

Implementation of a Master's in Translational Medicine (MTM) Program at The City College of New York (Work in Progress)

Mr. Jeffrey Stock Garanich Ph.D., The City College of New York

Jeffrey S. Garanich, Ph.D. is Director of the Master's in Translational Medicine (MTM) Program at the City College of New York (CCNY). In this role, his primary responsibilities include leading recruiting efforts to expand the Program's student base, engaging medical technology industry partners, and managing administration of a curriculum that trains students from diverse educational backgrounds in the core competencies required to successfully carry a medical technology from the lab bench through to the patient bedside. Prior to joining CCNY, Garanich served as Director Business Development with Actuated Medical, Inc. where he led investor and strategic partner engagements to accelerate device time to market and enhance sales of commercialized products. Garanich also previously worked as a Director at The Sapphire Group LLC, a holding company in New York City with assets in healthcare, new media, energy, education and unique innovations to support counterterrorism. Here, he led growth initiatives for multiple Sapphire portfolio companies, some of which began with company formation (founder level). Previous to Sapphire, Garanich spent six years with Boston Scientific Corporation. During this time, he progressed from a doctoral entry-level position to manage the day-to-day activities of five direct reports along with the operation of a corporate cell biology research laboratory staffed with ten scientists. He also worked with senior management to propose and develop a cross-Divisional collaboration network to improve communication and eliminate redundancies within the Company's billion-dollar research and development (R&D) organization and drive the completion of cross-disciplinary medical device R&D projects critical to products' commercialization. Prior to Boston Scientific, Garanich served as both Associate and Analyst with The Sapphire Group. In these roles, he was responsible for mergers and acquisitions and company-formation projects in the healthcare and media sectors and new client development in the medical device sector. Garanich holds a Ph.D. in Bioengineering and a B.S. in Mechanical Engineering, both from the Pennsylvania State University.

Dr. Lola A. Brown, The City College of New York

Lola Brown is a scientist, educator, and entrepreneur. She is an expert in the academic success of students in math and science, from kindergarten to post graduate, with a specialization in equipping PhD students with the tools to successfully complete their doctoral studies and obtain gainful employment in their area of interest.

Dr. Brown is currently an Adjunct Assistant Professor in Biomedical Engineering and the Assistant Dean of Academic Initiatives at The Grove School of Engineering at The City College of New York (CCNY). One of her major projects was the development and roll out of City College's master's program in translational medicine. In addition to her leadership role at CCNY, Dr. Brown has found time to reach out to the non-technical communities and share her passion for science and engineering education. She had an academic enrichment business for middle and high school students specializing in science, technology, engineering, and mathematics (STEM) and was a teacher at the Ron Clark Academy in Atlanta, Georgia. She has provided research mentorship and training to scores of undergraduate and graduate students throughout her career.

Lola obtained her bachelor of science from Brown University in biology where she conducted research studying tissue engineered heart valves. She took her master of science from the joint department of biomedical engineering at Georgia Tech and Emory University studying the stroke pathology in children with sickle cell anemia. She went on to complete her PhD in biochemistry as a NSF Graduate Research Fellow solving the structure of proteins involved in HIV. Immediately following the completion of her PhD, Dr. Brown began postdoctoral research in biomedical engineering at Yale University.

Her highly interdisciplinary training and skill set, which combines biomedical engineering, structural biology, and molecular biology, which makes her well suited to analyze projects from multiple perspectives. Lola has a deep commitment to teaching and mentoring and was awarded the 2009 "30 Under 30" Award

for her science outreach efforts. Lola is committed to contributing to STEM education in a manner that values high achievement and meaningful community impact.

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Undergraduate biomedical engineering (BME) design courses offer students the opportunity to leverage their classroom-based training to develop a medical technology in a team-based environment. While these courses provide valuable experience in the development of medical technologies, they typically focus exclusively on the design process, contain teams comprised of students with similar educational backgrounds, and do not examine the full spectrum of components required to bring a new medical product to market. Intellectual property, cost analysis, and regulatory affairs, for example, each play a tremendous role in the commercialization of a medical technology and are often not of significant focus in an undergraduate biomedical design course. In addition, employers seek candidates with a comprehensive understanding of the medical technology commercialization process which is not covered comprehensively in undergraduate BME curricula. To meet these needs, universities across the country have begun to implement degree-granting graduate programs in medical innovation. Many of these programs have focused their recruiting efforts and curricular design on candidates with an engineering background. However, the advent of makerspaces available to the general public, initiatives designed to teach youth computer programming, and the increasing technology savvy of younger generations denote a marked shift toward future professional generations that are more technologically sophisticated. In recent years, several universities, including ours, have developed entrepreneurship centers to provide students with a hands-on experience and expand their commercialization training by offering non-degree enrichment programs that train students in the fundamentals to bring a new technology to market. There have been fewer efforts, however, to provide a degree offering program that trains these technology-savvy physicians, scientists, and engineers in the comprehensive process to bring a medical technology to market. We developed the new one-year Master's in Translational Medicine Program at The City College of New York (CCNY MTM; first class enrolled in Fall 2015) to provide educational value by training students from engineering, life science, or pre-medicine backgrounds in the core competencies required to successfully develop and commercialize a new medical technology.

Curriculum

CCNY MTM is offered in a one-year Fall-Spring-Summer sequence and addresses two primary objectives:

1. To provide graduates with the tools and skills needed to bring solutions to interdisciplinary biomedical problems to market.
2. To provide graduates with experiential learning opportunities needed to work in interdisciplinary teams.

The curriculum contains 30 credits and is organized such that content from courses focused on the technical, clinical, business, and regulatory issues involved in the translation of a medical technology from the lab bench to the patient bedside are synthesized into a group BioDesign project that spans the length of the program. Refer to Table 1 for a detailed semester-by-semester breakdown of the CCNY MTM curriculum.

Fall	Spring	Summer
BioDesign 1: Need Finding and Screening	BioDesign 2: Conceptual Innovation	BioDesign 3: Translational Solutions
Intellectual Property, Regulation and Quality Assurance	Translational Challenges in Diagnostics, Devices and Therapeutics	
Translational Challenges in Medicine	Engineering, Entrepreneurship and Business Leadership	
Biomedical Ethics and Responsible Conduct of Research	Translational Research Design	
Cost Analysis and the Business of Translation (Winter Intersession)	Elective Course or Independent Project	
Elective Course		

Table 1: CCNY Master’s in Translational Medicine Program Curriculum

BioDesign

BioDesign is a three semester course sequence and the foundation of CCNY MTM. The program has several clinical partners to source BioDesign projects ranging from computer application development to biomechanical device design. There is no set financial cost assigned to clinical partners in association with their project sponsorship. They may accrue such costs on a case-by-case basis, for example, associated with maintenance of intellectual property generated from a project. The BioDesign sequence is administered to address four primary learning outcomes:

1. Identify and address unmet needs in the prevention, screening, diagnosis and treatment of diverse diseases and disabilities.
2. Demonstrate basic skills to manage an interdisciplinary team that is developing a new medical technology.
3. Communicate effectively as a member of an interdisciplinary team.
4. Demonstrate experimental skills in creating a working prototype of a new medical technology.

In the first semester, teams of three to five students are formed and purposefully comprised of students from diverse academic backgrounds. This is done to provide students with the opportunity to learn from each other’s expertise and prepare for the inter-disciplinary environments that await them upon graduation. Teams select a BioDesign project based on their interest and availability, develop an in-depth understanding of the unmet clinical need, define a corresponding need statement and design specifications, and ideate multiple design concepts to address the need. Teams present their design concepts to the clinical sponsor near the end of the first semester with one design selected for further development. In the second semester, teams utilize their \$1500 budget (provided by the program) and access to the school’s manufacturing equipment to develop a functional prototype of the chosen design concept. Teams ideally spend a majority of the final semester collecting initial validation data with their prototype in a clinical setting.

Fall Semester

Fall classes provide the students with significant context as they develop their design concepts. For example, with respect to intellectual property, students learn how to search and read patents for technologies that may address the clinical need for their project and are able to refine their designs accordingly.

Spring Semester

As teams transition to building a functional prototype, Spring coursework allows them to identify and refine market segments and thereby assess the commercial potential of their technology and become versed in the concepts essential to clinical research. Students may replace the elective course with an independent project that supplements the core curriculum and is overseen by one of our local clinical or industrial partners.

Summer Semester

In the final semester, teams focus solely on final refinement of their functional prototype and collection of initial clinical data. These data are reviewed with the project sponsor and used to determine next steps, which may include design modifications, filing of intellectual property, and continued collection of clinical data.

Knowledge Integration

At the conclusion of each semester, teams provide a comprehensive progress update to the CCNY MTM Steering Committee which is comprised of senior administrators and faculty. These updates provide students the opportunity to gain experience with synthesizing the multiple aspects of their project into a succinct update to a senior leadership board.

Admission Requirements

Prospective students must have completed a STEM-concentrated degree with a 3.0 or higher grade point average, in order to be considered for admission to the program. In addition, they must provide scores from a graduate school exam along with transcripts from all post-secondary institutions, two letters of recommendation, a curriculum vitae, and personal statement.

Graduation Requirements

In order to graduate from CCNY MTM, students are required to successfully complete the entire curriculum as defined above and submit a comprehensive written summary of their BioDesign project, in the format of a business plan, at the conclusion of the final semester.

Inaugural 2015-2016 Class

Four students who completed their undergraduate study at CCNY were admitted to the inaugural class in Fall 2015. All successfully graduated in Summer 2016. This cohort was comprised of

two biomedical engineers, one pre-medical student, and one biochemist. Although we have limited cases from which to draw, we did not observe a marked difference in performance by students from different educational backgrounds.

Program Evaluation Criteria

Job Placement

One student from our inaugural class conducted an independent project with a nationally ranked top hospital for orthopedics and later accepted a full-time clinical research position with the same group. Another student from this first class began medical school upon completion of the program, fulfilling his long-term objective. The remaining graduates from the first class are pursuing opportunities in the medical technology industry and doctoral programs.

Adherence to Program Objectives and Learning Outcomes

We are presently building out a curriculum matrix so that we are able to evaluate adherence to the program objectives and the associated learning outcomes defined earlier, beginning in Fall 2017.

Course Surveys

We administered course-specific surveys to our current cohort of four students at the end of the Fall 2016 semester. Surveys were comprised of multiple choice and open-ended questions. Multiple choice questions requested student feedback such as the knowledge they gained in a given subject area, impact and relevance of given topics with respect to their future interests, and their competence in a given skill set. Open-ended questions asked students to discuss topics such as the element(s) of a course that provided them with the most and least educational value and changes they would recommend making to a course moving forward.

Multiple choice results, although limited, suggest that students perceived knowledge and competence gain in a majority of subject areas and skill sets covered. Students used the open-ended questions to voice appreciation of the availability of and mentorship from the BioDesign faculty and suggestions to better match BioDesign projects to student skill sets and incorporate BioDesign projects into other program coursework.

Moving Forward

We are excited to realize the potential of the novel program that we have developed. We recognize, though, that there are challenges to be addressed by the administrators, faculty, and students. To date, approximately half of the students who have enrolled in the program have a BME background with the remainder equally comprised of students with pre-medicine and life sciences backgrounds. We must market the program in such a way to maintain this desired diversity in students' educational background. We must also acknowledge and address the associated challenge of making the BioDesign curriculum available to students with varying levels of technical experience.

Acknowledgments

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- Gilda Barabino, PhD, Dean, Grove School of Engineering; Berg Professor, Biomedical Engineering
- John A. Blaho, PhD, Director, Industrial-Academic Research, CUNY Central Office of Research; Adjunct Professor, Biomedical Engineering
- Abhishek Datta, PhD, Scientist/Chief Technology Officer, Soterix Medical; Adjunct Professor, Biomedical Engineering
- Joan M. Dorn, PhD, Medical Professor, CUNY School of Medicine; Chair, Department of Community Health and Social Medicine
- Neeti Mitra, MS, MIPMM, Patent Agent(IN), University Research Commercialization Manager, Technology Commercialization Office, CUNY
- Mitchell Schaffler, PhD, CUNY and Wallace Coulter Distinguished Professor, Biomedical Engineering; Chairman, Biomedical Engineering
- Sabriya A. Stukes, PhD, Assistant Director, CCNY MTM Program
- Maurizio Trevisan, MD, MS, Dean, CUNY School of Medicine
- Ashiwel Undieh, MPharm, PhD, Associate Provost for Research; Medical Professor, CUNY School of Medicine
- Maribel Vazquez, ScD, Associate Professor, Biomedical Engineering