CURRENT TRENDS IN TEACHING DESIGN-THINKING IN MEDICAL SCHOOLS, AND OUTCOMES FROM THE UT SOUTHWESTERN BIOMEDICAL INNOVATIONS PROGRAM

by

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ABSTRACT

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Background*: With the proliferation of new medical technologies and the emergence of career clinician innovations, many major American medical centers have recognized the need to foster innovative thinking amongst their students. To this end, several medical schools have integrated design-thinking and innovation initiatives into their curriculum. UT Southwestern's Biomedical Innovations (BI) program is one such initiative.*

Objective*: This thesis project seeks to explore the current landscape of teaching biomedical technology innovation in medical schools, as well as the efforts, outcomes, and next steps of UT Southwestern's own Biomedical Innovations program.*

Methods*: The Biomedical Innovations program encompasses a pre-clerkship enrichment elective, a Scholarly Activity in Biomedical Innovations, and an optional Distinction in Biomedical Innovations. Program success is measured by student participation, faculty participation, and post-course surveys. Additionally, recent UT Southwestern graduates who previously completed an innovation course were surveyed to assess their comfort with the core competencies of design-thinking.*

Results*: Since 2011, over 140 students have completed a pre-clinical innovation enrichment elective; after finishing the course, 39 of those students chose to remain involved as student facilitators. Post-course survey data shows that the majority of students either strongly agree or agree that they have a better understanding of biomedical innovation after finishing the course. This data also identifies course organization as an area for improvement. Recent alumni survey data indicates comfort with the core principles of biomedical innovation amongst former students in clinical practice. Survey responses from former student facilitators show that working as a facilitator helped develop key leadership skills.*

Conclusion: *UT Southwestern's Biomedical Innovations program is in alignment with current trends in teaching design-thinking in medical schools. The consistent interest shown by the student body, the positive post-course survey results, and the influence the course has had on recent alumni demonstrate the success of the BI program. As faculty support and institutional memory continue to grow, the Biomedical Innovations program can prepare students to address the problems facing modern medicine with new and innovative technologies.*

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CHAPTER 1 – INTRODUCTION

The Need for Teaching Biomedical Innovation in Medicine

In 2011, a committee composed of members from the National Academy of Science, the National Academy of Engineering, and the Institute of Medicine was tasked to identify the actions necessary to ensure the United States remained a leader of scientific enterprise in the 21st century. Their report, entitled *Rising Above the Gathering Storm,* concluded that "a primary driver of the future economy…will be innovation, largely derived from advances in science and engineering."[1] This message has proven incredibly prescient; as disruptive technologies and products have flourished, medicine in America has fundamentally changed such that medical devices are commonplace. Many major American medical centers have recognized the need to foster innovative thinking; this is exemplified both by the formation of medical incubators designed to tackle problems in healthcare delivery, and the emergence of career clinician-innovators who dedicate their time toward the ideation and development of new technologies.[2,3] This commitment to innovation has prompted academic medical centers to reflect on their role in training the next generation of innovative physicians.[4] In order for physicians to thrive in the modern medical landscape, it will be imperative that academic medical centers integrate teaching in design-thinking and interdisciplinary problem-solving into formalized curricula. This thesis project seeks to explore the current landscape of teaching biomedical technology innovation in medical schools, as well as the efforts, outcomes, and next steps of UT Southwestern's own Biomedical Innovations program.

Background

While many interpretations of the word *innovation* exist, one succinct definition is "creativity with a purpose."[5] Within the realm of medicine, this can mean anything from product changes, process changes, or distribution changes that tackle the challenges of access, quality, and affordability.[6] High-impact examples can be found both in the realms of procedural device innovation (such as the invention of percutaneous coronary intervention in the 1970s) and digital technology innovation (the emergence of patient portals, such as MyChart, to provide higher quality out-patient care).[7] Despite the inherent uniqueness of individual inventions, many of the core steps involved in bringing these ideas to fruition are shared. This suggests the utility of a general education in biomedical technology innovation, wherein the process of inventing can be codified and taught.

The two main educational foci underlying teaching in innovation are design-thinking and entrepreneurship education.[4] The former has been well defined by product design programs within the field of engineering; in general, design-thinking courses focus on project based learning, wherein multidisciplinary teams identify a pressing clinical need, formulate an idea to solve that need, and engage in an iterative cycle of prototyping and testing to create a functional device. Further downstream in the innovation pathway is the need for a device or product to be commercialized, bringing its treatment benefit to a larger audience. This involves understanding regulatory steps necessary to bring a device to market, and the commercial steps needed to secure funding for the device. Understanding the entrepreneurship skills necessary for this transition is a vital aspect of biomedical technology innovation.

Within both processes exist several core competencies that effective clinician innovators must master. The textbook developed by Stanford's Biodesign program, "*Biodesign, the process*

of Innovating Medical Technologies" outlines these competencies as twenty-nine core-activities, including (but not limited to) "Needs Statement Development", "Stakeholder Analysis", "Market Analysis", "Ideation and Brainstorming", "Concept Screening", "Regulatory Basics", "Prototyping", "Marketing and Stakeholder Strategy", and "Business Plan Development".[8]

Outside of these competencies, several additional elements have been identified as important in supporting teaching in biomedical innovation. One is the need for interdisciplinary support, both to supplement medical practitioners with skills in engineering and business, and to introduce disruptive ideas that challenge traditional dogma. This often takes the form of a professionally diverse faculty body, composed of physicians, engineers, regulatory experts, and entrepreneurs. In a study evaluating attitudes toward interdisciplinary teaching in medicine, Spoelstra et al. suggests that courses in innovation could prepare future physicians to work in interdisciplinary teams later in their careers.[9] Another important element is the creation of a physical "innovation environment." This space allows innovators to interact and share ideas with one another, while also providing the tools necessary for the core steps of brainstorming and prototyping. Often this is manifest in "makerspaces", which provide the machining tools necessary for iterative prototyping.[10]

Current Landscape of Innovation Programs in Medical Schools

Institutions with programs focusing on teaching medical students biomedical technology innovation skills will subsequently be discussed to better characterize the current academic landscape. The programs currently described in the literature make use of various leadership and curricular structures in pursuit of their common goal of molding future clinician innovators.

One common approach is to offer an elective course in biomedical innovation to medical students in the preclinical phase of education. At Emory University School of Medicine, students can participate in the "Innovation and Entrepreneurship in Medicine Elective," a 3-month course tailored to second-year medical students. This student-organized course includes both a lecture series with guest-lecturers teaching the concepts of design-thinking and entrepreneurship as well as a project, wherein teams of three medical students evaluate a startup company. MBA students provide input on these projects, but are not formal team members. Course feedback showed that students were most likely to agree with the statement "I am interested in innovation and startups, and were least likely to agree with the statements "I understand regulatory and reimbursement aspects of health tech" and "I understand legal aspects of health tech".[11]

Another successful student-organized program is the University of Utah's "Bench To Bedside Program". This program takes the form of a yearlong design competition, wherein multi-disciplinary teams from University of Utah's schools of medicine, business, and engineering collaborate. Teams are formed each August during a social "kick-off" event, facilitating the sharing of ideas between students from all schools. Working with the University of Utah's Center for Medical Innovation, these teams are expected to explore clinical settings and determine an unmet clinical need for which they can develop a device solution. Throughout the year, teams participate in didactic workshops on topics such as idea generation, prior art search, prototyping, and venture capital; these workshops are taught by faculty across the University of Utah system. The program culminates in a formal competition night, in which a panel of faculty and community-members judge the created devices, and award a grand prize of $15,000 to the top team. Two self-identified strengths of this program are the ability to pull from diverse talent sets across a major university system, and the funding commitment from local

sponsors and entrepreneurs. In its first three years, the "Bench To Bedside" program had 207 student participants making up 45 teams; 39 provisional cover letter patents were filed, and 12 limited liability companies were formed.[12]

While the two examples above represent relatively shorter-term commitments (3-8 months), several academic medical centers have created longitudinal innovation programs that continue throughout the duration of medical school. A study published by Niccum et al. looked at such programs of longer duration in attempt to identify common curriculum and teaching methods. A total of 13 programs were identified among the 158 American allopathic medical schools, 10 of which have curriculum greater than 1 year in duration. Common shared elements included formal faculty leadership, the requirement of a capstone project, and formal recognition to graduates. Additionally, common educational methods of active learning and interdisciplinary teams were identified among each of these programs.[13]

One example is Sidney Kimmel Medical College's College within a College Design Track, or *JeffDesign*. The first design program in the United States specifically targeted toward medical students, *JeffDesign* is a 3.5-year track existing concurrent with the regular medical curriculum, and offers graduating students a formal certificate in design. The program is split into *Years One and Two*, in which students learn core principles of design-thinking through group workshops and modules, and *Years Three and Four*, in which students complete a design project. This curriculum has been recognized nationally by the American Medical Association, and several products and patents have emerged from this program.[14]

While the focus of this thesis is on innovation programs existing within the traditional four-year medical curriculum, it is important to note there are several independent biomedical innovation programs in existence. Johns Hopkins offers a one-year Masters of Science,

Bioengineering, and Design degree; while this program is primarily made up of engineering students, they are grouped with physicians from the Johns Hopkins School of Medicine, and the experience involves intensive medical immersion to better understand clinical needs. Students in this program work on two distinct projects, one focusing on healthcare needs in advanced markets, and a second focusing on low-resource settings. In its first four years, the program graduated 61 students and launched five startups.[15]

Special mention should be given to the Biodesign program at Stanford University. While Stanford does not appear to offer a formal design program within the medical student curriculum, the one-year Biodesign Innovation Fellowship is the cornerstone program of Stanford Biodesign, and arguably the academic medical innovation community at large. This program is available to physicians and engineers who have already obtained graduate degrees, and is suited for professionals seeking careers in innovation. The program begins with a "boot-camp" focusing on didactic lectures and a "mini-project," prior to an intensive clinical immersion period where unmet clinical needs are identified. Fellows spend the remainder of the training focusing on iterative prototyping under the mentorship of real world health-technology innovators and executives. In its first 12 years of existence, graduates from this program have gone on to establish 26 companies, with an estimated impact on hundreds of thousands of patients.[16]

In reviewing these programs, it is clear that instruction in innovation is beginning to take hold in medical education. The ideas and aspirations of these initiatives have informed the Biomedical Innovations program at UT Southwestern, the goal of which is to provide students with a systematic approach to the exploration, design, and implementation of new biomedical technologies.[17]

CHAPTER 2 – METHODS

History of Innovation Programs at UT Southwestern

The Biomedical Innovations (BI) program represents the culmination of several years of curriculum development in the field of innovation at UT Southwestern. Starting in 2008 as the Innovating Healthcare Solutions (IHS) pre-clerkship enrichment elective, this program has focused on exposing medical students to the process of standardized design-thinking through hands-on, active learning experiences.[18] Born out of a recognized need for fostering skills in creativity and service, this elective contained pathways focused on product design, global health, and community health innovations. The elective spanned 8 months and featured a series of didactic lectures taught by a combination of UT Southwestern faculty and local leaders in the fields of engineering and business. Concurrently to the lecture series, students were expected to complete a design project, in which they either prototyped a device or presented a public-health intervention in response to a clinical need. Originally, clinical needs were identified and refined by students within in the course. However, this step was found to be time intensive and difficult to complete in an extra-curricular elective alongside the time commitment of the medical school curriculum. Thus, a complementary Clinical Needs Finding enrichment elective was created, wherein students involved in research and shadowing projects over the summer could submit clinical needs to course facilitators electronically. Facilitators would then present these needs to the IHS teams in the fall for further development.

To understand the impact of IHS on the ultimate development of the BI program, it is important to note the culture of innovation built by student facilitators. Partnerships with engineering departments at University of Texas Arlington and University of Texas Dallas were established, allowing undergraduate engineering students to advise teams in the prototyping and

design stages. The Texas Manufacturing Assistance Center (an affiliate of UT Arlington) was also involved to provide expertise in the fields of regulatory processes and intellectual property. Health Wildcatters (a local healthcare startup accelerator) and UT Southwestern's Office of Technology Development were also involved in both shaping the curriculum and advising product teams. Through the creation of these partnerships, the IHS program created the interdisciplinary and cross-institutional collaborations necessary for promoting and teaching the concepts of design-thinking.

In its first seven years, the Innovating Healthcare Solution course found success among the student body. Successful projects from the product design track included *Endocaddy*, a sterile device that allows for organized storage of wires and catheters during endovascular surgery, and *Easy-C,* a device that assists in cesarean section deliveries by using an inflatable balloon to dislodge the fetal head when lodged in the birth canal.[19,20] Additionally, student feedback was very positive for the project-based teaching and for the opportunity to learn about a process outside of the typical medical curriculum. However, certain obstacles were encountered with the IHS course design. After finishing the course, interested students who wished to continue their projects lacked formal support and mentoring. Additionally, despite the implementation of the Clinical Needs Finding enrichment elective, students still had difficulty finding a clinical need substantial enough to sustain a worthwhile design project. Finally, despite partnerships within UT Southwestern, the course was primarily student-led. While this structure allowed the curriculum to adapt quickly to student needs, the changing time-commitments of medical students led to an inconsistent quality in the educational product. While the IHS course succeeded in its goal of exposing medical students to the basic concepts of design-thinking, there

was an opportunity to expand the program to serve students seeking additional experiences and training in innovation.

Such an opportunity arose with the implementation of a new curriculum at UT Southwestern in the fall of 2015, entitled "The Foundation for Excellence Curriculum." This new curriculum shortened the Pre-Clerkship period from two years to eighteen months, divided into three six-month semesters (PCI, PCII, and PCIII). Additionally, students were given a twelve-week block during their 18-month Clerkship period to complete a Scholarly Activity. This aspect of the curriculum was implemented with the goal that "a required Scholarly Activity, under the guidance of a faculty mentor, fosters students' analytical skills, enhances self-directed learning and oral and written communication skills, and ultimately trains students to be better physicians."[21] While traditional scholarly activities in basic and translational research were proposed, the need for non-traditional options to accommodate a wider range of student interests was appreciated. This lead to the creation of scholarly activities in fields such as medical education, community medicine, quality improvement, and global health. Seeing this curriculum reform as an opportunity to expand the scope of teaching innovation at UT Southwestern, the IHS student leadership elected to reorganize into Biomedical Innovations, a longitudinal program with a capstone Scholarly Activity.

Biomedical Innovations Program Overview

The Biomedical Innovations program at UT Southwestern is designed to be an in-depth longitudinal experience that focuses on both didactic teaching of innovation skills and active learning through design projects.[22] Per the Biomedical Innovations master planning document, the mission statement of the program is "to teach medical students the critical thinking skills,

communication tools, and technical resources necessary to address a healthcare need by inventing a new device or system that improves outcomes."[23] We believe that through this program, we will not only give students the resources and support necessary to become clinician innovators, but also foster a culture of innovation among the greater UT Southwestern community. Key outcomes to assess the success of the program include student participation in the program, as well as participant surveys and feedback.

The track begins with the Introduction to Biomedical Innovations pre-clerkship enrichment elective, a two-semester course taken during the PCI and PCII semesters. Student facilitators are identified by the end of the first semester, and are expected take on a leadership and mentoring role as they coordinate the elective during their PCIII period. During the Clerkship period, students interested in continuing to pursue the program are encouraged to utilize clinical needs finding skills taught in the enrichment elective to identify needs and develop problem statements. The Scholarly Activity is embedded in the 18-month Clerkship period, during which students can pursue a Scholarly Activity project in Biomedical Innovations. This is a twelve-week period, wherein students shepherd their own design project from conception to completion. Students wishing to continue work on their project after completion of their Scholarly Activity block may devote additional time during the Post-Clerkship period. If the project is deemed worthy, the student can receive a formal "Distinction" in Biomedical Innovations upon graduation. To help with the prototyping and device testing required for an iterative design process, a formal Makerspace has been established on the UT Southwestern South Campus. This Makerspace provides design teams access to 3-D printing and machining tools, and provides the Biomedical Innovations program a physical home on campus.

Methods of Instruction

The Introduction to Biomedical Innovations course is offered as an enrichment elective during the Pre-Clerkship period. Class size is historically approximately 20 students, though the minimum and maximum allowed are 10 and 65. Teaching in this course is done through a lecture series featuring UT Southwestern faculty, as well as prominent members of the local innovation community. Alongside the didactic portion of the class is the expectation to complete a team-based design project, allowing for active, hands-on learning.

In the Biomedical Innovations Scholarly Activity, education is provided via interactions with a project mentor, as well as engineering faculty and students. Prior to the start of the Scholarly Activity period, students are expected to meet with the track director to identify potential projects and submit a project proposal; this allows the twelve-week period to be dedicated to concept generation, prototype design, and presentation of the work. While students who have completed the Introduction to Biomedical Innovations enrichment elective are encouraged to participate in the Scholarly Activity, completing the enrichment elective is not a pre-requisite for the Scholarly Activity.

While no formal Biomedical Innovations elective is currently offered in the Post-Clerkship period, students may continue their work for class credit as part of the "Direct Research" elective. In this course, students receive instruction through interactions with their project mentors, and are required to submit a formal summary of their work after 4 weeks.

Requirements for Distinction in Biomedical Innovations include a written thesis and an oral presentation of cumulative work. Students are guided through these steps by a self-selected thesis committee, which includes a minimum of three UT Southwestern faculty members.

Introduction to Biomedical Innovations Enrichment Elective – Curriculum and Structure

The Introduction to Biomedical Innovations course is offered as a pre-clerkship enrichment elective during the PCI and PCII periods. The only pre-clerkship enrichment elective to span two semesters, this course provides an in-depth exposure to the principles of innovation and entrepreneurship, and is open to all pre-clerkship students. Like the IHS course, Introduction to Biomedical Innovations is primarily facilitated by pre-clerkship students who have completed some or all of its curriculum. In contrast to the IHS model, faculty support has been formalized, with regular progress reports to program leadership within the UT Southwestern faculty. This hybrid model allows students to gain valuable administrative and leadership skills as course facilitators, while also providing institutional support and year-to-year consistency. Additionally, student facilitators are allowed creative license to modify and grow the elective, reinforcing student buy-in and ownership within the program.

The didactic portion of the class is presented via a series of one-hour small group lectures. Concurrent with the lecture series, students are expected to meet milestones regarding their design project. Specific lecture topics with learning objectives, as well as design project assignments, are presented below. It is worth noting that these objectives represent the cumulative work of many years of student facilitators, and make up the living document that is used to guide the course:

PCI SEMESTER

Session 1: Introduction to Biomedical Innovation

- Provide a brief overview of the course goals and expectations
- Describe and define innovation and the common traits of innovators
- Use examples of past projects to explain how needs are discovered and addressed
- Explain the mentor-mentee relationship and shadowing experiences
- Introduce available clinical needs and survey student interest in each

Assignments: Students will complete the clinical needs survey online to be placed into teams and receive mentor assignments. Students should also register for the course on Moodle.

Session 2: Clinical Needs Finding

- Introduce the fundamentals of needs-finding
- Understand the relationship between an observation, a problem, and a need
- Know the three parts of a need statement: problem, population, and outcome
- Understand that need statements are solution-independent
- Appreciate the importance of unbiased observation and thick descriptions
- Understand the importance of background research before problem-solving

Assignments: Student teams will contact their assigned mentor to establish a meeting time within the next two weeks. At this meeting, students should seek additional context to understand the clinical need and gain an appreciation for the currently utilized approaches used by physicians or patients to solve the problem. Students are also encouraged to request shadowing opportunities that help demonstrate and clarify the clinical need.

Session 3: Team Dynamics and Project Planning

- Learn the benefits of having teammates from different backgrounds and perspectives
- Address the need for accountability to the team
- Explore the role of communication tools (e.g. GroupMe, Wunderlist) in group organization
- Learn how to break down deliverables into small manageable pieces and assign them appropriately based on team roles
- Team Activity: Teams compete to design and build a 3-dimensional structure using an unorthodox set of rules provided by the speaker. The activity is made challenging by limited resources and other restrictions on communication and team roles.

Assignments: Students continue scheduling shadowing experiences to understand their clinical need, including the scope, constraints and impact.

Session 4: Need Statements/Innovation Corps

- Learn how to write and refine need statements from the problems identified while shadowing
- Confirm that need statements are solution independent
- Practice 'up-scoping and down-scoping' to obtain a need statement that is neither too narrow nor too broad
- Learn research strategies and how to use databases for the purpose of understanding the terminology, technology, physiology, and economics of the need
- Team Activity: Teams will be given a few blank 'Need Scope Pyramid' forms and asked to fill them out with varying renditions of the needs that they have identified.

Assignments: Teams should meet to discuss observations from shadowing and develop a needs statement that appropriately describes their assigned clinical need.

Session 5: Stakeholder Analysis and Scope of Invention

- Define stakeholders: anyone who has a stake in the outcome of the problem you are studying.
- Understand the importance of designing a solution which will substantially alter the outcome for a population experiencing the need/problem
- Ensure that the barriers to using a solution must not be too high: stakeholders should want to adopt your solution
- Learn how to perform a cycle of care analysis
- Recognize that patients, caregivers, hospitals, companies, and even governmental bodies all have a stake in solutions

Assignments: Teams should begin meeting with the specific purpose of developing preliminary solutions to the assigned clinical need.

Session 6: Idea Generation and Note Taking

- Be aware of the aspects of an appropriate brainstorming environment: brainstorming sessions emphasize quantity of ideas and free flow and avoid judgment
- Learn some tools and techniques to use for brainstorming, such as generalizing the problem to identify similar problems and established solutions
- Learn how to process the ideas generated in a brainstorming session (idea clustering, dot voting)
- Learn about methods for keeping notes on your ideas

Assignments: Teams should continue meeting to develop preliminary solutions to the assigned clinical need. Record all reasonable solution approaches in preparation for the Fall Needs-Finding and Solutions Presentation.

Session 7: Intellectual Property Considerations

- Learn how to protect your ideas at UT Southwestern and at the national level
- Know the definitions of intellectual property and patents
- Become familiar with the different types patents
    - Utility, design, plant, etc.
- Understand the importance of patenting your ideas
- Understand the requirements of patentability
    - Utility, novelty, obviousness
- Learn how to conduct a patent search
- Learn the process of filing a patent (with examples)

Assignments: Teams should continue brainstorming and honing solution concepts for the Fall Needs-Finding and Solutions Presentation. Also begin discussing whether patent protection is a necessary step in the development and commercialization of your solutions.

Session 8: Prior Art Searching

- Learn the available resources to research pre-existing patents and inventions
- Develop a sense for the organization of patent materials by classification
- Identify the classifications (IPC, UPC, etc.) that are most fitting for your solutions

- Understand the content of patent materials and how to read them for the purpose of determining the patent eligibility of your own solutions

Assignments: Teams should conduct a prior art search to explore pre-existing solutions for their clinical need. Assemble a list of the most relevant and informative prior art for your team's solutions so that these resources may be used to anticipate good and bad design approaches in addition to anticipating patentability.

Session 9: Think Tank Day

- Report to K2.216 at noon for an introduction to the Biomedical Innovation Makerspace
- Learn the variety of equipment, tools, and rules of the Makerspace
- Meet with your team in the Makerspace to continue project activities

Assignments: Continue developing solutions concepts and begin brainstorming the materials that your team will require to build preliminary prototypes.

Session 10: Prototyping

- Define prototype and understand how it differs from a model
- Understand the purpose and uses of prototypes
- Identify 4 main prototype practicalities that must be planned prior to initial prototyping
    - Create product specifications/requirements, consider materials, prepare a budget, have a work timeline
- Understand the cyclic relationship between specifications and prototype design
- Understand the uses of different types of prototypes for different kinds of designs and be able to choose appropriately
- Become familiar with fabrication resources that are available at UT Southwestern
- Learn how to work with engineers and industrial designers in order to produce designs meeting design criteria
- Identify the basic techniques for low-fidelity prototyping
- Be able to determine and apply the relevant techniques for your project
- Understand the difference between breadth vs. depth in prototyping

Assignments: Teams should continue brainstorming prototype logistics, including design specifications, materials, budget and work timeline. Students are encouraged to utilize the BI Makerspace for prototyping.

Session 11: Think Tank Day

- Meet with teams in the Makerspace to continue project development
- Develop your team's slide deck presentation for the Session 12 Clinical Needs and Solutions Presentation

Assignments: Finalize slide deck presentations for Session 12: Needs Finding and Solutions Presentation.

Session 12: Needs Finding and Solutions Presentation

- 10-minute upper limit on each presentation
- 5-minute Q&A following each presentation
- Faculty and mentors will be in attendance

PCII SEMESTER (note: there are no formal assignments in this semester - teams are expected to continue work on their projects)

Session 1: Customer Validation for Healthcare Solutions

- Know the PDSA and DMAIC models for healthcare quality improvement initiatives
- Understand user studies, as well as cohort, case-control and randomized controlled trials
- Be able to determine appropriate variables and methods to measure them for your specific project

Session 2: Mini-Grants and Project Funding

- Understand common sources of grant funding for device research
- Be able to calculate the direct and indirect costs of a device research project
- Know the best practices for grant writing, including useful campus resources

Session 3: Market Analysis and Licensing

- Learn the benefits of anticipating the potential market and target markets
- Identify sources of market data and trends in the medical space
- Be able to determine the target market for your own specific project and approximate its size
- Understand the basics of an intellectual property license
- Identify appropriate potential licensees for your specific project

Session 4: Think Tank Day

- Work with your teammate to anticipate possible customer validation studies that will be required to validate your device
- Conduct a short review of market data for medical devices similar to your own
- Continue prototyping work-up

Session 5: Generating University Support for Advanced Device Development

- Know the campus resources and personnel that are available to assist prototyping, validation, IP securities and regulatory guidance
- Identify the specific contacts that relate to your specific project and hedge them to develop a support network for the project

Session 6: Start-Up Preparations and Financing

- Understand the characteristics of a market offering that create an opportunity for start-up success
- Know the components of a medical start-up team and expectations for the IP license
- Understand the sources of commercial research funding, including angel investors, venture capital and loans

Session 7: Think Tank Day

- Contact the support personnel from Session 5 who may be useful to the forward momentum of your project

- Continue prototyping work-up

Session 8: Regulatory Considerations for Medical Devices

- Understand the various FDA device classifications and anticipate the appropriate classification for your own device
- Develop the skill to estimate useful equivalents at the FDA
- Appreciate the cost and timeline for FDA trials of a medical device

Session 9: Solutions: From Concept to Reality

- Understand the pipeline to take a clinical need past prototype phase to generate commercial interest and engage FDA trials
- Know the general activities and best practices for testing a medical device in the clinical setting

Session 10: Think Tank Day

- Develop your team's slide deck for the Final Symposium
- Finish designing and assembling a demonstration model for the Final Symposium

Session 11: Final Symposium

- Each team will have 12 minutes to present their clinical need and prototyped solution
- Each presentation is allotted a 4-minute Q&A follow-up
- Judges will provide feedback on the need, solution, prototype, delivery and professionalism

Scholarly Activity in Biomedical Innovations – Curriculum and Structure

With the introduction of the "Foundations for Excellence" curriculum, all UT Southwestern medical students complete a Scholarly Activity during their Clerkship period.

Learning objectives for the Scholarly Activity in Biomedical Innovations are as follows:

- Learn to assess and validate unmet needs in the medical environment
- Understand market assessment and the competitive evaluation of existing technologies
- Understand techniques for analyzing and valuing intellectual property
- Gain an appreciation of the process for taking a medical device from invention to market
- Develop basic hardware and software prototyping skills
- Work as a team in a simulated startup environment[17]

Through this activity, the student applies the following iterative process of design-thinking; they must refine needs, formulate problem statements, evaluate existing solutions and their

shortcomings, determine the socioeconomic impact of the problem, generate and evaluate ideas, and create a functional prototype. Upon completion of the Scholarly Activity in Biomedical Innovations, students are expected to deliver a specific product, device, or patent.

Three months prior to the start of the student's Scholarly Activity period, interested students are expected to meet with the track director and program advisors to discuss specific interests, identify possible projects, and define clinical mentors. Two months prior to the start of the Scholarly Activity period, students submit a project proposal to the track director (*Appendix 1*).

For the dedicated Scholarly Activity period itself, time is spent applying the design-thinking process to their chosen project, including concept generation, business planning, and prototype design. Students are expected to meet with the project mentors during this time to ensure progress is being made. In week 10, students are expected to deliver a summary draft of their project to the track director for review. In week 12, students formally present their project to mentors, track leadership, and community leaders in innovation.

At the conclusion of the 12-week Scholarly Activity, each student submits a 5-10 page summary of their project detailing outcomes, recommendations, and lessons learned. While students are encouraged to submit their findings to conferences or for publication, this is not a formal requirement. The final paper is graded according to guidelines established across all Scholarly Activity tracks; a holistic grade of Pass or Fail is assigned based on the student's cumulative work.

Distinction in Biomedical Innovations

While every UT Southwestern student is expected to complete a Scholarly Activity project as part of the "Foundations for Excellence" curriculum, those seeking to "distinguish

themselves in their scholarly pursuits above and beyond" the base curriculum may complete a formal Distinction program.[24] These are offered in each of the Scholarly Activity disciplines, and students who complete the tracks are recognized at graduation with the degree of "Doctor of Medicine, with Distinction in" their chosen field.

As the first students eligible to obtain a "Distinction in Biomedical Innovations" in the new curriculum will not graduate until 2019, the exact requirements for Distinction are defined but untested. The proposed process is as follows: applications for Distinction are due by January 1st of the year preceding graduation; they must include plans for Scholarly Activity, as well as a timeline to complete the additional Distinction requirements. Also included in this application are a proposed thesis committee and an updated CV highlighting activities relevant to the BI program. In each of the established Distinction tracks, students must complete twenty-four weeks of full-time work in their chosen discipline. This can be done by completing the Introduction to Biomedical Innovations enrichment elective (counting for 8 weeks), a twelve-week Scholarly Activity, and a four-week independent research elective in the fourth year.

In addition to the dedicated didactic time, Distinction students are required to submit a written thesis to their thesis committee, as well as present their work at a campus wide conference. Theses in all Distinctions are required to be at least 30 pages, and should include project rationale, methods, results, and conclusions. Due to the inherent project-based nature of biomedical innovation, theses are encouraged to take the form of a business plan or in-depth study of a student invention. In this format, students can explore the clinical need addressed by the project, the prototyping process they underwent, the market forces and stakeholders that shape such a product, and their plan for taking the product to a greater consumer market.

Evaluation of the Biomedical Innovations Track

As we approach the first opportunities for students to pursue advanced instruction in innovation, it is instrumental that we have tools to measure the success of the program. One metric to measure the strength of the program is the level of student and faculty participation over the years. Additionally, end-of-course survey data on the Innovating Healthcare Solutions and Introduction to Biomedical Innovations pre-clerkship enrichment electives has been collected for several years. These surveys are anonymous, and make use of a five point Likert Scale; a response of strongly agree is scored 5 points, while strongly disagree is scored 1 point. Students are also encouraged to submit free-response comments as part of their survey; these comments were also reviewed.

Given the history of innovation programs at UT Southwestern, there are several individuals who have been involved in these programs as medical students who are now practicing physicians. To evaluate the impact innovation training has had on their current careers, recent UT Southwestern graduates who completed the IHS program were asked to complete a survey outlining their comfort with the core competencies of design-thinking, as well as their future career goals (*Appendix 2 & Appendix 3)*. These surveys feature Likert scale-surveys as described above, as well as opportunities for free response.

CHAPTER 3 – RESULTS

Student Participation

Records dating to 2011 show that innovation programs at UT Southwestern have enjoyed continued student participation. Course records show that over 140 students have completed a pre-clerkship elective in innovation (either Innovating Healthcare Solutions or Introduction to Biomedical Innovations). Additionally, 39 of those students elected to take on leadership roles as student facilitators. Individual class rosters sizes from each semester of the course are available starting in 2014, and are presented in *Table 1*.

In its first year, the Scholarly Activity in Biomedical Innovations was completed by 3 students. Each of these students had previously completed the Introduction to Biomedical Innovations enrichment elective. Three more students are currently scheduled to complete the Scholarly Activity in the upcoming academic year. Additionally, current participants in the Biomedical Innovations pre-clerkship elective were asked if they plan to pursue the Scholarly Activity in Biomedical Innovations; 2 students "strongly agree" with this statement, and 4 students "agree" with this statement.

Regarding the Distinction in Biomedical Innovations, each of the 3 students who have previously completed the Scholarly Activity plan to complete the Distinction requirements.

Faculty Participation

Until the most recent iterations of the course, faculty participation in innovation programs has varied on a year-to-year basis. However, for the 2017-2018 Introduction to Biomedical Innovations enrichment elective, a survey was designed to compile a list of faculty physicians who could provide clinical needs and mentor student design teams (*Appendix 4*). After being

approved by the UT Southwestern Deans Office, this survey was distributed to the entire faculty body. This survey yielded 21 unique responses; each of these responders then received a follow-up email to clarify their goals within the program. From this process, 12 faculty mentors were chosen to have their ideas further developed, and to serve as mentors for student design teams.

Post-Course Survey Data

Post-course survey data exists for the pre-clerkship innovation enrichment electives from 2014 to present. Regarding the 2014-2015 course, nineteen students completed a nine question Likert Scale survey. When asked if "The course met the learning objectives stated in the syllabus," 31.6% of students expressed they strongly agree, and 52.6% of students expressed they agree (mean = 4.16, SD = 0.68). Additionally, 47.4% of students strongly agree that they "would recommend this elective to future students," and 36.8% of students agree they would recommend the course (mean = 4.21, SD = 0.97). The lowest rated element of the course was its organization (mean = 3.39, SD = 1.24). The remainder of the results can be found in *Table 2*. Free response survey comments note that a strength of the 2014-2015 course was the opportunity for small-group work, while course organization was noted as an area for improvement.

Regarding the 2015-2016 course, twenty-one students completed the end-of-course survey. An additional question was added to this year's survey; 52.4% of respondents strongly agreed with the statement "I am more familiar with and have a greater understanding of Biomedical Innovation," while 47.6% of students agreed with this statement (mean = 4.52, SD = 0.51). Again, the majority of students either strongly agreed (57.1%) or agreed (28.6%) that they would recommend this elective to future students (mean = 4.38, SD = 0.86). Course organization continued to be one of the lowest rated components (mean = 3.95, SD = 1.20). The remainder of

the results can be found in *Table 3*. Qualitative free response comments note the strengths of the program to be course speakers, interactive lessons, and the opportunity for hands-on work with new ideas. Areas for improvement included organization, structured project mentoring, and project selection.

Regarding the 2016-2017 course, fourteen students completed the end-of-course survey. The majority of students either strongly agreed (50%) or agreed (35.7%) that they were more familiar with Biomedical Innovation (mean = 4.36, SD = 0.74). Class organization in the course was evaluated slightly higher this year, with 35.7% strongly agreeing and 42.9% agreeing that the "course and its various components were well organized" (mean = 4.14, SD = 0.77). The remainder of the results can be found in *Table 4*. Free response comments noted strengths to be the freedom to pursue individual projects, while the process of finding a clinical need worthy of a project was cited as a weakness.

Survey Data from Recent Alumni

Through analysis of past class rosters, a total of 94 recent UT Southwestern graduates who had taken the IHS enrichment elective were identified. With the help of the Office of Alumni Affairs, these former students were invited to participate in an electronic survey via email, asking if their involvement in the elective prepared them to use certain innovation core competencies in their current positions. 27 of the 94 graduates had also served as course facilitators, and received a slightly different survey containing questions assessing leadership growth. Additionally, alumni were asked if there were currently involved in medical device development.

A total of 10 responses were collected, 5 from former students, and 5 from former facilitators. 80% of respondents are currently in residency training programs, while 20% are involved in post-residency careers. Regarding future career goals, 40% of respondents plan to pursue careers in academic medicine, another 40% plan to pursue private practice, and 20% plan to pursue a career in consulting or entrepreneurship. Of the 10 respondents, 2 noted that they are "currently involved in medical device development, biomedical innovation, or healthcare startups," while 3 reported that they would like to be involved in these activities, but were limited by time and available opportunities.

When asked about the relevance of the skills they learned in IHS to their current positions, the majority of the respondents believed the skills to be relevant (mean = 3.9, SD = 0.87). Regarding comfort with the core competencies of biomedical innovation, respondents felt they were best prepared to utilize skills in clinical needs finding (mean = 3.8, SD = 0.78) and giving presentations (mean = 3.88, SD = 0.78). Conversely, the core competencies that scored the lowest were prototyping (mean = 3.22, SD = 0.44) and writing a business plan (mean = 3.22, SD = 1.09). Interestingly, scores from former facilitators were higher than former students in all core competencies, with the exception of brainstorming/idea generation and cultural sensitivity. Full results of this survey are summarized in *Table 5*.

In the former facilitator group, the majority of responses regarding development of leadership skills were either strongly agree or agree. The highest scoring skill was "communicating with faculty" (mean = 4.88, SD = 0.40), while the lowest scoring skill was "managing group finances" (mean = 4, SD = 1). Full results of this survey are summarized in *Table 6*.

Table 1: Course enrollment data for the pre-clerkship enrichment electives "Innovating Healthcare Solutions" and "Introduction to Biomedical Innovations".

Course Enrollment Data		
Course		Number of Students Enrolled
Innovating Healthcare Solutions	First Semester 2014-2015	28
	Second Semester 2014-2015	19
Introduction to Biomedical Innovations	First Semester 2015-2016	22
	Second Semester 2015-2016	21
	First Semester 2016-2017	17
	Second Semester 2016-2017	14
	First Semester 2017-2018	22

Table 2: Survey data from the Innovating Healthcare Solutions Enrichment Elective conducted in the 2014-2015 academic year, including percentage of student responses (SA = 5, SD = 1), mean response, and standard deviation.

Innovating Healthcare Solutions Elective (2014-2015) Survey Data n=19	SA	A	N	D	SD	Mean	Standard Deviation
The course met the learning objectives stated in the syllabus.	31.6%	52.6%	15.8%	0.0%	0.0%	4.16	0.69
The course and its various components were well organized.	16.7%	38.9%	22.2%	11.1%	11.1%	3.39	1.24
The lecture(s) and group(s) helped me learn.	21.1%	52.6%	15.8%	10.5%	0.0%	3.84	0.90
The clinical relevance of the course material was apparent.	26.3%	57.9%	10.5%	5.3%	0.0%	4.05	0.78
The individual faculty members were effective teachers for the course.	26.3%	57.9%	10.5%	5.3%	0.0%	4.05	0.78
The length of each session was ideal.	26.3%	42.1%	26.3%	5.3%	0.0%	3.89	0.88
The length of each session fit well into my schedule.	31.6%	42.1%	15.8%	10.5%	0.0%	3.95	0.97
The group size was appropriate for the format of this elective.	47.4%	42.1%	5.3%	5.3%	0.0%	4.32	0.82
I would recommend this elective to future students.	47.4%	36.8%	5.3%	10.5%	0.0%	4.21	0.98

Table 3: Survey data from the Introduction to Biomedical Innovations Enrichment Elective conducted in the 2015-2016 academic year, including percentage of student responses (SA = 5, SD = 1), mean response, and standard deviation.

Introduction to Biomedical Innovations Elective (2015-2016) Survey Data n=21	SA	A	N	D	SD	Mean	Standard Deviation
The course met the learning objectives stated in the syllabus.	47.6%	47.6%	4.8%	0.0%	0.0%	4.43	0.60
The course and its various components were well organized.	42.9%	28.6%	14.3%	9.5%	4.8%	3.95	1.20
The lecture(s) and group(s) helped me learn.	42.9%	23.8%	19.0%	14.3%	0.0%	3.95	1.12
The clinical relevance of the course material was apparent.	52.4%	28.6%	19.0%	0.0%	0.0%	4.33	0.80
The individual faculty members were effective teachers for the course.	42.9%	42.9%	14.3%	0.0%	0.0%	4.29	0.72
The length of each session was ideal.	38.1%	33.3%	23.8%	4.8%	0.0%	4.05	0.92
The length of each session fit well into my schedule.	42.9%	33.3%	19.0%	4.8%	0.0%	4.14	0.91
The group size was appropriate for the format of this elective.	57.1%	33.3%	9.5%	0.0%	0.0%	4.48	0.68
I would recommend this elective to future students.	57.1%	28.6%	9.5%	4.8%	0.0%	4.38	0.86
I am more familiar with and have a greater understanding of Biomedical Innovation.	52.4%	47.6%	0.0%	0.0%	0.0%	4.52	0.51

Table 4: Survey data from the Introduction to Biomedical Innovations Enrichment Elective conducted in the 2016-2017 academic year, including percentage of student responses (SA = 5, SD = 1), mean response, and standard deviation.

Introduction to Biomedical Innovations Elective (2016-2017) Survey Data							
n=14	SA	A	N	D	SD	Mean	Standard Deviation
The course met the learning objectives stated in the syllabus.	42.9%	50.0%	7.1%	0.0%	0.0%	4.36	0.63
The course and its various components were well organized.	35.7%	42.9%	21.4%	0.0%	0.0%	4.14	0.77
The lecture(s) and group(s) helped me learn.	42.9%	35.7%	14.3%	7.1%	0.0%	4.14	0.95
The clinical relevance of the course material was apparent.	35.7%	35.7%	28.6%	0.0%	0.0%	4.07	0.83
The individual faculty members were effective teachers for the course.	35.7%	57.1%	7.1%	0.0%	0.0%	4.29	0.61
The length of each session was ideal.	50.0%	50.0%	0.0%	0.0%	0.0%	4.50	0.52
The length of each session fit well into my schedule.	71.4%	28.6%	0.0%	0.0%	0.0%	4.71	0.47
The group size was appropriate for the format of this elective.	71.4%	28.6%	0.0%	0.0%	0.0%	4.71	0.47
I would recommend this elective to future students.	57.1%	35.7%	0.0%	0.0%	7.1%	4.36	1.08
I am more familiar with and have a greater understanding of Biomedical Innovation.	50.0%	35.7%	14.3%	0.0%	0.0%	4.36	0.74

Table 5: Compiled survey data from alumni on the effectiveness of the Innovating Healthcare Solutions Enrichment Elective, including average responses (strongly agree = 5, strongly disagree = 1) and standard deviations from all respondents, former students, and former facilitators.

IHS Former Student and Facilitator Survey Data – Innovation Skills	All Respondents n=10		Former Students n=5		Former Facilitators n=5	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
The skills I learned through my involvement in IHS have been relevant in my current position.	3.90	0.88	3.60	0.89	4.20	0.84
My involvement in IHS has prepared me to use the following Biomedical Innovation skills in my current position:						
Clinical Needs Finding	3.80	0.79	3.60	0.89	4.00	0.71
Writing Needs Statements	3.44	1.01	2.80	0.45	4.25	0.96
Market and Stakeholder Analysis	3.63	0.92	3.25	0.50	4.00	1.15
Brainstorming/Idea Generation	3.70	0.95	3.80	1.10	3.60	0.89
Prototyping	3.22	0.44	3.25	0.50	3.20	0.45
Writing a Business Plan	3.22	1.09	2.60	0.89	4.00	0.82
Regulatory Process	3.44	0.73	3.20	0.45	3.75	0.96
Presentation Skills	3.89	0.78	3.60	0.89	4.25	0.50
Group Dynamics	3.67	0.87	3.60	0.89	3.75	0.96
Cultural Sensitivity	3.75	0.71	3.75	0.96	3.75	0.50

Table 6: Survey data assessing development of leadership skills amongst former facilitators, including percentage of student response (SA = 5, SD = 1), mean response, and standard deviation.

IHS Former Facilitator Survey Data – Leadership Skills n=5	SA	A	N	D	SD	Mean	Standard Deviation
Being a IHS course facilitator has better prepared me to do the following in my current role							
Write Lesson Plans	50%	25%	0%	25%	0%	4.00	1.41
Mentor Students	60%	40%	0%	0%	0%	4.60	0.55
Communicate with Faculty	60%	40%	0%	0%	0%	4.60	0.55
Communicate with Administration	80%	20%	0%	0%	0%	4.80	0.45
Network with community leaders in your field	60%	40%	0%	0%	0%	4.60	0.55
Manage group finances	25%	25%	50%	0%	0%	3.75	0.96
Plan events	60%	40%	0%	0%	0%	4.60	0.55
Research Literature	40%	40%	20%	0%	0%	4.20	0.84

CHAPTER 4 – DISCUSSION AND FUTURE DIRECTIONS

In a recent report to Congress, the Medicare Payment Advisory Commission noted that total U.S. spending on medical devices in 2013 totaled $172 billion, and that the medical device industry was responsible for approximately 330,000 to 365,000 jobs in America. This report also notes that physicians are heavily involved in the development of new medical devices, both to help guide initial design of new products, and to solicit feedback on existing products.[25] As modern medicine becomes increasingly cross-disciplinary and reliant on technology, the modern medical school needs to prepare its medical students to not only exist, but thrive in this new landscape. By molding clinician innovators, academic medical centers can equip students with the skills needed to take advantage of emerging technology to solve complex healthcare problems with innovative, patient-centered solutions.[2] This opportunity explains the recent proliferation of innovation and entrepreneurship programs throughout American medical schools.[13] These programs are instrumental in not only providing students a problem-solving skillset they can use throughout their careers, but also in establishing a culture of innovation within the medical center. Most importantly, new inventions represent potential gains for patients. The Stanford Biodesign Innovation Fellowship alone claims that its inventions have directly affected more than 440,000 patients, with another 1,000,000+ patients aided by solutions initiated by program alumni.[26]

The BI program at UT Southwestern aims to expose students to the fundamentals of design-thinking, entrepreneurship, and innovation, as well as equip them with the skillset needed to address pressing needs in healthcare. While the Biomedical Innovations program was not identified in Niccum et al.'s review of innovation and entrepreneurship programs, it shares many characteristics with those initiatives.[13] Similarly to the programs described in the article, the BI

program enjoys leadership from a diverse set of faculty (UT Southwestern clinical faculty, Office of Technology and Development, UT Dallas Department of Engineering), is largely project-based, and puts heavy emphasis on active learning through hands-on product design. While it is difficult to determine student involvement in the full Biomedical Innovations program due to its recent implementation, involvement of the student body in the Introduction to Biomedical Innovations enrichment elective appears to be similar to the national median; approximately 9% of the UT Southwestern student body is involved in the course (~20/~240), compared to the national median of 7%.

While the Biomedical Innovations program is in-line with current trends in teaching design-thinking in academic medical centers, there are notable elements that set the program apart. While the BI program relies heavily on faculty support for product mentorship and expert teaching, the Introduction to Biomedical Innovations pre-clerkship elective has been entirely designed and led by medical student facilitators. Knowing the needs of their classmates, these student facilitators can design a curriculum that has been rated to be clinically relevant and well suited to student schedules. These students tend to have interest in product design (as evidenced by former facilitator survey responses), and are able to develop leadership skills while furthering their own education in innovation. This form of peer-teaching has been utilized in other aspects of medical education, to similar positive effects.[27] Survey data supports this conclusion, as former facilitators agreed that the skills they learned in program were relevant to their current careers, and that their involvement in the course helped grow key leadership skills. One potential disadvantage to student leadership is class organization, which has consistently received the lowest ratings on class surveys. This lack of organization is partially due to quick changes in leadership, as it can be difficult for past facilitators to communicate information to the next

group. As student facilitators change each year, it is instrumental that a sense of institutional stability within the Biomedical Innovation program exists. Ideally, this stability is formed by dedicated faculty support, as well as in-depth curriculum documents to help ease transitions in student leadership.

Overall, the Biomedical Innovations program has found success at UT Southwestern. Each iteration of the pre-clerkship enrichment elective has enjoyed significant student interest and participation. From 2014 to present, between 14 and 21 students have completed the enrichment elective each year, and approximately 4 students each year choose to help shape the culture of innovation at UT Southwestern as student facilitators. It is worth noting that each year sees a slight decrease in student participation between the first and second semester; possible explanations for this decrease include increased rigor of the medical school curriculum in the PCII semester, or possible refining of student interests after the first few months of medical school. Additionally, the Introduction to Biomedical Innovations course does involve a greater time commitment than most other enrichment electives; it is possible that some students drop the course upon recognition of this time commitment. Despite this attrition, those who complete the course tend to score it highly on post-course surveys. Students continue to report that the class succeeds in meeting its learning objectives, and that the course is clinically relevant. One free response comment from the 2014-2015 class reads, "In no other elective can you find such a great combination of clinical experience and innovation." While organization continues to be a weakness, the continuing work in improving the program's institutional memory aims to make improvements in this area.

One theme that emerges from the free-response comments is an appreciation for the design project each student is expected to complete. One comment from the 2015-2016 class

cites an example of excellence in the elective as, "The interactive lessons...Having an elective where we actually applied ourselves and had to create and present something was extremely rewarding." Traditionally, the pre-clerkship medical school curriculum is primarily composed of didactic lectures, with limited opportunities for active learning. This stands in stark contrast to the clinical curriculum, in which experiential learning is fundamental to clinical rotations. This transition from classroom learning to experiential learning is often seen as a major transition in the growth of a medical student.[28] By providing pre-clerkship students early exposure to a hands-on learning environment, it is possible that the BI program is preparing students for the experiential learning that will come to define their future careers. Moving forward, it will be interesting to assess if participation in the Biomedical Innovations program has a measurable impact in helping students transition to the experiential learning of the clinical curriculum.

While the pre-clerkship enrichment elective has seen wide participation, the Scholarly Activity and Distinction in Biomedical Innovations programs have been pursued by a smaller, yet passionate, group of students. Feedback from students previously eligible to pursue these activities show that two deterrents are the lack of a worthy project, and an unclear path to mentorship. However, it is possible that both obstacles will become less onerous with the implementation of the faculty survey in the 2017-2018 enrichment elective class. By identifying faculty mentors who have a clinical need they are passionate about, this survey may provide students with the projects and support needed to pursue successful Scholarly Activity and Distinction projects.

Another limitation worth considering going forward is the method by which the program is evaluated. Currently, the Introduction to Biomedical Innovations elective is evaluated at the end of the course with a survey using a 5-point Likert scale. While this information is helpful in

guiding the global direction of the course, it does not provide insight on whether individual courses within the curriculum are well received. Moving forward, it will be beneficial to supplement the end of course survey with surveys following each class; this will allow facilitators to determine which core competencies in innovation are being well conveyed, and which could be improved. Additionally, there is no readily available data detailing the number of successful products and patents the BI program has produced. While conflicts regarding intellectual property complicate this matter, data on patent production would be worthwhile in justifying continued support for the program. Given the potential reliance on patents as evidence of productivity for academic clinician-innovations, this could be particularly important in future years.[2]

While the success and career direction of students who have completed the Biomedical Innovations program are an excellent potential measure of program success, the limited response to the IHS Former Student and Facilitator surveys illustrates the difficulty in obtaining this data. While the responses received give insight into the goals of program alumni, it is difficult to justify making changes to the current program structure based on this small sample size. One potential reason for the limited response is that the majority of program alumni are currently involved in residency training programs. The time-intensive nature of these programs likely limits one's ability to respond to surveys. Additionally, as these programs are heavily clinical, it is possible that some program alumni who wish to ultimately pursue careers in entrepreneurship or device development are unable to do so while in training. To this end, it would be valuable to survey program graduates following completion of their clinical training to see if their attitudes toward a career in innovation have changed.

In looking at the future of the Biomedical Innovations program at UT Southwestern, there are a few additions that could prove invaluable for years to come. First, while students have access to the Stanford Biodesign textbook, no formal syllabus exists for UT Southwestern's Biomedical Innovations program. Course facilitators are pursuing the creation of a formal syllabus; this document would expand upon the learning objectives currently outlined in the curriculum, while also explaining how to best utilize resources unique to UT Southwestern throughout the design process. This document could be used as a reference for students as they progress through the program, and support the program's institutional memory. Additionally, as no students have yet completed the Distinction in Biomedical Innovations, the program's structure is untested. While deliverables from previously established Distinction tracks, such as clinical research, are available online, no such information yet exists for Biomedical Innovations. It is possible that this lack of visibility is responsible for the program not being included in Niccum et al.'s review of medical school innovation programs. Moving forward, it will be valuable to define the exact expectations associated with the Distinction in Biomedical Innovations, and to have these expectations visible for review.

In summary, the Biomedical Innovations program at UT Southwestern represents an exciting opportunity for medical students interested in innovative technologies and device development to develop the skillset needed to become successful clinician innovators. These students are not only taught the fundamentals of design-thinking and entrepreneurship, but also challenged to apply their knowledge to solve real-world clinical problems. To date, the program has succeeded in encouraging the growth of innovators at an early stage of their careers, and will no doubt continue to do so thanks to the support of UT Southwestern's growing innovation community. Ultimately, the Biomedical Innovation program, and others like it, will produce

physicians able and eager to tackle the problems facing modern medicine, and create technologies that provide benefits to their patients.

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APPENDIX 1 – SCHOLARLY ACTIVITY PROJECT PROPOSAL FORM

Scholarly Activity Project Proposal
Biomedical Innovation

Student must have mentor review and sign this form once completed

IDENTIFYING INFORMATION

STUDENT:		STU ID:	
FACULTY MENTOR:		BLOCK/DATES:	
MENTOR DEPT.		ADMINISTRATIVE ASSISTANT TO MENTOR (IF APPLICABLE):	

PLEASE LIST COLLABORATORS	ROLE (MED STUDENT/ RESIDENT / ENGINEER / ENTREPRENEUR)	CONTACT INFORMATION

**THIS AREA IS FOR OTHERS WHO MIGHT HAVE ALSO WORKED ON THIS PROJECT*

PLEASE NOTE: WE WILL WORK TO MATCH YOU WITH TECHNICAL AND BUSINESS MENTORS IF NEEDED

PROJECT INFORMATION

PROPOSAL IS FOR A NEW PROJECT ☐ THIS STUDENT WILL JOIN AN EXISTING PROJECT ☐

PROJECT TITLE	
IRB OR IACUC	*Study #: (if appropriate)*
BACKGROUND	*Describe the clinical need you are trying to address. How did you identify this need? Why is this an important area for new technology development or innovation?*
HYPOTHESIS/SPECIFIC AIMS	*In a single sentence, describe your proposed solution and how it addresses the need identified above. State the specific aims necessary during your scholarly activity to advance your proposed solution from idea to evaluated prototype (3-4 aims).*

DEVELOPMENT ACTIVITIES	*For each of the aims identified above, describe the specific task necessary to achieve each aim. Use words that lay practitioners will understand. What tasks will be your responsibility and what tasks will your mentor assist you with? What resources will you need to complete the work? Will you be conducting evaluation studies on new or existing technology? If so, how will you obtain data required to support your novel innovation? Will evaluation include clinicians, patients, or animals? If so, is there an IRB or IACUC study number associated with this project? About 150-200 words.*
POSSIBLE CONCLUSIONS/DISEASE RELEVANCE	*Summarize how proposed innovation fits into the context of existing clinical practice. Describe possible beneficiaries of the new technology/innovation and the value of this work on patient care or medical education/training. If applicable, also list any companies or types of companies that may have a commercial interest in the need you identified.*
PROPOSED TIMELINE OF GOALS AND OBJECTIVES	*DEADLINES WITHIN THE ROTATIONS THAT BOTH STUDENT AND MENTOR NEED TO MEET.* *WEEK 1- ORIENT TO DEPARTMENT* *WEEK 10- SEND DRAFT TO MENTOR* *WEEK 12- COMPLETE EVALUATION OF PROGRAM AND STUDENT* IN THE SPACE BELOW, PROVIDE A PRELIMINARY WEEKLY TIMELINE OF ACTIVITIES NECESSARY TO MEET THE DEADLINES ABOVE

During this elective, the mentor and student understand that the student is to spend a full time effort in actively working in the biomedical innovation setting. In order to get credit for this elective, the student will need to submit a final summary of the work done and the mentor will need to submit an evaluation of the student's progress.

Signatures		
	Student :	**Mentor:**

APPENDIX 2 – IHS FORMER STUDENT SURVEY

Innovating Healthcare Solutions - Former Student Survey

* Required

1. **Name** *

_____

2. **What was your position when you were involved as with IHS?** *
Mark only one oval.

- ◯ MD Candidate
- ◯ PhD Candidate
- ◯ MD/PhD Candidate
- ◯ Other: _____

3. **When did you take the IHS course?** *
Check all that apply.

- ☐ 2011-2012
- ☐ 2012-2013
- ☐ 2013-2014
- ☐ 2014-2015
- ☐ Other: _____

4. **Which track were you involved in?** *
Check all that apply.

- ☐ Medical Technology
- ☐ Global Health
- ☐ Community Health
- ☐ Other: _____

5. **Which of the following elements were present in the course when you were a student?** *
Check all that apply.

- ☐ Clinical Needs Finding
- ☐ Writing Needs Statements
- ☐ Markets and Stakeholder Analysis
- ☐ Brainstorming/Idea Generation
- ☐ Prototyping
- ☐ Writing a Business Plan
- ☐ Regulatory Process
- ☐ Presentation Skills
- ☐ Group Dynamics
- ☐ Cultural Sensitivity

Innovating Healthcare Solutions - Former Student Survey

6. **What is your current full-time employment?** *
   Mark only one oval.

   - ◯ Residency Program
   - ◯ Fellowship Program
   - ◯ Post-Doctoral Research Fellow
   - ◯ Consulting
   - ◯ Other: _____

7. **What is your ultimate career goal?** *
   Mark only one oval.

   - ◯ Practicing Physician - Academic Practice
   - ◯ Practicing Physician - Private Practice
   - ◯ Laboratory Research - Principal Investigator
   - ◯ Laboratory Research - Industry
   - ◯ Consulting
   - ◯ BioTech Industry
   - ◯ Other: _____

Innovating Healthcare Solutions - Former Student Survey

For each of the following statements, please rate your level of of agreement.

8. **The skills I learned through my involvement in IHS have been relevant in my current position:** *
   Mark only one oval per row.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
_	◯	◯	◯	◯	◯	◯

9. **My involvement in IHS has prepared me to use the following Biomedical Innovation skills in my current position:** *
   Mark only one oval per row.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
Clinical Needs Finding	◯	◯	◯	◯	◯	◯
Writing Needs Statements	◯	◯	◯	◯	◯	◯
Market and Stakeholder Analysis	◯	◯	◯	◯	◯	◯
Brainstorming/Idea Generation	◯	◯	◯	◯	◯	◯
Prototyping	◯	◯	◯	◯	◯	◯
Writing a Business Plan	◯	◯	◯	◯	◯	◯
Regulatory Process	◯	◯	◯	◯	◯	◯
Presentation Skills	◯	◯	◯	◯	◯	◯
Group Dynamics	◯	◯	◯	◯	◯	◯
Cultural Sensitivity	◯	◯	◯	◯	◯	◯

Innovating Healthcare Solutions - Former Student Survey

11. **What barriers have you encountered in getting involved in medical device development, biomedical innovation, or healthcare startups?**

Innovating Healthcare Solutions - Former Student Survey

12. **Please elaborate on your current involvement in in medical device development, biomedical innovation, or healthcare startups:** *

Innovating Healthcare Solutions - Former Student Survey

13. **Are you currently involved in a leadership role?** *

Mark only one oval.

- ◯ Yes *Skip to question 14.*
- ◯ No *Stop filling out this form.*

Innovating Healthcare Solutions - Former Student Survey

14. **Please elaborate on your current leadership role:** *

APPENDIX 3 – IHS FORMER FACILITATOR SURVEY

Innovating Healthcare Solutions - Former Facilitator Survey

* Required

1. **Name** *

_____

2. **What was your position when you were involved as with IHS?** *
Mark only one oval.

- ◯ MD Candidate
- ◯ PhD Candidate
- ◯ MD/PhD Candidate
- ◯ Other: _____

3. **When were you a course facilitator?** *
Check all that apply.

- ☐ 2011-2012
- ☐ 2012-2013
- ☐ 2013-2014
- ☐ 2014-2015
- ☐ Other: _____

4. **Which track were you involved in?** *
Check all that apply.

- ☐ Medical Technology
- ☐ Global Health
- ☐ Community Health
- ☐ Other: _____

5. **What was your facilitator title? (Marketing Director, MedTech Director, etc)** *

_____

6. **As a Course Facilitator, which of the following were you involved in?** *
Check all that apply.

- ☐ Writing lesson plans for the elective
- ☐ Mentoring student project groups
- ☐ Communicating with faculty advisors
- ☐ Communicating with UTSW administration
- ☐ Networking with community leaders in innovation
- ☐ Managing group finances
- ☐ Planning events (e.g. Innovation Symposium)
- ☐ Researching literature to plan curriculum
- ☐ Other: _____

7. **Which of the following elements were present in the course when you were a facilitator?** *

Check all that apply.

- [ ] Clinical Needs Finding
- [ ] Writing Needs Statements
- [ ] Markets and Stakeholder Analysis
- [ ] Brainstorming/Idea Generation
- [ ] Prototyping
- [ ] Writing a Business Plan
- [ ] Regulatory Process
- [ ] Presentation Skills
- [ ] Group Dynamics
- [ ] Cultural Sensitivity

Innovating Healthcare Solutions - Former Facilitator Survey

8. **What is your current full-time employment?** *

Mark only one oval.

- ◯ Residency Program
- ◯ Fellowship Program
- ◯ Post-Doctoral Research Fellow
- ◯ Consulting
- ◯ Other: _____

9. **What is your ultimate career goal?** *

Mark only one oval.

- ◯ Practicing Physician - Academic Practice
- ◯ Practicing Physician - Private Practice
- ◯ Laboratory Research - Principal Investigator
- ◯ Laboratory Research - Industry
- ◯ Consulting
- ◯ BioTech Industry
- ◯ Other: _____

Innovating Healthcare Solutions - Former Facilitator Survey

For each of the following statements, please rate your level of of agreement.

10. **The skills I learned through my involvement in IHS have been relevant in my current position:** *

Mark only one oval per row.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
_	◯	◯	◯	◯	◯	◯

11. **My involvement in IHS has prepared me to use the following Biomedical Innovation skills in my current position:** *

Mark only one oval per row.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
Clinical Needs Finding						
Writing Needs Statements						
Market and Stakeholder Analysis						
Brainstorming/Idea Generation						
Prototyping						
Writing a Business Plan						
Regulatory Process						
Presentation Skills						
Group Dynamics						
Cultural Sensitivity						

12. **Being a IHS course facilitator has better prepared me to do the following in my current role:** *

Mark only one oval per row.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	N/A
Write lesson plans						
Mentor students						
Communicate with faculty						
Communicate with administration						
Network with community leaders in your field						
Manage group finances						
Plan events						
Research literature						

Innovating Healthcare Solutions - Former Facilitator Survey

13. **Are you currently involved in medical device development, biomedical innovation, or healthcare startups?** *

Mark only one oval.

- Yes *Skip to question 15.*
- No *Skip to question 16.*
- No, but I would like to be

Innovating Healthcare Solutions - Former Facilitator Survey

14. **What barriers have you encountered in getting involved in medical device development, biomedical innovation, or healthcare startups?**

15. **Please elaborate on your current involvement in in medical device development, biomedical innovation, or healthcare startups:** *

Innovating Healthcare Solutions - Former Facilitator Survey

16. **Are you currently involved in a leadership role?** *
Mark only one oval.

- ◯ Yes *Skip to question 17.*
- ◯ No *Stop filling out this form.*

Innovating Healthcare Solutions - Former Facilitator Survey

17. **Please elaborate on your current leadership role:** *

APPENDIX 4 – FACULTY SURVEY FOR MENTORS AND CLINICAL NEEDS

Confidential

Participant ID 1
Page 1 of 1

Biomedical Innovations Facilitator Program Survey

The Biomedical Innovations (BI) Elective and Distinctions Track wishes to assemble a group of UT Southwestern faculty physicians who are willing to propose project ideas and/or mentor student teams. During the BI program, teams of 3 - 5 medical students work to tackle assigned projects throughout the fall/spring semesters (approximately 9 months). The goal of the BI program is to introduce students to the world of medical technology development and commercialization. Teams in past years have succeeded in inventing tangible and practical technologies that are now patent pending. In most cases, the faculty mentor is a co-inventor on these technologies.

Commitment: Faculty are encouraged to meet with their student teams roughly every two weeks for approximately an hour and to field questions electronically as needed. Note that most projects result in real prototypes or proofs of concept that may pose value in commercial markets. Faculty mentors are optionally invited to two major student presentations throughout the duration of the course, including one Early Validation Presentation (11/23/17 at 5:00 PM) and one Final Prototyping Symposium in the spring (date TBD).

To learn more about inventorship as a faculty member at UT Southwestern, feel free to visit the UTSW Office of Technology Development FAQ page.

Response was added on 07/21/2017 9:43am.

Do you have an idea for a medical device/technology for BI students to consider as a Biomedical Innovations project?

◯ Yes ◯ No

Are you willing to mentor a team of 3 - 5 medical students through the fall/spring semesters?

◯ Yes ◯ No

Please provide a brief description (no more than 2 - 3 sentences) of your project or device concept.

Are you interested in mentoring a BI student team that already has a project assigned?

◯ Yes ◯ No

If you answered "Yes" to any of the questions above, please provide your contact information:

If you would prefer to discuss your idea confidentially or if you have already developed an idea for a medical device and would like to move forward with disclosing that idea to the Office for Technology Development, please contact Andra Blomkalns, andra.blomkalns@utsouthwestern.edu, Medical Faculty Liaison to the Office for Technology Development.

Please add any comments or suggestions below. If you prefer to be contacted individually with an answer to a question, please provide your contact information as well.

Please add any comments or suggestions below:

VITAE

Thomas Das (February 23rd, 1991 - present) was born and raised in Houston, TX. He graduated from Dartmouth College in 2013 with a major in Biology with high honors, as well as a minor in English. He began medical school at UT Southwestern Medical Center in 2014, where he soon developed a passion for medical education. After completing the Innovating Healthcare Solutions enrichment elective in his first year, Thomas helped lead the reorganized Biomedical Innovations program as a student facilitator. He will graduate in June of 2018 with the degree of M.D. with Distinction in Medical Education, and will begin residency in Internal Medicine at the Osler Medical Training Program at Johns Hopkins Hospital. Thomas hopes to pursue a career as an academic cardiologist, and plans to continue growing his clinical and teaching skills for years to come.