



BioHealth Innovation

Maryland's Commercialization Collaborative

Innovating with the Mid-Atlantic Federal Labs

Richard A. Bendis

President & CEO

8/28/2012

Cambridge, MD

www.BioHealthInnovation.org



State of Maryland: Federal Resources

- Maryland Federal R&D investment exceeding \$12 billion annually



- 59 Federal Laboratories, Centers, & Institutes in Maryland



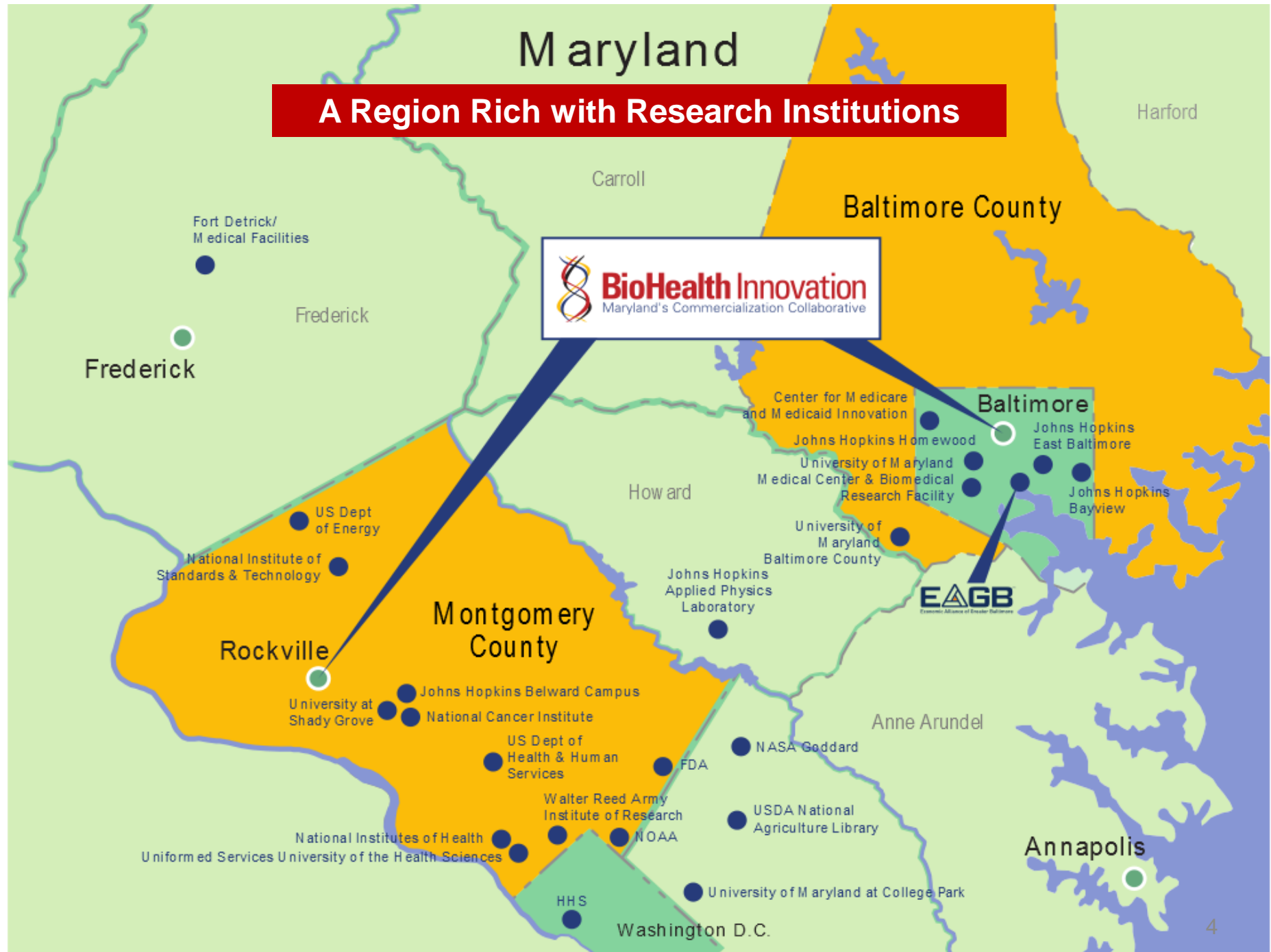
“The Region”--Central Maryland

Unrivaled Research Assets
Unfulfilled Commercial Promise



Maryland

A Region Rich with Research Institutions



Fort Detrick/
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

US Dept
of Energy

Howard

National Institute of
Standards & Technology

University of
Maryland
Baltimore County

Johns Hopkins
Applied Physics
Laboratory

EAGB
Economic Alliance of Greater Baltimore

Rockville

Montgomery
County

Johns Hopkins Belward Campus

University at
Shady Grove

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

Anne Arundel

HHS

University of Maryland at College Park

Washington D.C.

Annapolis

National Leadership



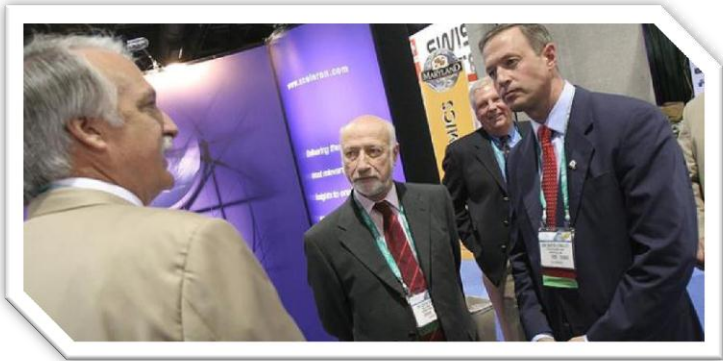
President Obama:

- **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



State Leadership



Maryland Governor O'Malley:

- **BioMaryland 2020**
- **Invest 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**

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



BioHealth Innovation

Maryland's Commercialization Collaborative

great seneca science corridor master plan

The Life Sciences Center



BioHealth Innovation
Maryland's Commercialization Collaborative

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

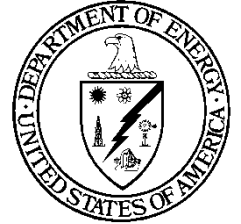
Connects regional innovation assets

Develops an entrepreneurial talent and support pipeline

Attracts funding for technology commercialization

Develops a continuum of innovation workforce

BioHealth Regional Innovation Cluster Assets



National Biodefense Analysis and Countermeasures Center

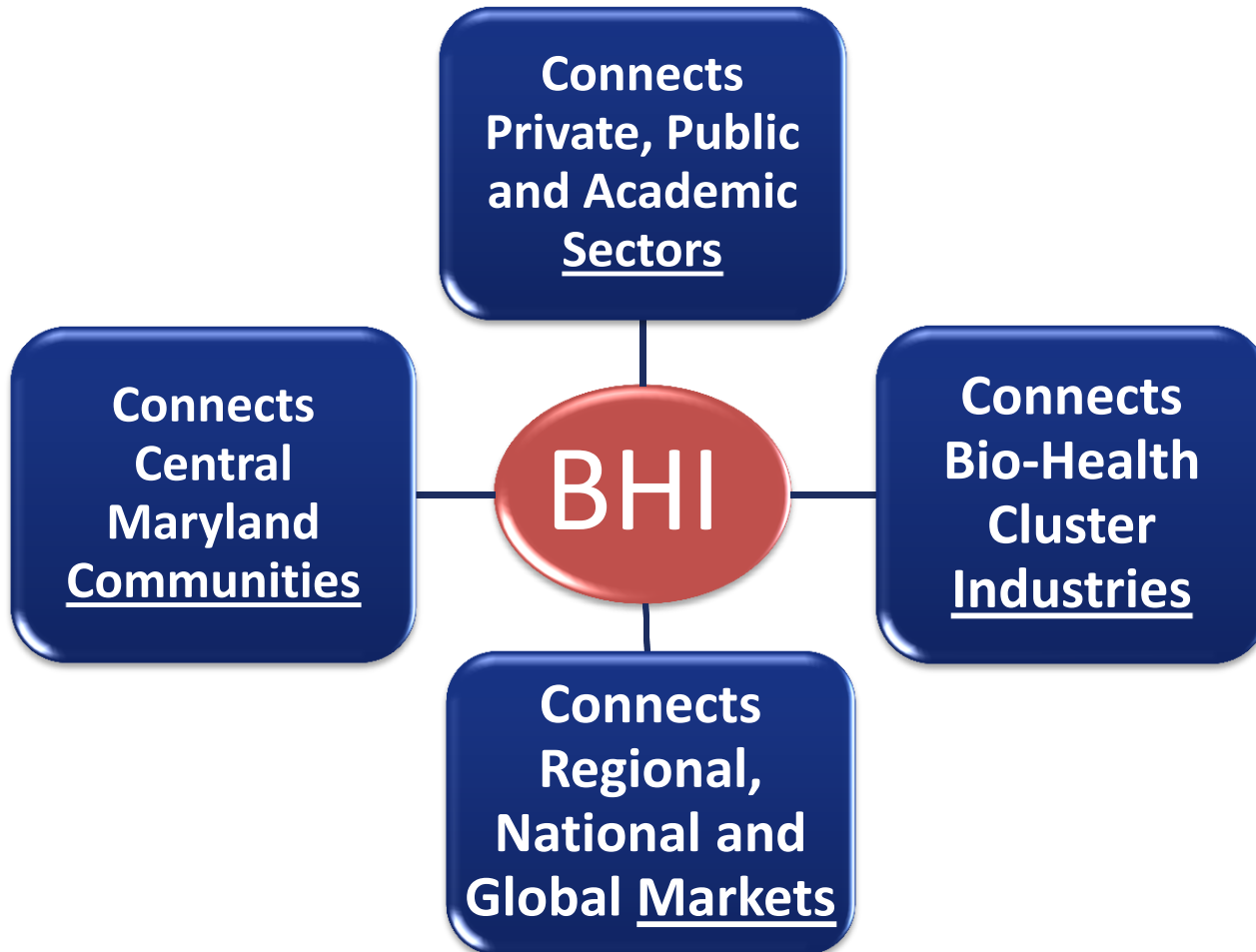


What is A Regional Innovation Intermediary?

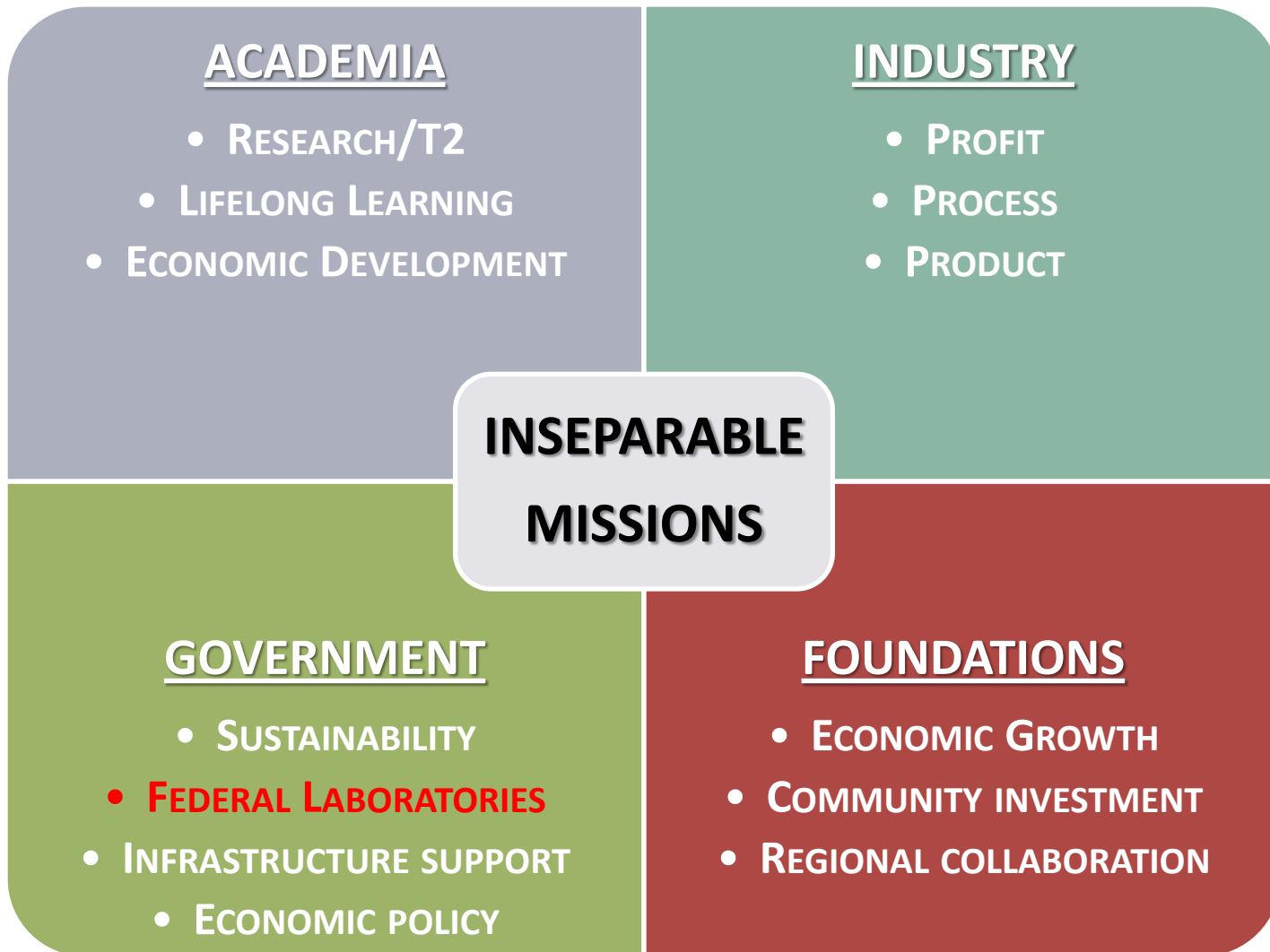
- An organization at the Center of the region's, state's and country's efforts
 - Align local technologies, assets and resources
 - Advance Innovation
- Regionally-oriented
- Private-public partnership, 501(c)(3) nonprofit
- Market-driven, private sector-led
- Neither a government initiative, nor a membership organization



BHI: An Innovation Intermediary that Connects Sectors, Industries, Communities, & Markets



Regional BioHealth Ecosystem Partners



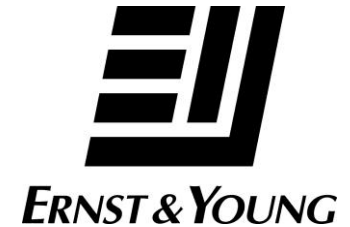
BHI Partners and Sponsors



JOHNS HOPKINS
UNIVERSITY



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EAGGB



VENABLE^{LLP}



BHI Board of Directors



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Senior Vice President of Global Operations, Qiagen



Richard Bendis
President & CEO, BioHealth Innovation, Inc.



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Commercial Operations, MedImmune



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Regional Managing Principal, Cassidy Turley

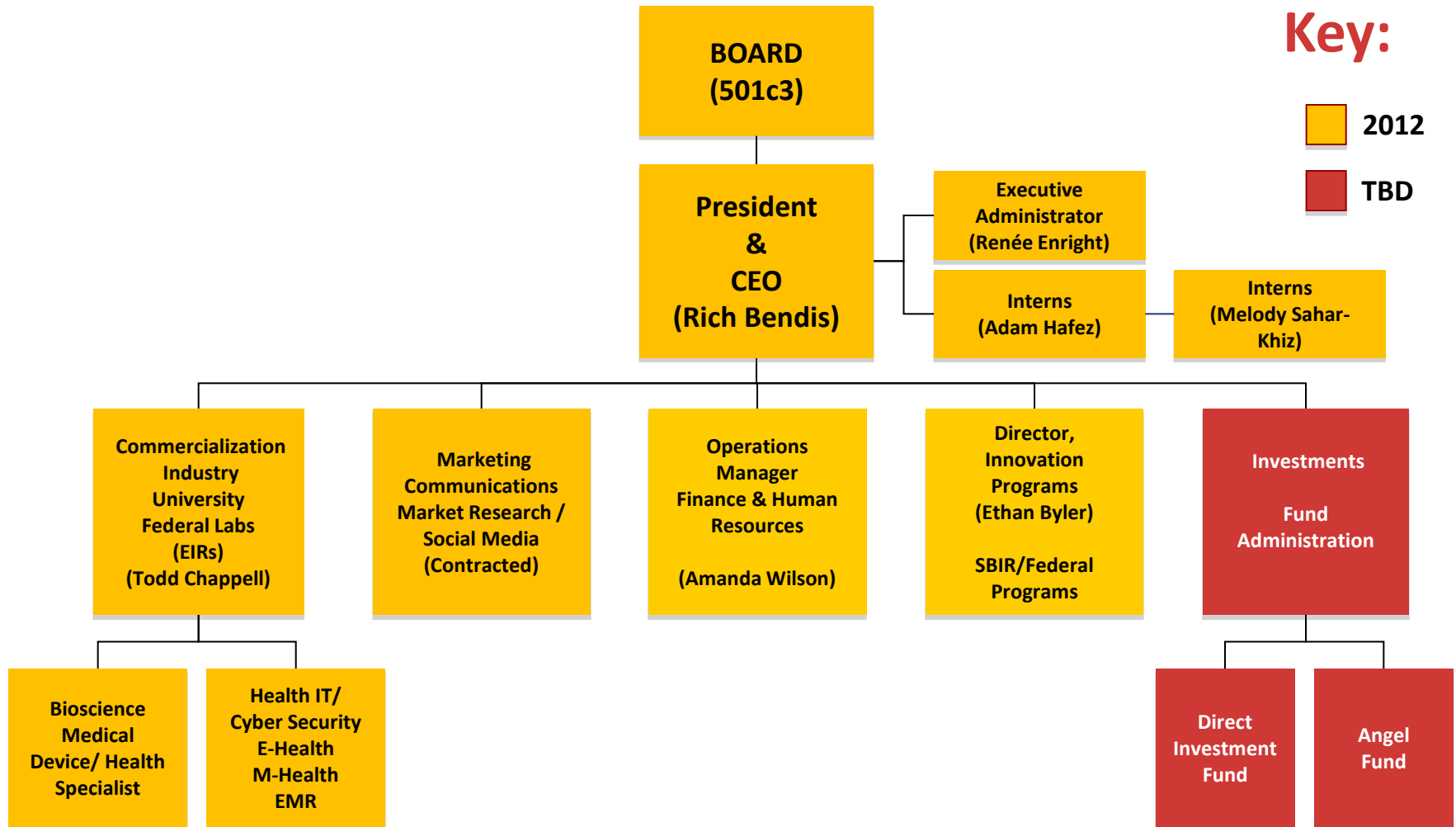


William E. Kirwan
Chancellor, University System of Maryland



Thomas Street
Assistant Chief Administrative Officer, Montgomery
County Government

BHI Organizational Chart



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)

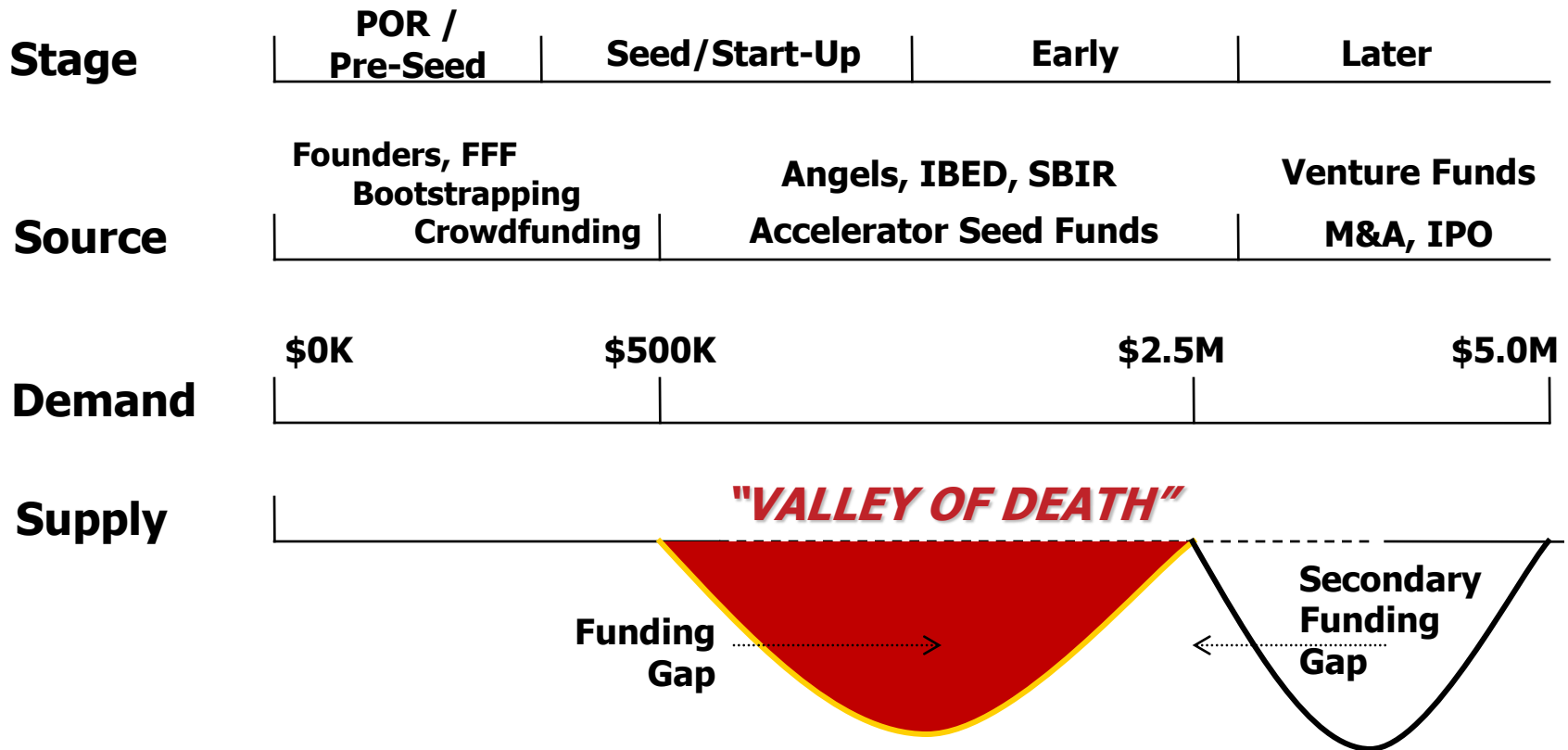
“It Works To Solve A Problem”

“I’ll Buy It”



Innovation Capital

“VALLEY OF DEATH”



Central Maryland Innovation Capital Map

Capital Sources by Investment Stage

Pre-Proof of Concept \$25K - \$1.5M (over 5 years)	Translational Research / Proof of Concept \$15K - \$2M	Proof of Commercial Relevance / Pre-Seed \$50K - \$500K	Seed / Start-Up \$50K - \$1M	Early Stage \$250K - \$2M	Later Stage \$2M+
<ul style="list-style-type: none"> NIH R01 NIH R03 NIH R21 Small Business Technology Transfer Research Grant (STTR) Phase I Innovate Maryland 	<ul style="list-style-type: none"> NIH Center for Accelerated Innovations (CAI) NCATS Cures Acceleration Network (CAN) Small Business Innovation Research Grant (SBIR) Phase I Maryland Stem Cell Research Fund (MSCRF) TEDCO University Technology Development Fund (UTDF) TEDCO TechStart Maryland Biotechnology Center's Translational Research Award 	<ul style="list-style-type: none"> Maryland Industrial Partnerships (MIPS @ UMD) Maryland Biotechnology Center's Biotechnology Commercialization Awards TEDCO Maryland Technology Transfer and Commercialization Fund (MTTCF) BHI SBIR/STTR Commercial Relevance Program (CRP) BHI Commercial Relevance Fund (CRF) 	<ul style="list-style-type: none"> Dingman Center Angels (UMD) TEDCO Johnson & Johnson Joint Investment Program Propel Baltimore Fund SBIR / STTR Phase II BHI Central Maryland Angel Fund National Association of Seed & Venture Funds (NASVF) Angel Capital Association (ACA) 	<ul style="list-style-type: none"> Maryland Health Care Product Development Corporation (MHCPDC) Invest Maryland: Maryland Venture Fund New Enterprise Associates (NEA) TDF Abell Venture Fund MMG Ventures LP Mid-Atlantic Venture Association (MAVA) 	<ul style="list-style-type: none"> Maryland Venture Fund Authority ABS Capital Partners Greenspring Associates Novak Biddle Venture Partners Sterling Venture Partners Harbert Venture Partners JMI Equity National Venture Capital Association (NVCA)

- Association of University Resource Parks (AURP)
- Association of University Technology Managers (AUTM)
- Licensing Executive Society (LES)

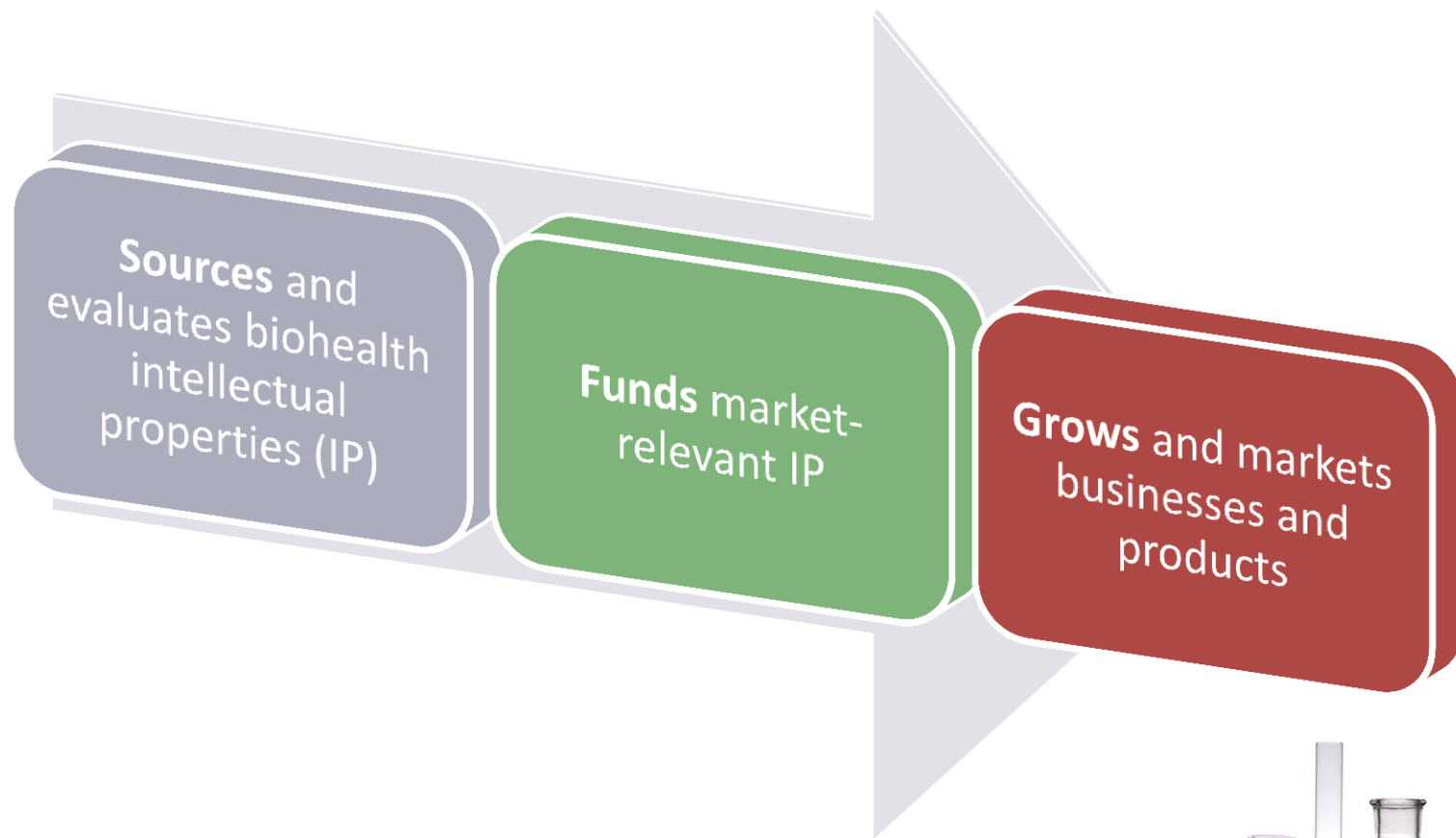
Funding Type Key

- Academic
- Accelerator
- Associations
- Federal
- BioHealth Innovation, Inc.
- Innovation-based Economic Development (IBED)
- State of Maryland
- Venture Capital

- ### Tax Credits
- Maryland Biotechnology Investor Tax Credit
 - Montgomery County Biotechnology Investor Tax Credit

How does **BHI** work?

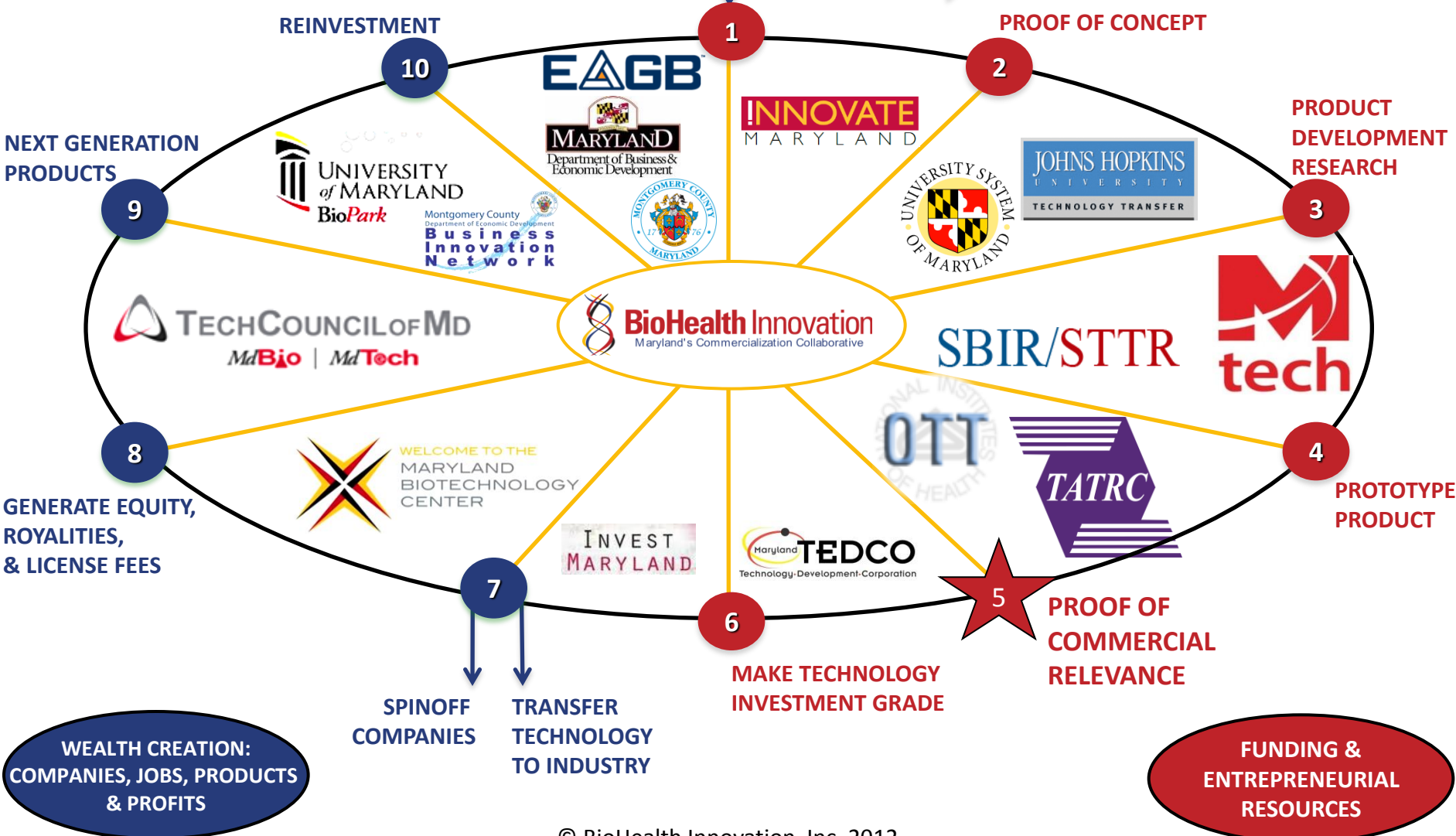
Commercialization Pipeline



BHI Commercialization Model

UNIVERSITIES, FEDERAL GRANTS, PRIVATE R&D, BASIC RESEARCH, INVENTIONS

 PUBLICATIONS
 PhD's
 TENURE
 PATENTS



Partnership Intermediary Agreements (PIA)



- **PIA between BHI and NIH's Office of Technology Transfer (OTT)** 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.



- **PIA between BHI and the Telemedicine & Advanced Technology Research Center (TATRC)** to capture USAMRMC and TATRC research outcomes and promote further research, product development, commercialization, and economic development opportunities.
 - TATRC has funded 241 MD based projects over the last 12 years.



Entrepreneur-in-Residence (EIR)

Proactively identifies and commercializes **market-relevant** intellectual properties from:

- Federal Labs
- Universities
- Private Sector



Todd Chappell

Progress (3 ½ months into Program)

- 55 Innovations identified and initially screened
- 7 Progressed to Secondary Analysis in BHI Pipeline (Safety & Efficacy Profiling, IP Diligence, Regulatory & Development Pathways)
- 26 No BHI Interest, 22 still Under Review



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**



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

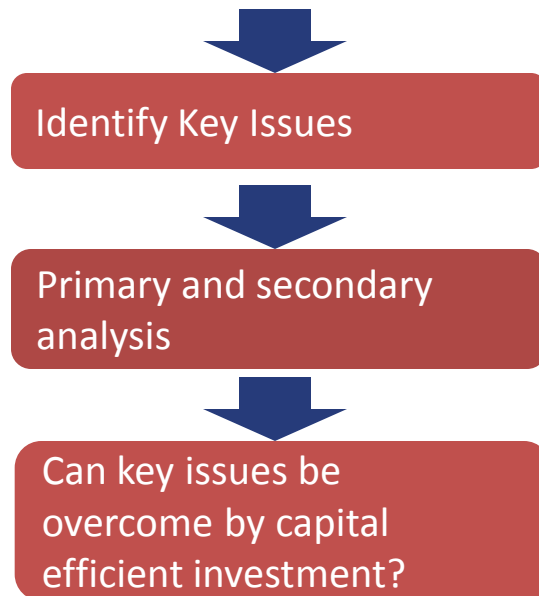
- **Intramural budget is approximately \$3B per year**
 - 6,000 scientists
 - 27 institutes and centers (ICs)
- **Three largest centers: NCI, NIAID, and NHLBI**
 - In aggregate represents more than half of invention filings
- **Centralized Office of Technology Transfer**
 - Responsible for patenting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



Early-Stage Analysis of Commercial Relevance

Selected Criteria for Value Proposition

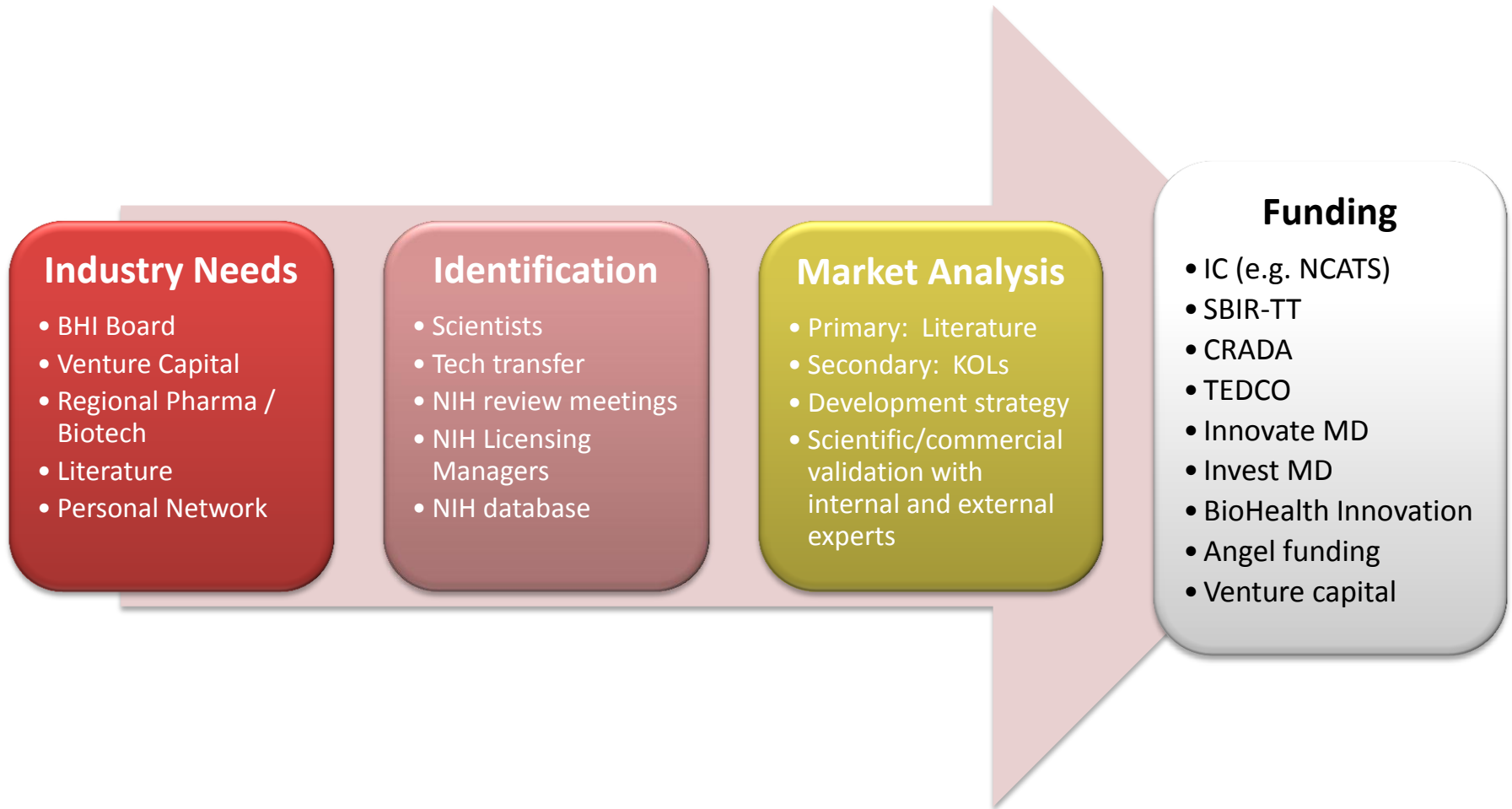
Differentiation	Efficacy Data	Market Size	Reimbursement
Safety Data	Unmet Medical Need	Stage of Development	Industry Interest
Intellectual Property	Competitive Landscape	Advantages for Clinical Development	Novelty



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?



BHI Commercialization Pipeline

STEP I: Innovation Exposures / Sourcing

- **Federal Labs**
- Academia
- Investor Groups
- Industry
- Personal Networks

STEP II: Screening

- Stage of Development
- IP Status
- Level of unmet medical need
- Industry interest
- Market size
- Competitive Advantage
- Scientific Reputation

STEP III: Secondary Analysis

- Disease Overview
- Safety Profile
- Efficacy Profile
- Market Differentiation
- IP Diligence
- Competitive Landscape
- Regulatory Path
- Development Plan

Step IV: Primary Analysis

- Commercial Expertise
- Industry Input
- Investor Input
- Regulatory Input
- Payer Interviews
- Third-party scientific expertise

Commercial Relevance

- **Investment**
- **Partnerships**
- **Funding**
- **SBIR/STTR**
- **NIH Collaboration**
- **Joint Ventures**
- **Licenses**



BHI News & Website



BHI Web site

The BHI Web site has news, an events calendar, research publications, regional organization feature stories and resources for the biohealth industry.

<http://www.biohealthinnovation.org>



BHI News

BHI's weekly e-newsletter highlights the Central Maryland Region's news articles, national biohealth trends and feature stories.

<http://www.biohealthinnovation.org/news>



Innovation Resource Guide

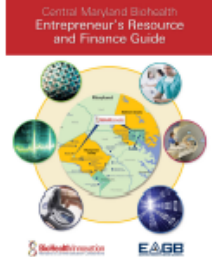
“Financing and Entrepreneurial Resource for Montgomery County and the Greater Baltimore Region”

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



Central Maryland Biohealth Entrepreneur's Resource and Finance Guide

- Provides **businesses and entrepreneurs** with information to access resources necessary to **grow** their biohealth businesses.
- **A-Z directory** of relevant businesses, organizations and resources for business assistance, economic development, innovation research, investment and technical assistance.
- A **comprehensive financing guide** designed to prepare businesses and entrepreneurs to navigate the complicated world of financing and investment.
- A **startup's guide to intellectual property** that will introduce entrepreneurs to the complex issues surrounding patents, trademarks, copyrights and trade secrets.
- The guide will be **free** and available in both **print and electronic** formats.



Benefits of Inclusion:

- Exposure to businesses, entrepreneurs, non-profit organizations and government leaders.
- Opportunity to market assistance and investment programs to a large audience.

Benefits of Sponsorship:

- Company logo printed on the inside cover of the guide.
- Exposure to 1,000s of businesses, organizations and government leaders through distribution of the guide.

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Economic Alliance
of Greater Baltimore
410-637-4105
mcombs@greaterbaltimore.org



Central Maryland Biohealth Entrepreneur's Resource and Finance Guide is a joint effort between BioHealth Innovation and the Economic Alliance of Greater Baltimore.

For more information, visit:

www.biohealthinnovation.org
www.greaterbaltimore.org

BHI Innovation Capital

- **SBIR/STTR Assistance Program** - The BHI SBIR/STTR Assistance Program (in development) will provide assistance to biohealth-driven companies in the Central Maryland region in preparing for high-quality SBIR/STTR grant proposals for submission to federal funding agencies.
- **BHI Angel Fund** - The BHI Angel Fund (in development) will be a member-managed private equity investment fund that bridges the gap between pre-seed investments and institutional venture capital serving the Central Maryland region entrepreneurial needs.
- **BHI Commercial Relevance Investment Fund** - The BHI Commercial Relevance Investment Fund (in development) will be a pre-seed and early-stage, equity-based innovation capital fund to help grow, attract, retain and connect Central Maryland biohealth innovation-based companies that need financing to grow their enterprises.



How is Success Measured?

BHI Metrics – First 5 Years

	Now	In 5 Years
VC Funding for Biotech	\$79 Million	\$150
Government Funding for Biotech	Increased SBIR proposals & success	Improve Maryland's ranking
Source Prospective Deals Annually	30	150

Improve return on R&D investment by leveraging equity investment

Create and retain 1,300 jobs

Recruit entrepreneurs, experienced managers and businesses

Commercialize biohealth technologies and create biohealth companies

BHI: The Triple Bottom Line

Grows high-paying jobs and businesses



Expands tax base; **improves** economic vitality



...and **Benefits** human health!

BHI Staff

Richard Bendis

President & CEO

(215) 593-3333

rbendis@bendisig.com

Todd Chappell

Entrepreneur-In-Residence

(978) 933-1622

tchappell@biohealthinnovation.org

Ethan Byler

Director, Innovation Programs

(301) 637-7952

ebyler@biohealthinnovation.org

Renée Enright

Executive Administrator

(301) 637-5372

renright@biohealthinnovation.org

Amanda Wilson

Operations Manager

(301) 637-0699

awilson@biohealthinnovation.org

Adam Hafez

Student Intern

(301) 637-7270

ahafez@biohealthinnovation.org

BioHealth Innovation, Inc.

22 Baltimore Road | Rockville, MD 20850

bhi@biohealthinnovation.org

