

Doing Business With ARPA-H

Industry Day

November 13, 2024

10:00 AM - 4:00 PM (ET)

Approved for Public Release: Distribution Unlimited



1. Why We're Here

Purpose and Expected Outcomes

Purpose:

Attend a virtual industry day event* centered on “Doing Business With ARPA-H”

Expected Outcomes

- Understand the sense of urgency for ARPA-H’s mission and focus areas
- Learn how ARPA-H applies unique R&D authorities to create flexible award instruments
- Identify how to locate and make submissions to current and future ARPA-H R&D opportunities
- Explore how ARPA-H is constantly improving its business processes
- Review ARPA-H’s solicitation instrument, including terminology and processes
- Obtain tips and lessons learned to assist with quality submissions



* Primary focus on the business aspects (not technical) of research and development (R&D) opportunities

Agenda - Main Session Topics

Topic #	Topic	Time (ET)
1	Why We're Here	10:00 - 10:10 AM
2	A Message From the ARPA-H Director	10:10 - 10:30 AM
3	A Message From the HHS Senior Procurement Executive	10:30 - 10:40 AM
4	Current Opportunities (GLIDE, CATALYST, OCULAB)	10:40 - 11:05 AM
BREAK		11:05 - 11:20 AM
5	Ways of Doing Business with ARPA-H	11:20 - 11:55 AM
6	Breakout Session 1 (see offerings on next slide)	11:55 AM - 12:30 PM
LUNCH BREAK		12:30 - 1:30 PM
7	Finding Opportunities	1:30 - 2:00 PM
8	Customer Experience Initiatives	2:00 - 2:20 PM
BREAK		2:20 - 2:35 PM
9	Innovative Solutions Opening (ISO) Process Overview	2:35 - 3:05 PM
10	Helpful ISO Resources	3:05 - 3:25 PM
11	Breakout Session 2 (see offerings on next slide)	3:25 - 4:00 PM

Agenda - Breakout Session Topics*

Topic #	Topic	Times (ET)
1	Work With Us Questions (Ask Me Anything)	Breakout Session Period 1: 11:55 AM - 12:30 PM Breakout Session Period 2: 3:25 - 4:00 PM
2	You Received an Award, Now What?	
3	Other Transaction (OT) Benefits	
4	Payable Milestones	
5	Intellectual Property (IP) Approach	
6	Teaming	
7	Affordability and Accessibility	
8	International Collaboration	
9	Accelerating Program Transition	
10	Engaging with Federally Funded Research and Development Centers and Government Entities	

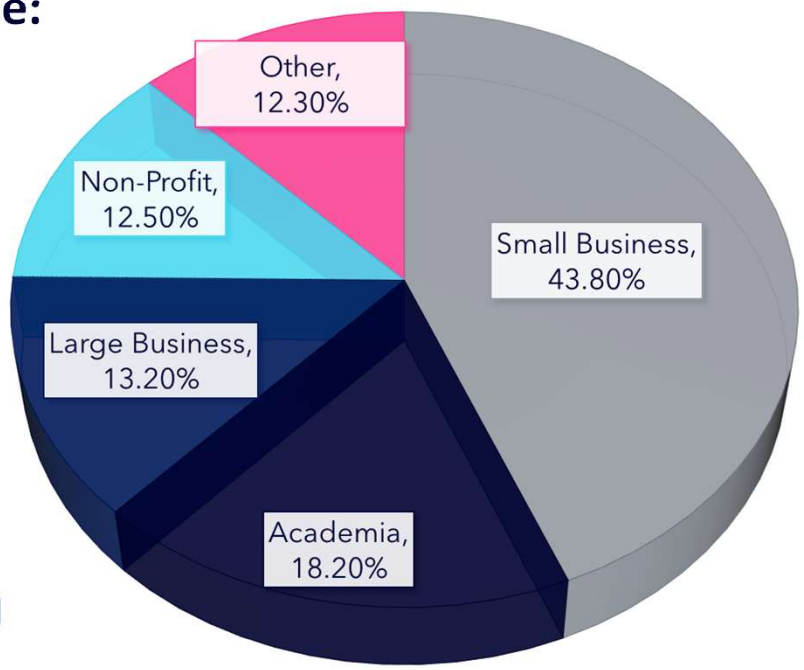
* All sessions are held at the same time per period



Registered Attendee Details

Total Registered: 1,916

Entity Type:



Preferred Topics (pre-event survey)

- Locating current/future opportunities*
- ARPA-H and its mission*
- Understanding ARPA-H authorities*
- Navigating ARPA-H's Solution Submission Portal*
- Other (breakout sessions)*

2. A Message from the ARPA-H Director

Mission

Accelerate better
health outcomes
for everyone.



ARPA-H Key Features and Authorities

ARPA-H has unique structures and legal authorities that allow it to **function like a business – quickly, nimbly, and decisively**

- ARPA-H is a **funding agency**
- **Independent** component of HHS
- No internal research labs; **disease agnostic**
- Generally, **fund outcome-based contracts**, not grants; accelerated award timelines
- Unique **FDA reimbursement authority**

FY 2022	FY 2023	FY 2024	FY 2025
\$1B	\$1.5B	\$1.5B	Request: \$1.5B



Lean and nimble management structure with autonomy in decision-making

ARPA-H Director **reports directly to HHS Secretary**



Term limits of 3-6 years bring urgency and idea flow

Flexibility in hiring allows ARPA-H to recruit at levels competitive with industry

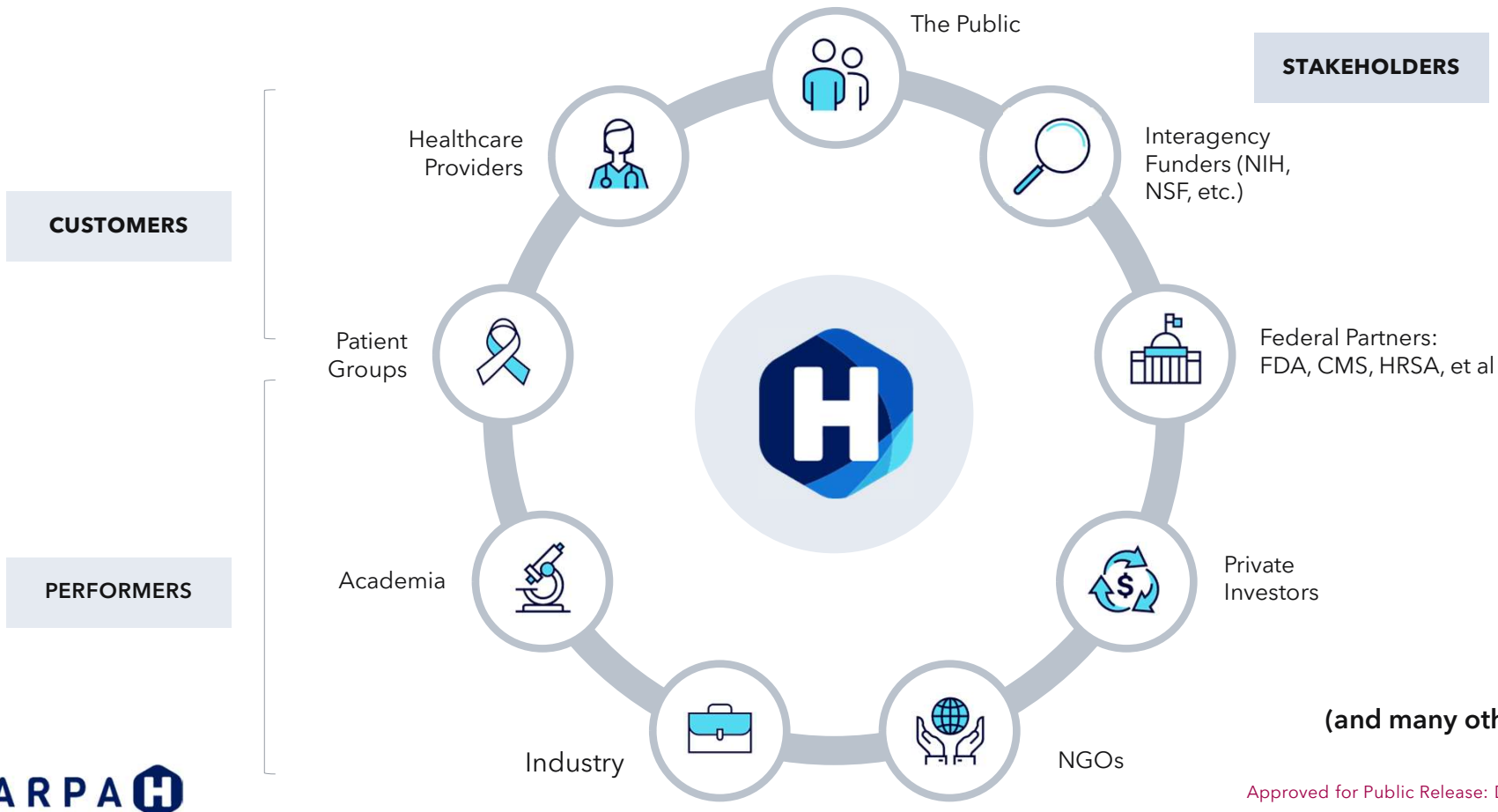


Bottom-up decision-making. Program Managers have autonomy to make decisions quickly.

ARPA-H is a problems focused organization



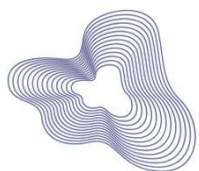
ARPA-H Accelerates the Entire Health Ecosystem



Mission Office Focus Areas

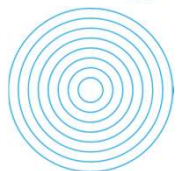
Further ARPA-H investment in these areas will generate asymmetrical benefits to the health ecosystem

Increasing the odds - at each step of the program lifecycle - that ARPA-H Solutions will transition to patients



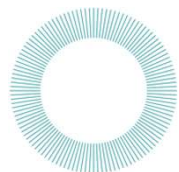
Health Science Futures (HSFO)

Expanding what's technically possible



Scalable Solutions (SSO)

Reaching everyone quickly



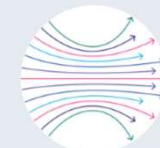
Proactive Health (PHO)

Keeping people from being patients



Resilient Systems (RSO)

Building integrated health care systems



Project Accelerator Transition Innovation (PATIO)

Ensuring programs and solutions transition, are commercialized, and are financially sustainable.



ARPANET-H

- Stakeholder and Ops
- Customer Experience
- Investor Catalyst



Program Lifecycle

From ideas to solutions in the real world



DESIGN PROGRAMS

- ARPA-Hard and well-defined problems in health
- Heilmeier framework
- High risk/High consequence
- Stakeholder Insights

BUILD A PERFORMER TEAM

- Solicit solutions from the community
- Find the best non-traditional, industry, and academics to solve
- Build new coalitions

EXECUTE & MEASURE

- Active program management against metrics
- Stakeholder engagement throughout to ensure transition
- Pivot resources when needed

LEARN & GROW

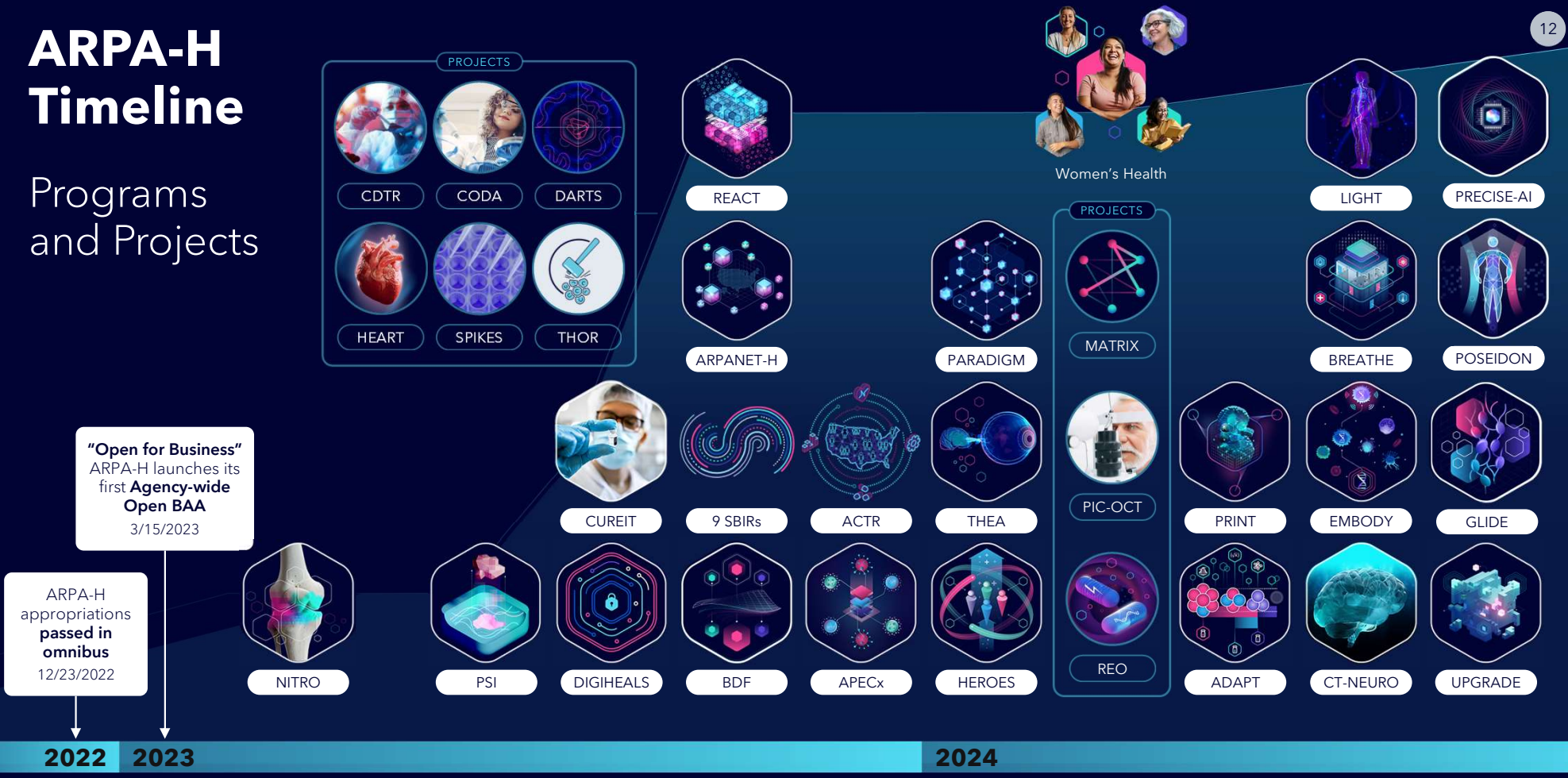
- Capture and share insights
- Technical honesty
- Advance the state of the art; 10x+ improvement, no incremental change

COMMERCIALIZE & TRANSITION

- Assist company formation or licensing
- Provide mentorship, connections to customers, investors
- De-risk investments

ARPA-H Timeline

Programs and Projects



ARPA-(H)eilmeier Questions

Towards a well-defined problem

- 1 What are you trying to do? What health problem are you trying to solve?
- 2 How does this get done at present? Who does it? What are the limitations of present approaches?
- 3 What is new about our approach? Why do we think we can be successful at this time?
- 4 Who cares? If we succeed, what difference will it make? What Health Outcomes are we accelerating?
- 5 What are the risks? That may prevent you from reaching your objectives? Any risks the program itself may present?

- 6 How long will the program take?
- 7 How much will the program cost?
- 8 What are our mid-term and final exams to check for success?
- 9 How will cost, accessibility, and user experience be considered to reach everyone?
- 10 How might this program be misperceived or misused (and how can we build trust and prevent that from happening)?



ARPANET-H: Hub & Spoke Network



ARPANET-H is a health innovation network that connects +500 members across a fragmented health ecosystem through projects, events, and collaboration opportunities.

Investor Catalyst Hub (located in Boston, MA):

Focused on navigating the complexities of the market landscape so innovations can transition from government support to commercial success.



Learn More

Customer Experience Hub (located in Dallas, TX):

Focused on engaging patients, providers, and stakeholders to bring them into the development and design process and enable faster, broader adoption of ARPA-H health innovations.



Learn More

Stakeholder and Operations Hub (located in Washington DC):

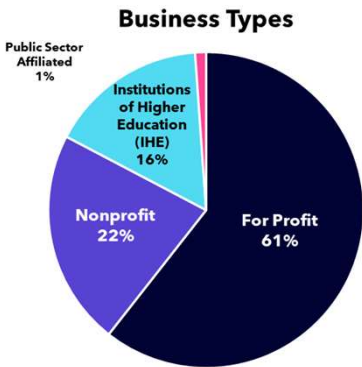
Focused on stakeholder engagements with our critical regulatory and legislative partners to support transitioning new health capabilities.



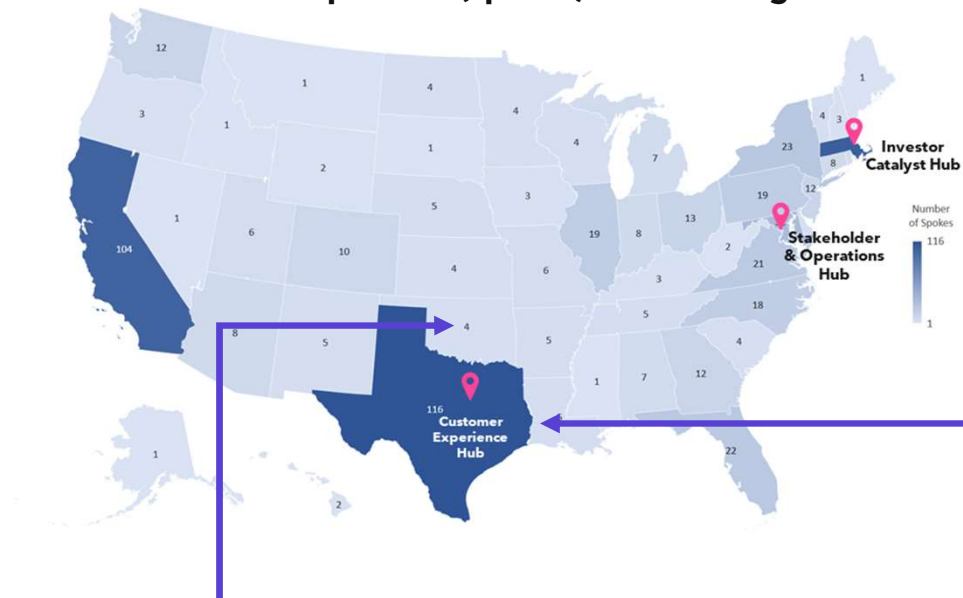
What if we had a national network of partners working to speed medical innovation to everyone?

ARPANET-H Network

Bridging disparate pieces of the health ecosystem & powering communities via ARPA-H



977 partners (spokes) and counting...



Spoke: The Engine



Customer Experience Hub

340+ small businesses (35%)
 185+ (19%) identify as:
 woman-owned,
 disadvantaged, service
 disabled and/or veteran-
 owned



Spoke: Cherokee Nation

ARPANET-H supporting our programs

Cherokee Nation was established as an ARPANET-H spoke through the Customer Experience Hub. This connection resulted in the NITRO program kicking off in the Cherokee Nation, the first R&D program to do so on Tribal Nation soil.



3. A Message from the HHS Senior Procurement Executive



Partnering with HHS

Enhancing the Health & Well-Being of the American Public

Ms. Katrina Brisbon
Department of Health and Human Services
Deputy Assistant Secretary for Acquisitions
Senior Procurement Executive

Doing Business with HHS



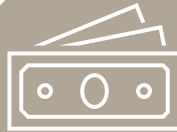
Mission

Evolving the Health & Well-Being of the American Public



Leveraging HHS Buying Power

Category Management



Spend

How Does HHS Spend and What Does HHS Buy

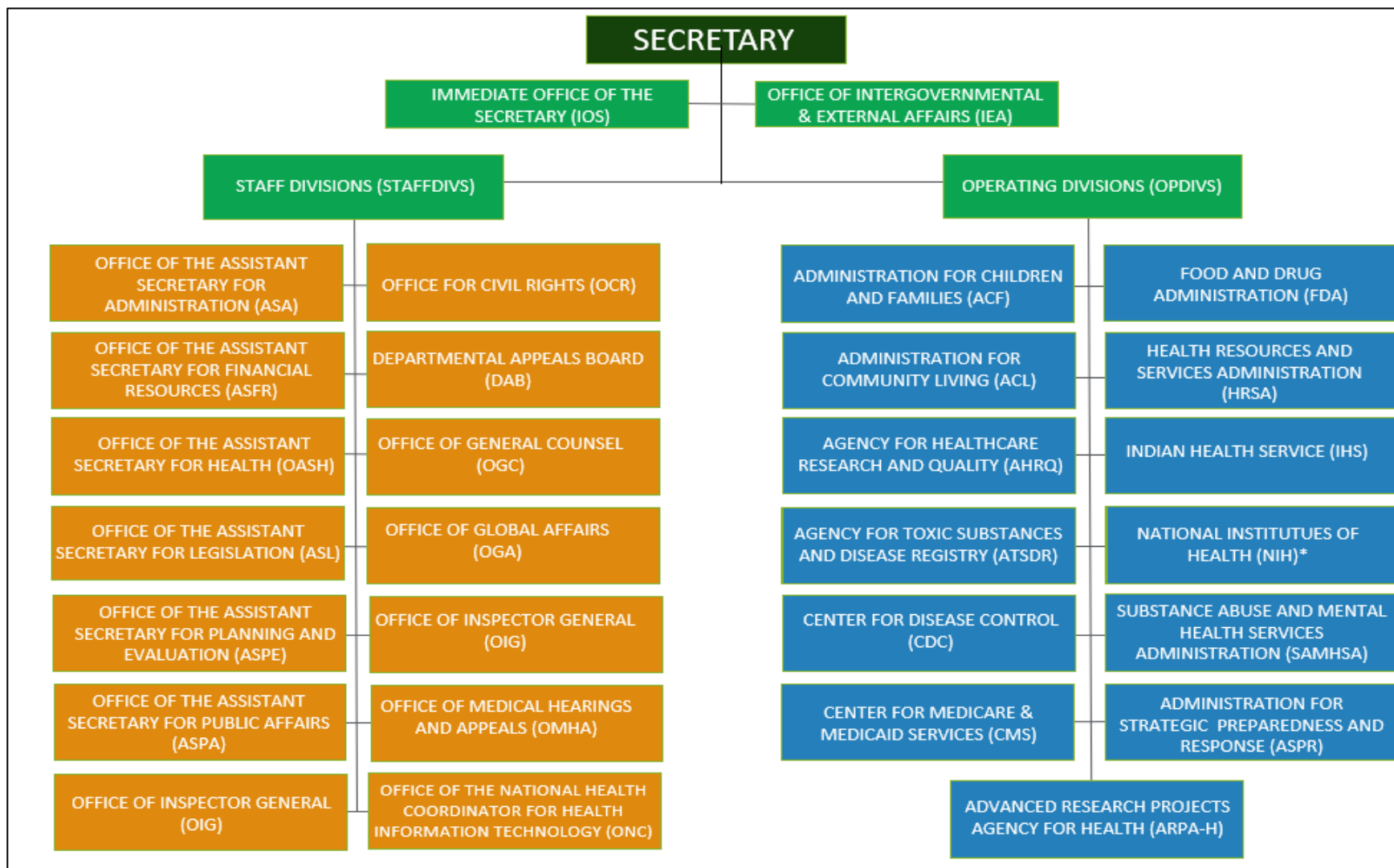


New Programs

Innovation and Industry Engagement

HHS MISSION

*The mission of the U.S. Department of Health and Human Services (HHS) is to **enhance the health and well-being of all Americans**, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.*



Highlighting HHS Mission Areas: Acquisitions Enables America's Health Care Programs



HHS's broad mission reaches into every aspect of American life, enhancing health & well-being from birth to life's end.

Center for Disease Control

Strengthening public health infrastructure to improve the overall health and resilience of communities.

Center for Medicare & Medicaid

Ensuring access to high-quality, affordable health care for all American

Food & Drug Administration

Ensuring safety of the nation's food supply & cosmetics

Indian Health Service

Ensuring access to equitable & comprehensive health services to Native communities

Health Resources and Services Administration

Improving health outcomes & achieving health equity for underserved, vulnerable, and geographically isolated populations

National Institutes of Health

Advancing knowledge & improving health through scientific discoveries that prevent disease & enhance treatment, resultantly improving public health globally

AHRQ

Improving patient safety, enhancing health care quality, and ensuring access to effective health services

ACL

Maximizing independence, well-being, & health of older adults and people with disabilities

ACF

Promoting self-sufficiency, child welfare, and equitable access to resources and opportunities for vulnerable populations.

Highlighting HHS Mission Areas: Acquisitions Enables America's Health Care Programs



HHS's broad mission reaches into every aspect of American life, enhancing health & well-being from birth to life's end.

ASPR

Strengthening the nation's health security & enhancing preparedness for public health emergencies.

ATSDR

Protecting communities from harmful health effects related to exposure to hazardous substances in the environment.

SAMSHA

Improving access to substance abuse prevention, treatment, and recovery services

ARPA-H

Driving transformative health innovations that support breakthroughs in medicine and health care



HHS FY24 SPEND BREAKDOWN BY OPERATING AND STAFF DIVISIONS

Level 1 GSA Taxonomy and FY24 spend by Operating and Staff Division. (Only includes obligations on FAR-based contracts)



Centers for Disease Control & Prevention



National Institutes of Health



Centers for Medicare & Medicaid Services



Assistant Secretary for Preparedness & Response



Administration for Children & Families



Food & Drug Administration

FY24 Total Spend	\$9.2B		\$8.0B		\$8.4B		\$6.3B		\$1.9B		\$1.7B	
Top 3 GSA Level I Categories ; Associated Spend (\$M)	1. Medical	\$7.0B	1. Professional Services	\$2.3B	1. Professional Services	\$4.6B	1. Research & Development	\$4.0B	1. Professional Services	\$1.7B	1. Information Technology	\$773.9M
	2. Professional Services	\$1.7B	2. Research & Development	\$2.2B	2. Information Technology	\$2.8B	2. Medical	\$1.7B	2. Information Technology	\$111.5M	2. Professional Services	\$662.6M
	3. Information Technology	\$743.5M	3. Information Technology	\$1.6B	3. Medical	\$655.8M	3. Professional Services	\$313.7M	3. Human Capital	\$63.6M	3. Industrial Products & Services	\$75.9M



Indian Health Service



Health Resources & Services Administration



Assistant Secretary for Administration



Substance Abuse & Mental Health Services Administration



Agency for Healthcare Research & Quality



Office of the Inspector General



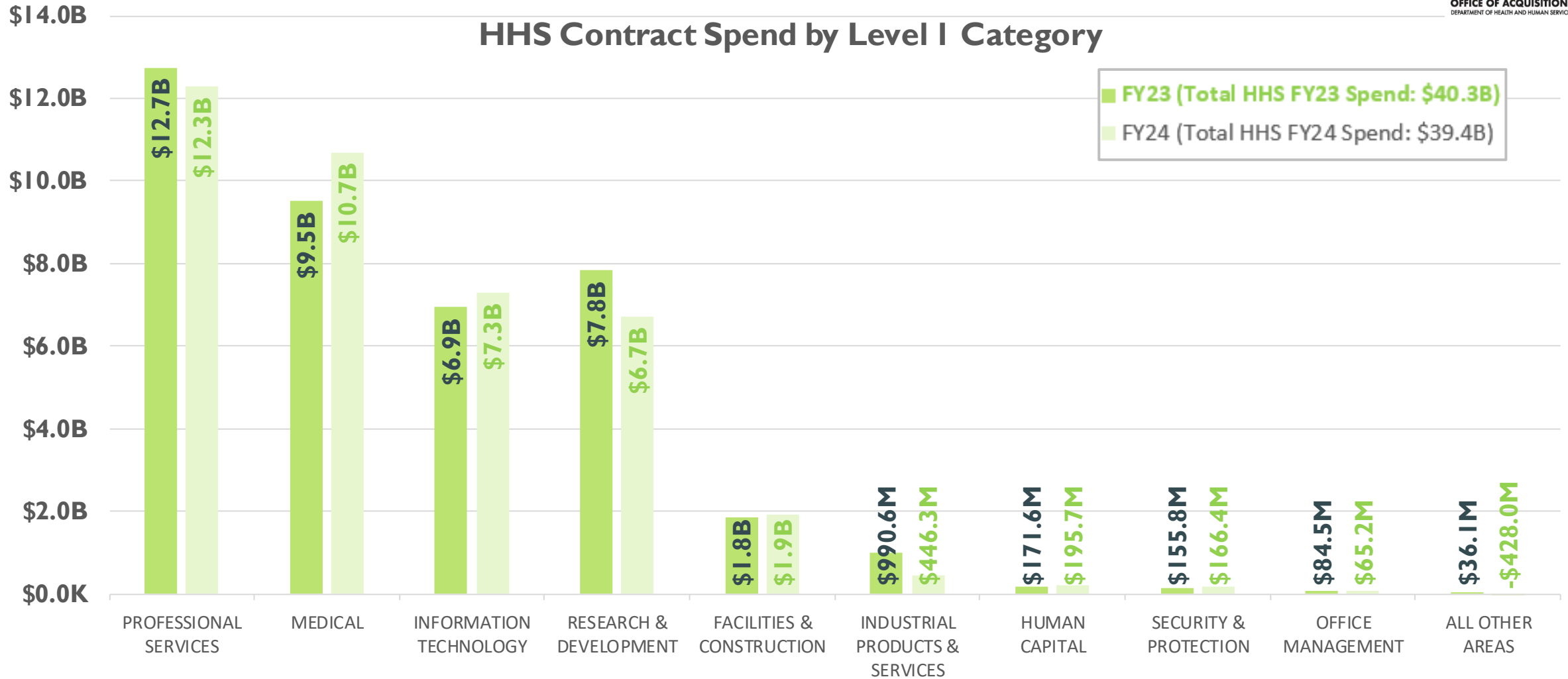
Advanced Research Projects Agency for Health

FY24 Total Spend	\$1.6B		\$578.2M		\$986.3M		\$345.3M		\$180.1M		\$94.3M		\$304.7M	
Top 3 GSA Level I Categories ; Associated Spend (\$M)	1. Medical	\$795.0M	1. Information Technology	\$295.2M	1. Information Technology	\$477.9M	1. Professional Services	\$307.1M	1. Professional Services	\$107.5M	1. Information Technology	\$61.1M	1. Research & Development	\$212.3M
	2. Facilities & Construction	\$347.0M	2. Professional Services	\$194.6M	2. Professional Services	\$327.8M	2. Information Technology	\$26.9M	2. Information Technology	\$38.1M	2. Professional Services	\$26.8M	2. Facility & Constructions	\$40.8M
	3. Information Technology	\$295.8M	3. Medical	\$67.1M	3. Medical	\$99.4M	3. Transportation & Logistics	\$8.8M	3. Research & Development	\$31.6M	3. Security & Protection	\$4.1M	3. Professional Services	\$39.6M

HHS Spend Comparison of FY23 and FY24 by Category



HHS Contract Spend by Level I Category



ARPA-H FY2024 OBLIGATIONS: OTHER TRANSACTION AGREEMENTS



OTHER TRANSACTION AGREEMENTS (OTAs)

TOTAL DOLLARS OBLIGATED: \$402.6M

TOTAL VALUE OF FY 2024 OTA AWARDS WITH OPTIONS: \$2.67B

Targeting the Market's Best for Health & Science

CATEGORY MANAGEMENT:

TARGETING THE FEDERAL MARKET'S BEST FOR HEALTH & SCIENCE

DEMAND MANAGEMENT PLAN

- Category Management Strategy
 - *Identifying optimal purchasing strategies for HHS mission needs and creating plans to increase efficiencies.*

STRATEGIC SOURCING

- Targeted “Mandatory Use” contracts to leverage the HHS purchasing power to find the best possible values & the right suppliers in the marketplace

PROGRAMS IMPACTING HHS INDUSTRY PARTNERS

New Programs



HHS Innovation Lab & Industry Liaison Program

Acquisition Innovation Lab

Driving value and supply chain optimization through continuous improvement and adaptation to changing market dynamics.

Industry Liaison Program

- Facilitating collaboration and communication
- Fostering mutually beneficial relationships through knowledge exchange research collaboration
- Facilitating the transfer of ideas and technologies



Fiscal Year 2024

13

HHS Procurement Organizations

68,355

Total Contract Actions

\$39,470,000,000

Annual Obligations on Contracts



OFFICE OF ACQUISITIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. Current Opportunities

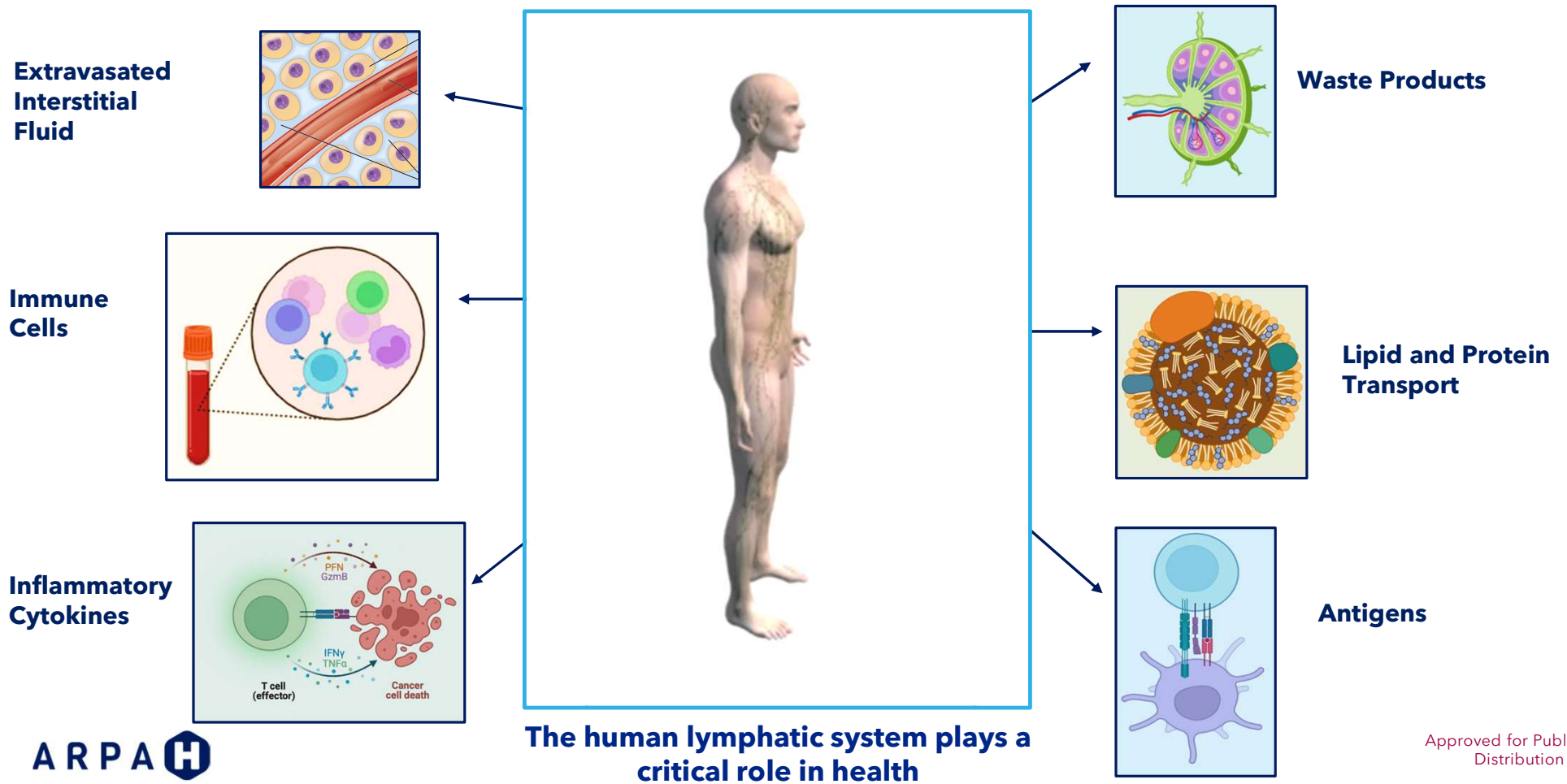


Lymphatic Portfolio

Kimberley Steele, MD, PhD

Program Manager, Health Science Futures Mission Office

The Human Lymphatic System In Health



Emerging Importance of Lymphatics in Health and Disease

CNS
 AD/Dementia/Aging
 CNS autoimmunity
 Cerebral small vessel disease
 Meningitis infection
 Hydrocephalous
 Traumatic brain injury

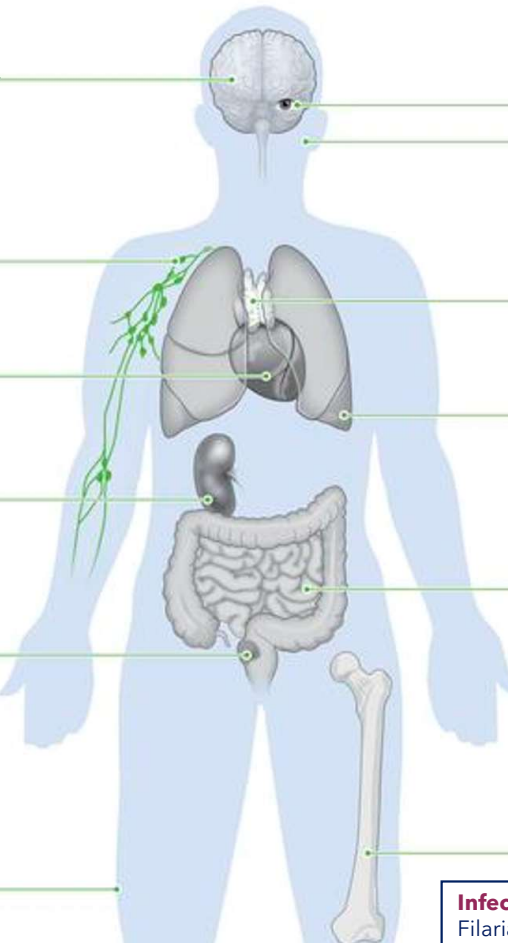
Lymphatic System
 Complex Lymphatic Anomalies:
 GLA, KLA, CCLA & GSD
 Castleman Disease
 Kaposi sarcoma
 Primary Lymphedema (40 + sub-categories)
 Vascular Anomalies

Cardiovascular System
 Myocardial infarction
 Heart failure
 Myocardial fibrosis
 Valvular disease
 Pericarditis
 Atherosclerosis
 Hypertension

Urologic System
 Kidney fibrosis
 Renal lymphangiectasia
 Nephrotic Syndrome
 Chronic cystitis
 Polycystic kidney disease
 Glomerulonephritis

Tumor Metastasis
 Melanoma
 Gastrointestinal cancer
 Breast cancer
 Prostate cancer
 Testicular cancer
 Squamous cell cancer
 Gynecological cancers (endometrial, ovarian)
 Colorectal cancer
 Lung cancer

Skin
 Lymphedema
 Lipedema
 Lymphangitis
 Scleroderma
 Atopic Dermatitis
 Eczema
 Aging
 Hair follicle
 Stem cell maintenance



Eye
 Uveitis
 Glaucoma
 Corneal transplants
 Neovascularization
 Retinopathy
 Optic nerve pathology

Ear, Nose, Throat (ENT)
 Adenopathy (lymph node swelling)
 Meniere's disease

Autoimmune Disorders
 Lupus
 Multiple sclerosis
 Sjogren's syndrome
 Rheumatoid arthritis
 Autoimmune inner ear disease

Pulmonary
 Pulmonary fibrosis
 Chronic obstructive sleep disorder
 Lymphangiomyomatosis (LAM)
 Pulmonary effusions
 Plastic bronchitis

GI System
 Inflammatory bowel disease
 Celiac disease
 Intestinal lymphangiectasia
 Diabetes
 Obesity
 Chylous ascites
 Liver fibrosis / cirrhosis
 Fatty liver disease
 Hypercholesterolemia
 Protein-Losing Enteropathy (PLE)

Musculoskeletal System
 Osteoarthritis
 Psoriatic arthritis
 Fibromyalgia
 Gorham-Stout disease

Infection
 Filariasis
 HIV, COVID, Tuberculosis
 Meningitis

Adapted from: J Clin Invest DOI: 10.1172/JCI171582

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We have diagnostic and therapeutic tools to assess and treat all our body systems... except our lymphatic system.



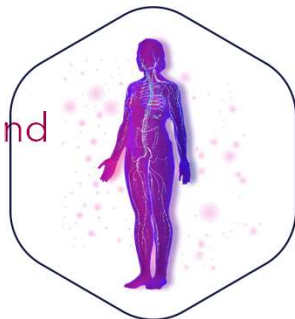
So, why not LYMPHATICS ?

Because we would need to MAKE THE INVISIBLE VISIBLE and it is a HARD problem to solve.

But if we could, we might be able to save millions of lives.

LIGHT

Lymphatic Imaging, Genomic, and Phenotyping Technologies



Vision: Create a diagnostic toolkit that is scalable, accessible, accurate, and clinically useful to detect lymphatic structure and function in health and disease.

Technology Focus Areas

- TA1. Diagnosis and monitoring through biomarker discovery
- TA2. Imaging technologies
- TA3. Prevention, prediction, and diagnostic confirmation through genetics, epigenetics, and models of lymphatic dysfunction

What if we could make the invisible lymphatic system visible?



GLIDE

Groundbreaking Lymphatic Interventions and Drug Exploration



22

Vision: To develop treatment options that address the underlying mechanisms of lymphatic dysfunction; either curing the disease state or safely stabilizing the disease and providing significant relief.

Technology Focus Areas

- TA1. Restore Flow Through Physical Interventions
- TA2. Normalize Function Through Targeted Pharmacologic, Gene & Cell Therapy

What if doctors were able to prevent and cure human disease by targeting the lymphatic system?

ARPA-H Lymphatic Portfolio Interest Areas

Lymphatic Health Interests*	Sprint for Women's Health	LIGHT Program	GLIDE Program	SBIR Topic LymphoLab Toolkit	SBIR Topic Ambulatory Edema Monitor
Meningeal Lymphatics, Glymphatic & CNS	○		○		
Lymphatic System-wide		○	○	○	○
Rare & Chronic Disease Required			○		
Multiple Indications Required			○	○	○
Diagnostics	○	○			○
Imaging Development	○ brain lymphatics only	○ whole body, excludes brain			
Biomarker Discovery		○		○	
Genomics Characterization		○		○	
Physical Intervention	○		○		
Targeted Therapeutics	○		○	○	
Gender Specificity	○				
First-in-Human Demonstrations		○	○		○
Addressing Barriers of Lymphatic Diagnosis & Treatment	○	○	○	○	○

*Represents interest areas only and does not reflect what has or will be selected for negotiation



GLIDE

into the future with...

Groundbreaking Lymphatic Interventions and Drug Exploration



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**Solution Summary deadline:
12/02/24**

QR Code links to:

- GLIDE Overview
- Proposer's Day Recording
- GLIDE Solicitation
- FAQs
- Teaming Profiles

Computational ADME-Tox and Physiology Analysis for Safer Therapeutics (CATALYST)

Dr. Andy Kilianski, Program Manager
Health Science Futures Mission Office

Vision: To revolutionize preclinical drug safety prediction by developing human-based models that accurately estimate toxicity and safety profiles for drug candidates. If successful, CATALYST will enable safer and faster drug development, particularly for rare disease populations.

Technology Focus Areas

- Data discovery and deep learning methods for drug safety models
- Living systems tools for model development
- In silico models of human physiology

Key Dates

- Program Launch: October 4, 2024
- Program ISO Released: October 16, 2024
- Proposers' Day: October 29, 2024
- Solution Summary Due: November 25, 2024, 5:00 p.m. ET



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What if we could predict drug safety and efficacy accurately before clinical trials even begin?

Ocular Laboratory for Analysis of Biomarkers (OCULAB)

Dr. Calvin Roberts, Program Manager
Health Science Futures Mission Office

Vision: To revolutionize how we think about continuous health monitoring and disease detection with a first disease target of dry eye disease (DED).

Technology Focus Areas

- Development of a continuous monitoring nanosensor for the tear duct
- Development of closed-loop therapeutic dosing device

Key Dates

- Program Launch: October 18, 2024
- Program ISO Released: TBD
- Proposers' Day: December 12, 2024
- Solution Summary Due: TBD



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What if your eyes were a
window to your health?

5. Ways of Doing Business With ARPA-H

Contracting Instruments (Per 42 U.S.C. 290c)

Other Transactions (OTs)

Cooperative Agreements (CAs)

Focus of today's event (research and development, or R&D, efforts)

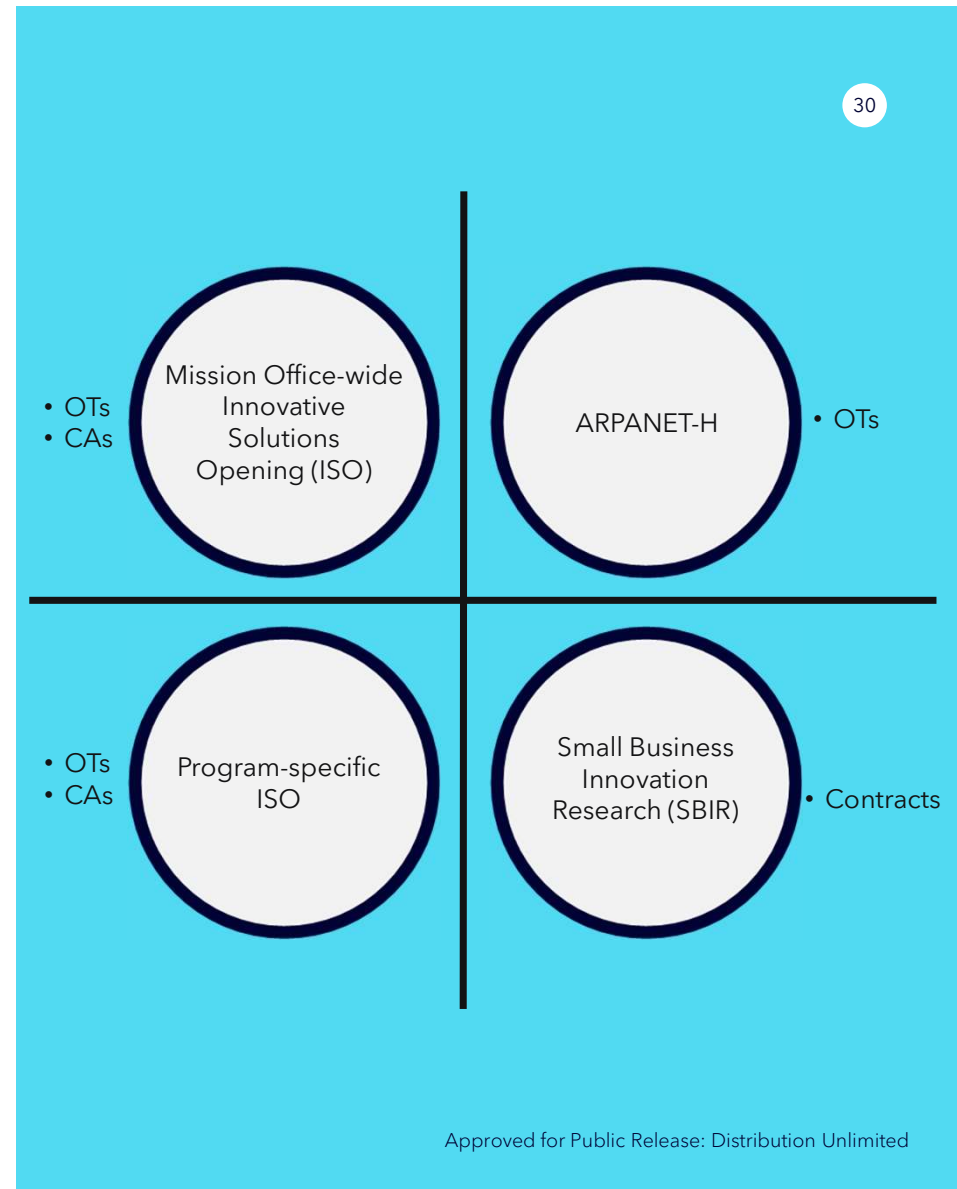
Contracts

Grants

Prizes

Potential Award Types Per Activity

- Will primarily use OTs and CAs for R&D efforts
- Will discuss ISOs and ARPANET-H more in main session and breakout sessions



Other Transactions (OTs)

Definition

Legally binding agreements (other than procurement contracts, grants, or cooperative agreements) between industry and the Gov't to conduct research and development efforts and promote innovation to achieve its goals.



When to Use

A project that requires creative relationships and practices with solutions providers, especially those that may not be interested in entering FAR-based contracts or federal financial assistance.

When the government requires innovative and flexible arrangements via a highly-collaborative environment with solutions providers.

A project that requires the use of a contract vehicle with characteristics similar to those within the commercial industry.

OT Advantages / Disadvantages



Advantages

- The most flexible authority when compared to contracts, cooperative agreements, and grants
- Instrument characteristics are similar to contracts within the commercial sector
- Processes based on negotiations rather than regulations/policies
- Bayh-Dole Act (Intellectual Property) does not apply → more flexibility
- Does not require excessive oversight or specialized accounting/audit requirements and systems



Disadvantages

- Some industry partners, primarily academic institutions, may not have experience with OTs
- Does not guarantee ARPA-H teams to complete awards faster than contracts, cooperative agreements, or grants

Cooperative Agreements (CAs)

Definition

A legal instrument (federal financial assistance) between a Federal awarding agency and a recipient or a pass-through entity and a subrecipient that:

- 1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value to carry out a public purpose authorized by a law of the US (and not to acquire property or services for the Federal Gov't or pass-through entity's direct benefit or use).
- 2) Provides for substantial involvement of the Federal awarding agency in carrying out the activity contemplated by the Federal award.



When to Use

A project that requires recipients to receive approval in a program activity stage before starting work on a subsequent stage.

When the government must provide specific direction or redirection of the work.

A project that necessitates government monitoring of recipient work to ensure compliance with requirements (beyond what's considered normal programmatic monitoring or stewardship).

CA Advantages / Disadvantages



Advantages

- Academic institutions and non-profits are familiar and comfortable with cooperative agreements (most have business practices and systems already set-up)
- May permit flexibilities including allowing up to 90-day pre-award cost, carryover of unobligated (unexpended) funds from one budget period to the next, and initiation by the recipient of a one-time extension of the PoP by up to 12 months
- Rebudgeting among direct cost categories where the transfer of funds does not exceed 10% or more of total costs of the most recently approved award
- Does not require HHS leadership pre-award approval



Disadvantages

- Mainly geared towards academic institutions (colleges and universities) and intended for early stage/basic research
- Not appropriate for acquiring prototypes - deliverables are generally reports only
- No exceptions to Bayh-Dole Act (Intellectual Property) → less flexibility
- Processes based on regulations/policies rather than negotiations
- Does not allow for the payment of profit or fee (exception under HHS policy allows for the profit/fee on SBIR/STTR grants)

Innovative Solutions Opening (ISO) Overview

- ARPA-H’s preferred solicitation instrument for R&D efforts (programs and projects)
 - Created by ARPA-H (unique to ARPA-H’s needs/mission)
 - A competitive process with award decisions focused on technical quality (best ideas > best price)
 - Submissions reviewed/evaluated on their merit (not compared with other submissions)
 - Does not originate from the Federal Acquisition Regulation (FAR) → provides more flexibility than Broad Agency Announcements (BAAs)
- Replaced the “Open Office BAA” used from March 2023 to March 2024
 - ARPA-H does not plan to use BAAs in the future
- ISO types:
 - Program-Specific ISOs (highest ARPA-H priority)
 - Mission Office ISOs



Proposer Eligibility

- Any entity capable of satisfying the government’s needs may complete a submission to an ARPA-H ISO (i.e., small businesses, large businesses, nonprofit research institutions, and academia to include Minority Serving Institutions)
- Potential prohibitions and limitations:
 - Federally Funded Research and Development Centers (FFRDC)*
 - Other government entities*
 - Federal government employees*
 - Non-US entities*
 - Concurrent award count (no more than three) → See individual solicitation language

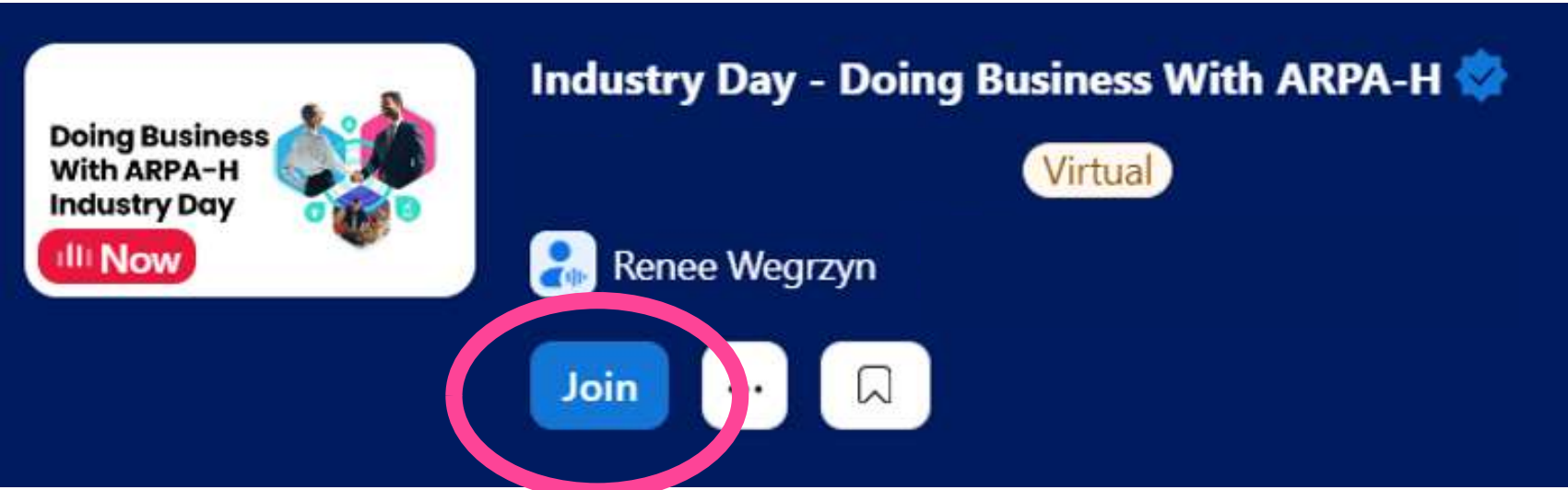
* Breakout sessions are available to provide more information on these topics



6. Breakout Period 1

Logistics for Breakout Rooms

- Join one of the 10 breakout sessions offered ("Session 1")
- The breakout session period is 35 minutes
- Ask questions in the chat
- All will rejoin main session room at 1:30PM (after lunch break)



Breakout Session Topics and Descriptions

Topic #	Topic	Description
1	Work With Us Q&A	Ask questions related to doing business with ARPA-H (“Ask Us Anything”)
2	You Received an Award, Now What?	An overview of typical post-award activities associated with ARPA-H research and development (R&D) efforts
3	OT Benefits	An overview of OTs and the expected benefits of using OTs
4	Payable Milestones	An overview of ARPA-H’s preference for payable milestones on R&D efforts
5	Intellectual Property (IP) Approach	An overview of IP and ARPA-H’s approach to IP
6	Teaming	An overview of teaming opportunities within specific ARPA-H programs and the importance of teaming with small business and Minority Serving Institutions (MSIs)
7	Affordability and Accessibility	An overview of affordability and accessibility and the importance to ARPA-H’s mission
8	International Collaboration	A session on opportunities for international collaboration, for both domestic and foreign proposers
9	Accelerating Program Transition	An overview of PATIO and the goal to transition health research innovations into solutions that reach everyone
10	Engaging with FFRDCs and GEs	Learn how ARPA-H can collaborate with FFRDCs and government entities

7. Finding Opportunities

How to Find Opportunities - Overview

- **Online:** ARPA-H.gov
- **Email:** Vitals Newsletter
- **Social Media:** ARPA-H accounts
- **SAM.gov:** Search function



How to Find Opportunities - Online

Online: ARPA-H.gov

Open Funding Opportunities Page

Provides a list of all currently open ARPA-H funding opportunities, including Program-Specific ISOs, Mission Office ISOs, Small Business Awards, and Research Sprints.

arpa-h.gov/engage-and-transition/open-funding-opportunities

Programs Page

Provides a list of all ARPA-H programs, including those with active solicitations and those that are closed.

arpa-h.gov/research-and-funding/programs

Mission Office ISOs Page

Provides links to the Innovative Solutions Openings for each of the 4 ARPA-H Mission Offices: Health Science Futures, Resilient Systems, Proactive Health, and Scalable Solutions.

arpa-h.gov/research-and-funding/mission-office-iso



How to Find Opportunities - Email

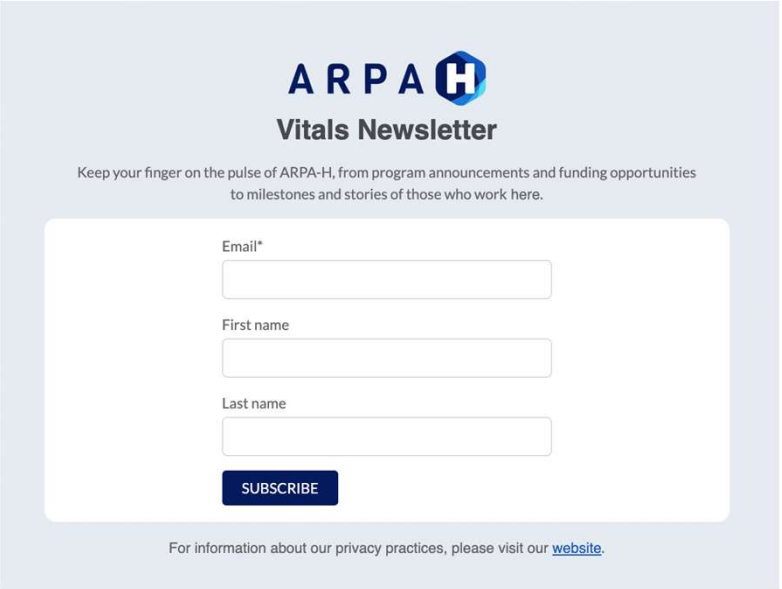
Email: Vitals Newsletter

Sign up on ARPA-H.gov

Provides bi-weekly updates about ARPA-H research opportunities and news direct to your email

Sign up using the footer bar of arpa-h.gov or visit the Vitals Newsletter sign up page:

engage.arpa-h.gov/arpa-h-vitals-newsletter-sign-up



The screenshot shows the ARPA-H Vitals Newsletter sign-up page. At the top, the ARPA-H logo is displayed above the text "Vitals Newsletter". Below this is a short introductory paragraph: "Keep your finger on the pulse of ARPA-H, from program announcements and funding opportunities to milestones and stories of those who work here." The main form area contains three input fields: "Email*" (required), "First name", and "Last name". A dark blue "SUBSCRIBE" button is positioned below the last name field. At the bottom of the form, a small link reads: "For information about our privacy practices, please visit our [website](#)."



The footer bar features a white rounded input field with the placeholder text "Enter email to subscribe (required)" and a blue rounded "Sign up" button.

How to Find Opportunities - Social Media/SAM.gov

Social Media: ARPA-H accounts

Follow on ARPA-H.gov

Provides regular updates about ARPA-H research opportunities and news through a variety of channels:

- **LinkedIn:** [ARPA-H](#)
- **Instagram:** [@ARPAHealth](#)
- **X/Twitter:** [@ARPA_H](#) and [@ARPA_HDirector](#)
- **YouTube:** [@ARPA-H](#)

Content tagging ARPA-H is viewed for potential amplification by the social media team.

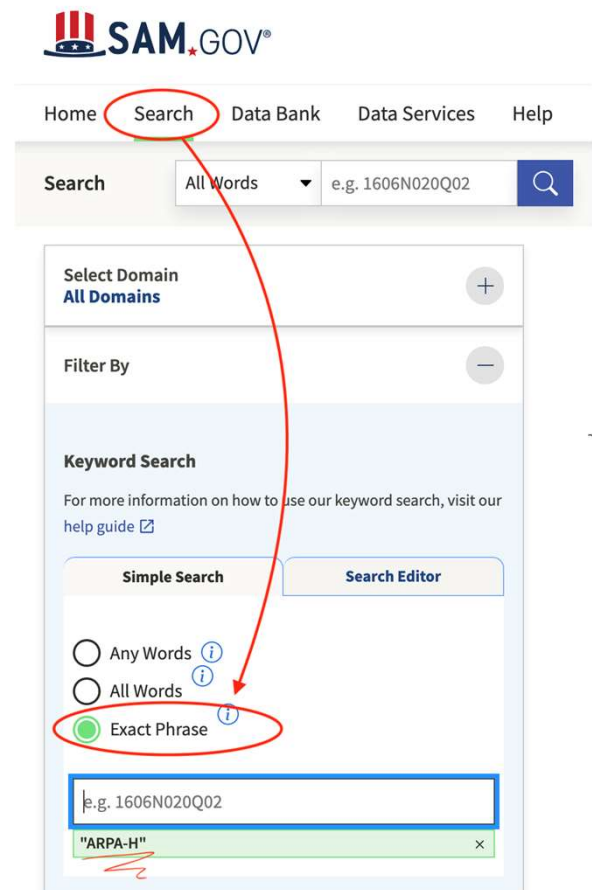


How to Find Opportunities - Social Media/SAM.gov

SAM.gov:

Search the exact phrase "ARPA-H"

- Provides an official government list of all ARPA-H funding awards both past and present
- Open [SAM.gov](https://sam.gov) search function, select "Exact Phrase," and enter "ARPA-H"



Live Demonstrations

- **ARPA-H Website**
 - Open funding opportunities
 - Submission Resources and FAQs
 - Vitals newsletter
- **Social media**



8. Customer Experience Initiatives

Customer Experience Initiatives - ARPA-H Website

Resources Page

- Funding awards process
- Common terms and definitions
- Sample forms and templates
- Frequently Asked Questions
- arpa-h.gov/engage-and-transition/submission-resources-and-faqs

UI/UX Redesign

- Improved navigation
- In-depth user testing
- Better data analytics
- New components and capabilities
- Design facelift



Customer Experience Initiatives - OT Community

- In July 2024, ARPA-H launched the OT Community
- Free for the public to access content at ARPA-H.gov
- Why?
 - Broadly speaking, OT authority is misunderstood across the federal government and is not being utilized to the greatest extent
 - There are limited OT-related resources (including training products) available to personnel within the federal government and industry
- Expected Benefits?
 - A community focused on OTs with active collaboration (i.e., training, mission assistance)
 - Timely access to relevant OT resources and information

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



Customer Experience Initiatives - ISO Process

- Health and Human Services (HHS) launched a large initiative in October 2023 involving many HHS Operating Divisions to enhance the customer experience relative to new or existing projects
- ARPA-H selected “the ISO process” for its project
 - Obtained feedback from internal subject matter experts and external submitters to initial ISOs
 - Conducted user testing of the ISO submission process through ARPA-H’s Solution Submission Portal
- ARPA-H updated its website, enhanced its submission portal, and changed business processes to enhance the customer experience for ISOs
- ARPA-H will remain flexible and constantly adjust based on performer feedback to operate with the most efficient and effective business processes

Customer Experience Initiatives - Performer Feedback

- ARPA-H is a bold and unique organization that plans to experiment with business processes to maintain efficient/effective business processes and keep barriers to entry low
- ARPA-H desires feedback from performers associated with R&D projects
- Performers may submit constructive feedback to DBWA@arpa-h.gov at any time during the performance period

9. Innovative Solutions Opening (ISO) Process Overview

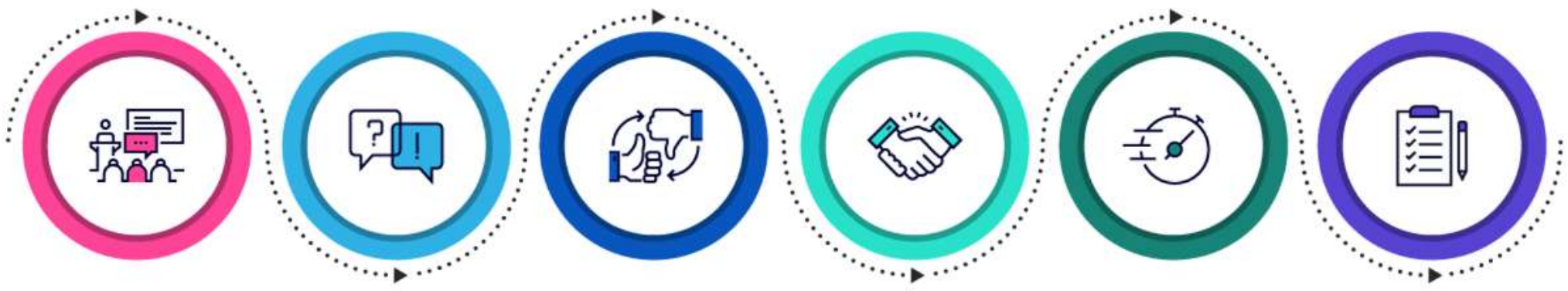
ISO-Related Terms and Definitions

Term	Definition
ISO	ARPA-H's unique solicitation instrument, which can either be in the form of a Program-Specific or Mission Office ISO
Program-Specific ISO	Used to solicit potential solutions for a specific ARPA-H program
Mission Office ISO	Used to solicit potential solutions that fall within a mission office area of research interest but may not be addressed by any specific ARPA-H program
Solution Summary	A concept summary document with minimal pages for proposers to submit to ARPA-H prior to investing resources for a full proposal submission
Full Proposal	A full application for a new or innovative idea
Pitch Presentations	A type of oral presentation that may be required of proposers (as an element of proposal evaluations)

ISO-Related Terms and Definitions (cont.)

Term	Definition
Encourage / Discourage	Potential feedback options from ARPA-H for solution summaries
Selected / Not Selected	Potential feedback options from ARPA-H for proposals
Non-conforming	Potential feedback option from ARPA-H for submissions that do not follow ISO instructions for proposals
Solution Submission Portal	ARPA-H website for solution summary and proposal submissions in response to active ISOs (registration required)
Other Transaction	An R&D award vehicle governed by 42 U.S.C. 290c(g)(1)(D)
Cooperative Agreement	A type of federal financial assistance instrument to transfer something of value to carry out a public purpose and not to acquire property or services (substantial involvement by ARPA-H is expected)

General Process Overview (for R&D efforts)



Planning and Initiation

ARPA-H identifies a broad research focus area or launches a specific research program

Solicitation

ARPA-H releases solicitations, usually in the form of an Innovative Solutions Opening (ISO)

Evaluation and Selection

Proposers submit solution summaries or full proposals and ARPA-H provides feedback

Negotiation and Award(s)

ARPA-H makes awards to submitter(s) after negotiating terms and conditions

Performance

Performers execute tasks and receive payment per agreement milestones and payment terms

Completion and Closeout

When the research is done, ARPA-H closes the agreement but provides ongoing product support



Program-Specific ISOs

- Used for most ARPA-H programs
- Draft ISO may be published until approved ISO is available
- Usually open for about 60 days (for solution summary submissions)
- Proposers' Day event likely (in-person and/or virtual)
 - Share information on the program and ISO process
 - Encourage team networking
- Programs usually involve phases over multiple years
- Multiple awards expected (OTs and/or CAs)
- Q&A about the program is usually available on ARPA-H's website and SAM.gov
- Generally include technical areas, objectives, phases, go/no-go phase checkpoints, and metrics

Program-Specific ISOs (cont.)

- A solution summary may be required prior to proposal submission
- Pitch presentations may be utilized as a part of the evaluation process
- Typical evaluation criteria*:
 - Overall scientific and technical merit
 - Proposer’s capabilities and/or related experience
 - Potential contribution and relevance to the ARPA-H mission
 - Price analysis
- Usually include format and instructions for required submission contents
- No reimbursement for solution summary submissions, proposal submissions, or Proposers’ Day attendance

* Order of evaluation criteria importance can vary by ISO



Mission Office ISOs

- One for each MO (“office-wide”)
 - Resilient Systems Office (ARPA-H-SOL-24-103)
 - Health Science Futures (ARPA-H-SOL-24-104)
 - Scalable Solutions (ARPA-H-SOL-24-105)
 - Proactive Health Office (ARPA-H-SOL-24-106)
- Usually open for multiple years (can be adjusted or renewed)
- Multiple awards expected (OTs and CAs)
- Solution summary required before proposal submission
- No reimbursement for solution summary or proposal submissions

Mission Office ISOs (cont.)

- ARPA-H intends to review solution summaries and provide feedback within 30 business days of solution summary receipt
- If encouraged for proposal submission, proposers will have 45 days to complete the submission
- Typical evaluation criteria:
 - Overall scientific and technical merit
 - Potential contribution and relevance to the ARPA-H mission
 - Proposers' capabilities and/or related experience
 - Cost realism
- ARPA-H intends to review proposals and respond to proposers within 60 days of proposal receipt

Conforming Proposals*

- Proposed concept applies to mission office interest area(s)
- Proposer meets eligibility requirements
- Proposal meets submission requirements
- Proposal meets content (attachments) and formatting requirements
- Proposer's concept not already funded (or selected for award negotiations) for another funding opportunity with ARPA-H or another government entity

* Non-conforming proposals may be removed from consideration (proposers will be notified via email)



Submitting on ARPA-H's Solution Submission Portal

1. Sign up for an account at <https://solutions.arpa-h.gov> (if you don't already have one)
2. Select **"Submit a Solution Summary"** or **"Submit Full Proposal"**
3. Select the applicable ARPA-H solicitation and enter the required information (i.e., submitter info, organizations, contacts)
4. Complete submission
5. Wait for a response or feedback from ARPA-H



Home | Submit Solution Summary | Submit Full Proposal

Submit a Solution Summary

* = required field



Live Demonstration

ARPA-H Solution Submission Portal

ARPA-H SOLUTIONS Home | Event Registration | Sign in

ARPA-H Solution Submission Portal

Sign Up Today

Already have an account? **Sign In!**

- Solution Summary: a concept summary document for proposers to submit to ARPA-H prior to investing resources for a full proposal submission.
- Full Proposal: a full application for a new or innovative idea.

The screenshot shows a central graphic with a hexagonal shape containing a family (a woman, a man, and a baby) surrounded by various medical and scientific icons like a microscope, a person in a lab coat, and a person using a microscope. Red circles highlight the 'Sign Up Today' and 'Sign In!' buttons, with red arrows pointing from them to the right.

For new users/accounts

For existing users/accounts



10. Helpful ISO Resources (FAQs, Lessons Learned, and Tips)

ISO FAQs

- **What is an Innovative Solutions Opening (ISO)?**

An ISO is a solicitation instrument uniquely created by ARPA-H to make awards for R&D projects (can be in the form of a Program-Specific or Mission Office ISO). ISOs are not bound by the Federal Acquisition Regulations or Federal assistance regulations.

- **What types of entities are eligible to submit to ISOs?**

Any entity capable of satisfying the government’s needs may submit to ISOs; however, there are some limitations for FFRDCs, other government entities, and non-US entities.

- **Can entities only submit one proposal to each Program-Specific ISO?**

Yes, entities (per UEI) may generally only submit one proposal to each Program-Specific ISO as the primary proposer; however, one entity may submit multiple solution summaries to each Program-Specific ISO. Separately, entities may propose within multiple teams as a teaming partner (sub-awardee).

- **Who reviews the technical merit of the solution summaries and proposals and how are reviewers selected?**

Reviewers may be ARPA-H Programs Managers or other qualified personnel from other government organizations. For each ISO, ARPA-H selects personnel deemed proficient in the pertinent research area(s). Non-government subject matter experts may be utilized to provide feedback as advisors on proposed solutions; however, they are restricted by contractual terms and non-disclosure agreements.



ISO FAQs

- **How are solution summaries and proposals evaluated?**

Solution summaries and proposals are reviewed as specified in each ISO. Solution summaries are not evaluated to the same extent as full proposals since they are only concept summary documents.

- **What is the maximum number of teams and/or people for each proposal?**

There is no maximum number of teams or people per proposal. It is the proposer's responsibility to propose a team comprised of personnel capable of meeting the proposed work.

- **Are international entities eligible to submit proposals for ARPA-H opportunities?**

Yes, international entities are allowed to submit proposals or collaborate with US entities as team members. Per 42 U.S.C. 290c, the ARPA-H Director shall prioritize awarding any contracting instruments to entities that will conduct funded work in the US and, where appropriate and practicable, encourage nondomestic recipients of contracting instruments to collaborate with domestic entities. In no case will ARPA-H evaluate proposals from or make awards to entities organized under the laws of a covered foreign country.

- **Are program metrics included in individual ISOs considered requirements and how will ARPA-H measure performance for performers?**

Program metrics included in ISOs are generally considered requirements and not subject to change. Proposers that do not propose to meet the metrics outlined in the ISO may not be selected for negotiation for award. ARPA-H will measure performance based on the agreement terms, as agreed upon by all parties of the agreement.



ISO Lessons Learned & Tips

- Visit ARPA-H's website for team members (primarily submitters) to get oriented with ARPA-H's ISO process and Solution Submission Portal
 - ISOs are not Broad Agency Announcements (BAAs) and are not used by other government entities
 - ARPA-H does not use eRA Commons for submissions
- Read the entire ISO before making a submission
- Programs are the lifeblood of ARPA-H; thus, Program-Specific ISOs are considered a higher priority than Mission Office ISOs
- Response times for ARPA-H to respond to Program-Specific and Mission Office ISO submissions will vary (resources and priorities)
- Make sure solution summaries and proposals are submitted to the correct area on ARPA-H's Solution Submission Portal
- Adhere to page limits and produce the required information outlined for each ISO and submission type (conforming)
- There is not currently a way for submitters to check submission status on ARPA-H's Solution Submission Portal (be patient for ARPA-H to respond)

ISO Lessons Learned & Tips (cont.)

- Programs ISOs are not all the same, as some have different requirements and metrics
- Submit early → submissions submitted after posted deadlines will be considered late and will not be reviewed (non-conforming)
- Not all questions can be answered promptly → it is better to submit a solution than to miss a deadline waiting for a response
- Solution summary responses are 'encourage' and 'discourage' → interested parties can still complete a proposal submission if they receive a 'discourage' response (purely at their discretion)
- For proposals, separate documents by type unless specifically asked for a bundle
- Proposers must be registered in SAM.gov (with UEI) to receive an award

Closure / Wrap-Up

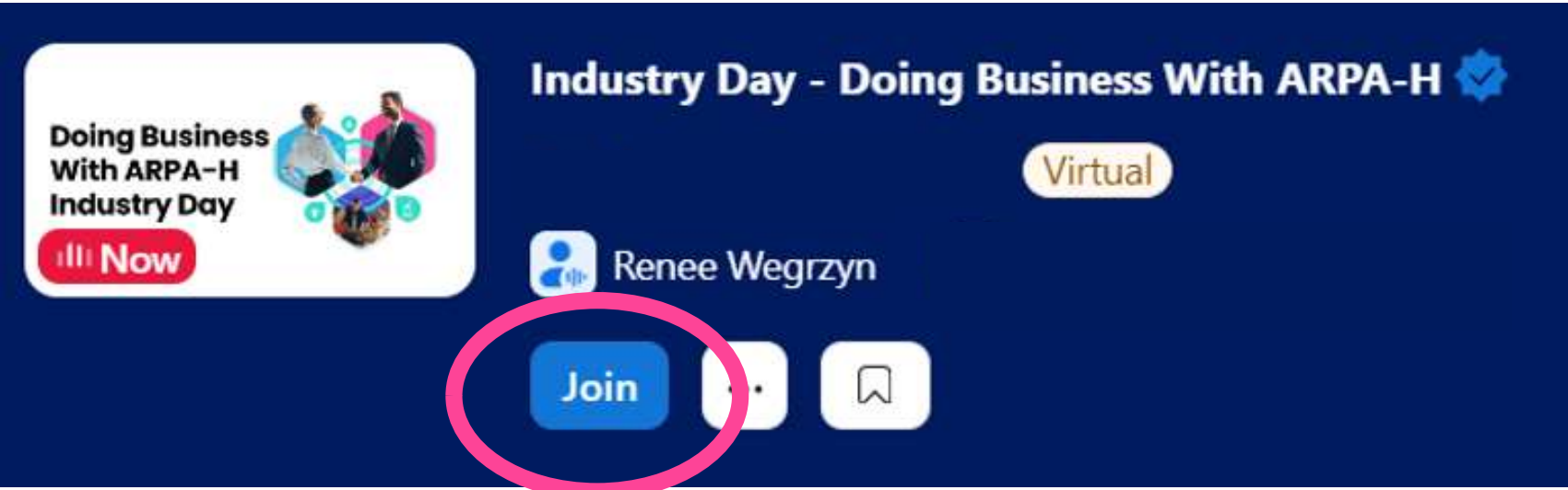
Closure / Wrap-Up

- Thank you for attending the virtual “Doing Business With ARPA-H” event
- We hope you learned more about ARPA-H’s mission, authorities, and R&D funding opportunities
- The following breakout session is our last event session
- We will **not** regroup after the breakout session
- Presentation content and Q&As will be available for viewing on ARPA-H’s public website after the event
- Email DBWA@arpa-h.gov if you have any questions about the event or would like to provide feedback
- Attendees will receive a post-event survey

11. Breakout Period 2

Logistics for Breakout Rooms

- Join one of the 10 breakout sessions offered ("Session 2")
- The breakout session period is 35 minutes
- Ask questions in the chat
- All can leave the event after breakout session



Breakout Session Topics and Descriptions

Topic #	Topic	Description
1	Work With Us Q&A	Ask questions related to doing business with ARPA-H (“Ask Us Anything”)
2	You Received an Award, Now What?	An overview of typical post-award activities associated with ARPA-H research and development (R&D) efforts
3	OT Benefits	An overview of OTs and the expected benefits of using OTs
4	Payable Milestones	An overview of ARPA-H’s preference for payable milestones on R&D efforts
5	Intellectual Property (IP) Approach	An overview of IP and ARPA-H’s approach to IP
6	Teaming	An overview of teaming opportunities within specific ARPA-H programs and the importance of teaming with small business and Minority Serving Institutions (MSIs)
7	Affordability and Accessibility	An overview of affordability and accessibility and the importance to ARPA-H’s mission
8	International Collaboration	A session on opportunities for international collaboration, for both domestic and foreign proposers
9	Accelerating Program Transition	An overview of PATIO and the goal to transition health research innovations into solutions that reach everyone
10	Engaging with FFRDCs and GEs	Learn how ARPA-H can collaborate with and government entities

**This concludes the event.
Thank you for attending!**

Questions or feedback?

Email:

DBWA@arpa-h.gov

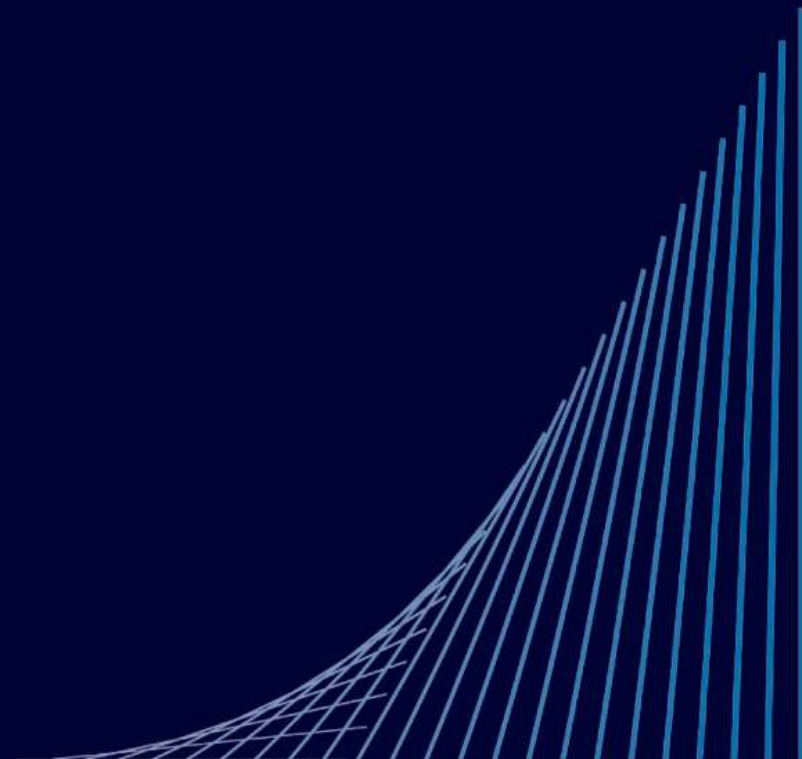
ARPA 

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 ...



ARPA H

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.

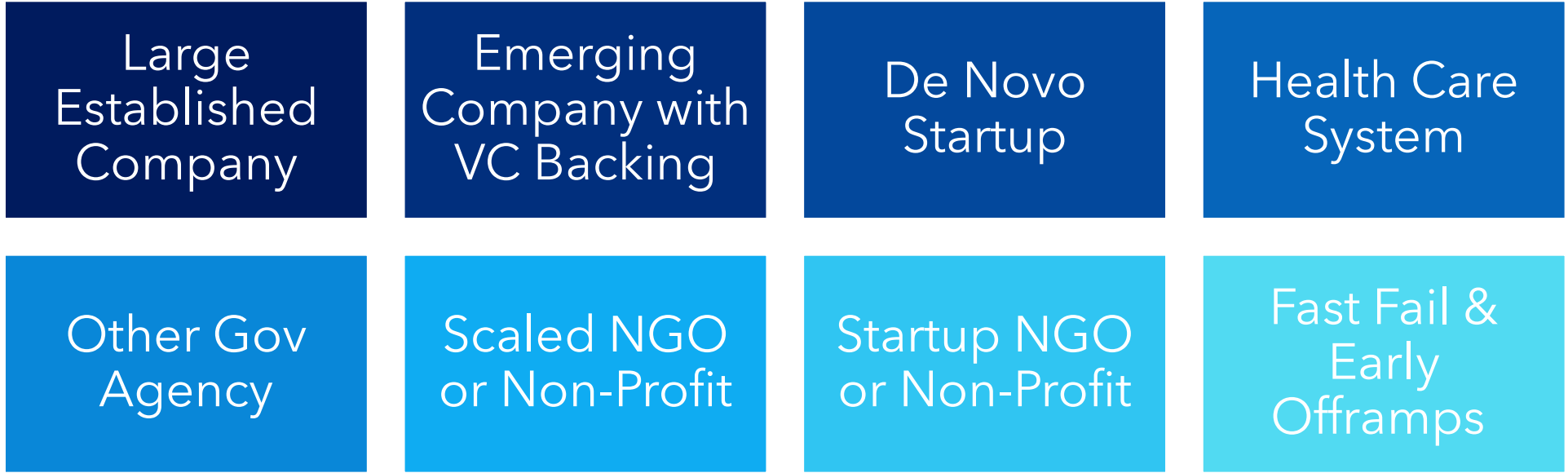


Since ARPA-H will not fund performers in perpetuity, PATIO's services increase the odds that solutions attract private investment and customers—to translate the breakthroughs



Where might the solution go after ARPA-H?

Work backwards: design with the end in mind



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%)



Statistics from "Top Reasons Startups Fail" Survey by CB Insights

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

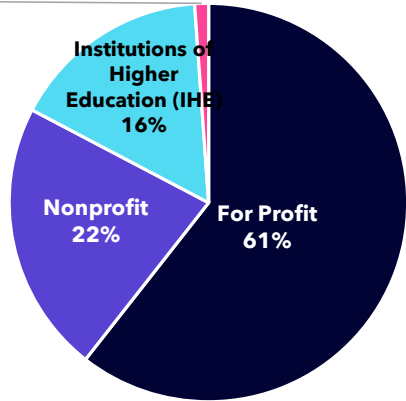
Join ARPANET-H to accelerate transition-focused R&D

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"

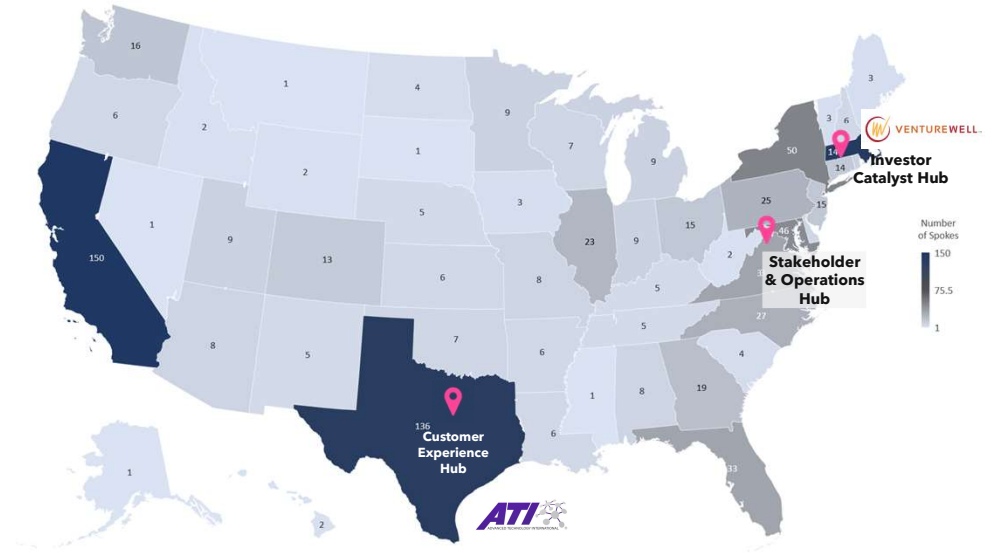
Public Sector
Affiliated
1%



-  **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



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

Approved for Public Release: Distribution Unlimited

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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



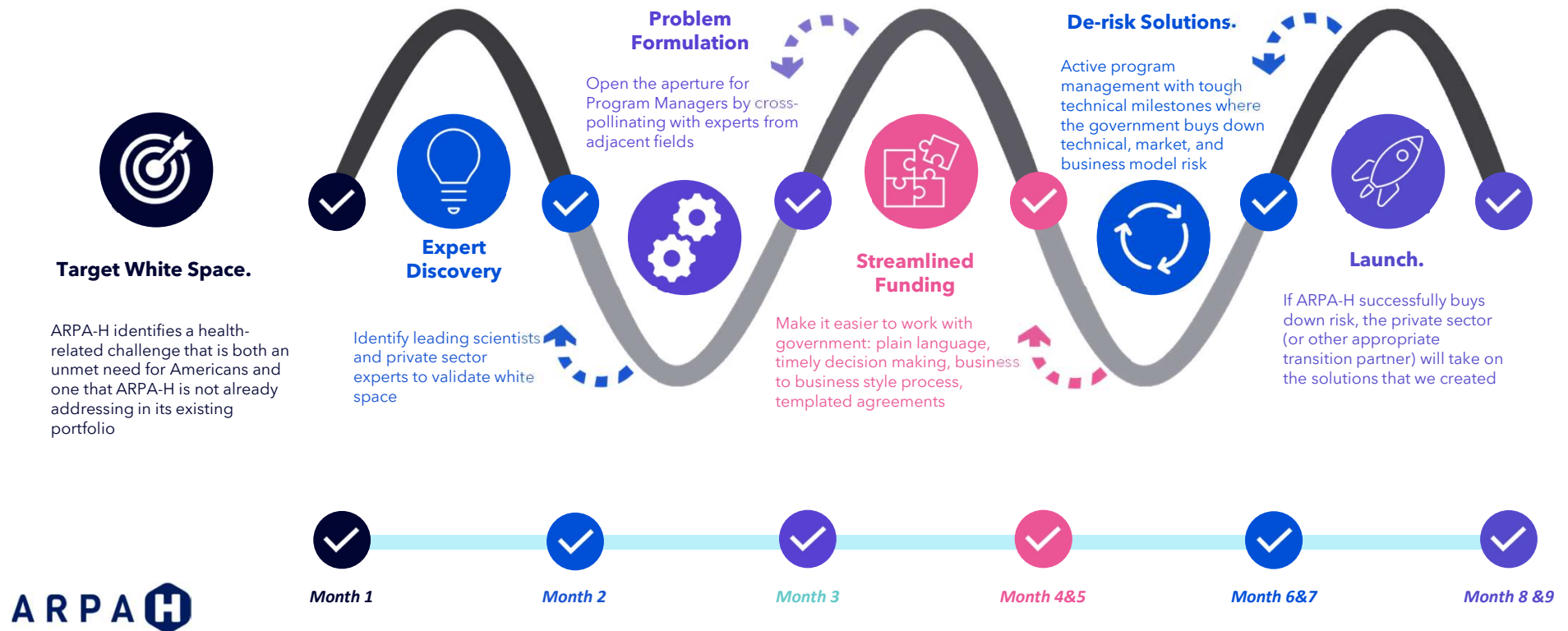
Jenica Patterson, PhD
Project Accelerator Transition Innovation Office
6. WILD CARD: Revolutionary Breakthroughs in Women's Health



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Participate in future ARPA-H Sprints

Rapidly Identify & Solve High-Value Challenges



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

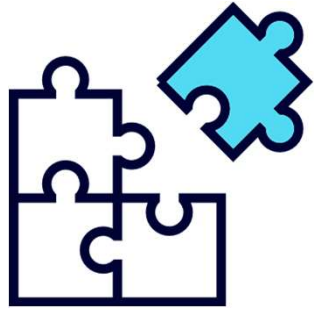
<https://arpa-h.gov/engage-and-transition>

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



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 

Affordability and Accessibility

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024



Why You're Here

- Understand how ARPA-H's success relies on solutions being affordable and accessible
- Learn how ARPA-H programs can incorporate affordability and accessibility factors



ARPA-H's Mission

- Accelerate better health outcomes **for everyone** by supporting the development of high-impact solutions to society's most challenging health problems

- For solutions to be available for everyone, the solutions must be **affordable** and **accessible**



ARPA-H's Strategy

- ARPA-H programs are required to establish plans to address potential misuse and disparities in health outcomes, affordability, and accessibility prior to launch
- ARPA-H prioritizes making solutions affordable and accessible to those in need through program design, contract structures, activation of a nationwide health innovation network, early patient and community engagement, and a focus on transition pathways
- ARPA-H is committed to advancing solutions within the agency and throughout its technical portfolio, that provide access for everyone, including but not limited to with respect to disability, geography, employment and insurance status, and socioeconomic status



ARPA-H's Strategy (cont.)

- Leverage an interdisciplinary approach and collaborative networks to create programs that address challenges to geography, distribution, manufacturing, data and information, thereby improving health care access and affordability
- Improve the scalability and affordability of health care solutions, bridge gaps in underserved areas, and extend remote access to expertise by developing location-specific interventions, telemedicine solutions, and mobile health clinics
- Accelerate the availability of critical health care technologies and make them more affordable for everyone



Affordability and Accessibility in Programs



Program Design

- Consider solution accessibility, cost, and unintended harm of solution
- Consider potential barriers to affordability
- Diverse stakeholder input during design phase



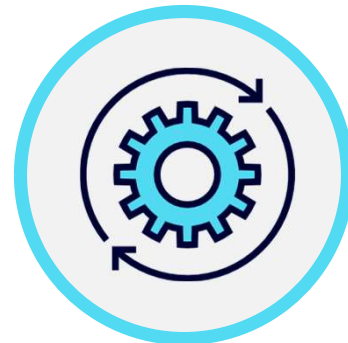
Example Performer Requirements and Selection

- Key performance indicators (KPIs)
- Data collection on impact and outcomes
- Action plans
- Diverse performer entities
- Performer relationship with community-based organizations



Program Implementation

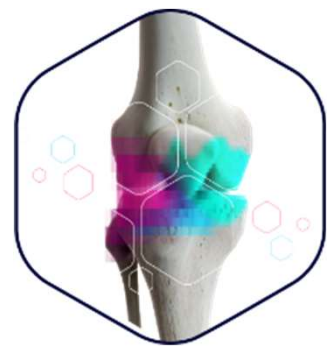
- Diversity in clinical trials
- Solution testing in diverse settings/among diverse end-users
- Community forums and feedback sessions
- Engagement with diverse community-based organizations



Graduation and Sustainment

- Ongoing monitoring of impact
- Ongoing tracking of metrics/data collection
- Annual reporting

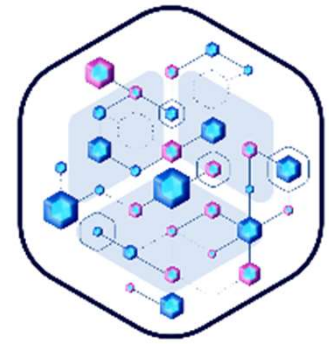
Program Examples



NITRO

Impact: Develop and ensure access to innovative osteoarthritis treatment, particularly in communities disproportionately impacted.

Affordability and Accessibility Performer Requirements: Integrated personnel conduct diverse clinical trials and compose insurance action plans. Additionally, created terms to drive down costs to the patient during and after the life of the ARPA-H funding vehicle.



PARADIGM

Impact: Create a new platform that delivers hospital-quality clinical, diagnostic, and essential medical services to rural America, bringing care directly to people across zip codes.

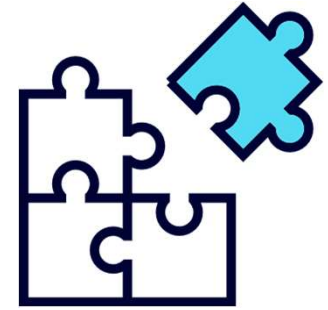
Affordability and Accessibility Performer Requirements: Performers are encouraged to conduct robust community engagement, create community viability plan to describe the demographics, and disparate needs in rural communities served by the care delivery platform.

All proposers must articulate how they will incorporate affordability and accessibility considerations (e.g., diverse user demographics and early and frequent engagement with stakeholder communities) into design, development, and testing of prototypes.



Session Takeaways

- For solutions to be available for everyone, the solutions must be affordable and accessible
- Programs will consider affordability and accessibility during program design, selection, and performance
- Review individual solicitations to identify affordability and accessibility metrics, factors, requirements, etc.





The four Mission Office-specific Innovative Solutions Openings (ISOs) include:



Proactive Health

Creating capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats whether viral, bacterial, chemical, physical, or psychological.



Scalable Solutions

Addressing challenges including geography, distribution, manufacturing, data and information, and economies of scale to develop impactful, timely, and accessible solutions.



Health Science Futures

Accelerating advances across research areas and removing limitations that stymie progress towards solutions for broad ranges of disease and conditions.



Resilient Systems

Addressing systemic challenges across the healthcare and public health landscape by investing in cutting-edge technologies that address long-standing gaps in the quality, efficacy, and consistent availability of care.

Mission Office-specific ISOs allow ARPA-H to fund health-related technology research and development outside of the traditional structure.

Innovative Solutions Openings funding opportunity **now open**



Apply Now

solutions.arpa-h.gov

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Q&A



ARPA 

Engaging with Federally Funded Research and Development Centers and Government Entities

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024



Why You Are Here

- Understand ARPA-H's policy and approach to working with:
 - Federally Funded Research and Development Centers (FFRDCs)
 - Government Entities (GEs)

- Learn more about:
 - Overlapping interests
 - Complementary capabilities
 - Conflict of interest and unequal access concerns
 - Clear lines for engagement



Federally Funded Research and Development Centers (FFRDCs)

Introduction

FFRDCs are unique organizations sponsored by the U.S. Government to meet specific long-term technical needs that can't be met as effectively by the government or private sector alone.

They operate as strategic partners, providing expert advice and technical expertise in research and development.

<https://www.nsf.gov/statistics/ffrdclist/#ffrdc>



FFRDC Characteristics



Government-sponsored



Public-interest Focused



Long-term Relationships



Comprehensive Expertise

Benefits

Impartial expertise: provide unbiased, high-quality research and development support tailored to the sponsor's needs.

Stability and continuity: maintain long-term stability and institutional knowledge, which is crucial for projects requiring sustained attention over many years.

Access to cutting-edge technology: often have access to advanced technologies and capabilities that might not be readily available in the private sector.

Flexible collaboration: can work in close partnership with their sponsors, adapting to evolving requirements and priorities and has access, beyond that which is common to the normal contractual relationship.

Types of FFRDCs

Research and Development Laboratories

Focused on applied research, development, and engineering

Study and Analysis Centers

Provide objective analysis and assessment to inform policy and decision-making

Systems Engineering and Integration Centers

Offer systems engineering and integration capabilities

Governance

Sponsorship and Oversight: Each FFRDC is sponsored by a specific government agency which provides oversight to ensure alignment with federal objectives and efficient use of resources.

Contracting Mechanism: FFRDCs operate under long-term contracts or agreements with their sponsoring agencies, which are periodically reviewed and renewed.

Regulatory Compliance: They adhere to federal regulations and policies, including those concerning security, intellectual property, and financial management.



Governmental Entities

- Government Entities (GEs) include Government agencies and employees, and business concerns or other organizations owned or controlled by one or more Government employees.
 - E.g. – NIH Institutes or Centers
- GE is a permanent or semi-permanent Federal organization (including support contractors) established by the executive or legislative branches of the government responsible for oversight and administration of a specific government function.
- GEs can also include gubernatorial and legislative offices from state governments, local governments and tribal governments.
- Examples of GEs include the Department of Homeland Security, the Central Intelligence Agency, the Federal Bureau of Investigation, State Governor Office, NIH Institutes and Centers, appropriately cleared OGE support contractors.



ARPA-H Policy

- Issued by ARPA-H Director, Dr. Renee Wegrzyn:
 - ARPA-H’s position is that FFRDCs and Government entities are not allowed to participate in ARPA-H awards under research and development (R&D) Other Transactions or Cooperative Agreements as either a prime or sub-performer, except in rare and special circumstances
- Specifically:
 - FFRDCs were established to produce thorough, independent analysis without competing interests that could lead to bias or the misuse of information. Due to the long-term relationship between an FFRDC and a sponsoring federal agency, as well as the nature of the work and services provided by the FFRDC, FFRDCs may often have access to Government employees, equipment, data, and property beyond what is typical for a contractor. **The Government’s position is that FFRDCs should not be able to leverage this access to compete with the private sector and should not be assigned work that could be carried out effectively by for-profit companies, except on a very limited basis.**
 - Government entities are prohibited from being awarded federal contracts due to:
 - conflicts of interest between employee interests and their Governmental duties,
 - organizational conflicts of interest, and
 - the appearance of favoritism or preferential treatment.



Solicitation Language

PROHIBITION OF PERFORMER PARTICIPATION FROM FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCs) AND GOVERNMENT ENTITIES

ARPA-H is primarily interested in responses to this solicitation from commercial performers, academia, non-profit organizations, etc. In certain circumstances, FFRDCs and government entities will have unique capabilities that are not available to proposing teams through any other resource. Accordingly, the following principles will apply to this solicitation.

- a) FFRDCs and government entities, including federal government employees, are not permitted to respond to this solicitation as a prime or subperformer on a proposed Performer team.
- b) If an FFRDC or government entity has a unique research idea that is within the technology scope of this solicitation that it would like considered for funding, submit research description to this e-mail address: ARPA-H [Mission Office] ISO@arpa-h.gov.
- c) If an FFRDC or government entity, including a federal government employee, is interested in working directly with the government team supporting the research described by this solicitation, that party should contact the ARPA-H [Mission Office] ISO@arpa-h.gov.
- d) If a potential prime Performer believes that an FFRDC has a unique capability without which its solution is unachievable, the potential prime Performer should be aware that it will have to provide documentation as part of its proposal submittal showing that it has exhausted all other options for ARPA-H to consider the inclusion of the FFRDC in the proposed solution.



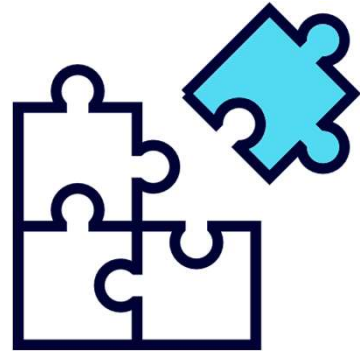
ARPA-H Policy Exception

A Program Manager can request a waiver:

- Must justify how FFRDC or Government Entity contributions can't reasonably be met by a private sector capability
- Must be approved in writing by Director of ARPA-H, or Deputy Director as delegated

Key Takeaways

ARPA-H's position is that FFRDCs and Government entities are **not** allowed to participate in ARPA-H awards under research and development (R&D) Other Transactions or Cooperative Agreements as either a prime or sub-performer, except in rare and special circumstances.





Q&A



ARPA 

Intellectual Property (IP) Approach

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024



Why You're Here

- Understand Intellectual Property (IP) within the context of the two most likely R&D award instruments proposers may receive from ARPA-H (Other Transactions, or OTs, and Cooperative Agreements, or CAs)

- Ask IP-related questions



Intellectual Property (IP)

- An intangible creation of the human mind, usually expressed or translated into a tangible form, that is assigned certain rights of property
- **Why is it important?**
 - Protection of IP is one of the few specific topics mentioned in the US Constitution (Article I, Section 8, Clause 8) grants Congress the right to create the patent and copyright system
 - The Patent and Trademark Office and the Copyright Office in the Library of Congress are two of the oldest civilian agencies in the Federal Gov't
 - The Founding Fathers wanted authors and inventors to share their creative works with society at-large with the understanding that their rights in those works would be protected for a limited period of time
- **What protects it?**
 - Federal Law
 - Patents, copyrights, trademarks, trade secrets
 - Includes Bayh-Dole, which allows universities, businesses, and non-profit organizations to own and commercialize inventions that are developed through federally funded research programs. *Only* applies to patentable inventions
 - State laws
 - Trade Secrets



IP Protection Methods

Four basic IP protection methods have been created...

Patent	Copyright	Trade Secret	Trademark
<ul style="list-style-type: none">• Protects new, unobvious, and useful inventions• Can include utility, design, and plant/animal patents	<ul style="list-style-type: none">• Protects original works of authorship embodied in a tangible medium of expression	<ul style="list-style-type: none">• Protects secret business information from unauthorized use or disclosure	<ul style="list-style-type: none">• Establishes exclusive rights to use marks that distinguish one's goods and services from another

In exchange for making IP public, authors and inventors are granted a limited monopoly to use their IP and prevent others from doing so within their permission.

Once the limited monopoly expires, however, the IP becomes available to society for any one to use within restriction.

IP Terms in ARPA-H Cooperative Agreements

- Comprehensive Cooperative Agreement terms and conditions: <https://arpa-h.gov/engage-and-transition/submission-resources-and-faqs>.
- Terms are prescribed at [2 CFR § 200.315 - Intangible property](#) and [45 CFR § 75.322 - Intangible property and copyrights](#)
- For patents, Government receives a license to practice the invention in accordance with implementation of the Bayh-Dole Act of 1980 (see [37 CFR part 401](#))
- For data, Government may obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and authorize others to do so for a Federal purpose



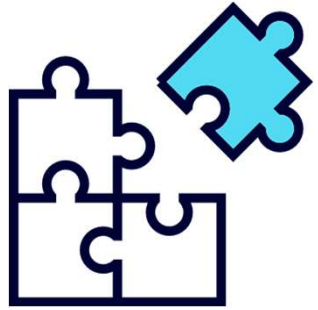
IP Terms in ARPA-H Other Transactions

- Allow terms to be crafted to align with the specific program/project requirements
- As a baseline, ARPA-H seeks a nontransferable nonexclusive license rather than ownership of the subject invention
- Tailored licenses for data
- Process-based tailoring (e.g., disclosure timeframes)
- Sample OT Agreement: <https://arpa-h.gov/engage-and-transition/submission-resources-and-FAQs>



Session Takeaways

- ARPA-H understands and is sensitive to how essential IP is to organizations in the biotech industry. Encouraging investors and creators, while balancing the public's interest, is the goal of the Federal Government.
- ARPA-H isn't looking to own IP created during performance and generally seeks a license in only the IP created during performance.
- ARPA-H's mission is to ensure technologies it invests in are affordable, accessible, and are commercialized.
- Traditional award instruments (i.e., contracts) have strict IP frameworks. ARPA-H intends to use OTs to maximize flexibility in finding IP arrangements that make the most sense for both parties.





Q&A



ARPA 

International Cooperation

For U.S. and non-U.S. proposers

Megan Frisk, PhD

Director, Division of International Affairs

November 13, 2024



ARPA-H International



While ARPA-H programs focus on the hardest problems faced in America, health issues exist everywhere and are often the same, regardless of borders.

ARPA-H is looking for innovative solutions **all over the world.**

International Cooperation Augments ARPA-H Programs

Force-multiplying R&D



Unique resources, talent, capabilities, facilities & infrastructure



Pilot, scale, or trial invention elsewhere



An enabling research and/or policy environment

Fostering Transition



Prospective investors & transition partners



Foreign markets & regulatory landscape



End users & patient populations globally

Collaboration Can Take Many Forms



Performer or team member



International spoke



Co-investment or in-kind contribution



Transition partner or pathway

International FAQs

Does ARPA-H fund international R&D?

Can ARPA-H directly fund a foreign entity?

Are all foreign entities eligible for ARPA-H funding?

**defined in the National Security Act of 1947 (50 U.S.C. § 3059) as Russia, Iran, North Korea, and China.*



More at arpa-h.gov/about/FAQs

International FAQs (continued)

What are the arrangements for intellectual property (IP) with foreign performers?

Are there any restrictions on onward technology transfer for performers with IP from ARPA-H funded work?

Examples of How to Engage with ARPA-H

For international collaborators



Mission Office-specific Innovative Solutions Opening (ISO)

- Submit your initiative ideas directly to one of the ARPA-H Mission Offices. These are awarded via Other Transactions or Cooperative Agreements for health-related technology research.



Program-specific Proposals & Teaming Pages

- Submit your proposal to one of ARPA-H's programs to become a performer or team member.
- Check out program teaming pages & Proposers' Days, too!



ARPANET-H

- Apply to be an international spoke in ARPA-H's health innovation network that connects people, innovators, and institutions.



Customer Experience Hub



Investor Catalyst Hub

Thank you!

Learn more at arpa-h.gov

Email us at international@arpa-h.gov

**Keep up-to-date through the
ARPA-H Vitals newsletter.**



Other Transaction (OT) Benefits

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024

Approved for Public Release: Distribution Unlimited



Why You're Here

- Understand ARPA-H intentions to use OTs for R&D efforts
- Learn more about Other Transactions (OTs), including their:
 - Benefits
 - Purposes
 - Key differences from traditional government contracts



Science & Technology (S&T) Community

Past

- Innovation fueled by the Gov't
- Commercial sector wanted to work with the government
- The government was the primary driver of technology innovation by making substantial research and development (R&D) investments



Present

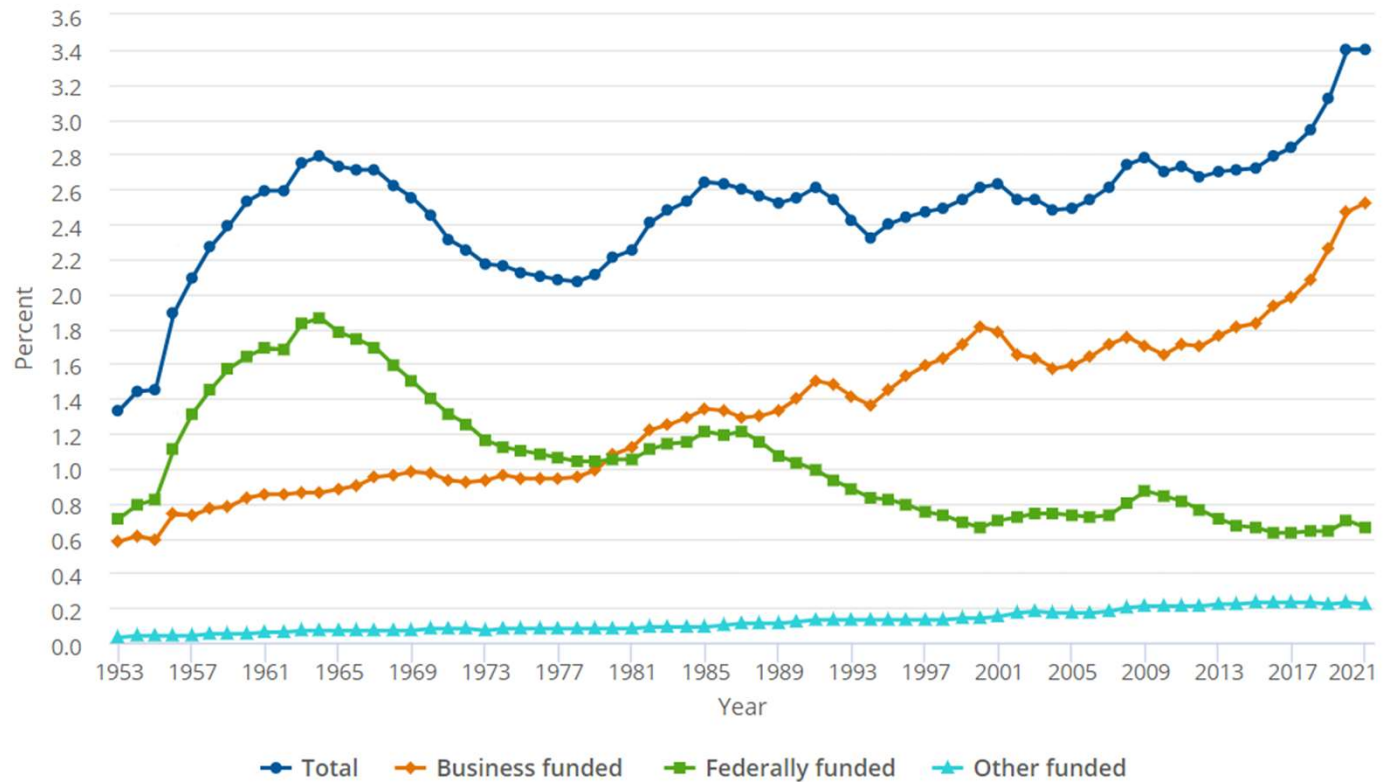
- Innovation fueled by the commercial sector
- Cutting edge commercial firms with large R&D investments are reluctant to work with the government
- Focus and pace of S&T innovation in leading technology areas have shifted from government to the commercial sector (industry spends nearly 10x more on R&D than the government)

R&D Findings

Ratio of U.S. R&D to gross domestic product, by source funds for R&D

1953-2021

Source: National Science Foundation (NCSES)



Impediments to Commercial Sector Participation

- Traditional procurement process is too slow, bureaucratic, and doesn't effectively incorporate commercial best practices
- Traditional procurement contracts (FAR-based contracts) are based on "regulation" rather than "negotiation"
- Government's cost-based pricing system is cumbersome
 - Specialized accounting and audit systems
 - Actual and perceived oversight excesses
- Small businesses and start-ups may be able to secure funding much more quickly and more easily from venture capitalists
- Government's approach to intellectual property (IP) and technical data rights can be overreaching

OTs - What They Are and What They Are Not

What They Are:

- Flexible/innovative/streamlined contract vehicles with characteristics similar to those within the commercial industry
- Require personnel with business acumen and negotiation skills (and OT training or experience)
- Require performance measurement and management (cost, schedule, and technical progress)
- Vehicles by which the Government Accountability Office (GAO) has limited jurisdiction to review decisions and protests



What They Are Not:

- Appropriate for all offices, divisions, and projects
- Procurement contracts (FAR-based), grants, or cooperative agreements
- Subject to all acquisition laws and regulations
- New vehicles available to the government
- One-size-fits-all vehicles with standard checklists
- Vehicles used strictly to avoid following the FAR
- Guarantee teams to complete awards faster than traditional contracts

OTs - Purposes and Potential Benefits

- Provide the flexibility to adopt and incorporate business practices similar to those within commercial industry
- Provide the government access to state-of-the-art technology solutions
- Foster new relationships and practices with solutions providers, especially those that may not be interested in entering into FAR-based contracts with the government
- Broaden the Public Health Industrial Base (PHIB), Defense Industrial Base (DIB), or other
- Encourage flexible, quicker, and cost-effective projects design and execution when compared to other vehicles
- Leverage commercial industry investments in science/technology and R&D
- Collaborate in innovative and flexible arrangements





OTs - What Laws and Regulations Apply?

Laws & Regulations that Apply to OTs	
False Claims Act - 31 U.S.C. § 3729	Antideficiency Act (ADA) - 31 U.S.C. § 1341/1342/1517
False Statements - 18 U.S.C. § 1001	Restrictions on Obtaining and Disclosing Certain Information (formerly Procurement Integrity Act) - 41 U.S.C. § 2101, et seq.
Civil Rights Act - 42 U.S.C. § 1981	Federal Property and Administrative Services Act - 40 U.S.C. Subtitle I
Clean Air Act - 42 U.S.C. § 7401	Debarment and Suspension - 2 CFR 376
Clean Water Act - 33 U.S.C. § 1251	Research Misconduct - 42 CFR 93
Endangered Species Act - 16 U.S.C. § 1531	Human Subjects Protections - 45 CFR 46
National Environmental Policy Act - 42 U.S.C. § 4321, et seq.	Humane Care and Use of Laboratory Animals - Public Health Service Policy

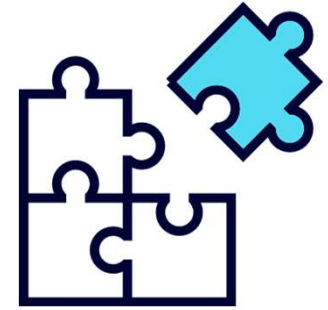


OTs - What Laws and Regulations Do Not Apply?

Laws & Regulations that Do Not Apply to OTs	
Competition in Contracting Act (CICA) - 41 U.S.C. § 3301	Buy American Act (in part) - 41 U.S.C. § 83
Truthful Cost and Pricing Data Act (formerly Truth in Negotiations Act) - 41 U.S.C. § 3501, et seq.	Antikickback Act of 1986 - 41 U.S.C. § 51-58
Cost Accounting Standards - 41 U.S.C. § 1502	Service Contract Act - 41 U.S.C. § 351 et seq.
Contract Disputes Act - 41 U.S.C. § 7102	Procurement Protest Process - 48 CFR 33.1
Procurement Protest System - 31 U.S.C. § 3551, et seq.	Federal Acquisition Regulation (FAR)
Bayh-Dole Act - 35 U.S.C. § 202-204	HHS Acquisition Regulation (HHSAR)

Session Takeaways

- Innovation is fueled by the commercial sector (vice the government)
- The commercial sector has spent more funding for R&D efforts than the government over the last two decades
- OTs are unique contracting vehicles that are not contracts, grants, or cooperative agreements and not subject to all acquisition laws and regulations
- OTs provide the flexibility to adopt and incorporate business practices similar to those within commercial industry
- OTs enable the government to collaborate with entities and leverage commercial industry investments in science/technology/R&D





Q&A



ARPA 

Payable Milestones

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024

Approved for Public Release: Distribution Unlimited



Why You're Here

- Understand the two types of payable milestone structures contemplated for Other Transactions (OTs)
 - Fixed milestones
 - Expenditure-based milestones

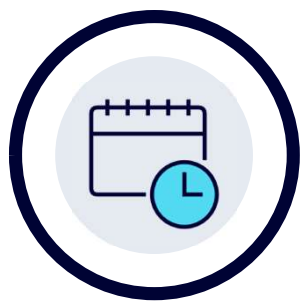


Payable Milestones Overview

Payment structure considerations...



Nature of the agreement



State or phase of the project/program



Risk or complexity involved



Established milestones



Performer's accounting system

Consider the Performer's current accounting system capabilities

Avoid imposing system requirement that cause the Performer to revise and/or add system(s)

Payable Milestones Overview (cont.)

Milestones must be clearly documented within each agreement.



Payment system developed to be more commercial- and industry-friendly



Adaptable and flexible (can be tailored to specifics of program or effort)



Great as an administrative tool for encouraging and tracking effort progress



May reduce administrative burden



Attractive to industry - may assist performers with cash flow

Payable Milestones (cont.)

- **Milestones should typically reflect observable technical events or other key actions**
 - Generally quarterly events (i.e., kick-off, management reviews, technical reports, final report)
 - Some activity significant to the progress of the project/program
- **Each milestone has a value that is negotiated at the time of award**
 - Value typically based on a good faith estimate to reach the milestone
 - Milestones may have to be prospectively adjusted as project progresses
- **Payment is dependent on achieving the associated milestone**
 - Achievement of milestones does not necessarily mean the technology or event was successful
 - Establish exit criteria for each milestone
 - Focus on the necessary effort to reach the milestone and perform the event
 - Even if the event or technology is a failure, the Performer should still be paid if they put in the necessary effort to be fully prepared

Payable Milestones (cont.)

Fixed Milestones
<ul style="list-style-type: none">• Each milestone amount is fixed at time of award• If the Performer achieves the milestone, it is paid the milestone amount (regardless of actual cost)

Expenditure-based Milestones
<ul style="list-style-type: none">• Milestones have an estimated amount, but payment may be based on actual costs• If the Performer achieves the milestone, it is paid based on actual costs (actual payments may or may not match the milestone award amounts)• Milestone award amounts may not match actual expenditures at the time payment is made

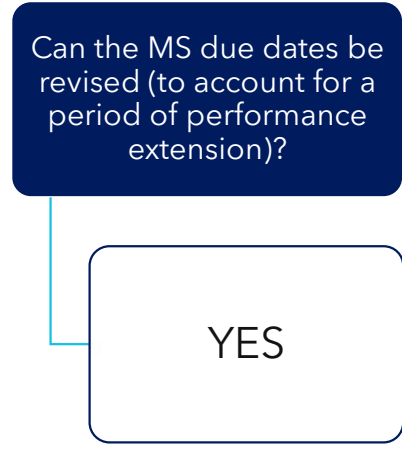
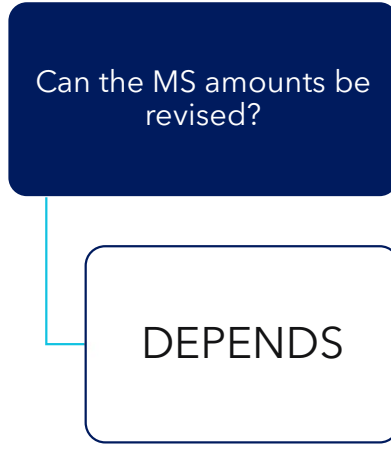
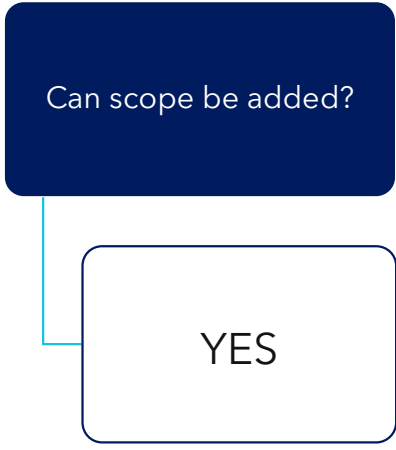
Milestone Payment Plan - Example

- Milestone plans may look identical (whether fixed or expenditure-based), but terms and conditions within agreements – specifically reporting requirements – will differ
- Expenditure-based approaches usually require the Performer to submit monthly status report on planned vs. actual expenditures, variation details, and “get-well” plans for large variations
- Throughout performance, both parties will need to meet periodically to adjust milestones – only future milestones – to ensure the project is on task

Milestone	Task(s)	Due Date (Months after award)	Milestone Definition	ARPA-H Payment
1	10	1	Kickoff and Program Management <i>Exit Criteria:</i> <ul style="list-style-type: none"> • Attend kick off meeting • Complete hiring of all required personnel; subcontract negotiations underway <i>Deliverables:</i> <ul style="list-style-type: none"> • Kickoff slides/materials • Project Plan for all tasks deliverables across milestones. • Report on progress of subcontract awards (DATA RIGHTS)	\$50K
Appropriation Data/Funding amount:				
2	4	3	Commercialization Plan <i>Exit Criteria:</i> <ul style="list-style-type: none"> • Meeting to develop commercialization strategy • Up to date on technical status reporting requirements <i>Deliverables:</i> <ul style="list-style-type: none"> • Report detailing initial commercialization & marketing plan (DATA RIGHTS)	\$100K
Appropriation Data/Funding amount:				



Administration Questions: Fixed Milestones



Administration of Expenditure-Based Milestones

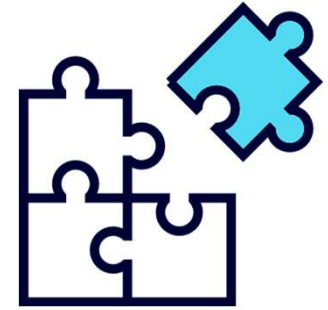
Milestone	Months After Award	Milestone Amount (Estimated at Award)	Planned Expenditures (Total)	Actual Expenditures (Total)	Amount Invoiced to Date
1	1	\$100	\$100	\$90	\$100
2	4	\$500	\$600	\$550	\$600
3	6	\$400	\$1,000	\$1,200	\$1,000
4	9	\$500	\$1,500	\$1,600	\$1,500
5	12	\$500	\$2,000		

Periodically, the government and performer should meet (regular and situational, if needed) to discuss payments and expenditures.

Find a way to ensure administration is not overly burdensome (for both the government and Performer). We recommend not adjusting milestone amounts at every milestone.

Session Takeaways

- There are key differences between fixed milestones and expenditure-based milestones
- Milestones should be tailored to the specific program or effort
- Milestones typically reflect observable technical events or other key actions (generally quarterly events like kick-off, management reviews, and technical reports)
- Milestone values are negotiated at time of award
- Payments are dependent on performers achieving milestones (focus is on the necessary effort to achieve the milestone)





Q&A



ARPA 

Teaming

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024



Why You're Here

- Discuss teaming, possible teaming structures (including advantages and disadvantages), and considerations when contemplating team structures for ARPA-H research and development efforts



Teaming

In complex acquisitions or programs/projects, it is rare that a single Performer can accomplish all tasks

Performers come together to accomplish a project for a variety of reasons

- Most common reason is to make money
- Goal may also be to create strategic alliances (short-term or long-term) in both Gov't and commercial sectors

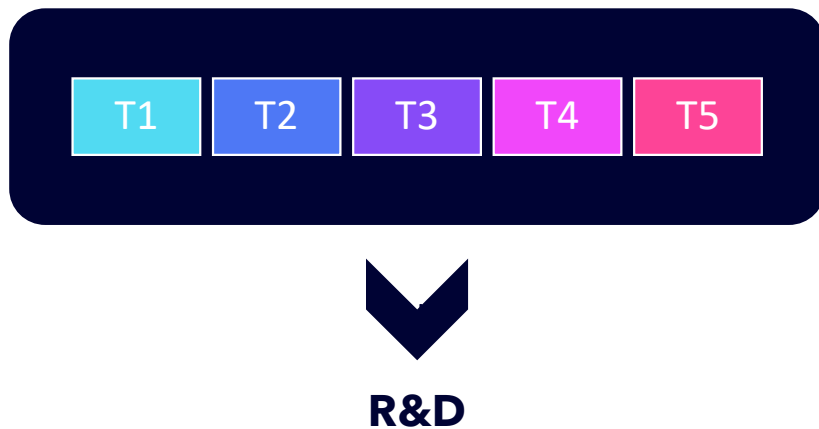
Commercial companies often work together in structures based on two different sets of market forces



Teaming Structures

Horizontal

- Multiple competitors who come together to accomplish a common goal or solve a common problem
- Resources plentiful, but trust may be an issue



Vertical

- Multiple performers who each play a role at a different stage of a product's life-cycle
- Symbiotic relationships, but time may be an issue



Teaming Structures (cont.)

There is a variety of team structures that might evolve but they tend to fall under three basic groupings



Each has its advantages and disadvantages

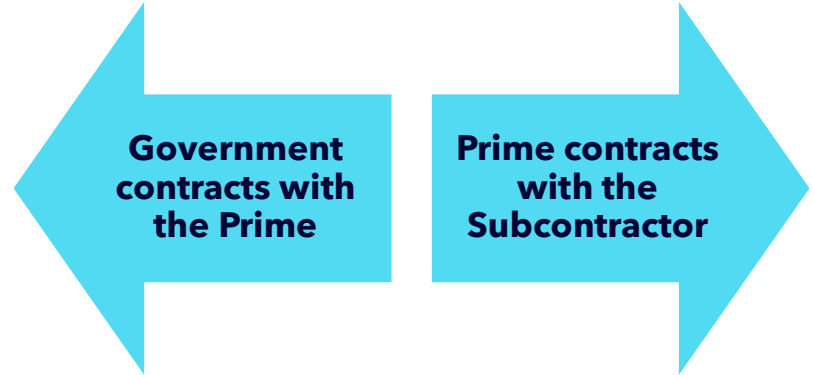
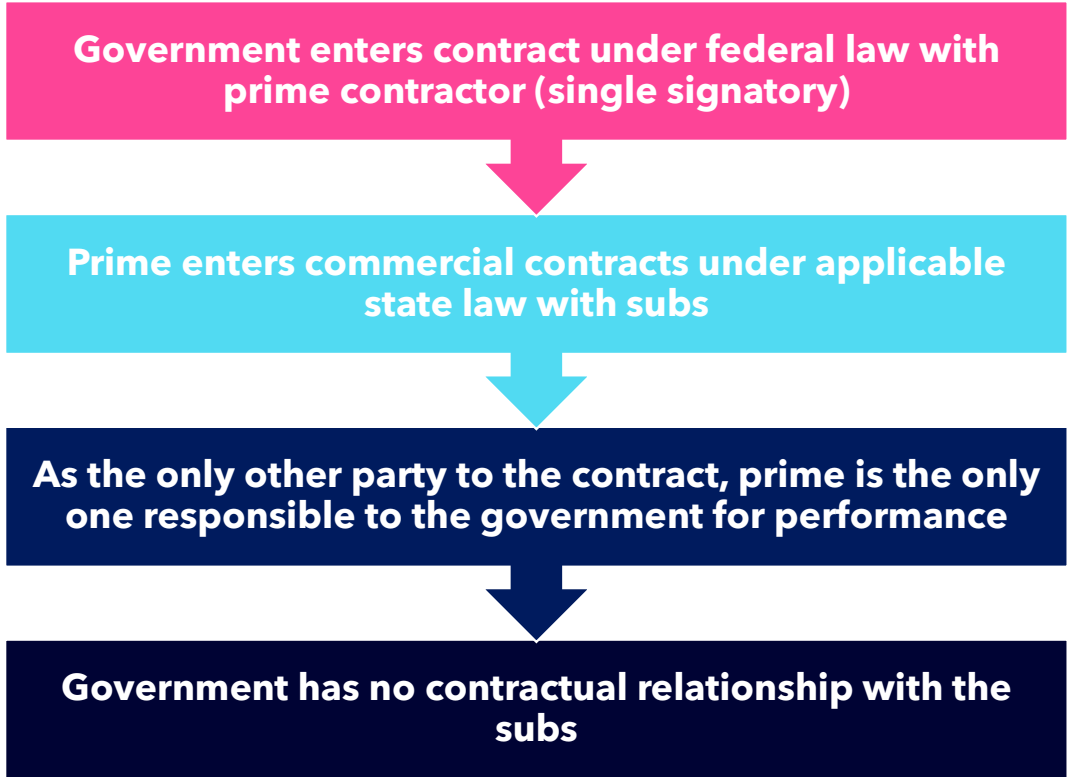
- Some entities are more familiar with the government
- Some work better in certain types of arrangements
- Some are easier to manage (either by the team itself or the government)

Teaming (Privity of Contract)

- Regardless of structure, before entering into an agreement, the government needs to understand the legal relationship it will have with the Performer team
- A contract law doctrine that prevents any person from seeking the enforcement of a contract or suing on its terms, unless they are a party to the contract
- Privity of contract = the signatories to the contract are the parties and only they will be bound to the contract terms



Privity of Contract in Prime/Sub Relationship



No privity of contract between the government and the subcontractor

Prime/Sub Relationships



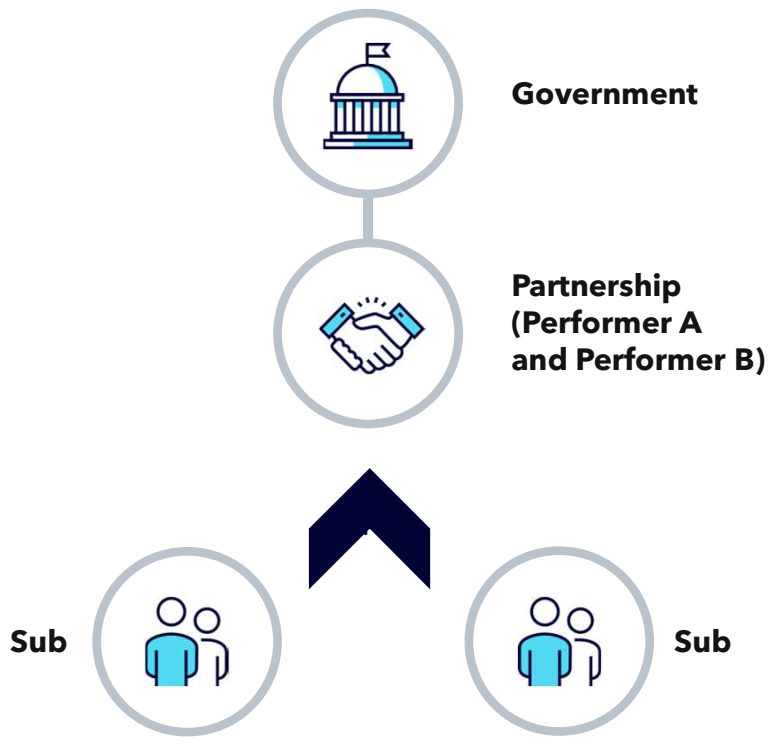
- ### Advantages
- The most familiar arrangement for most people
 - There is one person that is responsible to the government
 - There is only one person with whom to negotiate
 - The prime is responsible for managing the subs and addressing any issues
 - Only the prime can file suit with the government



- ### Disadvantages
- Creates an artificial separation between the government and sub-tier participants
 - If the prime does not perform, the whole thing falls apart
 - If the prime does not manage the team well, it can either fall apart or the government find itself in the middle
 - You cannot change leadership mid-program
 - There is a cost to having a prime (pass-through fee)

Privity of Contract with a Partnership

- Performer A and Performer B enter into a partnership relationship governed under state law
- Partnership becomes a separate legal entity and is treated like a separate person
- Both partners share jointly in the responsibilities and rewards of the partnership
- Government enters into a federal contract with the partnership
- Partnership enters into commercial contracts with the subs
- Government has the privity of contract with the partnership - and by extension each partner
- Government has no privity of contract with the subs



Partnership Relationships



Advantages

- The partnership is a legal entity so, in many ways, it's like dealing with a prime
- The partnership can leverage the resources and talents of all the partners
- The partnership determines how it will internally manage and present a united front to the Gov't
 - The terms of the partnership may allow new members to be added or some to leave the partnership
 - Leadership of the partnership can adjust and evolve with program progression
- The partners are generally jointly and severally liable for the partnership performance

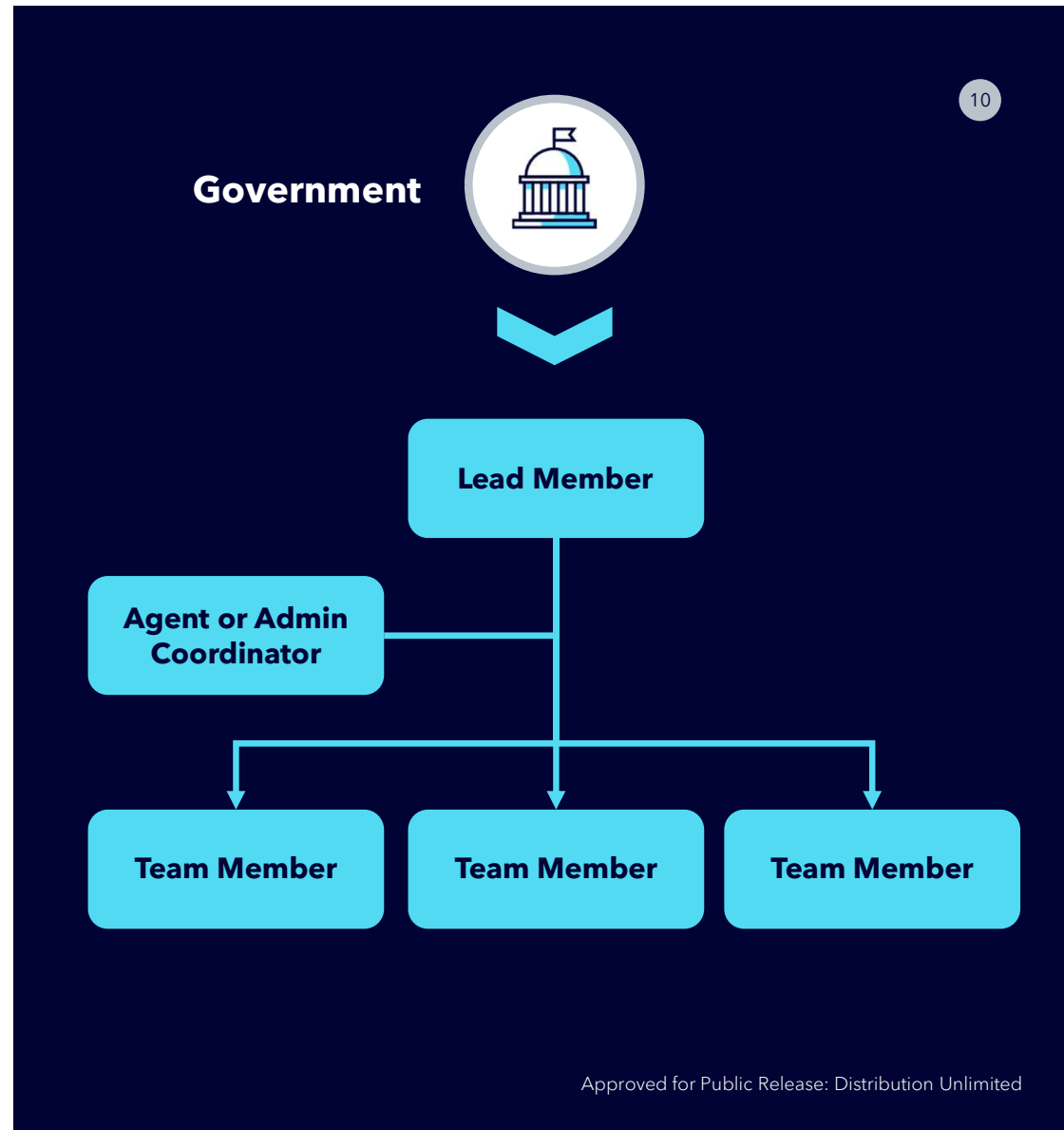


Disadvantages

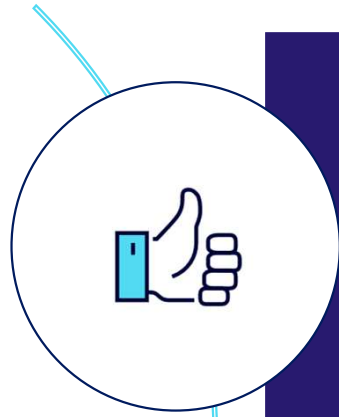
- The relationship of the partners can cause internal conflict(s)
- If the partners are usually competitors, they may not easily share info or work between them
- If the partners don't have an equal relationship - either in voting on partnership decisions or in benefits received - it can make for a difficult relationship
- The partnership needs to be established and formalized before negotiating with the Gov't (which can add time to the process)

Privity of Contract with a Multi-Party Team

- Team membership and dynamics defined by a contract signed by all members (i.e., Article of Collaboration)
- Team elects one member to act as their agent with the Gov't or hires an administrative coordinator
- Gov't signs agreement with the team as a whole (the team agent actually signs the agreement)
- Gov't has direct privity with all team members



Multi-Party Relationship



Advantages

- Because the team has chosen to work together collaboratively, the hope is that the alliance will be advantageous to all members and continue past this agreement
- Since the Gov't has signed the agreement with the entire team, it can have technical insight and visibility into all levels of technical and management actions
- If any resource sharing is required or leveraged, it will come from the team as a whole (how they choose to allocate the resource sharing is up to them)
- Since the team is bound to the Gov't and responsible for performance, the responsibility is on the team to self-police the effort and quickly respond to issues
- Leadership of the effort can change as the effort evolves



Disadvantages

- While the teams as a whole are the party to the agreement and the government has privity with all the members, it is still important that the membership select a strong leader to maintain the vision and effort direction
- Loose confederations and management by committee do not really work well
- The larger the team membership, the more important strong leadership and management is
- This type of relationship is relatively unfamiliar to the government and may cause some cultural problems

Teaming Best Practices



Generally, teaming works best if it's organic

Teams should generally "live" and flourish past government funding and involvement



There may be reasons for the Gov't to dictate a particular structure, but teams tend to work together better if the decision is left to them



Gov't should not be "matchmaking" or "marriage brokering"



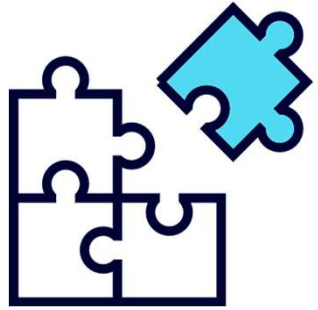
Gov't can encourage teaming via solicitations, Proposers' Days



Consider flexible teaming arrangements that may address different goals in different phases (as priorities shift during stages in a program or effort, consortia lead members may rotate in and out)

Session Takeaways

- For ARPA-H programs, it will be essential (in most cases) for performers to team together to address all aspects of a program/project
- There are several different teaming structures, including prime/subs, partnerships, and multi-party teams (each with advantages and disadvantages)
- Multi-party teams may be the best way to structure a team for ARPA-H efforts, as the structure:
 - allows for changes in performer leadership as needed throughout the evolution of a program,
 - allows direct access and communication between the Government and all performers on the team,
 - ensures that all key stakeholders are invested in the success of the project, and;
 - may facilitate the creation of alliances that outlast the ARPA-H funded project.





Q&A



ARPA 

You Received An Award, Now What?

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024



Why You're Here

- Gain an understanding of what comes next after receiving an ARPA-H award
- Familiarize yourself with some common terminology and administrative requirements
- Ask questions in a low threat environment



Post Award Expectations

- **Key Personnel** - fill key personnel as proposed for project
- **Communication** - open communication (risks, challenges, issues) needed for a successful project
- **Kickoff Meeting** - an opportunity for ARPA-H and the Performer team(s) to come together
- **Program Manager Involvement** - expected throughout performance (these are not grants). Typically, as meetings (i.e., monthly, quarterly) to monitor performance and collaborate



Post Award Expectations (cont.)



SAM Registration

- Performers are required to maintain an active registration in SAM for the life of the award.



Restrictions - Animal Subjects Research (ASR) & Human Subjects Research (HSR)

- No ASR or HSR related costs can be incurred without the required approvals.
- Animal Welfare Assurance, Institutional Animal Care and Use Committee (IACUC) approval, and a completed Vertebrate Animals Section.
- Federal-Wide Assurance and an approved IRB (Institutional Review Board).

Post Award Expectations (cont.)

- **Payments** - registration in Payment Management Services (PMS) is required to process invoices and receive payments (needed after award if new PMS registrant)
- **Milestones** - reflect observable technical events or other actions. The value of payable milestones is negotiated at time of award

Other Transactions (OTs)

- Fixed-payable milestones - payment triggered by successful performance of technical events
- Expenditure-based - may have to be prospectively adjusted during performance for value and performance objectives

Cooperative Agreements

- Payment is based on actual costs incurred or on a fixed milestone basis

Exit Criteria

- Information for how measure or evaluate milestones for "success." Success is focused on the effort needed to reach the milestone and perform the event and not necessarily if the technology is successful

- **Payable Milestones** - Milestone descriptions include completion criteria that articulate the basis for receiving payments and may include deliverables such as reports, demonstrations, tests, etc.



Post Award Expectations (cont.)



Publications/Press Releases
Please refer to the agreement terms & conditions regarding any prior approval requirements (days)



Reporting Templates
Connect with your ARPA-H technical contacts for templates/expectations



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



Responsibilities and Approvals
Please refer to the agreement terms & conditions for performer responsibilities and required prior approvals (e.g., requesting period of performance changes, invoicing instructions, expanded authorities, reporting requirements)

Expanded Authorities include carryover of unobligated balances from one budget period to the next; cost-related prior approvals for direct-cost items; no-cost extensions; pre-award costs; and transfer of performance of a substantive programmatic work to a third-party by sub-award or a contract under the Cooperative Agreement

Post Award Expectations (cont.)



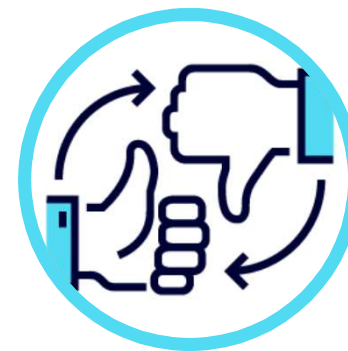
Deliverables

As identified in each agreement (milestone reports, commercialization plans, equity plans, final reports, etc.)



Modifications

Expected in an R&D environment & may include term extensions, funding actions, administrative changes



Options

If included in your agreement, options are negotiated up front and can be exercised bilaterally or unilaterally. Revisions to an upcoming option period may be negotiated during the project period of performance

Questions During Award Performance?

- **Grants Officer (GO) or Agreements Officer (AO)** - designated by the agency to conduct pre-award, post-award, and closeout activities. GO/AO is the only person that legally bind the Government, direct performer to start/stop work, modify agreement terms, or terminate an agreement
- **Program Manager (PM)** - The PM is the primary interface between performers and the GO/AO on programmatic issues. You have very likely already met or interacted with the PM and their team during negotiations and kick off
- **Grants/Agreements Officer Representative (GOR/AOR)** - provides technical assistance to GO/AO and assists in agreement administration. Not all awards will use an GOR/AOR
- Points of contact for the award are listed in your agreement



Session Takeaways

- Expect regular and open communication with ARPA-H during performance
- Important to understand the administrative requirements of your agreement including:

Deliverables

- Description, frequency, and submission instructions included in the agreement
- May include reports, demonstrations, test, etc.

Payments

- Register in PMS
- Refer to your agreement to find the payment structure (monthly invoicing, fixed-payable milestone, or expenditure-based arrangement)

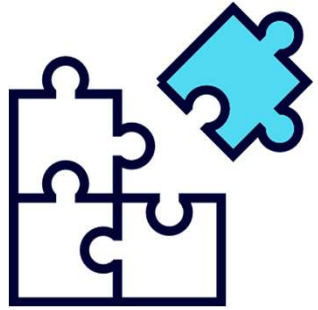
Modifications

- Common and may include funding actions, period of performance (term) changes, statement of work changes, or administrative changes (e.g., minor corrections, PM change, etc.)

Special T&C's

- HSR or ASR restrictions, required prior approvals, are expanded authorities allowed (cooperative agreements only)

- Review the agreement to find out who to contact if you have questions during performance. At a minimum, you will include the PM, GO/AO, and GOR/AOR (if applicable)





Q&A



ARPA 