

NOSI AI Supplement PI Meeting NIH Data Science Strategic Plan Overview

Dr. Susan Gregurick, Associate Director For Data Science, NIH 27 March 2024 Progress is accelerated when advanced scientific methods, such as new data analytics, are applied to data that includes everyone, and when new discoveries are rapidly and equitably adopted in clinical care.



Current Challenges in Data Science



Need for the generation of FAIR data in a manner that fosters greater sharing and integration of scientific results



Need for cost effective strategies for sustainable, secure, and accessible biomedical data repositories and knowledgebases



Need for acquisition and protection of data obtained from electronic health records and other real-world data that preserves privacy and enhances participant consent



Emergence of innovations in trustable artificial intelligence (AI) approaches that reduces bias and risks



Creating opportunities to explore new technologies and computing paradigms for biomedical research



Addressing disparities across institutions and regions in data science

Data Science in the next 5 years

- Improve Capabilities to Sustain the NIH Policy for Data Management and Sharing
- Develop Programs to Enhance Human Derived Data for Research
- Provide New Opportunities in Software, Computational Methods, and Artificial Intelligence
- Support for a Federated Biomedical Research Data Infrastructure
- **Strengthen a Broad Community in Data Science**

Capabilities to Sustain the NIH Data Management and Sharing Policy

Challenges

- Need for the generation of FAIR Data in a manner that will foster greater sharing and the integration of scientific results
- Need for cost effective strategies for sustainable, secure, and accessible biomedical data repositories and knowledgebases

Objectives to Address Challenges

Support the biomedical community to manage and share data
 Enhance FAIR data and greater data harmonization
 Strengthen NIH's data repository and knowledgebase ecosystem

Enhance Human Derived Data for Research

Challenges

- Need for acquisition and protection of data obtained from electronic health records, and other real-world data, that preserves privacy and enhances participant consent
- challenges in data quality, privacy and confidentiality, policy, regulatory, and ethical issues associated with healthcare and administrative data
- need to better understand the ethical, legal, and social implications of data linkage

Objectives to Address Challenges

- 1) Improve access to and use of clinical and real-world data
- 2) Adopt health IT standards for research
- 3) Enhance the adoption of social and environmental determinants of health for health equity

Interoperability with Human-derived Data

• Data exchange standards:

Fast Healthcare Interoperability Resources (FHIR®): a standards-based application programming interfaces (APIs) to facilitate health data collection and exchange across different health systems

Promotes the development of **patient-centric mobile health applications** or devices in the context of clinical research, as well as **clinical decision support**

Common data elements (CDE): standardized, precisely defined questions paired with a set of specific allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection

U.S. Core Data for Interoperability (USCDI): ONC requirements for healthcare data

Request for Information: Common Data Elements (CDEs)

NIH is soliciting public input on

- A set of minimum core CDEs;
- Additional CDEs for social determinants of health (SDoH) and clinical domains including autoimmune diseases and immune-mediated diseases;
- Technologies, tools and policies that could facilitate the use of NIH CDEs.

Due Date: April 20, 2024.





Read the RFI here: https://bit.ly/3T3Q3U3

Support for a Federated Biomedical Research Data Infrastructure

Challenges

• Creation of opportunities for exploration of new technologies and computing paradigms for biomedical research

Objectives to Address Challenges

- 1) Develop, test, validate, and implement ways to integrate NIH data and infrastructure
- 2) Ensure a robust and connected data resource ecosystem that includes collaborative data management platforms, curation, analysis, and sharing of data and metadata
- 3) Develop new capabilities for data search and discovery

Strengthen a Broader Community in Data Science

Challenges

• Develop and nurture data science talent from a diverse array of scientific interests and institutions

Objectives to Address Challenges

- 1) Increase training opportunities in data science
- 2) Develop and advance initiatives to expand the data science workforce
- 3) Broaden and champion capacity building and community engagement efforts
- 4) Enhancing data science collaboration within the NIH Intramural Research Program

Training, Workforce, and Community Engagement in FY23



New Opportunities in Software, Computational Methods, and AI

Challenges

- Emergence of innovations in trustable artificial intelligence (AI) approaches that reduces bias and risks
- Multi-dimensional data integration remains a significant challenge for biomedical and behavioral research

Objectives to Address Challenges

New opportunities to improve biomedical AI analysis
 Develop cutting edge software technologies
 Support FAIR software sustainability

Top Medical AI Procedures and Adoption





Example product: HeartFlow Analysis







Example product: LuminetricsCore





Example product:

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Example product: Perspectum LiverMultiScan



- Human–AI collaboration enables empathic conversations on mental health
- Use of GPT4 to Diagnose Complex Clinical Cases
- Characterizing the Clinical Adoption of Medical AI Devices through U.S. Insurance Claims

NEJM AI 2023; 1 (1) DOI: 10.1056/Aloa230003

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Accelerating Trustworthy Al

NATIONAL ARTIFICIAL INTELLIGENCE INITIATIVE

ADVANCING TRUSTWORTHY AI

Trustworthy AI (TAI) Playbook



U.S. Department of Health and Human Services Artificial Intelligence (AI) Strategy January 2021

https://www.ai.gov/strate gic-pillars/advancingtrustworthy-ai/

OVERSEEING AND IMPLEMENTING THE UNITED STATES NATIO



Promoting the Use of Trustworthy Artificial Intel Federal Government

A Presidential Document by the Executive Office of the President on 12/08/2020

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

OCTOBER 30, 2023

BRIEFING ROOM > PRESIDENTIAL ACTIONS

https://www.federalregister.gov/documents/2020/12/08/2020-27065/promotingthe-use-of-trustworthy-artificial-intelligence-in-the-federal-government

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https://www.hhs.gov/sites/default/files/hhsai-strategy.pdf

https://www.hhs.gov/sites/default/files/hhstrustworthy-ai-playbook.pdf

Blueprint for an AI Bill of Rights

I I OSTP

Man mong the great childinges posed to democracy today is the technology, data, and automated systems in ways that the rights of the American public. Too often, these tools are us limit our opportunities and prevent our access to critical resources on services. These problems are well documented, I.a. America and arous world, esstems supeosed to help with patient care have proven unsafe Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan January 2021

A U.S. FOOD & DRUG



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Goals of the Executive Order on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence



EO limplementation timeline

		90 days: 1/30/2024	180 days: 4/30/2024	365 days: 10/30/20	24
Objectives	Actions				
Establish Policies on Al in Health and Human Services	Establish Al Taskforce			ſ	
	Publish plan addressing use of automated and algorithmic systems in public benefits administration				
	 Develop strategic plan that includes policies and frameworks on responsible use of AI in healthcare and human services 				 HHS EO obligations will be met throughout
Advance Quality and Safety of Al in Health	Develop framework and strategy for quality assurance of Al–enabled technologies used in healthcare			•	process HHS AI Task Force will brief senior
	Develop framework and strategy to regulate use of AI in drug-development process (FDA)				leadership every three months
	Establish AI safety program (AHRQ)				 Note: Resource needs to execute plan not vet met:
Leverage Grantmaking to advance Al use	 Identify and prioritize grantmaking and other awards to support responsible AI development and use 				ability to meet ambitions will be
	Execute novel funding opportunities to advance responsible AI use (All Opdivs/StaffDIvs)				directly impacted by investment
Promote compliance with non- discrimination and privacy laws	Provide technical assistance on compliance with				levels
	Federal non-discrimination and privacy laws as it relates to use of AI in healthcare				
	 Issue guidance in response to complaints or reports of non-compliance with Federal nondiscrimination and privacy laws as they relate to AI 				

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence



Promoting responsible innovation, competition, and collaboration, includes **investments in AI-related education, training**, **development, research, and capacity,** while simultaneously tackling novel intellectual property (IP) questions and other problems to protect inventors and creators.



Establish a program to identify and **attract top talent in AI**, and other critical and emerging technologies, at universities, research institutions, and the private sector overseas and expedited adjudication of visa petitions and applications for overseas talent.



Launch a pilot program implementing the National AI Research Resource (NAIRR).



Support **2024 Leading Edge Acceleration Project** cooperative agreement awards to improve healthcare-data quality, support the responsible development of AI tools for clinical care, real-world-evidence programs, population health, public health, and related research.



Accelerate the National Institutes of Health Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program and showcasing current AIM-AHEAD activities in underserved communities.

HHS AI Task Force will:



Establish policies to both harness the potential and manage the risks of AI through the safe, equitable, responsible, and eth ical adoption and use of AI in health and human services



Advance Quality and Safety of AI in health through assurance standards and quality management processes



HHS will evaluate and deploy its policy and funding tools (e.g., grantmaking, contracting) as appropriate to advance and manage risk in the safe, equitable, responsible, and ethical development and use of AI across the health and human services delivery value chain



Provide public education across the healthcare ecosystem and constituents – from individuals to organizations and states – on AI development and use in health and human services delivery



Where AI offers the opportunity to accelerate the advancement of HHS' mission and the tools meet the Department's quality and equity standards, deploy and evaluate AI capabilities across HHS to drive process innovation and modernization

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White House. Fact Sheet: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence.

Accessed at: <u>https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/</u>

Core Team and Project Management Office

- Support Task Force (TF), including both Steering **Committee and Work Groups**
- Ensure internal accountability and drive progress
- Function as connective tissue. both across USG and with industry



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Examples of Progress

- **<u>Bridge2AI</u>** to generate new "flagship" datasets and best practices for machine learning analysis.
- <u>AIM-AHEAD</u> to enhance participation of underrepresented communities in AI/ML research.
- <u>ScHARe</u> to test AI bias mitigation strategies and to advance health disparities research.
- **DEMONSTRATE** to guide healthcare providers and systems in safe opioid prescribing.
- <u>CARD</u> to extract insights on disease risk and protective factors from large networks of data
- **Improved operations in health** through developing AI computation tools to improve screening



Support for AI-Enabled research

- Validation of Digital Health and Artificial Intelligence Tools for Improved Assessment in Epidemiological, Clinical, and Intervention Research (NOT-CA-24-031)
- Explainable Artificial Intelligence for Decoding and Modulating Neural Circuit Activity Linked to Behavior (NOT-MH-23-110)
- Advancing Data Science Research in HIV: Responding to a Dynamic, Complex, and Evolving HIV Epidemic with Artificial Intelligence/Machine Learning (NOT-MH-23-350)
- Advanced Computational Approaches to Elucidate Disease Pathology and Identify Novel Therapeutics for Addiction (NOT-DA-21-004)
- Harnessing Artificial Intelligence and Polypharmacology to Discover Pharmacotherapeutics for Substance Use Disorders (<u>RFA-DA-25-054 R43/R44</u>, <u>NOT-CA-24-031</u>, and <u>RFA-DA-25-053 R41/R42</u>)

NIH NIH Contributions to the NAIRR Pilot

Governance	 Experience developing and overseeing federated interoperability
NAIRR Open	 Integration of <u>ImmPort</u> datasets into the NAIRR Integration of Health Equity Action Network (HEAN) datasets and <u>ScHARE</u> analysis tools into the NAIRR
NAIRR Secure	 Integration of the Medical Imaging and Data Resource Center (<u>MIDRC</u>) and National COVID Cohort Collaborative (<u>N3C</u>) into NAIRR Secure.
Software Stack	 Coordinate with NSF and DOE a NAIRR software stack community workshop.
Classroom	 NIH Cloudlab and other platform tools leveraged in NAIRR
Outreach	 Leverage NIH networks to attract diverse users and data.

NIH Data and Computational Infrastructure Ecosystem



STRIDES / CloudLab





N3C: Translating Health Data Into Health Solutions



MEDICAL IMAGING AND DATA RESOURCE CENTER

New Opportunities in Artificial Intelligence Next 5 Years

The activities below will introduce new opportunities to support collaborations in developing socio-technical solutions, including guidelines and principles, for ethical AI, including new technologies and methods for foundational models.



- **Develop** social and technical solutions for ethical AI
- **Create** and validate an approach for using synthetic clinical datasets for AI
- Leverage new technologies and methods for AI and foundational models to accelerate biomedical and behavioral research
- \mathbf{P} **Develop** new AI technologies that will enable the translation of data to knowledge
- **Enhance** NIH capabilities in AI through partnerships across federal agencies and communities

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datascience.nih.gov

A modernized, integrated, FAIR biomedical data ecosystem

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Thank you for your time and attention