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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