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 -
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
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
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

Connects Private, Public and Academic Sectors

Connects Central Maryland Communities

Connects Bio-Health Cluster Industries

Connects Regional, National and Global Markets

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BHI Partners and Sponsors

Private Sector
- GSK
- AstraZeneca
- BD
- Adventist HealthCare
- SR-One
- Roche
- MedImmune
- Emergent BioSolutions
- Northrop Grumman
- Venable LLP
- Kaiser Permanente
- United Therapeutics Corporation
- M&T Bank
- Capital Management LLC
- Deloitte
- Perenx Inc
- DreamIt Health Baltimore
- GenVec
- Ernst & Young
- NEA
- Cassidy Turley / Commercial Real Estate Services
- Alexandria
- Sigma-Tau Pharmaceuticals, Inc.

Government
- Montgomery Economic Development Corporation
- University of Maryland Innovate Maryland Network
- Invest Maryland
- Frederick County Government
- National Heart, Lung, and Blood Institute
- National Institutes of Health
- BioMaryland
- Innovate Maryland
- EDA
- Maryland of Opportunity
- Frederick

Academia
- University System of Maryland
- bwtech@UMBC
- University of Maryland Ventures
- University of Maryland BioPark
- University of Maryland
- Johns Hopkins University
- MTech

NGOs
- Economic Alliance of Greater Baltimore
- Tech Council of Maryland
- TEDCO Technology Development Corporation
# BHI Board of Directors

<table>
<thead>
<tr>
<th>BHI Board of Directors</th>
<th>Pending</th>
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<tbody>
<tr>
<td><strong>Daniel J. Abdun-Nabi</strong>&lt;br&gt;CEO, Emergent BioSolutions</td>
<td><strong>Joel Marcus</strong>&lt;br&gt;CEO &amp; Founder &lt;br&gt;Alexandria Real Estate</td>
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<tr>
<td><strong>Michael J. Baader, Esq.</strong>&lt;br&gt;General Counsel &lt;br&gt;Greenspring Associates</td>
<td><strong>Beth Meagher</strong>&lt;br&gt;Director &lt;br&gt;Deloitte Consulting LLP</td>
</tr>
<tr>
<td><strong>Richard A. Bendis</strong>&lt;br&gt;President &amp; CEO &lt;br&gt;BioHealth Innovation, Inc.</td>
<td><strong>William E. Kirwan</strong>&lt;br&gt;Chancellor &lt;br&gt;University System of MD</td>
</tr>
<tr>
<td><strong>Kenneth Carter</strong>&lt;br&gt;Chair &lt;br&gt;Noble Life Sciences</td>
<td><strong>Douglas Liu</strong>&lt;br&gt;Senior VP of GO &lt;br&gt;Qiagen</td>
</tr>
<tr>
<td><strong>Dave Lemus</strong>&lt;br&gt;CEO &lt;br&gt;Sigma-Tau Pharmaceuticals</td>
<td><strong>Charles Morton</strong>&lt;br&gt;Partner &lt;br&gt;Venable LLP</td>
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<tr>
<td><strong>Chris Callaghan</strong>&lt;br&gt;Group VP, Healthcare Banking &lt;br&gt;M&amp;T Bank</td>
<td><strong>David Mott</strong>&lt;br&gt;General Partner &lt;br&gt;New Enterprise Associates</td>
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<tr>
<td><strong>Ronald J. Daniels</strong>&lt;br&gt;President &lt;br&gt;Johns Hopkins University</td>
<td><strong>John A. Sackett</strong>&lt;br&gt;President &lt;br&gt;Shady Grove Adventist Hospital</td>
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<td><strong>Jens Eckstein</strong>&lt;br&gt;President &lt;br&gt;SR One (GSK)</td>
<td><strong>J. Thomas Sadowski</strong>&lt;br&gt;President &amp; CEO &lt;br&gt;EAGB</td>
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<tr>
<td><strong>David M. Gillece (Secretary)</strong>&lt;br&gt;Regional Managing Principal &lt;br&gt;Cassidy Turley</td>
<td><strong>Reginald Seeto</strong>&lt;br&gt;VP, Partnering and Strategy &lt;br&gt;MedImmune</td>
</tr>
<tr>
<td><strong>Rick Ivey</strong>&lt;br&gt;Vice PresidentR&amp;D &lt;br&gt;BD Diagnostics</td>
<td><strong>Thomas Street</strong>&lt;br&gt;ACAO &lt;br&gt;MoCo Government</td>
</tr>
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<td><strong>Jens Eckstein</strong>&lt;br&gt;President &lt;br&gt;SR One (GSK)</td>
<td><strong>Judith Dunn</strong>&lt;br&gt;Vice President, Global Head of Clinical Dev. &lt;br&gt;Roche</td>
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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

### Stage

<table>
<thead>
<tr>
<th>POR / Pre-Seed</th>
<th>Seed/Start-Up</th>
<th>Early</th>
<th>Later</th>
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<tbody>
<tr>
<td>Founders, FFF</td>
<td>Angels, IBED, SBIR</td>
<td>Venture Funds</td>
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<tr>
<td>Bootstrapping</td>
<td>Accelerator Seed Funds</td>
<td>M&amp;A, IPO</td>
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<tr>
<td>Crowdfunding</td>
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### Source

- $0K
- $500K
- $2M
- +$5.0M

"VALLEY OF DEATH"

### Supply

- Funding Gap
- Secondary Funding Gap

BioHealth Gap Fund
# BHI Innovation Capital Map

<table>
<thead>
<tr>
<th>Pre-Proof of Concept</th>
<th>Translational Research/Proof of Concept</th>
<th>Proof of Commercial Relevance/Pre-Seed</th>
<th>Seed/Start-Up</th>
<th>Early Stage</th>
<th>Later Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>$25,000 - $1,500,000 (over 5 yrs)</td>
<td>$15,000 - $750,000 (over 3 yrs)</td>
<td>$3,000 - $500,000</td>
<td>$50,000 - $1,500,000</td>
<td>$200,000 - $2,000,000</td>
<td>$2,000,000+</td>
</tr>
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</table>

- NIH R01
- NIH R03
- NIH R21
- 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
- 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
- TEDCO Technology Commercialization Fund
- TEDCO Maryland Innovation Initiative - Phase 3
- SBIR/STTR Phase 2
- BioHealth Gap Fund
- Dingman Center Angels (UMD)
- BioMaryland Biotechnology Dev. Award - Translational Research
- TEDCO Patents Assistance Program
- TEDCO Technology Commercialization Fund
- TEDCO Maryland Innovation Initiative - Phase 3
- SBIR/STTR Phase 2
- BioHealth Gap Fund
- 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
- 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
- Federal
- Economic Development
- Private Capital

## Tax Credits

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

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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

1. Proof of Concept
2. Product Development Research
3. Prototype Product
4. Commercial Relevance Program
5. Proof of Commercial Relevance
6. Make Technology Investment Grade
7. Spin Off Companies
8. Transfer Technology to Industry
9. Next Generation Products
10. Reinvestment

Wealth Creation: Companies, Jobs, Products & Profits

Funding & Entrepreneurial Resources

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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.
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

<table>
<thead>
<tr>
<th>NIH</th>
<th>Industry</th>
<th>University</th>
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<tbody>
<tr>
<td>141</td>
<td>78</td>
<td>40</td>
</tr>
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</table>

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

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

MockV
Developing novel viral clearance kits to be utilized during process development biotherapeutics.

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

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

Mehr Medical
Moco-based Startup

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

MockV
Moco-based Startup

Mimetas
US-based Subsidiary of Dutch Company

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

N5 Sensors, Inc.
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 immunotoxins for the treatment of solid and liquid tumors.

Speed Biosystems, Inc.
Moco-based Startup

Baltimore

MockV
NHLBI

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

Miracle Medical
Mimetas

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

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MockV
NHLBI

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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
Keys to Small Business Success

**Courage**
The willingness to take risks

**Perseverence**
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 Concept Review
  - Ensure Appropriateness for the Federal Agency

- Application Technical Support
  - Guidance through Federal Registration Process

- Proposal Development
  - In-Kind Guidance on Proposal Best Practices

- Funding for High-Quality Proposals
  - Intensive Support with Professional Consultant

Funding Agencies

- NSF
- Bill & Melinda Gates Foundation
- USAID
- DARPA
- NIH (National Institutes of Health)
- NIH (National Center for Advancing Translational Sciences)
- BARDA (Biomedical Advanced Research and Development Authority)
- CDMRP (Congressionally Directed Medical Research Programs)
- USAMRIID (United States Army Medical Research Institute of Infectious Diseases)
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

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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.
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
<table>
<thead>
<tr>
<th>Company</th>
<th>Specialty</th>
<th>Location</th>
<th>JHU Affiliated</th>
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<tbody>
<tr>
<td>Aegle</td>
<td>Wearable biometric devices</td>
<td>Baltimore, MD</td>
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<tr>
<td>Avhanahealth</td>
<td>Practicing smarter medicine</td>
<td>Baltimore, MD</td>
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<tr>
<td>Cognuse</td>
<td>Mobile Cognitive Rehabilitation</td>
<td>Talinn, Estonia</td>
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<tr>
<td>Emocha</td>
<td>Mobile Information Platform</td>
<td>Baltimore, MD</td>
<td></td>
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<tr>
<td>Protenus</td>
<td>Protecting Patient Data</td>
<td>Baltimore, MD</td>
<td></td>
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<tr>
<td>REspi</td>
<td>Respiratory Medical Device</td>
<td>Athens, Greece</td>
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<tr>
<td>Patientfeed</td>
<td>Inpatient Care Collaboration</td>
<td>Pittsburgh, PA</td>
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<tr>
<td>Phobious</td>
<td>Augmented Reality Treatment</td>
<td>Barcelona, Spain</td>
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<tr>
<td>Quantifiedcare</td>
<td>Digital Workflow Management</td>
<td>Baltimore, MD</td>
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US Venture Capital Investment

2007

- **4,211** Deals
- **$31.9 billion** Investment
- **$5.4 million** Average Deal Size
- **410** Active* VC Firms

2014 (H1)

- **2099** Deals
- **$1.5 billion** Investment
- **$10.6 million** Average Deal Size
- **141** Active* VC Firms

*VC firms completing 4 or more deals per year

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US Angel Investment

2007

- 258,200 Angel Investors
- 57,120 Companies Financed
- $26.0 billion Angel Investment
- $478,000 Avg. Deal Size

% % % %

2013

- 298,800 Angel Investors
- 70,730 Companies Financed
- $24.8 billion Angel Investment
- $350,600 Avg. Deal Size
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
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 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
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.

**NIH**

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.

**Postdoc Conference & Career Fair**

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.

**FastTrac**

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™**

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

Not currently active
BHI: The Triple Bottom Line

Grows high-paying jobs and businesses

Expands tax base; improves economic vitality

...and benefits human health!
BHI Key Staff

BioHealth Innovation, Inc.
22 Baltimore Road | Rockville, MD 20850
bhi@biohealthinnovation.org

Richard Bendis
President & CEO
(215) 593-3333
rbendis@biohealthinnovation.org

Todd Chappell
EIR, NIH-OTT
(978) 933-1622
tchappell@biohealthinnovation.org

Ken Malone
EIR, UM Ventures
(601) 466-7050
kmalone@biohealthinnovation.org

Ram Aiyar
EIR, NHLBI
(301) 624-5505
raiyar@biohealthinnovation.org

Richard Moore
EIR, BD Diagnostics
(301) 637-3385
rmoores@biohealthinnovation.org

Ethan Byler
Director, Innovation Programs
(301) 637-7952
eblyer@biohealthinnovation.org

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

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

Adam Hafez
IT Manager
(301) 637-7270
ahafez@biohealthinnovation.org

Arielle Dolegui
Business Research Analyst
(301) 637-3381
adolegui@biohealthinnovation.org

Eric Norman
EIR Program Consultant
(301) 594-7219
Eric.Norman@nih.gov

Ashwin Kulkarni
EIR Intern
akulkarni@biohealthinnovation.org

Peter Parker
Research Intern
pparker@biohealthinnovation.org

Rebecca Farkas
EIR Intern
rfarkas@biohealthinnovation.org

Anthony Saleh
EIR Fellow
asaleh@biohealthinnovation.org

Tao Yu
EIR Intern
tyu@biohealthinnovation.org

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