July 15, 2015

The Honorable Jay Bhattacharya, MD, PhD
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

RE: NIH AI Strategy

Dear Director Battacharya:

Thank you for the opportunity to provide input on NIH's first-ever, institute-wide artificial intelligence (AI) strategy. The emergence of AI represents a once-in-a-generation leap forward in human capability, comparable in scale and consequence to the advent of electricity or the internet. With bold leadership, NIH has the potential to unlock revolutionary breakthroughs in science, medicine and human health.

We applaud your efforts to harness the full power of AI to accelerate discovery, improve outcomes and empower the American people. The opportunity is extraordinary: AI can compress decades of medical progress into years, democratize access to care and enable cures we once thought impossible. The United States must lead, not follow, in this global race. NIH's strategy can and should be the blueprint that ensures America remains the vanguard of biomedical innovation in the AI era.

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands helping support more than 18 million American jobs. CTA owns and produces CES® – the most powerful tech event in the world. CTA is the trade association representing more than 1200 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA's Health Division advances consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. The Division includes telehealth providers, personal health wearable companies, digital health technology companies, healthcare payers, health systems, and biopharmaceutical innovators. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and more – and they are poised to lead the next wave of American innovation with cutting-edge health technology.

Specific Responses

1. *Strategic Architecture*
    a. *Foundational themes (e.g., Data Readiness, Trust, Translation, Workforce) and pillars that should anchor the plan.*

As the NIH builds out a comprehensive AI strategy, CTA encourages the incorporation of fundamentals that have already been advanced by industry. CTA is an American National Standards Institute (ANSI) accredited standards development organization and along with our members and partners, have helped advance the use of technology in healthcare by driving industry consensus on issues we believe should be foundational themes of a comprehensive AI strategy. To date, CTA's Artificial Intelligence Committee has developed several health AI standards, including:

- [Definitions/Characteristics of Artificial Intelligence in Health Care (ANSI/CTA-2089.1)](#)
- [The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)](#)
- [The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)](#)

CTA continues to focus on developing additional industry standards to advance the adoption of health AI, to include current work underway on verification and validation for pre-market/pre-release and operations and monitoring for post-market/post-release application for predictive health AI.

As the NIH considers deploying AI for its own use, CTA encourages direct engagement with and use of industry-developed consensus-based standards that touch on critical and foundational issues such as trustworthiness and safeguarding and managing data.

6. *Reproducibility & Trust*
    a. *Community-driven standards, audit trails, or other approaches that can facilitate reproducibility and enhance transparency as well as trust across the AI life cycle.*

Trust

CTA standard [The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)](#) identifies three major expressions of how trust is created and maintained: Human Trust, Technical Trust, and Regulatory Trust. Human Trust focuses on fostering humanistic factors that affect the creation and maintenance of trust between the developer and the user. In other words, a product that is difficult to use may affect the ability to trust the outputs. Technical Trust focuses on the technical execution of the design and training of AI systems to deliver as expected. Finally, the principles of Human and Technical trust are embodied in law and regulations intended to prevent potential harm to the end user. The compliance and enforcement of the law and regulations by institutions are required to foster Regulatory Trust. Systemic trust is a positive side effect of designing AI systems with an understanding of and attempt to balance the circular nature of these concepts.

- Human Trust: ANSI/CTA 2090 calls for the following considerations to support Human Trust of AI:
    o Ensuring that the AI is appropriate for all intended users.
    o Understanding the extent to which humans verify the decisions made using AI.
    o Ensuring that safety mechanisms for AI features (including interface) are present
    o Identification of additional instructions and information on what and how data developed by the AI is shared to include readily accessible opt-in/out features.

    o ANSI/CTA 2090 also calls for specific considerations and requirements of explainability, user experience, and transparency to the levels of autonomy of the AI to support Human Trust.

- Technical Trust: ANSI/CTA 2090 calls for considerations and requirements related to the following elements support Technical Trust:
  - Data Quality & Integrity
  - Bias
  - Data Security
  - Privacy
  - Source
  - Access to Data

While the considerations and requirements related to Regulatory Trust are more aimed towards developers of AI, CTA does encourage the NIH to consider regulatory coordination with other health agencies, such as the Centers for Medicare & Medicaid Services (CMS) and the Food & Drug Administration (FDA), as to not undermine regulatory certainty for companies developing health AI tools.

Conclusion

In the global race for AI-driven biomedical progress, the United States must move confidently and decisively. NIH has the chance to become the flagship for ethical, high-impact health AI – setting the standards, defining the path and delivering results for the American people. CTA looks forward to supporting your efforts as a committed partner in shaping an AI strategy that makes the United States the undisputed global leader in lifesaving, life-extending and life-enhancing innovation.

Sincerely,

René Quashie
Vice President, Digital Health
Consumer Technology Association