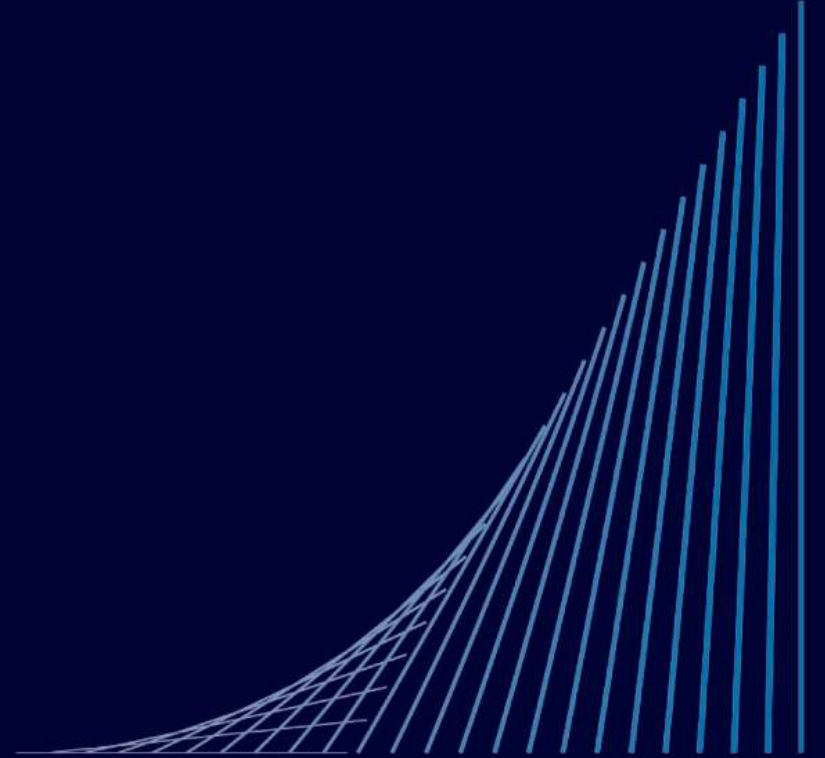


Accelerating Program Transition

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024

I want to talk to the hub and spoke network to ...



Why You're Here

- Understand the ARPA-H Project Accelerator Transition Innovation Office's (PATIO's) mission and capabilities
- Learn how to engage with PATIO as a member of the ARPANET-H network
- Gain insight into the value of PATIO's services as a performer, such as to improve the probability of product/technology success in the market



Project Accelerator Transition Innovation Office (PATIO)

Our Mission: PATIO increases the probability that ARPA-H funded health technologies **will reach all Americans** by identifying barriers and providing transition and commercialization services to program managers and performers.



Since ARPA-H will not fund performers in perpetuity, PATIO's services increase the odds that solutions attract private investment and customers—to translate the breakthroughs



Where might the solution go after ARPA-H?

Work backwards: design with the end in mind

Large
Established
Company

Emerging
Company with
VC Backing

De Novo
Startup

Health Care
System

Other Gov
Agency

Scaled NGO
or Non-Profit

Startup NGO
or Non-Profit

Fast Fail &
Early
Offramps

Many Successful Technologies Fail to Become Products and Get to Patients

Common reasons for market failure are not related to success of technology



Product Development

Will this program produce a solution to a stage that is ready to be applied?

- Manufacturability

Pricing/Cost issues (13%)

Poor product (7%)



End User / Market

Does anybody want to use or adopt the solution(s) from this program?

- Accessibility

No market need for product (32%)

Product mis-timed (10%)



Business Model

Can this program survive financially and compete in the wild?

- Reimbursement
- Pricing/Affordability

Got outcompeted (20%)

Flawed business model (18%)



IP / Licensing

Can anyone block this program based on IP from accomplishing its goals?

Legal challenges (17%)



Regulatory

Does a third-party need to approve some aspect(s) to make this program successful?

Regulatory challenges (17%)



Exit Plan

What is the transition, follow-on investment, and team required to reach the next inflection point?

No follow-on investment (45%)

Not the right team (12%)

Pivot gone bad (6%)

Burned out (5%)

Formula for Success = Embedded Private Sector Expertise

ARPA-H funded performers (Awardees) have access to PATIO acceleration and transition services



Transition Mentorship

Senior Independent industry experts partnering with PMs to advise as they address transition-related questions.

Meetings (i.e., monthly, quarterly, annually) to monitor performance and collaborate

DIGITALIS COMMONS



Executives in Residence

Fractional executives to support small business performers along the transition and commercialization path; senior leaders in their field, bringing years of experience commercializing technologies across life sciences and health care.

 **BioHealth Innovation**



Market Insights

Strategic Analysis to identify emerging trends in the health sector to help PMs shape programs and concepts, Identify unknown challenges in programs and then begins to solve for those challenges.

 **RTI**
INTERNATIONAL



Regulatory and Reimbursement Support

Regulatory and Reimbursement Consultants help PMs navigate known challenges in the solution development journey. (FDA, CMS, IP, Market Access).

Apply for ARPA-H Small Business Funding

- ARPA-H's Small Business Program (SBP) focuses on leveraging research advances for real world impact.
- Our SBP topics are generated by ARPA-H Program Managers and align with their programs.
- ARPA-H releases at least one SBIR/STTR solicitation each year with topics that are mission-oriented.
- Our program positions small businesses to commercialize technological solutions and products that are spun out from ARPA-H programs.

Learn more at our website →



ARPA-H SBP Advantages

6



- Simplified SBIR/STTR application process
- Expedited review process only takes a few months!



- Stable and predictable non-dilutive funding
- IP rights are retained by the small business
- ARPA-H SBP performers can utilize our suite of entrepreneurial services to help advance and commercialize technologies.



contact us! sbir@arpa-h.gov

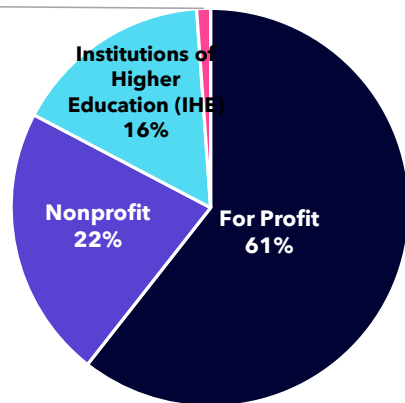
Join ARPANET-H to accelerate transition-focused R&D

ARPA-H Offices in DC, the Boston area, Dallas/Ft. Worth ("hubs") manage an ecosystem of 987+ members ("spokes")

900+ Organizations in the ARPA-H Network

3 ARPA-H "Hubs"

Public Sector
Affiliated
1%



Research Institutions 400+



Clinical Trials Specialty 230+



Health Systems 190+



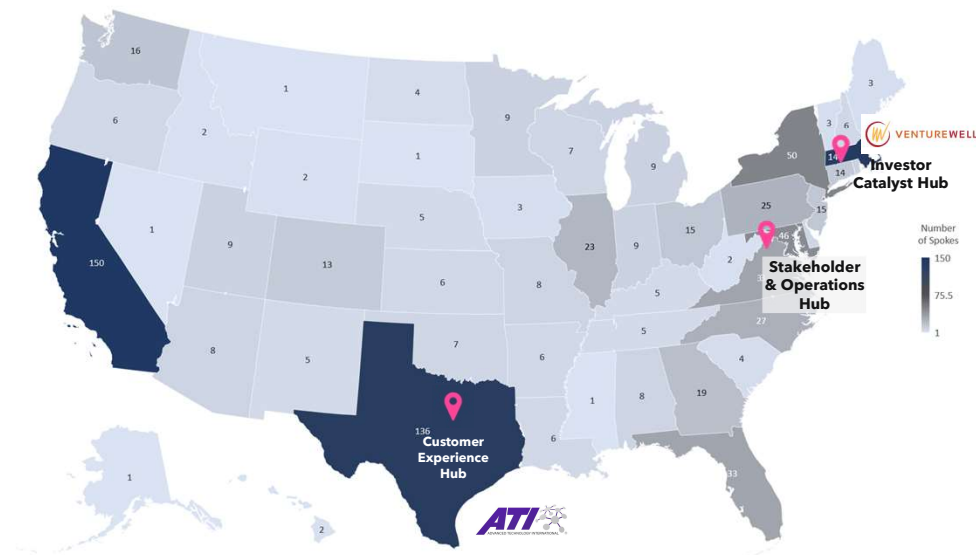
AI/ML Focused 170+



Med. Tech Manufacturers 85+

340+ small businesses (35%)

185+ (19%) identify as: woman-owned, disadvantaged, service disabled and/or veteran-owned



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*Statistics based on self-reported data; all data points as of 9/27/2024

Participate in a Network Survey and Help Shape Future ARPA-H R&D Efforts

Medical Imaging Data Marketplace



Problem

*Lack of data / data access
issues delay R&D*

Survey

How might ARPA-H partner with the FDA to unblock the 'data pipeline' to catalyze the development of AI/ML technologies for radiology and digital pathology while reducing regulatory timelines?

Results

- **117 Survey** responses (high value feedback)
- Strong demand for data from industry stakeholders
- Uncovered pain points and problems to for us to address
- Identified new technologies and companies in the space

Sprint for Women's Health

What if we could shatter the glass ceiling of biomedical and health research to improve health outcomes for women?

ARPA-H committed **\$100 million** to galvanize the innovator, investor, researcher, and patient advocate communities to spur innovation in women's health in 6 topics. ----->>>>>

Spark
\$3M award

Spark awards focus on transformative early-stage research efforts.

Launchpad
\$10M award

Launchpad awards accelerate later stage transformative health solutions.

Women's Health Topics Aligned by Program Manager



Darshak Sanghavi, MD
Resilient Systems Office
1. Women's Health at Home



Jessica Green, PhD
Resilient Systems Office
2. Prioritizing Ovarian Health Through Mid-Life to Prevent Disease



Daria Fedyukina, PhD
Health Science Futures Office
3. ARTEMIS – Advancing Research Through Enhanced Models for Investigating the Influence of Sex Differences on Health Outcomes



Kimberley Steele, MD, PhD
Health Science Futures Office
4. Advancing Women's Brain Health via Lymphatic Targeting



Ileana Hancu, PhD
Health Science Futures Office
5. Objective and Quantitative Measurement of Chronic Pain in Women

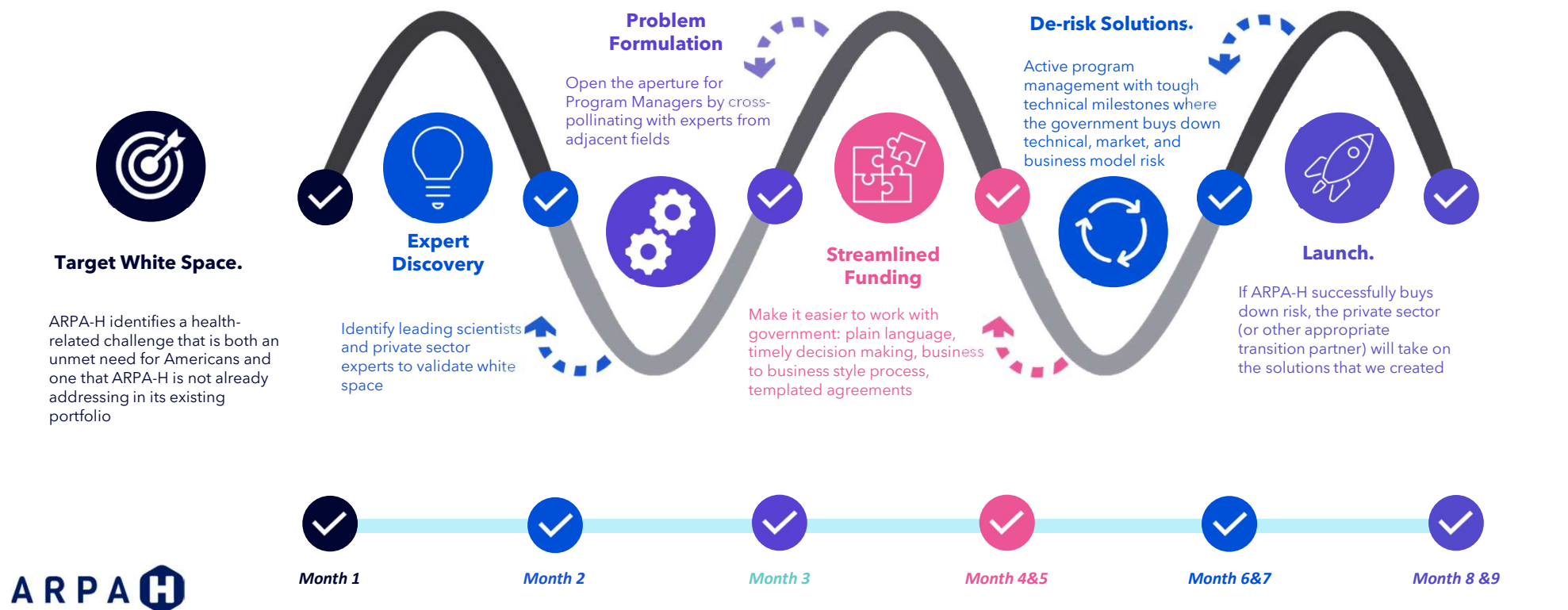


Jenica Patterson, PhD
Project Accelerator Transition Innovation Office
6. WILD CARD: Revolutionary Breakthroughs in Women's Health



Participate in future ARPA-H Sprints

Rapidly Identify & Solve High-Value Challenges



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Engage with PATIO

- Actions you can take to engage with PATIO today!

Join the ARPA-H Network: ARPANET-H

Respond to Network Surveys

Apply for Small Business Funding

Submit your solution to the next R&D Sprint

<https://arpa-h.gov/engage-and-transition>

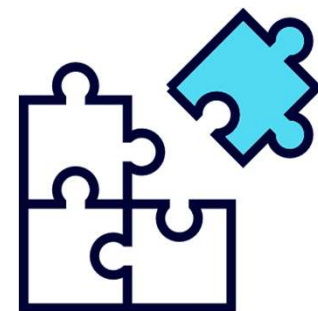
ARPA-H Awardees (“performers”) have access to PATIO acceleration and transition services



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Session Takeaways

- Network, Newsletters, Listservs. There are numerous easy and passive ways to stay engaged and updated on ARPA-H funding opportunities
- Although each ARPA-H Mission Office has funding opportunities, PATIO's funding opportunities are focused on accelerating funding to small businesses through "SBIR/STTR programs" and "Sprints"
 - These programs aim funding at critical gaps in research and development in healthcare and occur intermittently throughout the year
- ARPA-H awards are not the same as NIH grants → one key difference is that ARPA-H provides acceleration and transition capabilities to support downstream commercialization and successful market access



ARPA 