ARPA-H Today:

An up-to-date overview of the organization, its programs, Emory's lessons learned, and... more!

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SVPR Office of Research Development
March 21, 2024
What the Heck is an ARPA?

Do as much as you can, as fast as possible.
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 within NIH; not an Institute
- No internal research labs; **disease agnostic**
- **$2.5B appropriations**; budget independent from NIH
- Generally **fund outcome-based contracts**, not grants; accelerated award timelines
- **Bottoms-Up Problem Centric Approach** to address the toughest challenges in health

**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**. PMs have autonomy to make decisions quickly.

**ARPA-H is a problems focused organization**
Program Managers

• PMs given resources and authority to select a portfolio of projects that pursue multiple approaches to achieve a clearly defined goal

• PMs recruited from industry, top research universities & NIH and must bring bold, risky ideas

• PMs are on loan to ARPA-H for 3 years (with up to 3-year extension) and then return to permanent position

• Generally, will cover salary up to $400,000

• Lots of travel, but PMs are not required to officially relocate

• PMs will need to “retire” their grant work to work at ARPA-H

• ARPA-H is actively recruiting PMs; current target is 30

• Currently 14 PMs in place & not all have launched programs
Further ARPA-H investment in these areas will generate asymmetrical benefits to the health ecosystem.

Health Science Futures
Expanding what’s technically possible
Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.

Scalable Solutions
Reaching everyone quickly
Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.

Proactive Health
Keeping people from being patients
Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans’ health, whether those are viral, bacterial, chemical, physical, or psychological.

Resilient Systems
Building integrated healthcare systems
Develop capabilities, business models, and integrations to endure crises such as pandemics, social disruption, and economic instability. Resilient systems need to sustain themselves between crises - from the molecular to the societal - to better achieve outcomes that advance American health and wellbeing.

Project Accelerator Transition Innovation
Ensuring programs survive in the wild
Translating scientific and technical breakthroughs into real world products and services, ensuring they result in better health outcomes for all Americans.
1st ARPA-H award went to Emory.

ARPA-H’s Investment Portfolio Snapshot: What if...?

- **NITRO**
  - Novel Innovations for Tissue Regeneration in Osteoarthritis
  - What if we could make our joints heal themselves?

- **REACT**
  - Resilient, Extended, and Automated Cellular Therapies
  - What if your body could make its own medicine?

- **SPIKEs**
  - Synthetic Programmable Bacteria for Immune Directed Killing in Tumor Environments
  - What if programmable bacteria could be directed to kill cancer inside the body?

- **DIGIHEALS**
  - Digital Healthcare Security
  - What if we had resilient healthcare infrastructure with advanced digital security for data, software, and devices?

- **PSI**
  - Precision Surgical Interventions
  - What if surgeries fixed problems flawlessly, the first time?

- **PARADIGM**
  - Platform Accelerating Rural Access to Distributed and Integrated Medical Care
  - What if we could deliver advanced hospital-level care to every rural county in America?

- **HEROES**
  - HealthCare Rewards to Achieve Improved OutComES for All
  - What if we could create a sustainable national healthcare market that rewards prevention?

- **DARTS**
  - Defeating Antibiotic Resistance through Transformative Solutions
  - What if we could identify antibiotic-resistant bacteria in minutes?

- **CUREIT**
  - Curing the Uncurable via RNA-Encoded Immunogene Tuning
  - What if incurable diseases could be treated by tuning your immune system?

- **THEA**
  - Transplantation of Human Eye Allografts
  - What if we could cure blindness?
Emory University Received 1st ARPA-H Award

New federal agency selects Emory as first recipient of funding to drive groundbreaking health research

As Part of President Biden’s Unity Agenda, Biden Cancer Moonshot Announces Launch of ARPA-H’s CUREIT Project Led by Emory University to Develop New Tools to Strengthen the Immune System and Save Lives

New ARPA-H project aims to improve patient outcomes across cancer and a broad range of diseases, using mRNA technology to train our immune systems to be more effective

Today, the Biden Cancer Moonshot is announcing the launch of “Curing the Uncurables via RNA-Encoded Immunogene Tuning” (CUREIT), a project that aims to develop generalizable mRNA platforms that can be harnessed to train the immune system to more effectively fight cancer and other diseases, ultimately saving lives. CUREIT will be led by a team at Emory University in Atlanta, Georgia, with up to $24 million in new funding from the Advanced Research Projects Agency for Health (ARPA-H). We are thrilled to announce our first award from the Advanced Research Projects Agency for Health (ARPA-H) Open BAA. This bold effort - named CURE-IT - seeks to enhance the body’s immune system through gene modulation to treat some of the toughest diseases, including cancer and autoimmune disorders like lupus. Congrats to Philip Santangelo Emory University and teams!
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-traditionals, industry, and academics to solve
- Build new coalitions

**Execute & Measure**
- Active program management against metrics; PM = CEO
- 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

Approved for Public Release: Distribution Unlimited
Program Formation: Emory’s Perspective

**Program Manager**
Program Manager identifies a difficult health-related challenge that is ripe for solving.

**Challenge**
The challenge should NOT be easily solvable through traditional activities.

**Program Launch**
A Program Manager seeks – and oversees – several groups of performers aiming to solve the same problem in unique ways.

**Performers**
Performers compete to carry out their potential innovative solutions to the challenge.
Program Formation: Emory’s Perspective

Launch process VARIES!
- Special Notice
- Draft solicitation issued (includes anticipated Abstract due date)
- Proposer’s Day Held (hybrid)
- Final solicitation issued

Submission process is at PM’s discretion
- Abstract submission phase (required and/or recommended)
- ARPA-H review of abstracts
- Invitations or encouragement to submit full proposals issued (detailed & individualized feedback; do NOT submit if not invited or encouraged)
- Lots & lots & lots of work
- Full Proposals Submitted

Performers
Performers compete to carry out their potential innovative solutions to the challenge

Awarded \|
Not Awarded //
ARPA-H Applicant Process

**Call for Solutions Released**
BAAs most common; modules to master agreements

**Proposers’ Day**
Attend proposers’ day for overview with PM and networking; hybrid or virtual formats

**Abstract or Solution Summary Due**

**Wait**
Wait to be invited or encouraged for a full proposal; PMs do some social engineering

**Full proposal**
Submit full proposal, if invited or encouraged. (Stop, if not invited / encouraged)

**Award**
Award received! Get ready!

**Launch**
Rapidly launch project, deliver on-time results, expect for monthly reports/collab with PM

**Program Call Released**

**Proposers’ Day**

**Pitch!**

**Wait**

**Full Proposal**

**Award**

**LAUNCH**
Programmatic Timeline in Action: ADAPT

ADAPT
ADvanced Analysis for Precision cancer Therapy

Solicitation
- ADAPT Special Notice
- ADAPT Solution Summary
Solution Summary due date: March 29, 2024, 10:00 AM ET
- ADAPT Module Announcement
Proposal due date: May 6, 2024, 1:00 PM ET

Proposers’ Day
- Virtual Proposers’ Day will be held 12:00PM – 2:00 PM ET on March 15, 2024.
- Proposers’ Day registration is closed.
- Ask a Question
- Proposers’ Day recording
- Proposers’ Day slides
Programmatic Timeline in Action: PARADIGM

PARADIGM
Platform Accelerating Rural Access to Distributed and Integrated Medical Care

**Solicitation**
- PARADIGM Special Notice
- PARADIGM Draft Solicitation
- Abstract Due Date: Closed
- Full Proposal Due Date: April 26, 2024

**Proposers' Day**
Proposers' Day: February 15, 2024, 9:00 AM - 4:00 PM MST (11:00 AM - 6:00 PM EST) in Phoenix, AZ and virtually
- Proposers' Day registration is closed.
- Ask a Question
- Proposers' Day recording
- Proposers' Day slides
### ARPA-H's Project Management

#### Phase I (0-36 months)

<table>
<thead>
<tr>
<th>Stage 1 (0-6 months)</th>
<th>Stage 2 (7-36 months)</th>
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</thead>
<tbody>
<tr>
<td><strong>FY24</strong> Q3</td>
<td><strong>FY25</strong> Q1 Q2 Q3 Q4</td>
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<tr>
<td><strong>TA1: Therapy Recommendation Techniques</strong></td>
<td><strong>TA2: Evolutionary Clinical Trial</strong></td>
</tr>
<tr>
<td>6 academic performers</td>
<td>4 academic / cancer center performers</td>
</tr>
<tr>
<td>TA1.1 Build fusion pipeline</td>
<td>TA2.1 First tumor measurements</td>
</tr>
<tr>
<td>TA1.2 Develop discovery and resistance models</td>
<td>TA2.2 Launch clinical trial</td>
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<tr>
<td>TA1.3 Compile / load historic data</td>
<td>TA2.3 Measure PFS for SOC</td>
</tr>
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<tr>
<td><strong>Phase II (37-72 months)</strong></td>
<td></td>
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<td><strong>TA1: Therapy Recommendation Techniques</strong></td>
<td><strong>TA2: Evolutionary Clinical Trial</strong></td>
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<tr>
<td>Accelerated / semi-automated fusion pipeline</td>
<td>First validated biomarkers for clinical use</td>
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<tr>
<td>First resistance mechanism discovered</td>
<td>First validated biomarkers for clinical use</td>
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<tr>
<td>First therapy recommendation in clinical trial</td>
<td>First validated biomarkers for clinical use</td>
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<tr>
<td>3+ validated biomarkers</td>
<td>FDA submission(s)</td>
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<tr>
<td><strong>TA2: Evolutionary Clinical Trial</strong></td>
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</tr>
<tr>
<td>3+ validated biomarkers</td>
<td>50 patients clinical trial</td>
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<td>24 sites clinical trial</td>
<td>200 patients clinical trials</td>
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<tr>
<td>60 sites clinical trials</td>
<td>1000 patients clinical trials</td>
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<td>Measure PFS for SOC</td>
<td>First non-SOC therapy based on biomarker</td>
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<tr>
<td>2 performers &gt; 1 industry / NGO Algorithm Pipeline</td>
<td>Data lake</td>
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<td>Functional demo &amp; user interface</td>
<td>Ingest and linkage of new TA1 &amp; TA2 data</td>
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<tr>
<td>Platform launch for TA1 &amp; TA2</td>
<td>Launch public de-identified data lake</td>
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<td>Development standards for cloud lake</td>
<td>Launch public data lake</td>
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<td>First toolsets (report gen)</td>
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<td>Platform launch for public</td>
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<tr>
<td><strong>Independent Verification &amp; Validation</strong></td>
<td><strong>Performers Down-select</strong></td>
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*PFS = Progression free survival

Office of the Senior Vice President for Research
Emory Post-Submission Insights

Research Team Tips from ORD:

• DO let your research administration team know you submitted an ARPA-H abstract ASAP
• DO take advantage of ARPA-H’s “optional” abstract & solution summary deadlines – three to five pages can save a lot of work and heartache down the line!
• DO heed ARPA-H’s feedback & advice – they know what they want
• DO keep Emory support offices in the loop (contracts, OTT, RCRA, etc.) when preparing a full proposal
• DO your due diligence – don’t propose work ARPA-H has already done or ignore targeted objectives
• DO read the full solicitation 75,852,379 times
• DO use the “village” – full ARPA-H submissions are not a one-person show; ask for & fully utilize your team and resources
• DO move quickly & work to find the optimal balance between orchestrating the science and back office processes required to submit such a large proposal
ARPA-H: Support & Performance Model

**Support**
ARPA-H will provide contracts – not grants – for projects with well-defined endpoints. Additional support will be provided by Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.

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<th>Performer</th>
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**Performance**
Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals. Valuable lessons are learned and shared from each project.
Hubs & Spokes
Hub & Spoke Philosophy
ARPANET-H

ARPA-H Health Innovation Network
Awesome! What Does That Mean?
Emory Resources for Support Offices

ARPA-H Resources

The Advanced Research Projects Agency for Health (ARPA-H) is a research funding agency that supports high-impact research in support of transformative, sustainable, and equitable biomedical and health solutions for everyone.

ARPA-H Program Links

ARPA-H Website

ARPA-H Videos
Questions?

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ARPA-H PM Interest?
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