

July 15, 2025

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

The Radiological Society of North America (RSNA) appreciates the opportunity to provide comments in response to the National Institutes of Health (NIH) Request for Information (RFI): Inviting Comments on the NIH AI Strategy (NOT-OD-25-117).

As the leading global organization representing over 52,000 medical imaging professionals across 150 countries, RSNA plays a central role in advancing AI-driven innovation in healthcare. RSNA hosts the world's largest and most influential radiology conference each November in Chicago, Illinois, drawing tens of thousands of radiologists, researchers, and industry leaders from around the globe. This premier event serves as the definitive forum for showcasing cutting-edge AI applications in medical imaging, facilitating interdisciplinary collaboration, and fostering public-private partnerships that drive healthcare innovation.

Radiology and medical imaging are among the most data-intensive fields in medicine, and AI-driven technologies have already begun transforming clinical practice. Radiology has experienced the highest rate of AI tool development and deployment, with more than 76% of the over 1000 FDA-cleared AI algorithms designed for radiological applications. AI has the potential to significantly enhance diagnostic accuracy, streamline workflows, and improve patient outcomes. However, for these benefits to be fully realized, it is essential to strike a balance between fostering innovation and ensuring that regulatory oversight does not become overly burdensome while ensuring patient safety. RSNA supports policies that encourage AI adoption while allowing for necessary flexibility and efficiency in the regulatory process. As the world's premier biomedical research organization, the NIH is uniquely positioned to catalyze responsible AI innovation, foster public trust and fairness, and advance the integration of AI in clinical practice for the benefit of all patients.

Key Considerations for NIH's AI Strategic Plan:

Strategic Architecture

- *Modernize NIH Imaging Infrastructure*
 - The current imaging infrastructure, particularly at the National Cancer Institute (NCI), is fragmented and inefficient. It barely supports the clinical trials of today and is not equipped for the demands of tomorrow. There is currently no mechanism to integrate image annotation or AI models into standard imaging review workflows. NIH should prioritize investment in scalable, interoperable systems that support advanced imaging needs in clinical trials.

BOARD OF DIRECTORS | RSNA 2025 | 111TH ANNUAL MEETING | NOV. 30-DEC. 4, CHICAGO

Umar Mahmood, MD, PhD, *President*
Jeffrey S. Klein, MD, *Chair of the Board*
Carolyn C. Meltzer, MD, *Secretary-Treasurer*

Sanjeev Bhalla, MD
Anne M. Covey, MD
Adam E. Flanders, MD
Pari V. Pandharipande, MD, MPH

Tina Y. Poussaint, MD
Cynthia S. Santillan, MD
Jorge A. Soto, MD
Mark G. Watson, *Executive Director*

- *Fund Development of Large, Annotated Datasets*
 - NIH should support the creation of high-quality, and well-annotated imaging datasets across disease types and patient populations. These datasets are essential for developing and validating generalizable AI models and for reducing bias in clinical applications.
- *Create Sustainable Data Infrastructure for Research Imaging*
 - As medical imaging datasets grow in size and complexity, NIH investment is critical to reducing barriers in data engineering and access. While existing repositories like the Cancer Imaging Archive are valuable, they fall short on current research needs. NIH should fund secure, modern infrastructure—such as centrally hosted, metadata rich “sandboxes” that support storage, computation, and collaboration. By allowing researchers to work with extremely large datasets more efficiently, these platforms would accelerate reproducible AI research without the need to move massive data volumes.
- *Support De-identification Standards and Tools*
 - NIH should fund scalable anonymization pipelines and develop standards for de-identification that reduce the burden on participating sites while preserving essential metadata. Building upon tools such as RSNA’s Clinical Trials Processor could serve as a foundation.
- *Implement Prospective QA and Real-Time Feedback Infrastructure*
 - Most imaging quality assurance in clinical trials is retrospective, which limits the ability to intervene when problems occur. NIH should invest in prospective QA tools, including automated validation of imaging parameters during acquisition and real-time detection of technical issues.

Research & Innovation Actions

Advancing AI Innovation through Targeted Research and Development: AI’s success in healthcare depends on a strong foundation of research and implementation support. While many AI tools are technically sound, radiologists often encounter challenges when integrating these tools into real-world clinical workflows. NIH is well positioned to bridge this gap by investing in research and infrastructure that improves the usability, effectiveness, and adoption of AI across a variety of healthcare settings.

RSNA recommends that the NIH prioritize:

- Foundational research to develop optimized AI algorithms capable of addressing a broad spectrum of diseases and conditions.
- Implementation science research to evaluate AI’s effect on efficiency, safety, diagnostic performance, workflow dynamics, and patient and provider behavior.
- Translational research to refine AI integration into clinical workflows while maintaining efficiency, quality, and safety.
- Human-AI teaming studies to characterize optimal interaction models between radiologists, referring clinicians, and AI tools.
- Expansion of data and reporting standards to enhance interoperability and support comprehensive AI performance tracking.
- Research on how to best integrate AI into existing imaging reporting systems, electronic health records, and clinical decision support platforms.

Facilitating & Validating AI in Healthcare Delivery; Reproducibility & Trust

Fostering Trust Through Robust Validation and Transparency: AI adoption in radiology and the broader healthcare ecosystem hinges on trust—among clinicians, patients, and regulatory bodies. To cultivate this trust, post-deployment monitoring of AI tools must be standardized, with clear mechanisms for evaluating real-world performance and safety. RSNA urges NIH to include provisions in its Strategic Plan that:

- Support ongoing validation studies of AI models in different clinical settings and new multicenter, prospective validation trials using real-world imaging data across varied populations, medical imaging devices, and healthcare settings/institutions.
- Support research and development (R&D) and implementation efforts to develop and deploy AI systems that are explainable and interpretable by both healthcare professionals and patients.
- Support the creation and maintenance of AI benchmark frameworks. Ongoing support for public challenge datasets and hidden test partitions will drive transparent comparison and reproducible reporting.
- Encourage collaboration between research agencies, regulatory agencies, professional societies, and healthcare institutions to ensure continuous oversight that prioritizes transparent reporting that ensures AI efficacy and safety, while avoiding unnecessary bureaucratic hurdles.

Partnerships & Ecosystem Building

Addressing AI Education and Workforce Development Needs: As AI tools become increasingly embedded in clinical practice, equipping radiologists and other healthcare professionals with the necessary knowledge to critically evaluate, interpret, and utilize these technologies is paramount. RSNA encourages NIH to:

- Develop federally supported AI literacy programs tailored for healthcare professionals.
- Collaborate with professional societies to implement standardized training and certification pathways for AI competency in medicine.
- Support ongoing education initiatives to ensure that providers and patients understand the implications of AI integration in care delivery.

Reducing Barriers to AI Adoption through Smart Regulation and Industry Collaboration: AI has the potential to improve efficiency and quality of care, but its successful implementation requires a regulatory approach that encourages—not stifles—innovation. RSNA encourages NIH to collaborate with the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy (ASTP) to:

- Ensure support for regulatory science research that equips federal, state, and local regulatory entities with cutting-edge information needed to develop a regulatory approach that encourages innovation while protecting patient safety.
- Streamline regulatory pathways to accelerate AI approvals while maintaining high safety and performance standards.
- Foster partnerships between industry, academia, and government to ensure AI tools reach the clinical environment swiftly.
- Ensure that AI regulation is adaptable to the fast-evolving nature of AI technologies, avoiding excessive red tape that could slow progress.

Strengthening Public-Private Partnerships for AI Development and Deployment: RSNA has a long history of spearheading initiatives that drive technological progress in medical imaging. We stand ready to collaborate with NIH and federal stakeholders to advance AI-enabled innovation. RSNA's contributions to AI development include:

- Leading the adoption of DICOM imaging standards in the early 1990s, accelerating the digitization of radiology.
Supporting the Integrating the Healthcare Enterprise (IHE) initiative to improve interoperability between diagnostic systems and electronic health records.
- Developing foundational semantic standards, such as RadLex (<https://radlex.org/>) and RadElement (<https://radelement.org/>), that enhance machine readability of medical imaging data.
- Organizing AI challenge competitions since 2017, attracting global researchers to develop and validate AI algorithms for disease detection and classification.
- Collecting, processing and annotating large medical imaging datasets for AI challenges and research (<https://mira.rsna.org/>).
- Helping organize and supplying data to the Medical Imaging Data Resource Center (MIDRC - www.midrc.org), which aggregates and annotates medical imaging data for AI research and validation.

RSNA appreciates the opportunity to provide comments regarding NIH's AI Strategic Plan. We value the NIH's leadership in accelerating R&D and translation of AI discoveries to improve patient care. Radiologists are deeply invested in developing AI that is accurate, trustworthy, fair, and clinically impactful. RSNA stands ready to support the NIH as the agency develops its AI Strategic Plan and is prepared to serve in an advisory capacity, collaborate on data-sharing initiatives, and facilitate AI research and education through our established programs. We urge NIH to adopt an integrated approach to AI research and education that fosters innovation while ensuring patient safety.

Sincerely,



Jeffrey Klein, MD
Chair of the Board
Radiological Society of North America