



BioHealth Innovation, Inc. Introduction

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BioHealth Innovation, Inc.

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Rockville, MD



BioHealth Innovation Maryland's Commercialization Collaborative

www.biohealthinnovation.org

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:

- 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
- 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

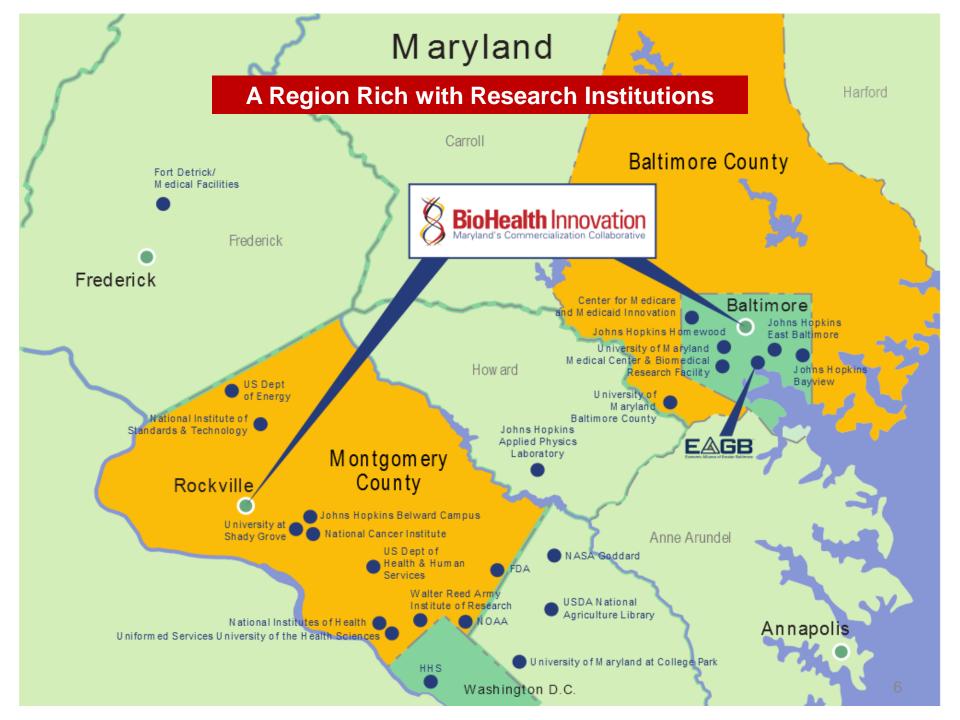


"The Region"--Central Maryland

Unrivaled Research Assets Unfulfilled Commercial Promise







BioHealth Regional Innovation Cluster Assets



Maryland's Commercialization Collaborative

Challenges to Innovation Economy

BHI Value Proposition

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

Connects regional innovation assets

Develops an entrepreneurial talent and support pipeline

Attracts funding for technology commercialization

Develops a continuum of innovation workforce



What is A Regional Innovation Intermediary?

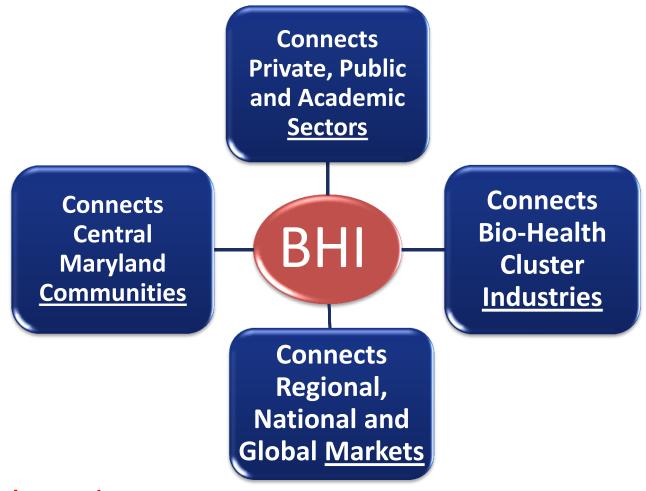
- An organization at the Center of the region's, state's and country's efforts
 - Align local technologies, assets and resources
 - Advance Innovation



- Regionally-oriented
- Private-public partnership, 501(c)(3) nonprofit
- Market-driven, private sector-led
- Neither a government initiative, nor a membership organization

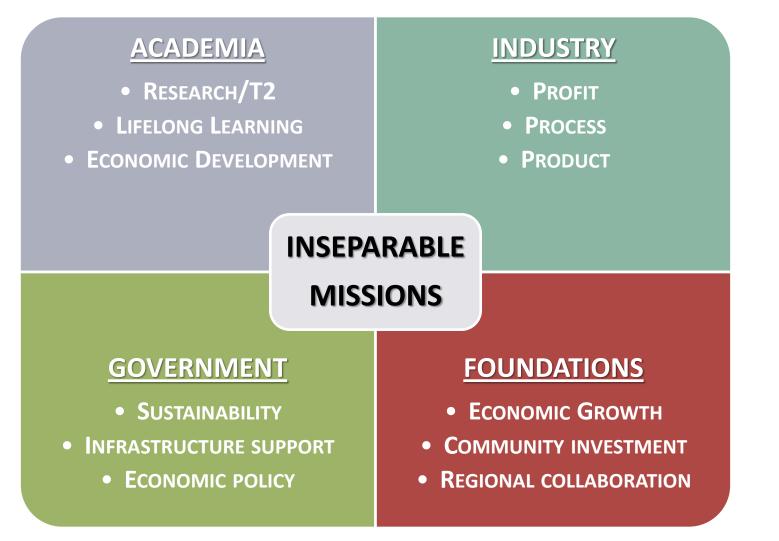


BHI: An Innovation Intermediary that Connects <u>Sectors, Industries, Communities, & Markets</u>





Regional BioHealth Ecosystem Partners





BHI Partners and Sponsors



Marvland's Commercialization Collaborative

BHI Board of Directors

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

Richard Bendis President & CEO, BioHealth Innovation, Inc.

Scott Carmer (Chair) Executive Vice President of Commercial Operations, MedImmune

Kenneth Carter Chair, Noble Life Sciences

Ronald J. Daniels President, Johns Hopkins University

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



William E. Kirwan Chancellor, University System of Maryland

Douglas Liu Senior Vice President of Global Operations, Qiagen

David Mott General Partner, New Enterprise Associates

Jerry Parrott Vice President, Corporate Communications and Public Policy, Human Genome Sciences

William G. Robertson (Treasurer) President & CEO, Adventist Healthcare

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



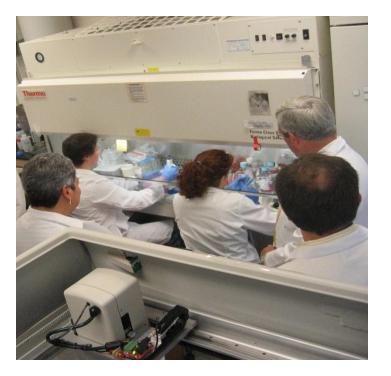




Innovation Paradigm Shift

PROOF OF CONCEPT (Technological Feasibility) Laboratory Push

"It Works!"



PROOF OF COMMERICAL RELEVANCE

(Market Pull)

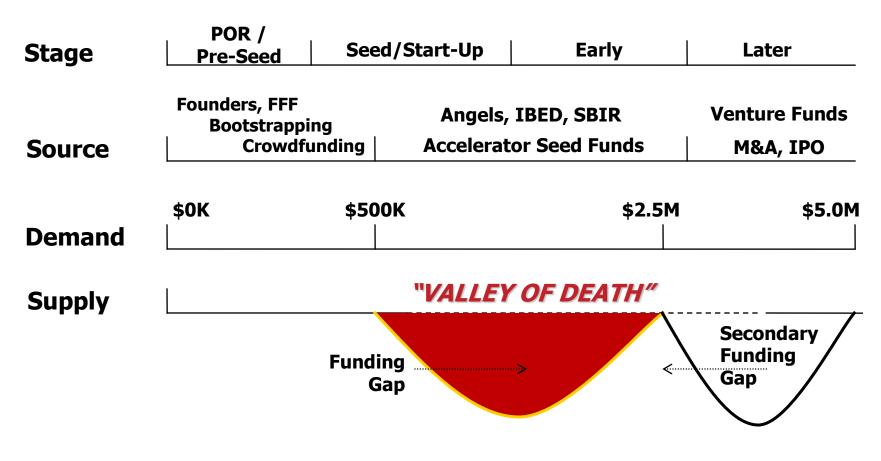
"It Works To Solve A Problem"

"I'll Buy It"





Innovation Capital "VALLEY OF DEATH"



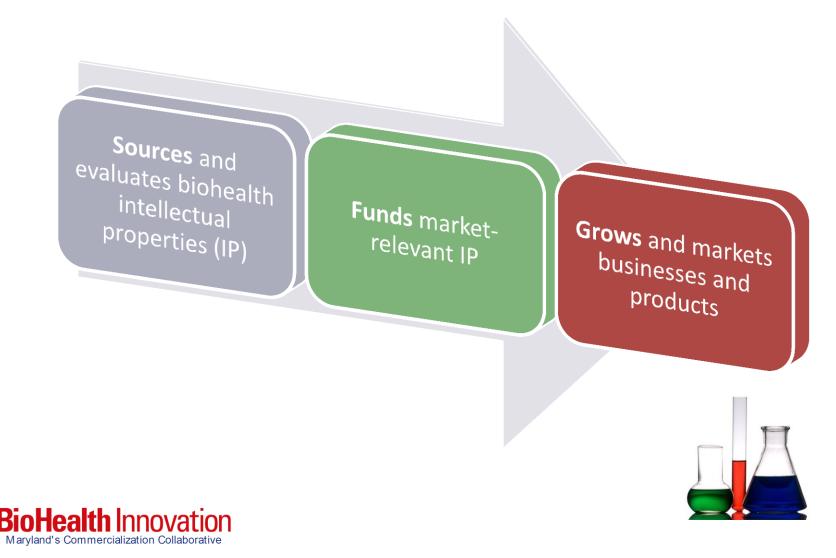


Connect Funding Sources at Every Stage to Fill Gaps

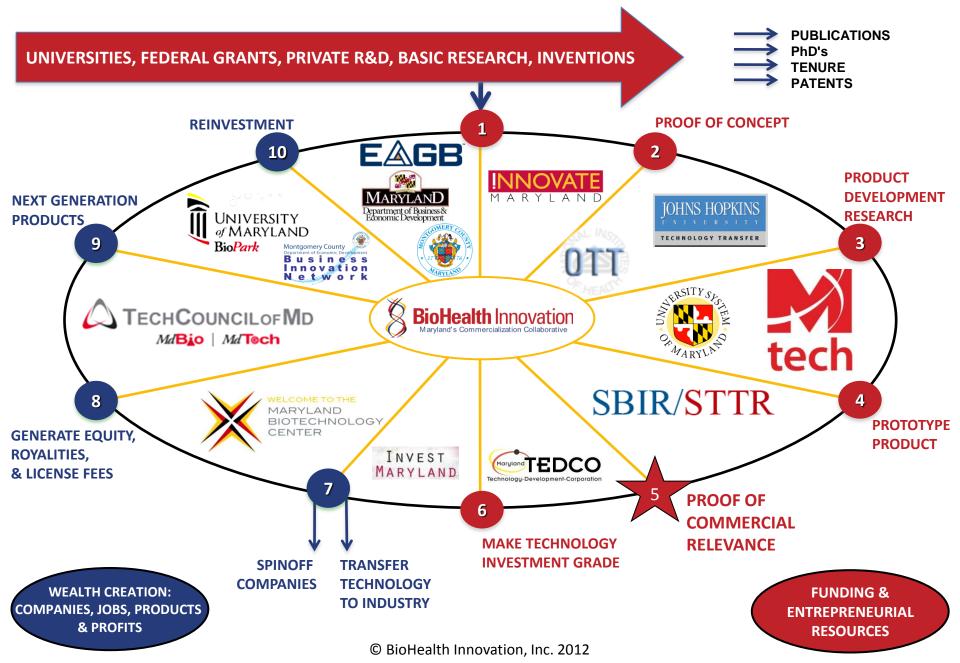
| DREAM | CONCEPT | APPLIED | COMMERCIAL RELEVANCE | STARTUP | ROLL OUT | GROWTH |
|--|---------|-------------|-------------------------|---------|-------------|---------------------------------|
| FoundersFFF Bootstrapping Crowdfunding | Seed | Accelerator | IBED | Federal | ANGEL | vc |
| VISA VISA Series Series Crowdfund NICKSTARTER | NEA. | | | | a | NEA. H. I. G. BIOVENTURES |
| RocketHub | | | | | | |



How does BHI work? Commercialization Pipeline



BHI Commercialization Model



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 membermanaged 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.



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)

- 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



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 liasion 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 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



Example of EIR Interaction



Maryland's Innovation Initiative

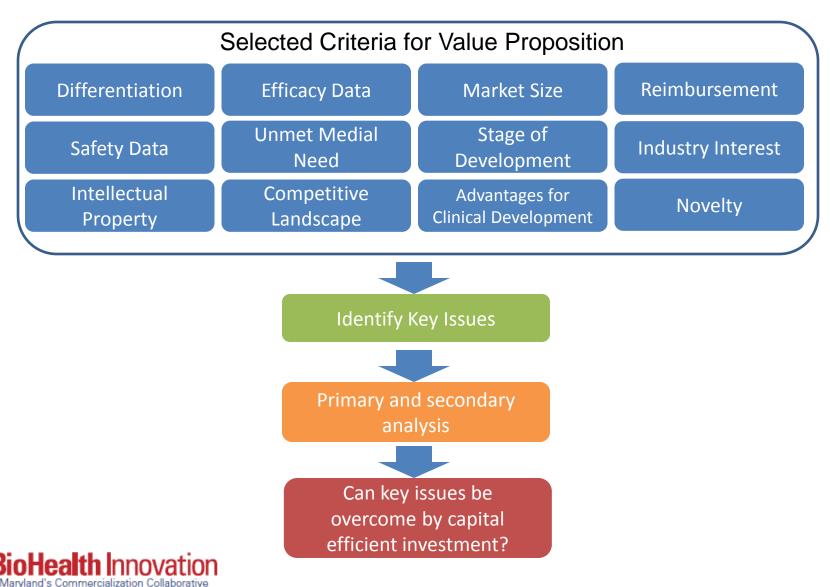
- \$5.8M budget
- 5 University partners
- 5 University site miners
- 40 University pre proof-ofconcept technologies funded
- \$25-\$150K funded per technology





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

Early-Stage Analysis of Commercial Relevance



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?

Industry Needs

- BHI Board
- Venture Capital
- Regional Pharma / Biotech
- Literature
- Personal Network

Identification

- Scientists
- Tech transfer
- NIH review meetings
- NIH Licensing Managers
- NIH database

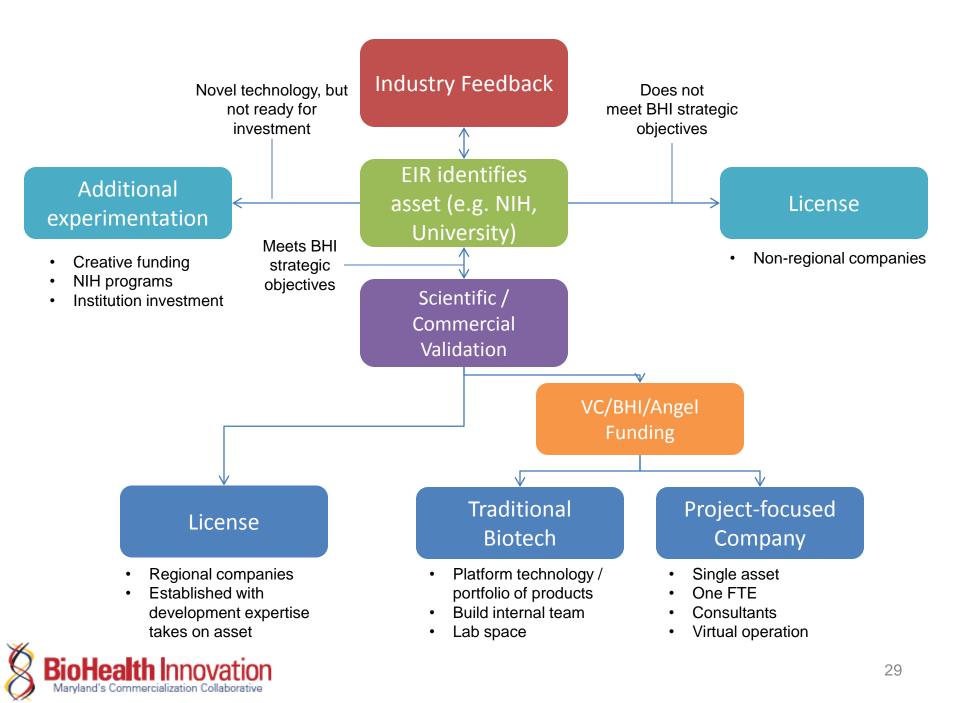
Market Analysis

- Primary: Literature
- Secondary: KOLs
- Development strategy
- Scientific/commercial validation with internal and external experts

Funding

- IC (e.g. NCATS)
- SBIR-TT
- CRADA
- TEDCO
- Innovate MD
- Invest MD
- BioHealth Innovation
- Angel funding
- Venture capital





Funding Mechanisms

SBIR/STTR



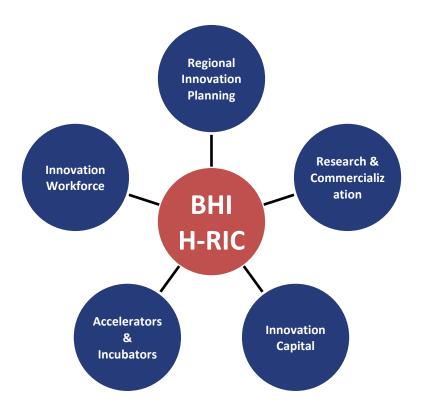
National Institutes of Health NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES



- 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



BHI H-RIC Model

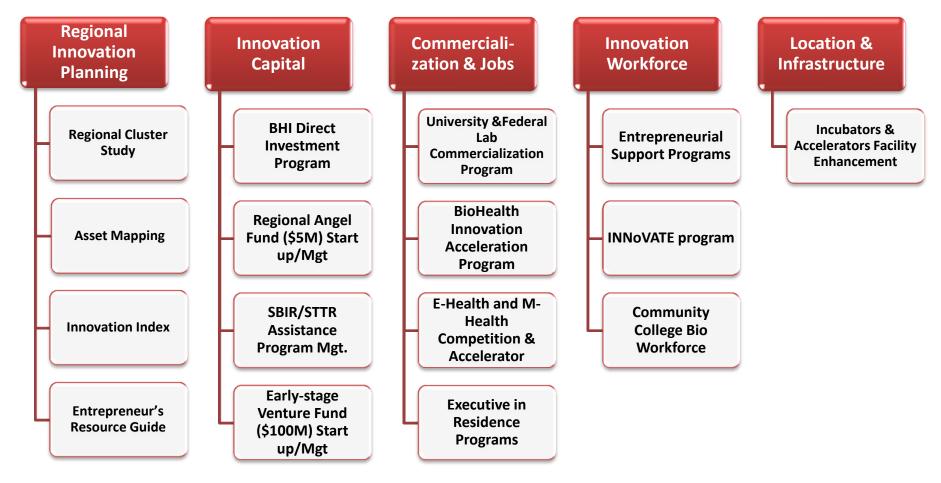


Health Regional Innovation Cluster (H-RIC)

- Regional, cluster-based economic development model
- Modeled after the Department of Energy's Regional Innovation Cluster
- Connects innovation assets to related industries
- Advances human health and economic prosperity



BHI Road Map & H-RIC Implementation Strategy



BHI Resources



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







BHI & EAGB Innovation Resource Guide

This guide will include the Entrepreneur and Innovation Resource Network, Innovator Finance Guide, and the Startup's Guide to Intellectual Property.

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

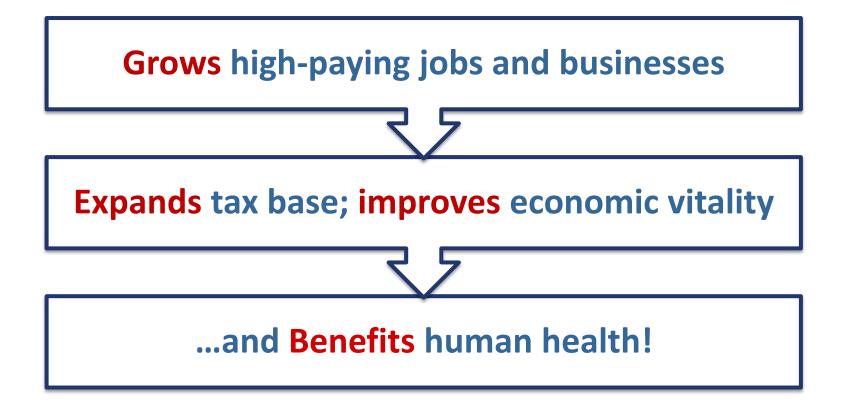
Create and retain 1,300 jobs

Recruit entrepreneurs, experienced managers and businesses

Commercialize biohealth technologies and create biohealth companies



BHI: The Triple Bottom Line





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