



BioHealth InnovationSM
Maryland's Commercialization Collaborative

Turkish Delegation Visit to the State of Maryland

Richard Bendis

3/12/2013

www.BioHealthInnovation.org

“The Region”--Central Maryland

Unrivaled Research Assets
Unfulfilled Commercial Promise



State of Maryland: Federal & University Resources



59 Federal Laboratories, Centers, & Institutes in Maryland

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



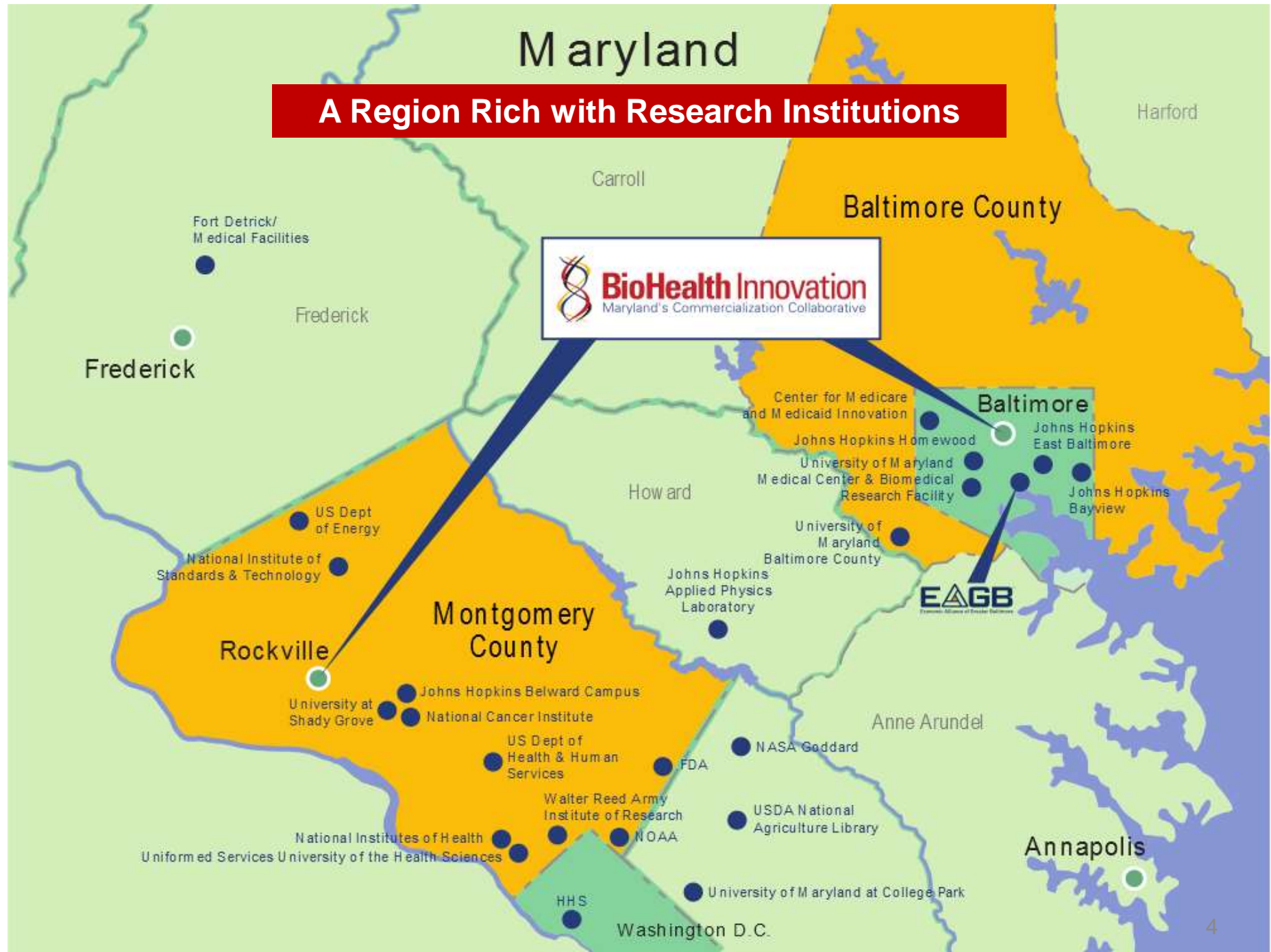
JHU and USM represent another \$3.5 billion in annual R&D

Maryland

A Region Rich with Research Institutions



BioHealth Innovation
Maryland's Commercialization Collaborative



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 spin-offs from federal and university R&D

BHI Value Proposition

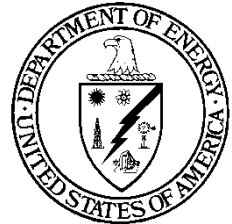
Connects regional innovation assets

Develops an entrepreneurial talent and support pipeline

Attracts funding for technology commercialization

Evaluate commercially relevant federal and university technology for new spin-offs

BioHealth Regional Innovation Cluster Assets

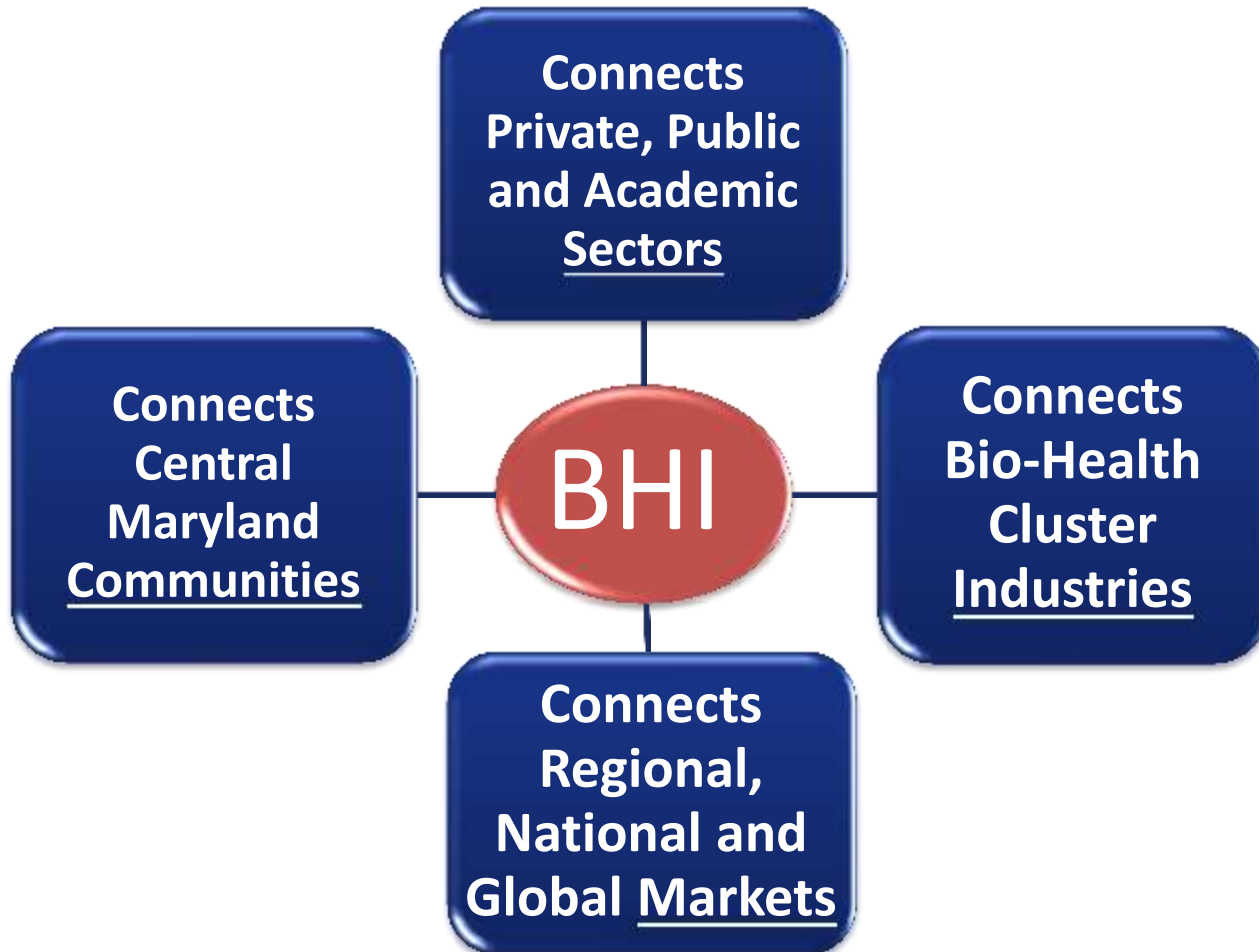


What is A Regional Innovation Intermediary?

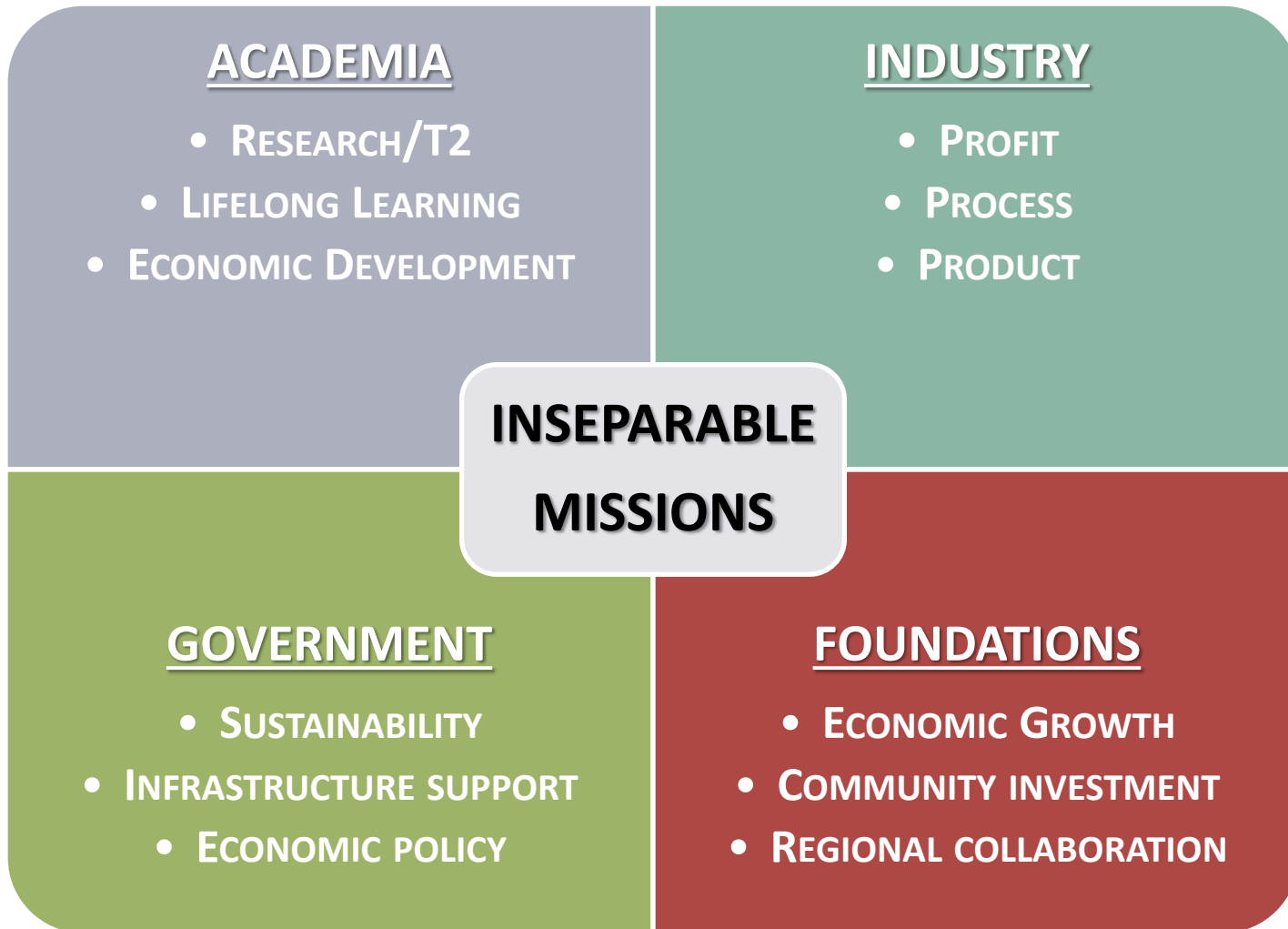
- An organization at the Center of the region's, state's and country's efforts
 - Align local technologies, assets and resources
 - Advance Innovation
- Regionally-oriented
- Private-public partnership, 501(c)(3) nonprofit
- Market-driven, private sector-led
- Neither a government initiative, nor a membership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



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



Regional BioHealth Ecosystem Partners



BHI Partners and Sponsors



JOHNS HOPKINS
UNIVERSITY



NEA



VENABLE[®]LLP



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Ronald J. Daniels
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Thomas Street
Assistant Chief Administrative Officer, Montgomery
County Government

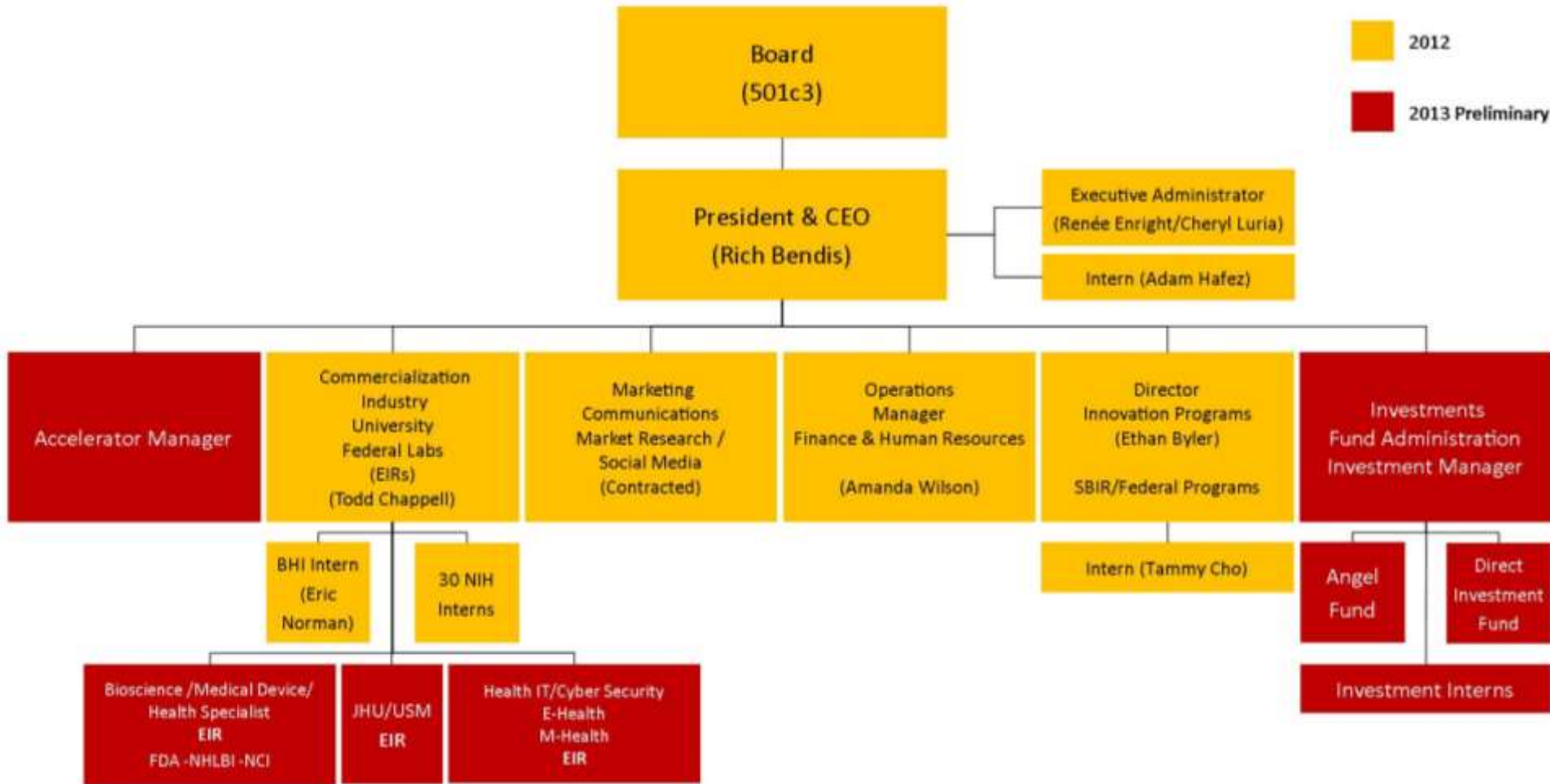


Jens Eckstein
President, SR One (GSK)



BHI Organizational Chart

2012
 2013 Preliminary



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)

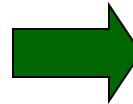
Laboratory Push

“It Works!”

PROOF OF COMMERCIAL RELEVANCE
(Market Pull)

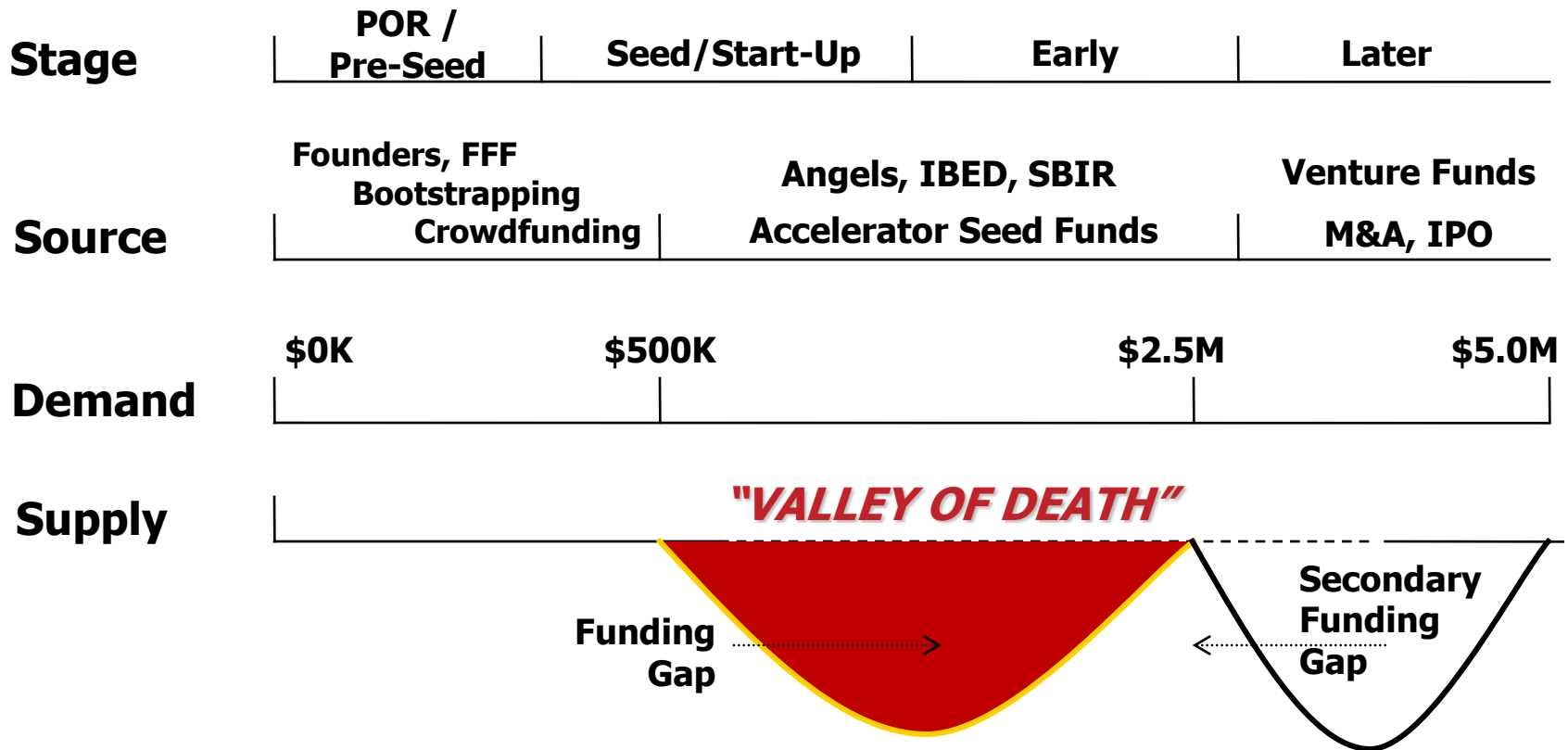
“It Works To Solve A Problem”

“I’ll Buy It”



Innovation Capital

“VALLEY OF DEATH”





Capital Sources by Investment Stage

3/6/2013

Pre-Proof of Concept \$25K - \$1.5M (over 5 years)	Translational Research / Proof of Concept \$15K - \$750K (over 3 years)	Proof of Commercial Relevance / Pre-Seed \$3K - \$500K	Seed / Start-Up \$50K - \$1.5M	Early Stage \$250K - \$2M	Later Stage \$2M+
<ul style="list-style-type: none"> NIH R01 NIH R03 NIH R21 Maryland Innovation Initiative (MII) (Managed by TEDCO) 	<ul style="list-style-type: none"> NCATS Cures Acceleration Network (CAN) SBIR/STTR Grant Phase I Maryland Stem Cell Research Fund (MSCRF) TEDCO Technology Validation Program JHU-Coulter Translational Research Partnership 	<ul style="list-style-type: none"> Maryland Industrial Partnerships (MIPS @ UMD) Maryland Biotechnology Center's Translational Research Award TEDCO Technology Commercialization Fund MII Phase 2 Grant MII Phase 3 Grant ★ BHI SBIR/STTR Commercial Relevance Program (CRP) 	<ul style="list-style-type: none"> Dingman Center Angels (UMD) Propel Baltimore Fund SBIR / STTR Phase II ★ BHI Central Maryland Angel Fund ★ BHI Commercial Relevance Fund (CRF) 	<ul style="list-style-type: none"> Maryland Health Care Product Development Corporation Invest Maryland: Maryland Venture Fund Maryland Biotechnology Center's Biotechnology Commercialization Awards Abell Venture Fund MMG Ventures LP 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)
- Association of University Technology Managers (AUTM)
- Licensing Executive Society (LES)
- Angel Capital Association (ACA)
- Mid-Atlantic Venture Association (MAVA)
- National Venture Capital Association (NVCA)

Funding Type Key

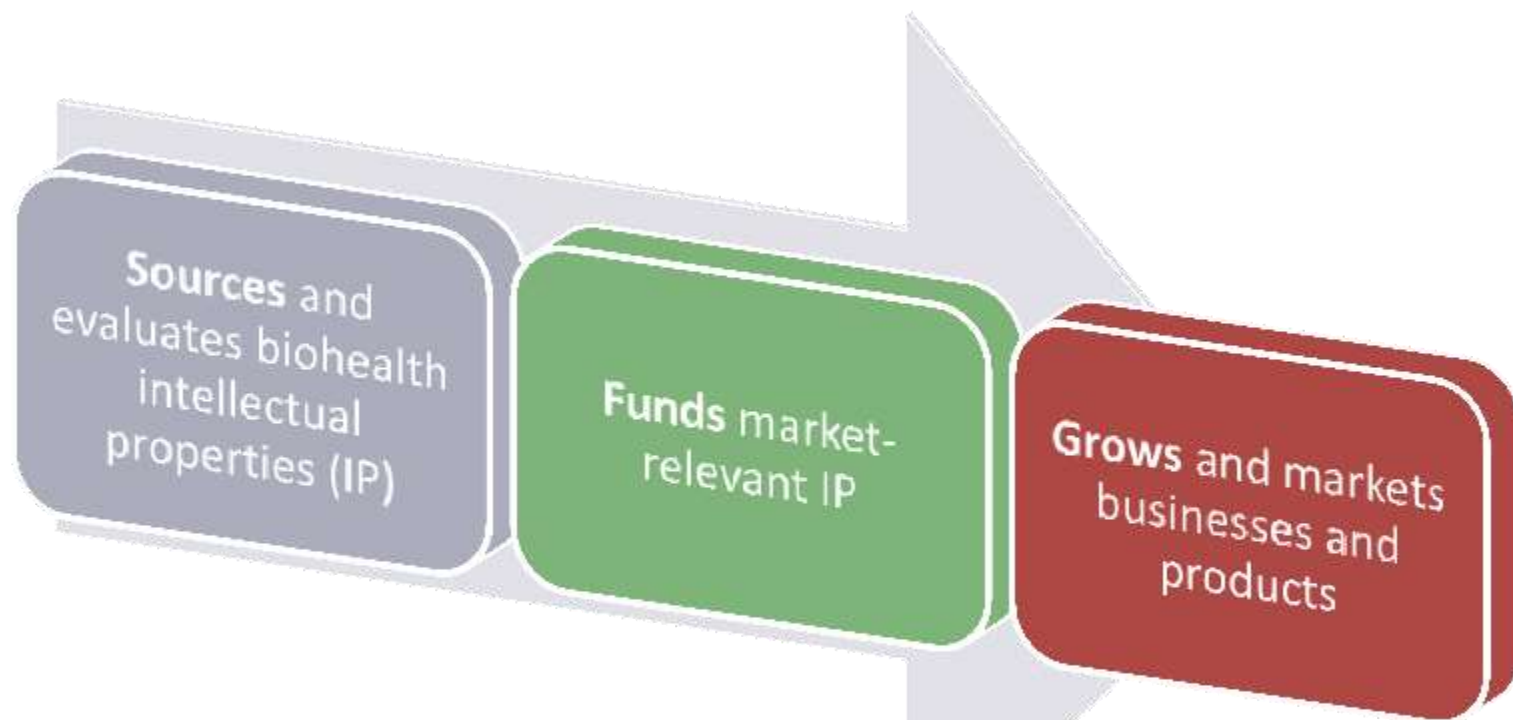
- Academic
- Accelerator
- Associations
- Federal
- ★ BioHealth Innovation, Inc.
- Innovation-based Economic Development (IBED)
- State of Maryland
- Venture Capital

Tax Credits

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

How does **BHI** work?

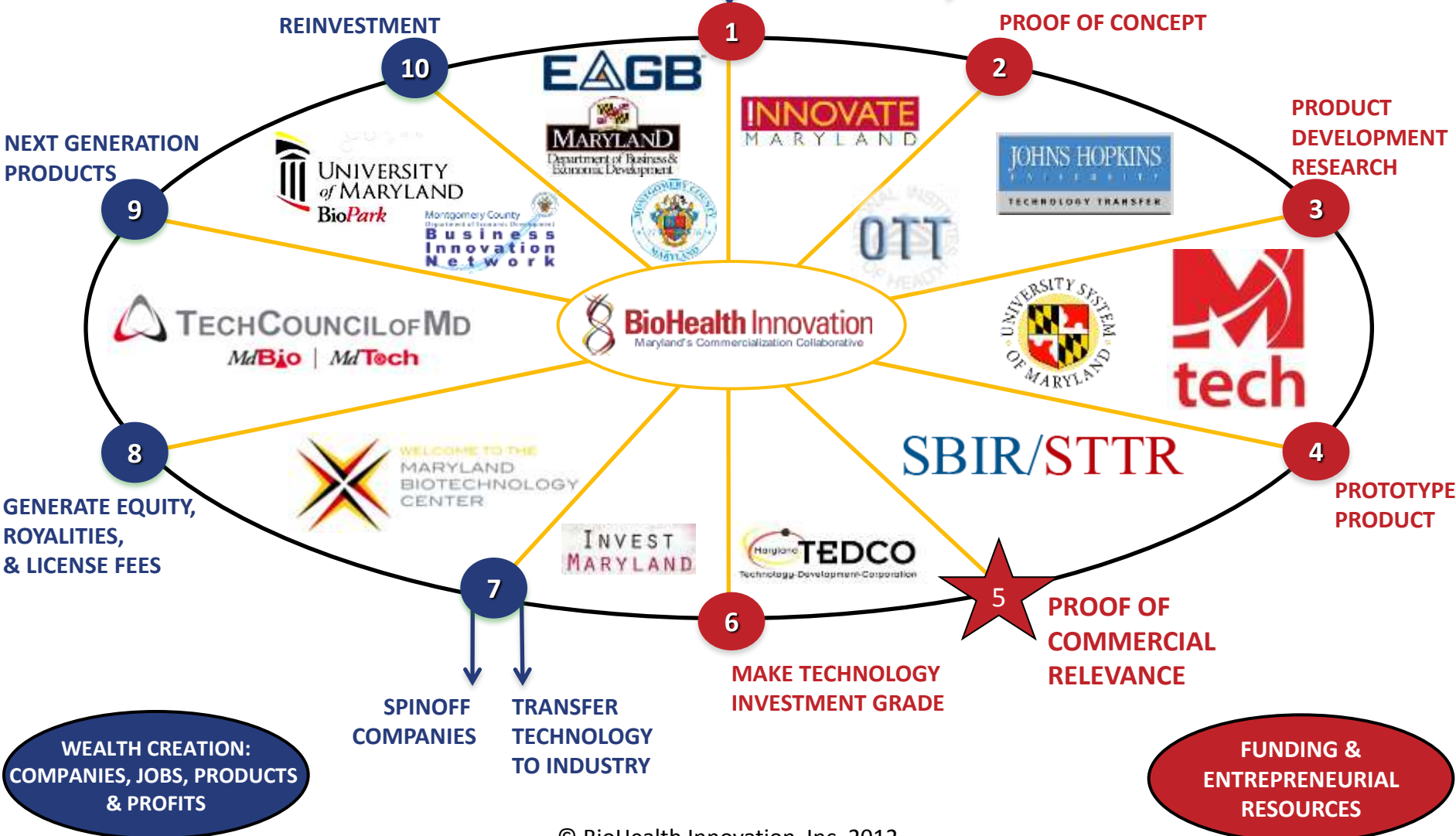
Commercialization Pipeline



BHI Commercialization Model

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

PUBLICATIONS
PhD's
TENURE
PATENTS



BHI Deal Goals

VC Regional History:

Last decade the region: ***\$79.8 million per year****
in biotechnology venture financing (2003-2010).

Goal:

150 prospective deals annually

Fund:

25% or 35 deals per year

Avg. Investment:

\$4.3 million per start-up

Targeted VC Annual Investment

\$150,000,000

*This includes an estimated \$57.7 million per year in Montgomery County, and \$22.1 million per year in the rest of the state.

SEED
CAPITAL



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/MOU between BHI and FDA** to assist in evaluation and potential commercialization of FDA technology through a dedicated EIR is being negotiated.



- **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)

- 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 (10 months into Program)

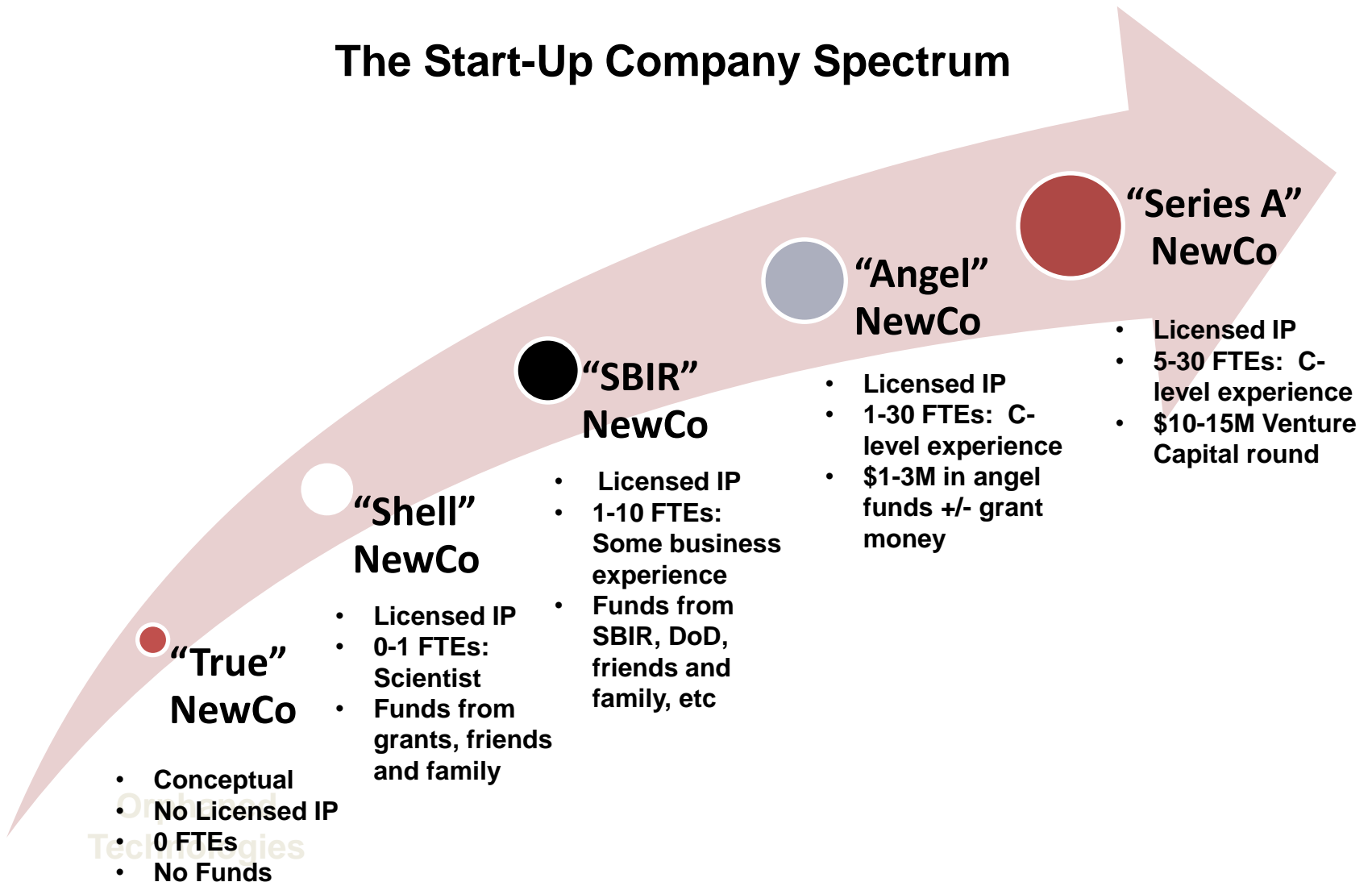
- 97 Innovations identified and initially screened
- 63 Progressed to Secondary Analysis (Safety & Efficacy Profiling, IP Diligence, Regulatory & Development Pathways) and 12 to Primary Analysis
- Entered into consulting agreement with Perceptive Navigation
- Entered into agreement with Advanced Personalized Diagnostics, LLC
- Option Agreement for stem cell technology (JHU)
- Goal to fund the operation of more EIRs

EIR Criteria

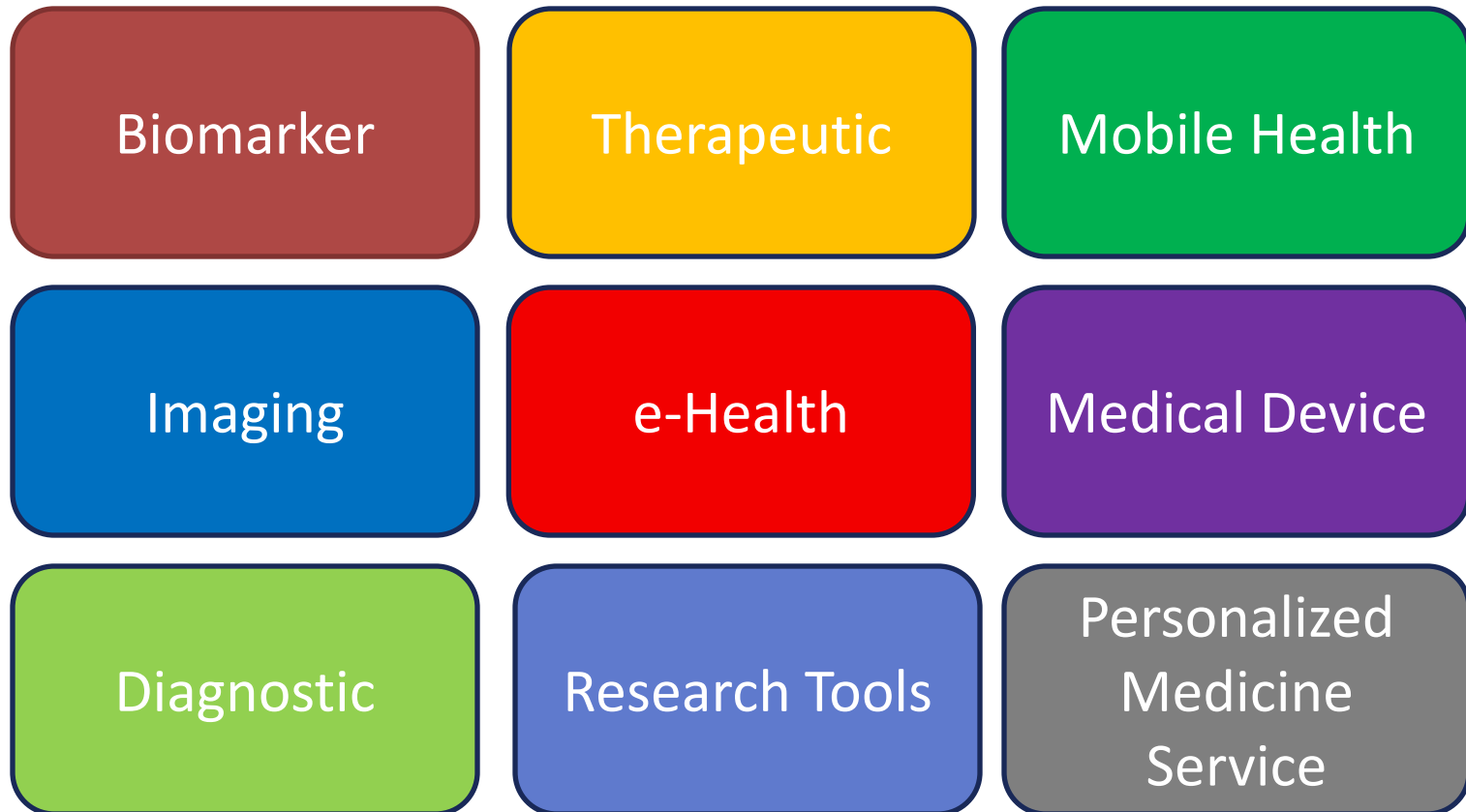
- **Senior management in an early stage life sciences startup**
 - **Entrepreneurial life science start up or spin out activity**
- **Management in a organization that specializes in startup companies**
- **Experience in a seed stage venture capital firm**
- **Served in a business development role in 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 Value Proposition

The Start-Up Company Spectrum



Different Technologies = Different Strategy



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**

Maryland Universities/EIR Interaction



Maryland's Innovation Initiative

- **\$5.8M budget**
- **5 University partners**
 - 1-5
- **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**
- **Creating a JHU/USM EIR**
- **BHI creating Commercial Relevance Advisory Board**

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**

EIR Expansion 2013



National Heart
Lung and Blood Institute
People Science Health

National Heart Lung and Blood Institute



National Cancer Institute



Food and Drug Administration

JOHNS HOPKINS
UNIVERSITY



University EIR



Health Information Technology EIR



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

Identify Key Issues

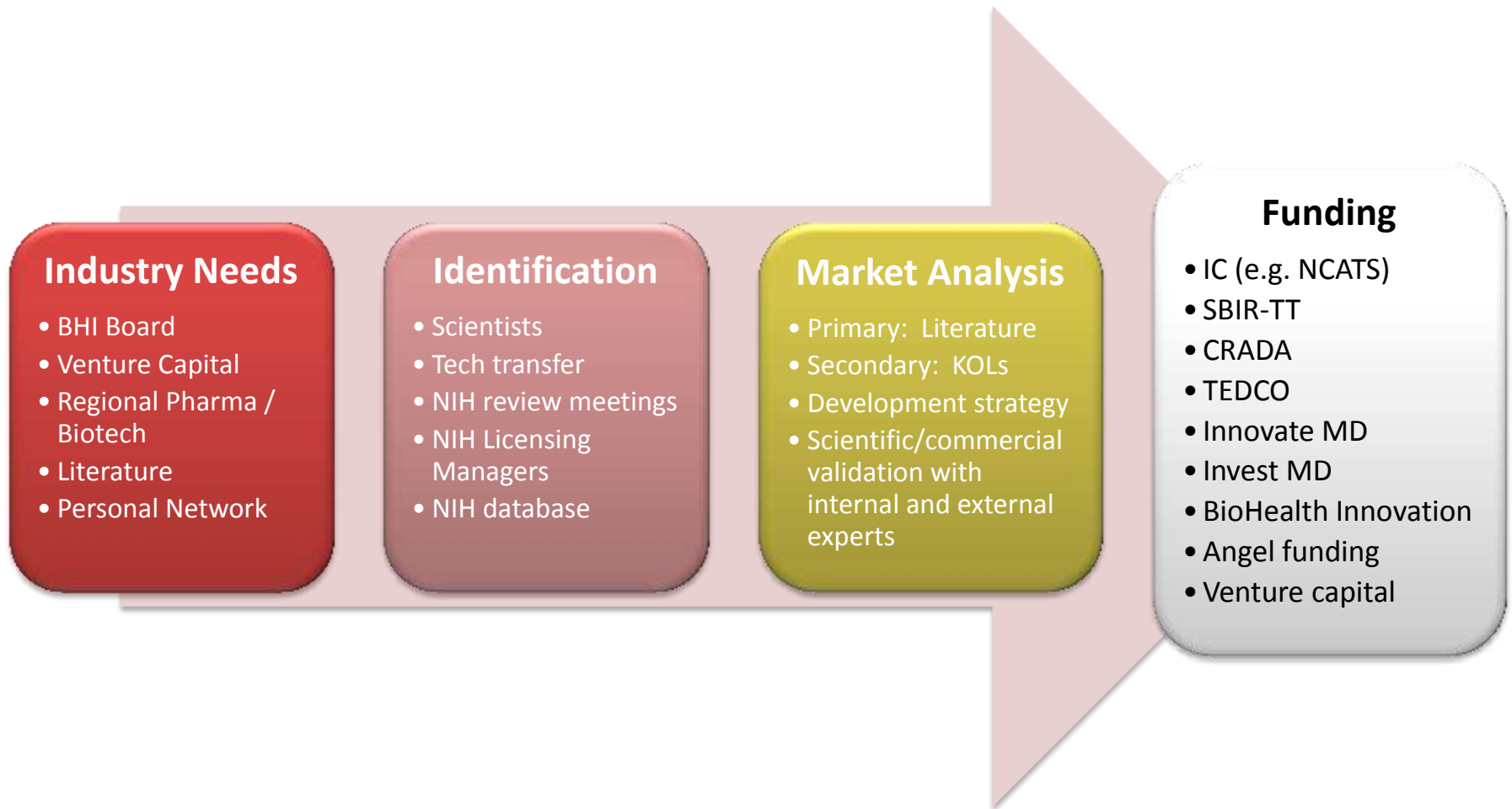
Primary and secondary
analysis

Can key issues be
overcome by capital
efficient investment?

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 Client Companies

Advanced Personalized Diagnostics, LLC



Advanced Personalized Diagnostics, LLC (APD) is devoted to providing personalized services to guide development and cancer treatment decisions.

Ahead Research, Inc.



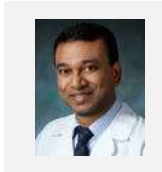
Ahead Research, Inc. is the parent company of the Symcat service that is delivered as a web and mobile application that matches patients to healthcare providers using data driven algorithms.

Mimetas



Mimetas develops and markets Organ-on-a-Chip solutions for the pharmaceutical industry.

Perceptive Navigation, LLC



Perceptive Navigation LLC is a medical device development company that intends to create medical devices related to image-guided, minimally-invasive niche markets.

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.

Maryland SBIR/STTR Awards: **NIH** Success Rates

Phase I:
Ranked 32nd in Nation

Phase II:
Ranked 36th in Nation

State	Phase I		State	Phase II	
	Success Rate	Total Funding		Success Rate	Total Funding
Massachusetts	23.4%	\$187,274,728	Massachusetts	39.0%	\$229,682,498
North Carolina	21.7%	\$57,184,183	North Carolina	46.9%	\$74,995,397
Michigan	20.6%	\$36,269,084	Michigan	40.2%	\$50,861,560
Pennsylvania	20.6%	\$65,590,113	Pennsylvania	41.7%	\$77,613,326
Ohio	20.5%	\$48,984,571	Ohio	36.6%	\$49,296,383
California	19.4%	\$299,818,982	California	37.2%	\$299,169,067
Maryland	18.8%	\$93,826,896	Maryland	35.6%	\$90,984,136
Texas	17.1%	\$62,222,413	Texas	37.3%	\$67,019,062

Maryland ranks 19th in population in the US

BHI Commercial Relevance Program for SBIR / STTR and other Federal Funding

1. SBIR/STTR Pre-Application Form submitted by small businesses online @ BHI
2. Scoring and feedback provided on Pre-Application by 3 qualified reviewers from a national pool using an online evaluation system
3. Company receives feedback on concept moving forward on whether articulated as a strong project
4. Up to \$3,000 financial grant considerations offered to assist in preparing full SBIR/STTR submission using Consultants, Technical Writers, or other service providers

BHI SBIR/STTR:

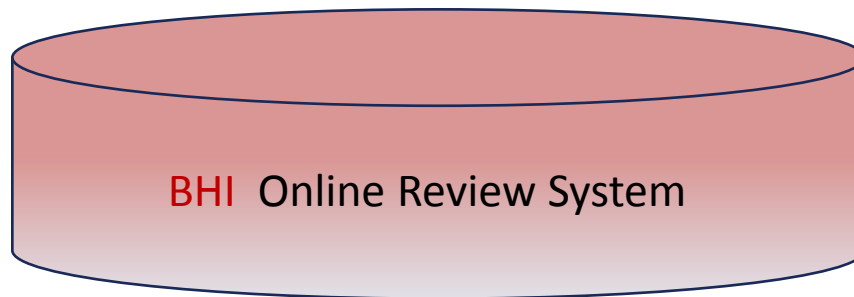
Proof of Commercial Relevance (PCR)



Central Maryland
SBIR Candidates

1. Phase I Awardees
2. Pre-Phase I (Phase Zero) – Early Commercial Relevance Indication

*Companies
Invited by BHI to
submit SBIR
concept*



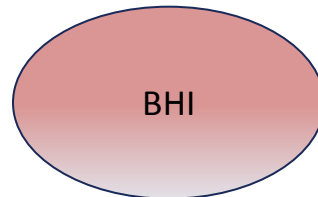
BHI Online Review System



Scientific
Experts



SBIR
Consultants



BHI



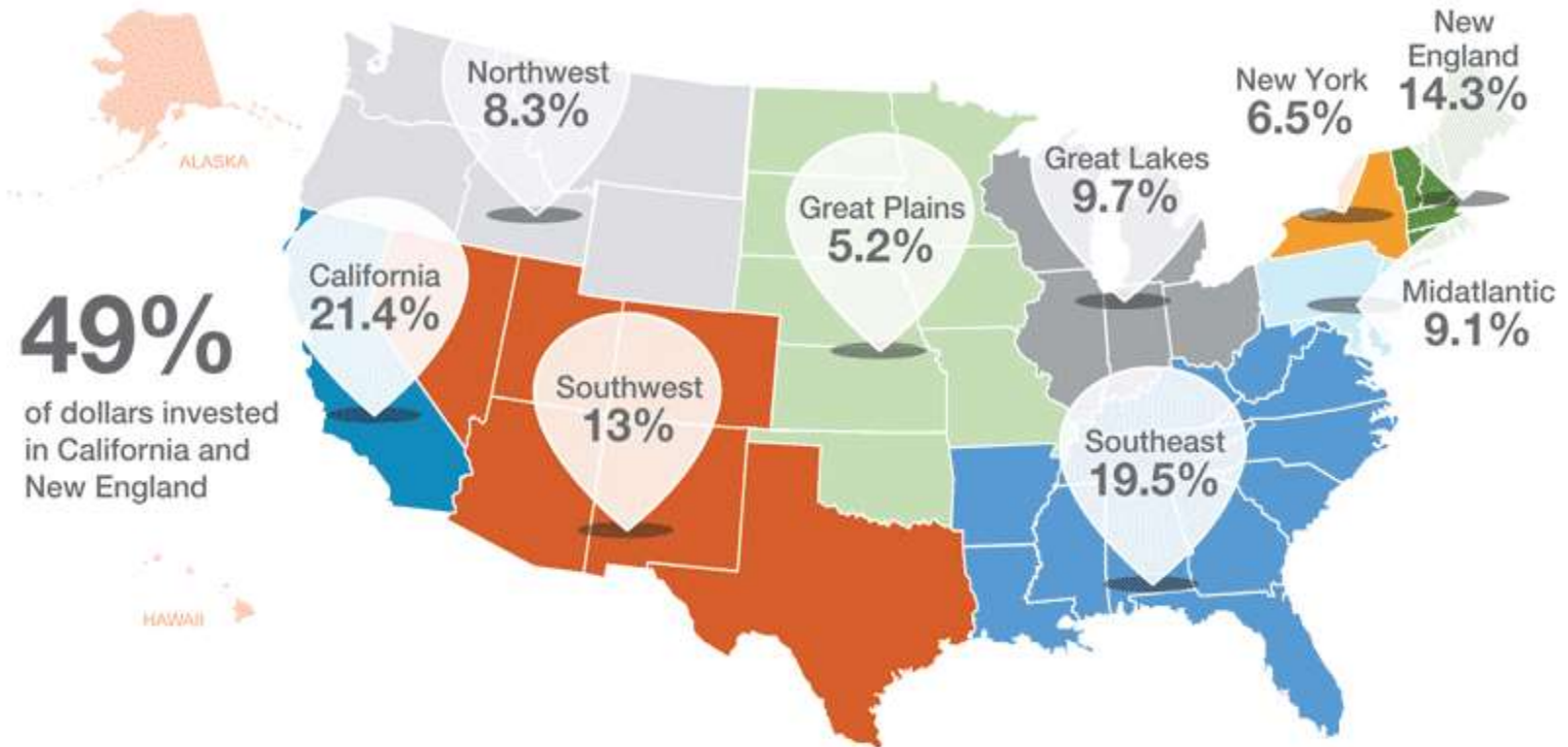
Full
Proposal
Preparation
Assistance

*Mentoring
\$\$\$*

*Reviews, Feedback, Troubleshooting,
Strategy*

US Angel Deals in Q3 2012

by Region



Pre-money valuation for early stage angel group deals dropped by \$1 million to \$2.6 million over the previous quarter. (Halo Report 2012)

The increasing importance of Angels

- ✚ 300,000+ angels are investing \$30 billion per year in close to 50,000 ventures
- ✚ 100+ Angel Groups formed nationwide in last 5 years
- ✚ In many cases, Angel Groups are becoming alternatives to early stage VCs and incubators
- ✚ No dedicated Angel Funds in Maryland

Angel Fund Competitive Advantages

Individual Angels	Angel Groups	Angel Funds
<ul style="list-style-type: none">▪ Typically poor returns▪ Why:<ul style="list-style-type: none">▪ Lack of expertise▪ Generally weak due diligence▪ Less eyes on deal▪ Intensive workload▪ Inadequate diversification	<ul style="list-style-type: none">▪ Performance – a bit better:<ul style="list-style-type: none">▪ Increased chance of an expert at the table▪ More people available to share due diligence▪ More eyes on deal	<ul style="list-style-type: none">▪ Competitive advantages to get attractive returns:<ul style="list-style-type: none">▪ Only do deals where expert is leading deal▪ Higher quality due diligence▪ More eyes on deal▪ Vote process selects only the best deals▪ Professional Administration▪ Diversification▪ Follow-on reserves

BHI Angel Fund

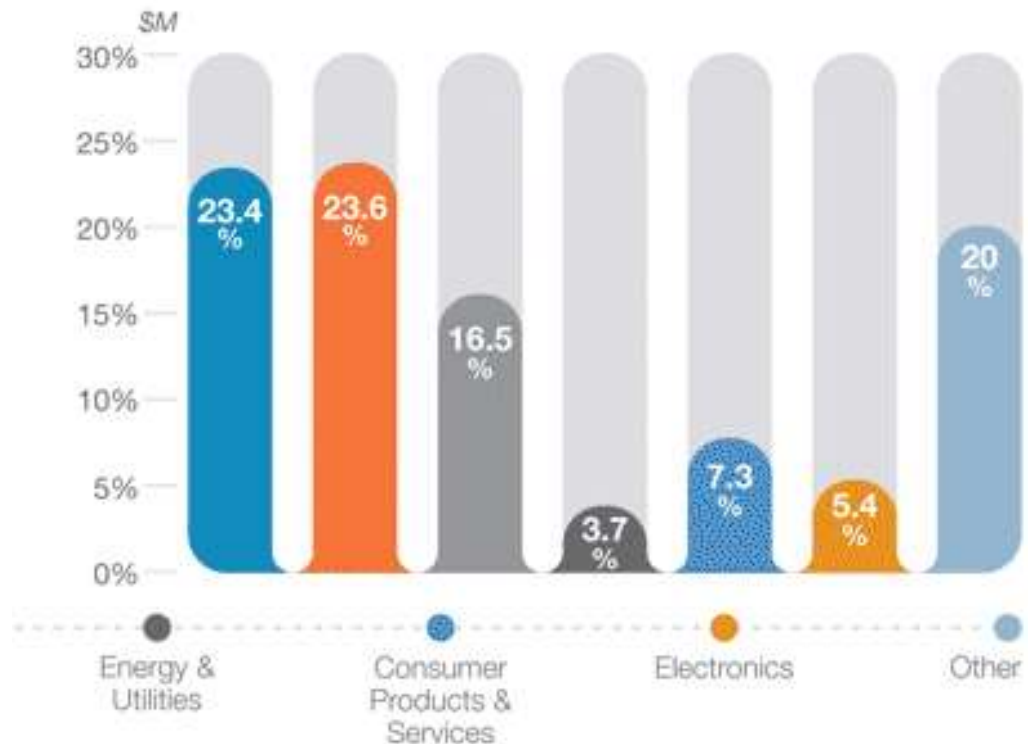
- ✚ Maryland has no organized, dedicated professionally managed biohealth angel fund
- ✚ Over the past 15 years, high-technology angel investing has become more professional, organized, and more visible.
- ✚ When angels co-invested with other investors, the median round size was nearly \$1.6 million, the highest since the second quarter of 2011 (Halo Report)
- ✚ Planning a BHI managed accredited angel investor fund; Initial target fund size of \$3M - \$5M
- ✚ 2013 – Assembling Private Placement Memorandum; Identify Investors

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



Healthcare companies receive largest share of dollars; Mobile share jumps 6% over Q2 2012



Source: Q3 2012 Halo Report

Health IT Accelerator

- ✚ A Health IT Accelerator is an intensive 12-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.
- ✚ No HIT accelerators currently in Maryland
- ✚ Located in a Central Maryland Co-Working space
- ✚ Retain promising high growth HIT entrepreneurs in MD

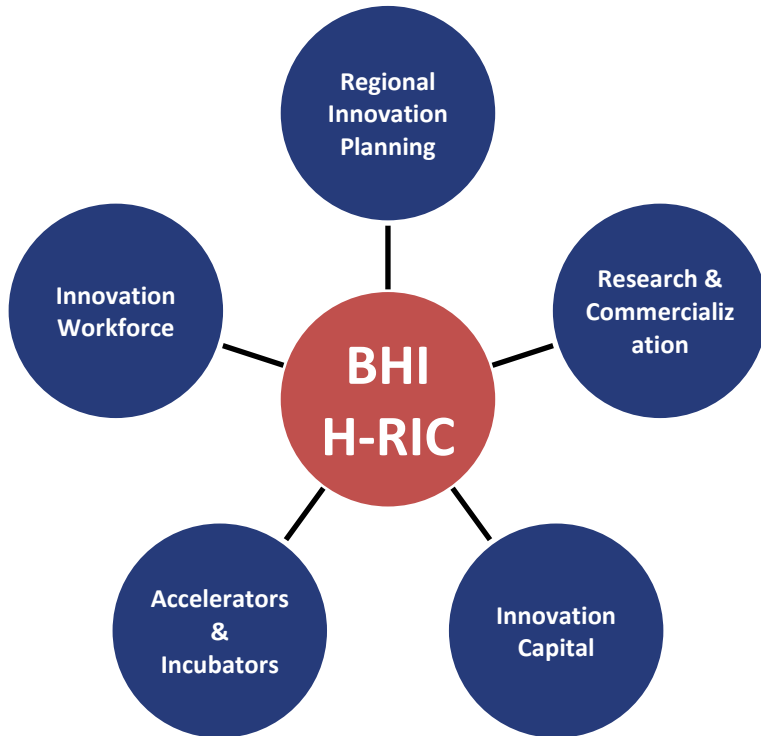
Health IT Accelerator



Year 1 Accelerator

1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter
Complete Market Analysis of Sector and Opportunity			
Assemble Management Team, Mentors, Technologists, Supporting Business Professionals for the Health IT Accelerator			
	Finalize Program Processes, Protocols & Agreements		
	Publicize and Market the First Class and Opportunity (90 Day Process)		
		Launch of first Health IT class	
			Graduation Event with Investors

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 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

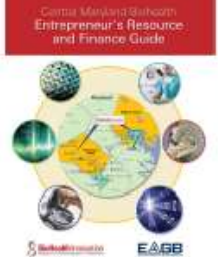
“Financing and Entrepreneurial Resource for Montgomery County and the Greater Baltimore Region”

- 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.

Benefits of Advertisement:

- Half-to-full-page detailed ads available to market your company or organization.
- Exposure to 1,000s of businesses, organizations and government leaders through distribution of the guide.

To advertise, sponsor or be included in the guide, please contact:

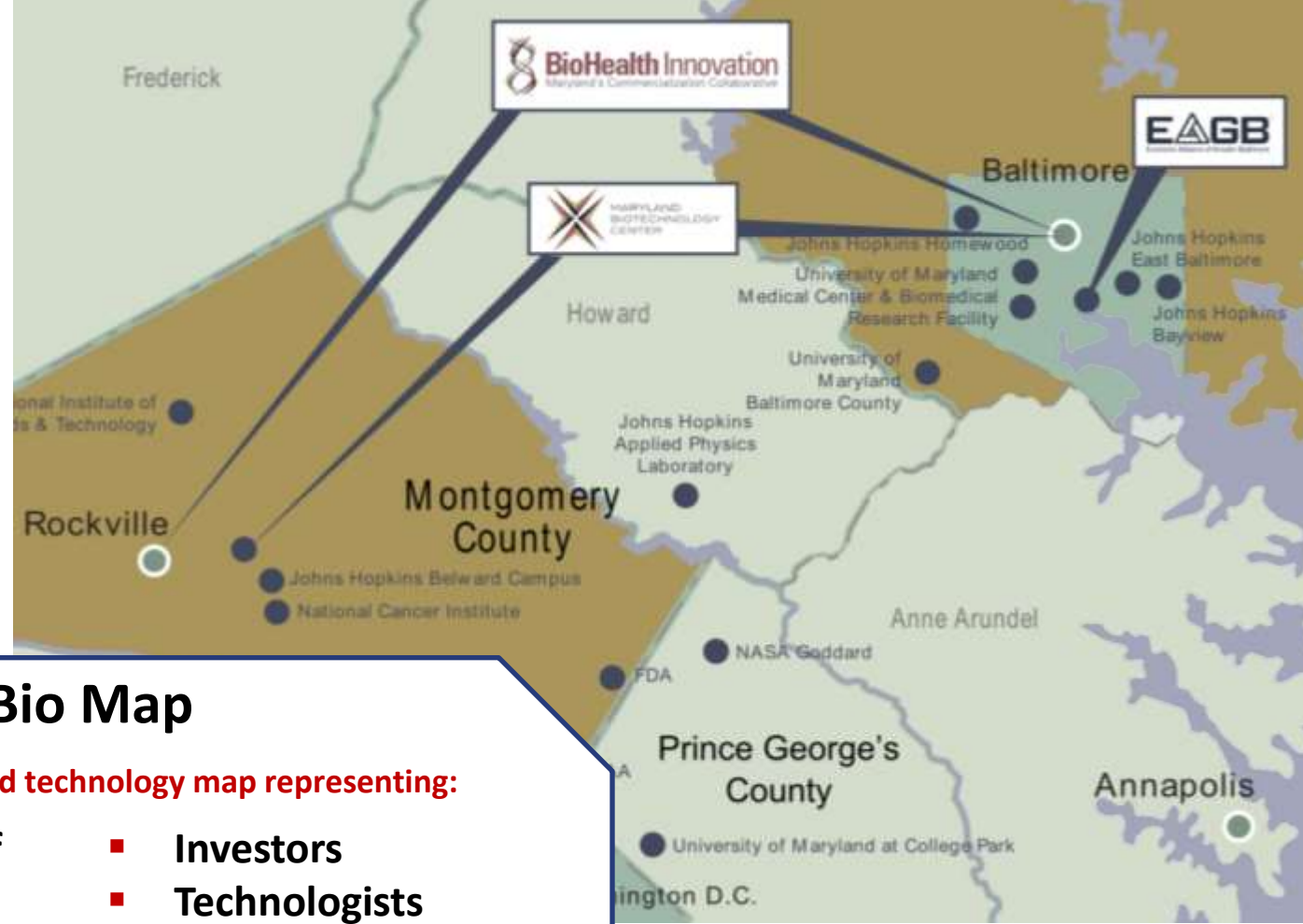
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Central Maryland Biohealth Entrepreneur’s Resource and Finance Guide is a joint effort between BioHealth Innovation and the Economic Alliance of Greater Baltimore.

For more information, visit:

www.biohealthinnovation.org
www.greaterbaltimore.org



Central Maryland Bio Map

Interactive bioscience and technology map representing:

- Communities of entrepreneurs
- Academia
- Researchers
- Government
- Investors
- Technologists
- Seasoned industry leaders

The map is a platform for collaboration and economic growth as individuals from inside (as well as outside) of the community are able to participate in the benefits.

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!

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