Federal AI Action Plan Marks A Shift For Health And Bio Fields

By **Mehrin Masud-Elias** (September 3, 2025)

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The second Trump administration's "Winning the Race: America's AI Action Plan,"[1] **released** by the White House Office of Science and Technology Policy on July 12, marks a major shift in how artificial intelligence will be regulated, funded and deployed across various sectors.

For the healthcare and biomedical research communities, this is not just a road map — it's a set of directives, albeit in broad brush strokes, with legal, operational and ethical consequences in the years to come.

The AI plan takes off much, if not all, of the guardrails from the now-rescinded 2023 executive order on AI by the Biden administration,[2] and significantly expands federal commitments across agencies such as the National Institutes of Health, National Science Foundation and U.S. Food and Drug Administration, etc.

These mandates have the potential to affect how AI will be developed, validated and governed in the context of scientific and medical discovery, including human subjects research.

The AI plan reflects the Trump administration's view that overregulation of AI, especially in its nascent phase, will stymie its progress and make the U.S. less competitive in comparison to countries such as China.

To that end, in the section of the AI plan titled "Pillar I: Accelerate AI Innovation," the federal government plans to go as far as withholding AI-related funds and resources from states that promulgate, in the current administration's view, burdensome AI regulations.

Undoubtedly, for legal counsel and others involved in structuring academic, biomedical and life sciences research collaborations, whether intra-institutional or with industry partners, managing regulatory compliance, negotiating AI-related intellectual property, and so on, this is a pivotal moment.

The AI Plan

The AI plan outlines an aggressive, federally coordinated AI strategy that emphasizes rapid deployment in strategic sectors, including healthcare and biomedical research, through expanded funding, infrastructure investment and agency-specific mandates.

Core themes include treating AI as a national security asset, accelerating AI-driven scientific discovery, prioritizing large-scale and federated data access, expanding adaptive AI tools in partnership with industry, and streamlining FDA oversight of AI-enabled medical products.

While implementation details remain fluid, the AI plan makes clear that AI integration is no longer optional — it is expected.

AI's Potential to Transform Scientific Research

The AI plan reflects the currently prevailing view that AI is poised to fundamentally change how science is conducted. Current AI systems can already generate breakthroughs like novel protein structures and other bioengineered materials. As AI evolves, it may assist in formulating hypotheses and designing experiments, thus speeding up scientific discovery.

However, this potential will only be realized if scientific inquiry itself — especially the required infrastructure — adapts. The AI plan notes that the current scientific practice is often labor-intensive, and the Trump administration, along with AI proponents, believe that scaling up experimentation will be critical to match AI's predictive capabilities. This shift demands both engineering innovation and reimagined scientific organizations.

As such, the AI plan recommends the following policy actions:

- Support the development of automated, cloud-enabled laboratories across diverse scientific fields via collaborations between federal agencies, the private sector and research institutions.

- Use long-term funding mechanisms to back focused-research organizations and similar entities that utilize AI and other emerging technologies to drive fundamental science.

- Encourage researchers to publicly share high-quality datasets by evaluating past data-sharing efforts during funding reviews.

- Require federally funded scientists to disclose nonsensitive, nonproprietary datasets used in AI-based research and experiments.

Strategic Importance of High-Quality Scientific Data for AI

Based on the AI plan, the Trump administration views high-quality data not just as fuel for data-driven, scientific research but as a critical national asset in the global AI race.

While other nations — including strategic adversaries such as China — are rapidly collecting vast amounts of scientific data, Trump wants the U.S. to lead by creating the world's most robust and AI-ready scientific datasets.

However, achieving this in practice may prove challenging when it comes to striking a balance with individual rights, civil liberties, privacy and confidentiality, not to mention the disparate, socioeconomic impact of a dramatically scaled-up AI infrastructure, e.g., energy-intensive data centers, on the climate and affected communities.[3]

On the data front, the recommended policy actions in the AI plan include the following:

- Charge the National Science and Technology Council's Machine Learning and AI Subcommittee with recommending baseline quality standards for diverse scientific data types (e.g., biological, chemical, physical) to ensure suitability for AI model training.

- Enforce the Confidential Information Protection and Statistical Efficiency Act of 2018 by issuing Office of Management and Budget regulations to promote a presumption of data accessibility, expand secure access, break down federal data silos and enhance AI-driven evidence-building while protecting confidentiality.

- Set up secure compute environments within the NSF and U.S. Department of Energy to enable sensitive AI research requiring controlled access to restricted federal datasets.

- Create an online gateway via the NSF's National Secure Data Service demonstration project to provide both public and agency access to AI use-cases involving restricted federal data.

- Lead an initiative to perform whole-genome sequencing of "life on Federal lands," which is not defined but is meant to encompass "all biological domains" residing in such territories, which can eventually help train powerful biological foundation AI models.

Importantly, unlike the Biden AI order, there is no call for the U.S. Department of Health and Human Services or any other relevant agency to develop a legal or ethical framework to govern synthetic data generation and use.[4]

Additionally, projects involving federated, cross-institutional AI-related arrangements (e.g., learning, training, research, etc.) will require careful structuring, especially when training data is locally controlled by one institution.

Also, IP rights to models trained on synthetic datasets — or for that matter, any datasets — remain unclear, raising the potential for disputes in collaborative settings.

Legal counsel advising on AI in medical research must now consider a rapidly expanding list of risk vectors from co-ownership of IP where algorithms are co-developed by public and private actors to compliance with evolving Institutional Review Board and FDA mandates for AI-enabled interventions and cross-border AI governance issues for training models on international genomic or data from patient electronic medical records at hospitals.

FDA Regulation of AI-Enabled Medical Products

Relatedly, the FDA recently finalized its guidance titled "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," offering manufacturers a clear framework for meeting cybersecurity requirements under Section 534B(b) of the Food, Drug, and Cosmetic Act.[5]

Targeting "cyber devices" — those with internet connectivity and software that may be vulnerable to cyber threats — the guidance emphasizes integrating cybersecurity into device design from the outset, a principle aligned with privacy by design.

It also calls for transparency, requiring manufacturers to inform users about potential risks and security controls, and to document design controls appropriate to the device's complexity and connectivity.

In addition to high-level recommendations, the FDA outlines detailed technical expectations for threat modeling, cybersecurity assessments and risk management. Appendices to the guidance include specific guidelines for implementing security controls. While the focus is on premarket submissions, the recommendations apply broadly to digital health technologies.

National Biosecurity Risk Mitigation

As AI accelerates breakthroughs in biology — from novel therapeutics to new industrial applications — it also introduces serious biosecurity risks. Advanced AI tools may enable malicious actors to design and synthesize dangerous pathogens or biomolecules.

To counter this, the AI plan identifies the need for a multilayered national strategy, emphasizing both technological safeguards and strong regulatory enforcement. Core to this effort is the requirement that federally funded institutions use nucleic acid synthesis tools and protocols — enforced through regulation, not voluntary compliance.[6]

To further mitigate risks, the OSTP is tasked with uniting government and industry stakeholders to establish data-sharing mechanisms that can flag potentially fraudulent actors across synthesis platforms. In parallel, ongoing national security-related AI evaluations will be conducted through partnerships among the U.S. Department of Commerce's Center for AI Standards and Innovation, national security agencies, and academic research institutions.

The Trump administration expects that these coordinated efforts will not only strengthen domestic safeguards but also support the development of internationally aligned biosecurity norms.

How Counsel Can Steer AI Governance, Integration and Compliance

For counsel advising research institutions, life sciences companies or healthcare systems, the AI plan transforms AI integration from a discretionary innovation to a regulatory and contractual imperative. Three practitioner priorities stand out.

Contract Modernization

Existing templates for data-sharing, IP allocation and collaborative research will need AI-specific clauses covering synthetic data rights, federated learning governance and dynamic algorithm outputs. Expect negotiations over ownership and licensing of AI-trained models to intensify, especially in multiparty or cross-border collaborations.

Proactive Compliance Alignment

Even in the absence of detailed federal standards, counsel should anticipate forthcoming rules by aligning practices now with the AI plan's stated expectations, e.g., "baseline quality standards" for scientific data, the FDA's cybersecurity-by-design mandates, etc. Participation in agency-led sandboxes may help test compliance approaches while offering early regulatory intelligence.

Risk and Governance Integration

AI introduces new vectors for IP disputes, privacy breaches and biosecurity risks. Embedding AI risk management into institutional governance — from IRB oversight to board-level strategy — will be critical. Given the AI plan's global posture, cross-border data flow restrictions must be mapped alongside U.S. regulations such as the Health Insurance Portability and Accountability Act.

In short, the AI plan's policy shift demands that counsel operate not just as compliance monitors but as strategic architects of AI-enabled research ecosystems.

The competitive advantage will lie with those who can integrate legal foresight into operational AI deployment before government mandates arrive. For better or for worse, AI is no longer just a scientific or technical asset — it is now a regulated system with legal infrastructure requirements.

The AI plan signals the federal government's intent to operationalize its AI policies in the most sensitive domains, including healthcare and biomedical research.

For these industries, the stakes are not hypothetical — they are here, federally endorsed, and potentially rapidly enforceable. As with the space race,[7] with the AI plan we in the U.S. have now officially taken the first steps toward where no human has gone before.

Mehrin Masud-Elias is counsel at Arnold & Porter Kaye Scholer LLP.

[1] America's AI Action Plan at https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf and America's AI Action Plan: What Full Steam Ahead Means for Your Company | Advisories | Arnold & Porter at https://www.arnoldporter.com/en/perspectives/advisories/2025/07/americas-ai-action-plan.

[2] Federal Register :: Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government at https://www.federalregister.gov/documents/2020/12/08/2020-27065/promoting-the-use-of-trustworthy-artificial-intelligence-in-the-federal-government.

[3] Ethical Issues of AI - PMC at https://pmc.ncbi.nlm.nih.gov/articles/PMC7968615/.

[4] Highlights of President Biden's Executive Order on AI and Its Impact on Health Care | AHA at https://www.aha.org/advisory/2023-11-21-highlights-president-bidens-executive-order-ai-and-its-impact-health-care.

[5] Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions | FDA at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions and Virtual and Digital Health Digest | Publications and Presentations | Arnold & Porter at https://www.arnoldporter.com/en/perspectives/publications/2025/07/virtual-and-digital-health-digest

[6] The Perfect Storm of AI-Assisted Biotech Research and Bioengineered Materials: Biosecurity Complian.ce and Risk Management | Advisories | Arnold & Porter at https://www.arnoldporter.com/en/perspectives/advisories/2024/10/biosecurity-compliance-and-risk-management.

[7] The Cold War's Impact on the Space Race: A Comprehensive Overview at https://www.worldhistory.org.uk/cold-war-space-race.