



## Blue LINC Learning Objectives

Based on the textbook, [Biodesign: The Process of Innovating Medical Technologies](#) by Zenios, Makower, and Yock.

### IDENTIFY

1. Needs finding (Weeks 1-4)
  - a. Strategic focus and team development
    - i. Understand that innovators must choose a strategic focus that aligns with their interests as well as the mission and strengths of the team.
    - ii. Learn the steps involved in choosing a strategic focus.
  - b. Observation and problem identification
    - i. Understand the difference between observations, problems, and needs in the clinical setting.
    - ii. Learn how to utilize observation skills when looking at processes, procedures, and events in order to identify problems that will result in significant clinical needs.
  - c. Needs statement development
    - i. Learn how to translate a problem statement into a clinical need statement by reducing each problem to a simple, causal factor.
    - ii. Understand the importance of targeting a specific outcome in a need statement without being dependent on a specific solution or defining the scope too broadly or too narrowly.
    - iii. Understand the different categories of need statements and how these can impact solution risks and benefits.
2. Needs screening (Weeks 5-6)
  - a. Disease state fundamentals
    - i. Understand the importance of disease state analysis and the fundamental factors to consider.
    - ii. Learn how to effectively search for and summarize this information into a useful format to aid the needs screening process and to establish credibility when speaking to external stakeholders.
  - b. Treatment options
    - i. Appreciate the value of understanding treatment options for a given disease state.
    - ii. Know how to effectively research treatment options and summarize this information into a useful format.
    - iii. Understand how to perform a gap analysis that can lead to the identification of areas for improvement within the treatment landscape.
  - c. Stakeholder analysis
    - i. Learn to identify important stakeholders based on the direct and indirect interactions of all parties involved in financing and delivering care to the patient.
    - ii. Understand how each stakeholder is affected by the medical need and determine their requirements in how the need is addressed.
    - iii. Identify which stakeholders can benefit and which are adversely affected by addressing the need to anticipate any potential conflict.
  - d. Market analysis
    - i. Learn how to perform market segmentation based on various criteria and how to define the market size and competitive dynamics in each market segment.
    - ii. Learn how to analyze how well customers' needs are currently being addressed in each segment and their willingness to pay for alternate solutions.
    - iii. Know how to identify which key market segments to target.
  - e. Needs filtering
    - i. Understand how to develop a needs ranking system for data obtained through observations and research that identifies needs which align with the strategic focus.



- ii. Learn how to outline the criteria a solution must meet to satisfy the highest priority needs.

## **INVENT**

### 3. Concept generation (Weeks 7-10)

- a. Ideation and brainstorming
  - i. Understand the role of ideation in the context of the biomedical/biotech innovation process.
  - ii. Learn the basics of brainstorming and how to plan, organize, and execute a brainstorming session.
  - iii. Be trained in brainstorming approaches and tips specific to biomedical technology innovation
- b. Concept screening
  - i. Understand how to organize the thoughts, ideas, and concepts generated in the brainstorming sessions and subsequently present these in a meaningful way.
  - ii. Learn to objectively analyze and compare solution concepts against the need specification to determine the best concepts to pursue.

### 4. Concept selection (Weeks 1-3)

- a. IP basics
  - i. Understand the different types of patents, including the provisional, utility, and design patents.
  - ii. Recognize the requirements of patentability with respect to existing technologies/patents, including practical aspects of the filing process.
  - iii. Develop familiarity with internet-based patent search databases
  - iv. Learn about the potential for international patent coverage.
  - v. Appreciate issues surrounding inventorship and ownership, especially if the work is performed at the university
- b. Regulatory basics
  - i. Learn about the FDA as an agency, and how and why they operate
  - ii. Understand the FDA medical device classification system
  - iii. Learn about the two main regulatory pathways for medical devices: 510(k) and PMA.
  - iv. Develop a basic understanding of requirements for regulatory approval within and outside of the US.
- c. Reimbursement basics
  - i. Obtain a high-level understanding of the insurance and reimbursement system for medical devices in the United States.
  - ii. Learn how to identify appropriate codes supporting the reimbursement of existing medical devices relevant to a need.
  - iii. Understand the status and process of reimbursement for existing medical devices that address the medical need under consideration.
  - iv. Evaluate differences between US-based private and public payers, as well as international public payers.
- d. Business models
  - i. Develop an understanding of the different types of business models and approaches that are typically utilized in the medical device field, including their relative advantages and disadvantages.
  - ii. Determine how to choose an appropriate business model based on the unique characteristics of the chosen solution and its customers.
- e. Prototyping
  - i. Understand how to approach prototyping and how to evaluate potential pitfalls prior to beginning the prototyping to maximize efficiency



- ii. Become familiar with prototyping tools and techniques and identify which of these would be critical to the chosen solution concept.
- iii. Understand how to use prototyping to create design requirements and analyze the technical feasibility.
- iv. Learn the importance of an iterative approach to building on previous prototypes and transform into increasingly advanced prototypes.
- f. Final concept selection
  - i. Understand how to use the data gathered to this point to effectively evaluate the solution options and select the final solution concept.
  - ii. Recognize how to apply an approach, such as the Pugh method, and develop a concept selections matrix to decide on a final concept

## IMPLEMENTATION

### 5. Development Strategy and Planning Product Environment Strategy (Weeks 4-5)

- a. IP strategy
  - i. Learn the ins and outs of filing provisional and utility patents, including:
    - 1. When to and how to involve a patent attorney
    - 2. How to file international patents
    - 3. Defensive versus offensive IP portfolio strategies
    - 4. Freedom to operate (FTO)
    - 5. Patent litigation
    - 6. Managing patents over time
- b. Research and development strategy
  - i. Learn to define R&D milestones by:
    - 1. Prioritizing certain milestones
    - 2. Recognizing challenges associated with each milestone and developing strategies to address these challenges
- c. Clinical strategy
  - i. Learn to create a clinical strategy for early non-clinical, pre-clinical, and human clinical studies.
  - ii. Learn the goals and processes involved in organizing different types of clinical studies, including human clinical trials.
- d. Regulatory strategy
  - i. Learn when and how to work with the FDA, particularly:
    - 1. Pre-market approval versus 510(K) pathways
    - 2. Developing a global regulatory strategy that can be integrated with the approach to the FDA
    - 3. Recognizing and learning to avoid common regulatory mistakes

### 6. Financial Strategy (Weeks 6-7)

- a. Reimbursement strategy
  - i. Learn how to develop a successful reimbursement strategy for medical devices.
    - 1. Design studies that show the medical benefit of the device, to generate the evidence to support reimbursement.
    - 2. Obtain the necessary codes, coverage determinations, and payment rates for a new technology.
- b. Marketing and stakeholder strategy
  - i. Learn the role that marketing plays in commercializing a new technology.
  - ii. Identify key stakeholders and their attitudes towards a specific need and/or a new solution.
    - 1. Define value propositions that differentiate the product from other solutions.



2. Develop a marketing communication strategy to convey the product's value propositions to stakeholder groups.
  - iii. Develop a company pricing strategy to capture value.
  - c. Sales and distribution strategy
    - i. Learn to develop a company sales and distribution model for reaching customers that is appropriate for a particular offering, either:
      1. An indirect model or a direct model.
  - d. Competitive advantage and business strategy
    - i. Learn to define a competitive advantage and how to develop business strategies that capitalize on this advantage.
7. Integration (Weeks 8-10)
- a. Product launch and implementation strategy
    - i. Combine all assets from Stage 4 (intellectual property, reimbursement model, regulatory model, and business model) with strategies from Stages 5 and 6 (intellectual property strategy, regulatory strategy, reimbursement strategy, and financial strategy) to develop a sustainable competitive business advantage for a successful product launch and implementation.
  - b. Operating plan and financial model
    - i. Develop an operating plan and a financial model (which combines a revenue model and cost projections) to support business planning.
      1. Learn to make appropriate medtech-specific assumptions.
      2. Identify strategic and tactical issues.
    - ii. Learn to perform a proxy company analysis, to improve the operating plan and financial model by comparing with those of a more established, related company.
  - c. Business Plan development
    - i. Learn to develop a business plan to manage the new venture and to communicate with potential investors, partners, and employees.
  - d. Funding sources
    - i. Identify funding sources for innovators.
    - ii. Learn about the valuation models used by investors.
  - e. Licensing and alternative pathways
    - i. Learn about development pathways for a medtech invention that are alternatives to a stand-alone business.
    - ii. Learn the key aspects of partnering, licensing, and sale/acquisition deals.

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