be used to anticipate good and bad design approaches in addition to anticipating patentability.

Regulatory Considerations for Medical Products

Monday, November 12 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Understand the various FDA device classifications and anticipate the appropriate classification for your own device
- Develop the skill to estimate useful equivalents at the FDA
- Appreciate the cost and timeline for FDA trials of a medical device

Speaker

- Darold Tippey (Advisor, TMAC)

Attracting Stakeholders: Financing and Valuing the New Venture & Introduction to Venture Capital & Deal Structure, Deal Terms

Monday, November 18 2019: 12:00-1:00 PM; D1.100

Learning Objectives

- Friends, Family, Fools, Angels, VC's.
- Financing the Venture
- Sources of Finance
- Time & types of financing vs. Stage of Venture
- What to expect from a Venture investor
- Networking
- The Do's and Don'ts of fundraising
- Where venture capital "fits",
- Criteria to get venture financing,
- Economic impact of venture capital,
- Concept of milestone funding
- Deals: concepts & terminology
- Valuing the company
- Understanding Term sheets

Speaker

- Jackie Kimzey (UT Dallas Naveen Jindal School of Management)

Assignments:

- Case discussion: Founder-CEO Succession at Wily Technology (HBS 9-805-150)

Final Presentation Outline & Pitching Tips

Monday, November 25 2019: 12:00-1:00 PM; D1.106

Learning Objectives

- Final Presentation Outline
- The Art of Pitching

Speaker

- Paul Nichols (UT Dallas Institute for Innovation and Entrepreneurship)

Assignments

Prepare for Quick Pitch presentations

Quick Pitch Day

Monday, December 2 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Quick Pitch Presentations

Speaker

- Ann Majewicz Fey, PhD (Course Director & UTD/UTSW Engineering)

- Course Facilitators

Intro to Spring BI & Makerspace 101

Monday, December 9 2019: 12:00-1:00 PM; D1.102

Learning Objectives

- Transition from clinician as entrepreneur
- Transition to clinician as project manager, liaison to technical team
- Intro to UTSW Makerspace
- Makerspace safety
- Makerspace access

Speaker

Ann Majewicz Fey, PhD (Course Director & UTD/UTSW Engineering)
Course Facilitators