TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

April 2019

ETT System – Data Quality

Data Quality: A Continuous Process for the Entire Organization

Falguni Sanghani, Sapient

The new Enterprise Technology Transfer (ETT) system will combine data from several legacy systems to create an NIH-wide system of record for technology transfer. To support an efficient data migration and ensure the effectiveness of the new system, a robust investment in data quality is essential. For this reason, a number of data quality initiatives are already in process or planned for 2019. These initiatives include assessment of existing data and correction of identified issues before the migration, as well as detailed plans for seamlessly combining the existing data sets and removing duplicate records.
The assessment activity is currently focused on the OTT TechTracS database, and includes identification of a number of different issues:

- Incomplete data – most frequently this means empty fields within a data record.
- Improperly formatted data – this problem is found most frequently in date fields (e.g. "2/13/19" instead of "02/13/2019").
- Erroneous data – data is clearly out of range (e.g. millions when thousands are expected, or "2109" when "2019" is expected).

Correction of these issues is accomplished by working closely with a variety of SMEs who can determine the proper value for the incorrect data and provide advice on the best way to make the necessary changes to the database.

The planning activity consists of mapping all of the data tables and data fields in the legacy databases to the tables and fields planned for the new ETT database. Once the databases are mapped to each other, the logic for comparing and combining records is developed with a concern for ensuring that all unique data is retained while also preventing creation of duplicate records. The data quality team is currently working on approaches to manage the substantial duplication of person and company records across all of the legacy systems. Another essential element of the data quality effort is to preserve an "audit trail" for all changes that are made to the data, so that any problems or concerns can be investigated and (if necessary) reversed after the migration. The audit trail for data changes is being maintained primarily with ticketing systems.

In This Issue

ETT System – Project Acquisition Process

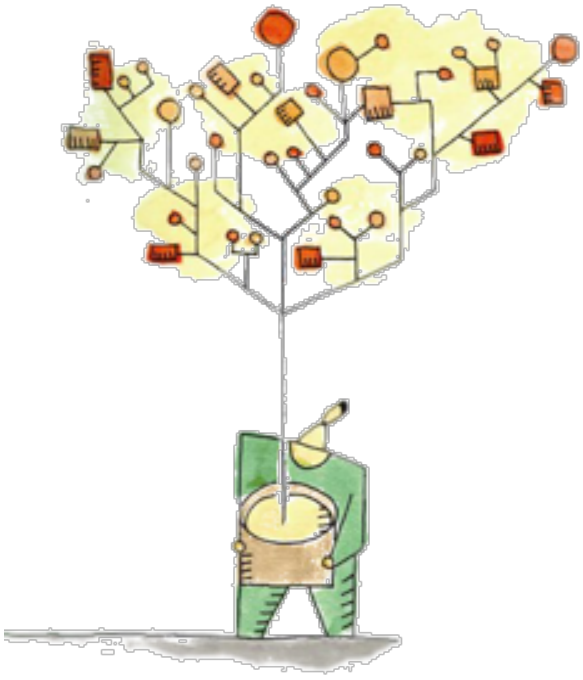
Project Acquisition Process Wrapping Up

David Vismer, Sapient

As the acquisition process for the new Enterprise Technology Transfer (ETT) system works through its final steps, the procurement team, led by Tim Leahy, is working to ensure that all potential vendors and systems have received a full and fair review and that the selected system meets all the needs of the NIH technology transfer community and provides the best value to the organization. In order to deliver the system as quickly as possible after the award, the team is using this opportunity to plan out the implementation process and to prepare the existing systems for migration to the new ETT system. It is anticipated that the contract will be awarded within the next few weeks and the team will begin the implementation process.

As the ETT requirements team continues to document all the business processes, system needs and critical features of the new ETT system, they are beginning to prepare all the documentation necessary for the migration and minor customizations needed for the ETT system for the unique needs of the NIH technology transfer community. The time spent now, documenting detailed business rules and data dependencies will significantly reduce the effort required during the migration and implementation phases of the project, and will ensure that the new system provides all the functionality that users have come to expect.

If you have any questions about the project or would like to volunteer your time to share your expertise in our focus groups, please ask your supervisor to reach out to the ETT Project Governance Group for more information.



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

NIH TechTracS Update

Bill Bigelow, Sapient

While the NIH Technology Transfer community awaits the rollout of the Enterprise Technology Transfer (ETT) system, NIH TechTracS continues to function as the system of record for Patent and Licensing data. As processes change or problems are identified, the NIH Office of Technology Transfer (OTT) updates NIH TechTracS with new features and fixes in an attempt to make the user experience more efficient. The most recent update which included several enhancements and bug fixes was deployed to the Production system on February 22, 2019.

As users may have noticed, NIH TechTracS has been experiencing system wide or functional outages in recent weeks. These outages have at times impacted the Law Firm Portal (LFP) functionality as well. Some of the issues are application based, but the majority of them are due to NIH network connectivity and/or hosting issues. With the help of NIH Center for Information Technology (CIT), we have developed a notification system so that our database administrators will be alerted to any connectivity issues or server issues which could impact our application or database. This allows OTT to address the issues quickly and, in most cases, before the end users even notice the issue.

Going forward, the goal of OTT with regard to TechTracS is to ensure system stability and data integrity in preparation for the migration to the new ETT system. This means that there are no current plans for enhancements or updates between now and the cutover to ETT. For any issues with NIH TechTracS, we encourage users to submit an NIH Service Desk ticket identifying NIH TechTracS as the application and providing as much information describing the issue as possible. These tickets notify the entire team, so the response should be much faster than just sending an email to one person. In many instances, the ticket can be resolved without further information, but we may reach out if needed. The submission of service tickets also helps us to identify patterns or repetitive issues so that incidents can be resolved quicker and, if needed, permanent solutions can be implemented.

We are proud to support the needs of the NIH Technology Transfer community and we will continue to ensure that NIH TechTracS is running as efficiently as possible as we move toward the new ETT system.

What are the 10 Rules of Technology Transfer?

Steven Ferguson

Though the original article describing the "10 Rules of Technology Transfer" appeared in R&D Magazine now more than fifteen years ago, the "rules" that they cite are still very relevant today for our own NIH programs. Although not the same as the more formal "rules" we must deal with daily from the Code of Federal Regulations (CFR) or the United States Code (USC), the advice and guidance they provide is very useful. Let's take a look at these "10 Rules" again and see how they connect to our local practice.

Rule 1 -- Don't Over-Value the Value of Technology -- A complaint sometimes heard is that research institutions have unrealistic expectations for their technologies based solely upon the initial innovation. NIH mitigates such risks for licensees through many post-discovery contributions via research collaborations, SBIR/STTR or other company funding or even contribution of various translational and clinical resources. Not taking equity and having a historical database of 35 years' worth of comparable transactions helps us in this regard as well!

Rule 2 – Fully Understand Your Target Market – Having a good understanding of the potential commercial market for the technology and the various companies active in it is key to finding the best licensing or collaboration partner for your technology. Help or advice with market research can be obtained from marketing groups within IC tech transfer offices and OTT or using the resources at the NIH Library.

Rule 3 – Hire Good People To Make Your Deals -- People managing the negotiations of a technology transfer agreements ideally have a strong technological background, along with a good business understanding and some legal background. Patent, licensing and collaboration agreement experience are clearly a plus with this at NIH as well and are complemented with various available internal training and education programs including the "Advanced Studies in Technology Transfer " program at the FAES Graduate School.

Rule 4 – Look For Win-Win Solutions -- The best technology transfer partnerships are often those where the technology provider and the corporate partner have complementary capabilities that together result in a strong technology being efficiently developed, skillfully manufactured and effectively distributed to address market needs. At NIH best results have occurred where the agency, the inventors and the corporate partner are all incentivized and energized by the relationship.

Rule 5 – There Is Still Plenty Of Room – Every day is a new day in science and still another chance to find novel solutions to important medical problems. At NIH, this now even includes even re-purposing older discoveries for new treatments. For NIH technology transfer it is important then to partner both early and often since you never quite know where your next therapy or vaccine will be coming from -- but like an express train there is always another one on its way!

And Technology Transfer Rules 6-10? Look for them in the next issue of the newsletter!

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

Ask Steve – Q&A

ServiceNow Interface Changes

Chris Mahoney, Sapient

As the needs of the NIH technology transfer community evolve and our services adapt to meet those needs, the technical support team wants to ensure the method for submitting service tickets stays current. As a result, a few changes have been made to the ServiceNow service ticketing system over the past few months. These changes have been developed by reviewing the types of tickets seen in the system and taking steps to improve the quality of our support.

To date, changes have been made to:

- Create a streamlined, single interface for all OTT Applications.
- Create a new custom interface – geared at helping users select the right application and report the issue/request as quickly as possible.
- Integrate the ability to submit a ticket for another user.

And beginning on Thursday, April 17, we introduced the option to request changes to Distribution Lists that are managed by Office of Technology Transfer staff. We introduced this option because:

- People get new roles and responsibilities every day – we want to keep our lists current and you know first when a person's responsibility change.
- Keeping these distribution lists current allows us to communicate proactively about the good work we are all doing but it also allows us to connect with people whenever we experience an issue.
- You can now use ServiceNow to request we add or remove individuals on Office of Technology Transfer managed distribution lists.

To see the new interface, simply click https://itservicedesk.nih.gov, find the Office of Technology Transfer (OTT) radio button (you may have to scroll down), and click through the applications.

The technical support team will continue to make changes to this interface as services evolve and as needs change.

OTT SharePoint Site Upgrade and FAQ

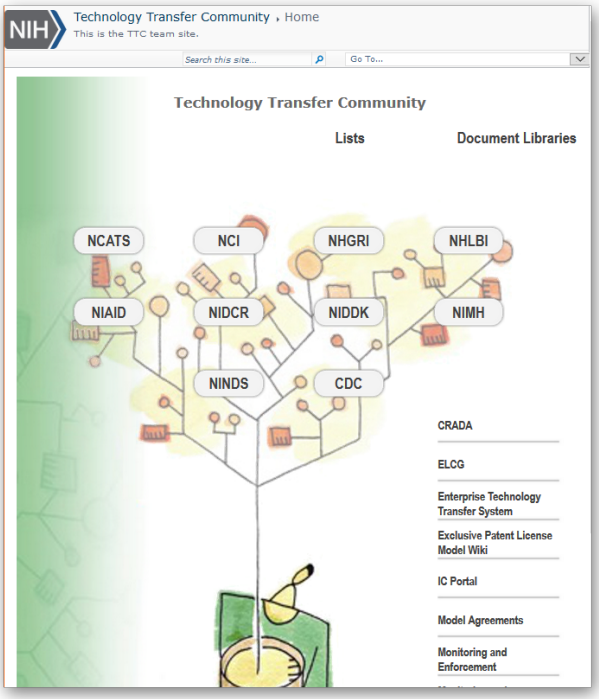
Terry Goodell and Mitchell Ha, Sapient

As you all know, on March 26th 2019, OTT SP Administration rolled out the upgrade to the theme and navigation to some of the SharePoint sites. A limited number of NIH technology transfer staff members needed assistance in using the new layout, and finding links to some of the content. If you have any other questions or issues , please submit a NIH helpdesk ticket (https://itservicedesk.nih.gov/support/) to be assigned to the Office of Technology Transfer (OTT) → SharePoint.

We would like to take this time to thank all the people who actively participated in testing, providing feedback, and giving us great suggestions.

Eggerton Campbell (NHGRI)	Whitney Hastings (FDA)
Kathleen Carroll (NCI)	Tara Kirby (NIAID)
John Devany (NHLBI)	Charlene Maddox (FDA)
Kevin Doran (OTT)	Ajoy Prabhu (OTT)
Vincent Feliccia (NIAID)	Jill Roering (OTT)
Tedd Fenn (NCI)	Betty Tong (NIDDK)
Charles Gerfen (NIMH)	Sury Vepa (NCATS)
Bruce Goldstein (OTT)	Enid Wagstrom (OTT)

Details on this SharePoint site upgrade along with screenshots, are available here, or by clicking the image below.



An Overview of the Annuity Management System (AMS)

Laura Lane-Unsworth, OTT

Computer Packages Inc. (CPI) provides our patent annuity payment services. As part of that service they provide access to their AMS. AMS, is a web-based system, which provides OTT and the ICs with on-line and real-time access to their annuity data at any time. It allows the ICs to review upcoming annuities and provide annuity instructions.

AMS improves the annuity decision process by providing the IC and LPMs with an effective and efficient means to review their patent portfolio. It also provides current online annuity data, which is available to the designated IC personnel, that includes additional information such as abstract from public data and web links to claims and drawings.

The AMS contains tools that aid in making decisions regarding annuity payment:

- Current data.
- Annuity information with links to patent office claims and drawings.
- Ease of entering instructions.
- Both the Inventor and Abstract fields may be expanded to provide more information. Click the + symbol to expand either of these fields.
- The App No link directly accesses the application at the patent office web site showing more information about the application such as drawings and claims. If there is no link, a web site is unavailable for that application.
- As instructions are entered, the costs and savings are summed up in the Total fields. The Total Amount reflects the total cost of all cases marked with a pay instruction per page. The Total Cost Savings reflects the total cost of all cases with a negative instruction per

The process of entering instructions into AMS is summarized in the work instruction which can be accessed by clicking here.

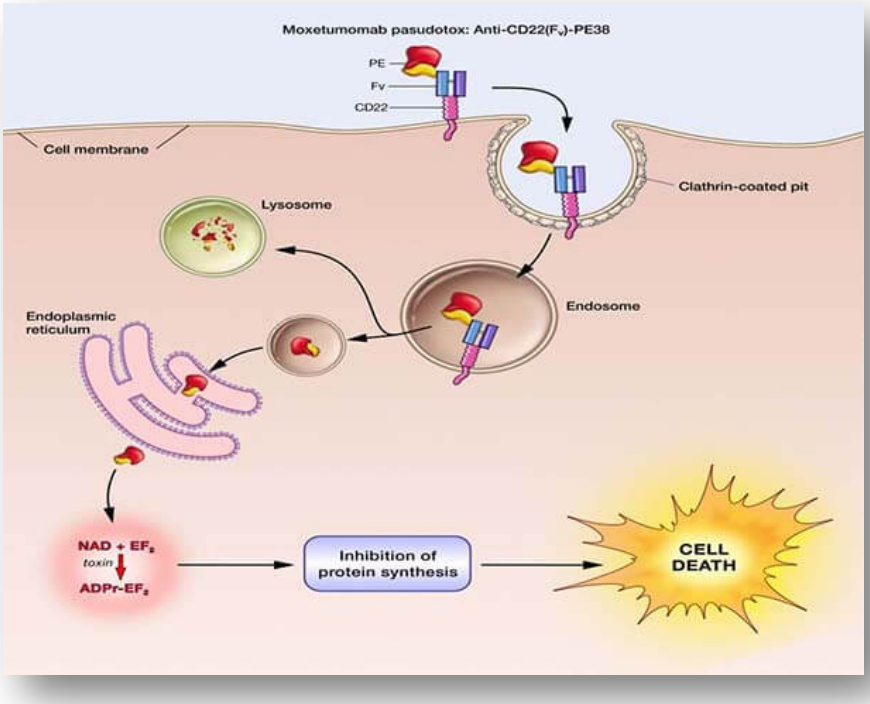
Moxetumomab Approved by FDA for Hairy Cell Leukemia

Michele Newton, NCI

In September 2018, the Food and Drug Administration (FDA) approved moxetumomab pasudotox (Lumoxiti), a first-in-class, bacterial toxin–based drug, for the treatment of some patients with hairy cell leukemia (HCL). Technology Transfer played an important role in facilitating the development path of moxetumomab, which was originally discovered by Ira Pastan, M.D., and colleagues in NCI's Center for Cancer Research (CCR). NCI Technology Transfer negotiated the license for the technology with the commercial partner that further developed it into a product, as well as the collaborative agreements necessary to support NCI-investigator-lead clinical trials.

The development of moxetumomab is "an excellent example of the persistence in pursing research, believing in the potential of a technology, and giving a technology time to mature", commented David Lambertson, the Technology Transfer Manager responsible for managing the multiple patents for the technology, as well as negotiating the license associated with the newly approved FDA therapy.

The first patent associated with moxetumomab was filed in 1986. Through the years, Dr. Pastan's commitment to study and develop immunotoxins involved filing multiple patents and collaborating with several industry partners to advance the technology. Adding complexity to the TT, the company to whom the technology was exclusively licensed in 2004 was sold and acquired multiple times. This required TTC to amend the license and CRADA several times. Ultimately, the long road from discovery to FDA approval resulted in a new treatment for some patients with Hairy Cell Leukemia (HCL), a rare disease. To learn more about moxetumomab, see: Moxetumomab Approved by FDA for Hairy Cell Leukemia



FLC Rookie of the Year Honors

NCI TTC Fellow Receives "Rookie of the Year" Honors from Federal Laboratory Consortium (FLC) Mid-Atlantic Region (MAR)

Michele Newton, NCI

TTC's Sidra Ahsan, Ph.D. received the FLC MAR "Rookie of the Year Award". The award recognizes the efforts of an FLC laboratory technology transfer (TT) professional who has demonstrated "outstanding work in the field of TT in a manner significantly over and above what was called for in the normal course of their work during the past year". The nominee must have three years or less experience in a TT position.

FLC Honors NCI TTC

NCI Honored with 2018 "Educational Institution and Federal Laboratory Partnership Award" from FLC MAR

Michele Newton, NCI

At its 2018 annual meeting, the FLC MAR awarded NCI for "NCI Immunotherapy Fellowship Co-sponsored by Society for Immunotherapy of Cancer". "The award exemplifies what is possible through engaged partnerships, in this case TTC, NCI CCR investigators, a CRADA partner and a non-profit", commented Michael Pollack, the Technology Transfer Manager who was part of the team that helped develop a creative solution to make the fellowship possible.

Congratulations to the FLC award winners:

NCI Scientific Team: Drs. James Gulley, Marijo Bilusic, Ravi Madan, and Christian Hinrichs

NCI TTC and NCI Ethics: Drs. Michael Pollack, Laura Henmueller, Kathleen Carroll and Mr. Eric Hale

SITC: Dr. Howard Kaufman

Pictured: Kathleen Carroll, Michael Pollack (NCI TTC) and Howard Kaufman (SITC)

Combating Biliary Tract Cancer

NCI Investigator-Led Studies Lead to 2018 FDA Orphan Drug Approval for Immunotherapy for Biliary Tract Cancer

Michele Newton, NCI

In 2010, TTC negotiated a CRADA between NCI and EMD Serono (the U.S. arm of Merck-KGaA Darmstadt, Germany) to allow for preclinical and clinical studies of several EMD Serono proprietary agents. One of the agents studied under this CRADA is M7824, "an investigational bifunctional immunotherapy that combines a TGF-β trap with the anti-PD-L1 mechanism in one fusion protein. Designed to combine co-localized blocking of the two immunosuppressive pathways, M7824 is thought to control tumor growth by potentially restoring and enhancing anti-tumor responses" (Merck press release). James Gulley, M.D., Ph.D., NCI Center for Cancer Research, outlined CCR's role in facilitating the December 2018 FDA orphan drug approval for this rare cancer:

- First-in-human study, with all dose escalation, done at the NCI.
- NCI CCR investigators showed that M7824 trapped all the TGF-beta molecules at all the timepoints being studied. Liang Cao, Ph.D., NCI CCR, developed and validated the assay that demonstrated this.
- Safety and preliminary evidence of activity done at the NCI.
- While NCI did not participate directly in the biliary tract cancer (BTC) cohort, NCI conducted entirely the biomarker cohort. This research is yielding data on mechanism.
- Preclinical data derived from NCI investigator-led studies demonstrated that M7824 could mediate ADCC (antibody-dependent cell-mediated cytotoxicity), could revert mesenchymal/ stem-like cells, etc.

Dr. Gulley, the coordinating PI of the international study, serves on the safety monitoring committee. TTC's Dr. Michael Pollack manages the complex technology transfer activity under the CRADA. The CRADA was amended several times to allow for additional areas of study, including funding for a new Immunotherapy Fellowship in Cancer.

NCI Featured in MedNous

MedNous
Managing European Medical Innovation

NCI as an Industry Partner Featured in March edition of MedNous

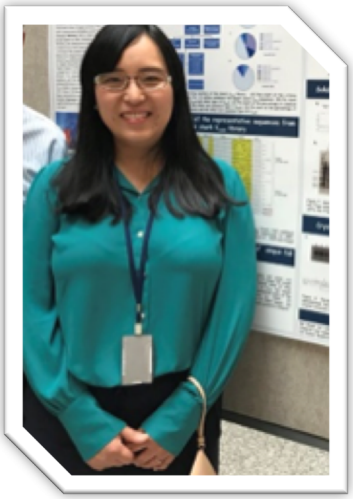
Michele Newton, NCI

The European medical innovation journal, *MedNous,* featured a story in its March issue entitled "NCI and Industry: Moving Innovations from the Lab to Patients" authored by Michael Salgaller and Michele Newton. *MedNous* is both a print and online publication.

Click here to see the news item published on the OTT website for details.

Comings and Goings

Donna Bialozor retired on December 31st from the NCI TTC where she was the Senior Technology Transfer Manager. She retired very happily and with a new grandson that just arrived in December. Her tech transfer expertise is already being missed by our community but we do wish her well in her ongoing work as a registered yoga instructor. *Namaste!*



Hejiao Bian, Ph.D. joined NCI TTC's Invention Development and Marketing Unit in November 2018. Bian received her Ph.D. in Biochemistry from Boston University School of Medicine. In December 2018, she received a Fellow's Award for Research of Excellence (FARE) for research conducted while working in Dr. Mitchell Ho's lab at NCI's Laboratory of Molecular Biology. Bian's project focused on construction and next-generation sequencing analysis of a phage-displayed nurse shark single domain antibody library. She intends to present her work at an international antibody engineering therapy meeting using the travel fund awarded to her. The FARE award will provide an opportunity for her to meet with the leaders in the field and learn the most recent progress in immunology oncology translational research. Importantly for her work with TTC, it also provides opportunity to learn about technology valuation and market landscape analysis, knowledge that will enhance her ability to market NCI technologies to potential collaborators and licensees.

In March 2019, **Rebecca Erwin-Cohen, Ph.D.** joined NCI TTC Frederick. In December 2016, she 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.

Pragnesh Mistry, Ph.D. joined NCI TTC in January 2019 and is supporting various NCI labs in LICB, LCMB, and DCCPS. Pragnesh received his Ph.D. in Immunology from the University of Maryland School of Medicine and completed his postdoctoral fellowship at the National Institute of Arthritis and Musculoskeletal Skin Diseases in Dr. Mariana Kaplan's lab. His research background includes drug discovery, TLR biology, neutrophil biology, and autoimmune/autoinflammatory diseases.