



BioHealth Innovation

Maryland's Commercialization Collaborative

FLC&EIR

5/1/2012

Pittsburgh, PA

www.biohealthinnovation.org

“The Region”--Central Maryland

Unrivaled Research Assets
Unfulfilled Commercial Promise



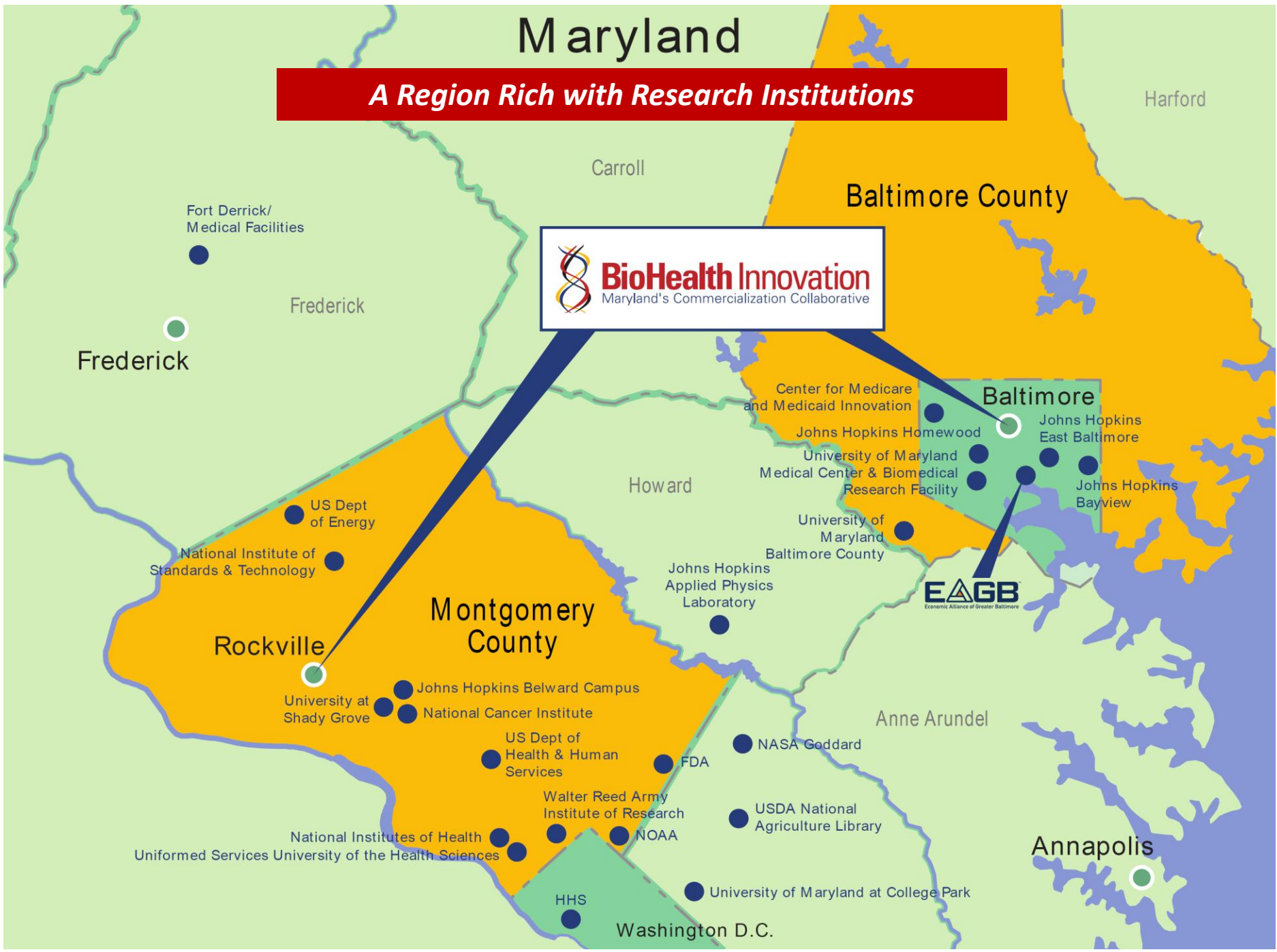
Maryland

A Region Rich with Research Institutions



BioHealth Innovation

Maryland's Commercialization Collaborative



Fort Derrick/
Medical Facilities

Frederick

Frederick

Carroll

Baltimore County

Harford

Center for Medicare
and Medicaid Innovation

Baltimore

Johns Hopkins Homewood

Johns Hopkins
East Baltimore

University of Maryland
Medical Center & Biomedical
Research Facility

Johns Hopkins
Bayview

Howard

University of
Maryland
Baltimore County

Johns Hopkins
Applied Physics
Laboratory

EAGB
Economic Alliance of Greater Baltimore

National Institute of
Standards & Technology

US Dept
of Energy

Montgomery
County

Rockville

University at
Shady Grove

Johns Hopkins Belward Campus

National Cancer Institute

US Dept of
Health & Human
Services

FDA

NASA Goddard

Walter Reed Army
Institute of Research

USDA National
Agriculture Library

National Institutes of Health
Uniformed Services University of the Health Sciences

NOAA

HHS

University of Maryland at College Park

Washington D.C.

Anne Arundel

Annapolis

The Problem--A National Challenge

America is falling behind the world it invented because we are:

- **Out-educated**
- **Out-built in infrastructure**
- **Out-invested in R&D**

by countries in both Europe and Asia.

--*“That Used to Be Us”* by Thomas Friedman, 2011

The Reverse Brain Drain

- ***“Opportunities in China Lure Scientists Home”*** --The Washington Post, February 20, 2008
- American returnees to India cited as reasons for going “back” to where they came from:
 - ***Better Economic Opportunities***
 - ***Family Ties***
 - ***Better Access to Markets***

National Leadership



President Obama's Bioeconomy Initiatives & America Invents Act (2011)

- **America Invents Act**
- **Center for Advancing Translational Sciences** in NIH to advance commercialization (NCATS)
- Develop a **National Bioeconomy Blueprint**
 - Support R&D investments
 - Facilitate the transition from research lab to market
 - Reduce barriers, increase speed and predictability of regulatory process, and reduce cost.
 - Update training programs and align academic institutions incentives
 - Identify and support the development of PPPs and pre-competitive collaborations

Challenges to Innovation Economy

Lack of connection of innovation resources

Lack of an entrepreneurial culture and C-level executives

Lack of early-stage funding for commercializing technologies

Lack of a STEM Workforce

BHI Value Proposition

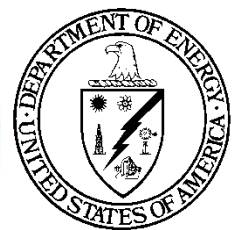
Connects regional innovation assets

Develops an entrepreneurial talent and support pipeline

Attracts funding for technology commercialization

Develops a continuum of innovation workforce

BioHealth Regional Innovation Cluster Assets



What is A Regional Innovation Intermediary?

- An organization at the Center of the region's, state's and country's efforts
 - Align local technologies, assets and resources
 - Advance Innovation
- Regionally-oriented
- Private-public partnership, 501(c)(3) nonprofit
- Market-driven, private sector-led
- Not a government initiative, nor a membership organization



Regional BioHealth Ecosystem Partners



BHI Partners and Sponsors



JOHNS HOPKINS
UNIVERSITY



NEA®



BHI Funding Sources:

- *private sector*
- *universities and foundations*
- *public sector*



BHI/EIR Technology Focus

- Therapeutics
- Diagnostics
- Medical Devices
- Healthcare Services
- E-Health
- Mobile Health
- Electronic Medical Records
- Health Informatics
- BioHealth Cyber Security



Innovation Paradigm Shift

PROOF OF CONCEPT

(Technological Feasibility)

Laboratory Push

“It Works!”

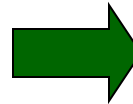


PROOF OF COMMERCIAL RELEVANCE

(Market Pull)

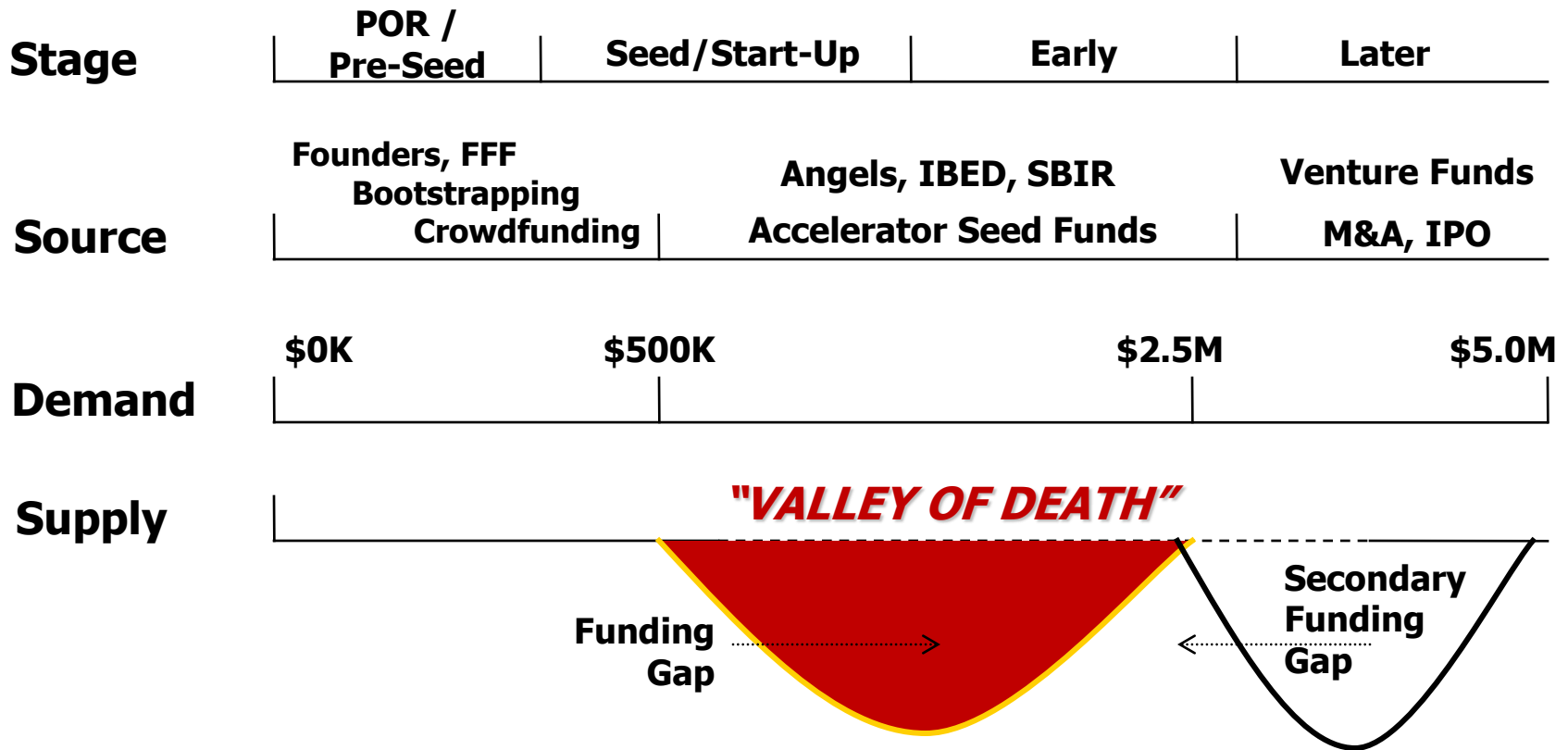
“It Works To Solve A Problem”

“I’ll Buy It”



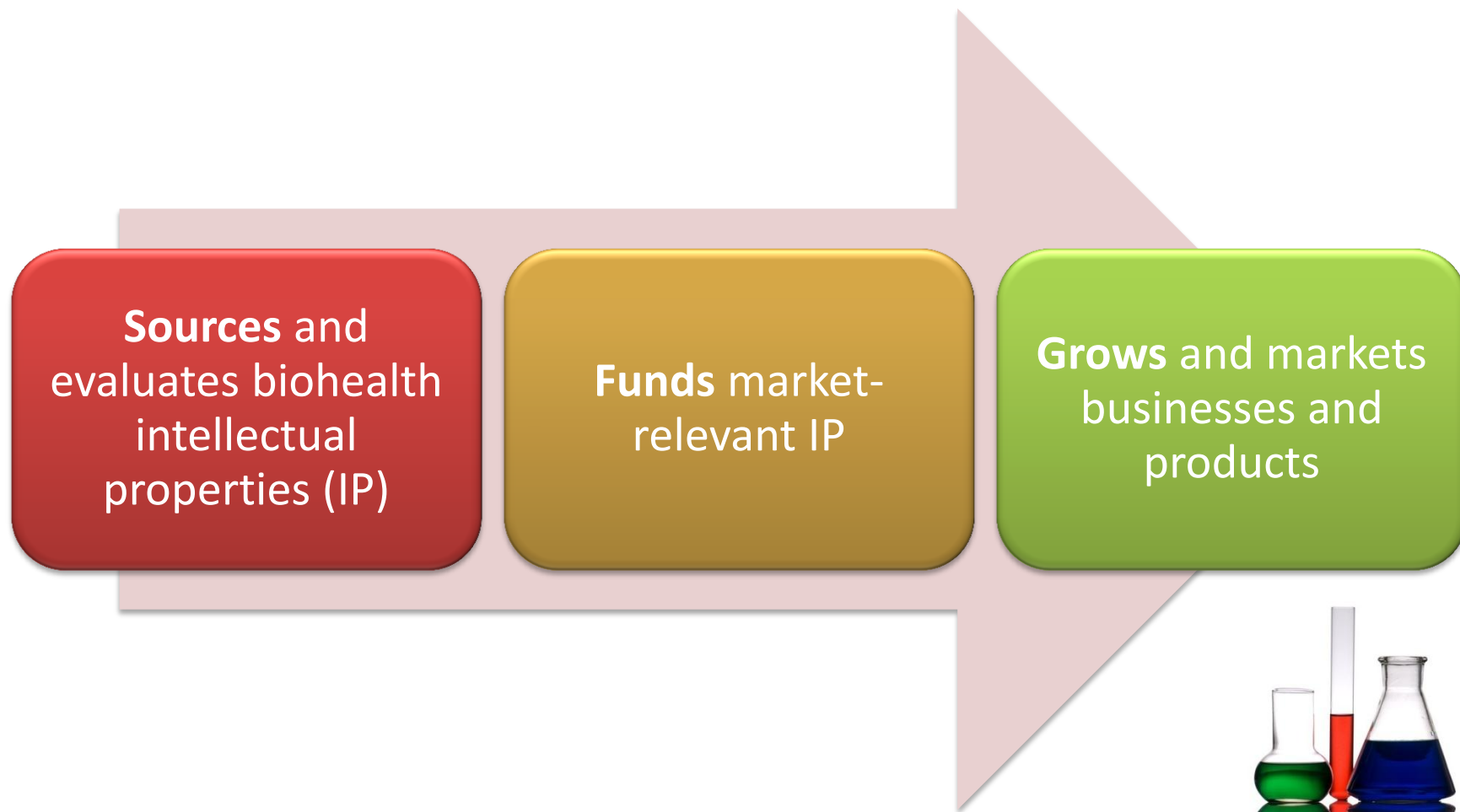
Innovation Capital

“VALLEY OF DEATH”



How does **BHI** work?

Commercialization Pipeline



Partnership Intermediary Agreement (PIA)

- PIA between BHI and NIH's Office of Technology Transfer that supports the 27 NIH institutes' \$3 billion intramural research and the Food and Drug Administration.
- **To promote and foster cooperative research and accelerate technology commercialization among NIH/FDA, businesses, and universities.**

Entrepreneur-in-Residence (EIR)

- Identify market viable biohealth assets
- Act as liaison among federal labs, 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
- Create new BioHealth companies

EIR Criteria

- **Senior management in an early stage life sciences startup**
 - **Entrepreneurial life science start up or spin out activity**
- **Management in a organization that specializes in startup companies**
- **Experience in a seed stage venture capital firm**
- **Served in a business development role in a high performing university or business development organization that successfully formed new ventures**
- **Served in a business development role, product development role, or other capacities for biotech products or services that enable substantial knowledge of the earliest stages of development for a new technology startup company**

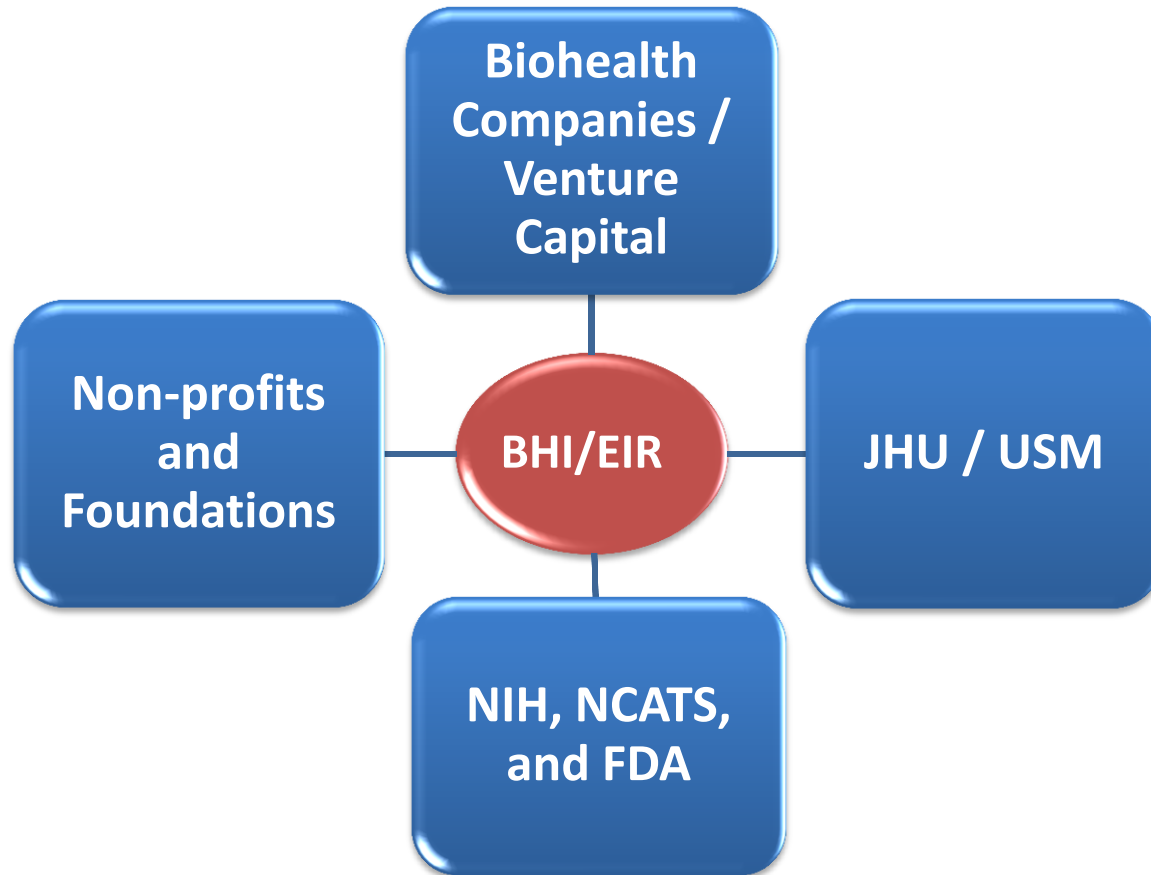


EIR Expectations



- **Assist OTT in the evaluation of existing technologies**
 - **Provide an entrepreneurial perspective to OTT in its evaluation of new licensing proposals**
 - **Advise OTT on opportunities for new ventures based on NIH/FDA technologies**
 - **Assist with developmental strategies**
 - **Mentor scientists to help ensure their research becomes commercially valuable**
- **Identify market viable innovations from NIH and other regional institutions**
 - **Act as liaison among regional biohealth stakeholders and NIH**
 - **Primary and secondary commercial analysis of lead technologies**
 - **Develop novel technologies that are at conceptual stage**
 - **Act as catalyst to license most interesting technologies and fund start-up companies**

EIR: Fulfilling the BHI Mission to Connect Industry, Academia, and Community



Example of EIR Interaction

!INNOVATE

Maryland's Innovation Initiative

- **\$5.8M budget**
- **5 University partners**
- **5 University site miners**
- **40 University pre proof-of-concept technologies funded**
- **\$25-\$150K funded per technology**



- **Regular meetings between BHI/EIR and site miners**
- **BHI identifies most commercially relevant technologies**
- **BHI and INNOVATE MD partnership opportunities**

EIR Integration into NIH System

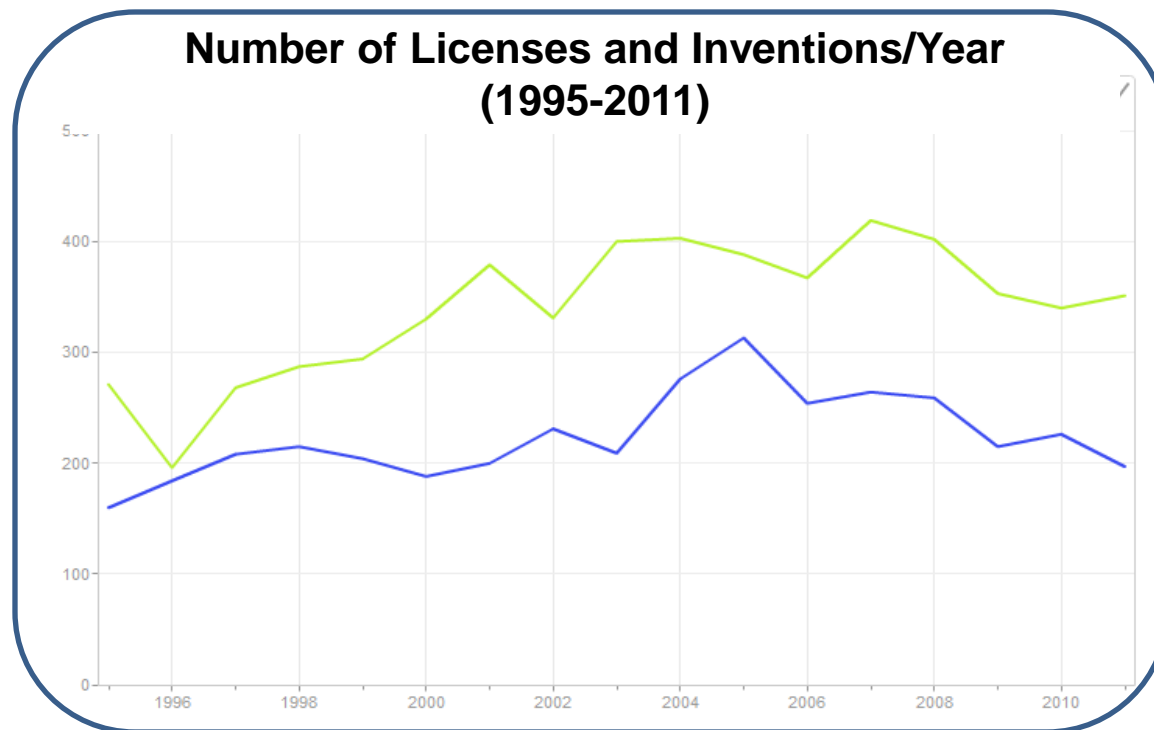
- **Office at the central Office of Technology Transfer (OTT)**
 - Volunteer status
 - Report to Director and Deputy Director of centralized OTT
 - Full access to NIH campus and staff
- **Active participant in Technology Review Groups at top three institutions**
 - Review of patent prosecution decisions for new and existing inventions
- **Active participant in Technology Development Coordinator meetings**
 - Key decisions on selected technologies
- **Access to database (SYNAPSE) detailing invention filings**

NIH Overview

- **Intramural budget is approximately \$3B per year**
 - 6,000 scientists
 - 27 institutes and centers (ICs)
- **Three largest centers: NCI, NIAID, and NHLBI**
 - In aggregate represents more than half of invention filings
- **Centralized Office of Technology Transfer**
 - Responsible for patenting
 - Technology transfer specialist at each institution
 - ~150 licensing staff members at NIH

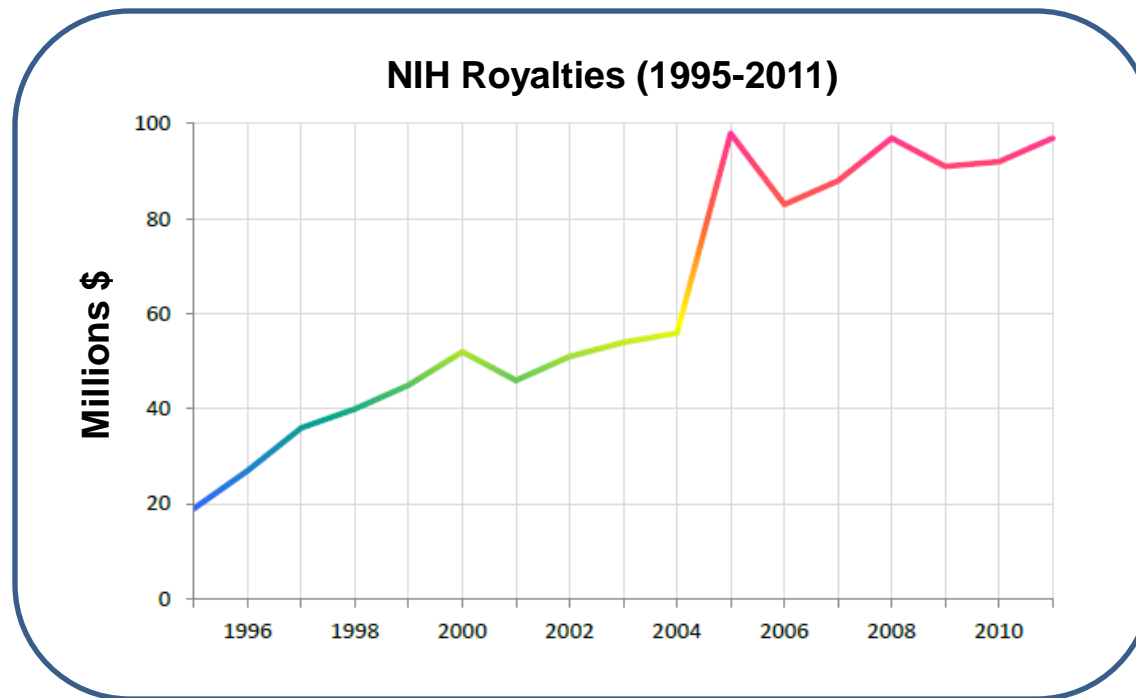
NIH License Statistics

- **351 invention disclosures in 2011**
- **197 licensed agreements in 2011**
- **25% of licenses in 2011 were 'commercial patents'**



NIH License Statistics

- More than 400 licenses reported sales of products in FY11 with combined total annual sales approaching \$6B
- 22 FDA approved drugs and biologics were developed under licenses from NIH in the last 40 years



NIH Success Stories

Top 5 Commercially Successful Therapeutic / Vaccine Inventions (by royalty to NIH)



1. Protease Inhibitor for Treatment of Drug-Resistant HIV-1



2. HPV Vaccine Based Upon Recombinant Papillomavirus Capsid Proteins



3. Monoclonal Antibody for Treatment of RSV



4. Proteasome Inhibitor for Treatment of Multiple Myeloma



5. Nutritional Supplement to Treat Macular Degeneration



Experience to Date

- **Clear need and desire for commercial perspective and expertise**
- **No dedicated person going through opportunities systematically**
- **Current OTT process not optimized for successful licensing**
- **Entrepreneurial spirit not part of organizational culture**
- **Significant number of technologies will need further development prior to license / start-up companies**

Identifying Opportunities

Lead Approach (NIH)

Technology Review Committees

Technology Transfer Branch Chiefs
and Licensing Managers

Successful Scientists

Systematic Approach (NIH + Other Institutions)

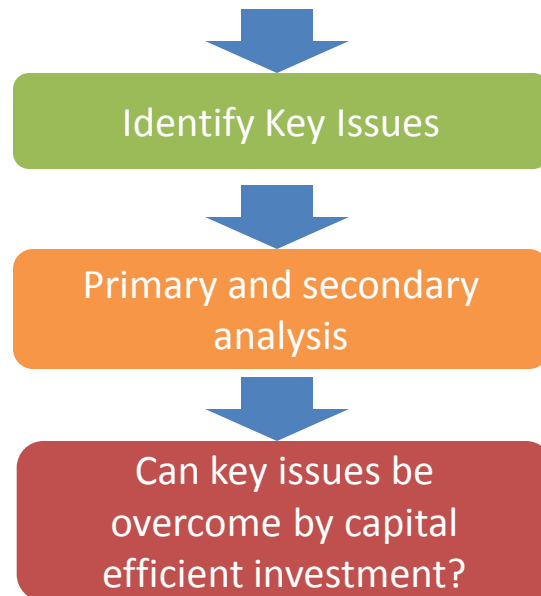
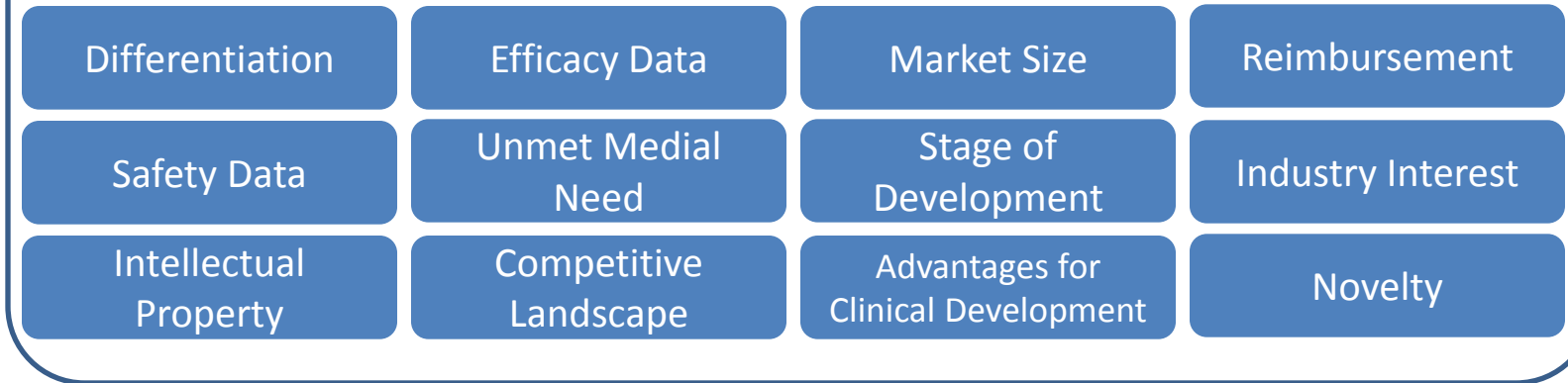
Evaluation of market needs from
regional players

Directed analysis using database
and meetings with scientists

Commercial, development, and
funding analysis

Early-Stage Analysis of Commercial Relevance

Selected Criteria for Value Proposition



Scientific and Commercial Committee

BHI Board Members

Industry Experts

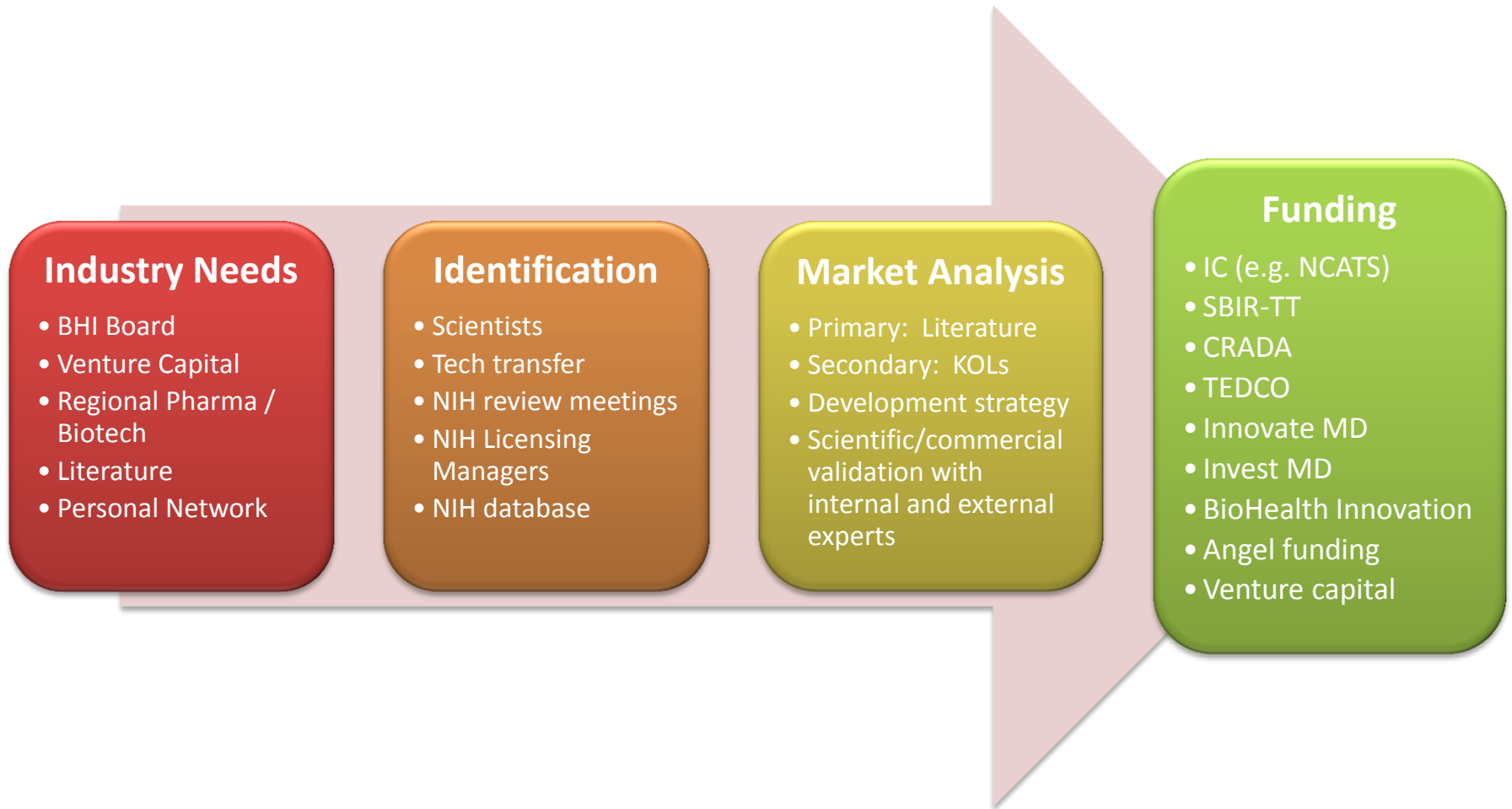
Thought Leaders

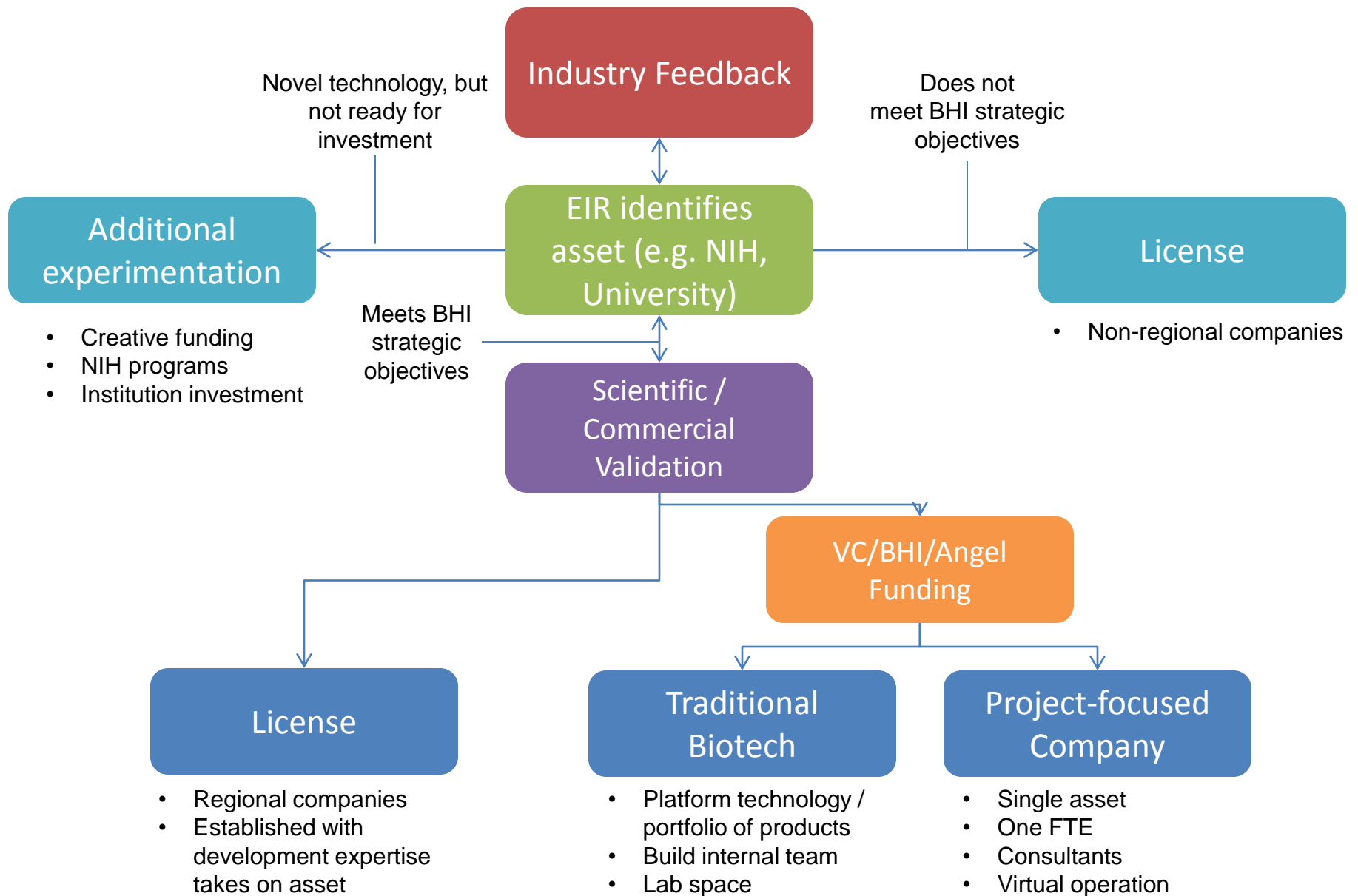
Venture Capital

Key Considerations for Technology Focus

- **Clear unmet need that benefits public health**
- **First-in-class, best-in-class therapies**
- **Target therapeutic areas that reflect strategic objectives**
- **Clinical development advantage**
- **Relevance to strategic needs**

What is the Overall Process for Licensing / Creating Company?





Funding Mechanisms



- **Institution or Center participates in direct funding of innovation**
- **Cooperative Research and Development Agreement (CRADA)**
 - Written agreement between a private company and a government agency to work together on a project
 - Allows the Federal government and non-Federal partners to optimize their resources, share technical expertise, share intellectual property emerging from the effort, and speed the commercialization

EIR Key Issues

- **Managing expectations and keeping BHI mission focus**
- **Linking EIR with internal commercial and scientific expertise**
- **Types of biohealth technologies to initially target**
- **Structure of companies to initially target**
- **Role of non-BHI, regional biotechnology companies**

EIR Next Steps

- **Introduce the EIR concept to additional BHI stakeholders / ICs**
- **Continue to get embedded into the NIH system**
- **Forge relationships with non-NIH organizations and institutions**
- **Identification of private sector needs**
- **Initiate commercial evaluation of innovations**
- **Identify and present diversified pilot projects to key stakeholders**
- **COMMERCIALIZE!**

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