

THE TECHNOLOGY NETWORK

The Global Community of Knowledge Regions



The Importance of SMEs in the BioHealth Sector

Riyadh, Saudi Arabia
November 6th, 2013

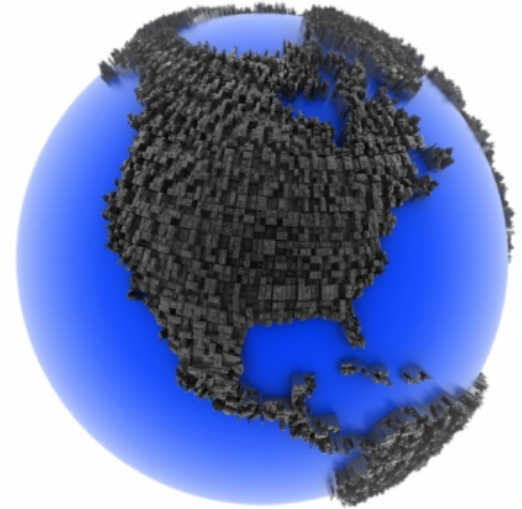
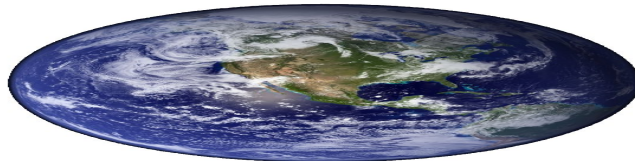
Richard Bendis
President & CEO





The World According to Friedman

Hot, Flat, and Crowded





Global Innovation Imperative

- Innovation is Key to Growing and Maintaining a Country's **competitive** Position in the Global Economy and to address Global Challenges
- **Collaboration** among Small and Large Businesses, Universities, and Research Institutes is Essential for Innovation & Commercialization
- **New Institutions and New Incentives**, are increasingly important to support collaboration and foster innovation
- Competitive advantages are increasingly tied to human capital and innovation
- **Economic growth** is closely related to education/ workforce, energy, climate change, environmental, natural resource, geopolitical issues & entrepreneurship



**OPEN INNOVATION
MATTERS**



The Six Driving Forces of Change

- Commoditization
- The Digital Revolution
- Social Media-ization throughout society
- Global Open Innovation
- The Turbulent World
- Acceleration (or running faster to stay in the same place)





Why is Innovation Essential?



**“INNOVATION
DISTINGUISHES
BETWEEN A LEADER AND
A FOLLOWER.”**

- STEVE JOBS

INNOVATION is the creation and transformation of knowledge into new products, processes, and services that meet market need....and interactions, entertainment forms, and ways of communicating and collaborating



“Never before in history has innovation offered promise of so much to so many in so short a time.”

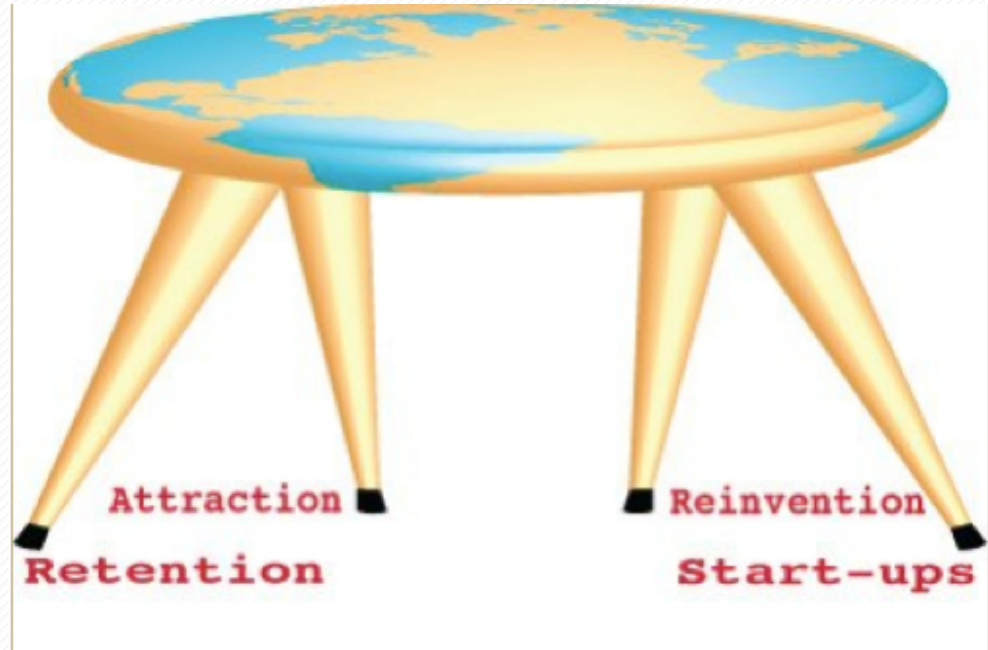
Bill Gates - Microsoft





Economic Development

- Economic Development is like a
- 4 - legged stool:
 - **Attraction**
 - **Retention**
 - **REINVENTION**
 - **Grow Your Own**
- IBED requires patience and persistence, continuity and consistency
- Working with early-stage companies takes time
- A balanced portfolio economic development strategy is best!





Innovation Ecosystem

INPUT

Knowledge
Creation

Basic
& Translational
Research

Proof of Concept

“INTERACTION FIELDS”

Human Networks

Education/ Human Resources

Networks of Funds

Regional Clusters

University-Industry
Collaborations

Research Parks

IP Strategies

Federal Laboratories

Proof of Commercial
Relevance

OUTPUT

Jobs

Wealth
Creation

Commercialization

New Products &
Services

New Markets

Companies

Wealth Creation

The concept of the **Innovation Ecosystem** stresses that the flow of technology and information among people, enterprises and institutions is key to a vibrant innovation process.



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.





Small Business 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**



Small Business Keys to 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

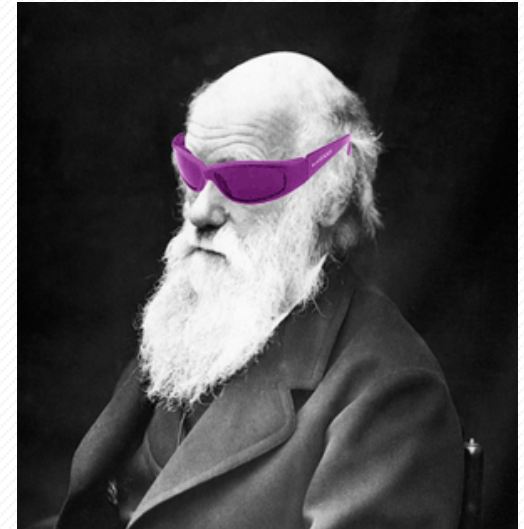
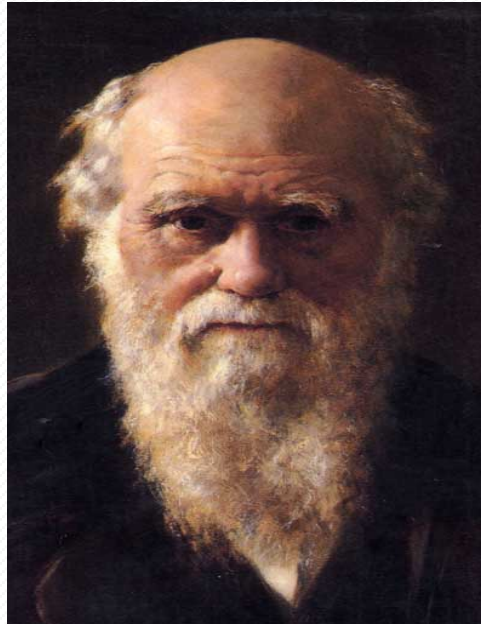
www.entrepreneur.com/dbimages/blog/entrepreneurship-risk.jpg



Change is Inevitable

“ It is not the strongest of species that survive, nor the most intelligent, but the ones most responsive to change.”

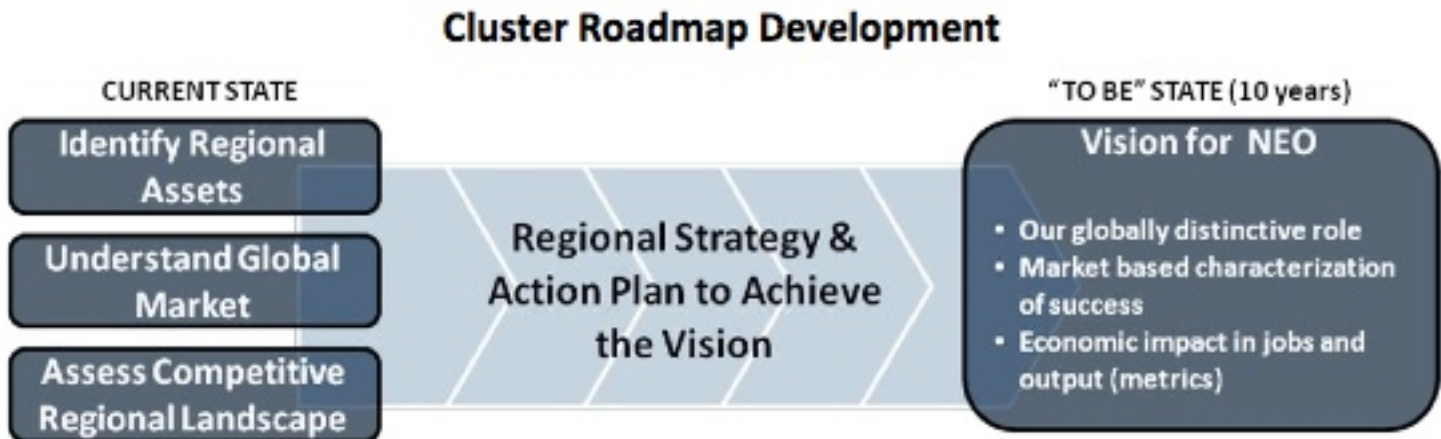
Charles Darwin





What is A Road Map....Why is it needed?

- A roadmap answers the *question* “*Where do we want to be and how to we get there?*”
- A cluster roadmap *provides strategies and action* plans to best *achieve a vision of the future shared by a critical mass* of industry-related organizations.
- The strategies and action plans are developed according to the unique strengths of the cluster and region as compared to a global market opportunity.





How BHI stimulates SME development in Maryland



BioHealth InnovationSM
Maryland's Commercialization Collaborative

An introduction to BioHealth Innovation
an Innovation intermediary



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

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



JOHNS HOPKINS
UNIVERSITY





The Region — Central Maryland

- Unrivaled Research Assets -
- Unfulfilled Commercial Promise -



National Institutes
of Health



JOHNS HOPKINS
UNIVERSITY



National Heart, Lung,
and Blood Institute



Maryland

Baltimore County

Frederick

Frederick



BioHealth Innovation
Maryland's Commercialization Collaborative

Montgomery County

Howard

Baltimore

Center for Medicare and Medicaid Innovation

Johns Hopkins Homewood

University of Maryland Medical Center & Biomedical Research Facility

University of Maryland Baltimore County

Johns Hopkins Applied Physics Laboratory



Johns Hopkins East Baltimore

Johns Hopkins Bayview

US Dept of Energy

National Institute of Standards & Technology

The Universities at Shady Grove

Johns Hopkins Belward Campus

National Cancer Institute

Rockville

US Dept of Health & Human Services

National Institutes of Health

Uniformed Services University of the Health Sciences

Walter Reed Army Institute of Research

NOAA

FDA

NASA Goddard

USDA National Agriculture Library

University of Maryland at College Park

HHS

Washington D.C.

US Dept of Defense (Pentagon)

Virginia

Prince George's

A Region Rich with Research Institutions



What is A Regional Innovation Intermediary?

An organization at the Center of the region's, state's and country's efforts to:

- 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



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



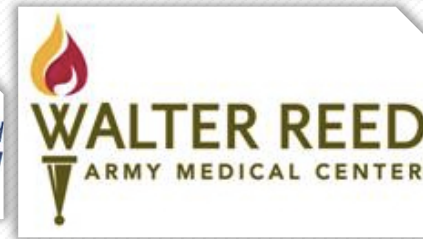
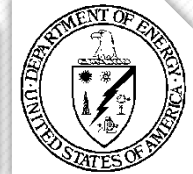
BHI Technology Focus

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



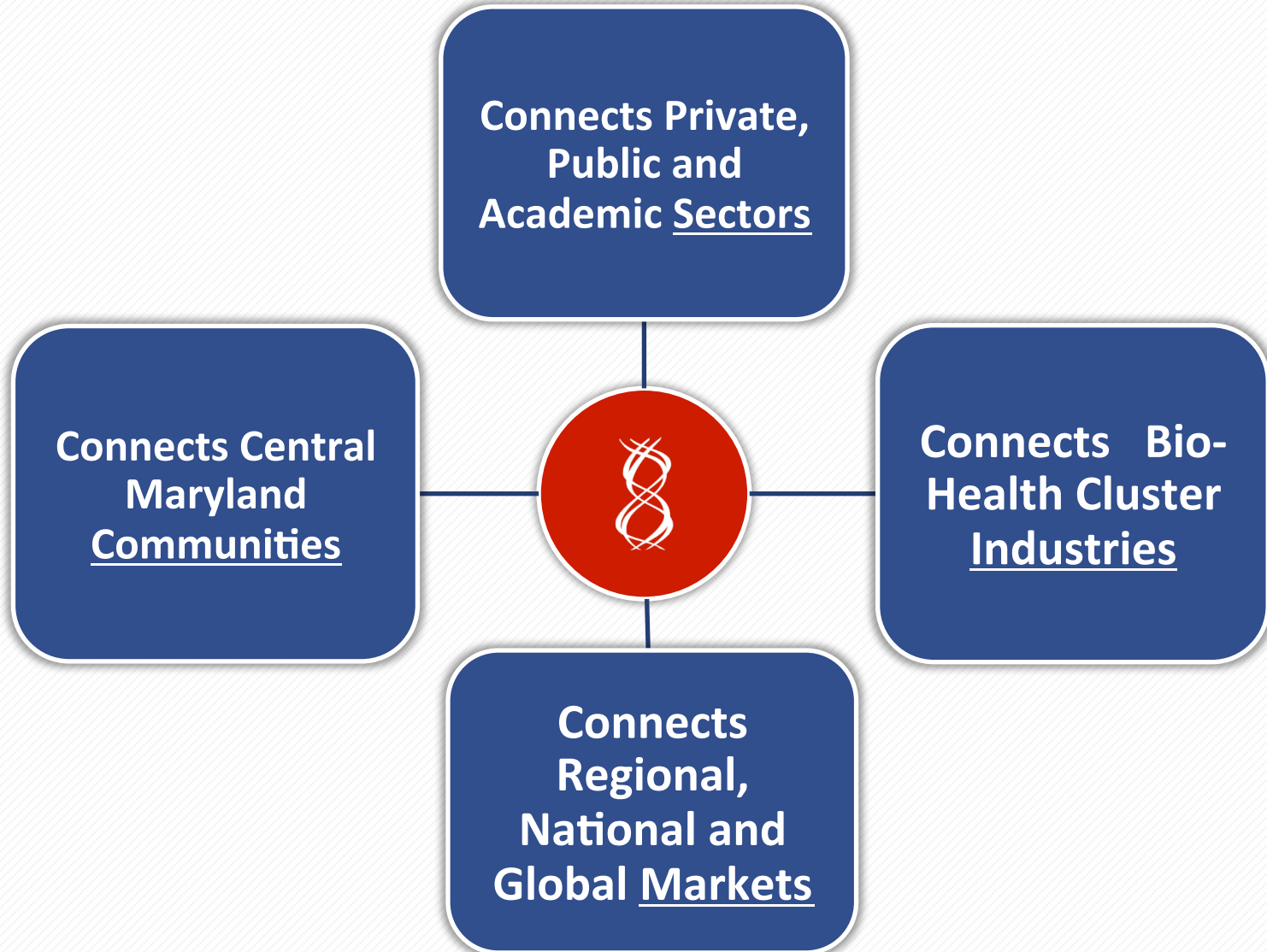


BioHealth Regional Innovation Cluster Assets





BHI: An Innovation Intermediary that Connects





Regional BioHealth Ecosystem Partners





BHI Partners and Sponsors





BHI Board of Directors



Daniel J. Abdun-Nabi
CEO, Emergent
BioSolutions



Michael J. Baader, Esq.
Managing Director
Venable LLP



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



Scott Carmer (Chair)
Exec. VP of Com. Operations
MedImmune



Kenneth Carter
Chair
Noble Life Sciences



Cynthia L. Collins
CEO
Clarient, GE Healthcare



Scott Dagenais
Senior Vice President
M&T Bank



Ronald J. Daniels
President
Johns Hopkins University



Jens Eckstein
President
SR One (GSK)



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



Rick Ivey
Vice President R&D
BD Diagnostics



William E. Kirwan
Chancellor
University System of MD



Douglas Liu
Senior VP of GO
Qiagen



David Mott
General Partner
New Enterprise Associates



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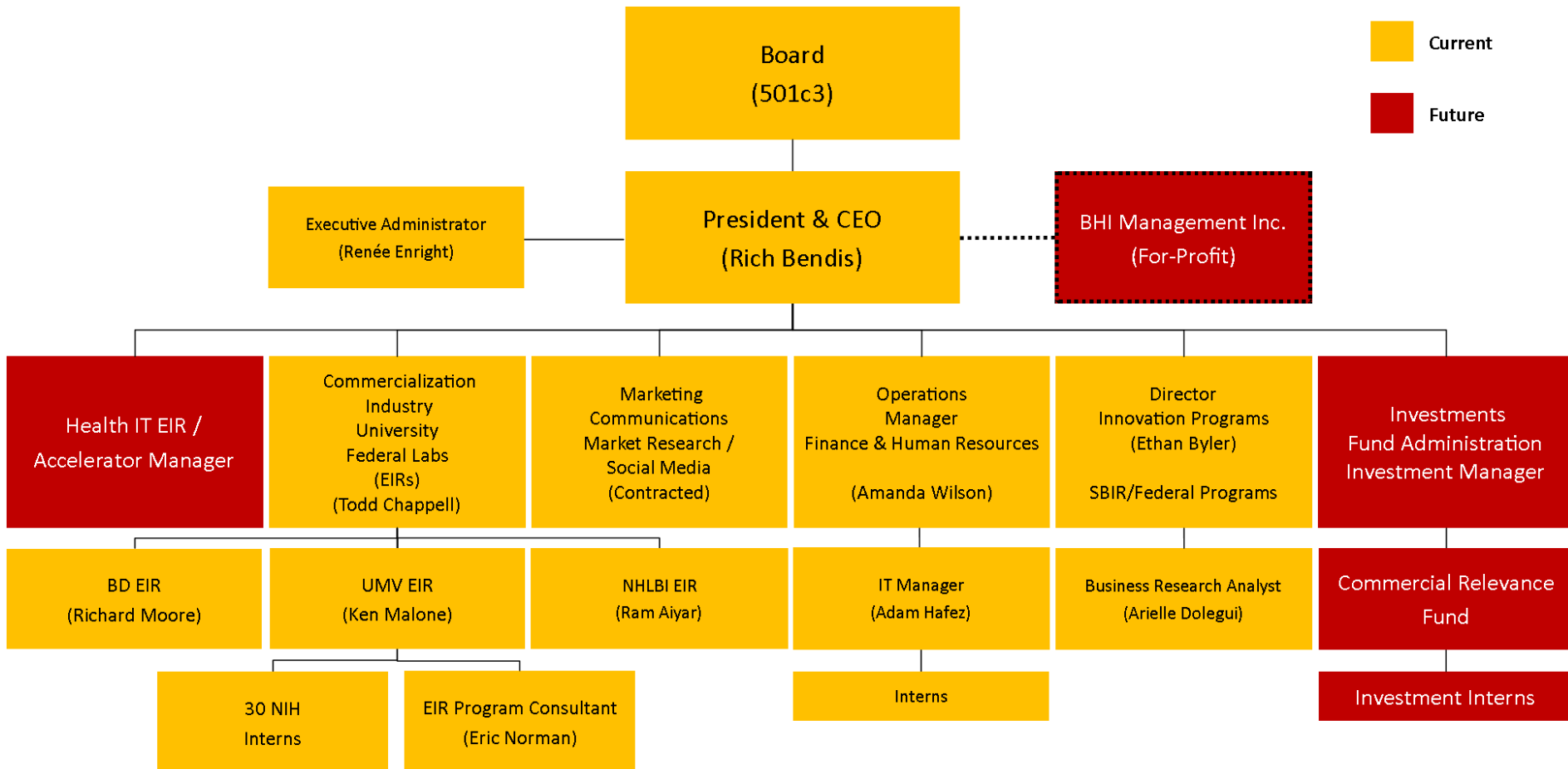
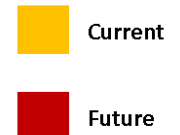
J. Thomas Sadowski
President & CEO
EAGB



Thomas Street
ACAO
MoCo Government



BHI Organizational Chart





BHI Commercial Relevance Advisory Board

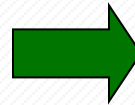
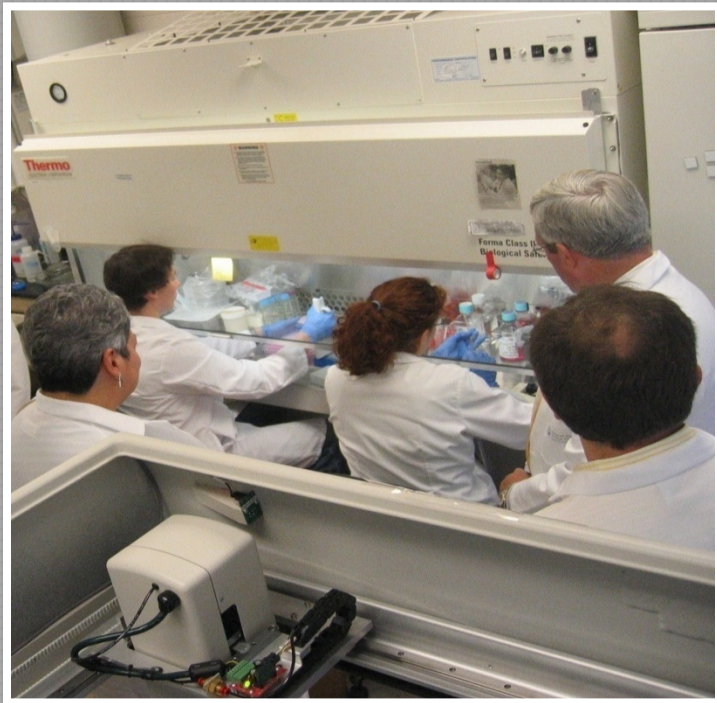


- 31 experienced biohealth professionals assisting BHI in evaluating market-relevant research and product development opportunities
- The CRAB will help determine the commercial applicability of emerging entrepreneurs, companies and their science or technology.



Innovation Paradigm Shift

PROOF OF CONCEPT
(Technological Feasibility)
Laboratory Push
"It Works!"

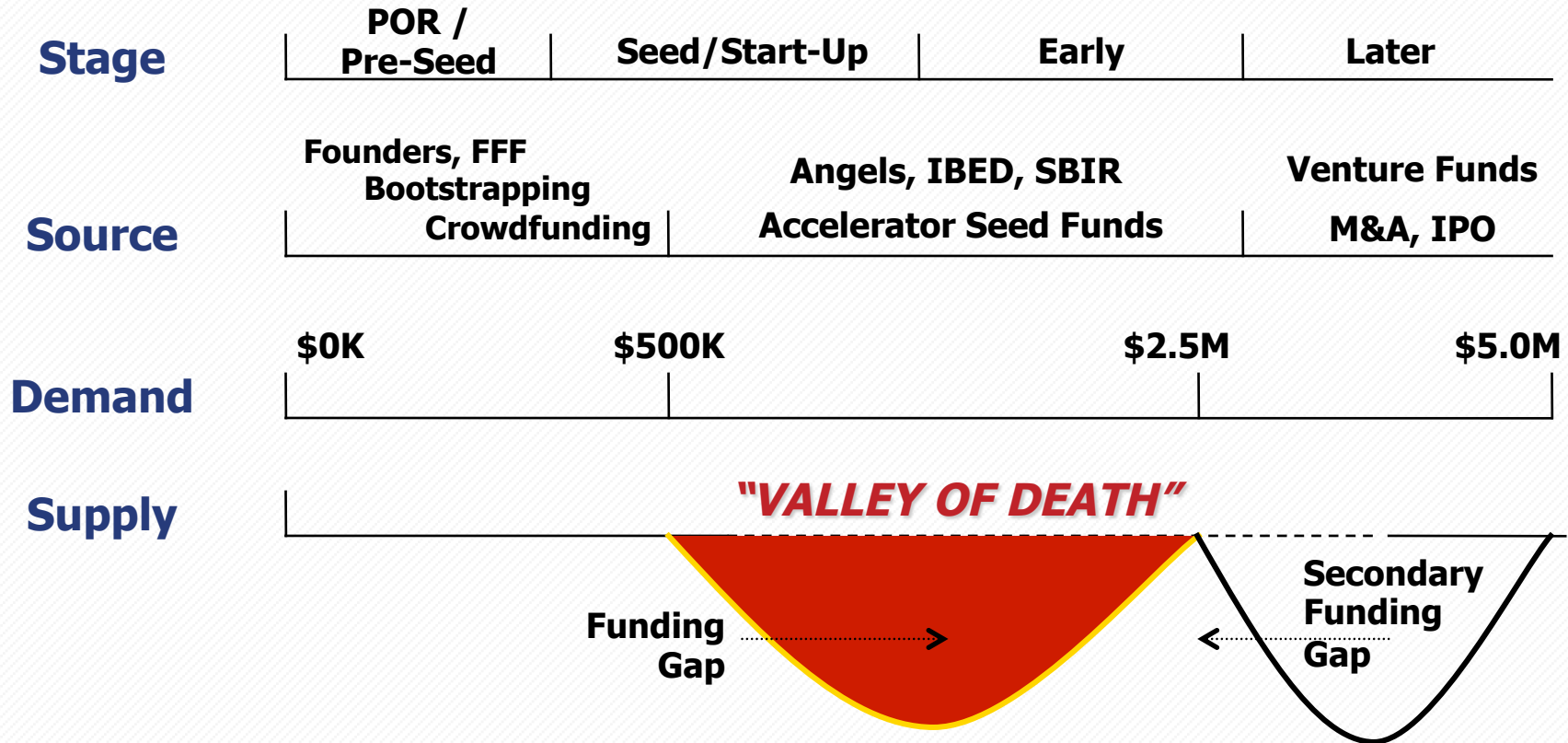


PROOF OF COMMERCIAL RELEVANCE
(Market Pull)
"It Works To Solve A Problem"
"I'll Buy It"





Innovation Capital Valley of Death





BHI Innovation Capital Map

Capital Sources by Investment Stage

4/12/2013

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 \$200K - \$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) TEDCO Technology Commercialization Fund MII Phase 2 Grant MII Phase 3 Grant ★ BHI SBIR/STTR Commercial Relevance Program (CRP) ★ BHI Commercial Relevance Fund (CRF) 	<ul style="list-style-type: none"> Dingman Center Angels (UMD) Propel Baltimore Fund BioMaryland Center Biotechnology Development Awards - Translational Research SBIR / STTR Phase II ★ BHI Central Maryland Angel Fund 	<ul style="list-style-type: none"> Invest Maryland: Maryland Venture Fund BioMaryland Center Biotech - nology Development Awards - Commercialization Maryland Health Care Product Development Corporation 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
- State of Maryland
- Associations
- Federal
- ★ BioHealth Innovation, Inc.
- Economic Development
- Private Capital

Tax Credits

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



BHI Commercialization Pipeline

Sources and
evaluates biohealth
intellectual
properties (IP)

Funds market-
relevant IP

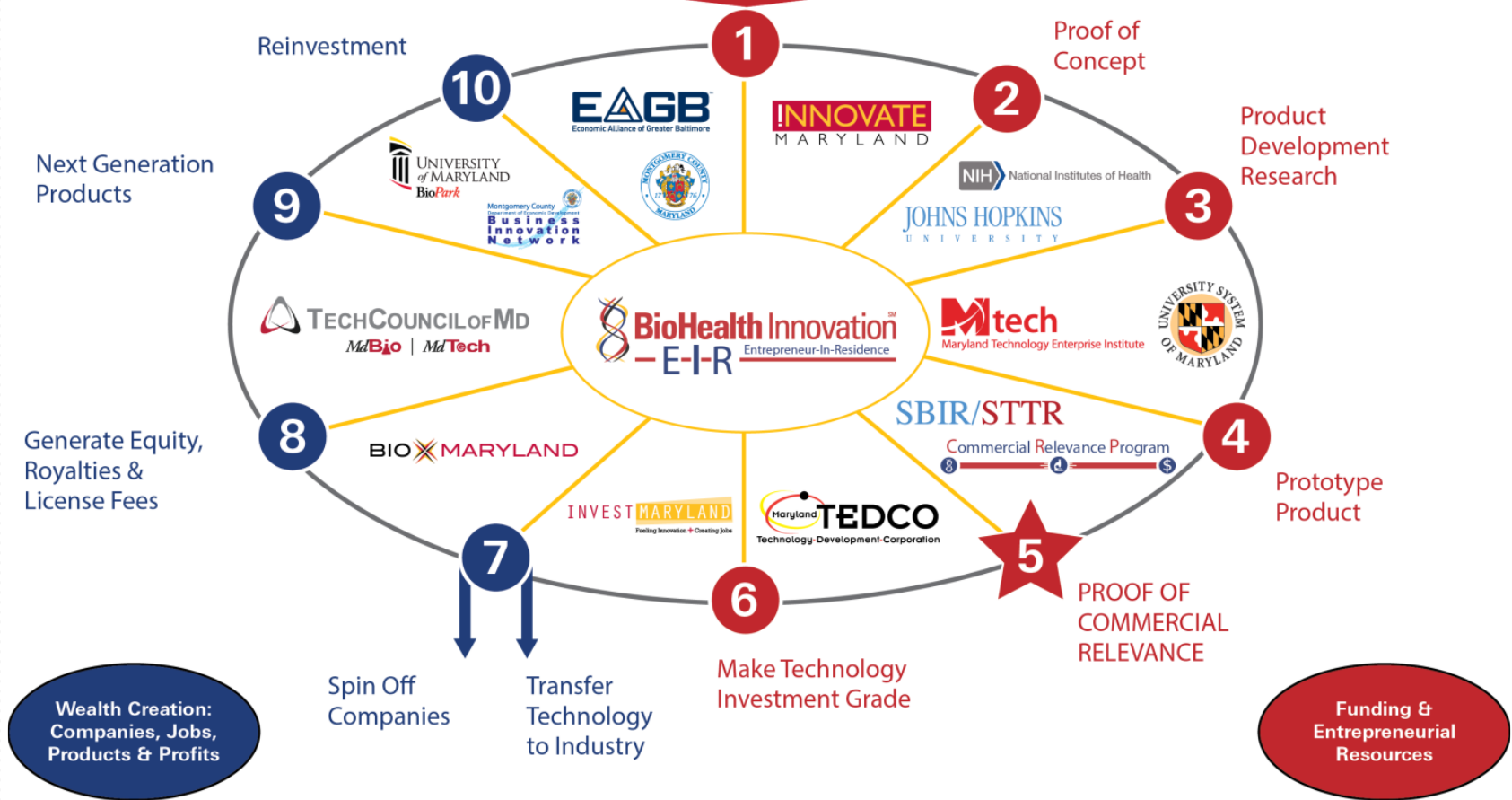
Grows and markets
businesses and
products





BHI Commercialization Model

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





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.



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.



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



Todd Chappell

Progress (1+ Years into Program)

- 97 Innovations identified and initially screened
- 72 NIH and 31 industry technology reviews conducted in 2013
- Entered into consulting agreement with Perceptive Navigation
- Entered into agreement with Ahead Research, Living Discoveries, Mimetas, N5 Sensors, and Perceptive Navigation
- 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**



BHI 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.



Rich Moore (BD Diagnostics)

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.



The Startup Company Spectrum

Startup Spectrum

BHI Sweet Spot



Idea
Technology



True NewCo
Inventor
IP



Early Stage
Inventor
IP
Non-Dilutive Funding



Seed Stage
Management Team
IP Portfolio
Seed Funding
Proof-of-Principle



Series A
Management Team
IP Portfolio
VC Funding
Technology De-risked





Different technologies = Different Strategies

Biomarker

Therapeutic

Mobile Health

Imaging

e-Health

Medical
Device

Diagnostic

Research
Tools

Personalized
Medicine
Service



EIR Expectations



National Institutes
of Health

- 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



BioHealth InnovationSM
Maryland's Commercialization Collaborative

- 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

!NNOVATE

Maryland's Innovation Initiative

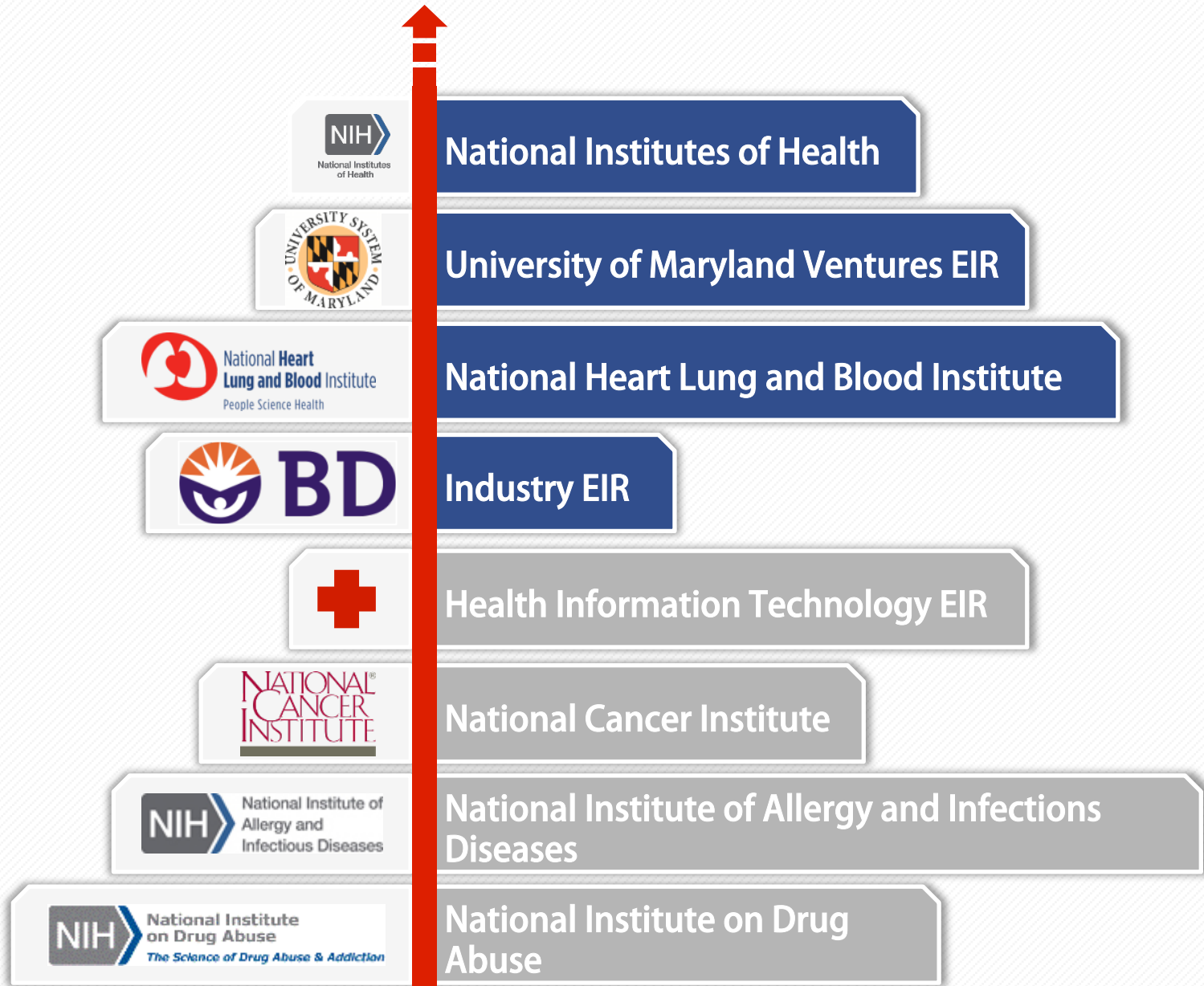
- **\$5.8M budget**
- **5 University partners**
- **5 University site miners**
- **40 University pre proof-of-concept technologies funded**
- **\$25-\$150K funded per technology**



- **Regular meetings between BHI/EIR and site miners**
- **BHI identifies most commercially relevant technologies**
- **BHI and INNOVATE MD partnership opportunities**
- **BHI Commercial Relevance Advisory Board (CRAB)**



EIR Expansion 2013

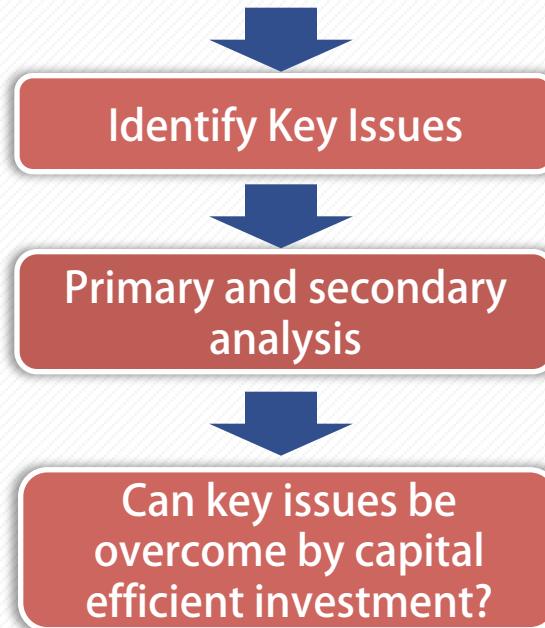




Early Stage Analysis of Commercial Relevance

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



Small Business Innovation Research (SBIR) Grant

- \$2.5 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 \$150,000 and \$1 million
- Non-dilutive

SBIR/STTR
SMALL BUSINESS INNOVATION RESEARCH
SMALL BUSINESS TECHNOLOGY TRANSFER



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.

Metrics:

- Review 60 federal funding proposals per year
 - Conduct 20 intensive assistance projects in 2013
 - Track success measures through scoring, dollars, and leverage assistance.
- **BHI Angel Fund** - The BHI Angel Fund (in development) will be a member-managed private equity investment fund serving the Central Maryland region entrepreneurial needs.
- **BHI Commercial Relevance Investment Fund** - The BHI Commercial Relevance Investment Fund (in development) will help grow, attract, retain and connect Central Maryland biohealth innovation-based companies that need financing to grow their enterprises.



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

Source: Q1 2013 Halo Report

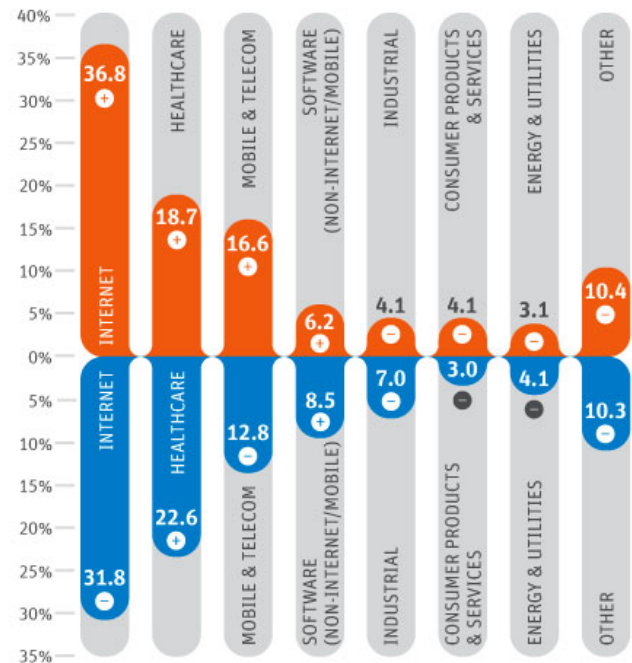
4 Mobile Sector Still Hot

Deals and Dollars



in Internet,
Healthcare
and Mobile

% of deals



\$m invested

- + Indicates an increase over Q1 2012
- Indicates a decrease from Q1 2012



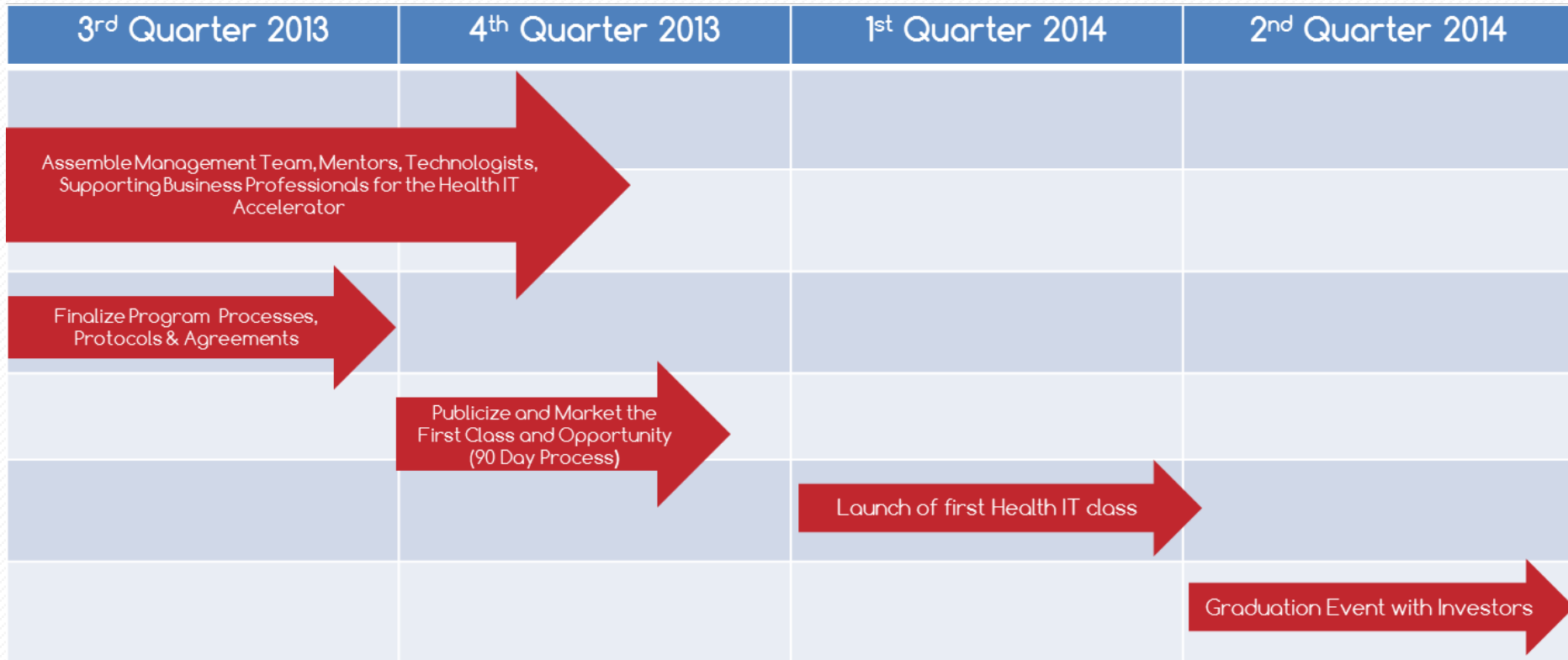
BHI Health IT Accelerator

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.

- No HIT accelerators currently in Maryland
- Partner with Dreamit Ventures/JHU
- Located in a Central Maryland Co-Working space
- Retain promising high growth HIT entrepreneurs in MD
- Scheduled to launch in January 2014

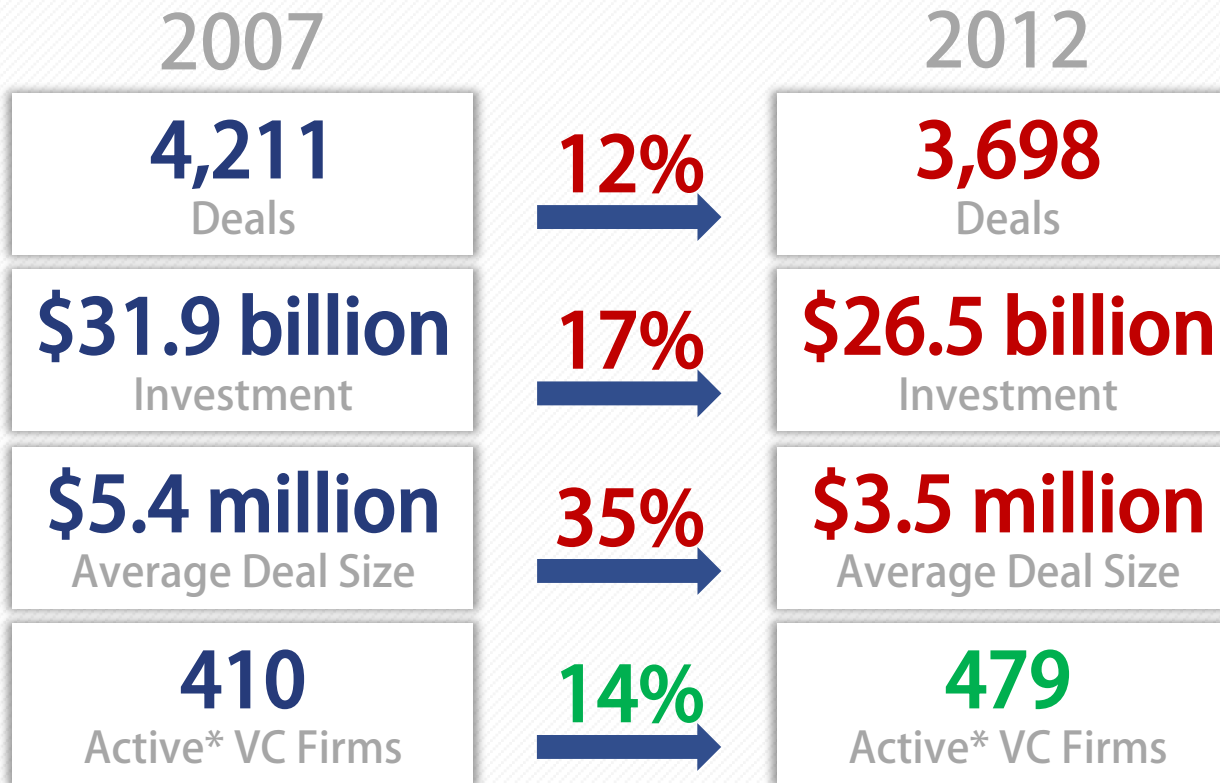


DreamIt Health Baltimore Accelerator





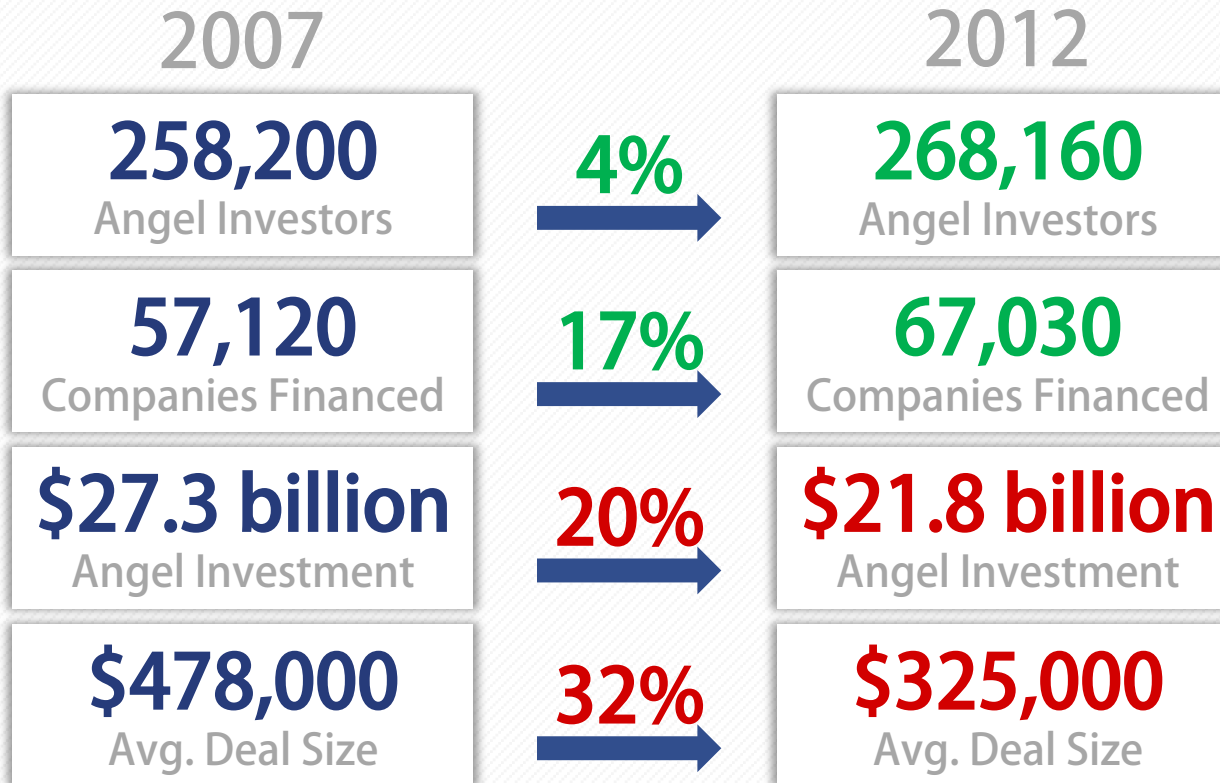
US Venture Capital Investment



*VC firms completing 4 or more deals per year



US Angel Investment





BHI Commercial Relevance 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 \$10,000,000 to \$20,000,000 initial fund
- Expectation: 30% of companies generating 10x the original investment
- 2014 — Identify Investors



BHI International Partnership with CFLD

华夏幸福基业

CHINA FORTUNE LAND DEVELOPMENT



- A professional enterprise group in investment and operation of industrial areas
- Entered into a Memorandum of Understanding (MOU) with BioHealth Innovation
 - Chinese-American EIR
 - Health Information Medical Technology Accelerator
 - Early Stage BioHealth Venture Capital Investment Fund



BHI President & CEO Rich Bendis after signing the MOU with CFLD President Ho



BHI International Soft Landing

- For **international** companies that want access to US agencies such as the NIH, FDA, MCNS, and others.
- Establish international EIRs to accelerate innovation
- Receive all the help necessary to establish a US subsidiary

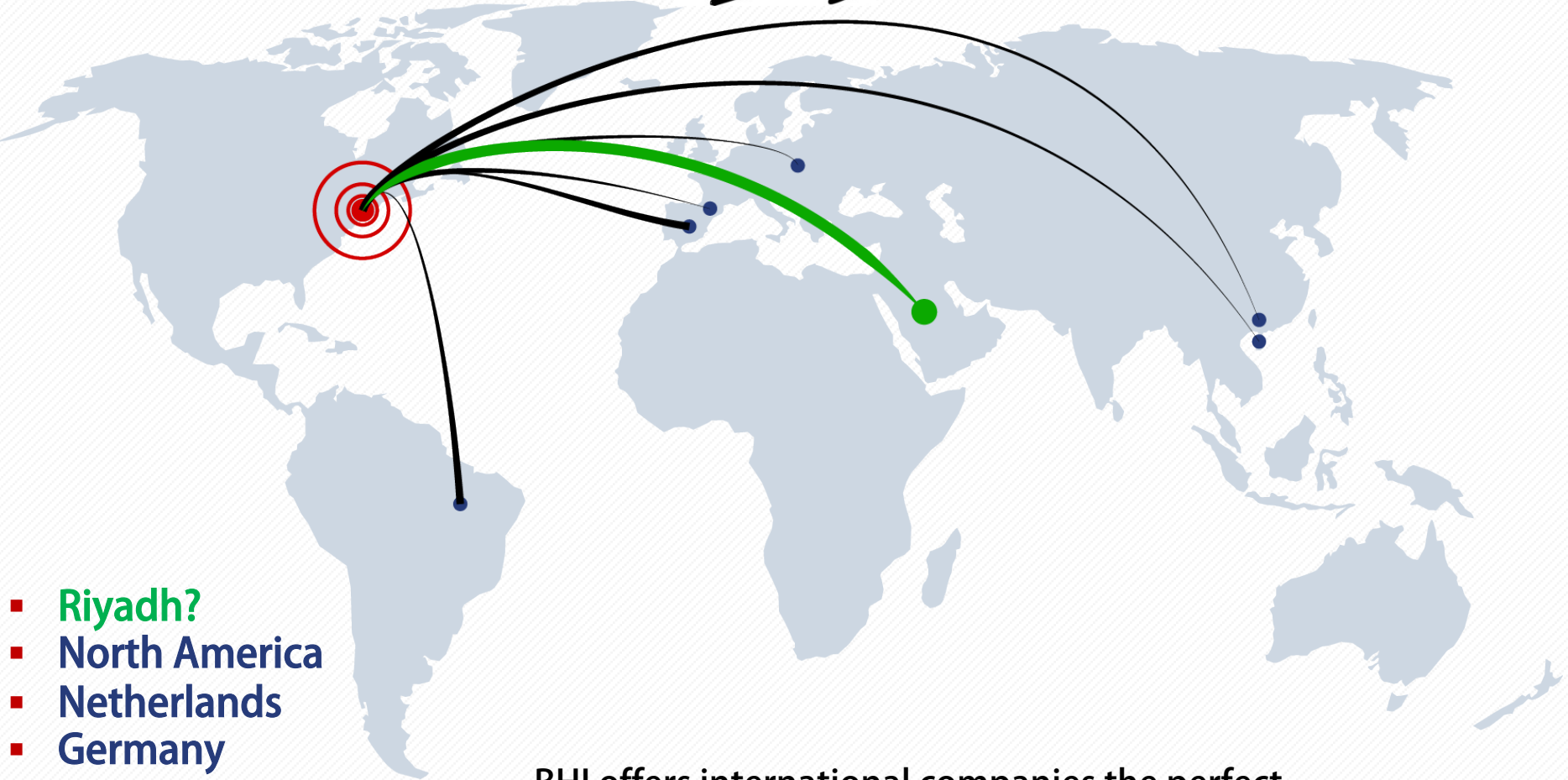


Mimetas

- Created a new US subsidiary
- BHI is an equity partner
- Primary objective is to conduct business activities and research



BHI International Soft Landing

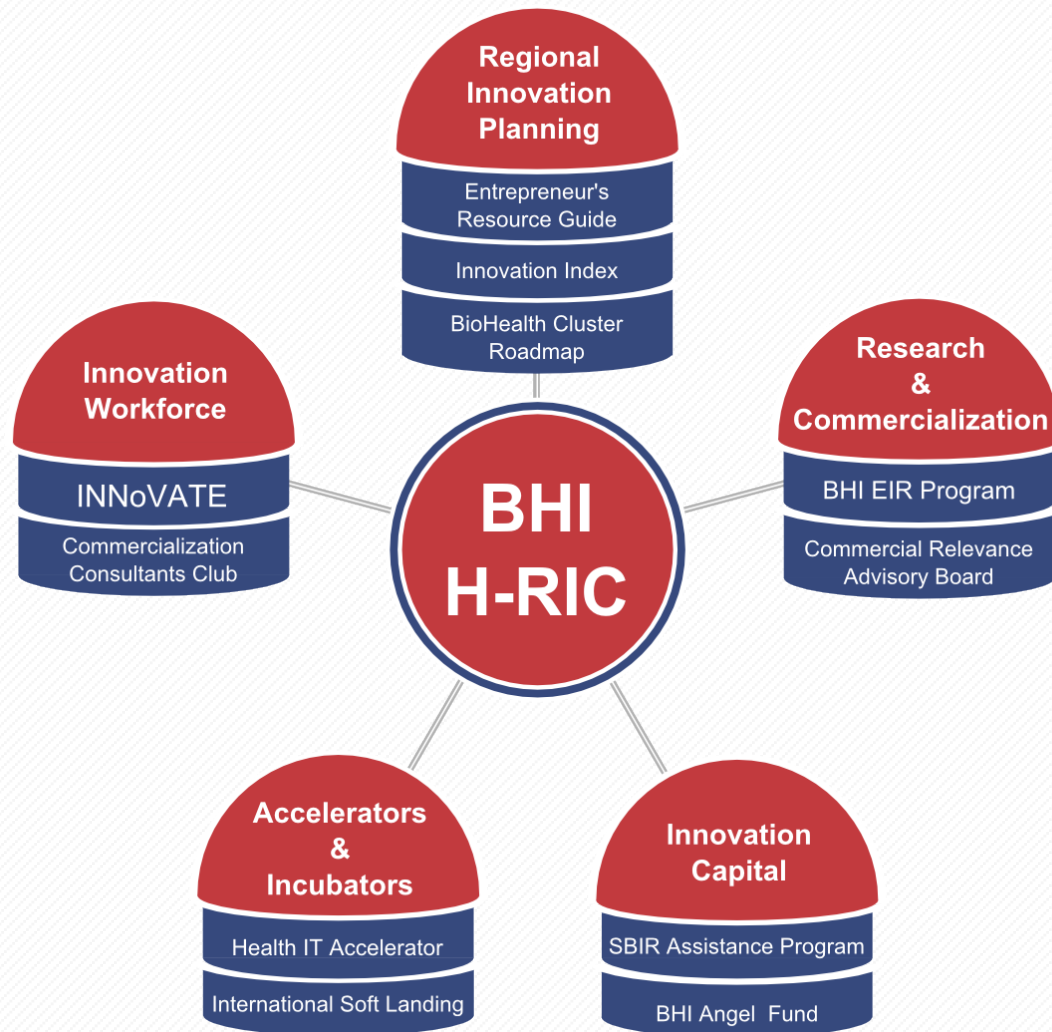


- **Riyadh?**
- **North America**
- **Netherlands**
- **Germany**
- **China**
- **Korea**
- **Portugal**
- **South America**

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



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

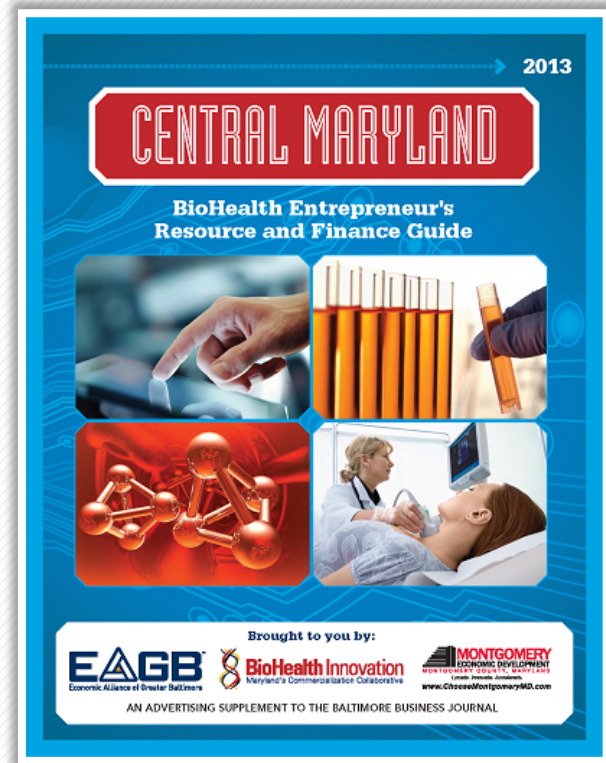


Entrepreneur's Resource and Finance Guide



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 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

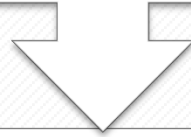
BHI's weekly e-newsletter highlights the Central Maryland Region's news articles, national biohealth trends and feature stories.

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

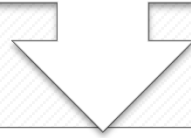


BHI: The Triple Bottom Line

Grows high-paying jobs and businesses



Expands tax base; improves economic vitality



... and Benefits human health!



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