IIH TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

April 2025

Interview with TTCF Chair: Yogi Prabhu

Richelle Holnick, OTT

Can you tell us about your background prior to NIH?

I hold a BS (Microbiology and Biochemistry) and an MS (Biochemistry) from the University of Mumbai, India. After spending a few years teaching Pharmacy undergraduates, I moved to Germany to pursue research, where I earned my PhD in Natural Sciences from the University of Cologne. Upon completing my thesis, I relocated to the United States to conduct postdoctoral research at the NICHD at NIH. I continued my research career as a senior scientist at the University of Maryland, Baltimore (UMB). In 2013, I joined NCI's TTC as a CRTA fellow, followed by a more permanent role at NIAID TTIPO in 2017.

What led you to a career in technology transfer?

Following my postdoctoral research, I began exploring alternative science careers. Through informational interviews with several TT professionals at UMB, NCI, and OTT, I found the field of technology transfer particularly intriguing. It offered a unique blend of science, business, and law enabling the translation of scientific discoveries into real-world solutions. Fast forward 10 years later, I am happy to have made this career transition.

What is your favorite part of working for the NIH?

Having spent over 16 years at the NIH in various capacities—from postdoctoral and technology transfer fellowships to a career in technology transfer—I have come to appreciate the myriad opportunities to contribute to NIH's mission, which aligns closely with my core values. The most rewarding aspect has been the privilege of leading several impactful projects instrumental in bringing FDA-approved therapies to market.

What led you to volunteering as the TTCF chair?

Since my time at the NIH TT, I have found these forums to be incredibly informative and enriching, providing me with a broader perspective on the work we do and the value we bring to scientific advancement and public health. I have been considering volunteering in this role for while now, and I must admit, a friendly nudge from our former TTIPO Director, Dr. Michael Mowatt, played a role.

(Continued on page 3)



Yogi Prabhu

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Technology Transfer to Developing Countries: TT With The Human Element: MenAfriVac®

Richelle Holnick, OTT

Recent NIAID TTIPO retiree Peter Soukas has been invited to present at the April 25th OITE Workshop on behalf of the Biotech Interest Group (BIG). He will be presenting Technology Transfer to Developing Countries: TT With The Human Element: MenAfriVac[®].



Credit: PATH/Gabe Bienczyck



Credit: MenAfriNet

Even retirees can still support NIH Tech Transfer - so stay alert, we may be calling on you in the future!

If you are interested in learning about this success story ahead of his presentation, you can read more about it on our awards page: **MenAfriVac**

Is there anything you would like to change or institute during your tenure as TTCF chair?

Along with our current TTCF VC, we are considering a few enhancements to the forum in the upcoming year(s). While we will continue to cover our standard topics such as licensing, patenting matters, community updates, and available resources, we aim to introduce a more interactive format, including panel discussions and additional segments to discuss topics of interest.

What do you like to do in your free time?

I enjoy taking long walks, spending time with my family (especially my daughter who's a teenager now!), playing Sudoku, and binge-watching Netflix.

Can you share a fun fact(s) about yourself?

I have a passion for travel, can almost speak five languages, and enjoy retail therapy. I also have a spiritual side that is perfectly in sync with my name.

Is there anything else you would like to share?

I am truly honored to have the opportunity to serve in this role and am committed to continually enhancing the value we bring to the forum.



Ushuaia- Patagonia



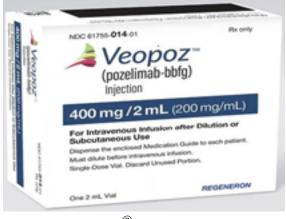
Isla Martillo

FLC Impact Award Honors NIAID Team Behind First FDA-Approved Drug for Ultra-Rare Genetic Disease

Dylan Drobish, NIAID

In 2016, researchers at NIAID were the first to identify CHAPLE disease—a rare genetic disorder leading to deficiency in the complement protein CD55. Just 8 years later, successful, coordinated technology transfer efforts between the public and private sector have allowed us to go from the initial identification of CHAPLE to FDA approval of its first treatment option Pozelimab (Veopoz[®]) by Regeneron.

In recognition of these outstanding efforts, NIAID has received a 2025 Impact Award from FLC.



Veopoz[®], Credit: Regeneron

A nationwide network comprising over 300 federal laboratories and research centers, FLC aims to foster scientific breakthroughs that drive economic growth by creating new industries, businesses, and jobs via technology transfer. The FLC Impact Award honors laboratories whose technology transfer efforts have made a tangible lasting impact on the populace or marketplace ranging from a local to a global scale.

Dr. Michael Lenardo, former Chief of the Molecular Development of the Immune System Section at NIAID's Laboratory for Immune System Biology (LISB) and lead inventor on the CHAPLE technology, noted that most individuals diagnosed with CHAPLE disease are children who face severely debilitating symptoms and life-threatening complications. "I saw first-hand the transformational clinical improvement that pozelimab achieves in those [living with] CHAPLE. The approval of pozelimab is a milestone to celebrate."

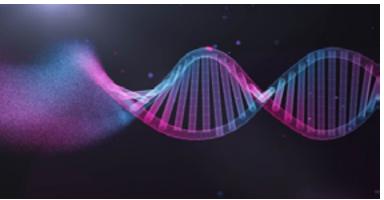
From the clinical coordinators attending to the complex needs of trial participants, to the team members who fought for compassionate use abroad to obtain the data needed to promote research into novel agents, to the NIAID Technology Transfer and Intellectual Property Office (TTIPO) specialist who worked tirelessly to negotiate agreements that best served the public—efforts at each stage were significant.

Following initial discovery of the disease by Dr. Lenardo's laboratory in 2017, multidisciplinary experts at TTIPO worked with the research team to file a patent application covering methods for the diagnosis and treatment of CHAPLE. TTIPO also worked with the team to navigate the next crucial phase of development—a 2019 collaboration with Marmara University to investigate the off-label use of eculizumab (FDA-approved for another genetic disease in the inflammatory bowel disease spectrum) in 16 people with CHAPLE. Recognizing the need to deliver an effective treatment as quickly as possible to those with the greatest need, co-inventor on the initial CHAPLE discovery Dr. Ahmet Ozen concurrently worked to secure compassionate use of eculizumab for patients with CHAPLE, an initiative funded by the Turkish Health Ministry.

In January 2019, TTIPO began working with internal and external stakeholders to develop NIAID's patented technology under a CRADA. Under the CRADA with Regeneron, funding was secured to conduct a 2-year Phase II/III trial examining the safety and efficacy of Regeneron's proprietary compound pozelimab (Veopoz[®]) in 10 people with CHAPLE at NIH Clinical Center.

After the trial's successful completion, Regeneron filed a biologic license application (BLA) with the U.S. FDA, which was accepted by the FDA under its priority review program. On August 18, 2023, the FDA registered pozelimab (Veopoz[®]) as the first approved treatment for CHAPLE disease.

Although CHAPLE disease affects fewer than 100 known people worldwide, this success story serves as an inspiration—and model—for future initiatives aimed at tackling rare and complex health challenges through meticulous research and strategic partnerships.



Along with the clinical/research team led by Dr. Lenardo, the team of dedicated specialists at TTIPO managing the technology portfolio will be formally honored at a special ceremony during the 2025 FLC National Meeting in May.

FLC Impact Awardees include the following current and former NIAID

personnel: **Yogikala Prabhu**, PhD, **Cecilia Pazman**, PhD, **Cosimo Fuda**, PhD, JD, and **Richard Williams**, PhD (TTIPO); **Michael Lenardo**, MD, **Heather Moorman**, **Mary Magliocco**, **Sarah Weber**, **Ahmet Ozen**, MD (LISB); and **Ivan Fuss**, MD (Laboratory of Clinical Immunology and Microbiology).

*Dr. Michael Lenardo served as Chief of the Molecular Development of the Immune System Section at LISB and as Co-Director of NIAID's Clinical Genomics Program until June 2024. Dr. Lenardo currently serves as the Chief Scientific Officer for Calico Life Sciences, LLC.



Federal Laboratory Consortium for Technology Transfer

FLC Impact Award

National Academy of Inventors Fellow Application Opens Soon

Richelle Holnick, OTT

The National Academy of Inventors (NAI) selects a group of fellows each year from research universities, governmental and non-profit research institutes worldwide. The NAI is a member organization made up of over 4,000 Senior Members and Fellows spanning more than 250 institutes worldwide, including NIH. Its purpose is to encourage inventors with patents issued from the United States Patent and Trademark Office (USPTO), enhance the visibility of technology



innovation, and help to translate the inventions of its members to the benefit of society.

The NAI Fellows are extremely accomplished individuals who together hold more than 38,000 U.S. patents, have generated over 13,000 licensed technologies, and created over \$2.2 trillion in revenue based on their discoveries. You can view the current list of NIH Inventors in the NIH Tech Transfer Inventor Showcase. This past year, NAI added two more NIH inventors, Drs. Carlos Zarate, Jr. and Peter Basser.

Zarate is Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of Experimental Therapeutics and Pathophysiology Branch (ETPB) at the NIH National Institute of Mental Health (NIMH) and Clinical Professor of Psychiatry and Behavioral Sciences at The George Washington University. Zarate has had a prolific career researching the treatment of mood and anxiety disorders, most recently licensing an invention that led to the development of the first FDA-approved drug for treatment-resistant depression (Spravato®). Basser is a Senior Investigator in the Section on Quantitative Imaging and Tissue Sciences at the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). Basser is widely known for the invention, development, and clinical implementation of MR diffusion tensor imaging (DTI), diffusion tensor "streamline tractography," and other quantitative MRI methods for performing in vivo MRI histology or "microstructure imaging".



We look forward to having future nominations for fellows from the NIH pool of talent. OTT plans to submit a few of the past Phil Chen lecturers as we believe this is a wonderful recognition of NIH's inventors and the tech transfer program as a whole. More information on the NAI Fellow program is available on the NAI website. Submissions for this year's cohort of NAI fellows opens May 1st and runs until the end of July. We hope to see the number of NAI Fellows representing the NIH grow! Need some help preparing a NAI nomination of your favorite NIH inventor? Let us know how we may assist!

Tech Transfer University Reruns

Nikki Guyton, NCI

There will be no live Tech Transfer University (TTU) in 2025. Pulling off TTU each year takes an incredible amount of time and dedication from senior tech transfer experts, and unfortunately they do not have enough time to dedicate to the project this year.

However, the PowerPoint slides and recording of each session from TTU 2024 are available! You can find all of the materials in the <u>TTU 2024 Teams Channel</u>. If you have any trouble accessing them, please reach out to Nikki Guyton at darackn@mail.nih.gov.



We expect the TTU to be back up and running in 2026 and look forward to connecting with you all then!

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. Help

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:

<u>Biotech</u>

Mechanical Engineering

Chemistry

Software

April 2025

NIH Technology Transfer Community Newsletter

FLC National Meeting – Now Virtual and Free

Richelle Holnick, OTT

The Federal Laboratory Consortium's (FLC) 2025 National Meeting will now be held in a virtual format in response to the February 26th Executive Order and its impact on travel and spending. While we will surely miss the opportunity to network with our colleagues from across the nation, this is a great opportunity for even more attendees to participate.

The virtual event will kick off on May 13th, however, the event will now be spread out more than the traditional meeting, making it easier to attend sessions during the workday. Additionally, this year's National Meeting will be free to attend! This is a great opportunity for anyone in the NIH Tech Transfer community to increase their knowledge.

A few NIH tech transfer experts will be presenting at the meeting, including:

- **Michael Salgaller**, *Buying Into the Buy Side Technology Transfer Business Development from the Other Side of the Table*
- Whitney Hastings, Best Practices Working with University and Contractor Researchers Under Bayh-Dole
- **Steven Ferguson**, *Technology Transfer Beyond the Lab: Using Professional Societies to Further Develop Your Career* and *License Agreements*

You can find the new <u>schedule on the FLC website</u>, along with <u>registration information</u>.

Friendly Reports Reminders

Amanda Wingo, OTT

report, dashboard, etc. The review/ dashboard descreted here dashboard	iewing ports se remember to test any reports or rds you requested so ey can be promoted to e ETT production environment.
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ETT Receives Authority to Operate

Terry Goodell, Sapient



The Enterprise Technology Transfer (ETT) system has received the official Authority to Operate (ATO)! The purpose of the ATO process is to review a system's security protocols to ensure that it is safe for that system to process, store, or transmit NIH data. Due to the extensive size of ETT and the records it manages, it took two years to compile the ATO package and prepare it for submission. It took the assessors two additional years to review the package. During this time, ETT was able to be operational under a provisional ATO.

ETT's ATO package was comprised of 24 policy and process documents, detailing how OTT safeguards all of the data in ETT. It details all 1,100 security controls within ETT; which ensure the security and safety of the system. There are 100 artifacts included in the ATO submission package, which are made up of 100s of pages of documentation about the system. The ATO review included months of meetings where members of the ETT team and the assessor went over the entire package line by line. Each requirement was read and a response was created from the assessor



(sometimes requiring a system change or to further explain). All of this was then documented in the assessment system.

The ETT team is very pleased to have closed out the ATO process.

How NIH and FLC Are Driving T2

Whitney Hastings, NCI

Over the past year, the NIH has actively engaged with the Federal Laboratory Consortium (FLC) community and broader tech transfer ecosystem. Through events that drove networking and exposure, access to valuable resources and key marketing to drive innovation,

foster collaboration, and provide valuable resources. Here are some key highlights:

Spotlighting Federal Innovation on Capitol Hill

In Washington, D.C., the FLC partnered with the Congressional Research & Development Caucus to host Federal Innovation Driving National Progress, an event co-chaired by Rep. Bill Foster and Rep. Jim Baird. The panel featured FLC Chair Whitney Hastings, Vice Chair David Kistin, Host Agency Representative John Bittman, FLC Executive Director Paul Zielinski, and IonQ's VP of Sales Mark Solomon. Together, they underscored the vital role of federal research in driving economic growth, advancing technology, and strengthening national security.

NIH at BIO 2025

NIH will be at the Biotechnology Innovation Organization (BIO) International Convention, the largest global biotech event. Through an FLC-hosted booth, NIH will have prime visibility to connect with industry partners and showcase federal lab innovations.

Exclusive Market Intelligence for FLC Members

Through a benefit available to FLC members, NIH was able to take advantage of exclusive access to two powerful market research platforms: GlobalData and Frost and Sullivan. GlobalData is a premier intelligence provider delivering in-depth market research and data-driven insights across key industries, including medical and pharmaceutical sectors. Frost & Sullivan is a leading analysis firm offering industry expertise in healthcare, life sciences, aerospace, and defense, helping members navigate emerging trends and business strategies.

NIH Voices on The Transfer Files

NIH leaders made a significant impact in Season 1 of the FLC's Transfer Files podcast, with more guests from NIH and HHS than any other agency! Featured episodes included:

- Steve Ferguson (<u>Ep. 3</u>)
- Vladimir Popov (<u>Ep. 8</u>)
- Tara Kirby (<u>Ep. 13</u>)
- Michael Salgaller (<u>Ep. 16</u>)
- Ami Gadhia & Balki Balakrishnan (<u>Ep. 17</u>)

NIH Awardees in the 2025 FLC Awards



This year, NIH labs received two of the highly competitive

FLC Awards. NIAID won the Impact Award for Pozelimab: First FDA-Approved Drug for an NIH-Identified Ultra-Rare Genetic Disease, and Frederick National Laboratory won the Interagency Trans-Disciplinary Partnership Award for the ATOM (Accelerating Therapeutics for Opportunities in Medicine) Collaboration. Congratulations and well done!



Don't Miss World Intellectual Property Day!

Richelle Holnick, OTT

World Intellectual Property (IP) Day is April 25th. This is a global event dedicated to industry inventors, creators, and entrepreneurs and how they achieve their goals through the use of IP. To celebrate, the Licensing Executives Society (LES) is hosting a free webinar to bring people together, drive change, and inspire a more innovative future from 1pm to 2:30pm EST.

Speakers include:

- Evelyn Chen, LES President, Senior Counsel, IP Rights and Licensing, Ericsson
- Pauline Newman, Federal Circuit Judge
- **Paul Redmond Michael**, Former Chief Judge, United States Court of Appeals for the Federal Circuit
- Judge Randall Rader, Expert and Educator
- Senator Thom Tillis, United States Senator from North Carolina
- Professor Jonathan Barnett, University of Southern California Law School
- Robert Armitage, Intellectual Property Consultant

Moderator:

• Raymond Van Dyke, Attorney, Van Dyke Intellectual Property Law

For more information and registration, head over to the World IP Day website.



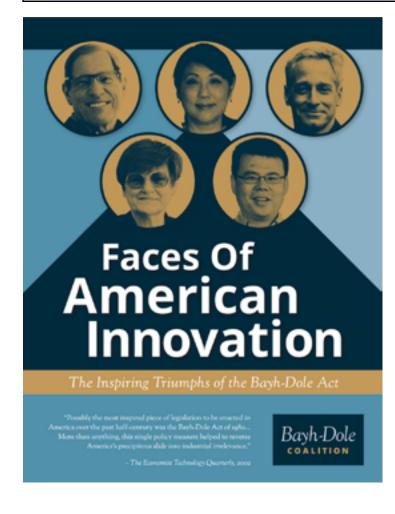


Faces of American Innovation Award Ceremony Richelle Holnick, OTT

The Bayh-Dole Coalition is hosting their third-annual "American Innovator Award" ceremony to "recognize individuals whose achievements exemplify the personal commitment, sacrifice, risk, and determination required to move a federally-funded invention from the laboratory into the marketplace where it can benefit the public."



This event is a great opportunity to meet other local technology transfer-affiliated professionals!



The event is on June 4, 2025 from 9am-11:25am ET at the Royal Sonesta on Capitol Hill. The event agenda is as follows:

- 9:00-9:30 AM: Continental breakfast
- 9:30-9:35 AM: Opening remarks

• 9:35-10:30 AM: Induction of new Bayh-Dole Coalition Hall of Fame member & 2025 Bayh-Dole Coalition American Innovator Award Ceremony

• **10:40-11:25 AM:** Panel — The Legacy and Future of the Bayh-Dole Act (moderated by Joseph P. Allen)

The morning session will be followed by a Bayh-Dole Coalition members-only afternoon session; which continues on Thursday with sessions on Capitol Hill to brief the "*Faces of American Innovation*" report and an afternoon of meeting with members of Congress to discuss Bayh-Dole Coalition priority issues.

You can register for the American Innovator Award ceremony on the <u>Bayh-Dole Coalition website</u>.

TechToons Wayne Pereanu, OTT





NO ONE NOTICED THE OFFICE CLEANING ROBOT BECAME SELF-AWARE UNTIL IT HIT 2 MILLION FOLLOWERS AND DROPPED A SUNGLASSES COLLAB





ON HIS FIRST DAY BACK AT THE OFFICE, MARTIN LEARNED TWO THINGS: I) COFFEE AND DONUTS ARE FREE IN THE BREAK ROOM 2) PARKING IS A FULL-CONTACT SPORT

Comings & Goings





arisa "Risa" Gearhart-Serna has joined NIAID **TTIPO** as a Technology Transfer and Patent Specialist. She has a PhD in Pathology from Duke University and an MBA from the University of the People. Her career in tech transfer began as a Technology Transfer Fellow at Duke's Office of Translation and Commercialization. Following this, she served as an Innovation Fellow and Technology Transfer Manager at the National Cancer Institute's Technology Transfer Center. Most recently, she was a Business Development and Marketing Associate for the Life Sciences at Stanford University's Office of Technology Licensing. Risa currently lives in New York City with her partner Daniel, along with their husky and rabbit. She is so excited to rejoin the NIH technology transfer community, the remarkable research and public service mission are unparalleled!

Bruce Goldstein has retired from his position as Director of NHLBI's Office of Technology Transfer and Development (OTTAD). Bruce started his career at NCI as a Technology Transfer Specialist in 1996 before coming to OTT in 2005 where he started as a Senior Policy Advisor and ended as the Assistant Director of Monitoring and Enforcement before accepting the NHLBI OTTAD Director position. The NIH Technology Transfer Community is grateful for all of Bruce's years of service and many accomplishments.



Mahmudul "Maha" Haque has joined NCI as a Fellow. He is a pharmaceutical scientist with expertise in immunology, inflammation research, and drug discovery. He holds a PhD in Pharmaceutical Sciences and Molecular Medicine from Washington State University. Maha has contributed to preclinical research, focusing on signal transduction, target validation, and developing in vivo models for cardiometabolic and inflammatory diseases. During his postdoctoral tenure at Merck he worked on identifying novel therapeutic targets and evaluating the efficacy of lead compounds in preclinical disease models such as gout, NASH, and obesity. Fun Fact: he is an avid musician who plays lead guitar in a band.

NIH Technology Transfer Community Newsletter

Comings & Goings



Pragnesh Mistry has left his position as a Technology Transfer and Patent Specialist at NHLBI for a new position at Skysong Innovations at Arizona State University as a Licensing and Business Development Associate. Our best wishes to Pragnesh in this new role!



Yarol A. Salata is retiring from her position as a Lead Technology Transfer and Patent Specialist at the NIAID Technology Transfer and Intellectual Property Office (TTIPO). Carol joined NIAID TTIPO in 2003 after working as a Licensing and Patent Manager in the Infectious Diseases Working Group at the NIH Office of Technology Transfer. She has also worked as a Business Specialist at the National Institute of Standards and Technology and was a biotechnology Patent Examiner at the United States Patent and Trademark Office. Before entering the intellectual property field, Carol studied positron emission tomography as a postdoctoral researcher at Brookhaven National Laboratory. She graduated with a PhD in Organic Chemistry from SUNY Stony Brook and a BA in chemistry from the University of Pennsylvania.



Peter Soukas has retired. Peter's NIH career started in August 1998 during the heady days of Cre-*lox* mice, Dr. Varmus, Maria Freire, and the sequencing of the human genome. The vast majority of Peter's career was in infectious diseases, specifically with and at NIAID. Peter was assigned NIAID/LID from the start of his career as well and continued until March 2025, when he took early retirement. Peter was lucky to work with Sabin and Lasker award-winning scientists during his tenure at NIH and complete the license agreements for MenAfriVac and its successor and the Butantan dengue vaccine, which will launch in 2025. Peter's career would not have been possible but for the support and assistance from Steve Ferguson, OTT/IDME management and NIAID/TTIPO Branch A management.

NIH Technology Transfer Community Newsletter