

Technology Transfer: Sharing the TTO Experience



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National Institutes of Health

The Nation's Steward of Medical & Behavioral Research

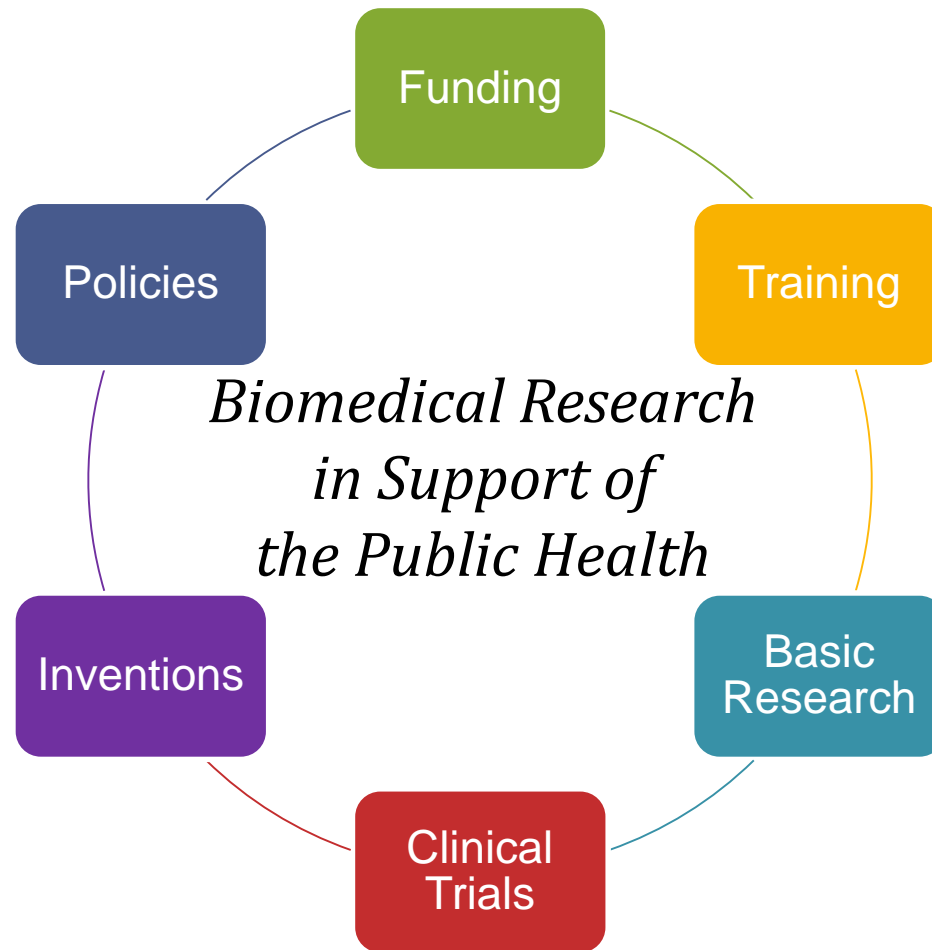


Premier biomedical
research institution
in the United States

Annual Budget =
\$32.3 billion

Engine for Research & Innovation

National Institutes of Health



Technology Transfer

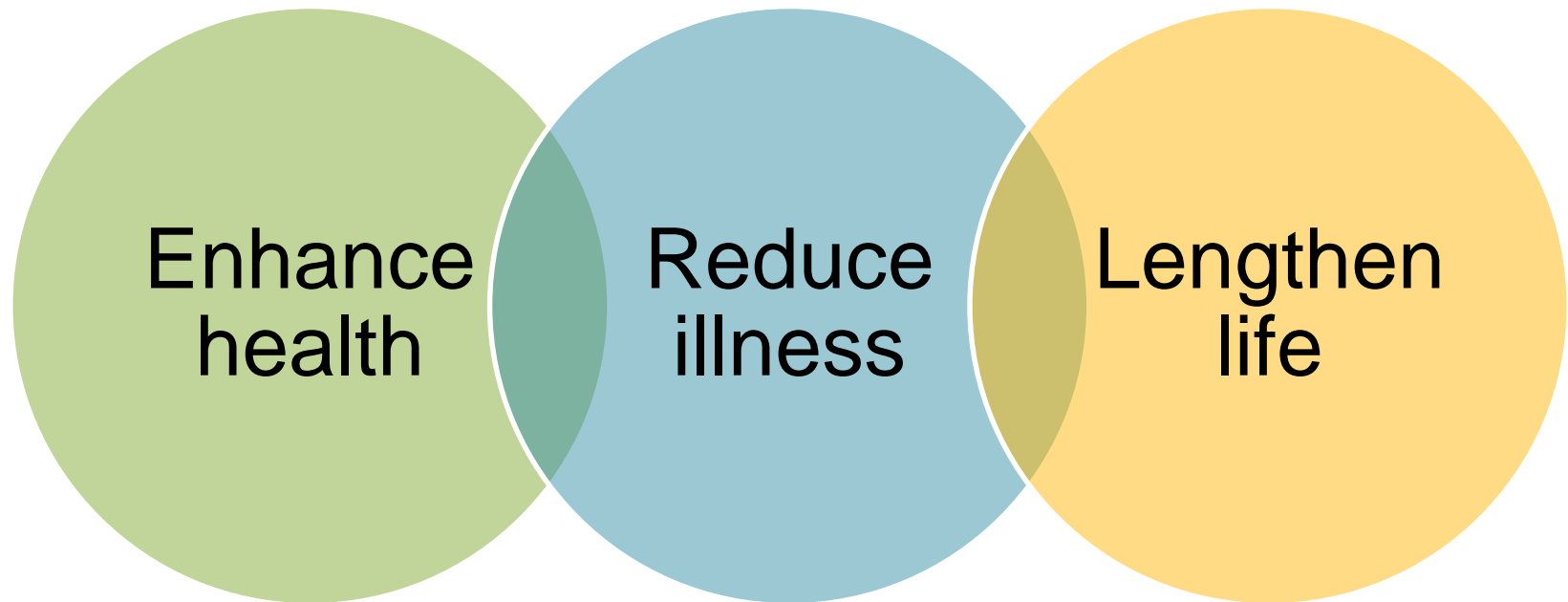


What Does This Mean?

- * Movement of information, materials, and technologies from the research laboratories to the commercial enterprise *

- * To support further research and develop new products to improve public health *

Technology Transfer Supports NIH Fundamental Mission



Technology Transfer Mission

To improve public health through the management of National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) inventions — and in doing so serve a leading role in public sector biomedical technology transfer policy and practice.



Core Components of the NIH Mission

- **Extramural Research** - Supporting research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout United States and overseas
- **Intramural Research** – Conducting research in its own laboratories
- **Training** - Helping train research investigators
- **Communication** - Fostering communication of medical information



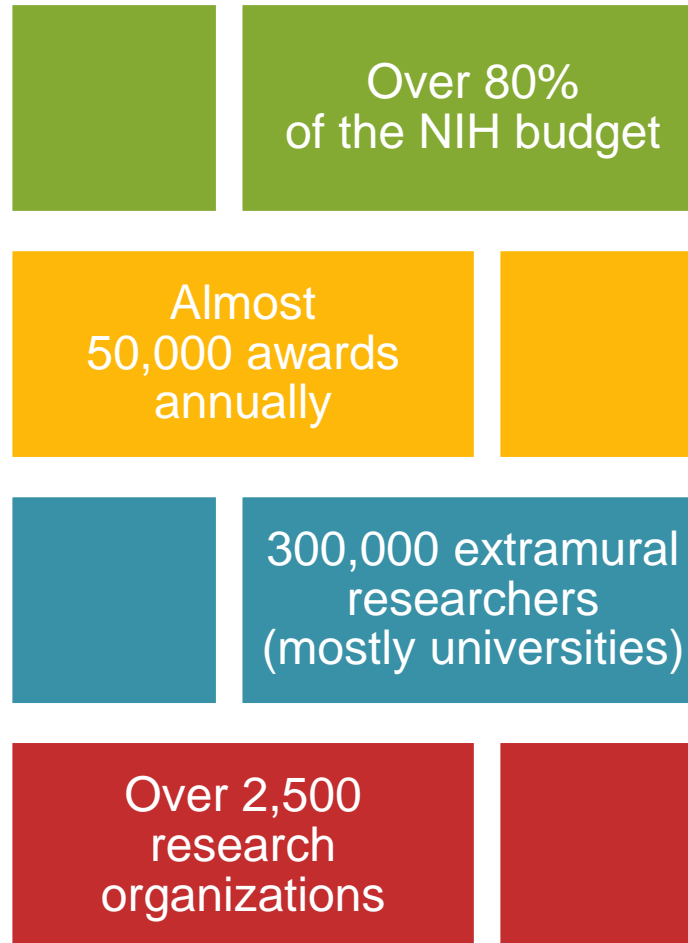
Technology Transfer Goals

- Utilize IP appropriately as incentive for commercial development of technologies
- Attract new R&D resources
- Obtain return on public investment
- Stimulate economic development
- Benefit the public health



Extramural Research

Supporting Research Worldwide



Scientists Funded Globally



Importance of Global Health Research



Intramural Research

Biomedical Research and Training

Approximately 10%
of NIH budget

More than
2,000 active projects

More than
6,000 scientists

Collaborative
research

Patent/License
technologies

CRADA – Cooperative Research and Development Agreement

*Collaboration between Government lab
and outside party*

- Government provides expertise, equipment, materials
- Collaborator provides same and possibly money
- Provides Collaborator with right to elect option to exclusive license to new inventions



Examples of Products Developed Under NIH CRADAs

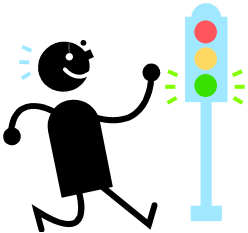
| Product | Company | Use |
|------------------------|----------------------------|---|
| FluMist [®] * | MedImmune | Influenza vaccine |
| Havrix [®] | GlaxoSmithKline | Vaccine against hepatitis A |
| Taxol [®] | Bristol-Myers Squibb | Treatment of solid tumors and Kaposi's cancer |
| Thyrogen [®] | Genzyme Therapeutics | Adjunct to thyroid cancer treatment |
| Velcade [®] | Millennium Pharmaceuticals | Treatment of multiple melanoma |
| *Not based on NIH IP | | |

Technology Transfer

- Utilize IP appropriately as incentive for commercial development of technologies
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Patenting Policy



Seek patent protection if:

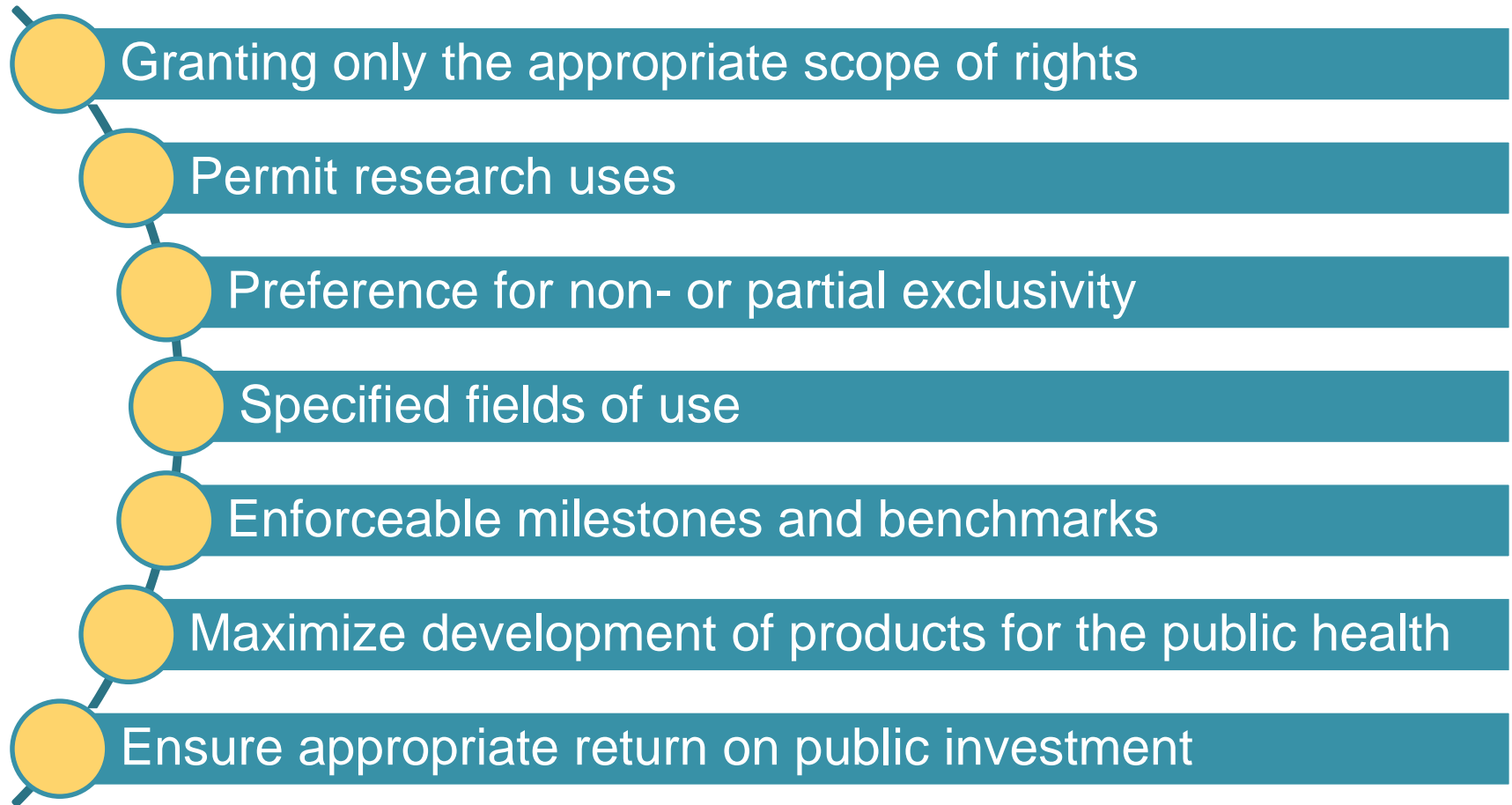
- ▶ Facilitates availability of the technology for preventive, diagnostic, therapeutic, or other commercial use
- ▶ Further research and development is necessary to realize the technology's primary use
- ▶ Commercial or public health value of the technology warrants the expenditure of funds
- ▶ Research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



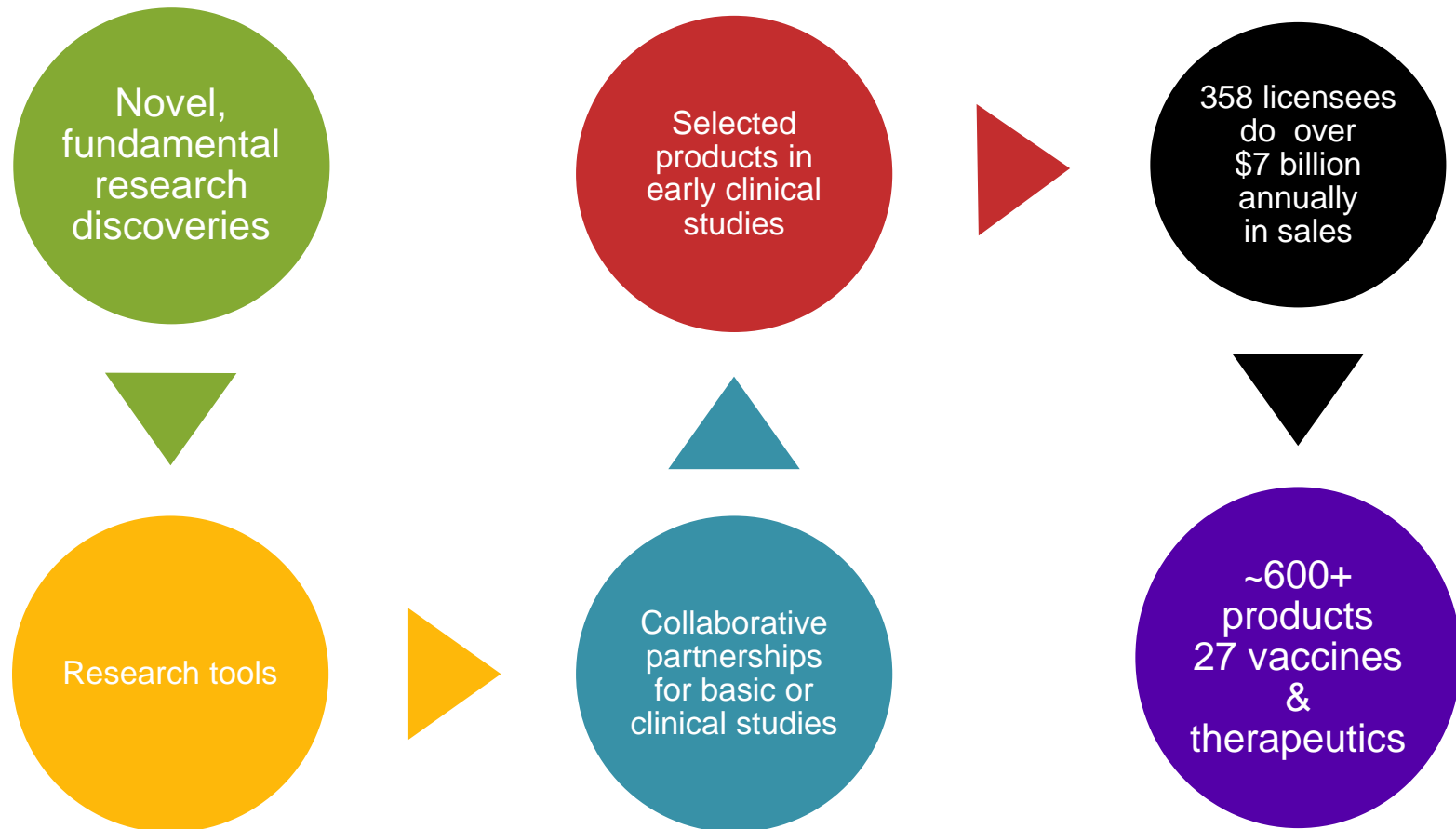
Do not seek patent protection if:

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

NIH Product Licensing Principles



Characteristics of the NIH Intramural Research Program “Pipeline”



NIH License Types

- Exclusive Patent Commercialization
- Non-exclusive Patent Commercialization
- Non-exclusive Patent Internal Use
- Start-Up Exclusive Evaluation Option
- Start-Up Exclusive Patent Commercialization

- Commercial Evaluation License
- Biological Material Commercialization
- Biological Material Internal Use
- Interference or Dispute Settlement
- Inter-institutional

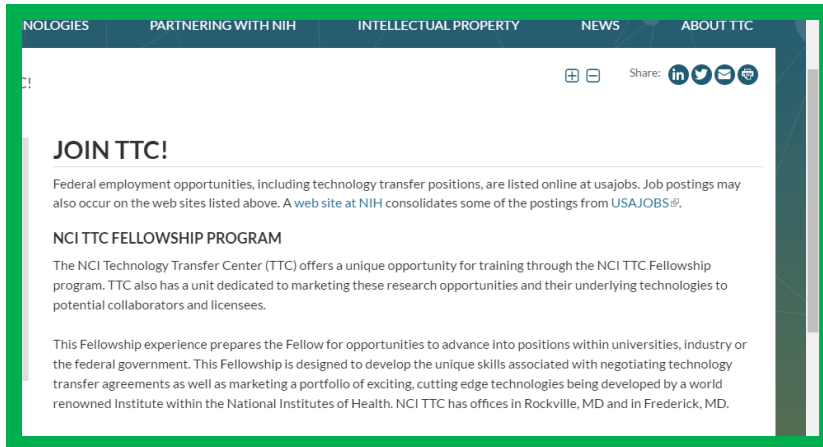
Licensing to University Start-Ups



Technology Transfer Training Programs

- “Advanced Studies In Technology Transfer” certificate program for individual students at FAES Graduate School at NIH
(http://faes.org/grad/advanced_studies/technology_transfer)
- “International Technology Transfer Mentoring Program” for university tech transfer & agency officials
(<http://www.ott.nih.gov/international-mentoring-opportunities>)

NCI & NIAID Fellowships in Tech Transfer



JOIN TTC!

Federal employment opportunities, including technology transfer positions, are listed online at usajobs. Job postings may also occur on the web sites listed above. A [web site at NIH](#) consolidates some of the postings from USAJOBS®.

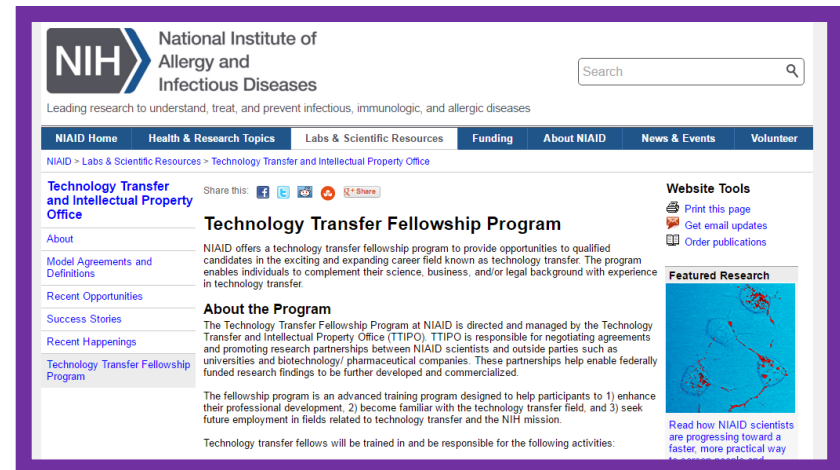
NCI TTC FELLOWSHIP PROGRAM

The NCI Technology Transfer Center (TTC) offers a unique opportunity for training through the NCI TTC Fellowship program. TTC also has a unit dedicated to marketing these research opportunities and their underlying technologies to potential collaborators and licensees.

This Fellowship experience prepares the Fellow for opportunities to advance into positions within universities, industry or the federal government. This Fellowship is designed to develop the unique skills associated with negotiating technology transfer agreements as well as marketing a portfolio of exciting, cutting edge technologies being developed by a world renowned Institute within the National Institutes of Health. NCI TTC has offices in Rockville, MD and in Frederick, MD.

<http://www.niaid.nih.gov/LabsAndResources/techDev/Pages/techTransFellowshipPrg.aspx>

<https://techtransfer.cancer.gov/aboutttc/jointtc>



NIH National Institute of Allergy and Infectious Diseases

Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases

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Technology Transfer and Intellectual Property Office

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Technology Transfer Fellowship Program

About

NIAID offers a technology transfer fellowship program to provide opportunities to qualified candidates in the exciting and expanding career field known as technology transfer. The program enables individuals to complement their science, business, and/or legal background with experience in technology transfer.

About the Program

The Technology Transfer Fellowship Program at NIAID is directed and managed by the Technology Transfer and Intellectual Property Office (TTIPO). TTIPO is responsible for negotiating agreements and promoting research partnerships between NIAID scientists and outside parties such as universities and biotechnology/ pharmaceutical companies. These partnerships help enable federally funded research findings to be further developed and commercialized.

The fellowship program is an advanced training program designed to help participants to 1) enhance their professional development, 2) become familiar with the technology transfer field, and 3) seek future employment in fields related to technology transfer and the NIH mission.

Technology transfer fellows will be trained in and be responsible for the following activities:

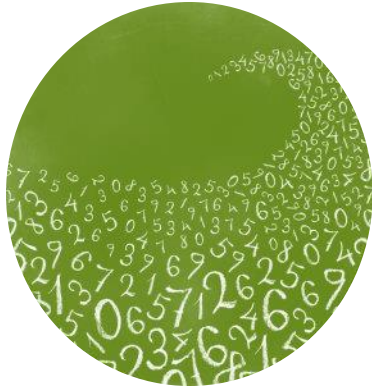
Website Tools

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- [Get email updates](#)
- [Order publications](#)

Featured Research

Read how NIAID scientists are progressing toward a faster, more practical way to develop new drugs.

Intramural Portfolios (FY15)



- 292 invention disclosures
- 151 U.S. patents issued
- 257 licenses executed
- 1,300+ active licenses
- \$147.1 million in royalties collected

Intramural Portfolios

- 101 CRADAs executed (NIH only)
- >600 products developed to date
(27 vaccines and therapeutics)
- Over \$1.2B in royalties collected to date



Licensed Products – Diagnostics



- AcuTect[®]
- BRACAnalysis[®]
- HIV Test Kits
- NeoTect[®]
- Parvovirus B19 Immunoassay
- PathVysion[®] HER-2 DNA Probe Kit
- Pathway[®] Her-2/neu (4B5)
- Thyrogen[®]

Licensed Products – Therapeutics

- Didanosine
- Fludara[®]
- Hivid[®]
- Kepivance[®]
- NeuTrexin[®]
- Prezista[®]
- Sporanox Oral[®]



- Synagis[®]
- Taxol[®]
- Velcade[®]
- Videx[®]
- Vitravene[®]
- Zenapax[®]
- Zevalin[®]

Licensed Products – Vaccines

- Certiva[®]
- Cervarix[®]
- Gardasil[®]
- Havrix[®]
- Hepatyrix[®]
- LYMERix[™]
- RotaShield[®]
- Twinrix[®]



Licensed Products – Other

Also –

- Consumer Products
- Devices/Instrumentation/Software
- Research Reagents
- Veterinary Products

View the [Product Showcase](#) on the OTT web site for more details



For Further Reading



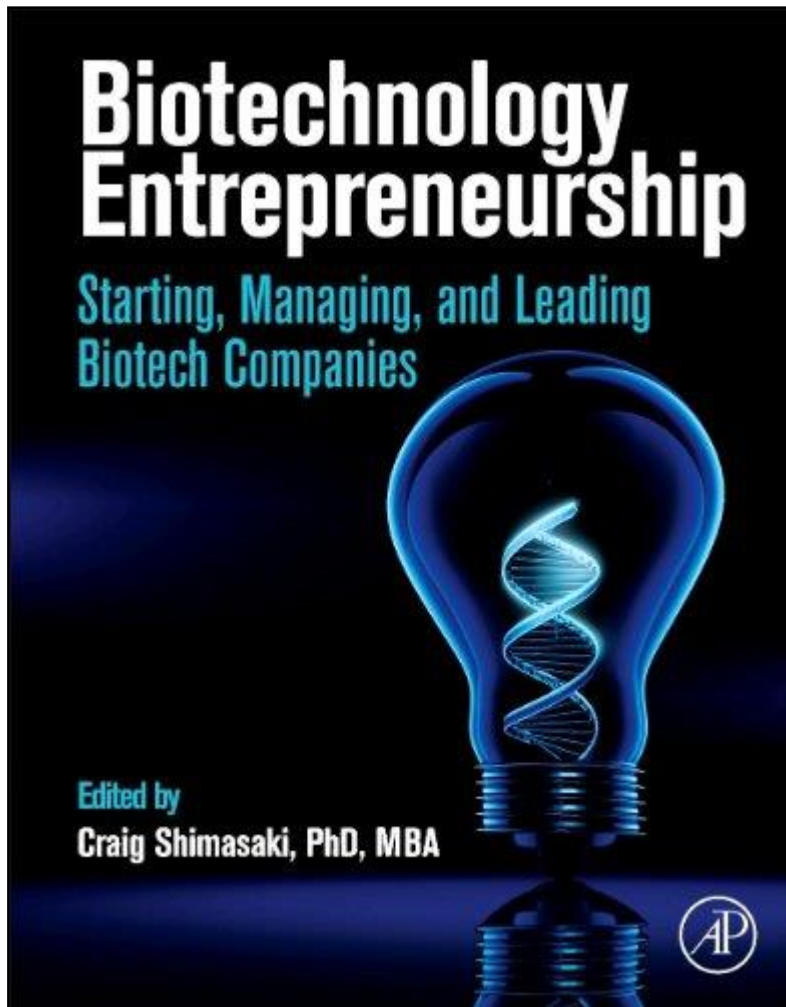
“Partnering with the NIH: Now part of the ‘Value Proposition’ for start-ups”

Journal of Commercial Biotechnology (2012)

18, 60–67.

Available on OTT web site

And From the BIO Bootcamp ...



“Licensing the
Technology:
Biotechnology
Commercialization
Strategies Using
University and
Federal Labs”
(Chapter 14)

Available on OTT web site

Ways to Find -- Licensing Opportunities



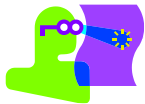
iPhone/iPad app —

<http://www.ott.nih.gov/service/iphoneipad-app>



RSS feed —

<http://www.ott.nih.gov/rss>



Searchable database —

<http://www.ott.nih.gov/opportunities>



e-Brochures —

<http://www.ott.nih.gov/service/technology-specific-brochures>



Federal Register —

<https://www.federalregister.gov/>



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

And A Special Thanks To:



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