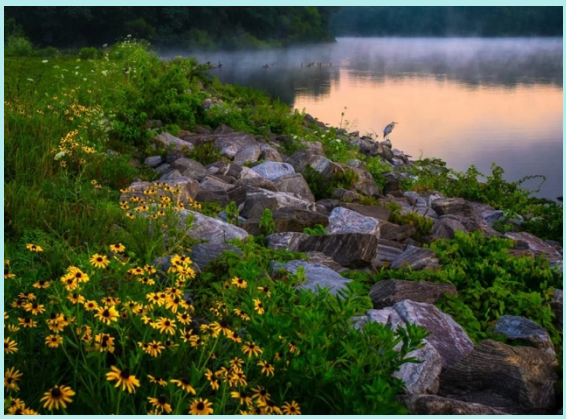
TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

July 2019

NIMH Research Results In New FDA-Approved Treatment For Depression!



In This Issue

Please forward articles and newsletter suggestions to Ajoy Prabhu (ajoy.prabhu@nih.gov)

Spravato approved by FDA for severe depressive disorder

Ketamine Research at NIMH Results in FDA-Approved Nasal Spray Spravato® for Treating Severe Depression in Treatment-Resistant Patients

Aditi Sengupta Banerjee, Marketing Unit, OTT

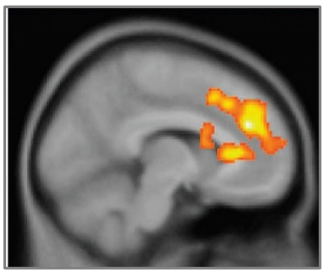
Treatment resistant depression is a growing health concern. In 2006, NIMH's psychiatrist Dr. Carlos Zarate discovered that a single intravenous dose of the "club drug" ketamine could produce significant antidepressant effects in most of the test subjects and remission in about a third of these patients. This groundbreaking invention paved the way for the development of Spravato, the esketamine (s-enantiomer of ketamine) based nasal spray, by Janssen Research & Development LLC of Johnson & Johnson. Dr. Husseini Manji, global head of Janssen's neuroscience division and former NIMH scientist, showed esketamine has rapid and robust antidepressant effects at a low intermittent dosage that can be emitted by a nasal spray.

Dr. Zarate is discussing depressive symptoms

Esketamine will be marketed under the trade name, Spravato®.

Ms. Jennifer Wong at the NIMH Technology Transfer Office played a key role in the process of commercializing Dr. Zarate's groundbreaking discovery by: (1) exchanging confidential information between NIMH and Janssen through one broad Confidential Disclosure Agreement (CDA); (2) managing the Inter-Institutional Agreement (IIA) to simplify administration of rights jointly owned with collaborators; and (3) building a strong, well-rounded patent portfolio. The technology is protected by three NIH patents (8,785,500, 9,539,220 and 9,592,207) in the US with foreign patents pending in Japan, Korea, Hong Kong and Israel. "Since the inception of NIMH's technology transfer office approximately 33 years ago, its patent on intranasal ketamine as a treatment for depression is the first technology from NIMH's patent portfolio that has resulted in an FDA approved drug", said Ms. Wong. Spravato has received FDA approval with "Fast Track" and "Breakthrough Therapy" designations as a novel treatment for severe depressive disorder on March 5, 2019.

Over 300 million people worldwide are suffering from chronic depression. It is the leading cause of disability in US and can be fatal as suicide kills more than 45,000 Americans annually. Previously marketed serotonin reuptake inhibitors were slow and mostly nonbeneficial with serious side-effects. 30-40% of the patient population also showed resistance to those antidepressants. Spravato shows promising anti-anhedonic effect within 40 minutes that sustained up to 14 days and so can be immensely useful in acute crisis like imminent risk of suicide. Further research is still needed to elucidate the involved genes, biomarkers and molecular mechanism.



PET scan superimposed on anatomical MRI revealed ketamine rapidly restored depressive disorder by boosting activity in the dorsal anterior cingulate cortex (yellow).

Ask Steve – Q&A

What are the 10 Rules of Technology Transfer? (Continued)

Steven Ferguson, OTT

But wait there's still more? Consider now the remaining "10 Rules of Technology Transfer" from R&D Magazine that we first examined in the previous newsletter:

Rule 6 -- Test The Market -- Feedback from a prospective user is invaluable in deciding whether to proceed or continue with a patent filing for a new technology. However, often this gets overlooked in our rush to meet a filing deadline to "protect" the technology. But what if the likely user is not even interested? For example, I-Corps programs at NIH and other federal labs requires participants to do at least 100 interviews with potential customers prior to proceeding with commercialization. Marketing groups at the ICs and OTT can assist in helping you get this type of feedback.

Rule 7 – When You Commit, Commit – It's very important to have all the components in an R&D organization on the same page in order to successfully transfer a technology for commercialization. This means that when the deal is finally signed, resources at the institution need to be aligned and available to support the project in the time frame that will provide for its successful implementation. For NIH, this means that licensing, collaborations, clinical trials or SBIR efforts must not have conflicting goals for a given technology. Consensus and coordination thus are important to tech transfer success.

Rule 8 – Don't Trivialize The Legal Aspects -- Though the goal of the tech transfer programs is collaboration and commercialization to improve public, this all rests on a well-established legal underpinning. With patent law, contract law, procurement law, regulatory law, administrative law – there is certainly plenty of guidance around to help us. The legal tools are important to support and move projects along in development in a proper manner not only at NIH but also at our partners.

Rule 9 – Understand The System -- To be an excellent tech transfer representative of NIH tech transfer you need to know the product (NIH) as well as the systems that support our overall tech transfer program. If you don't know the "rules of the road" and how to "navigate NIH", how can you expect potential partners to do so? Take the time to learn the key elements of NIH processes or systems so you can help speed up negotiations, transactions, collaborations and the like to help really make a difference in public health.

Rule 10 – Use Every Resource – Technology transfer remains strong and growing at NIH because our potential partners can connect to a surprisingly wide variety of resources across of number of IC programs. Indeed, it is hard for a potential partner NOT to find AT LEAST something relevant to their business here at NIH. Not interested in CRADA today? Well instead then how about a research tool, SBIR funding, contracting opportunity, access to a repository, clinical trials, drug or vaccine candidate and the list goes on. Repeat business, repeat customers and long-term relationship building is essential to tech transfer successes and our extensive and varied resources are key.

Well, that's the "10 Rules" -- what do you think?

Have your own licensing question or a discussion topic for an upcoming Licensing Forum session?
Just ask Steve!

OTT impacts on NIH and CDC Technology Marketing

Aditi Sengupta Banerjee and Ajoy Prabhu, Marketing Unit, OTT

The Marketing Unit (MU) at OTT promotes NIH and CDC inventions to the private sector. After the decentralization of technology transfer activities in 2015, the MU started to concentrate on the OTT website by featuring recent "hot" inventions and showcasing NIH and CDC resources that would help in commercialization of discoveries. Efforts are also made through technology showcases, marketing campaigns, technology scouting and global ideas exchange hub. As a result, several potential licensees and CRADA partners are being connected to the technology transfer managers in different Institutes and Centers (ICs) via the Marketing Unit.

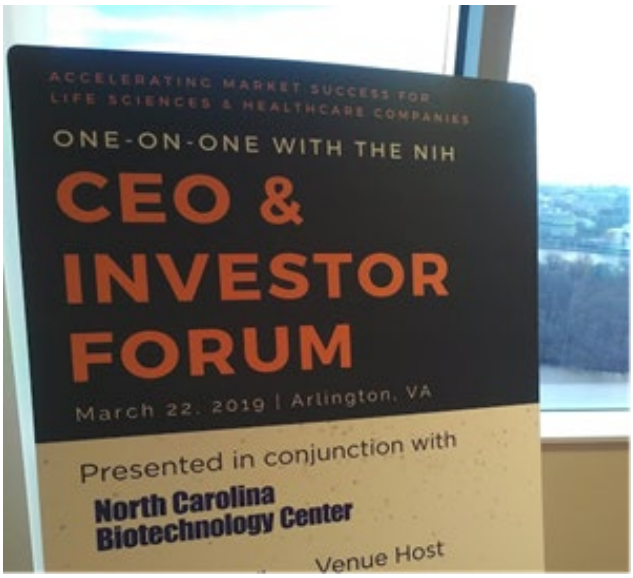
Over the last few months, we have been assisting National Heart, Lung, and Blood Institute's (NHLBI) Office of Technology Transfer and Development on writing a couple of their marketing abstracts and conducting market research for their technologies. We have also evaluated National Institute of Dental and Craniofacial Research (NIDCR) technologies for targeted marketing by examining competitive advantages, commercial applications and stage of development. We identified a motivated business start-up, who is now closely working with NIDCR's Office of Technology Transfer and Innovation Access (OTTIA) on a probable exclusive license agreement. Our team developed strategic tools for targeted marketing of NIH technologies by producing non-confidential marketing materials and executive summaries. Similarly, through OniX, a technology broker, we have been able to identify a potential CRADA partner for NIAID.

In addition to the above ICs, we are currently working with NIDCD, NIEHS, NICHD and NIAID in their marketing projects. We invite other ICs as well to reach us at OTT's MU if you have any need to supplement your marketing activities.

Tasks Undertaken	TOTAL
Write Abstracts	4
Conduct market Research on specific technology or platform technologies	14
Find Companies for a specific technology	2
Coordinate IC-company interaction for companies looking to license/partner with NIH-CDC	2
Help technology brokers "push" NIH-CDC technologies to potential licensees	9

NCI Technology Transfer Center (TTC) Organizes First Ever Mid-Atlantic Venture Association (MAVA) CEO & Biotech Forum Featuring NIH Tech Transfer

Michele Newton, NCI



The NCI TTC's Invention Development and Marketing Unit (IDMU) worked with three of the region's major economic development entities and trade associations – MAVA, VABio (Virginia), and NCBio (North Carolina) – to put on the first CEO & Biotech Forum featuring NIH Tech Transfer Offices. It was held at Sands Capital Ventures in McLean, VA on March 22.

This was one of several events during the year in which IDMU's professional network was leveraged to benefit tech transfer across the NIH. IDMU's Michael Salgaller moderated and presented at the event. Afterwards, he had one-on-one meetings with several potential CRADA partners and licensees, such as:

- Camras Vision – a Virginia optical device company with technology relevant to NEI
- Dualogics – a North Carolina company with a bispecific antibody engineering platform
- Origent Data Sciences – a Virginia company focused on predictive data analytics
- Sands Capital Ventures – a venture capital company investing in early-stage technology start-ups

Pictured at left, other presenters included:

- **Rick Williams**, NIAID Technology Transfer and Intellectual Property Office (TTIPO)
- **Sue Ano**, NINDS TT
- **Misha Shmilovich**, NHLBI TT
- **Vlado Knezevic**, NIDDK Technology Advancement Office

NCI TTC organizes first ever MAVA Forum

NCI TTC's IDMU Organizes 2019 Hagerstown Technology Showcase

Michele Newton, NCI

NCI TTC IDMU worked with the Fort Detrick Alliance to organize the Hagerstown Technology Showcase on March 21 held at Hagerstown Community College. The event highlighted how to work with the NIH to access licensable technologies and collaborative opportunities – as well as funding programs through the NIH Small Business Innovation Research (SBIR) Program. IDMU's Joe Conrad moderated and presented at the event. Other presenters included:

- **Haiqing Li**, NIAID Technology Transfer and Intellectual Property Office (TTIPO)
- **Ajoy Prabhu**, NIH OTT
- **Misha Shmilovich**, NIHLBI TT
- **Mike Pieck**, NIHLBI SBIR
- **Ashim Subdee**, SBIR NCI
- **Adam Sorkin**, Entrepreneur in Residence, NIAID SBIR
- **Joseph Lyndon**, NIA, Division of Geriatrics and Clinical Gerontology (DGCG)

The event was well-received. Several attendees remarked that they made valuable connections and plan to follow-up.

Pictured below- Showcase Presentation by Ajoy Prabhu, OTT

Closure of 6011 Executive Blvd

Building Closed, but OTT Still Open for Business!

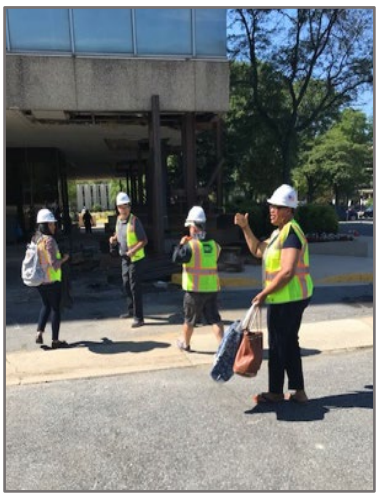
Ajoy Prabhu and Karen Rogers, OTT

On April 18, 2019, OTT staff and others using 6011 Executive Boulevard building were informed that some of the steel columns supporting the facility will require repairs. The cause appears to be the combination of a shallow water table and the long-term exposure to deicing salt. Montgomery County officials informed the owners that the building would need to be vacated until repairs were completed.

Despite some inconveniences, OTT staff quickly transitioned to telework status and are making good use of teleconferencing and Skype. Staff continue to provide timely service to the NIH Technology Transfer Community. Limited staff donned hard hats, safety glasses and vests one day and were allowed back into the building briefly to retrieve critical work items. Critical mail service has been diverted and is being managed by OTT staff from the OIR Administrative Office. FAES classes were also relocated until the repairs can be completed.

We would like to thank you for your support during this time and the NCI Technology Transfer Office staff for arranging conference rooms and printing documents for on-site meetings as needed.

At present, the OD Executive Office advises that the building re-occupancy date is set at around mid-August 2019. Till then, if anyone within the TT community needs to get a hold of an OTT staff member, it might be best to contact them via email and/or Skype.



OTT staff visiting Executive Boulevard office

Tips from the Royalties Administration Unit – Licensed Material Shipment Information

Simmone Henry, OTT

You've worked hard to negotiate that new agreement and the licensee needs the licensed materials quickly. By providing all related shipping information, you can help speed up the process. The Royalties Administration Unit (RAU) is receiving new license agreements that do not contain the material description and materials contact/shipping information. It's important that the Licensing and Patent Manager include this information prior to routing new license agreements to RAU staff.

It's RAU's role to authorize the shipment of materials according to the terms of the agreement. Generally, materials are shipped upon execution of the license agreement and when the initial royalty payments of the agreement are received. As the negotiator of the agreement, you play a role in making sure that the material is available, and RAU has the information needed to authorize the shipment. This includes entering the materials description and shipping information in TechTracS before routing to RAU.

Why is this critical?

Shipment to the licensee will be significantly delayed if RAU doesn't know what materials need to be sent, where the materials need to be sent and who needs to ship the materials.

Is the licensed material available?

Before a license is executed the Licensing and Paten Manager must check with the repository or inventor to make sure the materials and quantity are available.

Where should I put the materials information in the License Agreement?

- Definition Section of the License Agreement

> "**Materials**" means the following biological materials including all progeny, subclones, and unmodified derivatives thereof:
>
> _____, as described in
>
> _____
>
> _____ and developed in the laboratory of _____ at the **IC**.

Where should I put the shipping information in the License Agreement?

- Appendix A (Let's keep this as the standard)

What Information should be included in Appendix A?

- Licensee's Shipping Contact (information or questions regarding shipping should be directed to the Licensee's Shipping Contact)
- Licensee's Shipping Contact:
  - Name & Title
  - Phone & Email
- Shipping Address
  - Company Name, Address & Department
  - Shipping Carrier

APPENDIX A – SHIPPING INFORMATION

The Licensee's Shipping Contact: information or questions regarding shipping should be directed to the Licensee's Shipping Contact at:

_____ _____
Shipping Contact's Name Title

Phone: O_____ Fax: O_____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____
Company Name & Department

Address:

_____

_____

_____

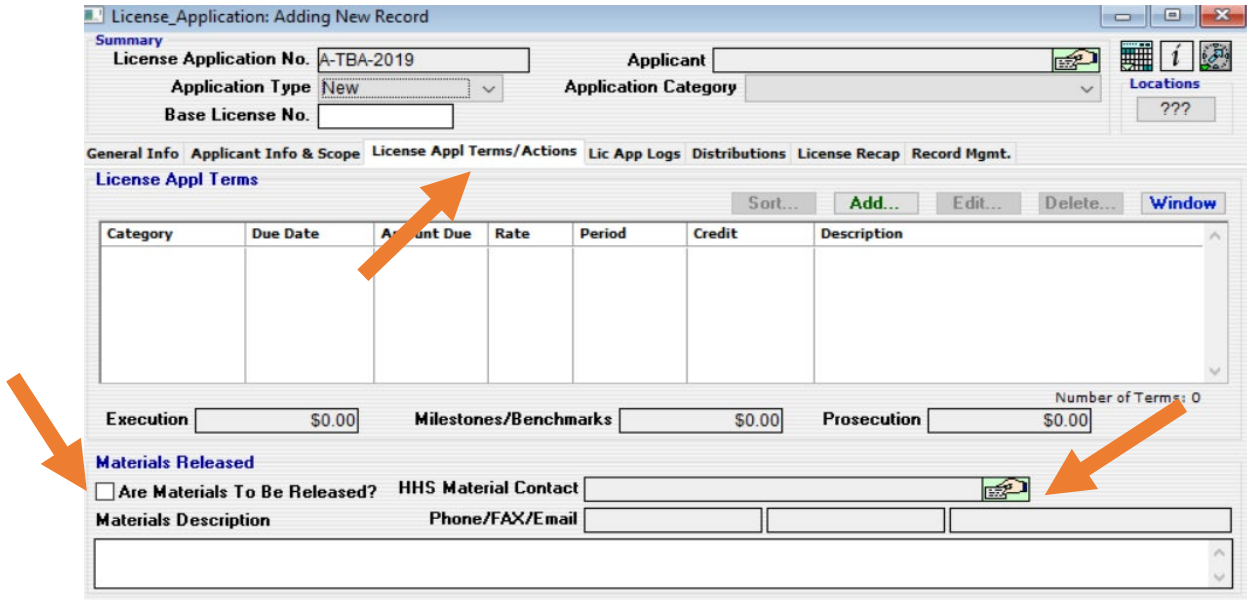
_____

The Licensee's shipping carrier and account number to be used for shipping purposes:

_____

Where do I enter the materials shipment information in TechTracS?

- License Application Record
  - License **Appl Terms/Actions** Section
  - Check the **Are Materials To Be Released** box
  - Enter **HHS Material Contact** (lab contact that will ship materials to licensee)
    - **Phone/Fax/Email**, and **Materials Description**



Do I still need to provide this information if it's an outside organization (such as Kerafast, Inc.) is shipping the materials?

- Yes! The RAU staff will notify the licensee when to order the materials and authorize the outside organization to ship.

Are there exceptions and special needs?

Absolutely! Please send an email to RAU staff when materials are sent prior to routing to RAU or if special instructions are needed.

Comings and Goings

In March 2019, TTC Frederick welcomed a new fellow, **Rebecca Erwin-Cohen**, Ph.D. In December 2016, Erwin-Cohen received her Ph.D. in Epidemiology from Walden University, specializing in infectious diseases. Rebecca comes to the TTC from a research postdoctoral fellowship at the NCI in Dr. Howard Young's lab. During that time, Rebecca also served in the Technology Transfer Ambassador Program. Her research background includes cytokine signaling, vaccine development, extensive work with pre-clinical animal models, and autoimmune/autoinflammatory diseases.

Abritee Dhal, Ph.D., a TTC fellow since June 2017, accepted a position as a permanent technology transfer manager (TTM) in January 2019. Since joining TTC, Dhal has actively participated in several TT working groups and is currently a team lead and mentor for the Technology Transfer Ambassador's Program (TAPP). As a TTM, she supports CCR laboratories and PIs.

In January 2019, **Taryn Dick**, Ph.D. accepted a permanent TTM position based in TTC's Frederick office. During her TTC fellowship that began in July 2017, she split her time between TTC's Invention Development and Marketing Unit (IDMU) and docket work for Frederick investigators. Currently she is a team lead and mentor for TTAP and continues to support NCI Frederick-based PIs and laboratories.