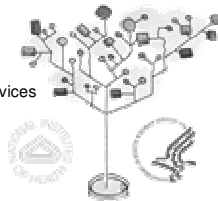


Partnerships in Technology Transfer: The NIH Experience

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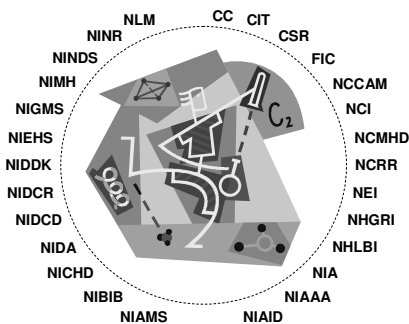


NIH OTT—TIFAC/DST
IPM Workshops
Indo-US S&T Fund
February, 2006

NIH Mission

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

The National Institutes of Health 27 Institutes and Centers



National Institutes of Health

Basic Biomedical Research in Support of the Public Health

- ⌘ Funding
- ⌘ Training
- ⌘ Basic Research
- ⌘ Clinical Trials
- ⌘ Inventions
- ⌘ Policies

Extramural Research

Long tradition of interaction between
Government, Academia, and Industry

- ⌘ Over 82% of the NIH budget
- ⌘ Over 46,000 awards annually
- ⌘ 35,000 Extramural researchers
(mostly universities)
- ⌘ Over 3,000 organizations

Intramural Research

- ⌘ Approximately 9% of NIH Budget
- ⌘ More than 2,000 active projects
- ⌘ More than 6,000 scientists
- ⌘ Collaborative research
- ⌘ Patent/License technologies

Office of Technology Transfer - OTT

- ⌘ Located in the Office of the Director, NIH
- ⌘ Dr. Mark Rohrbaugh, Director
- ⌘ Staff of ~81 persons – PhD, JD, MBA
- ⌘ 14 patent contract firms

OTT Goals

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

Technology Development at the Institutes and Centers

- ⌘ Offices in Institutes and Centers
- ⌘ Technology Development Coordinators
- ⌘ Work closely with scientists
- ⌘ Scientists report inventions
- ⌘ Provide scientific and programmatic input into licensing and patenting decisions by OTT
- ⌘ Negotiate Collaborative Agreements, CTAs, MTAs
- ⌘ Royalties flow back to support further research

OTT Tasks

- ⌘ Effective R&D Partners
- ⌘ Licensing Technologies of NIH & FDA Intramural Labs
 - Diagnostics, Therapeutics, Medical Devices, Animal Models
 - Infectious & Chronic Diseases
 - General Medicine Technologies
- ⌘ IP Policy for HHS: NIH, CDC, FDA

NIH Portfolio

- ⌘ ~200 products developed to date (20 vaccines and therapeutics)
- ⌘ Over 84% licenses – non-exclusive
- ⌘ Over 86% licenses – U.S. firms
- ⌘ Over 52% licenses – small companies

NIH Licensed Products

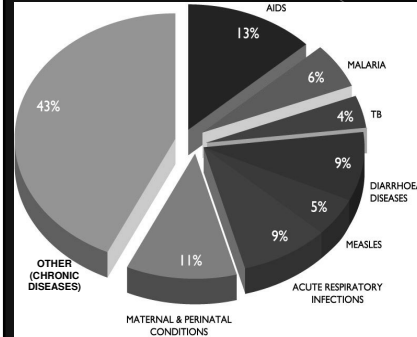
AcuTect™ AIDS Test Kit Alfaxan® injectable anaesthetic for cats/dogs Apodasi™ (ddI) Beaucage Reagent BIOMAX Multi-Blot Kit BRCA1 Diagnostic Certiva™ CHAPS Generic ddI delayed-release capsules Fludara® Fecolator Havrix® ImmunoWELL® Kepivance™ KLEPTOSE® (betacyclodextrin) Matrigel® Invasion Chamber Mirakelle™ NeoTect™ NeuTrexin® OcuVite® PreserVision™ ParaSight 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™

Relevance of Technology Transfer to Institutions in Developing Countries

- ✍ Innovation of all types
- ✍ National, regional and global needs
- ✍ Reduction of the burden of disease worldwide
- ✍ 10/90 GAP

Deaths in Developing Countries:

2 out of 3 deaths among children and young adults in Africa and South-East Asia are due to 7 causes



'Health A Key To Prosperity: Success Stories in Developing Countries; Joint UN Report, 2003

Global Health Challenges

- The historic 90:10 rule – only 10% of the research resources go to diseases that account for 90% of the global disease burden
- Cardiovascular; Cancer – lots of R&D
- Malaria, TB, leishmaniasis, Chagas, rotavirus - little
- Each year, 2 million lives lost to TB, 3 million to AIDS (95% of infections in developing world), 2 million to malaria

New Trends & PPPs

- Rockefeller Foundation, Gates Foundation, WB, IDB, International Donors
- Results driven, non-profit, partner with many types of organizations to get the job done
- Shift to significant funding of non-profit pharma companies
- Public Private Partnerships (PPPs) or Product Development Partnerships (PDPs)
- Means more and new potential partners for NIH technology commercialization (and for its licensees)

Partners for Global Health

NIH OTT currently active exploring ways to enhance the process of transferring technologies to institutions in:

- Asia
- Latin America
- Africa
- Eastern & Central Europe

Collaborative work with institutions in developing countries has revealed needs and opportunities for transfer of **NIH** technologies related to:

- HIV/AIDS
- Tuberculosis
- Malaria
- Dengue
- Pertussis
- Meningitis
- Rotavirus
- Typhoid Fever
- Cancer
- Diabetes
- Medical Devices & Animal Models

Key factors in International Technology Transfer Negotiations

- Cultural sensitivity – including languages
- Transparency & Information sharing
- Knowledge of S&T status
- Team approach
- Flexibility
- Commitment
- Patience
- **Trust**



OTT has already transferred technologies to and/or has negotiations in progress with institutions in:

- India
- China
- Korea
- Mexico
- Brazil
- South Africa
- Egypt
- Argentina

NIH licenses to India: 2003-05

- ✍ Indian Immunological LTD
 - recombinant carrier proteins for conjugated vaccines
- ✍ Serum Institute of India LTD
 - Rotavirus human-bovine vaccine
 - Pertussis
- ✍ Shantha Biotechnics LTD
 - Rotavirus human-bovine vaccine
 - pertussis vaccine
- ✍ Bharat Biotech International LTD
 - Rotavirus human-bovine vaccine
 - pertussis vaccine

NIH licenses to India: 2003-05

- ✍ Biological E
 - Rotavirus human-bovine vaccine
 - Dengue tetravalent vaccine
- ✍ Panacea Biotec LTD
 - Dengue tetravalent vaccine
 - Hair growth factor
- ✍ BIOMED LTD
 - Pertussis vaccine

Inter-Institutional Approaches

- ✍ **Conjugated Meningococcal Vaccine** – PATH and WHO, produced in India (**Serum Institute**) for distribution in Sub-Saharan Africa, Latin America, Caribbean, Asia, Middle East, Eastern Europe
- ✍ **Biological materials for conjugated vaccine typhoid fever** to the International Vaccine Institute (IVI) in partnership with the **Serum Institute**-India and Biopharma, Indonesia for distribution in Asia

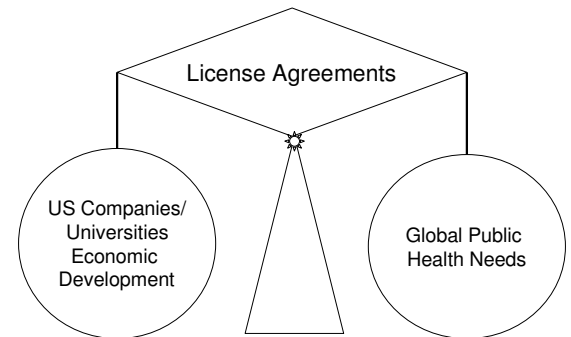
Multi-licensing Approach

- ✍ **Human-Bovine Rotavirus Vaccine**
- ✍ Multiple Institutions in:
 - India
 - China
 - Brazil
 - United States

Holistic Approach

- ✍ Participating institutions should have
 - Some level of R&D capabilities
 - Clear objectives to address national and regional public health needs
- ✍ Need to work with public and private institutions in those countries

Equilibrium Act



RESEARCH & DEVELOPMENT

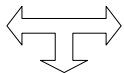


INNOVATION



HEALTH TECHNOLOGIES

ACCESSIBLE DRUGS,
DIAGNOSTICS,
THERAPEUTICS



POVERTY
REDUCTION &
POTENTIAL
ECONOMIC GROWTH

REDUCTION OF
DISEASE BURDENS
(INFECTIOUS &
CHRONIC)

NIH CONTACTS

- NIH <http://www.nih.gov>
- OTT <http://www.ott.nih.gov>
- FIC <http://fic.nih.gov>
- NIAID <http://www.niaid.nih.gov>
- NCI <http://www.nci.nih.gov>
- CRISP <http://crisp.cit.nih.gov>
- TT Training <http://ttraining.od.nih.gov>
- Clinical Trials <http://clinicaltrials.gov>

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Technologies for Global Public Health

