HHS AI Strategy + Real-World Debate on AI in Health Care: What Researchers Should Know

The U.S. Department of Health and Human Services (HHS) has released a national **Artificial Intelligence (AI) Strategy** to guide how AI is used across health care, public health, and medical research. The strategy aims to modernize government operations, improve services, and accelerate innovation—all while using AI responsibly to benefit patients and the public. It promotes a unified OneHHS approach to governance, infrastructure, workforce development, research quality, and better health outcomes.

The framework centers on five pillars:

1. Strong governance and risk management
2. User-focused infrastructure
3. Workforce development and burden reduction
4. High-quality, reproducible science
5. Modernized care and public health delivery

Alongside the strategy, HHS published an **AI Compliance Plan** to meet federal requirements for safe, transparent, and trustworthy AI use. The plan focuses on building public trust, reducing barriers to innovation, and strengthening oversight across the Department.

Why this matters for medical research:
The AI Strategy highlights reproducibility, scientific standards, and governance—issues central to rigorous clinical and translational research. The emphasis on safe, effective, and equitable use of AI tools signals that federally supported studies will increasingly need to consider documentation, validation, bias monitoring, and post-deployment evaluation in AI research workflows.

AI Is Already Rushing into Health Care — And Regulation Isn't Keeping Up

A *Harvard Gazette* article highlights how AI is spreading rapidly across clinical settings and raises questions about **who should regulate it**. Experts note:

- AI tools range from administrative supports to clinical decision aids and patient-facing chatbots.

- Most medical AI currently isn't reviewed by federal regulators (e.g., FDA), leaving individual hospitals to validate and monitor systems on their own. This creates **uneven oversight** and can be **expensive and burdensome**, especially for smaller or rural hospitals.

The article also points out that:

- Rapid innovation can outpace thoughtful regulation, risking ethical issues and bias.
- Current guidelines from accrediting bodies are a start but may put too much onus on individual facilities.
- There's a broader debate about whether government agencies, accreditation organizations, or a mix of both should set standards and enforce them.

Why this matters for research:
Medical research increasingly overlaps with AI deployment in the real world. Studies that develop or evaluate AI tools (e.g., diagnostic algorithms, predictive models, natural language systems) must grapple with:

Regulatory uncertainty: Lack of clear rules affects study design, approval pathways, and translation into clinical use.

Implementation variability: AI performance may differ across settings (large academic centers versus smaller clinics), creating challenges for generalizability and equity.

Ethical concerns**:** Bias, informed consent, transparency, and public trust are not just regulatory talking points—they are scientific and ethical research issues.

What This Means for You as a Researcher

- **Expect evolving expectations around AI validation, monitoring, and governance** in funded research proposals and publications.
- **Consider regulatory context early** in study design, especially for tools intended for clinical decision support or patient interaction.
- **Build in equity and bias evaluation plans**—these are likely to be central to how AI tools are judged scientifically and ethically.
- **Engage in public and policy discussions** (like the HHS request for information on AI in clinical care) to help shape how research evidence is used in regulation.

Public Input Requested on AI in Clinical Care

HHS is asking for public input on how AI should be adopted and used in clinical care. Through a **Request for Information (RFI),** the Department is seeking feedback to guide future policies related to regulation, reimbursement, and research and development.

Researchers, developers, clinicians, and patients are encouraged to share real-world experiences—both successes and challenges—with AI tools used in clinical settings. Input from the research community can help shape how AI-enabled interventions are studied, evaluated, and integrated into care. The public comment period is open for 60 days from the date the notice was issued (2/23/2026).