Accelerating Biomedical Innovation in Academia: Leveraging Academic Discoveries to Meet the Needs of Both Faculty and Students

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A. Abstract

Faculty and students have unique educational and professional needs and priorities. Faculty traditionally focus their efforts on research, service, and teaching on the path toward promotion and tenure, with less emphasis placed on translating findings outside of the lab during their academic training. Alternatively, graduate students seeking careers in industry or as entrepreneurs have a keen interest in innovation and commercialization and hope to develop skills in this area. Unfortunately, it can be difficult to address the opportunities and challenges of commercialization and entrepreneurship while also meeting the demands of academia. Our objective was to develop a course to meet the unique needs of both groups by providing students with real-world experience in technology commercialization while at the same time providing Faculty with structured support to bring their discoveries and innovations to patients. In collaboration with the Columbia-Coulter Translational Research Partnership, we created a semester-long course, "Lab-to-Market: Accelerating Biomedical Innovation" aimed at providing interdisciplinary teams, comprised of students and faculty, with an introduction to the specialized frameworks and essential tools necessary for biomedical technology commercialization. This course successfully met the needs of both students and Faculty by providing students with an immersive real-world training in technology commercialization, while also providing Faculty with additional support on translating their academic discoveries. This paper describes an interdisciplinary program and course capable of nurturing student-faculty teams, educating future generations of innovators and entrepreneurs, and leveraging the billions of dollars invested in cutting-edge academic research to help bring technologies out of the lab and into the real world to benefit human health.

B. Introduction

Innovation in Academia. The U.S. invests billions of dollars in research at institutions across the country with the goal of benefitting society [1]. However, even the most promising technologies often fail to reach patients due to the high-risk path biomedical technologies face moving from the lab to the market [2]. In addition, faculty and graduate students have unique educational and professional needs and priorities. Faculty traditionally focus their efforts on research, service, and teaching on the path toward promotion and tenure, with less emphasis placed on translating findings outside of the lab. Alternatively, graduate students may be seeking careers in industry or as entrepreneurs and often have a keen interest in innovation and commercialization with hopes to develop skills in this area. Given these differing objectives, it can be difficult to address both the opportunities and challenges of commercialization and entrepreneurship while also meeting the demands of academia. However, there has been a palpable shift on our campus, and across other campuses, in the academic culture toward valuing patents and commercialization toward tenure and career advancement [3]. Our objective was to develop a course capable of meeting the unique needs of both groups by providing students with real-world experience in technology commercialization while at the same time providing faculty with structured support and education around what it takes to bring discoveries and innovations to patients.

History and Context. Our institution has an established, successful biomedical accelerator program, the Columbia-Coulter Translational Research Partnership, aimed at supporting commercial development of early-stage biomedical technologies. With generous support from the Wallace Coulter Foundation, the Department of Biomedical Engineering and the School of Engineering and Applied Science have partnered with the Office of Technology Transfer and the Columbia University Medical Center to provide funding and mentorship to clinician-engineer teams working to address unmet clinical needs through the creation and translation of biomedical technologies. By fostering collaboration between biomedical engineers and clinicians while focusing specifically on the commercialization of medical devices, diagnostics, and healthcare IT, the program has served as an effective catalyst in the development and validation of biomedical technologies.

Now entering its sixth year, the program has provided education and in-kind resources to over 95 clinician-engineer-led teams and direct funding of over $4M to 35 projects. Of these funded projects, six have spun out of the university into start-up companies, having raised $9M to date, and five have been licensed to established companies in industry, with one already having received FDA approval and in clinical use. In addition, funded projects have secured an additional $49M in government and foundation grants awarded to faculty to further support translational research efforts on these projects within the University.

However, the program did not initially have a mechanism for educating participating clinician-engineer teams or for supporting students. Thus, we saw a valuable opportunity to leverage an existing accelerator model to increase student engagement in innovation and entrepreneurship while also extending an interdisciplinary approach to include education for faculty and students.

While the course was originally envisioned as a series of workshops aimed at faculty interested in commercializing biomedical technologies, it quickly became apparent that, although eager to learn the material and motivated to work towards translational research, faculty had limited time due to competing professional needs and priorities, especially with regard to efforts in research, service, and teaching. Faculty expressed enthusiasm about workshop content but often felt the workload and project management required to successfully move a technology forward were daunting.

At the same time, graduate students in both the Schools of Engineering and Business were seeking opportunities to engage with real-world technologies in which they could develop skills around innovation and commercialization to support efforts at finding careers in industry or as entrepreneurs. Thus, we developed a course aimed at meeting the unique needs of both graduate students and faculty by providing education and support toward translational research and technology commercialization, and contributing to the overall common goal of bringing innovative discoveries to patients.

To place this course in a larger context, other existing medical technology innovation programs have shown success with their needs-driven approach and training programs toward identification of unmet clinical needs and the invention and implementation of new solutions [4]. As a result, our program adopted a similar approach and curriculum for graduate students, as previously described [5]. These existing programs aim to develop *new* medical technologies and generally have a focus on *student*-led inventions. Our aim was to complement this approach by also getting students involved later in the commercialization process by placing them on teams based on *existing* technologies/ideas developed by clinical and engineer *faculty*. This will be the focus of the current investigation.

C. Methods

An Interdisciplinary Approach. In collaboration with our existing biomedical accelerator program, we created a semester-long elective course, "Lab-to-Market: Accelerating Biomedical Innovation" aimed at providing interdisciplinary teams with an introduction to the specialized frameworks and essential tools necessary to move envisioned biomedical technologies from the lab to the market. Graduate students from the Schools of Engineering, Arts & Sciences, and Business were embedded in project teams comprised of clinical and engineering faculty and others (e.g., post-doctoral fellows, research scientists) and centered on existing University technologies. The overall goal of the course was to provide participants with an experiential learning opportunity in product commercialization based on a real-world technology.

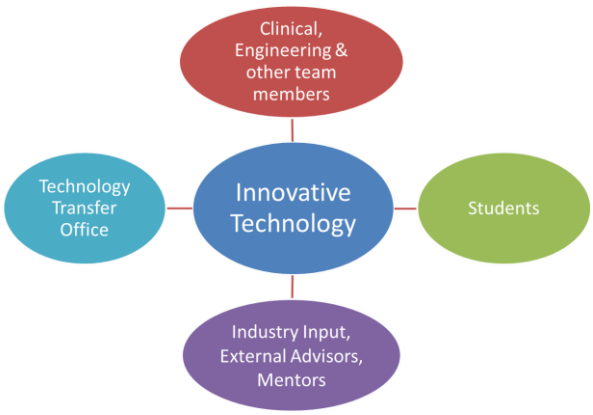

Figure 1. Our interdisciplinary approach

Course Participants. Team formation was achieved through faculty project applications, student applications, ranking of top projects, and facilitated networking to optimize matches. Teams of clinicians and engineers with an existing or envisioned technology submitted a preliminary application to the biomedical accelerator program and advanced to the semi-finalist round based on the stage of their technology and the strength of their intellectual property (IP), with priority given to later stage technologies with stronger IP positions.

Project teams that moved forward were presented with the opportunity to participate in a semester-long course designed to support them as they worked through the iterations necessary to create a plan for market readiness and a full proposal application for funding consideration. Although participation in the course was not required in order to submit a full proposal application, it was "strongly recommended," and 95% of applicants chose to participate in the course. Applicant teams were given the option of having existing students working on their projects take the course for credit or having additional students assigned to their teams.

In order to engage students, information about the course was posted on student listservs through the Schools of Engineering and Business. In order to register for the course, interested students submitted a brief statement of interest and a resume, and then ranked the projects they sought to work on. Project teams and students were then matched accordingly.

Course Objectives, Structure and Content. The two major learning objectives of the course were: 1) to succinctly describe the unmet clinical need, stakeholder requirements, and business opportunities and risks related to the technology and 2) to package and pitch the idea to best position it for partnership and follow-on investment. Participants also gained exposure to the technical, economic, social, and public policy issues involved in the commercialization of medical devices and therapeutics.

Each weekly course session included a lecture and team presentations and featured practical exercises and group feedback supplemented with content on topics applicable to

commercialization success, including an introduction to Value Proposition, Competitive Market Landscape, IP Strategy, Regulatory Roadmap, and Reimbursement Plan (**Table 1**). Course content was supplemented by assigned readings [6]. At the end of the course, teams were invited to submit a full proposal application for funding support.

Lab-to-Market Course Topics
Unmet Need
Stakeholder Analysis
Value Proposition
Market Landscape
Product and IP Position
Regulatory
Reimbursement
Path-to-Market
Business Model
Pitchcraft

Table 1. List of topics covered in the Lab-to-Market course.

Teams were also supported by a peer learning environment and a coaching network of functional and domain experts. Seasoned industry executives and serial entrepreneurs provided advice, feedback, and guidance on the issues teams faced in pursuing a path to commercialization.

Course Evaluation and Feedback. Assessment of learning outcomes, course dynamics, and effectiveness was achieved through anonymous pre- and post-course surveys of participants (**Table 2**). The survey included three short answer questions to determine role on the team, area(s) of expertise, and intention/history of attendance. Following the role identification questions were ten questions aimed at ranking knowledge gained from the course. Then, following the same ranking format, five questions aimed to determine participant enthusiasm over aspects of the course, such as excitement to network or to hear other teams present. The survey concluded with a final question on how valuable each respondent found various components of learning before and after the course. The post-course survey included two additional questions regarding what the participant liked and disliked about the course.

	Questions	**Responses**
1	**What is your role in the course?**	Engineering Student
		Business Student
		Engineering PI
		Clinical PI
		Other (please specify:)
2	**What is your primary area of expertise?**	Patient care
		Engineering
		Biology
		Chemistry
		Tech Transfer

		Business/Entrepreneurship
		Other (please specify:)
3	**How many of the course sessions do you plan to attend?**	None
		1 to 2
		3 to 4
		5+
4	**How much do you agree with the following:** • I am knowledgeable about what it takes to commercialize medical technologies. • I am knowledgeable about the regulatory issues that accompany a medical device. • I am knowledgeable about how to assess the market landscape for a medical device. • I am knowledgeable about how to evaluate the business opportunity for a medical device. • I am knowledgeable about the intellectual property uses that accompany a medical device. • I am knowledgeable about the reimbursement issues that accompany a medical device. • I am comfortable giving a presentation to an audience. • I am comfortable giving a scientific presentation to an audience. • I am comfortable giving a business pitch to an audience. • I am comfortable networking with individuals outside of my discipline.	Strongly Disagree
		Disagree
		Neither Agree Nor Disagree
		Agree
		Strongly Agree
5	**How much do you agree with the following:** • I am looking forward to gaining a deeper understanding about early stage tech commercialization. • I am looking forward to making new connections that will be helpful in the future. • I am looking forward to helping my team better position our project for commercial success. • I am looking forward to learning and listening to the other teams present their projects. • I think the Lab-to-Market course will be fun.	Strongly Disagree
		Disagree
		Neither Agree Nor Disagree
		Agree
		Strongly Agree
6	**How valuable do you find the following components for learning?** • Readings • Homework Assignments • Group Work • Feedback from Instructors • Feedback from Experts	Not Valuable
		Somewhat Valuable
		Valuable
		Highly Valuable
		N/A

	• Feedback from Peers • Lectures	
7	**Additional comments/suggestions:**	
8	Post-survey ONLY: **What did you like about the course?**	
9	Post-survey ONLY: **What could be improved about the course?**	

Table 2. Pre- and post-course survey questions and possible responses.

D. Results

I. Pre- and Post-Course Survey Data

Results from the pre-course and post-course surveys are presented in Figures 1-8. For the pre-course survey, 21 out of 28 students responded, and 25 out of 56 faculty responded. For the post-course survey, 17 out of 28 students responded, and 14 out of 56 faculty responded. Results are presented as mean and standard deviation. T-tests were performed between pre-course and post-course results to determine statistical significance ($p<0.05$). Cohen's effect size (d) was calculated to determine the magnitude of the difference between groups, independent of sample size (0.2=small effect size, 0.5=medium effect size, 0.8=large effect size). For both pre- and post-course surveys, student respondents were separated from faculty respondents and analyzed accordingly.

Students. Compared to before the course, student scores after the course reflected substantial increases in self-assessed knowledge in all areas of product commercialization (**Figure 1**). The areas in which students made notable gains included overall product commercialization ($p<0.0001$, $d=2.7$), regulatory issues ($p<0.0001$, $d=1.47$), assessing the market landscape ($p<0.0001$, $d=1.66$), evaluating the business opportunity ($p<0.0001$, $d=1.85$), IP issues ($p<0.001$, $d=1.27$), and reimbursement issues ($p<0.0001$, $d=1.87$). In addition, students reported a notable improvement in their ability to give public ($p=0.01$, $d=0.84$), scientific ($p=0.05$, $d=0.64$), and business pitch presentations to audiences ($p<0.001$, $d=1.19$) (**Figure 2**). The course also allowed students to become more comfortable networking with individuals outside their discipline ($p=0.06$, $d=0.65$) (**Figure 2**).

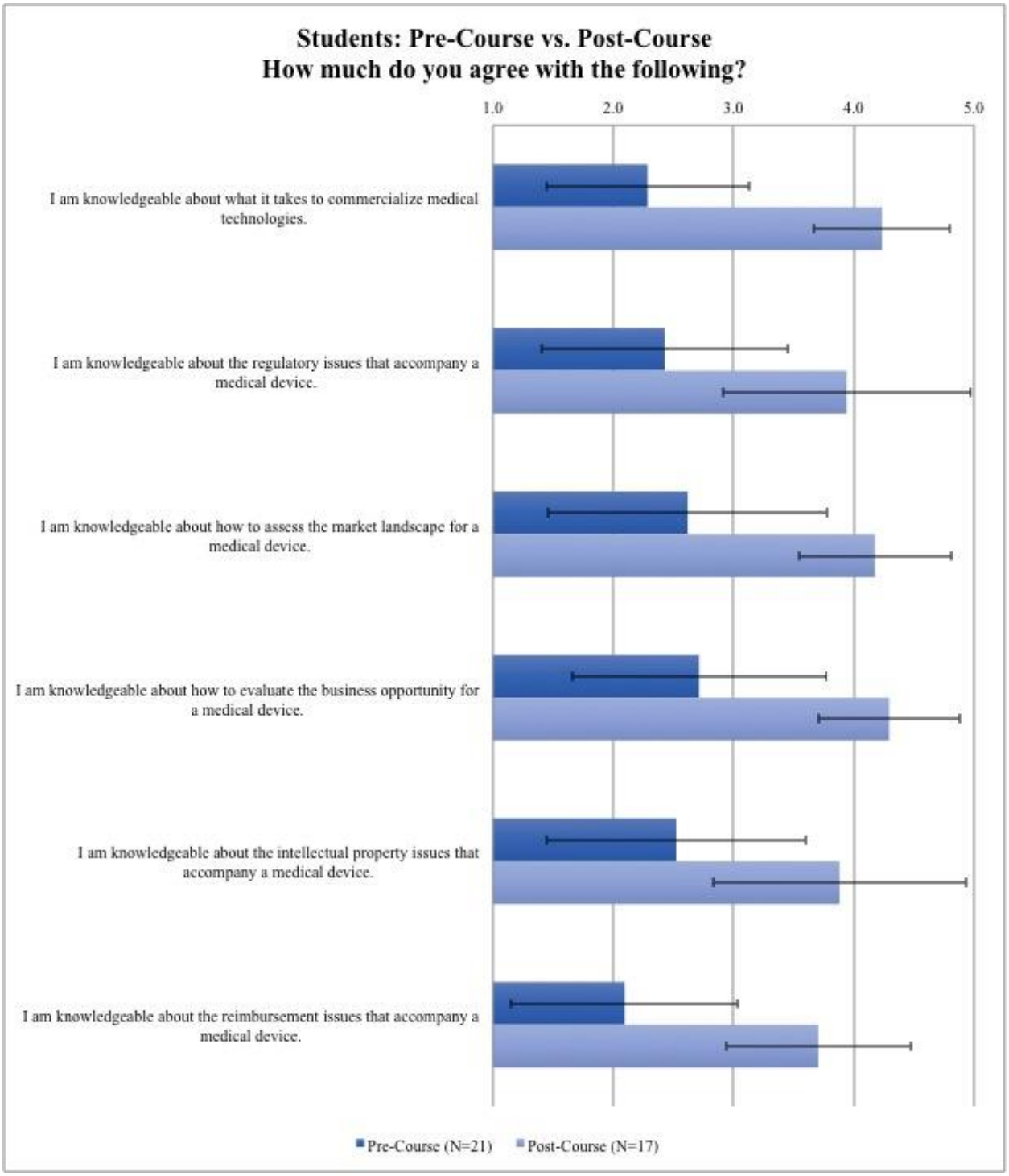

Figure 1. Results suggest students felt more knowledgeable about commercializing a medical technology and the regulatory issues and the market landscape accompanying a medical device after the course. Students also felt more knowledgeable about the business opportunities, IP issues, and reimbursement issues accompanying a medical device after the course.

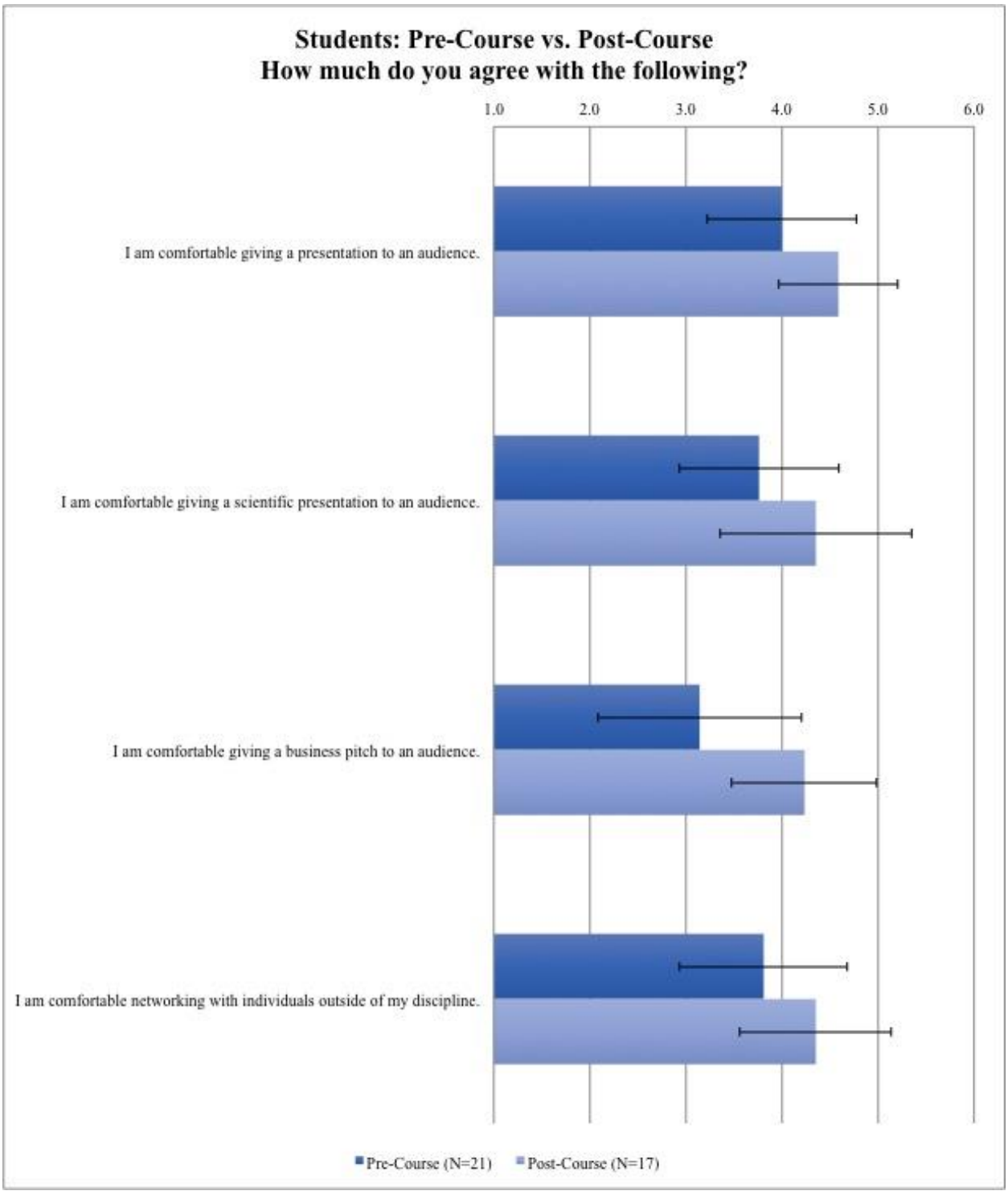

Figure 2. Results suggest students felt more comfortable with their presentation and networking skills after the course.

Faculty. Compared to before the course, faculty scores after the course also reflected substantial increases in self-assessed knowledge in all areas of product commercialization (**Figures 3**). The areas in which faculty participants made notable gains included commercialization ($p<0.0001$,

d=1.72), regulatory issues ($p<0.0001$, d=1.9), assessing the market landscape (p=0.0004, d=1.43), evaluating the business opportunity (p=0.002 d=1.17), IP issues (p=0.01, d=0.99) and reimbursement issues ($p<0.0001$, d=1.88). Faculty participants also reported a substantial improvement in their ability to feel comfortable giving business pitch presentations to audiences (p=0.02, d=0.86) (**Figure 4**). No differences were observed in their ability to give a public presentation (p=0.72) or give scientific presentations (p=0.64) nor in in their networking ability (p=0.87).

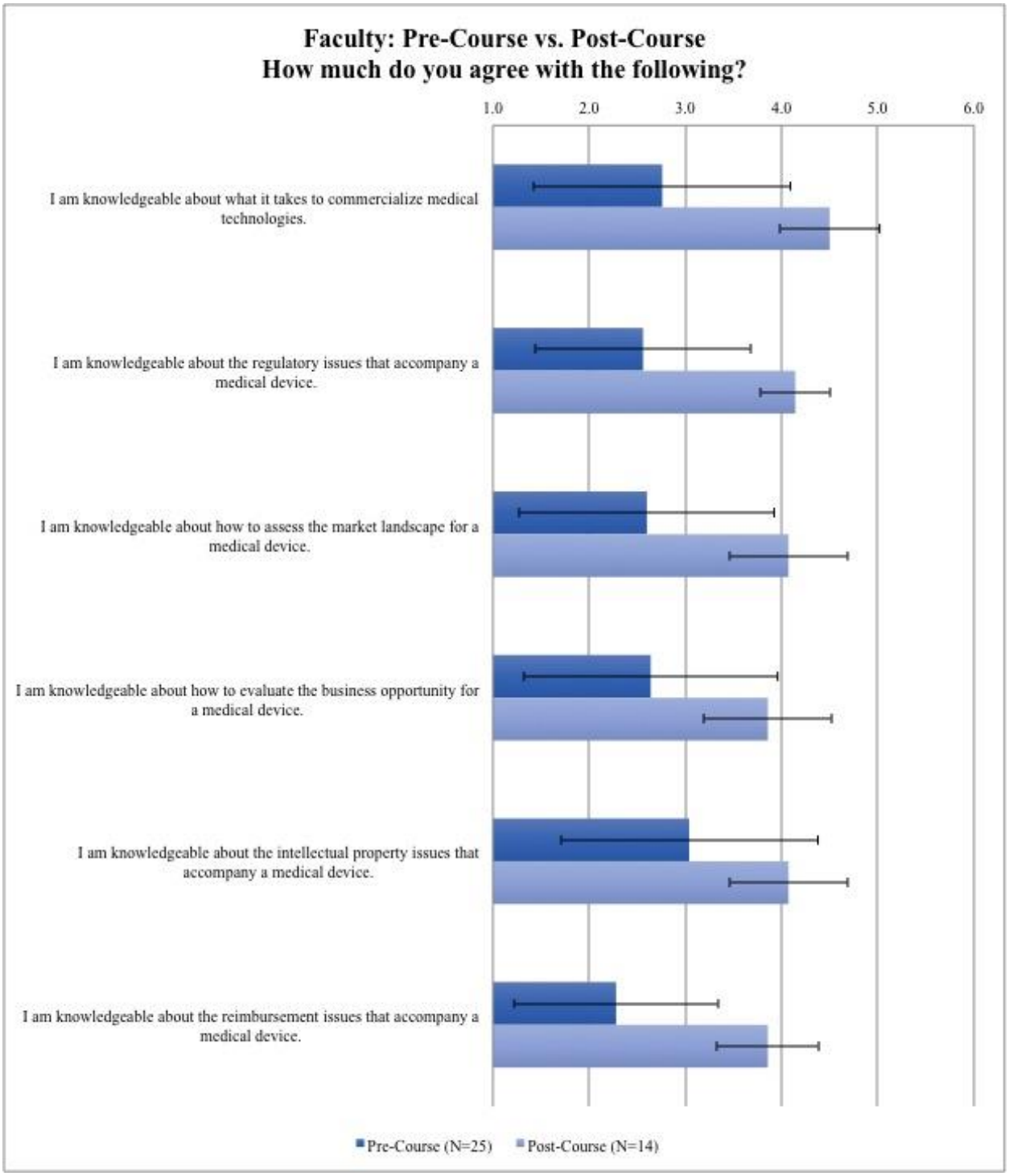

Figure 3. Results suggest clinical and engineering faculty members felt more knowledgeable about commercializing a medical technology and the regulatory issues and the market landscape accompanying a medical device after the course. They also felt more knowledgeable about the business opportunities, IP issues, and reimbursement issues accompanying a medical device after the course.

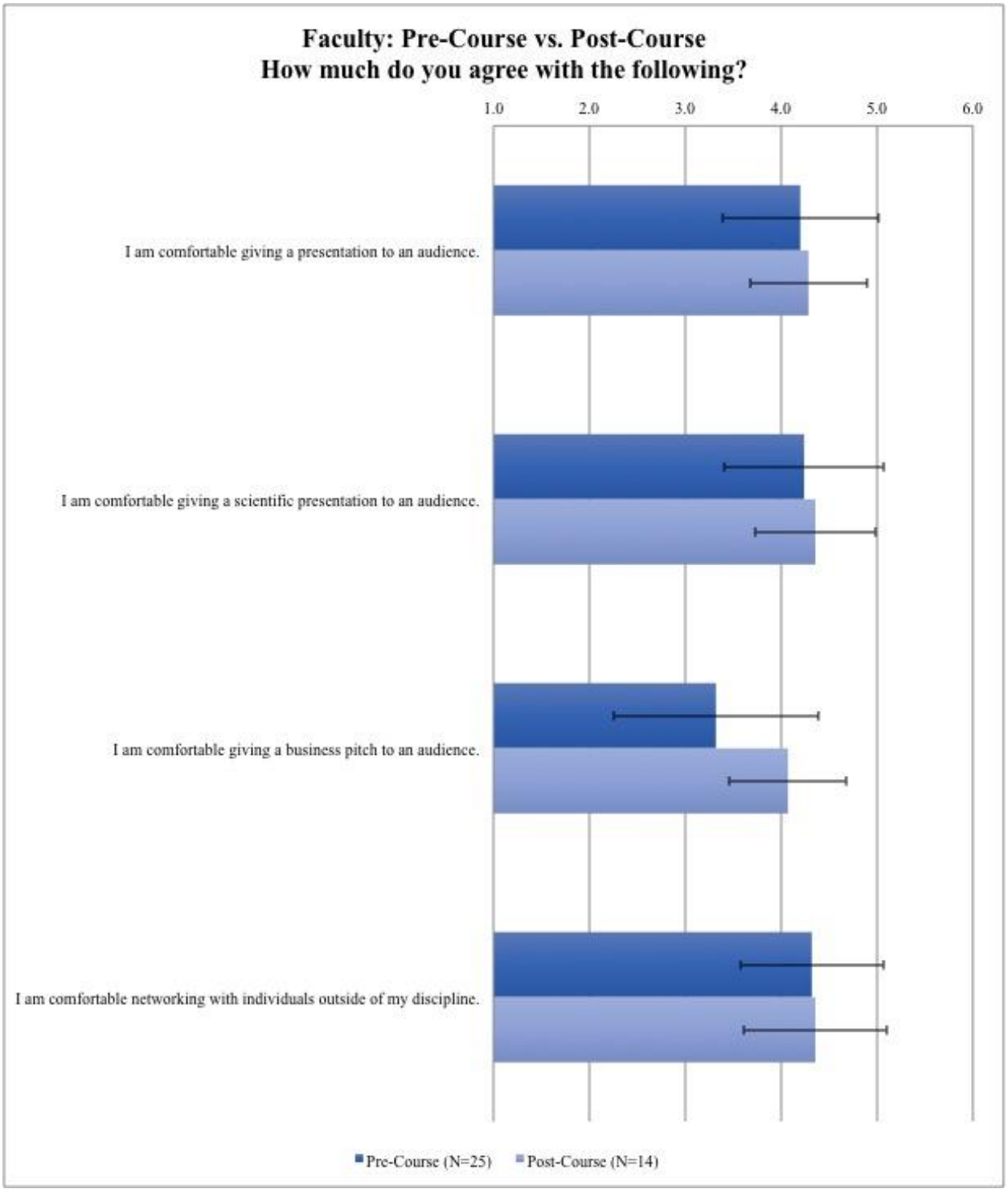

Figure 4. Results suggest clinical and engineering faculty members were more comfortable with their ability to give a business pitch following the course.

II. Written Feedback

In the long response section of the survey, students and faculty had to opportunity to express their thoughts on the course's strengths and weaknesses. Overall, students and faculty rated the course as well organized and effective. Notable themes found among the respondent's comments included positive responses to the weekly in-class pitches, interdisciplinary benefits, ability to speak with experts, and organization of the course. The opportunity to pitch every week seemed to greatly improve participants' confidence and presentation skills. Participants found the visiting experts from different fields incredibly valuable towards sharpening their ideas for their technology. Many participants reported that the enthusiasm and expertise of the instructors was essential to the success of the course and their projects. Students found it was especially effective to present weekly pitches of their products to an interdisciplinary committee of product commercialization experts for valuable feedback. When asked about the course's weaknesses, the respondents suggestions predominately revolved around making admittance to the course more selective. Representative comments grouped by theme are presented below.

Weekly in-class team presentations:

> *"Weekly presentations were time-consuming and painful to prepare for but were very helpful in forcing us to think about issues and explore fields that we were not familiar with."*
>
> *"Got to pitch every single week, that really increased my presentation abilities."*
>
> *"Good practice presenting and understanding what goes into a pitch."*
>
> *"It was very well structured, and the experience of giving a presentation and having to answer questions every week prepared us well."*

Interdisciplinary benefits:

> *"I think it is a great course and bridges a gap in scientific training that is useful for commercialization of medical innovations."*
>
> *"The course was an excellent forum for learning a different part of funding from a business perspective. Our student was amazing, and an important part of the team."*
>
> *"I really appreciated the sequential but rapid progression toward creating the final pitch. Having had basically no prior business experience, I benefitted greatly from this approach."*
>
> *"Amazing class for engineering students and a really unique opportunity. Proud to put this on my resume and it has already influenced my thoughts about my future career path. Such a great experience to focus on the business/marketing side of medical design rather than the technology. Feel like the experiences I had and knowledge I gained will be very translatable in industry. Interacting with business advisors and stakeholders also taught me so much about the product I was working on."*

"As a Ph.D. student in engineering, this is the first class I have ever taken (including my undergraduate and master's degree courses) that forced me to think about what I will do with my Ph.D. after I complete the degree program. So many opportunities were presented throughout the course… While I enjoyed working on my specific project each week, I am taking away much more than the understanding of a single technology. This course has inspired me to pursue a career in technology transfer, and I will continue to engage in similar coursework and business opportunities throughout my Ph.D. in order to gain a better understanding of this field."

A few students and faculty expressed concerns that some teams had more pressing unmet needs than others. This caused these survey respondents to suggest that course admittance be based primarily on the importance of the invention's unmet need.

Suggestions for selective course admittance:

"Some of the projects presented really do not have a pressing Unmet Need, so I think that the projects should have an initial screening for medical importance."

"The program should be more selective in terms of commercialization potential up front. It was frustrating to be on a team for a device that wasn't at all ready for commercialization, with an advisor who wasn't particularly interested in commercializing it."

Regarding the ability to speak with experts:

"I think the course provides a rare opportunity to speak with experts from a variety of different fields and pick their brains about what makes a viable business / technology. This type of access to experienced financial and medical device professionals is invaluable. It can be a very efficient and effective way to jump start incredible medical ideas."

"Having guest experts come in every week really added credibility to the program. Feedback from instructors and advisers was spot-on."

"The business advisers were very helpful."

"I liked the guest speakers that gave lectures each week. I also liked receiving feedback from business experts."

Regarding administration and organization of the course:

"Thanks for organizing the class so effectively."

"The administration of the course and the instructors, TA's, and the reading make the course one of the best I have ever taken. The energy and excitement and expertise are palpable and infectious. The way that information was developed was really inspiring."

"Lectures covered a wide variety of topics from bench to market. Assignments were tailored to the actual proposal. Directors/leaders/TA's of the course were fantastic - great positive and motivating attitude, helpful and responsive to questions/concerns and directed us to other contacts for further help. In class presentations were fun and engaging."

General feedback on the course:

"Excellent class, by far the best I've taken at Columbia!"

"Great class, very much enjoyed it and have been recommending it to others."

"I liked seeing other research that was going on around my field at Columbia."

III. Value of Pedagogical Components

Before and after the course, students were assessed on what teaching components they found most valuable. Value assessments were based on a four-point scale: 1 being least valuable and 4 being highly valuable. After the course, students found homework assignments and group work to be slightly more valuable than expected (**Figure 7**). Students found feedback from peers to be less helpful than anticipated (**Figure 7**). Of the seven teaching components assessed, students found feedback from experts to be the most valuable teaching component of the course (**Figure 7**).

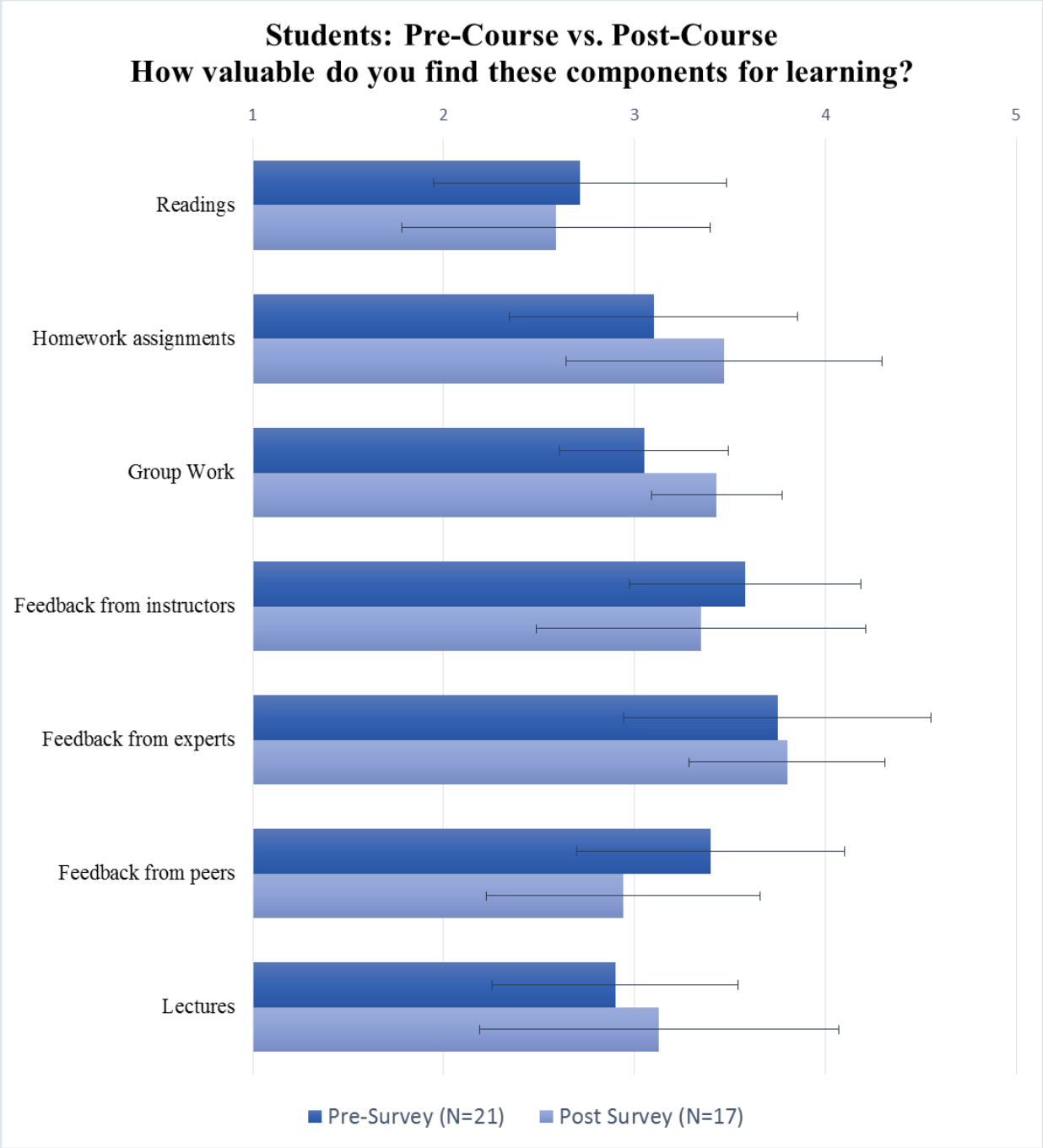

Figure 7. No significant differences were observed in what students felt was valuable for learning before and after the course. (1=least valuable, 4= highly valuable). Results suggest that students found feedback from experts to be the most valuable learning component of the course.

IV. Overall Outcomes

Of the 28 teams that participated in the course, 8 were chosen by the judges for funding support. However, many teams not selected for funding remain active. All participants appeared to benefit from the educational components, business advice, and mentorship from experts provided by this course.

E. Discussion

This article described an interdisciplinary semester-long course aimed at meeting the unique needs of both graduate students and faculty by providing structured support for technology commercialization and contributing to the overall common goal of bringing innovative discoveries to patients.

Results from pre- and post-course evaluation reflected substantial increases in knowledge in areas of product commercialization for all participants. Faculty reported that student support on project teams was a critical driver toward their ability to move the project forward while balancing multiple other demands of academia; and students reported that the course provided them with a real-world experience in technology commercialization and in some cases influenced their career path. Both faculty and students reported an improvement in their ability to pitch their technology to stakeholders and potential investors. The interdisciplinary approach, peer-learning environment, course structure, and feedback from experts and stakeholders all seemed to be critical components for learning and success.

Interdisciplinary approach. By requiring clinicians, engineers, and students to collaborate on a single technology, a variety of expertise is available to support the advancement of a biomedical invention from bench to market. In partnering with innovative and experienced technical teams working to develop a commercialization plan for an envisioned technology, students played an active and crucial role in identifying the clinical need, stakeholder requirements, and business case in an attempt to increase commercial potential for a given technology. Faculty brought real-world experience and expertise, and group work was essential for a team's success. Successful teams created and sustained positive and open communication between group members and course instructors. The ability to interact with a students and other team members from other disciplines is both crucial for moving a technology forward as well as an important skill for both students and faculty to develop. Participants were also able to work with and network with individuals outside of their discipline, broadening awareness of the ecosystem around commercialization and entrepreneurship and opening up opportunities for current and future potential ventures and employment.

Peer-learning environment. Constructive feedback from other participants created a flow of information and expertise throughout the classroom. Through weekly presentations in breakout sessions and facilitated networking, students and faculty were able to meet, learn from, and teach each other. This frequent interaction of the teams participating in the course allowed for an open and engaging learning community and exchange of thoughts and ideas across disciplines.

***Course structure*.** Through the process of preparing and presenting weekly pitches, participants gained experience and confidence creating and delivering compelling presentations and communicating with a diverse audience. Lectures introduced participants to weekly topics and provided an opportunity for questions and answers, and guest speakers highlighted real-world case studies and experiences.

***Use of feedback from experts and stakeholders*.** When assessing what components of learning were most valuable for such a diverse pool of students, the respondents collectively reported that

feedback from experts was the most valuable didactic aspect of the course. Teams were given the opportunity to present weekly to an array of experts and business advisors in product commercialization about their team's invention and commercialization plan, and were given direct feedback on their strengths and weaknesses. Teams were also encouraged to speak with stakeholders and potential customers in order to assess the market and how effective their technology would be as a solution, with the allowance for teams to pivot in response to market feedback.

Increasing demand and future directions. This course was piloted for biomedical engineering students in 2015 (N=4). In 2016 (from which data was reported in this paper), enrollment increased (N=28) and expanded to multiple disciplines including business, engineering (biomedical, mechanical, and electrical), medicine, and biology. In 2017, enrollment expanded further (N=36) to include business, engineering (biomedical, mechanical, electrical), biology, public health, biotechnology, and medicine. Future iterations of the course will likely include other disciplines as well, including the school of nursing and additional life sciences departments, with the goal of expanding the education and mentorship provided by this cross-campus, interdisciplinary biomedical accelerator.

F. Conclusions

This course successfully met the needs of both students and faculty by providing students with an immersive real-world training in technology commercialization, while also providing faculty with additional support for translating their academic discoveries. While at times logistically challenging, the multi-disciplinary approach seemed to improve participant experience immensely and increased overall satisfaction with the course.

G. Acknowledgements

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