National Center for Advancing Translational Sciences

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NCATS OFFICE OF STRATEGIC ALLIANCES

FEDERAL TECHNOLOGY TRANSFER:

MEASURING IMPACT, INNOVATION & EFFICIENCIES WORKSHOP

REPORT

May 13 & 14, 2021

Contents

Conference Overview

Technology Transfer (TT) encompasses a wide range of activities aimed at dissemination of knowledge and discoveries to the benefit of the public. For example, strategic alliance and TT functions at the National Center for Advancing Translational Sciences (NCATS), a federal laboratory, include activities aimed at enhancing collaboration, innovation, and acceleration to advance the science of translation, the process of turning observations into interventions to improve health. In the United States, new knowledge and discoveries can originate either at universities or institutes receiving federal grants or funds (*i.e.*, federally funded) or at federal laboratories (*i.e.*, federally owned). Although both types of innovative entities use similar TT mechanisms to disseminate knowledge and discoveries, the laws, regulations, polices, and guidelines governing each of them can differ, resulting in significant divergence in the way the entities operate, implement, and evaluate their TT.

The workshop aimed to present diverse perspectives on (a) ways of evaluating the contribution and impact of Technology Transfer Office (TTO) activities, outputs, and outcomes (*e.g.*, agency-specific, economic, and public health) to their institutional/agency mission and (b) models, tools, and examples of measuring structural and functional efficiencies and innovations of TTOs. The goals of the workshop were to enhance awareness and knowledge among stakeholders about different perspectives and tools to identify TTO activities and outputs, as well as outcomes that help an agency's mission while capturing the entirety of the U.S. government's TT objectives. Various stakeholders' voices, practitioners' perspectives, and policymakers' visions were shared. Each of the four sessions over the two-day workshop focused on unique but interrelated topics.

Opening Remarks

Welcome by Dr. Joni Rutter

Dr. Joni Rutter welcomed all to the workshop, presented an overview of the two-day agenda, and thanked the NCATS Office of Strategic Alliances (OSA) for organizing this timely event. The workshop aimed to discuss what works well and what does not work well in relation to measuring the success of TT and aligning successes to an agency's mission. Dr. Rutter stated that the mission of NCATS is to take on translational projects that advance the science and address the bottlenecks in the translation of that advancing project. TT is at the forefront of these advances. Dr. Rutter also stated the need to measure scientific advances and successes, as well as their impact on patients and on the economy. An important question to ask is how different stakeholders' perspectives are playing into different roles in TT. The first panel of Day One of the workshop was intended to examine various stakeholders (patient groups, investors, and entrepreneurs) and how TT can meet their expectations to get technologies and innovations out to the public quickly and efficiently. The second panel on Day One was intended to examine the impact of TT on an agency's mission, and topics would investigate the theory and current practices related to impact on TT assessments, followed by presentation of some recent case studies and discussion of the pros and cons of different approaches.

Dr. Rutter noted that on Day Two of the workshop, the panels would focus on innovation in the TT space and looking beyond the traditional TT metrics for evaluating impact and success. Dr. Rutter thanked all the panelists and moderators for their participation in the workshop. In closing, Dr. Rutter referred to Alie Ward's "Ologies" podcast, where "smart people are asked stupid questions." The podcast series highlights that there are no stupid questions and that this workshop is an opportunity to learn.

This metrics workshop was timely, particularly in light of the unprecedented achievements of the last 14 months. Dr. Rutter discussed the government's response to COVID-19 and suggested that perhaps lessons from that response can help TT in moving the science quickly and efficiently. Also, she raised the question of how to bring those lessons into the science conducted. The discussions around COVID-19 have been center stage around the world; Dr. Rutter asked what the implications were. To have a successful TT ecosystem, she reiterated the need to "raise all boats" that are diverse and inclusive and that work together; so much of science and technology revolves around relationships, and TT is at the forefront of these interactions. Evaluating these efforts will help scientists learn, improve, and monitor the impacts of TT to affect the overall health of the public.

Overview by Lili Portilla

Ms. Lili Portilla welcomed the audience to the NCATS Federal Technology Transfer Metrics Workshop. She explained that this workshop had been in the planning stages for some time. In 2019, the NCATS Advisory Council challenged everyone at NCATS to look at innovative ways to measure the success of NCATS programs and initiatives. The fact that the workshop included 350 registrants demonstrates the broad interest among other TT professionals outside of NCATS in the topic of metrics. Ms. Portilla noted that over these two days attendees would hear from various experts, practitioners, and users interacting in the TT field.

Ms. Portilla stated that the TT field is not static, but rather is fluid; science and engineering innovations put TT at the intersection of helping translate these ideas into something that improves — and in some instances saves — lives. OSA hoped that the workshop would open opportunities for diverse and inclusive

discussions, as well as collaboration across everyone involved in the federal, academic, and industry TT ecosystem.

Ms. Portilla thanked the entire staff of OSA for all their hard and tireless work in putting this event together. She also gave special recognition to Sury Vepa, Rebecca Erwin-Cohen, Laura Joell, and Chris Dillon for their efforts. Ms. Portilla introduced Mr. Joseph P. Allen. In 2008, he founded Joseph Allen & Associates, a consulting firm specializing in technology management/Intellectual Property (IP) issues. Mr. Allen served on the U.S. Senate Judiciary Committee for Senator Birch Bayh (D-IN), who secured passage of the groundbreaking Bayh-Dole Act in 1984, which fostered research and development (R&D) partnerships between the federal government, universities, and industry.

Keynote Address

Protecting and Promoting Public/Private Sector Partnerships Is Critical to Our Future

Joseph P. Allen

Mr. Joseph Allen stated that the timing of this workshop was terrific and the topic very critical because metrics are crucial to the performance of TT, and they are a way to convey the results of the work of TT professionals to the public, media, and Congress. Mr. Allen cited a Biotechnology Innovation Organization (BIO)/Association of University Technology Managers (AUTM) economic impact study of academic patent licensing from 1996 to 2017. It found that licensing of academic patents has contributed $1.7 trillion to the U.S. economy while creating 6 million (M) jobs. In addition, an average of three new companies are formed and three new products are commercialized every day in the United States from federally funded technologies. Mr. Allen discussed his involvement with establishing the Bayh-Dole Act, which *The Economist Technology Quarterly* called "perhaps the most inspired piece of legislation in the past half century." Prior to Bayh-Dole, few federally funded inventions were being developed and not a single new drug had been commercialized when the government took patent rights away from their creators under the previous patent policy. Further, the United States was losing ground in critical technology fields to foreign competitors, particularly Japan and Germany. Now the United States leads in every field of technology, and one reason is that the public and private sectors were integrated after the Bayh-Dole Act injected the incentives of patent ownership into the federal R&D system.

Mr. Allen also discussed the combined responses of the United States federal government and private sector to COVID-19. He noted that Nobel Prize–winning economist Michael Kramer of the World Bank calculated that the United States would lose $12 trillion (T) over 12 months of the pandemic and that accelerating vaccine development by one month was worth $500 billion (B), not counting mortality and health issues. Mr. Allen noted the unprecedented speed of creating the COVID-19 vaccine in less than a year, when it normally takes 3 to 4 years just to get to a vaccine candidate, so the economic impact was enormous — not to mention the impact on human health. Mr. Allen also mentioned that Moderna's technology was based on IP that they held for more than 15 years. Without patent protection, whether it would have been developed is highly doubtful, and certainly not at that speed. He also discussed his concerns with the Biden Administration's decision to support efforts to suspend patent protection rights to COVID-related therapies to spur vaccine production for developing countries. He noted that breaking patents was not a good precedent to set and could create bad will with U.S. public–private partnerships (PPPs); these companies entered into partnership at great risk and cost and fully complied with all the rules of their partnerships, taking the government at its word. Ironically, the barrier to producing more COVID-19 vaccines is the lack of greater manufacturing capability to produce a complex vaccine, not patent protection.

Mr. Allen also pointed out that U.S. small businesses drive the system and assume huge monetary risk, often by "betting the farm" when it comes to drug development. Better metrics are needed to help make the case to the public that federally funded technologies are creating a phenomenal Return on Investment (ROI) for the United States and that the public is benefitting from them with new therapies and cures, as well as significant economic growth. Mr. Allen remarked that TT professionals need to share these successes with policymakers and the public. He noted that 15 years of hard work was required for cancer researcher Dr. Jim Alison to develop a breakthrough technology against great odds, which he could not have done without the active support and encouragement of his TT office to pursue IP

protection for his technology on immunotherapy when his science was seen as too far-fetched. Dr. Alison won a Nobel Prize for this work in 2018. Without patent protections and the incentives and authorities of Bayh-Dole, this discovery would have remained "on the shelf," benefitting no one.

Mr. Allen ended the address referencing a cancer survivor, Betsy duParry, who hugged Senator Bayh at the 25th anniversary of the Bayh-Dole Act, stating that "without your law, I would not be alive today!" In closing, Mr. Allen stated that the work done during COVID-19 is an important TT story. The government worked with industry to create a vaccine for free. More stories like the response to COVID-19 need to be told.

Question and Answer

- TT professionals need to do a better job explaining the realities of getting a drug into the market and to patients.
- More stories from the patient's perspective and voice are needed.
- Bayh-Dole was never intended to be used for government-imposed price control of federally funded technologies.

Panel I: Federal Technology Transfer Stakeholder Expectations

Moderator: Anton Simeonov

The first panel, "Federal TT Stakeholder Expectations," included Anton Simeonov, NCATS Scientific Director, as moderator and the following panelists: Ron Bartek, President, Friedrich's Ataxia Alliance; Ravi Rao, Biotech Entrepreneur; Elizabeth Stoner, Executive Partner, MPM Capital; and Katharine Ku, Chief Licensing Advisor, Wilson Sonsini.

Patient Advocates' Experiences, Expectations and Perspectives in Working with TTOs

Mr. Ron Bartek

Mr. Ron Bartek began the discussion by expressing his gratitude for including a patient advocate's voice on the panel. He said that although organizations like his are frequently involved in patient advocacy, they are seldom parties in TT. Furthermore, patient advocacy experiences vary widely from institution to institution. He noted that different TTOs have different incentives. Government agencies, with NCATS as an example, are motivated by the public good rather than institutional parochial interests. Academic institutions vary greatly in this regard.

Each institutional type has strengths and weaknesses. National Institutes of Health (NIH) involvement can help attract investors. Also, when NIH has tools in-house, then timelines are attractive, and results are authoritative (*e.g.*, high-throughput screening) for collaborating partners. A weakness of government TTOs is the time involved, particularly when work is outsourced or contracted out; then timing is especially difficult. Mr. Bartek cited an example in which his foundation was working with an academic inventor who was pitching a prospective industry partner and seeking NIH support; the CEO's response was that by the time NIH could get them to Phase I, the company would need to get to Phase III. Mr. Bartek said that patients need government to operate at warp speed with all projects, not just COVID-19, but he understands the challenges of that.

Mr. Bartek discussed the strengths of academic TTOs, specifically those where like-minded institutional leadership and culture exist. He said that academic TTOs are interested in doing what is best for each stakeholder as quickly as possible. They typically demand fewer upfront royalties, leading to long-term benefits for everybody, including their own institution. Some are willing to employ an express license or option to license. Some academic investigators are good at "working the system" to get things done efficiently. Mr. Bartek noted that performance through academic TTOs can vary, and some offices have weaknesses, too — particularly some of those that seek total indemnification or impose large legal fees at the outset, which can lead to long delays and lost opportunities. Some TTOs are victims of their own success, where they expect every subsequent project to yield profitable results immediately or in the very near term. For example, some very large institutions sometimes do not pay attention to small projects or entities despite their promise. Mr. Bartek's experiences also varied based on the type of project or program involved. In his experience, the transfer can go very quickly and inexpensively where there are bio-sample cell lines and animal models and where no third parties are involved. Mr. Bartek believes that if a third party is involved, then the transaction can be far more difficult, resulting in unfortunate damage to the patient community.

Perspectives of an Internal Stakeholder

Dr. Anton Simeonov

In addition to moderating the panel, Dr. Anton Simeonov provided the internal stakeholder perspective as the scientific director of NCATS and leader of a laboratory group. Dr. Simeonov stated that most intramural research at NCATS involved collaborations, which necessarily implied the existence of other entities that could include individuals from outside NCATS, sometimes outside of the country. Dr. Simeonov estimated that the NCATS intramural division engaged in more than 150 to 200 collaborations. Thus, each research team would have multiple collaborations. He expressed gratitude to OSA for helping set up the agreements that enabled the scientific work. Dr. Simeonov stated that TT is not all about licensing, but also about material transfer agreements (MTAs), research collaboration agreements (RCAs), and cooperative research and development agreements (CRADAs) — which can be complicated — and so his team has tried to work with OSA from the first day to negotiate an agreement. He mentioned the culture of interaction, trust, and mutual education between the scientific staff and OSA. The expectation was around flexibility and fit-for-purpose research agreements, disposition of invention reports, and education. Dr. Simeonov mentioned that OSA had to consider and evaluate not just technologies for small molecules, but also protocols, cell lines, antibodies, manufacturing techniques, and so on when considering patent protection. Inventors hope that TT is attuned to all these categories. He said at NCATS, TT projects practically always have an outside co-inventor, so staff have had to account for that other institution, its principal investigator (PI), and TTO. OSA has been responsible for examination of the overall portfolio for research divisions. OSA had also created a review committee for patent filings. Constant dialogue and joint work occurred between the scientists and OSA. To that end, OSA staff were included in internal scientific meetings. He stated that he has enjoyed a "really great partnership with OSA." NCATS has functioned as a start-up within the government, with no traditional PI tenure model. NCATS scientists have not engaged in hypothesis-driven research, but rather they have performed translational work in a team science environment. This model applied to how they have worked with OSA colleagues in jointly strategizing how to work with various partners.

Understanding and Influencing External Stakeholders

Dr. Ravi Rao

Dr. Ravi Rao began his talk by mentioning his extensive TT experience before becoming a biotechnology entrepreneur. His first exposure to TT was at the University of Pennsylvania. On the industry side, he led the group that was tasked with these collaborations at MedImmune. Dr. Rao underscored the importance of relationships and primarily spoke to human elements and about how a "deal is a journey of building human relationships."

To increase efficiencies in the deal, he outlined five key ingredients or guideposts to completing the deal and a sixth in managing the relationship after the deal is signed. Dr. Rao stated that understanding and assessing the deal is important. He said the whole transaction is very smooth when the TT person recognizes the significance of timelines. Significant differences exist between industry stakeholders and TT, and thus TT should understand who is on the other side. Each side must be educated to create transparency and increase deal efficiency. Investigation is required to understand who the decision makers are on the TT side. One of Dr. Rao's best experiences was with a federal laboratory that explained timelines and tradeoffs. He also underscored how critical process mapping is to TT.

Perspectives of a Venture Capital Investor

Dr. Elizabeth Stoner

Dr. Elizabeth Stoner shared her perspective from a financing point of view. Dr. Stoner began by stating that federal TTOs have the reputation of being slow and that the most difficult part is the necessary comment period that comes with exclusive licensing of federally owned IP. She said that this cannot easily be changed but thought she should comment on that. She went on to say that TTOs acquire reputations and are clearly under various pressures. Some federal TTOs are easy to work with and some are not. As other panelists stated, she echoed the sentiment that the relationship with the TTO is critical. All should discuss the concept of making the deal to closing the deal. The TTO should know clearly and be transparent about what it wants. Sharing a template and explaining to the customer where there is no flexibility (*i.e.*, in institutional template language) is helpful. Another complex area is where the founder-inventor fits into those discussions, particularly regarding their involvement in and expectations from the deal. Sometimes inventors can facilitate the process, and sometimes they can create roadblocks. Knowing what "good" looks like from the point of view of the investor is important. Beginning with reasonable terms is a good way to get to the end, as is having open dialogue rather than a tough negotiation. Dr. Stoner said that a pet peeve of an investor is when a term sheet with redlines is handed to them without any explanation or rationale for the edits. She said that having this context would drive the deal to closure much more quickly.

Dr. Stoner explained the difference in economics between dealing with a venture capital–backed company and a pharmaceutical company. Investors in a company want equity and will not pay much upfront, whereas pharma may. The plus side of working with investors was that the asset will get to move forward, which may not be the case with pharma, where the asset could be deprioritized because they have a much bigger pipeline. Venture capitalists and pharma have different perspectives that TTOs need to consider.

Upfront alignment in how IP management occurs is required, even prior to negotiation of a license. Some companies will want to be lean, and others will want to "put the kitchen sink" into the patent application, thereby driving up patent expenses. The new company and TTO should work together to manage the IP, and the new company should have significant input because it will be paying for the IP after the deal is signed.

Dr. Stoner concluded her talk by stating that the goals of the TTO and new company are totally aligned because both want to establish a revenue-generating company as quickly as possible to address an unmet need for patients.

Differences: Federal and Academic Technology Transfer

Ms. Katharine Ku

Ms. Katharine Ku, the final panelist, shared her experiences in the TT field. Ms. Ku was the executive director at the Stanford University Office of Technology Licensing for almost 27 years. She is familiar with NIH TT overall and specifically at the National Heart, Lung, and Blood Institute and NCATS — as well as at the National Institute of Standards and Technology (NIST) and Oak Ridge National Laboratory — thus, she has a broad understanding of the federal TT system. Her current role is with a law firm, where she generally advises start-ups that are trying to pull technology from universities and federal laboratories. She said that TT is a complex process that most people do not understand. Federal laboratories often are compared to academic laboratories, but federal laboratories have restrictions. She discussed the mission

of the university versus that of the federal laboratory. University laboratories perform a public service and often have an economic development aspect. Each federal laboratory agency has its own mission. Most universities have a wide variety of inventions. Physical science inventions are handled very differently from life science inventions.

The mission of TT for both academic and federal laboratories is to transfer technology for public use and benefit. Academic institutions are interested in financial return, but federal agencies want to ensure fairness of access. Financial return is one measure, but it should not be the only measure.

Universities do not want inventions to lie fallow in publications. Thus, universities broadly market inventions and make them known to the community. While academics are becoming more focused on financials, it is important to keep in mind that federal laboratories cannot even take equity in a deal.

Academic laboratories have constraints, with publications often prioritized first and patent filings considered second. Additionally, they have students. Federal constraints include the formality of the process and that taking a license from a federal laboratory is governed by federal law. For some companies, this may be a daunting process. With federal laboratories, there is more scrutiny for exclusive licenses, including the determination of whether an exclusive license is justified. Federal laboratories are constrained by conflict-of-interest (COI) policies and a cap on royalty shares. It is also much harder for federal laboratory scientists to transfer "know-how." Universities also have COIs, but they are much more flexible and allow faculty to consult with companies within a certain amount of time. University TTOs are typically interested in equity, whereas federal agencies cannot participate in equity.

Ms. Ku outlined what makes an effective TT:

1. Do what is best for the technology — sometimes it is exclusive license, sometimes non-exclusive, but *something* should be done. If the technology remains in the laboratories, then it will not get to the public. This point should be at the core of how a TTO makes decisions.
    - Federal laboratories could release more guidance; however, it needs to be applied consistently and to be transparent.
    - Federal laboratories should engage in clear, consistent, and transparent processes.
    - Federal laboratories should provide the community with an assessment of how long everything will take.
2. Take reasonable risks. Note that no deal is perfect.
    - The license agreement is the beginning of a long-term relationship. Many factors are unforeseen, so expect amendments.
    - In Ms. Ku's opinion, the license is a business transaction even though it is a legal document. She further stressed the need to use good judgment. For example, Stanford University took a risk on the students who started Google, even though they had no business experience, but their technology changed the world.
3. A good philosophy is to plant as many licensing seeds as quickly as possible.
    - Foster good relationships and good customer service with a wide variety of stakeholders (*e.g.*, inventors, administration, commercial entities). TT is a "people" business even though it is very technical. One way to measure this aspect is to conduct customer surveys. Ms. Ku said that if ratings were 5 or above (out of a 1–10 rating), then customer service was good. If problems are revealed, addressing them right away is important.

- Be reasonable, flexible, and results-oriented — which is sometimes difficult for federal TT but worth the effort.

Questions and Answers

Q1. Has anyone looked at the ratio of times from invention disclosure to license and times from drug candidate discovery to U.S. Food and Drug Administration approval?

- Dr. Simeonov said that this is a complex question and that he does not have the data to answer it. With different inventions, first and foremost, it takes time, and the process is non-linear. Furthermore, organizational units move at different speeds (*e.g.*, start-up company vs. Pfizer).
- Ms. Ku said that the drug development process is not one that TT can control. Therefore, TT just has to get it to a company. Since TTOs do not have control of how long it takes, they just have to put the technology in the hands of someone who will try.
- Dr. Rao added that a deal should be closed quickly because science evolves quickly, so the sooner the deal is closed, the sooner the journey of the drug can be started.
- Dr. Stoner stated that the contract is very good and needs to be present, but when discussions and disagreements require referring to the contract, that is a bad sign. TT professionals set up the relationship and put the processes in place; the contract is the pathway to get there but should not get in the way.
- Ms. Ku noted that in her experience, what the contract says does not matter if the relationship is strong, because the parties can work things out — and what the contract says does not matter if the relationship is bad, because the contract will not make a bad relationship good.

Q2. Mr. Bartek, are there one or two aspects of partnership with the government that seemed to slow the TT process?

- Even when the government has been slow, partnership is still very helpful to their foundation.

Q3. Dr. Stoner, how should TTOs present to MPM capital?

- Many opportunities come from relationships. MPM has relationships with academic TTOs, and many TTOs know what MPM is looking for. However, when an academic TTO is not yet part of a relationship, then it is best to start with "what are you looking for." Some venture capitalists focus on early-stage technologies, some on oncology, some on past proof of concept, and others on devices. Understanding what venture capitalists are looking for is the first step. Set up meetings for a specific part of the portfolio, as opposed to showing everything that may be in the portfolio at that time. Try to learn the other side's interest.

Q4. Dr. Rao, how important is the champion on the other side of the PPP?

- Public private partnerships require champions on both sides of the deal, as well as trust and transparency. But in the end, the partnership itself is really the champion of the deal, with each side lending strength to the relationship.
- Political capital can be burned by moving the goal posts.

Q5. Think of yourselves going through a day in the life of a TT professional; how would you manage the conflicting demands?

- Dr. Simeonov recommended knowing the portfolio and needs of stakeholders, as well as co-location of TT and laboratory personnel at NCATS promotes a greater understanding of the needs and mission of each group with respect to both generating IP and protecting it (*e.g.*, relationships and dialogue).
- Mr. Bartek suggested nurturing relationships.

Q6. Mr. Bartek, patient groups have venture arms — how has this worked for foundations?

- Mr. Bartek stated that he would rather let professionals take care of the IP and business side.
- It is important to build translational tools and give academics the assets needed because they want them to enter into clinical trials for the benefit of patients.

Panel II: Impact of Technology Transfer on Agency Mission

Moderator: Dr. Mark Rohrbaugh

Dr. Mark Rohrbaugh introduced the panel topic and provided the overall goal for the speakers: to highlight theories and current practices that assess and measure the impact TT has on the mission of federal agencies. He mentioned the use of case studies and other approaches that are employed in such analyses. He stated that a great number of changes have occurred in federal TT over his career. For example, in the area of technology impact, the development of the internet and new biomedical technologies and drug products are notable. Changes in the definition of patentable subject matter have taken place, such as in the case of diagnostics or gene sequences. Even the management of PPPs has evolved, where improved methods of outreach and collaboration management have been impactful. Universities and nonprofits have done much work in measuring the impact of TT, and although some of those findings are transferable to the federal laboratories, Dr. Rohrbaugh acknowledged the differences. The complexity and challenges of looking at the impact of federal TT versus TT in academic settings are also due to the laws, regulations, and other unique requirements for technology management in federal agencies. Also, each federal agency may have its own unique mission, policies, and authorities. Federal agencies tend to be more siloed in their technology focus than universities. For example, the technologies at the U.S. Departments of Agriculture (research on new seed and plant varieties) or Energy (power grid research) and NIH (biomedical research) all will be managed differently based on the agency mission. At NIH, the study of technologies originating from intramural versus extramural technologies will employ different outcome measurements. The intramural program (11% of the total NIH budget) has contributed toward nearly 30 drug products, starting with Fludara and Videx in 1991 to the most recent Ebola monoclonal antibody treatment. For NIH, the recent re-delegation of authority and decentralization of TT to the Institute level in 2015 has been a positive change in patenting and licensing. The decentralization has allowed the TTOs in each Institute to manage TT in line with its mission. Although many different indicators of TT success — both micro and macro — have been studied, sufficient studies on the contributions of particular groups, such as postdoctoral fellows, are lacking.

Dr. Rohrbaugh presented preliminary data on research that he and his colleagues carried out on inventions reported under the NIH Small Business Innovation Research (SBIR)/Small Business TT Research (STTR) grant programs from 2000 to 2014. The focus is on the role of government funding on outputs of inventions and patenting. The preliminary data from the 2000 through 2014 NIH small business grants show —

- 18,636 SBIR/STTR applications were funded in the 15-year period.
- 9% of these grants reported patented inventions.
- A National Library of Medicine algorithm was used to map the grants to product type instead of disease.
- Product categories included devices, biochemical analysis, drugs/biologics, and social and data science.
- STTR grantees reported slightly more patents than SBIR grantees on a proportional basis.
- Grantees reported more patents associated with Phase I grants than with proportionate numbers of Phase II grants.

Assessing Differences Between University and Federal Laboratory Postdoctoral Scientists in Technology Transfer

Professor Donald Siegel

Prof. Donald Siegel spoke about the need to focus attention and study the role of postdoctoral fellows in TT. His presentation dove into findings from literature on university TT; the National Academies of Science, Engineering, and Medicine (NASEM) study of TT at federal laboratories; and a Kauffman Foundation study that compared postdoctoral fellows at universities and federal laboratories and their roles in TT. The Kauffman study was a major focus of Prof. Siegel's talk.

Ample literature is available on university TT and can be found in the *Journal of Technology Transfer* and other journals of innovation. Managerial and public policy implications also can be found in such research. From such literature — and by looking at TT practice — the following are shown to be critical to university TT:

- Networks matter: Sociologists note that "star scientists" and their networks, including postdoctoral fellows and students, play an outsized role in TT and commercialization.
- Incentives matter: Institutions where faculty receive favorable treatment regarding royalty distribution generate more TT activity from faculty.
- Institutional policies and structure matter: Decentralization of TT at universities (similar to NIH) leads to more TT activity, perhaps due to proximal support.
- Cultures of departments and institutions matter in promoting TT.
- Having a complete entrepreneurial ecosystem around a campus can boost TT.
- Universities are focusing more on entrepreneurship than on patenting and licensing.
- By educating faculty, TTOs can lead to more TT activity, including commercialization and entrepreneurship.

The literature on university TT has been dominated by economists, sociologists, and management professors who have focused primarily on the macro- and institutional-level perspectives. A focus on the micro-level perspectives is needed, as is more attention on the individuals involved in TT. The community needs to examine the "black box" of key managerial and organizational practices. Such micro issues that need further study include —

- Organizational justice or workplace fairness (individual treatment by the TTO)
- Role conflict, including COI issues
- Entrepreneurial identity and motivation
- Work-life balance
- Diversity, inclusion, and equity
- Championing and leadership

Interestingly, psychologists and organizational behaviorists have studied the above issues, but none of these variables have been assessed in the context of TT. These issues also must be studied in federal laboratories, especially as they relate to postdoctoral fellows. Prof. Siegel emphasized several times that postdoctoral fellows play a critical role in TT but rarely receive much attention or study.

In the second part of his talk, Prof. Siegel discussed a TT study conducted by a committee convened by NASEM. This committee consisted of economists; IP experts and lawyers; federal laboratory, agency, and contractor officials; people with an industry perspective; and TT managers. The economists included leading experts on innovation and the digital economy and eminent law professors who study patents and copyrights, which are both important in software and digital products. The committee focused its discussions on how to improve TT of digital products from federal laboratories. Key observations and recommendations from the NASEM committee include —

- Broaden the definition of TT for federal laboratories, beyond patents/licenses.
- Heterogeneity is observed across laboratories and agencies, and mission, mandate, and TT approaches vary.
- The government's ability to assert IP rights is key to advancing commercialization.
- Only limited data are available about TT in federal laboratories, at both organizational and individual levels.
- Congress should allow government-owned/government-operated facilities (GOGOs) to copyright software; at present, only government-owned/contractor-operated facilities (GOCOs) can.
- A significant expansion of data collection in federal laboratories is needed at both organizational and individual levels.
- Collect outcome data — not just TT transactions — at the organizational level.
- Collect individual-level data about incentives, rewards, organizational justice, and other micro issues.
- Much of these data are available in the university TT context, but none are available at the federal laboratory level.

The third part of Prof. Siegel's talk summarized a Kauffman Foundation report based on a field study that included interviews from 46 postdoctoral fellows and PIs. Study details and qualitative findings from these 46 structured interviews included —

- Study participants were drawn from two universities and four federal laboratories (two GOGO and two GOCO).
- Federal TT uses a wide variety of mechanisms, including CRADA, patents and licensing, Work for Others agreements, User Facility agreements, MTAs, SBIR/STTR, and publication and data sharing.
- Federal TT is much more restrictive than university TT, although new entrepreneurial initiatives are increasing in federal TT.
- No bypassing of TTOs occurs at federal laboratories, unlike at university laboratories.
- PIs can enable and drive greater TT participation from postdoctoral researchers and junior scientists; otherwise, the latter play a minor role in TT.
- Postdoctoral fellows are very engaged in TT if encouraged and induced by the PIs, especially if that encouragement is coupled with entrepreneurial development and training.
- Cognitive dissonance and role conflict are experienced by federal laboratory scientists, who are torn between an entrepreneurial pull and their own dedication to research and the agency mission.

- Federal scientists take their mission seriously, and their research goals are driven by agency mission and public service.
- Contractors are important in TT and should be given expanded consideration when collecting more data.
- There is a strong need to collect data about federal TT at both the micro or individual level and the macro or organizational level to peer into the "black box" of what influences TT, both positively and negatively.

In closing, Prof. Siegel emphasized the need to "look inside the black box" of organizational practices as it relates to TT. A significant expansion of data collection at both the individual and organizational levels is needed.

Macro, Micro, and Change the Terrain

Ms. Lori Pressman

Ms. Lori Pressman's talk covered three topics: macroeconomic perspective, aggregated case studies (synergies, probabilities of success, timelines), and best practices.

In her presentation, Ms. Pressman relied on excellent examples of success and analogies to drive the talk. She began by highlighting examples of how global data sharing can enable scientific advances. She pointed out that the complex networks of biological systems and economic transactions have a lot in common. Both are highly interconnected, and no single output or result has a single input or cause. Nonetheless, both biologists and economists study their respective systems, observe and publish patterns, and offer predictions. Input-output (I-O) analysis is a tool used by economists around the world to track patterns of economic transactions and estimate key macroeconomic metrics (*e.g.*, gross output, gross domestic product [GDP], and jobs). Patterns are tracked within specific industries, such as agriculture, chemistry, or computers. In the United States, the Bureau of Economic Analysis (BEA) observes and publishes the patterns in the form of industry-specific ratios and multipliers. A TT organization's licensees' product sales can be used, in conjunction with the BEA I-O ratios and multipliers, to estimate the macroeconomic impact of TT activities.

Ms. Pressman then presented an example of applying this approach to academic TT activities using AUTM Survey data. To run the model, assigning industries to the products sold by AUTM Survey respondents' licensees and reported under the Survey was necessary. The study assumed that the licensees were in research-intensive industries, such as pharmaceuticals and information technology. The study also made assumptions, using BEA data, about these research-intensive industries' patterns of production and sales — in particular, (1) whether the production occurred domestically or internationally and (2) the position of the products in a value chain, such as the last sale or an intermediate sale. The result of the study on the economic impact of TT on the U.S. economy between 1996 and 2017 was quite striking. Over those 22 years, the contributions to GDP because of TT activities amounted to almost $865B, and the number of jobs supported or created in that same period could be as high as 5.9M. The TT contribution to industry gross output during these 22 years was a whopping $1.7T in 2012 dollars!

Ms. Pressman presented her analysis of the various GDP trends over a 21-year period from 1997 to 2017, in which she compared the growth of various sectors. Contributions to GDP from products and services that resulted from academic TT grew on par with — and for some time periods faster than — contributions to GDP from research-intensive industries, at approximately 4 percent per year. For comparison, U.S. GDP as a whole grew at roughly half that rate over the same time period. Because

virtually all products reported under the AUTM Survey are young (because they age out of the reporting requirements in the license agreements), the study illustrated that young products contribute disproportionally to GDP growth, as do the products of research-intensive industries, a strong endorsement of how the knowledge economy contributes to U.S. economic well-being. As patent life runs out, AUTM members' royalty revenue stream runs out, and the impact of the products is no longer visible using the I-O model. However, the societal benefits of these products and the relationships formed during the TT activity itself continue. In absolute terms, the visible contribution of AUTM products to overall GDP may be modest — a few tenths of a percent of GDP — but their impact on the overall economy is much larger.

Ms. Pressman asked how to measure TT's impact in the absence of any license revenue or other quantitative revenue flow, then offered probabilities of success and speed of the project as other measures of impact. An example of the impact of PPP on success rates of clinical trials is visible through the findings of Project ALPHA (Analytics for Life-sciences Professionals and Healthcare Advocates) at the Massachusetts Institute of Technology Sloan School of Business. According to the Project ALPHA study, the presence of nonindustrial partners improves the probability of study completion. As the number of non-industry partners grew from zero to six, the probability of success of the jointly conducted clinical trials grew from 50% to 80%. Ms. Pressman presented data from clinicaltrials.gov about PPPs to demonstrate that about 20% of interventional oncology drug clinical trials from September 2007 to September 2019 involved an overlap in support by both industry and non-industry participants. Although the proportion of industry-alone trials increased in the transition from Phase I to Phase II to Phase III (as the costs of the clinical trials increased), non-industry participation occurred in all phases of clinical trials. Sociologists have pointed out the value in diverse connections. Indeed, organizations with diverse portfolios of well-connected collaborators are found to have the largest effect in shaping the field. Such a sociological analysis of the number and diversity of collaborations sustained by an organization may provide another way to measure the impact of TT, in addition to such quantitative measures as license revenue. "If you want to influence the outcome, have really good connections," Ms. Pressman noted. Collaborations and partnerships are important for TT and translational science.

Regarding biological insights and their role in project success, Ms. Pressman emphasized that having multiple partners will bring more biological insights into any project. Project ALPHA found that oncology clinical trials that incorporated biomarkers were 10 times more likely to lead to an approved drug than trials that did not include biomarkers.

TT databases store dates of transactions and various milestones achieved during commercialization, and by studying them one can study how the speed of commercialization is affected by different variables, such as product type, deal exclusivity, and policy framework. Ms. Pressman presented on the differences in the timing of license execution: Exclusive licenses are signed considerably before products are commercialized, whereas nonexclusive licenses are "just in time" licenses. Exclusive licenses create an incentive for risk-taking when there are considerable developmental hurdles. In such situations, licenses will need to be secured well ahead of product commercialization. Going by product types, a comparison of clinical diagnostic products (Clinical Laboratory Improvement Amendments versus *in vitro* diagnostic products) and biological reagents shows that the latter get to market within 6 years of the patent priority date, whereas diagnostic products may take 7 to 10 years past patent filing. The more complex the clinical diagnostic product, the longer it takes to reach the market. Ms. Pressman concluded by emphasizing the importance of data rights management. As the current state of patent law remains unclear, thus weakening patents, expertise managing other types of IP, such as data and software, is more important, particularly when this non-patented IP is jointly owned. By embracing skillful management and sharing of data and software, all parties benefit. Returning to the metaphor of seeing

the event horizon of a black hole following coordinated data acquisition, sharing, and analysis, Ms. Pressman concluded by saying, "You never know what you will see."

TechLink's National Economic Impact Studies: Measuring Impacts, Innovations, and Effectiveness

Dr. Michael Wallner and Mr. Jeff Peterson

Dr. Michael Wallner introduced TechLink, which has operated within a Partnership Intermediary Agreement (PIA) with the Department of Defense (DoD) since 1999. TechLink has carried out 16 economic impact studies (EIS) for various federal agencies, including an EIS of DoD licensing and a 2018 study of the National Cancer Institute (NCI) SBIR/STTR program. In its studies, TechLink measures economic impacts and TT impacts, as well as other quantitative and qualitative impacts. One of several studies it conducts every 3 years is the DoD licensing EIS to understand the impact of TT on the War Fighter. Dr. Wallner shared success stories and challenges faced by TechLink in conducting these studies. He emphasized that the company achieves a minimum 90% response rate on its surveys and questionnaires, driven mainly by persistent researchers. Senate committees use the TechLink reports in their discussions. Some major challenges faced by TechLink include getting clearances for the release of final reports from agency officials and getting background historical data from the federal agencies. Many times, the data available to the federal TTOs are not computerized, especially older records. Often TechLink must approach the same companies for data over and over again, and in doing so, it faces respondent fatigue. Maintaining its high response rates of 90% or better in its studies so that the study conclusions are sound and valid is challenging. IMPLAN is an economic modeling tool employed by TechLink, and readers of the report may show skepticism about the model, as well about the select outputs produced in the report.

The studies benefit from strong methodology for data collection including follow-up, persistence, survey structure, and extensive networking. To increase respondents' comfort level and compliance, TechLink secures an official letter from the sponsoring agency and, to assure participants of confidentiality, pledges to report on data in the aggregate only. The company has extensive experience using databases to track personnel. These methods use concise surveys to reduce the burden on companies being surveyed. The direct survey inputs are used for IMPLAN modeling, in addition to using public-facing reports as inputs, all of which result in additional outputs. Dr. Wallner described the survey elements in the economic impact of TT studies. These elements would include the company's products and services, follow-on R&D, and new product development. The surveys also would delve into such details as sales amount, economic sector served, and manufacturing locations. Benefits to the company — including access to capital, follow-on financing, or other benefits of working with the federal agency — would be probed. The survey also would ask the company about what motivated it to partner with the federal government for the technology and how the process can be improved in the future.

Mr. Peterson then discussed the IMPLAN model, which is an economic impact assessment software system that relies on an I-O model and is used for economic impact analysis. TechLink focuses on domestic economic data using sales volumes, location, and time of impact. Every economic sector has a bill of goods, and the IMPLAN output represents the series of end results through the sales. The time of impact is a limitation because respondents will not be able or willing to provide sales-by-year data. The request for this data may drive down survey response rates and is therefore not collected. Impact is captured as spending, value added, jobs, income, and taxes. The three types of impacts are direct (the initial sale), indirect (purchasing of supplies, raw materials), and induced economic impact (consumer spending by workers involved in the value chain of the product). This is a simple but effective way of

pointing out that the economic impact of TT is not just the direct revenue impact from the sale of the licensed product, but all of the indirect impact and the induced impact. The IMPLAN model helps TechLink to go from the survey inputs obtained from the companies that do TT with the Federal Agency to estimating the economic impact of the TT relationship on society as a whole. In the field of medicine, for example, one may need to factor in other variables such as health expenses saved, quality of life, productivity increase, etc. Indeed, the IMPLAN model needs to be used carefully depending on the industry and the sector of the economy served by the technology being transferred.

Dr. Wallner then ended the presentation with some data and success stories which can be used to promote and obtain support for SBIR/STTR and TT programs. The NCI SBIR/STTR program was evaluated by the IMPLAN model in 2018 and included an analysis of 670 Phase II awards. The report concluded that the economic impact was substantial, including total sales of $9.1B, economic output of $26.1B, tax revenue of $2.9B, and the creation of 108,000 new jobs that generated $8.1B in labor income. TechLink makes videos and 2–3-page brochures for each success story that they complete.

Knowledge Transfer from Federally Funded Research and Development Centers

Professor Albert Link

Prof. Albert Link spoke about knowledge transfer and Federally Funded Research and Development Centers (FFRDCs). TT is a part of Knowledge Transfer (KT), the latter term coined by the European commission. Up to this point, mechanisms of TT studies existed, but not many have focused on consequences of TT. As an exception, the nonprofit Research Triangle Institute (RTI) has conducted a study to look at the consequences of TT and also has developed some case studies. Most studies that cover TT look at academic institutions, and the public-sector R&D performed in federal laboratories often is missing in present studies.

Prof. Link pointed out the limited studies that show that, in general, increase in public sector R&D is consistently productive. For example, a 10% increase in public-sector R&D leads to a 10% to 25% increase in patent applications. When looking specifically at FFRDCs, a 10% increase in R&D funding leads to a 21.5% increase in scientific publications and an 8.5% increase in the postdoctoral fellow population. However, the consequences of these increases in patents, publications, or numbers of postdoctoral fellows are not followed up. Such data on consequences clearly are needed, in addition to data on the mechanisms.

FFRDCs are contractor-operated federally owned R&D centers. These are a catch-all for capabilities not met by the federal government or the private sector alone. Prof. Link provided several examples of studies conducted at NIST, including the use of metrology, which is the study of measurement science. NIST initiated this metrological study by asking if there is a relationship between calibration tests and some aggregate measure of productivity. A 10% increase in calibration tests at NIST was associated with a 0.32% increase in the U.S. multifactor productivity interest. Although this productivity increase may seem small, its implications for economic efficiencies are large. Expanding studies that can illuminate the implications of publicly funded R&D and show the ultimate impact on the economy from federal R&D dollars is important.

The economic impact of public-sector investments can be studied through KT, TT, and any improvements seen in infrastructure technology. However, other avenues of measuring impacts — such as conferences,

CRADA spillovers, and following the consumers of KT and TT — can provide additional valuable information. As an example, Prof. Link pointed out that artificial intelligence (AI) is one area where investments can be valuable. In such an emerging area as AI, there is value in understanding KT generally and the nontraditional methods of TT, rather than straightforward TT. The impact of AI may be illustrated by "looking at the consequences of those who use AI."

Questions and Answers

Q1. What about researchers who want to incubate or advance their technology further to obtain greater value for technology even though there is a licensing deal on the table?

- Ms. Pressman responded, "Work with the customer you have. It's rare to find more than one." She added, "Marketing consists of finding the other two people in the world who care, one of whom is sitting in front of you."
- Dr. Rohrbaugh commented, "A good day in TT occurs when a company shows interest in your technology." For academic institutions, licensing allows a company to share the developmental risk rather than placing it solely on one party.

Q2. What can be done to create more parity and inclusion in offices that do not have resources to transfer their technologies?

- Prof. Link pointed out that the focus by federal laboratories is on big laboratories and offices. "What I see as something that is really going to help is the partnership between AUTM and the Federal Laboratory Consortium (FLC)," he added.
- Ms. Pressman recommended asking scientists to "go to a conference that is a little bit more applied…. Inventors would come back with business cards leading to licenses."

Q3. Dr. Wallner, if a federal TTO wants to engage with TechLink on a project or study, how can they be best prepared to address some of the challenges you noted?

- Dr. Wallner asked the questioner to contact TechLink, who can guide them through the process. The first step is to create a partnership intermediary agreement (PIA), review or release the final reports, and make sure the U.S. Government Accountability Office is aware of the study and involved with it. If releasing the report by a certain date is desirable, make sure to have time to address any security concerns. Data collection methods and making sure stakeholders understand the modeling, process, and expectations are other areas to consider.

Q4. Dr. Rohrbaugh, do you have any experience in measuring health impacts of collaborations that may or may not create technologies?

- Dr. Rohrbaugh admitted that they are tricky, but some case studies and examples exist, such as the *Hemophilus influenzae* type b vaccine or use of cancer drugs.

Q5. What are some ways to include diversity and inclusion to impact an agency's mission?

- Ms. Pressman replied, "Fan the nuggets or nucleation sites." Start with something small and build on it. Engage in transferring something small but valuable, and make it the beginning of a relationship. Using small nucleation sites of TT can expand the number of participants in the system as a whole.
- Dr. Rohrbaugh recommended talking to students, such as undergraduates, about career paths and telling them about TT.

- Dr. Wallner commented that, from a program diversity perspective, the task is to determine which IP an agency is supporting so it knows what its portfolio looks like.
- Prof. Link pointed out that the other side is the demographic makeup of TTOs in terms of race, gender, and education that led them to the position. "TT is not a major at most universities," he explained. Education, mentorship, and building on successful models of training and recruitment, along with a conscious push to look for diversity and inclusion, will go a long way.

Q6. Are the huge basically macro studies not making very generalized assumptions?

- Mr. Peterson commented that, speaking about the regional and state perspective of the IMPLAN model, the limitations are stated openly, and results are resource dependent. It is a decision-making tool that provides an estimate that can be made as accurate as possible, but he acknowledged that it is generalized.
- Prof. Link explained that studies of mechanisms for TT at an agency level need to be conducted, but not all agencies want to find results.
- Prof. Siegel pointed out the need for individual or micro-level data, but noted that people do not want to be compared. This is something that needs to be overcome to examine managerial and organizational issues.
- Prof. Link commented that one legitimate fear that stops micro-level studies is "How is management going to use this data?"
- Prof. Siegel agreed that this is exactly what people are afraid of. Not knowing what that data will be used for impedes data gathering at a local level.
- Ms. Pressman recommended following the astronauts and sharing data; the data is there in various places and in various formats. Data sharing will help, and such an analysis at the local micro level is doable.
- Dr. Rohrbaugh pointed out that statutory or regulatory criteria for federal laboratories dictate what needs to be reported, but additional criteria can be helpful. For example, AUTM created the Better World Project (BWP) more than a decade ago, to illustrate the impacts of research commercialization on the world by sharing success stories.

Opening Remarks – Day 2

Dr. Sury Vepa

Dr. Sury Vepa from OSA, NCATS, provided the welcome remarks for Day Two of the workshop. Dr. Vepa remarked that to be successful, TTOs must be dynamic and innovative about their own internal processes and consider how those processes align creatively with their practices and Institutional objectives. He raised some interesting questions for consideration: How innovative are TTOs? What is the "secret sauce" that makes a TTO innovative? Can be it measured and replicated?

Panel III: Innovation at Technology Transfer Offices

Moderator: Dr. Susan Ano

While introducing the subject matter of the panel session, Dr. Susan Ano stated that, as organizations responsible for managing scientific innovation, it is imperative that TTOs themselves be dynamic and active participants in innovation ecosystems. Dr. Ano commented on ways the innovation occurs, including innovation as the outcome of groups that work together or as the result of groups working to build on what has come before. She further mentioned that innovation often happens in different locations through actions of unconnected individuals. Dr. Ano highlighted the importance of being aware of innovation activities and conversations to effectively manage TT activities for each organization.

Federal TTO Innovations

Mr. Paul Zielinski

Mr. Paul Zielinski's presentation provided context for how TT innovations have evolved in common across agency directions. Mr. Zielinski commented that looking at TTO innovations is like shining a light on the field (a sort of "selfie"). He characterized innovation as a constantly changing and moving activity, with the marketplace ultimately deciding which innovations create value. Mr. Zielinski reviewed recent federal legislative and executive initiatives aimed at accelerating federal TT.

Mr. Zielinski briefly discussed a presidential memorandum released by the Obama administration in 2011 and its intended goals and mandated actions. This memorandum required each federal laboratory to prepare a plan highlighting new or creative approaches to TT, list all available federally owned inventions in a database, enhance data quality and accessibility, and take steps to enhance engagement with external stake partners. This memorandum and other laws, as a part of the Presidential Management Agenda, resulted in the creation of the Lab-to-Market (L2M) and Cross-Agency Priority (CAP) Goals. L2M CAP Goals listed strategies aimed at enhancing innovative efforts from federal agencies, including discoverability and ease of licensing of federally owned inventions, development of human capital, enhanced utilization of federal laboratories, and maximizing the economic impact of such federal programs as SBIR. Mr. Zielinski suggested that the Trump administration, while keeping some of the previous administration's strategies, added or refined a few others in the L2M effort. For example, the revised strategies included identification of regulatory and administrative impediments to federal TT, increased emphasis on engagement with the private sector, and improved metrics.

Mr. Zielinski presented the results of a data call from July 2018 in which each federal laboratory and the FLC reported on its innovative efforts to improve TT under different L2M CAP strategies. Under the category of Regulatory and Administrative Improvements, he described efforts such as CRADA Builder, T2

Playbook, Inventor Tool Kit, Xpress License, data agreements, and IP bundling. Under Private-Sector Engagement, he highlighted ecosystem connections, such as clusters, open campus, R&D parks, facility user agreements, outreach efforts (such as FedTech and T2 University), PPPs, and voucher and other commercialization programs. He then discussed programs under the Entrepreneurial R&D Workforce effort, such as National Science Foundation's Innovation Corps (I-Corps), COI and leave polices, fellowship programs, training, Executives in Residence (EIRs), National Science Foundation internships, and the NIH BEST (Biomarkers, EndpointS, and other Tools) program. Under TT Tools and Services, he discussed websites, partnership intermediaries, and the FLC Business TechLink and Laboratory Partnering Service. He provided further examples under different TT areas that are improving federal TT (such as Ocean Tomo, Dept. of Energy Agreement to Commercialize Technology (ACT), the NIST Science and Technology Entrepreneurship Program, Challenges, EIR, and the FedTech research license).

Mr. Zielinski concluded his presentation by discussing FLC offerings that are aimed at promoting, educating, and facilitating federal TT efforts, such as FLC Business, T2 mechanisms, newsletters and outreach, Notices of Intent, PlayBook, CRADA Builder, a locator service, the national meeting, eGroups, certification, and workshops and technical series.

In summary, Mr. Zielinski described an overall framework and context from the Executive Office of the President for the past decade to accelerate federal TT and innovation. He discussed unique approaches that have been developed, many of which have become common and others that have been less successful. He suggested that understanding how these innovations can be characterized into key areas and how they relate to the big-picture government strategy may assist in launching future efforts.

Innovations at the NCI Technology Transfer Center

Dr. Thomas Stackhouse

Dr. Thomas Stackhouse briefly introduced the NCI and its Technology Transfer Center (TTC) and how the NCI TTC supports TT efforts of other Institutes and Centers (ICs) of NIH as part of a service that his office provides. NCI, part of NIH, is the federal government's principal agency for cancer research and training. NCI's mission is to lead, conduct, and support cancer research across the nation to advance scientific knowledge and help all people to live longer, healthier lives. The TTC supports the TT activities for NCI and serves nine other NIH ICs. The TTC also manages the IP created at the Frederick National Laboratory for Cancer Research. The TTC's mission is to enable and guide collaborative R&D through partnerships, exchange of important research resources, invention review, assessment and development, and licensing to advance today's discoveries into tomorrow's medical care. Through several innovative approaches and new programs, the TTC's team has developed and piloted several opportunities for its scientific staff to gain knowledge about TT, as well as to provide an opportunity to learn and explore entrepreneurship in the health care field.

Dr. Stackhouse talked about ways that the NCI TTC looks at opportunities to conduct outreach, as well as in-reach. He then provided information about the type and the volume of work his office performs, including some statistics on inventions (about 125 per year), CRADAs (about 50 per year), licensing (about 160 new per year) and transactional agreements, showing that the TTC is a very active and busy office. He highlighted the importance of activities supporting research infrastructure as a significant part of his office's services and some of the products that came out of NCI research and involvement of TTC in these successes. He noted that his office does much more than patenting and licensing.

Dr. Stackhouse then went on to illustrate the opportunities identified for innovation during stages of the TT process (the research phase, IP protection phase, market identification phase, license or collaboration

phase, commercialization phase, and the impact) that could enhance outreach and in-reach. Dr. Stackhouse described some of the specific programs or initiatives that his office would consider innovative and provide significant value.

The Invention Development and Marketing Unit (IDMU) in the TTC was created to address a need for streamlining outreach and marketing activities. This unit is resourced to carry out some of the activities that are related to taking early-stage technologies of NCI and its servicing partners and guiding them into a place where they are marketable. Additionally, the unit raises public awareness of opportunities at NCI, manages communications and social media, and develops various marketing tools, such as technology webinars and a showcase. This unit reaches out to both domestic and international stakeholders and acts as the main conduit for digital media, conferences, and webinars. IDMU also designs and conducts information webinars that include inventors, making this an opportunity for industry and potential partners to engage with NIH scientists and learn about exciting research. IDMU makes it possible to reach out to entrepreneurs, investors, foundations, advocacy groups, and technology scouts; listen to their needs; and inform them of opportunities, which was not possible previously because of staff's other commitments. This unit also makes it possible to conduct global outreach through attending and presenting at conferences, trade missions, and economic development group meetings. IDMU also enables a strong digital media and communication presence (via Twitter, LinkedIn, and its website). Webinars are another tool that IDMU organizes, and these help reach out and find potential licensees and collaborators in an engaging manner. These tools provide opportunity for stakeholders to engage NIH inventors and to provide feedback about a given technology.

The TTC Invention Development Program (IDP) is a small gap fund to advance technologies into the development pipeline. Many early-stage NCI technologies require proof-of-concept studies and additional preclinical studies (*e.g.*, animal studies, toxicity studies). In a small way, by funding these studies, IDP helps NCI make more informed patenting and marketing decisions. Furthermore, IDP enables better understanding of future research needs, enables proof-of-concept testing, provides feedback from outside parties, and reduces the risk for partners. IDP enables inventors to receive input from key opinion leaders and enables additional preclinical development.

The Annual Technology Showcase, which is currently in its fifth year, enables inventors to present their technologies to all types of stakeholders and engage with industry. In addition, at this showcase, the Technology Transfer Ambassador Program (TTAP) fellows provide presentations on technologies that they are managing, and this gives them a unique training opportunity to be in front of experienced investors and entrepreneurs and advocate for a technology — TTAP is a 1-year part-time training for a postdoctoral fellow in a laboratory to learn about TT and entrepreneurship. This showcase provides a unique opportunity to engage with NIH's scientists in a smaller and much more engaging setting. Dr. Stackhouse commented that this is a very valuable activity of TTC, and it has won several awards.

Dr. Stackhouse also highlighted some of the special initiatives that are currently in pilot phase. These initiatives are aimed at reaching into NCI's own organization and reducing the disconnect between TT staff, scientific staff, and leadership. He described the Transition-to-Industry Fellowship, an opportunity for a postdoctoral fellow to work both in a laboratory and at TTC (80-20 effort). This fellowship allows the fellows to continue development toward commercialization of an invention, while at the same time learning from TTC staff how to make it commercially viable. This program is a joint effort with NCI's Center for Cancer Research (CCR) and SBIR.

Advancing Innovations through Mentorship (AIM) is an initiative inspired by the I-Corps, focused on customer- and market-driven discovery, which was carried out in collaboration with NCI's TTC and SBIR, as well as NCATS. This program — which involved teams of inventors, TT staff, and fellows — helped the

team learn what the market needs for their product or technology. AIM received enthusiastic support from the participants, and all participants benefitted from the program.

The Startup Challenges Program with Center for Advancing Innovation has been in existence since 2013, and four challenge competitions were successfully completed. These challenges resulted in the formation of 42 start-ups around patented federal technologies, 14 of which are still operating, and raised over $20M in funding. This program won a U.S. Department of Health and Human Services Secretary Award and has proven to be a great way to train entrepreneurs.

Dr. Stackhouse concluded his presentation with a mention of the well-established NCI TT Fellows program. This program includes about 12 fellows at any given time, and they can spend up to 5 years working in TTC on TT. It has been so successful that many other federal TTOs implemented this program in their own offices. Alumni of this program are much sought after for their expertise in TT, and many continue in the same field after the fellowship experience.

Strategies for Accelerating the Lab-to-Market Process

Mr. Orin Herskowitz

Many universities have become increasingly active in not only receiving inventions, filing patents, and marketing and licensing technologies, but also in supporting those technologies and start-ups more fully as they attempt to cross the so-called "valley of death." Mr. Orin Herskowitz presented some of the ways that Columbia Technology Ventures and the whole Columbia University innovation ecosystem have been experimenting with launching more and stronger commercial innovations faster than ever.
Mr. Herskowitz discussed which initiatives have worked, which have failed, and which are currently underway.

Mr. Herskowitz started his presentation by positing that unlike many who think that strong TTOs need to be innovators, he thinks that to be successful, one can also be a fast follower. He observed that one of the unique attributes of TTOs of both academic and federal laboratories is that they share their experiences and one can adapt them and use them to their own benefit. He offered to share all ideas and experiences of Columbia with anyone interested.

Mr. Herskowitz mentioned that he would focus on Columbia's efforts on helping inventions cross the valley of death — the gap between government and foundation grants that support basic research of ideas and products and the product development, marketing, and sales where venture capitalists and industry play a significant role. This gap is where many inventions die, and so Columbia has focused its efforts on trying to get as many inventions as possible through this valley of death. Columbia calls these efforts "launching more and stronger start-ups, faster." Although it is true that IP is important for start-up (necessitating IP awareness and education for start-ups), Columbia's experience is that start-ups are more important for developing Columbia inventions, which was evident from the greater proportion of licenses (more than 60%) with start-ups compared to licenses with big pharma, and the majority of Columbia's successful technologies started their life as a start-up. Furthermore, many academic inventions are too early and too risky for industry, so start-ups are necessary for bringing early inventions to market. In the past, Columbia supported about 5 to 10 start-ups a year, but today Columbia facilitates around 15 to 25 start-ups annually. Many of them received significant funding and many even went public through initial public offerings.

Mr. Herskowitz discussed the ways Columbia manages to launch more and stronger start-ups faster and investigated what stops great ideas from getting to market. Columbia adapted many programs from other

TTOs and tried to improve them. Each of the initiatives addresses a specific stage of innovation or a step of the valley of death: ideation, validation, education, and launch. An early-stage invention needs many things to be viable and get to market, such as customer discovery, entrepreneurship education, a specific problem that needs it needs to solve, access to mentors, coaches and investors, prototyping, validation capital, connection to venture baked entrepreneurs, access to venture capital money, and early technical and business hires. In the absence of one or two of these, the technologies may not survive.

Columbia tried to systematically address each of these needs with specific initiatives. For example, Columbia launched a core facility (with three to four full-time equivalent staff [FTEs]) to help launch and run these L2M technology accelerators. Launching accelerators in a systematic way — not a typically serendipitous manner — requires coordination of many skills and activities, such as a sponsor willing to put up money, experts in a field, access to people who know how to do it, people with communication skills, mentors, and judges. Columbia realized that to do this consistently, a core facility that can coordinate these requirements is a must. Currently Columbia has several accelerators, each focused on a specific market (oncology, data, materials, diagnostics, therapeutics). Each of these is formed with a strong sponsor, such as IBM, Corning, Takeda, ACT, or Sumitomo. With all this experience, today Columbia is ready to launch an accelerator in a very short time when a proper sponsor is identified and, in fact, is launching three new ones in the autumn of 2021 (in computational drug discovery, rare diseases, and pandemic preparedness). All these accelerators run in a very similar fashion. Applications are invited through an open call, followed by a selection of some these by external industry or venture capitalist judges. Selected applicants run through an entrepreneurship boot camp and connect to mentors and advisors, then are provided some validation capital to complete experiments needed to get critical data. At the end of this phase, the applicants make a pitch to venture capitalists.

Another program that Columbia implemented to address the validation stage is the Executives in Residence (EIRs) program, in which a small number of experts are invited to be EIRs. They typically rotate every few years, and currently Columbia is not paying these EIRs — rather, they are volunteering their time and expertise through a nondisclosure agreement. The EIRs meet students and faculty and advise them on their inventions and how to make them commercially viable. The past EIRs have become an excellent source of an expert advisory network for Columbia.

Next, Mr. Herskowitz discussed the program that provides custom feedback, where needed, to inventors and scientists. Here, mostly in engineering fields, the faculty or students have inventions that do not yet have a clear market, and this program provides an opportunity for these inventors to present their technologies to experts and industry partners who will provide feedback about the utility of their inventions. Columbia also offers training to entrepreneurs through such courses as IP for Entrepreneurs, and this course material is available on its website. This is a very popular course, and feedback shows that participants benefit significantly from this course.

Columbia's experience has shown that many of the L2M programs, although they work well at getting a start-up company launched, are not sufficient to help the start-ups grow post launch. To address this, Columbia designed a L2M Business Operations Intensive in which L2M partners with industry experts to offer business operations intensive courses to its portfolio teams that are in the process of entering the marketplace. These courses provide guidance on the fundamentals of standing up and expanding a successful early-stage venture.

Students often are recognized as an amazing, underused resource. Mr. Herskowitz discussed a series of student internship programs geared to both train and use students in technology commercialization and entrepreneurship activities. These programs, a great source of workforce training programs, include the Columbia Technology Ventures (CTV) Fellows program, Columbia L2M Student Venture Program,

CTV/L2M Summer Internship Program, and the Columbia Program for Diversity & Inclusion in Commercialization and Entrepreneurship (DICE). Columbia also trains students to prepare pitch materials to be used by Columbia faculty inventors.

Columbia is a member of Academic Venture Exchange (AVE), a consortium of experts from various academic institutes who help one another and fill the gaps in technology development. Discounted and Deferred Rates from Startup Attorneys is a program in which certain law firms have agreed to provide Columbia start-ups valuable services at lower costs. Annual pitch days, standardized license terms, and support for SBIR/STTR applicants are some of the other programs that Columbia is implementing to help start-ups cross the valley of death.

Mr. Herskowitz concluded his presentation by telling the audience that Columbia University and Columbia Technology Ventures are always looking for new good ideas. Toward this, they periodically evaluate their initiatives and retain or improve what is working and discard what is not working. Columbia is always experimenting with an open mind and is flexible and agile.

Developing Learning Agendas at Technology Transfer Offices

Ms. Vanessa Peña

The process of TT — whereby research discoveries in the form of knowledge, capabilities, and technologies are transferred to other parties — is critical to the federal government's ensuring that funding to support R&D ecosystems provides benefits to taxpayers and leads to societal impacts. Common challenges in assessing the effectiveness of federal TT activities include the varied context for TT given the specific agency missions and goals; the complexity of industry- and discipline-specific factors influencing outcomes; the limitations in the comparison of metrics and their interpretation; the limitations in evaluating economic impacts and other ROI measures; and issues with temporality in data collection. An innovative approach to address these challenges has been the development of learning agendas focused on federal agency capacity for building evidence and improving the measurement of impacts from technology transfer activities. This presentation discussed the concept of learning agendas, how they can be developed for federal TT agendas, and actionable steps to accomplish this goal.

Ms. Vanessa Peña focused her presentation on points from her forthcoming article on ways to understand the impacts of various innovative practices to support federal TT and be better informed about what works and what does not work. This knowledge, Ms. Peña stated, is necessary for organizations to develop flexibility and agility, as well as to experiment and innovate.

Ms. Peña stated that because of bipartisan initiatives to better understand results from federal funding in general and federal research funding in particular, the U.S. Congress passed the Foundation for Evidence-Based Policymaking Act of 2018, which mandated certain evaluation-focused efforts across several federal agencies. This act required that applicable agencies submit a report to Congress detailing a systematic plan for their evaluation efforts to address priority policy questions, as well as designating an evaluation officer for their agency to coordinate evidence-based activities. Following this, the Office of Management and Budget (OMB) issued guidance on the development of learning agendas that provide an approach for growing evidence-building capacity to improve an agency's programs and activities. This approach was innovative as an internal way to look at processes within TTOs and think about ways that federal agencies can institute and formalize learning agendas for their TT activities.

Learning agendas are a continuous process for building evidence and start with engaging stakeholders and reviewing available literature and other forms of information for what is already known about a

certain form of activity, topic, program, or initiative that results in identification of priority questions (knowledge and gaps). Identification of priority questions helps to develop specific plans (learning agendas) to address gaps and decisions regarding resource allocation, new initiative development, and so on. These specific plans are then executed, and the resulting information is disseminated to broad internal and external stakeholders of a TTO or agency or externally to further engage and update the learning agendas. The above-mentioned steps have been similar to current practices for strategic planning and prioritization being practiced across an agency, including by R&D programs and some TTOs. Thus, the current capacity can be used largely to implement learning agendas and evidence-building capabilities within an organization.

Ms. Peña discussed in detail the main components of what a learning agenda for a TTO might look like. The key components can include the following: identification of strategic goals and objectives; identification of priority questions; activities to address a priority question; timing of learning agenda activities; data, methods, and approaches to answer a priority question; and anticipated challenges and proposed solutions to provide evidence to support priorities.

Ms. Peña highlighted some of the considerations for developing learning agendas for TT; they included alignment with strategic planning and budgeting activities already underway within the agency, engagement and communication with stakeholders, and data collection and expectation-setting to external communities that can support the learning agenda's goals. Ms. Peña concluded her presentation by providing some points that a TTO can leverage in developing its learning agendas. She pointed out that it would be useful for a TTO to connect with the agency's designated evaluation officers, integrate TT priorities into the agency by aligning the learning agendas with broader strategic planning efforts, coordinate development of agendas across agencies and working groups to create a community of practice to share best practices and models, and engage with established research communities experienced in evaluation science to support implementation of the learning agendas. In closing, she said that learning agendas can support innovative activities within TTOs by supporting experimentation and implementation of new ideas that work and have impact.

Questions and Answers

Dr. Ano started the discussion by pointing to the long time that innovation can take and the inevitable changes that can happen during that time and asked Ms. Peña how these sudden and unexpected changes can influence learning agendas and how these need to be accounted for and mitigated. Ms. Peña acknowledged the inevitability of change during implementation of any learning agenda program and used COVID-19 as an example of how agencies were forced to pivot to respond to a global emergency. She also used the example of unexpected departures of key personnel that could impact the learning agendas of an organization and reemphasized the need to recognize these situations as part of the identification of priority questions (gaps and knowledge) and account for these in plans and data collection, analysis, and dissemination protocols. Dr. Stackhouse responded that one must continuously look for gaps and opportunities to improve. He used Startup Challenges that the NCI TTC office implements and how they constantly evaluate this program as an example that their office uses to address these types of situations. Mr. Zielinski mentioned that one way to address the unexpected changes is to learn from the collective knowledge and experiences of the community — noting that there was no point in "reinventing the wheel" — and share experiences with others. Mr. Herskowitz emphasized that the TT community would be much better off if the collective knowledge were used more optimally.

Dr. Ano then asked for panelists' thoughts on better ways of benefitting from collective experiences of the community or, more specifically, on how to be more interactive and dynamic in sharing information

and experiences in an engaging fashion. Dr. Stackhouse commented on the benefits of this workshop and the need to have more similar meetings. Mr. Herskowitz noted the importance of AUTM and other such events for new ideas and sharing experiences and how these immensely help Columbia implement new innovations. Mr. Zielinski noted that networking is one of the most critical elements of TT, and developing new and effective ways of achieving the networking efficiencies to virtual environments is of vital importance.

Dr. Ano then opened the discussion to the audience; the first question was about the impact of COVID-19 on TTO innovation. Dr. Stackhouse highlighted how the COVID-19 pandemic had necessitated a rapid pivot of his staff to attend to and facilitate the transfer of clinical and biological materials rapidly and quickly, and this experience has taught them to reevaluate their process and eliminate redundant steps and increase efficiency. Also, the need for rapid data sharing required that they improve both data infrastructure and methods of sharing, while being sensitive to the privacy and proprietary nature of data. Mr. Zielinski highlighted the negative impact on collaborations but the positive impact on communications and wondered about how they can join once the pandemic is over. Mr. Herskowitz pointed to the lessons Columbia learned about remote working and how that influences productivity. He also suggested that once the pandemic is over and offices reopen, an effort will be made to implement some of the experiences of work during pandemic into the regular in-person work culture. Ms. Peña mentioned the potential positive impact of COVID-19 and resulting improvements of remote working technologies in helping some of the TT programs reach a broader audience.

The final question for the panel asked what they think is the most valuable TT tool. Mr. Zielinski pointed to CRADAs as the most often used tool in federal TTOs. Mr. Herskowitz mentioned internship programs that provide human capital as the most beneficial tool that their office uses, and Dr. Stackhouse agreed with that assessment. Ms. Peña highlighted partnership intermediaries as a significant tool that could help the TT community.

Panel IV: Measuring Efficiencies and Effectiveness Beyond Traditional Metrics

Moderator: Dr. Michael Mowatt

Dr. Michael Mowatt suggested that the TT community must look at the metrics that are useful to the strategy and must gauge effort (expended) versus impact (achieved). The number of transactions completed, patents obtained, and royalties received can be counted or measured easily, but Dr. Mowatt asked what is examined when measuring impact — such as how institutions and society have benefitted. Some options include research advances, biomedical innovations, beneficial products, and services, but he wondered if other options are possible.

One story from the National Institute of Allergy and Infectious Diseases (NIAID) speaks to the effort expended and illustrates the impact of those efforts. Through collaborations reaching back to the early 2000s, researchers at the Vaccine Research Center (VRC) have been studying all sorts of viruses, including the coronaviruses that have previously caused Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). Studying those previous zoonotic incidents helped the VRC prepare for what they viewed as an inevitable pandemic — specifically by identifying ways to rapidly produce medical interventions. This work resulted in a technology that allowed researchers to stabilize the spike protein of coronaviruses. When the genetic sequence for the novel SARS-CoV-2 virus became available on January 10, 2020, VRC researchers and their collaborators used their previously developed approach to model the structure of the spike protein.

NIAID's TTO put in place agreements to enable a research reagents repository to facilitate rapid dissemination of critical research tools and negotiated more than 80 MTAs and 21 license agreements for commercial development, including vaccine delivery platforms of multiple manufacturers. The result was multiple useful vaccines within 12 months of actual discovery of the disease-causing virus. The story illustrates the impact of partnerships: TT work in partnership with researchers, partnerships between researchers and other academic collaborators, and partnerships with industry have all resulted in a very productive endeavor.

Key Metrics for Tech Transfer Offices and How to Use Them

Ms. Laura Schoppe

Stories often speak louder than numbers do! Ms. Laura Schoppe discussed how organizational analyses — covering policies and procedures, interviews, and performance data analysis and culminating in observations, recommendations, and actionable strategies (data tracking and key metrics) — can provide key metrics to TTOs. Metrics help people proactively manage organizations by informing and educating and helping organizations respond to change, and ultimately they are used to make informed, evidence-based decisions. Ms. Schoppe noted that it is probably not effective at any level if the *only* time you assess, or measure, effectiveness is when there is a new boss or administration. Even goal setting by an uninformed new leadership can be reactionary if the existing team does not see or understand where the goal numbers have come from. This inevitably leads to a reactive or defensive posture. Alternatively, a proactive posture that leads to better management, planning, and strategy would be to conduct annual analyses.

Ms. Schoppe explained that a best practice would be to conduct analyses every year, which allows intimate familiarity with the data, helps identify trends, informs decisions based on data, and — perhaps

most important — provides the ability to avoid surprises. She advised TTOs to manage proactively and measure frequently.

Ms. Schoppe noted that internal data will be the most important for the bottom line. For federal laboratories, that could mean by department, laboratory, or agency. Other sources include the Federal Laboratory TT Database and the AUTM Survey. She further noted that it is not necessarily fair to compare agency to agency either — the data and research goals may be different, and certainly the agency missions are different. However, a fair comparison could be center to center (under the NIH umbrella, for example) or even program to program (*e.g.*, NCI's CCR). One problem is that the most recent data in the Federal Laboratory TT Database are from 2015, and those data do not include research expenditure, which is a key parameter for normalizing data across agencies and understanding ratios of how different agencies spend funds.

Ms. Schoppe discussed why it is important to understand one's "AMMO" before setting up a peer group for comparison or deciding what metrics to present. The AMMO is composed of the **A**udience who will be looking at the data, the **M**essage or information that the audience cares most about, the **M**echanism for how the data are best presented to the audience, and the **O**utcome desired from that audience as a result or consequence of the presented information. Several audiences may need to be considered (*e.g.*, administration, legislature, public), each of which has different interests (*e.g.*, what data are presented and how) and from each of which different outcomes are desired (*e.g.*, support for more staff, approval of the next fiscal budget).

She noted that identifying the correct peer group for comparison and then normalizing the data helps define defensible criteria and helps make the comparison "apples to apples," focused, and related back to the agency mission. Data normalization, or scaling the data to a common denominator, most typically research expenditure (RE), is imperative to be able to discern performance efficiencies and issues. For example, one type of normalization is to normalize the number of invention disclosures per $10M in REs, which leads to a standard research organization trend of one invention per $4M in RE. Ratios also can provide performance insight (*e.g.*, licensing income per license, invention disclosures per staff, licensing income per legal fees).

Understanding the impact of the research pipeline (*e.g.*, investment to innovation to strategy to deals and returns) on the activities and metrics the TTO can control is also an important component of communicating the performance of the office to its stakeholders.

The TTO has little, if any, control over investment dollars for the agency or the innovations of the scientists. However, the TTO does manage the activities that influence strategy and deals. Some suggested metrics to help analyze the effectiveness of the TTO's operation include —

- Research Expenditures (RE) Total — select peers with similar missions and research funding levels and as normalization denominator
- Licenses Executed per $10M RE — process efficiency
- Licensing Income per $10M RE — portfolio value and negotiating skills
- Invention Disclosures per $10M RE — inventor participation
- Invention Disclosures per TTO FTE — staffing level
- Licensing Income per License — portfolio value and negotiating skills
- Running Royalty Income per Royalty Licenses — monitoring agreements

- Licensing Income per Legal Fees — process efficiency
- Reimbursed Legal Fees per Total Legal Fees — policy and negotiating skills
- Licenses to Start-ups per Total Licenses — policy and economic development

Modernizing Metrics

Dr. Courtney Silverthorn

Dr. Courtney Silverthorn provided a robust assessment of how metrics can provide important information on return on investment (ROI), identify impediments to innovation at the public–private sector interface, and streamline or accelerate transfer of technology from Lab-to-Market. She recommended asking the questions "What problems in TT does the government need to solve?" and "What ideas do the stakeholder communities need to bring forward?"

When NIST was putting together a green paper to relay actions pertinent to removing unwarranted impediments, two findings were key. First, access to federal technologies, knowledge, and capabilities through a public access federal portal was critical; and second, metrics to capture broad TT outcomes and impacts of federally funded R&D were needed. This second topic was focused more on economic impact to help align data collection with agency mission and global measures of benchmark performance.

A key message from the green paper was that stakeholders (federal and partner organizations) understood that metrics are important, but that entities and agencies did not necessarily know how to "do" them, which speaks broadly to the conversations occurring as a focus of this metrics workshop. An additional issue is that changes to metrics currently collected under the Stevenson-Wydler Act — and how those metrics are reported out — are outside of the scope of current legislation. New changes proposed in the ROI legislative package include adding works registered for copyright protection (*e.g.*, software); CRADAs and Space Act agreements; Other Transaction Authority under Title 15; IP available for licensing; and facilities, equipment, or services available to the public. The proposed new legislative package would remove royalty-bearing license characterizations, time from license request to execution, statistical information on earned royalties, and disposition of royalty income from reporting requirements because those data do not accurately reflect TT activities or are already controlled by statute with which agencies must comply.

Process changes are proposed to include disconnecting metrics reporting from the OMB budget submission, allowing online data reporting to facilitate timely release of information, and updating IP/facilities information annually (presumably these reports would be disseminated via the FLC Business Portal).

Other changes include standardizing definitions of terms for specific metrics as part of the 2020 federal TT reporting guidance revisions, including to ensure that everyone is reporting the same things ("apples to apples"), as well as adding options for reporting beyond the statutory metrics, including research and academic dissemination, scientific and TT training, collaboration and research activities, and other miscellaneous data that may be agency- or mission-specific.

Another study funded by NIST also shed light on how TT is discussed. Elements most important to the public included the number of jobs created, amount of taxpayer monies being spent, average salary per job created, number of new businesses started; and public revenues generated per public dollar spent. Factors least important to the public included number of events held each year by organizations; number of scientific papers published; number of people attending educational workshops, classes, and webinars;

number of patent applications filed; and individual success stories of impact, rather than reporting numbers and statistics.

Reverse Engineering Technology Transfer and Assessing Key Processes and Activities

Dr. David Waldman

Dr. David Waldman presented a different viewpoint on assessing TT metrics; Dr. Waldman approaches the problem from a business school perspective and noted that although the title of the presentation speaks of "engineering," he is not an engineer. He noted that this approach allows him to ask, "What are important activities that are currently missing from traditional TT metrics, as well as managerial and organizational factors that might predict those activities and traditional metrics?"

Traditional metrics include patenting, licensing, and involvement in CRADAs. However, a systemic evaluation of *activities* that are likely to be associated with these traditional metrics currently is lacking. Such activities include conducting clinical trials, meeting with people from industry (*e.g.*, angel investors, entrepreneurs, former members of federal laboratories, or venture capitalists). Furthermore, not enough attention has been paid to the managerial and organizational factors that could predict the extent to which laboratory scientists engage in these activities and ultimately achieve the traditional metrics. As an example, prior research in university settings at the individual scientist level revealed that the concept of organizational justice is an important yet understudied factor in relation to TT activities and traditional outcomes (*e.g.*, patenting and licensing). Organizational justice is all about how people perceive being treated fairly and respectfully (*e.g.*, in a licensing royalty, or even on a personal level in dealing with others in the laboratory). Although such research has not, to date, been conducted at federal laboratories, it is likely that such variables as perceptions of organizational justice are important. Accordingly, individual scientists in federal laboratories must be surveyed to identify the management and organizational issues that may be either facilitating or impeding the pursuit of TT.

In addition to organizational justice, relevant managerial and organizational factors may include championing leadership, entrepreneurial identity, and education and communication from the TTO (for example, transparency about the royalty formula and timely responses to scientists). Other issues may also be relevant, such as work–life balance and how scientists deal cognitively with potential conflicts of interest when considering whether to pursue TT.

Dr. Waldman discussed some upcoming work that he has planned for the short term, which includes a plan to execute a pilot study to collect managerial and organizational survey data (including nontraditional metrics) from both GOGO and GOCO laboratories. For the longer term, he briefly described plans in progress to expand the pilot study to a broader audience (more laboratories) and to conduct widespread training efforts to emphasize managerial and organizational best practices (aimed at PIs, TT professionals, and strategic laboratory leaders).

Lessons from Across the Pond

Mr. John Fraser

Four decades after the passage of the Stevenson-Wydler Act (1980) and the Bayh-Dole Act, it is clear that federal TT professionals know what they are doing — and they do it well (and in high volume) — but Mr. John Fraser asked why and how TT professionals communicate the *value* of what they do.

Mr. Fraser presented some ideas that U.S. TTOs could learn from the United Kingdom. He noted that in the United Kingdom, the impact of research was included as part of the conversation of the ROI of research. Applicants applying for university research funding were asked to include an impact statement, to be judged by peers, and these statements accounted for 20% of the score for funding. He further noted that in the United Kingdom, several types of impact could be considered, including cultural, economic, societal, environmental, health, legal, political, educational, and technological impact.

Mr. Fraser noted that KT from research to impact flows through multiple channels. One lesson learned from this was that context matters. Some KT channels are formal, papered arrangements, and the IP licensing is only a small part of the whole KT process relevant to the cost, but it is highly focused on improving the economy through the use of the IP with both existing and potentially new companies. The impact must be measured in the context of the rest of the organization, not just the laboratory activities. KT indicators are a measure of the performance of the whole organization and not of the KT office, per se, because KT and impact are not the sole purview of the KT office — although that is a service function of the research organization as a whole, the mission, environment, priorities, and support of the research organization determine its activities and performance.

Another lesson Mr. Fraser learned from the United Kingdom was that starting with poor materials cannot lead to making or licensing something of value.

Mr. Fraser noted that the impact of an invention or technology flows beyond the licensor and the licensee. TT professionals must find ways to study the impact because they are the only people with the insight to conduct such a study, and no one else will conduct such studies. He recommended that such studies need to be expansive, but also explicit and specific in what is measured and the successes claimed. Furthermore, TT professionals need to make the impact meaningful to the audience by framing it in terms that they understand and value. TTOs must follow through with the descriptive impacts (societal, economic, health, and so on) and what is further needed to continue and/or improve, which forms part of the request for support.

Mr. Fraser concluded with the take-home message that brainstorming with others outside of the U.S. TT community can provide a different perspective. Any metrics created to measure the impact and value of TT activities likely will use a mixture of stories, case studies, and metrics (sheer numbers). Finally, the value of these activities must be communicated to stakeholders; TT professionals cannot just "communicate the metrics" and still fulfill their communication duties.

Questions and Answers

Q1. Mr. Fraser proposed that a TT professional meeting with President Biden would not convey the importance and value of the field to him by talking about the metrics.

- Mr. Fraser encouraged the audience to think of President Biden as an individual American they are trying to convince that TT is important. Metrics are only a small tool to describe TT, so it is better to give him examples of how the activity has led to products that save lives or improve corporate global competitiveness. Another issue is that the community conveys facts and concepts for new products, but does not appeal to the emotions of listeners. To fully convey the impact of TT, it would be useful to gather a small group from Madison Avenue and ask them how to communicate the value and impact. Such a group likely would combine a message based on facts with an appeal to the emotions of the listeners — a much more holistic approach that may better impress an audience than straight facts. Creating an emotional appeal helps convey the scientific argument in a way that is meaningful and impactful.

Q2. How do we move from metrics to impact?

- Dr. Silverthorn responded, "I don't necessarily think it's a straight line between metrics and impact. Rather, I encourage us to think about our TT metrics as data — and data require analyses. That analysis is really what gets us to the 'story.'" She emphasized the need to invest the resources, time, and personnel to get the information to the people who can conduct that analysis to build the story. Several people have spoken over the course of these 2 days who operate in this space (*e.g.*, TechLink). L2M has been building a pipeline of interagency research on TT topics, but it takes roughly 3 years from concept development to final report. She concluded, "It's not something that we just 'connect the dots,' but rather something that we have to build up over time and build a steady stream of impacts coming out of the data that we collect."
- Ms. Schoppe speculated that the process is a combination of elements — looking at the trend of the metrics — so that if something new is implemented, metrics can illuminate elements of the impact from before and after the implemented change. One aspect is who is the audience for the explanation or story, what is the intended message, and what is the desired action. A presentation would be tailored differently if given to scientists versus legislators, for example, to show them what is relevant to them rather than overwhelming them with everything. Yet including the human element in those success stories, coupled with the data to back it up, is still important.
- Dr. Waldman commented, "So often, we think in scientific terms, because we're scientists, statisticians, or whatever. But as a professor, I have to worry about communicating with people who aren't scientists — undergraduates, for example." He explained that anecdotal examples are more engaging to undergraduate listeners than descriptions of his research in university TT. Anecdotes are helpful to provide context in a way that broad audiences can understand and are a good way of communicating something specific and technical to a broad audience.

Q3. Dr. Silverthorn, wasn't one of your takeaways that the public didn't really care much about success stories?

- Dr. Silverthorn acknowledged that success stories polled quite low, and noted that the point about audiences matters particularly in this context. The public cares about success stories that matter to them; things need to connect on a personal level. If a member of the public has a family member with a specific illness and they hear a medical success story about how a federal laboratory contributed to the development of that diagnostic or therapeutic, then that matters to them on an individual level. "But across the entire, broad space, just throwing out success stories to the public doesn't really hit the mark," she concluded.

Q4. What are we doing, or should we be doing, to measure and promote diversity in the inventor pool and in TTOs?

- Ms. Schoppe pointed out that AUTM has a special interest group for women inventors, and they are gathering statistics currently framed more on women right now because AI algorithms are better suited right now to identify women's names than minority names. Minority status is a little bit more complicated and may not be determined by a name, for example. TT professionals are much more aware than they used to be about implicit bias in TT — responses that might have occurred in past times based on a woman's name as a licensing manager that may have changed the reaction. Awareness has been raised over the last several years, and now TT practitioners are acutely aware of and recognize that they may have had some implicit bias. The numbers show that there is a slight increase already in the number of women getting patents, but more

substantial increases will take time. Ms. Schoppe noted, "I think the training that we've taken is super important in helping encourage participation of those underrepresented groups in order to get to more equal ground."

- Mr. Fraser recently led a workshop on how the field can increase the participation of junior faculty and women in TT activities. One takeaway from that workshop is that women appreciate being invited to participate, whereas men will more readily join a project.
- Dr. Waldman expressed his strong belief in pure affirmative action. Affirmative action involves recruitment efforts — not actual selection or quotas, but special recruitment efforts, as well as intentionally using tools like AI or federal laboratory corollary programs to draw in more women, minorities, and people of color into those kinds of programs and special efforts. Devoting resources to such processes would be helpful.

Q5. If you look at the TT process — from discovery through to product — what the public sees is the product, and they may not have any idea that the invention began in a government laboratory. How do you deal with that?

- Mr. Fraser suggested that this is a story best told by the companies that take the invention to actual product. Taxol was an unusual example, in which the company did not acknowledge that the first iteration of the drug was a university invention.
- Dr. Silverthorn emphasized the importance of considering this point relevant to the differences between federal laboratories and universities. There is a length of time between when R&D dollars go into an effort at an agency and come out on the other side as a product or service. One of the things that matters is budget consistency; a university budget may be consistent over the time frame it takes to go from discovery to product, but federal budgets may vary widely based on administration priorities, Congressional budgets, and so forth. The National Aeronautics and Space Administration is a good example of this; funding opportunities are very high one year, and then within 3 years, funding decreases and the company is left "holding the bag."
- Ms. Schoppe referred to the audience aspect and encouraged companies to tell the story and disclose the role of a federal laboratory or university in the final product. As for the pharmaceutical industry, showing that a product was the result of collaboration and that the company is developing the product as a type of public service is in its best interest.
- Mr. Fraser referenced a study by Ashley Stevens and Dr. Rohrbaugh asking how many approved drugs originated from federal funding; the answer was roughly 190 or about 18% of all new molecular entities, with the most discoveries (about two dozen) attributed to NIH. "There are ways to communicate this, stories to share," he commented.

Closing

Ms. Mojdeh Bahar

Ms. Mojdeh Bahar summarized the talks that were heard throughout the two days of the workshop. She discussed Mr. Allen's comments on Bayh-Dole and Mr. Zielinski's comments regarding the presidential memorandum and in-reach and outreach activities. She noted that culture also plays a role in monitoring the appropriate mission metrics. Culture is ingrained, and TT professionals must know the culture of their agency. Federal agencies need to create a culture of innovation, and the leadership needs to create a culture where this is ingrained; this is an ideal goal for the laboratory's TT program. Federal laboratories have an agency mission that they must adhere to, and everyone needs to be aligned with it, including TT. Ms. Bahar discussed the need for federal laboratories to speak to their various internal and external stakeholders and to include Congress. She noted the importance of working closely with other parts of the organization, including the agency's grants and SBIR offices. Ms. Bahar noted that to have a learning agenda, alignment with the mission is needed so that technologies can be used to benefit the public. Noting where the TTO sits on the organizational chart and whom it reports to also is important, as this may affect the type of metrics that are collected. Regarding how the philosophy of the TTO is valued within the agency, Ms. Bahar stated that all agencies need to report some required metrics. The individual agencies should measure what is important to them and the mission of their individual organization. Ms. Bahar encouraged listeners to think of metrics as another communications tool and consider the message they wish to communicate to the specific audience and the story they want to tell. She also stated that an agency's technology focus helps to develop appropriate metrics to use. For example, platform technologies and translational technologies are measured differently, and they each have a different narrative that one may want to communicate using specific metrics. In closing, Ms. Bahar noted that TT is both multifaceted and interdisciplinary. It is the intersection of law, business, and science, which makes TT diverse in thought. However, TTOs need to do a better job of getting the workforce within TT to be more diverse and inclusive. TT professionals play many roles — communicator, teacher, and supporter of science — and should celebrate the fact that they impact science in a variety of ways.

Question and Answer

Q1. As TT professionals, how do think the way you communicate with your researchers has changed from 20 years ago?

- Ms. Bahar stated that how TT professionals communicate has changed significantly since the field started. Researchers at the bench are more engaged and understand the importance of TTOs in communicating their ideas to the public.