1. Course Objectives

This course provides ideation tools and methods utilized by the medical device industry at the “fuzzy front end” of new product development. The course focuses on discovering and documenting clinical needs through structured observation techniques. Student teams will use these techniques in a classroom setting to (1) develop and document clear statements of clinical needs and requirements, (2) apply innovation tools used in the industry to develop and document technology-based solutions.

Clinical faculty will be invited to discuss potential projects with students, who will then have an opportunity to observe in the clinic and apply new skills to real-world problems. Students will have the opportunity to work in teams with a “clinical mentor” on a project requiring the application of novel technology.

To achieve these objectives, the course will employ a combination of lectures and “hands-on” exercises using the tools and methods. The class will be divided into teams to encourage a manageable “learn by doing” environment, similar to project teams normally found in industry.

Topics include:

- Design thinking concepts and practical techniques
- Methods for “needs finding” and identifying and clarifying problems
- Ethnographic research, “voice of the customer” and stakeholder identification
- Group brainstorming and concept generation methods
- Prototyping and simulation for developing solutions
- Concept affinitization techniques
- Morphological analysis (traversing a complex design space)
- Human factors considerations in medical products
- Managing innovation in the medical device industry
- Business considerations in medical products (market analysis, financial assessment, entrepreneurship)
- Issues in product development (IP, regulatory & reimbursement issues)

The course will be of interest to students planning careers in the medical device new products industry in a technical or managerial capacity. The course will also be of interest to industry practitioners who wish to enhance their skills in medical product concept generation, requirements definition, and the business aspects of new products for the clinical environment. In addition, the course should be of interest PhD students or researchers who wish to understand the needs of clinical practitioners, medical
industry stakeholders, and others involved in the design, manufacture, and commercialization of medical products.

2. Course Materials

The course will be taught by members of the Bioengineering faculty with the assistance of medical product industry professionals and clinicians from the University of Pittsburgh School of Health Sciences and UPMC. Slides and other materials will be available primarily on Courseweb (http://courseweb.pitt.edu). The texts for the course are “BIODESIGN, The Process of Innovating Medical Technologies” (2nd edition, by Yock, Zenios and Makower, Cambridge University Press) and “The IDEO Field Guide to Human-Centered Design”. The Biodesign book can be ordered online through Amazon or through the Campus Bookstore. It can also be ordered as an e-book for use with an electronic reader (see www.ebiodesign.org). Two copies have been put on reserve in the Engineering Library in Benedum Hall as reference books. For those who prefer not to own this valuable text, the first edition can be accessed online for free through the University of Pittsburgh Library System (PittCat). We have also placed a copy on the BOX, assuming that you will download it only for your personal use during the course. We are permitting students to use the first edition as a text, but the second edition has many new examples, case studies, and up to date reference materials that will enhance the educational experience.

Most of the work assignments will be posted via Courseweb or email. Piazza is also built in to Courseweb and will be used for communications between instructors, student teams, and individual students. Most of the lectures, homework assignments and results, reference materials will be posted on Courseweb. There will also be a DROPBOX for the course, which will require you to respond to an “invitation” in order to access. Your team will have a separate partition on the course DROPBOX for you to post homework assignments. Everyone will have access to the postings of all the teams. We have done this to encourage the sharing of best examples and to promote learning among all teams. There will also keep a shared folder on www.BOX.com for the posting of certain large documents and video files.

3. Course Admission

The course is open to qualified graduate students in the Swanson School of Engineering, Schools of Health Sciences, Katz Graduate School of Business, and the School of Law. Admission is competitive and must be secured with “permission of instructor”. Senior level undergraduates may also be considered for admission.

4. Grading and Evaluation

Individual and team performance will both be considered in the grade for the course as evaluated by the instructor, lecturers, clinical mentors, and other advisors provided by the CMI (Center for Medical Innovation). 60% of the grade will depend on the quality and content of the clinical class project. There will also be reflective exercises throughout the course, intended to demonstrate integration of learning. The latter may be in the form of presentations, papers, or group discussions, which will count as 20% of
your grade. The remaining 20% will be based on individual participation, contributions to discussions and feedback from classmates and instructors.

5. Academic Integrity:

It is the ethical responsibility of students to identify the original sources of work submitted. More information at: http://www.cfo.pitt.edu/policies/policy/02/02-03-02.html

6. Special Note on Declared Disability

If you have a declared disability for which you are or may be requesting an accommodation, you are encouraged to contact both your instructor and Disability Resources and Services, 216 William Pitt Union at 412-648-7890 or 412-383-7355 (TTY) as early as possible in the term. DRS will verify your disability and determine reasonable accommodations for this course. A comprehensive description of DRS services can be obtained at www.drs.pitt.edu
Week 1

SUBJECT AREAS: INTRODUCTIONS, ORIENTATION

- Introductions and overview of Medical Product Ideation course. (content, grading, expectations, team structure)
- Discussion of potential clinical projects.
- Office of Technology Management presentation on University treatment of Intellectual Property (IP).
- Hands-on introduction to design thinking concepts: “Re-inventing the Name Tag” workshop.

We will instruct how to complete the CATME “team maker” survey. We have been using this software tool to set up teams of 4 to 5 students based on interests, calendar availability for meetings, and other factors such as problem solving style and other personality factors. After the CATME software provides an optimal team selection, we will announce the team membership. We hope to do so by Week.

Students will require permission to move from one team to another if they can make a convincing argument that membership in another team would provide a better fit of skills and personality. We will require each team to select a “point person” to maintain efficient communications. Being a “point person” does not necessarily imply a team leader role.

CONTENT

Introduction and course orientation.

- Discuss purpose, goals, logistics of the course.
- How to use CATME “team maker” survey
- Clearances for clinical project participation.
- Potential clinical projects.
- Professional MS programs.
- Selected results from previous classes (Medical Product Ideation, Medical Product Development).

Intellectual Property Protection at Pitt

Guest lecturer will review the basic rules of Intellectual Property at the University of Pittsburgh. It is important to understand the rules and requirements that will affect the protection of patentable inventions that could result from student teams working on projects with clinical mentors.
Introduction to “Design Thinking” principles and techniques: Reinventing the Name Tag

- Design thinking is a term used to encompass a set of strategies and practical techniques for inventing effective solutions to human needs. In particular, it emphasizes a human-centered approach to innovation and a focus on broad, creative thinking, prototyping and empirical experimentation as cornerstones of developing new ideas and making them into effective solutions to real-world problems. Characteristics of effective design thinkers include empathy, integrative and interdisciplinary thinking, optimism, a bias toward action, embracing experimentation and collaboration.

In this “60-minute introduction to design thinking,” you will work in teams to design and prototype your first “product” in the class—one that is both imaginative and practical.

Name tags serve a very useful purpose, especially when a large group of people first meet. But they’re pretty boring, and you don’t learn much about a person from a name tag. You’re going to change that. In the process you’ll receive a hands-on introduction to core principles of design thinking, gain experience building low-resolution prototypes and get to learn interesting things about your fellow classmates.

ASSIGNMENTS:

Students will bring proof of submission of the following documents. The expectation is that all of the requested documents will have been submitted to Dr. Gurevich. These documents are required in order for the student to work in a clinical site under the direction of a clinical mentor. The Associate Dean’s office will inspect the originals and retain a photocopy of each document. The Act 33, 34, and 73 clearances are the same as for “educators” in Pennsylvania. For additional guidance, see the following URL.

http://www.dhs.pa.gov/provider/childwelfareservices/childabusehistoryclearanceforms/index.htm

1. Copy of the online training HIPAA Completion Certificate - UPMC Information Privacy and Security Awareness Training for Students, Trainees, Health Professionals and Other Individuals Who Are NOT UPMC Employees (submit only once).
2. Copy of the Pennsylvania Child Abuse History clearance (ACT 33).
3. Copy of the Pennsylvania Criminal Record Check clearance (ACT 34) (Volunteers/education)
4. Copy of the FBI Fingerprint Criminal History Clearance (ACT 73). (Education)
5. Health Screens and Immunizations, including TB screening.
6. Certificate of Completion of seminar in Clinical Site Conduct.

Reading Assignment for Week 1: Complete by Week 2

Chapters 1-2 of Yock (Biodesign).

Chapter 1: Needs Finding
Chapter 2: Needs Screening


This article is a brief but very rich introduction to design thinking with multiple examples of its successful use to develop solutions to problems. Tim Brown is the CEO and president of IDEO, one of the world’s leading design firms (it designed the first Apple mouse) and a partner with Stanford University’s Institute of Design (d.school).

“The IDEO Field Guide to Human-Centered Design” Pages 1 through 25, Introduction and Mindsets (pdf available on BOX)

(Note that this a highly visual document, so this is perhaps the equivalent of just 7 pages of text.)

Finally, visit the website below for an interesting process description for needs finding:

Week 2

WORKSHOP: NEEDS FINDING & ETHNOGRAPHY FOR IDEATION

Workshop will cover VOC (Voice of the Customer) research techniques and case studies. Discussion of systematic processes for VOC research. The key concepts of ethnography will be introduced so that students will be able to apply them systematically in projects with the clinical mentors during the problem statement phase. The teams will also have a practical workshop on the use of “paper prototyping” as part of concept definition.

- Establishing objectives
- Choosing methods
- Planning visits
- Interviewing & observing
- Knowledge mining
- Shadowing, video observation, behavioral mapping
- Using Prototypes to assess concepts

Reading Assignment for Week 2: Complete by Week 3

- Read the Daedalus Ethnography Field Guide (available on BOX and CourseWeb) and be prepared to discuss in class, along with application of methods to your clinical projects.

- Read “The IDEO Field Guide to Human-Centered Design” Pages 27 through 73, Methods: Inspiration through Case Study: Vroom

- Read pp. 50-96 in this excerpt from Sheila Mello’s book “Customer Centric Product Definition”. It describes some process steps for determining customer needs and for defining product requirements based on those needs. Please read this in advance of Dr. Uber’s workshop in Week-3. The methods outlined in Mello’s book have been adapted for use by many new product companies. A copy of Mello’s book is on reserve in the Engineering Library. [http://tinyurl.com/Mello-book](http://tinyurl.com/Mello-book)
Week 3

WORKSHOP: ETHNOGRAPHY, NEEDS FINDING, CUSTOMER IMAGE, CONCEPT SCREENING

This workshop covers the use of systematic observation in general workplace environments. Ethnography is a discipline augmented by a set of tools to record observations about the workplace (physical and temporal characteristics, human interactions with other people and tools, and processes used to perform work). Understanding this critical tool will help in the discovery of customer needs in the domain of medical devices and systems.

Guest Lecturer

- Introduction to ethnographic research and its role in “needs finding” and problem definition.
- How to study an environment of use, processes, interactions of people & things utilizing unbiased observations.
- Interviewing, focus groups, time-motion studies.
- Capturing unstructured data and observations (use of sketches, video & audio).
- Organizing and structuring masses of data using affinity methods.
- Finding themes, formulating problem statements and communicating results.

Guest Lecturer

- This exercise should give the student an appreciation for simple, but powerful, observation tools to use in almost any unstructured environment, including most clinical settings. The goal is to prepare you to be a keen observer of the work performed in a clinical setting. It will help you to identify the real (but sometimes latent) needs that may differ significantly from the clinician’s preconceived notions. When you get into the project phase of this course with a clinical mentor, this practical exercise will prove to be of indispensable value.
- Here is how the practical exercise will be conducted:
  - One “demonstration team”, selected by the instructor, will develop a topic based on a shared lesson developed by Dr. Uber. The other “observation teams” will make careful and complete notes about the process and team dynamics exemplified by the “demonstration team”. A video camera will be used to record the demonstration team while they are working for about 30 minutes.
  - A standardized method will be used for recording the observations in a simple written format. The many notes will be sorted and grouped using an “affinity” technique to identify major themes.
  - A succinct title or heading for each group of will be developed for each cluster of affinitized notes. Further use of the grouping process will provide insight into themes and problem statements that are an essential part of needs finding and problem identification.

Week 3 ASSIGNMENT A: Due Week-5

Choose one of the two assignments listed below.
1. The team will communicate with their clinical mentor to do an initial observation and/or an interview to determine clinical practice in the environment of interest. Students will use the observational techniques from Dr. Uber’s workshop. They will work with the clinical mentor to gain access to the clinic for observations and interviews with others in the clinical environment, including physicians, residents, technologists, nurses, and ancillary health care workers. The purpose of this section is to get acquainted with the clinical mentors, and to start planning a project that will make use of the observational techniques learned in the previous classroom sessions. The clinical mentors will arrange for site visits by the student teams within the clinical environment to allow for observations. If a clinical observation is selected, however, you will not be able to take photos or videos in areas where patients or patient records could be recorded. It will be possible to capture images in working spaces where patients/records are not present.

2. If it is not possible to meet with the clinical mentor at this time, the team will select a public environment (such as a restaurant, a bus stop, a library, or any other place where some form of human societal activity is taking place) to do some unobtrusive ethnography for no more than two hours. The team will make extensive notes, sketches of the environment, photos or videos (preferred) to capture and describe the activities taking place in the selected environment.

Using the techniques elucidated in today’s lecture and exercise, the teams will develop a PowerPoint presentation to describe the methods used to collect data, a description of the observed environment, the purpose(s) of the activities conducted in the environment, the primary themes discovered by observing activity in the environment, and possible unmet needs (or problems) identified.

The team slides will be turned in by email to the instructor no later than noon on Week 5. We are not requiring the slides for this exercise to be presented to the class, but the work will be graded. The intent is to show your team’s mastery of the tools provided in Week-3. You have two weeks to complete the assignment. If your team is able to conduct the ethnography in the clinic as described in option (1), then you are ahead of the game. Option (2) is provided in case there are logistical difficulties in your initial communications with your clinical mentor.

Here are more detailed instructions:

- Demonstrate evidence of your team’s collective thought process and approach to the situation you plan to observe. This includes the “set of questions” mentioned in the slide…what activity you are observing, how your team structured the work, and how you planned, conducted and recorded your observations. Please maintain a time-log and make that part of your team’s observation.

- Provide sketches, photos/videos, or audio recordings in the physical environment where the observed activities occur. Even video clips or snapshots with a Smartphone are acceptable.

- Prepare the “Customer Image Diagram”, which is basically the affinitization and theme categorization. You are permitted to use small (1” x 1”) yellow stickies on 11x17 or 8.5x14 sheets
to keep your expenses down. Please photocopy the sheets with all the original yellow stickies. Also, provide a copy of the affinitized groupings with headers. If you do more than one round of grouping with new headers, please provide a copy of all the intermediate results.

- Put your results into a PowerPoint slide deck...no more than 10 slides.

Reading Assignment for Week 3: Complete by Week-4

Alberto Savoia “Prototype It” (pdf available on BOX and CourseWeb)

“The IDEO Field Guide to Human-Centered Design” Pages 75 through 131, Methods: Ideation through Case Study: Asili (on BOX)
Week 4

WORKSHOP: EXPERIENCE PROTOYPING AND “PRETOPYPING”
SIMULATION AND THE SYSTEMS ENGINEERING PERSPECTIVE

- Experience Prototyping and Pretotyping: “Make sure you are building the right “it” before you build “it” right”
- Simulation and the systems engineering perspective
- Introduction of the First-Person Perspective Design Evaluations, to be presented during the Oct. 18 Week-8 session: “The Good, the Bad and the What-Were-They-Thinking?”

This week we’ll engage in an interactive, hands-on workshop exploring techniques that can enhance design thinking and prototyping. We’ll also discuss medical simulation and systems-engineering concepts relevant to medical product development.

- **Experience prototyping** and **pretotyping** (or “pretendotyping”) are methods to rapidly and inexpensively help determine what the right “it” is before you decide to build “it” (whatever “it” may be). These techniques have been pioneered at IBM, Palm, IDEO, Google, Stanford and other top design environments. We’ll engage in a hands-on exercise that will let you quickly and experientially explore and test design assumptions and help answer the question “Should we build it?” before proceeding to “How do we built it?”

We’ll begin by looking at some classic examples of how simple prototypes made with basic materials and methods have provided significant insight in creating new systems and products—or in some cases not creating a new product or feature when the results of pretotyping indicated it was an idea that didn’t have the traction hoped for. Three of our design dictums will be “Bias toward action”, “Show, don’t tell” and “Fail early, cheaply and often.” We will discuss the perhaps surprising benefits of early, cheap and frequent failure.

You’ll then receive brief descriptions of potential ideas for a new device, software or system. Working in teams and using the sticky-note ideation technique, you will generate ideas about the proposed product, clarify use cases for the product, and develop a plan to explore feasibility and potential pitfalls. You’ll then be provided with a wide range of simple prototyping materials and tools which you will use to create dynamic pretotypes to test your ideas—essentially a fast, low-cost experiment to test assumptions and elicit unknowns. Teams will then present and discuss your results and their implications.

Time permitting we will then additionally build on this exercise with an opportunity to role play/simulate how to prevent “rapid convergence to a solution” in discussions with your “customer” or clinical mentors.

- Prototyping often involves various kinds of simulation. Medical simulation is now a well-established field and simulation techniques and resources can support every stage of the design
process, from ideation through various levels of prototyping to beta-testing and end-user/customer training. We’ll discuss some benefits and examples.

• We’ll also discuss **systems engineering**: fundamentally, the big-picture view of how to design a system that considers both human users and technologies, the environment and context in which a system is used and maintained, and how the design of a complex system can be facilitated by effective partitioning into more manageable chunks. Understanding and defining “the system” you are working with can also provide insight regarding who your stakeholders are and how to design for their needs.

• We’ll wrap up by introducing the **First-Person Perspective Design Evaluation: The Good, The Bad and the What-Were-They-Thinking?**, to be presented in teams in three weeks on Week 7.

Design is a ubiquitous part of everyday life. What is good and bad design? You know it when you experience it. For the next 3 weeks, you’ll observe and consider what are examples of good and bad design you encounter in your daily life, collect your observations as a team, then share examples with the class in Week 7. The goal is to enhance your own awareness of factors that contribute to good design, and to collectively identify (via “crowdsourcing”) some generalized characteristics of good (and poor) designs.

**ASSIGNMENT (Both parts due Week-7)**

**Part 1**  Develop initial pretotypes for your projects based on one or more clearly defined use cases. Be prepared to present your physical prototypes, along with any supporting media (videos, images) as part of your workshop in Week 7.

**Part 2**  Research examples of good and bad product design for presentation in the workshop in Week 7.

1. Over the next week, as you use devices, systems and services in your daily life, be especially conscious of those you find to be well designed and those not. When you use a device, what makes it work well? What makes the experience effective, easy, intuitive? What devices or systems impress you as elegant, cost-effective or simply really great solutions to a need or problem?

Conversely, which devices, systems or services frustrate you? Why? What are the particular features that are broken, poorly designed or just not fit for use by humans?

This is a **first-person perspective** exercise. Draw examples only from those devices, systems or services you personally encounter and are familiar with.

Come up with at least 2 or 3 examples each of well-designed and poorly-designed things. **Be specific** in your choices and evaluations: for example, don’t generically present “automobiles” as a good design—what are the particular features of a particular car—or subsystem of a car—that make it a good experience to use? We especially welcome your finding examples of things that are so ill-designed you find yourself wondering, “What were they [the designers/engineers] thinking?”
2. Have a team meeting in about two weeks (a week before the presentation) and share and discuss your examples. **Choose one example per team of good design and one example of bad design.**

3. Prepare a team demonstration/presentation showing and describing in detail your two examples. You will have 5 minutes (max) to present on Week 7. Your presentation should enable the class to really see a person or persons using the device, system or service in action—consider carefully ways to do this. For example, if you wish to discuss a relatively portable device, bring it to class. To show something being used in its native environment beyond the classroom or campus, use images and/or video to make your demonstration. Video can be a very effective tool to show a person using/experiencing a device or system. Your presentation should clearly demonstrate the good/bad points of the design.

If your example is an object you bring to class you can use the document projector to display it to the class. Be sure to demonstrate its functionality when in actual use. For example, if the system is an app on a smartphone, you should actually show the use of the app. Please familiarize yourself with the BEH 320 document projector and **rehearse and test your presentation technique in the classroom prior the class!**

You may use slides, sound, role playing, or other methods to effectively show the benefits or limitations of the designs.

4. Address the following questions in your presentation:

   • What examples of good/bad design did you consider, and why did you select the ones you did as the best/worst of the group?
   • What specific factors make the good example good?
   • What factors make the bad example bad?
   • What specifically would you do to improve the bad example?
Week 5

USE OF PERSONAS IN IDEATION
VISUAL COMMUNICATION AND PRESENTATION FOR DESIGN
CREATIVE CONFIDENCE AND TEAM DYNAMICS

Week 3 Assignment A due today by 12pm (noon)

- Use of “Personas” in prototype ideation (see Daedalus Ethnography Field Guide, section 17, pages 105 – 107.)
- Workshop exercise on personas and prototyping
- Visual Communication and Presentation for Design: tips and techniques for effective design presentations.
- In-class viewing of David Kelly’s TED Talk “Creative Confidence,” followed by class discussion.
- In-class viewing of “Extreme by Design” video (Stanford d.school).
- Class discussion of teamwork, communication and team dynamics. Sample topics include roles and personality types, how to offer constructive feedback, how to get going as a team, and what to do to get “unstuck” when you run into roadblocks.
Week 6

SUBJECT AREAS: DESIGN & MORPHOLOGICAL ANALYSIS
How to navigate a design space and select concepts from a universe of choices.

Introduction to morphological analysis.

Lecture: Brainstorming and Creativity Tools

- Exercise #1 – Identify morphologic analysis dimensions for ideation and brainstorming
  - Working in groups, frame your project and develop a set of dimensions for ideation and brainstorming. Next, brainstorm some options for each dimension and generate a morphologic analysis table.

- Exercise #2 – Use morphologic analysis to identify and organize potential solutions.
  - Using a project from the previous exercise, use the morphologic table to identify and organize potential solutions. Aim for 3 to 5 solutions if possible.
  - Consider team roles and dynamics while you do the work.
  - Focus on process as well as content (plan before you begin)

Be prepared to share and report out on your work at the end of the session.

Dr. Hirschman and Mr. Griffiths will be available for facilitation support and questions
Week 7

**Student team presentations: “First-Person Perspective Design Evaluations: The Good, the Bad and the What-Were-They-Thinking?”**

Present your team demonstration showing and describing in detail your two examples of good and bad design. 5 minutes (max). Remember that your presentation should enable the class to really see a person or persons using the device, system or service in action—plan effective methods to do this, including use of video.

**Student workshops**

We will divide into groups of two teams each. The first team in each group will discuss the items outlined below, with the second team acting as reviewers. After 1 hour of this interaction, the teams will switch roles for an additional hour. This methodology has worked quite well in the past.

- Present the results of your ideation and prototyping applied to your clinical projects.  
  **Presentation of a physical prototype/prototype in the context of one or more clearly defined use cases is required.** By “physical” we mean something more than words—a prototype could be a physical artifact, a simulation of an app, or role-playing a service improvement.
- Report on results of interaction and communications with clinical mentors.
- Students will thoroughly describe the process they used in the early ideation work for their project areas.
- Students will discuss “failures” documented during the ideation process. Why did some concepts work while others were discarded? What were lessons learned? Did you experience an example of an early “fail” that led to an even better idea?
- Teams will describe morphological analysis and the potential design space.
- Some teams will be preselected to present to the entire class the results of your clinical problem definition. Show a hierarchy of possible clinical problem statements from most specific to most general. Discuss the problem statement you have determined is most likely to lead to one or two useful, feasible technical approaches that solve the clinical problem statement. Slides or other visuals are recommended for this presentation but not required.
Week 8

SUBJECT AREA: STUDENT PRESENTATIONS – CLINICAL PROJECTS PHASE I

Phase 1 Student Team Project Planning Presentations

This will be a working session devoted to clarifying the goals and expectations of the team projects that will be accomplished with the guidance of a clinical mentor. The ultimate goal of the team projects is to present the results of research, observation, and ideation which your team utilized to address a clinical need guided by a physician mentor. It is expected that the teams will use the methods provided in the workshops on needs finding and ethnographic research.

Prior to the Phase 1 presentations it is expected that the teams will have negotiated the selection of all projects. No two teams are permitted to select the same clinical project, although the mentors can work with several teams. I am requesting each team’s “point person” to compile a brief statement of the problem selected by his/her group. These statements should be sent by email to your instructor before this class to allow any adjustments to be made. Although presentation slides (PowerPoint) are encouraged at this session, your team should select a spokesperson to describe what problem you have selected and why.

Phase 1 working session and discussions

1. Understand the clinical need or problem with the help of the clinical mentor, if possible. If scheduling difficulties prevent your team from meeting with or effectively communicating with the clinical mentor, it will be acceptable to lay out a project outline based on their presentation slides and any additional research the teams may have done independently. Teams will communicate an understanding of how the need or problem is currently addressed in the clinical environment, and where current approaches fall short. Ideally, this research would include observations, interviews and ethnography in the clinical environment. You will all be introduced to these tools in the lectures and workshops that follow.

2. Develop a clear statement of stakeholder requirements (must haves, nice to haves).

3. Develop a concise problem statement (one or two paragraphs) to clearly define the clinical need and the problem you intend to address.

4. Your team must develop a project plan, including a list of major milestones, and a timeline.

5. Summarize your results for Phase 1 in a PowerPoint presentation representing your best effort as a team. Although one spokesman from the team can deliver the entire presentation, it is preferable to have each team member present at least one sub-section. **Each team will be allotted 15 minutes for the Phase 1 report with 5 minutes for Q&A.**
INDUSTRIAL INNOVATION CASE STUDIES and TECHNOLOGY RESOURCES

CMI co-PI’s: examples of clinical product innovation. Some of our more successful CMI project teams will describe how they went about ideation and progressed into projects with commercial potential. (Dr. Kevin Bell and Dr. James Irrgang)

Industry Guest workshop

Week-10

SUBJECT AREAS:  MARKET RESEARCH, SEGMENTATION, COMPETITIVE ANALYSIS

The goal of this session is to provide some examples of processes for determining the needs of potential customers (clinical users, patients, insurers, developers) in the earliest stages of medical product definition. Another goal is to provide an overview of the use of market research to determine the commercial viability of a product concept. Emphasis will be placed on not just finding market data points, but being able to synthesize multiple data points to create and synthesize novel market sizing and segmentation.

Guest Instructor will provide a lecture/workshop on “Determining the market potential of new products”. The class will be prepared to discuss assigned readings and a case study selected from the medical device industry. Teams will talk through a brief slide presentation of analysis and conclusions. The exercise will provide the students with an understanding of the following issues, which can be applied to the team projects:

- How to understand the Voice of the Customer through market research, databases, and analysis of competitive products.
- How to create real and perceived value from an innovation or invention.
- How to determine market size and market segmentation.
- Determine how to construct per unit pricing projections
Week 11

SUBJECT AREA: REGULATORY and QUALITY ISSUES IN PRODUCT DEVELOPMENT

This session covers important regulatory issues with clinical translation, including the role of government regulatory agencies (FDA, FCC, European Union, CMS). Product liability, risk management, and the importance of human factors will also be covered in this session with real-world examples from the medical products industry.

CONTENT:

   Guest Lecturer

   Case study from Yock (Regulatory issues)

Week 12

SUBJECT AREA: Student workshop and presentation

Team Work

Working Session for Teams (time to work on FINAL project preparation, coordination). Get feedback from instructors and peers.

Week 13

Pre-holiday working session:

Because the Thanksgiving break is coming up, some class members may be travelling to join family celebrations. Therefore, no new material will be introduced in this class. We will use the time for the teams to work on projects (presentations, white papers), and to receive coaching and critique from instructors.
Week 14

SUBJECT AREA: MEDICAL PRODUCT EXECUTIVE PANEL

Moderated panel discussion

Student Q&A opportunity

CONTENT:

This will be an interactive panel discussion with some outstanding members of the medical product development community. We hope that this panel will provide an exciting opportunity to hear their experiences in translating innovative ideas into commercial ventures. Others on the panel are well known for their contributions to medical product business development and financing. There will be opportunity to have your issues and questions addressed in a moderated panel discussion.
Week 15

All whitepapers and slide presentations are due by 5pm for all teams.

SUBJECT AREA: FINAL TEAM PROJECT PRESENTATIONS AND WHITEPAPER (Group #1)

Reviewers, Judges: Course instructors, clinical mentors, invited guests. In addition, students will act as peer reviewers using a standard evaluation form on Google Drive.

WHITEPAPER GUIDELINES:

In addition to the PowerPoint presentations, each team will submit a “Whitepaper” following the CMI pre-proposal format. A copy of the “CLINICAL CONCEPT QUESTIONAIRE” form can be downloaded from the Center for Medical Innovation website at:

http://www.engineering.pitt.edu/Sub-Sites/Centers/CMI/_Documents/clinical_concept_questionnaire-v7-12-12/

PRESENTATION GUIDELINES:

Each team will have up to 30 minutes with an additional 5 minutes Q&A to present their projects to a panel of faculty advisors, clinicians, and guests. The faculty advisors will be selected from the leadership team of the CMI (Center for Medical Innovation). The clinicians will be the project mentors (or their designated representatives). Guests may include industry representatives selected by the course instructor.

The format and expected content for the presentations will be specified early in the course. Each team will be evaluated on approach & strategy, compelling content, and completeness. Although the presentations represent an early stage in the life of a product concept, the potential for successful commercialization, as evidenced through the use of business planning tools, will also be evaluated.

Requirements for final presentation:

- This is the final PowerPoint presentation by each team delivered to a review panel (clinical mentor, CMI advisors, and your classmates). It should summarize the methods used and the conclusions drawn during the conduct of the clinical project. It will include a set of recommendations for future implementation of your solutions to the clinical need/problem. Each team will be allotted 30 minutes for the final presentation with an additional 5 minutes Q&A.

Evaluation criteria for presentations:

1. Understanding of clinical need as demonstrated by research. 25%
2. Effective use of ideation tools. 25%
3. Novelty, utility, and feasibility of technical solutions. 20%
4. Commercial strategies (regulatory, reimbursement, marketing). 10%
5. Teamwork. 10%
6. Quality of content, completeness, and style of presentations. 10%
Expected content of final presentation:

1. Refine the information and analysis required in Phase 1, including a clear problem statement resulting from your observations, interviews, and other research on the clinical need identified with the air of your “clinical mentor”.

2. Discuss the ideation methods your team used to develop at least two novel (but feasible) technical approaches to address the clinical need or problem. You will be introduced to some useful technical tools and capabilities of the Swanson School of Engineering by Dr. Joe Samosky.

3. Demonstrate how your several technical approaches would benefit patients and improve over existing methods.

4. Make a case for the commercial viability of the preferred concepts. This includes a statement of the market and its various segments, the competitive environment, and the results of a preliminary patent search using one or more of the searchable patent databases.

5. If possible, the clinical mentor or representative will be present to comment on the approach and initial findings.

All student teams will be presenting their work on the selected clinical concept or need identified by their clinical mentor. Final presentations will include at least two preferred technical approaches to addressing the clinical problem, a preliminary patent research to uncover prior art and to understand the competitive environment. Strategies for regulatory, reimbursement and business strategy will be included. Presentations will employ PowerPoint slides to fully explain and describe the following issues:

- How the team selected the concept or clinical need. (What thought process went into deciding on the problem).
- What research and/or observations were used to determine the clinical needs to be satisfied.
- Further refine, document and report on the clinical problem, requirements and constraints.
- Report on the process used to narrow the search for viable solutions to the clinical problem.
- Report on the commercial market potential, competitive analysis, regulatory/ reimbursement hurdles, and initial patent analysis.
- Discuss the risks, hazards, and potential liability issues with the proposed solutions.

The instructor will evaluate the presentations and offer feedback to the student teams with the help of other CMI team members.

Presentation Guidelines:

1. Discuss the ideation methods your team used to develop at least two novel (but feasible) technical approaches to address the clinical need or problem.
2. Demonstrate how your several technical approaches would benefit patients and improve over existing methods.

3. Make a case for the commercial viability of the preferred concepts. This includes a statement of the market and its various segments, the competitive environment, and the results of a preliminary patent search using one or more of the searchable patent databases.

4. If possible, the clinical mentor or representative will be present to comment on the approach and initial findings.

Week-16

SUBJECT AREA: FINAL TEAM PROJECT PRESENTATIONS AND WHITEPAPER (Group #2)