

Expanding the NIH's translational record in infectious, immunologic, and allergic diseases

The National Institute of Allergy and Infectious Diseases' (NIAID) Technology Transfer and Intellectual Property Office (TTIPO) has been instrumental in advancing innovation, continuously building on the institute's record of scientific excellence with its partners.

For over 60 years the NIAID, a part of the US National Institutes of Health, has conducted and supported basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. Key to this mission is the ability to rapidly exploit new research opportunities and address domestic and global health issues, including emerging public health threats.

To support these translational activities, NIAID established the TTIPO, a one-stop resource for internal stakeholders and external organizations interested in partnering with NIAID to access, develop and manage the translation of research discoveries into medically beneficial products. The expert advice and resources provided by TTIPO along the translational continuum, from discovery to product, have led to major breakthroughs, ranging from vaccines and therapeutics to diagnostics for infectious diseases and immune disorders.

TTIPO seeks to expand NIAID's innovation pipeline with existing and new partners in infectious disease areas (e.g., dengue, Zika, Ebola, influenza, methicillin-resistant *Staphylococcus aureus*, and HIV/AIDS), bio-defense (e.g., smallpox and anthrax), and immune-mediated diseases (e.g., asthma and allergy).

Research excellence

NIAID has a long record of excellence in immunologic, allergic, and infectious disease research performed under the auspices of its extramural and intramural research divisions.

Extramural research funded by NIAID includes a combination of managed grants, contracts, and cooperative agreements supporting research on allergy, immunology, transplantation, microbiology, infectious diseases, and AIDS at academic and research institutions in the United States and around the world.

NIAID has two intramural arms, the Division of Intramural Research¹ and the Vaccine Research Center². These focus on basic, applied, and clinical research carried out within NIAID laboratories in Maryland and at the Rocky Mountain Laboratories in Montana. The basic research agenda centers on the broad themes of advancing knowledge about the immune system, defining mechanisms responsible for abnormal immune function, understanding the biology of infectious agents and the host response to infection, and conceiving novel strategies to prevent and treat infectious and immune-mediated diseases.

The applied research agenda focuses on new vaccine development for infectious agents ranging from AIDS to influenza and Ebola. NIAID's priority remains

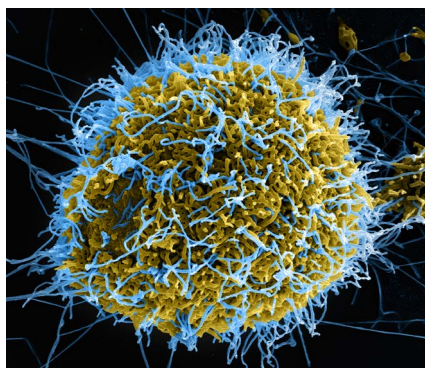


Figure 1: Color micrograph of the Ebola virus.

NIAID's translational infrastructure allows the institute to prepare for and rapidly react to domestic and global public health challenges such as the spread of the Ebola virus.

the development of vaccines against AIDS, malaria, and tuberculosis, but other targets include naturally arising pathogens such as the dengue, West Nile, and Zika viruses and bioterrorism threats such as smallpox.

"TTIPO's work underpins NIAID's significant impact in the global health arena and its meaningful contribution to the US economy through collaborations with the biotechnology, pharmaceutical, and non-profit sectors," said Michael R. Mowatt, TTIPO's director.

Translation on a mission

TTIPO provides NIAID with advice on intellectual property, commercialization, and partnering. Its activities include identifying opportunities for NIAID to access research resources (e.g., through material or information exchanges, conditional gifts, and research collaborations) and advancing the development and commercialization of NIAID discoveries (e.g., through patenting and licensing). TTIPO manages a growing portfolio of 400 patent families, over 30% of which it has successfully licensed. In addition to licensing, TTIPO manages formal research collaborations with both nonprofit and commercial partners using a variety of contract mechanisms.

Through partnerships, TTIPO's activities have produced many beneficial products, including viral vaccines (e.g., Dengvaxia (CYD-TYV) for dengue; Havrix (hepatitis A vaccine), Twinrix (hepatitis A and hepatitis B recombinant vaccine), and Hepatyrix (combined inactivated hepatitis A and polysaccharide typhoid vaccine) for hepatitis A; Rotashield (rotavirus vaccine); and Imrab (rabies vaccine, killed virus)), antiviral

therapeutics (e.g., Synagis (palivizumab) for respiratory syncytial virus), veterinary vaccines (e.g., Raboral V-RG rabies vaccine), and diagnostics (e.g., AccuPlex4 for Lyme disease and Ridascreen for norovirus).

Small business innovation

In addition to the partnering mechanisms, NIAID also offers an attractive opportunity for small businesses to engage with it through its Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program. This program awards over \$120 million annually and provides small businesses with an opportunity to engage in research and development with the NIAID. The SBIR/STTR program is one of the largest sources of early-stage technology financing in the United States, and NIAID's program is an important avenue for translation of infectious disease and immune disorder interventions³.

Resources for industry and academia

Besides funding research, NIAID also provides many resources to advance the discovery and development of diagnostics, therapeutics, and vaccines at no cost.

These resources include preclinical and clinical services for new vaccines and therapeutics; bioinformatics databases for genomics, proteomics, and immune epitopes; research reagent repositories of organisms, cells, tissues, small molecules, biologics (e.g., antibodies), and cell lines; animal models; unique biocontainment facilities; and services for producing current good manufacturing practice (cGMP)-grade products, among others⁴.

1. NIAID. Division of Intramural Research. *National Institute of Allergy and Infectious Diseases* <http://www.niaid.nih.gov/about/organization/dir/> (2016).
2. NIAID. Vaccine Research Center. *National Institute of Allergy and Infectious Diseases* <http://www.niaid.nih.gov/about/organization/vrc/> (2016).
3. NIAID. Small Business Program. *National Institute of Allergy and Infectious Diseases* <https://www.niaid.nih.gov/researchfunding/sb/> (2016).
4. NIAID. Resources for Researchers. *National Institute of Allergy and Infectious Diseases* <https://www.niaid.nih.gov/labsandresources/resources/> (2016).

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