NIH TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

January 2024

ETT Honored with Innovation & Data Excellence Awards

Richelle Holnick, OTT

The Enterprise Technology Transfer (ETT) System Implementation Team has been recognized by both the Federal Laboratory Consortium (FLC) for Technology Transfer's **National Technology Transfer Innovation Award** as well the HHS Distinguished **Federal Data Modernization Award.** These are two very prestigious honors that the ETT team is grateful to have received.

The FLC annually awards federal laboratories for outstanding technology transfer achievements and winning this award highlights the creative approach the ETT team had to take to customize the commercial off-the-shelf system that was chosen as the base system for ETT given that NIH's portfolio was larger than standard systems were prepared to handle. Bringing a new system of record online for NIH Tech Transfer may not sound innovative, but having nine separate systems caused information silos, different policies and procedures for documenting information in the systems, and duplication of effort. When information can easily flow between the ICs, it allows for knowledge sharing at scale. ETT makes tech transfer at NIH more efficient, which in turn helps move more inventions from the lab to market to ultimately better public health.

In addition to winning the FLC award, the ETT Implementation Team has received an Honorable Mention for the HHS Distinguished Federal Data Modernization Award as part of the inaugural 2023 HHS Data Excellence Awards. These awards were created this year to honor individuals and teams whose creative and collaborative efforts led to innovative solutions to the Department's data challenges. They highlight data driven approaches for initiatives to better serve the American people. With data as a cornerstone of the NIH mission, putting data to work in cross-agency teams was recognized and celebrated.

In This Issue

ETT Awards

Most data migrations are one to one or two to one, however, loading the data into ETT was a nine to one database migration. Normalizing the individual datasets in each database was a four-year effort due to the size of these databases and the need for substantial cleanup and standardization of individual IC and combined data sets. While data condensing and cleanup work is still ongoing with the Data Quality Working Group, the team is grateful to have received these recognitions for the extensive work it took to merge the legacy databases and create a centralized repository of all NIH technology transfer data.

Mark Rohrbaugh: Reflecting on His Career at NIH

Richelle Holnick, OTT

What first attracted you to a career in technology transfer?

***MR*:** Before coming to NIH, I worked as a scientist for two start-up biotechnology companies, each of which laid-off scientists during financial crunches. At one company, I was a co-inventor of a hepatitis B vaccine invention that was filed internationally. (Eventually, after the company flopped, BMS bought the application and then abandoned it.) When I came to NIH in 1991 to work in grant review at NIAID, I missed the intersection of science and business. After exploring a career pivot, I enrolled in GW law school at night with a focus on intellectual property law. Half-way through I applied for a job opening with the NIAID technology transfer office and have never looked back.

Mark Rohrbaugh

You have worked at NIH for 32 years; what kept you passionate for your work at the NIH?

MR: As a scientist, I am still thrilled to learn about NIH scientists' new discoveries and to assist them when those discoveries have the potential for development as new biomedical products. The work in technology transfer at the intersection of biomedical research, business, and law is both exciting and gratifying at NIH in great part because our goal is to improve public health. For a similar reason, I have enjoyed working on the development and application of policy to ensure that we balance our public health goals with the incentives for industry to invest in the high-risk effort of product development.

You were director of NIH Office of Technology Transfer (OTT) from 2001 to 2013, when it managed the patenting and commercial licensing for NIH, FDA, and CDC inventions. HHS technologies were very successful during your tenure. In 2013, OTT licensees reported a combined total of $7B in sales of licensed products, what do you think led to this success?

Learn more about Dr. Phil Chen through our past interview with him!

MR: The adage of standing on the shoulders of giants rings true here. The giants are the HHS inventors, Phil Chen who launched NIH technology transfer in the late 1980s, the talented technology transfer professionals who came before me, and those with whom I have worked. Only a few products manufactured under patent licenses from NIH generate the large financial returns. As such, the successes are the larger number of new therapeutics, vaccines, diagnostics, devices, and research tools, regardless of sales figures, developed in the private sector utilizing HHS inventions. One can never predict accurately at the NIH lab stage which technologies will ultimately be safe and effective and how doctors and patients will utilize them.

Out of all of the products or projects that went to market from an NIH lab thanks to the technology transfer process, is there one that you are particularly proud of?

MR: Is this like picking your favorite child!? The one I was most directly involved with from the

time I started working in NIAID technology transfer though the time as OTT director was the first vaccine for rotavirus, which led to reduced suffering and death of children world-wide. While the NIAID vaccine technology reached the market first, it was withdrawn due to safety concerns. It was proof of principle, however, that the technology could prevent disease. OTT licensed other strains of the attenuated virus vaccine developed at NIAID and CDC for access in low- and middle-income countries. Second for me would be the HIV diagnostic technology from NCI that was co-owned with Institut Pasteur. I was involved in the latter part of its portfolio management including a settlement of 3-way patent interference between NIH, Pasteur and Chiron/Novartis—the company's patent lost to the NIH application.

After stepping down as the OTT director, you became the Senior Advisor for Technology Transfer and Innovation. What have been some of the most challenging issues in technology transfer from a policy perspective and what advice or "lessons learned" for this area might you now give your colleagues?
MR: Every American is concerned about the ability to obtain high priced prescription drugs, but some groups focus on NIH to find the solution through pricing controls in its intramural licenses of early-stage inventions or march-in to take away exclusivity in extramural licenses. While those proposals may sound rational on the surface, they don't consider the options biomedical investors have in this high-risk environment. Rarely does a company require a license from NIH; most often, they choose to license a technology, and they have choices other than NIH -funded inventions. That said, we should continue our practice, and consider new ways, of structuring licenses to reduce burdens on the uninsured and under-insured world-wide without sinking the technology from the start.

How would you describe the impact of technology transfer at NIH?

MR: Significant!! We published a paper earlier this year in which my colleagues and I tracked FDA approved drugs and biologics that utilize inventive technology licensed from government labs or non-profit research institutions world-wide, such as universities and research hospitals. Through the year 2016, the NIH IRP had the largest number of products (27) developed from any single institution's inventions. More up-to-date information on these products can be found on the NIH Tech Transfer website.

You will have retired by the time we publish this interview. What are you looking forward to most in your retirement?
MR: My retirement will not involve closing the door on technology transfer. I want to stay connected through AUTM and possibly some contract work. With more time on my hands, I hope to volunteer with local charitable organizations and continue my history research—the first resident of my home in Adams Morgan was a retired civil war general, Napoleon Jackson Tecumseh Dana. With a name like that, he was destined to be a general.

New TTC Director Named

National Cancer Institute

Suzanne Frisbee

NCI selected Suzanne Frisbie, Ph.D. as the next director of the Technology Transfer Center (TTC) beginning in October 2023. Dr. Frisbie served as acting TTC director from June – October 2023, following the retirement of Dr. Thomas Stackhouse. Prior to her current role, she served as an associate director within TTC.

Dr. Frisbie began the first part of her career at NCI in 1997 as a technology transfer (TT) fellow and ended her time at NCI in 2010 as a unit supervisor. During that time, she became an NIH expert on human subjects in TT agreements, teaching the first NIH Technology Transfer University session on human subjects in 1998 and continuing this throughout her NIH career. She was responsible for the creation and adoption of the "umbrella" Cooperative Research and Development Agreement (CRADA) concept that is currently used across the agency.

NIH NATIONAL CANCER INSTITUTE Technology Transfer Center

From 2010 - 2019, she served as the first deputy director of the National Institute of Allergy and Infectious Diseases (NIAID) Technology Transfer and Intellectual Property Office (TTIPO). Her accomplishments included fully defining the new role of deputy director, as well as setting up and managing a new fellowship program and new paralegal team. In 2019, she returned to NCI as an associate director in TTC, a role she held for four years.

Dr. Frisbie graduated magna cum laude from Mount Holyoke College with a B.A. in biochemistry and obtained her Ph.D. in biophysical chemistry from Georgetown University. Prior to entering the TT field, she was a senior staff fellow in the intramural research program at NIAMS.

"We are very fortunate to have Suzanne's deep scientific expertise, outstanding leadership skills and public service commitment at this pivotal time for cancer science," commented NCI Executive Officer, Donna Siegle.

New TTC Director Named was originally published by the National Cancer Institute.

NIH NATIONAL CANCER INSTITUTE

Maximizing NIH's Levers to Catalyze Tech Transfer

Abby Rives, Office of Science Policy

NIH funding is critical in stimulating new knowledge and discoveries driving innovation across sectors, and the agency is committed to thinking carefully about its role in making federally-funded inventions accessible to the public. To that end, on July 31, 2023, NIH hosted a workshop on **Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer** focused on how NIH, as a research institution, approaches patenting and licensing of inventions. The workshop panels loosely tracked the path an invention can take from discovery to licensing: and panelists explored how NIH decides what to patent and license, who NIH partners with, and how NIH negotiates those agreements. Throughout the day, panelists shared perspectives on how NIH can best approach these questions to fulfill public health goals. NIH invited tech transfer professionals from inside and outside NIH, as well as patient advocates, academics, legal experts, and industry. There was also a separate oral public comment period and opportunities for written public comments.

The NIH Office of Science Policy (OSP) organized the workshop. During the workshop, each of these NIH staff delivered presentations: Amy Petrik, Senior Technology Transfer and Patent Specialist at NIAID's Technology Transfer and Intellectual Property Office; Michael Shmilovich, Senior Licensing and Patenting Manager at NHLBI; Sue Ano, Director of the NINDS Technology Transfer Office; Andrew Burke, Senior Technology Transfer Manager at the NCI Technology Transfer Center; and Tara Kirby, Director of OTT. Daniel Reich, Senior Investigator in the NINDS Translational Neuroradiology Section; Penny Burgoon, Director of Policy, Communications and Education at NCATS; Matt McMahon, Director of the NIH Small Business Education & Entrepreneurial Development Office; and Courtney Silverthorn, Associate Vice President, Science Partnerships at the Foundation for the National Institutes of Health each moderated one of the workshop panels. And Surekha Vathyam, Deputy Director at NIAID's Technology Transfer and Intellectual Property Office; Michael Salgaller, Supervisory Technology Analysis and Marketing Specialist at NCI; and Krishna Balakrishnan, Director of the NCATS Office of Strategic Alliances served as panelists.

As to what comes next, NIH will prepare a written report from the workshop which is expected to identify areas for further exploration, and a recording of the webcast is available.

Panel from the workshop

NIH Again Wins "Deals of Distinction" Award

Steve Ferguson, OTT

The Licensing Executives Society (LES) has recognized with its "Deals of Distinction" Award licenses granted by the NIH intramural research program to uniQure, N.V. based in Amsterdam along with its global partner CSL Behring. As a result of these licenses, on November 22, 2022 the U.S. Food and Drug Administration approved Hemgenix®, the **world's first gene therapy for hemophilia B.** It represents an historic achievement based on more than two decades of research and clinical development through a government/ industry partnership and license agreements.

Hemophilia B is a serious genetic bleeding disorder that is a result of insufficient levels of blood clotting Factor IX, which is a protein needed to produce blood clots to stop bleeding. Previously, treatment involved intravenous (IV) infusions of Factor IX replacement products to aid the body's ability to stop bleeding and prevent future bleeding episodes.

Hemgenix® itself is a one-time gene therapy for the treatment of adults living with hemophilia B. It is an Adeno-Associated virus (AAV) vector-based gene therapy for adults with Hemophilia B, or otherwise have a life-threatening risk of hemorrhage, or have repeated spontaneous bleeding episodes. The gene is expressed in the liver to produce Factor IX protein which then allows patients to increase their own blood levels of Factor IX which in turn limits bleeding episodes.

Hemgenix was developed and launched by NIH's licensee uniQure, N.V., and its sublicensee CSL Behring. NIH's contributions from NHLBI and NIDCR scientists were a method of delivering a heterologous nucleic acid or gene of interest to target cells using an Adeno-Associated Virus of serotype 5 (AAV5) as well as a novel method of producing the virus in insect cells.


Prince Alexei Romanov

So why is this so important? For example, we know today that Prince Alexei Romanov, son of Tsar Nicholas II, and heir to the Russian throne suffered from hemophilia B. From an early age, Alexei was prone to prolonged bleeding and his family feared that he wouldn't make it through his first month of life. The disease didn't kill Alexei, however it impacted not only the Romanov family but also probably Russian history. Alexei's frail condition encouraged his mother Tsarina Alexandra to keep close company with the Russian mystic Grigori Rasputin, who claimed to wield healing magic. With no medication such as Hemgenix or other treatments available at the time, Alexandra tried to do everything possible to treat or cure her son. According to some historians, when Rasputin used his close relationship with the Romanovs to influence bureaucratic affairs in his favor, the public grew increasingly suspicious of the regime, possibly hastening the Russian revolution in 1917.

Could this "Deal of Distinction" winner have perhaps prevented the Russian revolution? We'll never know the answer to that, but it is certainly very interesting question on which to speculate!

The Nagoya Protocol and How it Impacts Technology Transfer

Mukul Ranjan, NIAID

The Convention on Biological Diversity (CBD) entered into force on December 29, 1993. This UN instrument is the only international instrument comprehensively addressing biological diversity. The Convention's three objectives are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilization of genetic resources.

The Nagoya Protocol (NP), a supplementary agreement to the CBD, was implemented on October 12, 2014 to further advance the implementation of the third objective: The fair and equitable sharing of the benefits arising out of the utilization of genetic resources (GR). The NP sets out obligations for its contracting parties to take steps to ensure access to genetic resources, benefit-sharing and compliance and was intended to provide 'greater legal certainty and transparency.'

Credit: Leibniz Center, Germany

The CBD and Nagoya together formalize the right and the authority of each country to govern the access to GRs within their territory, controlling and monitoring their use. The right is based on the users' compliance with Access and Benefit Sharing (ABS) rules, that is users of GR and associated traditional knowledge shall utilize them only upon "legal" access. More specifically, where the provider country has adopted ABS domestic measures, as more and more countries are doing, users shall seek an express authorization for access, Prior Informed Consent (PIC) and shall share the benefits arising from their utilization with that country "in a fair and equitable way," based on a binding agreement on Mutually Agreed Terms (MATs).

It was encouraging that the NP did address issues concerning scientific research and expanded the reach of the CBD, defining 'utilization of genetic resources' as 'research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'. The term 'research and development' is not further defined. Furthermore, under the Nagoya Protocol, the term "genetic resources" means "genetic material of actual or potential value". "Genetic material" in turn means "any material of plant, animal, microbial or other origin containing functional units of heredity." One important caveat is that the CBD and the Nagoya Protocol do not apply to human genetic resources.

As you can imagine the broad definition of "genetic resources" and "utilization" encompassing research and development, will cover any non-human materials collected in a Nagoya compliant country. This raises problems for entities doing international research as they have to follow the Nagoya specific laws of each country and provide benefits in exchange for access to such materials.

The CBD established a framework for ABS associated with the use of genetic resources and

some forms of traditional knowledge but there was little guidance in the CBD on what constituted equitable benefits and how to regulate and manage ABS. The Nagoya Protocol helps in providing additional clarity with a list of possible types of benefits. For example, the Nagoya Protocol lists such non-monetary benefits, which are all that non-profit entities like the NIH can provide, as sharing of results, collaboration in scientific research and development programs, particularly biotechnological research activities, education and training, access to databases, transfer of knowledge about the genetic resources, institutional capacity-building, training related to genetic resources, access to scientific information, research directed towards priority needs such as health, and institutional and professional relationships.

The Nagoya Protocol also encourages the separation of academic and commercial research, as well as priority for public health, although these distinctions are not as visible in the national legislation being implemented.

Even for non-pathogenic microorganisms, the implementation of the CBD and Nagoya Protocol creates daunting challenges for science. The CBD framing is particularly problematic for microbial research. For example, the scientific definition of biodiversity hotspots is based on high diversity and habitat loss of vascular plants as a proxy for all biodiversity while biodiversity hotspots and local endemisms have not been detected for many microorganisms which display a biogeography very different from macroorganisms. Microorganisms also tend to be very mobile, with large biomass, widely dispersed and not limited to national boundaries.

These treaties and national laws implementing them, pose a challenge to the free flow of materials and genetic sequence data and it is likely that technology transfer offices will be first ones to see this. Under these laws, if a researcher wants to collaborate or access materials (plant, animal or microbial) they will need to first get permission (PIC) and then negotiate what they are willing to provide in return (MAT) before access is granted.

An area of considerable debate and concern is the push to include not only physical materials but also any genetic sequences derived from them under these laws.

Credit: Wayne Pereanu

For better or worse, ABS has now spread to many other international treaties and is widely accepted by the global community. For example, the Pandemic Accord being negotiated at the WHO by various countries, has ABS language for access even to pathogens under a pandemic and is leading to prolonged negotiation about how this will play out in practice.

NIAID was first confronted with this issue when trying to access pathogens during the MERS, Zika and Sars-CoV-2 outbreaks. Countries had just begun to implement national laws under the NP and many of these provided criminal penalties if they were broken. It became difficult or in some cases impossible to execute MTAs with institutions in these countries.

The NP also creates challenges for US investigators engaged in basic or non-commercial research because its unclear what financial benefits if any will accrue from such early-stage research. Furthermore, because the US is not a signatory to the treaty, it has not created an infrastructure to assist its researchers in navigating this issue, as has been done in the EU countries.

Technology Transfer Featured in Podcast

National Cancer Institute

Inside Cancer Careers, a new podcast from NCI's Cancer for Cancer Training (CCT), shines a light on the exciting world of cancer research training and career opportunities. The most recent podcast features technology transfer at the NCI in a two-part episode focused on TTC's Technology Transfer Fellowships and the Transition to Industry (T2I) Fellowship.

In part one, TTC Unit Supervisor, Laurie Whitney, Ph.D. and TTC Innovation Manager, Laura Prestia, Ph.D. discuss:

- Technology transfer as a career path.
- How to contribute to cancer research efforts away from the bench.
- The importance of technology transfer at NCI.

For those interested in applying to the fellowship, TTC has current openings in the Negotiator track.

In part two, Sabina Kaczanowska, Ph.D. and Trang Vu, Ph.D., recent T2I fellowship alumni, discuss their experience in the program. Hear about how it impacted their careers working in translational cancer research or pivoting into industry. T2I is funded by NCI's Center for Cancer Research. The program is led by TTC in partnership with NCI Small Business Innovation Research (SBIR) and CCT.

T2I is open to NCI CCR trainees with applications accepted each November.

Learn more about about these programs by listening to the podcast, or by searching for NCI's Center for Cancer Training Inside Cancer Careers on your favorite podcast app.

Technology Transfer Featured in Podcast was originally published by the National Cancer Institute.

One Year of ETT

Terry Goodell, Sapient

The Enterprise Technology Transfer (ETT) system's first year of operation was exciting and successful, but also brought new challenges and many new enhancements. The team is very appreciative of the community for taking the time to work with us as we navigated operating this brand-new system of record for NIH T2.

The ETT team, including the various working groups that help steer the priorities and features of the system, were hard at work this year. To give you just a taste of what it takes to run ETT, we grouped the work the ETT Team does into three buckets, **User Support, System Development, and Operations and Maintenance:**

User Support	System Development	Operations & Maintenance
Troubleshooting • Maintain Knowledge Base • Track user support requests • Verify problems • Validate solutions • Document needed changes	*Document Requirements* • Determine user needs • Identify alternatives • Select best solution • Translate business need into technical specs	*Authority to Operate (ATO)* • Control configuration • System documentation • Assessment support
Data Quality Support • Monitor quality metrics • Assist standards development • Document/validate issues • Validate solutions • Apply corrective action	*Conduct Impact Analysis* • Business Process Modeling maintenance • Entity Relationship Diagram development • Change request review	*Security* • Vulnerability scan response • Penetration test response • Certificate updates
Inteum Coordination • Escalate problems • Clarify requirements • Set priorities • Consolidate user feedback	*Create Custom Analytics* • Dashboards • Grid filters • Custom datasets and reports	*Patching* • Windows patching • .NET patching • Minuet code updates • LFP code updates
	Conduct QA/Testing • Maintain test cases • Validate ETT/LFP changes • Validate Minuet changes • Develop automated tool	*Training* • Create/maintain demo videos • Conduct in-person training • Maintain user guides • Maintain Tips & Tricks

All of this work helps to keep the system running, helps users learn and easily access the system, and allows for enhancements to be made. A few of these enhancements included:

ETT Selected Enhancements:

- Display related Agreement ID(s) on a Payment Record
- Database triggers to update date and status fields automatically
- Creating new data fields on different parts of the system records
- Change labels (names) on data fields to reduce confusion about which fields to use
- Create/modify Sentinel rules to make sure that alerts go to the right people at the right times
- Add new record types to pick lists to allow better tracking/filter of records
- Modify grid filters to lock (prevent editing of) approved versions

Law Firm Portal (LFP) Selected Enhancements:

(The LFP connects our contract law firms to ETT.)

- Ability to add or remove listed items when uploading documents
- Update deliverables
- Display Activity owner (NIH Technical Representative) under search results
- Implement sorting for all LFP search results
- Change data displayed on Payable search results form
- Add drop-down fields to provide lists of approved values for selected data fields
- Modifications to Prosecution Contract Grid View to improve usability
- Modify display of financial information to allow negative values

Take a look at our 'ETT Wrapped' on the following page to see what a year of ETT development work looks like!

Credit: istock/pressureUA

ETT Deployments

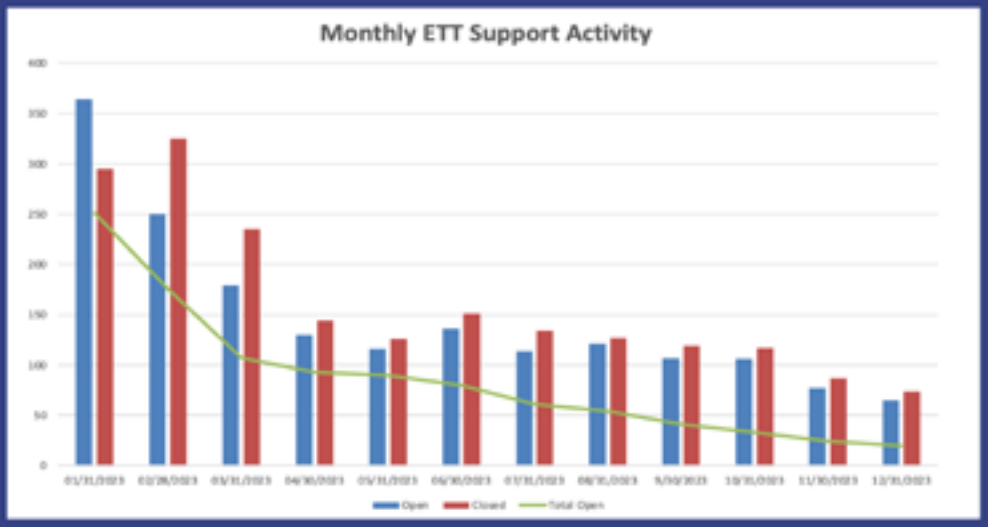
153 Enhancements

17 Maintenance Updates

LFP Deployments

21 Enhancements

14 Maintenance Updates



Meetings

- Data Quality Working Group: 47
- Governance: 25
- Tech Transfer Users Group: 21

Company and Contact Records

- 2,984 Contacts Condensed
- 1,285 Companies Condensed
- 4,001 Contacts Created
- 942 Companies Created

DASHBOARDS

70 Developed

High Volume Usage:

- NIH Docket - Agreements Dashboard
- NIH Docket - Invoice Dashboard
- NIH Docket - Patent Prosecution Dashboard
- NIH Docket - Upcoming Patent Filings

REPORTS

15 NIH Custom Reports Developed

High Volume Usage:

- Related License Report
- Royalty Distribution Form

QUERY GRIDS

157 Developed

High Volume Usage:

- RAU OFM Reconciliation Report
- MEU Monitoring Sales Report
- NIAID Missing Abstracts with 3rd Party Prosecution

FORM TEMPLATES

169 Developed

High Volume Usage:

- Royalty Invoice
- MEU Sales Report Reminder

GRID FILTERS

927 Developed

ANALYTICS ANALYSIS BUILDER REPORTS

7 Developed

ETT Wrapped

New Product Added to NIH Collection

Richelle Holnick, OTT

GSK came to campus in November and delivered an empty box of Arexvy® to the National Institutes of Allergy and Infectious Diseases (NIAID). Arexvy is their newest vaccine product, indicated for active immunization for prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. It is the first RSV vaccine for older adults to be approved anywhere in the world. This product is based upon a discovery out of NIAID's Vaccine Research Center.

GSK representative, Phil Dormitzer, delivering an Arexvy box to NIAID's Director, Dr. Jeanne Marrazzo

The Office of NIH History and Museum has taken over management of the NIH Technology Transfer product collection. We are excited to add Arexvy to the growing collection! We have dozens of products licensed from NIH technologies, but there are a number that we have yet to receive. With your help and MEU's we hope going forward that companies can be reminded that sending an empty product after their first commercial sale is part of their license contract. It is great for us to have sample products based upon NIH license agreements as physical representations of the technology transfer program!

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

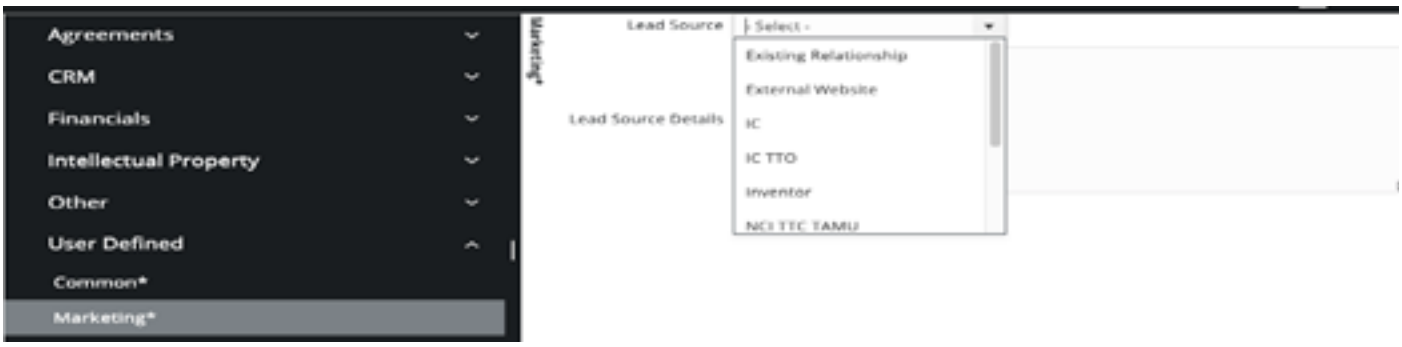
Documenting Lead Sources on License Agreements

Richelle Holnick, OTT

A wonderful new field has been added to the agreement record in ETT. The 'lead source' field will allow for documentation of where the license applicant or collaborator initially heard about the opportunity they have chosen to pursue. While this information is collected on the license agreement document, it has yet to have a home in ETT.

Utilizing this new field in ETT will allow your IC to run a report on where leads are coming from. This will allow new insights into what marketing strategies are effective and where time is best spent. OTT also does a substantial amount of marketing and promotion on individual technologies and would really appreciate being able to track the full life cycle of these efforts.

Within the Agreement record, under User Defined -> Marketing you will find a 'Lead Source' drop-down. You can also put any additional details in the 'Lead Source Details' free text field.



Products Licensed by NIH Featured in FLC Virtual Hospital

Richelle Holnick, OTT

The Federal Laboratory Consortium for Technology Transfer has created a new LabTech in Your Life virtual tour, this time featuring a hospital! This virtual tour allows viewers to see examples of technologies commonly found in hospitals that came out of federal labs. The goal of the FLC virtual city is to give recognition to how many products we are surrounded by that are the result of federal innovation. NIH is proud to have 14 products featured in the virtual hospital!

Check out the FLC hospital tour and see if you can spot all 14!

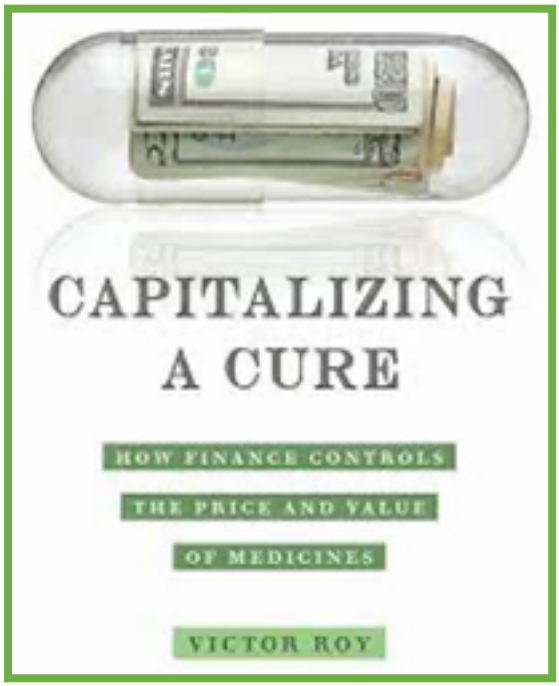
Book Review: *Capitalizing a Cure - How Finance Controls the Price and Value of Medicines*

Ashley Stevens, Focus IP Group, LLC

Mark Rohrbaugh brought this book to my attention.

It was written by Victor Roy who did his residency at Boston Medical Center, though years after I had retired from BU/BMC. He seems to have given up the practice of medicine for working in the sociology and policy sides of medicine and is currently a post-doctoral fellow in the National Clinician Scholars Program at Yale.

It's about Sovaldi® and Harvoni® , the sofosbuvir drugs that revolutionized the treatment of Hepatitis C, that were developed by Pharmasset, the Emory spin-out acquired by Gilead for $11 billion, one of the truly great acquisitions of all time. Todd Sherer from the Emory tech transfer office has a starring role in the tale.



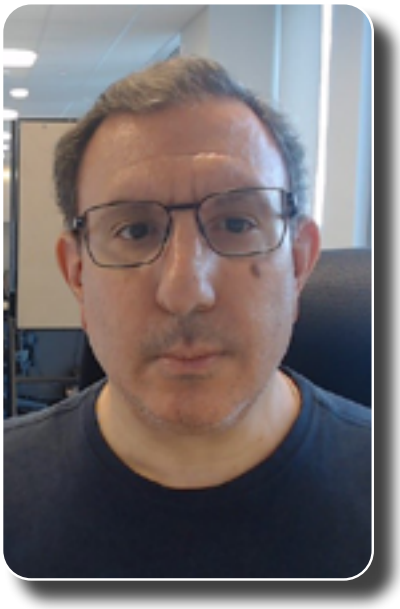
Roy does a fine job of describing the history of Pharmasset and Gilead. Although he identifies the role of publicly financed research in the development of sofosbuvir and the incredible creation of wealth that resulted (and the public sector research institution (PSRI) role in the creation of the HIV drugs developed by Gilead that enabled it to buy Pharmasset for $11 billion) he acknowledges that Pharmasset discovered sofosbuvir by itself. His objective is to identify why the drugs cost $1,000 per pill. His conclusions are insightful and apply to the full spectrum of patent-protected drugs, not just those that result from PSRI research, important at a time when the Biden administration has singled out PSRI-discovered drugs for special treatment.

You can "buy" the book as a Kindle download on Amazon, and I use parentheses because it's free. I found two minor errors, which I've pointed out to Victor, but I couldn't put the book down and I recommend it to you all.

Credit: iStock/SpicyTruffel

NIH Tech Transfer Featured in LES Webinar Series

Richelle Holnick, OTT



Peter Soukas

The Licensing Executives Society (LES) has highlighted NIH Technology Transfer activities in three of the programs from its recent webinar series. Leading things off on August 3rd was NIAID's **Peter Soukas** who spoke about technology transfer to developing countries, with "***TT With the Human Element: MenAfriVac®***". MenAfriVac® is a low-cost meningitis vaccine designed for use in sub-Saharan Africa. The pioneering vaccine, and the first one for developing countries that does not require constant refrigeration, is based upon a patent license from the NIH and FDA to PATH and was subsequently sublicensed by PATH to the Serum Institute of India under the Meningitis Vaccine Project, a partnership of PATH and the World Health Organization. The presentation on this topic was especially notable as it was also a previous LES "Deals of Distinction" winner for NIH.

Steve Ferguson

The second presentation in the series was "***Beyond the Contracts - Measuring the Actual Impact of a Patent Licensing Program***" given on November 29th by OTT's **Steve Ferguson**. This program described how NIH engaged RTI International, a nonprofit research institute, to develop new methods for characterizing and measuring the impact of technologies developed by NIH's Intramural Research Program. The RTI team created models to illustrate how technologies licensed from NIH to firms contribute to the stimulation of the U.S. biomedical innovation system, economic activity, and national and global public health. With this study NIH has been able at last to show the true value of its licensing program and its full range of impacts over the course of more than 30 years of technology transfer activity.

Andy Burke

The third LES webinar presentation given in 2023 featured NCI's **Andy Burke** discussing Yescarta's® journey from development to licensing. Entitled "**Getting to Yes(carta)**", the presentation on December 12th addressed two topics related to licensing efforts of NCI. The first, a case study on the CAR-T product axicabtagene ciloleucel (sold under the brand name Yescarta®), covered the development history of this ground-breaking therapy from the NCI technology transfer perspective. The second was a discussion of NCI's exclusive licensing practices as they concern important technologies in the adoptive cell therapy space and how federal licensing statutes have been used to maximize utilization and public benefit of these inventions.

Have an idea for a future LES webinar presentation that you might like to give? Please see Steve Ferguson for more details!

FLC in the Southeast

Sharon Soucek, NIEHS

Dr. Sharon Soucek, who holds a day job as the Director of NIEHS Office of Technology Transfer, was elected as the Southeastern Regional Coordinator for the Federal Lab Consortium for Technology Transfer (FLC) in July 2023. A major component of the FLC Executive Board (EB) consists of Regional Coordinators for the six FLC Regions. The Southeastern Region encompasses the following states: AL, FL, GA, KY, LA, MS, NC, SC. The FLC Southeast Region is home to over 40 federal laboratories and over 300 federal facilities of the Centers for Disease Control and Prevention, the National Institute of Environmental Health Sciences, Departments of Defense, Homeland Security, and Energy; the Environmental Protection Agency (EPA); and the National Aeronautics and Space Administration (NASA), among others.

The purpose of the FLC is to promote, educate and facilitate federal technology transfer. Under the facilitate pillar there are three subcommittees: Strategic Alliances Committee, Industry Engagement & Technology Partnerships Committee, and Regional Program Committee. Through the assistance and advocacy of Regional Coordinators (RCs), Deputy Regional Coordinators (DRCs), and other key members, the FLC reaches federal laboratories, industry, and academia on a local level and provides tailored networking opportunities based on the scientific and technological needs of that geographic area.

The regions provide a unique opportunity to highlight federal labs outside of the Mid-Atlantic area. With the help of the FLC, RCs can spread the word about the work that federal labs take on in regional events that may not be exposed to the breadth of technologies across the US. If you come across an event that takes place in the Southeast (or even in other regions) and would like NIH representation through the FLC, don't hesitate to reach out to your regional coordinator, Sharon!

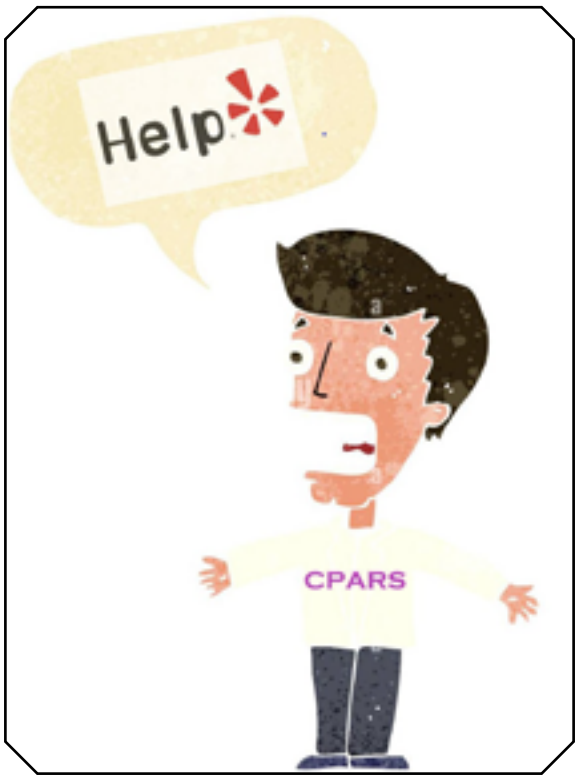
Dr. Sharon Soucek, Director of NIEHS OTT and FLC Southeast Regional Coordinator manning the FLC booth at NC IDEA Ecosystem Summit 2023

★★☆

Yelp Us Out: Your Help Counts in Law Firm Feedback!

Amber Rush, OTT

The Patent Legal Services (PLS) Team is seeking your feedback on the performance of work conducted by the law firms by rating Quality, Schedule, Cost and Management. Microsoft Forms is our PLS Yelp- a platform where your words, whether glowing or critical, play a pivotal role in shaping the storyline. By using the survey tool, you contribute to a collaborative dialogue that enables us to address performance concerns, fulfill annual CPARS reporting requirements and manage the PLS Master Contract.



Your considered evaluations are vital, and we genuinely appreciate the time and consideration you invest.

If you have any questions about the contract performance management surveys, please reach out to your IC's COR or Amber Rush.

To view and fill out the Performance Management Surveys see the links below:

Biotech

Mechanical Engineering

Chemistry

Software

Credit: Wayne Pereanu

FLC Video Highlights Partnership Resulting in Commercialization of Axicabtagene Ciloleucel

National Cancer Institute

A new video produced by the Federal Laboratory Consortium (FLC) as part of their Labs in Action series highlights a successful NCI partnership to develop and commercialize axicabtagene ciloleucel, a highly personalized CAR T-cell immunotherapy for the treatment of cancer. Axicabtagene ciloleucel was approved by the FDA on October 18, 2017 for patients with large-B-cell lymphomas whose cancer has progressed after receiving at least two prior treatment regimens.

Axicabtagene ciloleucel was developed by Steven Rosenberg, M.D., Ph.D. (Chief, Surgery Branch, Center for Cancer Research, NCI) and his colleagues. The technology was licensed to Kite Pharma, Inc., now a Gilead Company, as part of a broader research agreement for further development and commercialization after promising early-phase clinical trials conducted at NCI. "The technology transfer office has been vital to our ability to move from the laboratory into widespread clinical application," commented Dr. Rosenberg. The video also features the technology transfer perspective of the TTC technology transfer managers involved. Watch the video produced by the FLC to learn more about the partnership and development of axicabtagene ciloleucel, distributed by Kite as Yescarta®.

Dr. Steven Rosenberg and a colleague in the lab at the NCI Surgery Branch
Credit: Screenshot from FLC-produced video

ANNUAL REPORT TRIVIA

Test your knowledge of FY22 T2 activities with our quiz. The first correct response will receive homemade ice cream for their office* with their choice of flavor. Click this graphic to answer the questions!

How many people attended the 2022 NCI/FNL Tech Showcase in person?

What disease has NIEHS partnered with ChromaDex to research and develop therapies for?

Which IC won the 2022 FLC Award for Excellence in Technology Transfer?

How many agreements does NCATS OSA typically execute annually?

What did a collaboration between NINDS, NIA, and the Jackson Laboratory make broadly available to the research community?

*Office must be based in the DMV to receive the award

Comic: ETT's Birthday Party

Wayne Pereanu, OTT

THE TEAM QUICKLY REALIZED THAT CELEBRATING ETT'S BIRTHDAY WITH A VIRTUAL CAKE WAS A REAL MISTAKE!

Comings & Goings

Aditi Sengupta Banerjee, Ph.D. has left her position at NCI/CTEP (Cancer Therapy Evaluation Program) as a Scientific Program Manager to join FDA/CBER (Center for Biologics Evaluation and Research) as a Primary Reviewer and Regulatory Project Manager. She was a Technology Transfer Fellow in the Marketing Group at NIH OTT before joining CTEP. Aditi received her Ph.D. in Molecular Virology and Cancer Cell Biology from Jadavpur University, India and worked as a postdoctoral fellow at NCI and NIAID before joining OTT.

Michael Mowatt, Ph.D. is retiring after 35 years with the National Institute of Allergy and Infectious Diseases. Mike is retiring from federal service to start the next exciting chapter in his remarkable journey, but not before a warm send-off. Mike joined NIAID in 1988 as a Senior Staff Fellow in the Laboratory of Parasitic Diseases, Division of Intramural Research, expanding the training in molecular and cellular biology of parasitic protozoans that he began at the Rockefeller University. He made the move to NIAID's Technology Transfer Branch in 1995 and has led the organization, now called the Technology Transfer and Intellectual Property Office (TTIPO), since 2001. Look for our interview with Mike in the next edition of the newsletter!

Lynn Onyebeke has joined NCI as a Fellow. She earned her J.D. degree from the University of Virginia School of Law in May 2021. After graduating, she worked as an intellectual property associate at a law firm for two years. During her time at the law firm, her work involved drafting and reviewing a variety of agreements and conducting IP diligence for mergers and acquisitions. Lynn is passionate about strengthening efforts to combat health diseases and she is aiming to do so through TTC's fellowship program.