“The Region” - Montgomery County

Unrivaled Research Assets
Unfulfilled Commercial Promise
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
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 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
Regional BioHealth Ecosystem Partners

**ACADEMIA**
- Research/T2
- Lifelong Learning
- Economic Development

**INDUSTRY**
- Profit
- Process
- Product

**GOVERNMENT**
- Sustainability
- Infrastructure Support
- Economic Policy

**FOUNDATIONS**
- Economic Growth
- Community Investment
- Regional Collaboration

INSEPARABLE MISSIONS
BHI Partners and Sponsors
<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daniel J. Abdun-Nabi</td>
<td>CEO, Emergent BioSolutions</td>
</tr>
<tr>
<td>Michael J. Baader, Esq.</td>
<td>Managing Director, Venable LLP</td>
</tr>
<tr>
<td>Richard A. Bendis</td>
<td>President &amp; CEO, BioHealth Innovation, Inc.</td>
</tr>
<tr>
<td>Scott Carmer (Chair)</td>
<td>Executive Vice President of Commercial Operations, MedImmune</td>
</tr>
<tr>
<td>Kenneth Carter</td>
<td>Chair, Noble Life Sciences</td>
</tr>
<tr>
<td>Cynthia L. Collins</td>
<td>President &amp; CEO, GenVec</td>
</tr>
<tr>
<td>Scott Dagenais</td>
<td>Senior Vice President, M&amp;T Bank</td>
</tr>
<tr>
<td>Ronald J. Daniels</td>
<td>President, Johns Hopkins University</td>
</tr>
<tr>
<td>Jens Eckstein</td>
<td>President, SR One (GSK)</td>
</tr>
<tr>
<td>David M. Gillece (Secretary)</td>
<td>Regional Managing Principal, Cassidy Turley</td>
</tr>
<tr>
<td>William E. Kirwan</td>
<td>Chancellor, University System of Maryland</td>
</tr>
<tr>
<td>Douglas Liu</td>
<td>Senior Vice President of Global Operations, Qiagen</td>
</tr>
<tr>
<td>David Mott</td>
<td>General Partner, New Enterprise Associates</td>
</tr>
<tr>
<td>Jay Ridder</td>
<td>Office Managing Partner, Ernst &amp; Young</td>
</tr>
<tr>
<td>William G. Robertson (Treasurer)</td>
<td>President &amp; CEO, Adventist Healthcare</td>
</tr>
<tr>
<td>J. Thomas Sadowski</td>
<td>President &amp; CEO, Economic Alliance of Greater Baltimore</td>
</tr>
<tr>
<td>Thomas Street</td>
<td>Assistant Chief Administrative Officer, Montgomery County Government</td>
</tr>
</tbody>
</table>
Budget

• Total FY '13 Funding: **$1,702,617.16 from 20 funders.**
  (This does not include potential federal grant funding or commitments from new charitable donors.)

• Montgomery County is contributing $500,000 to BHI in 2013, which represents 29.4% of the organization's total FY '13 funding.

• The County's contribution to BHI is leveraged 3.4 times.

![FY' 13 Total BHI Funding Pie Chart]

- Montgomery County
- Other Funding
BHI Office – The Wire Hardware Store

BioHealth Innovation's office located in Rockville, Maryland by the Rockville Metro Station.

• Co-located with

MBDC
Montgomery Business Development Corporation
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”
30 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.
BHI Commercialization Model

1. PROOF OF CONCEPT
2. PRODUCT DEVELOPMENT
3. RESEARCH
4. PROTOTYPE
5. SBIR/STTR
6. MAKE TECHNOLOGY INVESTMENT GRADE
7. TRANSFER TECHNOLOGY TO INDUSTRY
8. GENERATE EQUITY, ROYALTIES, & LICENSE FEES
9. NEXT GENERATION PRODUCTS
10. REINVESTMENT

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

PUBLICATIONS
PhD's
TENURE
PATENTS

WEALTH CREATION: COMPANIES, JOBS, PRODUCTS & PROFITS
FUNDING & ENTREPRENEURIAL RESOURCES
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.
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 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
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 (1 Year 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
Maryland Universities/EIR Interaction

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

- UMV EIR: Ken Malone
- 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)
NIH EIR Expansion 2014

• Request for funding to create an EIR network due to the success of NIH OTT EIR (considered “one of the highlights of the year” in their report)

• Suggests placing EIRs at all major components of biomedical research at NIH

• Working with Kevin Kelly, a lobbyist retained by Montgomery County
EIR Expansion 2013

- National Institutes of Health
- University of Maryland Ventures EIR
- National Heart Lung and Blood Institute
- National Cancer Institute
- Health Information Technology EIR
- Industry EIR
NIH PostDocs

30 NIH Postdocs and Interns helping Todd Chappell identify and evaluate technologies.

• Provides applied training for post-doctoral fellows, research scientists, and other professionals who want to start life science-based companies.

• Participants learn to:
  • Evaluate the commercial potential of a technology
  • Create a business operational plan
  • Articulate their investment opportunity to investors/business partners
NIH National Heart, Lung and Blood Institute (NHLBI)

- Potential Entrepreneur-in-Residence
- Center for Accelerating Innovation (TBD within 2 months)
What is the Overall Process for Licensing / Creating Company?

**Industry Needs**
- Stage of Development
- IP Status
- Level of unmet medical need
- Industry interest
- Competitive advantage
- Scientific reputation
- Market Size and Differentiation

**Identification**
- Scientists
- Tech transfer
- NIH review meetings
- NIH Licensing Managers
- NIH database
- Existing Companies

**Market Analysis**
- Literature Review
- Investor Input
- IP Diligence
- Physician Input
- Regulatory Input
- Reimbursement Input
- CRAB Input

**Funding**
- IC (e.g. NCATS)
- SBIR-TT
- CRADA
- TEDCO
- Invest MD
- BioHealth Innovation
- Angel funding
- Venture capital
## BHI Client Companies

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Perceptive Navigation, LLC</strong></td>
<td>Medical Device: Develops medical devices related to image-guided, minimally-invasive markets</td>
</tr>
<tr>
<td><strong>Advanced Personalized Diagnostics, LLC</strong></td>
<td>Personalized Cancer Care: Offers chemosensitivity profiling services to provide personalized treatment plans</td>
</tr>
<tr>
<td><strong>Mimetas</strong></td>
<td>Pharmaceutical: Organ-on-a-Chip solutions as an early screening model to predict toxic side effects and drug efficacy</td>
</tr>
<tr>
<td><strong>Ahead Research, Inc.</strong></td>
<td>Personalized Diagnostics: Web/Mobile application that matches patients to high quality healthcare providers</td>
</tr>
</tbody>
</table>
### Capital Sources by Investment Stage

<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>$25K - $1.5M (over 5 years)</td>
<td>$15K - $750K (over 3 years)</td>
<td>$3K - $500K</td>
<td>$50K - $1.5M</td>
<td>$200K - $2M</td>
<td>$2M+</td>
</tr>
</tbody>
</table>

**Pre-Proof of Concept**
- NIH R01
- NIH R03
- NIH R21
- Maryland Innovation Initiative (MII) (Managed by TEDCO)
- 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

**Translational Research / Proof of Concept**
- 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)

**Proof of Commercial Relevance / Pre-Seed**
- Dingman Center Angels (UMD)
- Propel Baltimore Fund
- BioMaryland Center Biotechnology Development Awards - Translational Research
- SBIR / STTR Phase II
- BHI Central Maryland Angel Fund

**Seed / Start-Up**
- Invest Maryland: Maryland Venture Fund
- BioMaryland Center Biotechnology Development Corporation
- Abell Venture Fund
- MMG Ventures LP
- TDF

**Early Stage**
- 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)

**Later Stage**

### 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
- Federal
- BioHealth Innovation, Inc.
- Economic Development
- Private Capital

### Tax Credits
- Maryland Biotechnology Investor Tax Credit
- Montgomery County Biotechnology Investor Tax Credit
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.
BHI SBIR/STTR: Commercial Relevance Program (CRP)

Central Maryland SBIR Candidates

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

Companes Invited by BHI to submit SBIR concept

Scientific Experts
SBIR Consultants
BHI

Reviews, Feedback, Troubleshooting, Strategy

Full Proposal Preparation Assistance
Mentoring $$$
BHI offers international companies the perfect starting point to create US based subsidiaries by connecting them with BHI’s extensive network.
Mimetas

Pharmaceutical
Organ-on-a-Chip solutions as an early screening model to predict toxic side effects and drug efficacy
Paul Vulto and Jos Joore

Pieris AG

Therapeutics
Pieris AG is an independent, clinical stage biotechnology company working to create safer, more efficacious and more convenient protein therapeutics.
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: Q3 2012 Halo Report
Montgomery County Initiatives

Health IT Roundtable

- March 19th, 2013
- Done in conjunction with DED
- Involved 10 Health IT Entrepreneurs identifying what their needs were
Health IT Accelerator

- A Health IT Accelerator is an intensive 12-16 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

- Located in a Central Maryland Co-Working space

- Retain promising high growth HIT entrepreneurs in MD
Central Maryland 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
Upcoming Events

BioHealth Innovation, Inc. presents the upcoming Investor/Partnership Day at Johns Hopkins School of Medicine. This time, we would like to invite your company as one of the presenters on this day.

Location
Hopkins BioTech Park
Rangos Building
855 North Wolfe Street
Floor #1 Idea Room

Date and Time
Wednesday, May 15th
6:30am - TBD

Description
BHI - JHU Investor/Partnership Day

Wine after Work at the Wire

You are cordially invited...

Please join Rich Bendis, Ken Carter, Cindy Collins, and the BHI team for our first CEO wine tasting event. Come mingle with other CEOs in the local biotech community. We will provide light appetizers and ask that you bring a bottle to share.

If you know of another business leader who would enjoy this event please let us know and we will extend the invitation.

Directions:
The BHI office is conveniently located within walking distance from the Rockville Metro Station. When driving, the BHI office is accessible only from Rockville Pike (Hankord Drive 2013) by making a turn onto Church St. and driving until it becomes Baltimore Road. Our office is located on the corner. Parking is available in an adjacent lot.

Where:
BHI at the Wire
22 Baltimore Road
Rockville, MD 20850

Time:
5:00pm - 7:00pm

RSVP:
Renée Efron
renée@biohealthinnovation.org

Montgomery County Small Business Awards

Join the Montgomery County Department of Economic Development to celebrate small businesses. Attend the inaugural Small Business Awards program.

The awards luncheon will provide countless opportunities to show your appreciation for the estimated 35,000 small businesses of Montgomery County—businesses that contribute directly to the strength of the area’s economy. Eight awards will be presented to eight distinct companies:

- Innovative Company of the Year
- Information Technology Company of the Year
- Start-up Business of the Year
- Workforce Award
- Montgomery County: Innovation Network Company of the Year
- Small Business Award (1-49 Employees)
- Small Business Award (50-99 Employees)
- Small Business Award (100+ Employees)

Start thinking about your nominations today!

Related Resources
- Event and Registration Information
- 2013 Small Business Awards Nomination Form
- Bookkeeper Information

Friday, May 24 • 11:30am - 2:00pm • Marriott Bethesda North Conference Center, 4811 Marriott Road, North Bethesda, Maryland 20852
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
BHI: The Triple Bottom Line

- **Grows** high-paying jobs and businesses
- **Expands tax base; improves** economic vitality
- **...and Benefits** human health!
BHI Staff

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