

innovate /'nɒvət/ v.
ideas, etc. 2 (often
□ **innovation** /-'veɪʃ(ə)n
adj. **innovative** adj.
/'veɪʃ(ə)ri/ adj. [Latin
novus 'new']
Chancery

LICENSING AND PATENTING AT THE NIH

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Office of Technology Transfer • National Institutes of Health
U.S. Department of Health & Human Services

Technology Transfer at NIH



What does this mean?

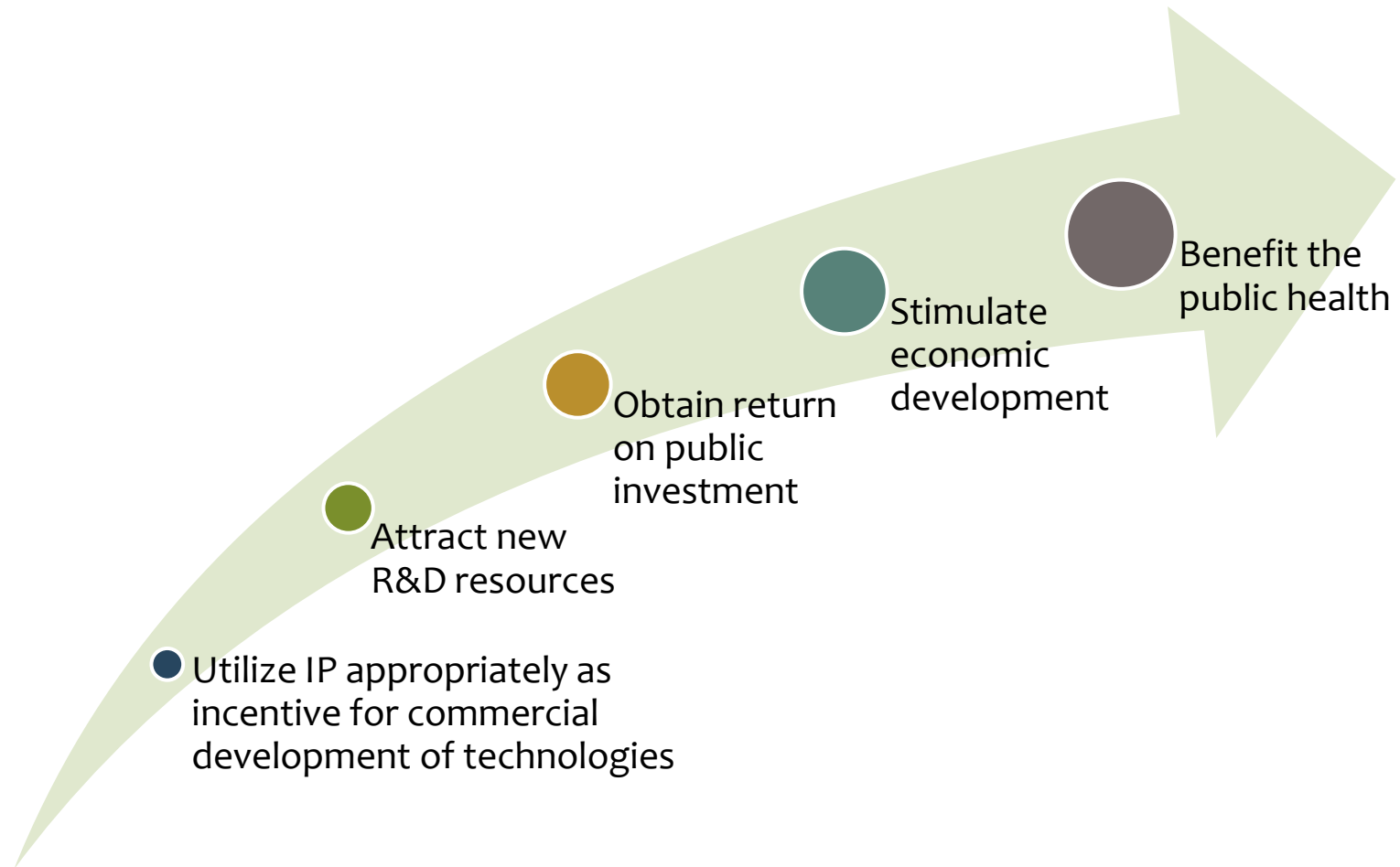
Movement of information, materials, and technologies from the research laboratories to the commercial enterprise

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

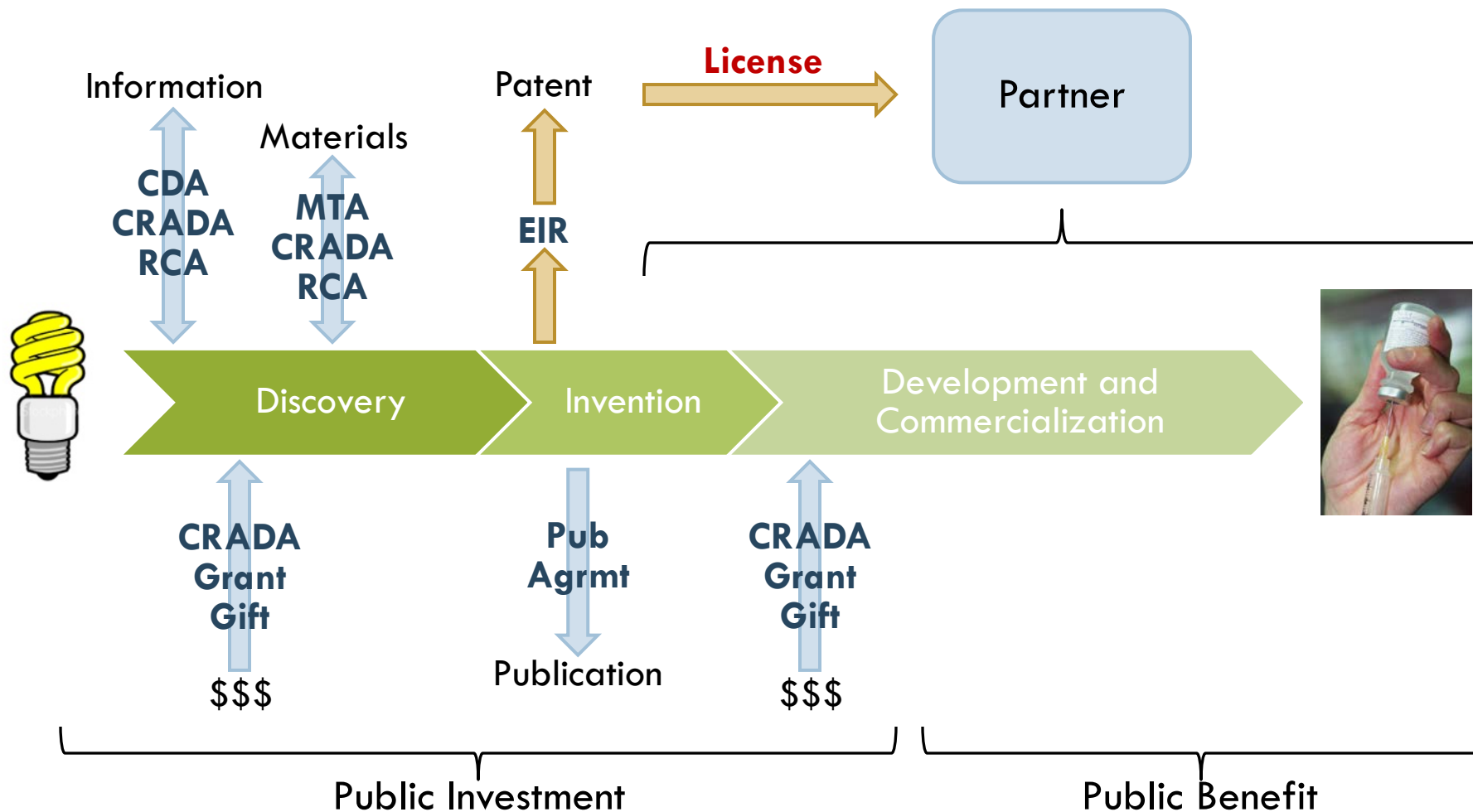
OTT Mission

The mission of OTT is to improve public health through the management of National Institutes of Health (NIH) and Food and Drug Administration (FDA) inventions and in doing so serve a leading role in public sector biomedical technology transfer policy and practice.

OTT Goals



Technology Transfer: Discovery to Marketplace



Types of Intellectual Property

Intellectual Property



Patents

Protects new embodiments of useful ideas, plants, and designs for a fixed, limited term (~20 years)

OTT



Copyrights

Protects original works of authorship fixed in a tangible medium of expression for the author's life plus 70 years



Trademarks

Protects marks that identify the source of goods or services for as long as the mark continues to be used in commerce

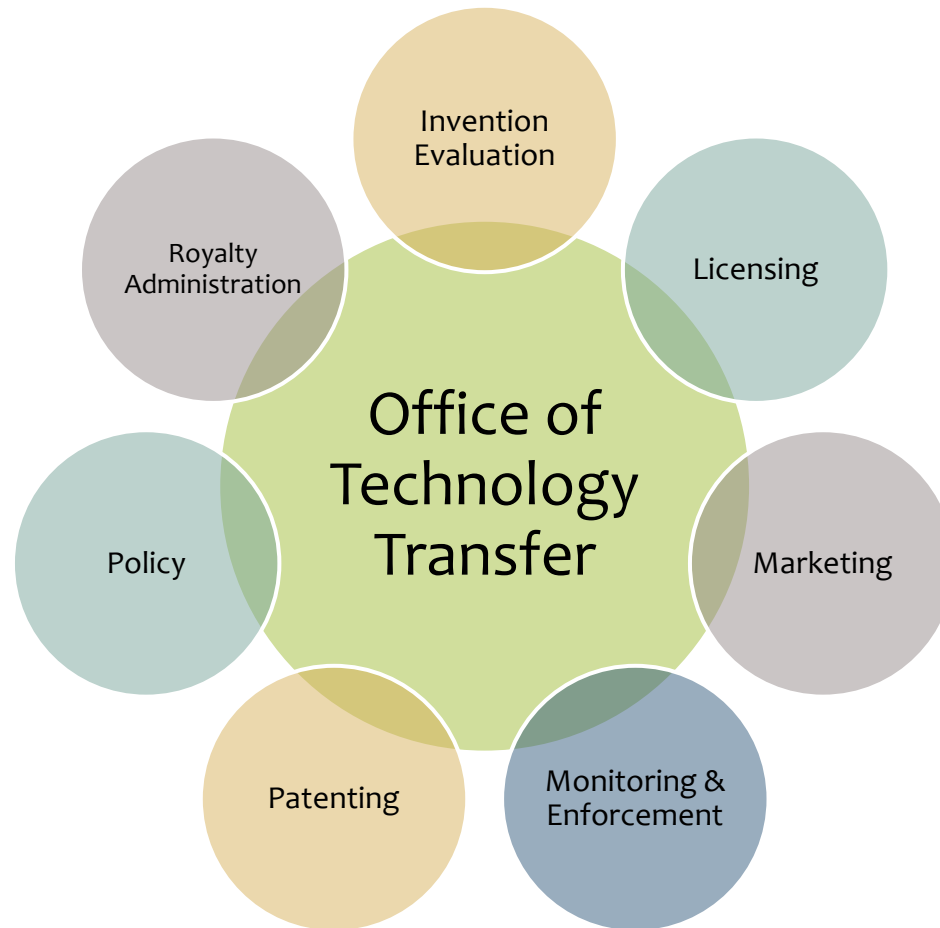
OGC



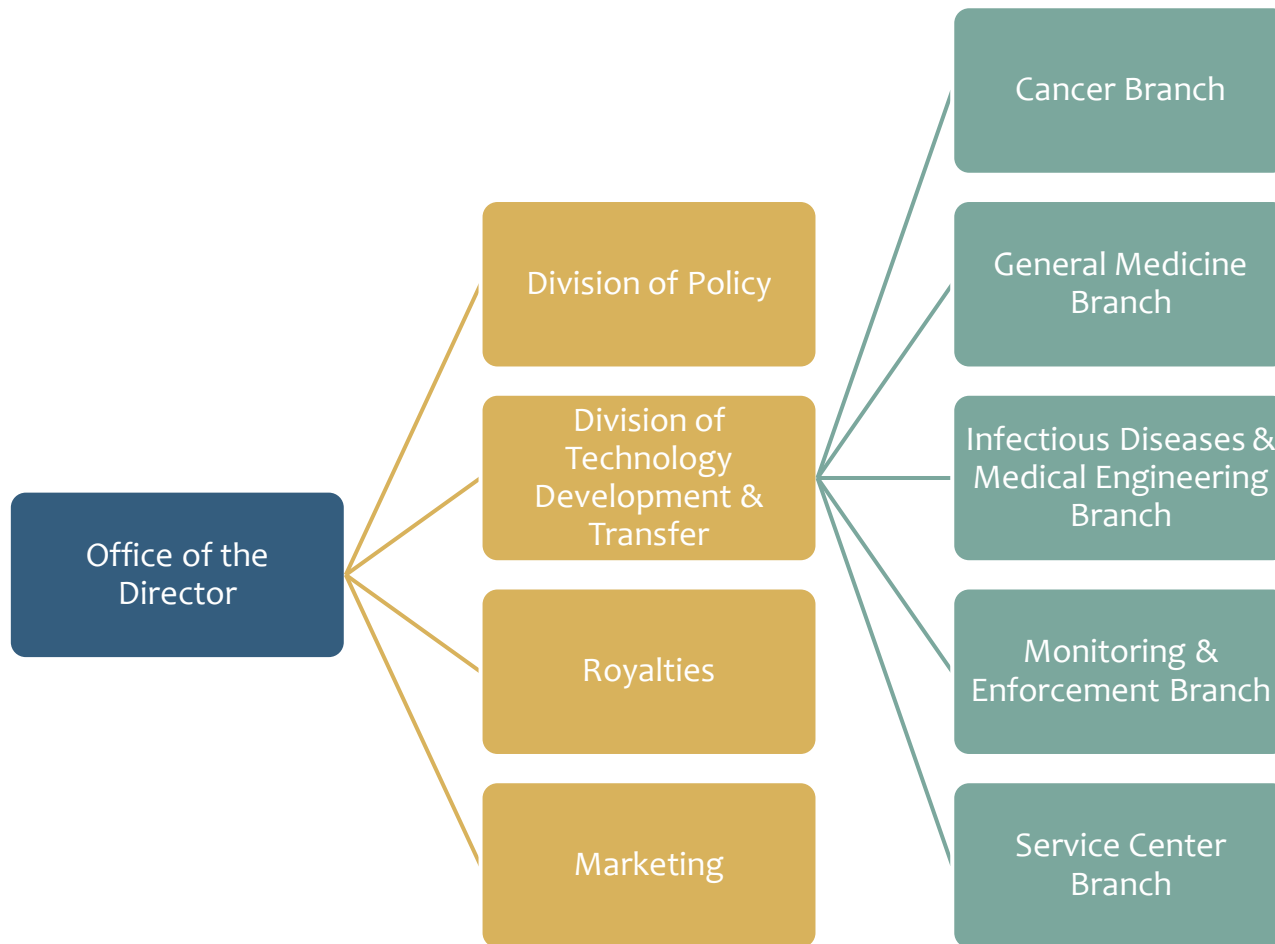
Trade Secrets

Protects commercially valuable, protected information for as long as it remains secret and valuable

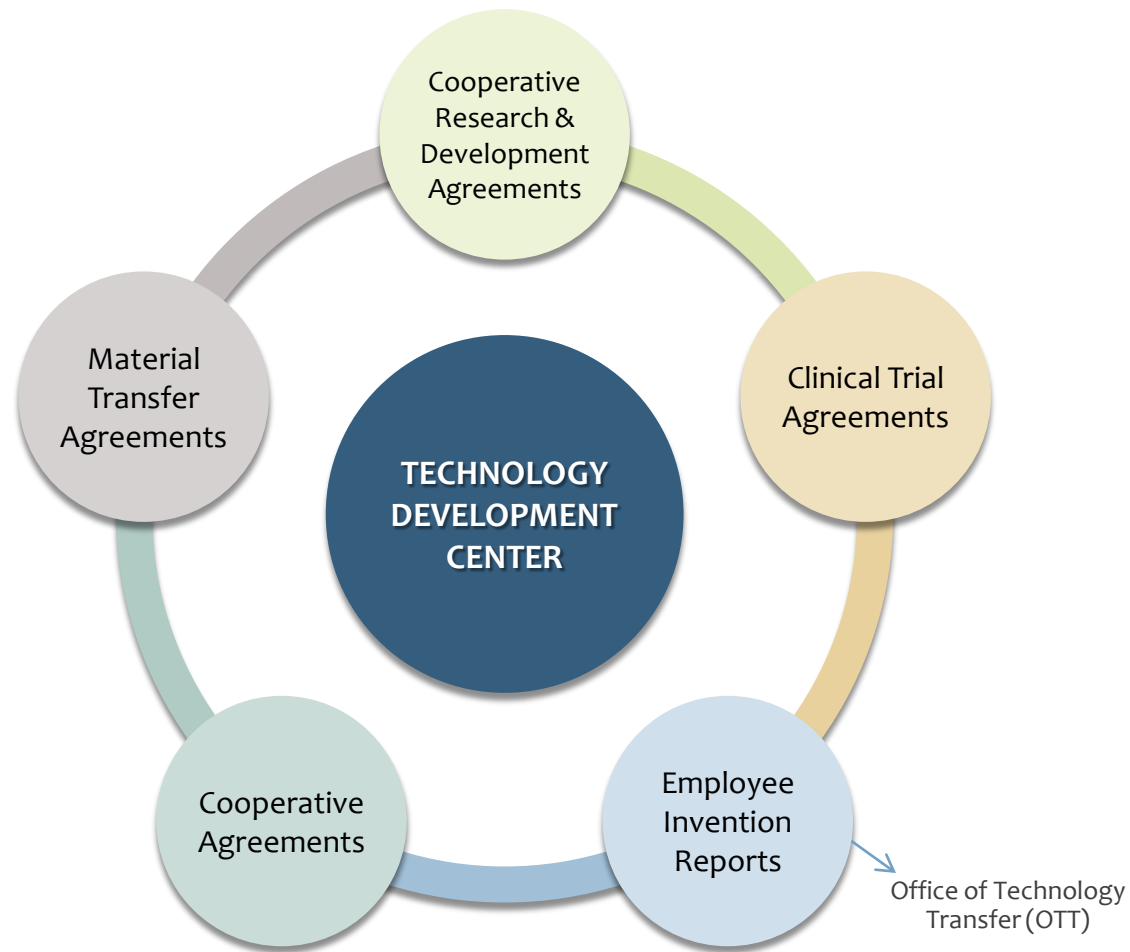
Centralized Technology Transfer



Organizational Structure



Technology Transfer in the Institutes



NIH/FDA Intramural Portfolios (FY11)

- 351 invention disclosures
- 131 U.S. patents issued
- 197 licenses executed
- 1,300+ active licenses
- \$96.9 million in royalties collected

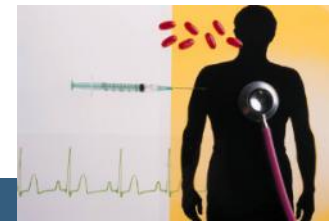


NIH/FDA Intramural Portfolios (FY11)

- 68 CRADAs executed (NIH only)
- 346 active CRADAs (NIH only)
- ~600 products developed to date (26 vaccines and therapeutics)
- Over \$1B in royalties collected to date



Examples of NIH Licensed Products



□ Therapeutics

- ▣ Prezista[®]
- ▣ Velcade[®]

□ Diagnostics

- ▣ HIV Test Kits
- ▣ Thyrogen

□ Vaccines

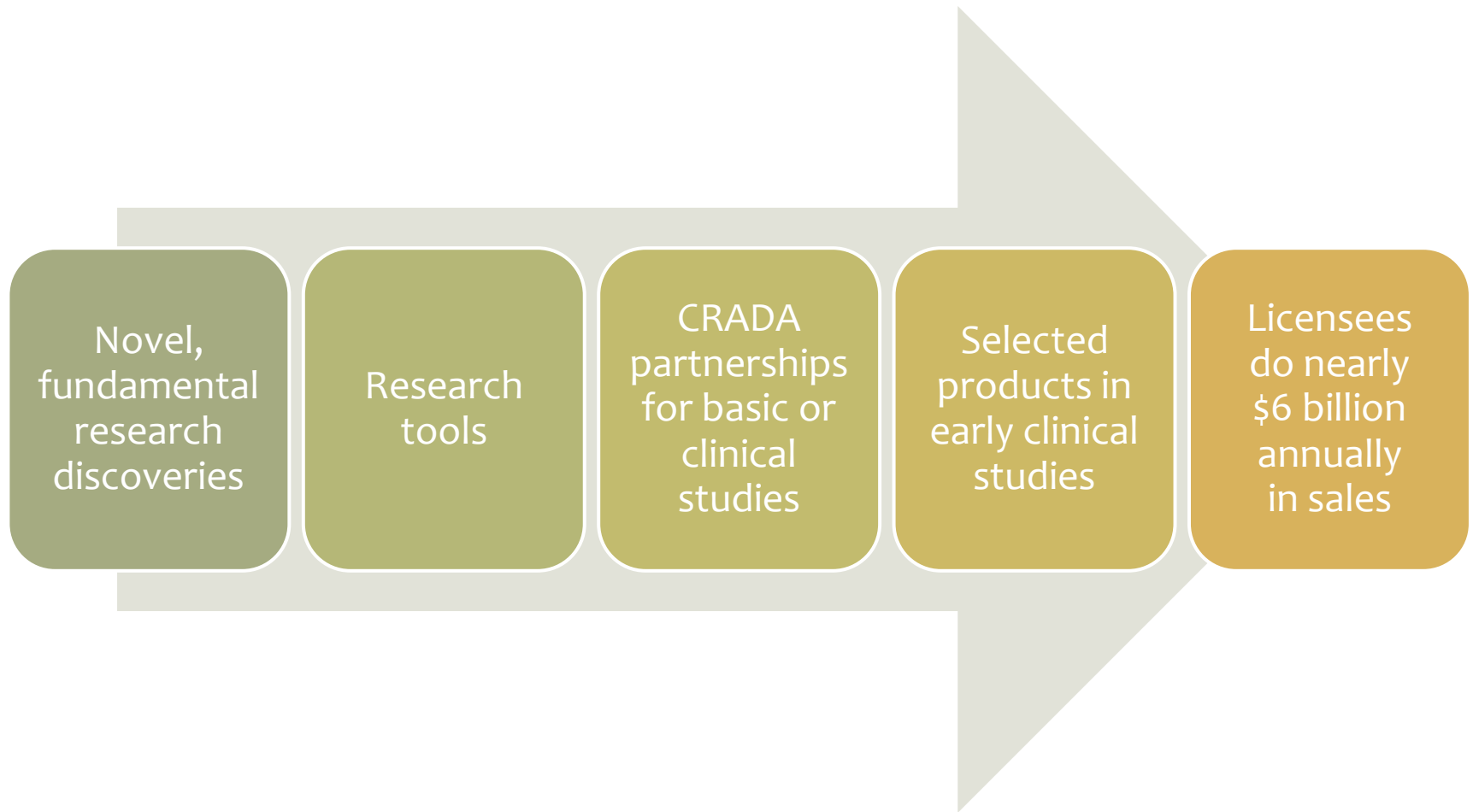
- ▣ Cervarix[®] and Gardasil[®]
- ▣ Twinrix[®]

... as well as

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

For details, see the “Product Showcase” on the OTT Web site.

Characteristics of the NIH Intramural Research Program “Pipeline”



Technology Review

Options:

- Seek patent protection
- License without a patent
- Dedicate to public domain if licensing not beneficial to the public health
- Waive rights to inventor
- Wait for additional data

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

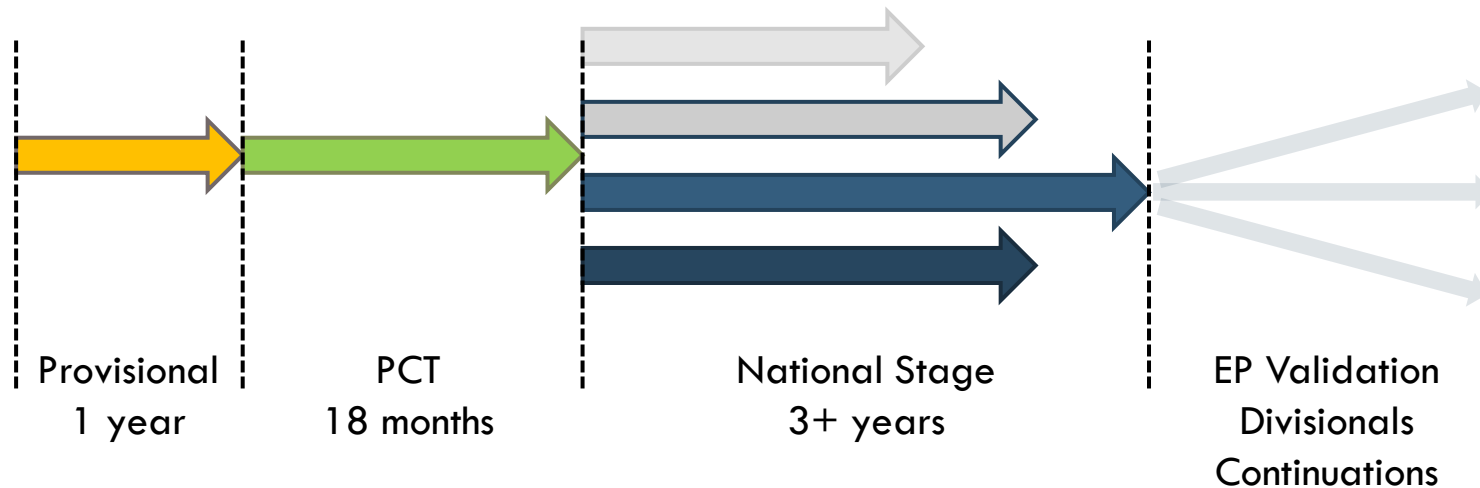
✗ Do not seek patent protection if:

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

Assessing the Technology

- Identify core feature(s) and potential uses for technology
- Evaluate fit with policies, institution goals (e.g. NIH patent policy)
- Determine contribution to the public
- Consider inventor's future plans
- Review potential market
- Patentability

General Patenting Timeline



- Evaluate patents at impt milestones
 - ▣ PCT filing
 - ▣ National Stage filings
 - ▣ EP Validation
 - ▣ Continuations/divisionals
 - ▣ Annuities
- General criteria to consider
 - ▣ Patentability issues/strength of IP
 - ▣ Ongoing research/collaborations
 - ▣ Licensing activity
 - ▣ Current market landscape
- Summarize relevant points and share with inventors, institutes, licensees

Research Tools

- A research tool is any material or method that can be used to further investigation into biological systems or pathways or which can be used to identify potential new pharmaceutical products.

Examples:

- Animal models
 - Cell lines
 - Antibodies/hybridomas
 - Screening methods
-
- Research tools are generally not patented by NIH when solely for discovery research, or when readily usable or distributable without further development.

Licensing

- Mechanism by which rights to make, use and/or sell a technology are transferred to for-profit entity for commercial development and/or use
- Consolidation of responsibilities
- Governed by federal statutes and regulations

Licensing of Federally Owned Inventions

- Limited to patented or patentable inventions assigned to the Government
- Includes non-patented materials, software and other research tools
- Excludes know-how
- Excludes trade secrets
 - Government is not in business, so has no trade secrets of its own
- Availability of technologies is made public
 - Notice in the Federal Register
 - On OTT web site and RSS feed
 - On various online technology marketing sites
 - Other marketing activities

NIH Product Licensing Principles

- Preference for non- or partial exclusivity
- Grant only the appropriate scope of rights
- Specified fields of use
- Permit research uses
- Enforceable milestones and benchmarks
- Maximize development of products for the public health
- Ensure appropriate return on public investment

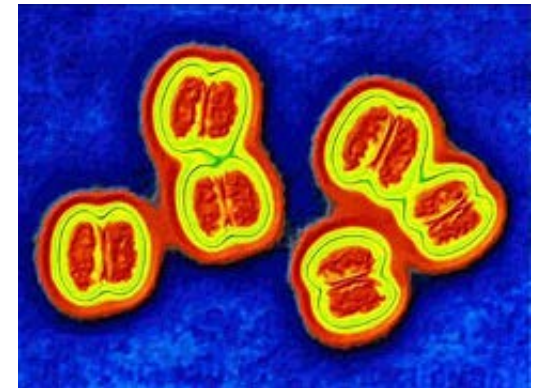




International Licensing Case Study: *Hope at 50 Cents a Dose*

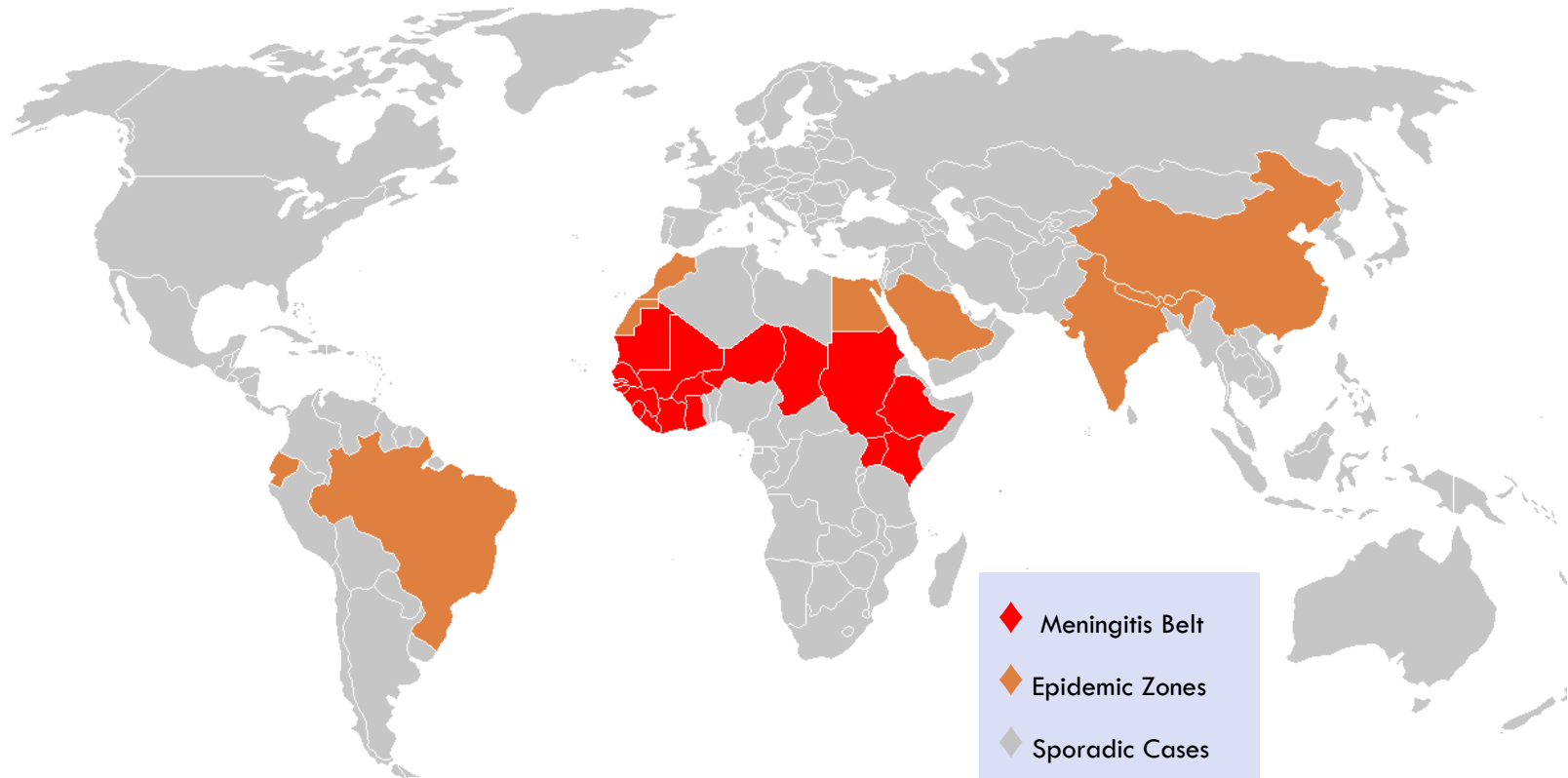
Meningococcal Meningitis

- Bacterial infection that attacks the meninges (lining) of the brain
- Fatal in 50% of cases if untreated
- May also result in mental retardation, deafness, epilepsy, or limb amputation



Neisseria meningitidis
Photo: Public Library of Science (PLoS)

The Meningitis Belt



Between 1995 and 2004, outbreaks resulted in 700,000 cases of illness and 60,000 deaths

Total population at risk:
~ 350 million

Why is meningitis so deadly?

- Antibiotics often unavailable in poor countries most affected by the disease.
- Limited effectiveness of current vaccines available in Africa
 - Do not protect infants
 - Immunity lasts only 2-3 years
 - No herd immunity (does not prevent transmission of bacteria)
- Vaccines administered reactively, after an outbreak is underway

However, the technology for developing more effective vaccines has been available for over *ten years*.

Why is there no effective vaccine?

A: Very limited commercial market outside of Africa.



Reproduced from the MVP web site at <http://meningvax.org>, 2010

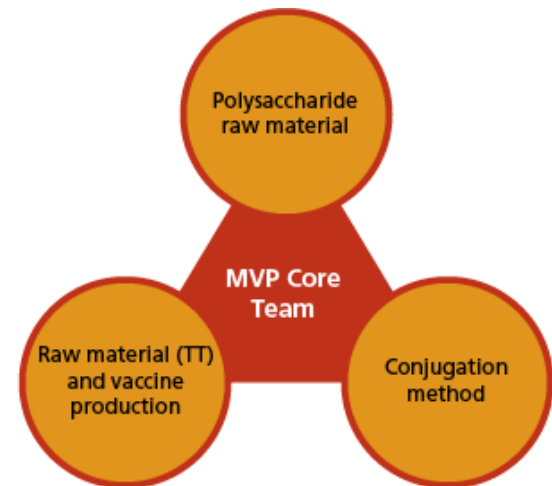
- Predominant bacterial strain in Africa different from strains in Europe and the Americas
- Key barrier - vaccine price must be less than \$0.50/dose

“Please, don't give us a vaccine we can't afford. That is worse than no vaccine.”

Hassane Adamou, Secretary General for the Nigerian Ministry of Health

Meningitis Vaccine Project (MVP)

- Partnership between PATH and World Health Organization
 - ▣ Focused on eliminating meningitis in sub-Saharan Africa
- Strategy: Develop consortium to develop low-cost vaccine



Reproduced from the MVP web site at <http://meningvax.org>, 2010

- Partners:
 - Materials suppliers
 - Synco Bio Partners
 - Serum Institute of India Ltd
 - Technology
 - Center for Biologics Evaluation and Research, US FDA
 - Manufacturer
 - Serum Institute of India Ltd

Solution: MenAfriVac®

- Conjugate vaccine
 - ▣ Protects infants
 - ▣ Long-lasting protection (>10 years)
 - ▣ Herd immunity
- \$0.40 per dose
- 250 million doses over 10 years to inoculate all individuals between 1 and 29 years of age



Reproduced from the MVP web site at <http://meningvax.org>, 2010

PHS Contribution Critical

- Method for improved yields of conjugated vaccines from FDA
(Dr. Carl Frasch and Dr. Robert Lee, CBER)
- Exclusive license to MVP
- PATH - FDA collaboration to co-develop technology

Licensing Strategy

- Public-private partnership – typical guidelines don't apply
- Territory limited to low- and middle-income economies
- Allows sublicensing for manufacturing and sales of vaccine (Serum Institute of India)
- Very low upfront costs
- Minimal royalties on sales
- Planning – patent protection in countries important for manufacture (India, Brazil, China, and South Africa)

MenAfriVac® Launch

- Burkina Faso – December 2010
 - Launched by President Blaise Compaoré, with WHO Director-General, Dr. Margaret Chan
 - First country to launch nationwide campaign
 - 10 days, over 10 million children and young adults vaccinated
 - "Le bon vaccin«
- To date, over 45 million vaccinated in Burkina Faso, Mali, Niger, Cameroon, Chad, and Nigeria
- Goal: 265 million vaccinated by 2016

Public Health Impact

- Focused, product-driven approach
- Overcome commercial barriers through a public-private partnership
- Each party contributes a piece to the puzzle
- Establish relationships and enable collaborations



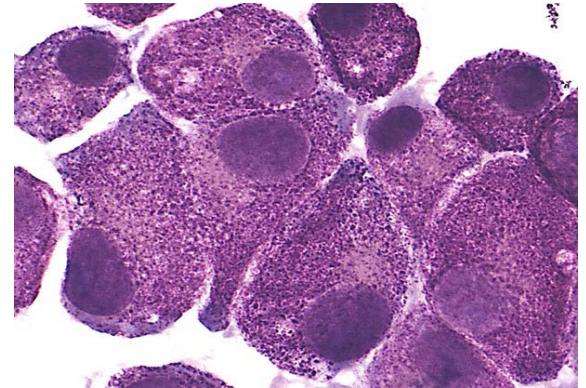
Reproduced from the MVP web site at <http://meningvax.org>, 2010



Patents Aren't Everything: Biological Materials Licenses

LAD2 Mast Cell Line

- ❑ Discovered in 2001
- ❑ Derived from human mast cell leukemia tissue
- ❑ Not patented, per NIH policy on research tools
- ❑ Unique tool for studies of allergy and inflammation – closely resembles primary mast cells
- ❑ 46 executed agreements so far, to companies around the world (and hundreds of MTAs)
- ❑ Technology transfer award



Synagis® - Helping Infants and Parents Breathe Easier

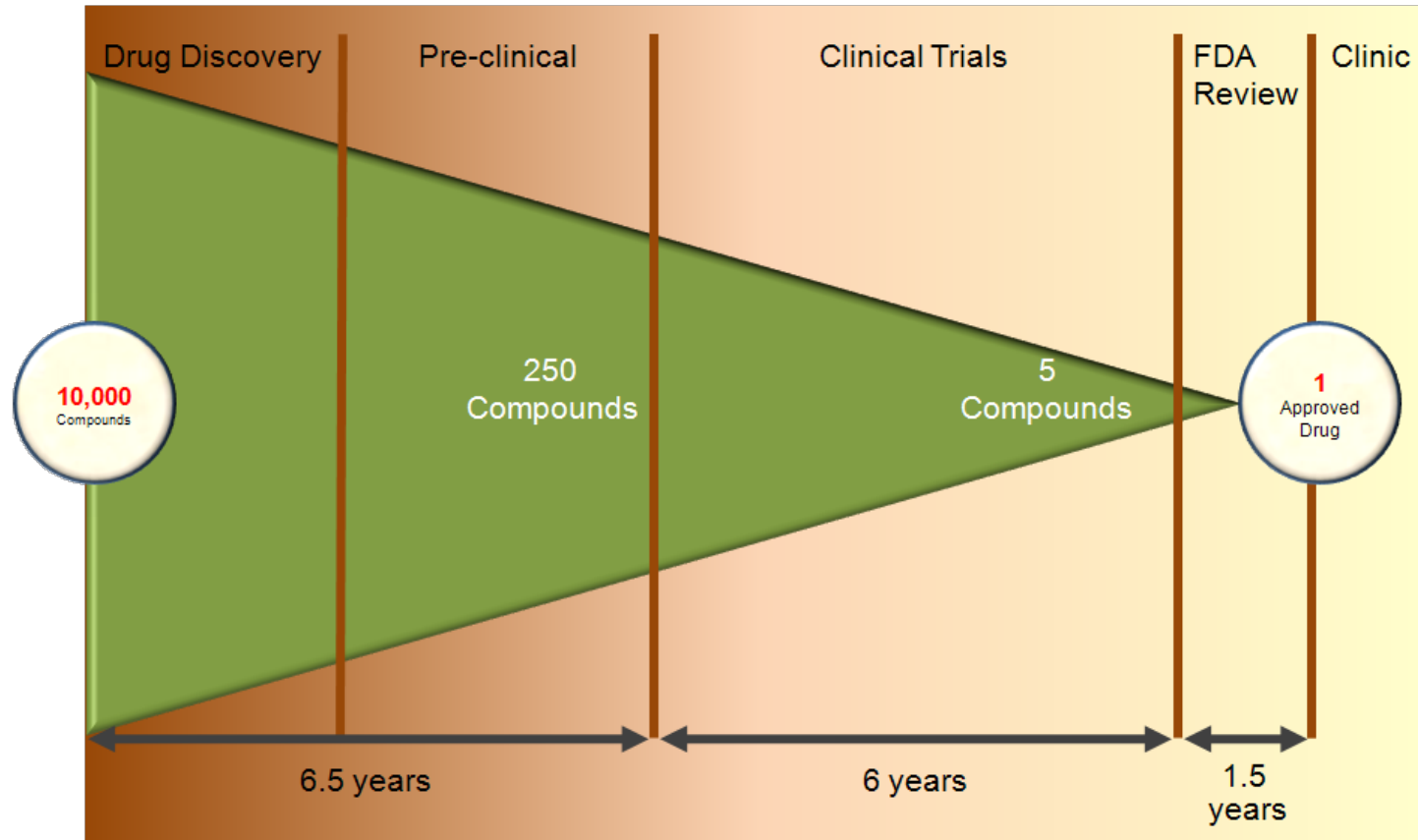
- Prevents Respiratory Syncytial Virus (RSV) in high-risk infants
- RSV is the leading cause of pneumonia and severe, sometimes fatal, respiratory tract infections in young children
- Unpatented antibodies, cells licensed to MedImmune in 1993 via a Biological Materials License
- First monoclonal antibody to be licensed by the FDA
- Meets a significant public health need (no vaccine is available for this disease)



Bridging the Gap: NIH Initiatives for Early-Stage Technologies



The Problem



Development costs: 800 million to 1.2 *billion* USD!

NIH Initiatives for Early-Stage Technologies

- Start-up Licenses
- Non-Profit Licenses
- Small Business Innovative Research Technology Transfer Grants (SBIR-TT)
- Entrepreneur-In-Residence
- Programs at the National Center for Advancing Translational Science (NCATS)

NIH Start-Up Licenses

www.ott.nih.gov/startup

- One-year trial period, starting October 1, 2011 (just renewed)
- Scope: drugs, vaccines & therapeutics for US market
- Start-ups: 5:5:50
 - < 5 yrs old
 - < \$5M capital raised
 - < 50 employees
- Exclusive Option License: 1 Year , \$2k fee
- Patent Commercialization License
 - Fees deferred for 3 years or liquidation event
 - Defer prior patent costs and 50% of new ones
 - Milestones with no fees
 - 1.5% royalties on sales; 15% sublicense rate

Non-Profit Licenses

- For nonprofits with demonstrated commitment in providing broad global access to technologies
- Scope: drugs, vaccines, therapeutics and diagnostics to prevent, diagnose or treat neglected tropical diseases, HIV, TB and malaria
- Exclusive or non-exclusive
- Patents or biological materials
- Terms:
 - Upfront fee of \$2,000
 - Milestones with no fees
 - 50% of patent costs
 - Modest royalties on sales, depending on exclusivity

Small Business Innovative Research - Technology Transfer

- US Government program
- Awards available to US small businesses—
contracts and grants
- Novel type of SBIR contract - envisioned
commercial product incorporates technology from
NIH
- Analogous to spin-off with gap funding
- Goal is for awardee to take a license and continue
commercialization

Small Business Innovative Research - Technology Transfer

- Now in its second year
- 4 NIH institutes getting involved
- 3 technologies were recently advertised under this program for Phase 1 funding
 - ▣ Cancer diagnostic drug
 - ▣ Tissue microarray
 - ▣ Cell-based cancer therapy
- Projects start fall 2012

Entrepreneur-in-Residence

- Partnership with BioHealth Innovation, a regional public-private partnership focused on commercializing biohealth innovations and increasing access to early-stage funding.
- Based at Office of Technology Transfer
- Activities
 - Identify and market viable biohealth assets
 - Act as liaison among academic, industry, venture capital, and non-profit
 - Detailed commercial evaluation of most valuable technologies
 - Provide early-stage developmental strategies
 - Nurture relationships with scientists, mentor to ensure research becomes commercially valuable, and track progress
 - Identify creative funding to advance exciting, novel technologies

National Center for Advancing Translational Sciences (NCATS)

- Established in FY 2012 to develop innovative methods and technologies to enhance development of diagnostics, devices and therapeutics
 - ▣ Extramural and intramural
 - ▣ Emphasis on collaborations
- Resources for NIH investigators:
 - ▣ Molecular Libraries Program
 - Large-scale small molecule screening capacity, medicinal chemistry and informatics
 - ▣ Therapeutics for Rare and Neglected Diseases (TRND)
 - A resource to help advance rare and neglected disease drug discovery projects from academia or industry
- NCATS also has its own intramural research program





Thank You

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