



SBIR series with SBA: Commercialization, and the Path Ahead

Rich Bendis

President & CEO

BioHealth Innovation, Inc.

8/27/2014



The Region – Central Maryland

- Unrivaled Research Assets -
- Unfulfilled Commercial Promise -

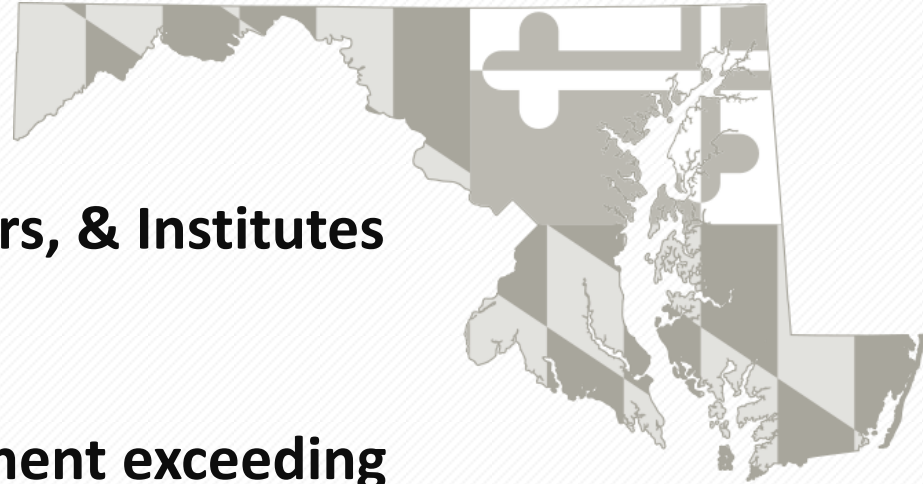


National Institutes
of Health



State of Maryland: Federal & University Resources

- **Population: 5.9 million people**
- **59 Federal Laboratories, Centers, & Institutes in Maryland**
- **Maryland Federal R&D investment exceeding \$12 billion annually**
- **97.5% of all businesses are Small Businesses**

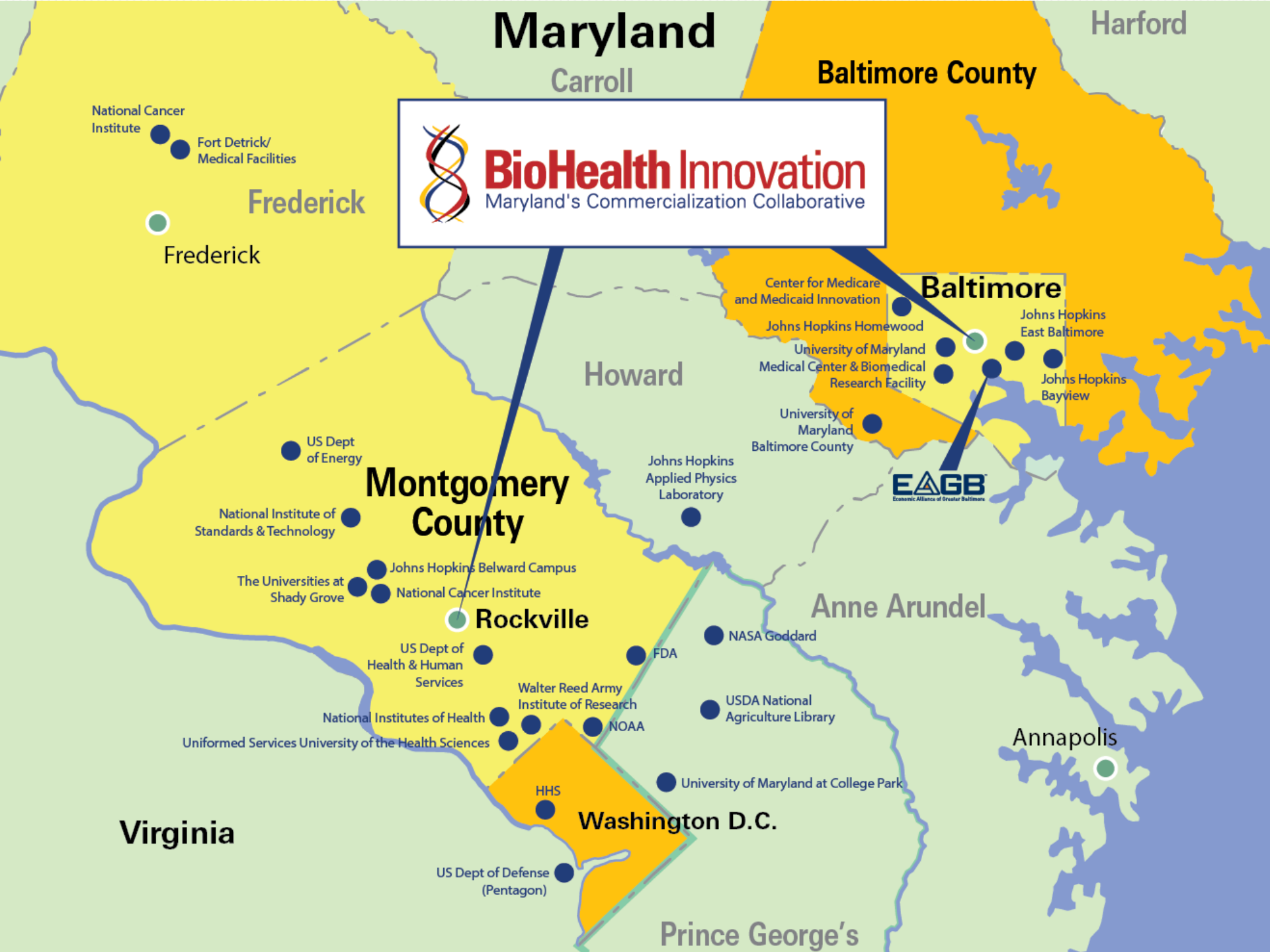


JHU and USM represent another \$3.5 billion in annual R&D



JOHNS HOPKINS
UNIVERSITY





BioHealth Innovation

Maryland's Commercialization Collaborative

National Cancer Institute
Fort Detrick/
Medical Facilities

Frederick

Frederick

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

University of
Maryland
Baltimore County



Johns Hopkins
Applied Physics
Laboratory

US Dept
of Energy

**Montgomery
County**

National Institute of
Standards & Technology

Johns Hopkins Belward Campus
The Universities at
Shady Grove

National Cancer Institute

Rockville

US Dept of
Health & Human
Services

FDA

NASA Goddard

Walter Reed Army
Institute of Research

NOAA

USDA National
Agriculture Library

National Institutes of Health
Uniformed Services University of the Health Sciences

HHS

University of Maryland at College Park

Annapolis

Washington D.C.

US Dept of Defense
(Pentagon)

Virginia

Prince George's

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 spin-offs from federal and university R&D

BHI Value Proposition

Connect regional innovation assets

Develop an entrepreneurial talent and support pipeline

Attract funding for technology commercialization

Evaluate commercially relevant federal and university technology

BioHealth Regional Innovation Cluster Assets



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NEA
New Enterprise Associates*

MARYLAND OF OPPORTUNITY. SM

EAGB



APL
The Johns Hopkins University
APPLIED PHYSICS LABORATORY

BIO X MARYLAND

MaBio



NATIONAL
CANCER
INSTITUTE



NCATS NIST

Center for Medicare & Medicaid
INNOVATION



Rockville
Economic Development, Inc.
Known for the Companies We Keep

USDA

HHMI
HOWARD HUGHES
MEDICAL INSTITUTE



National Biodefense Analysis
and Countermeasures Center

TIGR
THE INSTITUTE FOR GENOMIC RESEARCH

FDA



J. Craig Venter
INSTITUTE



Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

BioHealth Innovation is an Innovation Intermediary

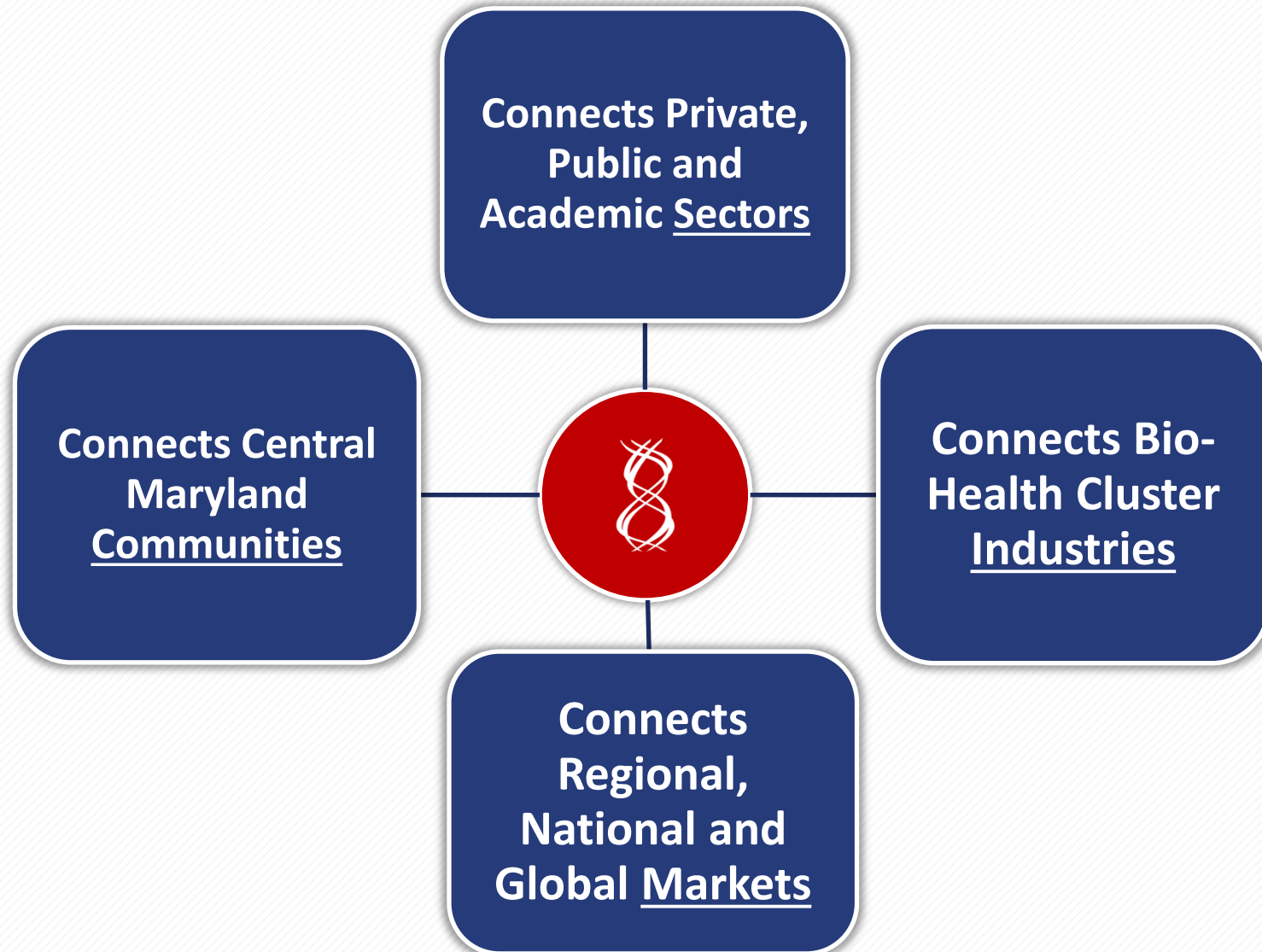
An private-public partnership, serving as an innovation intermediary in Central Maryland with a mission to:

- Advance local technologies, assets and resources
- Accelerate innovation



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

BHI: An Innovation Intermediary that Connects



BHI Partners and Sponsors

Private Sector



Government



Academia



NGOs



BHI Board of Directors



Daniel J. Abdun-Nabi
CEO, Emergent
BioSolutions



ALEXANDRIA

Joel Marcus
CEO & Founder
Alexandria Real Estate

Pending



Michael J. Baader, Esq.
General Counsel
Greenspring Associates



Beth Meagher
Director
Deloitte Consulting LLP



Judith Dunn
Vice President, Global
Head of Clinical Dev.
Roche



Richard A. Bendis
President & CEO
BioHealth Innovation, Inc.



William E. Kirwan
Chancellor
University System of MD



Kenneth Carter
Chair
Noble Life Sciences



Douglas Liu
Senior VP of GO
Qiagen



Dave Lemus
CEO
Sigma-Tau Pharmaceuticals



Charles Morton
Partner
Venable LLP



Chris Callaghan
Group VP, Healthcare Banking
M&T Bank



David Mott
General Partner
New Enterprise Associates



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President
Johns Hopkins University



John A. Sackett
President
Shady Grove Adventist Hospital



Jens Eckstein
President
SR One (GSK)



J. Thomas Sadowski
President & CEO
EAGB



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



Reginald Seeto
VP, Partnering and Strategy
MedImmune



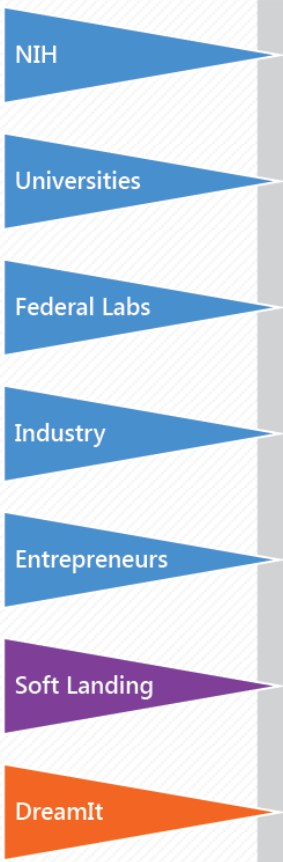
Rick Ivey
Vice President R&D
BD Diagnostics



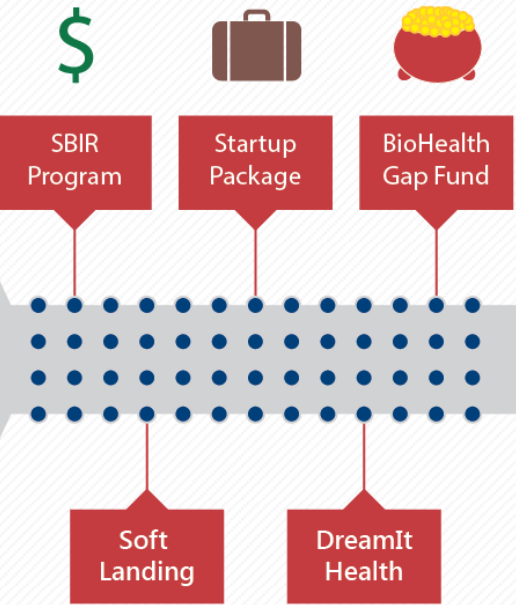
Thomas Street
ACAO
MoCo Government

BHI Program Structure

SOURCES



BHI Assistance Programs



Strategic Programs

Financial Sponsors

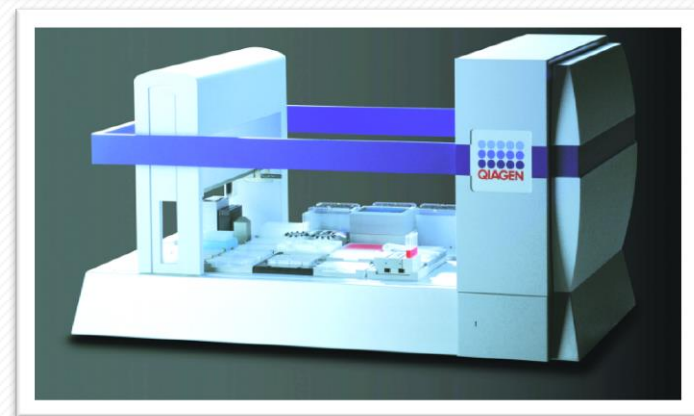
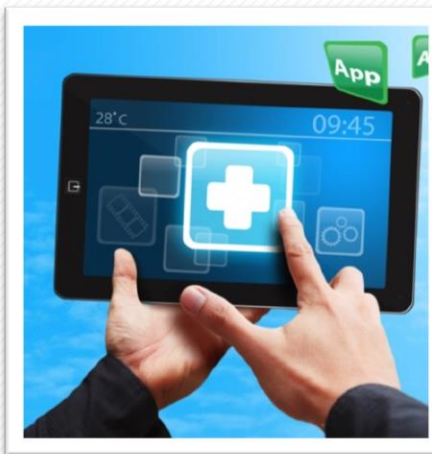
OUTCOMES

- ★ Technologies Progressed
- ★ Company Growth
- ★ Risk Capital
- ★ New Startups & Spinoffs
- ★ Partnerships
- ★ Mergers & Acquisitions
- ★ Leveraged \$
- ★ Regional Branding
- ★ Jobs
- ★ Economic Development



BHI Technology Focus

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

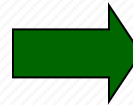
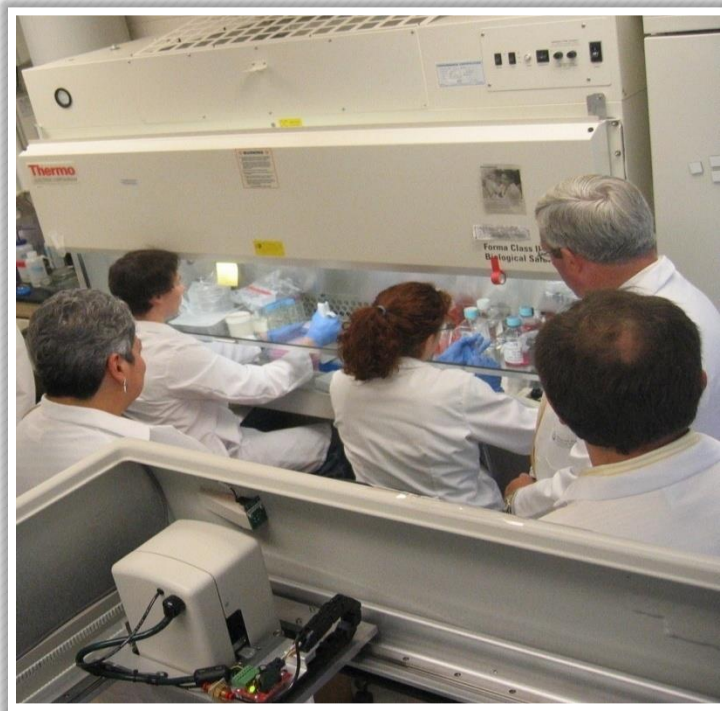


Innovation Paradigm Shift

PROOF OF CONCEPT
(Technological Feasibility)

Laboratory Push

“It Works!”



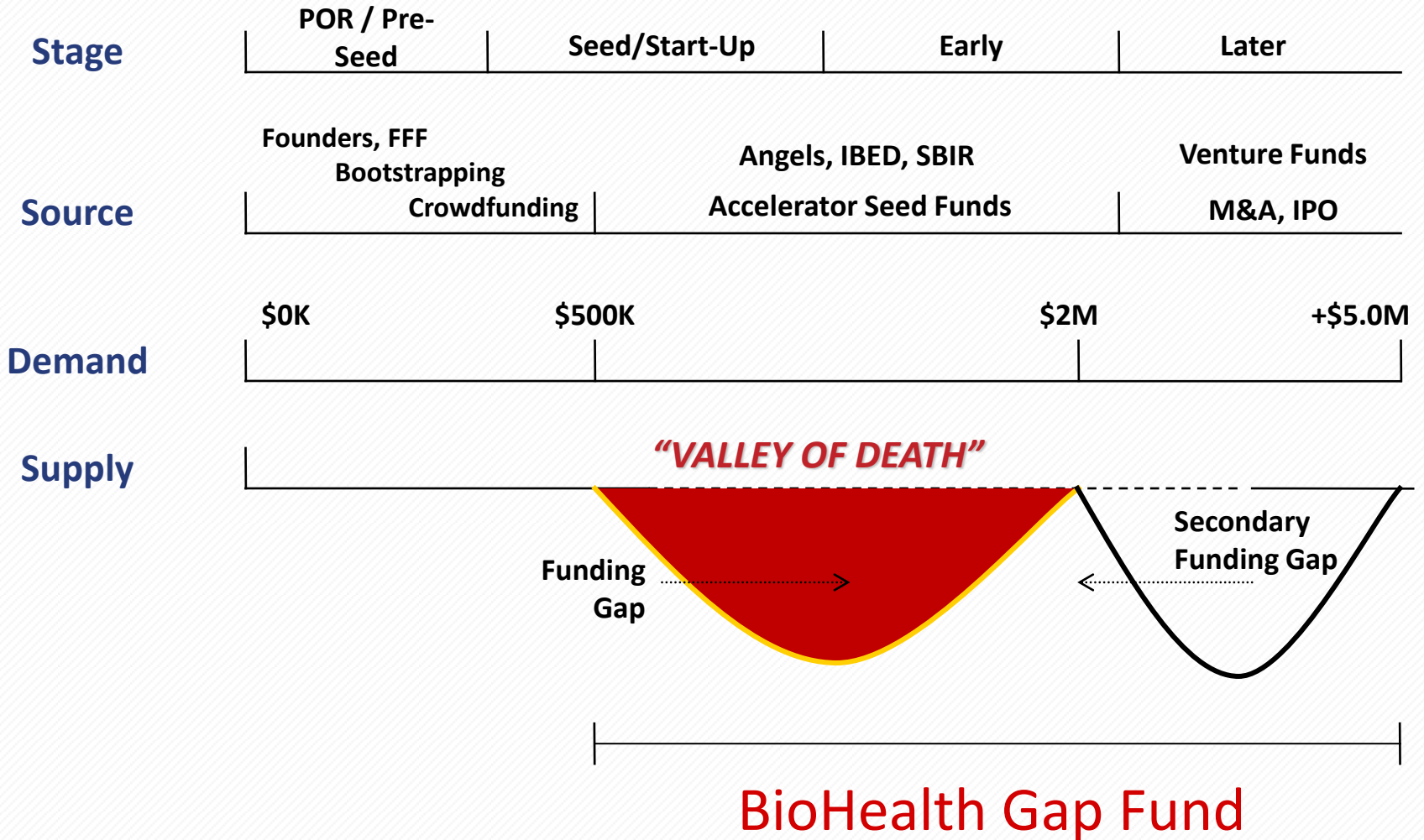
PROOF OF COMMERCIAL RELEVANCE
(Market Pull)

“It Works To Solve A Problem”

“I’ll Buy It”



Innovation Capital Valley of Death



BHI Innovation Capital Map

Pre-Proof of Concept \$25,000 - \$1,500,000 (over 5 yrs)	Translational Research/ Proof of Concept \$15,000 - \$750,000 (over 3 yrs)	Proof of Commercial Relevance/Pre-Seed \$3,000 - \$500,000	Seed/ Start-Up \$50,000 - \$1,500,000	Early Stage \$200,000 - \$2,000,000	Later Stage \$2,000,000+
<ul style="list-style-type: none"> NIH R01 NIH R03 NIH R21 	<ul style="list-style-type: none"> SBIR/STTR Grant Phase 1 NCATS Cures Acceleration Network (CAN) Maryland Stem Cell Research Fund (MSCRF) - Various TEDCO Technology Validation Program - Proof of Concept TEDCO Maryland Innovation Initiative - Phase 1 JHU - Coulter Translational Research Partnership 	<ul style="list-style-type: none"> Maryland Industrial Partnerships (MIPS @ UMD) TEDCO Maryland Innovation Initiative - Phase 2 Maryland Stem Cell Research Fund (MSCRF) - Pre-Clinical TEDCO Technology Validation Program - Market Assessment ★ BHI SBIR/STTR Commercial Relevance Program (CRP) 	<ul style="list-style-type: none"> Dingman Center Angels (UMD) BioMaryland Biotechnology Dev. Award - Translational Research TEDCO Patent Assistance Program TEDCO Technology Commercialization Fund TEDCO Maryland Innovation Initiative - Phase 3 SBIR/STTR Phase 2 ★ BioHealth Gap Fund 	<ul style="list-style-type: none"> Propel Baltimore Fund TEDCO Veterans' Opportunity Fund Invest Maryland: Maryland Venture Fund BioMaryland Biotechnology Dev. Award - Commercialization Maryland Health Care Product Development Corporation Abell Venture Fund MMG Ventures LLP TDF 	<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 New Enterprise Associates (NEA)

Associations

Association of University Resource Parks (AURP)	Angel Capital Association (ACA)	Mid-Atlantic Venture Association (MAVA)	National Venture Capital Association (NVCA)
Association of University Technology Managers (AUTM)			
Licensing Executive Society (LES)			

Funding Type Key

- Academic
- State of Maryland
- BioHealth Innovation, Inc.
- Federal
- Economic Development
- Private Capital

Tax Credits

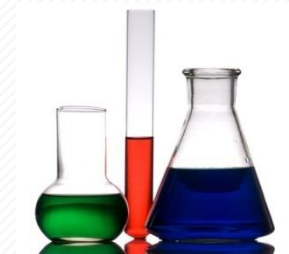
- Maryland Biotechnology Investor Tax Credit
- Montgomery County Biotechnology Investor Tax Credit

BHI Commercialization Pipeline

Source and evaluate biohealth intellectual properties (IP)

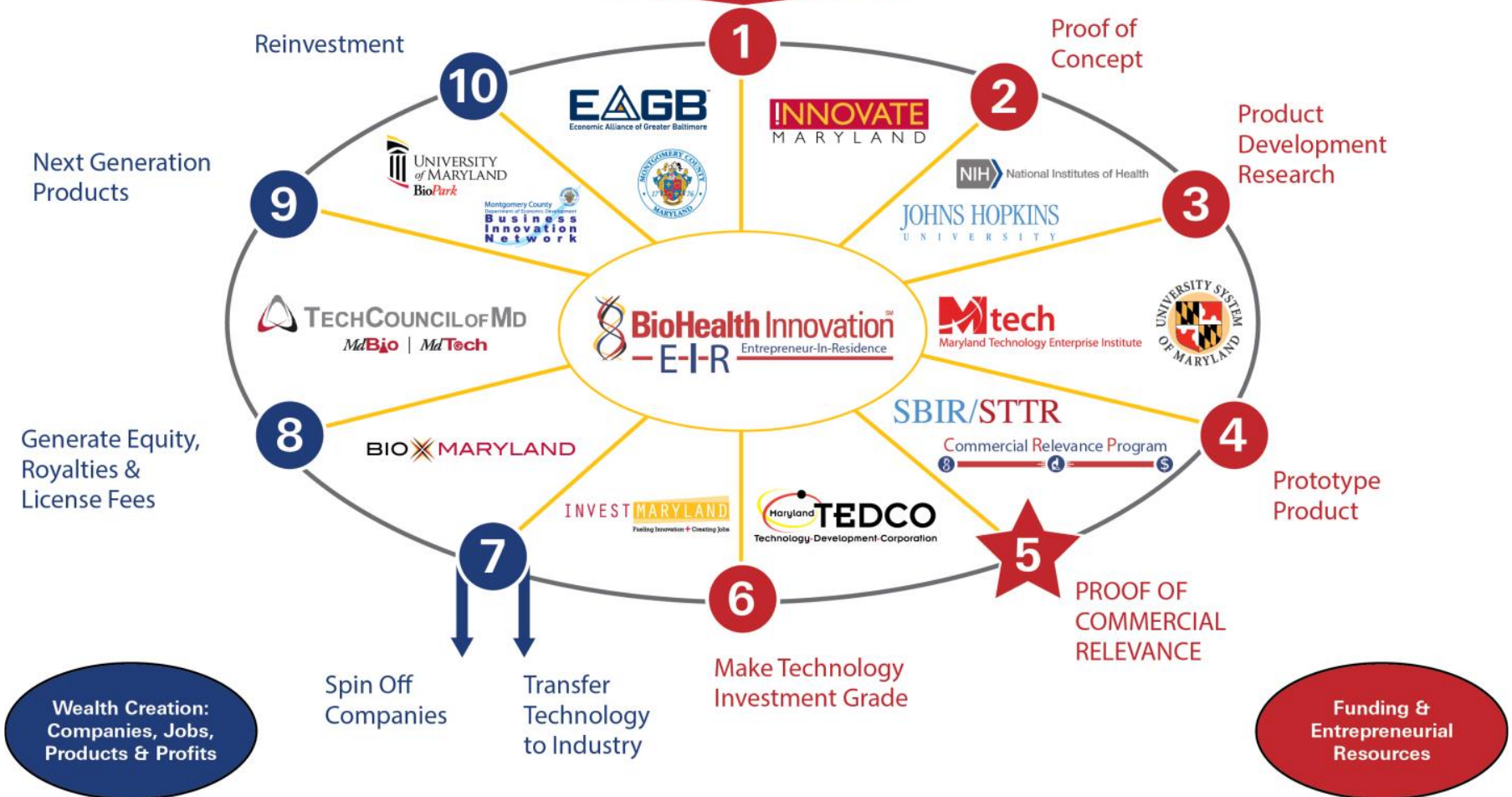
Identify funding for market-relevant IP

Grow and market businesses and products



BHI Commercialization Model

Inventions patented through Universities, Federal Labs, Private R&D, and Basic Research



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Partnership Intermediary Agreements



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.

BHI Entrepreneur-in-Residence Program

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

2014 Status



141 78 40
NIH Industry University

Technology Reviews
Conducted

7
EIRs



12

Current Clients

3

Pending Clients

3

Potential New
Clients

Goals

- Grow portfolio to 15
- Add 2 new EIRs
- Create 5 spinouts or tech placements
- Develop educational programs
- Two funding or partnering deals
- Client Progression

Who are the Entrepreneurs-in-Residence?



Todd Chappell (NIH-OTT)

Todd assists the Office of Technology Transfer (OTT) in the evaluation of existing technologies, provide an entrepreneurial perspective on new licensing proposals from start-up companies, advise on opportunities for new ventures, assist with developmental strategies, and mentor scientists to help ensure their research becomes commercially valuable.



Ken Malone (UM Ventures)

Ken has built his career on creating economic value from science. Whether it was developing new business lines for global corporations or spinning out new ventures from universities, he has engaged in the commercialization of hundreds of new products in advanced materials and life sciences.



Ram Aiyar (NHLBI)

Ram assists the National Heart Lung and Blood Institute (NHLBI) in translating disruptive science into commercially viable technologies. He works with the relevant stakeholders within the NIH to develop commercial plans and/or develop licensing opportunities such that the NIH technologies can be translated into commercially viable entities that will solve unmet medical needs of patients.



Dr. Rich Moore (NIH-OTT)

Dr. Moore previously served as the Chief Scientific Officer for OpGen, Inc. In that role, Dr. Moore provided leadership over multiple R&D functions, and led the company's Scientific and Clinical Advisory Boards. Prior to that, he spent 12 years at BD Diagnostics holding various positions, most recently as R&D Director, Systems Integration and Advanced Technology.



Dr. George Jiang

Dr. Jiang previously worked at Booz Allen Hamilton as a Team Lead and Senior Medical Advisor supporting the Office of the Assistant Secretary of Defense Health Affairs. He has R&D experience in academic, government, and military settings.

Pending:

NHLBI #2

NIAID

USDA Agricultural Research Service

BHI Client Companies



Avhana Health complements existing electronic medical records (EMRs) by extracting patient information and creating an adaptive checklist to guide care.

Baltimore



Developing a therapeutic platform that can be adapted to target a wide variety of cancers.

Moco-based Startup

Intravenous Solutions, Inc.

Early stage company focused on intravenous medical devices for hospital systems.

NYC



Developing and marketing Organ-on-a-Chip solutions for the pharmaceutical industry.

US-based Subsidiary of Dutch Company

Mehr Medical

Developing devices for cardiovascular procedures that will solve high unmet needs in the transcatheter valve replacement space.

NHLBI

MockV

Developing novel viral clearance kits to be utilized during process development bio therapeutics.

Moco-based Startup



Developing sensors that can detect harmful chemicals mixed in air in very small quantities, such as industrial chemicals, and other pollutants.

Licensee of UMCP and NIST



Developing medical devices related to image-guided, minimally-invasive niche markets.

JHU



Developing a platform vaccine like particle technology that has the potential to be used for various diseases including cancer.

NIH



Speed Biosystems, Inc. is developing novel immunotoxins for the treatment of solid and liquid tumors.

Moco-based Startup



India-based molecular information company with multiple powerful bioinformatics platforms.

India



MD Logix is currently developing a mental health assessment tool which could be effective in identifying at-risk students.

Small Business Facts

- **SME's employ over 50%** of the country's private sector workforce, hire 40% of high tech workers, such as **scientists, engineers, and computer workers.**
- The number of **women-owned firms continues** to grow at twice the rate of all U.S. **firms (23% vs. 9%)**
- 70% of SME's say retaining customers cheaper than getting new customers.
- **7 out of 10** new employer firms last about two years and about half survive five years.



Source:SBA

Small Business Biggest Obstacles

- Lack of willingness or ability to take **risks**
- **Time and effort** required
- Raising **capital**
- **Business management** skills
- **Knowledge** about how to start a business
- **Industry and market** knowledge
- **Pressure** to keep a stable job

www.entrepreneur.com/dbimages/blog/entrepreneurship-risk.jpg

Keys to Small Business Success

Courage

The willingness to take risks

Perseverance

The capacity to power through tough times

Ambition

The insatiable drive to reach your goal

Understanding

The knowledge to make wise business decisions

Innovation

The ability to improve on existing ideas

www.entrepreneur.com/dbimages/blog/entrepreneurship-risk.jpg

Small Business Innovation Research (SBIR) Grant

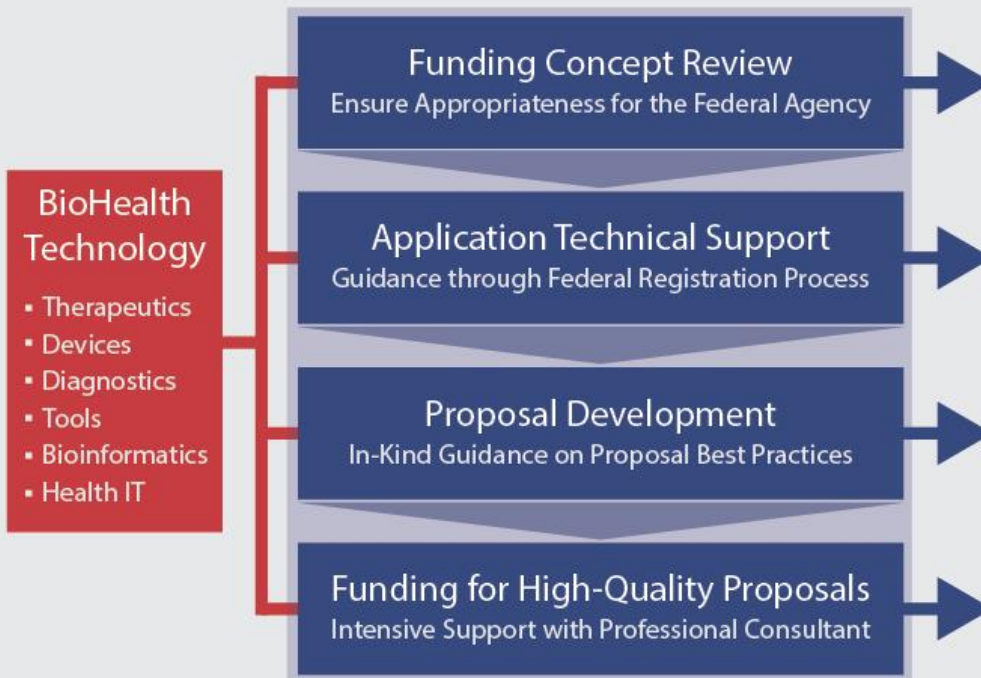
- \$2.2 billion annual United States Government program coordinated by the Small Business Administration provides grants or contracts to small businesses to spur technological innovation
- Grants awarded in 3 phases between \$100,000 and \$1.5 million
- Non-dilutive



BHI Federal Funding Assistance



Value Chain of Assistance



Funding Agencies

NSF

NIH
National Institutes of Health

NATIONAL CANCER INSTITUTE

NIH
National Center for Advancing Translational Sciences

BILKENT FUTURE REDUCTION AGENCIES
UNITED STATES OF AMERICA

EMERGING CHEMICAL BIOLOGICAL CAPABILITIES
U.S. ARMY MEDICAL RESEARCH INSTITUTE

BARD A
BIOLOGICAL ADVANCED RESEARCH AND DEVELOPMENT ACTIVITY

DARPA

BILL & MELINDA GATES foundation

USAID
FROM THE AMERICAN PEOPLE

USAMRIID
United States Army Medical Research Institute of Infectious Diseases
BioDefense solutions to protect our nation

NIH National Heart, Lung, and Blood Institute

CDMRP
Congressionally Directed Medical Research Programs
Department of Defense

BHI Federal Funding Assistance

Running Total – Small Businesses Assisted

93

**Total
Number
Reviewed**

34

**Grant
Proposals
Submitted**

4

**Not
Yet
Submitted**

32

**Not Further
Pursued by
Company**

23

**Flawed:
No Action
Taken**

BHI Startup Package

Corporate Legal



Intellectual Property



Accounting



Laboratory Space



Incubation



Banking



Payer Advisory Services



Grant Consulting



BHI Incubator

BHI interacts with companies and technologies at various stages in the biohealth industry from the results of basic research to companies currently selling products in the market. At these multiple levels of maturity, BHI evaluates whether the organization can help progress the scientist, inventor, entrepreneur, and/or business manager to support the growth of the entity.

We have a dedicated co-working space at our headquarters in Rockville where we support client companies with the goal of progressing the business model for the company.

The BHI Incubator is a member of MBIA, NBIA, and is a certified Maryland TEDCO Incubator.



MockV
Solutions



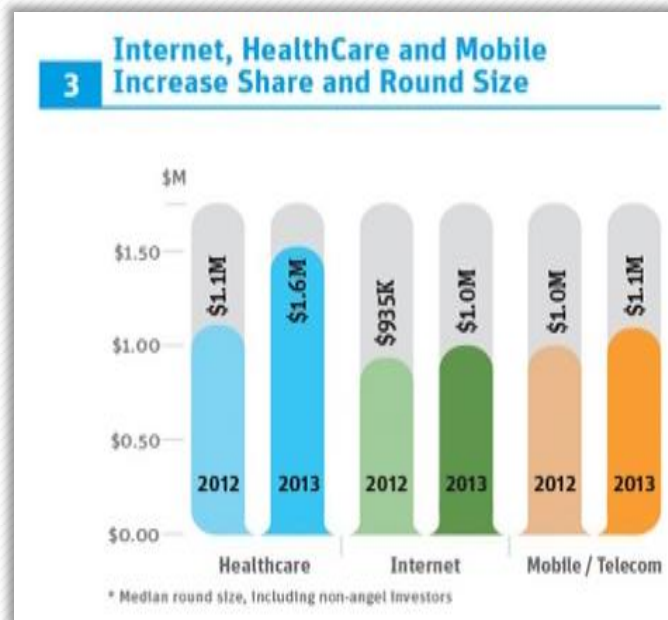
Strand
Genomics



Mimetas
US, Inc.

Health IT ... Booming

- Increased investments in the mobile and healthcare sectors helped boost the median size of angel and angel group syndicate rounds
- Mobile health technologies projected to be worth \$11.8 billion by 2018





- A Health IT Accelerator is an intensive 16 week program that admits top-recruited companies and entrepreneurs, provides a curriculum and network of experienced mentors in business, marketing and product development in the Health IT arena to “accelerate” top companies.

- Retain promising high growth HIT entrepreneurs in MD










- **Partners:**

- ❖ BioHealth Innovation, Inc
- ❖ Johns Hopkins University
- ❖ DreamIt Ventures
- ❖ Economic Alliance of Greater Baltimore
- ❖ Northrop Grumman
- ❖ Kaiser Permanente
- ❖ DBED

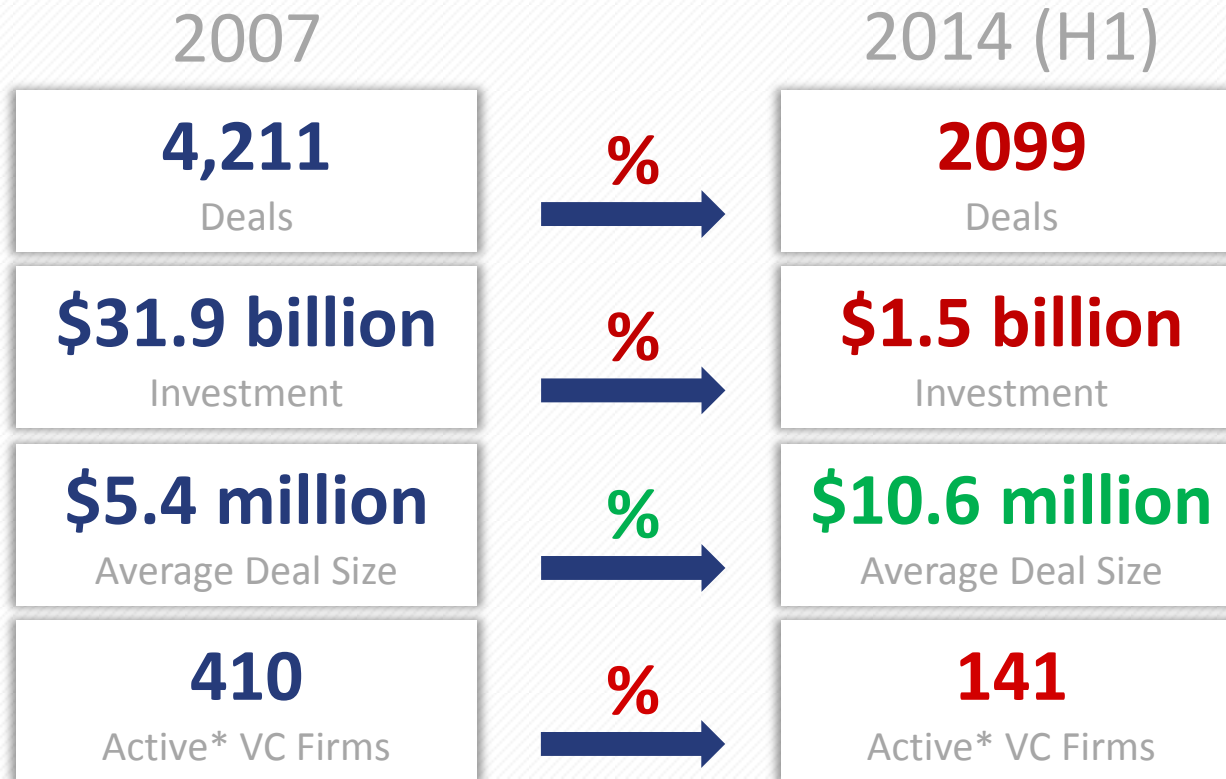


DreamIt Accelerator Companies

JHU
Affiliated

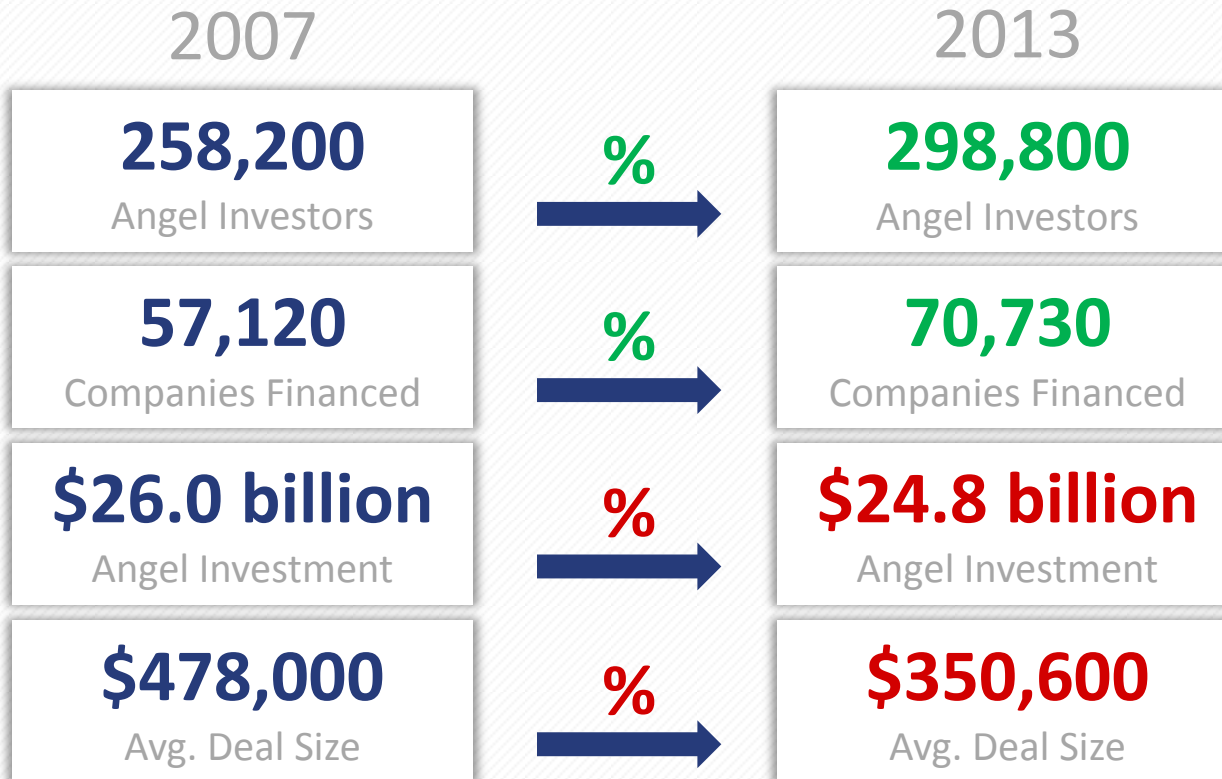
	<ul style="list-style-type: none"> ● Wearable biometric devices 	<p>Baltimore, MD</p> 
	<ul style="list-style-type: none"> ● Practicing smarter medicine 	<p>Baltimore, MD</p> 
	<ul style="list-style-type: none"> ● Mobile Cognitive Rehabilitation 	<p>Talinn, Estonia</p>
	<ul style="list-style-type: none"> ● Mobile Information Platform 	<p>Baltimore, MD</p> 
	<ul style="list-style-type: none"> ● Protecting Patient Data 	<p>Baltimore, MD</p> 
	<ul style="list-style-type: none"> ● Respiratory Medical Device 	<p>Athens, Greece</p>
	<ul style="list-style-type: none"> ● Inpatient Care Collaboration 	<p>Pittsburgh, PA</p>
	<ul style="list-style-type: none"> ● Augmented Reality Treatment 	<p>Barcelona, Spain</p>
	<ul style="list-style-type: none"> ● Digital Workflow Management 	<p>Baltimore, MD</p> 

US Venture Capital Investment



*VC firms completing 4 or more deals per year

US Angel Investment





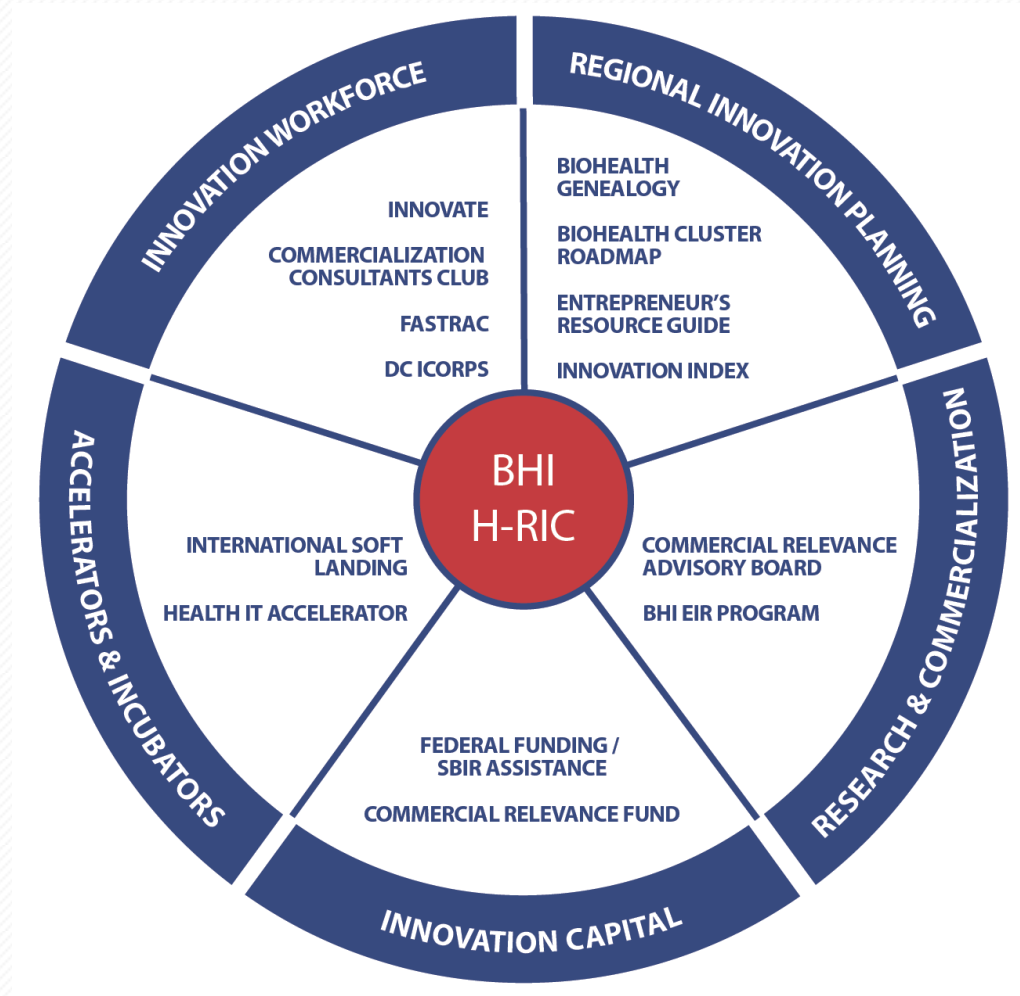
BioHealth Gap Fund

- Will provide direct seed and early-stage equity investments ranging from \$50,000 to \$1,000,000
- Focused on BioHealth companies that fall into the 4 categories: Therapeutics, Medical Devices, Diagnostics, and Health IT
- Goal: Achieve a \$5,000,000 to \$20,000,000 initial fund
- Expectation: 30% of companies generating 10x the original investment
- 2014 – Target first close

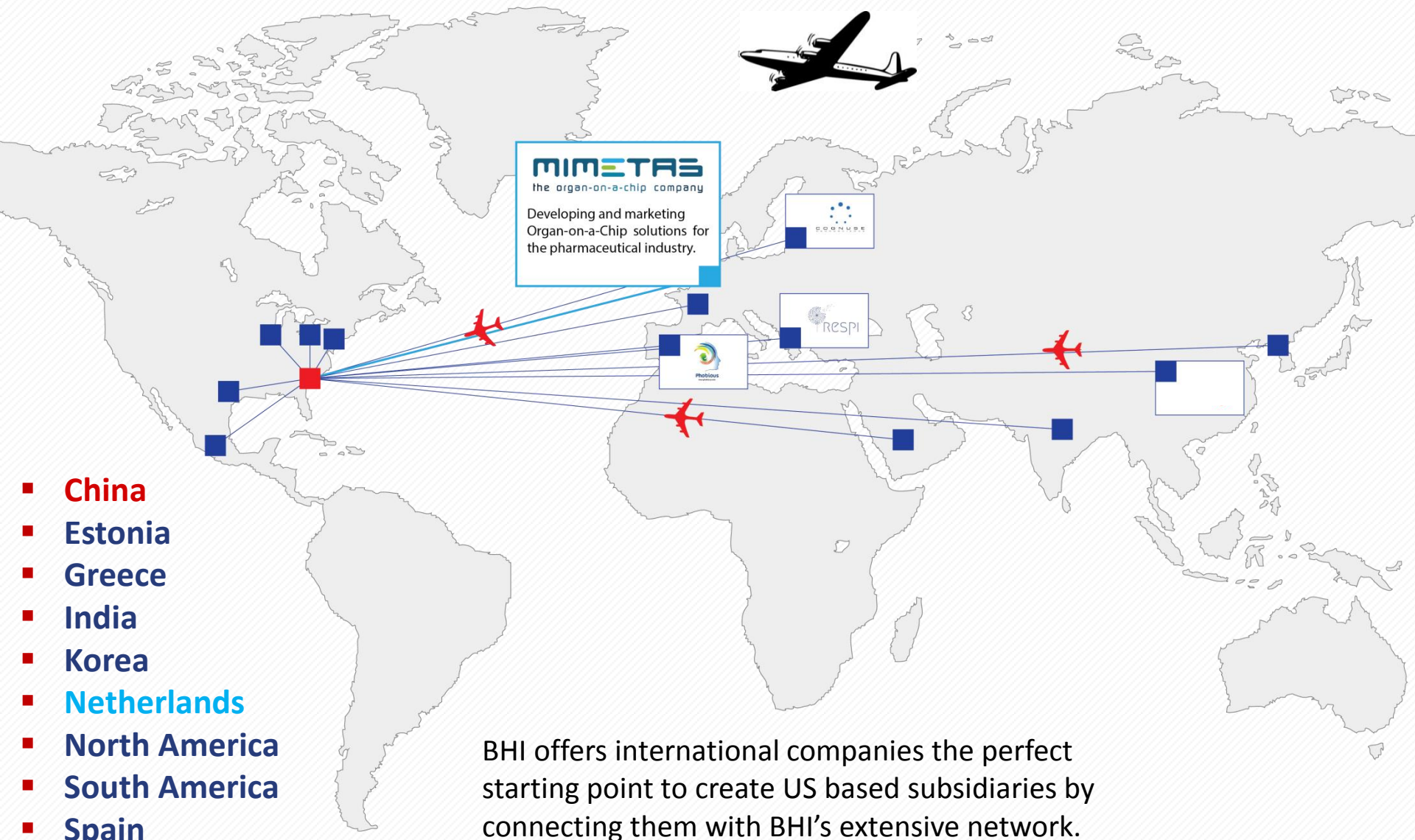
BHI H-RIC Model

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
- Focuses on proof of commercial relevance



BHI International Soft Landing



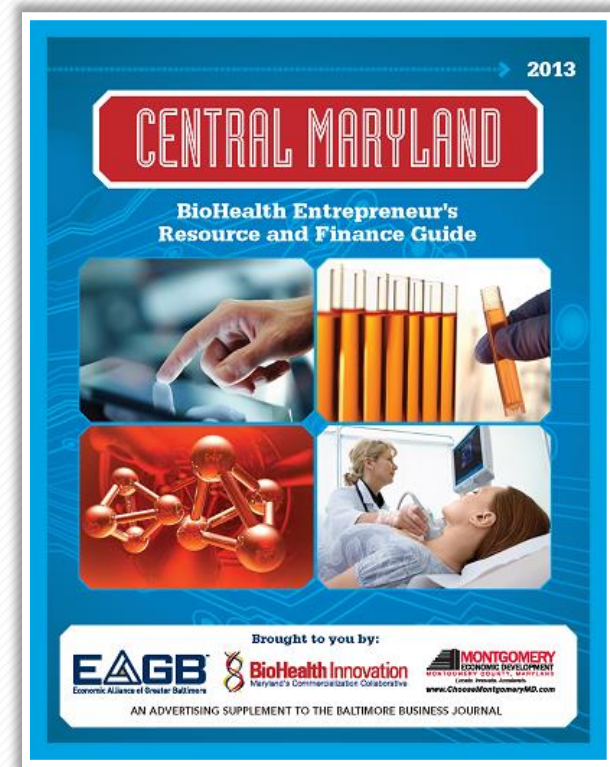
BHI offers international companies the perfect starting point to create US based subsidiaries by connecting them with BHI's extensive network.

Entrepreneur's Resource and Finance 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
- Federal Labs Listing



BHI Website and News



BHI Website

The BHI website 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>

Entrepreneur Training Programs



I-CORPS



DC I-corps is a custom commercialization program for biohealth related technologies and startup companies. The six-week program guides teams through a rigorous market assessment and validation process ultimately creating a viable business model.



National Institutes
of Health



The BHI Commercialization Consulting Club is a place where BHI's EIRs and Commercialization Consultants can discuss all aspects of the technologies being researched and make new networking connections.



The Postdoc Conference & Career fair is for current postdoctoral fellows working in Washington, D.C. area federal labs and universities, and for companies recruiting high-level S.T.E.M. (Science, Technology, Engineering and Mathematics) professionals.

KAUFFMAN | FASTTRAC.
Startup your idea.

Not currently active



The FastTrac program is a practical, hands-on, entrepreneur-learning program designed to help entrepreneurs hone the skills needed to create, manage, and grow a successful business.

INNoVATE™

Not currently active



The INNoVATE program provides applied training for postdoctoral fellows, research scientists, and other professionals who want to start life science based companies.

BHI: The Triple Bottom Line

Grows high-paying jobs and businesses

A large, hollow, downward-pointing arrow with a thin black outline, centered between the first and second text boxes.

Expands tax base; improves economic vitality

A large, hollow, downward-pointing arrow with a thin black outline, centered between the second and third text boxes.

...and benefits human health!

BHI Key Staff

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The Wire Hardware store
- BHI's Office Space

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