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Predoctoral and Postdoctoral Training Pipeline in Translational Biomaterials Research and Regenerative Medicine

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Abstract

The translation of biomaterial based and regenerative therapies from the laboratory to patients involves multiple challenges. One of the most pressing challenges is the educational one: to train a cohort of scientists and engineers capable of translating their discoveries from bench to market to clinic. To meet this need, translational training programs are being implemented globally at universities and as partnerships between universities and corporations. In this perspective, we describe two translational NIH T32 graduate and postgraduate training programs that augment the traditional approach to training early stage scientists and engineers. At the graduate level, Boston University developed and implemented the Translational Research in Biomaterials (TRB) predoctoral training program. At the postgraduate level, Rutgers, The State University of New Jersey, developed and implemented the Translational Research in Regenerative Medicine (TRRM) program for postdoctoral training. These programs are motivated by the need for training in translational research in the biomedical field, by young scientists' requests for such training, and by the fundamental challenges facing future discovery and clinical implementation of biomaterial-based technologies. The TRB program immerses trainees in the concept of translating an idea from the research laboratory to the clinic, introduces them to the challenges of such an endeavor, provides discussions with relevant faculty (for example, with businesses, patient care, or clinical trial experience), and educates them in the critical areas required for their future careers. Similarly, the TRRM program emphasizes translational research and the concept of "training without borders," which enables collaborations across several geographically dispersed institutions so as to make regional experts accessible regardless of where they are located physically. Both programs promote interdisciplinary research, expose young scientists and engineers to challenges outside of their specialty, and build interpersonal skills for cross-disciplinary communication. The TRB program focuses on quantitative science and engineering courses, together with translation-based courses in clinical trials and business. The TRRM program focuses on broadening the horizon of its trainees through exposure to a wider network of mentors than traditional postdoctoral

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programs, and by encouraging trainees to engage in collaborative research across at least two different laboratories. Both programs meet significant public health needs: the skills that trainees acquire are essential in future biomedical careers as they join teams that combine diverse backgrounds to meet a common goal in research, development, and ultimately commercialization.

Graphical Abstract

Keywords

biomaterials; regenerative medicine; translation; graduate education; predoctoral training; postdoctoral training

Biomaterials are revolutionizing the field of medicine. Since the first introduction of metal hip prostheses in the 1930s, biomaterials have been applied to an exponentially increasing number of clinical challenges and today are key components in drug delivery systems, diagnostic devices, and tissue engineering technologies.^{1–5} A combination of advances in basic science and engineering has enabled the development of new processing methods and compositionally complex materials possessing novel properties and enhanced performance characteristics. Simultaneously, the field of regenerative medicine has evolved from largely experimental concepts in tissue engineering in the late 1980s into stem cell and scaffold-based therapies for regenerating functional tissues, rather than treating diseases in the traditional sense.⁶ The challenges of successfully translating these biomaterials and therapies from the laboratory to the marketplace have also evolved.⁷ These challenges are scientific, translational, commercial, and educational,^{8–11} and thus we believe that the traditional approach to training early stage scientists and engineers—through primarily the scientific and engineering aspects of biomaterials and regenerative therapies—can be augmented through innovative translational training programs. This need is being recognized globally by a number of academic institutions that, with the support of national and international government and private funding agencies, have implemented translational training programs. One example is the Innovative Training Program funded by the European Commission through Marie Curie Fellowships, which enables fellows to collaborate with partners from academia and industry in preparation for bridging the divide between universities, research centers, and companies that focus on research innovation and entrepreneurship. Similarly, the Biodesign Innovation Fellowship program at Stanford University takes a project-based approach for trainees to find innovative solutions for current healthcare needs.

Another example is Dartmouth's PhD Innovation Program, which trains aspiring engineers to become entrepreneurs and translate their ideas into viable commercial products.

Furthermore, the National Institutes of Health (NIH) in the United States and National Institute of Health Research in the United Kingdom are each implementing translational training programs. Some other training programs, such as Synergy Scholars Program at Dartmouth College and Harvard Clinical and Translational Science Center, emphasize clinical aspects of translational training. More than 60 institutions in the United States have received support from the NIH through their Clinical and Translational Science Awards. Herein, we provide an in-depth look at two case studies of NIH funded T32 translational training programs: Boston University (BU) has created the Translational Research in Biomaterials (TRB) predoctoral training program, and Rutgers, The State University of New Jersey (RU), has created the Translational Research in Regenerative Medicine (TRRM) training program for postdoctoral trainees. Together, these programs exemplify an approach or pipeline for training young scientists/engineers in translation and toward developing their discoveries into clinically relevant therapies.

The TRB program was initiated as a pilot project in 2007 with funding from BU, and went on to receive support from the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the National Institutes of Health (NIH) in 2009, and again in 2015 through the T32 Training Program funding mechanism. The TRRM program began at RU in 2002 as a T32 postdoctoral training program funded by the NIH's National Heart, Lung and Blood Institute (NHLBI), transitioned in 2007 to NIBIB funding, and has evolved over 15 years (three cycles), with a fourth cycle planned. The goal of these programs is to train interdisciplinary, translational research scientists and engineers who understand the importance of communicating and collaborating with clinicians and industry experts at every stage of research and development, as well as being able to discern the broader issues of translating laboratory advances to the marketplace.

In this article, we describe our program elements, administrative structure, and trainee outcomes. Importantly, we share our experiences of what worked, what did not, and the challenges we overcame in conducting these experiments in educational/curricular development. The goal in sharing our findings is to: (1) enable other departments and programs to learn from our experiences and use this information to better serve their trainees; and (2) describe pregraduate and postgraduate PhD educational paradigms that, we hypothesize, have the potential to advance translational progress in the fields of biomaterials and regenerative medicine. The overarching objective is to promote discussion of training programs to facilitate progress in the field of translational biomaterials/regenerative medicine.

PROGRAM ELEMENTS AND TRAINING OBJECTIVES

TRB.

The TRB graduate student program combines traditional quantitative science and engineering training through coursework and laboratory research with career development, networking, and translational courses in clinical trials and business. It introduces students to the challenges of translating biomaterial discoveries and to the critical requirements for achieving clinical and commercial success (Figure 1). The TRB program focuses on the development of each trainee as she/he grows to become an effective translational scientist/

engineer by having the TRB program leaders and mentors work individually with each trainee to develop a tailored career plan (Individual Development Plan). TRB training is solidly grounded in the elements of a conventional graduate training program, including: promoting a research-intensive PhD thesis, ensuring instruction in the responsible conduct of research, encouraging trainees to attend local and national conferences, providing leadership for predoctoral trainees and enrichment opportunities via organizing and running a quarterly journal/seminar club and the annual symposium, as well as requiring students to identify and invite a luminary in biomaterials research to give the annual “Distinguished BU Biomaterials Lecture.” The TRB program has additional unique training elements that aim to do the following.

- Provide predoctoral trainees with a foundation in biomaterials and tissue engineering concepts that encourages innovation. The TRB program achieves this objective through a rigorous two-semester course in Biomaterials, which includes a laboratory section, a deconstructive design project on an existing medical device, and writing a mock “exploratory/developmental research grant” (R21). This type of NIH grant encourages the trainees (the “investigators”) to formulate novel, high-impact, high-risk ideas that have the potential to advance biomaterials research.
- Equip predoctoral trainees with the capacity to identify and meet translational challenges in biomaterials research by offering professional enhancement and translational courses at BU (e.g., Clinical Trials: Regulatory and Compliance Issues, and Bench-to-Bedside: Translating Biomedical Innovation from the Laboratory to the Marketplace). Industrial partnerships are integral to successful translation, and, therefore the TRB program coordinates with a preclinical contract research organization to run a “Pre-clinical Testing and Regulatory Issues Workshop.”
- Facilitate one-on-one and small group interactions with clinicians to learn, first-hand, the problems they face in the care of their patients—a key step in identifying the unmet clinical needs to be addressed—through informal meetings/dinners with health professionals and clinician comentors for each trainee.
- Enhance trainee–faculty interactions by providing mentor/mentee workshops whereby students learn ways to improve relationships with mentors, and constructive ways of dealing with problems encountered in the workplace. These workshops are centered around case studies or scenarios of challenging interactions between mentor and mentee and cover: (1) roles and expectations of graduate students and their advisors and mentors; (2) building productive mentoring relationships; and (3) resolving challenges. Importantly, this element provides a communication/interpersonal skills platform that they will use in their future careers in industry, government, or academia.
- Promote networking opportunities across colleges and departments, reaching into business, healthcare, and public spheres where the predoctoral trainees can

increase their scientific knowledge and hone their interpersonal skills via seminars and workshops, team-building activities, and training in ethics.

- Offer professional development workshops, personal coaching, and career mentoring to prepare the predoctoral trainees for their future careers. These activities encompass Individual Development Plans, career panel nights, workshops, and one-on-one interactions with the TRB's Associate Director for Professional Development (former Chief Technology Officer for the Surgical Division of Johnson & Johnson).
- Track the outcomes of TRB alumni by maintaining contact to determine career progress, and engage their involvement in and connection to the TRB through participation in development workshops and seminars. Over time, information gathered about our alumni will allow us to test the underlying hypothesis of our training grant: that early training in translational research fosters the translation of biomaterial laboratory discoveries into clinical applications.

TRRM.

The TRRM program was built around the concept that postdoctoral training programs, in addition to training in state-of-the-art research, must improve the chances of their trainees finding meaningful, science-rich employment across all sectors: academia, government, industry, and alternative career paths. The TRRM program for postdoctoral trainees has evolved over three five-year cycles, with a fourth cycle being pursued. The current cycle, "Training Without Borders: Translational Research in Regenerative Medicine" (2012–2017) focuses on two innovative features:

- Mentor postdoctoral trainees via a unique team of geographically dispersed faculty.
- Provide a training environment that combines conventional academic training (state-of-the-art science, proposal writing, responsible conduct of research) with training in translation and commercialization.

The result of this program is a community of learning across a geographically dispersed training community. The core strength of this program is its interdisciplinary breadth, providing its trainees with opportunities to conduct research on rationally designed biomaterials, bioactive microenvironments, cell profiling technologies, and regenerative biology. On the basis of best-practices derived from the prior cycles, the training program proposed for the fourth cycle (2018–2023) will retain the current structure, but with a revisited group of participating institutions and mentors, and a new paradigm: Bench-to-Business-to-Bedside (B³).

Although the term Bench-to-Bedside is often used to describe translation, the TRRM program extends this concept to offer the expanded exposure of Bench-to-Business-to-Bedside, requiring a mentoring constellation consisting of academic, industrial, and clinical subject matter experts (Figure 1). Therefore, the aspirational goal for TRRM is to create "B³-Trained" professionals: Scientists with expert problem-solving skills in their home disciplines, who are also entrepreneurial and possess crucial skills such as budgeting, project

management, running meetings, and writing effective nontechnical prose. This approach aligns with the recent focus of many federal funders on fostering translation. A critical element of such a program is described by the term innovation-primed science. Innovation-primed science refers to breakthrough, scientific ideas for which proof-of-concept has already been established. A trainee signing on to an innovation-primed science project has the realistic possibility to drive this project toward translation into a product or a clinically used therapy. Fostering B³-Trained professionals requires a unique training infrastructure, composed of not only of the traditional academic mentors (scientific or clinical faculty who lead top laboratories) but also of a Training Advisory Board (TAB) comprising experts in regenerative medicine and clinical practice, entrepreneurs, industrial scientists, investors, and leading subject-matter experts in translation and commercialization. The TAB effectively fills the expertise gaps among academic faculty mentors, by creating a mentoring constellation of academic, industrial, and clinical experts for each trainee.

PROGRAM STRUCTURE

Faculty Mentors.

The TRB program is housed and administered in the BU Biomedical Engineering (BME) Department. Although the majority of predoctoral trainees are in the BME PhD program, the pool of mentors is broad and highly interdisciplinary, involving scientists and engineers from both BU and the Boston University School of Medicine (BUSM). It is composed of 23 BU/BUSM faculty members from BME, Biochemistry, Chemistry, Electrical Engineering, Dermatology, Mechanical Engineering, Ophthalmology, Orthopedics, Pathology, and Radiology. As the Director/Principal Investigator (PI), Grinstaff has a joint primary appointment in BME and Chemistry, and a secondary appointment in Medicine, reflective of his focus on interdisciplinary, translational research. In response to trainee research interests, mentors from outside BU/BUSM have also joined the program. They include three co-mentors during the last five years (Ophthalmology, Schepens Eye Research Institute; Orthopedics, Beth Israel Deaconess Medical Center; and Surgical Oncology, Brigham and Women's Hospital). The common thread among this diverse community of training faculty and mentors is their broad and requisite background in biomaterials, as well as a strong track record of research funding, productivity, and mentoring experience.

The TRRM program, although based in the New Jersey Center for Biomaterials (NJCBM) at Rutgers University, is geographically dispersed by design. It is organized around a group of faculty mentors from regional institutions, who have already established collaborations with each other in the area of regenerative medicine in order to provide unique cross-disciplinary research experiences for postdoctoral trainees. In the current funding cycle (2012–2017), there are 14 faculty mentors from six institutions, including a wide range of schools and departments. All share a strong track record of funded research and postdoctoral mentoring. The program director is Joachim Kohn, a biomaterials scientist, and the program administrator is Hilton Kaplan, who is an MD/PhD with both clinical and industrial experience. The 14 core mentoring faculty comprise a mix of research scientists (8) and physicians(6), from the following institutions: Boston University, Case Western Reserve University, Massachusetts General Hospital-Harvard, Mayo Clinic, Princeton University,

and Rutgers University. This core faculty conducts advanced research in the fields of tissue engineering and regenerative medicine, with a strong track record of translation toward commercial products in partnership with industry.

Administrative Structure Supports Trainee Development.

The TRB program's main administrative unit is the Steering Committee (SC), which meets quarterly, with subgroups meeting independently as needed. The SC is composed of the Director/PI, a TRB trainee, the Assistant Dean for Outreach and Diversity, the Associate Director for Education, and the Associate Director for Professional Development. It is directly linked to the BME Department's Executive Committee through the participation of the Department Chair and the Chair of the Graduate Admissions Committee. The SC assesses all aspects of the program, including trainee recruitment and progress, trainee Individual Development Plans, faculty mentors, trainee activities, curriculum development, retention and outcomes of graduating trainees, and reports on the career progress of TRB alumni. Since starting the program, there have been four significant administrative improvements or additions. Early in the program, the administrative structure was streamlined from an Executive Committee and Graduate Committee to a single Steering Committee. In 2011, the School of Engineering's Assistant Dean for Outreach and Diversity was added to prioritize the recruitment of minorities (individuals from racial and ethnic groups that are underrepresented in biomedical research including: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders) and thereby create a stronger and more diverse cohort of trainees. The position of Associate Director for Education (ADE) was also added, to work with the TRB Director/PI in coordinating the program's training activities, including the implementation, monitoring, and ongoing development of the program as it evolves and grows in number. Finally, in response to trainee interest, the TRB program recruited an Associate Director for Professional Development (ADPD) with biomedical product commercialization and entrepreneurial experience. The ADPD coordinates the program's Professional Development activities which include lectures, workshops, job interview simulations, and personal coaching to help trainees define their career goals, identify ideal forms of professional contribution to their chosen field, develop professional skills and techniques, negotiate job offers, and successfully integrate into their career environments.

The TRRM program has two PIs and an active Steering Committee (SC), comprising the two PIs together with two faculty selected in each cycle. The SC reviews potential applicants for admission; and decides on any programmatic changes that may be required from time to time by majority vote. Finally, an External Advisory Board (EAB) is elected annually, comprising three senior faculty members from relevant institutions, including at least one clinician. The EAB monitors the program's progress and provides clearly defined recommendations each year for potential improvements. This ensures that the program iterates every year, building on past experiences and generating best-practices. The program explores and evaluates the benefits offered by a geographically dispersed faculty, relative to the extra cost and complexity of providing consistent training across multiple institutions. To create a "community of learning", the program includes a live online training course in stem cells and regenerative medicine, "RENEW", which each trainee is required to complete

during their fellowship. This course has become a popular way for the dispersed trainees to interact weekly as a group. The sense of belonging to a community of learning is further promoted by the annual T32 Immersion Workshop, where trainees and faculty gather at Rutgers University for a week-long series of didactic and social activities. To develop a critical mass for robust interaction, and to further stimulate collaborations, this event is organized in coordination with RESBIO, the NIH-funded Biomedical Technology Resource (P41) program operating at the NJ Center for Biomaterials. Both programs have similar scientific foci, and as RESBIO requires its own training and dissemination activities, pooling these communities creates a more vibrant event and generates a critical mass of 30–40 participants to maintain a Gordon Conference-style group dynamic. Finally, another approach to building a strong core community across distance is the inclusion of affiliate trainees, by inviting postdocs from mentors' laboratories to join their T32 colleagues in the various activities offered. This more than doubles the effective T32 community.

Trainee Populations.

TRB. Between 2009 and 2014, the BU TRB has had 13 interdisciplinary trainees (six women, seven men, 15% minority, 100% retention—defined as the number of trainee entering the program and graduating). These students come primarily from the large pool of training grant-qualified PhD applicants from BME, as well as students from Chemistry, Electrical Engineering, Mechanical Engineering, and other departments who are training grant-qualified and have research interests in translational biomaterials. The Director interviews each candidate because, while required, it is not believed that high grades (GPA >3.7 on a 4 point scale) and GRE (quantitative and verbal >1360) scores are sufficient to identify the individual trainee traits and experiences that will match and enrich the TRB mission. Specifically, a personal interview is aimed to offer insight into an applicant's character, her/his motivation in selecting a translational research training program, expectation for the PhD, and awareness about patient care and clinical needs issues. In addition to gathering important anecdotal details about a candidate's prior laboratory or work experience, publications, and presentations through the discussion, her/his thought process and response when an experiment does not work is explored. This aspect is particularly relevant because a great deal of research training—both traditional and translational—relies on resiliency and a willingness to learn equally from successes and failures.

TTRM.

Over the past 15 years, the TTRM has had 35 trainees (16 women, 19 men, 49% minority). The program encourages recent graduates or early postdoctoral candidates; and particularly those that aim to explore new research directions in the field, as opposed to those who simply wish to deepen their knowledge within their current focus areas. Applicants explore each core faculty's research interests and select a primary and a secondary mentor, at the same or different institutions, together with a detailed research proposal for the award period. Once these mentors agree to move forward, the trainee formally submits their proposal for consideration. The goal is for them to bring new skillsets to the lab, and to learn new ones in return. This does, however, mean that despite the high quality of the candidates

that are selected, they are generally not prolific publishers within their two-year terms (for research trainees) or one-year terms (for clinical residents).

Although at least one publication per year is required, the goal is to provide training in new areas for the participants, and this is evidenced by their significant successes in their subsequent career trajectories. For example, one alumnus of the program, an organic chemist, credits the program with giving him the background in cell biology and cell-material interactions and exposure to the challenges of translating discoveries from bench to bedside. Today, he is leading his laboratory as a tenured faculty member at a major research-intensive US university. His research has a meaningful chance to reach the clinic. Another past trainee entered the program with veterinary and research degrees. Now he is a senior veterinarian in a Department of Comparative Medicine Resources. He credits the program with integrating his areas of training and giving him a competitive advantage, not only in the past, but throughout his future career development either in academia or industry.

Both the TRB and TRRM programs are invested in the success of their trainees and have developed channels for continuous communication and review to help them meet their training goals. This involves establishing Individual Training & Development Plans (IDPs) at the start of each year, and reviewing these with the Director of each program, and their mentors, every six to nine months, in addition to their regular mentor meetings for research guidance. Information gathered from these discussions helps to evolve administrative practices, so that trainee selection, progress, development, and completion occur as successfully and efficiently as possible. In the TRB program, the director serves on the thesis committee of each trainee to ensure that the dissertation project incorporates sufficient quantitative, computational and/or analytical approaches in the context of addressing a translational question. Also, the student's research project must incorporate biological or physiological data against which quantitative analyses will be evaluated. In addition, the thesis must provide evidence that the predoctoral trainee can articulate the "big picture"; i.e., show an appreciation for how composition, structure, and properties of biomaterials translate to biological/clinical performance and, critically, how these may affect the success of achieving translation. This policy ensures consistency among the goals of the TRB training program and the student's research, course selections, and experiences. Finally, since Fall 2012, the TRB trainees have been encouraged to identify a clinician, clinician scientist, or public healthcare worker who would also serve as a co-mentor and/or member of her/his thesis committee. Even without this encouragement, TRB's first seven trainees were observed to have identified such a person for their dissertation committee. It is now a requirement for all trainees. This finding highlights two of our lessons learned: communication with clinicians at every stage of the biomaterial development process is one of the most important training aspects of the TRB, and the program benefits from an openness to trainee inputs.

TRAINEE OUTCOMES

General Observations.

One of the challenges of such interdisciplinary training grants, which focus on both research and translation, is to expand the success metric for our trainees from that of the more

traditional T32 training model. In the traditional model, the highest measure of success is for a trainee to ultimately become a tenure track professor at an academic institution. While this career goal is laudable and encouraged, having a professorship as the measure of success is highly limiting in programs such as TRB or TRRM. We argue that there is a need for highly trained, quantitative thinkers and motivated scientists and engineers in biomaterials development and/or regenerative medicine who are able to facilitate the translation of research breakthroughs into commercial products that benefit society. We also need scientifically trained experts who are ready to engage in diverse careers in industry, healthcare, and government, and scientists/engineers who achieve productive translational careers. These training goals cannot be adequately captured by the number of scientific publications produced by trainees, creating an urgent need to identify appropriate metrics for the success of translational training programs.

TRB Outcomes.

In terms of trainee outcomes, all of the graduated TRB trainees are employed as postdoctoral fellows or engineers/scientists in start-up biomedical companies. The average PhD completion time of these students was five years. As a group, the current TRB's 13 trainees have excelled on several fronts, from publications and presentations to patent applications and outreach. The metrics of the graduated trainees (8) include: publications (5/trainee); patents/patent applications (0.5/trainee); oral (3/trainee) and poster (13/trainee) presentations at local, national, and international meetings; 100% completion of coursework; participation in societal/community activities (e.g., President of the BU Student Association of Graduate Engineers and tutoring middle school students); and national fellowships/awards (0.75/trainee). The metrics are slightly above the graduates in the traditional BU BME PhD program (e.g., 4 publications, 2 oral presentations, 3 poster presentations, 0.15 patents, and 0.1 awards per student). TRB students have embraced the TRB curriculum, which goes beyond quantitative engineering to include business and clinical courses, as well as professional development. All trainees have been supported after their TRB funding ended through independently written fellowships (one NIH NRSA F31, three NSF GRFP awards, one US Pharmacopeial Global Fellowship Award, and one CIMIT Engineering Fellowship) or through the NIH R21/R01 grants of their mentors.

TRRM Outcomes.

Because of the focus on training for alternative careers, together with an acceptance requirement that trainees redirect their skillsets into new research areas, traditional metrics such as publications records have not been found to be the most relevant metric of TRRM trainees' successes. Instead, the successes of their career trajectories have been assessed. Over TRRM's 15-year period of operation, 26 of the 35 trainees could be tracked continuously. Of these, 12 have entered academia, where six are tenured or tenure-track professors. Two more recent trainees are in nontenure track positions and another two are in additional postdoctoral positions. The remaining 14 trainees have predominantly moved into industry, where their careers have rapidly advanced: One of the TRRM trainees has achieved a director-level position in a large corporation, and seven are senior scientists. None are unemployed and none have abandoned a science-rich career path.

The TRRM program has also contributed significantly to the training of physician-scientists. For example, one of the TRRM trainees had completed a plastic surgery residency when he entered the program to gain basic research experience that would enhance his approach to wound care and regenerative medicine. Today, this TRRM alum is the Founding Director of a prominent Regenerative Wound Healing Center, where he sees himself as “poised to bridge the widening translational gap between the basic and clinical sciences.” As another example, a neurologist and clinical fellow at one of the leading clinical institutions credits the program with providing specialized postgraduate training for physicians who have well-defined research interests. This alumnus benefited in particular from his training experience relating to industry and government relationships.

While the interpretation of results and statistics on small numbers is always problematic, the mentors of the TRB and TRRM programs take pride in their trainees’ individual accomplishments and in having the opportunity to mentor their training experiences.

FINDINGS AND CONCLUSIONS

TRB Program.

The TRB curriculum, faculty, and rotation portfolios have been greatly enhanced over the five years. The current TRB program continues to attract high caliber trainees who are goal oriented and dedicated to making tangible difference in how biomaterials are translated to the clinic. These trainees now focus on challenges in a range of clinical areas from tissue engineering and drug delivery to diagnostics. The involvement of clinicians has increased each year, and is an essential part of the training program. In partnership with the program Directors, trainees have also established a system to sustain activities beyond TRB, and therein, foster the themes of the TRB at Boston University at large. The TRB program has expanded the training mentor pool and matured the administrative approach based on experience and feedback. In short, the TRB program has succeeded in establishing a unique and empowering educational and training identity, and it has been leveraged to impact many other students and faculty members at Boston University.

TRRM Program.

The TRRM postdoctoral training program has focused on two innovative features. First, the implementation of the concept of a geographically dispersed training faculty, based on a unique team of mentors irrespective of their institutional affiliation. This made it possible to serve a wider range of highly qualified trainees who might not have been able to relocate to a specific institution; and for them to take advantage of strongly matched collaborators, and projects at all stages in the development pipeline. Second, the conventional training toward a tenured faculty position (state-of-the-art science, proposal writing, ethical conduct of research) was augmented with training in translational research and the pathways of commercialization. The current funding cycle (2012–2017) demonstrated that it is possible to create a “community of learning” across a geographically dispersed postdoctoral training program. Trainees were offered access to 14 research and clinical faculty across six partner institutions. Each year, the program supported six postdoctoral trainees through the NIH, complemented by three matched Rutgers positions and 8 affiliated postdoctoral associates

who were supported by other funding. The core strength of the program is its interdisciplinary breadth, providing trainees with opportunities to conduct research on rationally designed biomaterials, bioactive signaling microenvironments, cell profiling technologies, and regenerative biology of stem cells. Although these projects are anchored across a wide range of scientific disciplines, it is the co-mentoring arrangements and collaborations across the mentoring network that create unexpected synergies, true to the spirit of “training without borders”.

General Findings.

The three major findings of this curricular experiment are as follows: (1) It is essential that the training programs maintain flexibility in order to address the individual needs and interests of each trainee. This flexibility includes supporting the addition of new faculty who have an interest in the biomaterials and regenerative medicine areas, expanding the types of courses that can be taken by trainees, and being open to trainee inputs. For example, the TRB program has allowed the adoption of different courses (Managing and Improving Quality: Six Sigma Green Belt Certification instead of Regulatory and Compliance Issues) because these provide training on how to translate an idea to a product. Most recently, a student's request was granted to rotate with a faculty member who was not part of the original mentor group. This rotation opportunity proved to be excellent for the trainee, who has since joined the group and the faculty member is now a part of the TRB program. Similarly, in the TRRM program, flexibility has enhanced the training experiences. For example, one trainee's research benefited from switching primary and secondary mentors, and their home institutions, from their first year to their second. This was a strategic, planned approach incorporated into their initial individual plan, in order to allow them in their first year to acquire an important skillset, which they needed for their second year. On multiple other occasions, outside faculty were brought on as secondary “affiliate” mentors (from outside the pool of 14 primary faculty mentors), so that each trainee could benefit from the best possible mentoring arrangements available for their specific project.

(2) The programs work best when all the faculty mentors become stakeholders in the program's vision. This implies that the number of available mentors cannot be disproportionately large as compared to the number of NIH-supported trainees. Our fellow faculty mentors comment that it is highly rewarding to help advance new training paradigms.

(3) The trainees are interested in increasing their interpersonal communication skills so that they can better communicate with experts in other disciplines. They realize the importance of working with others to address complex health conditions. Through implementation of these findings, the TRB and TRRM programs are growing and evolving to meet the challenges of successfully translating biomaterial based and regenerative therapies from the laboratory to the marketplace.

Furthermore, several elements of the TRB and TRRM programs are worthy of consideration for incorporation into traditional PhD and postdoctoral training programs. For example, the coadvising of graduate students and the broader perspective of what constitutes an elective PhD course represent such elements. Similarly, for postdoctoral training, establishment of mentors outside of trainees' local micro-environments, identification of resources and

training opportunities present in other laboratories, and expanding their skill-sets to include management, running meetings, and writing effective nontechnical prose, are key lessons to install during their training to best prepare them for their future careers.

In addition to describing the TRB and TRRM programs, the goal of this perspective is to promote discussion of translational training programs within our community. The training of young scientists and engineers is our primary academic mission and a significant responsibility. We must be able to learn and adapt with the ever-changing landscape to provide our students and fellows the training to become future leaders, inventors, and translators in academia, government, and industry. In summary, we strongly believe that these new predoctoral and postdoctoral training models will accelerate the development of a highly creative and effective workforce of translational scientists and engineers who will strive to bring biomaterials and regenerative medicine products to the clinic, where they are critically needed.

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Biographies

Mark W. Grinstaff is the Distinguished Professor of Translational Research and a Professor of Biomedical Engineering, Chemistry, Materials Science and Engineering, and Medicine as well as the Director of the NIH T32 Program in Biomaterials at Boston University. Dr. Grinstaff's awards include the ACS Nobel Laureate Signature Award, NSF Career Award, Pew Scholar in the Biomedical Sciences, Camille Dreyfus Teacher-Scholar, Alfred P. Sloan Research Fellowship, and the Edward M. Kennedy Award for Health Care Innovation. He is a Fellow of the Royal Chemical Society, American Academy of Nanomedicine, and American Institute for Medical and Biomedical Engineering, and a Founding Fellow of the National Academy of Inventors. Over the course of his tenure, Dr. Grinstaff's groundbreaking research has yielded more than 275 peer-reviewed publications, more than 200 patents and patent applications, and more than 300 oral presentations. He is a cofounder of five companies, and his efforts and innovative ideas have led to one new FDA-approved pharmaceutical (Abraxane^{TM}) and three medical device products (OcuSeal and Adherus Surgical Sealants) that improve clinical care for hundreds of thousands of people. His current research activities involve the synthesis of new macromolecules and biomaterials, self-assembly chemistry, imaging contrast agents, drug delivery, and wound repair.

Hilton Kaplan is both a Plastic, Reconstructive, and Maxillofacial Surgeon and a Biomedical Engineer. Dr. Kaplan is Associate Director of the NJ Center for Biomaterials, Program Manager of the NIH T32 Program in Translational Research in Regenerative Medicine, Research Associate Professor at Rutgers University, and an Adjunct Professor in Regulatory Science at the University of Southern California. He has held leadership positions of increasing responsibility in industry, including Senior Medical Director at Allergan (Fortune 500 healthcare) and Vice President of Clinical Sciences at LifeCell (pioneers of tissue decellularization). Dr. Kaplan has a long history of passionately advocating for burn prevention and reconstruction (as a burn surgeon, founding board member of the nonprofit Grossman Burn Foundation, and adoptive father of a spirited burn survivor), and craniofacial reconstruction (as a founding director of the nonprofit Look-at-Us Alliance for Craniofacial Differences). His research focuses on neurosciences (nerve regeneration and neural prosthetics/implantable man-machine interfaces), and tissue engineering (decellularized composite tissues for limb and face allotransplantation).

Joachim Kohn is the Board of Governors Professor of Chemistry and Chemical Biology at Rutgers University, the Director of the NJ Center for Biomaterials, and Director of the NIH T32 Program in Translational Research in Regenerative Medicine. Dr. Kohn is a leader in biomaterials science and widely known for the development of tyrosine-derived, resorbable polymers, which are now used in several FDA-approved medical devices. Currently about 200 000 patients in the USA, Canada, Latin America, and Europe are using implants containing tyrosine-derived, resorbable polymers commercialized by REVA Medical and Medtronic. Kohn has authored over 200 peer-reviewed publications, 40 book chapters, and more than 70 issued U.S. patents. Since 2008, he directs the Rutgers-Cleveland Consortium of the Armed Forces Institute of Regenerative Medicine (AFIRM), a \$50 Million program funded by the Department of Defense. His current research efforts focus on the development of new discovery paradigms for revolutionary biomaterials using combinatorial and computational methods to optimize the composition, properties, and cellular responses of biomaterials for specific applications, particularly tissue engineering and drug delivery.

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Figure 1.

TRRM program provides innovation-primed research and training, to develop “B³-Ready T32 Trainees”.