BioDesign: Methods for Innovation in Biomedical Design

Identify, Invent, Implement

Summary
Medical device innovations that would have been considered science fiction a decade ago are already producing new standards of patient care. Innovation leading to lower cost of care, minimally invasive procedures and shorter recovery times is equally important to healthcare business leaders, educators, clinicians, and policy-makers. Innovation is a driver of regional economic development and wealth creation in organizational units ranging in size from the start-up to the Fortune 500 companies. In a broader context, the pace of translational research leading to product and service innovation is highly interdisciplinary, thus, new products and services result from team efforts, marked by a systematic, structured approach to bringing new medical technologies to market and impacting patient care. In this course we examine medical technology innovations in the context of (A) addressing unmet clinical needs, (B) the process of inventing new medical devices and instruments, and (C) subsequent implementation of these advances in patient care. In short, the student learns the process of “identify, invent, implement” in the field of BioDesign.

Course objectives

A. Learning objectives:
   - Learn how to validate medical needs.
   - Understand market assessment and the competitive evaluation of existing technologies.
   - Hone techniques for analyzing and valuing intellectual property.
   - Gain an appreciation of the process for taking a medical device from invention to market.
   - Refine individual oral and written presentation skills as it applies to biomedical.
   - Build basic Prototyping Skills
   - Learn the essentials of writing a business plan.
   - Build critical thinking skills.
   - Work as a team in a simulated “start up” environment.

B. Topics of focus:
   - Clinical needs assessment
   - Research
   - Intellectual property
   - Brainstorming
   - Assessing clinical and market potential
   - Developing patent strategies
   - Prototyping
   - Regulatory and reimbursement strategies
   - Stakeholders and market research
   - Biomedical ethics

Course materials

1. Textbook *Biodesign: The Process of Innovating New Medical Technologies*, Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel.
2. Handouts provided in class and downloaded from Case Western Reserve’s Blackboard.
3. Access to the Internet and an email account you read daily.
Class location and time

Nord Hall, Room 400  
6:00 pm – 9:00 pm, Tuesdays  
January 14, 2014 – April 22, 2014  
Final Presentations Tuesday April 29, 2014 (Reading Day)

SIS Class Number for Spring 2014: 4695

Instructors

As a highly interdisciplinary and applied course of study, BioDesign is team-taught by the instructors listed below, representing experience in medicine, engineering, and business. To draw upon some of the most current thinking and practice, many classes throughout the semester feature special guest speakers.

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In prior semesters, invited guest speakers have been from organizations such as:  
University of Minnesota  
University of Michigan  
University of Cincinnati  
OhioHealth Research & Innovation Institute  
University Hospitals/Case Medical School  
The Cleveland Clinic
Overview and approach

The field of biomedical engineering has experienced phenomenal growth since its inception as formal discipline with Universities a mere 4 decades ago. Indeed, in recognition of the value that the practical application of biomedical knowledge can yield, many regions of the country now strive to excel to become “centers of biomedic innovation” for regional economic development benefit, among other reasons. At the root of successful biomedical innovation are three facets of an ecosystem that are used to frame the current course of study:

- Many - if not a majority of – ideas leading to medical device innovation are derived from issues that arise during the daily activities of a clinician. Whether it is frustration with the use of a specific surgical instrument, processes that interfere with health care delivery, or materials inadequate for intended outcomes, an ecosystem where practicing medical professionals can engage with engineers is a primary precondition for fostering innovation.
- Medicine is a highly interdisciplinary field centered on patient care. Some of the most successful innovations are those with patient care objectives at the forefront of thinking (not research career objectives) based on an interdisciplinary mindset. Pretending does not do the trick; there is no substitute for cutting across organizational boundaries and genuinely embracing teamwork in the problem solution process.
- Despite many myths about innovation and creativity, quite a few processes related to medical device innovation are marked by systematic, structured approaches that can be learned. These are amenable to a University setting as each student can, in fact, acquire and improve the requisite knowledge and critical thinking skills on the subject.

The structure of this course provides each participant a hands-on, first-hand experience with the three principles of innovation described above; more concisely captured in the phrase: “identify, invent, and implement.” We have structured the course as a diverse mix of methods and activities that take place individually and in groups. The tentative outline of classes (see page 6) illustrates that lectures are really only one facet of this course. Since we will strive for (and measure) meaningful student input, so it is recommended you read the assigned chapters (or cases, or articles) before you come to class and spend some time thinking about the material and reflecting on issues with your colleagues. Come as prepared for class as you would if you were going to meet a patient.

In very short order it will be clear this class is not about the abstract presentation of theories, abandoned once the final exam has been completed. Rather, the course begins with an introduction on “unmet clinical needs.” The first assignment is centered on your individual efforts to shape and articulate a medical need through a formalized “needs analysis.” This initial phase of the course is followed almost entirely by team activity. Students are subsequently grouped into project teams (3-4 members/team) to drive forward projects culminating in a “pitch” to venture capitalists and a business plan submission. Throughout the semester it will become increasingly clear that the calendar and agenda (page 6) map very closely the principles outlined above.

We encourage you to develop your own concept map and adapt what we teach to your individual learning style; discuss this and debate with others. Biodesign is a “contact sport” and your ability and willingness to make meaningful contributions are an essential facet of course value. Share your concerns and ideas with the entire class, not just the person sitting next to you. This is your chance to focus on learning a very unique process. Many concepts in BioDesign are learned iteratively, so feel free to ask questions; besides, it will enhance your class participation grade.
Grading: Portfolio of tasks and weights

There is no “curve” for the grade earned under the assumption that each class participant is motivated to seek their “personal best” against a series of tasks and milestones, not competing against each other. Grades are a traditional 90-A / 80-B / 70-C or “Pass”/”Fail” depending on the way you registered for the course (i.e., School of Medicine is often P/F).

In this course, you are not measured by what you get as a grade for, say, the semester project, but rather by what you get out of the course itself. The more effort you give to this course, the more real life learning you will achieve. Essentially, the more you give to this course in terms of effort, participation, thought, and sweat – the more you will professionally benefit – much beyond just a grade.

1. Class Participation and Attendance 10%
   i. Attendance is essential in a course like this since this is a wonderful time to learn interactively, discuss issues with colleagues, check your knowledge of the material, and efficiently focus attention on specific class subject discussions.
   ii. Since class meets only once a week, one (1) unexcused absence will be permitted. Please email conflicts for excused absences in advance. For instance, some School of Medicine students are on “block” schedules that can be accommodated with advance notice.

2. Needs Analysis Assignment (Assignment 1) 15%
   i. All assignments, including the needs analysis, are listed on the course agenda (beginning on page 6) and must be completed on time. Follow the lecture plans carefully as there are several components to the Needs Analysis!
   ii. It is highly recommended that you carefully plan your schedule in the weeks ahead to ensure the presentation is completed on time. The first deadline will arrive quickly!

3. Concept Evaluation Assignments (Assignments 2, 3, & 4) 30%
   i. These assignments are designed to keep the team on track with the project and to think through each stage of BioDesign in a structured format. Assignment 2 will require the teams to present concept maps of their brainstorming sessions and a detailed market analysis of their solution/need. (10%) Assignment 3 addresses the lead concept and a rationale of the analysis that lead to the team selection. A lead IP claim is also expected. (10%) Assignment 4 should present a rudimentary first prototype & expected development pathway. (10%)

4. Peer assessment 10%
   i. Throughout the semester there are a variety of team assignments and activities. Your contribution to the team, commitment to constructive interactions, preparation for group exercises (reflecting knowledge, skills and abilities), emphasis on quality work, and contributions to deliverables will be subject to peer evaluation.
   ii. We will use the CATME system to establish the peer evaluation score. This system is an on-line system that requires you to answer a series of questions. We will have a mid-term peer evaluation to ensure everyone is able to use the CATME system, and to provide feedback so you can take corrective action on team performance prior to the final peer evaluation on Tuesday 22 April 2014, to be used in the final grade computation.

5. Business Plan Summary 35%
   i. The written Business Plan Summary is a key deliverable by each team. A significant demonstration of your competency in BioDesign is the ability to write a professional business plan summary; this will be a group exercise that will follow a prescribed format and timeline, with the deliverable a written report (15%).
   ii. As a “hands-on” course enabling class participants the opportunity to engage in facilitated real-world BioDesign experiences, external industry stakeholders are used to assist in assessment of competencies in biomedical product innovation. On Tuesday 29 April 2104 – in place of a written final exam -- student teams will present their business plan to a panel of venture investors. The panel’s assessment of each project in included in the course grade calculation (20%).
Special notes on laptops, cell-phones, and other mobile electronics

Despite recent changes in FAA policy, there is a “no-cell-phone” policy during class lectures:

a. Devices such as an iPhone or Blackberry should also be turned off.
b. Notes and slides will be available through Blackboard in advance or distributed in class.
c. If there is some special circumstance dictating that you need to be contacted by your cell phone or iPhone during a specific class, please notify the instructor in advance.
   i. We acknowledge that as a graduate level course some clinical participants have unavoidable professional responsibilities (resident on-call, etc.). In these cases we simply ask that, say, a pager be set on “vibrate” mode and that it is only a matter of quietly leaving the classroom if a call comes in.
   ii. The objective is not to impede a participant’s need to respond to professional calls, only that such contact is minimally disruptive to the class.
d. There will be specific sections in the class which will require you to use a computer or laptop to access information for research on your project and for moving it forward. In such cases, be prepared to have your computer ready for use.
e. However, an open laptop will not be tolerated during any other circumstance.
f. The Instructor will not “beg” or “pester” you to “please turn off all devices”; you will simply receive a zero for attendance for that class.

Ethics

Our student academic integrity policy has many of the elements you would expect from any high-quality educational institution. Case Western Reserve University has a well defined policy on violations of academic integrity (see: www.case.edu/gradstudies/downloads/AcadInteg.pdf and the website http://www.case.edu/gradstudies/current/policies.html). For your convenience, the following abstract represents select items cut-and-paste from various parts of University policy:

“If an instructor suspects a violation in the form of cheating, plagiarism, misrepresentation or obstruction, this is what must happen:
   o The instructor must confront the violator(s) with the suspicion, including the evidence and the report describing the violation.
   o At the end of this meeting, unless the instructor is convinced that no violation occurred, whether or not the student agrees that a violation occurred, both sign the report and it is submitted to the Office of Graduate Student Affairs.”

“If the violator(s) agrees that the violation occurred, the student checks the box so indicating, and signs the report. The instructor decides whether to impose a sanction or pass the case along to the academic integrity board. The minimum sanction the instructor may impose is failure in the work (NOT reduced credit). The maximum the instructor may impose is failure in the course. If this range doesn't seem appropriate, then the case should be referred to the academic integrity board with explanation.”

“If the student doesn't agree that a violation occurred, or if the student doesn't agree that the instructor's sanction is appropriate, then he/she checks the appropriate box so indicating, signs the report, and the case goes to the academic integrity board. The report with supporting evidence and explanation goes to the Office of Student Affairs and they schedule a hearing with the student.”

“It merits emphasis that the report should always be submitted, even if the instructor is the one to impose the sanction and no AI hearing is required. Otherwise a student could commit multiple violations and be treated by each compassionate instructor as a first-time offender. Policy for subsequent violations are different, and not in the hands of instructors.”
### Overview of Agenda and 2014 Calendar

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<td><strong>Needs Validation</strong></td>
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<td>S3. 28-January</td>
<td>Needs Screening: Validation</td>
<td>A3. One-Page Prelim Brief</td>
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<td>BioDesign Video link: Todd Brinton Lecture</td>
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<td>S5. 11-February</td>
<td>Concept Generation: Brainstorming and Prototyping Basics</td>
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<td>Intellectual Property Strategy</td>
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<td>Concept Selection with focus on Market Analysis</td>
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<td>Development Strategy and IP Claims Workshop</td>
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<td>Chapter 5, Section 5.3, pp.425-457.</td>
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<td>Fundamentals of Reimbursement</td>
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<td><strong>Concept Implementation</strong></td>
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<td>Course Review and Student Presentations to Investors</td>
<td>T6. Summary presentation</td>
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Assignment Due Dates to Remember

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<th>Assignment due date and session</th>
<th>Brief description (see session abstracts for more information)</th>
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<tr>
<td>A1 6:00 pm Tue 14 January</td>
<td>S1 Email in advance a Short Biography about yourself to share in during Session 1</td>
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<td>A2 9:00 pm Tue 21 January</td>
<td>S2 Before leaving class, Session 2, provide your Needs Topic List (top 3 choices)</td>
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<td>A3 6:00 pm Tue 28 January</td>
<td>S3 Present in class a one-page Preliminary Needs Briefing (with 2 questions)</td>
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<td>A4 6:00 pm Tue 4 February</td>
<td>S4 Present in class your Final “Needs” Briefing w/ your interest to team on topic</td>
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<tr>
<td>T1 6:00 pm Tue 18 February</td>
<td>S6 In-class presentation of Team “Needs Briefing” including clinical validation</td>
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<td>T2 6:00 pm Tue 4 March</td>
<td>S8 Team write-up for open discussion on concept selection and Market Analysis</td>
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<td>T3 6:00 pm Tue 25 March</td>
<td>S10 Team write-up for open discussion on Regulatory Issues</td>
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<td>T4 8:00 pm Tue 8 April</td>
<td>S12 Team workbook and preparation for open discussion on Project ProForma</td>
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<td>T5 6:00 pm Tue 15 April</td>
<td>S13 Team write-up for open discussion on Invention Disclosures</td>
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<td>-- 6:00 pm Tue 22 April</td>
<td>S14 Faculty coaching on final team presentations</td>
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<td>T6 4:00 pm Tue 29 April</td>
<td>S15 Team Summary Presentations to biomedical investment panel</td>
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Session 1 - Needs Identification

Executive Summary
For some technologists, the thrill of solving complex problems often transcends the importance or proper definition of the problem. Investors frequently encounter this situation -- there are a myriad of medical problems, but not all of them significant or of such a priority that a statement of need can be crafted. Absent a proper needs statement it is unlikely the subsequent problem solution has a compelling basis that will command the attention of key stakeholders (investors and clinicians alike!) in the health care ecosystem. The central theme of today’s class session is to understand the basic principles underlying the basic principles and practice of problem identification. This centers around technique (and preparation) for clinical observations, the ability to subsequently differentiate between problems and needs, and finally the (acquired) skills to articulate a problem amenable to methods for innovation in medical product design.

Learning Objectives

After reading and discussion sessions, the student should be able to:

- Understand the general framework of BioDesign as a structured course of study
- Articulate at least 3 important elements of BioDesign principles (identify, invent, implement) and why they matter.
- Recognize the 6 steps of the process for performing observations and identifying problems.
- Describe the difference – and reasoning for – needs analysis preceding the needs specification.
- Differentiate between observations, problems, and needs
- Understand key stakeholder perspectives and the impact on needs analysis.
- Identify the types of problems that often result in development of clinical needs

Links to Explore

Stanford BioDesign website

Assignments

- Assignment 1: Pre-Work for the first class! Submit a 1-paragraph biography (include a picture, please), and a one-paragraph summary of your learning objectives for this course. Note special due date: This is due in advance of Session 1 and must be submitted through Blackboard no later than 11:59 pm Monday January 13th so that a class profile can be compiled to hand out during Session 1.

Preparatory Reading

BioDesign Textbook: Chapter 1; Sections 1.1 and 1.2, pp.3-36
Session 2 - Needs Identification

Executive Summary
This class Session we take the discussion of observations and observed clinical problems to the next logical step: the development of a statement of need. While several aspects of today’s discussion may overlap previous topics, there is now a greater action orientation. That is, it is one thing to observe and quite another to translate the observations into a written statement. Although the novice might view this process as “a lot of guesswork” a sign of student success in comprehension is the understanding of what it is that makes a need statement too narrow, too broad, or self-limiting in form. Anticipating the in-class exercise to draft a needs statement, there is no question that reading Section 1.3 in advance will be critical to getting the most out of today’s session. In particular, the Case Study on Northwestern (p.43) along with the figure illustrating the “cascade of needs” (Figure 1.3.4 on page 46) should be thoroughly explored prior to the start of class. This will prepare you for the presentation you will need to make for Session 3.

Learning Objectives
After reading, discussion, and interactive class sessions, the student should be able to:
- Understand the clinical basics of peripheral artery disease to act as a background for the needs that are assigned to the teams
- Understand the major pitfalls associated with poorly developed need statement
  - Implicitly embedded solutions (“how” versus “what”)
  - Impact of constraints (needs that are too broad or too narrow).
- Describe the underlying process for translating an observed problem into a clinical need
  - Steps to shaping a needs statement
  - Outcomes and their role in the needs statement
- Outline the different types of needs and the relation to product “risk vs benefit”
  - Incremental need zone
  - Mixed need zone / “Blue-sky” need zone

Link to Explore
Johns Hopkins University BioDesign website (focus on global health)

Assignments
- Assignment 2: Select and submit prior to the end of today’s class session your “top-three” Needs Statements from the list that is distributed in class. Your preferences will be reviewed and subsequently a Need assigned to you by 5:00 pm Thursday January 23rd. Every effort will be made to match you with at least one of the Needs Statements of your choice (but no guarantees).
- Assignment 3: Before the next class, prepare a 1-slide presentation of your assigned need (from today, Session 2). You will provide a refined needs statement and two (2) clinician questions. Due date: Please make every effort to submit through Blackboard no later than 10:00 pm Monday January 27th so that these can be compiled and reviewed by faculty in advance of class on Tuesday January 28th.

Preparatory Reading
Biodesign Textbook: Chapter 1, Section 1.3, pp.37-55
Session 3 - Needs screening: Validation

Executive Summary
Once a need is identified and Needs Statement has drafted, it is essential to go through the Validation process. This step can be viewed as an “insurance policy” for the relevance for the need you will subsequently proceed to find a solution. In the zeal to work on and solve problems, the innovator may want to rush through the validation step, but this phase of “evidence based” inquiry is quite critical. Every word in the needs statement must be examined. Is every word necessary? Do certain words unnecessarily restrict or broaden the problem? Is language used that imbeds a solution? Accompanying this process is the need to gain multiple perspectives on the need; have you spoken with a variety of people who might face the same need but whose perspectives differ? How does a nurse see the need? And how does that compare with a patient’s view? The subject of “Validation” is best experienced first-hand (versus lectured about) so Session 3 features facilitated student activity to exercise and underscore key learning objectives.

Learning Objectives

After reading, discussion, and interactive class activity, the student should be able to:

- Identify pitfalls with poorly developed need statement
  - Assess if statements are too broad or too narrow
  - Assess if solutions are imbedded (“how” versus “what”)
- Demonstrate competency in translating and observed problem into a clinical need
  - Know the basic steps to shaping a needs statement
- Be able to prepare questions to assist in the validation process
  - Formulate multiple perspectives on the needs statement
  - Know the key stakeholders to communicate with

Link to Explore
Todd Brinton video on needs finding and validation


Assignments

- Assignment 3, due for class today: Present the refinement of the 1-slide needs statement with two questions for today’s guest clinicians; this assignment was discussed in Session 2. This is the same single slide you were asked to submit though Blackboard by 10:00pm Monday 27 January
- Heads-up! Assignment 4, due next class: Feedback from today’s Session should help you refine your development of the Needs analysis presentation. The presentation will be at our next class, Session 4, Tuesday 4 February and a copy of your final slides should be posted and are due right before class on Blackboard no later than 5:00 pm 4 February. The presentation is to be posted on Blackboard even if you will be using your laptop to present. Please see the Grading portfolio and weighting (page 4 of this syllabus) for more information.

Preparatory Video

BioDesign Link: Video (link above) is almost 2 hours in length!
Session 4 - Needs analysis:
Individual Summary presentations

Executive Summary

In this class Session we take let the class participants take the lead on the discussion of observations, problems, observed clinical issues, etc. that form the basis for class presentations on the Needs assigned in Session 3.

Presentations: Assignment 4

- **Due today via Blackboard before 5.00pm EST**: A powerpoint presentation of your “Needs Analysis”. This is worth 15% of your grading. Your ability to answer questions regarding your depth of knowledge about the need is critical in the grading process.
- **In class today**: During the class networking session, the goal is for tentative teams to be formed around common interest in a Needs statement. Within 2 days, a “communications coordinator” for each team should be identified, and that person will provide through Blackboard a summary of the team membership and the Need being addressed.
Session 5 - Concept generation: Brainstorming

Executive Summary

Often people will state that “I’m really not good at idea generation since I don’t have much creative genius” which perpetuates several unfortunate myths about the creative process. Today is not about the “ah ha” moment; and actually, idea creation (or “ideation”) will be shown to involve a number of skills the typical person can acquire. Very little actually happens “by accident” and in this Session we focus primarily on the brainstorming technique. Yes, many people have heard of this, but the context of medical technology puts a slightly different spin on the process. In particular,

a. A multidisciplinary team effort is required
b. Idea generation must be distinct from implementation probability
c. A systems approach is essential (regulatory, reimbursement, medical protocol, etc.)
d. The Needs Specification is crucial.

Indeed, the ideation process is iterative – particularly if some team members are new to the process – and any deficiencies in the Needs Statement (too broad, too narrow) will be obvious quite quickly. Ideation is a critical path and the gateway to product concept generation. If past BioDesign class experiences remain true, today’s hands-on session will not only be exceptionally productive session, but a great time for Team members to get to know each other better.

Learning Objectives

After reading and today’s brainstorming class activity, the student should be able to (taken directly from Biodesign, pages 176):

- Understand the role of ideation in the context of the biodesign innovation process
- Learn the basic methods of brainstorming and how to plan and execute a session
- Consider special approaches to brainstorming specific to biotechnology invention

Link to Explore

Wikipedia is useful in this case (still, peer review absent)

This, not exactly from Harvard, but interesting ideas:

Assignments

Nothing due for this session, but keep in mind the need to complete your first team assignment, T1

- Assignment T1, due next class, Session 6: In-class presentation of Team “Needs Briefing” including clinical validation

Preparatory Reading

Biodesign Textbook: Chapter 3, Section 3.1, pp.176-192
Review and understand highlights of Session 3.1 (p.193)
Prototyping Chapter 4, Section 4.5, pp.340-366
Session 6 - Concept selection: Intellectual property considerations

Executive Summary
Intellectual property (IP) is of fundamental importance if the innovation team wishes to secure capital and returns on the work to conceptualize and create a product. Of course, IP is not required – particularly if the effort being undertaken is for the so-called “greater good” – but for the majority of medical products you really can’t attract interest or attention to your ideas if there is not even the hope of IP protection. Central to securing one form of IP, a patent, are the claims of a patent – these are of central interest as they are the basis for your (temporary) monopoly over the product market. Today’s session therefore is highly focused on (A) IP strategy and (B) development of specific student skill in understanding how to create and critique Patent claims. In the past the interactive exercise has been of most benefit to students who have completed the assigned reading and we have populated this Outline with several reminders to ensure and encourage your advance preparatory effort.

Learning Objectives

After reading and today’s lectures, the student should be able to (taken directly from Biodesign, page 210):

- Understand the different types of patents, including the basic elements of provision and utility patents
- Recognize the requirements of patentability, including practical aspects of the filing process for medical devices.
- Develop familiarity with the patent search process
- Understand the fundamentals of international patent coverage

Link to Explore … we mean, really, explore these before class

You just have to jump on this extraordinarily important website
- http://www.uspto.gov
World intellectual property organization
- http://www.wipo.int/portal/index.html.en
Justia – Advancing the availability of legal resources for the benefit of society.
- http://www.justia.com/

Preparatory Reading

Biodesign Textbook: Chapter 4, Section 4.1, pp.210-271
A very long section, but is essential to read in advance so that the lecture sessions do not have to resort to being redundant tutorials – it is essential we be prepared to discuss the strategic aspects of claims development.

Assignments

Assignment T1, due in class today: In-class presentation of Team “Needs Briefing” including clinical validation
Session 7 - Concept generation: Concept screening

Executive Summary
At this point in the semester (we are 40% through the course already!) it should be evident the Needs Specification – the subject of the first 16% of class discussion – plays a central and unique role in BioDesign. The process of ideation to generate ideas is as disciplined a process as the (again, acquired) skill of screening and selection of concepts. Indeed the time invested by the innovator to methodically “downselect” ideas is not a wasted effort (no, it is not usually “obvious” the “right” answer), and, in fact results in the improved efficiency in due diligence of the few concepts. However, the unique aspect of BioDesign is that the Needs Specification is the backdrop and centerpiece of an efficient concept screening activity. The transition from ideation to screening involves three major steps:

- Principles of grouping and organizing ideas
- Formalized methods for organizing or “clustering” ideas (sometimes with software), and
- Mapping the clusters relative to the need.

All of this, then leads to a visual method for understanding if solution “clusters” are mapped to the need, or when visual gaps arise there become areas where further brainstorming may be needed. Today’s session will hopefully include a hands-on concept mapping session, but this may require additional work with faculty engaged outside the time allotted for today (Session 6).

Learning Objectives
After reading (well, we hope you read), discussion, and today’s demonstrations, the student should be able to:

- Understand this phase of the ideation process in the context as a structured methodology for filtering ideas that have emerged from the brainstorming session.
- Understand and have the ability to organize the output from a brainstorming session.
- Know the strategies (Table 3.2.1) and resources available to assist in concept mapping
- Specific emphasis on tools for concept mapping
- Summarize the relationships between concept mapping, concept screening, and concept selection.
- Recite at least three of the main benefits to rapid prototyping

Link to Explore
IHMC CMAP Tools
- http://cmap.ihmc.us/conceptmap.html
A survey of concept mapping
- http://datalab.cs.pdx.edu/sidewalk/pub/survey.of.concept.maps/

Assignments
- Heads-up! Assignment T2 due next week 11:59pm Monday 3 February 2014, to be submitted via Blackboard is a briefing document outlining the team Market Analysis.

Preparatory Reading for Today
Biodesign Textbook: Concept Screening: Chapter 3, Section 3.2, pp.193-204
Session 8 - Concept selection: Regulatory basics

Executive Summary
Those new to medical device design might be inclined to seek or emphasize product material selections that are “cost-effective.” While consideration of cost might make for a competitive product from the perspective of the manufacturer, this overlooks the role and value of regulatory agencies in the medical product development and launch process. It is often underappreciated the creation and subsequent growth in the regulatory power of the FDA throughout its brief history has frequently been a direct result of individuals harmed by mislabeled, untested, adulterated, or toxic products that were well-marketed, not well-tested – in this regard the FDA can be credited for “…help[ing] pull medicine into the modern era” (Hamburg 2010). Anticipating that most medical devices need to be cleared or approved by the FDA prior to being marketed for sale in the US, the advantages of low-cost materials are irrelevant if the device cannot be presented to the marketplace due to failed regulatory compliance. Today’s Session explores the context of FDA regulation from several perspectives since it was the unanticipated consequences of new technology – and the way the technology was brought to market -- that spurred the medical device regulatory framework as we have it today. Though the lectures and Session discussions it will emerge that regulatory concerns should not be marginalized as something the innovator “has to do,” but rather an important stakeholder throughout the innovation process.

Learning Objectives
After reading and today’s workshop activity, the student should be able to (taken directly from Biodesign, page 458):

- Understand the strategic risks and opportunities associated with the PMA and 510(K) pathways.
- Appreciate how and when to communicate with the FDA
- Consider how a global regulatory strategy can be integrated with the approach to the FDA.
- Recognize common regulatory mistakes and learn how to avoid them through the creation and implementation of a strong regulatory strategy.
- The steps in product development
- Design Freeze, design reviews, Verification and Validation, bench and preclinical testing requirements

A Very Important Link to Explore
US Food and Drug Administration Home Page

- http://www.fda.gov

InterCenter Tissue Engineering Working Group and the Tissue Engineering Initiative


Assignments
- Assignment T2 due last night 11:59pm Monday 3 February 2014, via Blackboard
  - Concept Maps and Market analysis on your brainstormed concepts

Preparatory Reading
Biodesign Textbook: Chapter 5, Section 5.4, pp.458-472
Session 9 - Concept selection: Development Strategy and Claims Workshop

Executive Summary

The FDA Approval process is under a lot of scrutiny by the agency itself and each product recall brings with it the question about additional data before any product is approved. The development process for any medical device includes careful bench validation, proof of concept both in preclinical as well as human subjects. Clinical trails are studies conducted using human participants by researchers in government labs, medical schools, or by pharmaceutical or medical manufacturers, to test how well a new drug, medical device, diagnostic tool, therapy, treatment or form of prevention works to improve health, cure disease, or improve quality of life. The goal is to test efficacy and safety. Students need to appreciate the complexities in planning, designing and executing a project from initial proof of concept to clinical trial and the implications of success or failure at each step. Building off previous lectures on intellectual property this lecture aims to involve the students in a process of developing lead claims on their lead concept. Guided by Case Tech Transfer personnel, this session is always engaging, immensely beneficial in its content and activity and fun at the same time.

Learning Objectives

After reading and today’s workshop activity, the student should be able to:

- Understand different types of clinical trials
- Understand the implications of clinical strategies in medical device development
- Be able to assess the most likely clinical strategy for their project

…. and as a direct result of class activities…

- Synthesize information from the readings and lectures to enable patent claims to be written.
- Critique patent claims for critical (and common) deficiencies
- Articulate a variety of stakeholder perspectives related to patent litigation strategies

Assignments

No written or oral reports due today …

- BUT, plan on Assignment T3 due next week 11:59 pm Monday 24 February 2014, to be submitted via Blackboard is a briefing document outlining the team consensus on Regulatory Issues. The document is needed in advance so it can be printed and distributed in class to facilitate the open discussion on this topic.

Preparatory Reading

Biodesign Textbook: Chapter 5, Section 5.3, pp.425-457
Session 10 - Concept selection: Reimbursement

Executive Summary

Creating a reimbursement strategy is challenging and complex. If no-one pays for your innovation, no one will fund it to begin with! Most companies and entrepreneurs will benefit from hiring the services of a reimbursement consultant. However, this lecture will enable entrepreneurs to assess and understand the field of innovation they are playing in, current coverages, gaps and opportunities.

Learning Objectives

After reading and today’s workshop activity, the student should be able to:

- Recognize that regulatory approval does not guarantee reimbursement
- Identify key players and payers!
- Know how to develop a reimbursement strategy
- Understand the steps involved in understanding an appropriate coverage determination

Assignments

Last night, you should have posted Assignment T3 due 11:59 pm Monday 24 February 2014, to be submitted via Blackboard; this is the briefing document outlining the team consensus on Regulatory Issues. The document is needed in advance so it can be printed and distributed in class today to facilitate the open discussion on this topic.

Assignment T3 counts for 10% of the grade. Your ability to provide detailed answers and rationale to your choices will impact the assessment of the teams decision-making process.

Preparatory Reading

Biodesign Textbook: Chapter 5, Section 5.6, pp.503-535
Session 11 - Concept Implementation: Financial Models and Operating Plan

Learning Objectives

After reading and today’s workshop activity, the student should be able to:

- Understand the process for developing an operating plan and cost projections
- Create a revenue model
- Identify key issues that should be reflected in the financial model
- Proforma proxy company analysis

Assignments

- Due next class (Session 12): Assignment T4 worth 10% of the grade, is an updated proforma to discuss in class, working with the faculty and your class colleagues in an open forum.
- So, nothing due today but also consider steps on the journey to preparing a draft form of your team’s invention disclosure, to be discussed as part of Session 13 on Tuesday 15 April.
- Start writing your business plan summary (due Friday 3 May!). The deadline is going to suddenly creep up on you!

Preparatory Reading

Biodesign Textbook: Chapter 6, Section 6.1, pp.612 - 656
Session 12 - Concept Implementation: Funding and the Business Planning

Learning Objectives
After reading and today’s workshop activity, the student should be able to:

- Identify different sources of funding
- Understand criteria of evaluation used by investors
- Learning simple valuation models used by investors
- Understand term sheets

Assignments

- Due today: Assignment T4 - Draft proforma on your team project due today to discuss in class in an open forum.
- So, nothing else due today but keep in mind and consider the steps on the journey to preparing a draft form of your team’s invention disclosure, to be discussed as part of Session 13 on Tuesday 15 April.
- Keep up with drafting parts of your business plan summary (due Friday 3 May!). The deadline is going to suddenly creep up on you!

Preparatory Reading
Biodesign Textbook: Chapter 6, Section 6.2 & 6.3, pp.657 - 707
Session 13 - Concept Implementation: Marketing and exit Strategies

Learning Objectives

After reading and today’s workshop activity, the student should be able to:

- Understand basic functions of marketing as they relate to commercialization of medical technologies
- Understand importance of understanding and evaluating attitudes and perceptions of key stakeholders
- Know how to define and assign a price to key value propositions

Assignments

- Bring to class today your draft due today, Session 13, Assignment T5, the briefing document outlining the team consensus on Inventions Disclosures and related intellectual property issues. If possible, send the document in advance so it can be printed and distributed in class.
  - As a back-up plan, bring the proforma for your team as we might continue working on it for another session with the faculty during the “third hour” of our class. Bring key questions as you reach closure on this topic.

- Next Class- Session 14 (Tuesday 22 April): We will walk through a dry-run of each of your presentations
  - You shall be presenting a final VC pitch to the faculty the week Tuesday 22 April. This shall serve as a practice session before you present to the actual VC panel during Session 15 on Tuesday 29 April. Your presentation will be thoroughly grilled by faculty and constructive and key advice shall be given to you by the faculty to make your final presentation as solid as possible. *Don’t personalize the feedback, understand the intent!*  
  - The business plan is due in about two weeks on Friday 3 May. You better start writing it if you already haven’t! The deadline is going to suddenly creep up on you!

Preparatory Reading

Biodesign Textbook: Chapter 5, Section 5.7 -65.8, pp.536-579
Session 14 - Concept Implementation: Coaching

Learning Objectives

After today’s workshop and mock presentation activity, the student should be able to:

- Understand components of a provisional patent and ways to make it stronger
- Understand how to make a VC pitch and receive critical feedback on missing elements

Assignments

- Due Today:
  
  - You shall be presenting a final VC pitch to the faculty today. Time limit is 20 mins + 15 min of Q&A. This shall serve as a practice session before you present to the actual VC panel during Session 15 Tuesday 29 April. You shall not be graded on today’s performance – so don’t worry about it. What you should do though is take the critique and shore up your strategy and presentation and strengthen the weak spots. You will also get some practice of what entrepreneurs go through in real life and “it ain’t pretty.”

  - The business plan is due very shortly. Bring any questions you may have to the class. The faculty are glad to help guide you.
Session 15 - Concept Implementation: Making the Pitch

Learning Objectives

After today's presentation activity, the student should:

- Have made their first real life VC pitch

Assignments

- Due Today:
  - You shall be presenting a final VC pitch to an external VC panel today. Time limit is 20 mins + 10 min of Q&A. You shall not be graded by the panelists but by the faculty. The grading of your presentation will be based on what has been taught in class and the progress that is achieved by your teams.
  - The business plan is due Friday 3 May. Please submit it using blackboard by 5.00pm today.