



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health

Slide Presentation Version

January 2025

Disclaimer:

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Introduction and use of the AI Strategic Plan¹

Introduction



Artificial Intelligence (AI)² technologies are making it possible to accelerate scientific breakthroughs, improve clinical outcomes, and enhance health and human services.

HHS plays a crucial role in the sector: an investor in research and discovery, a health industry regulator, a catalyst for innovation in delivering health and human services, a provider of healthcare and human services delivery, and a protector of patient safety, rights, and privacy. As AI adoption varies across industries within HHS's purview, a responsible approach for development and adoption is required.

This HHS AI Strategic Plan provides a framework and roadmap to ensure that HHS fulfills its obligation to the Nation and pioneers the responsible use of AI to improve people's lives.

1. Shorthand for the Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health
2. This Strategic Plan defines AI as outlined in 15 USC 9401(3): a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. While this definition will be used as the basis of this Strategic Plan, alternative definitions may at times be used by HHS Operating and Staff Divisions.

Use of the Plan

HHS will use the Strategic Plan to:



Prioritize resources



Align and coordinate efforts



Benchmark and assess progress



Signal priorities to industry, academia, and the public

There is significant increase in AI interest and activity across industries, within healthcare sector, and in government

Examples (non-exhaustive)



Across industries, there is a substantial increase in AI-related venture capital and private AI investments across industries



Within healthcare, there has been a significant uptick in enthusiasm and investment for AI activities



HHS is already active in use and oversight of AI both externally and in its internal operations

\$55 billion in VC and private AI investment in Q2 2024¹

42% year-on-year growth for generative AI investments projected through 2032²

\$30 billion raised by healthcare start-ups for AI over the last three years³

550 submissions to FDA for drug and biological products with AI components as of August 2024⁴

~1,000 AI/ML-enabled medical devices authorized by FDA as of August 2024⁵

8 AI/ML-enabled devices with separate payment established by CMS⁶

271 AI use cases identified internally across 13 agencies logged in HHS' AI Use Case Inventory in 2024⁷

1. <https://www.reuters.com/business/finance/ai-deals-lift-us-venture-capital-funding-highest-level-two-years-data-shows-2024-07-03/>

2. <https://www.bloomberg.com/company/press/generative-ai-to-become-a-1-3-trillion-market-by-2032-research-finds/>

3. <https://www.aha.org/aha-center-health-innovation-market-scan/2024-09-17-top-4-health-care-ai-investment-trends-watch>

4. <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/artificial-intelligence-drug-development>




5. <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

6. <https://www.nature.com/articles/s41746-022-00609-6>

7. https://www.healthit.gov/hhs-ai-usecases?search_api_fulltext=&page=1

AI has the potential to improve people's lives and to support HHS' broader mission in multiple ways

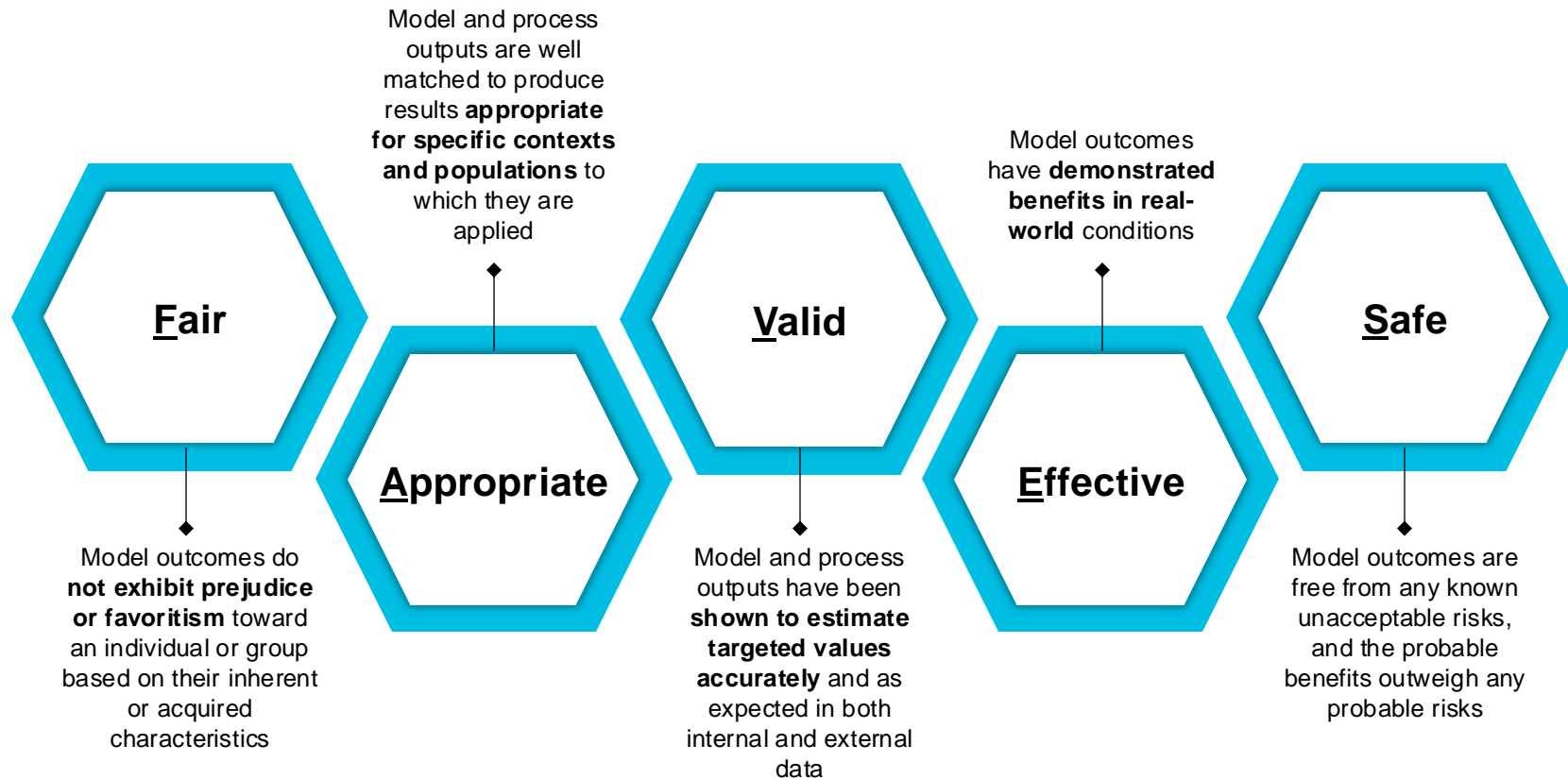
5 example opportunities for AI to improve people's lives and support HHS' broader mission

| Opportunity |  Accelerating scientific breakthroughs that could increase the quality and length of life |  Being used as part of a medical product or to develop medical products to improve safety and effectiveness |  Improving clinical outcomes and enhancing safety through innovations in healthcare delivery |  Improving equity and empowering participants through enhanced health and human services benefits delivery |  Forecasting risks and rapidly mobilizing resources to predict and respond to public health threats |
|---|--|---|---|---|--|
| Potential AI Application(s) Not exhaustive | Supporting the clinical discovery process offers hope to shorten development timelines and reduce costs | Supporting the ability to learn from data collected during clinical use to improve medical product accuracy and performance over time¹ | Rapidly processing expansive and disparate information to accelerate diagnoses and head off safety events | Assisting people in accessing health and human services , including those with limited English proficiency or a range of disabilities ³ | Creating global infrastructure to predict future disease outbreaks, enabling public health response teams to develop effective countermeasures |

1. <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>
2. <https://pubmed.ncbi.nlm.nih.gov/37904073/>

Ethical and responsible use of AI in the health, human services, and public health domains will be critical to mitigate risks

Risks are being considered through the lens of the **FAVES** framework



We note that risk of individual AI use cases or processes may also need to be assessed along dimensions not included in the FAVES framework

Specific risks will be considered in each domain-specific context, such as:

- Falsely identifying patient conditions¹
- Breaching confidentiality of patient information²
- Misdirecting use of resources³
- Unintentionally developing potentially harmful medical products⁴

Additional details appear in each chapter of the Strategic Plan

1. <https://openreview.net/pdf?id=6eMlzKFOpJ>
2. <https://www.hipaajournal.com/healthcare-highest-third-party-breaches/>
3. <https://www.hhs.gov/sites/default/files/public-benefits-and-ai.pdf>
4. <https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf>

HHS's vision is to be a global leader in innovating and adopting responsible AI to achieve unparalleled advances in the health and well-being of all Americans

Purpose

This AI Strategic Plan provides a framework and roadmap to ensure that HHS fulfills its obligation to the Nation and pioneers the responsible use of AI to improve people's lives



Goal 1

Catalyzing health AI innovation and adoption to unlock new ways to improve people's lives



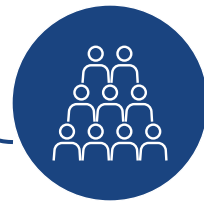
Goal 2

Promoting trustworthy AI development and ethical and responsible use to avoid potential harm



Goal 3





Democratizing AI technologies and resources to promote access



Goal 4

Cultivating AI-empowered workforces and organization cultures to effectively and safely use AI

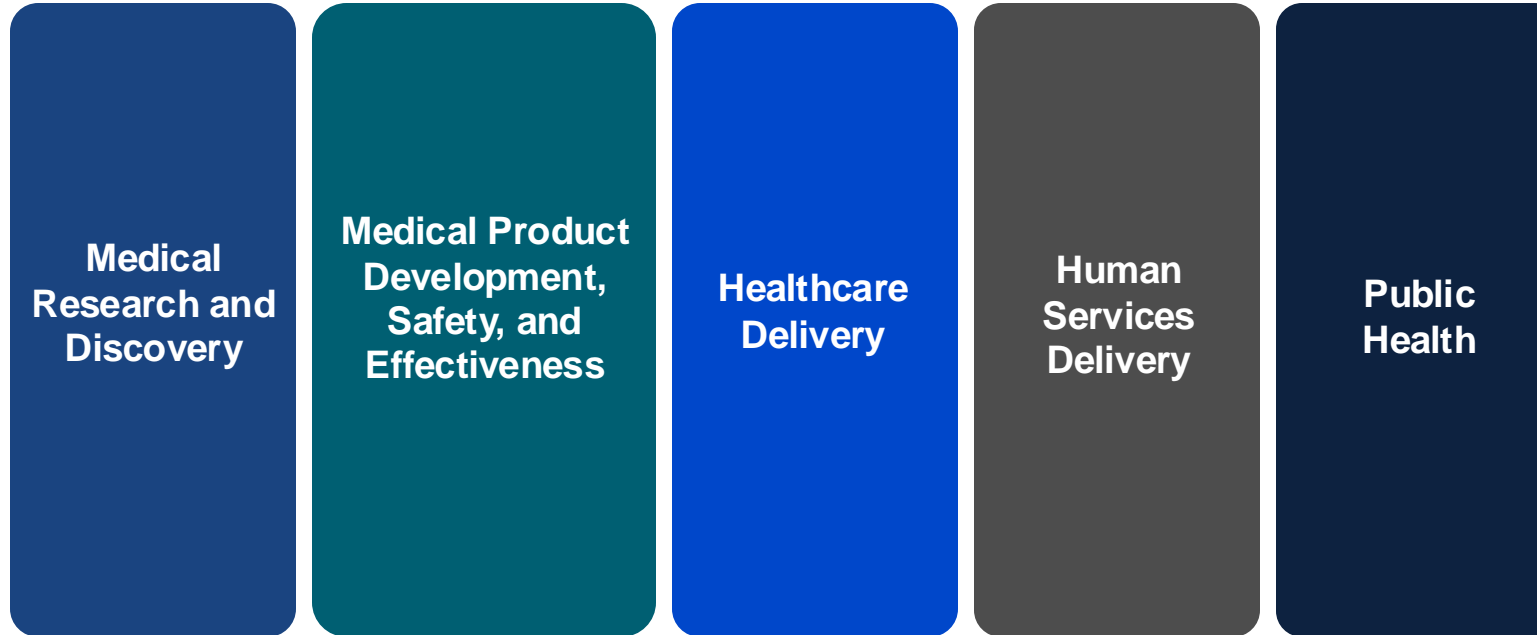
HHS themes of actions across the four goals

| Key goals that actions support | Themes of actions across chapters ¹ |
|--|--|
|  Goal 1 Catalyzing health AI innovation and adoption | <ul style="list-style-type: none">• Expanding breadth of AI use across the value chain in each domain• Modernizing infrastructure to implement AI and support adoption• Enhancing collaboration and public-private partnerships to promote AI adoption• Clarifying regulatory oversight and coverage/payment determinant processes for AI• Supporting gathering evidence on outcomes (e.g., efficacy, safety) of AI interventions and best practices |
|  Goal 2 Promoting trustworthy AI development and ethical and responsible use | <ul style="list-style-type: none">• Building and disseminating evidence that supports mitigating risks to equity, biosecurity, data security, and privacy• Setting clear standards that guide the use of federal resources in the context of trustworthy AI use• Supporting organizational governance for risk management of AI• Refining regulatory frameworks to address adaptive AI technologies• Promoting external evaluation, monitoring, and transparency reporting and fostering other mechanisms for quality assurance of health AI |
|  Goal 3 Democratizing AI technologies and resources | <ul style="list-style-type: none">• Increasing access to responsibly curated data and infrastructure, including providing support for organizations where appropriate• Supporting information-sharing mechanisms to disseminate standards, best practices, and foster collaboration to improve access• Developing user-friendly, customizable, and open-source AI tools• Enhancing capabilities of STLTs and other community organizations, including providing resources or other mechanisms where appropriate |
|  Goal 4 Cultivating AI-empowered workforces and organization cultures | <ul style="list-style-type: none">• Improving training in governance and management of AI• Developing and retaining a robust AI talent pipeline• Equipping professionals with access to resources and research to support their respective health and human services organizations• Using AI to mitigate labor workforce shortages and address burnout and attrition |

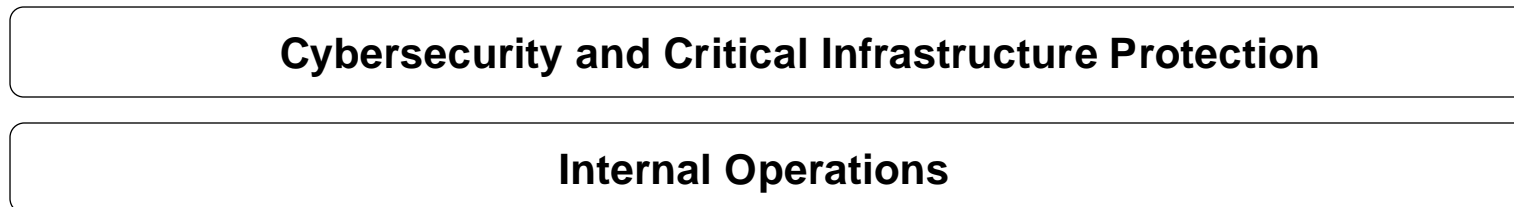
1. Not exhaustive, detailed Action Plans appear in each chapter of the full AI Strategic Plan

HHS' AI Strategic Plan is organized into five primary domains and two additional domains

Primary Domains



Additional Domains



In the full AI Strategic Plan, each of the primary domain chapters includes:

- Introduction and Context to AI in the domain
- Stakeholders Engaged in the Domain's AI Value Chain
- Opportunities for the Application of AI in the Domain
- Trends in AI for the Domain
- Potential Use-Cases and Risks
- Action Plan

Conclusion



The AI Strategic Plan supports HHS's ability to address future health and human services challenges.

As AI continues to evolve rapidly, HHS will adopt an equally dynamic approach, iterating on this Plan and overall AI efforts to stay ahead of developments and address emerging challenges.

This proactive stance will involve continuous risk assessment, stakeholder engagement, and the implementation of robust safeguards to ensure ethical and equitable AI use.

HHS encourages community partners, STLT governments, and other public and private sector partners to responsibly pioneer development and use of AI that improves health and human services for Americans.

HHS is committed to collaborating with stakeholders to build on the actions detailed throughout this Strategic Plan and address problems faced in health, human services, and public health, all while ensuring safe and responsible use through the guardrails discussed.

Summary of Actions by Domain Area

Medical Research and Discovery: Summary of Actions

Below is a summary of actions outlined in the Medical Research and Discovery chapter. A larger list of proposed near- and long-term actions is available in the AI Strategic Plan

Summary of Actions



Goal 1 Catalyzing health AI innovation and adoption

- Expanding the breadth of medical research and discovery AI use across disease areas and steps of the value chain
- Enhancing coordination across geographies to harness AI to improve medical research and discovery
- Fostering AI-ready data standards and datasets to bolster their usability for AI-empowered medical research and discovery



Goal 2 Promoting trustworthy AI development and ethical and responsible use

- Building and disseminating evidence to mitigate biosecurity, data security, privacy, and data collection risks
- Setting clear guidelines for safe and trustworthy AI use in medical research and discovery and the distribution and use of federal resources
- Enabling safe and responsible organizational governance of AI risk management and transparency



Goal 3 Democratizing AI technologies and resources

- Fostering intentional public engagement and public-private action to enhance sharing of best practices among all stakeholders
- Increasing accessibility to responsibly curated AI-ready data, models and algorithms, and tooling and infrastructure for all



Goal 4 Cultivating AI-empowered workforces and organization cultures

- Improving training in governance and management of AI in medical research and discovery
- Developing and retaining a robust AI talent pipeline in medical research and discovery

Medical Product Development, Safety, and Effectiveness: Summary of Actions

Below is a summary of actions outlined in the Medical Product Development, Safety, and Effectiveness chapter. A larger list of proposed near- and long-term actions is available in the AI Strategic Plan

Summary of Actions



Goal 1 Catalyzing health AI innovation and adoption

- Clarifying regulatory oversight of medical products
- Providing clarity on payment models
- Fostering public-private partnerships and intergovernmental collaborations to rapidly develop and share knowledge



Goal 2 Promoting trustworthy AI development and ethical and responsible use

- Refining regulatory frameworks to address adaptive AI technologies in medical devices
- Promoting equity in AI deployment to bolster safe and responsible use
- Addressing AI-enabled software outside current device regulatory authorities
- Fostering private or public mechanisms for quality assurance of health AI



Goal 3 Democratizing AI technologies and resources

- Enabling collaborative development through public engagement
- Aligning standards and information-sharing mechanisms across research and healthcare delivery



Goal 4 Cultivating AI-empowered workforces and organization cultures

- Improving training in the governance and management of AI in medical products
- Developing and retaining AI talent related to medical products

Healthcare Delivery: Summary of Actions

Below is a summary of actions outlined in the Healthcare Delivery chapter. A larger list of proposed near- and long-term actions is available in the AI Strategic Plan

Summary of Actions



Goal 1 Catalyzing health AI innovation and adoption

- Supporting the ability to gather evidence for effectiveness, safety, and risk mitigation of AI interventions and best practices for implementation in healthcare delivery settings
- Providing guidelines and resources on oversight, medical liability, and privacy and security protections to increase confidence for organizations to develop AI
- Ensuring developers and potential deployers of AI have clarity on coverage and payment determination processes to encourage development of AI



Goal 2 Promoting trustworthy AI development and ethical and responsible use

- Enhancing enforcement and clarify guidelines relating to existing requirements
- Providing guidelines and support related to organizational governance
- Promoting external evaluation, monitoring, and transparency reporting
- Enhancing infrastructure to ensure patient safety, security, and privacy



Goal 3 Democratizing AI technologies and resources

- Promoting equitable access through technical support for and collaboration with delivery organizations that provide services to underserved populations
- Providing support for healthcare delivery organizations to address core infrastructure and deployment challenges (i.e., technology, infrastructure, and data infrastructure) that improve AI readiness



Goal 4 Cultivating AI-empowered workforces and organization cultures

- Equipping healthcare delivery professionals with access to training, resources, and research to support AI literacy and expertise in their respective health system organizations.

Human Services Delivery: Summary of Actions

Below is a summary of actions outlined in the Human Services Delivery chapter. A larger list of proposed near- and long-term actions is available in the AI Strategic Plan

Summary of Actions



Goal 1 Catalyzing health AI innovation and adoption

- Unlocking resources for AI adoption and modernizing IT and tech infrastructure
- Ensuring data quality and availability for AI adoption



Goal 2 Promoting trustworthy AI development and ethical and responsible use

- Providing guidance to served populations on balancing risks with opportunities for AI applications and establishing participant trust



Goal 3 Democratizing AI technologies and resources

- Raising the floor of constituent digital literacy and digital penetration
- Identifying areas of cooperation across sectors to improve AI-related economies of scale



Goal 4 Cultivating AI-empowered workforces and organization cultures

- Improving human services employee digital literacy, talent, and openness to adopt new technology
- Using AI to mitigate labor workforce shortage in human services

Public Health: Summary of Actions

Below is a summary of actions outlined in the Public Health chapter. A larger list of proposed near- and long-term actions is available in the AI Strategic Plan

Summary of Actions



Goal 1 Catalyzing health AI innovation and adoption

- Encouraging research, development of guidelines, and identification of resources to support evidence generation and scale of AI in public health
- Modernizing infrastructure necessary to implement AI and support adoption



Goal 2 Promoting trustworthy AI development and ethical and responsible use

- Establishing guardrails to help ensure data quality and accuracy
- Standardizing data security policies across the public health ecosystem
- Advancing AI tools and techniques that consider and assess health equity from end to end



Goal 3 Democratizing AI technologies and resources

- Creating an environment that enables data sharing across the public health ecosystem
- Supporting AI adoption, development, and collaboration, especially for STLTs and community organizations who may have limited resources
- Developing user-friendly, customizable, and open-source AI tools to broaden access and accommodate a diversity of users



Goal 4 Cultivating AI-empowered workforces and organization cultures

- Augmenting and supporting the public health workforce to address burnout and attrition
- Promoting workforce AI education and community-based AI approaches tailored to each community's unique need

Cybersecurity and Critical Infrastructure Protection: Summary of Actions

Below is a summary of actions outlined in the Cybersecurity and Critical Infrastructure Protection chapter. A larger list of proposed near- and long-term actions is available in the AI Strategic Plan

Summary of Actions



Addressing the shortage of appropriately skilled cybersecurity workers to fill roles in health and human services



Supporting the standardization and alignment on best practices, especially in cybersecurity governance






Reducing and managing complexity in implementing new cybersecurity capabilities



Clarifying approach to navigate acute tensions between privacy and fairness and privacy and safety in health and human services

HHS Internal Operations: Summary of focal areas

Below is a set of focal areas discussed in the Internal Operations chapter. A list of proposed near-term actions is available in the AI Strategic Plan

| | Focal Areas | Description | Example |
|---|--|--|---|
|  | Governance | Adopting best practices throughout entire solution lifecycle to facilitate appropriate adoption and risk management | <i>E.g., governance guidelines for HHS divisions to implement AI within their scope</i> |
|  | Internal Process Improvement and Innovation | Establishing processes that facilitate the safe and effective use of AI across multiple workflows | <i>E.g., coordinating enterprise AI procurement approaches and toolkits</i> |
|  | Workforce and Talent | Enable individuals to perform their duties in a safe and effective manner, leveraging AI additive and reasonable tools | <i>E.g., collaborating with government-wide leaders for AI hiring strategy</i> |