



# **U.S. Department of Health and Human Services: Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health**

## **Overview Version**

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## Disclaimer

The U.S. Department of Health and Human Services AI Strategic Plan does not modify or interpret any requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, Food and Drug Administration (FDA) regulations, or others. Nor does this document constitute a guidance document within the meaning of Section 701(h) of the FD&C Act (21 USC. 371(h)), 21 CFR 10.115, or others. Further, this document does not establish any rights or obligations with respect to any member of the public.

# Executive Summary

*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.* The AI Strategic Plan (hereafter referred to as “Strategic Plan” or “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. This document represents the “Overview” of the Strategic Plan which contains the full details.

Artificial intelligence (AI) has or will directly or indirectly affect every American’s healthcare and human services experience in healthcare and human services. Therefore, the development and deployment of AI in health and human services settings should focus on providing tangible benefits for people who use or receive these services. Some of these potential benefits include but are not limited to:

- 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

Such potential does not come without risks. While AI could significantly improve many aspects of healthcare and human services, it also presents possible risks that could lead to adverse impacts or outcomes, such as algorithmic bias that may unintentionally reduce equity or breach protected information. Responsible AI use should ensure equitable access and beneficence, safeguard protected information, involve appropriate consent where applicable, and ensure appropriate human oversight where needed. Most notably, AI should be viewed as a tool to support and inform efforts rather than the sole answer to problems in the existing landscape.

HHS’s overarching objective is to catalyze a coordinated public-private approach to improving the quality, safety, efficiency, accessibility, equitability, and outcomes in health and human services through the innovative, safe, and responsible use of AI. HHS will accomplish this by focusing on four key goals:

1. **Catalyzing health AI innovation and adoption** to unlock new ways to improve people’s lives
2. **Promoting trustworthy AI development and ethical and responsible use** to avoid potential harm
3. **Democratizing AI technologies and resources** to promote access
4. **Cultivating AI-empowered workforces and organization cultures** to effectively and safely use AI

The following chapters will articulate existing and planned activities that support these goals. These actions are organized into themes that detail HHS’s aspirations for the future of AI as articulated in the table below.<sup>1</sup>

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

<sup>1</sup> Some themes and actions may be repeated across chapters when they apply across domains (detailed later)

To comprehensively articulate HHS’s roadmap for AI in health and human services, this Plan is organized into domains, including:

- *Primary Domains*, which represent specific parts of the HHS value chain, including:
  - **Medical Research and Discovery:** Fundamental and preclinical research on the basic mechanisms of disease and life processes, their translation to medical innovations and clinical applications,<sup>2</sup> and their context in healthcare delivery as a whole
  - **Medical Product Development, Safety, and Effectiveness:** Drug, biological product, and medical device development, clinical trials and regulatory approval, manufacturing, and ongoing safety and effectiveness monitoring
  - **Healthcare Delivery:** The provision of healthcare services to individuals and populations to diagnose, treat, manage, and prevent diseases and promote health and well-being, as well as financing to support this delivery
  - **Human Services Delivery:** The provision of social services and assistance to individuals and families to meet basic needs for health, welfare, self-sufficiency, safety, and well-being
  - **Public Health:** The protection and improvement of population well-being through disease prevention, life prolongation, and health promotion through the organized efforts and informed choices of society, organizations, public and private communities, and individuals
- *Additional Domains*, which are functional areas that span primary domains and are required to implement the Strategic Plan:
  - **Cybersecurity and Critical Infrastructure Protection:** The protection and advancement of systems’ security critical to health and human services functions to support the use of AI
  - **Internal Operations:** Policies, programs, and infrastructure used by HHS divisions for internal operations and functions, enabling the implementation of the Strategic Plan and adaptation to rapid technological advancements

To increase accessibility and utility to a broad set of readers, this high-level Overview was developed to accompany the Plan. This Overview **summarizes each domain**, discussing the context, opportunities for the application of AI, trends in the industry and across HHS, potential risks to AI adoption and implementation, and brief action plans that include policy, education, funding, and infrastructure efforts aligned to the four goals articulated above.

***The full Strategic Plan contains expanded information, including more detailed opportunities, trends, use cases, risks, and detailed action plans.***

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<sup>2</sup> HHS recognizes that the Medical Research and Discovery pipeline overlaps with Medical Product Development, Safety, and Effectiveness “development.” However, for purposes of this Plan, AI use in preclinical research will be addressed in Medical Research and Discovery. Further steps will appear in Medical Product Development, Safety, and Effectiveness. Additionally, information on biosecurity will appear in Medical Product Development, Safety, and Effectiveness.

# 1 Medical Research and Discovery

## 1.1 Introduction and Context

Medical research and discovery are critical to advancing the development of drugs, biological products, and medical devices,<sup>3</sup> including software-based behavioral interventions,<sup>4</sup> that improve patient outcomes and access to care in the United States (U.S.) and globally. This chapter focuses on the research and discovery of medical products<sup>5</sup> and AI in biomedicine. The next stages of the medical product lifecycle, including clinical trials, as well as research in other fields such as health systems, human services delivery, and public health are discussed in other chapters and are not in the scope of this chapter.<sup>6</sup>

According to the National Science Foundation (NSF), the U.S. is the largest performer of research, discovery, and development across industries worldwide, investing over \$800B, or 3.5% of its GDP, in 2021 alone.<sup>7</sup> Many stakeholders engage in or are impacted by medical research and discovery, including patients and caregivers, academic and private research organizations, and government agencies (e.g., STLTs). HHS divisions, such as ARPA-H, FDA, NIH, and others, conduct research and provide funding, guidelines, education, training, and other support to stakeholders within this realm.<sup>8</sup>

## 1.2 Opportunities for the Application of AI in Medical Research and Discovery

AI could support medical research and discovery in several ways, for example, to:

- **Bolster the impact potential of basic research** by examining links between diseases and pathological processes and generating novel biological insights that advance the frontier of human health.<sup>9</sup>
- **Increase accessibility of conducting medical research and discovery and lower costs** by capturing a potential value opportunity from AI adoption (e.g., up to \$26B annually in savings just for drug research and discovery as suggested by emerging evidence).<sup>10</sup> This could allow organizations with limited access to capital conduct innovative medical research and discovery and free up capital for reinvestment into additional pipeline activity.
- **Meet unmet patient needs and support breakthrough innovations** by expanding pipelines beyond current targets and in-focus therapeutic areas (TAs), which can improve patient outcomes and access.<sup>11</sup>

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<sup>3</sup> See Appendix A: Glossary of terms for the definitions of “drug,” “biological product,” and “medical device” used in the Plan.

<sup>4</sup> Note that some software-based behavioral interventions are medical devices under FDA’s statute, whereas others, such as those software functions that are “intended for maintaining or encouraging a healthy lifestyle” and are “unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition,” are not. See sections 201(h) and 520(o)(1)(B) of the Food, Drug, and Cosmetic Act.

<sup>5</sup> Drugs, biological products, and medical devices in this Plan are referred to as “medical products” when being discussed collectively. See Appendix A: “Glossary of terms” for the definition of “medical products” used in this Plan for additional details.

<sup>6</sup> Note that research pertaining to health systems, care delivery, and non-device behavioral interventions will be discussed in the “Healthcare Delivery” chapter; research pertaining to human services delivery will be discussed in the “Human Services Delivery” chapter; and research pertaining to public health will be discussed in the “Public Health” chapter. Furthermore, clinical trials will be discussed in the “Medical Product Development, Safety, and Effectiveness” chapter and are not in the scope of this chapter.

<sup>7</sup> [https://www.nsf.gov/nsb/news/news\\_summ.jsp?cntn\\_id=309719](https://www.nsf.gov/nsb/news/news_summ.jsp?cntn_id=309719)

<sup>8</sup> <https://www.hhs.gov/open/public-access-guiding-principles/index.html>

<sup>9</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC10018490/>

<sup>10</sup> <https://itif.org/publications/2020/12/07/fact-week-artificial-intelligence-can-save-pharmaceutical-companies-almost/>

<sup>11</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC3796018/>

- **Accelerate the timeline to develop new medical products** by combining robust biomedical and health datasets with advanced analytics technology to rapidly identify opportunities for potential new products that could proceed to clinical trials more rapidly.<sup>12</sup>

### 1.3 Trends in AI in Medical Research and Discovery

Though AI is on the rise across the medical research and discovery value chain, its uptake may be inconsistent across basic research, discovery, and preclinical studies. To date, some evidence suggests that the uptake of AI in medical research and discovery is higher in discovery (e.g., target identification and lead generation)<sup>13</sup> and lower in preclinical studies and basic research.<sup>14</sup> Newer technologies like agentic AI, however, can span multiple types of medical research and discovery AI use cases by acting autonomously or collaboratively with researchers to accomplish tasks across the full value chain.<sup>15</sup>

With respect to the TAs in focus for AI-enabled research and discovery, the industry may lack the proper incentives to invest in AI applications for new TAs or those with significant health needs and instead focus on TAs with the best market potential.<sup>16, 17</sup> This phenomenon may currently limit, however could present an opportunity for AI to expand medical research and discovery to less researched TAs and breakthrough innovation in others. On the other hand, AI is expanding medical research and discovery activity beyond the laboratory as non-traditional players start to participate (e.g., a tech company recently released a new protein-folding AI model).<sup>18</sup> Furthermore, investigators themselves are pioneering basic computational AI research to inform how AI can be used in biomedicine and health.<sup>19</sup>

However, leveraging these AI technologies at scale in medical research and discovery may present challenges due to the need for large volumes of high-quality data (much of which is fragmented and costly to curate) and expensive technical infrastructure (the costs of which are rising).<sup>20</sup> Without resolving data quality and infrastructure accessibility roadblocks, equitable and widespread uptake of AI in medical research and discovery may not reach its full potential.

### 1.4 Risks for AI Use Cases in Medical Research and Discovery

The use of AI in medical research and discovery may involve personal and confidential data, like digital specimen metadata and data (e.g., omics data) associated with and generated from human samples, which can present potential risks and ethical concerns. These include data breaches, privacy issues, biosecurity vulnerabilities (e.g., through dual-use research),<sup>21, 22</sup> and depending upon the data selected, bias propagation in care delivery settings, and other potential challenges. In particular, AI models and applications may present biosecurity and/or biosafety risks by enhancing the opportunity for the inadvertent or malicious development of novel threats to public health (e.g., harmful pathogens).<sup>23</sup>

<sup>12</sup> <https://allofus.nih.gov/news-events/research-highlights/all-of-us-artificial-intelligence-help-speed-up-search-for-promising-medicines>

<sup>13</sup> I.e., experimentation performed by computers.

<sup>14</sup> <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819343>

<sup>15</sup> <https://www.forbes.com/sites/bernardmarr/2024/09/06/agentic-ai-the-next-big-breakthrough-thats-transforming-business-and-technology/>

<sup>16</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC3796018/>

<sup>17</sup> <https://pubmed.ncbi.nlm.nih.gov/37479540/>

<sup>18</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC11292590/>

<sup>19</sup> <https://datascience.nih.gov/artificial-intelligence/initiatives>

<sup>20</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC6825414/>

<sup>21</sup> <https://www.nature.com/articles/s42256-022-00465-9>

<sup>22</sup> <https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/>

<sup>23</sup> [https://www.healthit.gov/sites/default/files/2023-12/Health\\_Sector\\_AI\\_Commitments\\_FINAL\\_120923.pdf](https://www.healthit.gov/sites/default/files/2023-12/Health_Sector_AI_Commitments_FINAL_120923.pdf)



The full Medical Research and Discovery chapter discusses example risks and use cases across the value chain, keeping in mind the FAVES (fair, appropriate, valid, effective, and safe) principles identified by the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology (ASTP) in their Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule Overview document.<sup>24</sup>

## 1.5 Action Plan

*Below is a subset of actions – including HHS actions to date and future actions – described in the full chapter in the Strategic Plan. HHS recognizes that this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

- **Catalyze health AI innovation and adoption:** Improving AI adoption in medical research and discovery could hinge on expanding use cases, encouraging AI in different disease areas, and promoting AI-ready data standards. HHS has been directing funding and resources toward intramural and extramural research programs that develop or leverage AI in medical research and discovery (e.g., NIH’s Bridge2AI and ARPA-H’s Transforming Antibiotic R&D with GenAI to stop Emerging Threats [TARGET] program).<sup>25, 26</sup> In the future, HHS plans to share data interoperability guidelines, engage the public, and continue prioritizing safe, responsible, and responsive AI in its funding of both intramural and extramural research programs.
- **Promote trustworthy AI development and ethical and responsible use:** AI use in medical research and discovery could present biosecurity, privacy, bias, and other risks. HHS has established platforms to reduce AI bias in research and discovery (e.g., via NIH’s Science Collaborative for Health Disparities and Artificial Intelligence Bias Reduction [SchARE]) and implemented the Executive Office of the President’s National Biodefense Strategy.<sup>27, 28</sup> Going forward, HHS will share national guidelines specific to health AI (e.g., protecting AI models and health data from adversarial attacks, data-sharing protocols that protect sensitive health information, mechanisms to reduce harm from misuse of predictive analytics), create sandboxes for industry collaboration, and explore using AI for dynamic AI risk assessment.<sup>29</sup>
- **Democratize AI technologies and resources:** Working directly with the public and making critical data tooling and infrastructure more accessible to stakeholders with lower access to capital could expand the opportunity to conduct AI-empowered research and discovery. HHS is engaging communities (e.g., NIH’s Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Research Diversity [AIM-AHEAD]) and standardizing research data (e.g., NIH’s Common Data Element Repository) to support this goal.<sup>30</sup> HHS will continue to promote public-private partnerships, support multi-institutional research collaborations, and ensure access to needed data and data infrastructure. Additionally, HHS will focus on equitable AI access, particularly for traditionally underserved populations (e.g., rural communities and people with disabilities), to help create a more diverse and inclusive research landscape where everyone can benefit from and contribute to scientific advancements.<sup>31</sup>

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<sup>24</sup> [https://www.healthit.gov/sites/default/files/facas/2024-01-18\\_HTI-1\\_Final\\_Rule\\_Overview\\_508.pdf](https://www.healthit.gov/sites/default/files/facas/2024-01-18_HTI-1_Final_Rule_Overview_508.pdf). Note that FAVES principles are discussed in the preamble describing one of the HTI-1’s many proposed and final rules.

<sup>25</sup> <https://commonfund.nih.gov/bridge2ai>

<sup>26</sup> <https://arpa-h.gov/news-and-events/arpa-h-project-accelerate-discovery-and-development-new-antibiotics-using>.

<sup>27</sup> <https://www.nimhd.nih.gov/resources/schare/>

<sup>28</sup> <https://aspr.hhs.gov/biodefense/Pages/default.aspx>

<sup>29</sup> See Appendix A: Glossary of terms for the definition of “sandbox” used in this Plan.

<sup>30</sup> <https://cde.nlm.nih.gov/home>, <https://datascience.nih.gov/artificial-intelligence/aim-ahead>

<sup>31</sup> <https://www.nature.com/articles/s41562-022-01406-7>

- **Cultivate AI-empowered workforces and organization cultures:** To help ensure long-term successful and safe adoption of AI in medical research and discovery, AI talent pipelines and organizational working models may need to be bolstered. HHS is developing talent internally (e.g., NIH’s Data and Technology Advancement [DATA] National Service Scholar Program)<sup>32</sup> and externally (e.g., NIH’s Administrative Supplements for Workforce Development at the Interface of Information Sciences, AI/ML, and Biomedical Sciences).<sup>33</sup> HHS will continue to promote apprenticeship programs focused on AI in medical research and discovery activities to bolster talent pipelines and share guidelines for AI governance to help organizations foster robust AI-enabled cultures.

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<sup>32</sup> <https://datascience.nih.gov/data-scholars-2023>

<sup>33</sup> <https://datascience.nih.gov/artificial-intelligence/initiatives/Workforce-Gap-Data-Governance-AI>

# 2 Medical Product Development, Safety, and Effectiveness

## 2.1 Introduction and Context

Medical products—a term used in this Plan to collectively refer to drugs,<sup>34</sup> biological products, and medical devices, including some software-based behavioral interventions<sup>35</sup>—play a crucial role in advancing health in the U.S. and globally. They are also a large part of the economy; according to the Centers for Medicare & Medicaid Services (CMS), U.S. prescription drug expenditures totaled \$406B in 2022.<sup>36</sup> Many stakeholders engage in or are impacted by medical products, including patients, providers, manufacturers, and STLTs who use, manufacture, or fund AI and healthcare provision. Notably, HHS divisions, such as FDA, NIH, ARPA-H, CDC, and CMS, may regulate or fund clinical trials, authorize the marketing of medical products, monitor safety, or contribute to innovation.<sup>37</sup> For example, as of August 2024, FDA authorized approximately 1,000 AI-enabled medical devices and over 550 drug and biological product submissions with AI components.<sup>38, 39</sup>

This chapter of the Plan will focus on HHS’s approach to AI use when AI is, or is within, the medical product, or when AI is used in clinical research, manufacturing, and safety monitoring. The terms “AI-enabled device” and “AI device” will be used interchangeably in this Plan to refer to one or both of (1) AI software that can perform a medical device purpose (e.g., diagnose, cure, mitigate, treat, or prevent disease) without being a part of a traditional hardware medical device; and (2) AI software that is part of or integral to a medical device.

## 2.2 Opportunities for the Application of AI in Medical Product Development, Safety, and Effectiveness

AI can be used as part of a medical product and across the medical product lifecycle to, among other things:

- **Accelerate clinical development timelines** by being deployed in medical product development (e.g., to assess biomarkers), which can speed up clinical trials, making new products accessible more rapidly.<sup>40</sup>
- **Improve representation in clinical trials** by identifying potential trial participants, which can help enroll a more representative trial population.<sup>41</sup>
- **Be part of a medical product or be the medical product itself** by augmenting care provision, supporting learning from data collected during clinical use, and ensuring medical products are safe and effective<sup>42</sup>

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<sup>34</sup> See Appendix A: Glossary of terms for the definition of “drug,” “biological product,” and “medical device” used in the Plan.

<sup>35</sup> Some software-based behavioral interventions are medical devices under FDA’s statute, whereas others, such as those software functions that are “intended for maintaining or encouraging a healthy lifestyle” and are “unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition,” are not. See sections 201(h) and 520(o)(1)(B) of the Food, Drug, and Cosmetic Act.

<sup>36</sup> <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet>

<sup>37</sup> <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>

<sup>38</sup> <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

<sup>39</sup> <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/artificial-intelligence-drug-development>

<sup>40</sup> <https://www.nature.com/articles/d41586-024-00753-x>

<sup>41</sup> <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>

<sup>42</sup> <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>

- **Strengthen supply chain and operations** through medical product manufacturers, distributors, and others deploying AI to help predict demand,<sup>43</sup> allowing them to mitigate and possibly prevent supply chain disruption shortages.
- **Enhance pharmacovigilance and postmarket surveillance and monitoring** by collecting and analyzing large datasets of adverse event reports, scraped social media data, and survey data which could improve oversight of patient safety, including AI-enabled devices.<sup>44, 45</sup>

## 2.3 Trends in AI in Medical Product Development, Safety, and Effectiveness

The uptake of AI in medical products is emerging along two overarching trends: (1) leveraging AI in the development, use, manufacturing, and other operations related to medical products and (2) embedding AI within products or as a standalone product. Along trend (1), the number of regulatory submissions to FDA for drug and biological products that include AI is growing.<sup>46</sup> In clinical trials, AI is emerging with specific applications in endpoint and biomarker assessment.<sup>47</sup> Additionally, AI is used to “detect patterns and anomalies” that may identify potential product safety issues, “unexpected benefits, or performance inefficiencies.”<sup>48</sup> Along trend (2), applications of AI-enabled medical devices have been expanding,<sup>49</sup> however, with a historical focus on radiology,<sup>50</sup> potentially due to predicate devices that streamline marketing authorizations. These trends provide context to inform HHS’s actions to safely advance the responsible use of AI across medical products.

## 2.4 Risks for AI Use Cases in Medical Product Development, Safety, and Effectiveness

Incorporating AI in medical products and their development, use, or other operations comes with a myriad of risks, which are discussed in the full Medical Product Development, Safety, and Effectiveness chapter. Among these risks, bias and patient safety may be critical given the potential application in clinical trials and provision of care directly to patients (e.g., via drugs and AI-enabled surgical tools),<sup>51</sup> with patient safety potentially having the highest risk. As part of this Plan, HHS will continue developing policies to manage medical products’ AI risks.

## 2.5 Action Plan

*Below is a subset of actions – including HHS actions to date and future actions – described in the full chapter in the Strategic Plan. HHS recognizes that this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

<sup>43</sup> <https://www.fda.gov/media/167973/download?attachment>

<sup>44</sup> See Appendix A: Glossary of terms for definition of “pharmacovigilance” used in this Plan.

<sup>45</sup> <https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/methods-and-tools-effective-postmarket-monitoring-artificial-intelligence-ai-enabled-medical-devices>

<sup>46</sup> <https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2668>

<sup>47</sup> <https://ascpt.onlinelibrary.wiley.com/doi/full/10.1002/cpt.2668>

<sup>48</sup> <https://jamanetwork.com/journals/jama/fullarticle/2825146>

<sup>49</sup> <https://rad.washington.edu/news/fda-publishes-list-of-ai-enabled-medical-devices/>

<sup>50</sup> <https://rad.washington.edu/news/fda-publishes-list-of-ai-enabled-medical-devices/>

<sup>51</sup> <https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/identifying-and-measuring-artificial-intelligence-ai-bias-enhancing-health-equity> “Bias” in this context is defined as systematic differences in treatment of objects, people, or groups in comparison to others, where treatment is any kind of action, including representation, prediction, or decision.

- **Catalyze health AI innovation and adoption:** Clarifying regulatory oversight of medical products and AI-enabled device payment models could help spur further AI adoption in medical products and their development. HHS has released guidelines, supported pathways, and directed funding toward the development of AI for medical products (e.g., FDA’s Clinical Decision Support [CDS] Software Guidance; NSF, NIH, and FDA’s FDT-BioTech). HHS will continue to advance AI by issuing guidelines on oversight, clarifying payment pathways, and prioritizing safe AI in resourcing programs.
- **Promote trustworthy AI development and ethical and responsible use:** Helping to minimize social biases caused by AI in medical products and their development while fostering quality assurance of health AI could advance safe and responsible AI use in the space. HHS has established programs that advance technological approaches and partnerships to ensure AI safety (e.g., ARPA-H’s PRECISE-AI, FDA and the Department of Veterans Affairs [VA] impending partnership to vet health AI tools).<sup>52</sup> Going forward, HHS will explore resourcing for research on AI bias and evaluate approaches to bolster AI quality assurance in medical products and across the medical product lifecycle.
- **Democratize AI technologies and resources:** Promoting collaborative engagement with the public and aligning data standards across industries could help expand access to AI technologies that can be leveraged in medical products and their development. HHS is engaging communities through partnerships and consultations (e.g., NIH’s AIM-AHEAD) and helping researchers to share and combine datasets through policies and platforms (e.g., NIH Common Data Elements),<sup>53</sup> which can improve the accessibility of AI in medical products and the medical product lifecycle. HHS will continue to promote multi-institutional partnerships and potentially release guidelines on data, metadata, and information-sharing principles to enable more widespread AI uptake in medical products and across the medical product lifecycle.
- **Cultivate AI-empowered workforces and organization cultures:** To help advance long-term successful and safe adoption of AI in medical products and their development, AI talent pipelines and organizational working models may need to be bolstered. HHS is developing human capital with AI skills related to medical products internally (e.g., FDA’s scientific internships) and externally (e.g., NIH’s DATA National Service Scholar Program). HHS will continue supporting apprenticeship and upskilling programs incorporating AI into medical products and across the medical product lifecycle to ensure a robust talent pipeline.

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<sup>52</sup> <https://www.nextgov.com/artificial-intelligence/2024/10/va-announces-creation-new-ai-testing-ground-fda/400681/?oref=ng-homepage-river>

<sup>53</sup> <https://cde.nlm.nih.gov/home>

# 3 Healthcare Delivery

## 3.1 Introduction and Context

U.S. healthcare delivery—which, in this Plan, refers to financing, direct patient care provision, and related administrative services—is a large and highly complex system. National health expenditures in the U.S. (including public health) were approximately \$4.5T in 2022, representing 17% of the U.S. economy and contributing to the employment of approximately 9% of the nation’s workforce.<sup>54, 55</sup> In the U.S., healthcare is delivered by licensed providers and predominately financed by payers (e.g., in 2022, 92% of patients in the U.S. had health insurance).<sup>56</sup> A range of HHS entities participate in the healthcare delivery ecosystem, including CMS, HRSA, SAMHSA, IHS, AHRV, and others, who are directly involved in facilitating healthcare delivery or providing guidelines, payment and funding, training, and other operational support to delivery partners.<sup>57</sup>

## 3.2 Opportunities for the Application of AI in Healthcare Delivery

The adoption of safe and trustworthy AI use has tremendous potential for the U.S. healthcare system to:

- **Improve the quality and outcomes** of patient care, for example, by enabling clinicians to monitor patients’ conditions for changes or detect undiagnosed diseases earlier.<sup>58</sup>
- **Improve the patient experience** through tailored customer service, access to increasingly sophisticated tools, and strengthened relationships with providers.<sup>59</sup>
- **Automate administrative processes** and reduce workforce burden and burnout.<sup>60, 61</sup>
- **Enhance equity and access to care** for underserved populations, for instance, using AI to help overcome language barriers and remediate diseases for at-risk groups.<sup>62, 63</sup>
- **Bend the cost curve** on national health expenditures by reducing administrative and medical costs, which reports indicate could result in savings of between \$200B and \$360B.<sup>64</sup>

## 3.3 Trends in AI in Healthcare Delivery

The adoption of AI in U.S. healthcare delivery is evolving rapidly—but not without challenges and mixed perceptions among stakeholders. Investment in health AI is growing, accounting for 25% of all healthcare venture capital funding and totaling over \$7B in 2023.<sup>65</sup> A survey of 100 healthcare executives indicated that over 70% were already pursuing or implementing AI.<sup>66</sup> However, in another survey, about 40% of physicians stated they were equally as enthusiastic as they were concerned about

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<sup>54</sup> <https://www.cms.gov/newsroom/fact-sheets/national-health-expenditures-2022-highlights#>

<sup>55</sup> <https://www.bls.gov/spotlight/2023/healthcare-occupations-in-2022/#>

<sup>56</sup> <https://www.cms.gov/newsroom/fact-sheets/national-health-expenditures-2022-highlights#>

<sup>57</sup> The full landscape of stakeholders and their roles in healthcare delivery with AI is detailed further in this Plan.

<sup>58</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC10916499/>

<sup>59</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC10734361/>

<sup>60</sup> <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/April2019PoPNewsletter.pdf>;

<sup>61</sup> [https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport\\_0.pdf](https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf)

<sup>62</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC9976641/>

<sup>63</sup> <https://www.cedars-sinai.org/discoveries/research-aims-to-improve-maternal-health-equity.html>

<sup>64</sup> [https://www.nber.org/system/files/working\\_papers/w30857/w30857.pdf](https://www.nber.org/system/files/working_papers/w30857/w30857.pdf)

<sup>65</sup> <https://www.svb.com/trends-insights/reports/artificial-intelligence-ai-in-healthcare/>

<sup>66</sup> <https://www.mckinsey.com/industries/healthcare/our-insights/generative-ai-in-healthcare-adoption-trends-and-whats-next#/>; Survey of executives from 100 healthcare organizations on their intentions to implement GenAI.

using it. Concerns included the potential deterioration of the patient-provider relationship and patient privacy.<sup>67</sup> Some survey results indicate that patients may have similar concerns about AI: a 2022 survey 60% of respondents indicated patients would feel uncomfortable with healthcare providers relying on AI.<sup>68</sup> In addition to these mixed perceptions, AI readiness differs across organizations, and healthcare delivery organizations often prefer partnering with vendors, such as technology companies, as only a few can play the role of both developer and deployer of AI. Many delivery organizations face limitations from heterogeneity in foundational data and technology systems,<sup>69, 70</sup> which would need to be addressed to effectively use AI at scale. Finally, uptake of AI varies across settings and clinical disciplines: AI is currently more widely used in some clinical disciplines (e.g., radiology) and in automating administrative use cases that require extensive manual overheads (e.g., documentation).<sup>71</sup> Despite this heterogeneity in use and readiness, AI still offers multiple opportunities to improve healthcare as described above and detailed further in the Healthcare Delivery chapter of the full Strategic Plan.

### 3.4 Risks for AI Use Cases in Healthcare Delivery

While there are a wide range of risks, the more acute risks in healthcare delivery include the re-identification of patient data and confabulation (models confidently providing incorrect answers)<sup>72</sup> that could result in unintended impacts. The Action Plan describes steps HHS will take to promote safe and trustworthy use, including clarifying and building regulatory structures and exploring additional levers (e.g., providing guidelines, resources, and education) to ensure delivery organizations are vigilant in risk mitigation.

### 3.5 Action Plan

*Below is a subset of actions – including HHS actions to date and future actions – described in the full chapter in the Strategic Plan. HHS recognizes that this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

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<sup>67</sup> <https://www.ama-assn.org/system/files/physician-ai-sentiment-report.pdf>

<sup>68</sup> <https://www.pewresearch.org/science/2023/02/22/60-of-americans-would-be-uncomfortable-with-provider-relying-on-ai-in-their-own-health-care/>

<sup>69</sup> <https://www.nejm.org/doi/full/10.1056/NEJMra2204673>

<sup>70</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8285156>

<sup>71</sup> A detailed discussion of AI use cases across value chains can be found in the full Plan.

<sup>72</sup> [https://ai.cms.gov/assets/CMS\\_AI\\_Playbook.pdf](https://ai.cms.gov/assets/CMS_AI_Playbook.pdf)

- **Catalyze health AI innovation and adoption:** HHS has been supporting innovation from early-stage evidence generation to payment for its eventual use. HHS divisions like NIH, AHRQ, and ARPA-H have collaborated on AI projects to enhance evidence gathering for AI and establish best practices in a delivery context.<sup>73, 74, 75</sup> Additionally, CMS pays for some AI-enabled devices<sup>76</sup> and is working on ensuring that existing coverage determination processes and payment pathways for innovations are clear to those developing AI applications. HHS will continue promoting AI innovation and adoption by supporting evidence development on effective and safe use and clarifying how existing regulations and statutes should be interpreted in the context of AI-enabled services.
- **Promote trustworthy AI development and ethical and responsible use:** HHS has implemented “Final Rules” (e.g., Nondiscrimination in Health Programs and Activities), guidelines, and regulations to enhance transparency and establish requirements for ensuring nondiscrimination in AI patient care decision-support tools.<sup>77</sup> ASTP is actively proposing and implementing policies that mandate transparency from certain health IT providers (e.g., those offering EHRs) regarding the AI-based technologies integrated into their products.<sup>78</sup> HIPAA also protects the privacy and security of PHI when providers use AI to deliver healthcare. To enable the safe use of AI, HHS will continue to study risks, provide guidance on interpreting risk guidelines and regulations, investigate instances of discrimination and privacy/security compromises, and support internal and external governance mechanisms (e.g., external AI audits).
- **Democratize AI technologies and resources:** HHS is working with STLTs through its Plan for Promoting Responsible Use of Artificial Intelligence in Automated and Algorithmic Systems by State, Local, Tribal, and Territorial Governments in Public Benefit Administration, which recommended how to: use AI to enhance public benefit program administration for recipients, encourage resource provision, improve education and partnerships with communities, and provide guidelines to ensure safety and equity.<sup>79</sup> HHS will work—within its existing authorities—to mitigate the growing “digital divide” in the healthcare sector by providing resources that increase underserved populations’ access to AI resources, raising the national baseline for foundational AI infrastructure, and researching AI impacts with and for patients in underrepresented populations.
- **Cultivate AI-empowered workforces and organization cultures:** HHS and its divisions already collaborate with the industry to enhance AI understanding, for example, through NIH’s AIM-AHEAD initiative, which increases diversity in AI research via partnerships and training. HHS will build the workforce’s AI capabilities by enhancing AI expertise in provider and financing settings, driving awareness and education of AI among clinicians, and working with leading researchers and the private sector to develop resources that enable healthcare delivery organizations to appropriately use AI in local settings.

<sup>73</sup> <https://pubmed.ncbi.nlm.nih.gov/38100101/>

<sup>74</sup> <https://pubmed.ncbi.nlm.nih.gov/37266959/>

<sup>75</sup> <https://pubmed.ncbi.nlm.nih.gov/38147523/>

<sup>76</sup> As of May 2024, CMS has established separate payments for at least 8 AI/ML-enabled devices through Current Procedural Terminology (CPT®), less than 5% of FDA-authorized, AI-based products. CMS has also approved New Technology Add-On Payment (NTAP) under the Medicare Inpatient Prospective Payment System (IPPS) for certain new devices leveraging AI.

<sup>77</sup> Specific provisions made in Section 1557 of the Patient Protection and Affordable Care Act.

<sup>78</sup> For example, <https://www.hhs.gov/about/news/2024/07/10/hhs-proposes-hti-2-rule-improve-patient-engagement-information-sharing-public-health-interoperability.html> see HHS’s HTI-2 rule.

<sup>79</sup> <https://www.hhs.gov/sites/default/files/public-benefits-and-ai.pdf>



# 4 Human Services Delivery

## 4.1 Introduction and Context

Human services delivery—which, in this Plan, refers to activities related to family and child support, populations with complex needs, the promotion of health and well-being, and community and economic development—encompasses programs accessed by more than 99 million Americans each year.<sup>80</sup> The ecosystem includes stakeholders from program participants to STLTs, CBOs, and HHS agencies, including ACF, ACL, CMS, HRSA, IHS, and SAMHSA.

AI presents opportunities to improve the lives of human services program participants through, for example, faster, more accurate application processing, more rapid benefits provisioning or improved program targeting and awareness. AI can also augment the work of the stakeholders who deliver these programs with program measurement and evaluation analytics, real-time translation, or workforce optimization platforms. In this Strategic Plan, HHS outlines a set of actions to catalyze AI use in human services, ensure it remains trustworthy, safe, and equitable, and cultivate a workforce highly skilled in the responsible use of AI in its activities.

## 4.2 Opportunities for the Application of AI in Human Services Delivery

The adoption of safe and trustworthy AI has the potential for the U.S. human services delivery ecosystem to:

- **Improve service experience and quality** through activities like enhanced program delivery, faster benefits provisioning, and improved call center support.<sup>81, 82, 83, 84</sup>
- **Increase the pace and quality of funds distribution** through, for instance, geospatial needs assessments and grant application synthesis and summary tools.<sup>85, 86</sup>
- **Enhance capabilities of the human services workforce** through, for instance, analytics and support tools for caseworkers.<sup>87</sup>
- **Increase the accessibility of services** and meet equity goals through efforts such as streamlined eligibility determination, live translation tools, and tailored public awareness campaigns.<sup>88</sup>
- **Enhance interoperability to improve care coordination** and create a more person-centered approach to human services, such as through integrated health and human services delivery systems.<sup>89</sup>

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<sup>80</sup> <https://aspe.hhs.gov/sites/default/files/documents/18eff5e45b2be85fb4c350176bca5c28/how-many-people-social-safety-net.pdf>

<sup>81</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC9723913/>

<sup>82</sup> <https://www.nber.org/papers/w31161>

<sup>83</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC7125114/> Studies done in a healthcare setting to predict outcomes and the potential need for follow-on service (e.g., readmission).

<sup>84</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC11161909/> Recently published survey of studies on the use of AI to predict outcomes.

<sup>85</sup> <https://www.sciencedirect.com/science/article/pii/S0740624X20300034>

<sup>86</sup> <https://www.apec.org/publications/2022/11/artificial-intelligence-in-economic-policy-making>

<sup>87</sup> <https://www.ajmc.com/view/improving-risk-stratification-using-ai-and-social-determinants-of-health>.

<sup>88</sup> Multiple vendors exist alongside publicly available solutions like Google Translate.

<sup>89</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC9723913/>

### 4.3 Trends in AI in Human Services Delivery

Many STLTs and CBOs are interested in the potential of AI and are actively developing new AI-related research and collaborations.<sup>90,91</sup> However, despite its potential, AI adoption in the human services sector remains low compared to other sectors.<sup>92</sup> While STLTs and CBOs are launching pilot use cases, many are limited in scope or geography or are internal, often focusing on administrative tasks rather than participant-facing use cases. The sector's slower adoption of AI is partly attributed to a reliance on pro bono collaborations or subsidized pilots and concerns about potential outsized negative impacts on target populations. These concerns include perpetuated data biases and the risks of AI inaccurately influencing decisions related to public benefits access.<sup>93,94</sup> Protecting human services participants' rights and safety is thus critical to ensuring AI remains trustworthy, safe, and equitable.

### 4.4 Risks for AI Use Cases in Human Services Delivery

Risks for AI use in human services delivery include third-party risk endangering participant data privacy, explainability and accountability risks when using AI to inform program decisions, and potential for bias in algorithms due to historical underrepresentation of human services participant populations. Additional risks and more details at each stage of the human services delivery value chain are provided in the full version of this plan. These risks are aligned with risk management and governance guidelines such as the risk framework discussed in HHS's **Plan for Promoting Responsible Use of Artificial Intelligence in Automated and Algorithmic Systems by State, Local, Tribal, and Territorial Governments in Public Benefit Administration**.<sup>95</sup> To ensure the trustworthy and safe use of AI, the Department outlines several mitigation strategies for effectively managing these risks which are outlined with more details in the full plan.

### 4.5 Action Plan

In the human services domain, many of HHS's most notable actions to date are captured in its Plan for the Responsible Use of AI in Public Benefits. This plan outlines recommendations for STLTs that covers all four of HHS's goals for AI in the sector. Example recommendations include creating guidelines on key enablers for promoting AI innovation and adoption, applying the NIST AI Risk Management Framework to public benefits provisioning, and providing guidelines for states to educate their workforce. Moreover, the plan mentions potential future actions related to AI use in public benefits and explores opportunities to drive responsible adoption and engage the public. In this chapter, HHS builds on the previous plan and suggests new potential actions that respond to the evolving AI landscape in human services.

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<sup>90</sup> <https://www.cpsai.org/pages/openBriefs> Center for Public Sector AI created a series of Rolling Prompts that invite public sector leaders to pose challenges and for others to comment with potential AI-enabled solutions.

<sup>91</sup> <https://www.sanjoseca.gov/your-government/departments-offices/information-technology/ai-reviews-algorithm-register/govai-coalition>

<sup>92</sup> Based on ACF's focus groups and conversations with human services delivery agencies and industry input on AI integrations in human and health services.

<sup>93</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC9976641/>

<sup>94</sup> <https://minorityhealth.hhs.gov/news/shedding-light-healthcare-algorithmic-and-artificial-intelligence-bias>

<sup>95</sup> <https://www.hhs.gov/sites/default/files/public-benefits-and-ai.pdf> Published in April 2024 (herein referred to as Plan for Promoting Responsible use of AI in Public Benefits or occasionally as "the previous plan").

*Below is a subset of actions – including HHS actions to date and future actions – described in the full chapter in the Strategic Plan. HHS recognizes that this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

- **Catalyze health AI innovation and adoption:** Increasing AI adoption in human services will require overcoming several challenges. For instance, smaller, less-resourced STLTs and CBOs lack available funds for AI adoption or IT enhancement. HHS has provided STLTs with support identifying funding opportunities, recommended enablers for AI adoption, and cultivated relationships with sector partners to promote AI adoption. Looking forward, HHS will provide guidelines to stakeholders to enhance their IT infrastructure and data quality and ensure readiness. The Department is also exploring ways to unlock resources for itself and other organizations to invest in AI and expanding partnerships with private-sector groups to create a coordinated approach to AI adoption.
- **Promote trustworthy AI development and ethical and responsible use:** AI may pose risks related to privacy, ethics, and safety for program participants, especially those from groups historically under- or misrepresented in data-powering AI applications. HHS has released multiple plans including the Plan for Responsible Use of AI in Public Benefits<sup>96</sup> and ACF policies on generative AI tools that encourage appropriate use of AI within the human services ecosystem. HHS plans to provide additional recommendations, including clarifying specific best practices for AI applications across the human services value chain, integrating safety and transparency requirements into funding mechanisms, and exploring opportunities to fund risk mitigation strategy implementation for human services stakeholders.
- **Democratize access to AI technologies and resources:** Human services organizations often work with underrepresented populations that face several barriers to access including low digital literacy and cross cultural alienation.<sup>97, 98, 99</sup> While AI has the potential to mitigate factors limiting access, given these challenges, it is vital to ensure that AI technologies are accessible to CBOs, STLTs, agencies, and others that are closest to communities. Existing HHS actions include frequent engagement with the public to collect feedback on use of AI in its programs and on pathways to improve access. HHS will take actions going forward, including engaging frequently with participant populations through advisory groups, making funding available for STLTs and CBOs to implement high-value AI use cases, and exploring creating open-source, publicly available AI toolkits.
- **Cultivate AI-empowered workforces and organization cultures:** Employee digital literacy and expertise are critical for meeting HHS’s goals for AI adoption<sup>100</sup> and could help address workforce shortages in human services.<sup>101</sup> Further, HHS is considering ways to monitor workforce changes resulting from using AI and addressing concerns over reduced interaction between staff and participants. HHS has recommended actions for STLTs to enhance their workforce’s digital capabilities and abides by Dept. of Labor workforce-related practices for responsibly adopting AI. HHS recommends establishing AI literacy training for human services staff, exploring funding for lower-resourced STLTs to conduct workforce training, and issuing guidelines on workforce preparedness for using AI human services.

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<sup>96</sup> <https://www.hhs.gov/sites/default/files/public-benefits-and-ai.pdf>

<sup>97</sup> <https://www.census.gov/newsroom/press-releases/2017/acs-5yr.html>

<sup>98</sup> <https://www.kff.org/racial-equity-and-health-policy/issue-brief/five-key-facts-about-immigrants-with-limited-english-proficiency/>

<sup>99</sup> <https://www.usda.gov/broadband#>

<sup>100</sup> [https://ssir.org/articles/entry/taking\\_on\\_tech\\_governance#](https://ssir.org/articles/entry/taking_on_tech_governance#)

<sup>101</sup> <https://www.bls.gov/ooh/community-and-social-service/social-workers.htm>

# 5 Public Health

## 5.1 Introduction and Context

Public health is defined as “the science and art of preventing disease, prolonging life, and promoting health through the organized efforts and informed choices of society, organizations, public and private communities, and individuals.”<sup>102, 103</sup> The U.S. public health ecosystem is anchored on the coordination and support of the federal government and STLTs and relies on the collaboration of a wide range of stakeholders, from providers, health systems, private partners, and researchers to non-profits and the general public to enact positive societal change. The COVID-19 pandemic and its after-effects highlighted severe challenges and gaps in this ecosystem, including (1) difficulty in rapidly collecting, sharing, and analyzing information, (2) rising health inequity and public distrust of science, and (3) longstanding resourcing and staffing strains, among others.<sup>104, 105</sup> The continuous integration of AI into public health could support rapid data analysis to improve disease monitoring, enhance public health response, and optimize the usage of public health’s often limited resources. Community engagement is critical to achieving “health for all,” and AI can be a tool to support public health professionals in taking a human-centered design approach.<sup>106</sup> Moreover, involving diverse populations, including those historically underserved, during AI development through participatory design and other mechanisms is critical to achieving equitable outcomes.

## 5.2 Opportunities for the Application of AI in Public Health

The adoption of safe and trustworthy AI has the potential for the U.S. public health ecosystem to:

- **Improve threat detection, data-driven decision-making, and the effectiveness of interventions** through enhanced research methods, data, and accelerated insight generation, especially to inform time-sensitive situations like infectious disease outbreaks.
- **Optimize allocation of limited resources and interventions, especially in public health emergencies**, to ensure the “right resources reach the right people at the right time” through real-time distribution planning and advanced predictive analytics to inform service delivery and reinforce supply chain resilience and agility.
- **Improve efficiency of public health operations and support public health workers to better serve their communities**, particularly by automating repetitive tasks, allowing health professionals to reallocate time to high-impact activities.
- **Enhance health equity and access to care for underserved populations**, for instance, by developing evidence-based and tailored communications to meet the needs of diverse populations (e.g., language, health literacy).<sup>107, 108</sup>

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<sup>102</sup> <https://pubmed.ncbi.nlm.nih.gov/17838891/>

<sup>103</sup> <https://www.cdc.gov/training-publichealth101/media/pdfs/introduction-to-public-health.pdf>

<sup>104</sup> <https://pubmed.ncbi.nlm.nih.gov/34558861/>

<sup>105</sup> <https://www.nejm.org/doi/full/10.1056/NEJMsb2021088>

<sup>106</sup> <https://www.who.int/publications/i/item/9789240095403>

<sup>107</sup> The state in which everyone has a fair and just opportunity to attain their highest level of health, regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors.

<sup>108</sup> <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2024.00050>

## 5.3 Trends in AI in Public Health

Technological advancements in AI are transforming public health and medicine by enabling early disease detection, real-time outbreak monitoring, and predictive modeling.<sup>109, 110</sup> Specific areas such as drug design informed by population data and AI-generated public outreach and communications tailored to local context have shown promising and immediate benefits,<sup>111, 112</sup> but scaling these and other use cases will take concerted efforts. The adoption of AI in these fields faces mixed reactions, with both enthusiasm and concern about its risks.<sup>113, 114</sup> As early as February 2022, there were already more than 4,500 scientific papers that referenced the use of AI and ML in pandemic response, including 239 on surveillance and 219 on forecasting.<sup>115</sup> Recently, over half of adults in a recent nationwide survey were unsure of the impact of AI on seeking health information online, and another 23% felt AI was doing more harm than good,<sup>116</sup> reflecting the diversity of opinions on AI adoption. The public health ecosystem currently has drastically different levels of AI readiness regarding infrastructure, resourcing, and knowledge.<sup>117</sup> Recent developments underscore a greater need for shared, high-quality data, technical expertise, and interoperable systems to fully realize the potential of public health AI.

## 5.4 Risks for AI Use Cases in Public Health

Given the vast complexity of public health domains, underlying disease processes, and involved parties, there exists a diverse set of barriers and risks associated with AI adoption. Many of these are not unique to public health and are discussed in more detail in other chapters. More unique to public health is the risk of causing harm through the spread of disinformation and misinformation and the potential consequences of AI error in high-risk situations like public health emergency response. To support the safe and trustworthy use of AI, HHS will continue to develop policies and guidelines to manage these risks and collaborate with others.

## 5.5 Action Plan

*Below is a subset of actions – including HHS actions to date and future actions – described in the full chapter in the Strategic Plan. HHS recognizes this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

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<sup>109</sup> <https://doi.org/10.3389/fpubh.2023.1196397>

<sup>110</sup> <https://doi.org/10.1186/s12889-022-14422-z>

<sup>111</sup> <https://pubmed.ncbi.nlm.nih.gov/33358699/>

<sup>112</sup> [https://www.cdc.gov/health-communication/media/pdfs/2024/10/AI-for-Good\\_Listen-Up\\_S2E5\\_Transcript.pdf](https://www.cdc.gov/health-communication/media/pdfs/2024/10/AI-for-Good_Listen-Up_S2E5_Transcript.pdf)

<sup>113</sup> [https://www.cdc.gov/pcd/issues/2024/24\\_0245.htm](https://www.cdc.gov/pcd/issues/2024/24_0245.htm)

<sup>114</sup> <https://www.hhs.gov/sites/default/files/public-benefits-and-ai.pdf>

<sup>115</sup> <https://blogs.cdc.gov/genomics/2022/03/01/artificial-intelligence-2/>

<sup>116</sup> <https://www.kff.org/health-misinformation-and-trust/poll-finding/kff-health-misinformation-tracking-poll-artificial-intelligence-and-health-information/>

<sup>117</sup> <https://ai.nejm.org/doi/full/10.1056/AI-S2400177>

- **Catalyze health AI innovation and adoption:** Unlike in healthcare delivery or research and discovery, where the private sector is adopting AI as a competitive advantage, AI implementation in public health is often driven by the public sector and hindered by resourcing constraints, workforce challenges, and fragmented or outdated data systems.<sup>118, 119, 120</sup> HHS will continue supporting existing ecosystem-wide infrastructure updates, like TEFCA™, a nationwide framework for health information exchange, and CDC’s DMI, which are essential for AI integration and effective public health action.<sup>121, 122</sup> Additionally, HHS will play a crucial role in promoting and supporting the uptake of AI use cases and their associated benefits across the ecosystem.
- **Promote trustworthy AI development and ethical and responsible use:** Many questions about privacy, ethics, and safety regarding AI are still being addressed, and HHS agencies have already released guidelines on some of these issues (e.g., CDC GenAI guidelines, NIH notice NOT-OD-23-149: Use of Generative Artificial Intelligence Technologies is Prohibited for the NIH Peer Review Process).<sup>123, 124</sup> HHS can further balance innovation with safe use by defining guardrails for AI, standardizing data security policies to protect sensitive information, and promoting AI use that advances health equity.
- **Democratize AI technologies and resources:** Equitable AI access, particularly for non-profits and STLTs that directly serve the public, can enhance care for traditionally underserved populations and is essential for cross-functional collaboration in public health. HHS can build traction on existing initiatives like ONC’s Health IT Certification Program and guidelines like the HTI-1 Final Rule, which support interoperability across the ecosystem. To further bridge the digital divide between those with and without technology access, HHS can leverage, as appropriate, incentives and policy levers for supporting increased data exchange and interoperability, fostering continual AI development and collaboration, particularly among STLTs and CBOs, and advancing the development of open-source AI resources and tools.
- **Cultivate AI-empowered workforces and organization cultures:** While AI cannot replace the essential cross-jurisdictional and cross-functional collaboration required for human-centered public health, it offers noteworthy potential to support an understaffed workforce by automating repetitive tasks and streamlining workflows. HHS is working to enhance AI understanding in the workforce, as exemplified by programs like NIH’s AIM-AHEAD initiative, which aims to increase diversity in AI through partnerships and training programs.<sup>125</sup> To integrate AI responsibly and effectively, HHS can champion AI use cases, create training programs, and foster environments for augmenting and supporting the public health workforce to address burnout and/or attrition and promote AI education and community-based AI approaches tailored to each community’s unique needs.

<sup>118</sup> <https://www.forbes.com/sites/glenngow/2024/05/12/ais-competitive-advantage-for-small-and-medium-enterprises/>

<sup>119</sup> <https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2023.1306274/full>

<sup>120</sup> <https://www.brookings.edu/articles/why-is-ai-adoption-in-health-care-lagging/>

<sup>121</sup> <https://www.cdc.gov/surveillance/data-modernization/index.html>

<sup>122</sup> <https://www.cdc.gov/data-interoperability/php/public-health-strategy/index.html>

<sup>123</sup> <https://www.meritalk.com/articles/cdc-heading-full-force-into-ai-realm-with-roadmap-draft-genai-guidance/>

<sup>124</sup> <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-149.html>

<sup>125</sup> <https://datascience.nih.gov/sites/default/files/AIM-AHEAD-RFI-Full-Report-to-NHLBI-11-5-21-508.pdf>

# 6 Cybersecurity and Critical Infrastructure Protection

## 6.1 Introduction and Context

Securing digital systems from cyber threats is crucial for realizing the benefits and minimizing the risks of emerging technologies. Without effective risk management, AI systems could risk patient, participant, and public safety, expose Personally Identifiable Information (PII), and erode public trust in healthcare and public health systems. However, with appropriate controls, the possible benefits of AI to the Nation's health and human services ecosystems are immense.

In cybersecurity and critical infrastructure protection, HHS assumes a dual role in cybersecurity as both a partner to the sector and a regulator. As the coordinator of Sector Risk Management Agency activities, ASPR coordinates HHS cybersecurity activities on behalf of HHS, including sector-wide cyber threat information sharing. Alongside HHS, all other organizations are responsible for maintaining their organizations' defenses and managing cyber threats.

## 6.2 Trends in Cybersecurity and Critical Infrastructure Protection

Cyber incidents are continually on the rise, and as of 2024, the frequency of cyber incidents affecting health systems has doubled since 2016,<sup>126</sup> causing system outages and endangering patient safety. Further, the cybercrime industry is large and sophisticated, with a history of using public health incidents like the COVID-19 pandemic to demonstrate its capabilities.<sup>127, 128</sup> AI, particularly generative AI (GenAI), is expected to magnify the industry's threats and increase vulnerabilities and potential for errors and accidents.<sup>129</sup> The rise in AI-driven threats coincides with an escalating risk of data breaches, fueled by the sector's growing need for and access to large datasets. Despite the evolving threat landscape, many traditional tools for combatting cyber threats are still effective;<sup>130</sup> however, organizations struggle to implement even traditional controls due to multiple challenges including workforce shortage, lack of standards and alignment on best-practices, implementation complexity, and tensions between privacy and safety.

## 6.3 Action Plan

*Below is a subset of actions described in the full chapter in the Strategic Plan. HHS recognizes that this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

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<sup>126</sup> <https://aspr.hhs.gov/cyber/Pages/default.aspx>

<sup>127</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC9212240/>

<sup>128</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC9755115/>

<sup>129</sup> <https://www.fbi.gov/contact-us/field-offices/sanfrancisco/news/fbi-warns-of-increasing-threat-of-cyber-criminals-utilizing-artificial-intelligence>

<sup>130</sup> <https://www.ibm.com/downloads/documents/us-en/107a02e952c8fe80>

HHS has already taken steps aligned with overcoming the challenges mentioned above, including active monitoring, data-sharing, and collaboration with under-resourced STLTs to improve cybersecurity capabilities. HHS has also released its Cybersecurity Strategy<sup>131</sup> and Cybersecurity Performance Goals,<sup>132</sup> which assist organizations in implementing highest-impact traditional cybersecurity measures. Further, the Department has issued guidelines to improve software transparency and is working with AI and cybersecurity experts through the Digital Health Security program to strengthen electronic health ecosystem and reduce complexity.

Going forward, HHS is considering additional actions, such as creating sector-specific cyber training and supporting under-resourced STLTs to augment their cybersecurity workforce through technical assistance or integration of cybersecurity requirements in funding mechanisms. To improve best practice alignment, HHS also intends to update policies and issue new guidelines for addressing compromised systems. Further, to reduce complexity in sector cybersecurity, HHS intends to enhance its Health IT Certification programs to include and educate on more aspects of healthcare IT systems. Finally, the Department will explore ways to help organizations within the sector navigate tradeoffs between cybersecurity protection and privacy.

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<sup>131</sup> <https://www.hhs.gov/about/news/2023/12/06/hhs-announces-next-steps-ongoing-work-enhance-cybersecurity-health-care-public-health-sectors.html>

<sup>132</sup> <https://hhscyber.hhs.gov/performance-goals.html>



# 7 Internal Operations

## 7.1 Introduction and Context

AI, including GenAI, presents wide-ranging opportunities for HHS. The Department's operating and staff divisions have been using AI to improve internal operations, enhance the execution of public-facing services, inform processes supporting safe innovation within HHS and for HHS domains, and increase workforce efficiency. The scale at which AI is used across HHS also introduces several risks, including data privacy and security, execution risk, and workforce management. Managing these opportunities and risks requires a formal, Department-wide approach. This approach to AI must also focus on change management and adaptability, as AI implementation and use can transform existing processes.

## 7.2 Action Plan

*Below is a subset of actions described in the full chapter in the Strategic Plan. HHS recognizes that this is an evolving space, and actions will continue to be evaluated as technologies and needs continue to change.*

HHS has taken several steps to establish the Department-wide approach to AI adoption in internal operations. These include hiring a permanent CAIO, creating the HHS AI Governance Board and Community of Practice (CoP), and compiling an inventory of internal AI Use-cases. HHS has also collaborated across the federal government to develop the "Workforce of the Future" strategy to prepare federal agency HR teams for impact of increased AI adoption. The Department has also taken steps to streamline its hiring processes for AI roles.

Going forward, HHS's Office of the Chief Artificial Intelligence Officer (OCAIO) will lead three focal areas needed to establish the HHS-wide approach to AI adoption in HHS's internal operations. These focal areas are governance, internal process improvement and innovation, and workforce and talent. Actions across these focal areas include working through the Governance Board and CoP to strengthen AI governance structures and Department-wide collaboration, coordinating the development of enterprise procurement approaches, and ensuring oversight of internal AI use. Further, the Department will collaborate with government leaders on development of an AI hiring strategy and gap assessment for AI skills, while working to improve AI literacy among HHS staff. Overall, the OCAIO will integrate actions in these three focal areas into major internal operations in HHS to create a cohesive strategy to deploy high-value, trustworthy AI within the Department.

# Conclusion

HHS aims to be a global leader in innovating and adopting responsible AI to achieve unparalleled advances in the health and well-being of all Americans. This Strategic Plan outlines the ways in which HHS intends to achieve that goal.

The use of AI in medical research and discovery, medical product development, safety, and effectiveness, healthcare delivery, human services delivery, public health, cybersecurity, and HHS's operations is no longer a speculative future but a present reality, driven by rapid technological advancements. In recent years, AI has become part of everyday life, including within the health, human services, and public health ecosystem. This evolution is evident in the ability of AI to serve as a tool that supports delivering high-quality care, streamlining drug development, speeding and improving health and human services communications, and more.<sup>133</sup> Moreover, AI can enhance health equity, for example through providing real-time, automated translation services for individuals facing language barriers or supporting individuals with disabilities through optimized speech patterns and fluent conversation.<sup>134</sup> The use of AI brings these and many additional promising benefits discussed throughout the chapters of this Strategic Plan, yet comes with a wide range of risks such as the potential for AI to propagate biases, misclassify patient needs, or breach confidentiality.

HHS is dedicated to not only fostering the adoption of AI to achieve enhanced outcomes but also protecting patients, caregivers, and all stakeholders from these and other potential pitfalls discussed in each chapter of the Strategic Plan. This commitment involves implementing robust measures to address these challenges while promoting the transformative potential of AI.

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 benefit and risk assessment, stakeholder engagement, and the implementation of robust safeguards to ensure ethical and equitable AI use. HHS will also continue to identify bold opportunities and collaborations within and across domains that have potential to improve people's lives. HHS divisions will continue to play crucial roles by issuing guidelines and policies, allocating resources, conducting outreach and education programs, and cultivating workforces.

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. HHS will continue to support engagement and transparency with partners to foster creating human-centered solutions with meaningful impact.

***As HHS aims to continue its leadership at the forefront of health, human services, and public health innovation to meet the dynamic needs of the American people, this Plan is just one foundational step supporting the Department's ability to address the challenges of tomorrow. HHS is committed to supporting AI that enhances the health and well-being of all Americans.***

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<sup>133</sup> <https://www.whitehouse.gov/briefing-room/blog/2023/12/14/delivering-on-the-promise-of-ai-to-improve-health-outcomes/>

<sup>134</sup> <https://www.forbes.com/councils/forbesbusinesscouncil/2023/06/16/empowering-individuals-with-disabilities-through-ai-technology/>