TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

January 2020

NIH Tech Transfer Graduate School Wins 2020 FLC Award

Advanced Studies in Technology Transfer Graduate School Program at NIH Wins 2020 FLC Award

Steven Ferguson, OTT

At the November 6, 2019 Federal Laboratory Consortium (FLC) Mid-Atlantic Region Meeting, the NIH and the Foundation for the Advanced Education in the Sciences (FAES) Graduate School at NIH received the FLC 2020 "Educational Institution and Federal Laboratory Partnership Award". The award was given for the development, in conjunction with technology transfer professionals at NIH, of a unique low-cost Advanced Studies in Technology Transfer Program to serve the needs of scientists or engineers who wish to gain expertise in patenting, licensing, collaborative agreements, and other fundamental intellectual property transactions as well as provide additional training to professionals already in the field.

The graduate school program comprises a 15-credit curriculum that may be completed in approximately two years, although students can complete the requirements at their own pace. The coursework culminates in an independent Capstone Project through which students will be required to demonstrate their knowledge of the theory and practice of technology transfer by completing a project of their design and choice at the NIH or in the regional community.

The Advanced Studies in Technology Transfer Program is open to persons with a bachelor's degree in science or engineering. Courses are offered in the evenings or on-line, making it convenient for working professionals and postgraduate fellows to seek additional training or gain expertise and experience in patenting, licensing, collaborative agreements, and other fundamental intellectual property transactions. The course instructors and guest speakers are leading practitioners in the field, including many from various federal laboratories in the FLC Mid-Atlantic Region, so students can simultaneously gain the necessary knowledge and build professional networks. It was noted at the award ceremony that it is difficult to find a laboratory in the Mid-Atlantic Region that does not have a technology transfer professional who has participated in this program as either a student, guest speaker or course faculty member. (Pictured: Lynn Johnson Langer (FAES Executive Dean), Steven Ferguson (NIH) & Connie Noguchi (FAES Dean).

In This Issue

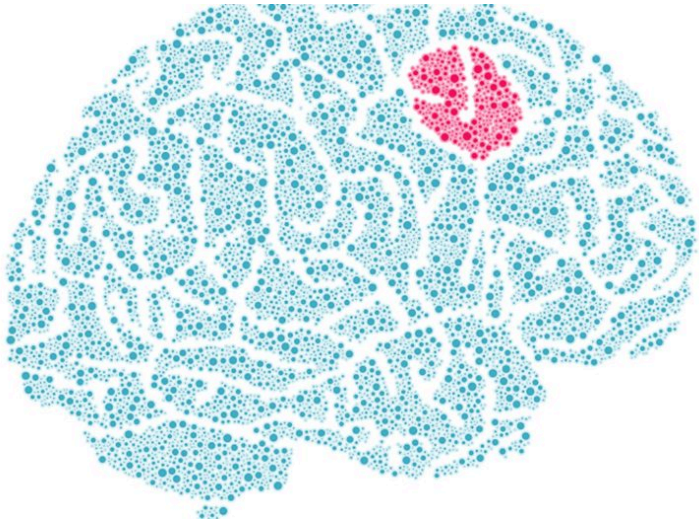
FDA and EMA grant orphan drug designation to Zotiraciclib for the treatment of glioma

Michele Newton, NCI

The U.S. Food and Drug Administration and European Medicines Agency granted orphan drug status in December to zotiraciclib for use in patients with glioma, a cancer of the brain that begins in glial cells (cells that surround and support nerve cells). Gliomas comprise about 30 percent of all brain and central nervous system tumors and 80 percent of all malignant brain tumors, and the types of gliomas include astrocytoma, ependymoma, and oligodendroglioma.

This designation is based on results from an ongoing NCI-sponsored phase 1 trial at the NIH Clinical Center. Jing Wu, M.D., Ph.D., Investigator in the Neuro-Oncology Branch, NCI, led the trial to evaluate zotiraciclib plus temozolomide for the treatment of recurrent anaplastic astrocytoma and glioblastoma.

Wu's team is now working with Mark Gilbert, M.D., to open the phase II study of zotiraciclib plus temozolomide versus temozolomide alone in recurrent high grade glioma patients through the Brain Tumor Trials Collaborative. NCI TTC's Michael Pollack, Ph.D., negotiated the clinical trial agreement with Tragara Pharmaceuticals (now Adastra Pharmaceuticals) to evaluate their agent, TG02, in the clinical trial. NCI TTC is working closely with the collaborators to facilitate the phase II clinical trial. Learn more: FDA Grants Orphan Drug Designation to Zotiraciclib for the Treatment of Glioma



Orphan Drug Designation to Zotiraciclib

NCI TTC Outreach and Matchmaking at the 2019 Texas Life Science Forum

Michele Newton, NCI

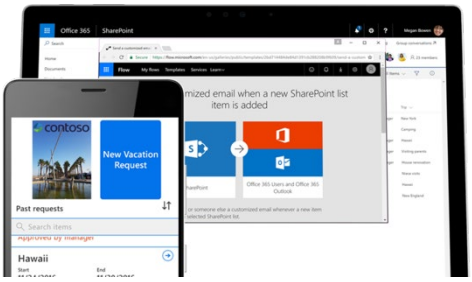
In December 2019, Joseph Conrad, Ph.D., J.D., represented NCI TTC at the **2019 TLSF** in Houston, TX. This two-day event brought together members from industry, emerging life science companies, academics, and investors. Dr. Conrad, a member of TTC's IDMU, presented "*The National Institutes of Health as a Technological Commercialization and Economic Development Partner*" at the Educational Symposium Session. He explained how companies can engage the NIH to in-license technologies to start companies, expand their product pipelines and/or collaborate with NIH PIs to develop new technology or validate an existing new technology.

He also met with 10 companies in a 1-on-1 speed dating-like event. While most were looking for funding opportunities, they were all surprised to learn that they could bring in NIH technology to expand their existing pipelines or possibly (under the right circumstances) validate their existing technology in a clinical setting. Some meetings resulted in additional introductions to VC companies looking for technologies to build companies around. Dr. Conrad also met/engaged six VCs and one state organization — all of whom had interest in working with NIH to gain access to technology and collaborative opportunities.

The IDMU is following up on several leads, including **Vitanova Biomedical** a small, San Antonio biotech company whose proprietary energy-based platform technology induces cancer-specific intracellular acidosis. The IDMU identified several techs for consideration by Vitanova. Upon review, Vitanova expressed interest in "Near-IR Light-Cleavable Antibody Conjugates and Conjugate Precursors" (E-245-2016, Dr. Martin Schnermann NCI PI). IDMU contacted Dr. Schnermann, and he was interested talking with the company. IDMU then facilitated a call between the parties, which resulted in the execution of a CDA. Currently, TTC is working with the parties to prepare a Commercial Evaluation License (CLE) for execution, as a first step in the collaborative relationship. As the relationship progresses, additional agreements may be considered as needed. TTC's Dr. Lauren Nguyen-Antczak is the Technology Transfer Manager (TTM) negotiating the license.

OTT SharePoint– A Year in Review

Terry Goodell, Sapient



Happy New Year! The OTT SharePoint Admin team is happy to share some high-level facts about our SharePoint environment, some milestones we achieved last year, and share our focus for the rest of FY 2020.

Quick Facts

Dating back to 2015, our team has been supporting the OTT SharePoint platform as well as collecting some metrics that we thought would be of interest. Here's a quick review of OTT SharePoint, by the numbers:

- IC's supported: 11
- Number of Sites, Libraries, and Pages Supported: 40 sites, 170+ pages, 5000+ documents

As the system usage grows, new users become familiar with the platform, and technology evolves – we strive to keep the system online and secure, while providing you with the necessary support you need to complete your daily technology transfer activities. We know that everyone has unique needs, special projects, and urgent deadlines, so our aim is to keep a platform that serves everyone's basic needs and do our best to work with individuals to help complete the task at hand.

Milestones

Last year, the SharePoint Admin team was tasked with migrating the existing SharePoint platform from one hosting service (ORS) to another one (CIT) while simultaneously conducting two major system upgrades. With your support (and patience), the team was able to complete this major milestone over three business days. This was no small effort and we know it impacted all of you, so here's what we accomplished:

- Migrated 120GB of content from ORS to CIT
- Upgraded from SharePoint 2010 to SharePoint 2013 to SharePoint 2016
- Triaged 65 tickets and worked with individuals to address specific questions, break fixes, and provide training
- Completed Migration and Upgrade one business day early!

We know there are still bugs (or thorns as we like to call them) and we are working hard to resolve them. Some of the bigger thorns we know you are experiencing are:

- **PDFs**: issues opening them, issues signing them – they are just problematic in general
  - We have a work around - but we are working on a permanent solution and will share that as soon as we have it
- **Alerts**: some old alerts were being sent out (in bulk) and then some specific alerts you had created were not being sent out
  - We resolved the bulk notifications that were sent out for old alerts
  - We worked with individuals to ensure that alerts you had set up, are actually getting delivered to you
- **Uploading Documents**: with the upgrade some people could not upload documents and the steps to complete it were not completely intuitive
  - We have created FAQ sheets and guides (with screen shots) to help users with this task (Migration User Guide and Common Request from the Migration)

We know there are other items that you all wish would work differently (or better) so please submit a helpdesk ticket referenced to *OD-NIH-OTT SharePoint Support*. The OTT Staff and subject matter experts are ready to support you. Please let us know if you have any questions.

Enterprise Technology Transfer System Update

Timothy Leahy, OTT

The Enterprise Technology Transfer System (ETT) software acquisition was finally completed on December 20th, when GAO dismissed the last remaining protest of the award to the Inteum Company. The ETT project team is now working closely with Inteum to complete the installation and configuration of their Minuet software as quickly as possible. Minuet is Inteum's newest software offering, featuring out-of-the-box compatibility with a wide range of browsers and devices, as well as a significant range of options for customization of user interfaces, reports, and integration with other systems. This flexibility will provide substantial benefits as we work to prepare the system for use across the entire NIH Technology Transfer community.

There are three major activities that must be completed before the system can go live:

- Installation and configuration of the Minuet system,
- data migration, and
- creation of a new law firm portal for the Minuet software.

We are currently targeting mid-June for the initial deployment of the Minuet system, with the intention of migrating OTT to the new system at that time, and then migrating the ICs to the system as quickly as possible after the initial rollout.

A critical element of both the implementation and ongoing operation of the ETT system is the creation of the Technology Transfer Users Group (TTUG). This group will act as the Product Owner for ETT, and will approve the final requirements for the implementation, and confirm that the final system meets all the approved requirements. After the system is online, the TTUG will continue to serve as the designated approver for all future requirements/system changes. A tentative list of ETT project activities is provided below (the timing and/or sequence of specific activities could shift as we progress through the implementation).

January	February	March	April	May	June
Begin analysis of legacy data sets to prepare for data migration	Set up ETT hosting environments in the cloud	Conduct practice data migrations to validate migration processes and timing	TTUG begins review of new LFP and refinement/finalization of requirements	Completion of Minuet configuration and LFP development	Final migration of NIH TechTracS data to ETT system
Investigate hosting options for the ETT system	Provide Minuet functional demo to the TTUG	TTUG continues documentation of Minuet configuration requirements	TTUG finalizes Minuet configuration requirements	TTUG performs User Acceptance Testing on ETT System	ETT system training begins for all users
Set up development environments for new Law Firm Portal (LFP) and finalize initial requirements	Begin documenting configuration requirements for the Minuet system with the TTUG				Initial go live for ETT system, OTT personnel transition to ETT system

We will be providing regular updates on the status of the implementation to the members of the TTUG so they can relay the information to their respective organizations.

NCI TTC's Invention Development and Marketing Unit (IDMU) Facilitates Connection to NINDS

Michael Salgaller, NCI

NCI's marketing unit (IDMU) efforts result in engagement with a company that could benefit from being connected to an NIH IC outside of those supported by the TTC Service Center, the IDMU routinely facilitates a connection such as this one with NINDS:

Company: AMAbiotics, a biopharmaceutical company that develops innovative microbiome-derived medicines to fight age-related diseases. Their research focuses on the Gut-Brain axis.

How IDMU Made the Connection: The IDMU delivered a webinar about partnering with the NIH to the New York Bio Association in October 2019. AMAbiotics reached out to IDMU's Dr. Michael Salgaller after the webinar.

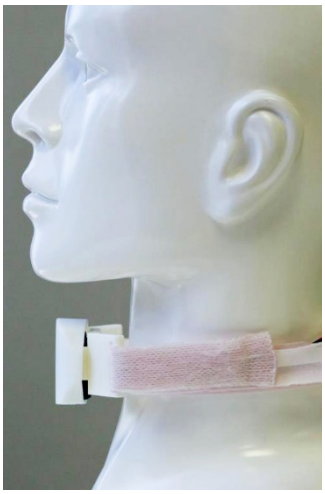
Status: Per IDMU's request, the company crafted a one-page summary with corporate and technical information, and a proposed research plan. Based on their interests, IDMU facilitated a connection with NINDS technology transfer. Subsequently, Dr. Sue Ano identified a PI and facilitated an introduction. Upon discussion in early January, though NINDS did not feel that it was quite the right fit at this time, they are open to reconnecting with AMAbiotics when the technology has further advanced.

A Safe and Efficacious Vibrotactile Stimulation Device for Stroke Patients

Aditi Sengupta Banerjee, OTT

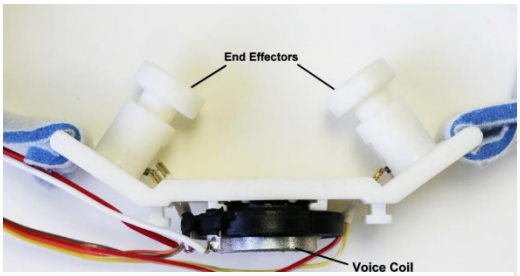
Swallowing is a rapid and precise neuromuscular activity crucial for maintaining adequate nutrition, hydration, and quality of life. Impairment of swallowing causes dysphagia that triggers the risk for choking, dehydration, malnutrition and pneumonia as food or drink enter the lungs. Dr. Christy L. Ludlow at Laryngeal and Speech Section of National Institute of Neurological Disorders and Stroke (NINDS) had significantly contributed to elucidate successful restorative management options for dysphagia during her tenure (1999-2009) at NIH. Her novel mechanism-based intervention on "Induction of volitional swallowing in chronic dysphagia post stroke" had won Clinical Center Award under NIH Bench-to-Bedside funded projects in 2005. Later she collaborated with Dr. Newlin Morgan at National Institute of Mental Health (NIMH) to develop improved vibrotactile stimulation device for volitional swallowing. The technology is protected by four NIH patents (7,606,623, 8,388,561, 8,579,839, and 8,852,074) in the US.

Dr. Christy Leslie Ludlow



The concept device can connect to Laryngostim App

Passy-Muir, Inc. had exclusively licensed this technology in 2011 and continued striving to develop a safe and efficacious dysphagia therapy device. The company has been working diligently with two engineering firms to reduce the size, to improve the certain features of the device for adjusting amplitude and frequency, and building Bluetooth wireless connectivity to the Laryngostim App. Over the past year, a few working feasibility models are designed and produced to enable clinicians to adjust and set amplitude, frequency, therapy duration, stimulation duration, and time between stimulation cycles.

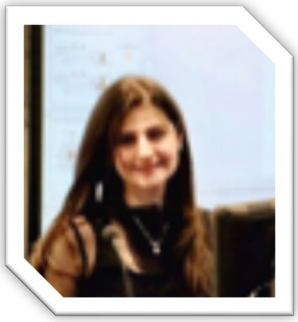


End-effectors to rest upon patient's larynx

The redesigning of the device had delayed the product development timeline, so Passy-Muir had appealed to OTT's Monitoring and Enforcement Unit (MEU) for possible extension of the license benchmarks. "The extension for their license agreement was needed when the company plans changed about assigning / sublicensing the project to a new company started by a former employee. Instead they have ended up keeping it with their re-dedicated efforts resulting in an improved design and planned re-submission to the FDA for approval", said MEU's Steve Ferguson.

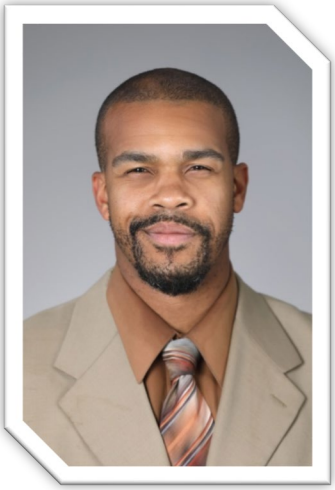
Presently, they are working with FDA regulatory attorneys to determine the medical device classification, scope of claims, and the filing requirements for the device for the marketing approval. The device holds significant potential as a therapeutic intervention in the rehabilitation of swallowing problems secondary to a stroke or following radiation for the treatment of head and neck cancer.

Comings and Goings



Hiba Alsaffar, Ph.D. joined TTC in October 2019 as a CRTA fellow. Hiba joined TTC from the Department of Molecular and Cellular Physiology of Albany Medical College Albany, NY, where she received her Ph.D. in Biomedical Sciences. Hiba is supporting various labs within NCI's Center for Cancer Research (CCR).

Anna Amar who used to be the Senior Intellectual Property Advisor, NCI has now been appointed the Director of the Division of Management Support, Office of Management Assessment (OMA), Office of the NIH Director, NIH. Anna's contributions in the TT community were invaluable. While we are sad to see Anna leave her TT role, we wish her all the very best in her new position at the OMA.



Anton Dawson, Ph.D. holds bachelor's degrees in both Chemistry and Biological Sciences from Virginia Polytechnic Institute and State University in Blacksburg, Virginia. He earned his doctorate in Pharmacology & Toxicology from Virginia Commonwealth University, in Richmond, Virginia in 2013 where he studied the role of nicotinic acetylcholine receptors in ethanol-responsive behaviors in mice. He relocated shortly afterwards to Montgomery County, Maryland to start a career in technology transfer.

Anton has technology transfer experience with federal agencies within the Department of Health and Human Services as well as the Department of Defense. Starting as a Special Volunteer at NHLBI, he moved on to National Cancer Institute contractor, Leidos Biomedical Research, Inc. in Fort Detrick, MD, to work as a technology transfer associate. He also served as a technology transfer specialist for contractors in service of the Uniformed Services University of the Health Sciences and Walter Reed National Military Medical Center at the naval base in Bethesda, Maryland.

Suna Gulay, Ph.D. joined in November 2019 as a CRTA fellow. Before joining TTC, she was a postdoc at NICHD for four years. She has a Ph.D. in Molecular Biology from the University of Maryland College Park. Suna also served as an NCI Technology Transfer Ambassador in 2019. She is supporting various labs within NCI CCR.

Melanye Johnson of HHS's NIH Branch will be leaving OGC soon. She has accepted a position as an Administrative Judge of the Trademark Trial and Appeal Board of the U.S. Patent and Trademark Office. Her last day with us will be January 31, 2020. While we all miss Melanye, this opportunity is a tremendous one and an affirmation of her skills and expertise as a trademark attorney. Melanye's contributions to OGC and to her clients are substantial.

Since joining OGC in January 2009, Melanye has served as the lead trademark attorney for OGC and as a member of the NIH Branch's intellectual property team. She has handled trademark, patent, copyright, and technology transfer litigation and counseling matters for NIH and other HHS operating and staff divisions. She played a key role in developing HHS's trademark portfolio and the successful registrations of hundreds of marks, including such notable ones as National Wear Red Day, Cancer Moonshot, 1-800-QUIT-NOW, and Health Insurance Marketplace. Melanye has also served on several OGC and HHS committees and presented on intellectual property matters at managers' conferences and attorney training meetings. Melanye's expertise, dedication, and trusted counsel were recognized with the OGC Excellence of Service Award in 2016. We wish Melanye good luck as she moves on to this new opportunity

Jenna Logsdon, Ph.D. joined TTC in October 2019 as a CRTA fellow. Jenna comes TTC from Northwestern University where she received her Ph.D. in organic chemistry and spent time in the Northwestern tech transfer office. She is supporting various labs within NCI CCR.

Theodoric Mattes, **Ph.D.** joined the CDC Team, in Branch C of NIAID's Technology Transfer and Intellectual Property Office (TTIPO) in October 2019. He completed his Ph.D. in Microbiology from the University of Georgia in 2018, where he studied the biosynthesis of coenzyme B12 in bacteria and archaea under Dr. Jorge Escalante-Semerena, Ph.D. Following graduation, he remained at UGA and joined Dr. Janet Westpheling, Ph.D.'s group, working on modifying Gram positive anaerobic organisms for fatty acid biosynthesis. In the summer of 2019, he completed an internship with the University of Georgia's Innovation Gateway, their technology transfer and business development team. His training included helping startups develop business models and perform customer discovery, including serving as a volunteer entrepreneurial lead for a prospective start-up during a session of Georgia's NSF-funded I-Corps Site program."

Jonathan Motley, Ph.D. joined TTC in October 2019 as a CRTA fellow. Jonathan recently received his Ph.D.in genetics and genomics from Duke University and completed coursework in the field of technology transfer. He is supporting various labs within NCI's CCR.

Alina Predescu, MBA joined the Office of Science Policy(OSP), Technology Transfer and Innovation Policy (TTIP) Division in October 2019 after completing the Presidential Management Fellowship at NIH. Alina joined NIH from the Johns Hopkins University Biochemistry Department. She supports OSP and TTIP projects.

Uri, Reichman, Ph.D. retired January 31st, 2020. Uri came to the NIH after 20 years of industrial career in the diagnostics industry, which followed 7 years of cancer research in Sloan Kettering Institute in New York.

Uri started at OTT on December 19, 1999, as an LPM. He became a Branch Chief of the Infectious Disease and Medical Engineering Branch (IDME Branch) at approximately the end of 2001. Served in that capacity until the end of 2008 (approximately). From 2009 served as a Senior Advisor for Licensing at OTT. In October 2015, when the reorganization occurred, moved to NHLBI as a Senior Licensing and Patenting Manager (Senior LPM).

Uri's tech transfer contribution is going to be missed by the community. Please join us in wishing Uri a very happy retired life.

Enid Wagstrom will be retiring February 29, 2020. Enid started at OTT on 13 Nov 2007. She was the receptionist for seven years, then moved to the Program Support Assistant in Monitoring & Enforcement and took on the responsibility as CRADA Coordinator.

Enid has been a key player in the M&E branch and now as a CRADA Coordinator. We wish her all the very best in her retired life.

Jennifer Wong, Ph.D. joined TTIP in August 2019 as an AAAS Science and Technology fellow. Jennifer joined TTIP from the St. Luke's Health System in Boise, ID, where she managed a biospecimen collection facility. Jennifer is supporting projects in TTIP and OSP.