SSTI

TBED Community of Practice Entrepreneurship Development Subcommunity

March 26, 2025

Casey Nemecek, Program Director, SSTI

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About SSTI & the TBED Community of Practice

- **Our mission:** SSTI strengthens initiatives to create a better future through science, technology, innovation and entrepreneurship.
- **Project goals:** Strengthen EDA awardees during period of performance + better-position for long-term success
- **Our audience:** State & local governments, non-profits, higher education, federal labs including all interested EDA awardees



Upcoming Meetings

- Lab-to-Market: April 8 at 2:00 PM ET
- Ent. Dev.: April 23 at 3:00 PM ET

<u>On the road</u>:

- InBIA: April 7-9 (Philadelphia)
- Global Entrepreneurship Conference: June 2-5 (Indianapolis)





SSTI Entrepreneurship Development TBED Community of Practice Entrepreneur-in-Residence Discussion



Rich Bendis Founder, President, and CEO BioHealth Innovation, Inc.

Wednesday, March 26, 2025





A Top 3 BioPharma Cluster in 2023 & 2024



Ranking Based on Five Criteria:

- **1. NIH Funding**
- 2. Venture Capital
 - Funding
- 3. Patents
- 4. Lab Space
- 5. Jobs

Top 10 U.S. Biopharma Clusters 2024

- 1. San Francisco Bay Area
- 2. Boston/Cambridge, MA
- 3. BioHealth Capital Region (Maryland/Virginia/DC Metro)
 - 4. New York/New Jersey
 - 5. Los Angeles/Orange County, CA
 - 6. San Diego
 - 7. Greater Philadelphia
 - 8. Raleigh-Durham, NC (Inc. Research Triangle Park, NC)
 - 9. Seattle
 - 10.Chicagoland



BioHealth Capital Region: An Overview of the BHCR – Where You Should Be



• Top Tier Research Universities

Including Johns Hopkins and the University System of Maryland provide a pipeline of talent & intellectual property

78 National Labs & Research Institutes

Including NIH, ARL, NRL, and NASA Goddard that receive \$19 billion annually and provide technical talent and a pipeline of tested, commercializable technologies

Regulatory & Governmental Bodies

Including FDA, CMS, and HHS provide thought leadership in the ecosystem and insight into what changes are next

Concentration of Science & Engineering Talent

From universities, national labs, and government positions with the technical skills to launch high-tech startups, especially with licensed intellectual property

Established Cluster of BioHealth Companies

Over 2,300 BioHealth companies in BHCR from multinational corporations to cutting edge startups



BioHealth Innovation an Innovation Intermediary

A public-private partnership, serving as an innovation intermediary in the BioHealth Capital Region with a mission to:

- Advance local technologies, assets and resources
- Accelerate innovation

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Globally connect sectors, industries, communities, and markets



Regionally-oriented Private-public partnership, 501(c)(3) nonprofit BioHealth Innovation Management, a for-profit subsidiary Market-driven, private sector-led and funded Neither a government initiative, nor a membership organization



Challenges to Innovation Economy

Lack of connection of innovation resources

Lack of an entrepreneurial culture & C-level executives

Lack of early-stage funding for commercializing technologies

Solutions for the Innovation Economy

Connect regional innovation assets

Develop an entrepreneurial talent & support pipeline

Attract funding for technology commercialization

Lack of spin-offs from federal & university R&D Evaluate commercially relevant federal & university technology

Regional BioHealth Ecosystem Partners





Meet Our Team 8 BioHealth Innovation



Rich Bendis President & CEO



Lynne Brisbane VP Finance, HR, Operations





Finance, HR, Manager of Operations



Mona Suliman Life Science Business Strategist

Residence

Chris Mathia

ARPA-H EIR



Bennett

Senior Life Science

Business Strategist





Strategist



Oliva Meyer NIH/OER Life Science Business Strategist



Marketing

IT/Systems



Entrepreneurs in Residence & Montgomery County Executives in Residence









Manager



Joseph DiCesare ARPA-H EIR

Albine Martin

BHI/JHU/EIR





Kuldeep Nolte

NIH/NIA/EIR





Deanne Randolph

Executive in

Residence







Jonathan Kay

Executive in

Residence

NHLBI/EIR



Sharon Knight ARPA-H EIR





Susan Solinsky



ARPH-A



Stephen Wolpe NIH Seed/ EIR





Maureen Richard ARPA-H EIR



NIH/NIA/EIR





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Loleta Robinson ARPA-H EIR

Ethel Rubin NIH/OER/EIR

Doug Liu

ARPA-H EIR

ARPA-H EIR







John Sullivan

Michael Thomas

Kimberly Martin

NIH/NHLBI/EIR



Kwame Ulmer

BioHealth Innovation Board of Directors

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MoCo, MD MoCo, MD

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NIH (Headquarters, Bethesda, MD) EIR Partnership Agreements



National Institutes of Health Office of Extramural Research



Lead NIH OER EIR EIR NH, SEED EIR EIR NH, SEED EIR NH, SEED EIR EIR NH, SEED EIR

NIH Consulting Entrepreneur Services Contract for 13 NIH Entrepreneurs-in-Residence





PIA between BHI and NIH's Office of Extramural Research (OER) that supports the 27 NIH institutes and \$48 billion extramural research budget to **promote and foster cooperative research and accelerate technology commercialization** among NIH businesses, and universities.



Exclusive BHI EIR Partnership with ARPA-H

BHI signed a PIA agreement with the ARPA-H, a \$1.5 Billion HHS Institute, to provide EIRs to their performers

- 1. BHI is providing part-time EIRs to ARPA-H funded Performers and Program Managers which started December 2023.
- 2. Strategic Collaboration: BHI and ARPA-H have joined forces to enhance the development and commercialization of innovative health solutions.
- **3.** Entrepreneurs-in-Residence (EIRs): BHI will provide EIRs with strategic guidance to ARPA-H Program Managers in crucial areas such as technology development, intellectual property, and small business needs.
- **4. Bridge to Market Realization:** The partnership aims to bridge the gap between innovation and market realization, ensuring that transformative health solutions reach those who need them most.
- 5. **Embedded Support:** EIRs will provide embedded support to ARPA-H funded performers, assisting in business plan development, commercialization strategy, market research, and more.
- 6. Transition to Market: EIRs will actively contribute to the transition of ARPA-H funded solutions into the market and identify new programs aligned with ARPA-H's primary mission.
- 7. Learn More: To explore this exciting collaboration further, read full announcement.



University EIR Commercialization Support







GEORGETOWN UNIVERSITY



University of California San Francisco



VZ VIRGINIA TECH





Montgomery County Executives in Residence

Montgomery County is funding BHI's work as part of its mission to grow the local life sciences cluster

Launched in November 2022 – inspired by BHI's well-regarded NIH program, which features over a dozen experts in various disciplines embedded within different institutes.

Goal is to provide impactful, life-sciences-specific services to a few local companies, opposed to general business assistance to many.

Jen Butler

The "MoCo" EIRs may provide:

- Technology Validation,
- Coaching on Clinical Development Plan,
- Assistance with Customer Discovery,
- Regulatory and Reimbursement strategies,
- Market Assessment,

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- Connections to Essential Service Providers.
- Identification of Key Opinion Leaders and Strategic Partners,
- **Business Development Networks**
- Non-Dilutive Funding Assistance, and
- Other Assistance to Launch and/or Advance the Business.

Montgomery County is also funding assistance from specialized experts, attorneys, and regulatory experts that cannot be provided by EIRs. Any early or growth-stage BioHealth company headquartered in Montgomery County may be eligible for free assistance.







Luis Gutierrez

Kevin Heller Jonathan Kay Albine Martin

Steve Wolpe

Testimonial: Solaxa – Bethesda, MD

Bethesda-based **Solaxa Inc.** is pioneering small molecule drugs (aminopyridines) to restore nerve function in both rare and non-rare diseases. Since its founding, the company has grown from a single full-time employee to a team of **17 professionals**, leveraging expert guidance from **BHI's Executive-in-Residence (EIR) Program** to accelerate its commercialization strategy.



Through the **MoCo EIR program**, advisors **Luis Gutierrez and Jennifer Butler** provided critical support in clinical development, fundraising strategy, and regulatory pathways. Their guidance helped Solaxa secure a **\$500K TEDCO investment**, **\$4.6M in angel funding**, and a **\$7.3M Department of Defense grant** to fund its **Phase III clinical trials**. Additionally, Solaxa received **Orphan Drug Designation** from the FDA and successfully submitted an **Investigational New Drug (IND) application**, clearing the way for clinical trials.

Recognized for its rapid progress, Solaxa was named "**Best of MoCo**" at the 2022 **Crab Trap Pitch Competition** and "**Venture of the Year**" by the **Maryland Tech Council** in 2023. Today, the company continues its groundbreaking work with its former EIRs now serving in fractional C-level roles.

"The MoCo EIR services helped us build momentum, attract top talent, and secure the funding and regulatory milestones necessary for our success."

— Christian Walker, Founder & CEO



Testimonial: Hememics Biotechnologies – Gaithersburg, MD

Hememics Biotechnologies, a Gaithersburg-based company specializing in graphene sensor technology, leveraged BHI's Executive-in-Residence (EIR) Program to successfully reposition its business strategy. Initially focused on diagnostics, the company faced lengthy FDA approval timelines. With EIR guidance, Hememics pivoted to a sensor technology company, enabling a more agile path to commercialization.



Under the mentorship of **Steve Wolpe, Albine Martin, and Jen Butler**, Hememics refined its **commercial strategy, investor pitch deck, and branding** to move beyond its original **COVID-era focus**. The team facilitated **introductions to investors and bankers**, supported **capital-raising efforts**, and helped the company **secure a term sheet for a drugtesting chip**, a key validation step for closing additional deals, including with the **Department of Defense (DOD/Defcon)**.

Thanks to these efforts, Hememics engaged with **Congresswoman April Delaney (6th District)**, who has pledged to assist in their capital raise. The company is now on the verge of securing the funding necessary to **expand into a new manufacturing facility**, marking its transition from an **R&D firm to a commercial manufacturer in Montgomery County**.

"The MoCo EIR services were invaluable in repositioning our business strategy and preparing us for investment. Without this support, we wouldn't be in a position to raise the capital needed to close our first deal and scale into manufacturing."

— John Warden, Founder & CEO



Testimonial: Cellphire – Rockville, MD

Cellphire Therapeutics, a **Rockville-based** biotech company, is advancing **freeze-dried and cryopreserved platelet** technologies with two products in clinical trials. With a **32,000-square-foot facility**, including state-of-the-art **clean-room manufacturing**, the company is now shifting from a **clinicalstage** biotech to **commercial readiness**—a transition supported by **BHI's Executive-in-Residence (EIR) Program**.



Under the guidance of **Jennifer Butler**, Cellphire received strategic **commercialization insights**, including **orphan drug designation timing, executive hiring, and commercialization strategy workshops**. Butler's mentorship helped **accelerate the hiring of commercial talent** and identify **a senior executive to join the team in June 2024**, positioning Cellphire for its first product launch.

Recognized as an **"Emerging Life Science Company of the Year"** by the Maryland Tech Council, Cellphire has leveraged **key industry connections and executive coaching** to **refine its commercial strategy** and avoid common pitfalls in the transition from R&D to market.

"Talk about value for MoCo's money! Jen Butler's insights, introductions, and executive guidance have significantly accelerated our commercialization efforts. Her mix of challenge and support has been instrumental in preparing our team for the leap ahead."

— Mike Gaffney, CEO, Cellphire Therapeutics



Testimonial: On Demand Pharmaceuticals – Rockville, MD

On Demand Pharmaceuticals (ODP), based in Rockville, MD, is redefining medicine production and supply chain resilience by integrating chemistry, AI, and innovative manufacturing to ensure reliable access to essential medications—even in times of shortage. As a pre-commercial stage company, ODP has worked with BHI's Executive-in-Residence (EIR) Program to refine its commercialization, pricing, and go-to-market strategy.



Under the guidance of **EIRs Jonathan Kay and Jennifer Butler**, ODP has received **strategic insights on commercialization**, including **market positioning**, **pricing research with hospital pharmacists**, **and messaging development** to prepare for **fundraising and product launch**. This collaboration has led to **data-driven pricing recommendations and refined positioning** to enhance market readiness.

"Jen and Jon have helped us refine our vision and better articulate our value proposition as we work toward securing funding. Their insights and external perspectives have been invaluable to ODP's growth." — Jarrod Borkat, Chief Strategy and Commercial Officer, On Demand Pharmaceuticals



Testimonial: AkriVita – Rockville, MD

AkriVita (formerly SeeTrue Technologies), based in Rockville, MD, is pioneering 3D-printed microcapillary needles for research, disease modeling, cell and gene therapy, and IVF. As an early-stage company, AkriVita partnered with BHI's Executive-in-Residence (EIR) Program to refine its corporate strategy, branding, and investor positioning to prepare for growth and funding.



With guidance from **EIRs Jonathan Kay, Luis Gutierrez, and Jennifer Butler**, the company underwent a **full rebranding**, including **a name change, website redesign, and the development of a corporate narrative, value proposition, and messaging framework**. The EIRs also provided **fundraising strategy insights, pitch coaching, and investor video scripting**, helping AkriVita strengthen its position in the market.

"The BHI MoCo EIR program has been invaluable to AkriVita's success, providing expert advice, strategic guidance, and hands-on support at a critical stage. Thanks to this program, we are now better positioned for growth, investment, and long-term success."

— Kinneret Rand-Yadin, Founder & CEO, AkriVita



Montgomery County Life Sciences Incentive Programs

- Biotechnology Investor Incentive Program Montgomery County provides a supplemental grant to investors in local biotech companies who qualify for the Maryland Biotechnology Investment Incentive Tax Credit (BIITC). Investors approved for the state credit automatically receive the county grant, disbursed between March and May for prior-year investments.
- SBIR/STTR Matching Grant Program The only county-level program of its kind, offering non-dilutive funding for life sciences startups:
 - Phase 0: Up to \$5,000 for technical assistance in SBIR/STTR applications.
 - **Phase 1:** Up to **\$25,000** for early-stage companies.
 - **Phase 2:** Up to **\$50,000** for businesses progressing to commercialization.
- BHI Executive-in-Residence (EIR) Program Montgomery County in partnership with BioHealth Innovation, Inc. (BHI), this program provides mentorship, commercialization support, and funding guidance to biohealth startups in Montgomery County.
- MOVE Grant Program Supports businesses signing their first lease or expanding by 500+ sq. ft. in Montgomery County, offering financial incentives to help companies grow in one of the nation's leading biohealth hubs.
- Montgomery County Economic Development Corporation (MCEDC)

These initiatives strengthen Montgomery County's position as a **top destination for life sciences growth, investment, and innovation.**

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BHI Federal Funding Assistance

- \$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 \$4.0 million
- Non-dilutive



BHI SBIR/STTR Assistance Program Overview

BioHealth Innovation, Inc. (BHI) is a leader in providing SBIR/STTR assistance to growth stage companies ready to advance their healthcare initiatives and commercialize new technologies. BHI works with our clients from beginning-to-end to provide a customizable experience dependent on their specific needs.

BHI boasts a 3x win rate compared to the national average!

SERVICES OFFERED

Full Development Program

BHI provides in-depth help throughout the entire writing, submission, and resubmission process. This includes (but is not limited to) strategizing, crafting specific aims and overall narrative, managing communication with program officers, developing the budget, and drafting components of the grant.

This program is project-based, not hourly-based.

Targeted Development Program

BHI commits to 10-20 hours providing feedback and general advice, editing research and commercialization plans, reviewing the budget, assisting with grant administration and rules, and advising on general strategy.

Grant Mapping

Whether you possess grant writing skills or not, identifying the right funding opportunity for your specific goals and situation can be challenging. BHI helps support companies in finding nondilutive funding through federal and nongovernment organizations to fuel your success, delivering options tailored to your unique circumstances.



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BHI International Soft-Landing Program

- U.S Subsidiary/Corporation Creation
- Business Development and Market Analysis
- Grant Funding/Non-Dilutive Funding Assistance
- Human Resource and General Administration Support
- Marketing and Promotion
- Pricing and Reimbursement
- Regulatory
- Resource Identification







Week 2025

11th Annual SAVE THE DATES BIOHEALTH SAVE THE DATES CAPITAL REGION SEPTEMBER 23rd, 24th, & 25th, 2025

BIOHEALTH CAPITAL REGION





Rockville, Maryland

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BHI Contact

1 Church Street, Suite 801 Rockville, MD 20850 301-637-7950 info@biohealthinnovation.org www.biohealthinnovation.org





We want to hear from you!

Take our survey: https://forms.gle/zVnUxJrPA18SE36t5

Staff contacts:

- TBED Community of Practice <u>tbedcop@ssti.org</u>
- Jerry Coughter <u>coughter@ssti.org</u>
- Casey Nemecek <u>nemecek@ssti.org</u>

More information: <u>ssti.org/tbedcop</u>





Thank You

<u>ssti.org/tbedcop</u> <u>tbedcop@ssti.org</u> Ways to engage

□ Join a subcommunity | <u>Sign up</u>

Participate in a TBED COP webinar June 25 @ 3pm – Immigration Pathways for TBED

□ Register for our annual conference Dec. 10-12 in Arizona | <u>Learn more</u>

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Announcements

- New subcommunity on Research Parks (hosted by AURP)
- Registration now open for SSTI 2024 Annual Conference!
 - December 10-12
 - Gila River Indian Community Reservation | Phoenix Metro, Arizona
- Share your feedback, take our survey





Announcements



Discussion topics & responses

Recent Webinars & Resources

- Recent webinar on TBED talent development ft. Lorain
 County Community College
- Resource roundup to support Build to Scale applications
- NADO Federal Grant Administration webinar series



Entrepreneurship ecosystem

Building partnerships

- Convene with ecosystem partners regularly to stay up-to-date on regional happenings
- Educate industry partners on your program to encourage referrals and readiness evaluation
- CEOs may not always be the best point of contact find individuals who lead innovation efforts within organizations



Entrepreneur pipelines

Recruiting new participants – "it's too good to be true"

- Be visible and build rapport early
- Work with universities to connect with students
- Leverage referrals from board members
- Search SBIR/STTR databases for potential service prospects

Entrepreneurship education & mentorship

- Founders seek mentors who understand and value their lived experiences
- Identify champions who can serve as role models



Funding & Sustainability

Federal funding landscape

- Ability to leverage existing awards when seeking additional funding (ex. from corporate partners or foundations)
- "Seed" funding to help programs identify revenue sources
- Limited operational capacity to manage multiple grants

Charging for services

- Demonstrate ROI to ensure audience sees value in participating
- Identify other areas where entrepreneurs need support (ex. human resources)



Storytelling

Communicating TBED strategies

- Group interest in aligning on common terminology to ensure clear communication and understanding
- Role of data in demonstrating value of programs to external audiences
- Consider your audience when promoting your program and tailor your 'story' accordingly (without losing sight of your core mission)



Additional topics

Event preferences

- Experiences adjusting to the return of in-person activities
- Consider needs of target audience(s) when developing program models

Talent development

- Concerns about workforce shortages in the life science & biotech sectors
- Challenges in retaining skilled/experienced technicians and PIs
- Interest in helping startup founders pivot into high-demand areas



Opportunities for future discussion

- Advancing equity in TBED program design
- State-level advocacy strategies
- Talent development & entrepreneurship education
- Foreign direct investment opportunities
- Cross-border collaborations



Tool & resource development

- Past experiences: What resources or tools have you found the most helpful and why?
- Current needs: What would most effectively support your work right now?
- Future involvement: How would you like to be involved in the development and improvement of these community resources?



Open topics from conference roundtable

Marketing & Communications

• How is your team structured to handle marketing & communications? What strategies have you found successful?

Cross-border & Immigrant Entrepreneur Support

• What programs or partnerships have you implemented? How do you navigate potential legal hurdles?

Youth-focused Entrepreneurship Development

• What types of programs have you found most effective for engaging young entrepreneurs?

Evaluation of Ecosystem & Resource Mapping

• How do you evaluate the effectiveness and impact of your ecosystem mapping? How do you ensure the map stays up-to-date?





Award Amount Match Amount

FY 2023 Build to Scale Venture and Capital Challenge Awards

Source: U.S. Department of Commerce, U.S. Economic Development Administration, summitpost.org Dollar Amounts are based on SSTI collection and analysis of EDA award data, and may not represent exact values. Locally matched dollars were not available for some awards (most notably in FY 2015 & 16).



SSTI



2023 Build to Scale Awardees

Questions from recent listening sessions

Mentorship Programs

• What strategies have you found effective for mentor recruitment and retention?

Entrepreneurship Training & Education

• What programs or partnerships have you implemented?

Program Evaluation & Feedback

• How do you collect and incorporate feedback into your program design? What methods do you use to evaluate the success of your program(s)?

Ecosystem & Resource Mapping

• How do you measure the impact of your ecosystem mapping? What processes are in place to keep your information current?

Broadening Entrepreneur Engagement & Pipelines

• What outreach strategies do you use to recruit entrepreneurs? How do you customize support to leverage regional assets and local needs?

Diversifying Funding Streams & Securing Matching Funding

How do you blend local and federal funding opportunities? What other revenue sources are you exploring?



Additional topics

- Working with investors
- Tech commercialization & entrepreneurship
- "Tools of the trade" walkthroughs (ex. Airtable, Salesforce, others)
- Federal funding video series

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Today's Speakers



Jon Atkinson Chief Executive Officer The Idea Village



Ashleigh Sparks

Development Manager The Idea Village

