Site Selection Proposers' Day

Director's Office

March 24, 2023
Virtual Presentation

Agenda

Eastern Standard Time

10:30 am – 11:00 am	**ZOOM Line Opens for Registered Participants**
11:00 am – 12:30 pm	**Government Briefings** • **Agency Vision** – Dr. Renee Wegrzyn • **Capability Need** – Mr. Craig Gravitz • **Acquisition Details and Next Steps** – Mr. Benjamin Bryant
12:30 pm – 1:00 pm	**Break**
1:00 pm – 5:55 pm*	**One-on-One Sessions** (15-minute max)

* Only available to Consortium Management Firms (CMFs) with advanced registration

ARPA H

Purpose and Expectations

Upload:

- Provide context to ARPA-H's need
- Share some answers to frequently asked questions

Download:

- Leverage market intelligence to adjust project scope and content for final solicitation through feedback and one-on-one engagements

ARPA H

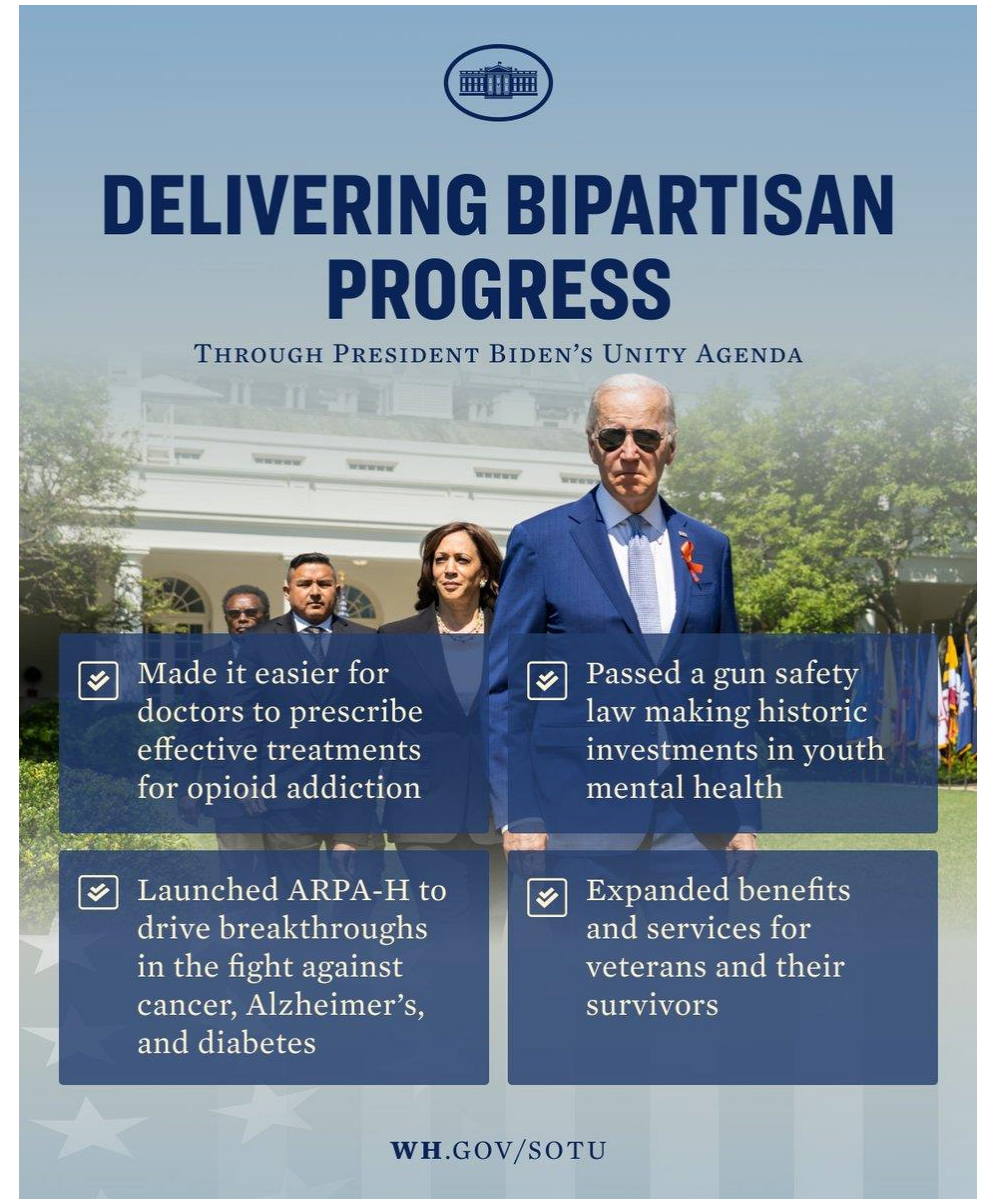# Agency Vision

Dr. Renee Wegrzyn

ARPA-H Director

ARPA **H**

Mission

Accelerate better health outcomes for everyone.

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President Biden's vision

"ARPA-H will pursue ideas that break the mold on how we normally support fundamental research and commercial products in this country."

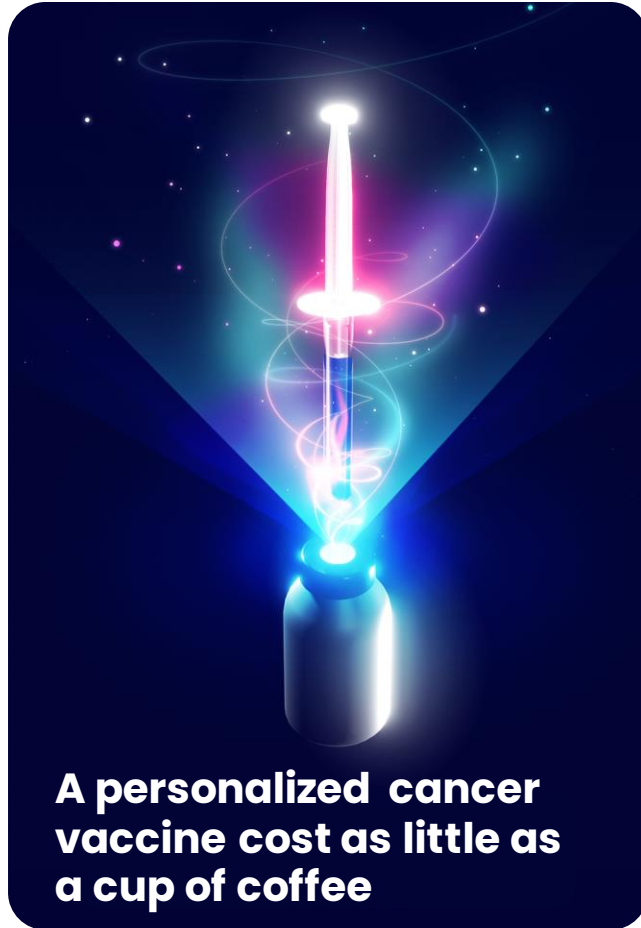- <u>President Biden Remarks, March 18, 2022</u>

Imagine if...

A personalized cancer vaccine cost as little as a cup of coffee
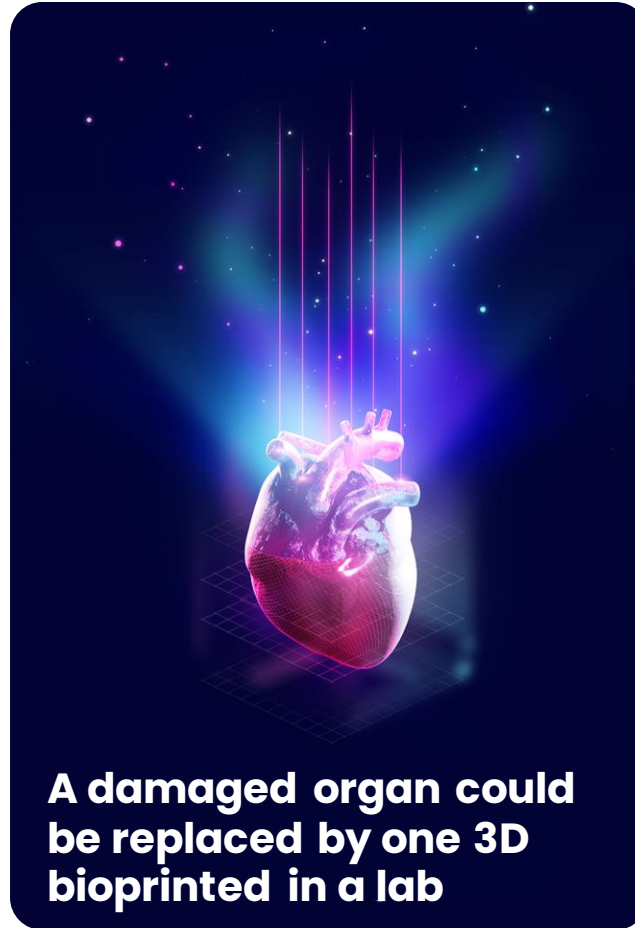
A damaged organ could be replaced by one 3D bioprinted in a lab
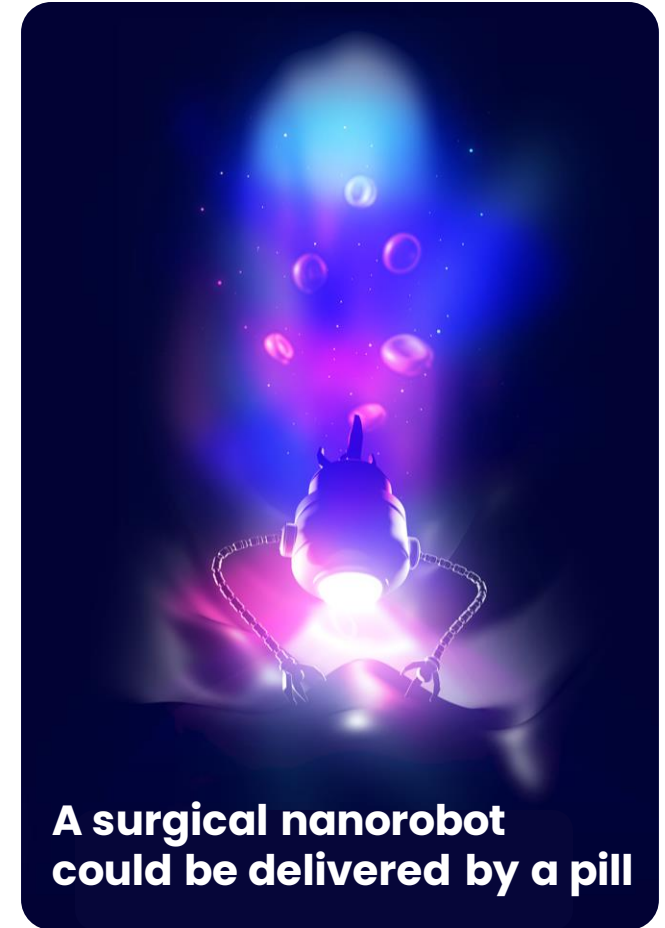
A surgical nanorobot could be delivered by a pill

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ARPA-H Health Ecosystem

The Public

STAKEHOLDERS

Healthcare Providers

NIH ICs

CUSTOMERS

Patient Groups

Federal Partners: FDA, CMS, HRSA, et al

Academia

Private Investors

PERFORMERS

Industry

NGOs

(and many others...)

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ARPA-H is Open for Business!
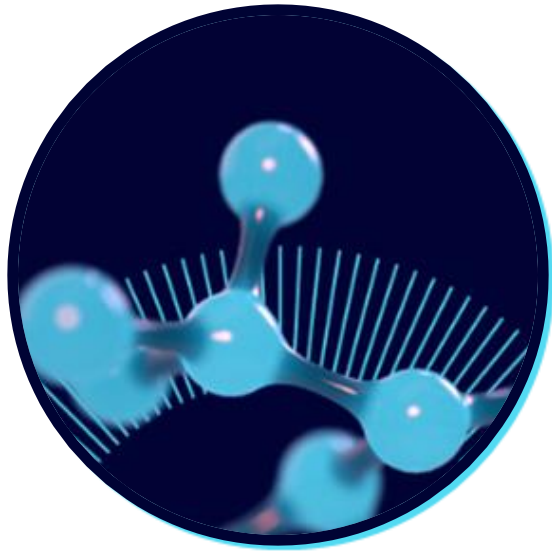
First BAA Announcement

ARPA-H opened its first Agency-wide Open BAA, seeking funding proposals for research aiming to improve health outcomes across patient populations, communities, diseases, and health conditions. The BAA calls for proposals to outline breakthrough research and technological advancements.

Open Broad Agency Announcement | ARPA-H SAM.gov

Site Selection

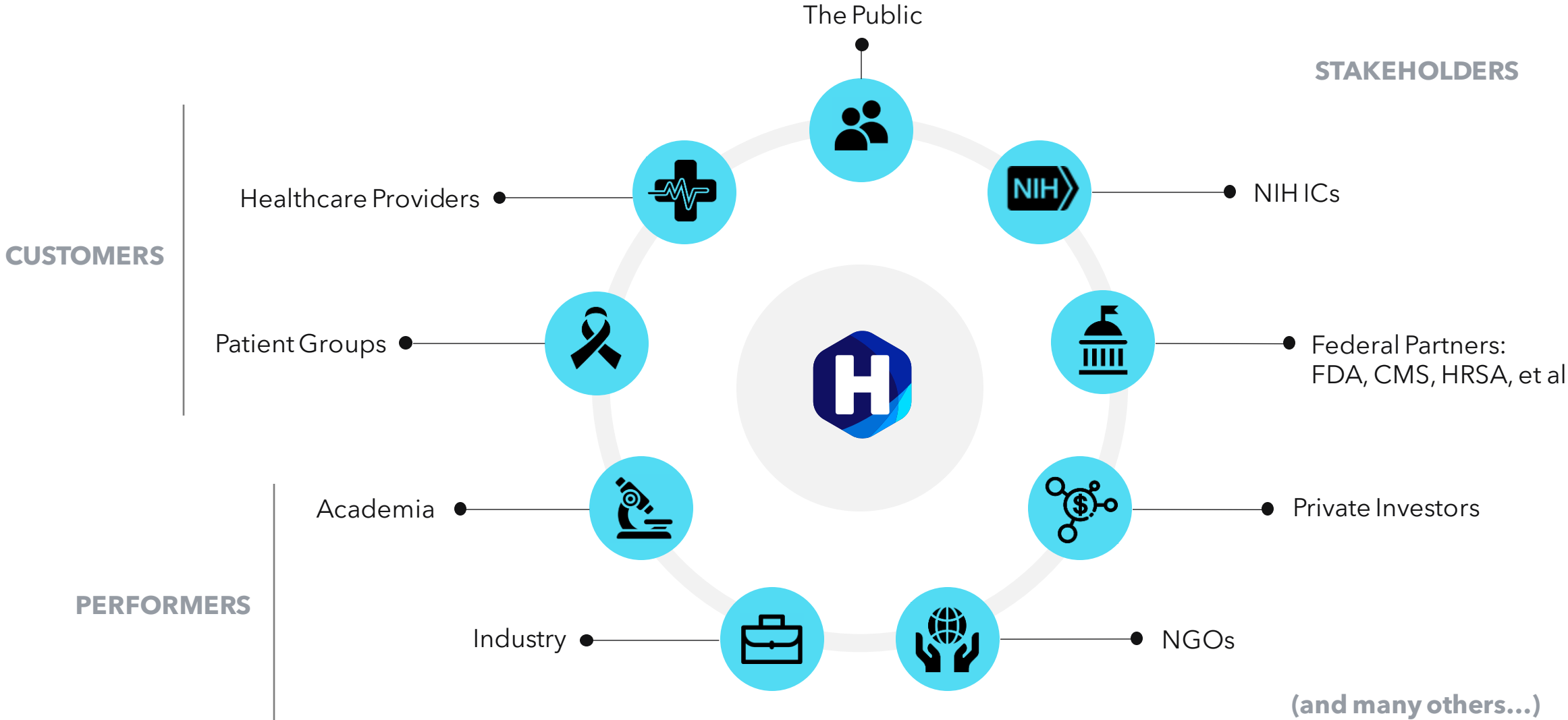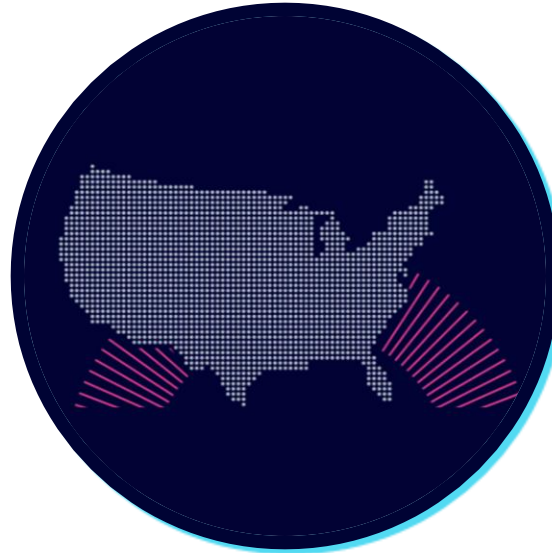ARPA-H seeks to establish sites in three geographic locations across the United States through the pursuit of a hub-and-spoke strategy. ARPA-H will solicit respondents to identify the geographic locations sites for Hubs No. 2 and 3, issuing a draft Request for Consortium Agreement (RCA), describing the approach to identify the unique locations and capabilities that best serve the ARPA-H mission.

Request for Proposals | ARPA-H & SAM.gov
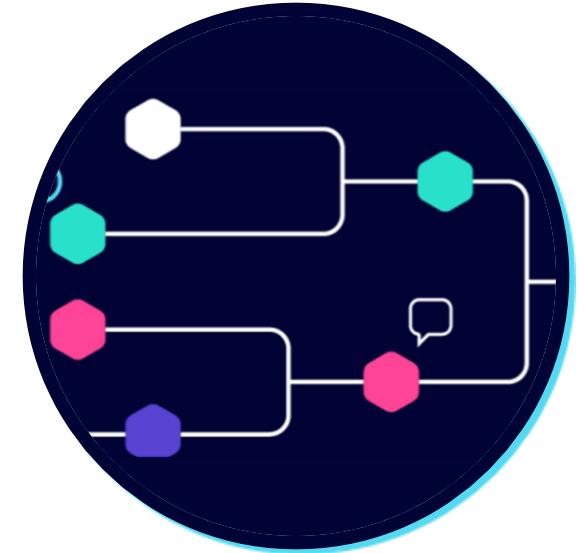
ARPA-H Dash

The ARPA-H Dash to Accelerate Health Outcomes, or "ARPA-H Dash," is launching to identify revolutionary evidence-based ideas to transform health. The ARPA-H Dash is a collaborative online competition open to bold thinkers across health and scientific communities and provides a simple, engaging, and impactful way to solicit the best ideas in the country to enhance the ARPA-H mission.

ARPA-H Dash | ARPA-H & Online Portal

ARPA H

ARPA-H Organization within HHS

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                    ┌─────────────────┐
                    │  HHS Secretary  │
                    └─────────────────┘
                   ╱           │
        ┌──────────────┐   ┌──────────────────┐
        │ NIH Director │---│ ARPA-H Director  │
        └──────────────┘   └──────────────────┘
                              │         │
                    ┌──────────────┐ ┌──────────────┐
                    │   Program    │ │ Business Team│
                    │   Managers   │ │   Members    │
                    └──────────────┘ └──────────────┘
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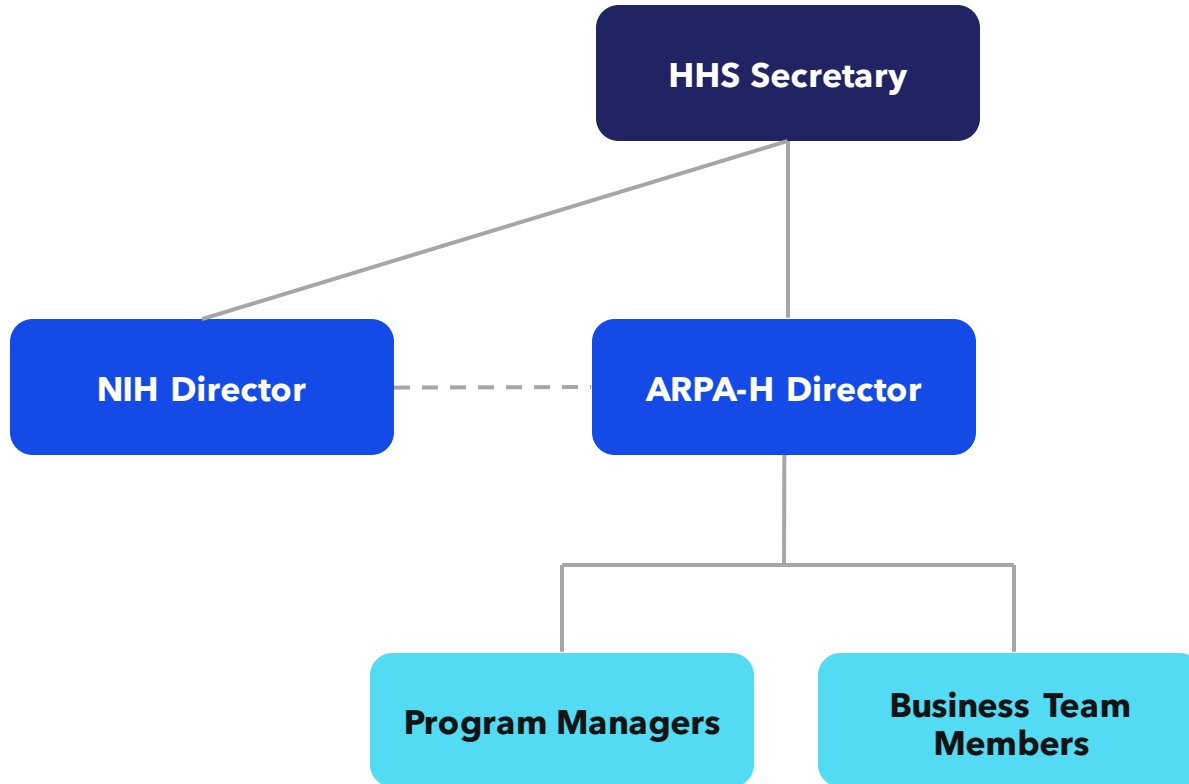
ARPA-H Key Features & Authorities

- ARPA-H is a Federal R&D Funding Agency

- Congress has provided $2.5B to start; funding independent of NIH

- Independent component of HHS within NIH, but not an Institute

- ARPA-H Director reports directly to HHS Secretary

- No internal research labs; disease agnostic

- Lean and nimble management structure

- Bottom-up Program Manager driven ideas and decision-making

- Prize Authority

- Not grant-based; focus on Cooperative agreements, OTAs, contracts

- High Risk/High Impact Research

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Organizational Attributes
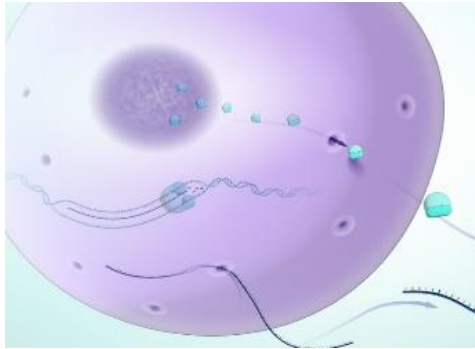
Nucleus of Org.

Facilitating the Future

PMs are the nucleus of the organization, and their energy and passion drive the mission.

ODs and DIRO "work for" the PMs to facilitate success.

PMs are responsible for the full program lifecycle, from new start proposal to transition.

Radical change

Evolutionary proposers need not apply

ARPA-H investments should seek to address seemingly impossible barriers in demonstrating "proof of concept" for solutions to major challenges – not incremental advances.
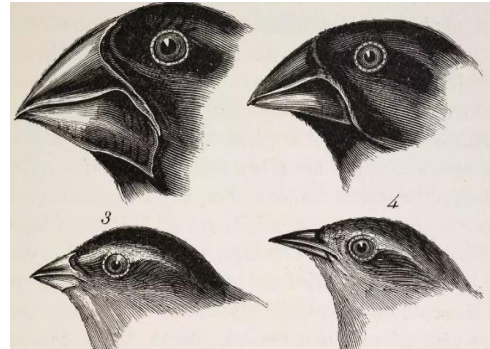
Projects should be high-payoff, high-risk, with the most forward-looking science and technology.

Autonomy

Programs are PM directed

Workshops, consultations, seedlings are encouraged, but no advisory/guidance committees

PMs should practice "full contact" management, with metrics/milestones for program, empowered to stop underperforming projects

PMs manage multiple programs, including programs they inherit from departing PMs

Term limits

A "projects" agency, not a career

Terms limited to 3 years (renewable once for 6 total years) for PMs, ODs, and DDs, allowing inflow of new ideas

Limits create urgency and focus on successful NSPs – aligned with office/agency

Limits remove incentives for empires, organization-building, span of control, bureaucracy, etc.

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ARPA Model: Program Formation

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.

PROGRAM MANAGER

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

PERFORMERS

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

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ARPA Model: Support and Evaluation

SUPPORT
Support for ARPA-H programs comes from funding, Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.
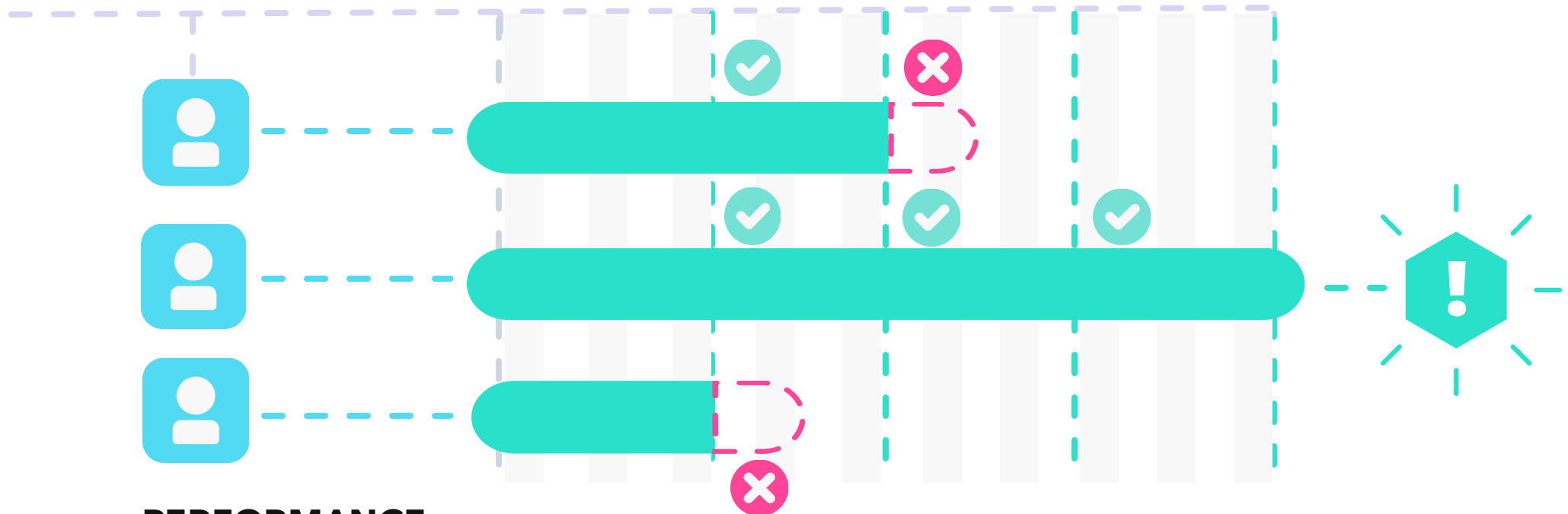
PERFORMANCE
Performance is assessed regularly. If results fail to measure up, a performer's work may be stopped, while more successful performers continue. Valuable lessons are learned and shared from each project.

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ARPA Model: Transition
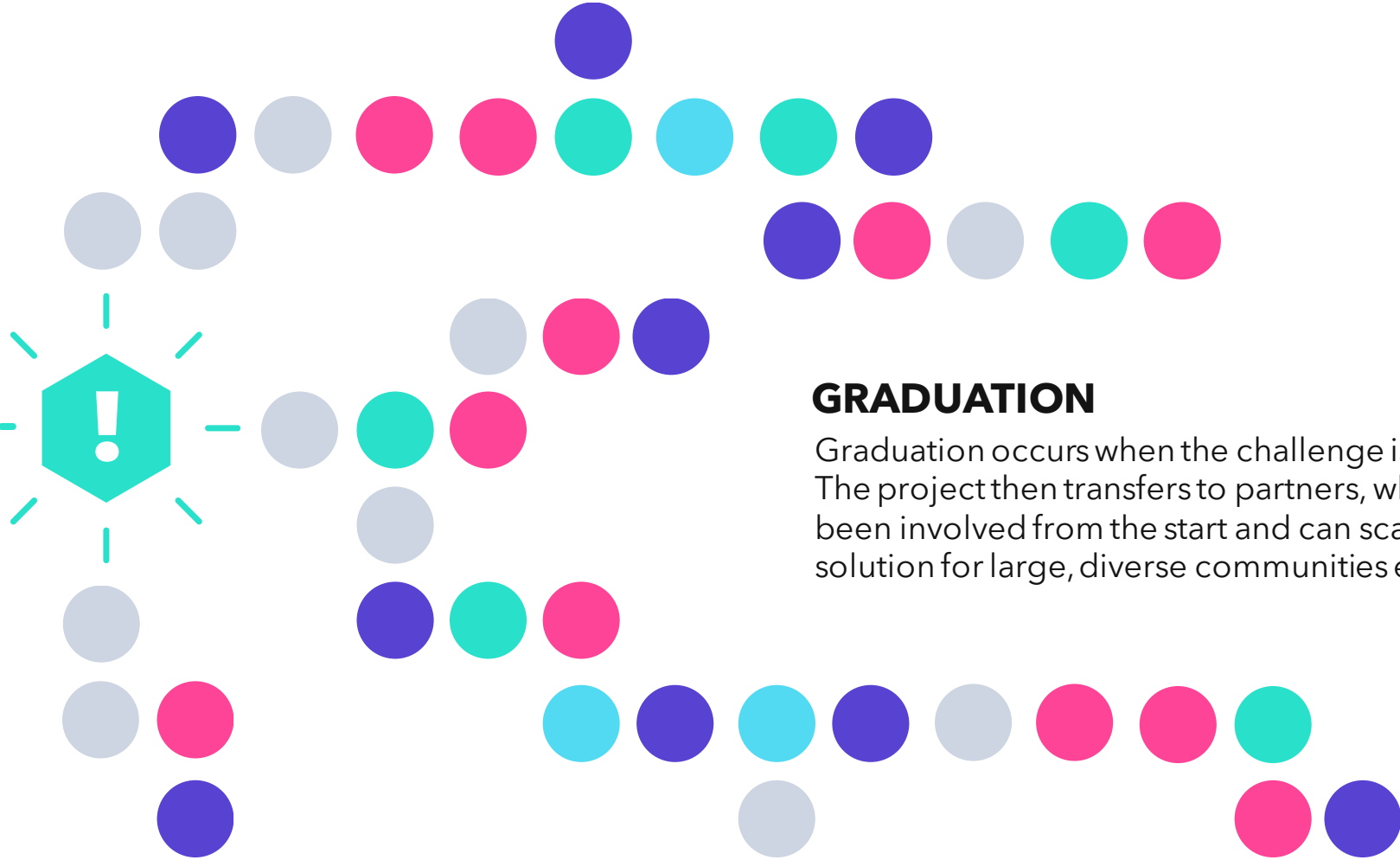
GRADUATION

Graduation occurs when the challenge is solved. The project then transfers to partners, who have been involved from the start and can scale the solution for large, diverse communities everywhere.

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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?

5   What are the risks? That may prevent you from reaching your objectives? Any risks the program itself may present?

6   How long will it take?

7   How much will it cost?

8   What are our mid-term and final exams to check for success?

9   To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?

10   How might this program be misperceived or misused (and how can we prevent that from happening)?

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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 licencing
- Provide mentorship, connections to customers, investors
- De-risk investments

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The Program and Program Manager Flywheel

PMs: 3-6 Years

Programs: 2-4 Years

PROGRAM MANAGERS

SOLUTIONS

PM joins with their vision to advance health outcomes
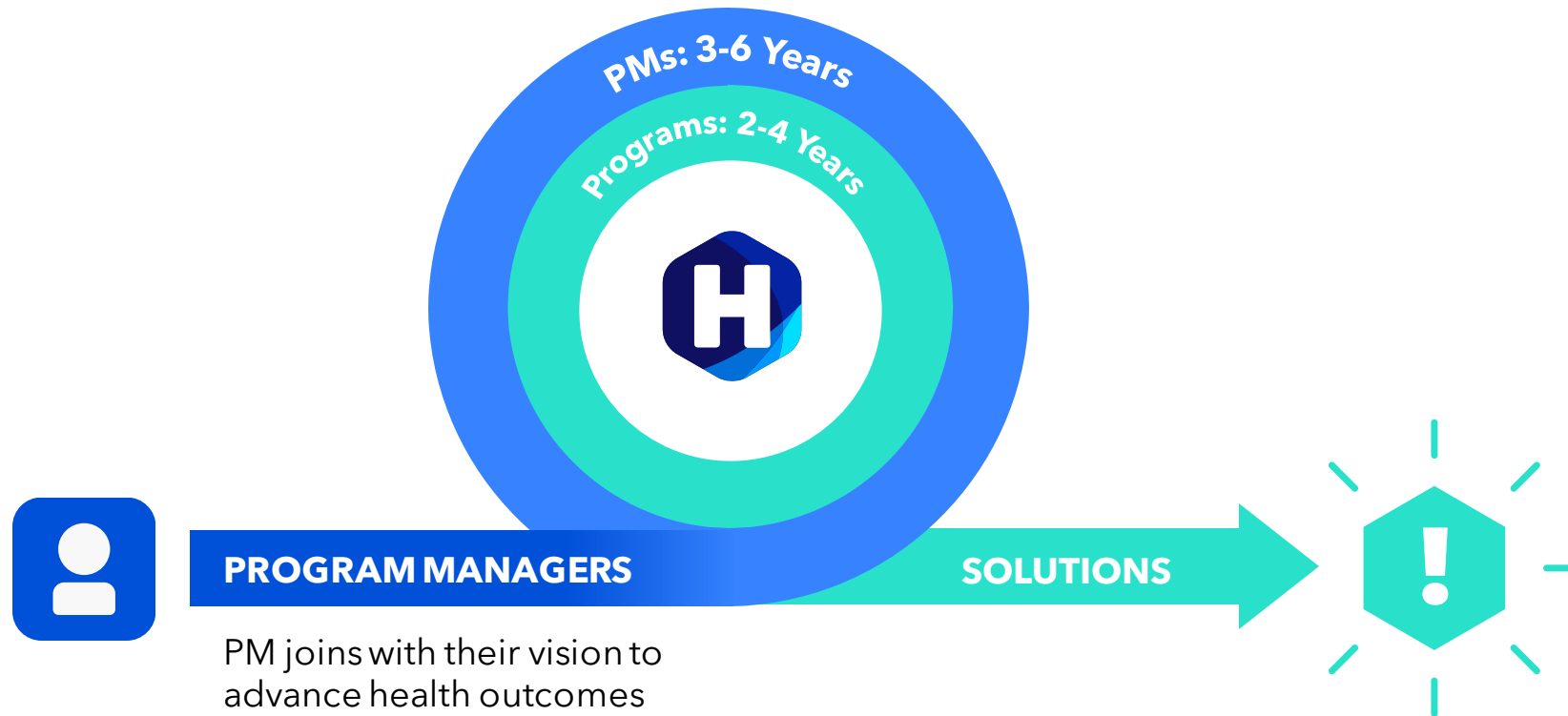
The ARPA-H portfolio is (1) a reflection of the program managers, (2) dynamic, and (3) will – and should! – change frequently

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Initial Mission Focus Areas
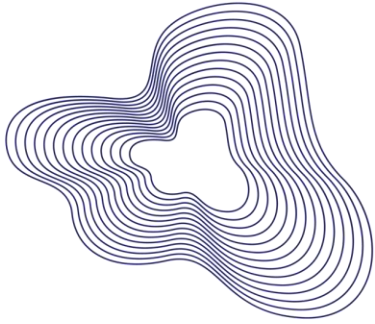
Health Science Futures

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
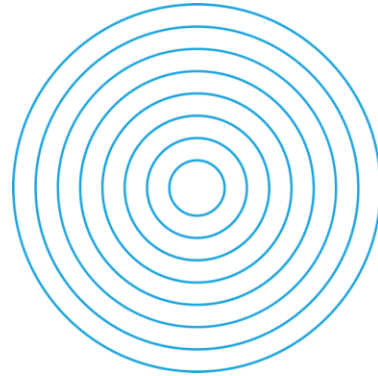
Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.
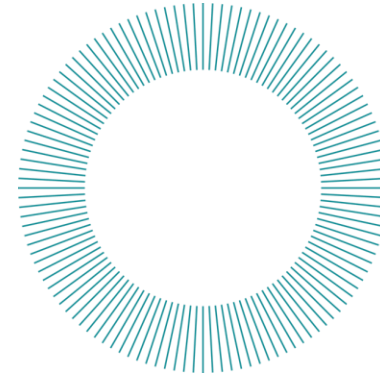
Proactive Health

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.
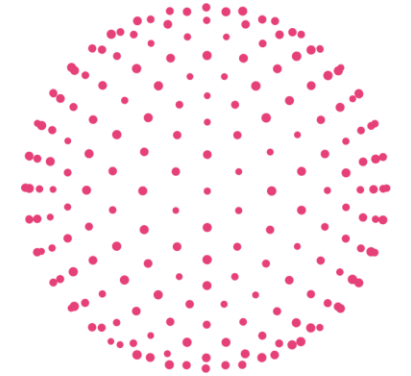
Resilient Systems

Building integrated healthcare systems

Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.

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Announcing:
Site Selection

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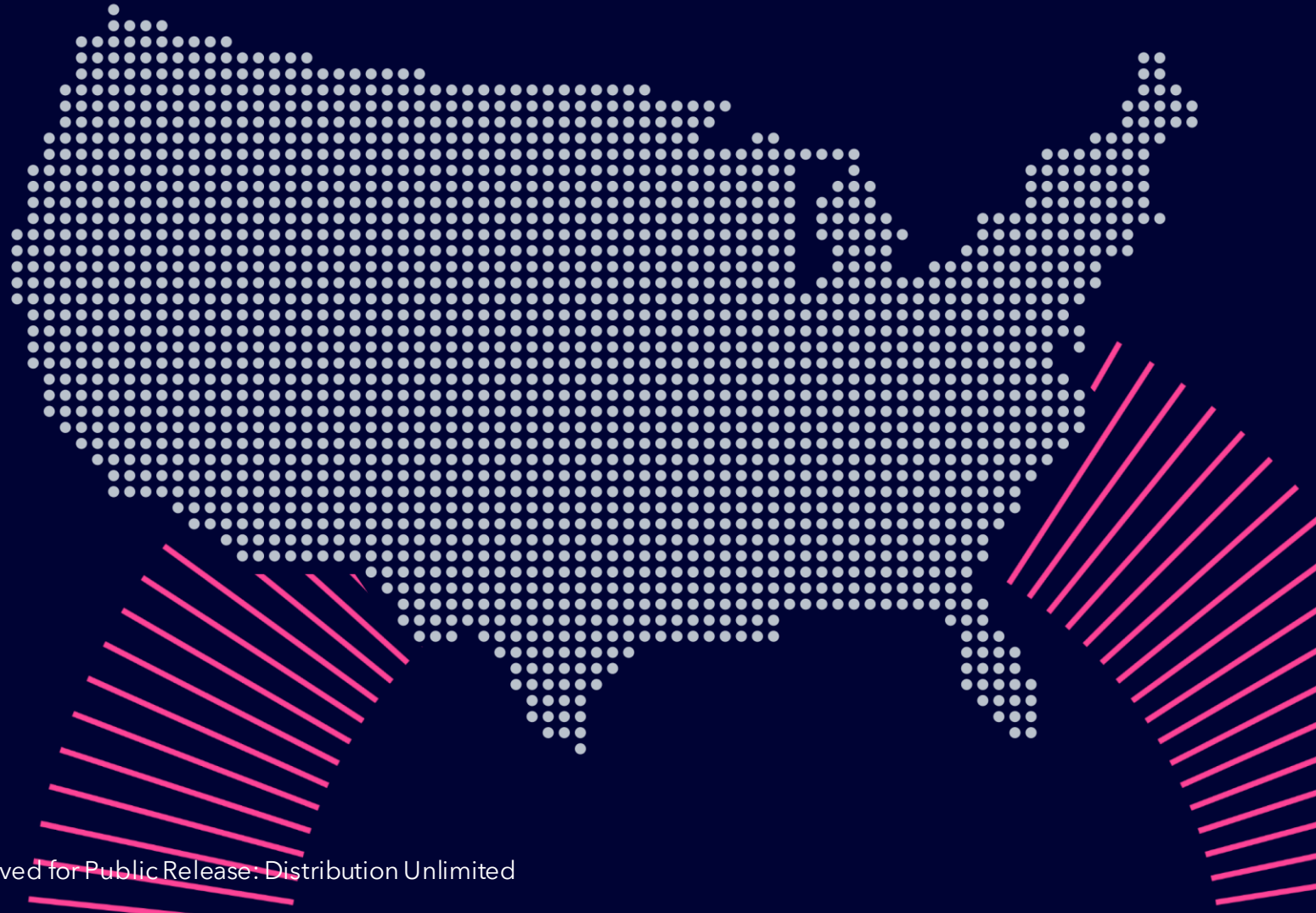
The Challenge

Many Americans live too far from healthcare centers.

Biotech centers aren't co-located with customers that need treatment the most.

Numerous diseases disproportionately impact vulnerable populations.

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Stroke Deaths Across the United States

Gaps in Health Across the United States

Stroke Death Rates, 2018 - 2020
Adults, Ages 35+, by County

Age-Adjusted Average Annual Rates per 100,000

- 3.6 - 61.4
- 61.5 - 70.6
- 70.7 - 78.4
- 78.5 - 89.3
- 89.4 - 177.5
- Insufficient Data

Data source and methodology found at: www.cdc.gov/dhdsp/maps/atlas/statistical-methods

Alaska · Hawaii · Guam · Northern Mariana Islands · American Samoa · Puerto Rico · US Virgin Islands · CDC
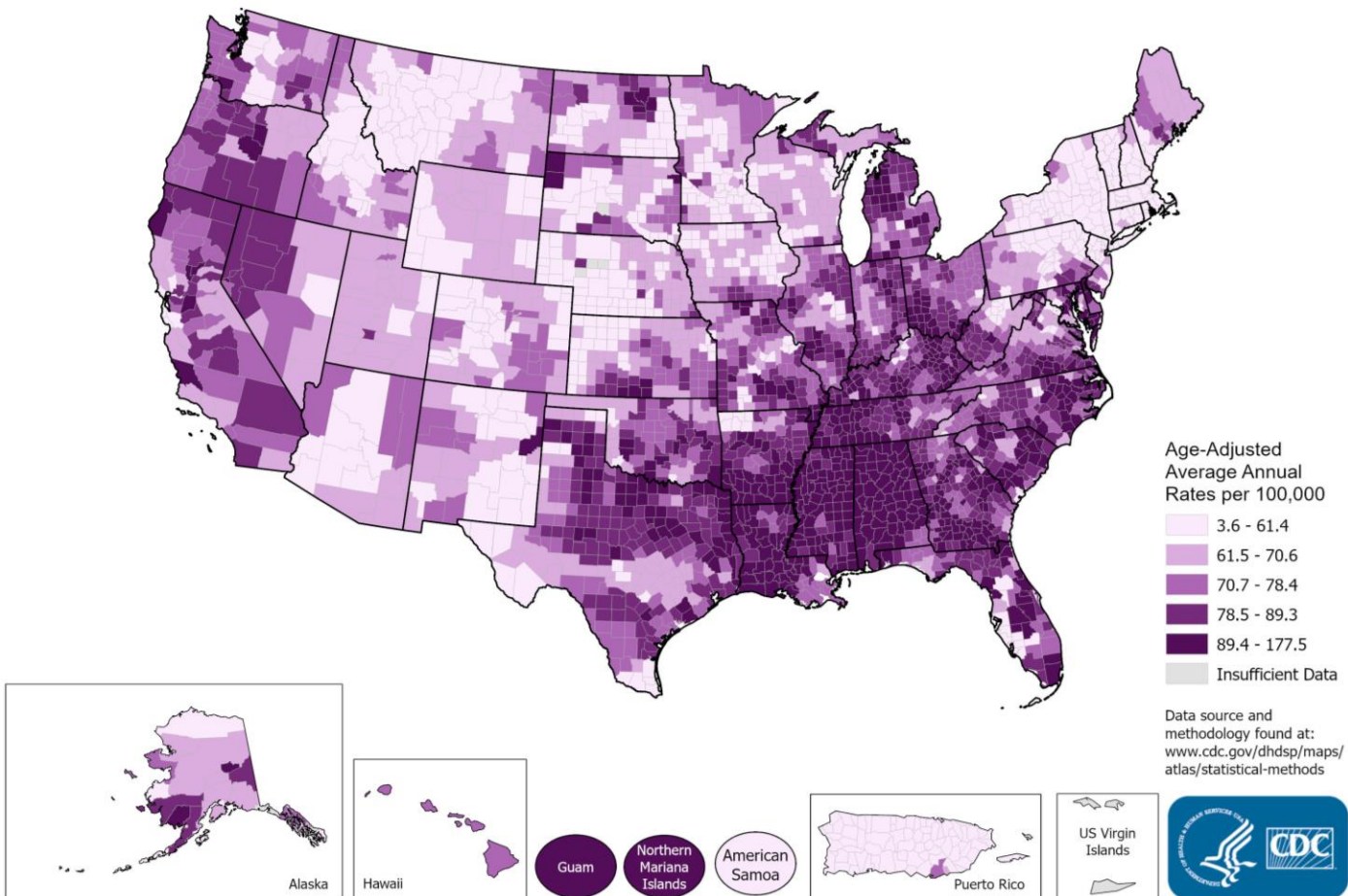
Geographic Patterns: Stroke Death Rates for 2018 through 2020 for Adults Aged 35 Years and Older by County.

The map shows that concentrations of counties with the highest stroke death rates – meaning the top quintile – are located primarily in the Southeast, with heavy concentrations of high-rate counties in Alabama, Mississippi, Louisiana, Georgia, Kentucky, Tennessee, South Carolina, Arkansas, Guam, and the Northern Mariana Islands.

Pockets of high-rate counties are also found in Alaska, Missouri, Oklahoma, Texas, West Virginia, Ohio, Michigan, Indiana, Maryland, North Carolina, and Florida.

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Geographic Distribution of Obesity Rates, 2021
Gaps in Health Across the United States

2021
Percent of adults aged 18 years and older who have obesity †

Value
- 24.7 – 30.4
- 30.5 – 33.9
- 34.0 – 36.1
- 36.2 – 40.6
- Data unavailable

Quantile
Legend Settings
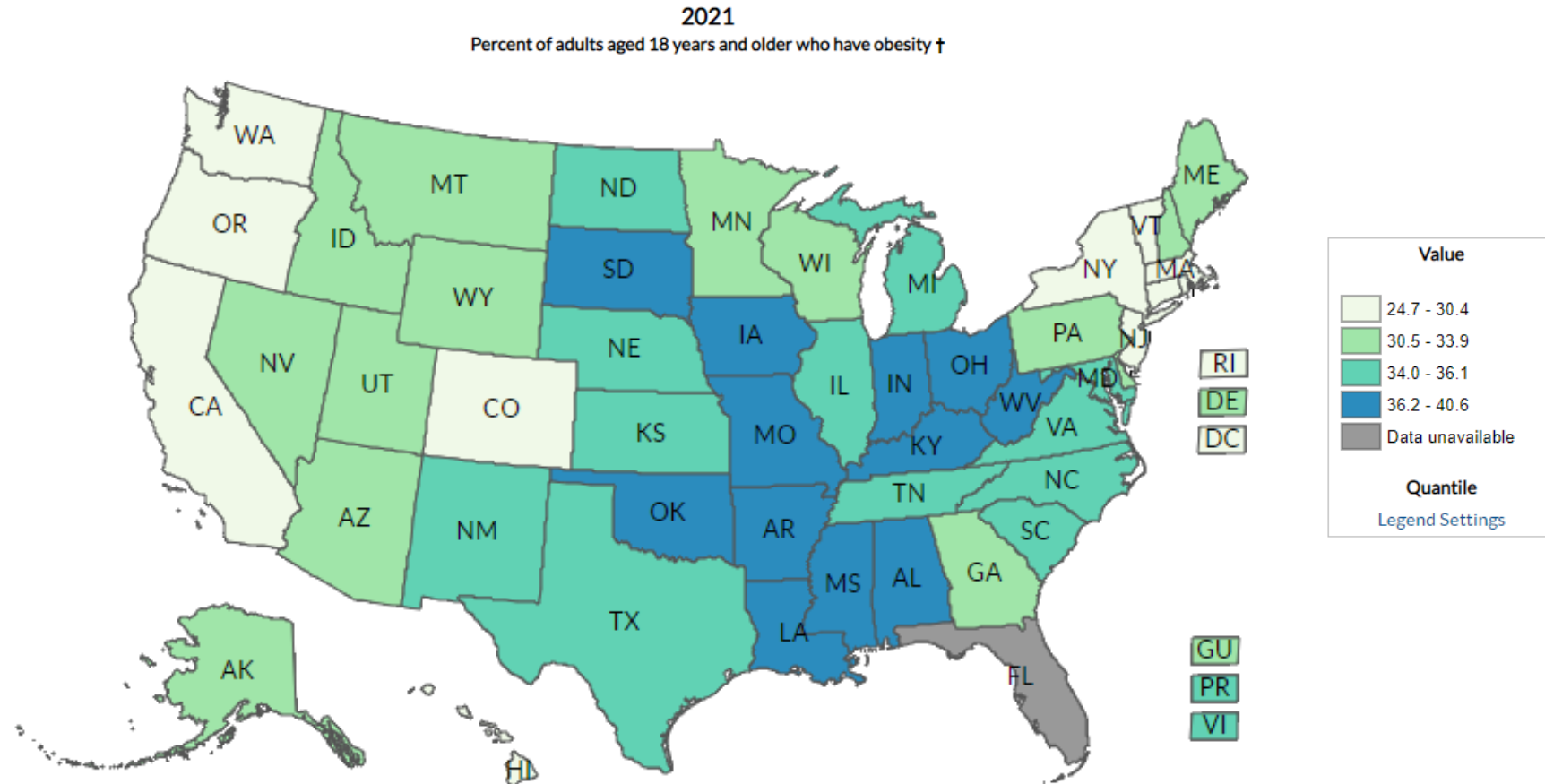
† Obesity is defined as body mass index (BMI) ≥ 30.0; BMI was calculated from self-reported weight and height (weight [kg]/ height [m²]). Respondents reporting weight < 50 pounds or ≥ 650 pounds; height < 3 feet or ≥ 8 feet; or BMI: < 12 or ≥ 100 were excluded. Pregnant respondents were also excluded.

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Preventable Deaths

Residents who die from preventable diseases
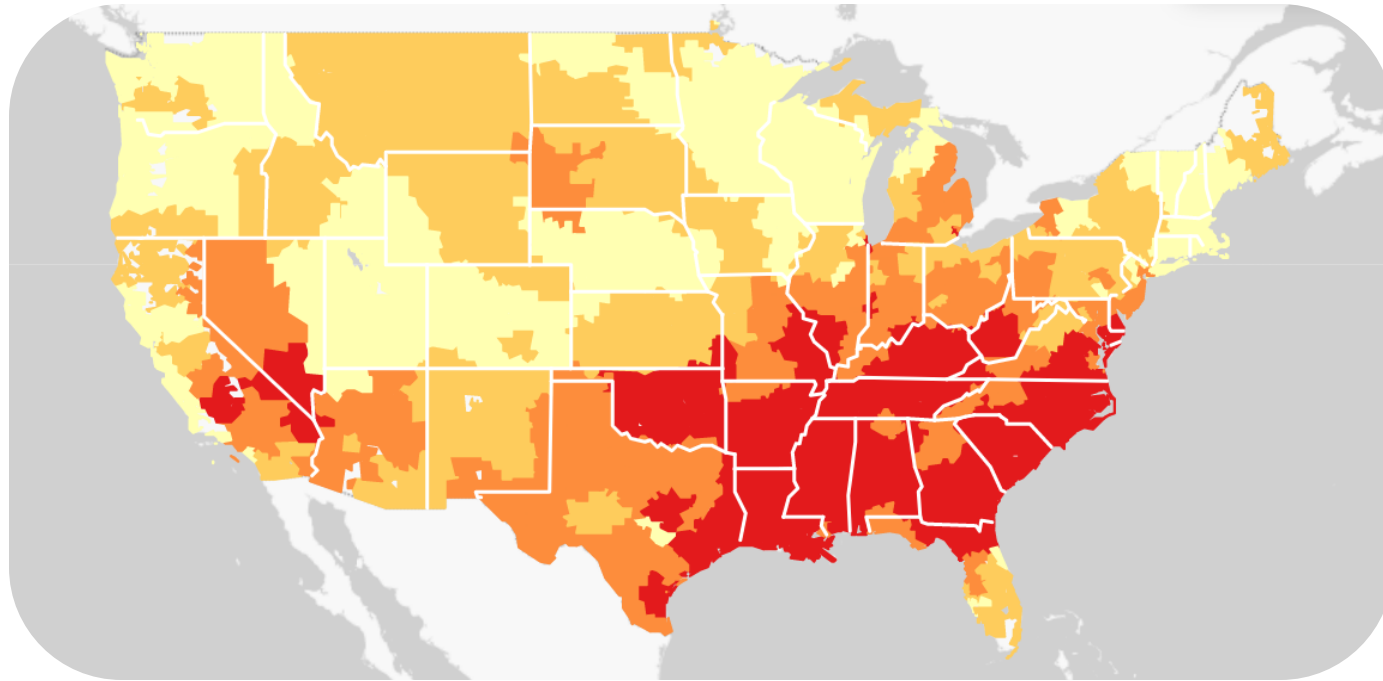
US Map divided into the nation's 306 healthcare markets

Communities broken down into four groups

Worst 25%   Best 25%

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Biotech Density | Cancer Mortality

Number of US biotech firms by state
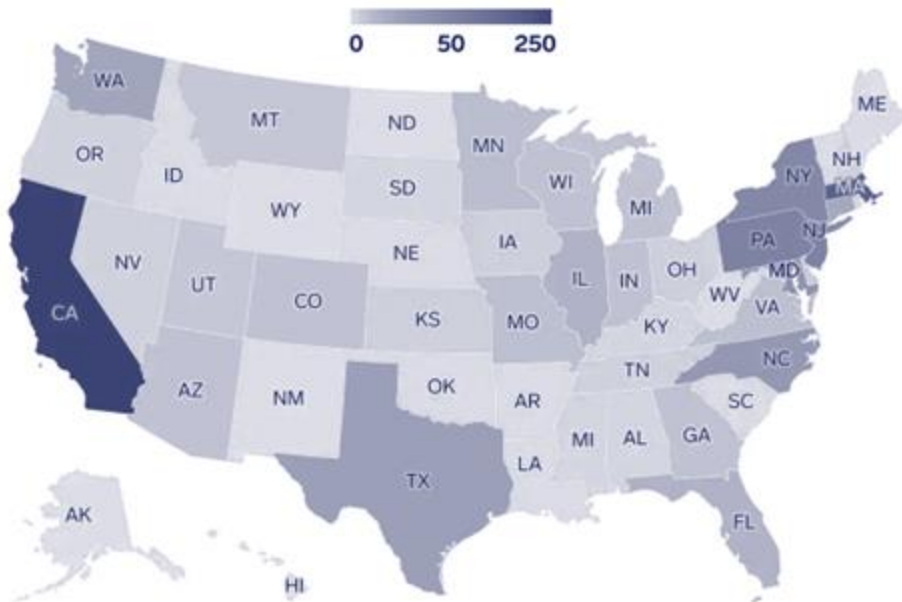
Most US biotech companies are concentrated in only a handful of places around the country, including the Boston and San Francisco areas.

Geographic variation in rates of cancer death in all US counties
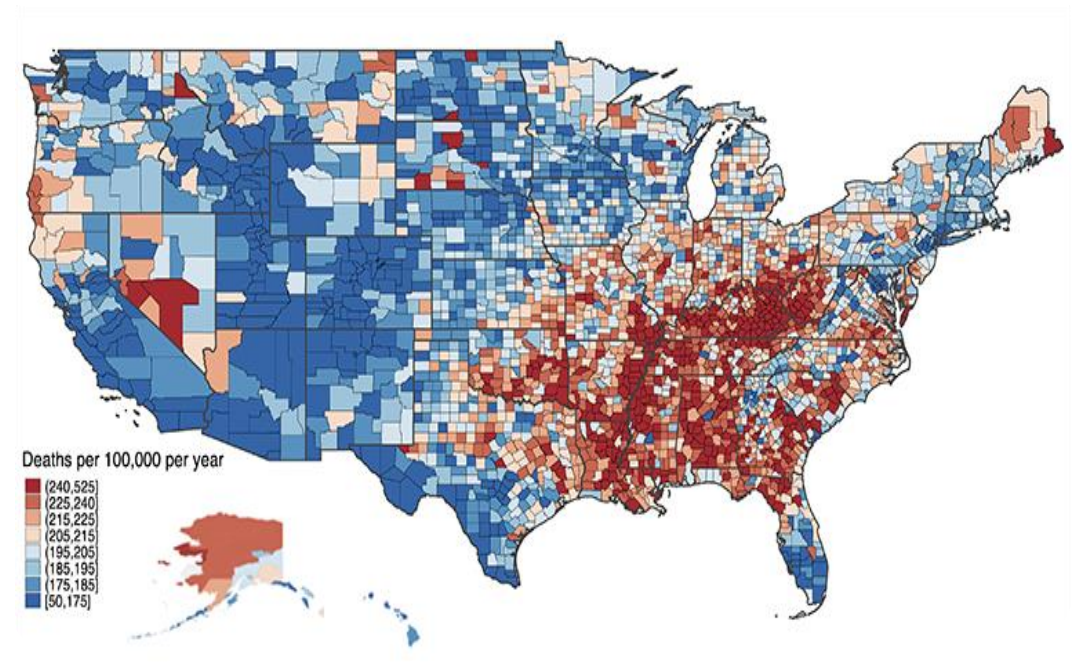
Cancer disparities remain substantial in the United States by geographic area and socioeconomic status. Red shows highest number of deaths per 100,000 persons by county.

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Consortium Management Firms registered for Proposer's Day

Teaming will be required to achieve geographic, demographic, and health target diversity.

ARPA-H Hubs and Nationwide Network of Spokes

Craig Gravitz

Director of the Project Accelerator
Transition Innovation Office

ARPA **H**

Transformative Health Solutions for all Americans

The importance of meeting people where they are

ARPA-H was launched to conduct R&D that accelerates **better health outcomes for all Americans**.

ARPA-H will work with **customers**, **stakeholders**, and **performers** in the health ecosystem in **many geographies** – urban and rural, in laboratories, clinics, and in homes – across the nation and even the globe.

ARPA-H staff and Program Managers are responsible to deliver transformational health solutions to **all Americans**. This means **meeting people where they are.**

ARPA **H**
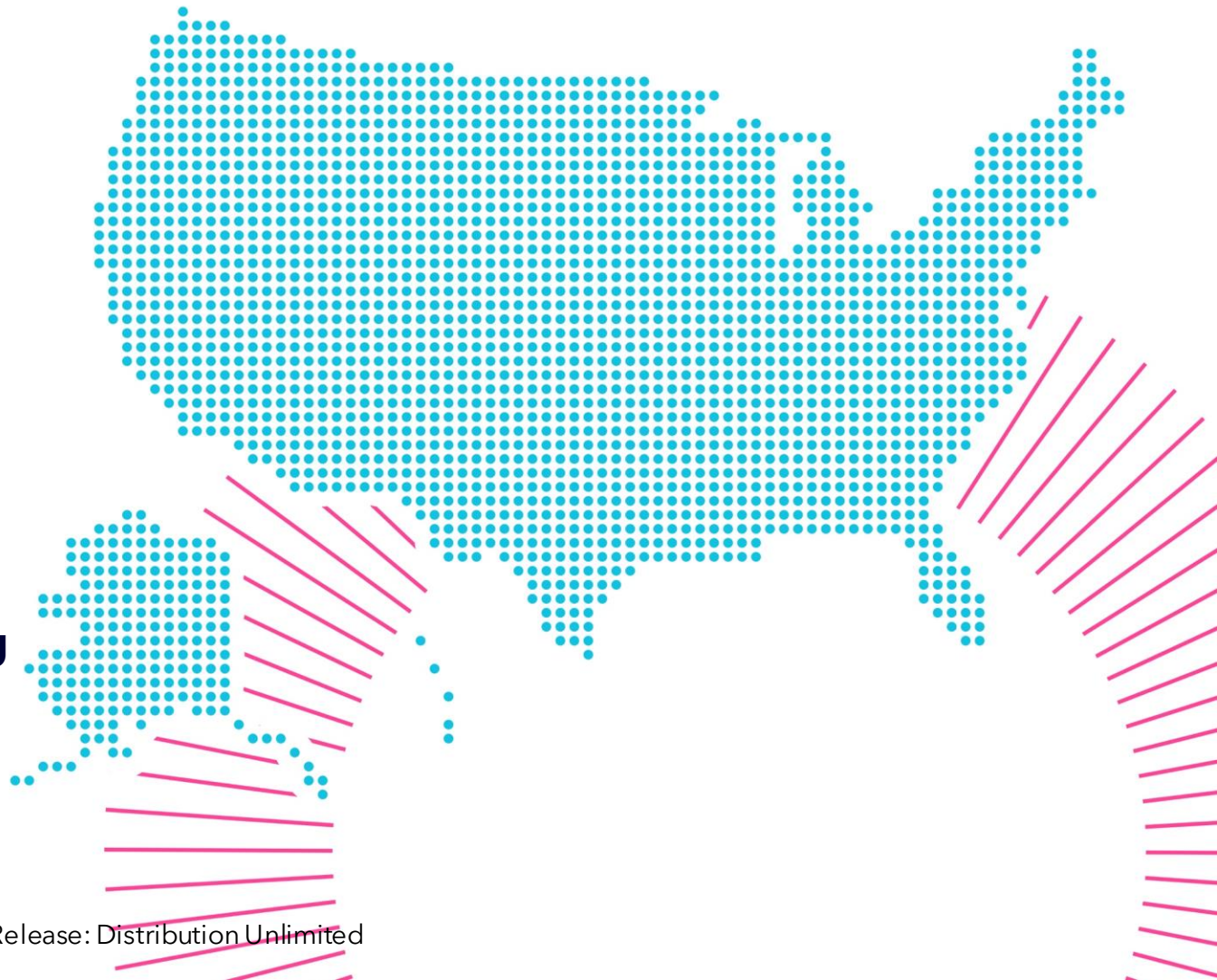
The Hub and Spoke Model
To create a national health innovation network

The **2023 Consolidated Appropriations Act** directs the agency to establish sites in **at least three geographic areas**.

The hub and spoke model will form a **network of people, institutions, and capabilities** across the country.

- **Hub**: To ensure the active transition of health innovation in an expedient, cost-effective, accessible and sustainable manner that reaches all Americans.

- **Spoke:** To ensure that Americans in every community benefit from ARPA-H solutions. Spokes are connected to appropriate hubs on an ongoing basis.

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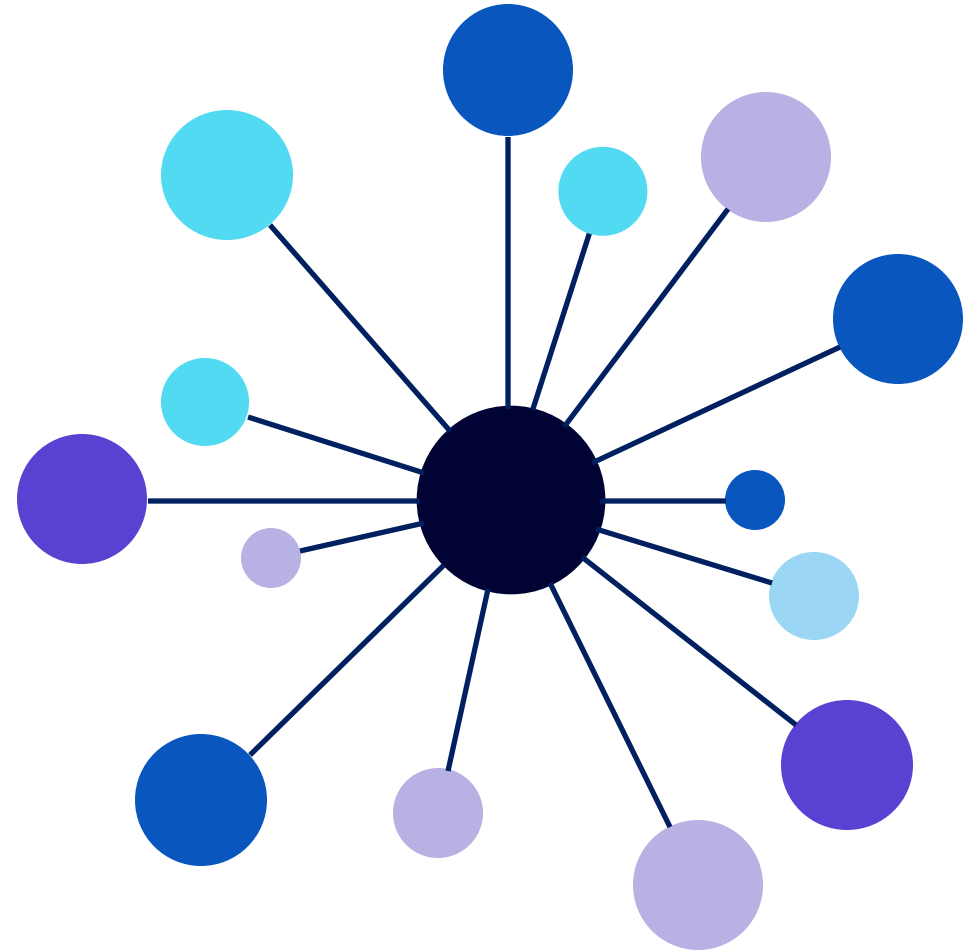
Why This Strategy?

To meet people where they are

- Allows us to test solutions with **different populations**, to ensure our technology is **truly scalable**.

- Allows program managers to have **physical manifestations** of their concepts and **pitch spokes** as part of their programs

- **Cost savings** by reducing the **administrative burden** on both government and performers.

- Enables subawards that operate at **business-to-business** speed and attract **non-traditional government** performers.

ARPA H

Request for Consortium Agreement
A call to identify ARPA-H sites

Included in this Solicitation

Stakeholder and Operations Hub

To engage key federal stakeholders to ensure success of program offerings from their inception. These partners contribute regulatory, legislative, and executive expertise to ARPA-H's efforts.

Customer Experience Hub

To focus on customer experience and drive user testing, adoption, and access to ARPA-H projects. The consortium will take a human-centered approach to design products and services that people need and want to use.

Investor Catalyst Hub

To help ARPA-H programs navigate the complexities of the business, transition, and regulatory landscape and provide resources to help performers bring their ideas to market.

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Hub #1– Customer Experience

Developing patient-centered solutions

This hub will take a **human-centered approach** to design products and services that people need and want to use. Some examples of activities might include:

- Immersive experiences
- User-testing of self-administered diagnostics
- Simulation of patient-centered care environment
- Rapid prototyping of health-tech devices
- Hosting inclusive patient listening sessions
- Patient-centered design
- Novel clinical trials

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Hub #2- Investor Catalyst

Overcoming common business problems

The goal for this hub is to ensure performers overcome business challenges, grow their operations through follow-on following, and **bring their products to market**. Some examples of activities might include:

- Office and lab space
- Mentorship and support
- Business development and networking
- Education and training
- Regulatory and legal support
- Intellectual property protection

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Spokes: Essential to Scale
Serving all communities

Network of consortium members **across the USA** to reach everyone. **Leverage** workforce pipelines, locations, and logistics. Offer more **specific** areas of **expertise** or **access** to different regions.

- May include rural hospitals and clinics, pediatric clinics, disproportionate share hospitals, long-term care and skilled nursing facilities, and rehabilitation centers.

- Geographically distinct from hub.

- Connected to appropriate hub on an ongoing and persistent basis, as programs demand.

*Not reflective of any determined hub or spoke locations
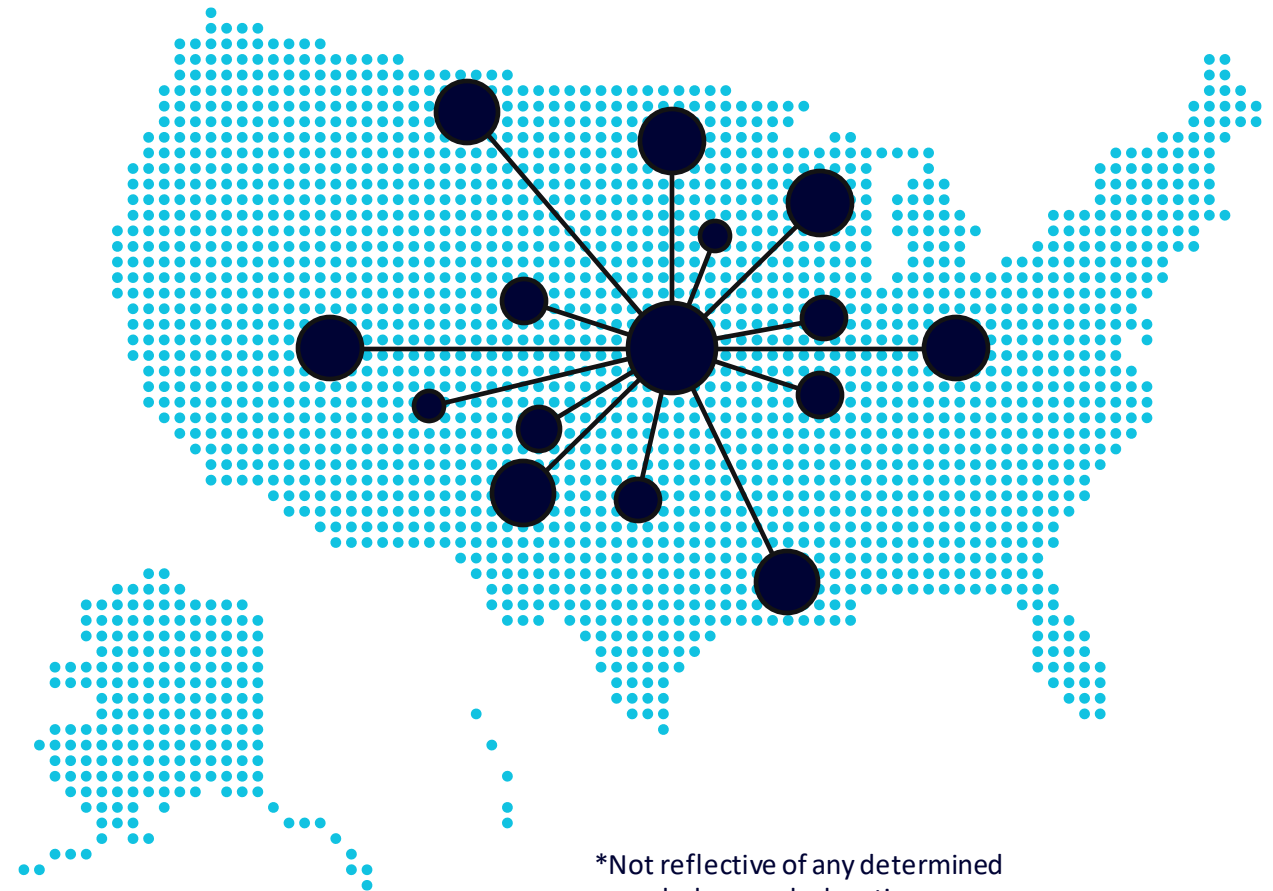
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Data Commons
The network effect

- *Learn.* Receive and report back data to ARPA-H.

- *Examples.* Clinical trials data, patient health outcomes data, other patient data (e.g., medical history, demographics, other clinical data), economic data including cost-effectiveness analyses and data on healthcare utilization (looking at financial impact of new health technologies), technology development data such as engineering or prototyping data, and regulatory compliance data.

- *Privacy, safety, security.* Shall follow Federal information security , privacy, and health IT standards to include, but not limited to, HL7 FHIR, HIPAA, and NIST cyber security standards.

*Not reflective of any determined hub or spoke locations

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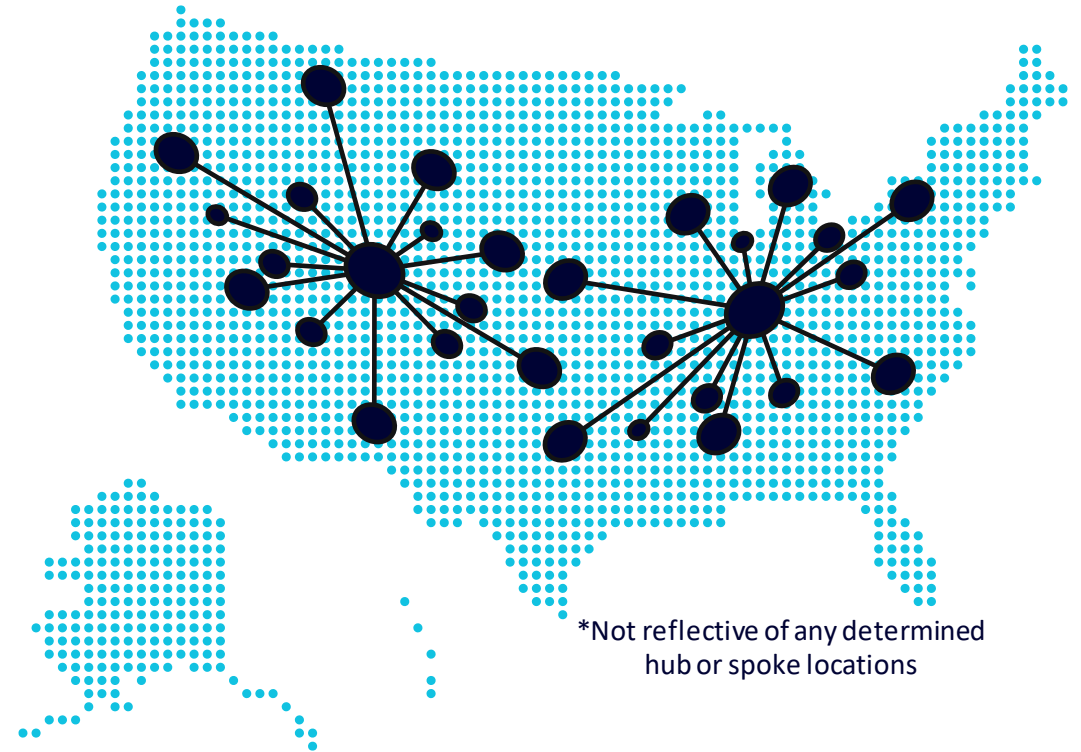
Concrete Examples – <u>Notional</u> PM-led Activities

Customers

- **Customer testing and evaluation**
  At-home wearable prototypes for monitoring motor health-related diseases – e.g., Parkinson's

- **Recruit patient cohort** that is geographically and demographically diverse for rare disease diagnosis – *network provides speed and scale*

Investors

- **Seek regional and founder diversity** to empower startups/performers from non-traditional locations and backgrounds - *so great ideas are not overlooked due to biases*

- **Leverage regional expertise** to create new solutions in large untapped markets

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Site Selection Process

Three phases. A series of down-selects.
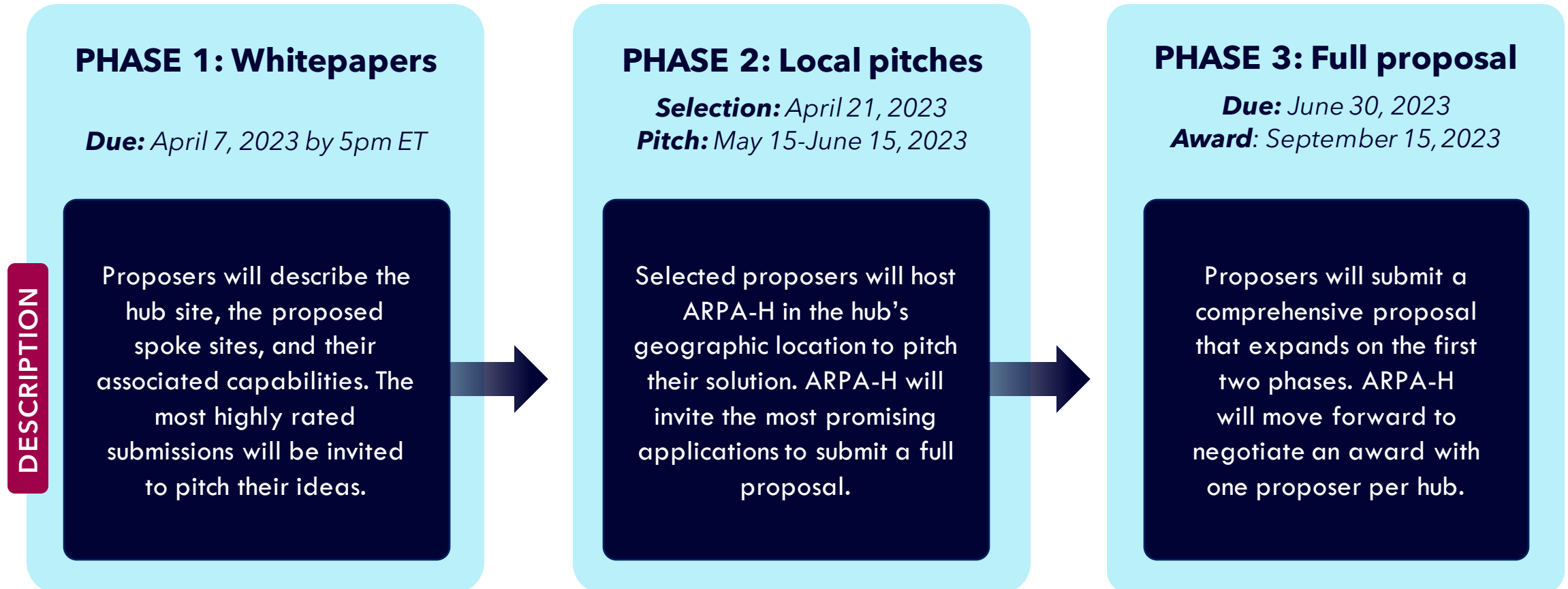
PHASE 1: Whitepapers

Due: *April 7, 2023 by 5pm ET*

DESCRIPTION

Proposers will describe the hub site, the proposed spoke sites, and their associated capabilities. The most highly rated submissions will be invited to pitch their ideas.

PHASE 2: Local pitches

Selection: *April 21, 2023*
Pitch: *May 15-June 15, 2023*

Selected proposers will host ARPA-H in the hub's geographic location to pitch their solution. ARPA-H will invite the most promising applications to submit a full proposal.

PHASE 3: Full proposal

Due: *June 30, 2023*
Award: *September 15, 2023*

Proposers will submit a comprehensive proposal that expands on the first two phases. ARPA-H will move forward to negotiate an award with one proposer per hub.

ARPA H

PHASE 1: Whitepapers

Due: April 7, 2023 by 5pm ET

Section 1: Hub Overview (Max Length: 3 pages)
- Proposed team and approach
- Experience, particularly experience managing federal consortia

Section 2: Spoke Overview (Max Length: 3 pages)
- Describe the specific spokes that will constitute possible geographically dispersed but mission aligned entities
- This section shall also include the CMF's strategy to reach out and include future spokes in their hub solution

Section 3: Data Commons (Max Length: 2 page)
- Proposed approach to establishing a data commons

Section 4: Rough Order of Magnitude (ROM) Pricing (Max Length: 1 page)
- Describes the basic unbundled prices
- All known costs associated with running the hub and managing the consortium

Section 5: Location Pitch Proposal (Max Length: 1 pages)
- Describe the proposed one-day site visit

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PHASE 2: Local pitches

May 15-June 15, 2023

DESCRIPTION

- ***Series of meetings that showcases the proposed local hub ecosystem***. Includes representatives from various organizations, including those proposed in the white paper, to demonstrate the variety of connections and offerings available in the area.
- ***Visits to local facilities, businesses, and other relevant qualities of the proposed location***. These visits will allow the agency representatives to see the unique offerings and resources available in the area, such as cutting-edge technology, specialized expertise, and unique infrastructure.
- ***Slide presentation.*** No longer than one hour. It describes the basic features of the proposer's solution including pricing and technical approach. This presentation must be concise (no marketing material) and clear.
- ***ARPA-H will provide immediate, direct feedback*** following this presentation to consider in a final proposal. This session is intended as give-and-take where all parties can assess alignment on various fronts.

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PHASE 3: Full proposal

Due: *June 30, 2023*

- Builds on previous submissions: whitepaper and pitch
- No longer than twenty-five pages, excluding the price proposal
- Includes a detailed project plan, budget, timeline, proposer's pricing arrangement for administering and managing project OT awards

ARPA**H**

Acquisition Details and Next Steps

Benjamin Bryant

ARPA-H Head of Contracting
Activity (Acting)

ARPA **H**

Acquisition Authorities

- We are working urgently to use the authorities given to us by Congress to **rapidly partner** critical performers with PM visionaries while applying fair competition to **drive value to the taxpayer**

- Other Transactions (OTs) are a critical tool to create **flexible arrangements** to increase **ability to partner** with performers

- A consortium is a **collection of entities** (contractors, nonprofits, academic institutions, etc.) and individuals working together to achieve a common goal or solve a defined challenge

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Other Transactions

Value of OTs

- **Attracts companies that would normally avoid Government business**
- **Attractive to contractors looking for elasticity in their agreements**
- **Invokes commercial practices (e.g., negotiating terms & conditions)**
- **Any apparent risk allows parties to change the terms to be more suitable to the party absorbing most of the risk**
- **Removes rigidity of traditional Government procurement**
- **Promotes trust and a spirit of cooperation with the health ecosystem**

ARPA**H**

Consortia

Value of Consortia

- Consortia enable extensive and established networks, including start-ups, to assist the government in its pursuit of innovation solutions and collaborations

- Consortium members managed by a single entity to significantly speed up research and development by moving at the speed of relevance through a process that is closer to business-to-business than government-to-business

- Drives close collaboration between government and innovator

- Consortia can help ARPA-H expand its network by connecting with partners in the health ecosystem (technically and geographically) now and in the future

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ARPA-H Request for Consortium Agreement: Structure and Key Roles

This **Request for Consortium Agreement (RCA)** is a solicitation to organize and operate two ARPA-H hub-and-spoke networks for a period of five years, consisting of a base year and four optional years. These networks have two important components:

1) The Hub site, which consists of a **Consortium Management Firm (CMF)** and local consortium members that offer capabilities relevant to the Hub, and

2) Spoke sites (a network of additional **Consortium Members**) that are geographically distinct from the hub site

Government Sponsor:
ARPA-H

Consortium Management Firm:
Prime Awardee of this effort

Consortium Members:
Sub awardees under this effort (*health innovation partners*)

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Government Sponsor: ARPA-H

- Awards OT to CMF for each Hub

- Establishes consortium objectives and guidelines to execute the consortium

- **Selects** projects for consortium based on ARPA-H needs

- **Approves** project OT award selection

- **Executes** project OTs

- Exercises options for sequential year activities and funding, as appropriate

- Appoints an ARPA-H federal employee to **oversee and participate in consortium activities**

- Responsible for day-to-day activities with subawardees, including monthly administrative and programmatic reporting, as well as an annual review

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Consortium Management Firm(s)- Prime Awardee

- Maintains a small, dedicated physical office space in a hub location that is suitable to conduct administrative actions related to the consortium and access to a flexible meeting space to host visiting ARPA-H employees

- Establishes processes for consortium application and membership terms; **No membership fees may be collected from hub consortium members**

- Executes consortium member agreements with each member organization

- Communicates ARPA-H capability requests to consortium members, which may include, but not be limited to: requests for subject matter experts, planning and executing program manager immersive experiences with customers, or any other request supporting program or transition activities

- Supports demo evaluation and determinations to advance to next phase of selection process

- Manages post-project OT award administrative activities on behalf of ARPA-H, such as monitoring deliverables, invoice/payment tracking, and reporting

- Manages a data commons that can receive and report back data to ARPA-H

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Consortium Members (Spokes): Subawardees

- Support ARPA-H program managers under this effort

- Entities both near the geographic region of the CMF and those that align with the hub but are located in another geographic region

- Comprised of broad array of health organizations, including but not limited to:

  o Traditional/non-traditional contractors
  o Non-profit organizations`
  o Academic institutions, including minority serving institutions

- Partner with other members to propose solutions

- Negotiate unique terms and conditions for individual projects

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Process flow

ARPA-H will award the Consortium Management Firm (CMF) for each hub a base OT agreement

The CMF will facilitate OT subawards to its consortium members via project OT agreements under the base agreement

Project OT agreements will be competed to the maximum extent practicable

ARPA-H retains decision-making authority to ensure ARPA-H mission needs, and the needs of the taxpayer are met

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Next Steps

Phase I (March – April)

- Draft RCA Questions Due
- Virtual Proposers' Day
- Release FINAL Request for Consortium Agreement(RCA)
- Electronic Submission of Whitepapers

Phase II (April – June)

- Initial Down Selections
- In-Person Pitches

Phase III (June – September)

- Full Proposal Submission Deadline
- Expected Date for Final Award Selection Notifications

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Selection Process

Phase I - **Submission of White Papers:** CMF proposers submit white papers that describe the hub site, the proposed spoke sites, and their associated capabilities. ARPA-H will invite CMF proposers to pitch in Phase II, based on the most highly rated submissions per the evaluation criteria

Phase II - **In-Person Pitch:** Selected proposers will host ARPA-H in the hub's geographic location to pitch their solution. Based on this assessment, ARPA-H shall invite the most promising applicants to submit a full proposal in Phase III

Phase III - **Full Proposal, negotiations, and award:** Proposers will submit a comprehensive proposal that expands on the first two phases. ARPA-H will evaluate the full proposal and anticipates that it will move forward to negotiate an award with one proposer per hub

Note: Non-selection at any of these phases does not prohibit a potential consortium member from participating as a spoke in the final award. Any given entity may propose as a hub or spoke site at any step of the process and may propose on more than one submission. ARPA-H intends to have a national presence that is representative of the settings and communities that it serves

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Evaluation Criteria

At each phase of the process, ARPA-H will use the same criteria and adjectival ratings to evaluate proposals.

- **Factor 1 – Technical Solution.** Demonstrates that the **technical acumen/domain expertise** align to ARPAH's goals. Demonstrates the **beneficial characteristics of the intended location and how they facilitate advancement** of ARPA-H's goals and functions. Shows the **value of the proposed technical capabilities** and how the capabilities will be **integrated** into the ARPA-H model to accelerate ARPA-H funded solutions. Demonstrates the degree to which the proposed location is a **health innovation center of gravity**

- **Factor 2 – Depth and Breadth of Hub-and-Spoke Network.** Demonstrates the ability to **tap into, build, and connect a nationwide network of partners**. Demonstrates the depth and breadth of the network (local and national), as well as the beneficial qualities and attributes of the proposed consortium members comprising the network

- **Factor 3 – Management of the Consortium.** Demonstrates a **comprehensive approach to manage the consortium**, to include detailed business and operations plans as well as experience supporting federal customers under consortia OTs. Demonstrates **deep expertise** to functionally operate the central hub and manage the spoke network to support ARPA-H's objectives and mission

- **Factor 4 – Cost/Price Realism and Reasonableness.** ARPA-H will consider cost and price in its decision to down select a proposer to the next phase and for award. ARPA-H will evaluate the **cost/price for realism and reasonableness**

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Thank you!

Link to RCA Site
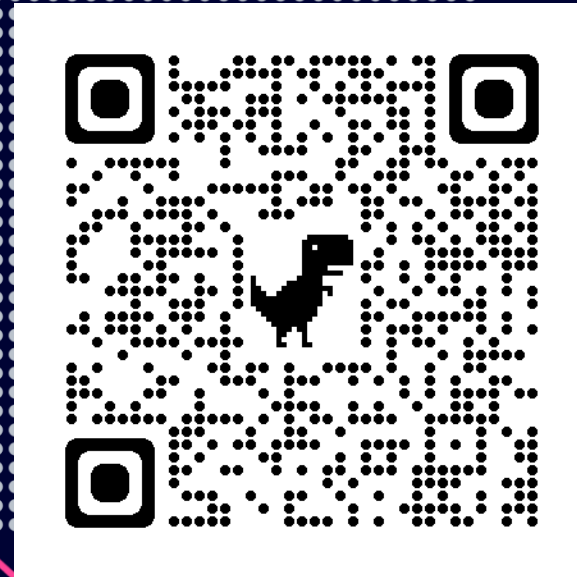
BACK-UP SLIDES

Acquisition Authorities and Other Transactions

- **What doesn't apply to OTs?**

  o Truth in Negotiations Act (Truthful Cost and Pricing)
  o **Cost Accounting Standards**
  o Contract Disputes Act
  o Procurement Protest Process
  o **Competition in Contracting Act (CICA)**
  o Cost plus a percentage of cost prohibition
  o Buy American Act (in part)
  o **Bayh-Dole Act (patents)**
  o FAR/HHSAR/Agency specific acquisition regulations (e.g., **Mandatory flow downs to subcontractors**)

- **Some laws still do apply**

  o Criminal Laws (false claims/statements)
  o Laws of general applicability (Civil Rights Act)
  o Laws that would apply to anyone doing business in the U.S. (e.g. environmental laws, import/export control)

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