July 15, 2025

Director Jay Bhattacharya, M.D., Ph.D.
Department of Health and Human Services
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Attn: Request for Information (RFI): Inviting Comments on the NIH Artificial Intelligence (AI) Strategy (NOT-OD-25-117)

Dear Director Bhattacharya,

Executive Summary

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input on the National Institutes of Health's first comprehensive Artificial Intelligence Strategy. As the professional home for over 5,500 informaticians and the leading organization advancing the science and practice of biomedical and health informatics, AMIA brings unique expertise to this critical initiative.

AMIA strongly supports NIH's ambitious three-stage progression from data analytics to autonomous biomedical AI systems. This strategic vision aligns with our organization's established AI principles, which extend traditional medical ethics with AI-specific requirements including explainability, interpretability, fairness, dependability, transparency, and accountability.[1] As documented in our "AI in Healthcare: Touchstones for Responsible Use," AMIA recognizes that while AI promises improved quality, safety, and care equity, risks of biases and lack of transparency pose safety threats if deployed without appropriate safeguards.[2]

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1. Strategic Architecture

Foundational Themes and Pillars

Data Readiness: AMIA recommends that NIH require all data generated through federal grants align with FAIR (Findable, Accessible, Interoperable, Reusable) principles as a funding condition.[3] Data used for AI must be of the highest quality, applied appropriately, and adhere to FAIR principles.[2] Individual privacy protections must be consistently maintained across clinical, research, and commercial use of health data.[2]

Trust and Transparency: AI must be a driver of transparency. Transparency in planning, designing, developing, validating, deploying, and monitoring AI tools is the primary way to avoid unintended consequences.[2] NIH should mandate explainable AI (XAI) methods including SHAP, LIME, and saliency maps for all federally funded AI research applications.[4] Current research shows that 60% of patients do not trust AI in their healthcare, requiring proactive measures to ensure accountability and demonstrated benefit.[2]

Translation: AMIA's extension of traditional medical ethics with AI-specific requirements provides a comprehensive framework for NIH adoption.[1] This includes "algorithmovigilance"—continuous monitoring of AI systems for effectiveness and equity throughout their operational lifecycle.[5] AI harm and unintended consequences must be reported, assessed, monitored, and mitigated with guaranteed response mechanisms.[2]

Workforce Development: AMIA positions informatics professionals as essential leaders in AI development and implementation.[6] NIH should collaborate with AMIA and other professional organizations to develop comprehensive AI competency frameworks spanning biomedical research, clinical care, and public health applications.[7]

Transition Actions and Milestones

NIH should establish clear criteria for progression between stages, including technical performance thresholds, safety validation requirements, and ethical review processes. AMIA's AI Evaluation Showcase Series provides a three-stage assessment model: Technical Performance, Usability and Workflow Integration, and Health Impact Evaluation.[8] The transition to fully autonomous AI systems requires unprecedented attention to safety, ethics, and oversight mechanisms through AI Centers of Excellence and institutional AI governance bodies.[9]

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2. Research & Innovation Actions

High-Impact Use Cases

Biomedical Discovery: AI applications in drug discovery demonstrate significant potential for accelerating biomedical research. AMIA's partnerships with pharmaceutical companies provide insights into effective AI implementation strategies.[10] NIH should prioritize AI applications that reduce drug development timelines while maintaining safety and efficacy standards.

Public Health Protection: AMIA's Health and Healthcare Equity Working Group has developed frameworks for applying equity lenses to informatics work, ensuring AI systems advance rather than exacerbate health disparities.[11] NIH should prioritize AI applications addressing social determinants of health and supporting vulnerable populations.

Clinical Decision Support: The informatics community invented clinical decision support and has championed its advancement through evidence-based approaches.[12] Our Touchstones emphasize that AI-generated decisions should not override point-of-care clinical decision-making, and AI tools should create personalized care plans.[2]

Mechanisms for Reproducibility, Reporting, and Benchmarking

AI system reproducibility requires comprehensive documentation of data sources, algorithm versions, training processes, and validation methodologies.[13] AMIA recommends that NIH establish mandatory reproducibility standards for all AI research, including requirements for code sharing, dataset documentation, and performance validation across multiple sites. Community-driven standards development provides effective models for consensus building.[14]

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3. Intramural–Extramural Synergy

AMIA's partnership with HL7 International and advocacy for FHIR specifications provides a proven model for AI-enabled data integration.[14] We recommend NIH adopt a "share now, standardize as needed" approach that prioritizes data exchange while building toward comprehensive interoperability.[15]

NIH intramural AI tools should be designed with extramural accessibility in mind, incorporating open-source licensing and comprehensive documentation. Collaborative research agreements (CRADAs) and SBIR/STTR programs provide proven mechanisms for technology transfer that should be expanded for AI applications.[16] Joint governance structures should include representation from informatics professionals, clinical practitioners, patient advocates, and industry partners.

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4. Operational Excellence

AI has groundbreaking potential to reduce oppressive administrative burden for providers and patients. AMIA's 25x5 Task Force has identified documentation burden as a

critical area where AI can make immediate impact.[17] NIH should minimize any possible increase in documentation burden caused by policies regulating AI tool use in healthcare.[2]

AI applications can streamline grant application processes and assist in peer review through reviewer assignment, conflict detection, and preliminary technical assessment while preserving human judgment for scientific merit evaluation. AMIA's "algorithmovigilance" framework provides essential guidance for ongoing AI system monitoring.[5] Key performance indicators should include user satisfaction, time savings, error reduction, equity metrics, and system reliability measures.

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5. Facilitating & Validating AI in Healthcare Delivery

AMIA's AI Evaluation Showcase Series provides a structured framework for AI assessment covering technical performance, usability and workflow integration, and health impact evaluation.[8] Our dual oversight framework distinguishing between commercially marketed and self-developed AI systems offers practical guidance for healthcare delivery validation.[9]

AMIA has submitted comprehensive comments to FDA on AI/ML software as medical devices, providing insights for NIH-FDA collaboration on AI validation standards.[18] Collaboration with VA and other federal healthcare systems provides opportunities for real-world validation across diverse patient populations. NIH should establish clear standards for clinical AI validation, including requirements for diverse dataset testing and long-term outcome monitoring, with special attention to equity considerations.

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6. Reproducibility & Trust

AMIA's collaboration with HL7 International demonstrates the importance of standards-based approaches to AI development.[14] NIH should prioritize FHIR-based integration standards that enable AI systems to access comprehensive patient data while maintaining security and privacy protections. Community-driven standards development provides effective models for consensus building.

Transparency requirements must encompass algorithm training data, model architecture, performance metrics, and decision processes. AMIA recommends that NIH establish clear audit trail requirements enabling comprehensive review of AI system decisions, with particular attention to bias detection and mitigation throughout the AI lifecycle.[19] Trust-building measures should include transparent communication about AI capabilities and

limitations, clear mechanisms for user feedback, and robust safeguards against bias and discrimination.

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7. Partnerships & Ecosystem Building

AMIA strongly encourages NIH to leverage the decades of real-world AI expertise of our members. AMIA's diverse membership spans healthcare companies creating AI tools, hands-on clinicians, and medical researchers.[2] Additionally, AMIA works closely with Harvard's Division of Clinical Informatics, the Coalition for Health AI (CHAI), the Health AI Partnership (HAIP), and the National Academy of Medicine (NAM).[2]

AMIA recommends that NIH work with the Assistant Secretary of Technology Policy and other federal agencies to improve integration of AI tools into EHR systems.[2] AI development requires international collaboration to address global health challenges and ensure interoperability across national boundaries.

NIH's AI strategy requires substantial computational infrastructure investments. AMIA recommends leveraging the STRIDES initiative's cloud computing capabilities while ensuring data security and compliance with federal requirements.[20] Governance frameworks should balance open science principles with the need to protect sensitive data and maintain competitive advantages.

Conclusion

AMIA commends NIH for undertaking this comprehensive AI strategy development and appreciates the opportunity to provide input based on our organization's extensive experience in health informatics and AI applications. The three-stage progression from data analytics to autonomous AI systems represents an ambitious but achievable vision that can significantly advance biomedical research and improve human health outcomes.

Success depends on maintaining an appropriate balance between innovation and safety, ensuring that AI development serves public benefit while addressing equity and ethical considerations. AMIA's established AI principles, evaluation frameworks, and professional expertise provide valuable resources for strategy implementation. We look forward to continued collaboration with NIH in advancing responsible AI development for biomedical research. If you have questions or require additional information, please contact Tayler Williams, AMIA's Senior Manager, Public Policy, twilliams@amia.org.

Sincerely,

Eileen Koski
Chair of the Public Policy Committee

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