



Innovating at NIH and Establishing ARPA-H

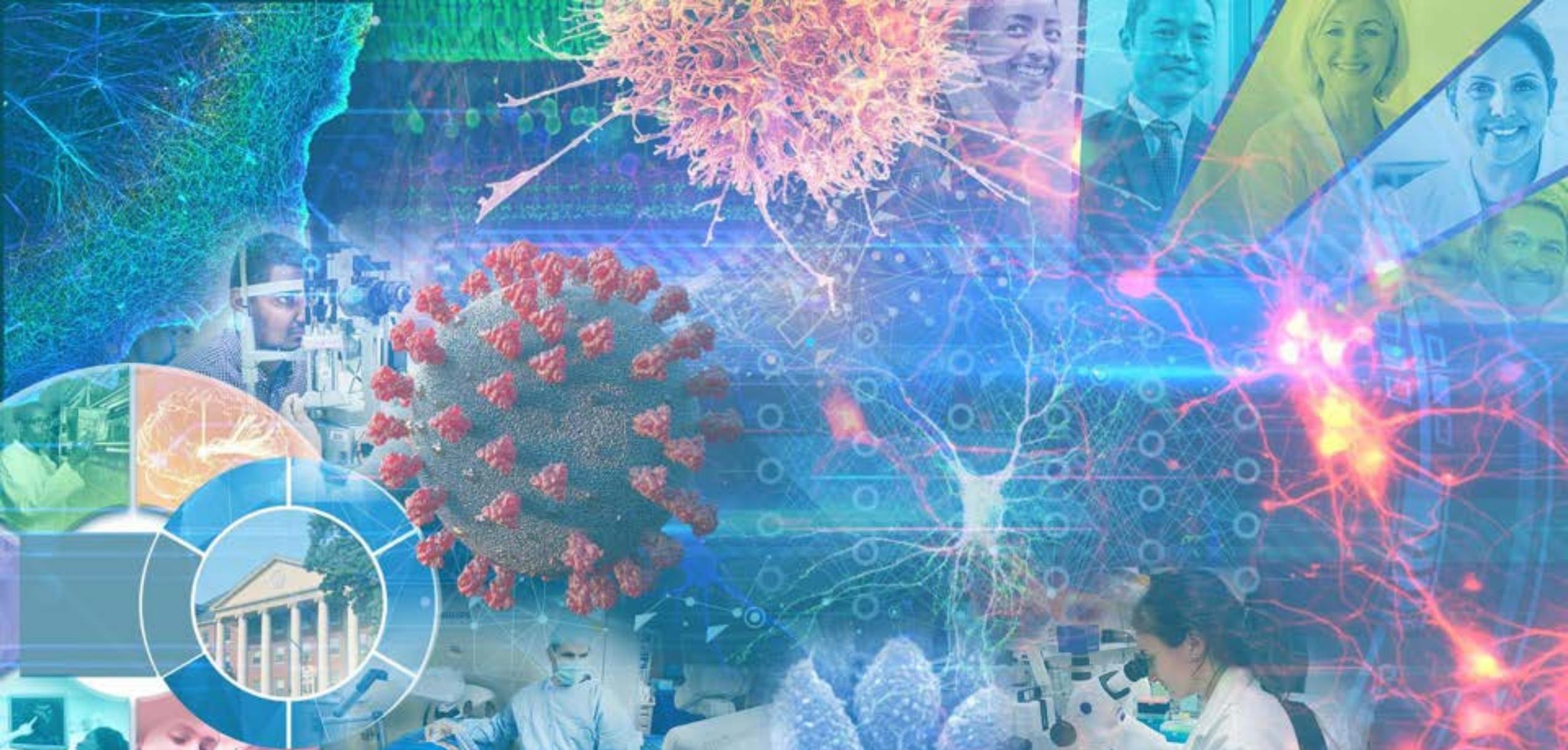
**Seoul Bio Economy Forum 2022
August 31, 2022**

Tara A. Schwetz, PhD

Acting Principal Deputy Director
National Institutes of Health



National Institutes of Health
Turning Discovery Into Health



COVID-19 Response

RADx Technology Program

Overarching Goal

Establish a robust R&D pipeline of innovative diagnostic technologies to increase national testing capacity

Innovate across the testing landscape

Expanding the number, type, access, and throughput of testing technologies

Optimize technology performance

Develop technology for a range of essential “Use Cases”

- At-home
- Point of Care (POC)
- Hospital
- Testing Laboratory



RADx Tech “Innovation Funnel”

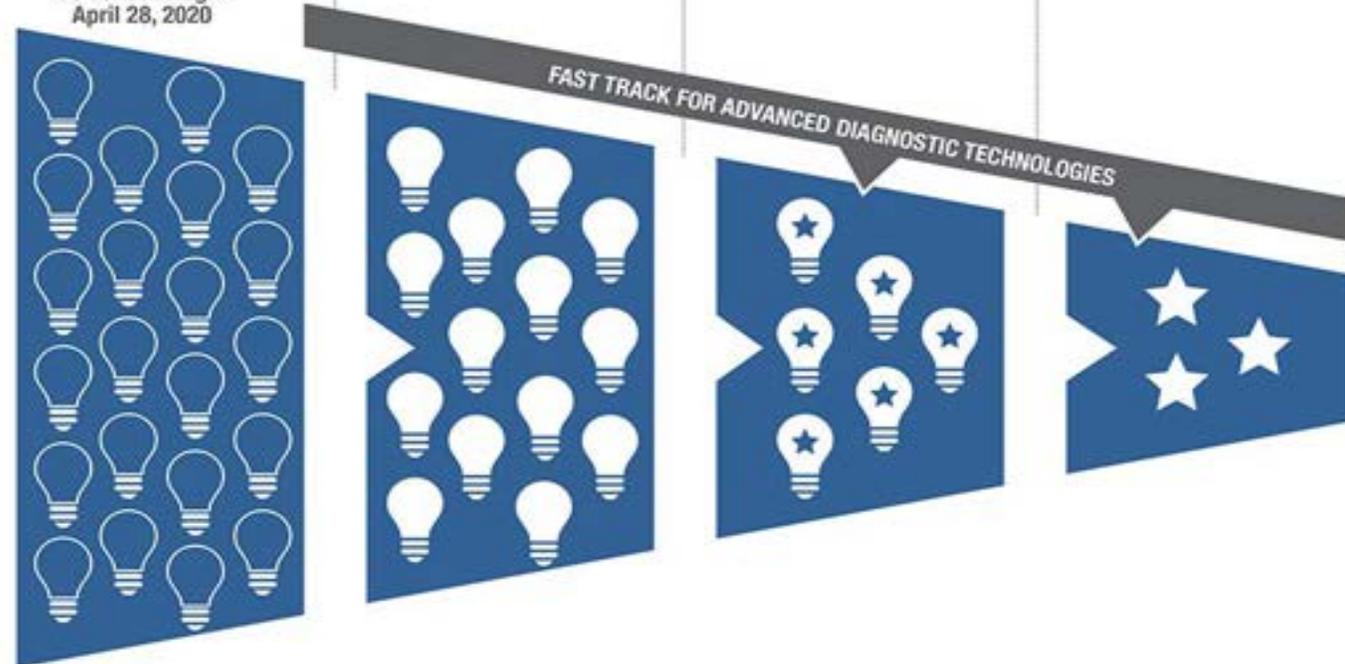
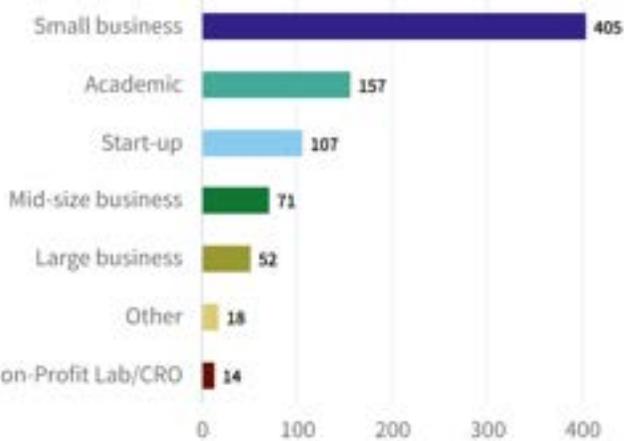
Stage-gated, milestone-based, prize award payments to **rapidly validate and de-risk novel technologies** through a seamless pipeline with parallel support from expert teams to address scientific/technical, clinical, accessibility & usability, regulatory, and commercialization requirements.



Rolling Submissions and Selections Begin April 28, 2020

5-6 Months

Submissions by Organization Type



Projects in each Phase

824

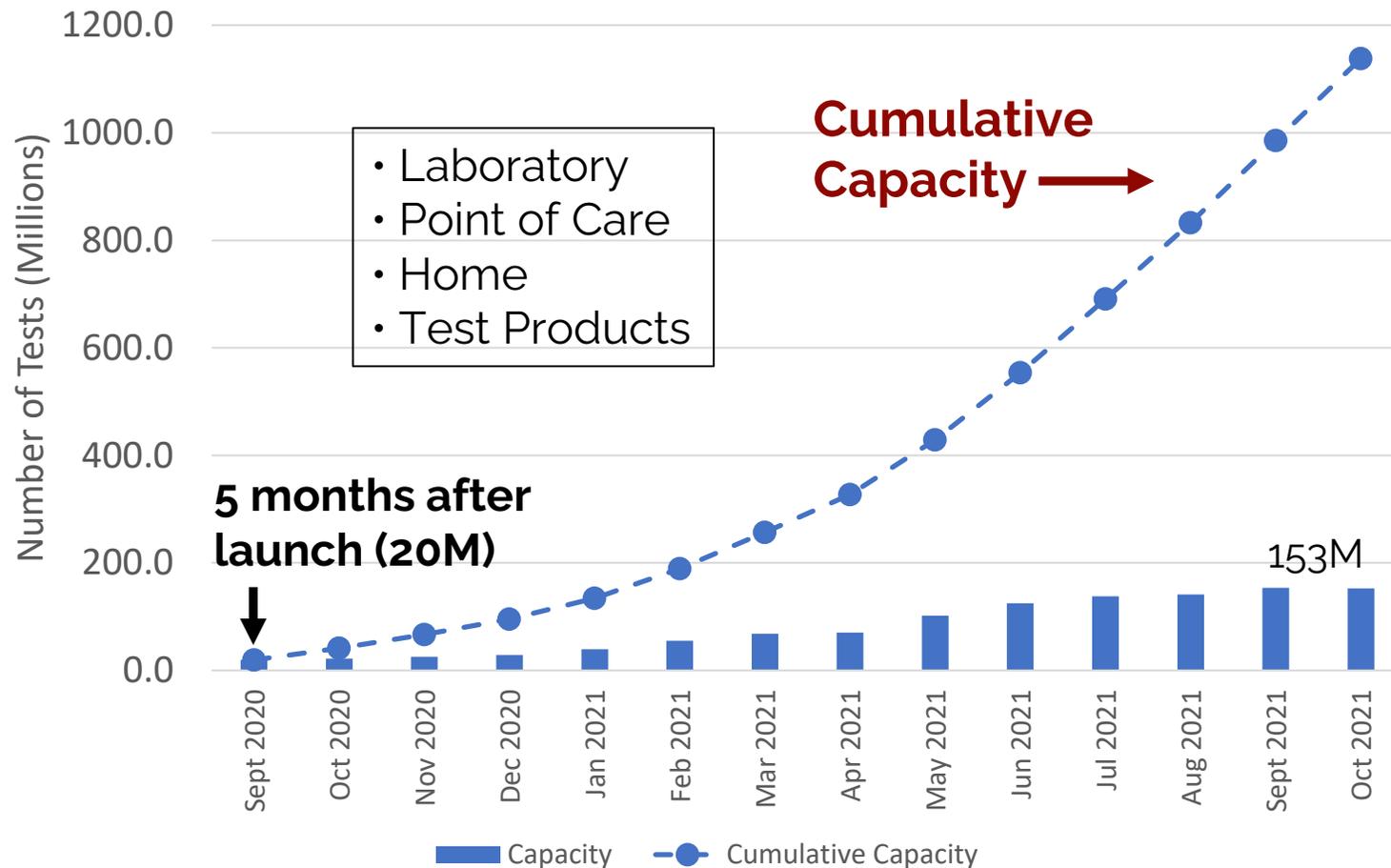
179

47

50

RADx Tech Impact: Capacity thru October 2021

Cumulative EUA Authorized Tests by Month



Major Milestones

- **1.14 billion capacity thru October 2021**
- ~5.1 M tests and products/day **October 2021**
- 34 EUAs; 1st OTC EUA, 4 “at home”
- >100 companies supported

~\$1.1 Billion: Special Congress Authorization (~\$600M in Phase 2)

NCATS National COVID Cohort Collaborative (N3C)

Rapid Access to Real-World Data Informs Urgent COVID-19 Questions

Public Dashboard

Sites: 75

Persons: 15 million

COVID Cases: 5.9 million

Clinical Observations: 1.6 billion

PASC/Long-COVID Risk

Use of AI/ML to identify risks

Difficulty breathing -- higher risk of PASC

Vaccination -- lower risk of PASC

RWE for mAb Effectiveness

Across Variants

Effectiveness of mAb treatment

Viral Variants and impact on interventions

Dissemination to communities

89% reduction in 28-day mortality

RWE Analyses (unpublished):

Long-COVID Tx and Paxlovid

Long-COVID Tx and Paxlovid

Paxlovid Rebound is low

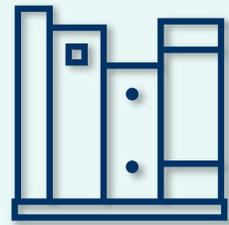
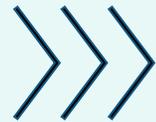


Cancer MoonshotSM

Cancer MoonshotSM : Accelerate Discovery, Increase Collaboration, and Expand Data Sharing



2017 - 2021



>2,000

Publications



>240

Research
Projects



>70

Consortiums
or Programs



49

Clinical
Trials



>30

Patent
Filings

Ending Cancer As We Know It

- 1 **Cut the cancer death rate in half within 25 years**
- 2 **Transform the meaning of cancer**
- 3 **Address cancer-associated inequities**



“The goal is to cut the cancer death rate in half in the next 25 years... and to turn death sentences into chronic diseases the people can live with.”

—President Joe Biden



Advanced Research Projects Agency for Health

Empower. Accelerate. Demonstrate.



Vision, Mission, and Approach

Vision

- Empower every American to realize their health potential

Mission

- Create & Accelerate high-impact health solutions for well-defined problems
- Demonstrate what health futures are possible for all

Approach



Listening Session Feedback - By the Numbers

- **5100+ Participants**
- **Nearly 250 Organizations**
- **15 Sessions**



Listening Session Feedback - What We Heard

Scientific Portfolio

- Complementarity to NIH
- Health equity & diversity
- Not disease-specific
- Data
- Commercialization

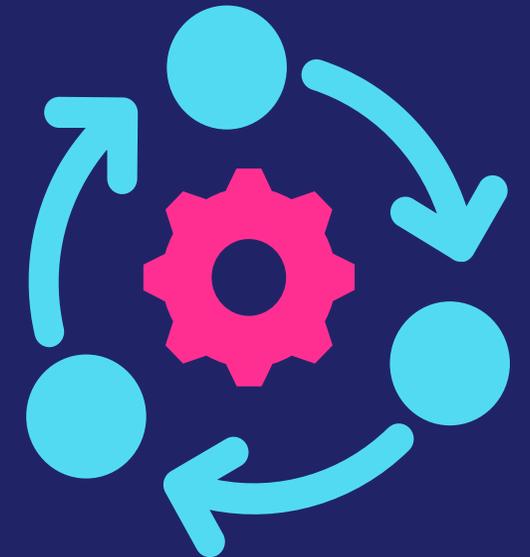




Listening Session Feedback - What We Heard

Streamlined Processes

- Stakeholder Engagement
- Multidisciplinary Partnerships



Summary Report Released



BRIEFING ROOM

White House and National Institutes of Health Release Report Summarizing the Listening Sessions with Stakeholders on the Proposed Advanced Research Projects Agency for Health



WHITE HOUSE OFFICE OF SCIENCE AND TECHNOLOGY POLICY
&
NATIONAL INSTITUTES OF HEALTH LISTENING SESSIONS FOR ARPA-H: SUMMARY REPORT

September 2021



ARPA-H Authorities

- Hiring outside civil service
- Program Managers for 3-6 yr terms
- Broad, flexible funding
- Exemptions from traditional review





FY22 Appropriations Language

For carrying out section 301 and title IV of the PHS 19 Act with respect to advanced research projects for health, \$1,000,000,000, to remain available through September 30, 2024: Provided, That the President shall appoint in the Department of Health and Human Services a director of advanced research projects for health (Director): Provided further, That funds may be used to make or rescind appointments of scientific, medical, and professional personnel without regard to any provision in title 5 governing appointments under the civil service laws: Provided further, That funds may be used to fix the compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code: Provided further, That the Director may use funds made available under this heading to make awards in the form of grants, contracts, cooperative agreements, and cash prizes, and enter into other transactions (as defined 11 in section 319L(a)(3) of the PHS Act): Provided further, That activities supported with funds provided under this heading shall not be subject to the requirements of sections 406(a)(3)(A)(ii) or 492 of the PHS Act: Provided further, That the Secretary may transfer the Advanced Research Projects Agency for Health, including the functions, personnel, missions, activities, authorities, and funds, within 30 days of enactment of this Act to any agency or office of the Department of Health and Human Services, including the National Institutes of Health: Provided further, That the Committees on Appropriations of the House of Representatives and the Senate shall be notified at least 15 days in advance of any transfer pursuant to the preceding proviso.



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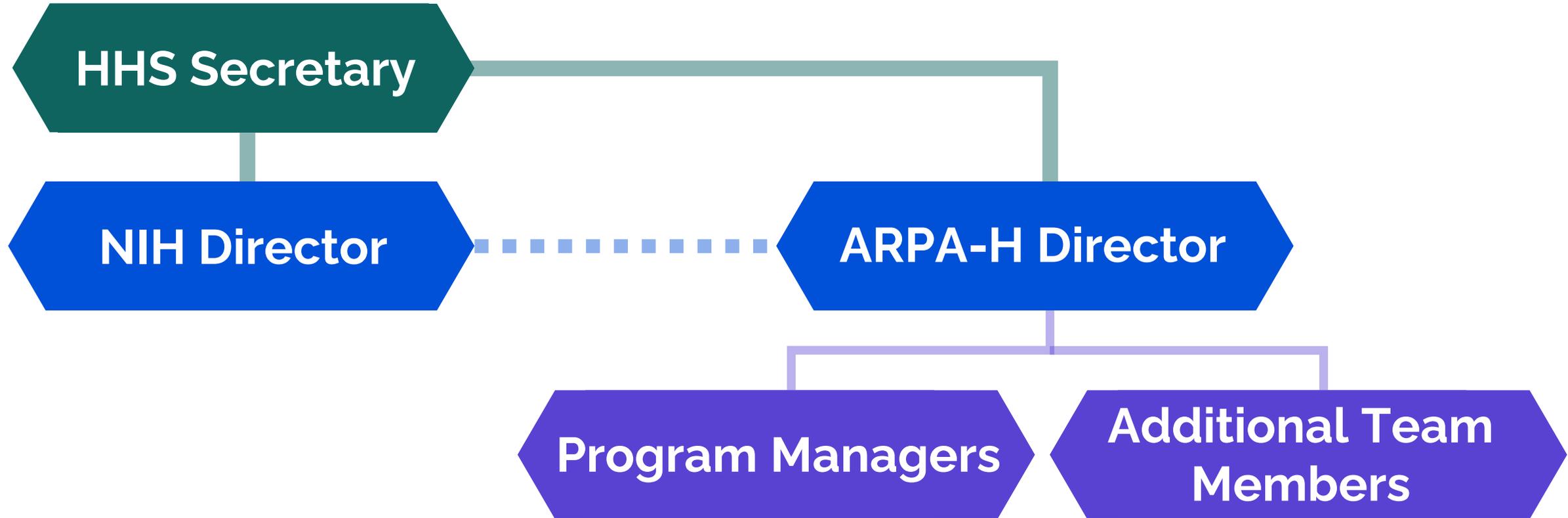
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ARPA-H Organization within HHS/NIH



ARPA-H Leadership



Acting ARPA-H Deputy Director Announced

Adam H. Russell, D. Phil.

- Chief Scientist at UMD's Applied Research Laboratory for Intelligence and Security (ARLIS)
- Former DARPA and IARPA Program Manager
- Social Anthropologist



ARPA 

Thank you!

