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MEET ARPA-H



The Advanced Research Projects Agency for Health is the newest ARPA, with a mission to transform healthcare.

By Stephen Speciale

How does a new federal government agency handle the challenge of advancing health research and accelerating better health outcomes for everyone?

For starters, it needs unique authorities for conducting business, a stellar workforce comprised of creative thinkers, and nimble bureaucracy allowing for rapid innovation.

The Advanced Research Projects Agency for Health (ARPA-H) is the newest Advanced Research Project Agency (ARPA), with a mission solely focused on health. The agency has reached many milestones since its inception by making initial business opportunities available and has ambitious plans for fiscal year (FY) 2024 and beyond.

This article highlights ARPA-H's contracting authorities, recent program and project initiatives, creation of an Other Transaction (OT) Community, and contracting-related lessons learned from starting up a new agency.

How ARPA-H Got Started

In March 2022 Congress enacted Public Law 117-103, which authorized the agency's establishment. ARPA-H's goals, functions, key personnel, authorities, and requirements are codified in 42 U.S.C. § 290c. It joins the network of ARPAs alongside other federal agencies (i.e., defense, energy, intelligence, infrastructure) known for funding cutting-edge, high-risk, and innovative projects to solve complex problems.

Inspired by the Defense Advanced Research Projects Agency (DARPA) model, Congress created ARPA-H to be flexible with a nimble strategy, remain undeterred by the possibility of failure, and drive breakthroughs to transform medicine and health. This includes equally prioritizing the pursuit of state-of-the-art technologies and ensuring the technologies reach customers. The agency has an office solely dedicated to translating technology advancements into real-world products and services, which will help bridge the so-called technology "Valley of Death."

ARPA-H teams place substantial importance on conducting sufficient market intelligence for opportunities to appeal to the appropriate potential performers and pursue the most impactful business approaches. The agency formally and informally communicates with industry, including proposer day events, participation at health-related conferences and conventions, and requests for information through SAM.gov.

The agency typically utilizes a three-headed approach with leadership, program managers, and contracting personnel participation at public-facing events to share ARPA-H's mission, highlight program-specific objectives, and outline available contracting mechanisms, respectively. Figure 1 provides additional information on ARPA-H.

Contracting Authorities, Funding, and Business Expectations

ARPA-H aims to address health problems that cannot readily be accomplished through traditional research or commercial activity. It does so with the authority to award OTs, cooperative agreements, grants, contracts, cash prizes, and partnership intermediary agreements (PIAs). ARPA-H can also enter into assisted acquisitions with other government entities, where appropriate, to obtain critical services that are in the best interest of the federal government and cannot be obtained as conveniently by ARPA-H through direct contracting with industry.

The agency's OT authority is very broad and can be used for research and development (R&D) efforts that

FIGURE 1. ARPA-H Facts and Figures



could involve research, prototyping, production, and additional activities that align with its goals. When using OT authority, ARPA-H must use competitive procedures to the greatest extent practicable and document that the authority is essential for project success.

The agency's OT authority is distinctly different from OT authority granted to other government entities such as the Department of Defense (DoD) and the National Institute of Health (NIH). For instance, resource-sharing arrangements as conditions for use does not apply, the term "nontraditional defense contractor" does not apply, and OT usage is not limited per fiscal year based on a percentage of appropriation amount.

The agency also has nontraditional funding when compared to other government entities. For FY

2022 and FY 2023, its appropriated funds each have a three-year availability period for obligations. The appropriated funds can be used for operations, programs, and other needs. Most other R&D-focused entities have funding available for two years. This longer-than-normal period provides ARPA-H flexibility when initiating programs, launching projects, making awards, and completing adjustments on efforts during periods of performance. ARPA-H expects future fiscal year budgets to have similar flexibility.

Given the diverse contracting authorities available, the agency expects to primarily award OTs and cooperative agreements for its R&D programs – the lifeblood of the agency. Quality and speed are major considerations as program managers serve term-limit appointments.

OTs are ideal for attracting a wider group of interested parties and allowing ARPA-H to negotiate terms, conditions, and intellectual property with awardees.

OTs also encourage flexible and cost-effective projects that will enable ARPA-H to broaden the public health industrial base (PHIB). Cooperative agreements allow for substantial involvement with awardees, such as site visits and regular performance assessments, during performance on financial assistance vehicles when compared to grants. The agency could also use prize challenges in certain scenarios to identify novel solutions to health-related problems or generate interest in new technologies or topic areas.

ARPA-H will use *Federal Acquisition Regulation (FAR)* procurement contracts in limited scenarios for services or infrastructure-related needs, such as professional support services, flexible coworking space, and information technology. The agency also plans to enter into interagency agreements for assisted acquisitions from other government entities as needed. These agreements will allow ARPA-H to leverage technology advancements, technical services, and professional services from the DoD, NIH, Department of Interior, National Aeronautics and Space Administration, and others as appropriate.

ARPA-H maintains a forward-leaning approach to maximize the exposure of each business opportunity. Besides SAM.gov, it leverages its public website (www.arpa.gov), an

ARPA-H email newsletter, LinkedIn, X (formerly Twitter), Instagram, and Facebook to market opportunities. Specific to new programs, the agency hosts proposer day events to share each program's missions, goals, and opportunities.

Additionally, leadership personnel regularly attend health and professional conferences to expand awareness and potential interest of the agency's initiatives and programs. For example, the ARPA-H Director participated in an "innovation alley" presentation at NCMA's July 2023 World Congress. ARPA-H highly values (and measures) responses from industry and utilizes feedback loop mechanisms for agency personnel to provide metrics for leadership to make informed decisions.

Recent Program Launches, Project Announcements, and Associated Awards

As a government start-up, ARPA-H launched programs and projects after its initial onboarding of key personnel and establishing basic operations. In March 2023, ARPA-H released its first major solicitation via a Broad Agency Announcement (BAA) in accordance with FAR 35.016.

The BAA was named an "Open BAA" as ARPA-H sought revolutionary ideas for its mission areas that were not covered by ARPA-H programs. The solicitation had an open-ended submission period for novel solutions from industry with potential award instruments including OTs, cooperative agreements, and FAR-based procurement contracts. The approach successfully lowered the barriers



to entry as the agency limited submissions to three pages and gave submitters the opportunity to select a preferred award instrument based on their needs.

ARPA-H received approximately 250 submissions within 90 days of the BAA release date and made its first award (cooperative agreement) within five months. Shortly thereafter,

it made additional awards via OTs and cooperative agreements with combined awards totaling up to \$305 million. These efforts were commendable as ARPA-H maintained

TABLE 1. Recent ARPA-H Program and Project Launches

PROGRAMS	
Program Name	Objective
Antigens Predicted for Broad Viral Efficacy through Computational Experimentation (APECx)	What if we could eliminate viruses as current and future health threats? This program aims to transform vaccine discovery by developing a computational toolkit to help design vaccines that target many viruses at once.
Biomedical Data Fabric (BDF) Toolbox	What if new data integration tools made it possible to extract more value out of data? This program aims to advance next-generation software tools to synthesize and speed the use of health research data.
Digital Health Security (DIGIHEALS)	What if we could strengthen the nation’s digital health infrastructure to protect against cyberattacks? This program aims to protect the U.S. health care system’s electronic infrastructure by preventing cyberattacks and lessening the effects of attacks to ensure patients continue to receive care.
Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO)	What if we could make our joints heal themselves? This program aims to unlock new futures for millions of people with osteoarthritis, with potential applications in a range of diseases and conditions that require regenerative breakthroughs.
Precision Surgical Interventions (PSI)	What if surgeries fixed problems, flawlessly, the first time? This program aims to improve the visibility of tumor tissue and other critical anatomical structures during surgery, reducing the chances of damage or need for re-operation.
Resilient Extended Automatic Cell Therapies (REACT)	What if your body could make its own medicine? This program aims to develop new technologies that will improve access, affordability, and patient self-care by automatically delivering treatments and monitoring for disease from within an individual’s body.
PROJECTS	
Project Name	Objective
ARPANET-H	Develop and maintain a health innovation network, connecting people, innovators, and institutions, to transition health research innovations into solutions that can reach all Americans.
ARPA-H Dash to Accelerate Health Outcomes	Identify revolutionary, evidence-based ideas to transform health through a collaborative online competition (prize challenge).
Partnership Intermediary Agreements (PIAs)	Facilitate partnerships to accelerate technology and transition of health-related innovations to the marketplace.
Small Business Innovation Research Awards	Enable revolutionary advances in science, technology, or systems (focused on small business concerns to stimulate innovation).

Source: Author

streamlined processes with a small group of technical reviewers and professional staff to evaluate submissions and select submitters for negotiations. ARPA-H expects to make additional awards for promising solutions in 2024 (likely OTs and cooperative agreements) and will maintain similar open solicitations within each of its mission areas going forward.

ARPA-H also released program-specific solicitations in 2023 when programs launched. Different than the Open BAA, the initial program solicitations had shorter open periods (i.e., 30 to 90 days) for submissions from interested parties and potential award types were to limited OTs and cooperative agreements. Awards associated with ARPA-H's initial programs are expected in 2024.

The agency initiated a one-of-a-kind nationwide health innovation network, known as ARPANET-H, comprised of regional hubs in Dallas, Texas; Cambridge, Massachusetts; and Washington, D.C. The hubs are collectively comprised of diverse stakeholders (i.e., researchers, entrepreneurs, investors, regulators) to support health innovation initiatives across the country. The model is intended to: a) develop health solutions that are accessible, needed, and readily adapted; b) speed the transition of innovative ideas into practical and available solutions, and; c) engage key federal partners to ensure the success of program offerings.

ARPA-H awarded two OTs to consortium management firms (CMFs) to manage two of the hubs. ARPA-H plans to award project OTs to entities

for efforts supporting each of the hubs. Although it is leveraging CMFs, the agency's arrangements are much different than the DoD's traditional arrangements with CMFs. For example, ARPA-H will not allow CMFs to charge fees, one-time or annually, for members interested in joining or remaining in consortia.

Also, the ARPA-H CMFs will be heavily involved with the development of the network, provide resources for member collaboration and interaction with the government, and help programs navigate business complexities. Lastly, ARPA-H will require CMFs to maintain physical space available for frequent member and stakeholder engagements. The agency established milestones to manage CMF performance over time and will collaborate with the CMFs to modify the arrangement structure and processes as needed.

ARPA-H also awarded three PIAs in 2023. The PIAs will facilitate public-private partnerships necessary to accelerate technology transfer and the transition of solutions to market. ARPA-H expects the PIAs to increase the likelihood of success with small businesses and academic on efforts throughout the program life cycle.

Table 1 provides additional information about some of the recent initiatives launched and/or completed in 2023. For clarification, programs are large-scale efforts with focused themes and goals that result in numerous awards. Projects, on the other hand, are individual initiatives, including network partnerships and other efforts that typically result in a single award.

In early 2023, the agency executed

a prize challenge that produced worthwhile and immediate results. The agency used a bracket-style competition to identify revolutionary, evidence-based ideas and concepts to transform health. The challenge was open to the public to obtain the widest interest and best possible submissions. In less than two months, ARPA-H announced, conducted, and completed the challenge, receiving over 500 submissions. The top eight submitters received cash payouts as prizes. ARPA-H made individual workshops available for the top four submitters to provide a venue for them to obtain feedback and further advance their ideas. Lastly, the challenge resulted in multiple Open BAA submissions and interest from individuals to apply for a program manager role at ARPA-H.

Prioritizing Equity, Transparency, and Competition

Although ARPA-H has immense flexibility in its forms of conducting business, it has a fundamental responsibility to be effective stewards of taxpayer money. The agency aims to accelerate better health outcomes for everyone; thus, it must ensure all business opportunities and practices are fair, moral, ethical, and in compliance with applicable laws and regulations.

ARPA-H must also be fully transparent with the White House, Congress, Health and Human Services (HHS) leadership, and the American public. Lastly, ARPA-H must diligently work to ensure the PHIB and potential performers have access to the same opportunities and treatment. This includes small

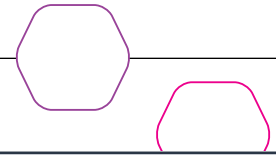


TABLE 2. Contracting-Related Lessons Learned

Get the Right People Onboard	People are an organization’s best resource. Leadership must ensure it onboards and maintains people that best fit the organization or team culture and possess sufficient work experience based on expected job duties. Especially for start-ups, organizations must be selective for government civilian and contractor support personnel. Find personnel who embrace change, solve problems, are willing to learn from one another, maintain a strategic risk-taking posture, and can lead complex projects. A team of qualified team members with diverse backgrounds and skill sets (i.e., OTs, cooperative agreements, intellectual property, services, business systems) can be the difference between a good team and a great team.
Prioritize Actions and Manage Risks	Every action or need cannot be the highest priority. If so, nothing will truly be a priority or get accomplished in an efficient or effective fashion. Organizations must prioritize actions. Establish clear objectives and metrics, if appropriate, for each action for leaders to make informed decisions and resources as needed. Consider using 30-60-90-day plans to frame expectations and measure performance. Lastly, employ risk management practices to identify, assess, and respond to risks. Maintain a proactive rather than reactive stance to help organizations achieve their missions and functions.
Business Infrastructure and First Impressions Matter	<p>Before launching programs and attempting to tackle the mission and goals, organizations must establish the appropriate business infrastructure and make sure it is in working order. This includes areas such as information technology (hardware and software), help desk support, physical and remote workspace options, human resources, financial management, purchase cards, and the travel program. Also, organizations must evaluate business systems needs, such as contract writing systems and those that house contracting files. Evaluate short-term and long-term needs, and implement interim solutions as needed until a steady state is reached.</p> <p>Organizations that do not have solid business infrastructures in place when they onboard personnel will cause personnel to be frustrated and not allow for business efficiencies, both of which could prevent the organization from achieving its primary objectives.</p>
Create Appropriate Guidance in Lieu of Excessive Policy	More is not necessarily merrier when it comes to policies. Policies, especially within the federal government, tend to limit choices, minimize process and procedural flexibility, require multiple reviews and approvals, and be challenging to maintain. Guidance, on the other hand, provides maximum flexibility and can help innovative organizations avoid unnecessary bureaucracy. Attempt to create appropriate guidance rather than excessive policies where possible.
Delegate Authorities to Lowest Levels Where Possible	Delegate authority to the lowest levels possible to prevent inefficiencies in approval processes and operations. For example, the ARPA-H Director was originally designated as the approval authority for OT use; however, upon HCA request, the Director delegated OT approval authority to the HCA. Additionally, the ARPA-H HCA was able to obtain unlimited warrant authority from the Health and Human Services (HHS) Senior Procurement Executive and permission to delegate the authority to qualified personnel at lower levels within the agency. These changes allowed ARPA-H to streamline processes via the elimination of additional approvals and prevention of unnecessary delays for project lead times.
Train Personnel on Acquisition and Contracting Topics	Develop content and provide training on acquisition and contracting topics relevant to personnel within the organization. These efforts will increase awareness of contracting authorities, influence appropriate personnel to complete necessary actions, increase understanding of project timelines, and help create/maintain efficient processes and operations. For example, ARPA-H developed and delivered training content on the federal acquisition process, roles and responsibilities for key stakeholders, OTs, and contracting officer representatives.
Celebrate the Wins No Matter the Size	Times can be chaotic for start-ups. It is easy to get caught in a vicious cycle where people and teams only focus on the next project or major milestone rather than celebrating achievements. To keep personnel engaged, motivated, and prevent burnout, leadership must acknowledge and celebrate wins (even the small ones). In almost all circumstances, the big accomplishments would not be possible without the small victories along the way.

businesses, small-disadvantaged businesses, non-profit research institutions, academic institutions, and minority serving institutions. ARPA-H is committed to expanding the PHIB by using competitive procedures to the maximum extent practicable and strategically making opportunities available to interested parties regardless of size, status, or geographic location.

Creation of OT Community

ARPA-H has personnel with significant OT and professional training experience and plans to frequently use its OT authority based on agency objectives. Through the process of creating a new entity and collecting OT experiences from personnel supporting other R&D organizations, ARPA-H determined a gap existed.

Since OT authorities vary across the federal government, OT authority is typically feared rather than embraced, and most have a misunderstanding of the authority and its intended uses. As a result, ARPA-H launched an OT Community in 2024 to enable active collaboration among government entity and industry personnel. Besides creating a public-facing website, it plans to share various OT resources, deliver multiple types of training events, and provide outreach opportunities. ARPA-H also plans to share additional details highlighting the OT Community when fully established.

Lessons Learned

ARPA-H's business innovation team has compiled many contracting-related lessons learned from supporting a new federal government agency. For

example, although the agency initially used BAAs per the FAR to receive submissions for initial program topic areas and revolutionary health-related ideas not specifically related to programs, it decided to create a unique solicitation process based on the plans to leverage OTs and cooperative agreements as the primary award instruments for R&D efforts.

As a result, ARPA-H developed a new, non-FAR-based solicitation name and process, called Innovative Solutions Opening," that provides more flexibility given its authorities and creative options of conducting business. The process will allow use of custom evaluation factors and procedures for each solicitation but still provide for fair and reasonable scientific reviews while maximizing the use of competitive procedures.

Specific to cooperative agreements, ARPA-H must still comply with HHS policy and Title 2 of the Code of Federal Regulations. Table 2 provides additional lessons learned, which can benefit new future federal government agencies or existing federal government entities, specifically those with unique contracting authorities.

Applying these lessons, ARPA-H plans to continue onboarding more program managers and launching new programs in FY 2024 and beyond. As a result, the business innovation team seeks additional team members – both government civilians and contractor support.

The team is specifically searching for personnel with OT and/or cooperative agreement experience who are willing to embrace change, take on challenging projects, and fully leverage unique authorities for conducting business. The team is also interested in detailee assignments (i.e., six-months) for qualified personnel currently supporting other government entities. Interested personnel can contact the author to inquire about available opportunities.

Conclusion

Revolutionizing health outcomes for everyone is a tough assignment, and ARPA-H is best positioned to achieve success with novel business approaches and considerable flexibility beyond traditional research means. Promising ideas and solutions are desired; however, breakthrough technologies that are prohibitively expensive and inaccessible will not allow the agency to achieve its goals. Success involves maximizing the use of its contracting authorities, enhancing processes and operations over time, and prioritizing equitable health solutions to benefit everyone. **CM**

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