

### **Two NIH Inventors Named NAI Fellows**

Richelle Holnick, OTT

Two National Institutes of Health (NIH) inventors, **Drs. Carlos Zarate**, **Jr.**, and **Peter Basser** have been selected as 2024 National Academy of Inventors (NAI) Fellows. NAI Fellowship is the highest professional distinction awarded solely to inventors.

The National Academy of Inventors is a member organization comprising U.S. and international universities, and governmental and non-profit research institutes, with over 4,000 individual inventor members and Fellows spanning more than 250 institutions. The 2024 Fellows hail from 135 research universities, governmental and non-profit research institutions worldwide and their work spans across various disciplines. They are not only phenomenal researchers holding



Dr. Carlos Zarate, Jr.

prestigious honors and distinctions but are also incredible inventors who collectively hold over 5,000 issued U.S. patents and whose innovations are making significant tangible societal and economic impacts today and will well into the future.



Dr. Peter Basser

**Dr. Peter 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). Dr. 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". Dr. Basser's work has transformed how neurological disorders and diseases are diagnosed and treated, and how brain architecture, organization, structure, and anatomical "connectivity" are studied and visualized. Dr. Basser was recently an NIH Distinguished Lecturer for the 15th Annual Philip S. Chen, Jr.,

Ph.D., Distinguished Lecture on Innovation and Technology Transfer hosted by the NIH. His talk was on <u>using water migration to probe brain structure and architecture.</u>

**Dr. Carlos A. Zarate, Jr.**, 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

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Sciences at The George Washington University. Dr. Zarate formed the Experimental Therapeutics and Pathophysiology Branch at the NIMH in 2009. Dr. 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®). Dr. Zarate's Branch conducts proof-of-concept studies utilizing novel compounds and biomarkers (magnetoencephalography [MEG] and polysomnography [PSG], positron emission tomography [PET], functional magnetic resonance imaging [fMRI] and magnetic resonance spectroscopy [MRS]) to identify potentially relevant drug targets and biosignatures of treatment response. He is a member of the National Academy of Medicine and was the NIH Distinguished Lecturer for the 16th Annual Philip S. Chen, Jr., Ph.D. Distinguished Lecture on Innovation and Technology Transfer hosted by the NIH. His talk was on developing novel medications for treatment resistant depression and bipolar disorder.





## The Transfer Files Podcast Features Multiple ICs Richelle Holnick, OTT

The Federal Laboratory Consortium's podcast, *The Transfer Files*, recently featured multiple ICs in different episodes. On the episode "Marketing From All Angles", Michael Salgaller from the NCI Technology Transfer Center's Technology Analysis and Marketing Unit discussed his role as the head of TAMU and the work they do to build connections between the NCI, NIH, and industry partners to foster licensing and collaboration. Michael shares some of the marketing strategies he uses at NCI and offers tips anyone can use to improve how they communicate, whether in a lab, an office, or beyond.

On the episode "How NCATS Accelerates Drug Discovery and Development", Krishna (Balki) Balakrishnan and Ami Gadhia discuss how NCATS breaks down the barriers that stand in the way of drug discovery and development from pioneering the use of human organoids to creating innovative collaboration models with external researchers. You'll hear real-world examples of success, like the development of metarrestin, a promising cancer treatment, and a partnership with Cincinnati Children's Hospital Medical Center that's driving advancements in therapies for rare blood disorders.

You can find both episodes on the <u>FLC website</u> or Spotify, Apple, YouTube, or other popular

podcast platforms.









## **An Interview with Karen Rogers**

Richelle Holnick, OTT

Karen Rogers, Chief, Licensing Compliance and Administration Unit, had a long and unique career following a non-traditional career path. Before her retirement in November, we interviewed her to get her advice for people no matter what job series they are in.

You had a bit of an untraditional career path – starting with a civilian position in the Air Force, then moving to the Loan Repayment Office at NIH, before coming to the Royalties Administration Unit at OTT. Do you have any advice for people on navigating their career, no matter what job series they are in?



Karen Rogers

KR: I started my Federal career in ADAMHA as a Student Intern (GS-2). Then moved to NIH for a couple of years serving in administrative positions, including management of the NIDDK Advisory Board. I worked as a civilian for the US Air Force for about 10 years, including a ground launch cruise missile base in Belgium. I then moved back to the NIH where I worked with the Office of Loan Repayment and Scholarship where I helped recruit the first cadre of Undergraduate Scholarship Program students. Finally I moved to OTT as the Royalties Administrator in 2005.

My advice: do the best you can to excel at the duties you are assigned for your current position, but then always be open to accepting new challenges above your grade level.

#### What first attracted you to a career at OTT?

KR: A promotion:).

You have worked in the federal government for over 40 years, and at OTT for 19 years, what has kept you passionate for your work?

KR: I enjoy finding efficiencies. Guess that is why I'm so enthusiastic about developing standard operating procedures. I also get a lot of satisfaction from helping and mentoring staff in OTT and the ICs.

You have worn many hats at OTT, including Acting Director (twice!), Chief of the Royalties Administration Unit, and most recently Chief of the License Compliance and Administration Unit. What are you most proud of from your time in these roles? KR: Probably working with OTT staff and the NIH Technology Transfer Community navigate the reorganization back in 2015.

Under your leadership, OTT has a 90% collection rate on average from licensees. Much of that success has been attributed to the "welcome package" licensees receive. Can you give us some insight on what this package entails and why you think it has helped OTT have such a high collection rate?

KR: It's not as much what the welcome package entails, but that we reach out to the licensee's staff that are responsible for paying the royalties. Many times, the negotiator is out of the picture once the license has been executed. The high collection rate is also reflective of the hard work done by the License Compliance and Administration Unit Team.

You will have retired by the time we publish this interview. What are you looking forward to most in your retirement?

KR: Spending more time with family at our cabin in West Virginia.



Wayne Pereanu, OTT's abstract writer, has now written over 1,000 abstracts to help fill the gaps for technologies that do not have a marketing abstract on record. He has worked his way through most of the ICs over the past three years, and is now focused on NCI and their service center clients. All marketing abstracts are sent for final review to their technology transfer manager prior to publication on the NIH Technology Transfer Community website.

Steve Ferguson, OTT

The "Top 10" list of best-selling cell and gene therapies published by Genetic Engineering & Biotechnology News (GEN) is featuring not one, but four (!) products based upon license agreements for technologies originating from the NIH Intramural Research Program. Featured and ranked on the GEN list are:



**Yescarta**® (axicabtagene ciloluecuel) from Kite Pharma, a Gilead Company Yescarta is a CD19-diercted genetically modified autologous T-cell immunotherapy for B-cell lymphoma treatment based on technology from the NCI.

FDA approval: October 18, 2017



**Abecama**® (idecabtagene vicleucel) from 2seventy bio and Bristol Myers Squibb Abecama is a B-cell maturation antigen-directed genetically modified autologous T-cell immunotherapy for multiple myeloma treatment based on technology from the NCI.

FDA approval: March 26, 2021



**Tecartus**® (brexucabtagene autoleucel) from Kite, a Gilead Company Tecartus is a CD19-directed genetically modified autologous T-cell immunotherapy for mantle cell lymphoma treatment based on technology from the NCI.

FDA approval: July 24, 2020



**Luxturna**® (voretigene neprarvovec-rzyl) from Spark Therapeutics (Roche) Luxturna is an adeno-associated virus vector-based gene therapy for retinal dystrophy based on technology from the NIDCR.

FDA approval: December 18, 2017

Congratulations to our intramural investigators and their technology transfer programs for such an impressive showing!



Manufacturing Yescarta® at Kite Pharma

## **WHO Southeast Asia Regional Office Conference**

Tara Kirby, OTT

I recently had the good fortune to participate in a workshop convened in Thiruvananthapuram, India, by the WHO Southeast Asia Regional Office (WHO-SEARO). This regional workshop, held Nov 19-21, 2024, focused on capacity building in technology transfer and publichealth oriented intellectual property licensing. It was a whirlwind trip – 24 hours of travel, followed by 2 days of meetings, then 24 hours back to home – but it was also a great opportunity to learn more about the challenges and opportunities encountered by funding institutions and innovators in this region.

Delegates attended from ten countries, and although the countries they represented varied greatly in population, resources, public health priorities, and capacity to support

Regional workshop for capacity-line technology transfer and public intellectual property licensing age to increase access to health technology.

Tara Kirby Presentation

public-health R&D, their shared drive to share knowledge and seek innovative solutions made for an energetic, highly productive meeting.



Workshop Discussions

As part of this workshop, I gave three presentations. The first provided an overview of NIH's intramural technology transfer program, highlighting strategies to maximize the public health impact of our licensed technologies as well as our efforts to improve transparency & communicate impact. The second drilled down on specifics about how NIH approaches licensing for early-stage technologies.

The last focused on ways for international institutions and companies to partner with the NIH and was part of a "field trip" to the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), where workshop attendees learned about SCTIMST's impressive research programs and work to promote research and development in biomedical engineering and technology.

The highlight of this trip for me was the chance to meet and engage with so many dedicated public



WHO-SEARO Meeting Attendees

health and technology transfer professionals, and to talk about how we might work together in the future. I'm looking forward to seeing NIH and the members of WHO-SEARO continue to grow this relationship, and exploring what we can achieve together!

# Making an Impact as TTIPO Director: Profiling Surekha Vathyam

Dylan Drobish, NIAID

After serving as Acting Director following the retirement of Michael Mowatt in 2023, Surekha Vathyam, Ph.D., began her official appointment as Director of the Technology Transfer and Intellectual Property Office (TTIPO) at that National Institute of Allergy and Infectious Disease (NIAID) on August 11, 2024.

Leveraging extensive experience spanning both the public and private sectors, Surekha has outlined several key objectives for TTIPO that directly align with the NIH-Wide Strategic Plan for Fiscal Years 2021-2025.

"Addressing increasingly complex global health challenges and achieving excellence in technology transfer requires a workforce that is both collaborative and adaptable. With over half of TTIPO staff joining since the COVID-19 pandemic, I have prioritized building a culture that transcends virtual borders and empowers grassroots efforts to improve how we operate. This culture enables us to meet global health needs more effectively and deliver innovative, efficient, and impactful solutions to both internal and external stakeholders."

Within weeks of her official appointment date, Surekha set the tone for her directorship at TTIPO's first in-person full-staff retreat since before the pandemic held at NIAID's Fishers Lane facility—a monumental undertaking given both the logistics of coordination and the breadth of topics covered. For two days in September 2024, TTIPO personnel engaged in intensive discussions with leadership on key themes to promote productivity and success, including improvements in operational efficiencies and the optimization of knowledge management resources. Beyond these internal themes, the full team of TTIPO professionals collaborated to discuss modern,

multifaceted approaches to strengthening stakeholder engagement.

The success of the meeting, as envisioned by Surekha, cannot be understated. Follow-up conversations have not only aided in establishing working groups for optimizing intraoffice functions but have also helped to raise awareness of TTIPO's role in championing the development and



TTIPO Retreat

commercialization of NIAID discoveries among researchers themselves. In October 2024, TTIPO professionals attended the annual Division of Intramural Research retreat to shed light on TTIPO's pivotal role in the translation of high-profile NIAID research from bench to bedside.

In an invigorating discussion related to her high-level experience in the industrial sector, Surekha emphasized how the insights she gained during this phase of her career will inform her approach to leadership at TTIPO.



Surekha Vathyam

#### Education

PH.D. in Biochemistry Johns Hopkins University

M.Sc. in Chemistry Indian Institute of Technology in Madras

B.Sc. in Chemistry Stella Maris College

#### **Prior NIH Experience**

#### National Cancer Institute, Technology Transfer Center

 Part of leadership team overseeing technology transfer operations

#### Office of Technology Transfer

 Managed a wide range of NIH and FDA inventions and intellectual property

#### **Prior Experience**

#### **US Patent and Trademark Office**

Patent Examiner

#### **Biotech Industry**

- · Director of Research and Development
- Director of Manufacturing

"During my tenure in industrial R&D, I learned just how critical it is to understand both your strengths and weaknesses. Streamlining the conversion of science to products without sacrifices in quality or effectiveness relies not just on scientific knowledge but also on a team's ability to leverage the most promising partnerships in a way that is mutually beneficial and—above all—places human health at the forefront."



## NIH Wins GOVTECH CONNECTS Digital Health Transformation Award

Richelle Holnick, OTT

The National Institutes of Health (NIH) Enterprise Technology Transfer (ETT) system was selected as a GOVTECH CONNECTS Digital Health Transformation Award Recipient.

The Digital Health Transformation Award recognizes Federal and Military Health IT programs that are harnessing the power of emerging technologies to advance their missions and spotlight the dedicated teams behind this groundbreaking work.

The ETT system revolutionized technology transfer at NIH by automating processes and centralizing data, eliminating duplicative work, and enhancing transparency across the ICs. Unlike most cloud-based systems, ETT operates securely behind the NIH firewall, ensuring robust data protection while maintaining compliance with security and policy guidelines—a strategic decision that required significant upfront effort but provides long-term security benefits. By simplifying workflows and reducing administrative burdens, ETT enhances engagement with NIH's licensees and collaborators, allowing the TTOs to focus on fostering innovation.

NIH was formally recognized at the Digital Health Summit '24 which took place on Wednesday, October 30, 2024. This event brought together leaders and innovators from across government and industry to celebrate transformative achievements in health IT.



NIH's Tim Leahy Accepting Award



Sapient's Terry Goodell and Tim Leahy



# Book Review: Managing Technology from Laboratory to Marketplace: Cheating the Valley of Death

Steve Ferguson, OTT

Authors: Sanford L. Moskowitz and Chris Erickson

Published: Springer Nature (2024)

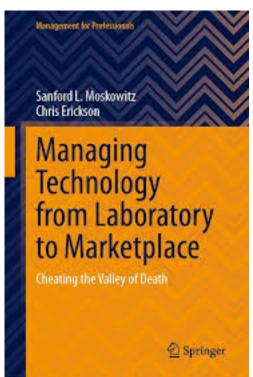
As tech transfer professionals in life sciences, we of course are painfully aware of the many difficulties and hazards that must be overcome for an innovation idea to reach the market as a product. Many of our own R&D projects (even when licensed to corporate partners) never fully make it from the laboratory to the clinic to the marketplace and thus never turn a profit or impact society in any meaningful way. These failed efforts are generally said to fallen in the "Valley of Death" – the gap between where research efforts end, and product launch begins. Attrition rates in life sciences (outside of research tools) are very high even here at NIH. While we are justifiably proud of the now nearly 50 FDA-approved drugs and vaccines to date based upon licenses from our program, our tech transfer offices though receive several hundred invention disclosures each year from our investigators.

So, have the authors really found a way for us to "cheat the valley of death"? Not exactly, of course. Instead, the book seeks to help us find a way to understand the "how & why" that permits certain research projects to success in entering the market while others falter. Using these insights, Moskowitz (a business school professor) and Erickson (a venture capitalist) try to guide researchers and tech transfer staff on how to optimize chances of successfully making the transition and having an innovation find a place in the market. Chapters of the book deal with such pragmatic issues: "Levers of Survival", "Targeting", "Competing", and "Expanding". A

particular theme here though these sections is the concept that creative marketing is key to successfully crossing the Valley of Death. Also noted in no uncertain terms is the concept that marketing high-tech products must be a primary task of the entire organization – an important concept as well to remember for tech transfer. While the book itself primarily uses case studies from the field of advanced materials (perhaps not as relevant to life sciences as one might like), it can still be useful as guide for helping us make our work truly translational from the laboratory to the marketplace and to achieve the healthcare impact we seek as an agency.



Credit: iStock/Евгений Харитонов



## **Wrapping Up ETT Enhancements for 2024**

Terry Goodell, Publicis Sapient

In 2024 ETT had dozens of enhancements, a few of the most popular have been:

- Improvements to the analytics features
- Improvements to the Form Letter Templates, including:
  - Adding a Custom Contact feature
  - Improvements to the template creation/editor
- · Adding the "Relate" functionality
- First Added IC/Division automation
- Adding an "Amendment?" toggle with automation for easier reporting
- Improvements to Grid Filter management
- Improvements to the Agreement Replication feature

After two years of use, we can understand more of the acute pain points of the everyday user and are making improvements to ETT to help smooth these points; while ensuring the critical data fields for annual metrics are kept complete and reliable.

#### In 2025, we plan to:

- Improve system performance, especially in high traffic areas.
  - We are already actively working with Inteum to optimize database performance in the areas that matter to NIH within both ETT and Analytics.
- Improve the user interface for ease of use with a focus on critical fields.
  - Add new features to modify User Defined Field tabs to highlight important fields, group related fields, and hide unused fields from view.
  - Add new features to hide out-of-date Managed List values.
  - Create additional flexibility by adding hover-over field tips and definitions.
  - Add features to set default columns across all Grids to help inexperienced users get started and explore new areas of the system.
- Re-focus on Sentinel to help with automated alerts and notifications, ultimately streamlining workflows.
- Continue to improve the ETT Dashboard Suite and tailor it to a variety of roles within the Tech Transfer community.
- Stabilize and improve the system architecture.

This is only a taste of what is to come. Keep a look out for our newsletter articles, TTCF meeting updates, and release note emails to find out what is being worked on. If you have any questions or requests, please email ETT\_Support@mail.nih.gov.



Credit: iStock/ Flashvector

# FLC Speaks to Congressional R&D Caucus on Importance of Federal Innovation

Michele Newton, NCI

In December 2024, TTC's Whitney Hastings in her role as Federal Laboratory Consortium (FLC) Chair, presented an event with the Congressional R&D Caucus, co-chaired by Rep. Bill Foster (D-

IL) and Rep. Jim Baird (R-IN). Along with FLC Executive Director, Paul Zielinski, and other panelists from industry and government, the panel spoke about how federal innovation translates to national progress and drives economic growth.

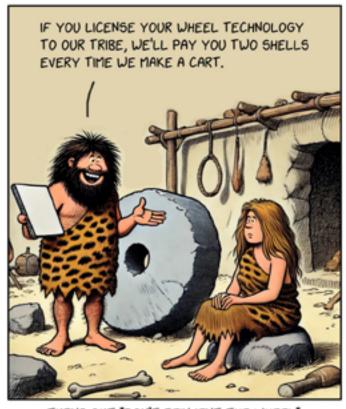


Whitney Hastings Presenting On FLC Panel

## In Memoriam - Vince Feliccia

As a community, we are sadden to hear of the passing of Vince Feliccia on January 3rd, 2025. He had retired from his position as the Branch Chief of Branch B, NIAID TTIPO in Spring 2022. Previously, he had worked for an intellectual property firm in North Carolina as a Patent Associate. Vince also worked in TTOs at the Johns Hopkins University School of Medicine and the University of Maryland Biotechnology Institute and was involved in research and development for Becton Dickinson and Company and the University of Maryland School of Medicine. Our condolences to his family.





TURNS OUT "DON'T REINVENT THE WHEEL"
WAS LESS ABOUT EFFICIENCY AND MORE
ABOUT AVOIDING A PREHISTORIC LAWSUIT.







SNOW GLOBE COMPANIES NOW HAVE TO PAY A ROYALTY EVERY TIME YOU SHAKE ONE UP

## **Comings & Goings**



**Kavita Battula** joins NIEHS with 20+ years of experience as a biotech patent attorney at law firms and in-house. Kavita has a BS in Molecular Biology from the University of Maryland and a JD from the University of Pennsylvania. She has prosecuted and litigated multiple patents in the pharmaceutical and therapeutics space and served as IP/corporate counsel at a gene-editing start-up. Kavita is an avid hiker, a certified Pilates/cycling/yoga instructor and an integrative nutrition coach. She is thrilled to have a role in NIEHS that allows her to leverage her skills and her passions to serve the community.



Sabarni Chatterjee is the new Deputy Director at OTT. He started out at OTT as a fellow in 2006 and took a short break at a DC patent law firm before returning and ultimately becoming a Senior Licensing Patenting and Manager. He moved to NCI TTC in 2015 and was promoted to Unit Supervisor in 2019. Most recently, Sabarni served as a Branch Chief at NIAID TTIPO. Throughout, he has dedicated time in multiple areas benefiting the TT community, including trans-NIH working groups, FLC projects, serving as a faculty member at the FAES Graduate School, and more.



Sabrina Hafiz has accepted a position at NIAID TTIPO as a Technology Transfer and Patent Specialist. Sabrina obtained her Bachelor of Science in Chemistry from University of Dhaka, Bangladesh and a Master of Science in Analytical Chemistry from University of North Texas. She earned her doctorate in Green Chemistry at University of Massachusetts Boston. She pursued a postdoctoral fellow at Institute for Bioscience and Biotechnology Research, where she studied antibody-antigen binding mechanism through infrared spectroscopic measurements. Sabrina joined TTIPO as a ORISE fellow in 2023. She has been helping to support the technology transfer needs of NIAID's VRC, IRF and LAD.



Roberta Hunt has joined OTT as a Monitoring & Enforcement Officer. Roberta has more than 30 years of experience in technology transfer, commercialization and innovation. She spent more than 20 years at Scripps Research where she ended her tenure as Assistant Director of Technology Development. At Scripps she managed all aspects of the licensing process from negotiating the agreements, through managing the relationship, financials, and compliance. For the last 5 years she worked at the Stevens Center for Innovation at USC, where she focused on agreement compliance including managing the external relationship, monitoring agreement and benchmark compliance, royalty distributions and terminations.



Rashmi Teja Punyapu has joined OTT as the new SharePoint Administrator. She will help migrate SharePoint sites, lists, and libraries to the SharePoint Online environment and assist with other related SharePoint tasks. Rashmi completed her Bachelor's degree in Information Technology and began working as a SharePoint Developer/Administrator in 2014. She has worked with Wells Fargo, Centers for Medicare and Medicaid Services, and many other government agencies.



Bonnie Wolfe recently joined the OTT Monitoring & Enforcement Unit as a Monitoring & Enforcement Officer. Previously, she was a Senior Technology Licensing Manager at the USC Stevens Center for Innovation where she focused on aligning patent prosecution strategy with an appropriate commercialization strategy to achieve maximum value from licensing life sciences technologies. Her background is in biology with an emphasis on molecular, cell and developmental biology.

## SAVE THE DATES

**MARCH** 

2-5

AUTM Annual Meeting

MAY

13-15

FLC National Meeting

