NIH TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

January 2022

Taking The Reins: Sharon Soucek Becomes New TDTC Chair

Richelle Holnick, OTT

Meet Sharon Soucek, the new Technology Development and Transfer Committee (TDTC) Chair! You might already know her as the Director of the National Institute of Environmental Health Sciences (NIEHS) Office of Technology Transfer, where she has been since 2019. I sat down virtually with Sharon so that we could all get to know her a bit better.

Sharon's been destined for a career like this her whole life – her first exposure to science in a business setting was when she showed up to her parents 'take your kids to work day' with a handful of caterpillars stuffed into her shirt pocket! From there she took on a bit of a more formal path – she worked many internships in undergrad, with her favorite being a small biotech company working on developing new antibiotics. From there she joined a biochemistry PhD program at Emory University with the intention of moving into industry. However, that plan changed when she ended up joining a basic science lab because of the interesting projects and an engaging mentor. Towards the end of her program, she was sitting in a journal seminar when someone mentioned that Emory's Office of Technology Transfer had a formal internship program.

Sharon got the internship and fell in love with technology transfer (who wouldn't?). As she wrapped up her dissertation, she got a call from the CDC to join their technology transfer office. At the CDC Sharon says, "I had some fantastic mentors that taught me the ins and outs of technology transfer in the federal government, and I got a crash course in infectious diseases."

Sharon joined the NIH technology transfer community in 2019. She was perusing USA jobs and saw an opening in North Carolina. She and her husband had previously discussed moving to North Carolina, so she decided to apply. Sharon recalls that she was at a new mom meetup with her 3-month-old son when she received a call from the NIEHS. It turned out to be a former colleague from the department of biochemistry at Emory offering her an interview. She of course ended up getting the job and joined the NIEHS Office of Technology Transfer as the director. Sharon is thrilled to find a career that lets her do science without worrying about failed experiments and publication counts!

Sharon really enjoys NIH's mission of helping people lead healthier lives and finds it incredibly gratifying. When asked about her favorite part about working here, she states "I enjoy working

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with a community of experts, from the scientists we support to my colleagues that are wonderful problem solvers. I especially like working at NIEHS because of the diverse science that's conducted. I'm excited when an invention hits my desk because it's often in an area I haven't researched before. We're also a growing office and it's satisfying to steer this ship with a talented team!"

As a new TDC, Sharon had many questions and everyone in the technology transfer community were quick to offer advice. When Sue Ano and Cecilia Pazman called on her to volunteer as the TDTC chair, she couldn't say no! Looking ahead at this coming year, Sharon says that she would love to make the TDTC meetings more interactive. She is planning on assembling panels comprised of people from different ICs and Agencies to discuss best practices in invention review, training, etc. She wants everyone, junior or senior, to have an opportunity to work across the community and will be on the lookout for projects to advertise. Sharon says, "I want members to know that my virtual zoom door is open so if you have a topic suggestion, successful initiative you want to share with the community, or would like to learn something new- I want to hear it!"

Lastly, it wouldn't be fun if I did not ask Sharon what she likes to do in her free time. She says that she has a deep appreciation for nature so if the sun is shining, you'll find her outside. (What a good thing she works on the NIEHS campus with that beautiful trail and pond!) Her personal goal is to grow as much fresh food as possible on their city sized lot. There's always something edible growing in their garden, and they recently got chickens!

Sharon's chicken coop

Painless Materials!

Melborne Moon, OTT

As a Royalties Coordinator, part of our job is to authorize and oversee the successful transfer of materials. Generally, this is a rather simple, straightforward process. However, when information is missing from the license or the language regarding materials is unclear, it can slow down the process.

Authorizing the Release

When a payment is received in Royalties, the Royalties Coordinator checks to see whether the payment triggers a materials release. If a release has been triggered, the Royalties Coordinator sends an email to the lab authorizing the release and requesting that the lab ship/supply the materials to the licensee.

When problems arise, it is generally because the Royalties Coordinator has not been supplied with the necessary information to create this email.

The language used for this email is auto-generated straight from TechTracS using the text that has been entered in the "Materials Information" field. The following information needs to be entered into this field:

- A detailed description of the materials
- The HHS Materials Contact Information
- The Licensee's Materials Contact Information
- Mailing address to which materials should be shipped
- The Licensee's Shipping Account Information

The first two items on this list should be entered into TechTracS by the Licensing and Patenting Manager before the license comes to us in Royalties for processing (see below).

The remaining three items are entered into the "Materials Information" field by the Royalties Coordinator using information found in the license in Appendix A: Shipping Information (see next page).

Missing Information

When either some or all of this information is missing when the license rolls over to us in Royalties, the Coordinator will need to reach out to the Licensing and Patenting Manager to request the missing information.

Generally, there is either one or two reasons why the information was omitted. Either the company already has the materials (in which case this needs to be made clear in the agreement), or the materials are being supplied by a 3rd party repository and the Licensing and the Patenting Manager may not think the information is necessary. In the latter case, while it is true that some details may not be necessary, the Royalty Coordinator still needs to send the authorization email

to a materials contact at the 3rd party repository, letting them know the licensee has met the requirements and they can provide the materials.

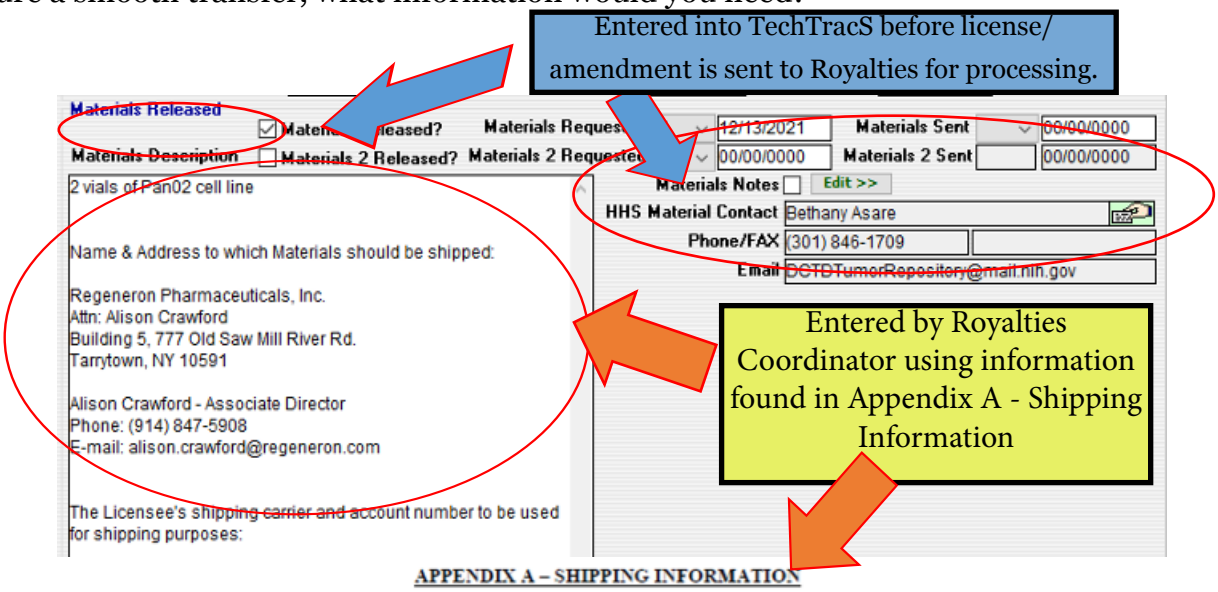
On occasion, I've also seen materials information omitted when the materials involve software. But, again, in this situation, the Royalties Coordinator will still need to send an email authorizing the release of the software. However, in this particular case, we would generally not need a shipping account or mailing address.

Materials Checklist

Before sending a Materials Agreement to Royalties, have you…

- Checked with the repository or inventor to make sure the material is available?
- Entered the HHS Material Contact in TechTracS?
- Entered a materials description in TechTracS?
- Checked off the "Materials Released" box in TechTracS?
- Included a fully filled out Appendix A – Shipping Information in the license?
- Made sure any additional information that would be helpful to the Royalties Coordinator is included in the license. For example: If any additional payment must be made by the licensee directly to a repository to obtain the materials.

In closing, we would ask that you put yourself in the Royalties Coordinator's shoes. If you needed to send an email authorizing the release and providing all the information needed to ensure a smooth transfer, what information would you need?



APPENDIX A – SHIPPING INFORMATION

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

Alison Crawford (Shipping Contact's Name) Senior Staff Scientist (Title)

Phone: (914) 847-5908 Fax: () E-mail: alison.crawford@regeneron.com

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

Regeneron Pharmaceuticals, Inc.
Company Name & Department

TTO Mentor Programs Match with NIH

Richelle Holnick, OTT

What do Boise, Idaho and Tuskegee, Alabama and Dhakka, Bangladesh all have in common? Each had research institutions with tech transfer office (TTO) staff matched with NIH for mentorship over the past year or so!

The TTOs themselves were quite varied in nature – from a public university (Boise State University) to a private one (Tuskegee University) to an overseas agency (International Centre for Diarrhoeal Disease Research). Though quite diverse in terms of both geography and research programs, each had the common thread of working with OTT's Steve Ferguson to tackle challenges and grow opportunities for their individual tech transfer programs during the past year.

The mentorship programs were organized through two organizations – the Association of University Technology Managers (AUTM) for the US-based institutions and Bio Ventures For Global Health (BVGH) for the international ones. The chair for the AUTM program even has an NIH T2 connection with Kim Griffith, formerly of NCI TTC and now at Northwestern University.

For the AUTM program, mentees could include students looking to move into technology commercialization, early-stage tech transfer professionals looking for career guidance, and even late-stage professionals looking to become directors. A new focus though has been minority-serving institutions looking to build tech transfer offices, create IP policies, or grow their small offices. The BVGH program arose as an outgrowth of their Virtual IP Training Workshop conducted with WIPO to train researchers and others in Africa on IP topics. OD's Mark Rohrbaugh served as one of the BVGH expert lecturers in that training.

Have you made your New Year's Tech Transfer Resolution yet? If not, consider then becoming a T2 mentor in 2022!

RAU Good-To-Knows

Simmone Henry, OTT

As we begin the new year, the Royalties Admininstration Unit (RAU) is committed to enhancing our communication between the ICs so that our administration accurately reflects your executed license agreements.

Here are some key reminders:

How do I find out if a Licensee is compliant?

Please send an email to the RAU addressed to Karen Rogers and copy Kevin Doran for clearance before executing a new license agreement or license amendment. At the same time, you can also send the request to Charlene Maddox, who will check for Monitoring and Enforcement compliance. For licensees to be in good standing, they should not have any outstanding royalties that exceed $100, and all reports have been submitted. This is a very successful way for the NIH and CDC to collect outstanding royalties and reports, so we appreciate your support.

When do RDFs need to be submitted?

ICs must submit a Royalty Distribution Form (RDF) for all new licenses and amendments, except for NIH Lead Inter-Institutional Agreements (IIAs).

Why is it important to know the availability status of materials when negotiating BMLAs?

Please determine and convey to your licensee the availability status of materials prior to executing Biological Materials License Agreements (BMLAs) to eliminate conflicts when materials are delayed for a significant amount of time (example 6 months). There are many instances in which licensees are unaware materials are not available at the time of paying royalties and that potentially leads to amending and/or terminating the license agreement.

Can we structure standard MAR language to eliminate the confusion on MARs due dates?

RAU receives license agreements with changes to the Minimum Annual Royalty (MAR) terms in the royalties section of the license that cause conflict in determining the due dates. The language below is preferred, but if you need to amend, please reach out to our team and we will be glad to help review the language to ensure we can administer the terms you negotiate.

Due Date January 1

(b) The first minmum annual royalty of two thousand dollars ($2,000) is due within sixty (60) days of the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1;

(c) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year; and

Due Date Effective Date of Agreement

(b) The first minimum annual royalty of five thousand dollars ($5,000) is due within ninety (90) days of the effective date of this Agreement;

(c) Subsequent minimum annual royalty payments of five thousand dollars ($5,000) are due and payable on each anniversary of the effective date of this Agreement; and

Creditable MARs

(c) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year;

Why do we need the TAX ID number included on the license agreement?

RAU can only refer U.S. based licensees to PHS Debt Collection if we have a tax ID number. It is much easier to get this number when they need the license than when they are in default.

Data Sharing Parody Song

As a fan of both technology transfer and scientific research data sharing, OD's JP Kim made the following data sharing songs. The first is a parody of Day-O titled Da-ta: The Scientific Data Sharing Song Parody and the second is a parody of Jump In The Line titled Share, Share, Share Your Data.

Have your own tech transfer parody song or music? Please share it with us!

Off Campus: Centers for Disease Control and Prevention

Richelle Holnick, OTT

The Centers for Disease Control and Prevention (CDC) is one of NIH's "sister" agencies under HHS. Their mission is focused on health promotion, prevention, and preparedness. The CDC is made up of Centers, Institutes, and Offices and is based out of Atlanta, Georgia, but has a variety of locations across the US. The CDC might have the most variety in their locations of all of HHS – including places such as Alaska and Puerto Rico. And of course Maryland because the NIAID TTIPO serves as the CDC's patenting and licensing service center!

The CDC was founded on July 1, 1946, as the Communicable Disease Center (also abbreviated CDC) under the Public Health Service. It was founded to prevent malaria from spreading, so Atlanta was chosen as the South had the largest mosquito population and malaria problem in the US at the time. At the time of its founding, the CDC worked out of one floor in a small building. A year later, the CDC acquired 15 acres of land from Emory University on Clifton Road. By 1951 malaria was considered eliminated from the US and the CDC began to expand and tackle other communicable diseases.

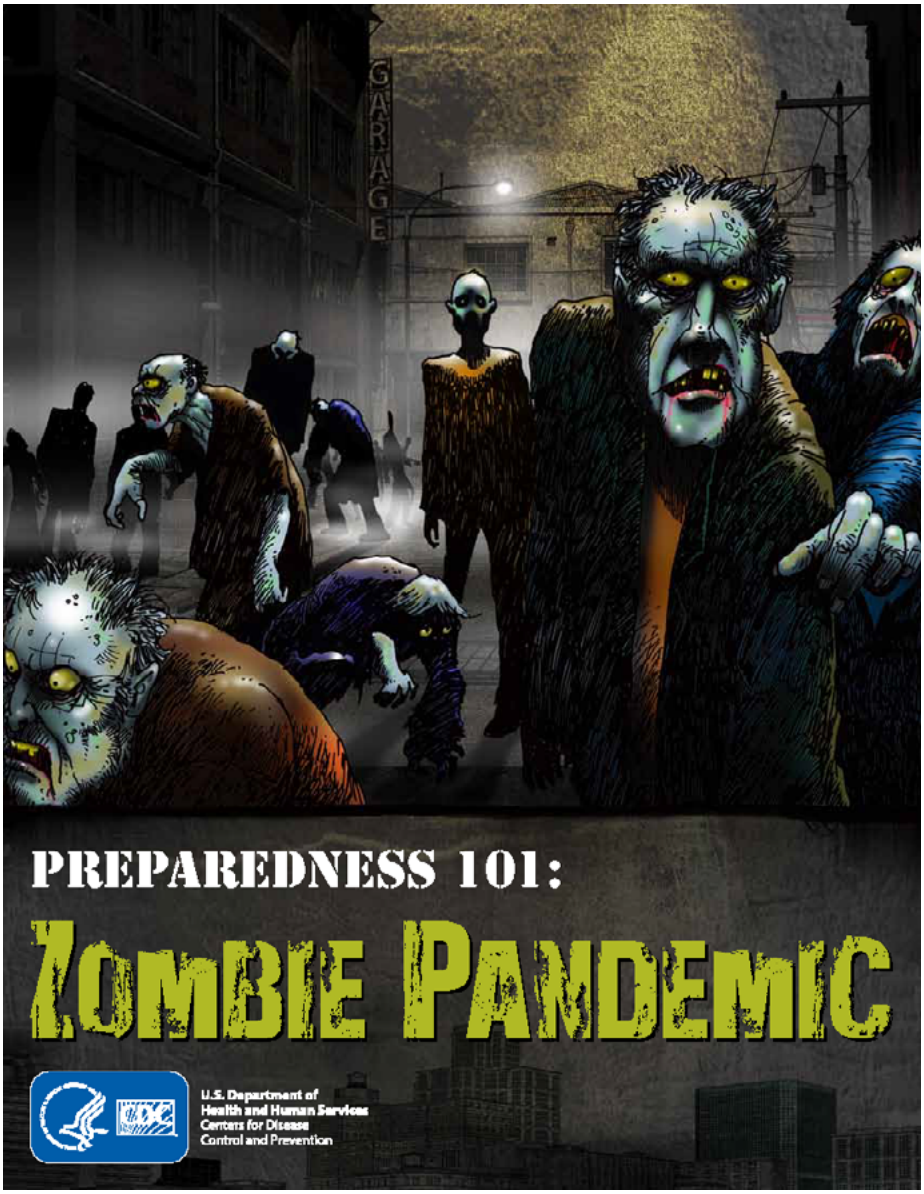
The National Institute for Occupational Safety and Health has their primary locations in Cincinnati, Ohio and Morgantown, West Virginia. The National Center for Health Statistics is primarily located in Hyattsville, Maryland, but also has a branch in Research Triangle Park in North Carolina (where you might remember from a previous Off Campus article that NIEHS has their primary location). The National Center for Emerging and Zoonotic Infectious Diseases' Division of Vector-Borne Diseases is based in Fort Collins, Colorado and has a branch in San Juan, Puerto Rico. They also have an Arctic Investigations Program based in Anchorage, Alaska.

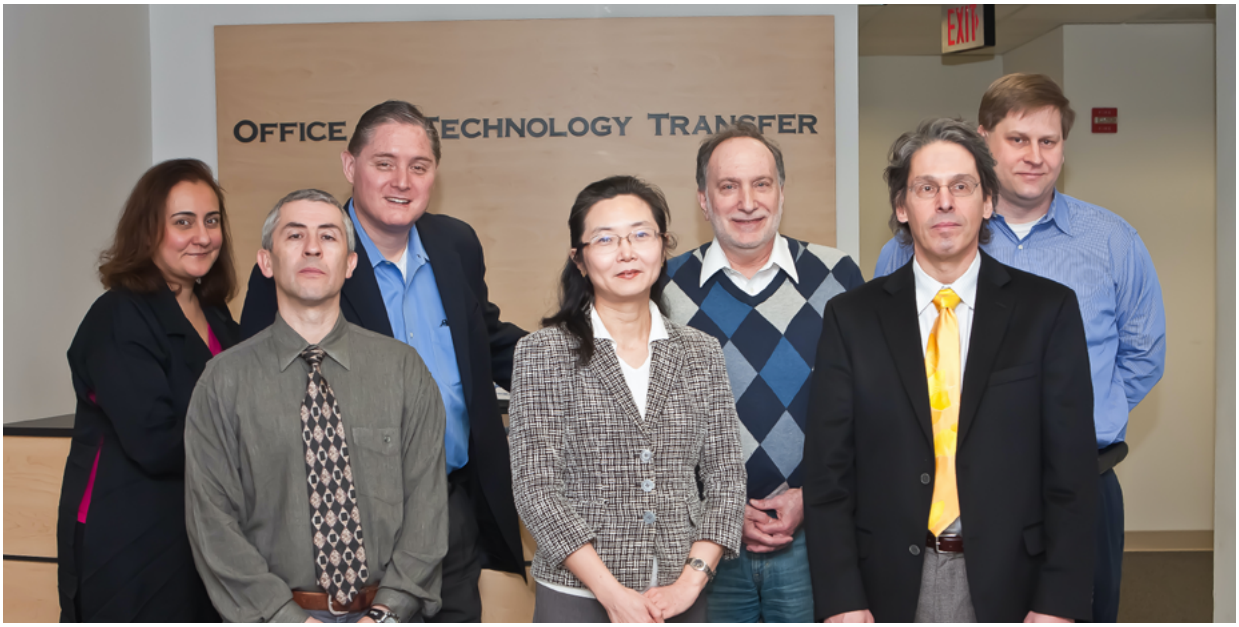
These institutes aside, the CDC's main campus is in Atlanta, Georgia on the CDC Roybal Campus (picture below). This campus is named after former congressman Edward R. Roybal. Congressman Roybal secured funding for every new CDC building for over a decade and had been an advocate for public health his entire career, starting when he was a public health educator with the California Tuberculosis Association. This campus was built to bring 23 different CDC locations in Atlanta onto two campuses, the Roybal Campus located on that same parcel of land on Clifton Road and the Chamblee Campus. At the time of the Roybal campus' dedication, then CDC director Jeffrey P. Koplan said "All his life, no matter where or at what level he sat, Edward R. Roybal has made the public's health his personal and professional priority. His leadership has prevented the illness and death of many Americans. Together, Edward R. Roybal and CDC are building for America's public health future."

Due to the nature of what the CDC researches, buildings on their campus can be especially unique.

As laid out in the CDC's 2025 master plan, they will be building a new high-containment continuity lab that will be a biosafety level-4 facility. This indicates it has the highest level of biological safety. This new facility will feature high-efficiency particulate air-filtered supply and exhaust air, air-pressure-resistant doors, pressure cascade zoning, effluent collection and treatment, and pressure-decay-tested coatings and penetrations. There will be high purity breathing air and chemical decontamination showers for research staff. Once construction is complete, this will be one of three facilities in the entire world designed and certified to facilitate diagnostic research on specific, select viruses.

The CDC is responsible for researching and helping to inform and protect the public from a wide variety of hazards, however one we never expected was a zombie apocalypse. In 2011, the CDC's blog published an article on how to prepare for a zombie invasion. The CDC regularly puts out information on how to prepare for natural disasters and thought that using a zombie theme would gather more people's attention due to the popularity of zombie's in the media at the time. The team decided that if you were prepared for a zombie apocalypse, you would be prepared for everything. If you would like to prepare yourself for a zombie apocalypse, you can find the CDC's recommendations here.





T2 Flashback Photo – Glybera® Wins 2013 FLC Technology Transfer Award

Steve Ferguson, OTT

In 2013 the NIH team responsible for the technology transfer used to help develop the first gene therapy ever approved in western markets-- Glybera (alipogene tiparvovec) -- was recognized with a Federal Laboratory Consortium (FLC) Mid-Atlantic Technology Transfer Award. Pictured (left to right) were: Mojdeh Bahar (OTT, now with NIST); Vincent Kolesnitchenko (NHLBI); Richard Rodriguez (OTT, now with NCI); Betty Tong (OTT, now with NIDDK); Alan Deutch (NHLBI, now retired); inventor Rob Kotin (NHLBI, now with Voyager Therapeutics); and Jeff Walenta (OTT, now with University of Colorado).

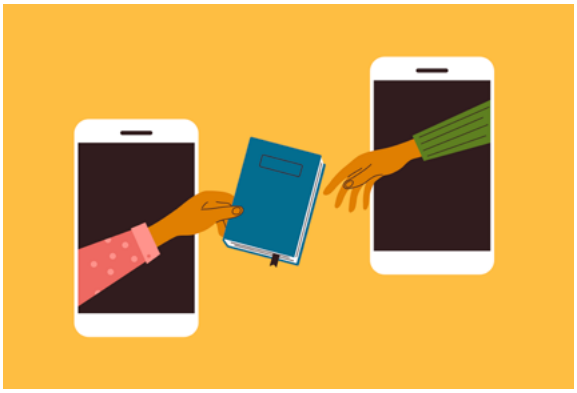
Glybera was a gene therapy treatment designed to reverse lipoprotein lipase deficiency (LPLD), a rare recessive gene disorder which can cause severe pancreatitis. Approved for sale by the European Medicines Agency in 2012 it was the first gene therapy treatment approved for sale in either Europe or the United States.

Although a tech transfer success story for its use of NIH's adeno-associated virus (AAV) vector delivery manufacturing method, Glybera turned out to be a commercial failure. The product ended up being unsuccessful for several reasons: the million dollar plus price tag to patients and payers; the high rarity of the LPLD disease itself; and of course its failure to achieve approval in the US. Only one dose was ever sold outside of a clinical trial and Glybera itself was withdrawn from the market in 2017.

The underlying NIH technology though still lives on with other gene therapy treatments still in development based upon the AAV vectors and vector manufacturing methods originally developed by Dr. Kotin and his colleagues at NIH.

Book Club: Bad Blood

Ami Gadhia, NCATS



John Carreyou outlines the rising glory and the. gory downfall of Theranos in his book, “Bad Blood: Secrets and Lies in a Silicon Valley Startup”. Carreyrou is the Wall Street Journal reporter who investigated this story and helped bring it to light.

Theranos claimed that their blood tests only required a finger-prick and could screen for a large number of diseases very rapidly, using their “Edison” devices. Elizabeth Holmes, a Stanford undergrad drop-out, founded this company for which she raised significant capital. She also managed to convince many influential individuals to serve on its board, including former Secretary of State, George Shultz. Holmes had the backing of individuals with clout, and she became the youngest self-made female billionaire of her time.

Holmes idolized Steve Jobs and wore a signature black turtleneck as one attempt to model his style. It’s important to note that Holmes and Jobs were in very different industries (biotech v. software). In the biotech industry, where the patients’ health and welfare is at stake, our sister agency (FDA) implements a robust regulatory system. Biotech doesn’t “beta-test” or go to market before all the “bugs” are fixed. It’s more important to test and validate than it is to hit the market in time for “Black Friday” or “Cyber Monday” and do design upgrades/updates later. This theme played out throughout the course of the book.

Holmes’ relationship with Ramesh “Sunny” Balwani, President and Chief Operating Officer (COO) of Theranos, is detailed in the book as well. Balwani made his fortune in a software start-up prior to joining Theranos. The book outlines Holmes and Balwani’s interactions with employees who tried to raise flags about the safety, efficacy, and the true development stage of the technology. One such employee included George Schulz’s grandson also played a pivotal role in bringing this story to light. Additionally, the book unveils Holmes’ scuffles with a DC patent lawyer and his family. This shines attention on alleged ethical issues that arose with patents.

This book was an engaging read because it touched on various aspects of our jobs. My neighborhood book club discussed this book (OUTDOORS, distanced and with masks), in October before Halloween. Pictured to the left is a sign from the event.

If you want to dive deeper into the story then check out the podcasts “The Dropout” and “Bad Blood: The Final Chapter”. Recently, Holmes was on trial for defrauding investors and patients, and the second podcast outlines recent trial updates. Holmes was found guilty And if you’re in the mood for a movie then grab popcorn and watch the HBO Documentary, “The Inventor: Out for Blood in Silicon Valley.” All entertainment and lightheartedness aside, this story was sad because it’s true. There are research and tech transfer lessons to learn from, which include: the importance of transparency and validation. We stress both at the NIH, and this story underscores why we do.

You can read Bad Blood for yourself via the NIH library here.

How Minuet Benefits TTOs Workflows

Tim Leahy, OTT

The new Enterprise Technology Transfer system (ETT) is being developed to take multiple standalone NIH databases and merge them into a single, consolidated system with enhanced capabilities. The system that serves as the base for ETT is a product named Minuet, created by Inteum. Many other technology transfer offices also use Minuet with great success.

In the coming weeks, ETT's major activities will revolve around working through seven iterations of end user acceptance testing with the Technology Transfer User Group (TTUG). The ETT team is creating detailed test cases for users to work through to make sure that the system works as expected. A selected group of users are working in the STAGE environment to make sure that the intended design will work for their organizations in real-world conditions. Any needed corrective actions that are identified through this testing will be implemented after the iteration is complete and included in later iterations for testing. The TTUG has completed the first iteration, *Manage Invention*, and has moved onto the second, *Manage Inquiry*. The TTUG is graciously using their time to help develop a system that will meet everyone's needs.

In the meantime, we can read comments from other technology transfer offices to see how Minuet is improving their work.

"Minuet is truly a great product. Being able to view most of the information on a single page, ability to create views/reports without even using the reporting tools just by sorting & filtering the columns and the ease of use is what makes Minuet a unique application. Inteum provides great training, the applications friendly user interface makes it very easy to learn and start using the product almost immediately. The hosted cloud option is a big plus as it eliminates the need for expensive servers, upgrades, fixes, etc."
-Yavuz A., Research Informatics for Operations (RIO), Informatics and Analytics (I&A)

"Straight-forward interface with plenty of areas to customize to meet our office's needs. Customized reports are easy to design and present only the data I want. The customer service is on point and always helpful."
-Laurent C., Intellectual Property and Program Manager

"Easy to use, intuitive and reliable system. Well supported by a team really eager to help and ensure the user experience is exceptional. It makes me and my colleagues work smarter and accurately record information following a robust methodology."
-Russell N., Deputy Director, IP Commercialization

"During evaluation, we found Inteum customers feel most listened to, compared to the competition." **– Former staff at Stanford University OTL**

"Emory OTT has helped to shape technology Publisher into what it is now. It is currently the core of our technology marketing efforts."
– Linda Kesselring, Emory University

“Don’t Act Like You Are Acting!” - Karen Rogers Wins OD Award

Richelle Holnick, OTT

When Karen Rogers was approached by Richard Rodriguez in 2015 to consider being the new Acting Director of OTT, she was surprised, but accepted and assumed the role the very next day. She dove into this position, helping to guide not just OTT, but to help the entire NIH Technology Transfer Community after the reorganization. OTT transitioned from having the lead in patenting and licensing to providing support to the ICs. When asked about this transition, Karen recalls that “This was a tough time for the NIH Technology Transfer Community, since change can be difficult. I’m proud of how the OTT staff stepped up and worked with the ICs.”

Throughout this time period, Karen led OTT as it provided access to systems, set up processes, trained IC TTO staff, launched the search for the new Enterprise Technology Transfer System, managed an increased workload with less staff, and generally kept the processing wheels turning throughout the transition. Karen described how the positive feedback from OTT staff and the ICs was very helpful in reinforcing that she was on the right track and wanted to especially recognize Tim Leahy for his invaluable support during her tenure and his “frank” counsel. She says that Tim gave her the perspective to help OTT work through the many challenges they faced.

Karen led OTT through great difficulties with the rapid shut down of the Executive Boulevard office due to building problems and work-from-home transition. She helped everyone transition and stay connected, which meant the office was more prepared when the second work-from-home order due to COVID-19 came. She helped guide OTT through those difficult times until October 2020 when she handed off her responsibilities to the new OTT Director, Tara Kirby. Karen says that she knew OTT would be in good hands as she had worked with Tara for a number of years and was happy to return full-time to her first loves – Royalties Administration and Monitoring and Enforcement.

During Karen’s first meeting with Michael Gottesman she asked for his words of wisdom. He advised **“don’t act like you are acting.”** Clearly she took his advice, as she was a wonderful and effective director. This past year Karen won an Office of the Director award for her outstanding leadership of OTT. Karen helped to not only keep OTT afloat amidst great change, but also made it a better place to work, more capable, and more responsive to customer needs. Throughout her 5-year tenure as Acting Director, Karen went above and beyond for OTT and the entire NIH Technology Transfer Community. OTT is lucky to still have her as the License Compliance and Administration Unit Chief.

Why I Got My Leadership Coaching Certificate

Lili M. Portilla, NCATS

After many years of procrastination, I finally made it happen – I got my Certificate in Leadership Coaching. I am going to give the COVID-19 pandemic 100% credit for motivating me in applying to the American University's Leadership Coaching for Organizational Performance (LCOP) Program. So, this past January, I virtually participated in the 5-month program. It was a terrific course and experience. Leadership coaching is partnering with "clients" in a thought-provoking and creative process that inspires them to maximize their personal and professional potential. Throughout my 30-year NIH TT career, I am frequently asked to provide career advice to up and coming TT professionals. The LCOP program has been a great way for me to formalize and develop these skills and "pay it forward" to others at NIH that helped me become a better leader and professional. Developing my coaching skills has also been very useful in helping my SBIR/STTR grantees. With my knowledge of drug and device commercialization and life science start-up pain points, I hope that my coaching will benefit scientific professionals and entrepreneurs to become effective and inspiring leaders with a heightened self-awareness and emotional intelligence (two attributes that are not necessarily focused on in scientific training programs). I really want to explore how my coaching can inspire a more diverse C-Suite that will translate into the development of more diverse treatments and cures for patients.

ICF International Coaching Federation

So, what's next for me in my coaching adventure? I am currently working on my required 100 hours of coaching to receive my Associate Coach Certification from the International Coaching Federation. I am really enjoying putting leadership coaching theories and processes into practice. I still have much to learn but I am up for the challenge. Let me know if you interested in learning more about the AU LCOP program or would like a free coaching session.

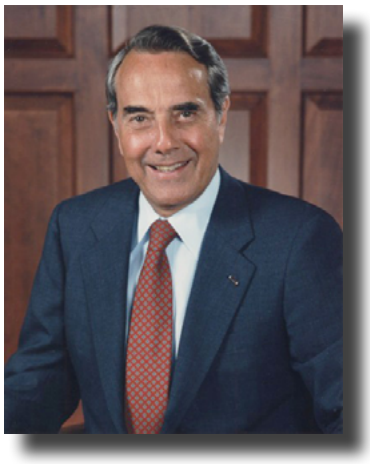
NCI TTC Staff Honored as Part of Team - 2021 NIH Clinical Center CEO Award

Michele Newton, NCI

Ken Rose, J.D. and Tedd Fenn, J.D. of the NCI Technology Transfer Center (TTC) manage the technology transfer and patent activities for the NIH Clinical Center. When the COVID-19 pandemic broke in 2020 and as it continued in 2021, their "fast and competent action" [as stated by the Principal Investigator] coordinating, drafting, and negotiating complex agreements with universities and companies enabled the Clinical Center to partner with many institutions across the globe to help diagnose COVID-19 patients and predict clinical outcomes quickly and accurately. For this work, the Clinical Center recognized Mr. Rose and Mr. Fenn as part of a team for outstanding achievements with a 2021 NIH Clinical Center CEO Award.

Bob Dole: Legend of the Technology Transfer Community Passes Away

Richelle Holnick, OTT



Bob Dole, former Kansas Senator and an important figure in technology transfer history, passed away on December 5, 2021. Dole served his country 78 of his 98 years, starting in World War II where he earned two Purple Hearts and continued on to a lengthy political career. He served a term in the Kansas House of Representatives and was the Russell County prosecutor for eight years. He then spent 36 years in Congress – 8 in the House of Representatives and 28 in the Senate. Dole's career culminated in him being the longest running Senate Majority Leader at the time of his retirement in 1996.

During his time in the senate, he worked on many important bills involving tax policy, nutrition programs, and the Americans with Disabilities Act, however, the technology transfer community remembers him for his landmark Bayh-Dole Act (BDA). Dole co-wrote this bill to incentivize private companies into working with the federal government in the technology transfer space. This act removed barriers and resulted in countless scientific advances from large increases in public-private partnerships and collaborations due to this act making these partnerships easier. University examples include Google, ETFs, and the nicotine patch. According to the Bayh-Dole 40 website, the BDA has increased U.S. economic output by $1.7 trillion and supported 5.9 million jobs.

After retiring, Dole continued serving his country through work with wounded veterans and fallen soldiers. President Bill Clinton presented Dole with the Presidential Medal of Freedom in 1997 where he jokingly said "I, Robert J. Dole, do solemnly swear… Sorry, wrong speech", pretending to be sworn in as he had just lost his bid for president against Clinton. Two decades later Congress awarded him with their highest honor, a Congressional Gold Medal. Dole is remembered for being a great legislator, tough negotiator, and a WWII hero. His passing was honored by lowering the White House and all public flags to half-staff.

The BDA recently celebrated it's 40th anniversary

Senator Bob Dole (right) and co-author Senator Birch Bayh (left)

Congratulations to the Five 2021 TTC Advancing Innovations Through Mentorship (AIM) Teams!

Michele Newton, NCI

The AIM curriculum, which was completed in October 2021, is based on the I-Corps™ at NIH that uses customer discovery (identifying & talking to commercialization stakeholders and prospective customers of the invention) to help researchers gain valuable insight on how to translate their technologies from the lab into the market. AIM helps scientists look at their research from the commercial perspective and supports TTC/lab team engagement to further develop a selected invention. Feedback from the teams, plus the results from AIM 2021 are coming soon!

Team 1:
Entrepreneurial Lead - Sabina Kaczanowska (NCI Post-doc & T2I Fellow)
PI - Rosandra Kaplan
TTM Mentor Role - Eric Cheng
Full Team Members - Cristie Contreras (Post-bac) & Wing-Hang Tong (TTAP Ambassador)
Technology - Genetically Engineered Myeloid Cells (GEMys) as a Platform to Enhance Anti-Tumor Immunity)

Team 2:
Entrepreneurial Lead - Eric Chun Hei Ho (NCI Post-doc & T2I Fellow)
PI - David FitzGerald
TTM Mentor Role - Abritee Dhal
Full Team Member - Suna Gulay French
Technology - EGFRvIII Antibodies for the Treatment of Human Cancer

Team 3:
Entrepreneurial Lead - Snehal Gaikwad (NCI Post-doc & T2I Fellow)
PIs - Beverly Mock & Jay Schneekloth
TTM Full Team Member Role - Lauren Nguyen-Antczak
Full Team Member - Nate Whitman
Technology - Small Molecule Anti-cancer Agents that Stabilize the MYC-G-Quadruplex

Team 4:
Entrepreneurial Lead - Anu Puri (NCI Staff Scientist)
PI - Mikhail Kashlev
TTM Mentor Role - Michelle Favila
Full Team Member - Jay Kline
Technology - Binary Lipid Bilayer-containing Vesicles comprising Embedded Cytotoxic Agents and Methods of Making and Using the Same

Team 5:
Entrepreneurial Lead - Md Masud Alam (NCI Post-doc)
TTM Full Team Member Role - Harmen Steele
TTM Mentor Role - Rose Freel
Full Team Member - Ricquita Pollard
Technology - E-181-2021 (Combination Immunotherapy with TLR4 Agonist with TLR2/6 Agonist Together with a STING Agonist and Anti-PD-L1 Cures Mice Bearing a Melanin Producing M3 Melanoma)

New Patent-Legal Services Survey Tool

Amanda Wingo, OTT

As we begin the new year, we are pleased to share that the Patent Legal Services (PLS) Team has leveraged a new tool to gather feedback on the performance of work conducted by law firms in key evaluation areas: Quality, Schedule, Cost Control, and Management. We have moved away from using SurveyMonkey for these reviews and are instead taking advantage of the user-friendly capabilities of Microsoft Forms. These new surveys provide a more streamlined user experience, while maintaining the same core questions as the previous surveys. One change to the surveys is that you must now complete one survey per law firm you are reviewing. For ICs dealing with multiple law firms, multiple surveys will need to be submitted, however, the process for doing so has been streamlined. Narratives are also now required, as they provide a comprehensive description of the rating chosen.

We remind and encourage the LPM/TTPS/TTMs to continue using the PLS Performance Management Surveys available through Microsoft Forms to provide ongoing feedback on the performance of law firms throughout the year(s). This will allow the tech transfer community to provide the law firms with substantive feedback, respond to performance issues and successfully manage the PLS master contract.

If you have any questions about the PLS Contract or the Performance Management Surveys, please reach out to your IC's COR or Amanda Wingo.

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

- Biotech Survey
- Chemistry Survey
- Software Survey
- Mechanical Engineering Survey

Working with Royalty Reports and Their Documents

Mitchell Ha, Sapient

Royalty Reports contain complex documents with data and calculations, usually as excel documents. These documents are uploaded as attachments to the royalty reports. These files are stored separately from the royalty reports, but they are tied together through a system ID.

There might be times when:

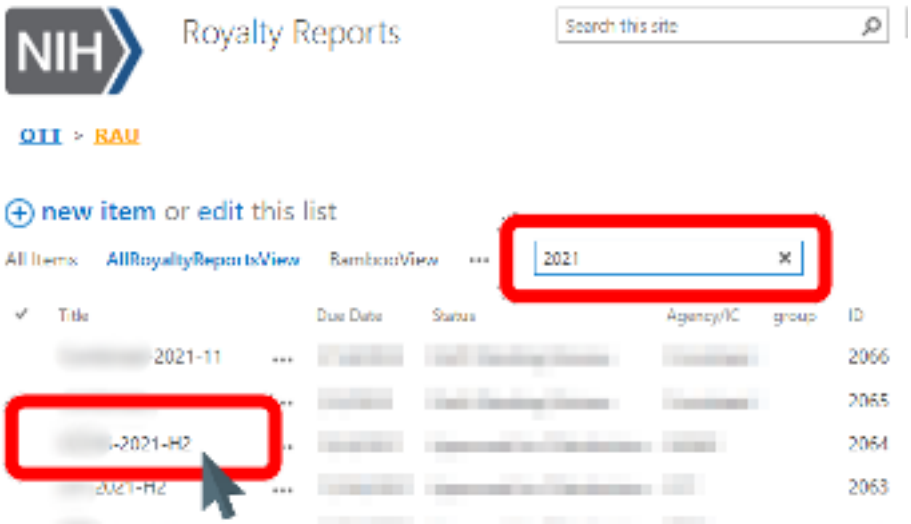
1. Documents cannot be uploaded and attached to the royalty report. When uploading documents, nothing happens and no documents are attached.
2. Documents can be uploaded but do not update the attached documents. The attached document versions remain static.

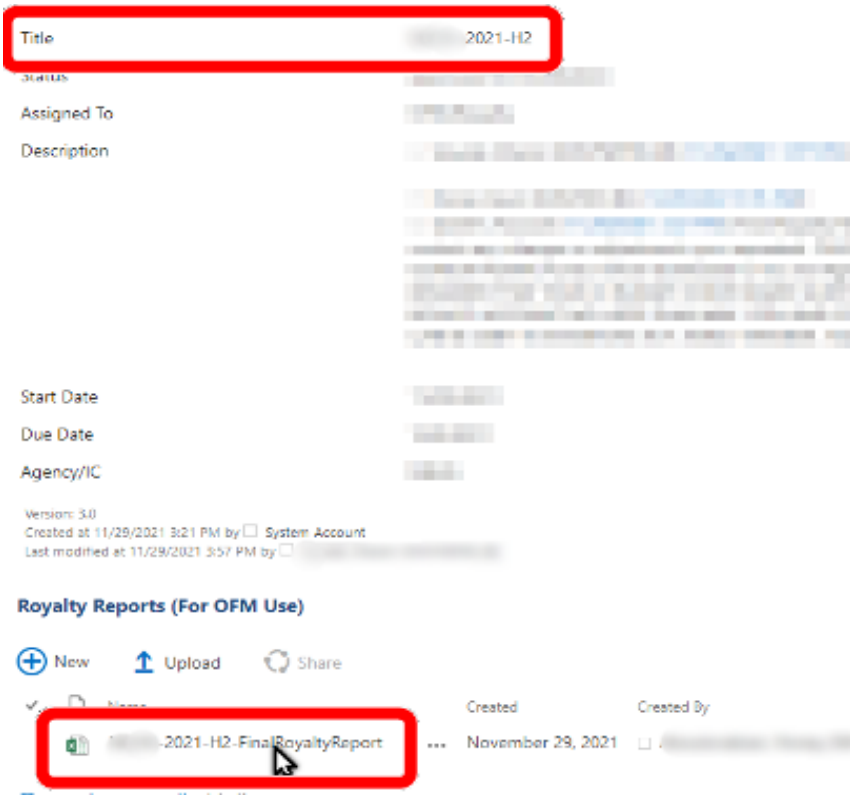
Likely reasons:

1. Uploaded documents did not have proper naming conventions. If the name of the documents do not match the royalty report, it will not attach to the license.
2. Documents were uploaded without a matching royalty report. These excel files become orphaned documents without a royalty report.

Troubleshooting

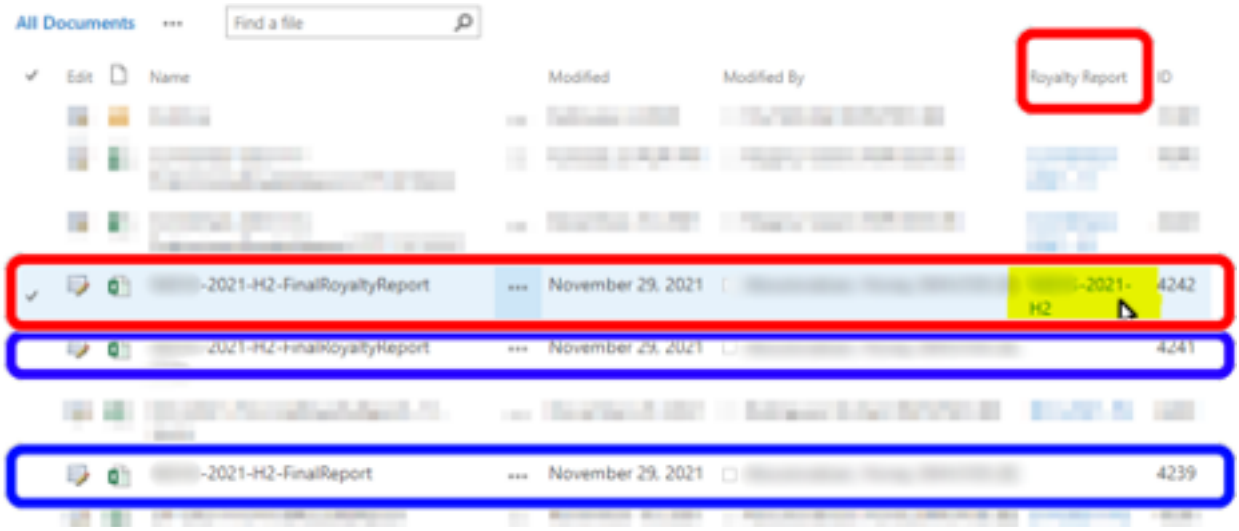
When troubleshooting a Royalty Report, we want to first track it down on the list. We can do that by either sorting the Royalty Report list or filtering the list. We can use the search box (upper right "2021") to filter the Royalty Reports. The cursor is pointing to the target Royalty Report:





The details of the Royalty Report only show one document attached (left).

The Royalty Reports have a dedicated repository for their documents. In this case, Royalty Report Documents. In the following view, we can see that this document does not have a Royalty Report referenced to it (the two Blue outlines have nothing under the Royalty Report column). The document with the Red outline is properly attached because there is something in the Royalty Report column (highlighted in yellow).



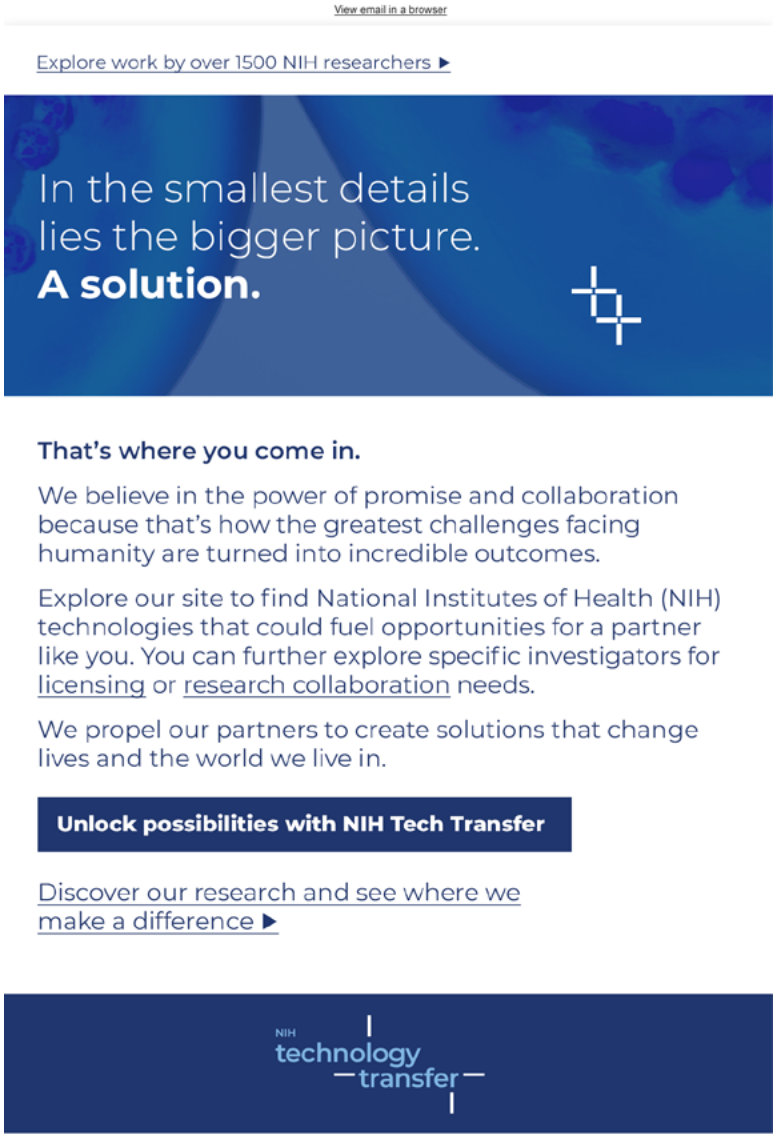
All three documents (one red, two blue) were supposed to be attached to the same Royalty Report. These two blue documents are “orphaned” documents because they are not attached to any Royalty Report. In this scenario, if new documents with the same name as the blue documents are uploaded, they will update the orphaned documents and not attach themselves to the Royalty Report. It is very important to correctly attach your documents to the Royalty Report to ensure your report is correct and documents are easy to find! If you experience this issue, jot down the Royalty Report number and the file name. Then create a ticket with the information at NIH Helpdesk assigned to *OD-NIH-OTT SharePoint Support*.If you have any OTT SharePoint related requests, please submit a helpdesk ticket referenced to *OD-NIH-OTT SharePoint Support*.

NIH Technology Transfer Community Website Awareness Campaign

Steve Ferguson, OTT

The NIH Technology Transfer Community Website team launched an email campaign in December to increase awareness of NIH as a premier technology transfer partner and drive traffic to the newly enhanced website. Previous research had highlighted a low awareness by industry of NIH's intramural technology transfer activities and showed a need for these awareness campaign activities.

An email was sent out in December through Fierce Biotech to their subscribers and a subsequent email was sent out through Biopharma Dive the first week of January. This approach was chosen to reach venture capitalists, investors, startups and biotech businesses that may have never considered partnering with NIH. Fierce Biotech and Biopharma Dive were selected as vendors based on their ability to reach this target market. The emails were created with a call to action to view the NIH technology transfer community website and to search through the database of available technologies. The email centered around the tag line "In the smallest details lies the bigger picture. A solution," with the subheader "That's where you come in." The messaging of this email campaign was designed to show potential partners that there is a space for them to collaborate with the NIH and invite them to search through our catalogue of opportunities.


View email in a browser

Explore work by over 1500 NIH researchers ▶

In the smallest details lies the bigger picture.
A solution.

That's where you come in.

We believe in the power of promise and collaboration because that's how the greatest challenges facing humanity are turned into incredible outcomes.

Explore our site to find National Institutes of Health (NIH) technologies that could fuel opportunities for a partner like you. You can further explore specific investigators for licensing or research collaboration needs.

We propel our partners to create solutions that change lives and the world we live in.

Unlock possibilities with NIH Tech Transfer

Discover our research and see where we make a difference ▶

NIH technology transfer

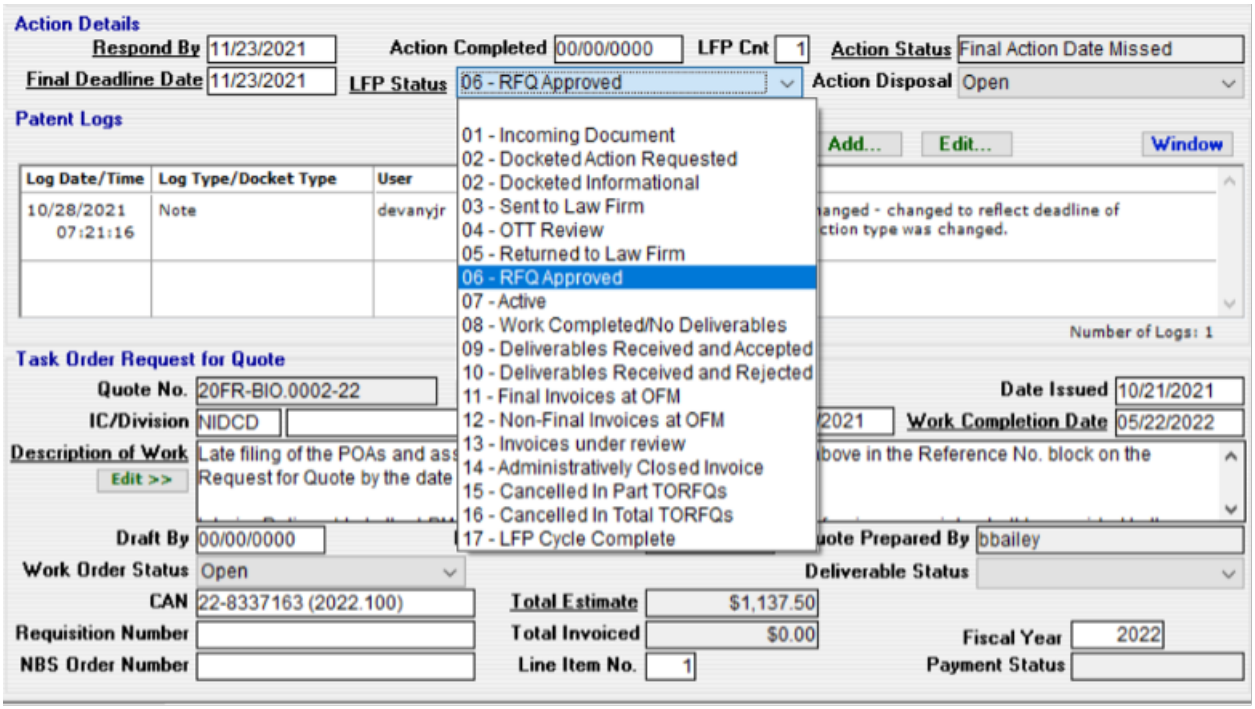
As the second email just deployed, we are not able to show metrics from this campaign yet, however, we are looking forward to updating the community on its success in the future. Pictured right, you can view the email that was sent.

As this campaign has driven many new eyes to the site, we want to keep it fresh with new technologies from your inventors! Please let us know if there is any way to assist your IC in publishing new marketing abstracts and if there are any technologies that you would also like to highlight through a news item and social media.

The Importance of the Law Firm Portal Status Field

Kyle Doss, OTT

The law firm portal (LFP) status field is the direct liaison between the contracted law firms and the NIH Tech Transfer community for patent prosecution related correspondence. The contracted law firms are unable to submit correspondence through the LFP if the status is incorrect in TechTracS; task order request for quotation (TORFQs) will simply not appear on their view of the website. This creates delays in reporting, unnecessary confusion among the users, and troubleshooting from the LFP Tech Support team when it may not be needed.



A brief outline of the LFP Status field.

The LFP Status field was added to NIH TechTracS when we transitioned from paper/email law firm correspondence to solely electronic law firm correspondence via the Law Firm Portal Website. The LFP status field was activated on 12/04/2017 and is used to track the activities of the Action_ Work_Order table. There are 18 unique values in the LFP status field, and each of the values is based upon different business rules.

LFP Status Flow

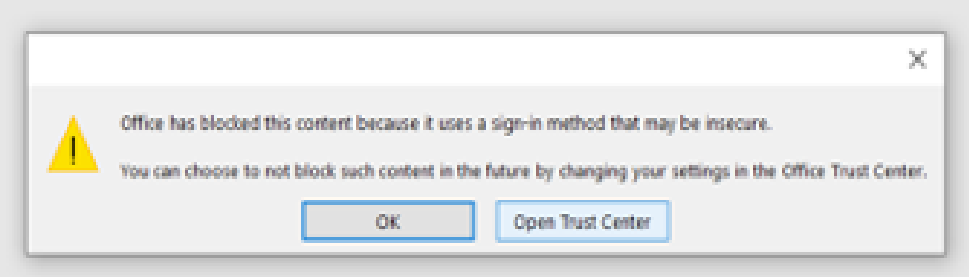
In theory, the LFP Status field should flow to multiple different values throughout the entire LFP cycle. These not only include manual updates, but automatic triggers based upon the various business rules mentioned previously.

For a detailed guide on the fundamentals of the LFP status field, who should interact with these statuses, and how these statuses interact with the Law Firm Portal website, please view this guide on SharePoint.

Trust Center Issue for MS Documents

Mitchell Ha, Sapient

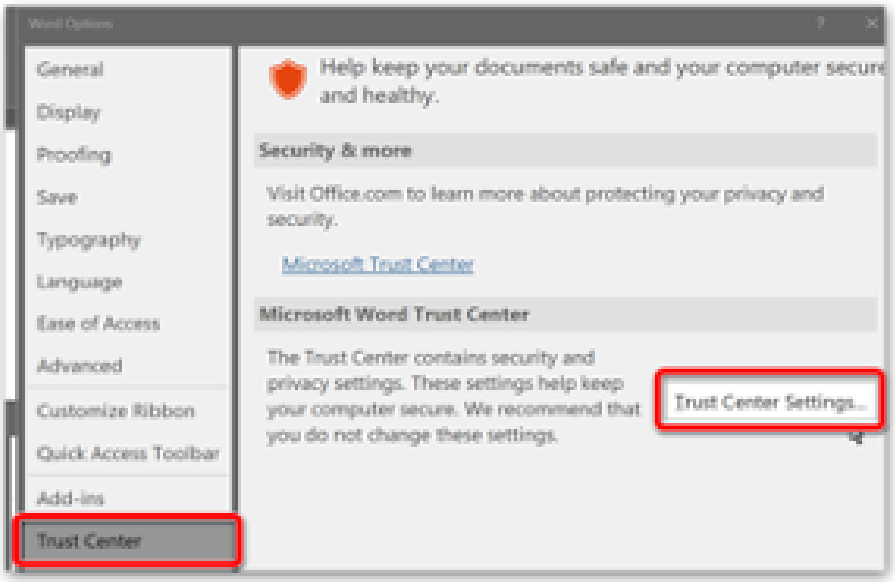
Have you experienced any difficulties accessing Microsoft Office documents under the OTT SharePoint site? You might have seen the following message box come up when trying to access a document (pictured right).



This was an unintended consequence from a Microsoft software patch that was released out of schedule. We are working with OIT and CIT to determine the root cause and possible preventative measures. Meanwhile, if you experience this issue, please follow the instructions below as a work-around.

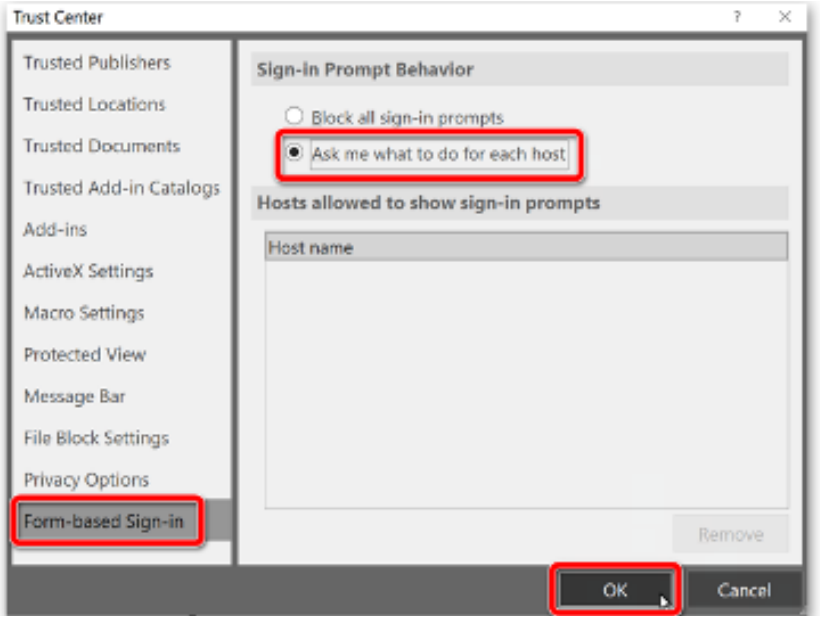
Trust Center Troubleshooting Steps

1. If you see the dialog box (right), click on "Open Trust Center.
   a. You can also get to the Trust Center by opening any blank Microsoft Office document (such as Word, Excel, and PowerPoint.) and go to File -> Options -> Trust Center.



2. Then go to Trust Center Settings -> Form-based sign-in.

3. Click on "Ask me what to do for each host" then OK.



This setting in Trust Center will prevent blocking of sign-in prompts. As you access safe sites within the NIH network, the list of safe hosts will be auto-populated depending on your interactions with the sites.

For further information, consult the link Updated Feature Restricting Form Based Authentication In Office Apps.

You are our priority, and we are working to preserve the continuity of your business processes. If you experience a sudden loss of access to the SharePoint site or documents, please submit a helpdesk ticket referenced to *OD-NIH-OTT SharePoint Support*.

Clara Barton and the Patent Office

Barry Buchbinder, NIAID

Clara Barton left her original profession as a teacher when a school board refused to give her a higher-paying position at a school that she had founded, hiring a man instead. She moved to Washington, DC, in 1854 and during 1854-1855 worked as a recording clerk at the Patent Office for Commissioner of Patents Charles Mason. Her salary was equal to that of the men employed in her office, $1,400 a year. At that time she was the only woman permanently employed by the federal government. She is believed to be the first female Federal employee to have received equal pay for equal work.

During the period of 1855-1857, the status of female government workers was uncertain. Secretary of the Interior Robert McClelland was opposed to women working in government offices. Miss Barton's position as a clerk was reduced to copyist. She was paid ten cents for each 100 words copied.

Miss Barton returned to her home state of Massachusetts and lived with relatives and friends when her position at the Patent Office was eliminated in 1857 by the Buchanan Administration. With the election of President Abraham Lincoln in the autumn of 1860, she returned to her former Patent Office position as a copyist. Her Patent Office career ended in 1861 as she became involved in the care of wounded civil war soldiers. This ultimately led to her founding of the American Red Cross.

AUTM Preview

AUTM's Annual Meeting is slated to take place February 20-23 in New Orleans. NIH Tech Transfer is sending a few speakers. Steve Ferguson will be co-chairing the Technology Valuation Course. Steve and Eggerton Campbell will be speaking on a panel about priority review vouchers. Karen Rogers and Bruce Goldstein will be hosting a panel titled "Show Me the Money", along with Kris Anton from Invotex, where they will present tried and true suggestions for royalties and monitoring and enforcement. Sending speakers to AUTM's Annual Meeting is a great recognition of our program and it reflects well on NIH Tech Transfer that we are so engaged with the broader tech transfer community.

NIH Librarian's T2 Tip of the Month - Web of Science

Josh Duberman, NIH Library

The Web of Science Core Collection™ is a Clarivate subscription-based cited reference database covering scientific, technical, medical, humanities & social science literature, available to NIH staff via the NIH Library. It indexes more than 21,000 journals from 1900-present, as well as books and extensive conference proceedings.

Web of Science records include complete citation counts for all articles and is the best cited-reference database to use for older literature pre-1996. Records can be searched for words, authors, affiliations/institutions and cited references; some records include abstracts. Citation ranking of publications can be very useful in identifying experts, and affiliation ranking can help identify companies interested in particular technologies. Web of Science has broad engineering literature coverage which can be very useful in researching medical devices and technologies.

The NIH Library offers classes on Web of Science. Vendor training resources include a quick reference guide, recorded seminars, and a self-guided course.

Contact Josh Duberman at jduberman@nih.gov for answers to any questions or training on Web of Science and other information resources. You may also click here for the NIH Library class schedule, or sign up for the NIH Library email news.

Keep Calm and Forward It On!

Charlene Maddox, OTT

Are NIH licensees sending you notices about product development delays or a recent merger or sales report or need consent to sublicense? If you're nodding your head yes, then send it to us, OTT's Monitoring & Enforcement Unit also know as MEU (rhymes with Ewe) at LicenseNotices_Reports@mail.nih.gov.

Working with Licenses/Agreements and Their Documents

Mitchell Ha, Sapient

Licenses need signed agreement documents and distribution form documents. Users upload and attach documents to the licenses. These files are stored separately from the licenses. But they are tied together through a system ID.

There might be times when:

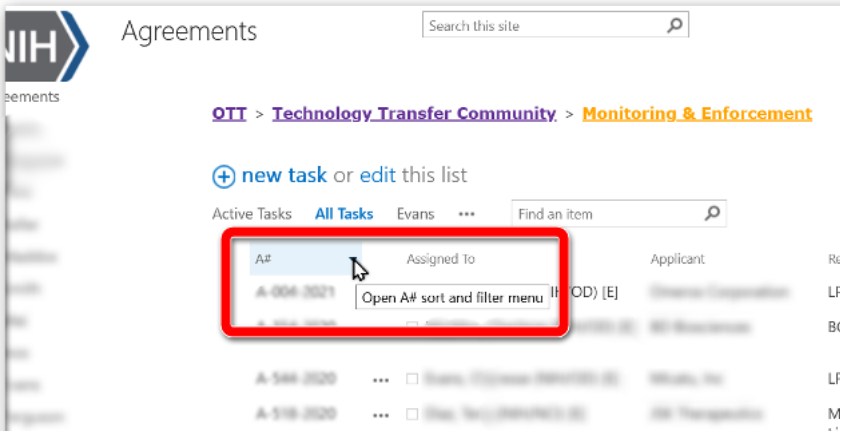
1. Documents cannot be uploaded and attached to the license. When uploading documents, nothing happens and no documents are attached.
2. Documents can be uploaded but do not update the attached documents. The attached document versions remain static.

Likely reasons:

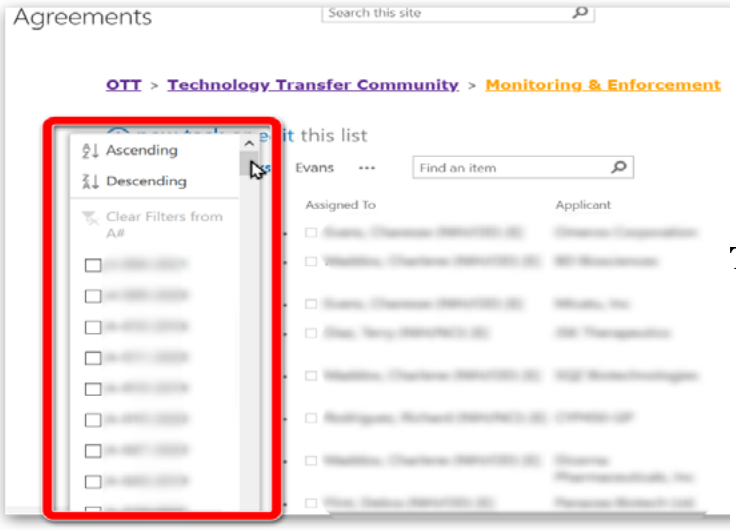
1. Uploaded documents did not have proper naming conventions. If the name of the documents does not match the license/agreement, it will not attach to the license.
2. Documents were uploaded without a matching license. These become orphaned documents without a license.

Troubleshooting

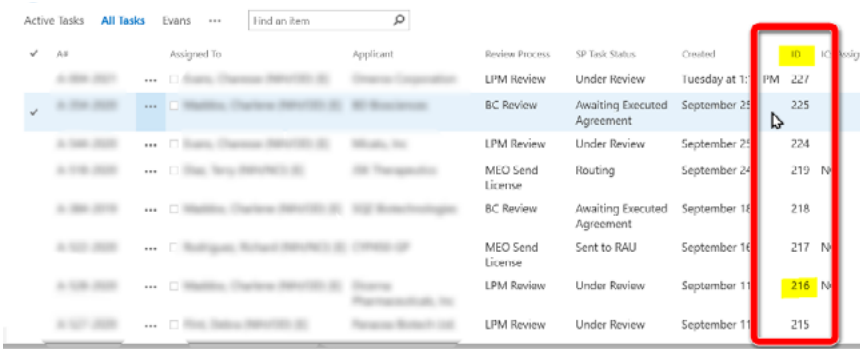
When troubleshooting a license or an agreement, we want to first track it down in the list. We can do that by either sorting the license/agreement list or filtering the list.



Click on the menu drop down for the column header. We are filtering the A# column in the picture. But, the same applies for Title columns.

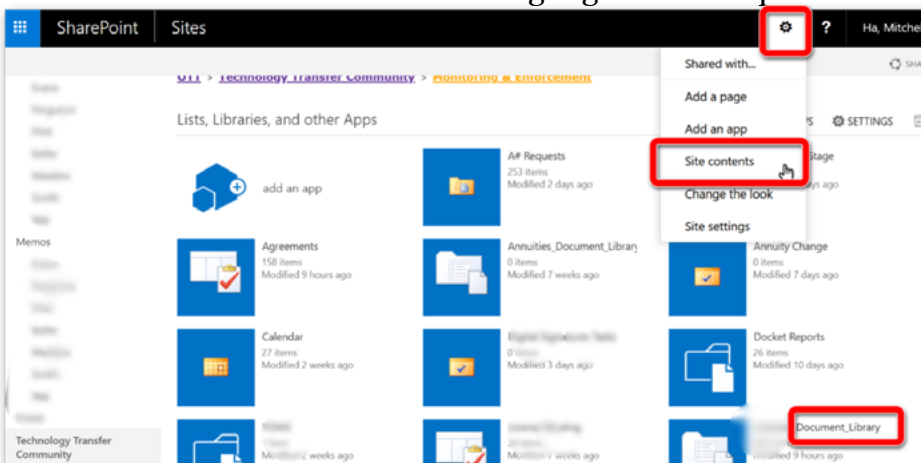


The user should see a list of eligible A#s.

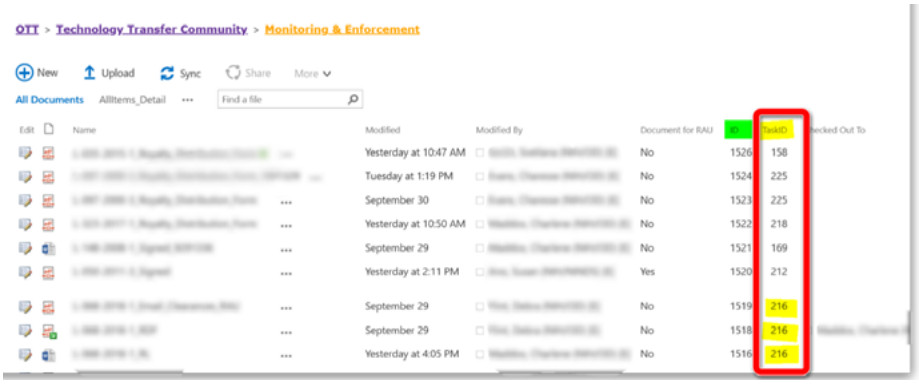


The Agreement ID is also known as a Task ID (recognized by the back-end system, independent of A#s) and it is displayed in certain list views. With the Agreement ID, we can see which documents are attached to the Agreement. For example, let us say the Agreement in question has an ID (or Task ID) of 216 as highlighted in the picture.

We can navigate to the document's repository by clicking on the Gear icon on the upper right-hand corner -> Site Contents ->License_Document_ Library. All Licenses and Agreements have a document repository name of "License_ Document_Library".

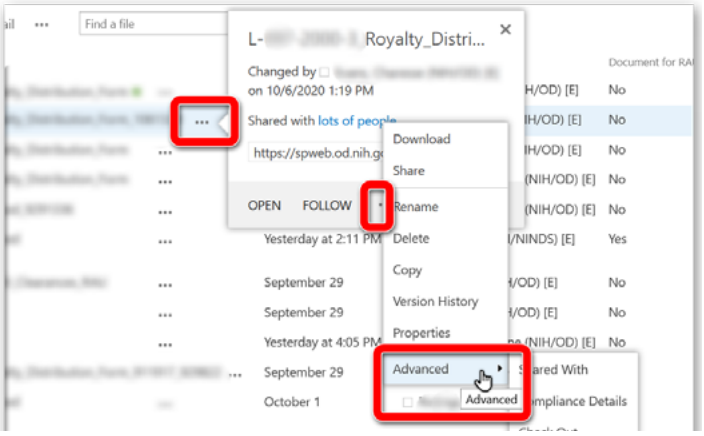


Once in the document library, we can sort or filter by the Task ID. The Task ID we are looking for in this example is 216.



Note that the items in the document library have their own *ID* which is an internal number assigned by the system. We can delete documents attached to Task ID 216 from the library. Or we can also check them out and edit them as needed.

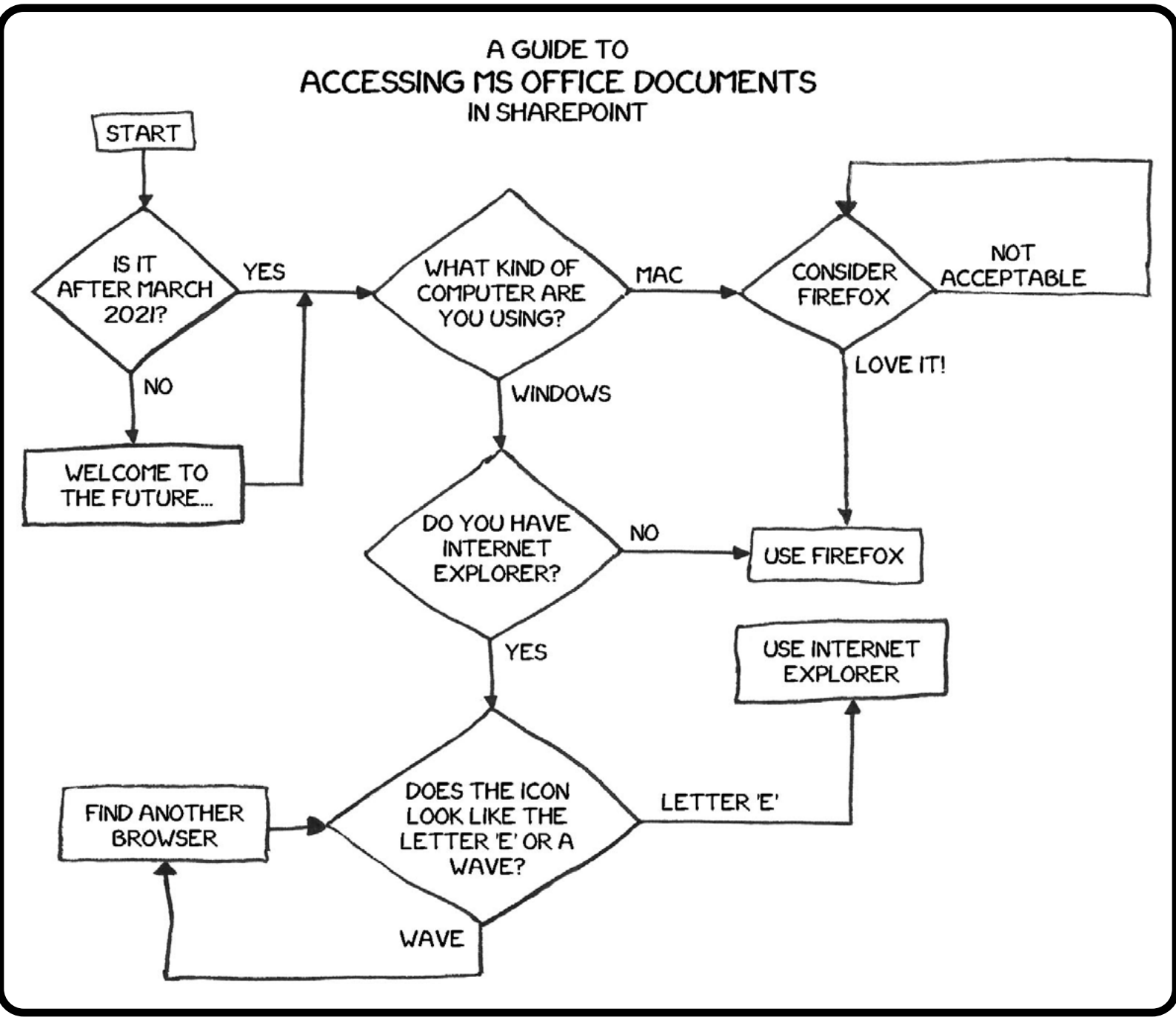
To do so, we would click on the "…" menu action button. This will bring up a dialog box with buttons at the bottom "Open Follow …" Clicking the third button "…" will bring up further menu actions such as Download, Share, Rename, Delete, Copy, Version History, Properties, and Advanced. The Advanced menu will bring up options such as "Shared With, Compliance Details, Check Out, Follow, and Workflows."



If you have any OTT SharePoint related requests, please submit a helpdesk ticket referenced to *OD-NIH-OTT SharePoint Support*.

Tech Toon

Wayne Pereanu, OTT



This Tech Toon was made by OTT's own Wayne Pereanu! If you have artistic skills, please consider submitting a cartoon for a future edition!

Comings & Goings

Lidia Beka joined NCI TTC as a CRTA in November 2021. Prior to joining TTC, Lidia served as a technical advisor for a law firm based in Connecticut. She assisted the firm with patent prosecution, drafting patent applications, and patent portfolio analysis for clients in the biomedical, mechanical and medical device fields. Lidia is also familiar with TTC from her experience as an alumna of the Technology Transfer Ambassadors Program (TTAP). Lidia received her Ph.D. in Molecular and Cell Biology from the University of Connecticut and completed her post-doctoral fellowship at NIAID.

Nicholas Bernier joined NCI TTC as a CRTA in November 2021. He recently completed his Ph.D. in Inorganic Chemistry at UCLA. His dissertation focused on boron neutron capture therapy, a cancer therapy based on the interaction between neutrons and boron-10 nuclei. Nicholas also has a B.S. in Chemistry from Fairfield University in Connecticut. He recently relocated from the LA area and is now living in Rockville close by to NCI's Shady Grove office. Nicholas is supporting various labs within NIA and NICHD.

Adam Dahl has joined OTT as a Project Manager. He graduated from North Dakota State University with a B.S. degree in Industrial Engineering & Management. Adam has over 16 years of experience in the public sector, including serving as a Project Manager at the U.S. Department of Health and Human Services' Office of Head Start (OHS) and U.S. Department of Labor, an Agile Coach at the U.S. Department of Homeland Security's Transportation Security Administration, and as a Scrum Master and Project Manager at the U.S. Customs and Immigration Services. In his spare time Adam likes to volunteer with Casey Trees and Food Rescue, take fitness classes at the YMCA, and tend to his indoor and outdoor plants.

Larissa (Risa) Gearhart-Serna joined NCI TTC in November as an Innovation Fellow. Risa comes to TTC after finishing a short specialized postdoc at Northwestern University's Lurie Cancer Center, where she was brought on to create 3D tumor organoid models for immediate use in a sarcoma immunotherapy lab. She graduated in July 2021 with her Ph.D. in Pathology from Duke University, where her dissertation was on polycyclic aromatic hydrocarbons, a class of ubiquitous environmental chemicals, and their impacts on breast tumor stage and progression. She has experience in academic technology transfer; she worked part-time in Duke University's Office of Translation and Commercialization from 2018-2021 as a Senior Technology Transfer Fellow. Risa obtained her B.S. in Biology and B.A. in Environmental Studies from Mills College in Oakland, CA.

Rebecca Goodman has joined the NIAID Technology Transfer and Intellectual Property Office as a Technology Transfer Patent Specialist. Previously, Rebecca worked in-house at various biopharma and clinical diagnostics companies as Senior Corporate Counsel for Patent and Licensing. In addition to her work as a consultant to start-up companies, Rebecca has law firm experience in both IP litigation and transactional matters. She also served as a Technology Transfer Officer at the University of California, Los Angeles. Rebecca earned a B.A. in Biology from Columbia University, a J.D. from the University of Southern California, an M.B.A. from the New Jersey Institute of Technology and is registered to practice before the USPTO.

Whitney Hastings is now a Senior Technology Transfer Specialist with NCI's Frederick Unit. She previously worked at the FDA as an Intellectual Property and Partnerships Manager where she helped expand the office to include patenting, licensing, and monitoring and enforcement. Prior to joining the FDA, she was a Licensing and Patenting Manager and Acting Branch Chief at OTT. At the Federal Laboratory Consortium Whitney currently serves as the Awards Committee Chair. Before working in tech transfer, she was employed in industry as an engineer with Corning and was a fellow in the NCI Nanobiology program. Whitney holds a B.S. in mechanical engineering from Clemson University, and completed her M.S. and Ph.D.in Mechanical Engineering at Johns Hopkins University.

Janette Lebron has been delegated as the new NIDA Technology Development Coordinator. Janette received her M.A. in Cellular and Molecular Medicine from Johns Hopkins University in 2009. Before joining NIDA IRP, she was a Scientific Project Manager in NIAID DIR for six years. She has been with NIDA IRP for over six years and has been the Scientific Program Coordinator in the OSD for the last two years.

Sarwat Naz joined NCI TTC as a Technology Transfer Manager in November. Sarwat is familiar with TTC from her participation in the inaugural Technology Transfer Ambassador Program (TTAP) cohort in 2017 and subsequently as a TTAP Senior Ambassador. Sarwat received her Ph.D. in Cancer Biology, Cell and Molecular Biology from the Indian Institute of Science and most recently she was a Research Fellow in the NCI CCR Radiation Biology Branch. She is supporting the tech transfer activities of various NCI laboratories.

Harmen Steele transfered his NIH Fellowship from NIAID's Rocky Mountain Labs, where he was behind the bench, to NCI's TTC after participating in the TTAP program. A native of Indiana, Harmen currently lives in Missoula, Montana, with Kelly (wife), Finnegan (12 year-old-son), and Rocco, the wonder dog. Harmen graduated from the University of Montana with a Ph.D. in Biochemistry and Biophysics. He holds undergrad degrees from Kennesaw State University and the University of North Carolina School of the Arts. In his free time, he enjoys camping, curling, cross-country skiing, board games, piddling around the house, and lawn maintenance.