



**What is a BioHealth Innovation Ecosystem
and how is it supposed to work?
May 9th, 2012**

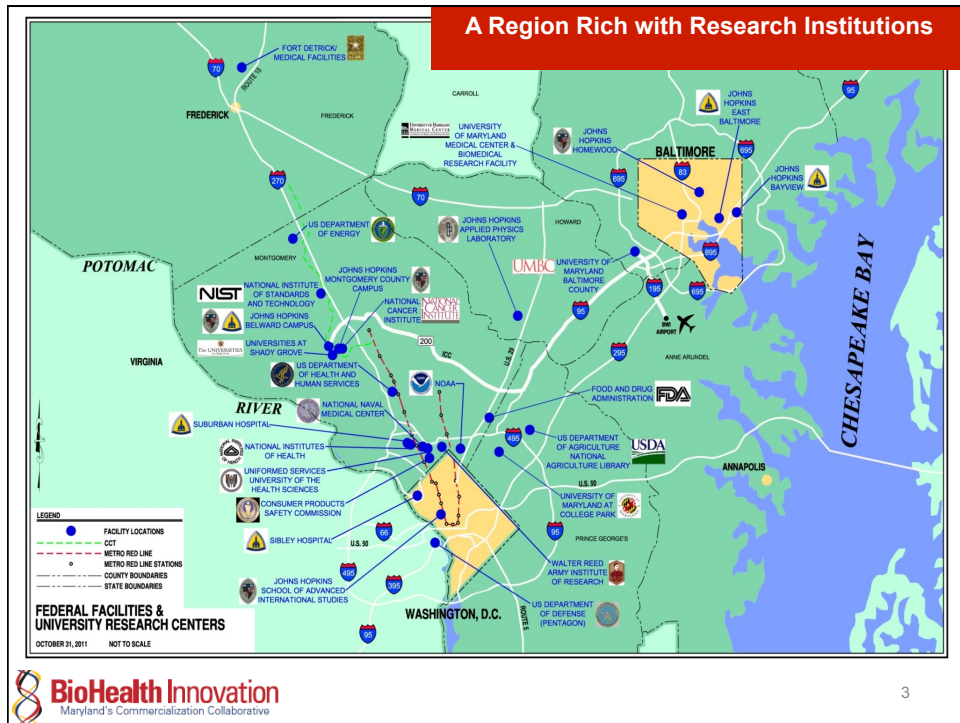
**Rich Bendis, Interim CEO, BHI
Dr. Mark Rohrbaugh, Director, NIH OTT**



“The Region”--Central Maryland

**Unrivaled Research Assets
Unfulfilled Commercial Promise**





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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**

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National Leadership



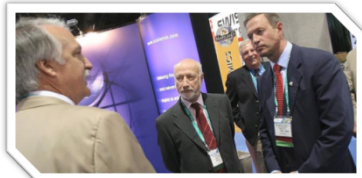
President Obama's Bioeconomy Initiatives & America Invents Act (2011)

- **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



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State Leadership



Maryland Governor O'Malley:

- **BioMaryland 2020**
- **Invest Maryland**
- **Innovate Maryland**

- **Maryland Biotechnology Investment Tax Credit** (\$6 m/yr)
- **BioMaryland 2020** blueprint
- **Invest Maryland** (\$70 million)
- **Maryland Life Sciences Advisory Board**
- **The Maryland Venture Fund**
- **Maryland Innovation Initiative**



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Local Leadership



County Executive Ike Leggett:

- Accelerate innovation & grow tax base
- Create a regional Montgomery County/ Baltimore Innovation Intermediary
- Support life science centers in the region



great seneca science corridor master plan
The Life Sciences Center



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

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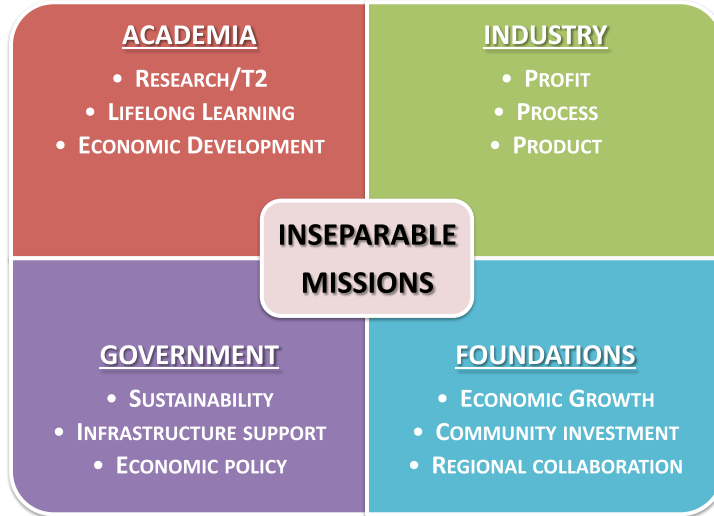
What is A Regional Innovation Intermediary?

- 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

Make the leap to a whole world of new opportunities

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Regional BioHealth Ecosystem Partners



BHI Partners and Sponsors



- BHI Funding Sources:**
- private sector
 - universities and foundations
 - public sector



BHI Board of Directors

Michael J. Baader, Esq.
 Managing Director, Venable LLP

William E. Kirwan
 Chancellor, University System of Maryland

Richard Bendis
 Interim CEO, BioHealth Innovation, Inc.

Douglas Liu
 Senior Vice President of Global Operations,
 Qiagen

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 Executive Vice President of
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 Public Policy, Human Genome Sciences

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 President & CEO, Adventist Healthcare

David M. Gillice (Secretary)
 Regional Managing Principal, Cassidy Turley

J. Thomas Sadowski
 President & CEO, Economic Alliance of Greater
 Baltimore

Thomas Street
 Assistant Chief Administrative Officer,
 Montgomery County Government




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"



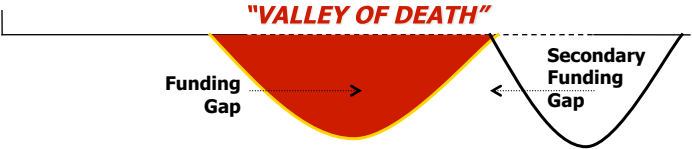
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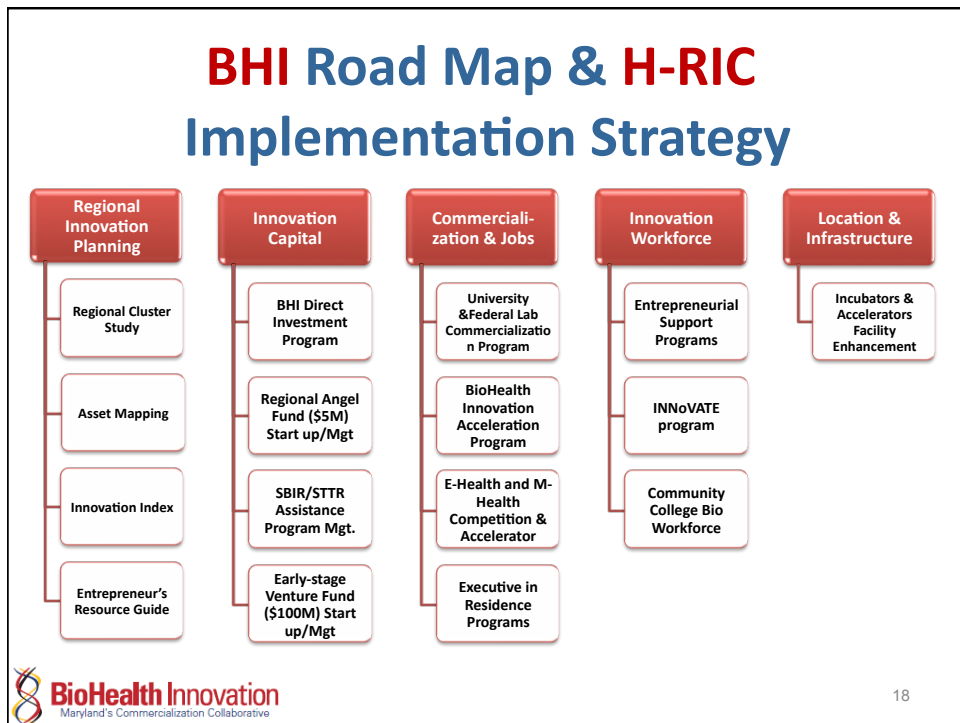
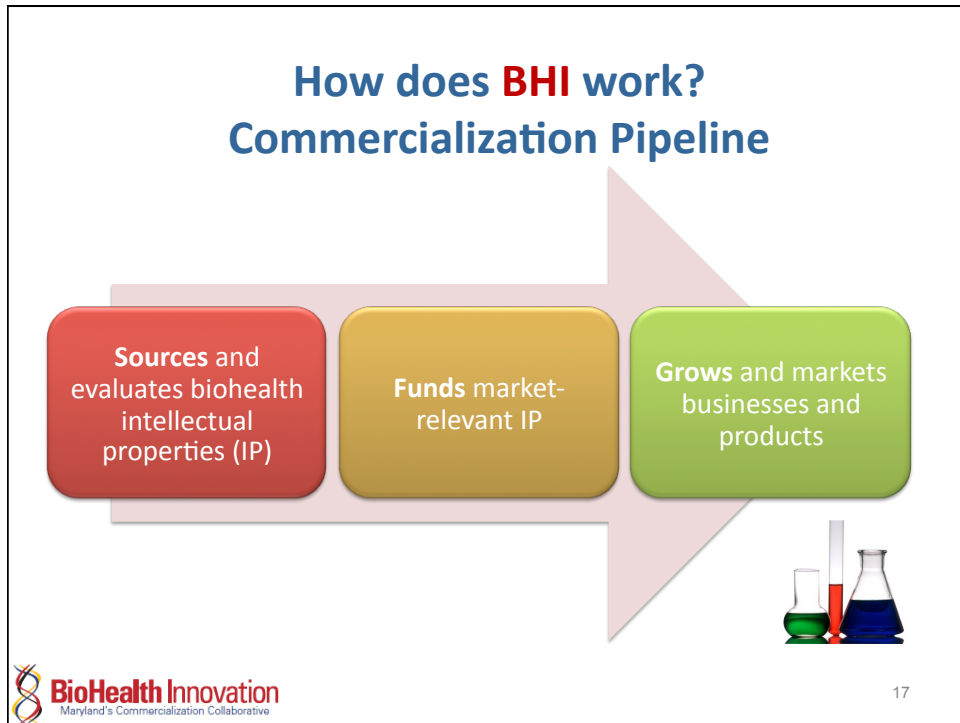
Innovation Capital

"VALLEY OF DEATH"

Stage	POR / Pre-Seed	Seed/Start-Up	Early	Later
Source	Founders, FFF Bootstrapping Crowdfunding	Angels, IBED, SBIR Accelerator Seed Funds		Venture Funds M&A, IPO
Demand	\$0K	\$500K	\$2.5M	\$5.0M
Supply	<div style="display: flex; justify-content: center; align-items: center;">  </div>			





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BHI H-RIC Implementation Strategy

Category	BioHealth Innovation Road Map Component
Regional Innovation Cluster Asset Analysis & Planning	
	Asset Mapping with GIS
	Innovation Index (Peer to Peer Baseline Benchmarking)
	Strategic Operating Plan
	Economic Impact Research Study
	Innovation & Entrepreneur's Resource Guide
	Program Gap Analysis
Innovation Capital	
	Develop Regional Angel Fund (\$5M)
	SBIR/SSTR Proposal Assistance Program
Commercialization & Jobs	
	E-Health and M-Health Competition & Accelerator
	***Executive In Residence Programs (Listed on Personnel Budget)
Innovation Workforce	
	Entrepreneurial Support Programs
	Maryland INNOVATE
	H-RIC Internship Program
Location & Infrastructure	
	International Soft Landing Incubator Program


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Innovation Resource Guide

“Financing and Entrepreneurial Resource for Montgomery County and the Greater Baltimore Region”

- Entrepreneur and Innovation Resource Network
- Innovator Financing Guide
- The Startup’s Guide to Intellectual Property


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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**



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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**

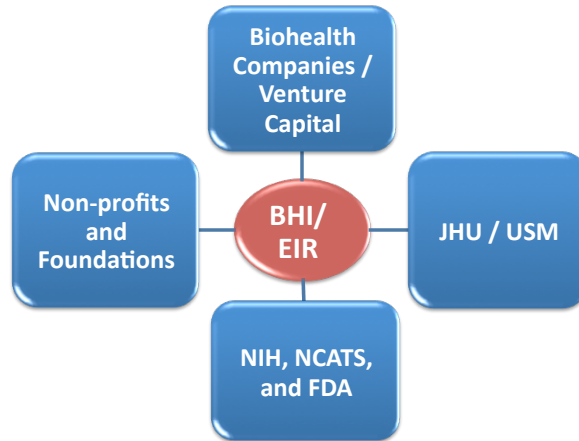


- **Identify market viable innovations from NIH and other regional institutions**
- **Act as liaison among regional biohealth stakeholders and NIH**
- **Primary and secondary commercial analysis of lead technologies**
- **Develop novel technologies that are at conceptual stage**
- **Act as catalyst to license most interesting technologies and fund start-up companies**



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



Example of EIR Interaction

!NNOVATE

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

BioHealth Innovation Maryland's Commercialization Collaborative

- 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

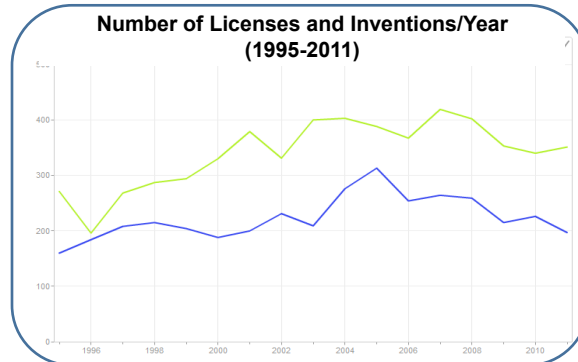
- **Office at the central Office of Technology Transfer (OTT)**
 - Volunteer status
 - Report to Director and Deputy Director of centralized OTT
 - Full access to NIH campus and staff
- **Active participant in Technology Review Groups at largest three institutes**
 - Review of patent prosecution decisions 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
 - 24/27 institutes and centers (ICs)
 - ~150 technology transfer staff at NIH
- **Centralized Office of Technology Transfer**
 - Responsible for patenting and licensing
 - Half of invention filings from NCI and NIAID, but many other important inventions come from our other 22 institutes. Valuable technologies and collaboration opportunities from all the Institutes with intramural programs.
- **Technology transfer specialist at each institute**
 - Responsible for industry collaboration agreements

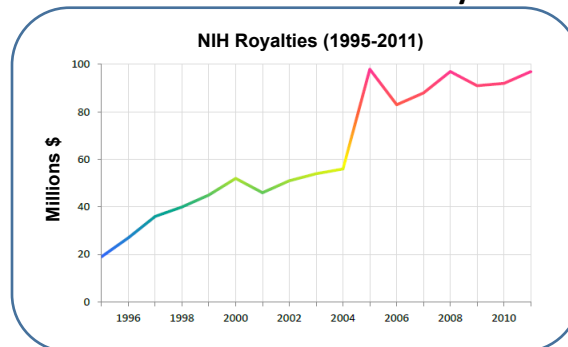
NIH License Statistics

- **351 invention disclosures in 2011**
- **197 license agreements in 2011**
- **43% of licenses were for product development and sale**



NIH License Statistics

- **More than 400 licenses reported sales of products in FY11 with combined total annual sales approaching \$6B**
- **70 products in commercial clinical trials in 2011**
- **21 FDA approved drugs and biologics were developed under licenses from NIH in the last 20+ 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



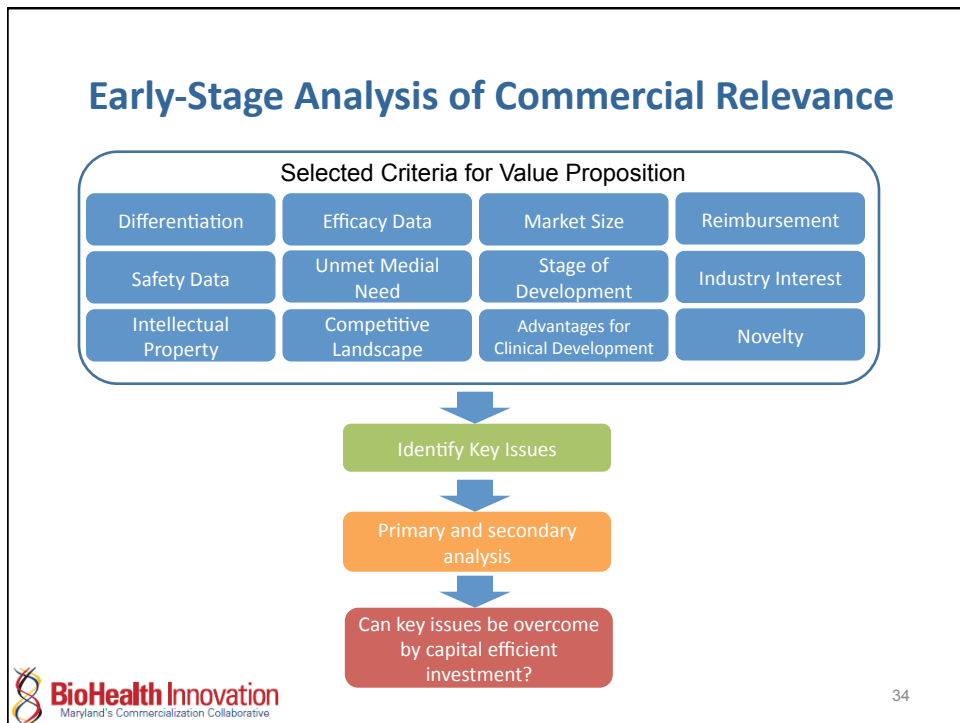
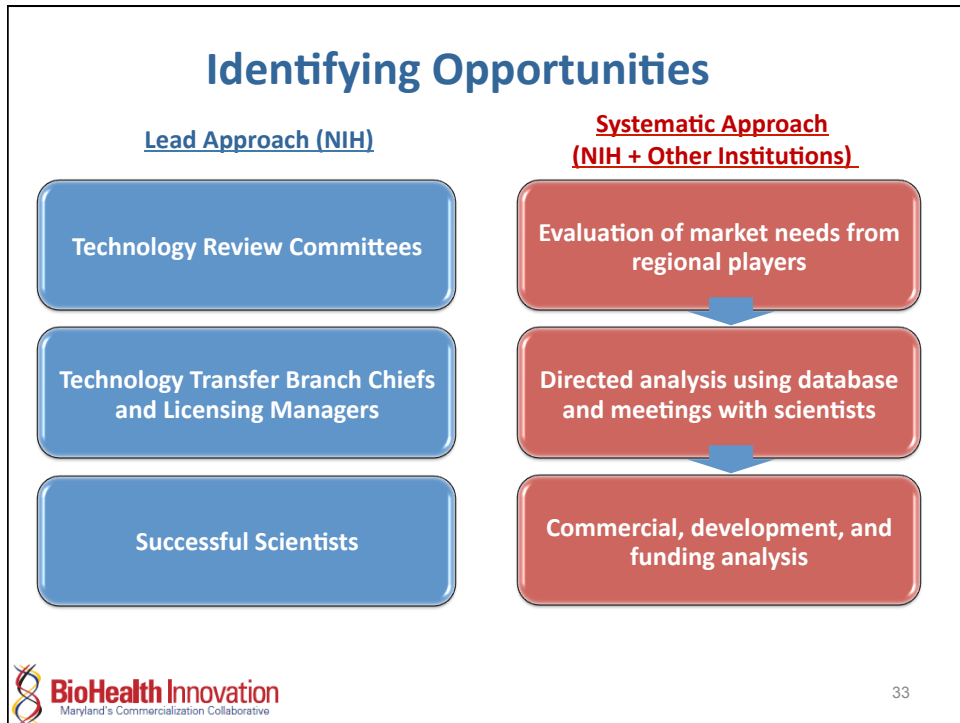
4. Proteasome Inhibitor for Treatment of Multiple Myeloma



5. Nutritional Supplement to Treat Macular Degeneration

Experience to Date

- **Clear need and desire for commercial perspective and expertise**
- **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**



Scientific and Commercial Committee

BHI Board Members

Industry Experts

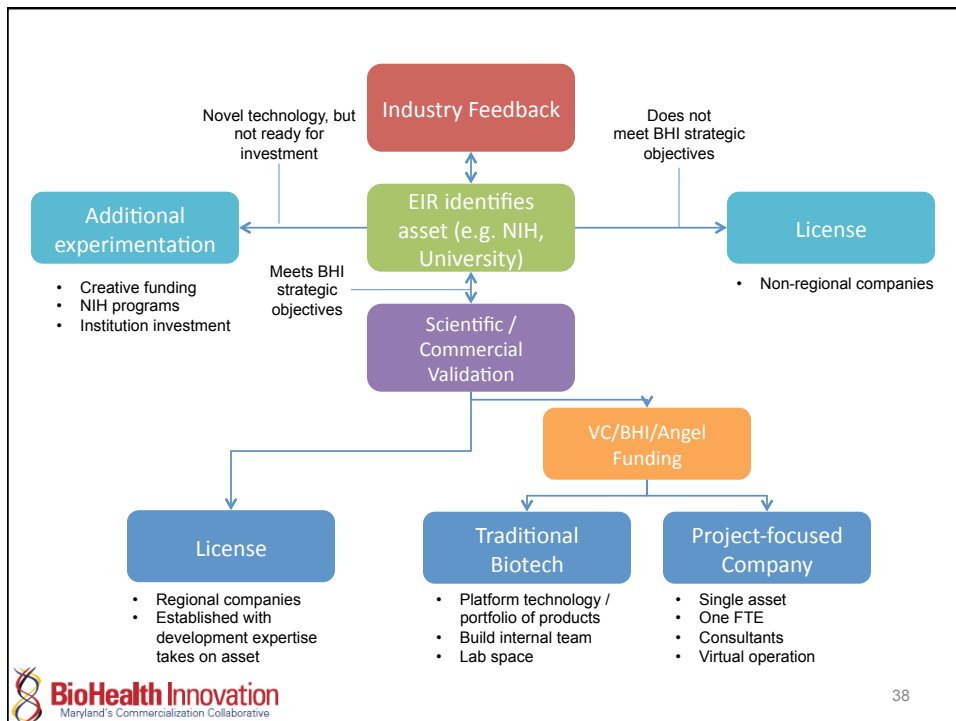
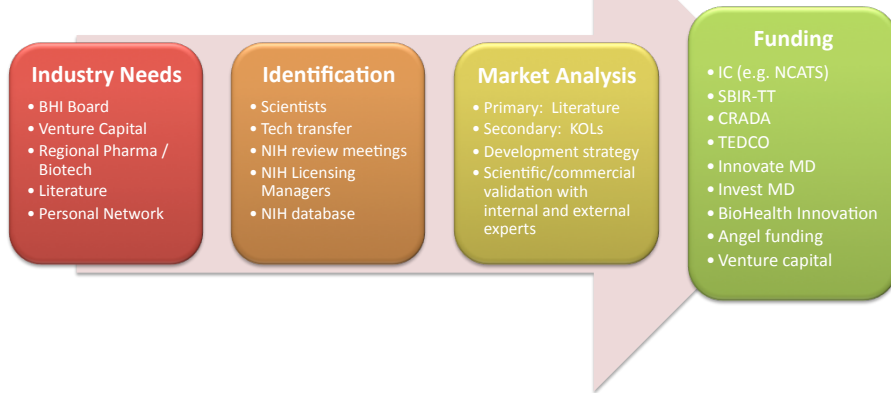
Thought Leaders

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



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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**



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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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