

**Eighth Annual Symposium on Translational Research in Molecular Pathology
&
2012 CBA Annual Conference in Maryland**



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE



BioHealth Innovation
Maryland's Commercialization Collaborative

BioHealth Innovation in Maryland

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President & CEO

10/2/2012

University of Maryland, Baltimore

www.BioHealthInnovation.org



BioHealth Innovation
Maryland's Commercialization Collaborative

“The Region”--Central Maryland



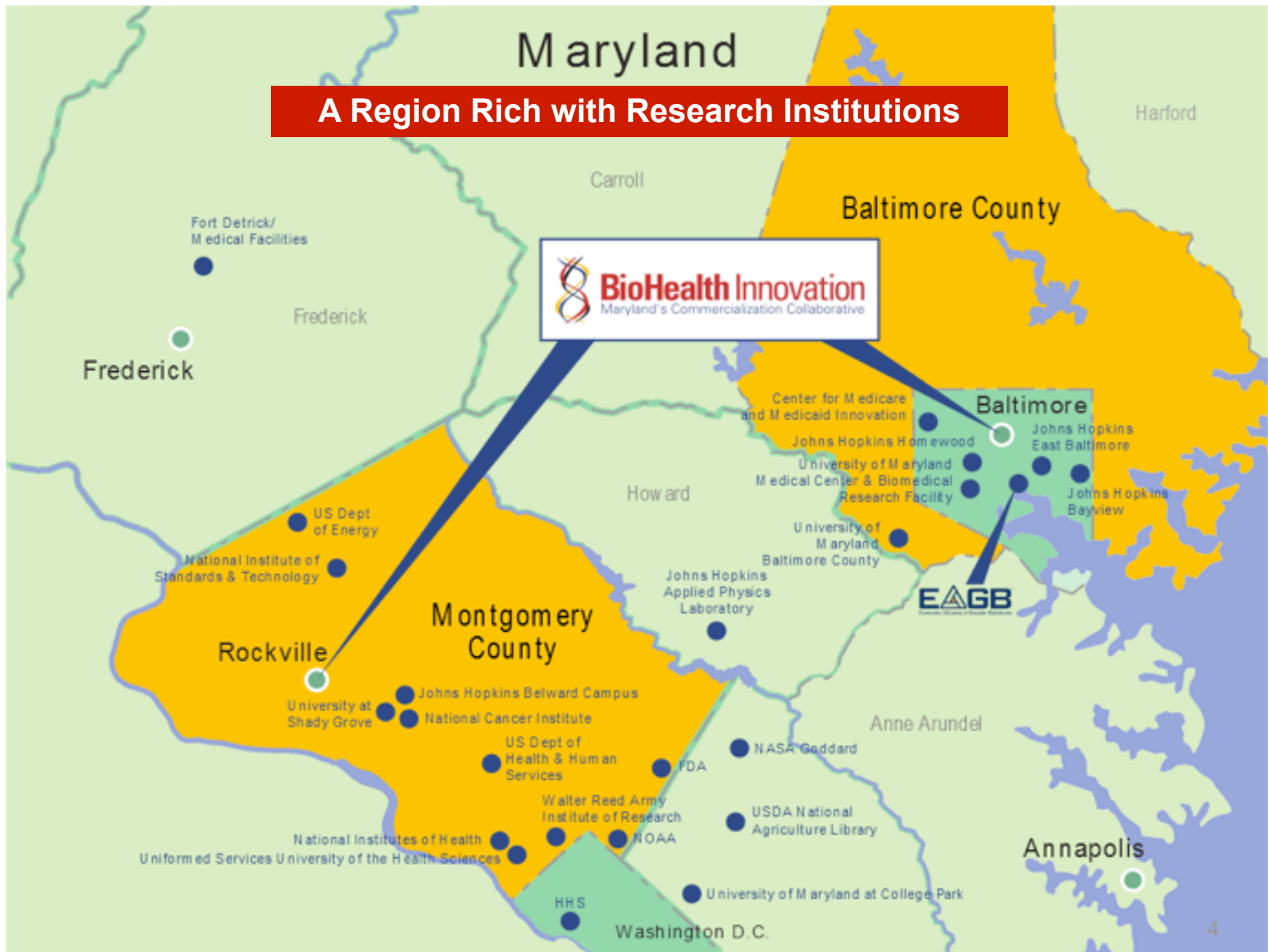
State of Maryland: Federal Resources

- **59 Federal Laboratories, Centers, & Institutes in Maryland**



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





Alignment of National, State, and Regional Policies



**Obama
Administration**



**Governor
O'Malley
(Maryland)**



**County Executive
Ike Leggett
Montgomery County**



**Stephanie Rawlings -
Blake
Mayor of Baltimore**

- Link Both State, County & City Strategies to Obama Administration Objectives
- Develop an integrated Regional BioHealth Economic Development and Transit Strategy
- Present the “Regional Job Generating BioHealth and Transit Plan” to the White House & partner with federal agencies and other stakeholder organizations as a “Showcase Model.”
- Develop structure & governance for the regional BioHealth innovation intermediary
- Obtain Priority Federal Funding for Region’s BioHealth Industry-Federal Labs-University Innovation Intermediary Pilot Plan
- Obtain Priority Federal Funding for the region’s Innovative “State of the Art” Comprehensive Rapid Transit Vehicle Plan (CCT et al)
- Develop a pilot BioHealth-Regional Innovation Cluster (H-RIC) program

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



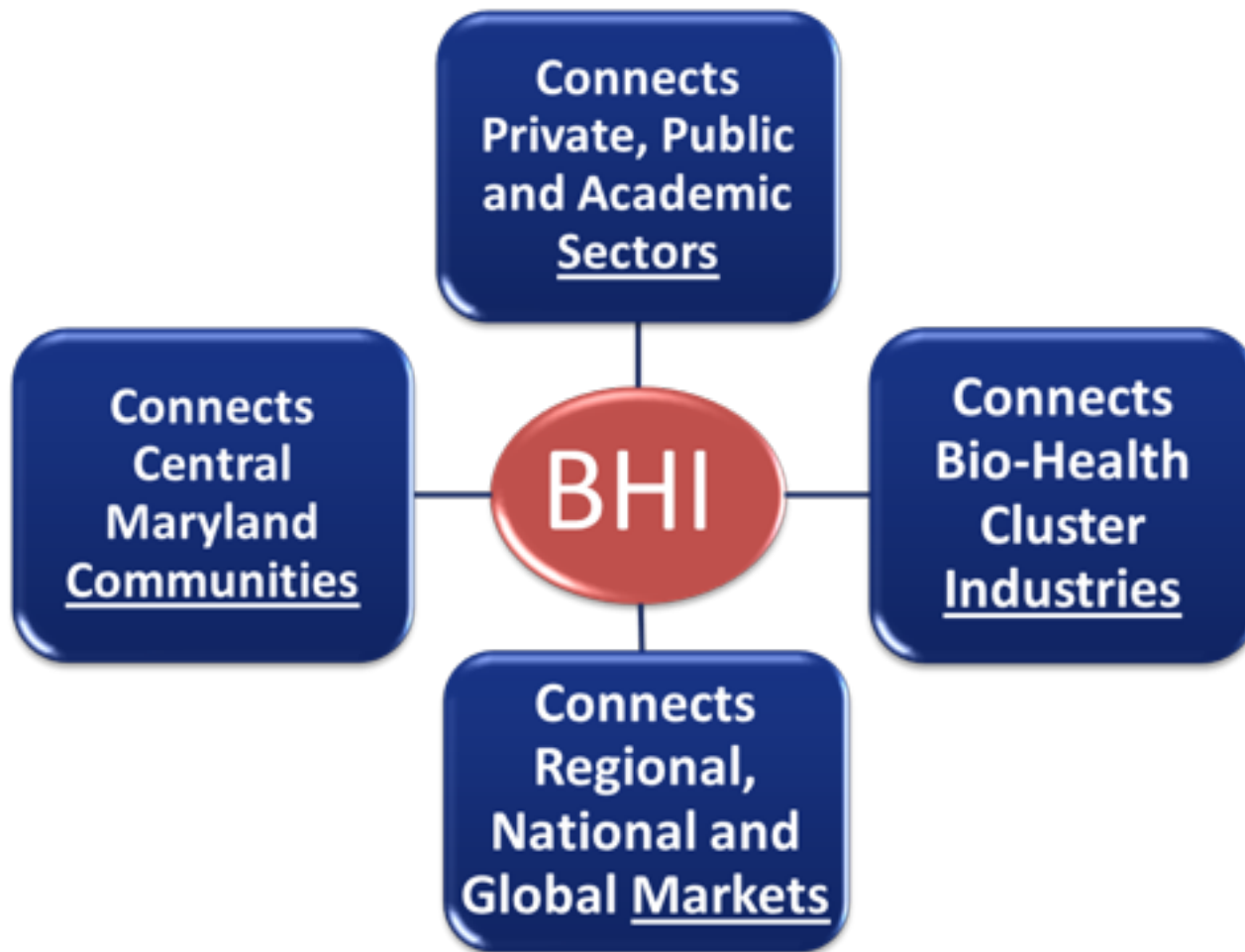
National Biodefense Analysis and Countermeasures Center



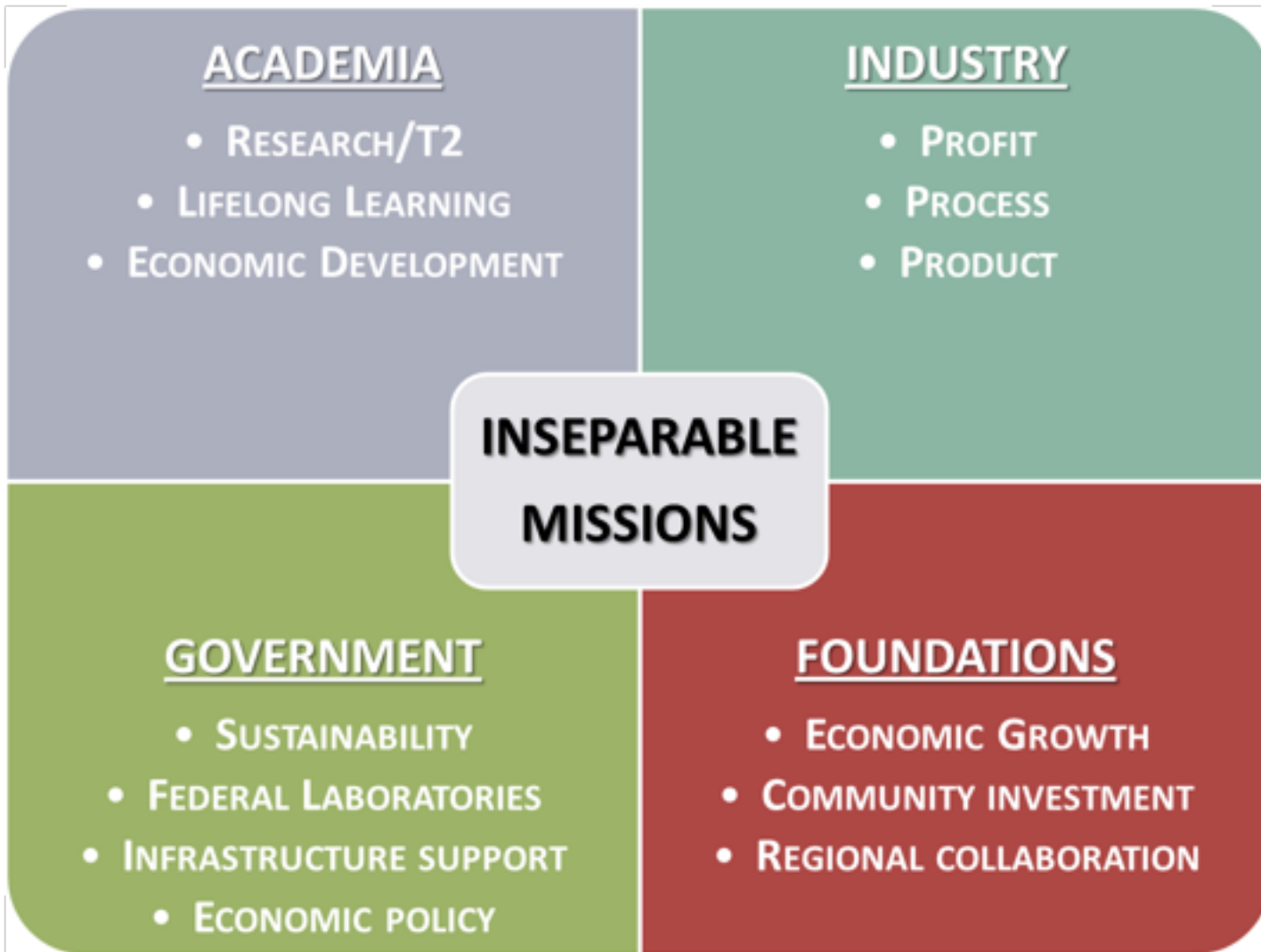
What is A Regional Innovation Intermediary?

- 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





Regional BioHealth Ecosystem Partners



BHI Partners and Sponsors



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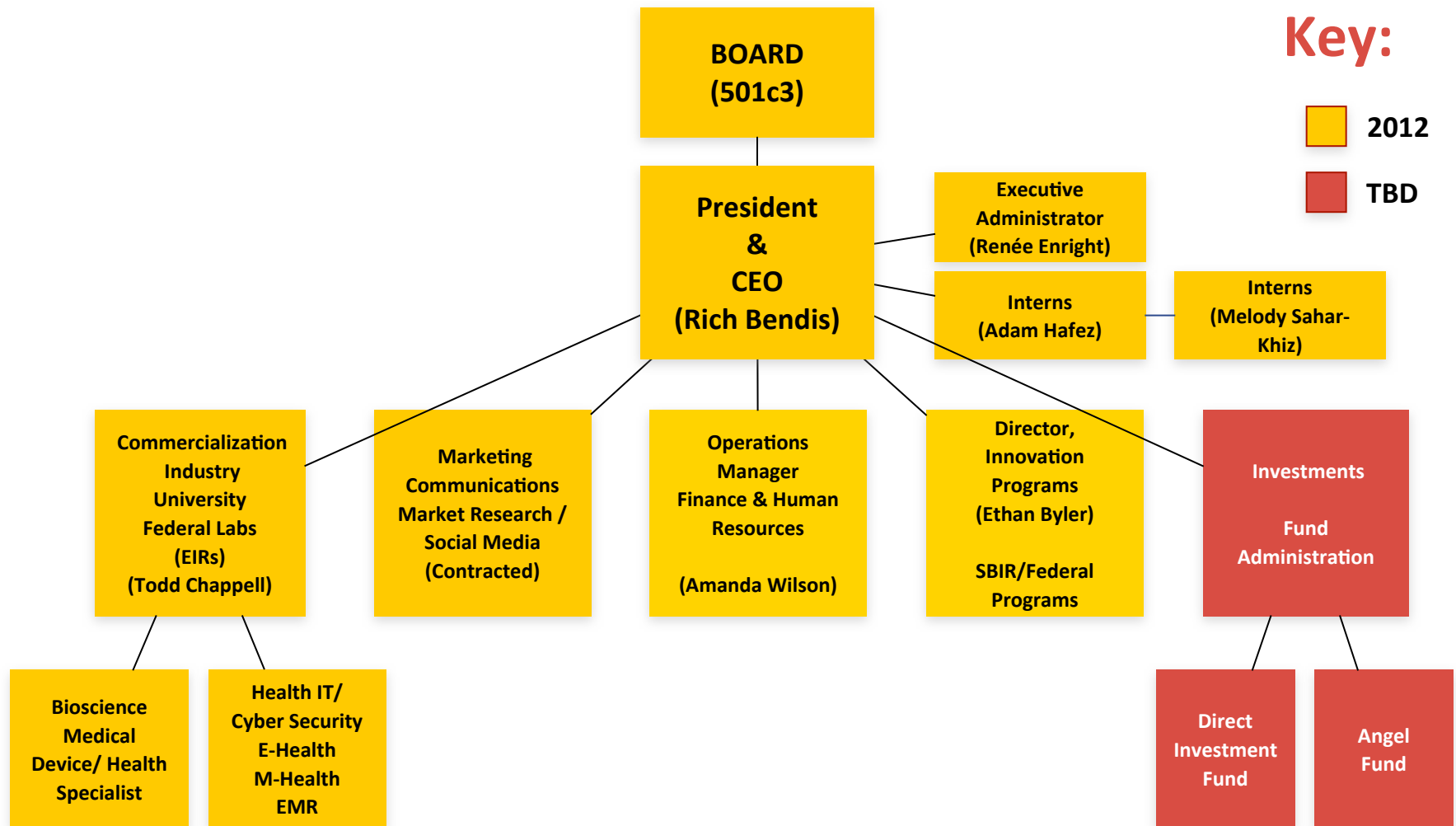
J. Thomas Sadowski
President & CEO, Economic Alliance of Greater
Baltimore



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

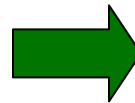
“It Works!”



PROOF OF COMMERCIAL RELEVANCE
(Market Pull)

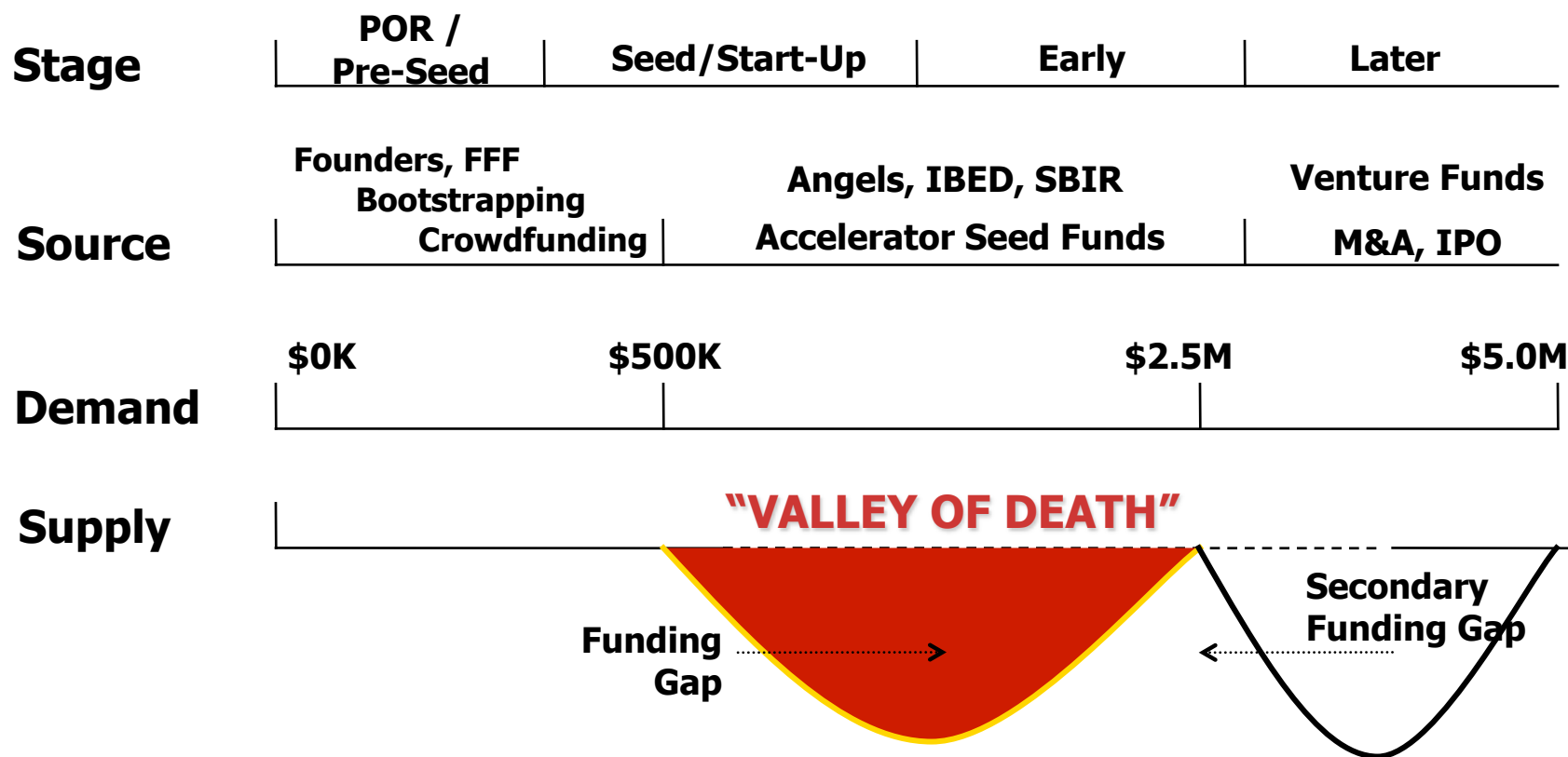
“It Works To Solve A Problem”

“I’ll Buy It”



BioHealth 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 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 	<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)

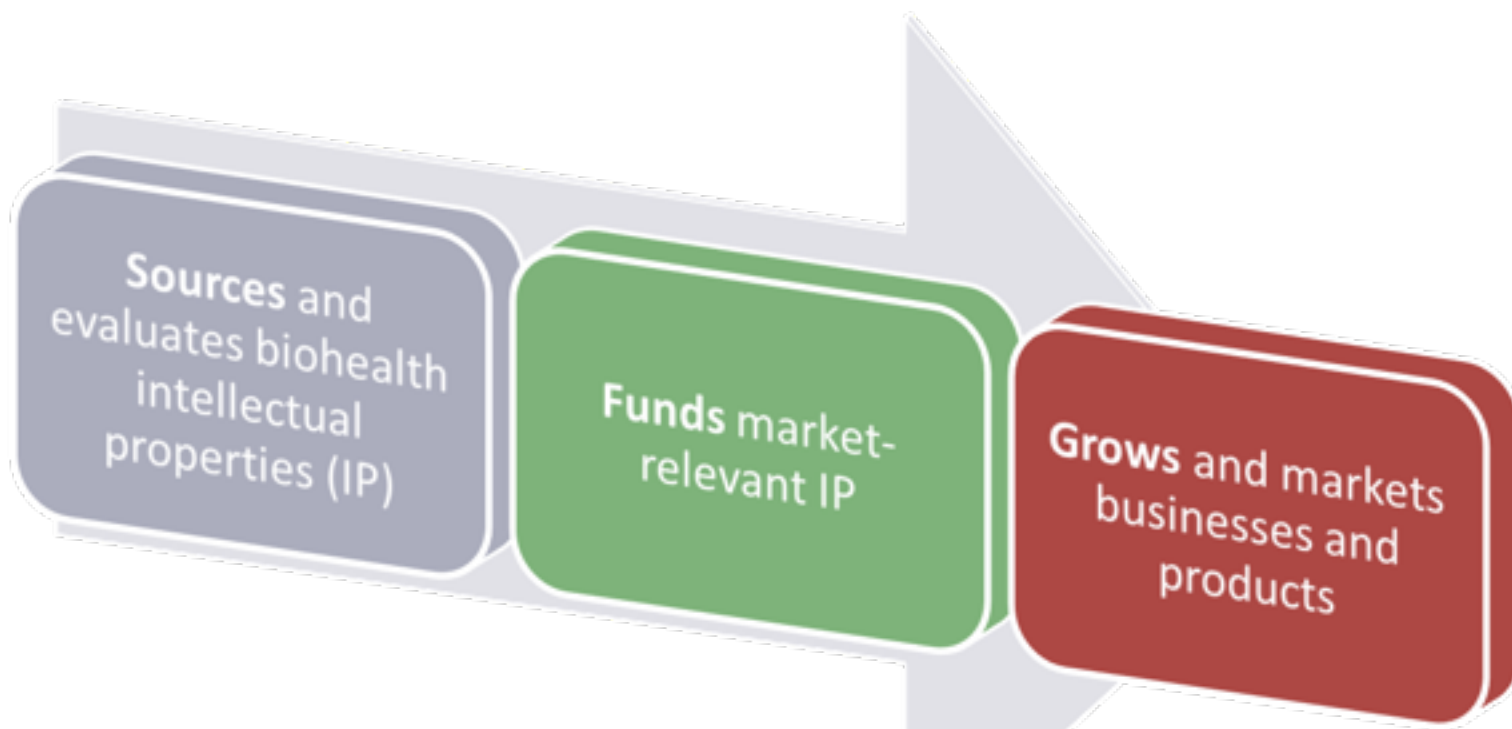
Funding Type Key

- 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?

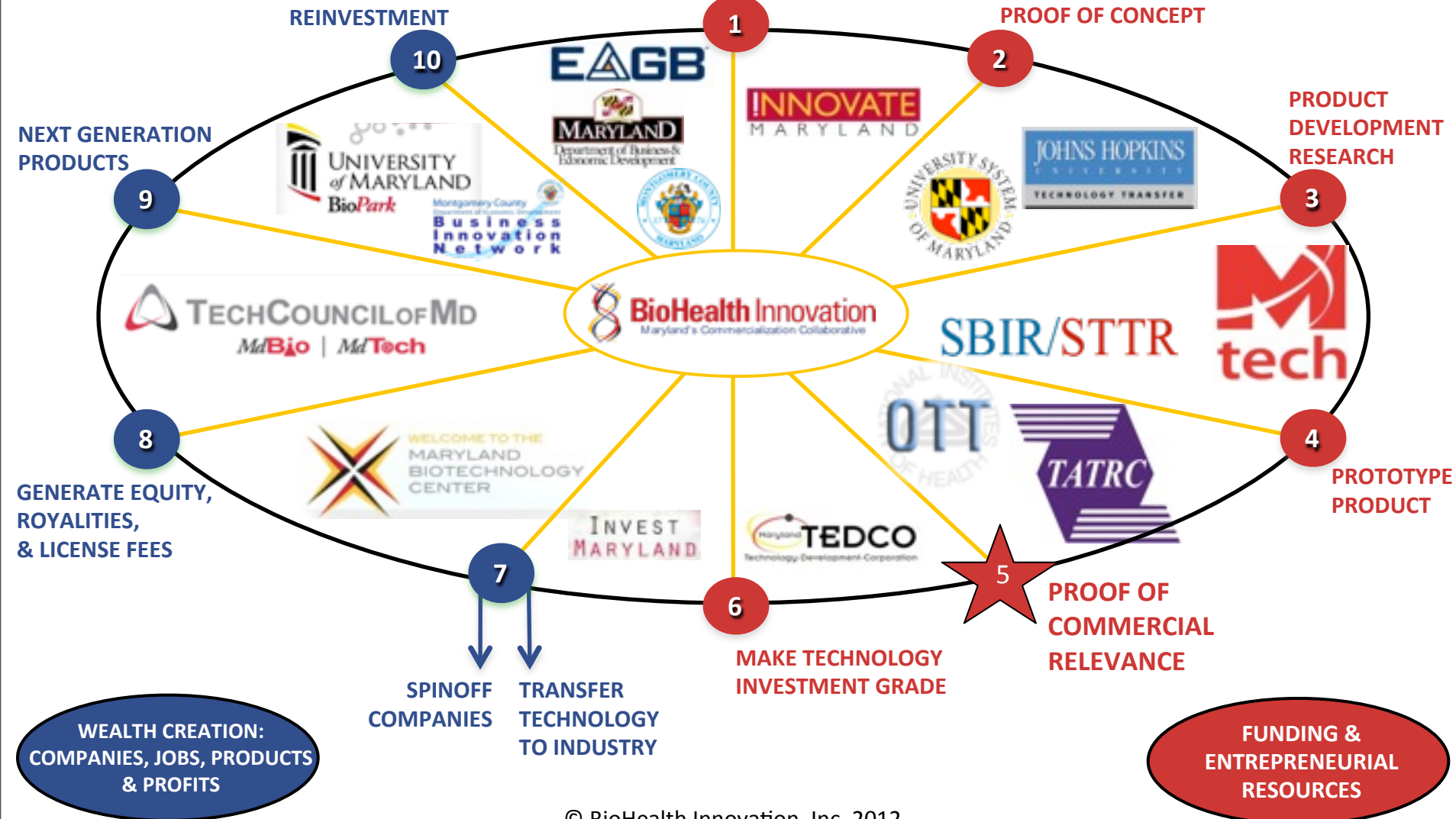
Commercialization Pipeline



BHI Commercialization Model

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

PUBLICATIONS
PhD's
TENURE
PATENTS



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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

Entrepreneur-in-Residence (EIR)

- A team leader who combines scientific, financial/VC and entrepreneurial management experience to:
 - Perform due diligence
 - Develop biohealth project-focused companies

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

- Federal Labs
- Universities
- Private Sector



Todd Chappell

Progress (4½ 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
- Goal to fund the operation of more EIRs

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**

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



BioHealth Innovation
Maryland's Commercialization Collaborative

Maryland Universities/EIR Interaction



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**



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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

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

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

Identify Key Issues

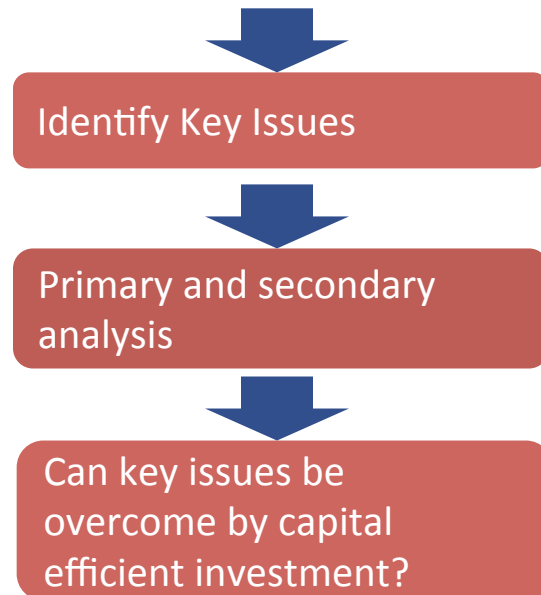
Primary and secondary
analysis

Can key issues be
overcome by capital
efficient investment?

Early-Stage Analysis of Commercial Relevance

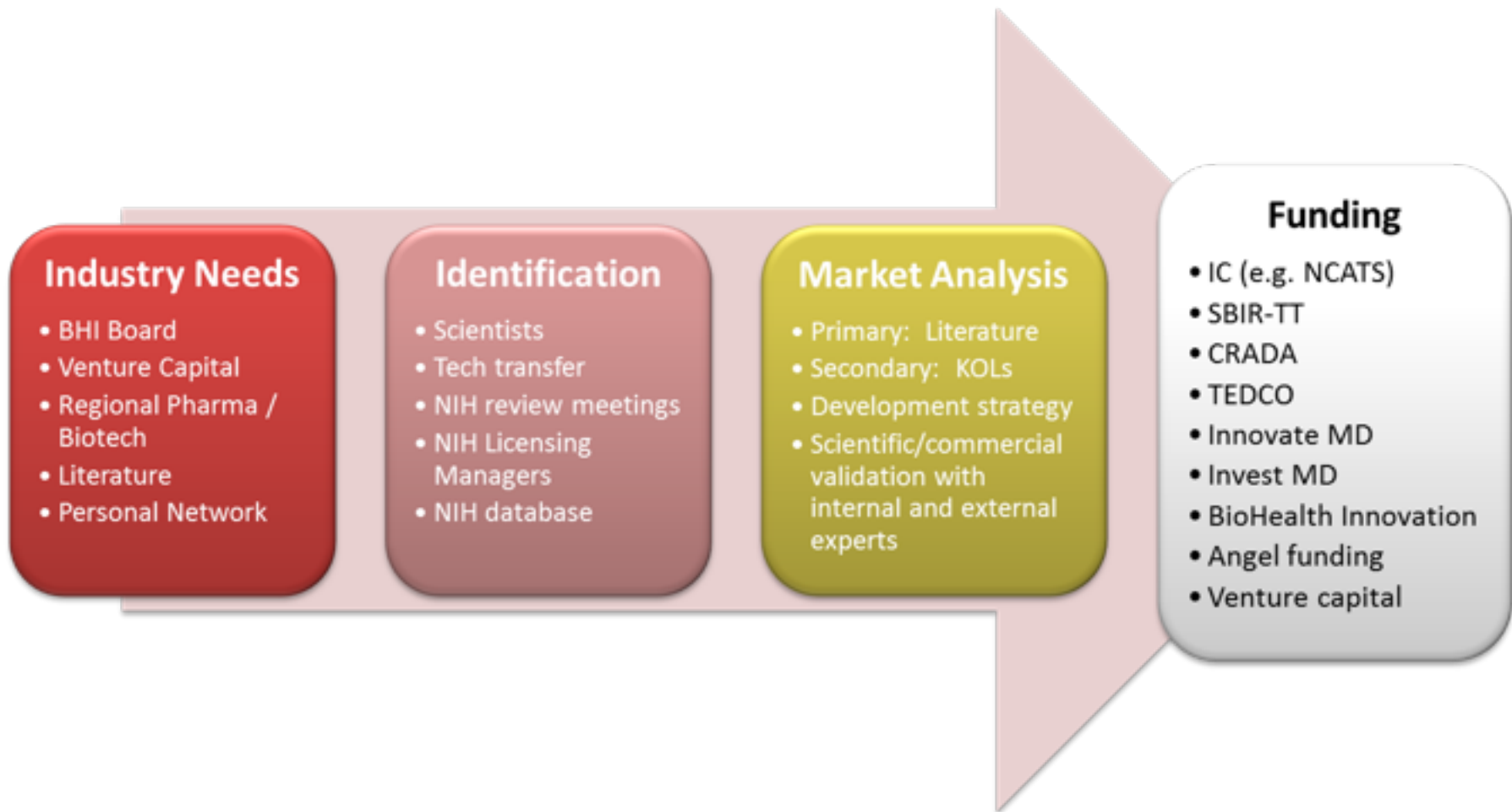
Selected Criteria for Value Proposition

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

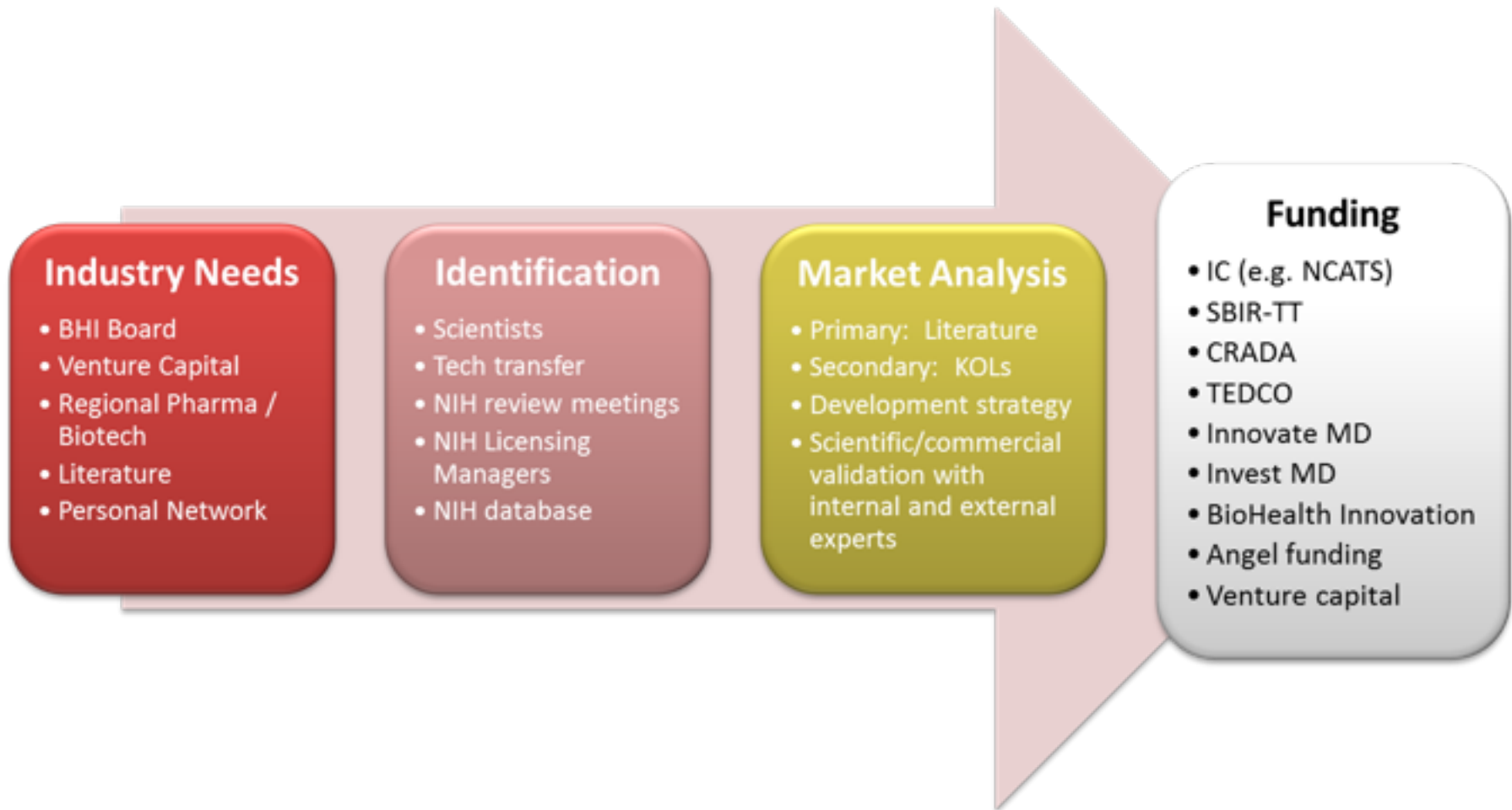


Key Considerations for Technology Focus

- **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?



**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 Commercialization Pipeline

STEP I: Innovation Exposures / Sourcing

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

STEP II: Screening

- Stage of Development
- IP Status
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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 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.

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.

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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

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

Maryland / China Connection



Tasly MOU with John's Hopkins University

- \$40 million investment
- 200 new Jobs and 430,000 sqft research, manufacturing, and education facility at the Shady Grove Life Sciences Center in Rockville



MedImmune and Wuxi Apptech Joint Venture

- Joint venture to develop and commercialize a biologic for autoimmune and inflammatory diseases in China



Qiagen signs agreement with Lepu Medical Technology

- Lepu will market Qiagen's diagnostics application in Chinese hospitals that incorporates Lepu's cardiac biomarkers to diagnose acute myocardial infarction



BioHealth Innovation
Maryland's Commercialization Collaborative

BHI: The Triple Bottom Line

Grows high-paying jobs and businesses



Expands tax base; **improves** economic vitality



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



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