TECHNOLOGY TRANSFER: THE NIH EXPERIENCE

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NIH Mission

To uncover new knowledge that will lead to improved public health

National Institutes of Health

Basic Biomedical Research in Support of the Public Health

- **Premier biomedical research institution in the United States**
- **Supports Intramural & Extramural research**
- **2008 Research Budget: Approx. $28 billion**
  - **Approx. 10% for Intramural (NIH) Research**
  - **Approx. 85% for Extramural Research**

National Institutes of Health

Engine for Biomedical Research and Innovation Basic

- **Training**
- **Basic Research**
- **Clinical Trials**
- **Inventions**
- **Policies**

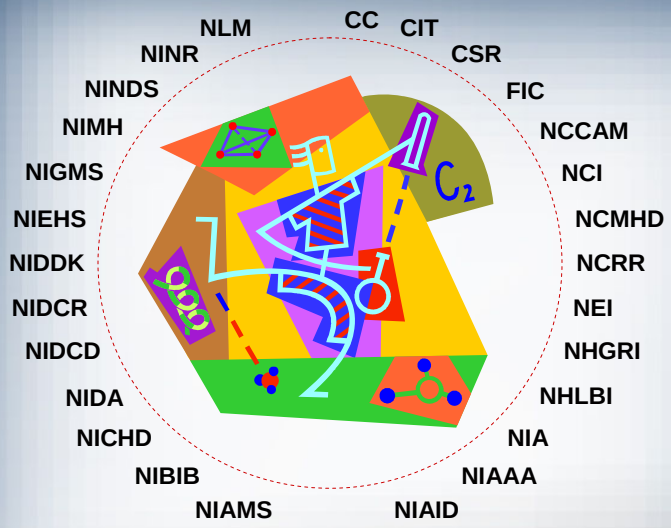
Extramural Research

- Almost 50,000 awards annually
- 325,000 Extramural researchers (mostly universities)
- Over 3,000 organizations
- NIH does not own inventions or control patenting/licensing of inventions (Bayh-Dole)

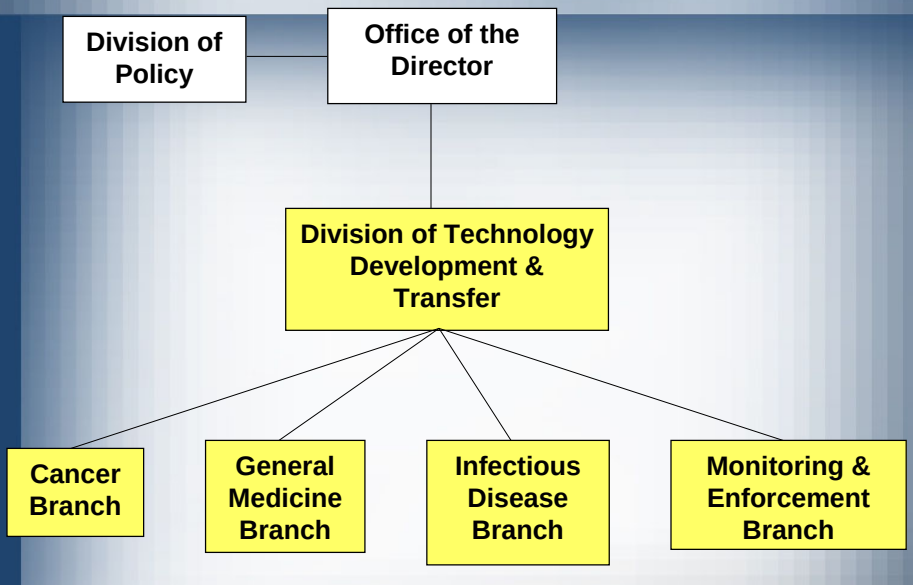
Intramural Research

- More than 2,000 active projects
- More than 6,000 scientists
- NIH owns inventions & controls patent/licensing of technologies

The National Institutes of Health
27 Institutes and Centers



Office of Technology Transfer (OTT) Organization



Technology Transfer

What Does This Mean?

- **Movement of information, materials, and technologies to academic and commercial parties.**
- **To support further research and develop new products to improve public health.**

Characteristics of the NIH Intramural Research Program "Pipeline"

- **Novel, fundamental research discoveries**
- **Selected products in early clinical studies**
- **Research Tools, Materials, & Knowledge**

Technology Transfer NIH Policy Issues

- Public health benefit is paramount
- Good science happens at NIH, academia and industry -- need mutual exchange
- IP necessary for product development
- Research tools (knowledge and materials) are part of that exchange

What Are Research Materials/Tools?

Resources used to further investigate biological systems or to identify new products (e.g., drugs)

Properties of Research Tools

- Useful lifecycle is generally short
- Does not require significant R&D
- Generally does not require IP incentive to make/use
- Desire broad access and availability

Examples of Research Tools

- Animal Models
- Cell Lines
- Bulk DNA Sequences
- Drug Targets
- Clones/Cloning Tools
- Libraries
- Software
- Databases
- Lab Techniques
- Antibody Reagents

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

Do not seek patent protection if:

- technology transfer does not require further R&D i.e. most research tools

NIH License Policy

- Non-exclusive where possible
- Exclusive when necessary
- Ensure appropriate scope e.g., specified fields of use or territories
- Ensure expeditious development e.g., via enforceable milestones and benchmarks
- Ensure continuing availability of tools and permit research uses

NIH Portfolio

- 400+ invention disclosures per year
- Over 2,500 pending/issued patents (88 U.S. Patents issued FY08)
- Over 2,000 active licenses (259 executed FY08)
- $97.2 million in royalties collected FY08
- Almost 1 billion dollars in royalties collected since FY95

NIH Portfolio

- ~250 products developed to date
- 25 FDA approved products since FY92
- Over 84% licenses – non-exclusive
- Over 86% licenses – U.S. firms
- Over 52% licenses – small companies

NIH Licensed Products

AcuTect™ AIDS Test Kit Alfaxan® injectable anaesthetic for cats/dogs Apodasi™ (ddI) Beaucage Reagent BIOMAX Multi-Blot Kit BRCA1 Diagnostic Certiva™ CHAPS Generic ddI delayed-release capsules Fludara® Fecolator Havrix® ImmunoWELL® Kepivance™ KLEPTOSE® (betacyclodextrin) Matrigel® Invasion Chamber Mirakelle™ NeoTect™ NeuTrexin® Ocuvite®PreserVision™ *Para*Sight F™ Parvovirus B19 enzyme immunoassay PathVysion™ HER-2 DNA Probe Kit PixCell™ Soluble Interleukin-2 Receptor SPORANOX® oral solution Squirrel Free™ capsaicin-treated birdseed Synagis™ Taxol® TAXUS™ coronary stent system Thyrogen™ TWINRIX® TransProbe-1® Velcade™ Videx® Vitravene™ ZENAPAX® ZEVALIN™

Groundbreaking FDA Approvals

• Merck	Gardasil (HPV Vaccine)
• Millennium	Velcade (multiple myeloma)
• MedImmune	Synagis (RSV mAb)
• Isis	Vitravene (Antisense CMV)
• Biotrin	Parvovirus B19 assay
• Coulter/IDEC	Zevalin (NH Lymphoma)
• PDL/Hoffman	Zenapax (Kidney Transplant)
• Diatide	AcuTect (DVT Imaging)
• Baxter/NAV	Certiva (DPT vaccine)
• Amgen	Kepivance (Chemo 2nd effects)
• Tibotec	Prezista (DR HIV Protease Inhib)

Effect of Bayh-Dole on University Community

- **Positive Aspects:**
  1) More products - Advances public health
  2) Economic development - Rise of Biotech Industry

Negative Aspects:

1) Goal/Mission change - Profit Centers

2) Less Collegial - Sharing Research Tools

NIH Guidance to Funding Recipients

- Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants & Contracts 1994
- Universal Biological Material Transfer Agreement (UBMTA) 1995
- Research Tool Guidelines 1999
- NIH Data Sharing Policy 2003
- NIH Policy on the Sharing of Model Organisms 2004
- NIH Best Practices for the Licensing of Genomic Inventions 2005

OTT/NIH Contacts

NIH **http://www.nih.gov**

OTT **www.ott.nih.gov**

Science. Ideas. Breakthroughs.