FLC&EIR
5/1/2012
Pittsburgh, PA

www.biohealthinnovation.org
“The Region”--Central Maryland

Unrivaled Research Assets
Unfulfilled Commercial Promise

[Logo images of various institutions]
A Region Rich with Research Institutions
America is falling behind the world it invented because we are:

- Out-educated
- Out-built in infrastructure
- Out-invested in R&D by countries in both Europe and Asia.

--“That Used to Be Us” by Thomas Friedman, 2011

The Reverse Brain Drain


- American returnees to India cited as reasons for going “back” to where they came from:
  - Better Economic Opportunities
  - Family Ties
  - Better Access to Markets
National Leadership

President Obama’s Bioeconomy Initiatives & America Invents Act (2011)

• America Invents Act

• Center for Advancing Translational Sciences in NIH to advance commercialization (NCATS)

• Develop a National Bioeconomy Blueprint
  – Support R&D investments
  – Facilitate the transition from research lab to market
  – Reduce barriers, increase speed and predictability of regulatory process, and reduce cost.
  – Update training programs and align academic institutions incentives
  – Identify and support the development of PPPs and pre-competitive collaborations
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

Maryland Department of Business & Economic Development

University System of Maryland

Montgomery County, Maryland

Johns Hopkins University

Economic Alliance of Greater Baltimore

Tech Council of MD

Maryland TEDCO

National Institutes of Health

NEA

National Cancer Institute

Welcome to the Maryland Biotechnology Center

Montgomery County, Maryland

Montgomery College

NCATS

NIST

Center for Medicare & Medicaid Innovation

Walter Reed Army Medical Center

Rockville Economic Development, Inc.

USDA

Howard Hughes Medical Institute

HHMI

National Biodefense Analysis and Countermeasures Center

FDA

USAMRIID

J. Craig Venter Institute

United States Army Fort Detrick

BioHealth Innovation

Maryland's Commercialization Collaborative
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
• Not a government initiative, nor a membership organization
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

BHI Funding Sources:
• private sector
• universities and foundations
• public sector
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”

<table>
<thead>
<tr>
<th>Stage</th>
<th>POR / Pre-Seed</th>
<th>Seed/Start-Up</th>
<th>Early</th>
<th>Later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>Founders, FFF</td>
<td>Angels, IBED, SBIR</td>
<td>Venture Funds</td>
<td></td>
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<tr>
<td></td>
<td>Bootstrapping</td>
<td>Accelerator Seed Funds</td>
<td>M&amp;A, IPO</td>
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<td></td>
<td>Crowdfunding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demand</td>
<td>$0K</td>
<td>$500K</td>
<td>$2.5M</td>
<td>$5.0M</td>
</tr>
</tbody>
</table>

The diagram illustrates the funding gap during the Seed/Start-Up stage, often referred to as the “Valley of Death.” This phase is critical as it requires additional funding, which is often difficult to secure. Sources of funding include investors, accelerators, and seed funds. The diagram highlights the challenge of bridging the gap between seed funding and early-stage venture capital. The BioHealth Innovation logo is shown in the bottom left corner.
How does BHI work?

Commercialization Pipeline

- **Sources** and evaluates biohealth intellectual properties (IP)
- **Funds** market-relevant IP
- **Grows** and markets businesses and products
Partnership Intermediary Agreement (PIA)

• PIA between BHI and NIH’s Office of Technology Transfer 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.
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
- Create new BioHealth companies
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
EIR: Fulfilling the BHI Mission to Connect Industry, Academia, and Community
Example of 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

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

• Intramural budget is approximately $3B per year
  – 6,000 scientists
  – 27 institutes and centers (ICs)

• Three largest centers: NCI, NIAID, and NHLBI
  – In aggregate represents more than half of invention filings

• Centralized Office of Technology Transfer
  – Responsible for patenting
  – Technology transfer specialist at each institution
  – ~150 licensing staff members at NIH
NIH License Statistics

- 351 invention disclosures in 2011
- 197 licensed agreements in 2011
- 25% of licenses in 2011 were ‘commercial patents’
NIH License Statistics

• More than 400 licenses reported sales of products in FY11 with combined total annual sales approaching $6B
• 22 FDA approved drugs and biologics were developed under licenses from NIH in the last 40 years
NIH Success Stories

Top 5 Commercially Successful Therapeutic / Vaccine Inventions (by royalty to NIH)

1. Protease Inhibitor for Treatment of Drug-Resistant HIV-1

2. HPV Vaccine Based Upon Recombinant Papillomavirus Capsid Proteins

3. Monoclonal Antibody for Treatment of RSV

4. Proteosome Inhibitor for Treatment of Multiple Myeloma

5. Nutritional Supplement to Treat Macular Degeneration
Experience to Date

• Clear need and desire for commercial perspective and expertise
• No dedicated person going through opportunities systematically
• Current OTT process not optimized for successful licensing
• Entrepreneurial spirit not part of organizational culture
• Significant number of technologies will need further development prior to license / start-up companies
Identifying Opportunities

**Lead Approach (NIH)**

- Technology Review Committees
- Technology Transfer Branch Chiefs and Licensing Managers
- Successful Scientists

**Systematic Approach (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

### Selected Criteria for Value Proposition

<table>
<thead>
<tr>
<th>Differentiation</th>
<th>Efficacy Data</th>
<th>Market Size</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Data</td>
<td>Unmet Medial Need</td>
<td>Stage of Development</td>
<td>Industry Interest</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Competitive Landscape</td>
<td>Advantages for Clinical Development</td>
<td>Novelty</td>
</tr>
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</table>

### Process Flow

1. **Identify Key Issues**
2. **Primary and secondary analysis**
3. **Can key issues be overcome by capital efficient investment?**
Scientific and Commercial Committee

- BHI Board Members
- Industry Experts
- Thought Leaders
- Venture Capital
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?

**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
Industry Feedback

EIR identifies asset (e.g. NIH, University)

- Additional experimentation
  - Creative funding
  - NIH programs
  - Institution investment

Scientific / Commercial Validation

- Does not meet BHI strategic objectives
- Meets BHI strategic objectives

License

- License
  - Regional companies
  - Established with development expertise takes on asset

VC/BHI/Angel Funding

- Traditional Biotech
  - Platform technology / portfolio of products
  - Build internal team
  - Lab space

- Project-focused Company
  - Single asset
  - One FTE
  - Consultants
  - Virtual operation

Novel technology, but not ready for investment
Funding Mechanisms

• Institution or Center participates in direct funding of innovation
• Cooperative Research and Development Agreement (CRADA)
  – Written agreement between a private company and a government agency to work together on a project
  – Allows the Federal government and non-Federal partners to optimize their resources, share technical expertise, share intellectual property emerging from the effort, and speed the commercialization
EIR Key Issues

• Managing expectations and keeping BHI mission focus
• Linking EIR with internal commercial and scientific expertise
• Types of biohealth technologies to initially target
• Structure of companies to initially target
• Role of non-BHI, regional biotechnology companies
**EIR Next Steps**

- Introduce the EIR concept to additional BHI stakeholders / ICs
- Continue to get embedded into the NIH system
- Forge relationships with non-NIH organizations and institutions
- Identification of private sector needs
- Initiate commercial evaluation of innovations
- Identify and present diversified pilot projects to key stakeholders
- COMMERCIALIZE!
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