New York University School of Medicine Drug Development Educational Program: 2-Year Benchmark

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Drug development (DD) is a multidisciplinary process that spans the translational continuum, yet remains an understudied entity in medical schools and biomedical science institutes. In response to a growing interest and unmet need, we implemented a DD course series that details identification of viable molecular targets, clinical trial design, intellectual property, and marketing. Enrollment is open to faculty, postdoctoral trainees, and MD, PhD, and MS students. After 2 years, 37 students and 23 students completed the fall and spring courses, respectively. Pre/post-surveys demonstrated gained knowledge across course topics, with mean survey scores increased by 66% ($p < 0.001$) after each course. Lectures for each course were consistently rated highly, with a mean course rating of 4.1/5. Through this program, trainees will have a more innovative approach toward identification of therapeutic targets and modalities. Furthermore, they will learn to integrate technology and biomedical informatics to find creative solutions in the DD process.

Study Highlights

WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?

✔ DD is a multidisciplinary process that has been becoming time-consuming and expensive over the last several decades, in part, due to potential drugs falling into the translational gap between discovery of new chemical compounds and clinical trials.

WHAT QUESTION DID THIS STUDY ADDRESS?

✔ This study evaluated if a DD Educational Program could effectively familiarize students, especially those at an early career stage, with the process of DD from identification of therapeutic targets all the way through to postapproval pharmacovigilance.

WHAT THIS STUDY ADDS TO OUR KNOWLEDGE?

✔ Students reported higher knowledge across all course domains, high relevance of both courses to their future careers, and gave high ratings to our multidisciplinary group of lecturers.

HOW THIS MIGHT CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?

✔ Graduates of our Drug Development Educational Program could be better prepared for a career in translational research and more able to find innovative ways to overcome the challenges of modern DD. Our program also serves as a model for other like-minded academic institutions to develop their own programs.

Drug discovery and drug development (DD) are often referred to as a pipeline that starts with a clinical question, moves to the laboratory, and, if successful, journeys through trials and production to clinics and patients, and, in the end, affects practice standards and guidelines. However, this process is rarely straightforward and can take between 10 and 15 years.1 Additionally, the cost to discover and develop one new drug has been increasing for the past several decades,1, 6 costing on average US $2.6 billion. This significant cost and time is due to many newly discovered chemical compounds falling into the translational gap, or failing to make it through clinical trials and become viable products that are available to the public. Only 1 of every 10,000 new chemical compounds identified during the discovery process is developed with the goal of advancing to human trials, and, in the end, only 10–16% of drugs that enter phase I trials are approved.1 Due to the cost, risk of failure, and development time that is often over half the length of a patent term, there is a trend among larger drug companies to invest at later stages of DD, when clinical proof-of-concept has already been established.1, 2 There has also been a trend for companies to focus on specialty medicines or biologics, as opposed to primary care medications, due to a higher unmet medical need and, therefore, more potential for profit.3 Collaborative partnerships between the pharmaceutical industry and academic institutions have been proposed as one method to make the DD process more efficient and cost-effective.1, 2 To this end, many drug companies have reorganized their infrastructure so that their research and development facilities are located in cities with large universities.

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creating hotspots for bioscience innovation. However, there is still the issue of overcoming the translational gap. From the industry perspective, pharmaceutical companies have recognized that the translational gap is a significant barrier to productivity and have designed translational medicine guides to improve their research and development process.

As DD epitomizes the translational research continuum, we believe that education, specifically an early career stage, is part of the solution. At the time of writing, there are no known DD programs within the 62 US active members of the Clinical and Translational Science Award/Clinical and Translational Science Institute consortium. We describe here our Drug Development Educational Program at The New York University-New York City Health and Hospitals Clinical and Translational Science Institute at the New York University School of Medicine.

METHODS

Our DD program was created in an effort to examine drug discovery and development with a fine lens and teach interested students about both successes and failures with the hope that those trained will go forward and improve the process. We were awarded an educational grant in response to a National Institute of Diabetes and Digestive and Kidney Disease educational program grant announcement (PAR-10-092); the program was created by centralizing, adapting, and expanding existing courses at New York University School of Medicine as well as opening enrollment to a more extensive NYU student base, with future plans to enroll externally. The goals are ultimately to teach a new generation of researchers and drug discovery/development career-minded individuals at the graduate and postgraduate level to harness novel bench-to-bedside empirical knowledge in their research and/or related endeavors using a multidisciplinary approach.

Our educational program is unlike standard pharmacology courses, in that our courses highlight the many essential and innovative features of the DD process and integrate all components of the translational continuum, from molecular signaling pathways at the bench to public health policies and practice standards. The curriculum focuses on both the scientific and “nonscientific” core tenets in DD and development with speakers from academia, industry, the economic and legal sectors, as well as those from government agencies. Currently, our DD program consists of two courses, one in the fall and one in the spring semester, both of which were first offered in the 2012–2013 academic year. The fall course, Drug Development in a New Era (course number: BMSC-GA 4419), focuses on topics at the later stages of DD, such as clinical trials and marketing. The spring course explores the nature of DD from the biomedical and biochemical perspectives. Students are taught principles of creating therapeutics in a laboratory, ranging from topics as diverse as glycosaminoglycan signaling pathways to RAS and AKT signaling in the therapeutic drug response. In contrast to the fall course, most lectures are taught by people with high-level scientific knowledge on topics with the potential to convey information that would be helpful in the design of new drugs from a bench standpoint (Table 1). Similar to the fall course, lectures run for 90 min with a 30-min discussion period.

Program assessment

Pre- and post-course surveys

On the first and last day of each course, students completed a seven-item (fall) or eight-item (spring) survey containing questions about their perceived knowledge of course topics (see Supplementary Files S1 and S2). Each survey also had one additional question asking about how relevant students thought the course was to their career (Figure 1). Of note, one knowledge question, which asked about identifying and categorizing drugs, was added to the course survey...
for the spring course during the second year of the program. Response options for each question were: nothing (1); almost nothing (2); some (3); and a great deal (4). Pre/post differences were compared on each individual knowledge question item as well as on a total knowledge score calculated by summing the score of each knowledge question. Pre/post differences in the career relevance question were analyzed separately.

Lecture ratings
On the last day of each course, students rated each lecture on four domains: content, presentation, relevance, and overall (see Supplementary Files S3 and S4). Response options for each domain were: poor (1); lower than expected (2); satisfactory (3); above expectations (4); and superior (5). The mean score of each domain was calculated for each lecture from individual students' scores. Then, a grand mean of each domain for the course was calculated using each individual lecture's mean score.

RESULTS
Course enrollment and career development support
During the first 2 years of our program, 37 students enrolled in the fall course, Drug Development in a New Era, including 11 MD/Masters of Science in Clinical Investigation students (30%), 11 PhD students (30%), 4 faculty (11%), 7 fellows (20%), and 3 MS students (9%). In these same years, 23 students enrolled in the spring course, Molecular Signaling and Drug Development. Of these, 21 were PhD students (91.3%), 1 was an MD/PhD student (4.3%), and 1 was faculty (4.3%). Enrolled students were eligible for support for career development opportunities, such as attendance at conferences, workshops, and fairs ($20,000--$25,000/year).

Pre/post-course surveys
Fall course: Drug development in a new era
Of 37 students who enrolled in the Drug Development in a New Era course across both years, 33 completed both the pre- and post-course surveys (89.2%). The responses to all of the individual knowledge questions and the career relevance question at both time points were not normally distributed (Kolmogorov-Smirnov $p < 0.001$; Shapiro-Wilk $p < 0.001$ for each item), therefore, nonparametric tests were used for data analysis. The pre-course total knowledge score was normally distributed (Kolmogorov-Smirnov $p = 0.20$; Shapiro-Wilk $p = 0.65$), but the post-course total knowledge score was not (Kolmogorov-Smirnov $p = 0.02$; Shapiro-Wilk $p = 0.03$), therefore, nonparametric tests were used for data analysis.

Pre/post differences in knowledge were analyzed using the Wilcoxon Signed Rank test (Table 2, Figure 1). There were significant differences in each individual knowledge question ($Z = -4.22$ to $-5.03$; $p < 0.001$) as well as the total knowledge score ($Z = -5.02$; $p < 0.001$).

Pre/post differences in career relevance were also analyzed using the Wilcoxon Signed Rank Test (Table 2, Figure 1). The mean pre-course career relevance score was 3.49 (0.69) and the mean post-course score was 3.48 (0.67), indicating that students thought the course was highly relevant to their careers. There was no difference between perceived career relevance ($Z = 0.00$; $p = 1.00$).

Spring course: Molecular signaling and drug development
Of 23 students who enrolled in the Molecular Signaling and Drug Development course across both years, 15 completed both the pre- and post-course surveys (65.2%). Similar to the Drug Development course, the responses to all of the individual knowledge questions and the career relevance...
Figure 1  Responses to pre- and post-course surveys for the Drug Development in a New Era course. Students were asked to rate their knowledge of course domains and perceived career relevance of the course on a four-point scale (nothing, almost nothing, some, or a great deal). There were significant self-reported increases in knowledge for all questions, however, there were no significant pre/post-course differences in perceived career relevance.

Table 2  Drug development in a new era pre/post-course surveys

| Knowledge questions                                                                 | 1       | 2       | 3       | 4       | 5       | 6       | 7       | Total knowledge score | Career relevance |
|------------------------------------------------------------------------------------|---------|---------|---------|---------|---------|---------|---------|-----------------------|-----------------|
| Pre-course mean (SD)                                                               | 2.51 (0.73) | 2.49 (0.73) | 2.08 (0.64) | 2.51 (0.73) | 2.46 (0.69) | 1.97 (0.73) | 1.95 (0.74) | 15.97 (3.65)          | 3.49 (0.69)     |
| Post-course mean (SD)                                                              | 3.76 (0.44) | 3.52 (0.51) | 3.73 (0.45) | 3.79 (0.42) | 3.30 (0.47) | 3.36 (0.55) | 3.71 (0.46) | 25.15 (2.11)          | 3.48 (0.67)     |
| Mean difference                                                                    | 1.24***  | 1.03***  | 1.65***  | 1.27***  | 0.84***  | 1.39***  | 1.76***  | 9.18***              | −0.01           |

Wilcoxon Signed Ranks Test; *p < 0.05. **p < 0.01. ***p < 0.001.

question at both time points were not normally distributed (Kolmogorov-Smirnov p ≤ 0.02; Shapiro-Wilk p ≤ 0.03). The pre-course total knowledge score was normally distributed (Kolmogorov-Smirnov p = 0.72; Shapiro-Wilk p = 0.07) and tests of normality obtained different results for the post-course total knowledge score (Kolmogorov-Smirnov p = 0.04; Shapiro-Wilk p = 0.35). Based on the nonnormal distributions of the data and the small sample size, nonparametric tests were used for data analysis.

Pre/post differences in knowledge were analyzed using the Wilcoxon Signed Rank Test (Table 3, Figure 2). There were significant differences in each individual knowledge question (Z = −2.98 to −3.34; p ≤ 0.003), except for the question about identifying and categorizing drugs that was added during the second year of the course (Z = −1.34; p = 0.18) and, therefore, answered by a small number of students (n = 4). There was also a significant difference in the total knowledge score (Z = −3.41; p < 0.001).
Table 3 Molecular Signaling and Drug Development Pre/Post-Course Surveys

| Question | 1     | 2     | 3     | 4     | 5     | 6     | 7     | 8     | Total knowledge score | Career relevance |
|----------|-------|-------|-------|-------|-------|-------|-------|-------|------------------------|------------------|
| Pre-course mean (SD) | 1.94 (1.03) | 2.18 (0.88) | 2.35 (0.86) | 2.12 (0.78) | 2.35 (0.70) | 2.00 (0.82) | 1.81 (0.75) | 1.82 (0.81) | 14.94 (5.09) | 3.65 (0.49) |
| Post-course mean (SD) | 3.33 (0.62) | 3.53 (0.52) | 3.21 (0.58) | 3.53 (0.52) | 3.60 (0.51) | 3.00 (0.0)  | 3.07 (0.70) | 3.40 (0.63) | 24.07 (2.49) | 3.47 (0.99) |
| Mean difference | 1.39” | 1.36” | 0.86’ | 1.42” | 1.25” | 1.00 | 1.25” | 1.58” | 9.13” | −0.18 |

Wilcoxon Signed Ranks Test; "p < 0.05. **p < 0.01. ***p < 0.001.

Figure 2 Responses to pre- and post-course surveys for the Molecular Signaling and Drug Development course. As in the fall course, students were asked to rate their knowledge of course domains and perceived career relevance of the course on the same four-point scale. There were significant self-reported increases in knowledge for all questions except question 6. Again, there were no significant pre/post-course differences in perceived career relevance.

Pre/post differences in career relevance were also analyzed using the Wilcoxon Signed Rank Test (Table 3, Figure 2). The mean pre-course career relevance score was 3.65 (0.49) and the mean post-course score was 3.47 (0.70), again indicating the high relevance of the course to students’ careers. There was no difference between perceived career relevance (Z = −0.59; p = 0.56).

Lecture ratings
Thirty students in the Drug Development in a New Era course completed the lecture ratings (81.1%). The mean rating for each domain was: content 4.04 (0.82), presentation 3.95 (0.89), relevance 4.12 (0.82), and overall 4.02 (0.84). These mean scores correlate to a rating of above expectations across all four domains, with most responses ranging from satisfactory to superior.

In the Molecular Signaling and Drug Development course, 16 students completed the lecture ratings (69.6%) and, again, the lectures were rated very highly, with mean ratings of: content 4.16 (0.85), relevance 4.24 (0.83), and overall 4.18 (0.81).
DISCUSSION
Limitations
As a newly developed program at a single academic institution, there are a number of limitations to our current program evaluation. First, we did not collect background information about the students who enrolled in either course, in terms of prior experience in DD, prior education in pharmacology, or why they chose to enroll in our DD program. Our sample size was also limited (n = 37 in the fall course and n = 23 in the spring) because there is only one session of each course offered per semester. Additionally, both pre- and post-course surveys as well as lecture ratings were not mandatory for students enrolled in the course. Although the Drug Development in a New Era course had a relatively high response rate (89.2% completed both pre- and post-course surveys, 81.1% completed lecture ratings), the Molecular Signaling and Drug Development course had lower responses rates (65.2% for the surveys, 69.6% for lecture ratings), which could reflect a lower interest in, or opinion of, the spring course. The pre- and post-course surveys were also limited in the type of data collected; they only ask about self-reported knowledge of each course topic and there are no quizzes or final examination to determine knowledge more objectively. Finally, as our DD program is relatively new, with the first courses running in the 2012–2013 academic year, we have not collected longitudinal data about how our program influences the career trajectory or research interests of students who have taken one or both courses.

Program evaluation and expansion
The course series is in its fourth year and we continue to collect course surveys and lecture ratings. The next step in evaluating our program includes better characterizing the prior experience of students who enroll in our courses in terms of their interest and prior experience with pharmacology and DD. We also plan on following up with students after graduating to determine their involvement in translational research, especially DD, and to survey them on their perceived impact of our program on their career trajectory and current work.

Due to increasing enrollment, we have expanded the DD program in several ways. First, we introduced another course entitled “Biotechnology Industry, Structure, and Strategy” in the spring 2015 semester. Second, we developed a New York State approved concentration and certificate program entitled “Health Innovations and Therapeutics” intended for students interested in health entrepreneurship (Table 4). Finally, we plan to extend our educational program to include more postdoctoral trainees by collaborating with NYU’s biomedical institutes and the Broadening PhD Career Awareness and Preparation, a new model for training scientist for careers outside of academia whose goal is to transform the nature of scientific training into a tailored program that maximizes quality and efficiency.

CONCLUSION
Our DD educational program is brimming with potential, as demonstrated by student reported-increased knowledge across all course domains, high relevance of course topics to their future careers, and consistently high ratings of our multidisciplinary lecturers. These successes and ongoing expansion make our program poised to produce researchers and clinicians capable of tackling the complex issues in modern DD and narrowing the translational gap. Our program also can serve as a model for like-minded academic institutions who aim to develop innovative, collaborative programs committed to shortening the path to developing new disease-modifying therapies and technologies in order to improve public health.

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Conflict of Interest. The authors declared no conflict of interest.

Previous Presentation. This study was presented as a Poster presentation entitled “New York University School of Medicine Drug Development Educational Program: 2-Year Benchmark” at the Translational Science Meeting, Washington, D.C., 16 April 2015.

| Year | Term    | Courses                               | Credits |
|------|---------|---------------------------------------|---------|
| Year 1 | Summer  | Clinical Research Methods             | 3       |
|       | Fall    | Introduction to Biostatistical Analysis| 3       |
|       |         | Drug Development in a New Era         | 3       |
|       |         | Advanced Epidemiology (Elective)      | 3       |
|       |         | Integrative Seminar                   | 1       |
| Spring|         | Biotechnology Industry, Structure, and Strategy | 3       |
|       |         | Molecular Signaling and Drug Development | 4       |
|       |         | Clinical Trials Design                | 4       |
|       |         | Biomolecular Medicine (Selective)     | 3       |
|       |         | Integrative Seminar + Independent Research | 1 + 1 |
| Year 2 | Fall    | Medical Informatics (Selective)       | 3       |
|       |         | Integrative Seminar + Independent Research | 1 + 3 |
| Spring|         | Integrative Seminar + Independent Research | 1 + 5 |
|       |         | Trending Topics Seminar               | 3       |
| Total |         |                                       | 35–45   |

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