National Institutes of Health: Improving Public Health Through Public Private Partnerships

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Humanitarian Objectives

Importance of Global Health Research

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: $27.3B
- $2.7B for Intramural (NIH) Research
- 27 Institutes and Centers
- 5,000 Intramural Scientists, 2,000 projects
- 35,000 Extramural (Mostly University) Funded Investigators at 3,000 organizations
NIH Intramural Program

• State-of-the-Art Clinical Facility Opens 2004
• Record of Breakthrough Technologies/Therapies
  • Artificial Mitral Valve
  • Cell Culture
  • Cure for Childhood Leukemia
  • Gene Therapy Clinical Trial
  • Anti-HIV drug therapy
  • hESC Characterization Facility
• Opportunities for Collaboration, e.g. Extramural Centers of Excellence (TB, HIV, malaria)
• BioDefense- technologies also available for public health needs worldwide
What Is “Technology Transfer?”

• The exchange of information, materials, or intellectual property rights;
• Between (and among) government, academic, or industry laboratories;
• To facilitate further research and commercialization
Technology Transfer Goals

• Benefit the Public Health
• Ensure Public Availability of New Technologies
• Utilize IPR Appropriately as Incentive for Commercial Development of Technologies
• Attract New R&D Resources
• Obtain Return on Public Investment
• Stimulate Economic Development
NIH Portfolio

- 2300 total pending and issued patents (179 issued ‘03)
- 1500 active licenses (205 executed ‘03)
- $54M royalties FY2003
- $400 million in royalties collected FY ’93-’03
- 250 active CRADAs (1300 to date)
- ~200 products developed to date
  17 vaccines and therapeutics
Measuring Success: Case Studies

• Public Health Impact—lives saved, cases averted, relief of pain and suffering
• Role of NIH Research and Role of Corporate Research
• Value and Role of Technology Transfer, e.g. Patents, Licensing, Collaborations
• Synagis, Havrix, Vitravene, ddI, Fludara
NIH Patent Policy

• To Facilitate Availability of Technology to the Public
  • High Public Health Priority
  • Practical Utility
  • Necessary for Investments in R&D

• Generally, NIH will NOT Patent if:
  • No further R&D is needed (ex. Research Tools)
  • Low Public Health or Commercial Priority
  • Hinders technology transfer/access to inventions
Licenses at NIH

• Allow entities to make, use, import and sell products utilizing IP & materials (w/ or w/o IP)
• Provide third parties the right to use NIH technologies
• Negotiated case by case
• Maximize development of products for the public health
• Ensure appropriate return on public investment
Core Licensing Terms

- Permit Research Uses
- Ensure Publication Rights
- Preference for Non-Exclusivity
- Specific Appropriate Fields of Use
- Sublicensing Requirements
- Royalties and Milestones
- Rigorous Monitoring
Attention to Public Health Needs

• “White Knight” Clauses to do public good in exchange for technology developed with public funds
• Requirements to develop markets outside of Europe and North America when public health needs particularly important
NIH License Types

- Exclusive Patent Commercialization
- Non-exclusive Patent Commercialization
- Non-exclusive Patent Internal Use
- Commercial Evaluation License
- Biological Material Commercialization
- Biological Material Internal Use
- Interference or Dispute Settlement
- Inter-institutional
Innovation
Infrastructure and Policy

- Workshops within the US and around the world
- Meetings in Washington, DC, with foreign delegations interested in US model of public-private partnerships
- Learn from developing countries and NGOs about interests in new technology, public health concerns, needs for infrastructure and TT training
TT in Developing Countries

- Exploring new ways of engaging countries and NGOs in transferring new technologies
- Identify biomedical research institutions, foundations and companies
  - Latin America
  - Africa
  - Asia
  - Transition Economies of Central and E. Europe
Needs and Opportunities to Transfer NIH Technologies

Emerging and Re-emerging Diseases

- HIV/AIDS
- Tuberculosis
- Dengue- tetravalent vaccine
- Marlaria
- West Nile
- SARS

Endemic Diseases

- Rotavirus- rhesus (BioVirx) and bovine
- Pertussis- acellular
Initial Successes

- Transfer of early-stage technologies to public and private institutions in India, China, and Mexico
- Negotiations in progress for Brazil, China, India, and South Africa

Multinationals

- Conjugated Meningococcal Vaccine – PATH and WHO, produced in India for distribution in Sub-Saharan Africa, Latin America, Caribbean, Middle East, Eastern Europe, and Asia
Malaria-related Technologies

- Design and Development of Marketing Plan
- Aggressive and Comprehensive
- Ultimately Assist Developing Countries, particularly Africa, Asia and Latin America
Holistic Approach

• Institutions participating in partnerships 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
Strategic Alliances

- International and regional organizations
- Private Foundations and Professional Societies
- E.g., WHO, PAHO, Inter-American Development Bank, USAID, PATH, MIHR, Rockefeller Foundation, Wellcome Trust, MSF, International Centre for Genetic Engineering and Biotechnology (ICEBG), and AUTM
TT Gaps

- IP management, IP law and policy, PPP
- Developing countries generating IP and adopting IPR paradigms to improve socio-economic development
- But increase need to understand commercialization process, acquire infrastructure and tools for TT, implement laws and policies conducive to TT in the best interest of the public
Training Needs

• Continuing need for NIH et al. to assist developing countries to create cadre of scientists and TT managers experienced in managing both in licensing and out licensing of technologies and their development

• Assessing ways to expand our capabilities, evaluate this model of TT and its impact

• Expect to work closer with WHO and other relevant partners in this effort
NIH CONTACTS

- NIH | http://www.nih.gov
- OTT | http://ott.od.nih.gov
- Sharing Biomedical Research Tools
  http://ott.od.nih.gov/NewPages/RTguide_final.html
- A Plan to Insure Taxpayers’ Interests are Protected
  http://www.nih.gov/news
- TT Training | http://tttraining.od.nih.gov
- Clinical Trials | http://clinicaltrials.gov

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