



# Technology Transfer in the NIH Intramural Research Program

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*OHSRP Education Series  
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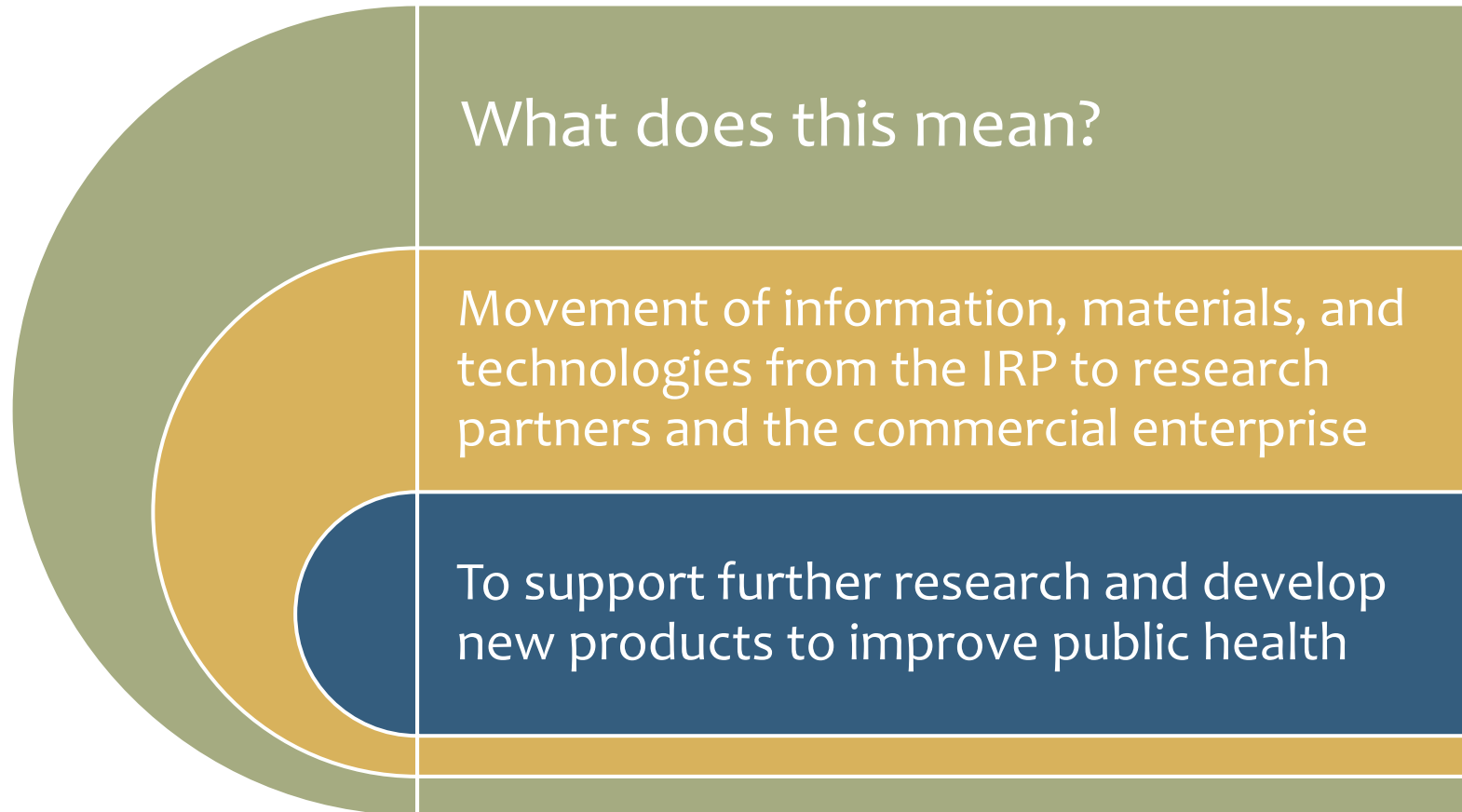
**National Institutes of Health**  
Office of Intramural Research  
Office of Technology Transfer

# Topics for Today

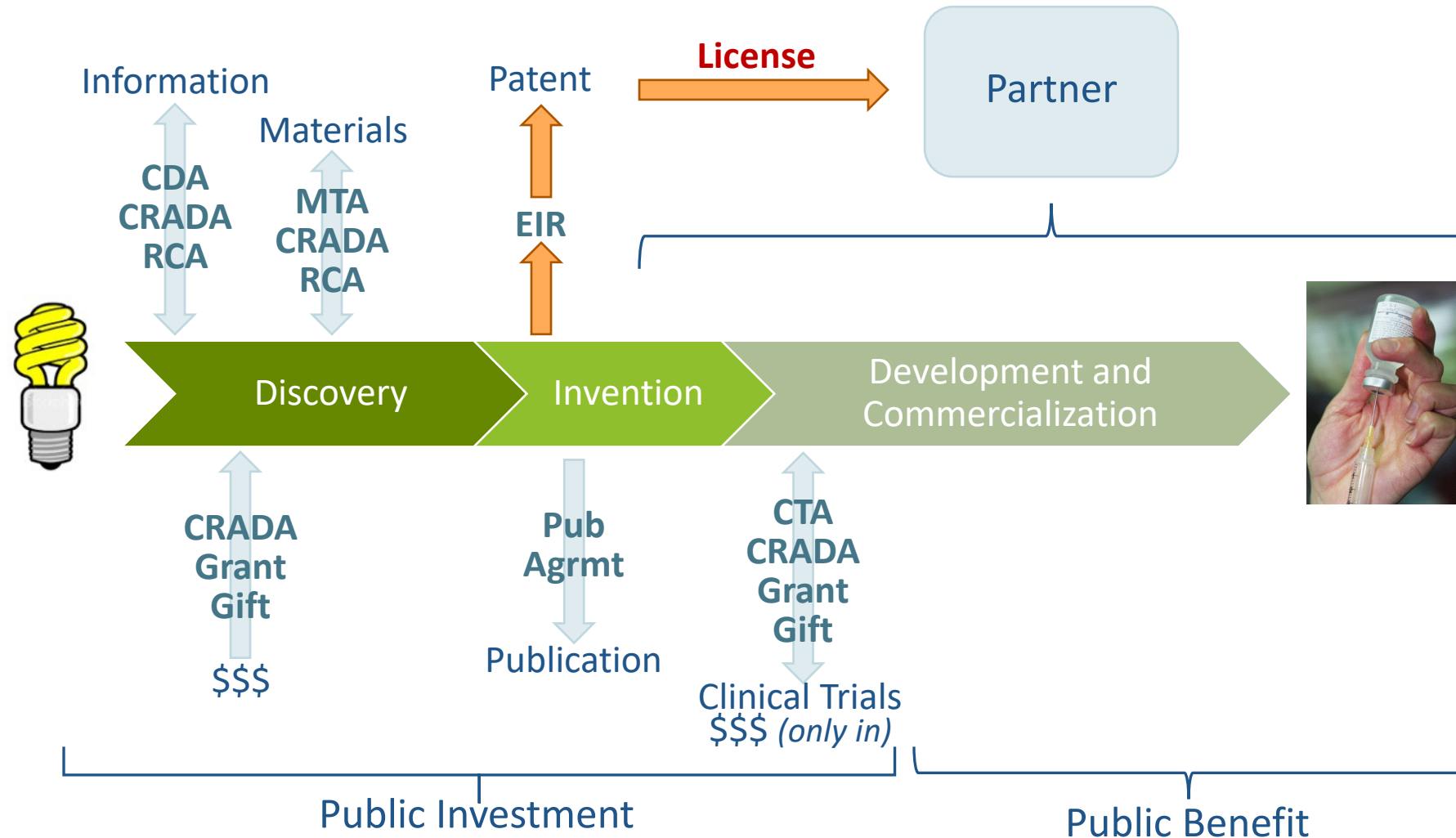
- What Does “Technology Transfer” Mean at the NIH?
- Quick Primer on NIH Patenting and Licensing
- How Technology Transfer is Organized in the IRP
- What, Exactly, Does NIH OTT Do?
- Technology Transfer Impacts in the Real World



# Technology Transfer at NIH



# Technology Transfer: Discovery to Marketplace



# NIH Intramural Program (IRP) By the Numbers



**~1,200** PIs  
**~4,000** Fellows



Projects  
**3000+** from  
**24** NIH ICs



New  
Agreements  
**~100\*** CRADAs  
**4500+** Others



U.S. Patents  
**187\*** Filed  
**2500+** Active



Licenses  
**273\*** New  
**2000+** Active

# Why Does the NIH Grant Licenses?



Utilize IP appropriately as incentive for commercial development of technologies



Attract new R&D resources



Obtain return on public investment



Stimulate US economic development



Deliver on laboratory goals/mission



Benefit U.S. and global public health

# When Does NIH Patent Inventions?



## Seek patent protection if:

- Facilitates availability of the technology for preventive, diagnostic, therapeutic, or other commercial use
- Further research and development is necessary to realize the technology's primary use
- Commercial or public health value of the technology warrants the expenditure of funds
- Research has a practical utility or a reasonable expectation of future practical utility



## Do not seek patent protection if:

- Commercialization and technology transfer can best be accomplished without patent protection

# What Does NIH License?

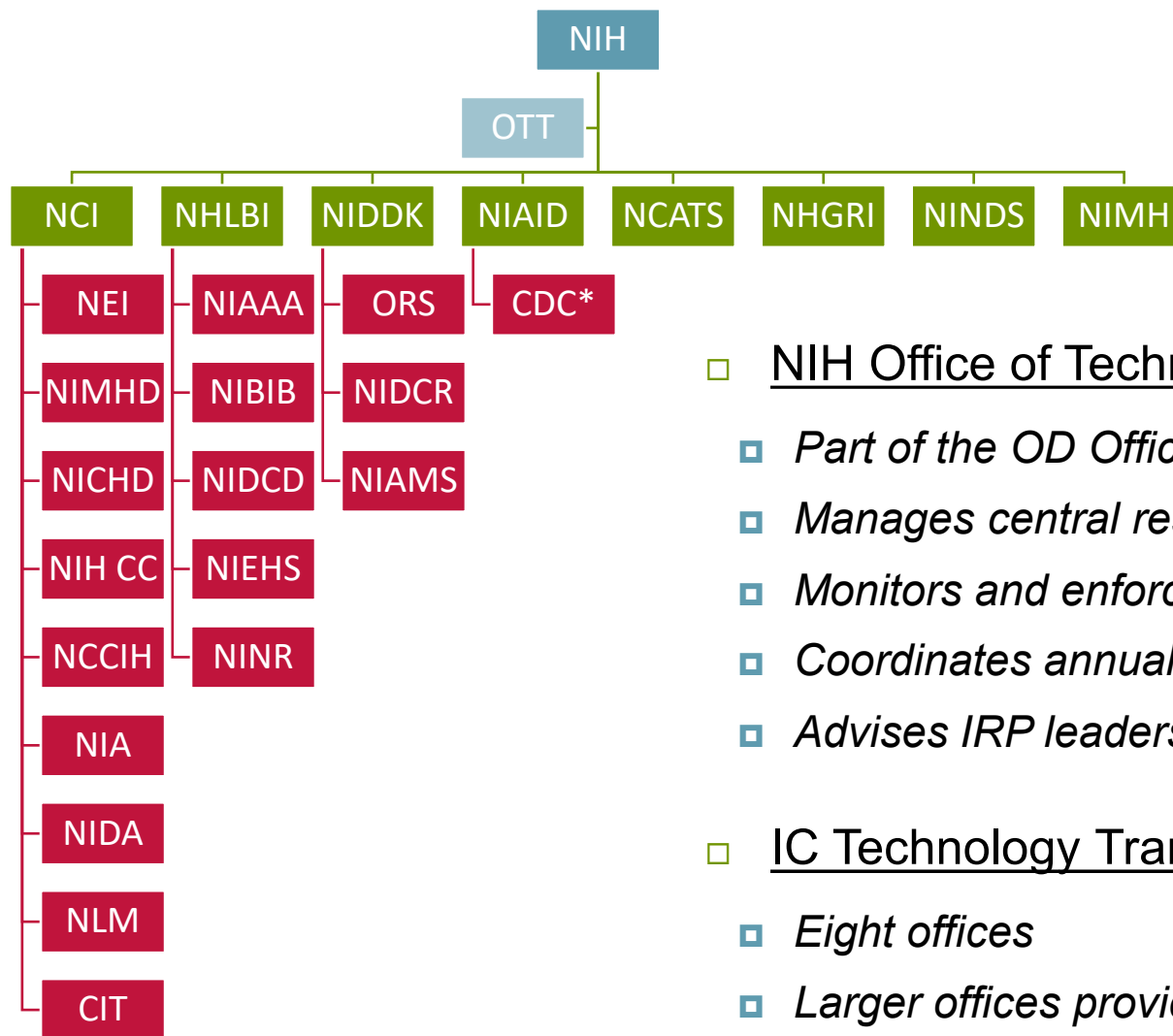
- Authority: 35 U.S.C. § 207-209, 37 C.F.R. § 404
- Limited to patented or patentable inventions assigned to the Government. This includes:
  - Patents
  - Unpatented materials (e.g., animal models, cell lines, antibodies)
  - Software



# NIH Licensing Process



# How Technology Transfer is Organized in the IRP



- NIH Office of Technology Transfer (OTT)
  - *Part of the OD Office of Intramural Research*
  - *Manages central resources and databases*
  - *Monitors and enforces licenses, collects royalties*
  - *Coordinates annual reporting & advises IRP leadership*
  - *Advises IRP leadership on technology transfer activities & policies*
  
- IC Technology Transfer Offices (TTOs)
  - *Eight offices*
  - *Larger offices provide TT services to smaller ICs (and CDC)*
  - *Work directly with intramural investigators*

# What IC Tech Transfer Offices Do

*IC TTOs work directly with investigators and IC programs to support technology transfer activities*

- Protect intellectual property
- Promote collaborations with academia, industry, nonprofits, and government agencies
- Negotiate agreements to support IC research programs
- Manage patenting & licensing activities
- Larger offices provide TT services to smaller ICs
- Primary focus is IRP, but some work with extramural programs
- Some TTOs manage IC-level SBIR/STTR functions



# What, Exactly, Does OTT Do?

*The Office of Technology Transfer (OTT) supports IC technology transfer offices, manages critical infrastructure, & coordinates trans-NIH activities for intramural technology transfer.*



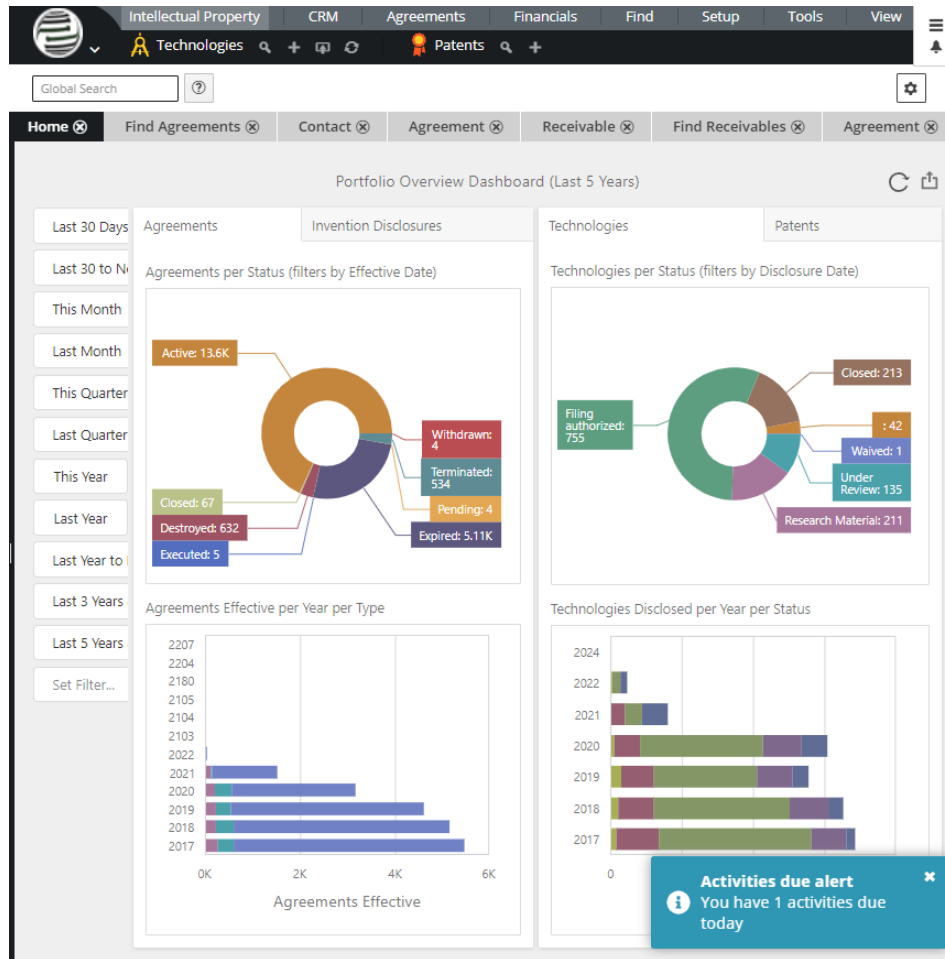
- Monitor and enforce NIH licenses, administer royalty collections.
- Manage the NIH-wide Enterprise Technology Transfer (ETT) system, containing data from eight IC TTOs & OTT, and other NIH-wide tech transfer IT systems.
- Manage the NIH-wide Patent Legal Services and Patent Annuities Services contracts and perform legal docketing services.
- Manage the Technology Transfer Community website.
- Conduct marketing and outreach on behalf of the NIH Technology Transfer Community
- Coordinate reporting to NIH, HHS, other agencies and Congress.
- Advise on technology transfer activities and policy.

# By the Numbers

- Current staff: about 45 employees + contractors.
- Responsible for IT systems that support hundreds of NIH users, as well as hundreds more contract staff and staff at outside.
- Manage patent records and annuity payments for over 1900 technologies.
- Monitor compliance for 2000+ licenses for inventions from 24 ICs.
- In FY 2025, administered over **\$1 billion** in royalty collections for NIH licenses  
(*typical range: \$100-\$400 million*)



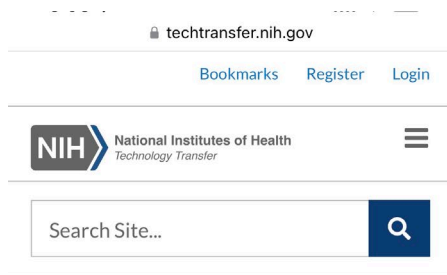
# Enterprise Technology Transfer System (ETT)



- Centralized, end-to-end NIH TT community enterprise system supporting activities related to NIH inventions, patents, licenses, agreements, and financials for hundreds of TT professionals
- Launched December 2022
- Combines data from 9 IC databases and OTT's database
- Supports Congressional and NIH requirements for reporting and data transparency
- Includes extensive customization to address IC-level specialized needs and increasing reporting and transparency requirements.

# Technology Transfer Community Website

- Resource hub for IRP tech transfer
  - Inventor information
  - Available technologies & collaborations
  - Model agreements
  - Policies
  - Metrics & reports
  - And more!
  - [techtransfer.nih.gov](http://techtransfer.nih.gov)



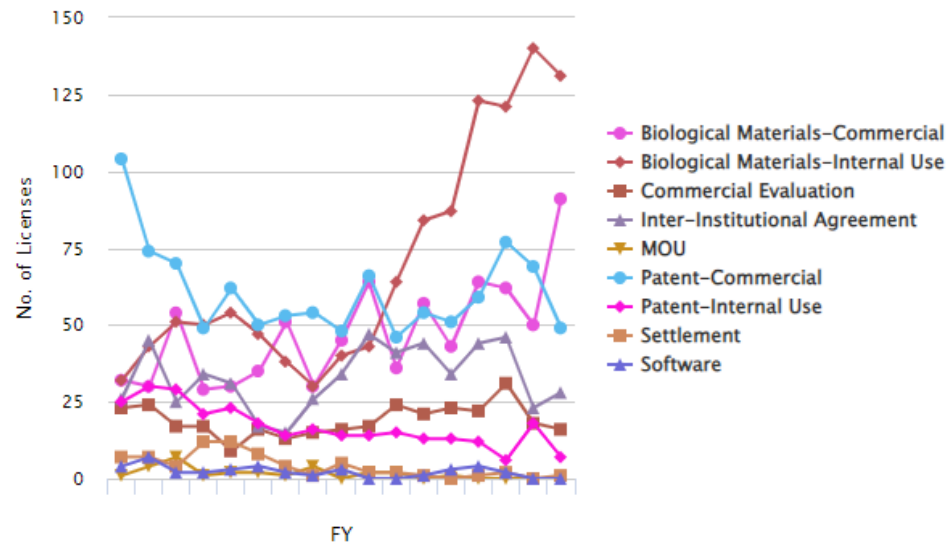
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Licenses in a Fiscal Year by Type of Agreement



**PUBLIC HEALTH SERVICE**  
PATENT LICENSE-NON-EXCLUSIVE

This Agreement is based on the model Patent License Non-exclusive Agreement adopted by the U.S. Public Health Service ("PHS") Technology Transfer Policy Board for use by components of the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA"), which are agencies of the PHS within the Department of Health and Human Services ("HHS").

This Cover Page identifies the Parties to this Agreement

The U.S. Department of Health and Human Services, as represented by  
**[Insert the full name of the IC]**

**Material Transfer Agreement for the Transfer of Organisms (MTA-TO) to Academic/ Not-for-Profit Organizations**

This is in response to RECIPIENT's request for the MATERIAL (specifically, the name of the gene or allele mutation that makes the organism(s) unique),

found within the [organism strain, species], and any unmodified derivative and unmodified progeny, as well as any biological materials (including, without limitation: zygotes, embryos, cells, tissues, fluids, etc.) which contain or incorporate the MATERIAL and are derived directly from the original organism or its unmodified progeny, to be used for the purpose of:

The PROVIDER requires that the RECIPIENT agree to and the RECIPIENT SCIENTIST acknowledge the following terms before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others who are not under the RECIPIENT SCIENTIST's direct supervision without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Material Transfer Agreement for the Transfer of Organisms to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from RECIPIENT's use, storage or disposal of the MATERIAL except that, to the extent permitted by law, the PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.
7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. If the RECIPIENT anticipates that it will generate cross-bred or genetically-modified organisms incorporating the PROVIDER's modified allele(s), RECIPIENT may transfer such cross-bred or genetically-modified organism(s) to non-profit institutions under the terms of a material transfer agreement that notifies the not-for-profit institution of the existence of PROVIDER's rights to the modified allele(s) and restricts the use of the transferred organism(s) by the not-for-profit recipient to teaching or not-for-profit research purposes only. This Agreement does not transfer any of PROVIDER's patent, invention, or other intellectual property rights in the organism(s) to RECIPIENT. Additionally, to the extent that any other party has any patent, invention or other intellectual property rights in the organism(s), these rights are not transferred to RECIPIENT by PROVIDER.
9. IF NIH is the PROVIDER, the following addenda may be attached (check all that apply):  
[ ] Annual Transfer Addendum, or [ ] Annual Transfer Agreement (not required for transfers within NIH), [ ] Other

12/2008 Updated 12/2020 Model MTA-TO

# License Compliance and Administration



## Lead: IC TTO

- IC negotiates & executes
- LCAU advises on
  - Compliance
  - Amended terms
  - Potential patent infringement

## Lead: OTT

- Monitor license for compliance
- Royalty administration
- Address licensee requests – e.g., negotiate amendment or approve sublicense
- Settle disputes
- Ensure NIH compliance
- IC approves significant license changes

## Lead: OTT

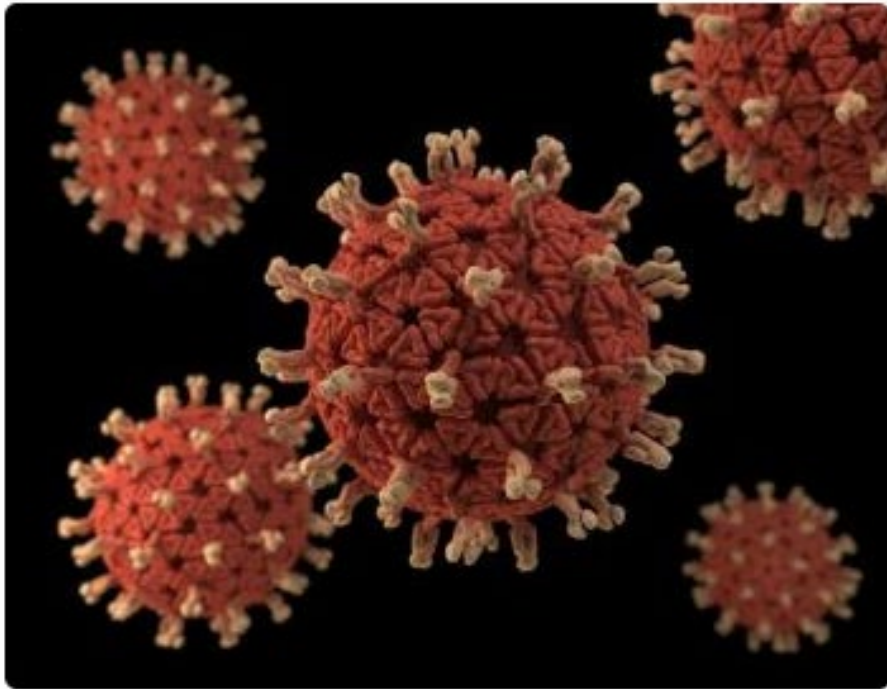
- Initiates termination procedures when warranted
- Ensures obligations are satisfied
- As needed: refer to debt collection or to Office of General Counsel

# Technology Transfer Impacts in the Real World

- Broad range of technologies reflecting intramural program's diverse research
- More than 1,000 products brought to market  
46 FDA-approved vaccines and therapeutics
- Licensed IP utilized in over 1,200 clinical trials
- Over 60% of NIH licenses are for research tools



# NIH-Based Products Have Broad Public Health Impact



## Infectious Disease

- COVID-19 vaccine (Comirnaty<sup>®</sup>)
- Ebola virus therapy (Ebanga<sup>®</sup>)
- Pneumococcal vaccine (Pneumosil<sup>®</sup>)

## Cancer

- Multiple myeloma therapy (Abecma<sup>®</sup>)
- Hairy cell leukemia therapy (Lumoxiti<sup>®</sup>)
- B-cell lymphoma therapy (Yescarta<sup>®</sup>)

## Other

- Progeria treatment (Zokinvy<sup>®</sup>)
- Ketamine spray for depression (Spravato<sup>®</sup>)
- Cholestatic pruritus therapy (LIVMARLI<sup>®</sup>)

# Snapshot: Rare Disease Therapy



- First FDA-approved drug (2020) to treat a premature aging disease, Hutchinson–Gilford progeria syndrome, and related syndromes.
- Children with this ultra-rare pediatric disease die by age 15.
- Made possible through the combined efforts of NIH, the Progeria Research Foundation, Eiger Biopharmaceuticals (& 2 other companies), and Boston Children’s Hospital

More information:

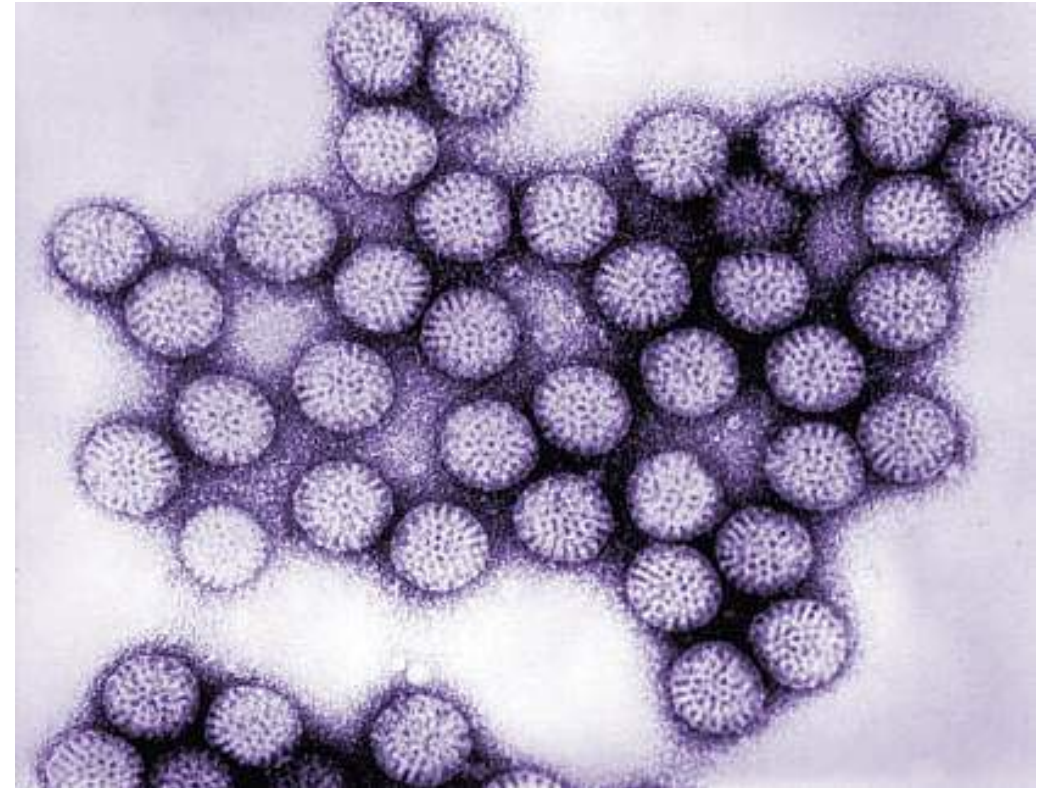
- NIH News Release: <https://www.nih.gov/news-events/news-releases/decades-nih-research-help-lead-first-fda-approved-treatment-progeria>
- NIH WALs Lecture, Jan 2024 - <https://videocast.nih.gov/watch=54012>



National Institutes of Health  
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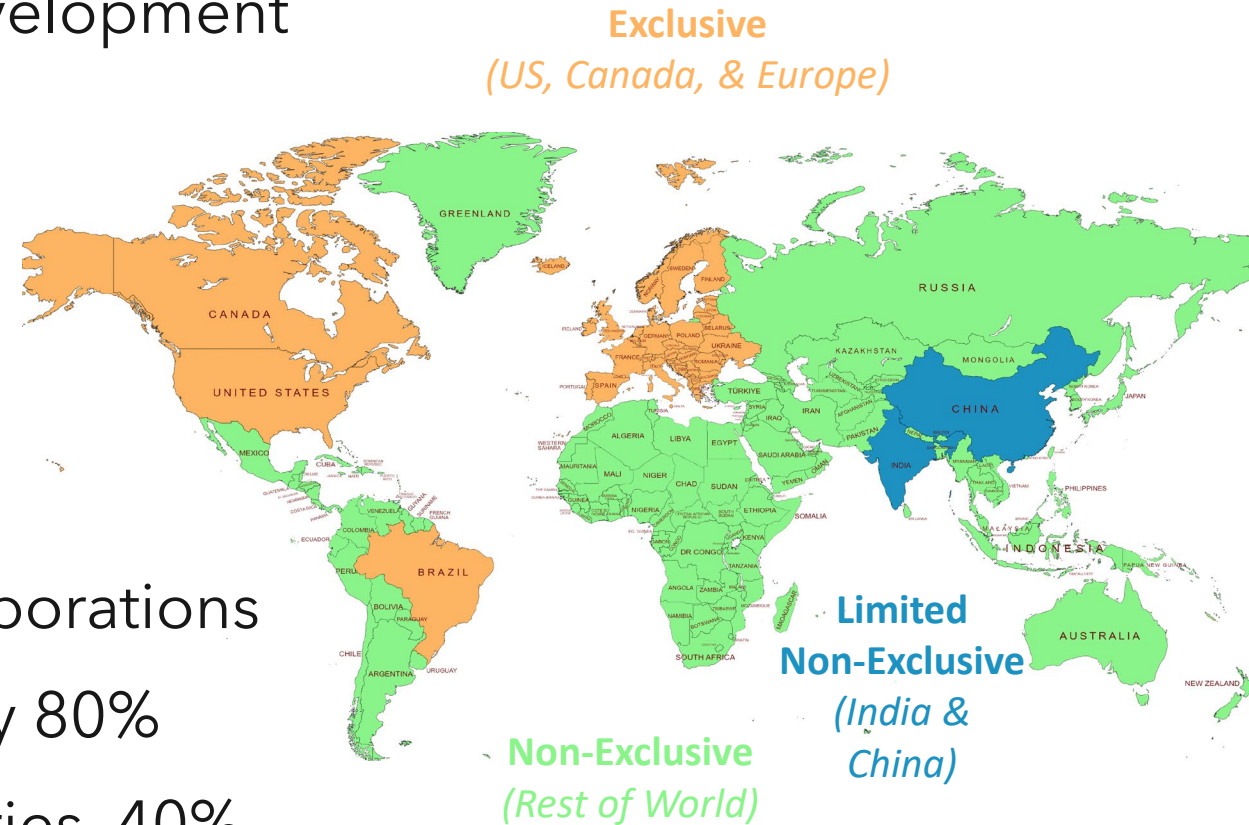
# Snapshot: Regional Licensing to Facilitate Access

- Rotavirus is a highly contagious virus that can cause severe diarrhea and vomiting, especially in infants.
- Before a vaccine was available, rotavirus was responsible for half a million child deaths each year
- Previous vaccine efforts failed, leading to NIH development of a 2<sup>nd</sup> generation vaccine



# Snapshot: Regional Licensing to Facilitate Access

- Maximize opportunity for successful development and global distribution of technology
  - 14 commercial licensees
    - Biological materials
    - Access to inventor for technical input
  - Regional expertise
  - Regional vaccine programs
- Establish relationships and enable collaborations
- Result in US: hospitalizations reduced by 80%
- ROW: available in more than 100 countries, 40% decrease in hospital admissions for young children, reduced deaths



Created with mapchart.net

*Thank You!*

*For more information, go to  
<https://techtransfer.nih.gov/>.*



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Office of Intramural Research  
Office of Technology Transfer

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lies the bigger picture.  
**A solution.**



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