Combined NIH-Wide Annual Reporting

on

Technology Transfer Activities

FY 2015

Contents

Introduction

In FY14, the NIH Technology Transfer Steering Committee recommended that authority and responsibility for the implementation and execution of patenting and licensing should shift from the centralized NIH Office of Technology Transfer (OTT) to the NIH Institutes and Centers (ICs). The Technology Transfer Steering Committee concluded that the reorganization would provide an opportunity to more closely align technology transfer expertise and decisions with the Institutes, Labs and Programs generating research materials and new scientific discoveries. This recommendation was accepted by the NIH Steering Committee and went into effect in October 2015. Throughout FY15, a great deal of work took place behind the scenes to prepare for and enable the reorganization of patenting and licensing at the NIH. For example, the NIH Technology Transfer Working Group was established and has been actively guiding the transition from a centralized to decentralized Technology Transfer (TT) program at NIH.

The reorganization of TT functions at the NIH called for the community to assess and redesign the processes in-place. The OTT started the process of switching from playing a central role in licensing and patenting to a more advisory one. In addition, the office opened up the central database (called NIH TechTracS) to the ICs and made sure that the various staff at the ICs could effectively use this important tool. Extensive training was provided to the technology transfer community in preparation for the reorganization. During FY15, the OTT also began preparations to transition to a service and support role to the ICs. Continued OTT administration of royalties, monitoring and enforcement, marketing, patent docketing, and technology transfer information systems function to foster more efficient and effective commercialization of NIH, FDA and CDC inventions.

In addition to the reorganization preparations, there are many notable scientific advancements that technology transfer professionals helped move forward in FY15. This report reflects the accomplishments of technology transfer at the NIH, and demonstrates TT's commitment to meeting the changing needs of its stakeholders and to facilitating collaboration and the commercialization of NIH scientific discoveries.

Mission Statement

The mission of Technology Transfer at National Institutes of Health (NIH) is to improve public health and safety through the management of NIH, Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) inventions and in doing so serve a leading role in public sector biomedical technology transfer policy and practice. NIH, FDA and CDC are agencies of the Department of Health and Human Services (HHS).

TT at NIH serves as a bridge that connects the inventive discoveries made by scientists in the NIH, FDA, and CDC intramural research programs to commercial partners that develop these technologies into products and services to benefit public health. Without this bridge, the public would not benefit from the full potential of these biomedical discoveries. TT offices[1] across the NIH apply their policies and practices to the management of HHS's inventions, including: the appropriate use of the patent system; marketing NIH and CDC technologies to identify appropriate commercial partners; negotiating licenses to ensure the timely development of technologies; and monitoring the progress of the development of the technology to ensure commercialization milestones are reached, products are brought to the market, and royalty fees are paid.

[1] Please see Appendix A for a list of all the HHS Technology Offices within the NIH that contributed towards this report.

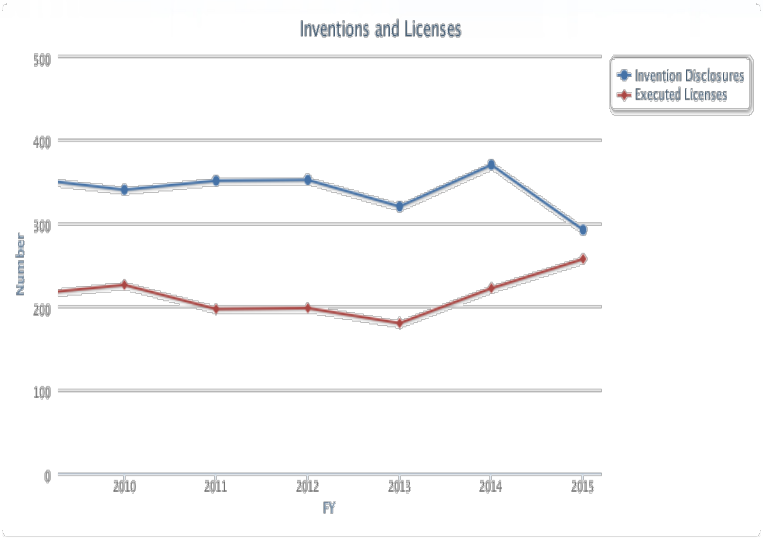
Inventions and Agreements

The technology transfer program at the National Institutes of Health is the focal point for implementation of the Federal Technology Transfer Act. Patented inventions made by NIH scientists are licensed to stimulate development of the inventions into commercial products. Unpatented research tools are also licensed to increase their availability to scientists. These activities support NIH's mission to benefit the public health and provide a financial return on public investment.

In addition, the technology transfer program negotiates terms for research collaborations between NIH and commercial and academic organizations. These collaborations leverage the strengths of each institution to advance basic and clinical research objectives. Technology Transfer also facilitates the transfer of thousands of research materials and data into and out of NIH. In FY15, NIH Institutes executed 5,826 of these collaboration and transfer agreements, including 101 new Cooperative Research and Development Agreements (CRADAs). CRADAs are an important mechanism used by NIH for many of the collaborations with industry. The new CRADAs combined with those active from prior years brought the total active CRADAs to 468, a 15% increase from FY14. This is the highest number of active CRADAs since NIH began reporting this data in FY06.

IP-Related Agreements in Numbers

- **292** - Number of **invention disclosures** that OTT received from the NIH, CDC and FDA intramural scientists.
- **275** - **License agreements executed**, **13** were **exclusive**.
- **12%** - The **increase** in the number of **non-US licenses executed** compared to FY14.
- **69** - **Licenses** issued to **small, US-based businesses**
- **86** – **Licenses** issued to **large, businesses**
- **24%** - **Increase** in number of **Commercial Biological Material Licenses** from FY14.
- **27%** - **Increase** in **licensing** of **patented inventions** for **commercial use** from FY14.



All the technology licensing activities led to a total royalty income of about $147 million, which is about a 7% increase from last fiscal year. Royalties are used by NIH Institutes to offset the costs for running a patenting and licensing program, and when available, to support mission-related activities. NIH is projecting that royalties will decline in FY18 – FY20 when certain licensed patents expire.

Readers of this report interested in more details on the above metrics, or who would like to learn more about yearly benchmarks tracked at the NIH such as Exclusive Licensing, breakdown of Licensees by Type of Business, First Time Licensees, number of Active CRADAs, etc., are encouraged to visit the NIH OTT website Metrics section at http://www.ott.nih.gov/tt-metrics. Charts displayed at this website are interactive. Viewers can zoom in, highlight, or disable certain metrics to gain greater insight.

In addition, readers can also interactively view the stories highlighted here along with all the various advances made in the Intramural Research Program (IRP) at the NIH. For viewing these, and other success stories, please visit http://irp.nih.gov.

Institutional Highlights

Towards a Healthier Tomorrow

Development of an Anti-obesity and Anti-diabetic Therapy

Scientists from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) Laboratory of Physiologic Studies and from National Institute on Drug Abuse (NIDA) have developed novel compounds that are non-brain-penetrant cannabinoid receptor-1 (CB1) antagonists, which in rodent models have potent anti-obesity, and anti-diabetic effects, but are devoid of behavioral side effects. They may also have additional beneficial effects in protecting against fibrosis and tissue damage. In 2015, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Technology Advancement Office (TAO) had advanced these patent applications, and also negotiated with multiple license applicants interested in further advancing clinical trials and development of these compounds as new therapeutics.

Scientists from the NIAAA Laboratory of Metabolic Control and from University of Oxford have developed a novel ketone ester compound that may provide delivery of optimal concentrations of ketone bodies directly to the brain and has potent anti-obesity and anti-diabetic effects. Using this ketone ester to increase the delivery and availability of ketone bodies may also have additional beneficial effects of protecting against neurodegenerative disorders, epilepsy, cognitive dysfunction, traumatic brain injury, radiation injury, free radical damage, and metabolic disorders and in enhancing physical performance. In 2015, the NIDDK TAO advanced licensing strategies and negotiations with its' collaborators and other parties interested in the therapeutic and commercial use of these novel ketone esters.

Women's Health Research

The work of National Institute of Child Health and Human Development (NICHD) in the areas of women's health and contraception has also benefited greatly from the services of the Technology Transfer Center (TTC), including management of the NICHD invention portfolio. Under a long-standing CRADA relationship with HRA Pharma, a number of co-owned patent applications have been filed by the CRADA partner directed to treating uterine fibroids and to methods of contraception; this includes an NICHD co-invention made in FY15.

Home Monitoring

Under a collaboration agreement, National Eye Institute (NEI) is accessing a commercial entity's ForeSee® home monitoring device to be used in conjunction with one or more NEI clinical trials. These trials include a trial on age-related macular degeneration (AMD), which is the third-largest cause of vision loss worldwide, and currently afflicts almost 10 million individuals in the United States alone. The device may provide a simple means to monitor dark adaptation as an early indicator of AMD. There is no therapy to restore vision loss due to retinal degeneration, but early intervention can slow AMD progression and associated retinal degeneration.

Non-invasive Blood Monitoring

NIDA and a commercial partner are working under a collaboration agreement to test a new blood micro-sampling device for human use. The effectiveness of the device will be evaluated based on a comparison of

standard blood analyses of blood drawn with the device or by traditional methods. The device would be less-invasive and have a safer sampling approach. In addition, the samples can be collected by participants themselves without requiring trained medical staff, as compared to traditional blood collections. This device may be useful in a variety of blood monitoring applications, including patient compliance with drug treatment regimens.

Regenerative Medicine

National Institute of Dental and Craniofacial Research (NIDCR) was the first institute within the NIH to license a stem cell for clinical application. Issuance of a patent was an additional brick in the foundation of this successful technology transfer effort. NIDCR had seven other patents issued this year.

Better Understanding Pneumonia, Sepsis and Trauma

Plasma gelsolin plays an important role in the regulation of inflammation and infection in humans and animal models. Decreased circulating concentrations of gelsolin are associated with poor prognosis in a variety of clinical conditions including pneumonia, sepsis and trauma. National Institute of Allergy and Infectious Diseases (NIAID) Technology Transfer and Intellectual Property Office (TTIPO) has negotiated and executed a Research and Collaboration Agreement (RCA) among NIAID, the NIH Clinical Center (CC) and BioAegis Therapeutics, Inc. to collaborate to elucidate the role of gelsolin in human diseases with significant inflammatory and infectious complications.

Anti-Inflammatory Study

National Institute on Aging (NIA) and Araim Pharmaceuticals, Inc. are collaborating under a CRADA to study the effects of a small anti-inflammation peptide in preclinical models to examine its potential to enhance and preserve life span and reduce tissue inflammation.

Evaluation of Proprietary Diabetes Drug

NIA and Peptron, Inc. are collaborating under a CRADA to evaluate Peptron's proprietary sustained release (SR) formulation of the Type 2 diabetes drug, Exenatide, in preclinical models. The project is directed to finding treatments for neurodegenerative disorders with currently unmet medical needs, such as Alzheimer's disease (AD), Parkinson's disease (PD), Traumatic Brain Injury (TBI), and Multiple System Atrophy (MSA).

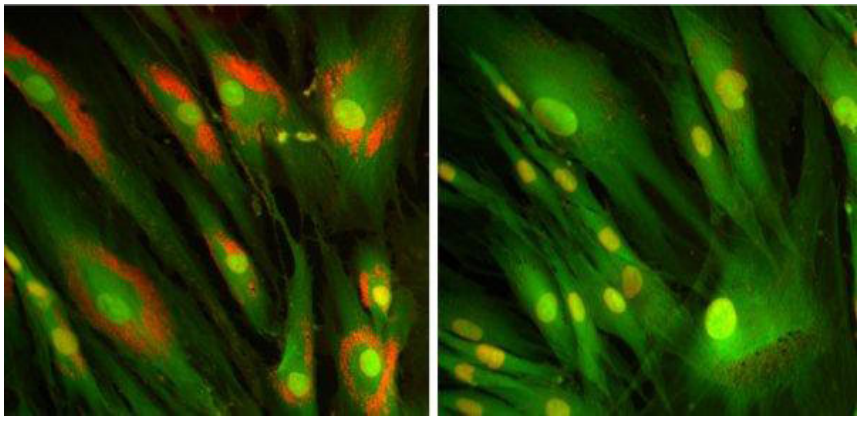
Mechanism Driving Compulsive Drinking

NIDA and a commercial partner are working under a collaboration agreement to test the effects of mifepristone, a selective progesterone receptor antagonist, on alcohol drinking in alcohol dependent and nondependent rats. Alcoholism is a disease characterized by a compulsion to seek and ingest alcohol, as well as a loss of control over intake and emergence of a negative emotional state during withdrawal. This project is directed to better understanding the mechanisms that drive compulsive drinking and potentially new means to modify alcohol associated compulsive behavior.

Advancing Discovery for Rare Diseases

Treating Niemann-Pick Disease

Lysosomal storage diseases comprise about 50 rare inherited disorders that usually affect children, and are often fatal. Fatty materials accumulate in the cells and tissues of the body, which can damage the brain, peripheral nervous system, liver, and other organs and tissues. A three-way collaboration between National Center for Advancing Translational Sciences (NCATS), NICHD and a newly launched biotechnology company, Vtesse, Inc., aims to develop treatments for Niemann-Pick Type C1 (NPC) and other lysosomal storage disorders. Under the CRADA, Vtesse is supporting the ongoing phase I clinical trial for NPC at the NIH CC, led by NICHD researchers who have been evaluating the safety of the drug cyclodextrin. NIH's orphan drug designations in the United States and Europe for the use of cyclodextrin for NPC1 have been transferred to Vtesse under the agreement. Vtesse is currently in the process of enrolling a total of 51 patients at approximately 20 sites throughout US, Europe and other locations. In addition to its Orphan Drug status in both the US and EU, cyclodextrin has received a Breakthrough Therapy designation status from the US FDA. In other studies, the NCATS team will optimize delta-tocopherol compounds for further testing as potential single treatments or as combination therapies with cyclodextrin. Vtesse has exclusively licensed several NCATS patent applications specifically for their use as new therapies for the treatment of lysosomal storage disorders, and will fund pre-clinical studies at NCATS to further optimize and develop these treatment options. NICHD will operate a site and participate in data analysis from all US and foreign sites. This trial may advance this compound type as the first FDA approved treatment for NPC. The basic research component is being conducted at NCATS and is directed to follow on indications.



In the image on the left, fibroblasts homozygous for mutations in NPC1 demonstrate an increased accumulation of red Lysotracker staining indicative of the storage disease. On the right, addition of cyclodextran rescues this lysosomal storage defect. (Image courtesy NIH Image Library)

Potential Treatment for Hereditary Inclusion Body Myopathy

Hereditary Inclusion Body Myopathy (HIBM) is a rare and slowly progressing muscle wasting disease for which there is no effective therapy. Scientists at National Human Genome Research Institute (NHGRI) and NCATS have jointly developed a small molecule, N-acetyl D-mannosamine (ManNAc), for the potential treatment and eventual reversal of this disease. New Zealand Pharmaceuticals (NZP) had earlier exclusively licensed this technology from NHGRI, and much of the pre-clinical validation of the molecule and Phase 1 human safety trials were completed with support through NCATS' Therapeutics for Rare and Neglected Diseases Program. The original NIH licensee, NZP, recently transferred the Investigational New Drug (IND) file and other future development rights to Escala Therapeutics. NHGRI and NCATS successfully facilitated this transfer in 2015. The Phase 1 human safety trials had already been completed, largely with NCATS' support,

and the Phase 2 trials were jointly started with NZP. With the transfer of the IND and the exclusive commercial license from NZP to Escala, and the latter's commitment to ManNAc, there is now a clear commercial path forward for treating HIBM with ManNAc.

Clinical Trials for Treatment of Giant Axonal Neuropathy

Giant Axonal Neuropathy (GAN) is a rare childhood disorder causes children to gradually lose the ability to balance themselves, move their muscles and to feel certain sensations. Most children born with GAN do not survive beyond their early 20s because of progressive impairment of their ability to breathe. In May 2015, the first patient was enrolled in a clinical trial conducted by National Institute of Neurological Disorders and Stroke (NINDS) for a gene therapy for the treatment of GAN. This trial was made possible through several NINDS technology transfer agreements and is the culmination of years of development of this technology by the non-profit organization Hannah's Hope Fund (HHF) and their partnership with researchers at the University of North Carolina at Chapel Hill (UNC) Gene Therapy Center, Bamboo Therapeutics and University of Pennsylvania.

NINDS researcher Carsten Bonnemann, who leads the trial at NINDS, stated that this effort is a fundamental step towards developing a treatment for GAN and is also paving the way for similar, gene transfer-based treatments for other neurological disorders in which nerve cells of the spinal cord and brain need to be targeted, including spinal muscular atrophy. Engaging to advance the impact of efforts such as this path-breaking treatment for individuals affected by neurological disorders is the core mission at the NINDS, and NINDS technology transfer is proud to play a role in helping move this technology forward.

Treatment of Glygogen Storage Disease

Under a CRADA, pre-clinical work is being pursued with a small biotech, Dimension Therapeutics, Inc., that is advancing a rare-disease therapy for Glygogen Storage Disease Type 1a (GSD1a) based on NICHD-developed constructs. NICHD is performing translational studies under the CRADA. Currently there is no FDA treatment for GSD1a, which, left untreated is lethal in children. Another CRADA was put in place for a preclinical project to test a family of seven proprietary compounds that inhibit necroptotic pathways. This project may lead to alternative strategies for treating NPC.

Helping Neuroscience

Neuroscience-focused Initiative

National Institute of Mental Health (NIMH) and NINDS are working together to establish a neuroscience-focused technology transfer collaboration designed to take advantage of the common neuroscience underpinnings that form the foundation of the ICs. This initiative is the latest among a variety of neuroscience-based collaborations at the NIH and seeks to utilize scientific, administrative, and technology transfer resources of both ICs to maximize impact, efficiency and effectiveness. Key to the success of this initiative will be interactions with the relevant stakeholders for technology transfer matters, including information collection and distribution, technology review and assessment, and outreach to the neuroscience community. Among the key accomplishments of FY15 was establishing a framework for an integrated database that combines relevant information for ease of access and to facilitate the coordinated efforts between the ICs.

Human Brain Collection Core (HBCC) and NeuroBioBank

NIMH technology transfer provided expertise in developing Material Transfer Agreement (MTA) templates for various initiatives designed to facilitate the distribution of samples to the scientific community for the study of the nervous system and mental disorders. The input provided by the office ensured that transfer of materials was in compliance with all NIH policies and that the individual programmatic needs of each initiative were met. These initiatives include the Human Brain Collection Core (HBCC) and the NeuroBioBank. Both programs were created to facilitate research advancement through the collection and distribution of human post-mortem brain tissue for the study of various neurological disorders. The NeuroBioBank is also supported by NINDS, NICHD and NIMH's collaboration with both ICs to provide technology transfer support for this program was instrumental in its development.

Translational Neuropsychopharmacology Task Force (TNTF)

The TNTF was created at NIMH to invigorate psychiatric drug discovery by facilitating and de-risking the discovery and development of novel treatments. The scope of this important NIMH initiative includes providing support for the discovery and development of new treatments for psychiatric disorders including target validation, biomarker development, IND enabling studies, and Phase I safety / tolerability and Phase II proof of concept studies. The TNTF is comprised of a panel of experts from the pharmaceutical industry and the NIH who critically review, prioritize and recommend new proposals for support by the NIMH. NIMH technology transfer has provided support for this initiative by identifying and assessing potential mechanisms of collaboration and by providing advice regarding patenting and licensing strategy.

Advancing Cancer Discovery

FDA Approval of Immunotherapy to Treat Rare Childhood Cancer

In March 2015, FDA approved dinutuximab (Unituxin) as part of treatment for children with high-risk neuroblastoma. The approval was based on the results of two major Children's Oncology Group (COG) research trials and culminates a remarkable collaborative research effort that spanned more than two decades of research. The search for a National Cancer Institute (NCI) CRADA partner for the commercial marketing of Unituxin began in April of 2009. The search and selection effort was orchestrated by NCI TTC. In July 2010, NCI and United Therapeutics Corporation (UTC) entered into a CRADA to conduct Phase 3 clinical studies (COG and UTC sponsored), and to transfer Unituxin manufacturing technology from NCI's Biopharmaceutical Development Program to UTC. Additional studies of Unituxin, a chimeric monoclonal antibody composed of a combination of mouse and human DNA will continue under the NCI/UTC CRADA.

Unituxin Injection
(Image courtesy NCI)

Furthering Development of Brachyury Vaccines

Presence of the brachyury gene has been identified as a diagnostic marker of certain malignant tumors. A Clinical Trial (CT) CRADA executed between NCI and Etubics Corporation in May 2015 allows NCI's Laboratory of Tumor Immunology and Biology (LTIB) to collaborate with Etubics in preclinical and clinical studies to develop Etubics' proprietary adenovirus platform for the treatment or prevention of human cancers.

This particular CT CRADA with Etubics is one of many agreements involving the development of brachyury vaccines, and it is representative of a larger technology transfer effort. Beginning in 2007, NCI developed investigational cancer vaccines that induce a specific, targeted immune response against cancer cells expressing the brachyury protein. Currently, NCI is collaborating with three commercial partners, including Etubics, to develop brachyury vaccines. These collaborations led to the rapid translation of these investigational therapeutic vaccines into the clinic, and these vaccines have the potential to revolutionize how researchers and physicians treat a wide range of cancers. In addition to the CT CRADA with Etubics Corp., NCI has executed CRADAs with Celgene Corporation and Bavarian Nordic, the other two commercial partners collaborating with NCI to develop brachyury vaccines with unique, proprietary, vector technology platforms.

Study anti-cancer, anti-inflammatory compounds

Bromodomain and Extra-Terminal motif protein (BET) inhibitors are a class of drugs with anti-cancer, immunosuppressive, and other effects. Under a CRADA, ConverGene and NCATS, through its Division of Pre-Clinical Innovation, will work together to further optimize ConverGene's small molecule BET inhibitors and differentiate them mechanistically. Drug Absorption, Distribution, Metabolism and Excretion as well as toxicity profiles of the molecules will also be improved to differentiate the new drugs from competitors' clinical stage BET inhibitors.

Combating Infectious Diseases

Diagnostic technologies-related initiative

NIDDK in conjunction with NIAID's Small Business Innovation Research (SBIR) program participated in a special Request for Applications (RFA) for diagnostic technologies developed in NIDDK or NIAID intramural laboratories. The peptide nucleic acid diagnostic developed in the Laboratory of Bioorganic Chemistry received four proposals, one of which was funded. The objective is to create a simple, accurate, inexpensive diagnostic for determining HIV viral load. The product prototype as proposed should not require trained medical workers to run the tests.

At NIAID, Dr. Stephen Leppla and his staff cloned a useful hybridoma cell line. This cell line is based on duplexes of DNA and RNA hybrids that in turn, are indicative of abnormal states such as viral infections. Kerafast, a Boston-based life sciences company, licensed this unpatented biological material in FY 2014 and made it commercially available. KeraFAST has since shipped more than 700 units to researchers in 28 countries across 5 continents.

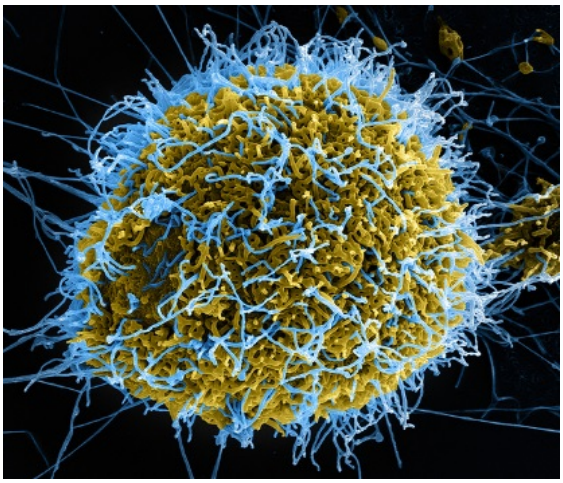
Anti- Hepatitis C Virus Therapy

Scientists from the NIDDK Liver Diseases Branch and from NCATS identified certain known antihistamines that also have activity against Hepatitis C virus (HCV). Among them was an over-the-counter drug called

chlorcyclizine (CCZ), approved in the 1940s to treat allergy symptoms. NIDDK has been advancing clinical studies of CCZ in the NIH CC. In addition, new molecules have been designed and tested based on this discovery and pending NIH patent applications have now been licensed to a commercial partner to show the safety and efficacy of these molecules as a new therapy against HCV, and to support further clinical trials of new HCV therapeutics. Interestingly, these molecules appear to be acting via a unique host-mediated anti-viral mechanism which might result in the identification of a new class of therapeutics.

Fighting Ebola

In FY15, the NIAID TTIPO continued to actively support NIAID in its fight against Ebola. 77 Ebola-related agreements were executed in FY 2015. These agreements included 1 CRADA, 17 Clinical Trial Agreements (CTAs), 5 RCAs, 7 Memorandum of Understanding Agreements (MOUs), 24 MTAs and 23 Confidentiality Disclosure Agreements (CDAs), providing wide ranged support for NIAID's research activities on Ebola. For example, 7 CTAs, 1 MOU and 1 CDA were signed in FY 2015 to support NIAID's research and collaboration on Chimpanzee Adenovirus vector (cAd3) Ebola vaccines. cAd3 Ebola vaccines were co-invented by Dr. Gary Nable, Dr. Nancy Sullivan and their staff in Vaccine Research Center (VRC), NIAID as well as inventors from US Army Medical Research Institute of Infectious Diseases (USAMRIID) and GlaxoSmithKline. These agreements were instrumental for the initiation of phase 1 and phase 1b clinical trials in Mali, UK and Uganda.



Ebola virus particle
(Image courtesy NIH Image library)

Due to the Ebola outbreak in West Africa, the NIH Director requested that NCATS help coordinate a drug screening project called the Ebola Global Call for Action in collaboration with organizations such as the European Federation of Pharmaceutical Industries and Associations, Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturer's Association (PhRMA). The purpose of the project is to determine if there are any industry-owned drugs (either under development or already on the market) that could be used to treat Ebola. NCATS served as the lead and coordinated the implementation of CDAs between 10 pharma and biotechs, NCATS, NIAID and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). NCATS, NIAID and USAMRIID Technology Transfer Office colleagues helped develop a common template that was used for early discussions between them and the joining pharma and biotech partners. After the CDAs were executed, subject matter experts from the NCATS, NIAID and/or USAMRIID initiated conversations with the pharma and industry partners to determine next steps. All the CDAs were negotiated and executed in a record 7 weeks period of time even as they required coordination with three other organizations.

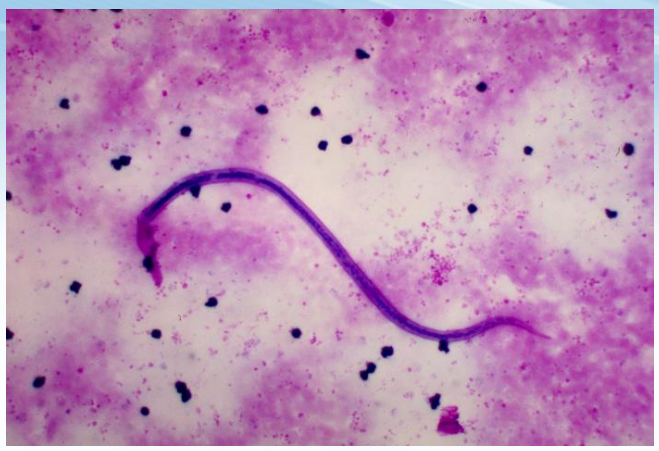
Vaccine against Dengue virus

Dengue is a mosquito-borne flavivirus present worldwide in tropical and semitropical regions. It is estimated that 500 million infections occur annually, resulting in more than 2 million cases of severe dengue and 21,000 deaths. An effective vaccine is a public health priority. TTIPO has negotiated and executed a CRADA between

NIAID and Merck Sharp & Dohme Corp. to collaborate to evaluate the safety and efficacy of prime-boost strategies for dengue vaccines, employing NIAID's tetravalent live attenuated Dengue virus TV- 003 and/or TV-005 vaccine formulation and Merck Sharp & Dohme Corp.'s, tetravalent subunit Vl80 vaccine formulation.

Detecting Filaria

Lymphatic filariasis (LF), commonly known as elephantiasis, is a devastating infectious disease. Filariasis is an infection caused by *Wuchereria bancrofti* (Wb123), a parasitic worm transmitted by mosquito bites. The current antibody tests used for monitoring in LF elimination programs suffer from poor specificity because of considerable geographical overlap with other filarial infections. Dr. Thomas Nutman and his staff in NIAID have found Wb123, an antigen specifically reacting with Wb with no cross reactivity against other closely related filariae. In addition, Wb123 is expressed primarily by the infective stage larvae of Wb so that it may detect the presence of filariae in the prepatent period before microfilariae are present in the blood and before clinical symptoms appear. InBios International, Inc. licensed this patented technology in FY 2014. Its Research Use Only (RUO) product, Filaria Detect™ system, is being used by researchers in more than 9 countries across 6 continents. Its In-Vitro Diagnostic (IVD) application is still under development.



***Wuchereria bancrofti* microfilaria in a thick blood smear (Image courtesy CDC)**

Helping Clinical Trial Sites

The NIAID TTIPO worked with several NIAID programs to improve procedures and strengthen collaborations. For example, TTIPO assisted the Division of Allergy, Immunology and Transplantation (DAIT) in implementing their CDA procedure with clinical site contractors. This procedure ensures the protection of confidential information when DIAT distributes third party's clinical reagents. TTIPO worked with the NIH Tetramer Core Facility (NTCF), a program supported by a NIAID contract, to review in-license agreements and patent rights of materials they distribute. The review led NTCF to improve their procedure to safeguard legal distributions of their materials.

Fostering Collaboration

Streamlining Data Sharing

Drug resistant bacteria and molds are on the rise in the U.S. NIH CC identified a need and TTC developed a custom template agreement designed to facilitate the more immediate transfer of databases to hospitals and other nonprofit entities with minimal time delay for negotiation. The template agreement provides an off-the-shelf solution for data sharing and use. The transferred information will provide more rapid identification of these disease organisms in patients leading to faster and more efficient treatments.

Streamlined NIH CRADA Process

NCI's commitment to speed-up the CRADA process resulted in streamlining changes that went into effect in the fall of 2015. NIH has eliminated some internal clearance steps resulting in time savings for these agreements.

Closer Collaboration with Pfizer

A collaboration between Pfizer's Center for Therapeutic Innovation (CTI) and the Joint Steering Committee (JSC) at NIH was formally established in October 2014. The purpose of this collaboration is to identify biologic compounds with activity in a pathway or target of interest to an NIH intramural researcher and to Pfizer. The aim is to move these compounds into the clinic for rapid testing. The CTI model is the first NIH-wide biologics initiative with a pharmaceutical partner that NCATS OSA has coordinated. NCATS, the primary point of contact for the Pfizer CTI Program, negotiated an NIH-wide umbrella on behalf of all NIH intramural researchers. As part of the CTI Program, the JSC provides quarterly updates about the program to the NIH Technology Transfer community and communicates each CTI solicitation to the Intramural Research Program (IRP), as well as clarifying scientific priorities for the CTI proposals. In fiscal year 2015, NCATS staff and Pfizer have selected two possible NIH IRP projects.

New Strategies to Drive Commercialization

Neuro Startup Challenge

NIH partnered with the Center for Advancing Innovation (CAI), a non-profit, to execute the Neuro Startup Challenge (NSC), a competition to commercialize neuro-related technologies from multiple NIH ICs including NCI, NIDA, NINDS, NICHD, and NIA. The winners of the NSC were announced in May 2015, and the winning teams are working to create their startup businesses.

The NSC was based on the award-winning Breast Cancer Startup Challenge model which is a new way to facilitate advancement of multiple federal technologies at one time. Collectively, the challenges helped to: create 27 startups; advance 23 cancer-related technologies; enable 109 teams to compete; train 1000+ entrepreneurs.

Nanotechnology Startup Challenge for Cancer (NSC2)

NCI, National Heart Lung and Blood Institute (NHLBI) and National Institute of Biomedical Imaging and Bioengineering (NIBIB) entered into an agreement with CAI to create a third startup challenge – the NSC2. The goal of the NSC2 will be to form startup companies to advance early stage nanotechnology technologies that require significant additional R&D before they would be ready for commercialization. Teams were able to enter the NSC2 when the challenge launched in October 2015.

Kudos and Recognitions

White House Office of Science and Technology Policy (OSTP)

- The NCATS Director and the NCATS Office of Strategic Alliances (OSA) Director were invited to a roundtable event to discuss how to develop Federal Labs. The event was a great opportunity for NCATS to showcase its programs. NCATS OSA worked closely with an OSTP Economic Policy Fellow in preparing agenda topics presented by the NCATS Director. The event generated several positive social media Twitter "tweets."
- The HHS and in particular, the NIH OTT was mentioned by the White House in the OSTP blog as the lead agency to make available NIH innovations and collaboration data in an open format that individuals and companies can leverage to accelerate commercialization of scientific discoveries at the NIH.

NIH Director's Award

- NIH OTT Staff received an NIH Director's Award for leading and overseeing the reorganization of technology transfer activities at NIH.
- NCATS OSA Staff received an NIH Director's Award for their initiative in the Ebola drug screening project as well as for collaborating with Vtesse, Inc. towards developing a treatment for Niemann-Pick Type C1.
- NIAID Technology Evaluation Advisory Committee (TEAC) was presented with a Merit Award for exceptional contributions to the valuation and management of NIAID technologies as a member of NIAID's Technology Evaluation Advisory Committee.
- NIAID Clinical Trial Agreement Working Group was recognized for updating and improving NIAID's Clinical Trial Agreement templates to reflect essential and important changes in regulations, policy, and practices.

Federal Laboratory Consortium (FLC) Mid-Atlantic Region

- NCI was selected for the following two 'Excellence in Technology Transfer' awards by the FLC Mid-Atlantic Region.
    - "Development of First Immunotherapy to Treat Chordoma, Rare Bone Cancer."
    - "Discovery to Commercialization: New Immunotherapy for Rare Childhood Cancer, Neuroblastoma."
- NCATS and NICHD were recognized for their role in collaborating with Vtesse, Inc. towards developing a treatment for Niemann-Pick Type C1.
- NIAID was recognized for contributions to the "International Technology Transfer Mentoring Program."

HHS Idea Lab - Ignite Accelerator award

In April 2015, the NIH OTT as well as CDC won an HHS Idea Lab - Ignite Accelerator award to streamline and enhance CDC technology transfer processes and inventor outreach. The Idea Lab provides start-up related guidance to teams over a 3-month period that culminates in a business proposal pitching event.

Appendix A

HHS Technology Transfer Offices

NIH OTT – NIH Office of Technology Transfer
http://www.ott.nih.gov

CDC - Centers for Disease Control and Prevention
CDC Office of Technology and Innovation

http://www.cdc.gov/od/science/technology

NCATS - National Center for Advancing Translational Sciences
NCATS Office of Strategic Alliances

https://ncats.nih.gov/alliances/about

NCI - National Cancer Institute
NCI Technology Transfer Center

http://techtransfer.cancer.gov

Service Center for:
- CC - NIH Clinical Center
- CIT - Center for Information Technology
- NCCIH - National Center for Complementary and Integrative Health
- NEI - National Eye Institute
- NIA - National Institute on Aging
- NIDA - National Institute on Drug Abuse
- NICHD - Eunice Kennedy Shriver National Institute on Child Health and Human Development
- NIMHD - National Institute on Minority Health and Health Disparities
- NLM - National Library of Medicine

NHGRI - National Human Genome Research Institute
NHGRI Technology Transfer Office

https://www.genome.gov/techtransfer

NHLBI - National Heart, Lung, and Blood Institute
NHLBI Office of Technology Transfer and Development

http://www.nhlbi.nih.gov/research/tt

Service Center for:
- NIAMS - National Institute of Arthritis and Musculoskeletal and Skin Diseases

- NIBIB - National Institute of Biomedical Imaging and Bioengineering
- NIDCD - National Institute on Deafness and Other Communication Disorders
- NIEHS - National Institute of Environmental Health Sciences
- NINR - National Institute of Nursing Research

NIAID - National Institute of Allergy and Infectious Diseases

NIAID Technology Transfer and Intellectual Property Office

http://www.niaid.nih.gov/labsandresources/techdev

Service Center for:

CDC - Centers for Disease Control and Prevention (CDC)

NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK Technology Advancement Office

http://www.niddk.nih.gov/about-niddk/offices-divisions/technology-advancement-office

Service Center for:

- NIAAA - National Institute on Alcohol Abuse and Alcoholism
- ORS - Office of Research Services

NIDCR - National Institute of Dental and Craniofacial Research

NIDCR Office of Technology Transfer and Innovation Access

http://www.nidcr.nih.gov/research/NIDCRLaboratories/Intramural_Technology_Transfer_Office

NIMH - National Institute of Mental Health

NIMH Office of Technology Transfer

http://www.nimh.nih.gov/labs-at-nimh/scientific-director/office-of-technology-transfer

NINDS - National Institute of Neurological Disorders and Stroke

NINDS Technology Transfer Office

https://tto.ninds.nih.gov