NIH TECHNOLOGY TRANSFER ACTIVITIES

Annual Report FY-2017

CONTENTS

MISSION STATEMENT

The mission of Technology Transfer at National Institutes of Health (NIH) is to facilitate partnerships with a wide array of stakeholders, and effectively manage the inventions conceived by scientists working at the NIH, Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). In doing so, NIH Technology Transfer supports the larger NIH mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Working on behalf of the NIH, the FDA and the CDC – all agencies of the Department of Health and Human Services (HHS), Technology Transfer offices[1] across the NIH apply responsive, and sometimes creative approaches to meet the needs of all parties involved, operating with a goal of moving scientific research and discovery forward for the benefit of public health. Technology Transfer at NIH:

- Protects U.S. intellectual property and the discoveries conceived by NIH, FDA and CDC intramural researchers. This includes working with researchers to determine if an invention warrants patent protection, overseeing the filing of Employee Invention Reports (EIRs), and coordinating the patenting filing and prosecution process.

- Serves as a bridge through marketing and communications, connecting the inventive discoveries made by scientists in the NIH, FDA, and CDC research programs to commercial partners with the capability of developing these technologies into products and services to benefit public health. Without technology transfer, the full potential of these inventions would not be realized, and the public would not receive the full benefit of these biomedical discoveries.

- Facilitates partnerships with outside parties to allow for joint collaboration.

- Negotiates licenses and collaborative agreements such as Cooperative Research and Development Agreements (CRADAS) to ensure the timely development of federal technologies, that contribute to society by driving economic growth and productivity; These collaborations leverage the strengths of each institution to advance basic and clinical research objectives.

- Monitors the development of these technologies to ensure commercialization milestones are reached, products are brought to the market, and royalty fees are paid.

- Facilitates the transfer of thousands of research materials and data into and out of NIH.

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

INTRODUCTION

In FY2017, the NIH Technology Transfer (TT) Community entered the second full year of patent and license decentralization, with the NIH Institutes and Centers (ICs) in control of patenting and licensing decisions, and the Office of Technology Transfer (OTT) serving a purely service and support function to the NIH Technology Transfer Offices (TTOs), the FDA and the CDC. Efforts by the community reflected a successful year, which are represented by the metrics presented in this report and in the OTT Web Site -- https://www.ott.nih.gov/reportsstats/ott-statistics. Particularly significant is the 14% increase in Cooperative Research and Development Agreements (CRADAs) and 15% increase in executed license agreements.

In the second quarter of 2017, the Health and Human Services (HHS) Technology Transfer Community saw the FDA assume all FDA technology transfer activities that were previously conducted by the OTT. Limited services were still being provided by the OTT to facilitate a smooth transition and the FDA TTO continued to participate in the Technology Transfer Policy Board and community collaborations. This marks the first year that FDA metrics and information are not contained in this report.

OTT continues to provide management and oversight of the collection and disbursement of royalties, monitor and enforce patent rights/licensing agreements, coordinate the payment of all patent annuities, market and communicate with existing and potential licensees, and provide legal docketing services. In addition, OTT continues to support the TT community through management of the NIH TechTracS, which is the system of record for all patent and license data and information, and the OTT SharePoint site, which assists the community with the transfer, collaboration and management of vital documents and information. The number of users of NIH TechTracS grew from 82, prior to the reorganization, to an all-time high 236. During this same time, the OTT SharePoint site saw an increase of 87 user to 516 users. System users are NIH and CDC-wide, with secure access points from across the country.

Because these systems are aging and there are still multlple shadow systems used by the decentralized TT community, the NIH has identified the need for a centralized IT platform to support technology transfer. To implement this new platform, the NIH Capital Improvement Fund has committed the necessary funding, through the OTT, to develop the Enterprise Technology Transfer (ETT) System. During FY 2017, subject-matter experts throughout the NIH TT Community came together to analyze the complex interrelationship between the various technology transfer offices, researchers and external stakeholders, and to dissect the complexity of the resulting system requirements. This ongoing improvement is the key to maintaining a system that will not only provide the functionality currently needed by the TT community, but also grow with the community, address new requirements as user needs evolve. We look forward to development of this new IT system in FY2018.

Our TT professionals promoted the development and commercialization of many notable scientific advancements in FY2017. This report reflects the accomplishment of technology transfer at the NIH and CDC, and demonstrates the community's commitment to meeting the changing needs of our stakeholders and facilitating the collaboration and the commercialization of NIH scientific discoveries.

INVENTIONS AND AGREEMENTS

The Technology Transfer (TT) Program at the National Institutes of Health is the focal point for implementation of the Federal Technology Transfer Act. Technology licensing specialists in the NIH Institutes and Centers license patented inventions to pharmaceutical, medical device and biotechnology companies in order to stimulate development of technologies into commercial products. These licensing specialists also transfer materials to non-profit research institutions and license for a fee to commercial entities unpatented research tools to increase their availability to the scientific community. These activities support the NIH's mission to benefit the public health and to provide a financial return on public investment.

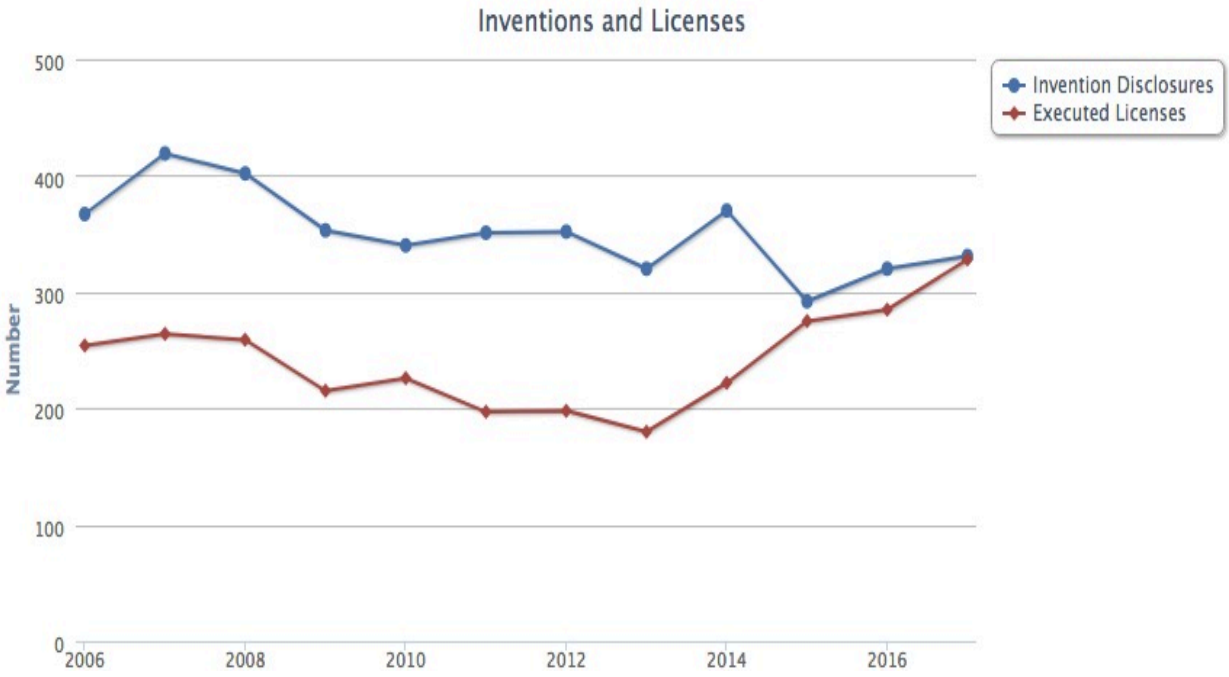
In addition, the Technology Transfer Program negotiates terms for research collaborations between NIH and commercial and academic organizations. These collaborations leverage the strengths of each institution to advance basic and clinical research objectives. Technology Transfer also facilitates the transfer of thousands of research materials and data into and out of NIH.

In FY17, NIH Institutes executed over 8,345 of these collaboration and transfer agreements, including over 110 new CRADAs. CRADAs are an important mechanism used by NIH for many of the collaborations with industry. The total number of active CRADAs jumped from 367 to 419, a 14% increase from FY16.

IP-Related Agreements in Numbers[2]

- 331 - Number of invention disclosures reported.
- 328 - License agreements executed, a 15% increase from last year.
- 35 - Exclusive License agreements executed.

[2] includes NIH and CDC data


Inventions and Licenses
Invention Disclosures
Executed Licenses
Number
500
400
300
200
100
0
2006
2008
2010
2012
2014
2016


Licensee for U.S. or non-U.S.
US
non-US
No of Licenses
250
200
150
100
50
0
2006
2008
2010
2012
2014
2016

INSTITUTE AND CENTER UPDATES

NCATS — National Center for Advancing Translational Sciences

The National Center for Advancing Translational Sciences (NCATS) Office of Strategic Alliances (OSA) had a 10% increase in Research Collaboration Agreements (RCAs) and 28% increase in CDAs executed from FY 2016 to FY 2017. In addition, there was a concerted effort to assure all agreements with term limits were either closed because the project had been completed, or amended to enable the project to continue. While some of these were template agreements, many required ample time for negotiations to terms acceptable to the NIH. Given the varied nature of NCATS' collaborations with industry, academia, patient groups, et al., many agreement negotiations require significant time and effort to educate our counterparts on the particulars and requirements of collaborating with the federal government, and particularly NCATS/NIH.

NCATS, NGYL1.org and Retrophin, Inc. CRADA

NGLY1 Deficiency is a rare and debilitating monogenic disease characterized by developmental delays, seizures, an inability to produce tears, and for which there are currently no approved therapeutic options. The National Center for Advancing Translational Sciences (NCATS), Therapeutics for Rare and Neglected Diseases (TRND) Biology Laboratory, along with patient foundation, NGLY1.org, and biopharmaceutical company Retrophin, Inc. are collaborating on a research plan to develop different assays for small molecule high-throughput screening in both an effort to better understand the biology of the disease, as well as identify potential small molecules to be developed as a therapeutic for patients suffering from NGLY1 Deficiency.

Development and Negotiation of Research Collaboration Agreement (RCA) and Inter-Institutional Agreement (IIA) between NCATS and the Universidad Pontificia Catolica (UPC) de Chile for Development of Alzheimer's Compounds

The NCATS Office of Strategic Alliances (OSA) helped establish an RCA for this long standing NCATS National Chemical Genomics Center project. NCATS and UPC investigators have developed two new selective and powerful inhibitors of the Kinase c-Abl, both of which pass the Blood Brain Barrier (BBB) and reduce the progression of cognitive impairment and neurodegenerative pathology of Alzheimer's disease in mice models. NCATS and UPC have developed new Intellectual Property (IP) on these two inhibitors so an Inter-Institutional Agreement (IIA) is being negotiated in order for NCATS to take the lead in filing patents and licensing the compounds. The IIA negotiation has also been an educational and mentorship activity for UPC.

Update on the CRADA/Exclusive License with Vtesse/Sucampo

This three way collaboration between the NCATS, National Institute of Child Health and Human Development (NICHD), and Vtesse, Inc., continues to further develop a treatment for Niemann-

Pick disease type C (NPC) and other lysosomal storage disorders. Vtesse was purchased by local Maryland biotech company, Sucampo. NCATS OSA staff worked closely with NCATS scientific staff in facilitating the involvement of this new partner into the collaboration. NCATS OSA worked closely with NICHD and Sucampo staff to amend and modify the research plan to include new studies that the parties wish to further develop.

NCI — National Cancer Institute

FDA Approval of Personalized Cancer Treatment to Cure Deadly Blood Cancers

The NCI, in collaboration with Kite Pharma, Inc. (acquired by Gilead Sciences in October 2017), developed a new FDA approved treatment shown to cure several types of deadly blood cancers. This unique therapy utilizes live cells, and harnesses the power of a patient's immune system to combat their cancer. A subset of a patient's own immune cells, called T cells, are genetically modified to recognize the cancer cells. The patient's cells are collected, modified and grown in the laboratory until they number in the billions. These programmed cancer-fighting cells are then re-infused into the patient, armed with the ability to potentially recognize and attack cancer cells. This treatment is a "live therapy" consisting of a single infusion.The target that these engineered cells recognize is called CD-19; it is expressed in B cells, a subset of immune cells.

NCI's Technology Transfer Center (TTC) played a proactive role in this discovery-to-commercialization story. It began with facilitating a partnership with an industry partner strongly committed to advancing this novel approach for the treatment of B-cell Non-Hodgkin Lymphoma (NHL). This led to negotiating a complex, clinical trial CRADA involving both pre-clinical studies and later clinical trials using treatments made under stringent Good Manufacturing Practices (GMP) conditions. Successful development of the technology required effective coordination of diverse, multi-disciplinary programs within and external to the NCI – comprising clinical compliance, regulatory affairs, GMP grade manufacturing, research scientists and TT professionals (including licensing, patenting and other technology transfer activities).

Kite's expertise enabled further development of the treatment and larger clinical studies in cancer patients. Armed with positive patient data from the early clinical trials, Kite submitted a Biologics License Application (BLA) to the FDA in March 2017 and was granted Priority Review.

The synergy of NCI's scientific/clinical expertise with Kite's clinical, regulatory, manufacturing, operation, and business capabilities was essential to the successful development and commercialization of this therapy and other products to address deadly cancers. Throughout the course of this TT process was a persistence to develop an immunotherapy that could benefit patients who are dying despite all other treatments. This is a significant medical breakthrough for this type of cancer. The impact of the successful clinical results that came out of this transfer was evidenced by the swift FDA approval of the therapy in October 2017.

FDA Approvals of Avelumab for Advanced Bladder Cancer and Merkel Cell Carcinoma

In March 2017, avelumab was approved for the first time worldwide for use in the treatment of Merkel cell carcinoma, a rare and aggressive type of skin cancer. In May 2017, avelumab (Bavencio®) received FDA approval for patients with urothelial cancer, the most common type of bladder cancer in the United States. Developed under a CRADA between EMD Serono and the NCI, NCI conducted clinical studies that resulted in the immunotherapy's approval for "second-line use in patients with locally advanced or metastatic urothelial carcinoma whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy." In addition, there are multiple clinical studies of avelumab in progress (being conducted both at the NCI and secondary locations) to evaluate its efficacy and safety for first line use and in combination with other therapies.

Under a CRADA, EMD Serono and Pfizer are co-developing avelumab in partnership with NCI. Avelumab binds to a protein called PD-L1, which is found on some cancer cells. It may block PD-L1 and help the immune system kill cancer cells.

The National Eye Institute (NEI) and French Startup Company Collaborate to Develop Device with Potential to Restore Sight to the Visually Impaired

NCI TTC negotiated a CRADA between the NEI and Pixium Vision, a French startup company. Under the CRADA NEI will conduct experiments to surgically deliver Pixium's proprietary Bionic Vision Restoration System ("PRIMATM") implants to the retina of experimental animals utilizing an NEI invented sub-retinal transplantation ("SRT") tool.

CRADA Paves Way for Eunice Kennedy Shriver National Institute Child Health and Human Development (NICHD) to Collaborate in Study of Therapy for Rare Disease

TTC negotiated a CRADA between the *Eunice Kennedy Shriver* National Institute Child Health and Human Development (NICHD) and CRISPR Therapeutics AG. Under this CRADA, (NICHD) and CRISPR will test a method for the direct repair of site mutations in a mouse model of the rare disease Glycogen Storage Disease Type 1a (GSD1a). GSD1a is an inherited disorder caused by the buildup of glycogen, a complex sugar. The accumulation of glycogen in certain organs and tissues, especially the liver, kidneys and small intestines, impairs their ability to function normally. The disorder impacts infants as early as three or four months.

Potential Therapy for Menkes Disease, Rare Pediatric Disorder, Gets Much Needed Commercialization Partner

In March 2017, NCI TTC helped execute a CRADA and an exclusive patent license between Cyprium Therapeutics, Inc. (Cyprium) and NICHD. The CRADA and License represent a significant translational step toward providing therapeutic options for patients with Menkes Disease, a rare genetic condition affecting copper movement through the body. If untreated, Menkes Disease causes death in children as young as three years old.

The CRADA and license agreement are structured to have parallel and complementary provisions that strengthen each other towards the primary objective of obtaining Food and Drug Administration (FDA) approval. The transferred technology includes regulatory assets, such as clinical data sets. It is the result of 20 years of research lead by NICHD's Stephen G. Kaler, M.D. With these agreements in place, NICHD and Cyprium will collaborate to further develop the technology, and Cyprium's expertise in regulatory process and commercialization should aid efforts to obtain FDA approval. The collaboration presents a significant opportunity to advance gene therapy.

CRADA Latest in Line of Collaborations Helping to Advance Personalized Cancer Immunotherapy

In January 2017, NCI executed a CRADA with Intrexon Corp. and Ziopharm Oncology, Inc. on behalf of the lab of Steven Rosenberg, M.D., Ph.D., chief of NCI Surgery Branch (SB). The CRADA is one of several collaborations between the NCI SB and external partners to study various proprietary T Cell Receptor (TCR) gene platforms for the insertion of TCRs for the treatment of cancer.

Rosenberg is one of the pioneers of personalized cancer immunotherapy and adoptive cell therapy (ACT) whereby:

- the patient's immune T cells are extracted
- the tumor-fighting cells demonstrating strong immune reactivity are selected and characterized
- the cells are expanded to the hundreds of billions
- and then the cells are re-introduced back into the patient to fight cancer.

Picture from CBS News: "Dr. Steven Rosenberg, a pioneer in the study of immunotherapy to fight cancers, at the National Cancer Institute"

using this approach. The Rosenberg Lab has developed proprietary methods to identify immunogenic mutations specific to each patient's cancer. Often numbering anywhere

These types of genetically unmodified T cells are known as tumor infiltrating lymphocytes (TILs), and Rosenberg's lab has demonstrated that several types of cancers can be cured

Steven Rosenberg Talks About Immunotherapy Discoveries During National Cancer Prevention Month

NCI's Steven Rosenberg was interviewed by several news organizations that highlighted the latest advancements in cancer research and discovery. See:

CBS News Immunotherapy, The Next Frontier in Cancer Treatment

from the tens to the hundreds, such mutations – also known as "neo-antigens" – that are in and unique to each patient. The challenge in developing a "personalized" cancer treatment is optimizing the process of insertion and expression of TCRs against neo-antigens into T cells, growing them, and re-introducing the cells back into the patient, to recognize the specific mutation in the cancer cell and destroy it. Rosenberg's laboratory has also developed in vivo techniques for generating these engineered anti-tumor T cells by transduction of genes encoding the TCRs into patients' own Peripheral Blood Lymphocytes (PBL) under conditions suitable for subsequent infusion.

Currently, the SB is collaborating with several companies, each bringing in a proprietary gene platform to optimize expression of mutation-specific TCRs into PBLs for the treatment of cancer. The principal goal of the CRADA with Intrexon/Ziopharm is to develop and evaluate adoptive cell transfer-based immunotherapies (ACT) using NCI proprietary methods for the isolation of tumor-reactive TCRs targeting unique, patient-specific, mutated neoantigen(s) and introduction of these TCRs into PBL's isolated from peripheral blood using proprietary Intrexon Non-Viral Sleeping Beauty Transposon and Transposases for the treatment of patients with solid tumor malignancies. The CRADA with Intrexon will use the non-viral Sleeping Beauty transposon/transposase for the generation of PBL genetically engineered to express one or more TCR(s) that recoginzie patients specific tumor mutations, or neo-antigens. This cutting edge treatment represents a novel class of cancer treatment as personalized medicine.

Data Transfer Agreement Template to Facilitate Data Collection for Melanoma Susceptibility

NCI TTC, worked with the NCI Division of Cancer Epidemiology and Genetics (DCEG) and the University of Chicago to develop a Data Transfer Agreement (DTA) template that involves access to 'data in the cloud.' The DTA template is for use among members of the melanoma genetics consortium (GenoMEL), comprised of 10-15 research groups located throughout the world. The University of Chicago controls a private, open-source cloud computing infrastructure to which GenoMEL members will be contributing and from which metadata will be analyzed to identify melanoma susceptibility genes. This collaborative project presents an opportunity to find melanoma susceptibility genes when the data are combined from a large quantity of samples and analyzed by individual groups specialized in an environment with consistent and common workflows. The DTA template includes considerations of human subject data residing in a cloud environment and can be used for future, similar projects.

Memorandum of Understanding (MOU) between NCI DCEG and AC Camargo Cancer Center for Cancer Research Collaborations

An MOU facilitated by NCI TTC between the NCI DCEG Clinical Genomics Branch and the A.C. Camargo Cancer Center in Brazil sets forth the framework to foster a collaborative research relationship to develop and exchange clinical, educational, prevention, and research programs for the treatment of cancer. It includes the development of a collaborative research program to advance the mission of impacting and improving cancer care in Brazil, the United States of

America, and throughout the rest of the world. The MOU is a non-binding agreement, and the parties will enter into more specific binding agreements involving or related to the agreed upon collaborative research activities.

MOU between NCI DCEG and the American Society for Colposcopy and Cervical Pathology (ASCCP) to Improve Cervical Cancer Screening and Management Guidelines

NCI TTC established a MOU between the NCI DCEG Clinical Genomics Branch and ASCCP. ASCCP is a non-profit medical organization committed to supporting research in guiding the simplification and improvement of cervical cancer prevention by developing and subsequently promoting clinical guidelines for cervical screening and management of screening abnormalities. The NCI conducts research that yields the cervical cancer risk estimates used by ASCCP consensus committees, in part, to create these guidelines. The current cervical cancer screening and management guidelines are complicated and therefore often not followed by clinicians. Therefore, ASCCP and NCI decided to work together under this MOU to improve cervical cancer screening and management guidelines.

MOU between NCI EDRN and Immunovia AB to Facilitate Cancer Biomarker Development

NCI TTC, worked with the NCI Division of Cancer Prevention (DCP) Early Detection Research Network (EDRN) to develop a MOU with Immunovia AB. Immunovia is a Swedish company with a mission to establish a blood-based test for early diagnosis of pancreatic cancer. NCI EDRN and Immunovia will work together towards a common goal of cancer biomarker development and validation with an aim to assist health care systems globally in achieving their full potential through exchanges of knowledge, technology, and other activities. The parties intend to identify validation projects and other joint opportunities designed to improve early cancer diagnosis – specifically, those related to the early detection of pancreatic cancer in the new, onset diabetes risk group.

Agreement Allows NCI to Contribute to Hispanic Community Health Study

A Data and Materials Distribution Agreement (DMDA) allows for NCI to contribute to the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). This Study is a multi-center observational longitudinal health study documenting the health status of ~16,000 adults in four Hispanic communities in the US and is supported by contracts with NHLBI. An investigator in NCI's Metabolic Epidemiology Branch (MEB) of the DCEG is examining plasma specimens from the complete cohort to look at predictors and potential confounders or effect modifiers of *Helicobacter pylori* (*H. pylori*) infection among the Study participants. *H. pylori* is the strongest known risk factor for gastric cancer, which disproportionately affects Hispanic populations in the U.S. and Latin America. Other studies have reported genome-wide associations of high levels of anti-*H. pylori* antibodies with variants with a protective effect on development of asthma. Samples collected within the HCHS/SOL cohort offer an opportunity to examine the seroprevlaence of *H. pylori* infection and its risk factors, along with spirometric diagnosis of asthma, and to conduct a GWAS for anti-*H.pylori* antibodies. This DMDA is the first Agreement

that NCI has made with the HCHS/SOL and has established a template for future collaborations with HCHS/SOL and NHLBI within this cohort.

NHGRI — National Human Genome Research Institute

Research Collaboration Agreement with Galyatech LLC

In April 2017, the NHGRI entered into an RCA with Galyatech LLC for a project titled "Analysis of the Efficacy of Gene Therapy for Niemann-Pick Disease Type C."

Research Collaboration Agreement with Albert Einstein College of Medicine and NCATS

In July 2017, the NHGRI entered into an RCA with Albert Einstein College of Medicine and NCATS for a research project focused on Hereditary Diffuse Leukoencephalopathy with Spheroids (HDLS).

Research Collaboration Agreement with Verge Genomics

In August 2017, the NHGRI entered into a Research Collaboration Agreement with Verge Genomics for a project titled "Transcriptomic Characterization of Cellular and/or Animal Models of Parkinson Disease."

Research Collaboration Agreement with NCATS and NIAID

In September 2017, the NHGRI entered into a Research Collaboration Agreement with NCATS and NIAID for a research project to explore the role of the microbiota in health and disease, and development models for translational microbiome research.

Research Collaboration Agreement with the Women & Infants Hospital of Rhode Island

In September 2017, the NHGRI entered into a Research Collaboration Agreement with the Women & Infants Hospital of Rhode Island for a project titled "Fetal DNA in the Maternal Circulation and Placental Apoptosis in Hypertensive Disorders of Pregnancy and Fetal Aneuploidy."

Agreements and Patents of Note

In FY 2017, the TTO staff reviewed **sixteen (16)** intramural EIRs and recommended that eight (8) be marketed as unpatented research tools (cell lines and animal models); five (5) directed to patentable subject matter, and three (3) required addition data before filing.

In FY 2017, the NHGRI TTO staff negotiated and executed nine (9) licenses and amendments.

In FY 2017, the NHGRI TTO staff negotiated and executed two (2) CRADAs.

In FY 2017, one (1) NHGRI patent was issued in the United States.

In FY 2017, five (5) NHGRI patents were issued in foreign countries.

NIAID — National Institute of Allergy and Infectious Diseases

Licensing Zika Vaccines

In May 2015, the Pan American Health Organization issued an alert for the first confirmed Zika virus infections in Brazil. Following subsequent increased reports of Zika cases in the Americas, the World Health Organization declared a Public Health Emergency of International Concern on February 1, 2016 which ended on November 18, 2016, because of clusters of microcephaly and other neurologic disorders in areas affected by Zika. There was no vaccine available to prevent Zika virus infection.

In December 2016, the Department of the Army published a Federal Register notice of its intent to grant an exclusive license to a Zika vaccine from the Walter Reed Army Institute of Research to Sanofi Pasteur, Inc. This announcement resulted in intensive public and political scrutiny, with six U.S. senators sending letters to top officials at the U.S. Army and Sanofi in June 2017 urging pricing assurances should the vaccine candidate make it to the market. Citing Zika's evolving epidemiology and BARDA's change in its funding support, Sanofi Pasteur announced on September 1, 2017 that it would not continue development of, or seek a license for, WRAIR's Zika vaccine candidate.

Since 2016, NIAID scientists have advanced the development of three Zika vaccine candidates by employing different scientific approaches. Each candidate, and associated intellectual property, received commercial licensing interest in 2017. In October of 2017, NIAID's Technology Transfer and Intellectual Property Office (TTIPO) took a critical first step toward memorializing one development and commercialization partnership by publishing a Federal Register notice of its intent to grant an exclusive license to patents on its Zika DNA vaccine to PaxVax, Inc.

NIAID's vaccine candidates are among those described in the US Government's Zika Vaccine Strategy, published by the Office of the Assistant Secretary for Preparedness and Response of the US Department of Health and Human Services. This strategy provides "multiple redundancies, expanded choice, and ensures short and long term maximal benefits to the public."

Low-cost Rotavirus Vaccine in Developing Countries

In 2013, 215,000 diarrheal deaths in children less than 5 years old were caused by rotavirus; most of which were in Asia and Africa, with around 22% in India. Although rotavirus vaccines are commercially available, affordability is a challenge in developing countries. Children in

developing countries are disproportionately at risk of dying from rotavirus-related infection, due in part to inadequate sanitation and inadequate access to intravenous rehydration therapy.

The late Dr. Albert Kapikian and his colleagues at the NIAID invented a human-bovine reassortant rotavirus vaccine which offers broad protection against five most common rotavirus serotypes. In addition, this vaccine is stable at room temperature and does not require cold-chain transport, delivery, and storage. In 2005, Serum Institute of India, one of the largest vaccine manufacturers in the world, obtained a patent commercialization license from NIH/NIAID to develop, manufacture and distribute this vaccine as the product called ROTASIIL.

In September 2017, ROTASIIL was found to be very safe, well tolerated and efficacious in a phase III clinical trial conducted in India. The Drug General Controller of India has reviewed the results of this study and approved the vaccine. The Government of India has subsequently ordered 3.8 million doses of ROTASIIL to use in the Universal Immunization Programme, which serves 26 million children in India. Serum Institute of India has 19 vaccines that are WHO prequalified and supplied to developing countries at low prices. It has the capacity to produce 100 million doses of ROTASIIL and is expected to supply ROTASIIL to other developing countries at low prices.

CDC - Develop Mosquito Trap for Control and Surveillance of Mosquitoes Including Carriers of Zika and Other Viruses

Viral and bacterial diseases spread by vectors (e.g., mosquitoes, ticks, and other insects) are a significant public health problem. Dengue, Zika, chikungunya, and yellow fever viruses are predominately transmitted by the *Aedes* species (*aegypti* and *albopictus*) mosquitoes. *Aedes* mosquitoes are adept at spreading these viruses as they have adapted to living in urban environments and feed during the times of day when people are most active.

Researchers within the Division of Vector-Borne Diseases at the Centers for Disease Control and Prevention (CDC) began development of a low-cost, pesticide-free method for controlling mosquito populations. The resulting invention is an autocidal gravid ovitrap (AGO trap) that consists of a five-gallon (10 L) plastic bucket with a modified lid containing a capture chamber, which has a glue board specifically designed to trap adult mosquitoes. Water and grass are placed in the bottom of the bucket; the decaying grass provides a natural attractant to pregnant mosquitoes looking for places to lay their eggs. However, once inside the trap, the females cannot successfully lay their eggs and are unable to escape. Other types of mosquito attractants may also be used.

The AGO trap requires no power, no pesticide, and is economical to manufacture. It has also shown efficacy for at least two months without changing the glue board or refilling the water/grass mixture, in marked contrast to weekly application of pesticides that can be unsafe for use around children, pets, and livestock. The AGO trap has been used by CDC researchers in

field trials in Puerto Rican sites since 2011, demonstrating a 60-80% reduction of *Aedes* mosquito populations and a 50% lower prevalence of chikungunya virus in test sites and neighborhood.

Through patent and licensing efforts by NIAID's Technology Transfer and Intellectual Property Office, which manages CDC's invention portfolio, CDC has licensed the related patent rights to a US company. CDC is also seeking additional commercial partners, both foreign and domestic, with the goal of distributing the AGO trap to as many people and communities as possible worldwide.

CDC – Sharing Zika Specimens and Diagnostic Technologies to Combat the Epidemic

The Centers for Disease Control and Prevention (CDC) has transferred Zika virus specimens and CDC-developed diagnostics to support the public health response for the Zika virus outbreak beginning in February 2016. By January 2018, CDC had shipped relevant Zika specimens to approximately 20 countries and 34 U.S. states and territories, and such efforts continue today. The CDC Technology Transfer Office (TTO) consulted and collaborated with interagency specimen sharing efforts as needed in addition to handling 186 transfer agreements - 160 Simple Letter Agreements (SLA) and 26 Material Transfer Agreements and transfers of its own. The different strains/isolates of the Zika virus are essential to further Zika research, increase knowledge about the virus, and support vaccine and diagnostic test development.

CDC was the first organization to develop and receive an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) for a Zika diagnostic assay (the Zika MAC-ELISA), which detects Zika virus antibodies in blood and cerebrospinal fluid. CDC is pursuing patent protection for key components of this assay. CDC has executed licenses with four major reference laboratories for clinical testing of patient samples and has also licensed this technology to a fifth company for mass production of an EUA-compliant kit for use by public health laboratories.

CDC has also developed and obtained an EUA for a PCR-based assay method (called CDC Trioplex) to detect Zika, dengue, and chikungunya viruses in patient samples, which would enable simultaneous, rapid testing of these three mosquito-borne diseases. CDC is pursuing a patenting and licensing strategy similar to that used for the Zika MAC-ELISA, with the ultimate goal of facilitating broad public access to reliable diagnostics for Zika, dengue, and chikungunya viruses simultaneously.

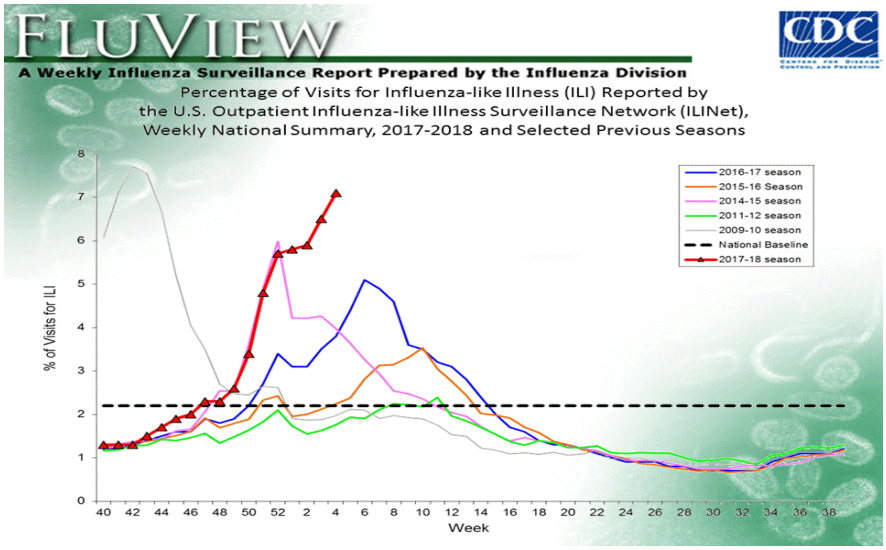
These transfers, memorialized in a variety of transactional agreements, were made possible through the joint efforts of the CDC's TTO and NIAID's Technology Transfer and Intellectual Property Office. The Federal Laboratory Consortium for Technology Transfer (FLC) recognized these important public health accomplishments with its 2017 FLC Excellence in Technology Transfer Award for "Zika Virus Specimens for Research & Development and Diagnostic Technologies."

CRADA - A Study of the CD300 Family of Receptors in Collaboration with Bristol-Myers Squibb Company

Under this Cooperative Research and Development Agreement (CRADA), NIAID and Bristol-Myers Squibb Company studying how CD300 receptors regulate inflammation, cancer and other human diseases. NIAID scientists have shown that CD300 receptors are directly involved in regulating the development of autoimmunity (CD300f), cancer (CD300f), inflammatory bowel disease (CD300f), and sepsis (CD300b). The goal of the collaboration is to develop CD300 biology tools and leverage them in murine models of cancer and/or inflammatory diseases to understand the role of CD300 immunoreceptors in the pathogenesis of different diseases.

Characterize Influenza A Virus Subtypes Circulated from 1889 to 1931

Influenza activity continued to increase in the United States in January 2018. By January 27, 53 influenza-associated pediatric deaths and 14,676 influenza-associated hospitalizations have been reported for the 2017-2018 season, highlighting the urgency of further understanding influenza pathogenesis and developing more effective countermeasures.



Under this Research Collaboration Agreement (RCA), NIAID and Johns Hopkins University are analyzing post mortem lung tissue samples from 1889-1931 to characterize which subtypes of influenza A viruses circulated during this period. The study will enable comparison of influenza viruses from the pre-1918 pandemic and early post-1918 pandemic period.

Identifying New Treatments for Tuberculosis

Tuberculosis (TB) is one of the top 10 causes of death worldwide. In 2016, 10.4 million people fell ill with TB, and 1.7 million including 250,000 children died from the disease. TB is caused by *Mycobacterium tuberculosis* bacteria. When people with lung TB cough, sneeze or spit, TB is easily spread through the air.

Multidrug-resistant TB (MDR-TB) is caused by bacteria that do not respond to isoniazid and rifampicin, the two most important anti-TB drugs. In 2016, MDR-TB, with 490,000 new cases, remains a public health crisis and a health security threat, underlining the critical need to identify new antibiotics. BARDA, NIAID and other partners such as Wellcome Trust of London co-founded CARB-X, Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator. CARB-X is one of the world's largest public-private partnerships focused on preclinical discovery and development of new antibacterial products to help address the threat of MDR-TB and other antibiotic resistant diseases.

WIPO Re:Search

Re:Search is an international research consortium led by the non-profit BIO Ventures for Global Health (BVGH) and the United Nations World Intellectual Property Organization (WIPO). Through this arrangement Janssen Pharmaceutica NV (Janssen) has opened segments of its molecule library – containing a set of 80,000 diverse, high-quality chemical compounds – to the global research community to enable collaborators to identify and advance promising drug candidates.

NIAID's Technology Transfer and Intellectual Property Office negotiated a Material Transfer Agreement (MTA) that will provide NIAID scientists access to Janssen's library. This first step toward the development of new anti-TB drugs will enable the identification of lead compounds on which advanced studies will be based.

Development and Manufacture of Rabies Vaccine with Ethiopian Public Health Institute

Rabies is a vaccine-preventable viral disease which occurs in more than 150 countries and territories. Infection causes tens of thousands of deaths every year, with over 95% occurring in Asia and Africa. 40% of people bitten by suspect rabid animals are children under 15 years of age.

Although effective human vaccines and immunoglobulins exist for rabies, these products are not readily available to those in need. Treating a rabies exposure, where the average cost of rabies post-exposure prophylaxis (PEP) is 40 USD in Africa, and 49 USD in Asia, can be a catastrophic financial burden on affected families in low income countries.

CDC has signed a non-exclusive license with Ethiopian Public Health Institute (EPHI) for a rabies virus vaccine strain. EPHI is a non-profit institution of the Ethiopian federal government established to carry out research on priority diseases, nutrition, traditional and modern medicine, and production of vaccines. This license allows EPHI to develop a method of mass production, and then produce and distribute this rabies vaccine to Ethiopian citizens at low cost.

Financial Resources

In FY 2017, NIAID received more than $8 million and $5.5 million under conditional gift agreements and Cooperative Research and Development Agreements, respectively, which were negotiated by NIAID's Technology Transfer and Intellectual Property Office.

NIDCR — National Institute of Dental and Craniofacial Research

NIDCR executed three CRADAs, eight license agreements, and over 100 transactional agreements, including MTAs and Confidentiality Disclosure Agreements. Eleven invention reports were evaluated.

NIDDK — National Institute of Diabetes and Digestive and Kidney Diseases

The NIDDK Technology Advancement Office (TAO) develops, negotiates, implements, and advises on numerous transactional agreements supporting both extramural and intramural programs at NIDDK. TAO also actively advances NIDDK technologies further along the development pipeline towards commercialization, including planning studies enabling Investigational New Drug Applications, engineering of device prototypes, and facilitating the use and distribution of new computer applications and software. TAO is also the service center for patenting and licensing for The National Institute on Alcohol Abuse & Alcoholism (NIAAA) and Office of Research Services (ORS) at NIH.

Highlights in FY2017 include:

- **Licensing.** Successfully negotiated several complex exclusive licenses to develop and commercialize NIH-patented technologies, including:
    - NIDDK's A3 Adenosine Receptor Agonists for neuropathic pain licensed to a biotechnology company
    - NIAAA's CB1 Cannabinoid Receptor antagonists for treatment of fibrosis, diabetes, obesity, and various metabolic disorders licensed with several biotechnology companies
    - Several Biological Material Licenses for research materials developed in NIDDK intramural laboratories and useful as research tools at several biotechnology companies

Leptin Know-How

Advanced numerous collaboration agreements around NIDDK's world-recognized leadership and know-how in Leptin-based clinical assays for developing a comprehensive comparison of all leptin assay technologies and to create an optimized clinical protocol widely accepted for all future Leptin studies

Point-of-Care Diagnostics

Negotiated a CRADA and non-exclusive license with a diagnostics company to create a new diagnostic platform using NIDDK's patented peptide nucleic acid technology to replace costly and time-consuming PCR-based diagnostics with a point-of-care chip-based colorimetric assay to be first used for HIV and infectious diseases in under-served 3rd world communities

Multi-Agency Collaboration

Spear-headed a government multi-agency collaboration between NIDDK, Center for Information Technology (CIT), FDA, and the HHS Venture Fund toward commercialization of NIDDK's *MIOS* technology (a scalable cloud-based system for continuous wireless monitoring and real-time reporting of the rodent home-cage environment and behavior)

EVS-ART Consultation and Dissemination

All government agencies are asked by OPM to have employees complete the yearly Federal Employee Viewpoint Survey (FEVS) and analyze large amounts of data requiring many hours of analysis and report generation. NIDDK staff created an easy to use Excel spreadsheet tool that can create detailed analysis and reports from FEVS raw data in just a few minutes. Our office developed and implemented non-exclusive IP protection strategies around NIDDK's EVS-ART survey tool and incentivizing its wide dissemination to other ICs and government agencies without the use of patents or trademark registration.

NIMH — National Institute of Mental Health

The NIMH/NINDS Technology Transfer Core consists of technology transfer staff from both institutes and was designed to take advantage of the common neuroscience underpinnings that form the foundation of each IC. Among the key accomplishments of 2017 was establishing a Technology Assessment Group comprised of NIMH/NINDS investigators to assist technology transfer staff in the review of technologies at various stages of the patent process. The initiative involves significant collaboration between intramural-extramural programs and is expected to result in a more robust patent portfolio for both NIMH and NINDS with technologies that have a high likelihood of being licensed. Formation of the group required several presentations to NIMH/NINDS investigators and extramural staff describing the initiative and various approvals from senior leadership. Additional efforts of the group include:

- Continued efforts to develop content for a new Technology Transfer Core Group website.
- Streamlining the agreement negotiation process by establishing standardized templates between the ICs and drafting Standard Operating Procedures for the various agreement types.

NINDS — National Institute of Neurological Disorders and Stroke

NINDS Technology Transfer Office negotiated agreements with Pfizer, UCB, GSK and Eisai for the transfer of large epilepsy datasets from previous clinical studies performed independently by these entities. The central goal of the meta-analysis is to study the influence of natural variability of seizures on study outcome. This research will provide clarity on whether the variability in seizure frequency is actually predictable. The study will also provide insight that can guide future clinical studies on epilepsy and the treatment of the disorder.

Under a clinical CRADA negotiated by NINDS Technology Transfer Office and executed in FY17, the National Institute of Neurological Disorders and Stroke (NINDS), an institute of the National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services, is collaborating with Audentes Therapeutics, Inc. as one site in a multi-site pre-Phase 1 prospective, non–interventional clinical assessment study in X-linked Myotubular Myopathy (XLMTM) subjects aged 3 years and younger (INCEPTUS).

NINDS Technology Transfer Office piloted a six-month agreement lifecycle assessment. This effort required documenting an agreement's movement through every step in the negotiation process and analyzing the data. Through these efforts, the office has established an average agreement lifecycle as the basis on which to assess the effectiveness of future initiatives to improve efficiencies. Additionally, this effort led to the identification of one process element that was changed to increase overall efficiency. The office had a nearly 90% resolution rate for agreements initiated in FY17.

INNOVATIVE COLLABORATIONS AND STARTUP CHALLENGES

NCI Forms Partnership with TEDCO

In 2017, NCI TTC signed a Partnership Intermediary Agreement (PIA) with TEDCO to allow the entities to partner and advance complimentary goals: promoting the development and licensing of NCI technologies and supporting collaborative opportunities with Maryland educational institutions and companies to commercialize products that benefit the public. The 2018 Technology Showcase was first effort under the agreement, allowing the entities to partner to create, plan and execute the inaugural event at the FNLCR.

Marketing NIH Inventions Through NCI TTC Webinar Program

NCI's TTC leverages a partnership with One Million Solutions in Health (OMSiH), a non-profit, to showcase NIH researchers and their technologies, providing them access to a targeted audience via a webinar-based approach. The webinar program provides an additional way for TTC to proactively market NIH intramural technologies. For a given webinar, TTC works to identify and develop an appropriate NIH technology story that is delivered by the NIH scientist/inventor. Through its large network, OMSiH brings the appropriate industry audience.

TTC's webinar is successfully identifying companies interested in collaborating with NIH to advance important technologies towards commercialization. For example, as a result of a webinar featuring two National Institute of Aging (NIA) inventions from Arya Biragyn, Ph.D., Laboratory of Molecular Biology and Immunology, TTC executed a CRADA in May 2017 between NIA and SIRNAX, INC. to develop the technology. In addition, TTC began negotiations for a license with another partner to develop another field for the same technology.

Launch of Startup 2.0, New Licensing Program for NCI and Institutes and Centers Supported by NCI TTC Service Center

A new startup license program launched in October 2017 by NCI TTC updates and enhances previous licensing options available to start-up companies. The new program aims to make it easier and more financially attractive for these companies to consider licensing a technology from NCI or any of the ICs supported by the NCI TTC Service Center.

"NCI Startup 2.0" offers a term-limited, exclusive Startup Evaluation Option License to start-up companies developing early-stage vaccine, therapeutic, device, and diagnostic technologies. To learn more about the program – including the criteria that companies need to meet to qualify, the license features, and the process for startups to obtain a license, please see Tech Transfer Startup Licenses.

Launching the updated startup licensing program was the result of months of work by two separate project teams. The teams were comprised of a variety of TTC staff who considered and analyzed the original program that was established by the Office of Technology Transfer. The

goal was to develop an enhanced program that met the unique needs of a startup company versus the licensing options available to larger companies and organizations.

"From some very diligent work and analysis of the original program, the two project teams were able to identify key issues that our original startup licensees found problematic," commented TTC Associate Director Richard Rodriguez. "One key factor was the original term of the startup option license which was 12 months. This was clearly insufficient time for our licensees to raise capital or concurrently conduct pre-clinical experiments. The new program provides 24 months which we believe will better assist our licensees in meeting their obligations. Other changes have been made that we believe will make it easier for our startup licensees to bring a product to the market."

NIH Startup Challenge Companies Achieve Important Milestones in 2017

Several startups created around NIH inventions as a result of the NIH Startup Challenges achieved important milestones in their quest to develop and commercialize NIH inventions. Notable achievements by three of the 21 active startups include:

Oncolinx launched from the Breast Cancer Startup Challenge

- Developing a monoclonal antibody to specifically kill a variety of cancer cells.
- Won $1 million startup investment prize as grand prize winner of the 43North Competition
- Named a winner of the Rice Business Plan Competition, MassChallenge, and MassBio.
- Earned two grants from NASA and the Center for the Advancement of Science in Space (CASIS) to carry out experiments aboard the International Space Station.
- Both co-founders – Riley Ennis and Sourav Sinha – named to Forbes "30 Under 30" Healthcare.

Cogentis Therapeutics launched from the NSC

- Developing first-in-class therapeutics to prevent neurodegeneration and restore brain function in patients with Alzheimer's, Parkinson's, frontotemporal degeneration, and other neurological disorders.
- Named a finalist in MassChallenge and the OneStart Americas Competition.
- Won the New Company/Technology Pitch Competition at the CNS Diseases Summit and the MIT-CHIEF 7th annual business competition.

Cambridge Cancer Genomics (formerly OneTest Diagnostics CCG), a startup launched from the Nanotechnology Startup Challenge (NSC2)

- Developed a point-of-care diagnostic device to detect circulating tumor DNA in blood samples and married it with smart genomics and artificial intelligence. Technology allows clinicians to determine a patient's response to chemotherapy months earlier than existing technology and can be potentially be used to better predict which therapeutic strategy to follow.
- Named one of "10 of the World's Hottest Start-Ups in 2016" by CNBC, graduated from Y Combinator in 2017 (seed funding program), and raised more than $4 million in seed funding to date.

About the NIH Startup Challenge Program: The Breast Cancer Startup Challenge was created by NCI in partnership with Center for Advancing Innovation (CAI). The NIH continued to partner with CAI to create additional startup challenges based on the BCSC model—The Neuro Startup Challenge (NSC) and the Nanotechnology Startup Challenge in Cancer (NSC2). Teams competed by creating business plans and delivering sales pitches to a panel of judges for an opportunity to form a startup based on NIH-conceived inventions. Winning teams worked to incorporate their startups, raise funding and negotiate a license with the NIH for their selected technology.

Project Data Sphere (PDS)

PDS is a free digital library-laboratory that provides one place where the research community can broadly share, integrate and analyze historical, patient-level data from academic and industry phase 3 cancer clinical trials.

The platform is available to researchers affiliated with life science companies, hospitals and institutions, as well as independent researchers interested in cancer research who can apply to become an authorized user. NCI's Division of Cancer Therapeutics and Diagnostics (DCTD) negotiated a Collaboration Agreement with PDS and 12 amendments to its current CRADAs with pharmaceutical companies to allow NCI-NCTN Data Archive clinical data to be visible through PDS.

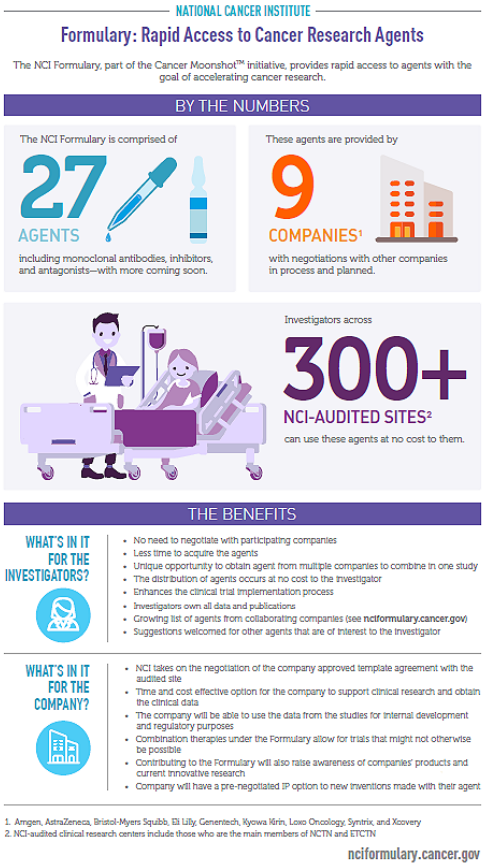
Moonshot initiative

NCI Formulary for Rapid Access to Cancer Research Agents

NCI's Division of Cancer Therapeutics and Diagnostics (DCTD) negotiated specific NCI Formulary CRADAs with, to date, nine pharmaceutical company collaborators that agreed to expand the use of their proprietary agents for studies supported by the NCI Formulary. The NCI Formulary CRADAs provide NCI-audited academic institutions access to these proprietary clinical agents,

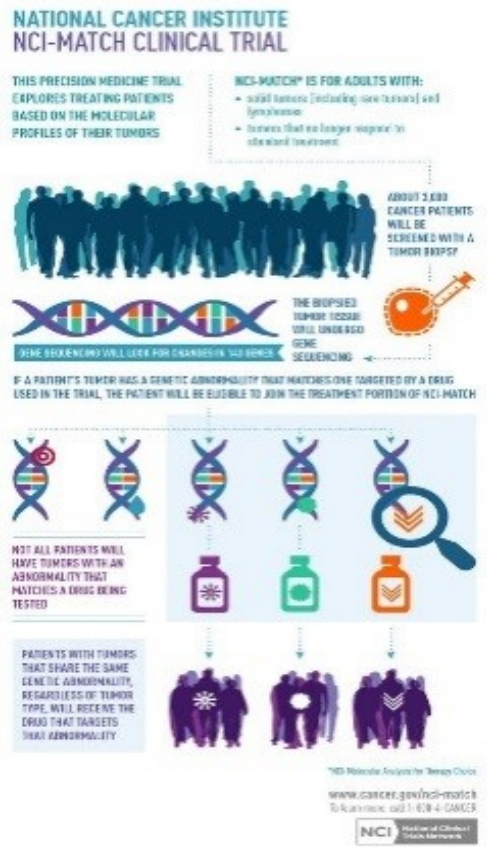
thereby eliminating the often-lengthy agent access process that occurs between such institutions and pharmaceutical companies.

Clinical agents within the NCI Formulary are available to investigators at NCI-audited clinical sites for the conduct of clinical trials under investigator-held INDs, as well as for pre-clinical research. DCTD's clinical trial infrastructure will facilitate conduct of the trials, from proposal submission and timely review by the collaborating pharmaceutical companies, to clinical agent distribution, serious adverse event reporting, and clinical data reporting. DCTD, NCI will also negotiate the MTAs between NCI and the clinical sites to transfer the clinical agents and formalize the expectations of each party.



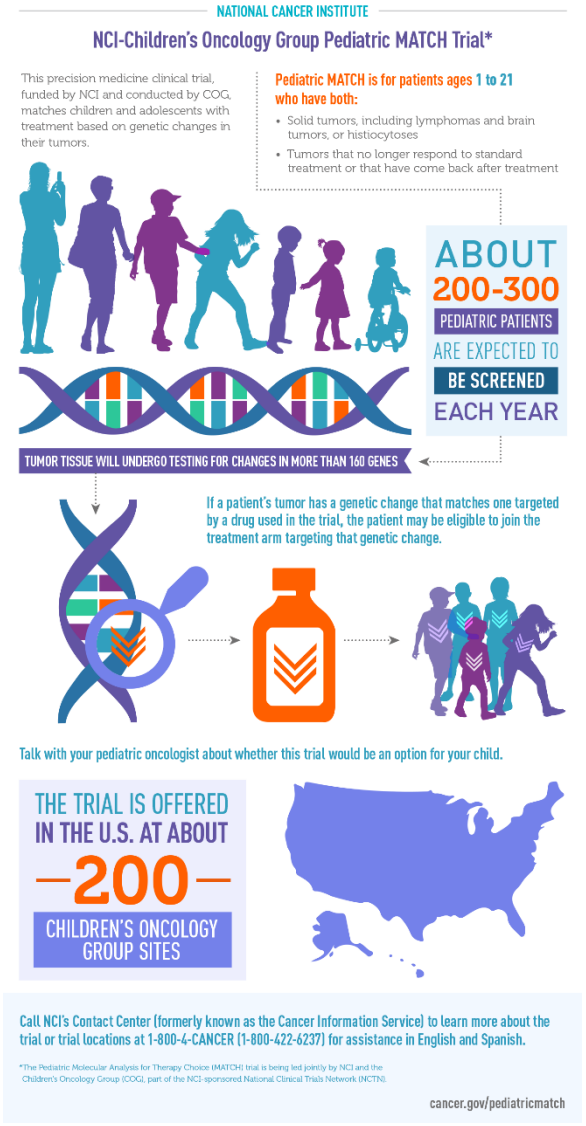
NCI-MATCH (Molecular Analysis for Therapy Choice) Trial

MATCH, is a precision medicine cancer treatment clinical trial being led by the National Clinical Trials Network (NCTN) Group ECOG-ACRIN. In this trial, adult patients are assigned to receive treatment, in NCI NCTN and National Community Oncology Research Program sites, based on the genetic changes found in their tumors through genomic sequencing and other tests. Patients whose tumors have genetic changes that match one of the treatments in the trial may receive that treatment. The trial seeks to determine whether treating cancer based on these specific genetic changes is effective. DCTD negotiated the more than 26 agreements that were required to bring in pharmaceutical agents or make available lab testing of clinical samples as part of initiating this new program.



NCI-Children's Oncology Group (COG) Pediatric MATCH

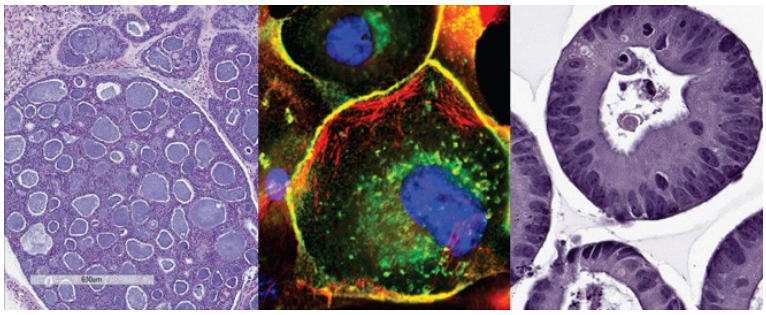
This nationwide precision medicine trial for pediatric cancers, coordinated through NCI's COG, part of the NCTN, is specifically designed for children and adolescents from 1 to 21 years of age. DCTD negotiated CRADAs with a number of pharmaceutical partners to bring in 8 different agents that are currently being used in the trial. Several additional agents are expected in the coming year.



Patient-Derived Xenograft Network (PDXNet)

PDXNet, Could Play Important Role to Prioritize NCI-IND Agent Combinations in Experimental Therapeutic Clinical Trials Network (ETCTN)

The PDXNet is a NCI program established to coordinate collaborative, large-scale development and pre-clinical testing of targeted therapeutic agents in patient-derived models to advance the vision of cancer precision medicine. The goals include: development of new PDX models and methods for preclinical testing of single agents and drug combinations; and using the newly established models as well as other existing well-characterized PDX models for studies of drug responses. It is expected that the outcomes of PDXNet research will be particularly important for the prioritization of combinations of agents in the portfolio of NCI-IND agents, which are evaluated clinically in the NCI sponsored ETCTN. DCTD assisted this mission by undertaking the necessary agreements to allow for agents to enter the program and to facilitate data sharing within the program.



Specialized Programs of Research Excellence (SPOREs)

NCI's SPORE grants involve both basic and clinical/applied science, and support projects that result in new and diverse approaches to the prevention, early detection, diagnosis and treatment of human cancers.

Each SPORE focuses on a specific organ site (e.g. skin cancer) or on a group of highly related cancers. SPOREs are designed to enable the rapid and efficient movement of basic scientific findings into clinical settings, as well as to determine the biological basis for observations made in individuals with cancer or in populations at risk for cancer. DCTD, NCI negotiated a master Material Transfer and Data Sharing Agreement with each of the five participating sites in the Skin SPORE as a party, enabling the sharing of materials and data between the different institutions within the program.

AWARDS, PRESENTATIONS AND PUBLICATIONS

NCATS Staff Highlights

Gadhia AD, Technology Transfer and Patenting Specialist, NCATS OSA, co-contributed a book chapter to Rare Diseases Epidemiology: Update and Overview Series: Advances in Experimental Medicine and Biology

The book discusses the fields of rare diseases research and orphan products development, and how they "continue to expand with more products in research and development status. In recent years, the role of the patient advocacy groups has evolved into a research partner with the academic research community and the bio-pharmaceutical industry. Unique approaches to research and development require epidemiological data not previously available to assist in protocol study design and patient recruitment for clinical trials required by regulatory agencies prior to approval for access by patients and practicing physicians."

Gadhia AD and co-author, Austin BA, wrote on the opportunities and challenges of new therapeutic uses for existing drugs. Gadhia AD focused on the patenting (method v. composition claims) and commercialization aspects.

Citation: Austin BA, Gadhia AD. New Therapeutic Uses for Existing Drugs. Adv Exp Med Biol. 2017;1031:233-247. doi: 10.1007/978-3-319-67144-4_14. PubMed PMID: 29214576.

NGHRI Staff Highlights

In August 2017, the NHGRI TTO began hosting a University of Maryland School of Law student as a Guest Researcher interested in intellectual property and patent law. Anna Solowiej and Eggerton Campbell gave a joint guest lecture on "Technology Transfer – an Alternative Legal Career?" in the related Externship Course for the students.

Eggerton Campbell, Licensing and Patenting Manager, attended the Association of University Technology Managers (AUTM) Essentials of Academic Technology Transfer, October 3-5, 2016 in Baltimore, MD.

Claire Driscoll, Director and Eggerton Campbell, Senior Licensing and Patenting Manager, co-taught a class in TECH 565 Biomedical Business Development Class for Scientists, directed to CRADAs and licensing, November 10, 2016, at NIH Technology Transfer University.

Eggerton Campbell, Senior Licensing and Patenting Manager served on the NIH Patent Contract Working Group.

Eggerton Campbell, Senior Licensing and Patenting Manager served as the NHGRI Representative on the NIH Exclusive License Consultation Group.

Claire Driscoll, Director, attended the Licensing Executives Society (LES) IP100 Executive Forum, February 26-28, 2017 in Phoenix, AZ.

TTO Staff organized and worked at a marketing booth at the Association of University Technology Managers (AUTM) Annual Meeting in March 12-15, 2017 in Hollywood, FL. The Staff handed out NHGRI marketing materials and discussed possibilities of collaborations with attending university and commercial partners. Staff also attended the conference while there.

Anna Solowiej, Senior Licensing and Patenting Manager, served on the Association of University Technology Managers (AUTM) Annual Meeting Planning Committee for a third term beginning March 2017, and was chosen as the incoming Chair of the Committee.

Anna Solowiej, Senior Licensing and Patenting Manager, organized and moderated a Career Development Forum panel at the 2017 Annual AUTM Meeting.

Claire Driscoll, Director, organized and presented at a workshop which was entitled "It Takes a Global Village: An Orphan Drug Development Case Study" at the 2017 Annual AUTM Meeting.

Anna Solowiej, Senior Licensing and Patenting Manager, served as the elected Vice Chair and then (starting in January 2017) as Chair of the trans-NIH, FDA, and CDC Technology Development and Transfer Committee, organizing monthly meetings and educational talks and coordinating various activities of the Technology Development Coordinators.

Claire Driscoll, Director, attended the Licensing Executives Society International 2017 Annual Conference, April 24-25, 2017 in Paris, France.

Anna Solowiej, Senior Licensing and Patenting Manager, attended the American Society of Gene & Cell Therapy's Clinical Trials Training Course on May 9, 2017 in Washington, DC.

Claire Driscoll, Director, and Eggerton Campbell, Senior Licensing and Patenting Manager, attended the Licensing Executives Society 2017 Spring Meeting, May 9-11, 2017 in Washington, DC.

Eggerton Campbell, Senior Licensing and Patenting Manager, attended the Association of University Technology Managers (AUTM) Central Region Meeting, July 10-12, 2017 in Chicago, IL.

Claire Driscoll, Director, served as the co-chair on the LESI program planning committee for the LESI 2018 conference to take place in San Diego in April 2018.

Claire Driscoll, Director, served as the NHGRI representative on the NIH Enterprise Technology Transfer governance group as well as on various work groups associated with the design, planning and implementation of an enterprise-wide system for the NIH technology transfer community.

Claire Driscoll, Director, co-hosted four Women in Licensing DC events during the year (Ms. Driscoll co-founded this group in 2015).

Claire Driscoll, Director, was interviewed for an article entitled "The Future of Technology Transfer" that appeared in Jan/Feb 2018 issue of Intellectual Assets Magazine (IAM).

NCI Staff Highlights

Tech Transfer Engagement with Potential Collaboration Partners at 2017 BIO International Convention

As part of a series of novel initiatives, NCI TTC exhibited at the annual BIO International Convention under the specially created banner of "Industry Partnerships" – raising awareness of how NIH works with companies to bring medical solutions to patients. TTC held dozens of 1:1 partnering meetings with pharma, biotech, entrepreneurs, investors, and economic development groups. TTC identified several potential commercial partners at the event interested in collaborating with and/or licensing NIH technologies. Interactions and negotiations with these potential partners are ongoing.

Pictured: Drs. Robert Sons, John Hewes, Michael Salgaller at NIH's booth at BIO.

Active marketing of TTC's intramural program at BIO and presentations given at events hosted by the Massachusetts Biotechnology Council (MassBio), Texas Life Sciences Forum, Diversity Alliance for Science, Ft. Detrick Alliance, and World Vaccine Congress are part of an ongoing, strategic campaign of outreach and education regarding the importance of NIH technologies.

First U.S.-Australia Emerging Cancer Biomedical Technologies Workshop

Over 70 top scientists from NCI and other institutions participated in the U.S.-Australia Emerging Cancer Biomedical Technologies Workshop, held June 13-15, 2017 at the Virginia Tech Research Center in Arlington, VA. Michael Salgaller, Ph.D., TTC Invention Development and Marketing Unit, served on the planning committee and spoke on TTC's role in facilitating partnerships between NIH researchers and external stakeholders. The purpose was bringing together U.S. and Australian scientists working in the cancer research field to discuss challenges and needs in cutting-edge, emerging cancer biomedical technologies. The event was co-sponsored by NCI's Center for Strategic Scientific Initiatives, AusTrade, and Virginia Tech. To encourage in-depth discussions and strong engagement of participants, the workshop consisted of brief

presentations of technologies and approaches followed by group discussions and reports. The workshop also included sessions and presentations on commercialization, relevant collaborative programs and funding opportunities. NCI research presenters included: Drs. Bruce Shapiro, Stephen Hewitt, and Nadya Tarasova. Acting NCI Director, Doug Lowy, Ph.D., offered remarks during an evening networking reception held by the Australian Trade and Investment Commission at the Embassy of Australia in Washington, DC. Michael Salgaller, Ph.D.

NCI and Frederick National Laboratory for Cancer Research (FNLCR) Inventors Pitch Discoveries at Inaugural Technology Showcase

Attendees of the 2017 Technology Showcase gathered in the Advanced Research Facility at the Frederick National Lab for Cancer Research on June 7.

Over 200 people attended the 2017 Technology Showcase, an inaugural event, held at the Advanced Technology Research Facility (ATRF) in Frederick, MD. Spearheaded by NCI's TTC, the event showcased technologies being developed at the NCI in Bethesda and Frederick, and the FNLCR, and aimed to encourage startup formation, technology licensing, and collaborations by companies, investors, and entrepreneurs. It also sought to increase awareness, outreach, and education about technology transfer and its important role in bringing medical solutions to patients. Attendees included the local scientific community, prospective investors, established companies, interested stakeholders, economic development groups, educators, and interested stakeholders seeking to learn about technology commercialization. The event featured short technology summaries presented by 10 NCI and FNLCR innovators, and presentations from

regional stakeholders involved with technology development and commercialization. Daryl Sampey, CEO of BioFactura, presented a success story of how his company benefited from NIH licensing. Concurrently, an interactive poster session by innovators and the new post-doctoral technology ambassadors featured opportunities for networking throughout the event. This event was held in partnership with the Frederick County Office of Economic Development, the City of Frederick Department of Economic Development, the Maryland Technology Development Corporation (TEDCO) and the Frederick Innovative Technology Center (FITCI). The Showcase concluded with a networking reception.

NCI Honored at Federal Laboratory Consortium Mid-Atlantic Region (FLC-MAR)

The FLC MAR honored NCI at its 2017 annual meeting, presenting NCI with three awards.

For Excellence in Technology Transfer

"Avelumab, New Therapy for Metastatic Merkel Cell and Urothelial Carcinomas"

Through a CRADA with EMD Serono, NCI played an instrumental role in developing and expediting regulatory approval of EMD Serono's checkpoint inhibitor, avelumab. Avelumab received FDA approval in 2017, only four years after EMD Serono and NCI added the study of avelumab to their CRADA. This was a remarkably fast developmental and regulatory approval timeline.

NCI:

- James Gulley, M.D., Ph.D., Branch Chief, Genitourinary Malignancies Branch, Center for Cancer Research (CCR)
- Jeffrey Schlom, Ph.D., Chief, Laboratory of Tumor Immunology and Biology (LTIB), CCR
- John Greiner, Ph.D., Staff Scientist and Head of Cytokine Group, LTIB, CCR
- Renee N. Donahue, Ph.D., Staff Scientist, Laboratory of Tumor Immunology and Biology, Center for Cancer Research, CCR
- Ravi A. Madan, M.D., Associate Research Physician and Clinical Director, Genitourinary Malignancies Branch, CCR
- Andrea B. Apolo, M.D., Investigator and Head of the Bladder Cancer Section, Genitourinary Malignancies Branch, CCR
- Julius Strauss, M.D., Staff Clinician, LTIB, CCR
- Isaac Brownell, MD, Ph.D., Investigator, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), formerly Investigator, Dermatology Branch, CCR
- Michael Pollack, Ph.D., Supervisory Technology Transfer Manager (TTM), NCI Technology Transfer Center (TTC)

CDC:

- Kevin Brand, J.D., TTM, CDC, formerly NCI TTC

Pictured left to right: NCI: Michael Pollack, Julius Strauss, James Gulley, Renee Donahue, John Greiner, Jeffrey Schlom, and Robert Griesbach, FLC MAR Coordinator

For Excellence in Technology Transfer

"Development of Large Scale Production, Anti-HIV Microbicide in Soya Beans"

Summary: HIV microbicides are not currently sold commercially, and many other HIV prevention techniques remain unavailable or unfeasible in developing countries where the disease is most prevalent. The technology transfer effort of developing large scale production methods of CV-N in soy beans helps to address this issue. The ability to produce CV-N in large quantities at low cost affords researchers the potential to develop effective HIV prevention methods worldwide.

NCI Scientific Team:

- Barry R. O'Keefe, Ph.D., Deputy Chief, Molecular Targets Laboratory (MTL), CCR, and Chief, Natural Products Branch, Division of Cancer Treatment and Diagnosis (DCTD)
- Michael R. Boyd, Ph.D., M.D., Chief, Laboratory of Drug Discovery, Research and Development, retired
- James B. McMahon, Ph.D., Chief, MTL, CCR, retired

NCI Technology Transfer Center (TTC):

- Bjarne Gabrielsen, Ph.D., Technology Transfer Manager (TTM), retired

- Mike Currens, Ph.D., Special Assistant to Developmental Therapeutics Program Associate Director, Office of the Director, DCTD, formerly with TTC
- Melissa Maderia, Ph.D., TTM, University of Illinois at Chicago, formerly with TTC

Partners:

- Elíbio Rech, Ph.D., E Genetic Resources department of EMBRAPA
- Rachel Chikwamba, Ph.D., Council for Scientific and Industrial Research (CSIR Biosciences)

Pictured: Michael Currens, NCI and Robert Griesbach, FLC MAR Regional Coordinator

For TT Rookies of the Year:

"Establishment of the First Federal Technology Transfer Ambassadors Program"

Pictured: TT Rookies Drs. Robert Sons, Laura Prestia and Alan Alfano; TTC Associate Director Dr. Thomas Stackhouse

Summary: Drs. Alan Alfano, Laura Prestia, and Robert Sons, technology transfer rookies at the National Cancer Institute's (NCI) Technology Transfer Center (TTC), established the first federal Technology Transfer Ambassadors Program (TTAP). The TTAP is a year-long, hybrid training/mentoring program for NCI post-doctoral scientists seeking professional and career development about invention development, commercialization, and entrepreneurship.

NCI TTC:

- Alan Alfano, Ph.D., TTM
- Laura Prestia, Ph.D., TTM
- Robert Sons, Ph.D., TTM

APPENDIX

DHHS Technology Transfer Offices

NIH OTT - NIH Office of Technology Transfer

https://www.ott.nih.gov

CDC - Centers for Disease Control and Prevention

CDC Office of Technology and Innovation

https://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

https://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

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

- Service Center for:
- NIAAA - National Institute on Alcohol Abuse and Alcoholism
- 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

https://www.niaid.nih.gov/research/technology-transfer-and-intellectual-property-office

Service Center for:

- CDC - Centers for Disease Control and Prevention (CDC)

NIDCR - National Institute of Dental and Craniofacial Research

NIDCR Office of Technology Transfer and Innovation Access

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

NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK Technology Advancement Office

https://www.niddk.nih.gov/about-niddk/offices-divisions/technology-advancement-office/Pages/default.aspx

Service Center for:

- ORS - Office of Research Services

NIMH - National Institute of Mental Health

NIMH Office of Technology Transfer

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

NINDS - National Institute of Neurological Disorders and Stroke

NINDS Technology Transfer Office

https://tto.ninds.nih.gov