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:

- “Needs finding” methods
- Ethnographic research and “voice of the customer”
- Group brainstorming and concept generation methods
- Affinitization techniques
- Morphological analysis
- 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 on Courseweb (http://courseweb.pitt.edu).

Textbooks and other materials can be purchased online or will be available in the Bioengineering library. (BIODESIGN, “The Process of Innovating Medical Technologies” by Zenios, Makower, Yock, Cambridge University Press). This 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). For those who prefer not to own this valuable text, it can be accessed online for free through the University of Pittsburgh Library System (PittCat).

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 (by competitive application) is limited to 30 students. 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 to the class and instructors.

5. 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)
- Group roundtable and introductions.
- Discussion of potential clinical projects.
- OTM presentation on University treatment of IP.

CONTENT

6:00-7:00pm: IP Requirements:
Andrew Remes, PhD. CLP, Licensing Officer, Office of Technology Management, University of Pittsburgh.

Dr. Remes 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.

7:00-8:00 pm (Dr. Hirschman)
- Introduction and course orientation.
- Discuss purpose, goals, logistics of the course.
- Introduction to CMI (Center for Medical Innovation).
- Clearances for clinical project participation.
- Potential clinical projects.
- Professional MS program
- Results from 2011-2013 classes (Medical Product Ideation and Medical Product Development)
- Results from 2013 (Clinical Bioengineering and Medical Product Prototyping)

8:00-9:00 (Students & instructors)
We will use the time to get acquainted with each other through a discussion of the students’ backgrounds, interests, and accomplishments that might be useful in medical product design. We need to understand the expectations of the students, what they hope to learn and to apply with the help of this course. Each student will talk for up to 2 minutes about his or her professional interests, special knowledge and technical skills, social skills, accomplishments, and a brief discussion of expectations of the course. After each student has had a chance to speak, the group will use this knowledge to start the process of dividing up into teams with 4-5 students each. You are encouraged to contact each other outside class before the Sept 2 session and to identify your team with a unique name (or a number if you prefer).

The self-selected groups will work together as project teams for the duration of the course. Students can move from one team to another if there is possibly a better fit of skills and personality. In the past, I
have students to teams based on a survey of personality traits. However, this year, I would like the teams to self-select based on compatible interests. It is also advisable for each team to select a “point person” for me and our TA to maintain efficient communications. Being a “point person” does not necessarily imply a team leader role.

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. Gurleyik. 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.

1. Copy of the HIPAA 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).
4. Copy of the FBI Fingerprint Criminal History Clearance (ACT 73).
5. Health Screens and Immunizations, including TB screening.
6. Certificate of Completion of seminar in Clinical Site Conduct.

A. Readings for Sept 2: Chapters 1-2 of Yock (Biodesign).

Chapter 1: Needs Finding

Chapter 2: Needs Screening

Visit the website below for an interesting process description for needs finding


The following link will take you to a rather extensive 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:

http://books.google.com/books?id=5grj0vv716EC&pg=PA98&lpg=PA98&dq=customer+centric+product+design+mello&source=bl&ots=sz75MSF8o-&sig=esPfbd0M80arC4sRIQqqGGZ0PA&hl=en&ei=dBVQToKXYfZgQe-oqn3Bg&sa=X&oi=book_result&ct=result&resnum=2&sqi=2&ved=0CCQQ6AEwAQ#v=onepage&q=customer%20centric%20product%20design%20mello&f=false
Week 2

WORKSHOP: CLINICAL CONDUCT, PROJECT GUIDELINES

6:00-7:00 PM  Dr. Roseann Granieri, MD will conduct the “Clinical Site Conduct Seminar” to cover the rules and guidelines for clinical conduct in the UPMC patient environments.” This interactive meeting will satisfy one of the UPMC clearance requirements, so try to attend the meeting to avoid a make-up session.

Dr. Roseann Granieri, MD  
Dept of Internal Medicine, UPMC  
Chair, School of Medicine Curriculum Committee  

7:00-9:00pm: Dr. Hirschman and Dr. Taylor

Discussion of unmet clinical needs and problem statements from clinicians given previously to students. Team formation exercise, clinical problem/ mentor selection, team discussion of project intent. Each team will select one preferred project/clinical mentor and two backups. The instructors will then work with the teams to sort out conflicting choices and to arrive at a mutually agreeable matrix of project choices for the remainder of the term. The student teams will consider which project has the most appeal to their collective interests and skill sets. The instructors reserve the right to modify team membership in order to achieve diversity of skills and backgrounds while preserving interests.

To date, the following clinicians have signed on as “clinical mentors”. You can explore their bios and research areas through an online search.

- Pamela Moalli, MD (Obgyn)
- J.Peter Rubin, MD (Plastic Surgery)
- Rabi Chaer, MD (Cardiology)
- Arjun Pennathur (Cardiothoracic Surgery)
- Brian Tillman, MD, PhD (Vascular Surgery)
- Stephen Emery, MD  (Obgyn, Fetal Intervention)
- John Comerci, Jr. MD  (Obgyn)
- Robert Kormos, MD (Cardiothoracic Surgery/ Heart transplant)
- Volker Musahl, MD (Orthopedic Surgery)
- John Waters, MD  (Anesthesiology)
Week 3

SUBJECT AREA: PROJECT SELECTION / INITIAL PRESENTATIONS

6:00-9:00 pm Project selection (team presentations). Student QA for clinicians’

CONTENT:

Each team will have up to 20 minutes to present a PowerPoint slide deck describing the project which has been selected and approved in the previous class. A template for the presentations will be provided.

Depending on availability, there will be Q&A with clinical mentors.
Week

WORKSHOP: ETHNOGRAPHY and NEEDS DISCOVERY

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.

CONTENT:
6:00-7:00 pm (Arthur “Ned” Uber III, Chief Scientist, BAYER, Inc Innovations Group)

- 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.

7:00-9:00 pm (Uber)

- 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.
ASSIGNMENT: 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 presentations will be turned in by email to the instructor

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.

• Each team will elect a spokesperson/presenter to do a 15 minute presentation with up to 5 minutes additional for Q&A in class
Week-5

SUBJECT AREA: ETHNOGRAPHIC RESEARCH PRESENTATIONS (student teams)

Each team will present for 15 minutes in class with an additional 5 minutes allowed for Q&A.

ASSIGNMENT:

For Week 6, student teams will develop a Phase I project outline for presentation to the class in Week 7. See the Week 7 syllabus notes.
Week 6

WORKSHOP: NEEDS FINDING & ETHNOGRAPHY FOR IDEATION

6:00-9:00 PM  Courtney Southard, Bill Bernstein (Daedalus, Inc)

Workshop will cover VOC (Voice of the Customer) research techniques and case studies. Discussion of systematic processes for VOC research:

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

Teams will experience hands-on contextual inquiry in practice session.
Week 7

SUBJECT AREA: STUDENT PRESENTATIONS – CLINICAL PROJECTS PHASE I

6:00 – 9:00 PM Phase 1 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.
Week 8

INDUSTRIAL INNOVATION CASE STUDIES and TECHNOLOGY RESOURCES

6:30-8:00 pm  Jeff Thompson - Director, Strategic Alliances at Aesynt; Cross Functional lead for Product Planning at Aesynt; and Vice President, Member Experience for the Product Development Management Association.

Topic: Case Studies in Innovation and Early Product Development at Aesynt

- **Who is Aesynt**
  - Company, products, markets, customers, Employees, and Ownership
  - History – Automated Healthcare, McKesson Automation, Aesynt

- **Who is Jeff Thompson**
  - Background and qualifications
  - Roles at Aesynt in new product development & innovation

- **Framing the Case study format – Interaction expectations**

- **Case Study 1 – Anesthesia RX**
  - Challenges at leadership levels introducing proper VOC techniques and transforming program expectations; challenges associated with defining and managing to minimum viable product. How to shift a development process to incorporate early VOC and market driven requirements
  - Resulting product is highly successful – meeting business goals and growing faster than market.

- **Case study 2 – Code name – “not so great”**
  - Launched product failure directly related to poorly designed (Too narrow) VOC.
  - Hindsight perspective of issues, land mines created, potential reaction points, and alternatives missed
  - Will use an analogy to increase class interaction and demonstrate key learning points. This will also illustrate how an analogy can be a useful tool in dealing with complex, emotion charged development strategy and tactic questions

- **Case Study 3 – Intentional Insight**
  - Introducing and applying ethnography at Aesynt (then McKesson)
  - Incorporating customers in ideation and early concept validation
  - How do you know your concept solves the right problems – before committing to full scale development?
Technology Resources Lecture will cover:

- Systems engineering approach to product design.
- Matching technology to humans.
- Introduction to resources and tools at Pitt for prototype development.

ASSIGNMENT:
Research examples of good and bad product design for discussion in workshop next week.
Week 9

SUBJECT AREA: BRAINSTORMING and CREATIVITY TOOLS

Using creativity tools to find many solutions.

6:00-7:30 PM: Tom Kubilius (Bally Design)

• Customer image and brainstorming workshop.

7:30-9:00 PM: Dr. Joseph Samosky

• Workshop will cover student presentations of good and bad design assigned previous week.
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.

6:00-9:00 pm (Dr. Donald P. Taylor, Adjunct Assistant Professor, Bioengineering, U of Pitt)

Dr. Taylor 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:

6:00-7:30PM: Larry R. Kopyta, RAC (VP Quality, Omnyx, Inc)

   Mr. Kopyta has decades of experience in quality engineering and regulatory affairs in the medical device industry (MEDRAD, Inc, Thermofisher, and Siemens Medical

7:30-9:00pm Bob Marshall (Director of Business Development, RQTeam, Inc)

   Real-world examples of best practices in regulatory disciplines.
Week 12

SUBJECT AREA: TRANSITION TO COMMERCIALIZATION / EXAMPLES

6:00-7:30 pm  Guest Lecture – Babs Carryer

Ms Carryer is Director of Education and Outreach with the University of Pittsburgh Innovation Institute. She has a long history of entrepreneurial work in the Pittsburgh community.

Her talk will cover the following topics:

Lean Launchpad method including Lean Startup for evaluating business strategy and plans. How to set up a business in the earliest stages.

7:30-9:00pm  Guest Lecture – Dr. Evan A. Facher

Dr. Facher is Director of Enterprise Development for the Innovation Institute.

His talk will cover:

How to do early business formation (LOIs, term sheets, early marketing and funding, SBIR programs and how to access them. How does business formation work in established companies and in startups.
Week 13

6:00-9:00 pm (Teams)

Working Session for Teams (time to work on project preparation, coordination). Get feedback from instructors.
Week 14

WORKSHOP: PITCHING AND PRESENTING

6-730 pm  Mr. Mel Perchesky

How to develop and deliver an elevator pitch. How to attract investors.

730-900 pm Dr. Donald P. Taylor

The University of Pittsburgh provides highly competitive and lucrative business competitions aimed at translational development projects. These are projects within research laboratories that have potential to be commercial products - where a significant majority of the basic research has been completed.

These competitions include the Randall Family Big Idea (1st place $20,000), Wells Student Healthcare Competition (1st place $10,000), PInCH (1st place $100,000), and the McGowan Institute Retreat Elevator Pitch Competition (1st place $6,000). In addition to the potential to win money to further development the business concept, participating students receive the following benefits:

- Visibility and exposure among senior administration interested in furthering the translational development ecosystem
- Networking with other students, faculty, and external constituents
- Experience presenting one’s commercial concept and receiving valuable constructive feedback

During this session Dr. Taylor will share presentation and abstract excerpts from prior winners in order to demonstrate how one develops a competitive entry.

During this session students will be able to:

1) Become familiar with all of the University competitions in order to determine which may be best suited to pursue

2) Enumerate the key aspects of a highly competitive competition entry

3) Differentiate between a translational development project and a basic research project
Week 15

SUBJECT AREA: MEDICAL PRODUCT ENTREPRENEURSHIP PANEL

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. Although the participants on the panel are not yet finalized, invitations have gone out or will soon be sent to the following outstanding people:

- Dr. Pratap Khanwilkar (Prof of Bioengineering and Director, Coulter TPII program)
- Dr. William Federspiel (Co-founder of ALung Technologies, Prof of Bioengineering)
- Dr. Eric Beckman (Founder of Cohera Medical)
- Ms. Catherine Mott, CEO, Blue Tree Angel Investors
- Mr. Mel Pirchesky (President & CEO, Eagle Ventures)
- Mr. Larry Miller (Executive in Residence, Innovation Works)
- Mr. Peter DeComo, CEO ALung
- Dr. Evan A Facher, Director/ Enterprise Development for Innovation Institute.
Week 16

SUBJECT AREA: FINAL TEAM PROJECT PRESENTATIONS AND WHITEPAPER

Each team will have up to 15 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 15 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.

6:00-9:00 PM

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.
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: