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Challenges and Opportunities for Commercializing Technologies in the Pulmonary Arena

An Official American Thoracic Society Report

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Abstract

"Translational medicine" has been a buzzword for over two decades. The concept was intended to be lofty, to reflect a new "bench-to-bedside" approach to basic and clinical research that would bridge fields, close gaps, accelerate innovation, and shorten the time and effort it takes to bring novel technologies from basic discovery to clinical application. Has this approach been successful and lived up to its promise? Despite incredible scientific advances and innovations developed within academia, successful clinical translation into real-world solutions has been difficult. This has been particularly challenging within the pulmonary field, because there have been fewer U.S. Food and Drug Administration–approved drugs and higher failure rates for pulmonary therapies than with other common disease areas. The American Thoracic Society convened a working group with the goal of identifying major challenges related to the commercialization of technologies within the pulmonary space and opportunities to enhance this process. A survey was developed and administered to 164 participants within the pulmonary arena. This report provides a summary of these survey results. Importantly, this report identifies a number of poorly recognized challenges that exist in pulmonary academic settings, which likely contribute to diminished efficiency of commercialization efforts, ultimately hindering the rate of successful clinical translation. Because many innovations are initially developed in academic settings, this is a global public health issue that impacts the entire American Thoracic Society community. This report also summarizes key resources and opportunities and provides recommendations to enhance successful commercialization of pulmonary technologies.

Keywords: commercialization; pulmonary; technology development; intellectual property; academic entrepreneurship

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Executive Summary

This report is based on survey responses from 164 participants within the pulmonary research community. The overall goals of the survey were to identify critical challenges that need to be addressed and to identify key resources/opportunities to assist academic commercialization efforts and ultimately enhance the efficiency of successful commercialization of pulmonary-related technologies initially developed in academic settings.

- The overwhelming majority (81%) of participants indicated a high level of interest in the development of new technologies and/or commercialization of products.
- Most participants believed that there were deficiencies in the availability of business- and finance-related training and resources; these were identified as significant challenges for building entrepreneurial ventures.
- Early career professionals reported the greatest need for both business and financial training and resources.
- Institutional seed funding was the most common source of funding for technology and product development among participants (57%), followed by government agencies (36%).
- Most participants reported the need for improved *in vitro* and animal models for preclinical efficacy testing and the need for regulatory agency–approved biomarkers. These limitations may also impede the efficiency commercialization efforts in the pulmonary arena.
- A significant number of participants believed that they did not have access to sufficient support for the design of investigational new drug–enabling studies or access to sufficient expertise to assist with regulatory approvals and/or submission of materials to the U.S. Food and Drug Administration (FDA).
- Responses to intellectual property (IP)–related questions were mixed. Early career professionals had the greatest need for IP–related training and resources and also reported the lowest level of technology transfer office (TTO) engagement (only 18% vs. 48% engagement among senior career professionals).
- Leveraging institutional support (incubators, accelerators, technology transfer offices (TTOs), and seed funding), together with external training and resources, were considered to be critical for successful commercialization efforts.
- Many intangible factors were considered to be instrumental successful technology development, including strong networks, connections to biotech/industry, and protected time for entrepreneurial efforts.

Introduction

"Translational medicine" has been a buzzword for over two decades. It refers to the bench-to-bedside enterprise of harnessing basic science knowledge to produce new technologies that enhance patient care. It has been defined as the effective translation of new knowledge, mechanisms, and techniques generated by advances in basic science. This research is then "translated" into new approaches for prevention, diagnosis, and treatment of disease, which is essential for improving health (1). The concept was intended to be lofty, to reflect a new integrative approach to basic and clinical research that would bridge fields, close gaps, and shorten the amount of time and effort it takes to bring novel discoveries to clinical application (2). The end goal of translational medicine is the generation of new technology that can be commercialized ("brought to market"). Has this approach been successful? Translational medicine remains challenging, because the timeline for product development is long and the process is fraught with high failure rates, resulting in escalating development costs. High attrition rates during the process of drug discovery have made it more difficult and expensive to bring new chemical entities to market. For every approved new drug, there are ~10,000 drug candidates generated (3). Furthermore, despite scientific advancements and enormous unmet medical needs in respiratory medicine, there have been fewer U.S. Food and Drug Administration (FDA)-approved drugs and higher failure rates for pulmonary therapies than for other common disease areas, including cardiovascular, metabolic, and neurological diseases (3).

The mission of the American Thoracic Society (ATS) is to improve respiratory health worldwide by advancing research, clinical care, and public health in pulmonary diseases, critical illness, and sleep disorders. In 2019, the ATS Respiratory Cell and Molecular Biology (RCMB) assembly initiated the Entrepreneurial and Innovation Working Group (2), which is composed of academic, biotech, and industry leaders in the commercialization of novel respiratory products and treatments. The overall mission of this working group is to facilitate support of entrepreneurship in academic pulmonary research and medicine. One of the goals of this working group was to identify challenges and opportunities that exist for the development and/or commercialization of novel technologies within the pulmonary arena. To accomplish this, the working group developed an anonymous web-based survey that was distributed to the ATS community. The overall goals of the survey were to *1*) identify critical challenges (gaps in training/resources) that need to be addressed to enhance the development and commercialization of pulmonary-related technologies initially developed in academic settings, *2*) identify key opportunities to assist academics in the commercialization process, and *3*) publish the survey results to bring awareness and resources to the broader ATS community.

Methods

The cochairs of the RCMB Entrepreneurial and Innovation Working Group submitted a workshop proposal, which was funded by the ATS to support the development and data collection for this project. The cochairs collaborated with working group members, survey experts, and the ATS to develop a web-based survey designed to assess challenges and opportunities for the commercialization of pulmonary products (biomarker, device, and preclinical drug candidates) initially developed in academic settings. The survey had 31 questions to assess demographics, expertise, and opinions of participants (*see* Appendix E1 in the data supplement). The survey included yes-or-no questions, scale-based assessments, and open-ended questions. A pilot study performed within the working group indicated that the average time to compete the survey was ~5 minutes. The survey was distributed to the ATS community through a web link via official ATS e-mail communications and remained open to participation for ~3 months. Potential conflicts of interest (COI) were disclosed and managed in accordance with the policies and procedures of the ATS.

Results

Demographics

The survey was completed by 164 participants. The highest participation was by clinicians or clinician-scientists (57%) and Ph.D. researchers (30%) from academia (Figure 1A). The participation from in-training (student, post-doc, fellowship), contract research organization, biotech, and pharmaceutical industry participation was <5% for each. Participation was highest at the senior career level (44%), followed by early career (31%), and midcareer (24%) (Figure 1B). Participants were asked to identify their major areas of disease focus (Figure 1C).

Participants were asked to provide experience level in patent filing, licensing technologies, and company formation. More than half of participants filed at least one patent (Figure 1D), 28% had at least one technology/product/IP that they developed that has been licensed to a company (Figure 1E), and 18% have founded a company (Figure 1F). Participants were also asked to rate their level of expertise in various areas (Figure 2).

Commercialization and Business Development

The overwhelming majority (81%) of those surveyed were interested in developing new technologies and/or the commercialization of products (47% strongly agreed and 34% agreed) (Figure 3A). Although some participants were neutral, only a fraction (<5%) were not interested in developing new technologies and/or the commercialization of products (Figure 3A). However, despite the strong interest among participants in developing and/or commercializing technologies, the majority expressed a lack of sufficient training and resources available to support these efforts. More than half (53%) disagreed with the statement that they had sufficient training related to the commercialization of technologies and/or products (Figure 3B). Similarly, most participants (57%) disagreed with the statement that they had access to sufficient business support and expertise to build entrepreneurial ventures (Figure 3C), disagreed with the statement that they had sufficient training and resources for developing a business pitch and/or a pitch deck (52%) (Figure 3D), and disagreed with the statement that they had access to

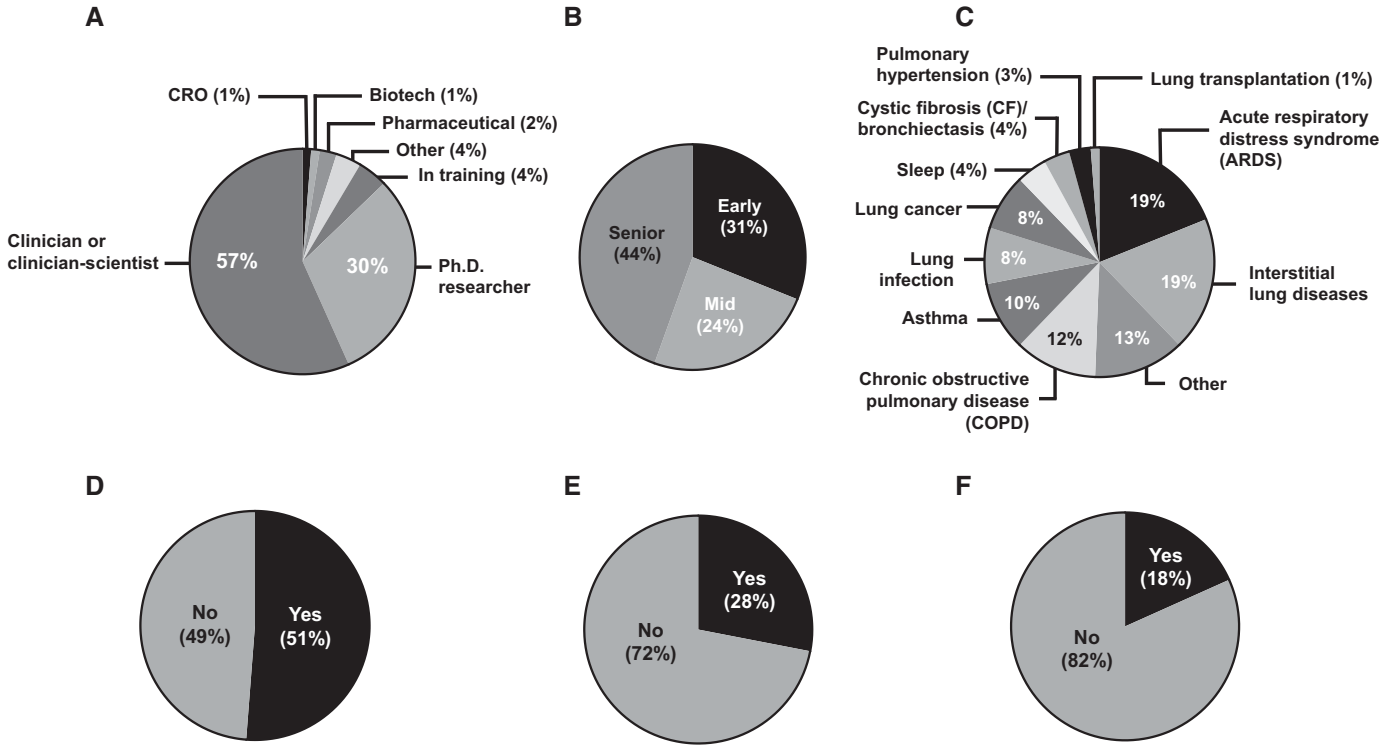

Figure 1. Demographics of study participants. (*A*) Study participants. (*B*) Career level. (*C*) Areas of disease focus. (*D*) Inventorship on 1 or more patents. (*E*) Licensed 1 or more technologies. (*F*) Founded a company.

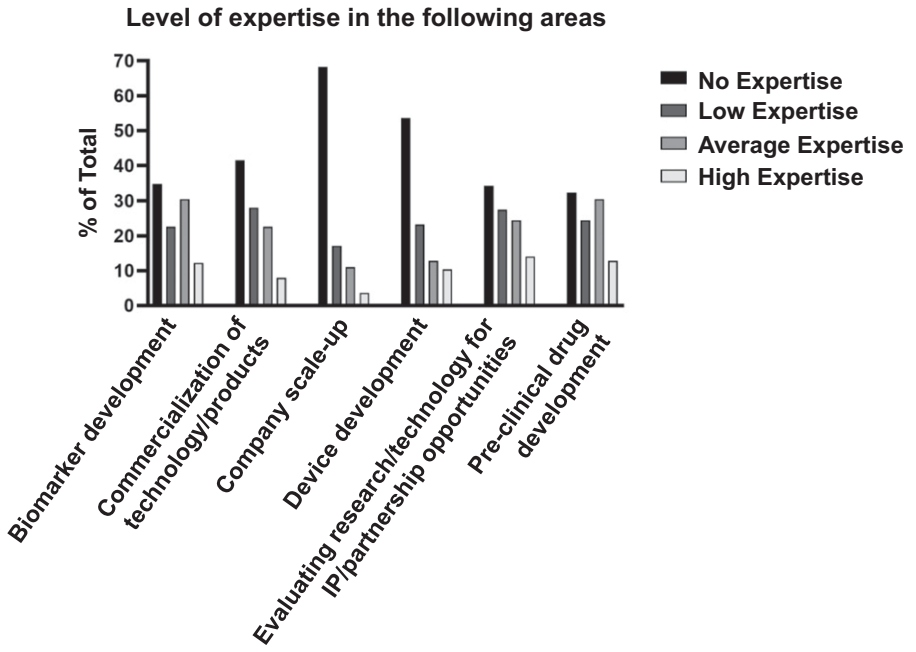

Figure 2. Expertise among study participants.

sufficient programs and resources to support the establishment of biotech/pharma partnerships designed to enhance commercialization efforts (51%) (Figure 3E). Importantly, when responses to the same questions were analyzed by participant career level, early career professionals consistently expressed the greatest need for training, resources, and/or programs in these areas, as compared with midcareer and senior career participants. Seventy-six percent of early career professionals indicated a lack of sufficient training related to product/technology commercialization (vs. 43% midcareer and 44% senior career), 70% reported insufficient business support and expertise to build entrepreneurial ventures (vs. 50% midcareer and 42% senior career), and 72% reported insufficient programs and resources to support biotech/pharma partnerships (vs. 45% midcareer and 41% senior career).

IP

When participants were asked how informed and up to date they were with existing IP policies, 40% believed that they were not informed and up to date, 39% believed that they were, and 20% were neutral (Figure 4A). When participants were asked if they had access to sufficient training related to IP and patent processes, the response distribution was similar: 42% believed that they did not, 32% believed that they did, and 25% were neutral (Figure 4B). When participants were asked if they had spent a significant amount of time engaging with their institutions' TTO, 46% had not, 36% believed that they had, and 13% were neutral (Figure 4C). When participants were asked if they had a positive experience working with their TTO, 31% believed that they did have a good experience, 25% believed that they did not, and 25% were neutral (Figure 4D). Overall, responses to IP-related questions were mixed. However, when participant responses were assessed by career stage, early career professionals demonstrated the greatest need for IP-related training and resources; 63% believed that they were not informed and up to date on IP policies (vs. 31% midcareer and 30% senior career), and 65% believed that they did not have access to sufficient training related to IP and patent processes (vs. 33% midcareer and 32% senior career). Interestingly, senior career professionals reported the highest level of engagement (48%) with their institutions' TTO, whereas 36% of midcareer and only 18% of early career professionals reported strong TTO engagement. Furthermore, 46% of midcareer and 33% of senior career professionals reported having a positive experience working with their TTO, whereas only 18% of early career professionals reported having a positive experience with their TTO.

Financial Resources

When participants were asked if they had access to sufficient financial resources to develop and commercialize new technologies and products, the majority (59%) of those surveyed believed that they did not, whereas 24% remained neutral and only 14% believed that they did have sufficient financial resources (Figure 5A). When asked about the availability of institutional seed funding versus funding from external sources, results echoed this global theme. Most participants reported that the availability of seed funding was insufficient at both the institutional level (50%) (Figure 5B) and/or from external sources (44%) (Figure 5C). Few participants believed that sufficient institutional (18%) and/or external (21%) funding was available (Figures 5B and 5C).

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are U.S. federal government funded contracts/grants. These nondilutive funds come from congressionally mandated programs specifically set aside for U.S. small businesses to engage in research and development activities that have strong potential for commercialization (8). Surprisingly, approximately half (49%) of the participants believed that they did not have access to sufficient programs/training for SBIR/STTR grant mechanisms, whereas the remaining half were split between feeling neutral (23%) or that they did have sufficient access to SBIR/STTR training/resources (24%) (Figure 5D). Academia was the most common source of funding for technology and product development among participants (57%), followed by government agencies (36%). Fewer participants reported receiving funding from other sources for technology and product development: industry (27%), private foundations (16%), venture capital (VC) (7%), or angel investors (5%) (Figure 6).

Other Potential Training and Resource Gaps

The majority of participants reported the need for improved *in vitro* (75%) (Figure 7A) and animal models for preclinical efficacy testing (73%) (Figure 7B) and approved biomarkers (77%) (Figure 7C). Almost half (44%) of participants believed that they did not have access to sufficient support for the design of investigational new drug (IND)-enabling studies (Figure 7D) or believed that they did not have access to sufficient expertise to assist with regulatory

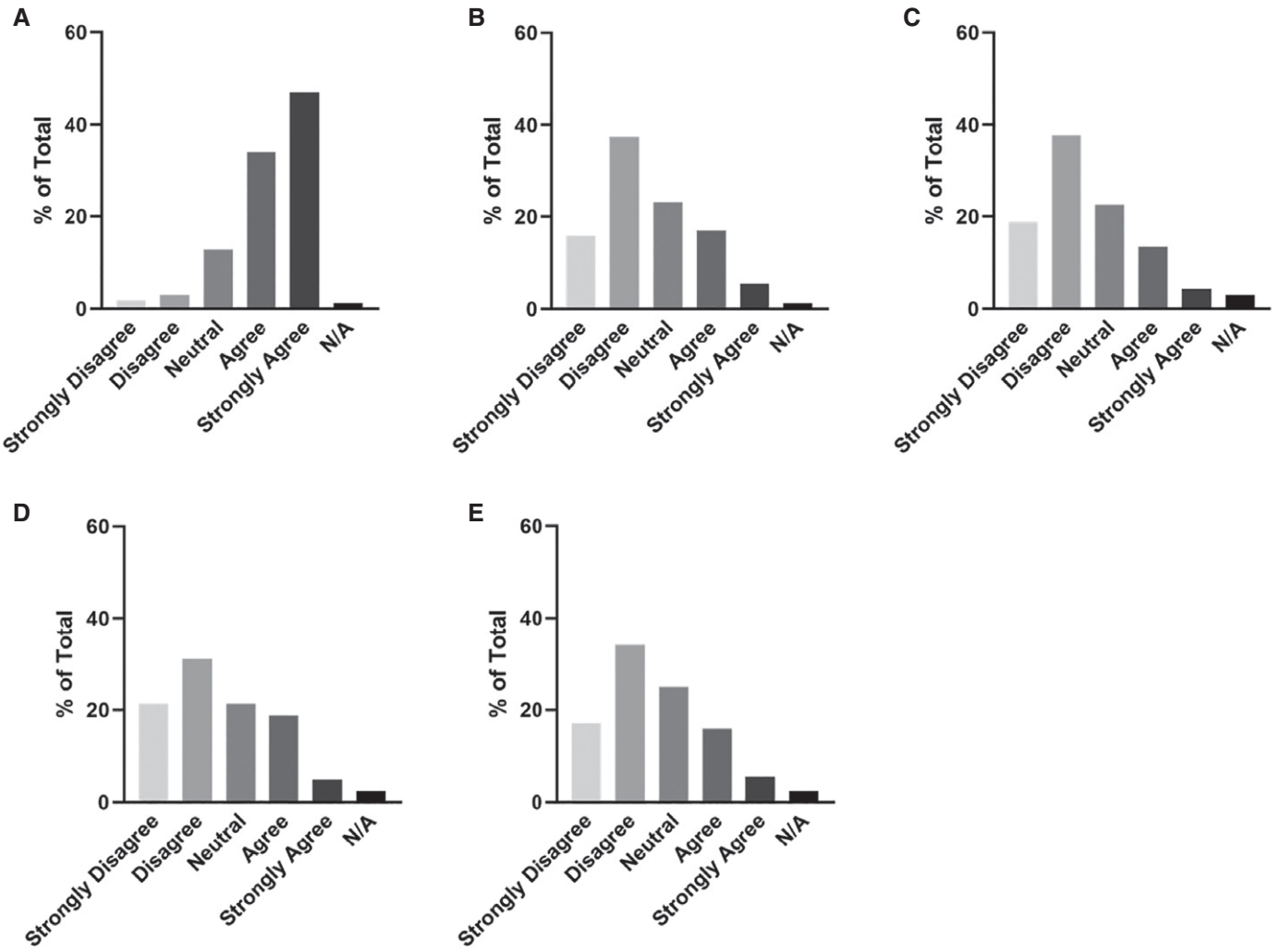

Figure 3. Business development–related interest and resources. (*A*) Interested in developing new technologies/products. (*B*) Access to sufficient training for commercialization of technologies/products. (*C*) Access to business support/expertise to build entrepreneurial ventures. (*D*) Access to sufficient training/resources to develop a business pitch deck. (*E*) Access to sufficient programs/resources to establish biotech/pharma partnerships to enhance commercialization.

approvals and/or submission of materials to the FDA (45%) (Figure 7E). Overall, these limitations may also impede the efficiency of pulmonary commercialization efforts.

Discussion

Translation of basic science discoveries into new products and treatments for patients still represents a major challenge, something that was particularly felt during the coronavirus disease (COVID-19) era. The accelerated timelines for approvals of new therapies during the pandemic demonstrates the impact that a global emergency can have on public policy, funding, and clinical and regulatory processes required for the approval of new medicines. Although it is understood that not every promising new therapy can expect to receive this sense of urgency, this phenomenon should be carefully studied for opportunities to improve the timeline of new products and therapies during nonpandemic times.

Although the striking majority (81%) of those surveyed were interested in developing new technologies and/or commercialization of products (drugs, devices, biomarkers), a key finding of the survey results was that most participants indicated that there were deficiencies in the availability of both business- and finance-related training and resources to support these efforts. The majority of participants believed that they did not have sufficient training related to the commercialization of technologies and products or access to sufficient business support and expertise to build entrepreneurial ventures. One participant commented that one of the main reasons entrepreneurial projects fail is "lack of business training/development and not thinking about what is needed for 'product development' versus scientific advancement." However, participants cited the National Science Foundation Innovation Corps program (https://new.nsf.gov/funding/initiatives/i-corps) as a key resource, which is a 7-week immersive entrepreneurial training program. Participants also cited the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (https://ncats.nih.gov/) as a key resource for

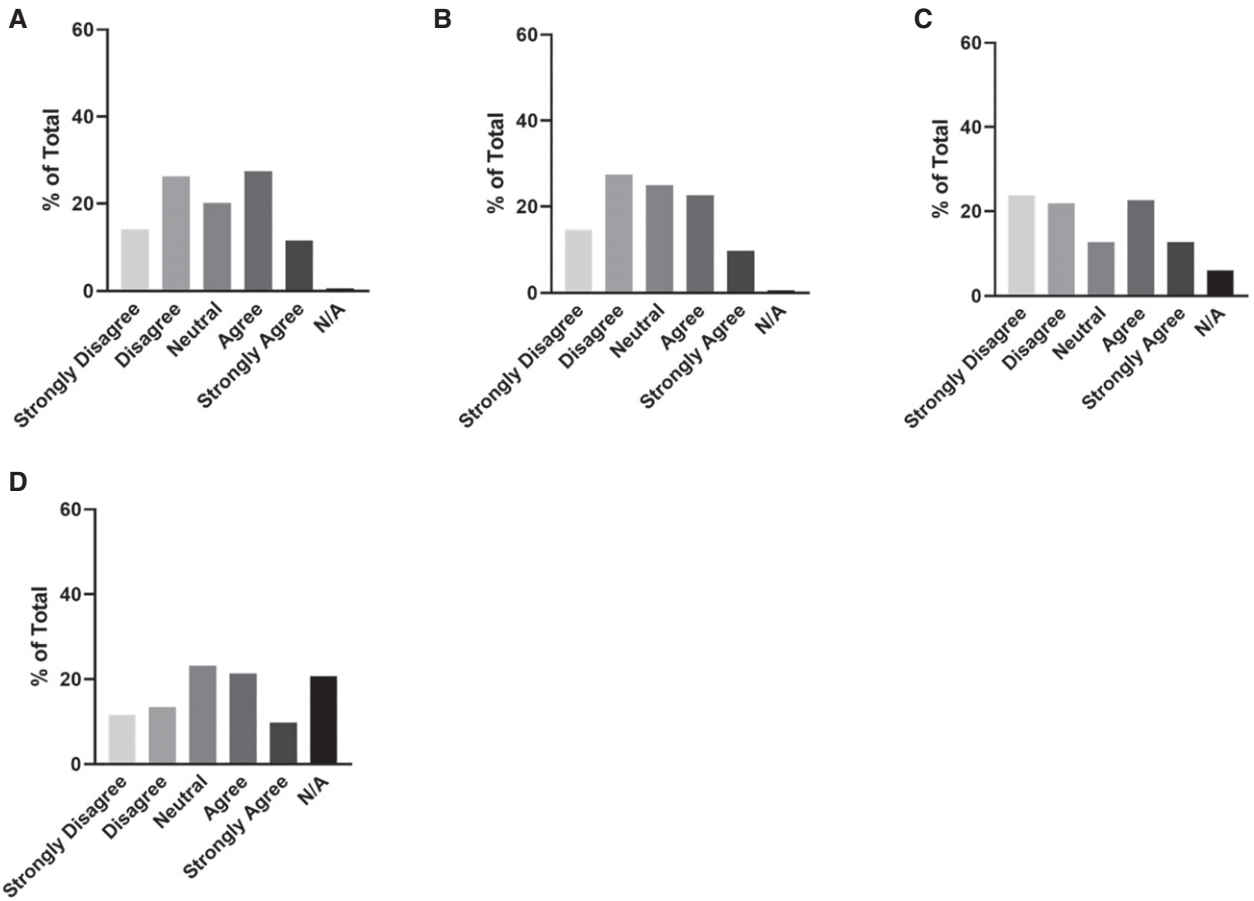

Figure 4. Intellectual property. (*A*) I am well informed and up to date with existing intellectual property policies. (*B*) I have access to sufficient training related to intellectual property and the patent process. (*C*) I have spent a significant amount of time engaging with my tech transfer office. (*D*) Working with my academic tech transfer office to develop/protect IP has been a positive experience. IP = intellectual property.

business-related training. The ATS has also recently offered a number of business-related training opportunities. The ATS RCMB Entrepreneurial and Innovation Working Group organized a full-day post-graduate course titled "Jump Start: A Beginner's Guide to Drug and Company Development in an Academic Setting," which was held at the ATS 2022 conference. Other ATS assemblies and the Drug/Device Discovery and Development Committee have organized technology development webinars. It is highly likely that ATS will continue to provide business-related training opportunities, and we encourage academic entrepreneurs to participate.

More than half of participants also believed that they did not have sufficient training and resources for developing a pitch deck. Many participants commented that a "well-developed pitch" is critical to the success of entrepreneurial ventures and conversely that "lack of mentorship in creating pitches" or a "bad pitch" were among the key reasons that entrepreneurial ventures fail. Participants also reported "product pitch competitions" and "accelerator programs and opportunities to present and pitch" as key resources. There are a number of regional, state, and national scientific business pitch/plan competitions, which are rapidly emerging and expanding, that academic entrepreneurs could engage in (4), including the Respiratory Innovation Summit hosted by the ATS International Conference. A list of 22 top biotech accelerators in the life sciences arena (based on various metrics) can be reviewed (5). The NIH Research Evaluation and Commercialization Hubs program includes eight proof-of-concept hubs with 51 academic centers from 12 states; this program offers entrepreneurial training, feedback from federal/industry experts, project management support, and funding support for early-stage projects. Overall, academic entrepreneurs are encouraged to seek out and take advantage of both opportunities within their region and/or state to leverage local resources as well as national opportunities (6). Although "seeking outside resources beyond the academic center" was cited by participants as being critical to gain business-related expertise, numerous participants also noted that use of resources within the local university were also critically important for commercialization success, including "institutional office of development/commercialization of technologies/products. … Tech transfer office/patent assistance … . University incubator." One participant noted that their university offered a "certificate of Entrepreneurship" program, which was considered to be a key training resource. Reaching out to institutional TTOs is also a good step toward identifying business opportunities/resources (7), because they typically provide training opportunities and

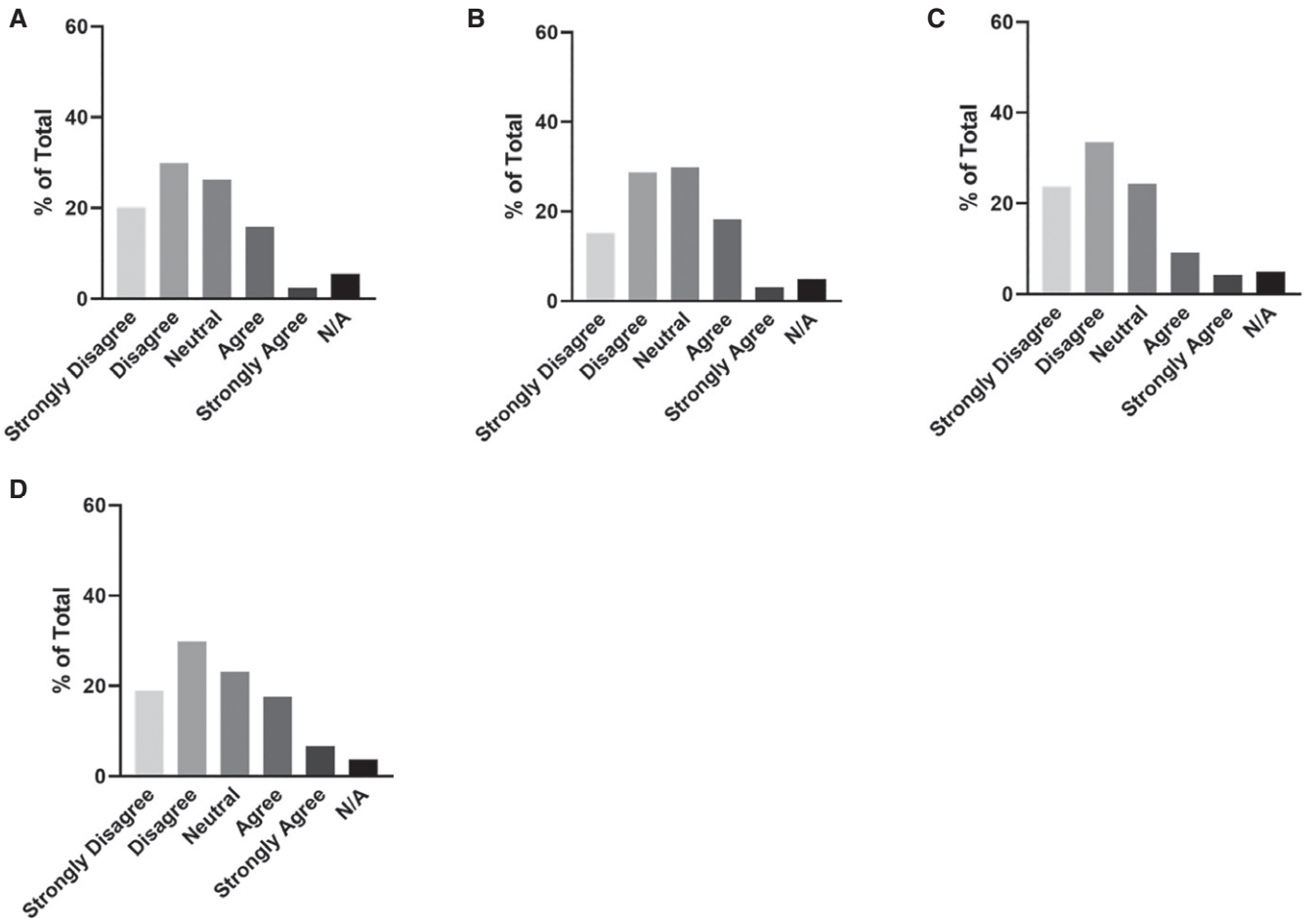

Figure 5. Financial resources. (*A*) Sufficient seed funding is available at my institution to develop new technologies/products. (*B*) Sufficient seed funding is available from outside my institution to develop new technologies/products. (*C*) I have access to sufficient financial resources to develop and commercialize technology/products. (*D*) I have access to sufficient programs/training in order to develop SBIR/STTR applications and/or other commercialization grant mechanisms. SBIR = small business innovation research; STTR = small business technology transfer.

are aware of local/national business/pitch competitions. Overall, seeking out academic, local, regional, and national resources/programs were considered instrumental for entrepreneurial ventures. These opportunities can also provide early-stage evaluation of technology development and its commercial potential; early-stage evaluation is critical for the long-term success of these efforts. A key step in commercializing an invention is to have a critical, independent, and thorough evaluation of IP as soon as possible after the disclosure stage. This evaluation serves as a roadmap for commercialization strategy, giving a clear direction to follow for securing a regulatory framework and practical timeline for bringing an asset to market.

Results also indicated that early career professionals demonstrated the greatest need for business-related training and resources. A midcareer professional commented, "Many investigators have ideas but lack the initial guidance to start the commercialization/company startup process. The initial 'boost' is vital," and a senior career professional commented, "There is a culture of drug/device development which is difficult for academic researchers to break into." These comments indicate that greater outreach geared toward engagement of early career professionals in these programs may be vital to the future success of commercialization.

Most participants also believed that that they did not have sufficient financial resources to develop and commercialize new technologies and products, including internal and external funding sources. These quantitative data were echoed by open-ended participant responses; 95 individual comments mentioned funding or investment as being critical to the success of a project and/or lack thereof being a major factor contributing to project failure. Institutional funding was the most common source of funding among participants, although most internal funding opportunities are typically smaller/seed fund mechanisms as compared with larger external funding mechanisms (9). Nonetheless, internal seed funding was cited as being critically important to the long-term success of a project. Government SBIR/STTR grants are a major source of external funding for academic entrepreneurs. Central to SBIR/STTR programs is the required partnership between small businesses and academic institutions, the goal being to bridge the gap between basic science and commercialization. According to NIH Reporter, the National Heart, Lung, and Blood Institute (NHLBI) Division of Lung Diseases (including the National Center on

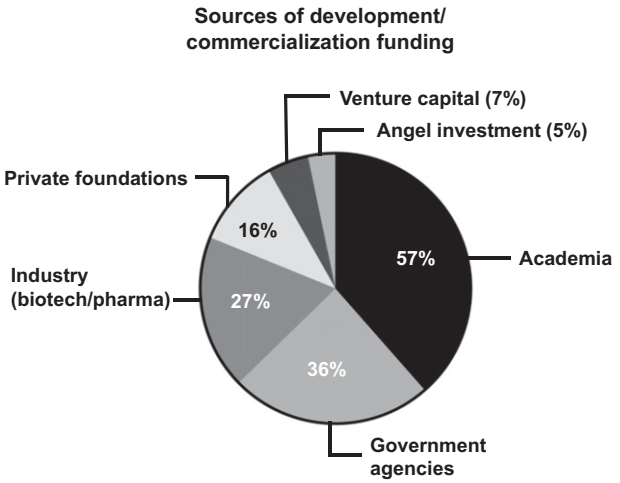

Figure 6. Sources of funding for technology development and commercialization.

Sleep Disorder Research) SBIR/STTR portfolio included >$113 million in funded awards from fiscal year 2019 to fiscal year 2022. Overall, SBIR/STTR programs are highly coveted and important sources of nondilutive funding for academic entrepreneurs seeking to develop and commercialize technologies and products, because these unique funding mechanisms are highly conducive to technology development originating from academic laboratories. However, most participants believed that they did not have adequate training and resources to develop SBIR/STTR applications. Participants cited SBIR/STTR training courses as being a critical resource. Many of these training programs are offered at the institutional level, and the NIH holds numerous information sessions and webinar training courses on a regular basis. The NIH NHLBI Innovation and Commercialization Office (I&C) (https://www.nhlbi.nih.gov/about/divisions/division-extramural-research-activities/office-innovation-and-commercialization) coordinates and serves as a central point of contact for the NHLBI Small Business Program; their mission is to accelerate the translation of discoveries and innovations into new biomedical products and services for heart, lung, blood, and sleep diseases and disorders. The NHLBI I&C office provides preapplication services for SBIR/STTR applicants, including guidance on proposal development, annotated forms to assist with completing and submitting the application, samples of successful applications, educational videos, and many other online resources. The NIH Applicant Assistance Program is a free, guided 10-week program designed to assist first-time SBIR/STTR applicants. Furthermore, the I&C office offers additional resources for funded NHLBI SBIR/STTR awardees in an effort to enhance translation of these existing innovations, including product development mentorship, pitch coaching, the SBIR/STTR Commercialization Readiness Pilot Program, and other support that is not typically supported though phase II mechanisms (e.g., preparation of FDA documents, IP strategy development, or clinical trial planning). Technical and Business Assistance programs (https://seed.nih.gov/support-for-small-businesses/technical-business-assistance-program) offer funding and consulting to help small businesses identify and address their most pressing product development needs (e.g., Needs Assessment Report provides a third-party unbiased assessment of a phase I project's progress in technical and business areas that are critical to success in the competitive healthcare marketplace). The Concept to Clinic: Commercializing Innovation Program is designed to provide medical device innovators with the specialized business frameworks and essential tools for successful translation of biomedical technologies from concept to market. Perhaps more effort should be made to make investigators (particularly early career investigators) aware of these opportunities. Local TTOs may need to work more closely with the NIH to disseminate these opportunities to academic entrepreneurs, and/or universities could embed this information as part of the orientation process for new faculty.

Participants also noted the use of consulting companies as a key resource to assist with the development and writing of applications. Indeed, many university TTOs have preferred companies that they can recommend. Although angel and VC funding mechanisms were a less common source of funding among participants, there are also a number of groups that specifically focus on university inventions and early-stage technology (8). It is also important to note that disparities exist with respect to VC funding; less than 10% of VC dollars go to women founders, and less than 1% go to Black founders (10).

Responses to IP-related questions were mixed: Some felt informed/up-to-date on IP policies and/or had positive experiences with their TTO, some did not, and some were neutral. It was not surprising that "exceptional IP around technology" was noted as being vital to successful commercialization. It is important to note that early career professionals who reported the greatest need for IP-related training/resources also reported having the lowest engagement with TTOs. Participants commented that being "willing to spend time with COI offices and tech transfer" was key to the success of a project, whereas "poor communication with tech transfer … not knowing what key data are needed to garner external interest in licensing" were noted as being reasons projects likely fail. Overall, strong engagement with institutional TTOs emerged as being instrumental to successful commercialization (11, 12). Furthermore, early career professionals may benefit the most from greater engagement with their local TTOs.

Building successful biotech/pharma partnerships also emerged as a critical factor influencing commercialization outcomes, which can provide critical feedback. The path for development is unique to each technology (e.g., preclinical drug candidate vs. device); thus, it is critical to gain insight from potential partners outside of academia. Participants made several comments regarding why projects succeed ("seeks out interested parties in biotech … shared endeavors between academia and industry") or fail ("investigator not equipped to find/advance partnerships with industry … failure to connect with interested partners … principal investigator and academic teams are not trained for early-stage technology development process. Thus, negotiations with investors or partners from Industry

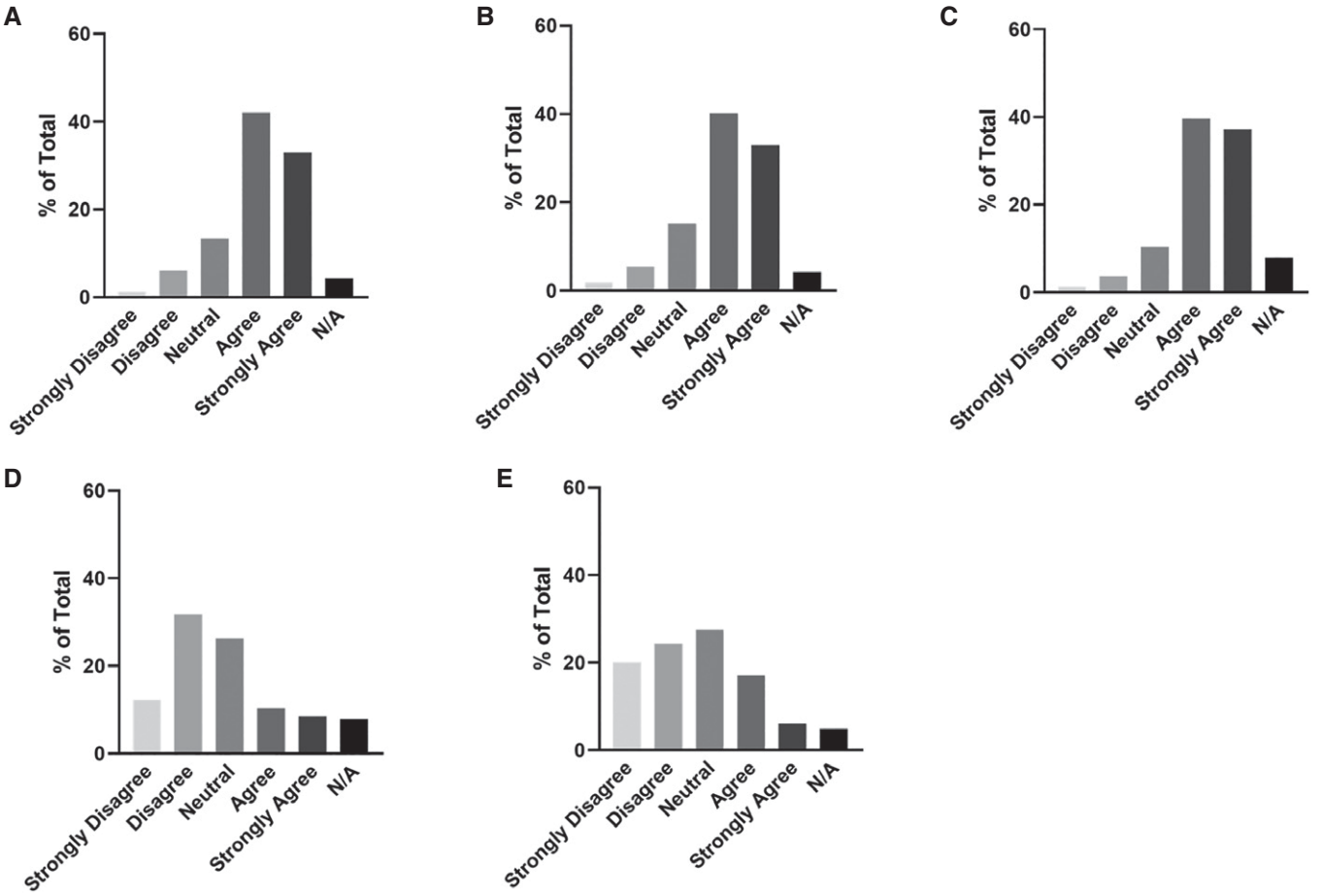

Figure 7. Other gaps in training and resources. (*A*) There is a need for improved in vitro models for pre-clinical efficacy testing in my disease focus area. (*B*) There is a need for improved animal models for pre-clinical efficacy testing in my disease focus area. (*C*) There is a need for biomarker panels approved by regulatory agencies for my area of disease focus. (*D*) I have access to sufficient support for the design of investigational new drug (IND)-enabling studies. (*E*) I have access to sufficient experience to assist with regulatory approvals and/or submission of materials to the FDA. FDA = U.S. Food and Drug Administration.

are not very productive and often result in deadlock"). Although this survey focused on identifying general challenges and opportunities for commercialization of technologies in the pulmonary and critical care arena, we recognize that there are various innovation sectors (e.g., devices, therapeutics, software), each with unique challenges and commercialization paths. Future studies could evaluate the specific challenges among these different innovation sectors.

Additional factors that were identified as being important for successful commercialization in the pulmonary space included the need for improved *in vitro* and animal models for preclinical efficacy testing and biomarkers. Furthermore, participants believed that they did not have sufficient support for the design of IND-enabling studies or regulatory expertise to assist with the submission of materials to the FDA; another study corroborates these findings (13). These deficiencies are likely to impede the efficiency of pulmonary commercialization efforts.

Open-ended questions identified several intangible factors that were instrumental to successful commercialization. Numerous comments indicated the importance of networking and including others "who have completed the process previously." The overall team surrounding the technology was also identified as a major factor driving successful outcomes. Participants commented, "We need to pair scientists with more business people … not understanding the 'journey' from research finding to pre-IND, and not knowing how to best package concepts and data to convince potential funders. Need a multidisciplinary team approach, like we have for complex patient populations." Introducing business development experts and previously successful academic entrepreneurs early in the process of technology development is beneficial for building feasible commercialization strategies that would shorten the time and cost of development.

Although this survey did not ask questions to quantitatively assess time demands for academic entrepreneurs related to commercialization efforts, responses identified this aspect as a major challenge: "Not having the bandwidth … Requirement of academic scientists to pursue funding instead of being focused on product development and commercialization … How much taking time to develop a project takes away from one's ability to get other research done, which results in a perceived loss of productivity by those who haven't had such experiences and therefore do not value such

things as fully-issued patents." It is likely that many academics believe that they do not have dedicated time to for commercialization efforts, which may impact their willingness and commitment to develop technologies. Furthermore, how tenure and promotion policies at a given institution value and/or incentivize commercialization-related efforts may also impact an individual's decision to commit to such activities.

Todd Sherer, Executive Director for the Office of Technology Transfer at Emory University, said, "these are the times of plenty for opportunities and organizations that support faculty driven startups and innovation." He is referring to the increased level of support for faculty that he has witnessed over the last 30 years. He goes on to say that "entire innovation ecosystems have emerged across our campuses, communities, and states to support entrepreneurial activity at all levels." What has not changed much is the reward structure that emphasizes peer-reviewed publication and grant support for academic faculty and the demands of the healthcare profession for clinical faculty. Sherer believes that faculty simply do not have the time to take advantage of the entrepreneurial programs that already exist because of the heavy demands of their teaching, research, and clinical duties. "Until we break the log jam between the need for faculty-driven commercialization and severe limitations on faculty time to purse these activities, we won't find our true potential within academia," he says. He also notes that these challenges tend to be even greater for women scientists and clinicians.

Conclusions and Future Directions

This report identified several major challenges that the community of pulmonary and critical care researchers and clinicians are facing in the technology development arena. Some of the most significant challenges identified include *1*) limited availability of business-related training and resources, *2*) the need for seed funding and financial resources for technology development and commercialization efforts, and *3*) gaps in other areas that impede the efficiency of technology development and commercialization efforts, such as the need for improved *in vitro* and animal models and the need for specialized expertise and regulatory support. Furthermore, early career professionals consistently reported the greatest need for training and resources. To enable and support the academic pulmonary community to innovate and enhance development and commercialization of scientific discoveries, more specialized training and resources, particularly related to business and financial needs. Furthermore, greater engagement and opportunities geared toward early career professionals will be critical to the success of the future generation of academic entrepreneurs. The development of larger teams and networks around the investigator and a given technology, including biotech/industry connections, is likely to fuel more efficient technology development and successful commercialization. Investigators should seek to leverage external resources and training opportunities coupled with strong engagement with TTOs and institutional offices (e.g., incubators and accelerators). Institutional seed funding appeared to be a critically important initial step toward the long-term success of commercialization efforts; thus, these funding sources must be valued and supported institutionally. Institutions may need to reevaluate how commercialization efforts fit into the traditional academic path to tenure to enable greater time commitments by investigators toward commercialization efforts. They also need to find more effective ways to assure that the support they offer faculty is appropriate, given the level of scientific and clinical activity at their institution. Expecting faculty to understand the gamut of activities from drug discovery to drug approval is not practical. Local innovation ecosystems should be more carefully structured to address the unique requirements of its faculties.

This official report was prepared by an *ad hoc* subcommittee of the ATS Assembly on Respiratory Cell and Molecular Biology. ■

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