



Innovation Collaboration with the Frederick National Laboratory for Cancer Research

October 10, 2012

Richard A. Bendis

President & CEO

www.BioHealthInnovation.org



Maryland

- 5.64 % of Gross State Product attributed to federal research and development spending (Source: SSTI, 2009 Data)
 - Highest of any State in the U.S.
- Maryland Federal R&D investment over \$12 billion annually
- 59 Federal Laboratories, Centers, & Institutes in Maryland



"The Region"--Central Maryland

Unrivaled Research Assets Unfulfilled Commercial Promise

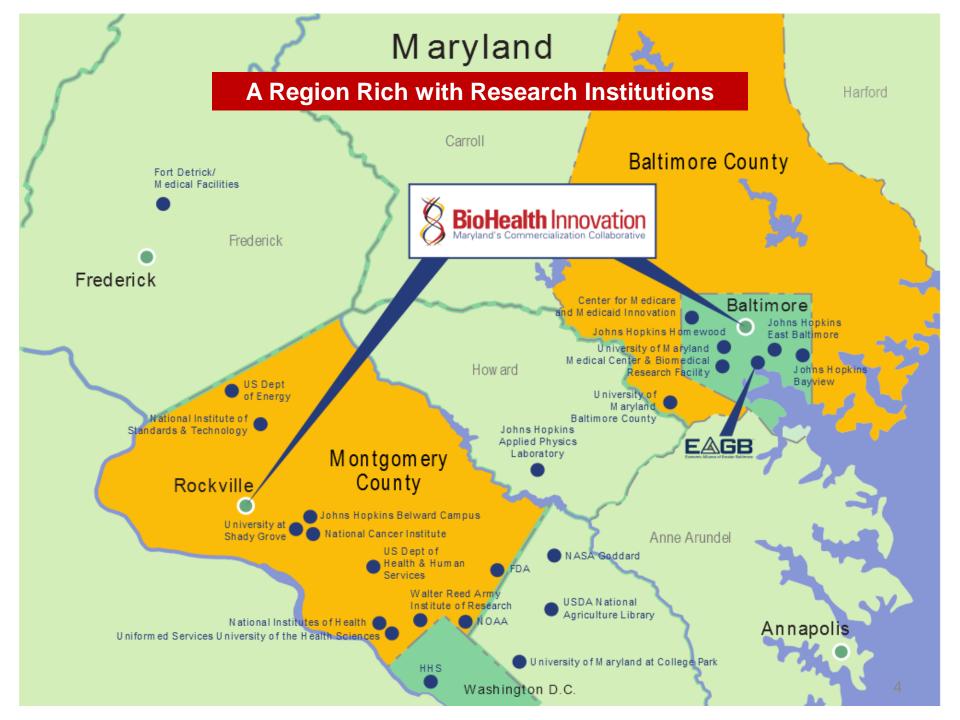












Alignment of National, State, and Regional Policies



Obama Administration



Governor O'Malley (Maryland)



County Executive lke Leggett Montgomery County



Stephanie Rawlings -Blake Mavor of Baltimore

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



Challenges to Innovation Economy

Lack of connection of innovation resources

Lack of an entrepreneurial culture and C-level executives

Lack of early-stage funding for commercializing technologies

Lack of a STEM Workforce

BHI Value Proposition

Connects regional innovation assets

Develops an entrepreneurial talent and support pipeline

Attracts funding for technology commercialization

Develops a continuum of innovation workforce



BioHealth Regional Innovation Cluster Assets















Technology-Development-Corporation

































National Biodefense Analysis and Countermeasures Center















What is A Regional Innovation Intermediary?

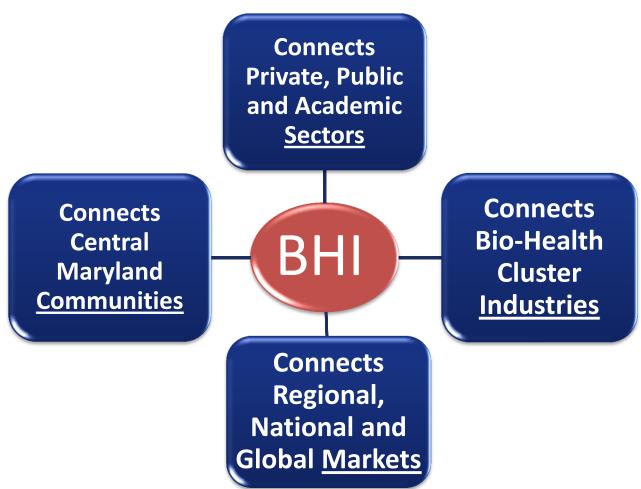
- An organization at the Center of the region's, state's and country's efforts
 - Align local technologies, assets and resources
 - Advance Innovation



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



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





Regional BioHealth Ecosystem Partners

ACADEMIA

- RESEARCH/T2
- LIFELONG LEARNING
- ECONOMIC DEVELOPMENT

INDUSTRY

- PROFIT
- PROCESS
- PRODUCT

INSEPARABLE MISSIONS

GOVERNMENT

- Sustainability
- FEDERAL LABORATORIES
- INFRASTRUCTURE SUPPORT
 - ECONOMIC POLICY

FOUNDATIONS

- Economic Growth
- COMMUNITY INVESTMENT
- REGIONAL COLLABORATION



BHI Partners and Sponsors







































BHI Board of Directors



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Managing Director, Venable LLP



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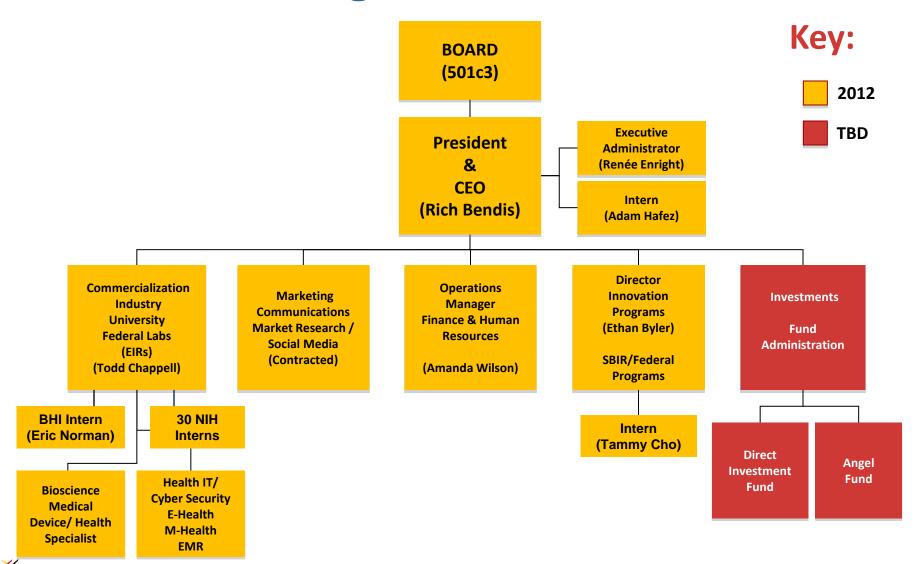


Thomas Street

Assistant Chief Administrative Officer, Montgomery County Government



BHI Organizational Chart



BioHealth Innovation

Maryland's Commercialization Collaborative

BHI/EIR Technology Focus

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



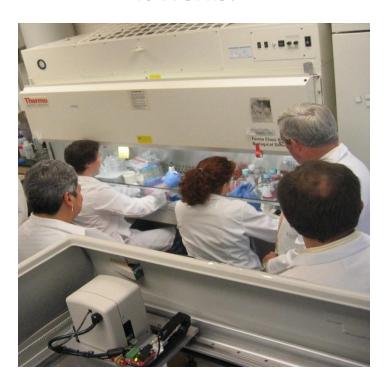




Innovation Paradigm Shift

PROOF OF CONCEPT
(Technological Feasibility)
Laboratory Push

"It Works!"





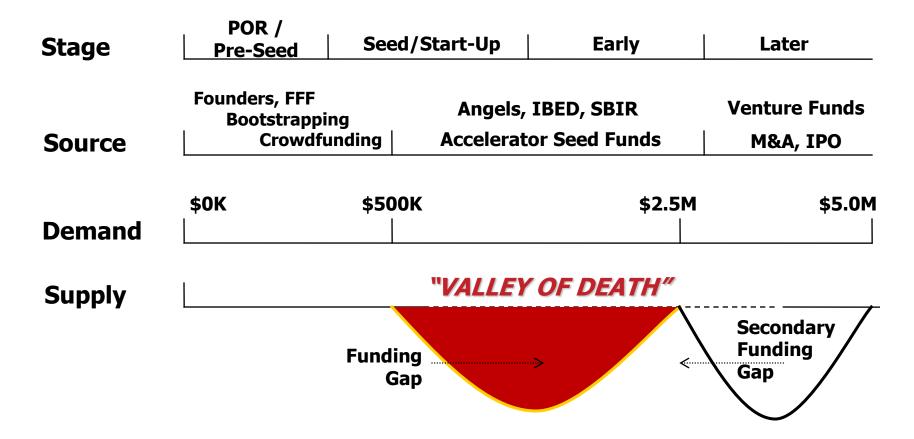
PROOF OF COMMERICAL RELEVANCE (Market Pull)

"It Works To Solve A Problem"
"I'll Buy It"





Innovation Capital "VALLEY OF DEATH"





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.



Central Maryland Innovation Capital Map

Capital Sources by Investment Stage

| Capital Sources by Investment Stage | | | | | |
|---|--|--|--|--|--|
| Pre-Proof of Concept \$25K - \$1.5M (over 5 years) | Translational Research / Proof of Concept \$15K - \$2M | Proof of Commercial Relevance / Pre-Seed \$50K - \$500K | Seed / Start-Up \$50K - \$1M | Early Stage \$250K - \$2M | Later Stage \$2M+ |
| NIH R01 NIH R03 NIH R21 Small Business Technology Transf Research Grant (STTR) Phase I Innovate Maryland | INIH Center for Accelerated Innovations (CAI) NCATS Cures Acceleration Network (CAN) Small Business Innovation Research Grant (SBIR) Phase I Maryland Stem Cell Research Fund (MSCRF) TEDCO University Technology Development Fund (UTDF) TEDCO TechStart Maryland Biotechnology Center's Translational Research Award | Maryland Industrial Partnerships (MIPS @ UMD) Maryland Biotechnology Center's Biotechnology Commercialization Awards TEDCO Maryland Technology Transfer and Commercialization Fund (MTTCF) BHI SBIR/STTR Commercial Relevance BHI Commercial Relevance | Dingman Center Angels (UMD) TEDCO Johnson & Johnson Joint Investment Program Propel Baltimore Fund SBIR / STTR Phase II BHI Central Maryland Angel Fund National Association of Seed & Venture Funds (NASVF) Angel Capital Association (ACA) | Maryland Health Care Product Development Corporation (MHCPDC) Invest Maryland: Maryland Venture Fund | Maryland Venture Fund Authority ABS Capital Partners Greenspring Associates Novak Biddle Venture Partners Sterling Venture Partners Harbert Venture Partners JMI Equity National Venture Capital Association (NVCA) |
| Association of University Resource Par Association of University Technology M Licensing Executive Society (LES) Academic BioHealth Innovation, Inc. Innovation-based Economic Development (IBED) Associations State of Maryland | | echnology Managers (AUTM) by (LES) | | New Enterprise Associates (NEA) TDF Abell Venture Fund MMG Ventures LP Mid-Atlantic Venture Association (MAVA) | |

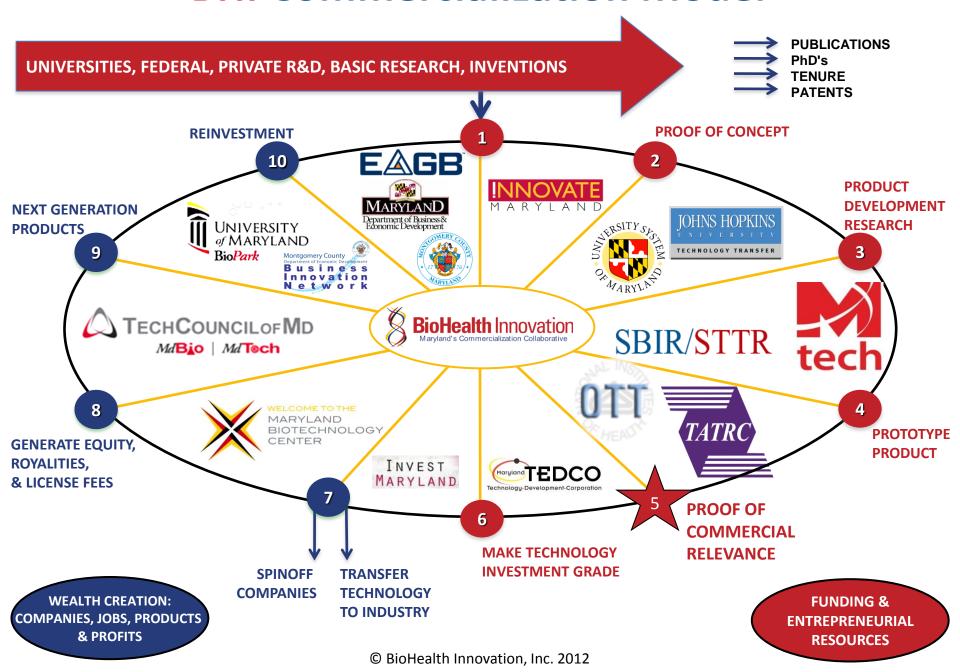


Federal

Venture Capital

Montgomery County Biotechnology

BHI Commercialization Model







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**
- Doing Business with the Federal Labs



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
- 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



Benefits of Inclusion:

- Exposure to businesses, entrepreneurs, nonprofit organizations and government leaders.
- Opportunity to market assistance and investment programs to a large audience.

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

For more information, visit:

www.biohealthinnovation.org www.greaterbaltimore.org







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



Partnership Intermediary Agreements (PIA)



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.



Entrepreneur-in-Residence (EIR)

- Identify market viable biohealth assets
- Act as liaison among federal labs, academic, industry, venture capital, and non-profit
- Detailed commercial evaluation of most valuable technologies
- Provide early-stage developmental strategies
- Nurture relationships with scientists, mentor to ensure research becomes commercially valuable, and track progress
- Identify creative funding to advance exciting, novel technologies
- Enable licensing and create new BioHealth companies



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:

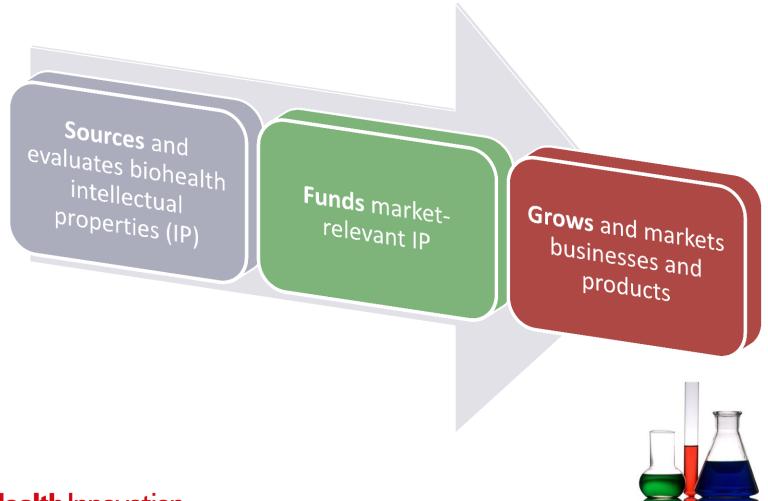
- Federal Labs
- Universities
- Private Sector

Progress (6 months into Program)

- 73 Innovations identified and initially screened
- 7 Progressed to Secondary Analysis (Safety & Efficacy Profiling, IP Diligence, Regulatory & Development Pathways) and 12 to Primary Analysis
- 32 No De-prioritized, 22 still Under Review
- Goal to fund the operation of more EIRs



How does BHI work? Commercialization Pipeline





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



Identifying Opportunities

Lead Approach (NIH)

Technology Review Committees

Technology Transfer Branch Chiefs and Licensing Managers

Successful Scientists

<u>Systematic Approach</u> (NIH + Other Institutions)

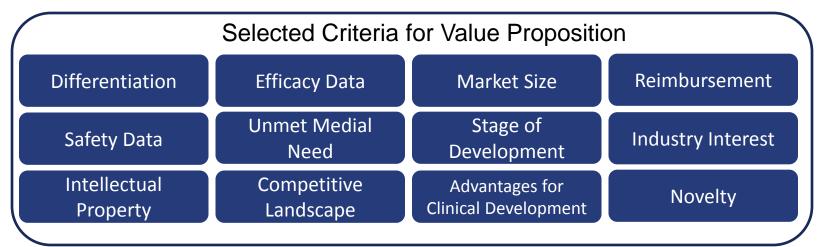
Evaluation of market needs from regional players

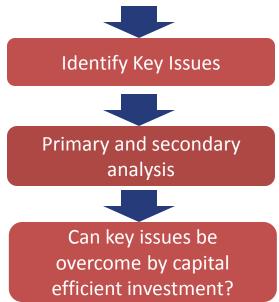
Directed analysis using database and meetings with scientists

Commercial, development, and funding analysis



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 biohealth areas that reflect strategic objectives
- Clinical development advantage
- Relevance to strategic needs



EIR Integration into NIH System

- Office at the central Office of Technology Transfer (OTT)
 - Non-clinical collaborator
 - Report to Director and Deputy Director of centralized OTT
 - Full access to NIH campus and staff
 - Training 30 NIH Interns & Fellows on Commercialization
- 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 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



Maryland Universities/EIR Interaction

INNOVATE Maryland's Innovation Initiative

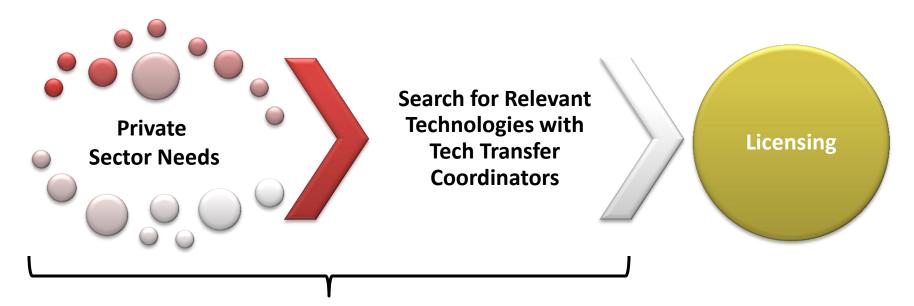
- \$5.8M budget
- 5 University partners
- 5 University site miners
- 40 University pre proof-ofconcept technologies funded
- \$25-\$150K funded per technology



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



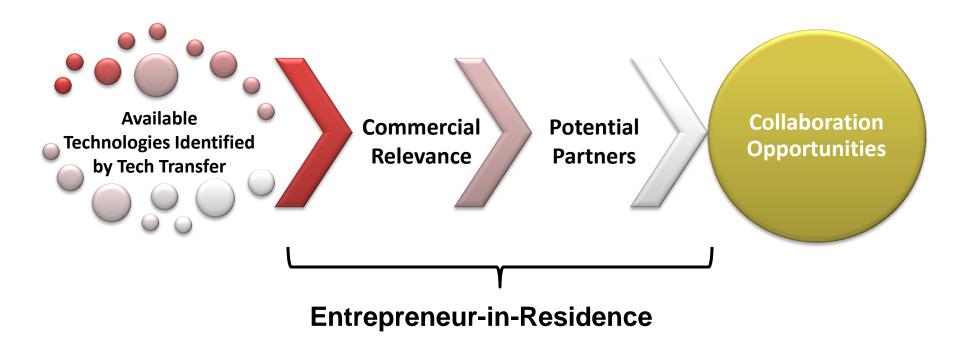
Licensing Opportunities



Entrepreneur-in-Residence



Collaboration Opportunities





Working Together Today!







Tech Transfer Speaker Series National Cancer Institute SBIR session

- SBIR Contract Solicitation Discussion today
- BHI promoting and working with NCI SBIR companies



BHI Partner Organization: MedImmune Partners With Cancer Institutes To Test New Antibodies





- **Cancer Research Institute (CRI)**
- **Ludwig Institute for Cancer Research**



BHI/NCI Collaboration Opportunities





- BHI/NCI Dedicated EIR
- BHI/NCI Commercial Relevance Opportunity Fund
- BHI/NCI Commercial Relevance Acceleration Team

Next Steps...



BHI Staff

Richard Bendis

President & CEO (215) 593-3333 rbendis@bendisig.com

Renée Enright

Executive Administrator (301) 637-5372 renright@biohealthinnovation.org

Todd Chappell

Entrepreneur-In-Residence (978) 933-1622 tchappell@biohealthinnovation.org

Amanda Wilson

Operations Manager (301) 637-0699 awilson@biohealthinnovation.org

Ethan Byler

Director, Innovation Programs (301) 637-7952 ebyler@biohealthinnovation.org

Adam Hafez

Student Intern
(301) 637-7270
ahafez@biohealthinnovation.org

BioHealth Innovation, Inc.

22 Baltimore Road | Rockville, MD 20850

bhi@biohealthinnovation.org



