TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

August 2018

ETT System – Update

ETT Project Teams Choreograph Efforts

David Vismer, Sapient

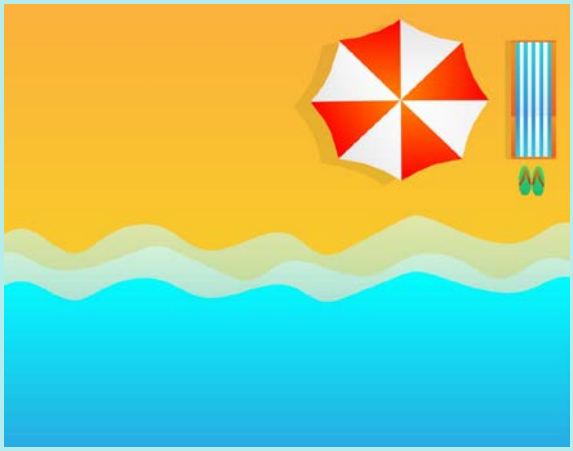
Building on the work that has been done over the past six months to document all the business processes, system needs and critical features of the new Enterprise Technology Transfer (ETT) System, the ETT project has moved into a new phase, choreographing the work of several teams and coordinating their activities to ensure that implementation of the new system can begin as soon as possible.

The procurement team, led by Tim Leahy, is leading the acquisition process, reviewing proposals submitted by software vendors to provide the base ETT system. The deadline for submissions is coming soon and the team expects to award the contract and begin the implementation process this year.

The requirements gathering process is also moving forward in parallel to the procurement process, ensuring that we can hit the ground running as soon as system implementation begins. The ETT project team is working through the management of law firm activities now, ensuring that the new system will provide a seamless integration between all the groups at the NIH who are involved in patenting and licensing process.

The third track of work, preparing for the migration of data from the existing NIH TechTracS system, as well as other systems in use at the ICs, is under way, documenting the data structures and business rules in use within the current systems, and building the tools and processes that will be used to migrate the data into the new system.

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.



In This Issue

Mailing Lists

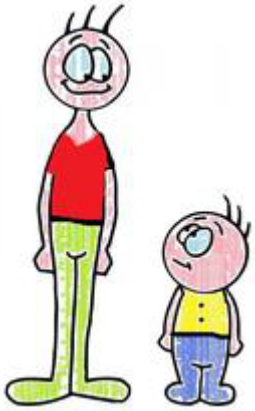
Long or Short

Karen Rogers, NIH-OTT

The Office of Technology Transfer maintains a number of e-mail listservs to help manage communication within our community. The **TDC-Long List** is open to any NIH, CDC and FDA staff that are interested in knowing about Technology Transfer. Typically, this is a forum for tech transfer-related information, training opportunities, job vacancies, and general information related to technology transfer happenings.

The **TDC-Short List** is limited to the IC Technology Development Coordinators, their alternates, Mark Rohrbaugh, the OTT Director/Deputy Director and the Chair of the TDC-Short Committee. Information exchanged through this forum is typically policy related, covers broader activities and procedures, and includes technology transfer community-wide requests for information or data.

The **NIH TechTracS User Group List** contains all staff that have been granted access to **NIH TechTracS**. This list is used to provide updates, system outages, and any information that would be of interest to NIH TechTracS users. If you have been granted access to the NIH TechTracS, you are automatically added to this list.



Updates to any of these lists can be requested by submitting a ticket through the NIH IT Service Desk at the following link: https://itservicedesk.nih.gov/

Training Update

Green Sheet Training Updated

Karen Rogers, NIH-OTT

The Royalties Administration Staff has updated the Green Sheet Training Step-by-Step guide to reflect new functionality. The new guide has been uploaded to the SharePoint Site at the following location (same as before).

https://spweb.od.nih.gov/OTT/DTDT/Training Program Specialist and Admin Training/Green Sheets Training for Program Specialists

It includes updates on where to locate back-up documents and how to run queries for the patent prosecution reports. Debbie Collins and Karen Rogers are available to help with any Green Sheet or Royalty questions.

"What are Priority Review Vouchers and why are they important for NIH technology transfer?"

Priority Review Vouchers (PRVs) are a Food and Drug Administration (FDA) program established to incentivize drug development for neglected tropical diseases, rare pediatric diseases, and medical countermeasures. Upon approval of a PRV-eligible drug, the sponsor is rewarded with a voucher that can be redeemed to have any future New Drug Application (NDA) or Biologics License Application (BLA) receive priority review status, shortening the FDA review cycle from 10 months to approximately six months. A PRV can also be transferred or sold, with prices ranging to date from $67 to $350 million.

The quicker review times allow a proprietary product to get to market faster and begin generating sales sooner and up to four months longer than expected without generic competition. Additionally the PRV can give the redeeming sponsor's product a competitive advantage by bringing it into the marketplace ahead of other medical treatments undergoing standard review at the FDA.

All of this is important for the NIH technology transfer program since PRVs can be a significant portion of the commercial value generated and then thus to be shared for technologies in NIH license agreements. Newer NIH license agreements concerning medical treatments eligible for PRV awards would typically now have "Priority Review Voucher Royalties" obligations due for either sale or use of the PRV by our licensee.

Note that PRV awardees can also be nonprofit organizations, not just companies. The Medicines Development for Global Health, for example, was just recently awarded a PRV for approval of moxidectin, a new treatment for river blindness, which affects people in sub-Saharan Africa.

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

Steve Ferguson, NIH-OTT

AAHRPP Language

New AAHRPP Language

Charles Gerfen, NIH-NIMH

Those among us that negotiate CRADAs for intramural clinical projects (and others) are already generally aware that the NIH's clinical programs are reviewed and accredited by a private nonprofit organization, the Association for the Accreditation of Human Research Protection Programs (AAHRPP). For those not aware, this group verifies that the research programs uphold rigorous standards for ethics, quality, and protections for human research. Accreditation is essential to support public trust that the researchers are committed to protecting the safety of those human subjects volunteering for the trial. In the US, all major IRBs and at least 65% of medical schools and universities conducting clinical research are accredited, with more seeking accreditation.

In 2014, to meet these standards and secure the AAHRPP's seal, the NIH added a paragraph to the Intramural Clinical-Trial CRADA model (¶4.4.2). This paragraph says that, for a two-year period starting when the protocol for the trial has ended, the CRADA Collaborator must continue to supply information relevant to the safety of the participating human subjects to the IC, which will be shared with the IRB. Ensuring everyone commits to that obligation is essential to protect the safety and well-being of the human subjects, who have risked their health and sometimes their lives in a project that, if all goes well, will eventually generate profits for the Collaborator.

The AAHRPP has recently informed the NIH that specifically setting a two-year reporting period is not mandatory. While the existing language remains our standard, the IC may negotiate another end-point, one that is either a different period or a specific triggering event. The ICs have discretion as to how to adjust the AAHRPP paragraph language; however, it cannot be deleted or eviscerated. The CRADA always must reflect the fact that completing the human-interaction part of the protocol does not end the obligation to share safety information with the IC's IRB, and the reporting period must be sufficient for the needs of the IRB. Accordingly, the absolute minimum period is the time needed to complete the data analysis specified in the protocol, though for highly unusual or riskier projects an IRB may feel a subsequent trigger-event is a more appropriate minimum.

Any questions about particular changes to this paragraph may be directed to Dr. Chip Gerfen, Chair of the NIH CRADA Subcommittee.

Annual Report

Check Out the Combined Annual Report on Technology Transfer Activities at the NIH and CDC!

Ajoy Prabhu, NIH-OTT

After months of hard work across the entire NIH and CDC TT community, the 2017 report on Technology Transfer Activities at the NIH and CDC was approved, and is live on the OTT web page. This report includes information about 2017 accomplishments such as the increase in users of NIH TechTracS and updates on the Enterprise Technology Transfer (ETT) System. The report includes not only updates from all the various ICs on the significant agreements executed last year, but also about other initiatives such as startup challenges and other innovative collaborations. The report ends with all the various accolades of the ICs.

Each year, information provided in this report is also used to develop the Federal Laboratory Technology Transfer Summary Report to the President and the Congress. Previous reports are available on the NIST web site.

This year's annual report was made possible thanks to the direct or indirect help from all the ICs. Special thanks goes out to (in no particular order), Mayra Alvarez, Mario Carranza, Haiqing Li, Sally Tilotta, Jenifer Wong, Sue Ano, David Bradley, Surekha Vathyam, Michele Newton, Tom Stackhouse, Rebecca Read, Karen Maurey, Kathleen Carroll, Michael Salgaller, Charlotte McGuinness, Nicole Guyton, Mark Rohrbaugh, Steve Ferguson, Aida Cremesti, Lisa Finkelstein, Charles Niebylski, Laura Lane-Unsworth, and of last but certainly not the least, Elaine Ray for making this happen.

ELCG Review

New Procedure for ELCG Review of Non-Complex PDs

Karen Rogers, NIH-OTT

Representatives from the intramural Technology Transfer Community (TTC), the NIH Office of Technology Transfer, and the Director, NIH Office of Intramural Research met to evaluate how the Exclusive License Consultation Group (ELCG) has functioned over the past year or so and if any modifications need to be made to how the ELCG functions. In addition, various members of the group raised concerns that the participants acknowledged, discussed thoughtfully, and agreed on a path moving forward.

Meeting Participants

Michael Gottesman (Organizer)
Mark Rohrbaugh (OD/OSP/TTIP)
Karen Rogers (OD/OIR/OTT)
Claire Driscoll (NHGRI)
David Bradley (NIDCR)
Charles Niebylski (NIDDK)
Richard Rodriguez (NCI)
Lili Portilla (NCATS)
Charles Salahuddin (NIMH)
Alan Deutch (NHLBI)
Michael Mowatt (NIAID)

ELCG Review

ELCG Review

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Also discussed was whether or not a change should be made to the current requirement that all IC Technology Transfer Offices (TTOs) present all Preliminary Determinations (PDs) and Federal Register (FR) notice objections for exclusive license to the ELCG before publishing notices in the FR and/or executing exclusive licenses. It was agreed that the ELCG, while only serving a consulting role, still provides valuable review and helpful advice. Maintaining the group ensures transparency, consistency and continuity in licensing practices across all TTOs now that the community operates in a decentralized manner. It was also agreed that the ELCG is a good forum for exchanging best practices and insights into more complex licensing activities.

With respect to presenting PDs to ELCG, two concerns were raised: 1) requiring review by the ELCG for every PD sometimes leads to delays in executing licenses; and 2) ELCG review of non-complex PDs is not necessary in most cases. It was agreed that from now on IC TTOs would identify non-complex PDs and could choose to bypass the ELCG for any such PDs. In these instances, the IC would be required to provide 48 hours (two business days) notice (by email) to the ELCG members of their IC's decision to proceed with the publication in the FR of the intent to grant an exclusive license. The draft PD and/or FR notice would be sent to the ELCG chair, who would then forward the document(s) or otherwise convey their location to the appointed ELCG representatives from the ICs, OTT and to the Special Advisor for Technology Transfer, representing the Deputy Director, for Intramural Research. The intent of the 48 hour-notice is to provide an opportunity for ELCG members to alert the IC before publication to any substantive issues or concerns regarding the PD and/or FR that would necessitate a formal presentation to the ELCG at one of their biweekly in-person meetings. No response within 48 hours from this group confirms that the IC is free to move forward.

It was also agreed that the community would revisit this new guidance in 6 months to determine if any changes need to be made to this guidance. With respect to presenting FR notice objections to ELCG, it was agreed that current procedures will remain in place.

Did You Know…

Tim Leahy, NIH-OTT

…that if you don't close out of NIH TechTracS completely, leave a record open, or keep the query editor running you "could" cause a problem with the nightly backup scans and prevent others in the community from logging in the next morning? Please help us keep the system up and running for the community by completely shutting down NIH TechTracS before you leave for the day.

NIH TechTracS

Comings & Goings

New TT Community Staff Member

Cecile Pham (NIAID/TTIPO)

In July, Cecile, an ORISE Fellow, started as a Technology Transfer Fellow for Branch C. Prior to joining TTIPO, Cecile worked at: (1) Booz Allen Hamilton, Inc. as a Contracts Administrator; (2) the Henry M. Jackson Foundation for the Advancement of Military Medicine as a Technology Transfer Agreements Specialist; and (3) Georgetown University's Office of Technology Commercialization as a technology transfer intern. Cecile earned her Master's Degree in Biotechnology from Georgetown University, and also has a paralegal certification.

Retirements

George Keller (OTT)

George retired from Federal service in March 2018.

Marguerite Miller (NIDDK)

Marguerite retired from Federal service in June 2018.

Suzanne Shope (CDC)

Suzanne retired from Federal service in June 2018.

Elaine Ray (OTT)

After a long career of 40 years in Federal service, including 28 years at OTT, we now bid a quiet adieu to our colleague Elaine Ray. As a long-time baseball fan she will now have the opportunity to see a bit more in the way of day games but we will still very much all miss her work as the versatile team player for the NIH tech transfer community.

As one of the few individuals ever so highly regarded as to have been hired twice by OTT (!), she brought considerable talent in graphic design, a strict attention to detail and an overall quiet persistence to both her job and the help she provided to her co-workers. Elaine was the "go-to" person for your Federal Register Notice, your marketing abstract for your technology, logistics details for your exhibit booth or even if you needed a striking (and award-winning) cover design for your annual office report. And of course, if you sent an email message to NIHOTT@mail.nih.gov, Elaine was your respondent who made sure you directly received the information you requested or were referred to the proper office at NIH.

For those of you that know Elaine well, you will understand that she asked that she be allowed to leave quietly and with no fuss. It is only appropriate though that we now give her a quiet shout out and a wee bit of recognition and congratulation in the very newsletter she designed for our community! *Au revoir Elaine.*

Please forward articles and newsletter suggestions to Jill Roering at roeringj@mail.nih.gov.