

National Institutes of Health: An International Perspective

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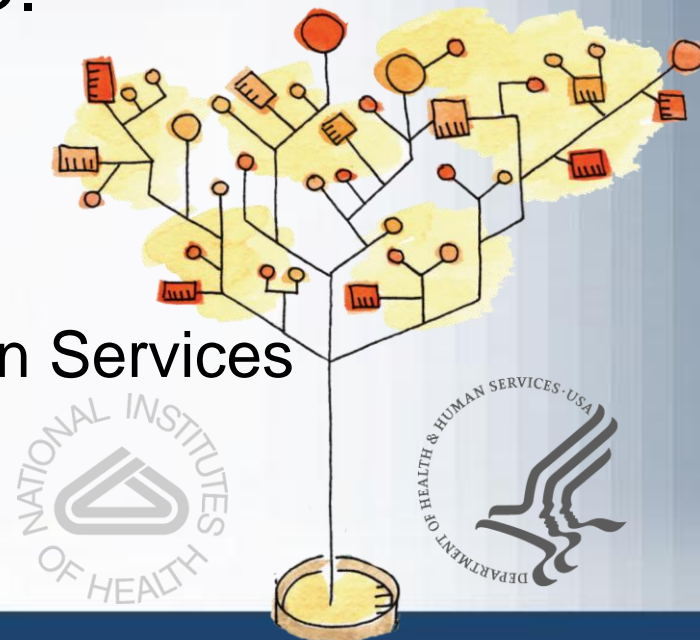
Director

Office of Technology Transfer

National Institutes of Health

U.S. Department of Health & Human Services

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NIH Mission

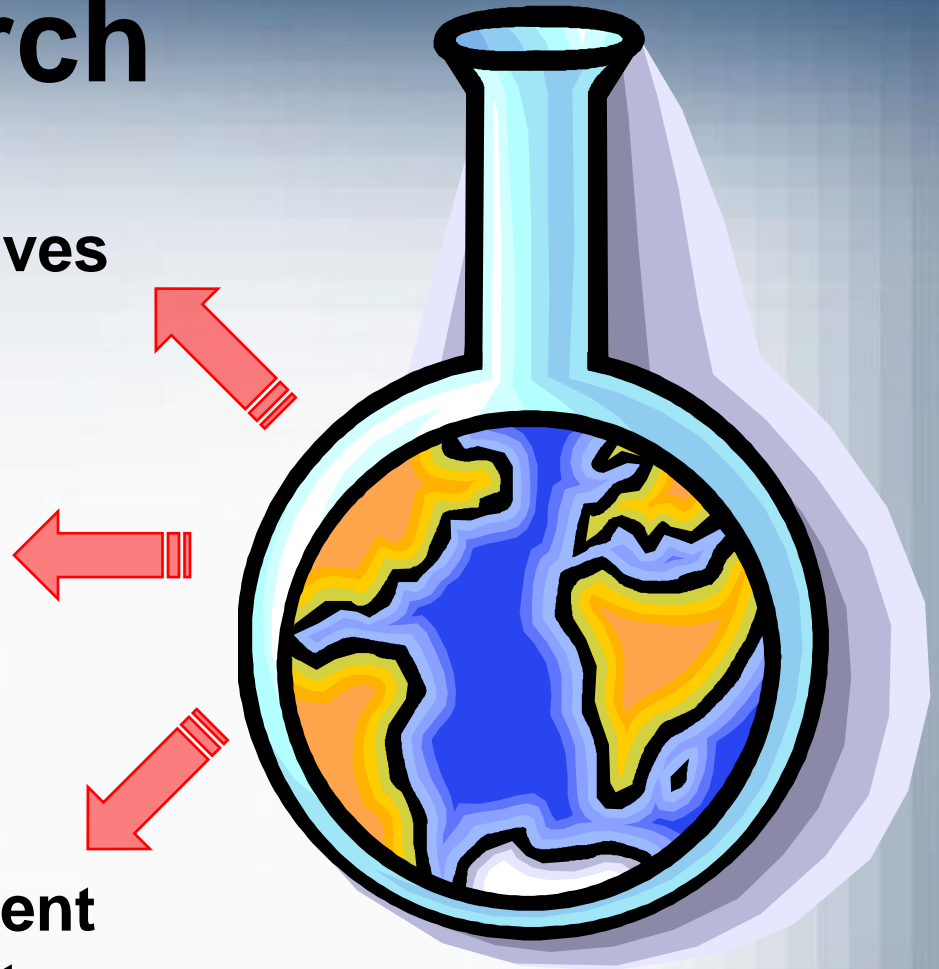
**To uncover new knowledge
that will lead to improved
public health world-wide**

Importance of Global Health Research

Humanitarian Objectives

**Globalization of
Health Problems
and their Relevance
to Domestic Health**

**Economic Development
and Political Stability**



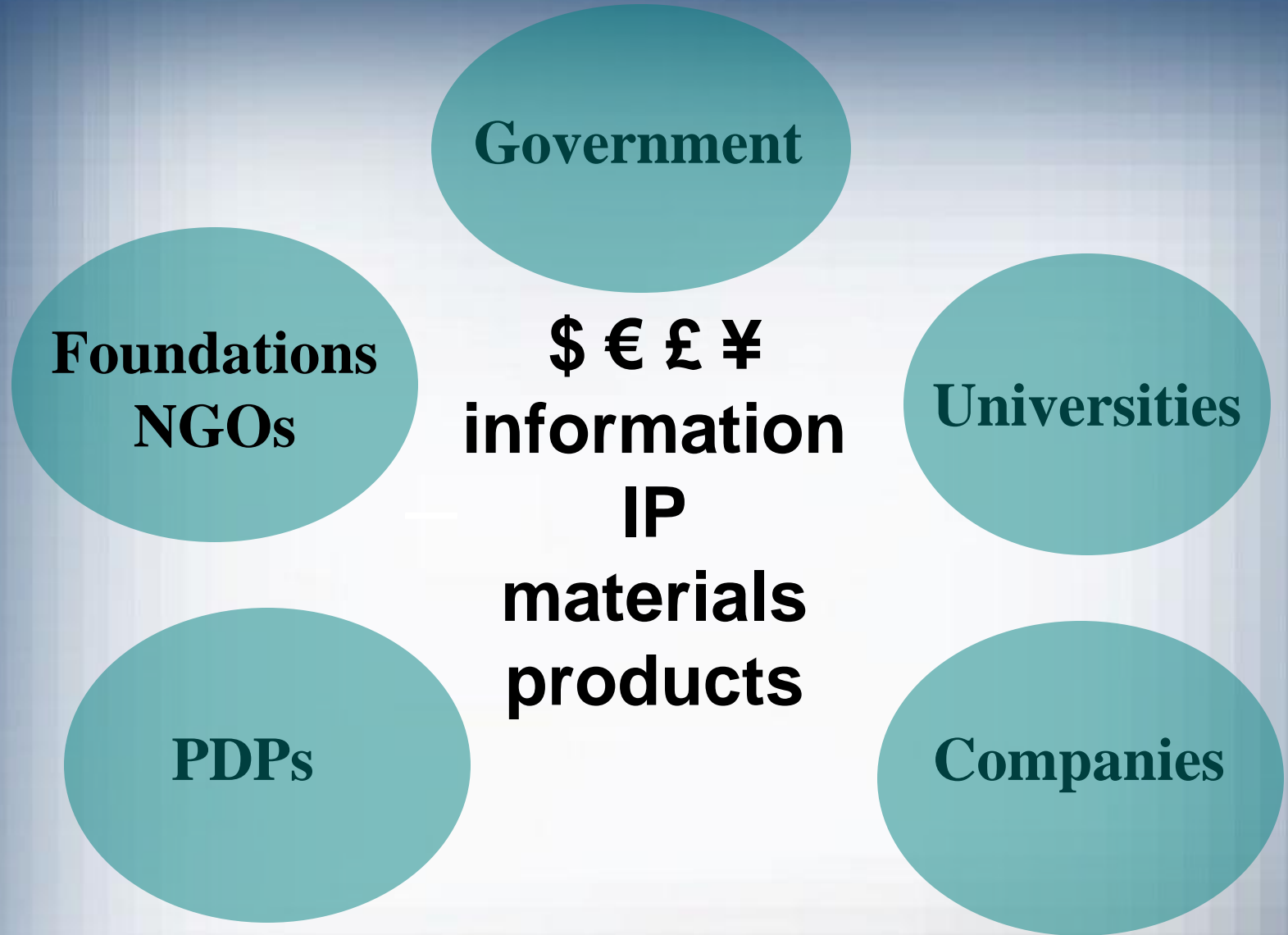
The NIH

Engine for Biomedical Research and Innovation

- Annual Budget: \$28B+
- 27 Institutes and Centers
- ~9% for Intramural (NIH) Research
- 6,000 Intramural Scientists, 2,000 projects
- 80%+ Extramural Research
- 35,000 Extramural (Mostly University) Funded Investigators at 3,000 organizations



Biomedical R&D



NIH Research Funding

- Mostly investigator initiated (bottom-up)
- Basic biomedical research
- Early stage development
- Small Business (SBIR/STTR)
- Assistance in developing new therapies
 - Unmet health needs
 - High risk and innovative
 - New uses of existing products
 - Combinations of products
 - Special populations in clinical trial networks

Extramural Research Resources

- Databases – long-term health surveys, genomics
- Grants and Contracts
- Repositories – Reagents, tissues and Compound databases
- Screening – In Vitro and Animal models
- Pharmacology and Toxicology testing
- Formulation and Manufacturing
- Clinical Research Lab Technology
- Clinical Trials

Examples of International Initiatives

- HIV Prevention Trials Network- non-vaccine preventative strategies 14 sites including Malawi, Tanzania, Uganda and Zambia
- Multilateral Initiative on Malaria- NIH and WHO facilitating multinational research cooperation
- AIDS Malignancy Consortium
- Capacity building and technology transfer to LDCs for neglected diseases
- Pneumococcal vaccine trial in The Gambia
- 77% effective

Biomedical Technology Transfer

- Scope:
 - Therapeutics, Diagnostics, Vaccines, Devices, Research Tools, etc.
- Unique Features
 - Extensive Regulatory Requirements
 - High Attrition Rates
 - Expensive R&D Cycle
 - Long Time to Reach the Market
 - Ethical Considerations

NIH Technology Transfer Goals

Benefit the public health

Utilize IPR appropriately as incentive for commercial development of technologies

Obtain return on public investment

Attract new R&D resources

Stimulate economic development

Characteristics of the NIH Intramural Research Program “Pipeline”

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

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 Gardasil® Generic ddI delayed-release capsules Fludara® Fecolator Havrix® ImmunoWELL® Kepivance™ KLEPTOSE® (betacyclodextrin) Matrigel® Invasion Chamber Mirakelle™ NeoTect™ NeuTrexin® OcuVite® PreserVision™ ParaSight F™ Parvovirus B19 enzyme immunoassay PathVysion™ Prezista™ 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™

Institutions in developing countries have identified opportunities for transfer of NIH technologies related to:

- HIV/AIDS
- Tuberculosis
- Malaria
- Dengue
- Diarrheal Diseases (Rotavirus)
- Meningitis
- Cancer (including HPV)
- Diabetes

OTT has already transferred technologies to, or has negotiations in process with:

- Brazil
- China
- Egypt
- India
- Indonesia
- Korea (for SE Asia)
- Mexico
- South Africa
- Nigeria
- PATH with WHO (for Africa)

Recent Int'l License Approaches

- **ddl** – PROTEIN, S.A. de C.V., MEXICO
- **Conjugated Meningococcal Vaccine:** PATH and WHO, produced in India for distribution in Sub-Saharan Africa, Latin America, Caribbean, Middle East, Eastern Europe and Asia
- **Conjugated vaccine against typhoid fever** to the International Vaccine Institute (IVI), Seoul, Korea produced with a public institution in Indonesia and a private entity in India for distribution in Southeast Asia; Innovative Biotech Ltd. (Nigeria)
- **Human-Bovine Rotavirus Vaccine** multi-licensing approach (9 institutions in India, China, Brazil, and US)
- **Varicella-Zoster virus vaccine** (chicken pox, shingles): Vacsera (Egypt)
- **Dengue vaccine:** Panacea (India)

NIH Contacts

NIH <http://www.nih.gov>

OTT <http://ott.od.nih.gov>

TT Training <http://tttraining.od.nih.gov>

Clinical Trials <http://clinicaltrials.gov>

CRISP <http://crisp.cit.nih.gov>

PubMed

PubChem <http://www.ncbi.nlm.gov>



Science. Ideas. Breakthroughs.