

26 May 2023 | News

White House Takes Steps To Advance ‘Responsible’ AI That ‘Upholds Democratic Values’

by [Brian Bossetta](#)

The White House Office of Science and Technology Policy has released an updated national strategic framework outlining priorities and goals for federal investment in AI. Industry executive Peter Shen weighs in on the plan.

Before the power of artificial intelligence can be harnessed for the benefit of all Americans, the risks that come with the technology must first be managed, according to President Joe Biden, whose administration has released a blueprint that aims to do just that.

The White House Office of Science and Technology Policy (OSTP) has released a report, the [National Artificial Intelligence Research and Development Strategic Plan](#), outlining a series of initiatives for federal investment in AI. The report, which has not been updated since 2019 – and prior to that, 2016 – was developed by the Select Committee on Artificial Intelligence of the National Science and Technology Council.

The report is part of a comprehensive plan the Biden-Administration recently [announced](#) to advance the “research, development, and deployment of responsible AI that protects the individuals’ rights and safety and delivers results for the American people.”

“AI shouldn’t replace the doctor or clinician, but it should be a companion to that doctor or clinician to aid or assist in diagnosing or treating the patient.” – Peter Shen

The administration says that “responsible” AI innovation “places people, communities, and the public good at the center, and manages risks to individuals and our society, security, and economy.”

In addition to promoting innovation, the administration says the updated report will help ensure the US leads in developing responsible AI.

The new strategic plan is not the first effort by the federal government to advance AI healthcare. Earlier this month, the FDA released a new discussion paper, “Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products,” which highlights collaboration on the technology between the FDA and other stakeholders, including industry, ethicists, academia, patients, and global regulatory authorities. (Also see "[FDA, CDER Discuss AI/ML In Drug Development In Discussion Papers](#)" - Medtech Insight, 15 May, 2023.)

The FDA’s Digital Health Center of Excellence is also collaborating with the Veterans Health Administration, precisionFDA, and UK Medicines and Healthcare products Regulatory Agency to develop artificial intelligence and machine learning models pertaining to cardiovascular processes in veterans. The program, the Veterans Cardiac Health and AI Model Predictions (V-CHAMPS) Challenge, seeks to train and develop AI/ML tools to recognize heart failure using artificially generated (synthetic) veteran health records. (Also see "[News We’re Watching: Cancer Screening Partnership, New Abbott Electrophysiology Head, V-Champs AI Challenge](#)" - Medtech Insight, 12 May, 2023.)

And outside the US, other governments are working to advance and regulate AI technology as well. The European Parliament, for instance, recently voted by a “large majority” in favor of 13 amendments to the European Commission’s Artificial Intelligence (AI) Act, which, if adopted, will set new compliance requirements for many medical devices. (Also see "[EU AI Act Amendments Get Green Light From Parliament Committees In Latest Vote](#)" - Medtech Insight, 11 May, 2023.)

The administration also issued a [request for information \(RFI\)](#) seeking input on mitigating AI risks. The RFI, the White House said, will support the effort in advancing a cohesive AI strategy.

Therapy Chatbots And Medtech Laws: Why AI App Developers Must Tread Carefully

By [Eliza Slawther](#)

02 May 2023 With the rise of AI chatbots enabling rapid access to personalized mental health support and lifestyle advice, app developers must know when a product is legally a medical device. Medtech regulatory lawyer Erik Vollebregt explains what EU law says, and how to avoid mistakes. [Read the full article here](#)

According to the OSTP report, understanding and mitigating the social and ethical risks that comes with AI is essential to taking advantage of its benefits.

Industry Response

But as government races to regulate AI, the technology is already rapidly spreading through private industry. Leading manufacturers, such as Siemens Healthineers and GE HealthCare, are already shaping an AI-powered healthcare future. (Also see "[Siemens Healthineers, GE HealthCare Race To Develop Next-Gen AI Solutions For Personalized Care](#)" - Medtech Insight, 8 May, 2023.)

And while industry often sees regulation as burdensome and a potential drag on innovation, Peter Shen, vice president of digital and automation at Siemens Healthineers, believes the White House plan is a step in the right direction.

“The initial impression is that this is positive for industry and for the healthcare industry in particular,” Shen told *Medtech Insight*. “We at Siemens Healthineers see this as a positive step to bring artificial intelligence to the forefront for healthcare providers and more importantly, for patients.”

In Shen’s view, the administration’s three areas of focus – research, development, and deployment – can help industry make the most of AI’s emerging technology, particularly in diagnostics so that detection of abnormalities and malignancies can be earlier and more precise.

Further, AI can address the growing problem of healthcare data processing – both in terms of the volume being generated and the practical applications of that data.



PETER SHEN

As Shen pointed out, one of the challenges facing healthcare is bringing together disparate sources of personalized data – such as images, laboratory and pathology reports – and combining them to create a genetic profile that can be tailored to treat an individual patient. AI, for instance, can help doctors in assessing individual risk of tumor growth in a patient with prostate cancer.

An example of an AI solution in practice is GE Healthcare’s AIR Recon DL reconstruction algorithm, which uses software to create sharper images by leveraging raw MRI data. GE Healthcare has 42 FDA-cleared medical devices that feature AI.

AI technology can also help clinicians stay up to date

with the latest treatment options, Shen said, by summarizing the breakthroughs that are happening within healthcare and within medicine – a task too daunting for humans alone.

Another challenge AI poses is its development, another pillar of the White House plan.

As Shen explained, current AI algorithms often fail to accurately reflect the patient population that the technology is being applied to because those algorithms are based on traditional methods of data collection and processing. This status quo can lead to errors in the technology's applications in the real world. However, these errors can be mitigated by making sure that algorithms are more accurately reflective of the patient population.

“So this intervention by the government actually allows us to put some guardrails around the development of AI, which is much-needed right now to ensure that we have the proper ground truth for the training of these AI algorithms,” Shen said.

Key Areas

One possibility for furthering the White House goal of achieving responsible AI is to study and adapt approaches from other fields, such as medicine, which already have robust governance and regulatory ecosystems. Institutional review boards that study AI could be adapted – such as an “Ethics, Scientific Integrity, and Society Review Board” – to help steer research into the development positive AI products.

In Shen's view, this makes sense. As he noted, healthcare and government already work together in many areas, such as medical device regulations, reimbursement policies, and various services that the healthcare industry provides to the public. And strengthening this already strong partnership is necessary for emerging technologies, such as AI.

“We need to expand that partnership and make sure that we're focusing on the right areas around healthcare,” he said. “From an industry perspective we are welcoming this renewed focus, especially on a new technology that's changing quite rapidly.”

The OSTP report also says random control trials, validation, and ongoing monitoring used for drugs and medical devices may provide models for AI governance more generally.

“Strategic federal investments in responsible AI R&D will advance a comprehensive approach to AI-related risks and opportunities in support of the public good.” – The White House Office of Science

and Technology Policy

Specifically, the national AI plan reaffirms eight strategies outlined in the 2019 and 2016 drafts and adds a ninth. The strategies are:

- Make long-term investments in fundamental and responsible AI research. Prioritize investments in the next generation of AI to drive responsible innovation that will serve the public good and enable the US to remain a world leader in AI;
- Develop effective methods for human-AI collaboration. Increase understanding of how to create AI systems that effectively complement and augment human capabilities. Open research areas include the attributes and requirements of successful human-AI teams; methods to measure the efficiency, effectiveness, and performance of AI-teaming applications; and mitigating the risk of human misuse of AI-enabled applications that lead to harmful outcomes;
- Understand and address the ethical, legal, and societal implications of AI. Develop approaches to understand and mitigate the ethical, legal, and social risks posed by AI to ensure that AI systems reflect US values and promote equity;
- Ensure the safety and security of AI systems. Advance knowledge of how to design AI systems that are trustworthy, reliable, dependable, and safe. This includes securing AI systems from cybersecurity and data vulnerabilities;
- Develop shared public datasets and environments for AI training and testing and enable access to high-quality datasets and environments, as well as to testing and training resources;
- Measure and evaluate AI systems through standards and benchmarks. Develop a broad spectrum of evaluative techniques for AI, including technical standards and benchmarks, informed by the administration's blueprint for an [AI Bill of Rights](#) and [AI Risk Management Framework](#);
- Better understand the national AI R&D workforce needs. Improve opportunities for R&D workforce development to strategically foster an AI-ready workforce in America;
- Expand public-private partnerships to accelerate advances in AI. Promote opportunities for

sustained investment in responsible AI R&D and for transitioning advances into practical capabilities, in collaboration with academia, industry, international partners, and other non-federal entities; and

- Establish a principled and coordinated approach to international collaboration in AI research. Prioritize international collaborations in AI R&D to address global challenges, such as environmental sustainability, healthcare, and manufacturing.

“Strategic federal investments in responsible AI R&D will advance a comprehensive approach to AI-related risks and opportunities in support of the public good,” the report says.

But perhaps the most important aspect in the development and regulation of AI is the assurance that it should not – and cannot – replace human beings.

“AI is not there to replace healthcare providers, but to be integrated into their routine clinical workflows,” Shen said. “AI shouldn’t replace the doctor or clinician, but it should be a companion to that doctor or clinician to aid or assist in diagnosing or treating the patient.”