

# ACCELERATING INNOVATION FOR BETTER HEALTH

## A MITRE FRAMEWORK SUPPORTING THE PROPOSED ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)

The federal government has made significant investments in a variety of domains to improve our nation's healthcare ecosystem. These investments have ranged from health information technology and patient-centered outcomes research, to expanded insurance coverage and a ten year reauthorization of the National Institutes of Health (NIH) that reinforced Congress' ongoing commitment that the U.S. continue to lead the world in funding ground-breaking biomedical research.

Thanks to such federal investments—and a robust commercial biomedical research and development sector—the United States has a strong foundation for rapidly advancing health innovation in ways that benefit all people. President Biden has proposed, in his Fiscal Year 2022 budget,<sup>1</sup> to create an Advanced Research Projects Agency for Health (ARPA H), a proposed agency within the NIH that would accelerate biomedical breakthroughs with “the potential to transform important areas of medicine and health for the benefit of all patients and that cannot be readily accomplished through traditional research or commercial activity.”<sup>2</sup>

This report describes the ecosystem improvements that will support ARPA-H's success, and the role that ARPA-H could play in measuring innovation gaps, prioritizing societal needs, and attracting private

capital alongside public funding. It outlines specific recommendations for the organization's underlying legal authorities, governance, and coordination of its policies and activities with other federal agencies and nongovernmental sectors. In addition, this report details a biomedical innovation framework, developed by MITRE, that proposes a system-level approach for accelerating biomedical innovation across the Department of Health and Human Services (HHS). Our framework was envisioned to support an integrated, efficient, and equitable health innovation pipeline energized by the federal government—a vision that the emergence of ARPA-H may substantially fill and move in exciting directions. The perspectives offered throughout this paper are informed by MITRE's decades-long experience supporting the Defense Advanced Projects Agency (DARPA's) research and development, operating six federally funded research and development centers (FFRDCs), and investing in MITRE innovation for the public good.



**Vision.** ARPA-H is established with the appropriate funding, authorities, and cross-agency collaboration priorities to:

- Lead a national conversation about unmet health needs.
- Identify critical innovation gaps and accelerate major biomedical breakthroughs with the support of a biomedical innovation framework.
- Apply federal authorities and resources—and create incentives to align private resources—to encourage the research and development required to generate biomedical breakthroughs that will improve health for all people across the nation.

**Authorize Autonomy and Focus on Outcomes.** To ensure that ARPA-H can realize this vision, focus the ARPA-H portfolio to consider health equitable outcomes, partnering with the Centers for Medicare and Medicaid Services (CMS) Innovation Center and a broad group of stakeholders to advance multi-payer initiatives to give providers and patients the tools they need to manage care and costs. Authorize ARPA-H with autonomy to establish an independent research agenda, manage a portfolio of projects with milestones and performance measures, and use other transactions authorities to accelerate decision making and optimize use of public funds.

## MITRE'S System-Level Framework for Accelerating Biomedical Innovation

MITRE has designed a Biomedical Innovation Framework to support a system-level approach for accelerating health innovation across the Department of Health and Human Services (HHS). Our framework was envisioned to facilitate an integrated, efficient and equitable health innovation pipeline energized by the federal government—a vision that the emergence of ARPA H may substantially fill and move in exciting directions. The United States possesses all of the ingredients needed to fuel that pipeline. What has been lacking, until now, is a transparent view of the federal government's goals in this endeavor, the tools to measure progress toward those goals, and leadership to focus and unite disparate efforts across the public and private sectors. The COVID-19 pandemic presented an opportunity to accelerate biomedical innovation when actions are aligned around a clear goal, shared measures of success, and desired outcomes. The framework provides a blueprint to replicate and scale those successes: to align major HHS agencies (e.g., NIH, FDA, CMS) to create a powerful engine for

progress and ideas, leading to innovative, safe, and effective biomedical products and services that fill existing gaps, improve outcomes, reduce disparities, and permit continuous innovation through four steps and a foundation of digitization:

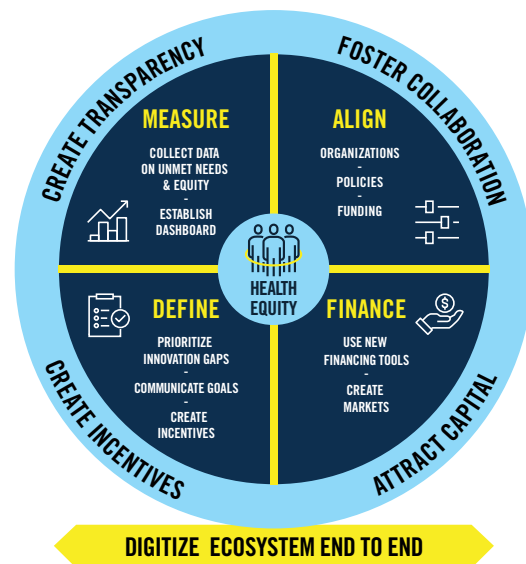
**MEASURE.** Collect data on unmet needs and equity and establish a dashboard to create transparent and readily available information about the biomedical innovation pipeline.

**DEFINE.** Prioritize innovation gaps, communicate goals, and create incentives to advance biomedical innovation that efficiently addresses unmet public health needs.

**ALIGN.** Align organizations, policies, and funding across key HHS internal stakeholders and the private sector to foster collaboration.

**FINANCE.** Engage modern finance tools routinely used in the private sector to help establish markets for government priority biomedical innovations.

**DIGITIZE.** Position ARPA-H to benefit from a coordinated, digital ecosystem that supports increased access to, and ultimate use of, information for an equitable view of health that empowers individuals and communities.



MITRE's Biomedical Innovation Framework:  
Measure, Define, Align, Finance, & Digitize

<sup>1</sup> White House Office of Management and Budget, *Budget of the U.S. Government for Fiscal Year 2022*. [Online] Available at: [https://www.whitehouse.gov/wp-content/uploads/2021/05/budget\\_fy22.pdf](https://www.whitehouse.gov/wp-content/uploads/2021/05/budget_fy22.pdf).

<sup>2</sup> F. S. Collins, T. A. Schwetz, L. A. Tabak, E. S. Lander. "ARPA-H: Accelerating biomedical breakthroughs." *Science*, July 9, 2021, vol. 373(6551), pp. 165–167

## About MITRE

MITRE is a not-for-profit organization chartered to work in the public interest for a safer and healthier world.

Since 1958, MITRE has operated federally funded research and development centers (FFRDCs) and performed both research and development and technical support for the Defense Advanced Research Projects Agency (DARPA). Since 2012, MITRE has operated the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare FFRDC (Health FFRDC), working across the Department of Health and Human Services (HHS) to stand up innovative programs and implement major legislative and policy changes.

Recent MITRE contributions to accelerating health innovation include:

- Since 2016, MITRE has been advancing thought leadership on a **Strategy for Accelerating Biomedical Innovation**. With input from government, academic, not-for-profit, and private-sector partners, MITRE devised and patented a way to measure the performance of the biomedical innovation ecosystem, using a system level approach to move innovation at the pace of science.
- MITRE supported the **Office of the Assistant Secretary for Health (OASH) to develop a data driven method to identify innovation gaps** by convening experts, identifying metrics such as public health burden and societal costs, and signaling to the private sector HHS's priorities for filling gaps.
- MITRE convened the **COVID-19 Healthcare Coalition**, with close to 1,000 private organizations combining expertise and resources, that uses a "decision dashboard" as a "source of truth" to track pandemic-related trends and assess progress against Coalition objectives such as alleviating constraints in the supply chain for masks, ventilators, and diagnostic test components.
- MITRE supported the **National Institutes of Health's (NIH's) Rapid Acceleration of Diagnostics for COVID-19 (RADx)**, which compressed a multi-year commercialization process into six months using performance-based contracts defined by time and regulatory milestones, a fast cycle for application review, and autonomy to redirect funds.
- MITRE, the American Society of Clinical Oncology, Inc. (ASCO®) and its nonprofit subsidiary, CancerLinQ LLC, among others, developed **minimal Common Oncology Data Elements (mCODE™)** to standardize and advance the interoperability of digital health data and help move toward a standard health record. MITRE and several other member organizations currently lead the Common oncology data element eXtensions Health Level Seven International Fast Healthcare Interoperability Resources Accelerator (**CodeX HL7 FHIR Accelerator**) to apply open-source structured data elements for oncology electronic health records to specific use cases and enable smarter data in the fight against cancer.
- MITRE published a **National Strategy for Digital Health**<sup>3</sup> in 2021 at the recommendation of the MITRE Health Advisory Committee, a group of visionary senior-level executives established to guide MITRE, and the Health FFRDC it operates, in identifying innovative solutions to transform the national health and human services enterprise.
- MITRE also recently published a **10-Point Action Plan: Sustaining a Biopharma Industrial Base for a More Secure Nation** with recommendations to mitigate risks from high-consequence events.