

# Demystifying AI Tools in Health Care: An Introduction for Federal Policymakers

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Thursday, September 19, 2024

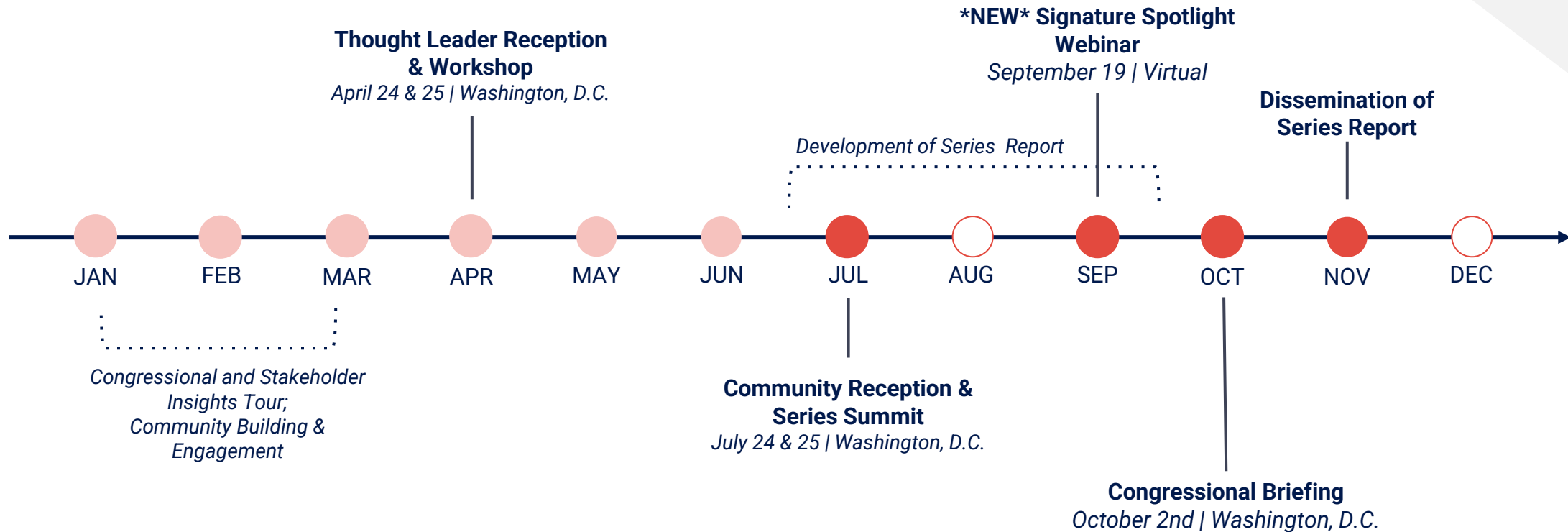


**Claire Sheahan, M.Sc.**  
President and CEO  
Alliance for Health Policy



# 2024 SERIES TIMELINE

## AI IN HEALTH – NAVIGATING NEW FRONTIERS



*\*All dates are TBC and subject to change*

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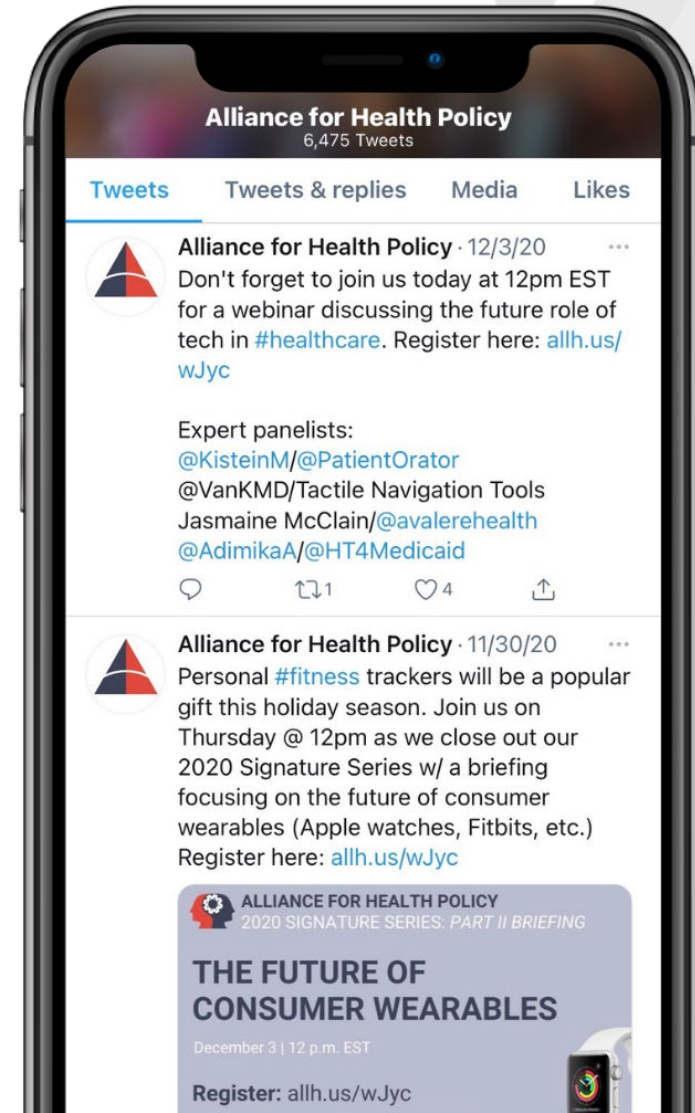
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# Artificial Intelligence (AI) Tools in Healthcare Let's Get Started!

**Lynn Shapiro Snyder, Senior Member**  
**Rachel Snyder Good, Strategic Counsel**

September 19, 2024

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- Legislative policy veterans with prior Capitol Hill experience
- Federal regulatory veterans with prior federal agency experience

# Presented by



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# Agenda



1. What do we need to know to get started?
2. What is AI and How is AI defined?
3. What are the current potential pitfalls and risks of AI Tool usage in health care?
4. What are the key considerations for policymakers, regulators and government end users of AI Tools?
5. How are key health care industry stakeholders responding to the impact of AI Tools?
6. Who is in responsible? Managing Enterprise Risk Through Robust Governance Frameworks



# What do we need to know to get started?

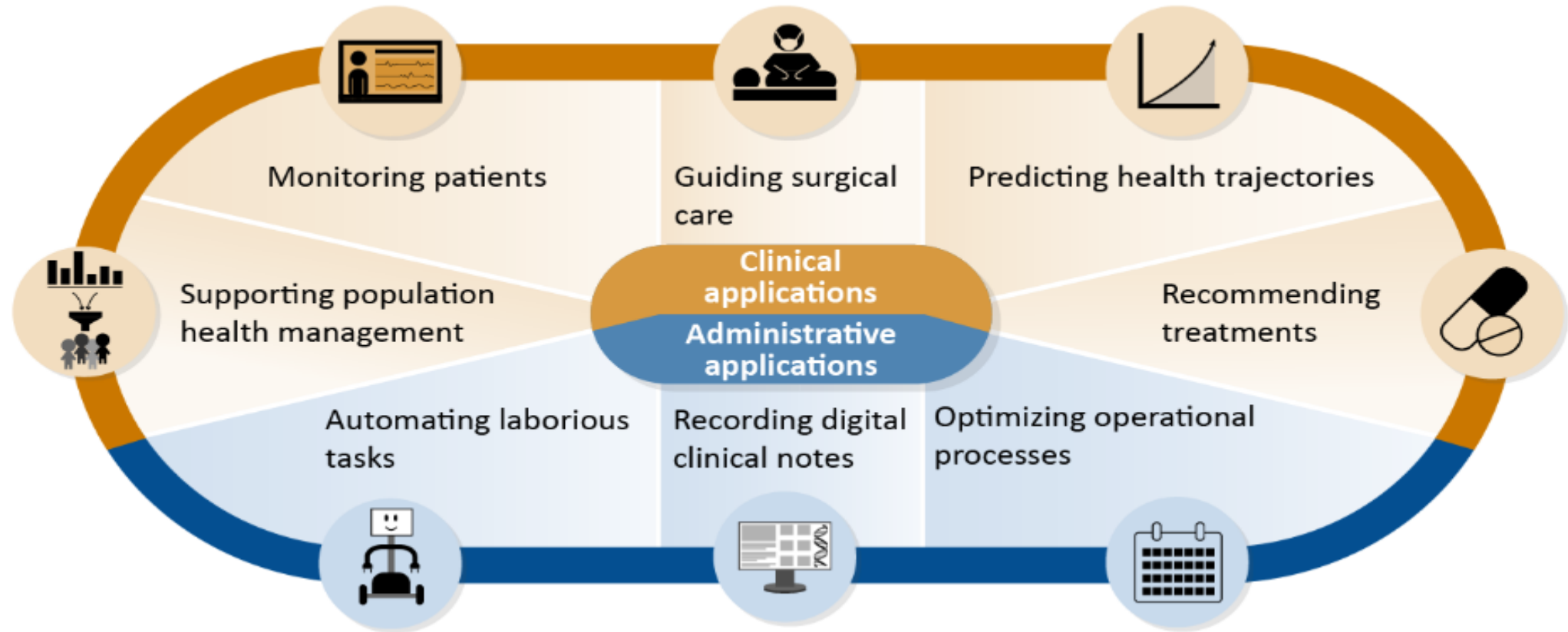
# Key Concepts

## Setting the Stage

- Clinical and Administrative Applications
- Existing Legal & Regulatory Landscape
- What are U.S. Policymakers generally concerned about when it comes to regulation of AI Tools?



# Setting the Stage: Clinical and Administrative Applications

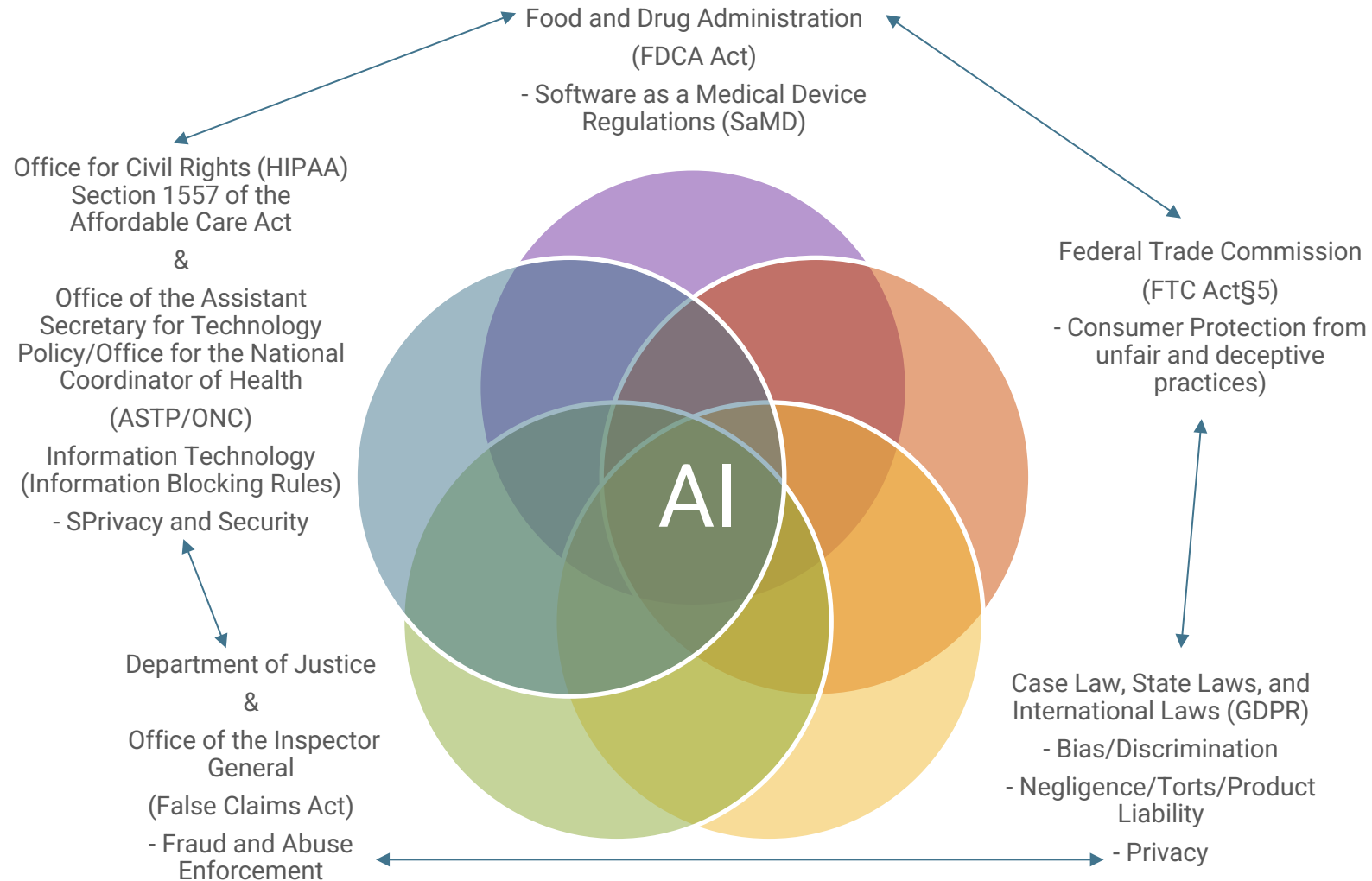


“Physicians who use AI will replace those who don’t.”

- Jesse Ehrenfeld, MD, President, AMA  
*Quoted in Politico*

*Source: Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care*  
Published: Nov 30, 2020.  
Publicly Released: Nov 30, 2020.  
GAO-21-7SP

# Setting the Stage: Existing Legal & Regulatory Landscape



# Setting the Stage: What are U.S. Policymakers generally concerned about when it comes to regulation of AI Tools?

**Bias**

**Accuracy**

**National Security**

**Data Privacy**

**Fairness/  
Barriers to entry**

**Algorithmic  
Transparency**

**Disruptive impacts to  
the Workforce**

**Adequacy of U.S.  
Expertise and  
Training in AI**

**Domestic and  
International efforts  
that would establish  
standards and testing  
benchmarks**

**The level of U.S.  
Federal investment in  
research and  
development**

**Impact on U.S.  
International  
Competitiveness**

**Limited supply of  
computational  
resources**



# What is AI and How is AI defined?

# Key Concepts

## Definitions

- Federal Government and Statutory Definitions
- Historical Overview - How did we get here?
- Key Terminology
- Where does the data come from?

# Current Federal Government and Statutory Definitions

Artificial intelligence (AI) enables computer systems to perform tasks normally requiring human intelligence - for example, recognizing patterns, learning from experience, drawing conclusions, making predictions, etc.

HRSA, HHS.gov



The term “artificial intelligence” means a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to—

- (A) perceive real and virtual environments;
- (B) abstract such perceptions into models through analysis in an automated manner; and
- (C) use model inference to formulate options for information or action.

15 USC 9401(3).

# How Did We Get Here?

1950

The Turing Test

1955

“Artificial Intelligence”

1956

Logic Theorist

1966

ELIZA

1973

Lighthill Report

Mid-1970s

Society of Mind

1982-1990

FGCP

1997

Deep Blue vs. Kasparov

2011

Watson & Siri

2017

Google’s Transformer

2018

BERT & GPT

2020

GPT-3

2021

DALL-E

2022

ChatGPT

2023

GPT-4 & Microsoft chatbot

2024

Enterprise AI



# A Few Key Terms

- **Deep learning** – learning from the structure of data, rather than from one specific algorithm
- **Generative AI** – Artificial Intelligence capable of generating text, images, videos or other data using generative large language models often in response to prompts. GenAI learn the patterns through inputted data and generate new data that has similar characteristics.
- **Hyperparameter** – a variable outside the model that affects the way a model learns
- **Hallucination** – an incorrect answer from the AI
- **Large Language Model (LLM)** – model trained on large amounts of text

**Machine learning** – a subset of AI dealing with development of algorithms that help machines learn in response to new data, without being explicitly programmed

- **Supervised Learning** – algorithm learns from labeled datasets with human intervention
- **Unsupervised Learning** – algorithm learns from unlabeled data sets
- **Parameter** – a variable inside the model that affects the way the model learns
- **Static AI** – the algorithm is trained offline and used as-is
- **Test data** – data used to test that the model is doing what it's supposed to do
- **Training data** – the data used to train the machine learning algorithm

# Where Does the Data Come From?

- It depends... on the **tool**, on the **time period**, and on the **quality way** in which the tool was created
- See, for example, class actions filed in the Northern District of California against OpenAi, Meta, Alphabet (Google's parent), and Microsoft
  - A.T. et al. v. OpenAI LP, et al., 3:23-cv-04557, filed 9/5/2023
  - Chabon et al. v. Meta Platforms, Inc., 3:23-cv-04663, filed 9/12/2023
  - P.M. et al. v. OpenAI LP, et al., 3:23-cv-03199, filed 6/28/2023
  - Silverman et al. v. OpenAI Inc., et al., 3:23-cv-03416, filed 7/27/2023
  - J.L. et al. v. Alphabet Inc. et al., 3:23-cv-03440, filed 7/11/2023

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*Counsel for Plaintiffs and the Proposed Classes*

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

PLAINTIFFS MARILYN COUSART;  
NICHOLAS GUILAK; PAUL MARTIN;  
BREONNA ROBERTS; CAROLINA BARCOS;  
JAIR PAZ; ALESSANDRO DE LA TORRE;  
VLADISSLAV VASSILEV; SEAN  
ALEXANDER JOHNSON; JENISE MCNEAL;  
N.B, a minor; LORENA MARTINEZ; JOHN  
HAGAN, individually, and on behalf of all others  
similarly situated,

Plaintiffs,

vs.

OPENAI LP; OPENAI INCORPORATED;  
OPENAI GP, LLC; OPENAI STARTUP FUND  
I, LP; OPENAI STARTUP FUND GP I, LLC;  
OPENAI STARTUP FUND MANAGEMENT  
LLC; MICROSOFT CORPORATION and DOES  
1 through 20, inclusive,

Defendants.

Case No.: 23-cv-04557-VC

**CLASS ACTION COMPLAINT**

1. VIOLATION OF ELECTRONIC COMMUNICATIONS PRIVACY ACT, 18 U.S.C. §§ 2510, *et seq.*
2. VIOLATION OF THE COMPREHENSIVE COMPUTER DATA ACCESS AND FRAUD ACT ("CDAFA"), CAL. PENAL CODE § 502, *et seq.*
3. VIOLATION OF THE CALIFORNIA INVASION OF PRIVACY ACT ("CIPA"), CAL. PENAL CODE § 631
4. VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW, BUSINESS AND PROFESSIONS CODE §§ 17200, *et seq.*
5. VIOLATION OF ILLINOIS'S BIOMETRIC INFORMATION PRIVACY ACT, 740 ILCS 14/1, *et seq.*



# What are the current potential pitfalls and risks of AI Tool usage in health care?

# Key Concepts

## Potential Pitfalls and Risks

- Overview of lawsuits
- Privacy and Data Security Risks
- Bias: Garbage In/Garbage Out

# Potential Pitfalls and Risks

## Litigation Risk



Insurers hit with lawsuits stemming from their use of AI Tools

Insurance providers contracted with subcontractors that use an AI Tool to approve and deny patient care. The insurers were using AI tools to minimize labor costs for processing insurance claims.

Class actions filed against Insurers allege defendants were aware AI Tools used to justify denials had very high error rates, denials weren't reviewed by clinicians, and policyholder appeal rates were very low.





# Potential Pitfalls and Risks

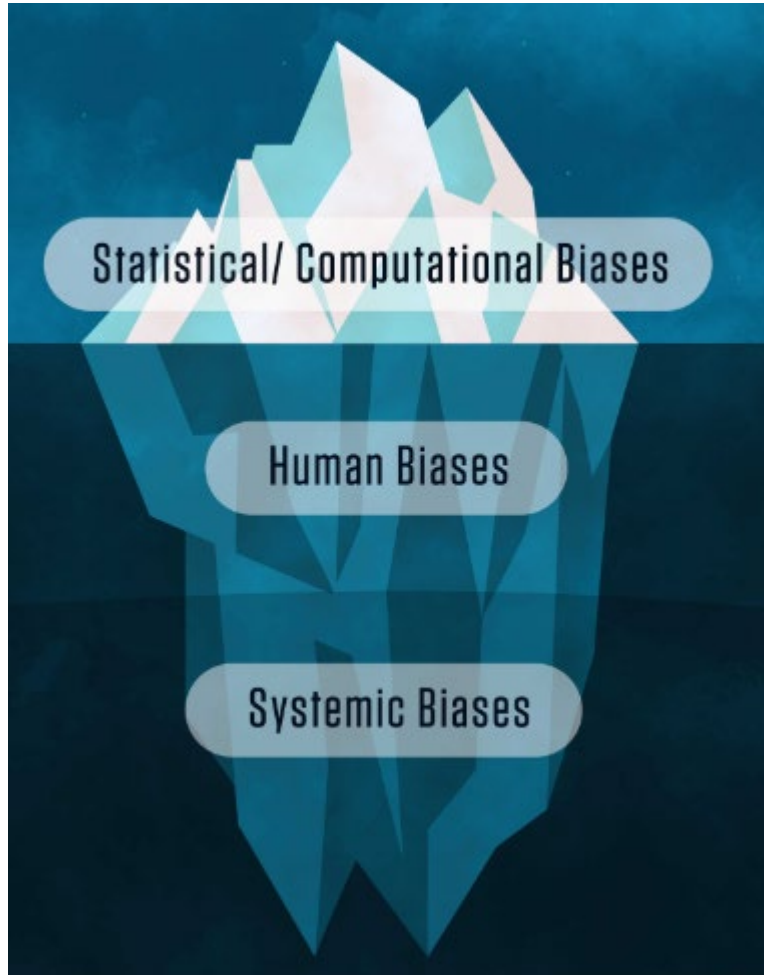
## Privacy and Data Security Risks

- **Data Rights and Intellectual Property:** Ensure adequate authority exists to use data to train AI, and then to own the resulting AI
- **AI Lifecycle: Cybersecurity Risk**
  - Unauthorized access and tampering with data integrity or AI functionality could negatively impact AI outputs
  - Ensure secure transfer and disposal of data
- **Bias: Garbage in-Garbage Out**
  - AI training hinges on quality inputs to produce reliable outputs with sufficient data integrity
  - Bias in AI training can lead to unreliable and potentially dangerous outputs



# Potential Pitfalls and Risks

## Bias: Garbage In, Garbage Out



- **Biased data**—computational and statistical sources of bias
  - Facial recognition that doesn't work as well with dark skin
  - Misrepresented scientific or medical prognoses
  - Distorted financial predictions for loan applicants
- **Human and systemic biases**
  - Companies and institutions operate in ways that disadvantage certain groups
  - A systemic bias may use a category of information to fill in missing information—such as substituting zip code for race

Source: NIST Special Publication 1270





# What are the key considerations for policymakers, regulators and government end users of AI Tools?

# Key Considerations

## Policymakers, Regulators and Government

- Key Ethical Principles
- White House Bill of Rights
- Congress
- White House Executive Order
- States
- Supreme Court

# Key Considerations

## World Health Organization (WHO)

- WHO Six key ethical principles for use of artificial intelligence for health
  1. Protect autonomy
  2. Promote human well-being, human safety and the public interest
  3. Ensure transparency, explainability and intelligibility
  4. Foster responsibility and accountability
  5. Ensure inclusiveness and equity
  6. Promote AI that is responsive and sustainable

# Recent Executive and Legislative Action to Regulate AI



October 2022

White House **Blueprint for an AI Bill of Rights**



June 2023

Senate **SAFE Innovation Framework For Artificial Intelligence**



October 2023

Biden Executive Order (EO) on **Safe, Secure, and Trustworthy Artificial Intelligence**



# White House AI Bill of Rights

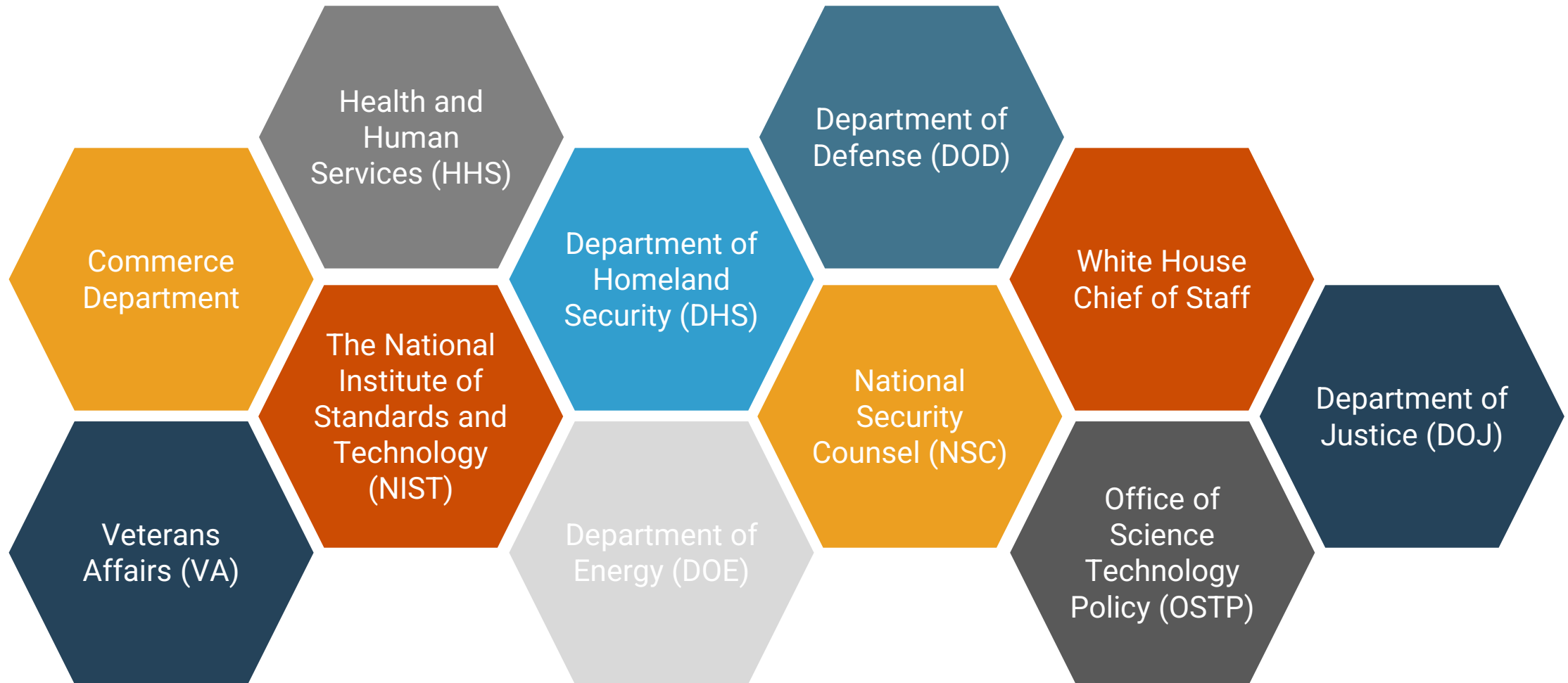
October 2022



- Safe and Effective Systems
- Algorithmic Discrimination Protections
- Data Privacy
- Notice and Explanation
- Human Alternatives, Consideration, and Fallback

<https://www.whitehouse.gov/ostp/ai-bill-of-rights/>

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



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

## Deadlines Created for Action



By April 27, 2024, HHS must consider what is required to advance Federal nondiscrimination laws by health and human services providers that receive Federal financial assistance.

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Independent regulatory agencies are encouraged to consider using their full range of authorities to clarify requirements and expectations related to the transparency of AI models and regulated entities' ability to explain their use of AI models.

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Within 60 days of the issuance each agency must designate a Chief Artificial Intelligence Officer to hold primary responsibility for their agency to coordinate their agency's use of AI, promote AI innovation in their agency, manage risks from their agency's use of AI



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

## Progress to date



HHS OCR Released final rule effective July 5, 2024, clarifying nondiscrimination requirements in health programs and activities as they apply to the use of AI, clinical algorithms, predictive analytics, and other tools.

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ONC (now the Assistant Secretary for Technology and Policy (ASTP)) released the HTI-1 final rule effective February 8, 2024, establishing first of its kind transparency requirements for AI and other predictive algorithms that are part of certified health IT.

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Assigned Chief Artificial Officers at each Federal Agency to hold primary responsibility – in coordination with other responsible officials- for coordinating their agency’s use of AI and promoting AI innovation in their agency.

# Senate Majority Leader Schumer SAFE Innovation Framework (2023) and Bipartisan Roadmap (2024)



- **Security:** Safeguard our national security with AI and determine how adversaries use it, and ensure economic security for workers by mitigating and responding to job loss;
- **Accountability:** Support the deployment of responsible systems to address concerns around misinformation and bias, support our creators by addressing copyright concerns, protect intellectual property, and address liability;
- **Foundations:** Require that AI systems align with our democratic values at their core, protect our elections, promote AI's societal benefits while avoiding the potential harms, and stop the Chinese Government from writing the rules of the road on AI;
- **Explain:** Determine what information the federal government needs from AI developers and deployers to be a better steward of the public good, and what information the public needs to know about an AI system, data, or content.
- **Innovation:** Support US-led innovation in AI technologies – including innovation in security, transparency and accountability – that focuses on unlocking the immense potential of AI and maintaining U.S. leadership in the technology.

# Congressional Themes Emerging in Legislation & Hearings

## Topics being debated in Congress

Regulating Federal Government use of AI	Disclosure, use in decision-making, federal employee training, etc.
National Security	Foreign use and regulation of AI, export controls for AI technology
Disclosure Requirements	Disclosure: from developer to deployer; developer/deployer to the public; developer/deployer to government
Prohibiting use of AI for certain applications	Surveillance, national security applications
Protecting against Bias in AI Decision-making	Especially for essential services like healthcare, housing, nutrition, etc.
Protecting Intellectual Property & Copyrights	High priority of artists, but all proprietary data is germane
AI Liability	Developer vs. deployer liability, who can take legal action
Election Security	E.g., AI can replicate the voice of elected officials from floor speeches
Fostering Innovation in America	Maintaining international competitiveness in an AI regulatory regime; promoting AI use for certain applications
Mitigating AI economic disruption	Mitigating job loss

# Highlighting Two AI Bills Pending in the 118<sup>th</sup> Congress

## Future of AI Innovation Act

- **Bipartisan/Passed out of Senate Commerce Committee July 31, 2024**
- **Authorizes the NIST AI Safety Institute to Develop AI Standards**
- **Creates New AI Testbeds with National Laboratories to Evaluate AI Models and Make Discoveries that Benefit the U.S. Economy**
- **Creates Grand Challenge Prize Competitions to Spur Private Sector AI Solutions and Innovation**
- **Accelerates AI Innovation with Publicly Available Datasets**
- **Creates International Alliances on AI Innovation and Standards**

## Protect Elections from Deceptive AI Act

- **Bipartisan/Reported out of Senate Committee on Rules and Administration May 15, 2024**
- **Would ban the use of artificial intelligence (AI) to generate materially deceptive content falsely depicting federal candidates in political ads to influence federal elections.**
- **Unanimous Consent request blocked by Senate Republicans**

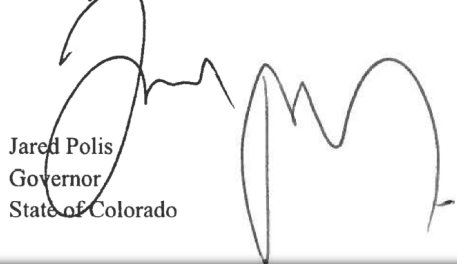
# What is happening in the States?

## ■ Colorado

- SB-24-205 - Passed
- The first state to pass a comprehensive [law](#) regulating artificial intelligence (AI) focusing on algorithmic discrimination. (implementation set for 2026)

I appreciate the goals of the sponsors to begin an important and overdue conversation to protect consumers from misunderstood and even nefarious practices in a burgeoning industry and the bipartisan efforts to bring this bill to me. However, I want to be clear in my goal of ensuring Colorado remains home to innovative technologies and our consumers are able to fully access important AI-based products. Should the federal government not preempt this with a needed cohesive federal approach, I encourage the General Assembly to work closely with stakeholders to craft future legislation for my signature that will amend this bill to conform with evidence based findings and recommendations for the regulation of this industry.

Sincerely,



Jared Polis  
Governor  
State of Colorado

CT, CO, CA and others are collaborating on fundamentals of AI legislation

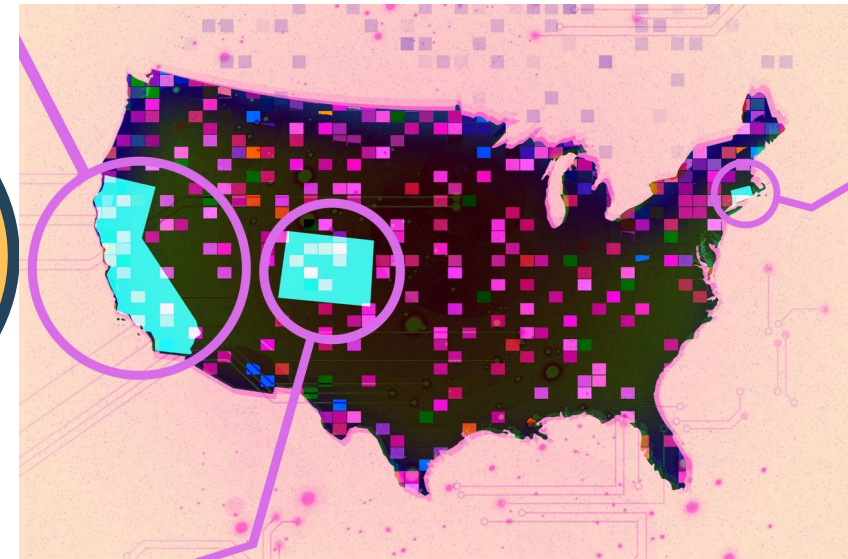


Illustration by Claudine Hellmuth/POLITICO (source images via iStock)

## Connecticut

SB-2 Failed to pass

Almost the first state to pass a comprehensive law regulating AI.

Had been working with Colorado.

Would have created new consumer protections for the use of generative AI and AI decision-making tech.



# Supreme Court Decisions and AI

## How Does the End of *Chevron* Deference Change the Relationship Between the Health Care Industry, Federal Regulators, and Congress?

### Key Takeaways

- Federal courts are no longer required to defer to federal agencies' reasonable regulatory interpretation of ambiguous federal statutes under the 1984 *Chevron*
- In this new *Loper* landscape, increased engagement at all points of the federal legislative and federal regulatory process is more important than ever, especially for those in the heavily regulated health care industry.

Categories: Health Care, HEAL<sup>®</sup>: Health Employment and Labor, Life Sciences  
Rachel Snyder Good, Philo D. Hall, Lynn Shapiro Snyder

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For example, Congress is currently working to determine how best to regulate artificial intelligence (AI). In May, after several AI Insight Forums with leaders from industry, government, and civil rights groups, Senate Majority Leader Charles Schumer and a group of bipartisan Senators released a [Bipartisan Roadmap for Artificial Intelligence Policy In The United States Senate](#). As lead *Loper* dissenter Justice Elena Kagan pointed out in oral arguments, AI will likely be the next "big piece of legislation on the horizon."

As Congress determines how to regulate AI, it will need to consider how best to delegate to the federal agencies any decision making where Congress lacks competencies. At EBG, our interdisciplinary [AI Working Group](#) is closely monitoring not just how Congress is approaching federal AI regulation, but also how the White House and federal agencies are regulating AI. We are particularly watching the use of existing statutes to regulate AI, as there will be increased scrutiny as to whether Congress could have contemplated regulating a technology like AI before generative AI was mainstream or in existence. With a heightened scrutiny of statutes that might have been used to regulate AI in the era of *Chevron* deference, we expect the decision in *Loper* to affect this dynamic and the way AI will be regulated.

AI is currently being used across the health care spectrum from patient care, to clinical decision support, to drug development, to billing, coding and reimbursement. How specific Congress is in delegating its legislative authority to implementing federal agencies will determine how AI regulation progresses.

It is important for the health care industry to understand this new dynamic not just for new legislative priorities, like AI, but also for existing federal statutes and proposed federal statutes.



# How are key health care industry stakeholders responding to the impact of AI Tools?

# Key Considerations

## Healthcare Industry Stakeholders

- Clinicians - American Medical Association (AMA)
- Academic Medical Centers and Tech Leaders – Coalition for Health AI (CHAI)
- State Regulators - Federation of State Medical Boards (FSMB)
- The Insurance Industry - National Association of Insurance Commissioners (NAIC)



# Response from Clinicians

## American Medical Association (AMA)

- [AMA to develop recommendations for augmented intelligence JUN 13, 2023](#)

“As augmented intelligence (AI) promises a new frontier in healthcare and medicine, the American Medical Association (AMA) is taking steps to advise on the immediate implications for the practice of medicine. Specifically, the AMA is encouraging better understanding of how AI may appropriately harness its vast potential to benefit patients – and decrease the administrative burden on physicians. At the Annual Meeting of the AMA House of Delegates, the nation’s physicians agreed to develop principles and recommendations on the benefits and unforeseen consequences of relying on AI-generated medical advice and content that may or may not be validated, accurate, or appropriate – and then advise policymakers to take action that will protect patients from misinformation.”

- [According to the AMA CPT Editorial Panel](#) the classification of AI medical services and procedures as assistive, augmentative or autonomous is based on the clinical procedure or service provided to the patient and the work performed by the machine on behalf of the physician or other qualified healthcare professional (QHP).
- **Assistive classification:** The work performed by the machine for the physician or other QHP is assistive when the machine **detects** clinically relevant data without analysis or generated conclusions. Requires physician or other QHP interpretation and report.

# Response from Clinicians (continued)

## American Medical Association (AMA)

- **Augmentative classification:** The work performed by the machine for the physician or other QHP is augmentative when the machine **analyzes** and/or **quantifies** data in a clinically meaningful way. Requires physician or other QHP interpretation and report.
  - **Artificial intelligence vs. augmented intelligence**
    - The AMA House of Delegates uses the term augmented intelligence (AI) as a conceptualization of artificial intelligence that focuses on AI's assistive role, emphasizing that its design enhances human intelligence rather than replaces it.
- **Autonomous:** The work performed by the machine for the physician or other QHP is autonomous when the machine **automatically interprets** data and independently generates clinically meaningful conclusions without concurrent physician or other QHP involvement. Autonomous medical services and procedures include interrogating and analyzing data. The work of the algorithm may or may not include acquisition, preparation, and/or transmission of data. The clinically meaningful conclusion may be a characterization of data (e.g., likelihood of pathophysiology) to be used to establish a diagnosis or to implement a therapeutic intervention. There are three levels of autonomous AI medical services and procedures with varying physician or other QHP professional involvement:
  - **Level I**—The autonomous AI draws conclusions and offers diagnosis and/or management options, which are contestable and require physician or other QHP action to implement.
  - **Level II**— The autonomous AI draws conclusions and initiates diagnosis and/or management options with alert/opportunity for override, which may require physician or other QHP action to implement.
  - **Level III**— The autonomous AI draws conclusions and initiates management, which require physician or other QHP action to contest.

[Autonomous Example: The CMS Final Rule establishes a national payment for CPT code 92229 that describes a fully autonomous diabetic retinopathy \(DR\) screening, including retinal imaging, DR detection based on international clinical standards and immediate reporting, in a single office visit during a diabetic patient's regular exam. The FDA-cleared this AI system. CMS confirms that AI can be used to close care gaps under the Merit-based Incentive Payment System \(MIPS\). CY 2022](#)

<https://www.ama-assn.org/system/files/physician-ai-sentiment-report.pdf>

# Response from Clinicians (Continued)

## American Medical Association (AMA)

### CPT: Artificial Intelligence Taxonomy for Medical Services and Procedures

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
<b>Primary objective</b>	Detects clinically relevant data	Analyzes and/or quantifies data in a clinically meaningful way	Interprets data and independently generates clinically relevant conclusions
<b>Provides independent diagnosis and/or management decision</b>	No	No	Yes
<b>Analyzes data</b>	No	Yes	Yes
<b>Requires physician or other QHP interpretation and report</b>	Yes	Yes	No
<b>Examples in CPT code set</b>	Computer-aided detection (CAD) imaging (77048, 77049, 77065-77067, 0042T, 0174T, 0175T)	Continuous glucose monitoring (CGM) (95251), external processing of imaging data sets	Retinal imaging (92229)



<https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures>

# Response from Academic Medical Centers and Tech Leaders

## Coalition for Health AI (CHAI)

- The Coalition for Health AI (CHAI) formed in April 2023 as a collective featuring non-profit medical institutions like Stanford, the Mayo Clinic, Vanderbilt, and Johns Hopkins alongside tech industry leaders like Google and Microsoft. CHAI now comprises more than 1,300 members and recently introduced its first CEO and board of directors.
- **GOAL: develop “guidelines and guardrails” to drive high-quality healthcare by promoting the adoption of credible, fair and transparent health AI systems.**
- **IDENTIFY** areas of interest and representative use cases.
- **DEVELOP** clear delineation of: Use cases and specific audiences / users of health AI systems AND Core principles that will guide evaluation criteria and standards of development.
- **PERFORM** an environmental scan and provide a common definition and catalog of evaluation criteria.
- **GUIDE** - Produce a stakeholder-driven implementation guide to drive the credible and transparent use of health AI technologies, reducing variation in current evaluation, monitoring and reporting methods.

# Response from State Regulators

## Federation of State Medical Boards (FSMB)

- [Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice Adopted by FSMB House of Delegates, April 2024](#)
  - **Section VI. AI Governance Through Ethical Principles**
    1. Transparency and Disclosure
    2. Education and Understanding
    3. Responsible Use and Accountability
    4. Equity and Access
    5. Privacy and Data Security
    6. Oversight and Regulation
    7. Continual Review and Adaptation of Law and Regulations
- **Section VII. Conclusion:** The incorporation of AI in medical practice presents tremendous benefits to patients and physicians alike. It also presents significant risk of harm to patients and physicians if it is developed and used irresponsibly. A sensible approach to the regulation of AI by state medical boards and its incorporation into practice by licensees holds greater promise of realizing AI's benefits while minimizing potential harms. Adherence to traditional professional expectations for the provision of medical care will help achieve the patient safety goals of physicians and state medical boards.

# Response from the Insurance Industry

## National Association of Insurance Commissioners (NAIC)

- **Pay particular attention to suggested contract terms and definitions**
- When contracting with third party vendors regarding External AI Tools:
  - Require third-party vendors, such as data and model vendors and AI system developers, to have and maintain a Compliance Program related to the creation and operation of the AI Tools.
  - Entitle Company/Organization to audit the third-party vendor for compliance.
  - Entitle Company/Organization to receive audit reports by qualified auditing entities confirming the third-party's compliance with relevant standards.
  - Require the third-party vendor to cooperate with regulatory inquiries and investigations related to the AI Tools.

<https://content.naic.org/sites/default/files/07172023-exposure-draft-ai-model-bulletin.docx>



# Who is responsible? Managing Enterprise Risk Through Robust Governance Frameworks

# Key Considerations

## Managing Enterprise Risk Through Robust Governance Frameworks

- Per [KPMG Generative AI Survey](#) of 225 senior business leaders at companies with \$1 billion or more in revenue, GenAI is dramatically shifting how leaders are charting the course for their organizations:
  - 71% are leveraging data in decision making, 52% say it is shaping competitive positioning, and 47% say it is opening new revenue opportunities.
  - Executives say AI investment and ROI will increase in the short term. 83% of respondents say their GenAI investments will increase over the next 3 years, and 78% are confident in the ROI of planned investments. **The Importance of Having a Compliance Program for the Creation and Use of AI Tools.**
- What Makes a Corporate Compliance Program “Effective”?
- Current Voluntary Compliance Frameworks to Consider
- Heat Map Exercise - Estimating Enterprise Risk on Creation and Use of AI Tools
- How Stakeholders can get started creating an Internal Voluntary AI Tool Compliance Program



# The Importance of Having a Compliance Program for the Creation and Use of AI Tools

Potential noncompliant use of AI Tools



Potential violation of existing laws

The goal to Mitigate Risk of Noncompliance

Federal Sentencing Guidelines



DHHS OIG Voluntary Compliance Programs

Compliance Committee decision-making often uses heat maps to estimate enterprise risk on creation and use of AI Tools

# What Makes a Corporate Compliance Program “Effective”?



## U.S. Federal Sentencing Guidelines



### Key Questions:

- **Is the program well designed?**
  - Risk assessment process
  - Policies and procedures to reduce misconduct
  - Program responsibility
- **Is the program effectively implemented?**
  - Commitment by Management and Board
  - Program resources
  - Exercise of due care / authority
  - Disciplinary mechanisms
- **Does the program actually work?**
  - Auditing and monitoring
  - Reporting and investigation systems
  - Response to and remediation of issues
  - Reporting to Management and Board

# Current Voluntary Compliance Frameworks to Consider

- In the healthcare industry context, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) has adopted the broad principles of the USSG 7 key criteria when creating its own **more specific 7 elements** of an effective voluntary compliance program for those companies that do business with HHS and handle sensitive health care information, such as health care providers and health care insurance companies. See [HHS OIG Compliance Guidance](#)
  1. Creating and implementing policies and procedures
  2. Designating a compliance officer and committee
  3. Conducting effective compliance training and education
  4. Operating effective lines of communication such as hotlines for reporting questionable conduct
  5. Conducting internal and external monitoring and auditing
  6. Enforcing standards through well publicized disciplinary guidelines
  7. Responding promptly to detected issues and undertaking appropriate corrective action

# Estimating Enterprise Risk on Creation and Use of AI Tools

(-) Impact →	1	2	3	4	5
Probability ↓	Negligible	Minor	Moderate	Significant	Severe
(81-100)%					AI clinical decision support tool for reading MRIs
(61-80)%				Cognitive assessment	
(41-60)%			Resume screener		
(21-40)%		Predictive orthopedic implant			
(1-20)%	Chatbot interview scheduling				AI analysis of EHR to propose billing codes

# How Stakeholders can get started creating an Internal Voluntary AI Tool Compliance Program?



- Choose stakeholders within the company and ask someone to chair the AI Compliance Committee.
- Draft a charter for the mission of the AI Compliance Committee, including detailing:
  - The members
  - The reporting structure within the company's overall governance structure
- Take an inventory of existing and/or desired uses of AI Tools within the company.
- Schedule committee meetings over a 4 – 6 month period, which includes:
  - Educating the members
  - Completing the heat map to achieve consensus around enterprise risk.
- Create an implementation plan, including written policies, procedures, and standards of conduct.
- Identify the auditing and monitoring team and develop the auditing/monitoring plan.
- Incorporate the concept of AI Tools in the company's overall compliance training materials.

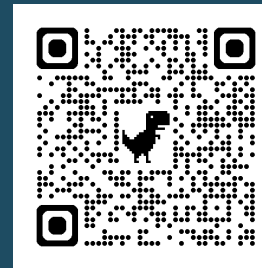
# Questions?

Lynn Shapiro Snyder | [lsnyder@ebglaw.com](mailto:lsnyder@ebglaw.com)

Rachel Snyder Good | [srgood@ebglaw.com](mailto:srgood@ebglaw.com)

To stay up to date on topics from today's presentation, please subscribe using the link below or scanning the QR code:

<https://www.ebglaw.com/subscribe>





# INDEX

# Who Are the Regulators?

- U.S.
  - Food and Drug Administration (FDA)
  - Federal Trade Commission (FTC)
  - National Institute of Standards and Technology (NIST)
  - National Institutes of Health (NIH)
  - Department of Justice (DOJ)
  - State laws
  - ASTP-ONC
  - OCR
- Canada
  - Health Canada





# Office of Civil Rights, HHS

New Final Rule Published May 6, 2024, based on section 1557 of the ACA



## § 92.210 Nondiscrimination in the use of patient care decision support tools.

- a) **General prohibition.** A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs or activities through the **use** of **patient care decision support tools**.
- b) **Identification of risk.** A covered entity has an **ongoing duty to make reasonable efforts to identify uses** of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.
- c) **Mitigation of risk.** For each patient care decision support tool identified in paragraph (b) of this section, a covered entity **must make reasonable efforts to mitigate the risk** of discrimination resulting from the tool's use in its health programs or activities.

Per Sec. 92.4, “patient care decision support tools” defined to mean “any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.”

# Duty To Identify Risk

## OCR Is Concerned About Proxies For Protected Categories



### The Trigger

“[I]f a covered entity does not know whether a developer’s patient care decision support tool uses variables or factors that measure race, color, national origin, sex, age, or disability but has reason to believe such variables or factors are being used, /or/ the covered entity otherwise knows or should know that the tool could result in discrimination, the covered entity should consult publicly available sources or request this information from the developer.”

### How might the provider become aware?



- ONC required transparency (more below)
- Reading federal rulemakings such as the proposed rule at issue here.
- Bulletins and advisories that HHS, including the Agency for Healthcare Research and Quality (AHRQ) and FDA, publishes
- Published medical journal articles
- Popular media
- Health care professional and hospital associations
- Health insurance-related associations
- Various nonprofit organizations in the field of AI

# How Does OCR Assess Your Vigilance?

## Big Beware



### OCR says the agency will consider:

- 01** the covered entity's **size** and resources;

---

- 02** whether the covered entity used the tool in the manner or under the conditions intended by the developer and approved by regulators, if applicable, or whether the covered entity has adapted or customized the tool; **[Off Label]**

---

- 03** whether the covered entity received product information from the developer of the tool regarding the potential for discrimination or identified that the tool's input variables include race, color, national origin, sex, age, or disability; **[Knowledge]** and

---

- 04** whether the covered entity has a methodology or process in place for evaluating the patient care decision support tools it adopts or uses, which may include seeking information from the developer, reviewing relevant medical journals and literature, obtaining information from membership in relevant medical associations, or analyzing comments or complaints received about patient care decision support tools. **[Compliance Program Specific to AI]**

# Mitigation Expected

## You Need A Plan

- 01 OCR expressed strong support in the final rule for “the National Institutes of Standards and Technology’s (NIST) Artificial Intelligence Risk Management Framework.

---

- 02 OCR also endorses the use of voluntary compliance programs: “covered entities may choose to mitigate discrimination by establishing **written policies and procedures** governing how clinical algorithms will be used in decision-making, including **adopting governance measures**; **monitoring any potential impacts** and developing ways to address complaints; and **training staff** on the proper use of such systems in decision-making. We encourage covered entities to take these and other additional mitigating efforts to comply with § 92.210.”



# Clinical Decision Support

## Exempt CDS is software that is:

1. **[Image and Signal Analysis are Regulated]** Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
2. **[Inputs]** Intended for the purpose of analyzing patient medical information or other information (such as peer-reviewed clinical studies and clinical practice guidelines); and
3. **[Outputs]** Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease.
4. **[Transparency]** Enables the HCP to “independently review” the basis for the recommendation, so that the HCP does not need to “rely primarily” on the recommendation in making a decision.

Sept. 2022 FDA Final Guidance

# ONC (Now Assistant Secretary for Technology and Policy (ASTP))

New Final Rule January 9, 2024

1

“Predictive decision support interventions” (predictive DSIs) are algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis.

2

“Source attributes” are categories of technical performance and underlying quality information used to create DSIs

3

Predictive DSIs must support 31 source attributes (compared to 13 for evidence based).

- Developers of Predictive DSIs must produce information, for example, about the intervention’s training data set, external validation process, and quantitative measures of performance, as well as the **process used to ensure fairness and eliminate bias** in the development of the intervention.

# ONC (Now Assistant Secretary for Technology and Policy (ASTP))

New Final Rule January 9, 2024

4

Health IT developers apply **intervention risk management** (IRM) for each Predictive DSI included in their health IT module. Health IT developers will need to analyze potential risks and adverse impacts by considering the DSI's validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy, and implement practices to mitigate those risks.

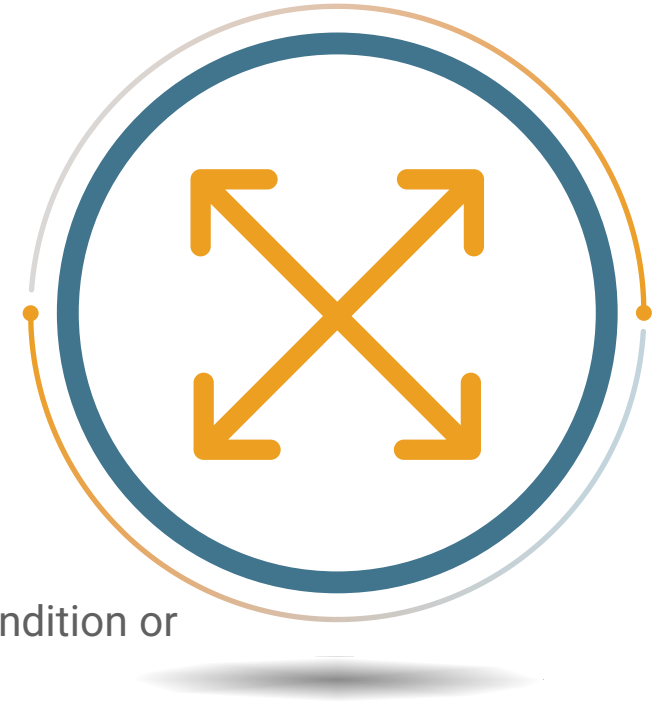
5

Developers must also submit summary information of IRM practices through **a publicly accessible hyperlink** that allows any person to access the summary information directly.

**Bottom line, in the rule, providers will have access to information about predictive DSIs in 2 places.**

# FDA's 2022 Guidance Extends FDA's Reach Dramatically

- Inputs cannot be innovative
  - The data must be well-accepted
- Outputs must be
  - multiple,
  - not ranked and
  - without time pressure
  - The software may not:
    - Provide information that a specific patient 'may exhibit signs' of a disease or condition or
    - identify a risk probability or risk score for a specific disease or condition
- FDA requires a high degree of transparency and explainability



**In February 2023, the CDS Coalition filed a Citizen Petition asking FDA to rescind the guidance. In April 2024, Senator Cassidy sent a letter to FDA challenging the legality of the guidance.**



# Examples of FDA Regulated Software Per CDS Guidance

- Software function that identifies patients with possible diagnosis of opioid addiction based on analysis of patient-specific medical information, family history, prescription patterns, and geographical data
- Software function that analyzes patient-specific medical information to detect a life-threatening condition, such as stroke or sepsis, and generate an alarm or an alert to notify an HCP



**Biased software is not safe and effective for those it is biased against.**

# FDA

## Food and Drug Administration – Safety and Efficacy

- April 2019 – proposed regulatory framework
  - “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)”
- January 2021 – AI Action Plan
  - “Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan”
- March 2023 – Draft guidance
  - “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions”
- May 2023 – Discussion papers
  - “Using Artificial Intelligence and Machine Learning in the Development of Drug & Biological Products”
  - “Artificial Intelligence in Drug Manufacturing”
- August 2024 – Oversight and coordination of drug-related AI activities at the Center for Drug Evaluation and Research (CDRE)

# Devices

FDA has cleared hundreds of healthcare AI algorithms for:

- Anesthesiology
- Hematology
- Cardiovascular
- Immunology
- Gastroenterology /Urology
- Microbiology
- General and Plastic Surgery
- Neurology
- Ophthalmic
- General Hospital
- Radiology

The screenshot shows the FDA website page for AI/ML-enabled medical devices. The page header includes the FDA logo and the text 'U.S. FOOD & DRUG ADMINISTRATION'. The breadcrumb trail reads: Home / Medical Devices / Digital Health Center of Excellence / Software as a Medical Device (SaMD) / Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. The main heading is 'Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices'. Below the heading are social sharing buttons for Facebook, X, LinkedIn, Email, and Print. A light blue callout box contains an update: 'October 19, 2023 update: 171 Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices were added to the list below. Of those newly added to the list, 155 are devices with final decision dates between August 1, 2022, and July 30, 2023, and 16 are devices from prior periods identified through a refinement of methods used to generate this list.' Below the callout, the text states: 'As technology continues to advance every aspect of health care, software incorporating artificial intelligence (AI), and specifically the subset of AI known as machine learning (ML), has become an important part of an increasing number of medical devices. One of the greatest potential benefits of AI/ML resides in its ability to create new and important'.



**Maia Hightower, M.D., MPH,  
MBA**

Founder and CEO  
Equality AI

# Responsible AI and AI Bias

AHP Demystifying AI Tools in Healthcare  
September 19, 2024

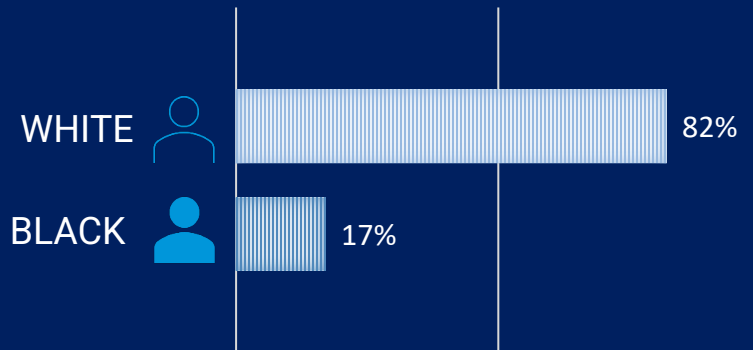
**Maia Hightower, MD, MPH, MBA,  
CEO, Founder  
Equality AI  
Maia.Hightower@equalityai.com**

# ALGORITHMIC BIAS...THE DARK SIDE OF AI

## THE PROBLEM

“AI can be sexist and racist – it’s time to make it fair”<sup>1</sup>

Dissecting racial bias in an algorithm used to manage the health of populations

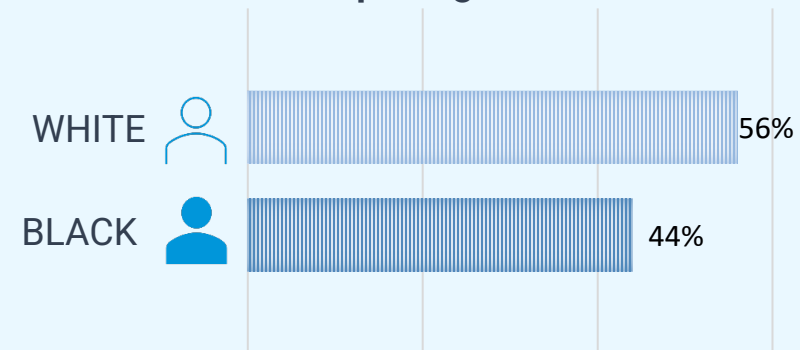


**Pre:** Black Patients were 50% less likely to be referred despite being equally sick”

## THE SOLUTION

**Fairness Metric: Statistical Parity**  
Bias Mitigation Method: Better Proxy Label

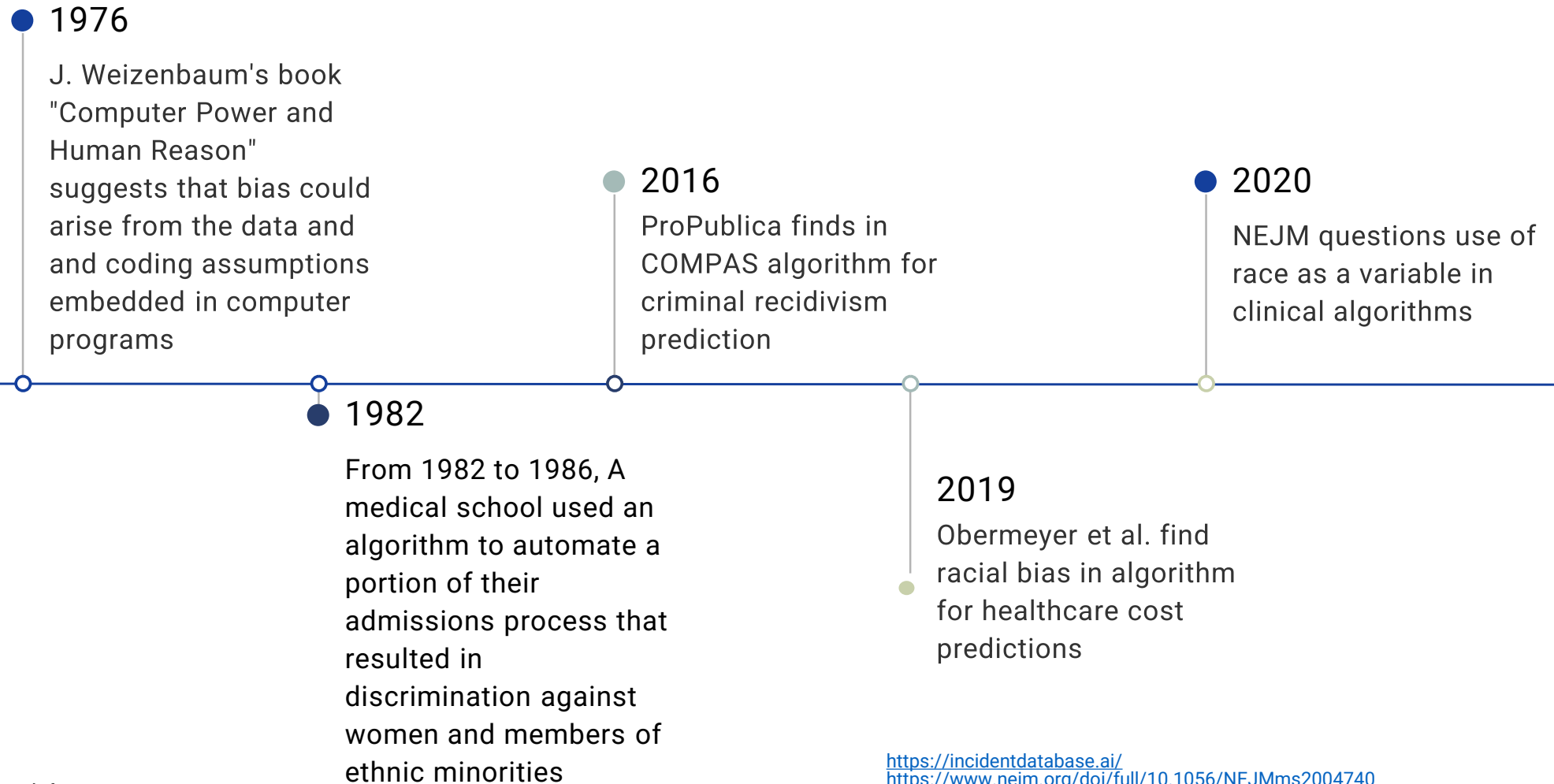
Fair AI ML Tools Eliminates the AI Racial Bias By Repairing the Model



**Post:** Black Patients were just as likely to be referred when equally sick

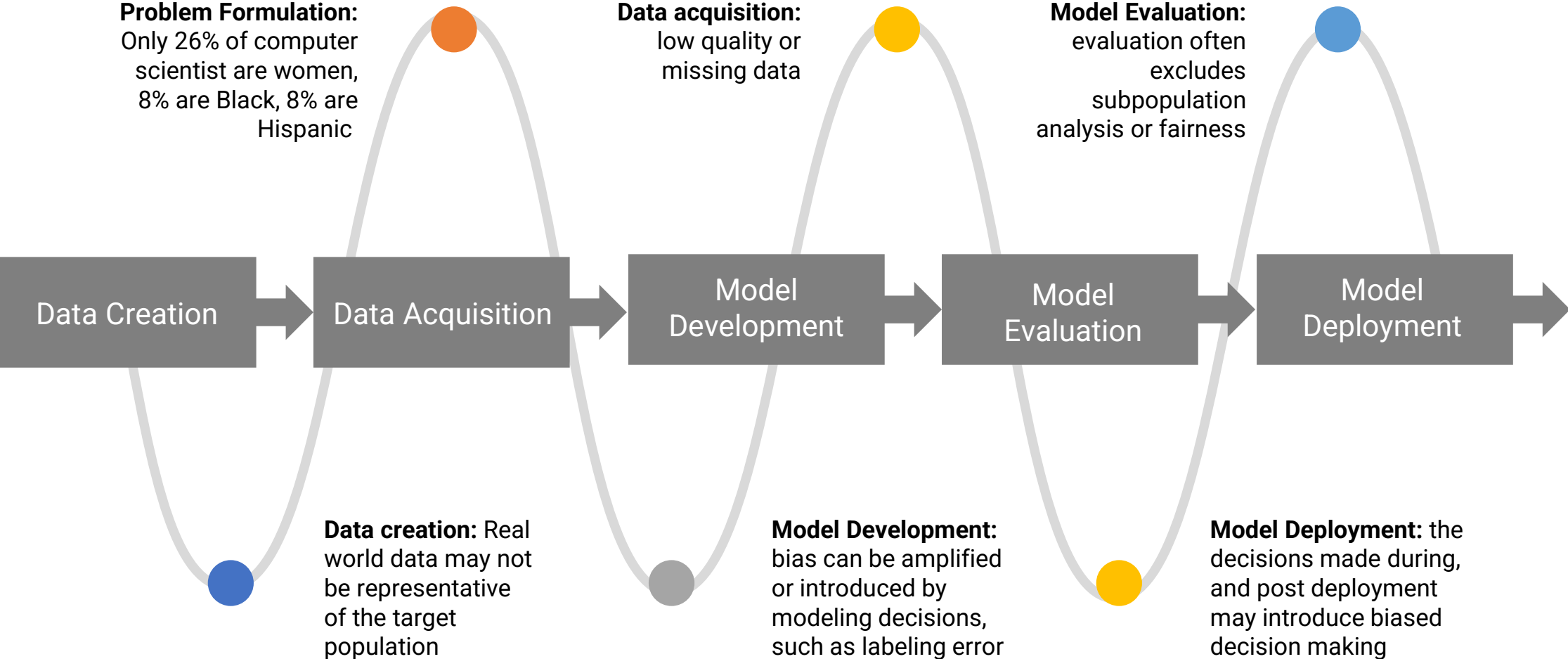
by Ziad Obermeyer, et. al, Dissecting racial bias in an algorithm used to manage the health of populations. Science 366. 447 (2019)

# TIMELINE OF ALGORITHMIC BIAS IN HEALTHCARE



<https://incidentdatabase.ai/>  
<https://www.nejm.org/doi/full/10.1056/NEJMms2004740>  
<https://www.science.org/doi/epdf/10.1126/science.aax2342>

# Bias Occurs Throughout The AI Lifecycle





# Practical Solutions: Bias Mitigation Methods

## Social Mitigation Methods

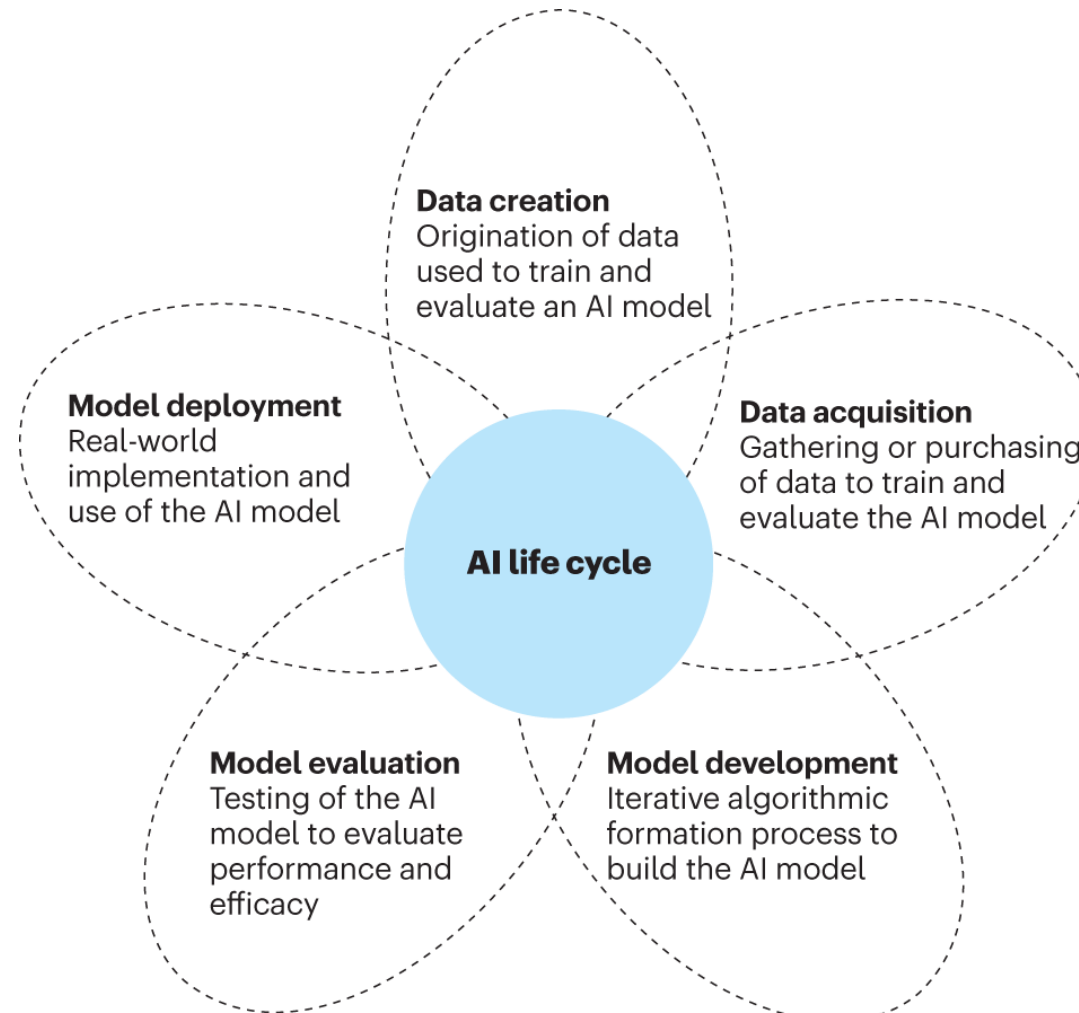
Diverse Teams

AI Governance

- Local Policy and Procedures
- Stakeholder Engagement
- Including Patients, Clinicians, Leadership, Ethicists

AI Regulations

- FDA QS & CBMP
- ONC HTI-1
- ACA 1557 & OCR
- CMS



## Technical Mitigation Methods

AI Standards

- Promoting the Use of Trustworthy AI in the Federal Government
- NIST AI Risk Management Framework

AI Evaluation & Bias Mitigation Methods

- EqualityML Toolkit
- AI Fairness 360
- Fairlearn

Monitoring for Outcome

# Role of Policy Makers in Promoting Responsible AI in Healthcare



## Advance AI Regulations

Define and incentivize adoption of AI risk management standards that prioritizes health equity



## Fund AI Evaluation Research, Education & Workforce Development

Fund research and training advances the use of AI for health equity

$$\text{Value} = \frac{Q}{C} \times E$$

## Incentivize Responsible AI Healthcare Delivery Models

For example, launch CMS Innovation Center (CMMI) model to test new payment and service delivery models that align AI with quality, health equity, and reducing total cost of care

# Questions?

**Maia Hightower, MD, MPH, MBA**  
[Maia.hightower@equalityai.com](mailto:Maia.hightower@equalityai.com)

AI Quality Assurance and Compliance Solutions for Healthcare



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## **Nicoleta Economou, Ph.D.**

Director of Duke Health AI Evaluation & Governance, Duke Health  
Scientific Director, Coalition for Health AI (CHAI)

# Advancing Trustworthy AI in Healthcare with Governance

Duke's Commitment to high-quality and ethical patient care

**Nicoleta J Economou, PhD**

Director of Duke Health AI Evaluation & Governance

Director of Algorithm-Based Clinical Decision Support (ABCDS) Oversight

September 19, 2024



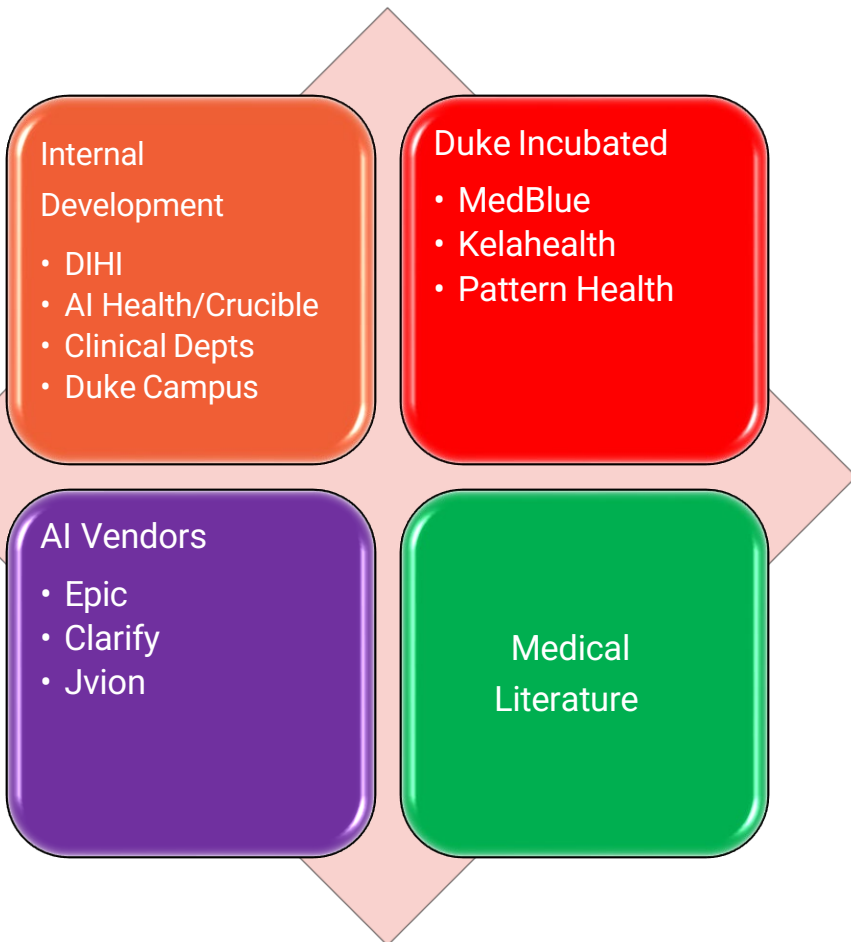
**DukeHealth**

AI Evaluation & Governance

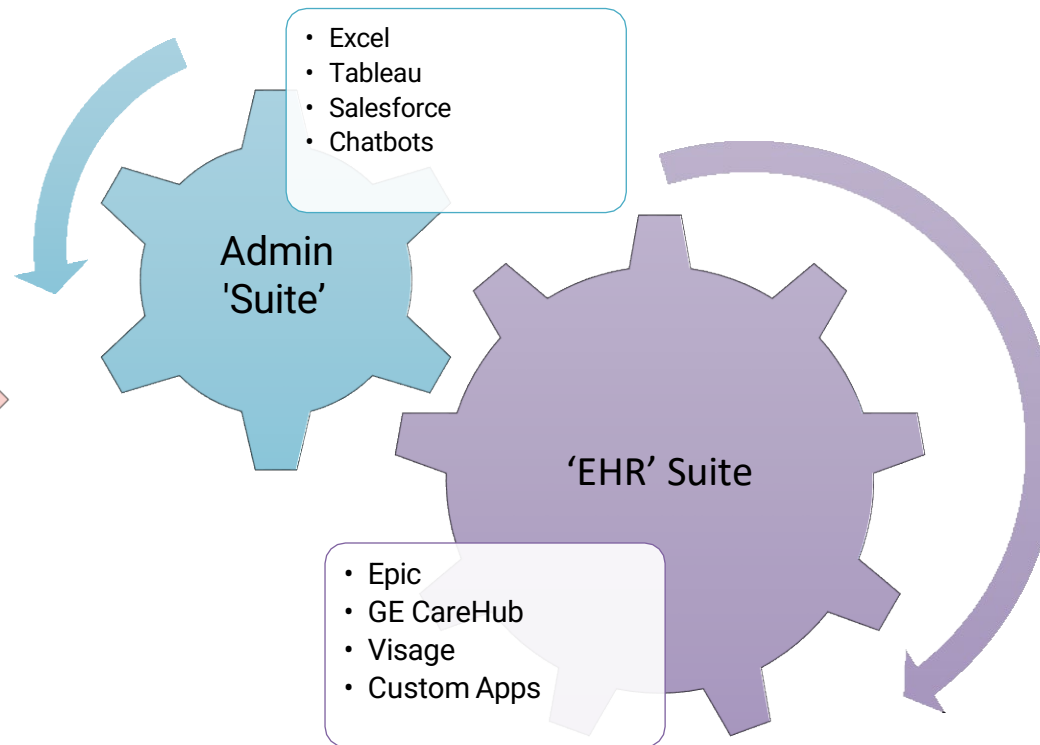


# Complexity of a Local Healthcare Environment

## Sources of Models



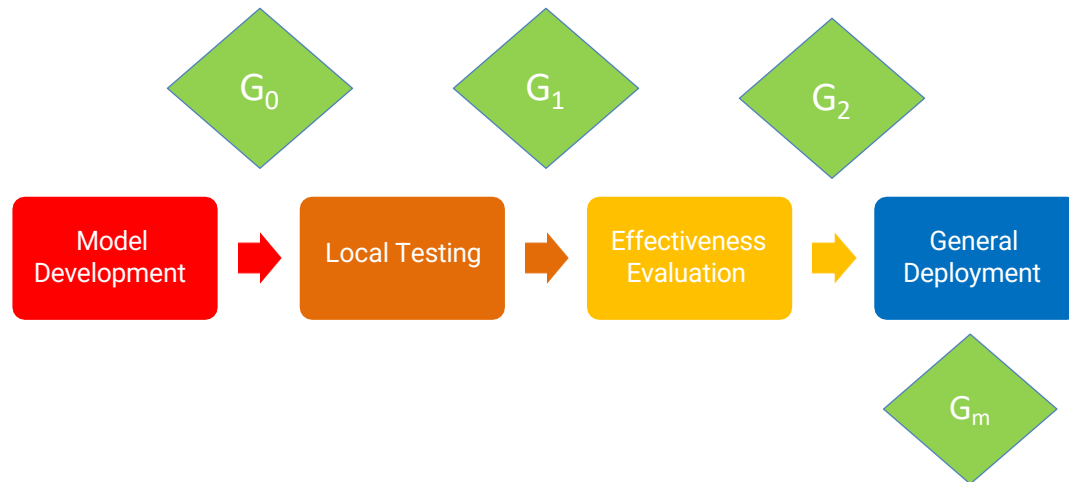
## Deployment Mechanisms



## Target Audience



# AI-Enabled Solution Lifecycle & Governance



*What are the clinical outcome and performance metrics?*

*How has the model been evaluated?*

*Who is the Clinical Owner?*

*Who will cover maintenance costs in production?*

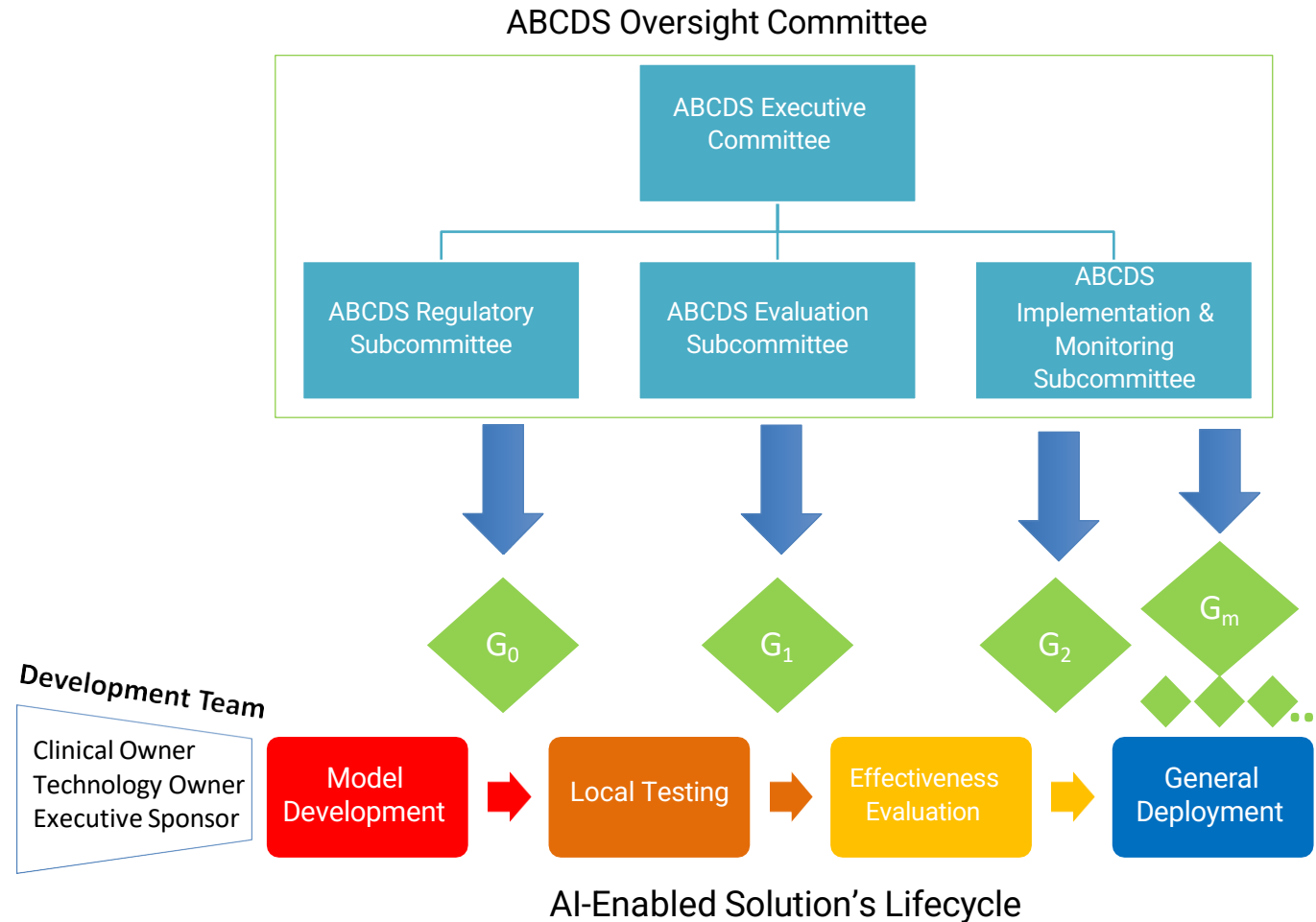
*Will this ABCDS tool be used outside of Duke Health?*

*How will the model be used in the clinic and how is it integrated with the workflow?*

...

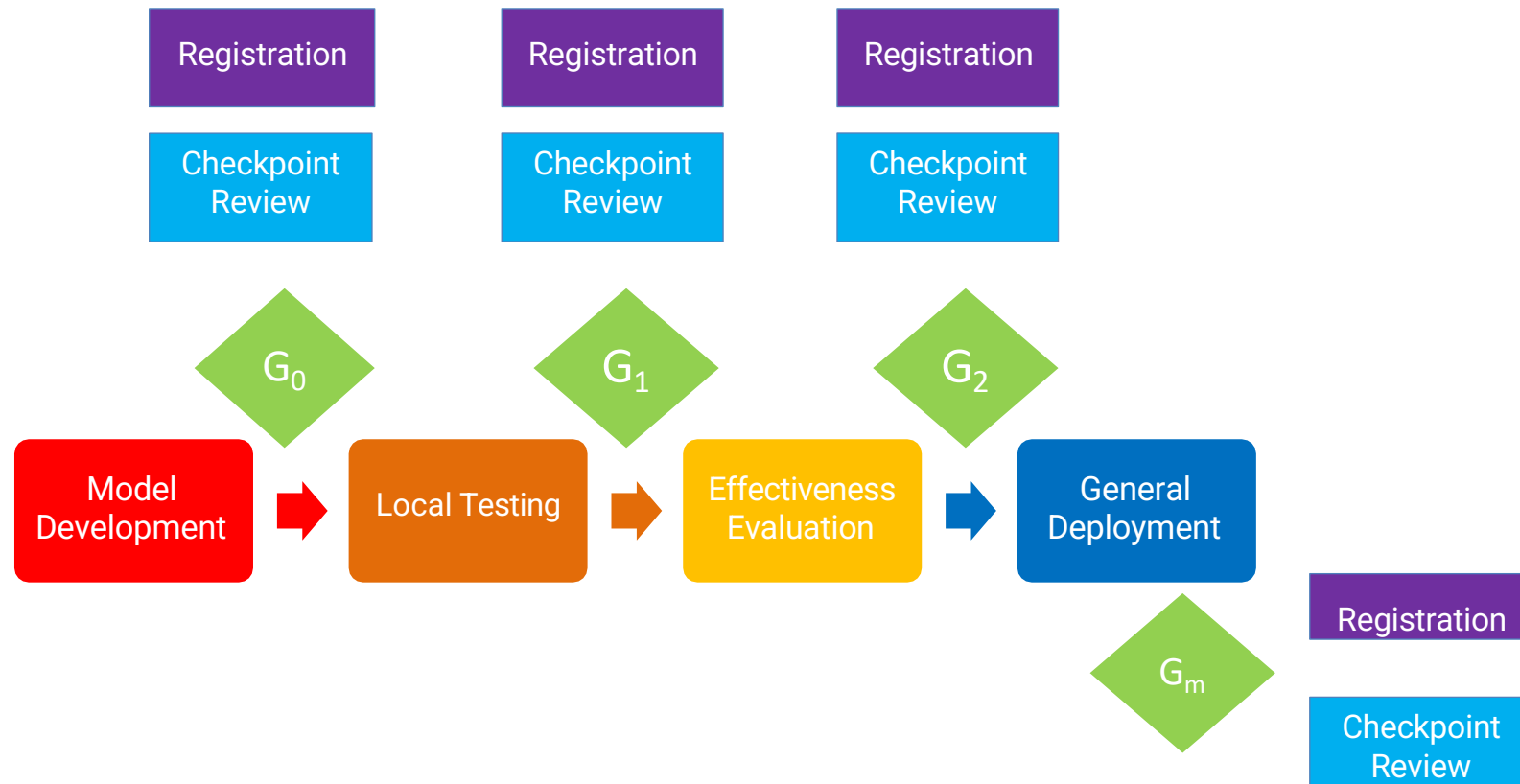
'Just-in-time' Check-Points (**G**ates) Help Development Teams Get Ready for What's Ahead

# ABCDS Oversight Governance Structure



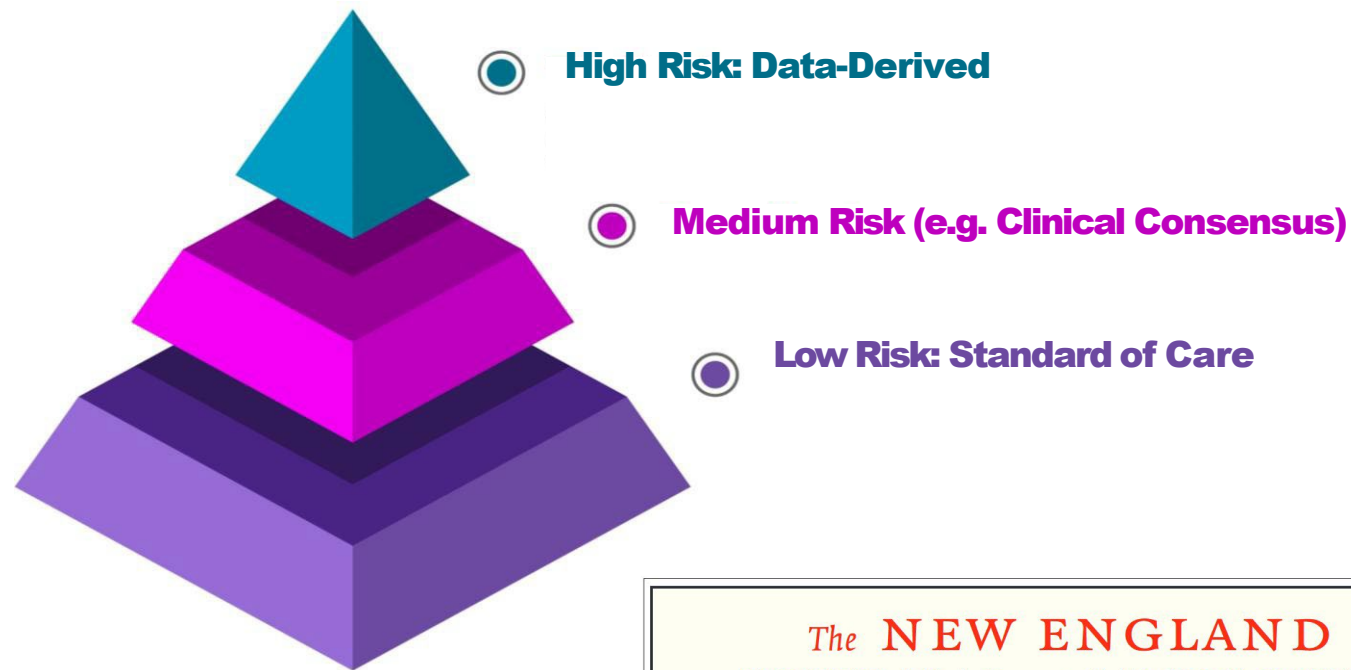


# Registration: Creating an Inventory of Algorithms



# Creating a Risked-Based Approach for Independent AI Review

All electronic algorithms that could impact patient care at Duke Health fall within the scope of the ABCDS Oversight Committee and must undergo registration



The **NEW ENGLAND**  
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ESTABLISHED IN 1812

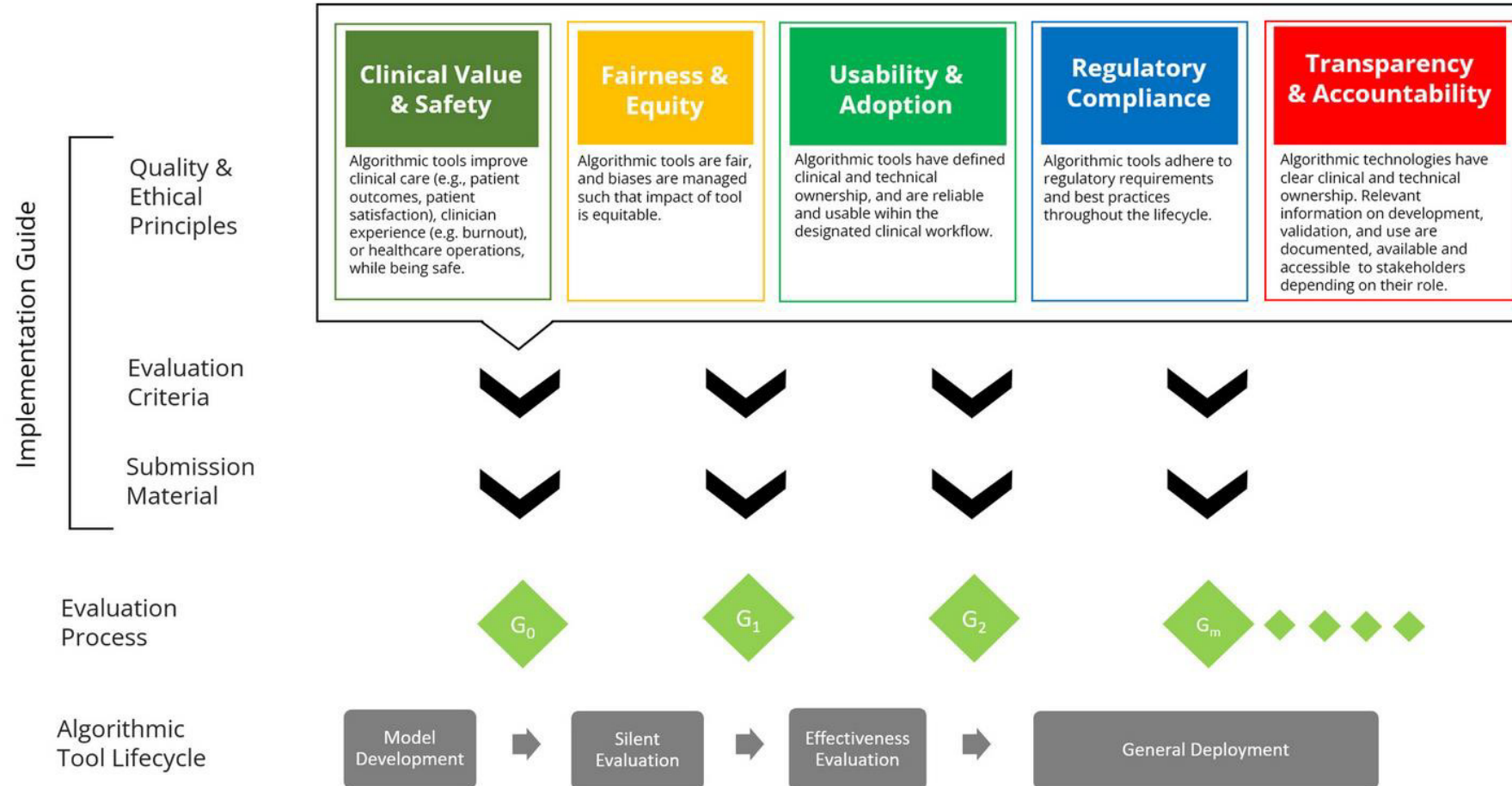
NOVEMBER 4, 2021

VOL. 385 NO. 19

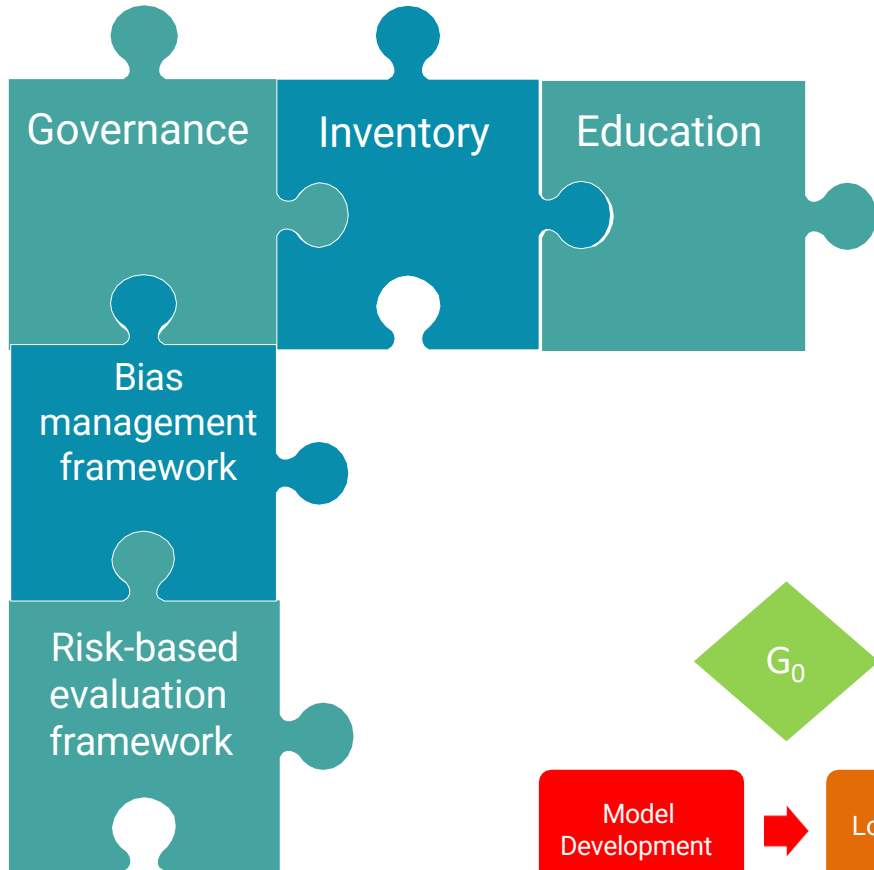
New Creatinine- and Cystatin C–Based Equations to Estimate GFR without Race

L.A. Inker, N.D. Eneanya, J. Coresh, H. Tighiouart, D. Wang, Y. Sang, D.C. Crews, A. Doria, M.M. Estrella, M. Froissart, M.E. Grams, T. Greene, A. Grubb, V. Gudnason, O.M. Gutiérrez, R. Kalil, A.B. Karger, M. Mauer, G. Navis, R.G. Nelson, E.D. Poggio, R. Rodby, P. Rossing, A.D. Rule, E. Selvin, J.C. Seegmiller, M.G. Shlipak, V.E. Torres, W. Yang, S.H. Ballew, S.J. Couture, N.R. Powe, and A.S. Levey, for the Chronic Kidney Disease Epidemiology Collaboration\*

# Checkpoint Review: Implementing Quality & Ethics with an Oversight Framework



# Operationalizing Trustworthy Health AI



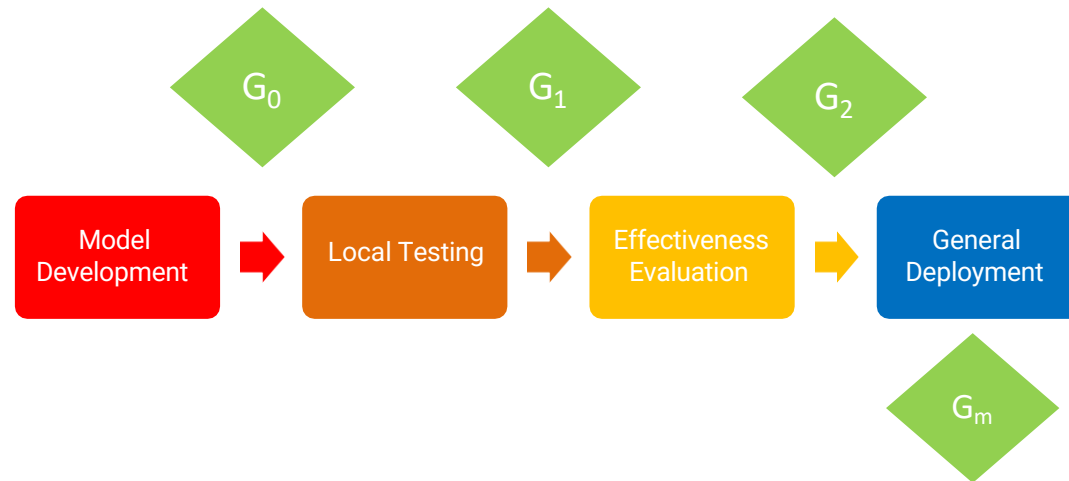
**JOURNAL OF NURSING SCHOLARSHIP** 

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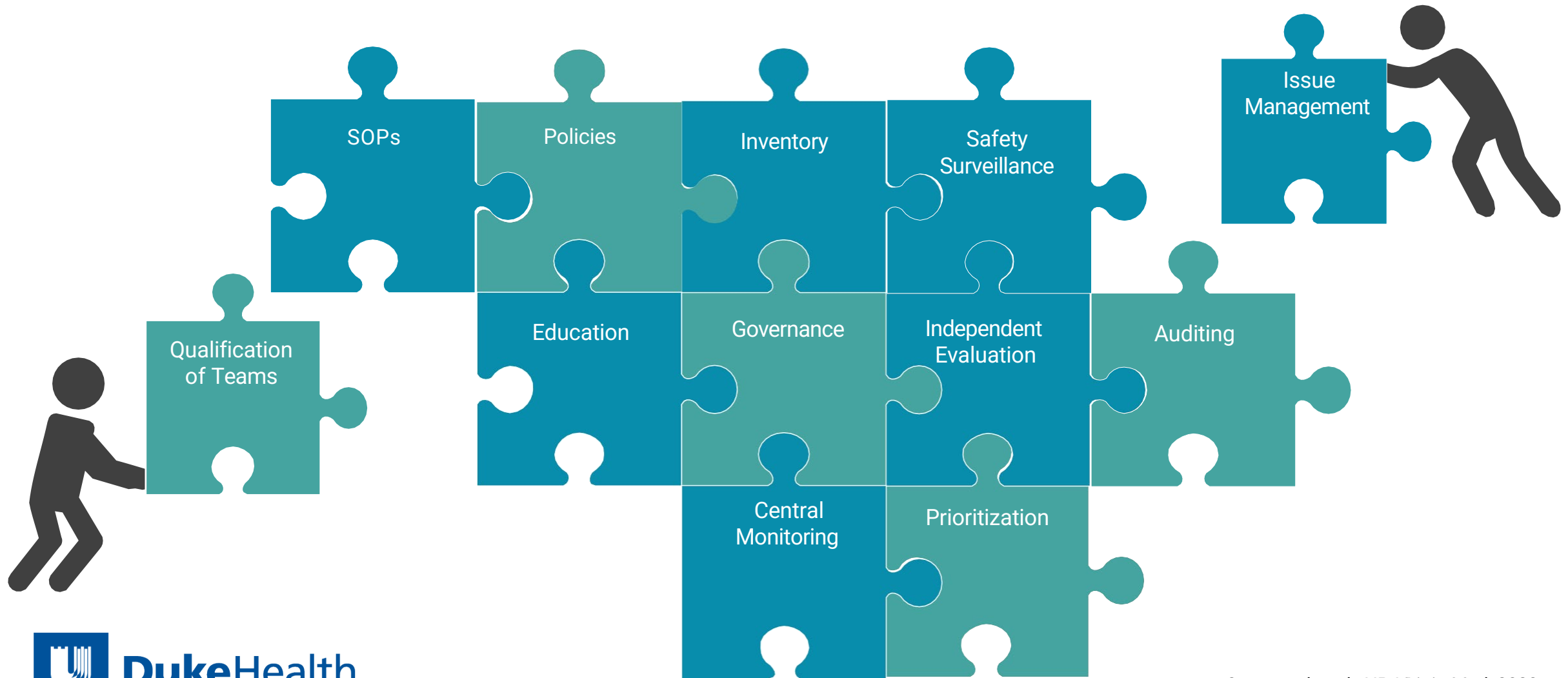
**Empowering nurses to champion Health equity & BE FAIR: Bias elimination for fair and responsible AI in healthcare**

Michael P. Cary Jr PhD, RN ✉, Sophia Bessias MPH, MSA, Jonathan McCall MS, Michael J. Pencina PhD, Siobahn D. Grady PhD, Kay Lytle DNP, RN, Nicoleta J. Economou-Zavlanos PhD

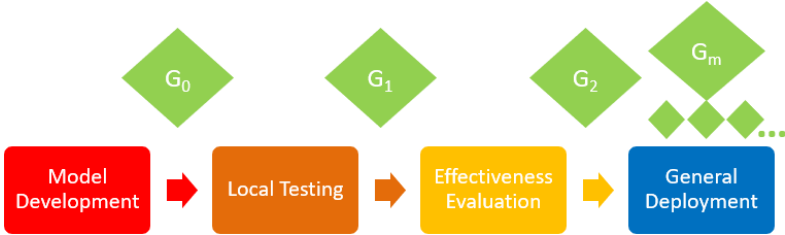
First published: 29 July 2024 | <https://doi.org/10.1111/jnu.13007>



# A Framework for High-Quality, Ethical AI Oversight

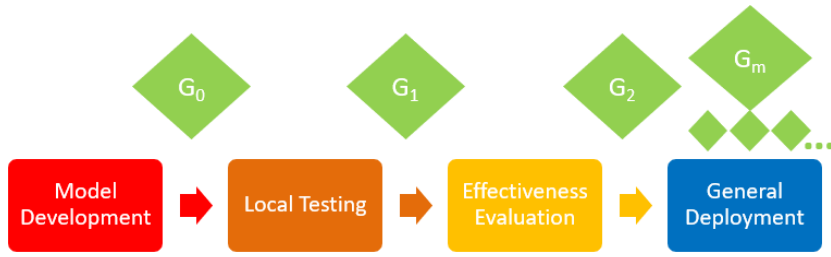


# Impacting How We Deliver Patient Care

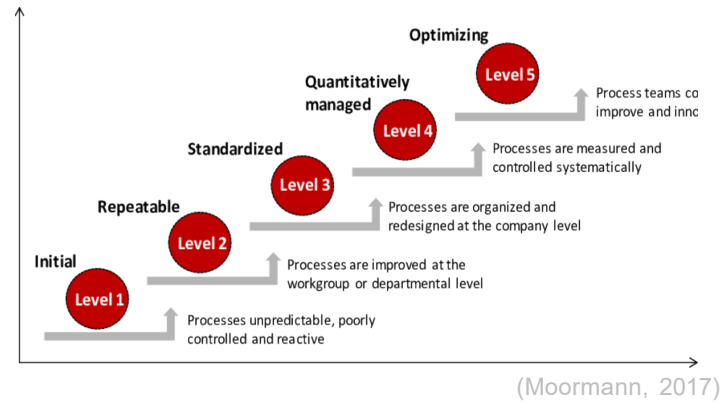




# Scaling Trustworthy Health AI Frameworks



*A Scalable Governance Framework*



*Assessing Health System Readiness*



*Including the patient voice*

**JAMA | JAMA Network**

**Viewpoint | AI in Medicine**  
August 12, 2024

## A Federated Registration System for Artificial Intelligence in Health

Michael J. Pencina, PhD<sup>1,2</sup>; Jonathan McCall, MS<sup>2</sup>; Nicoleta J. Economou-Zavlanos, PhD<sup>2,3</sup>

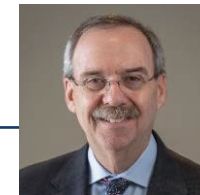
In 2000, a web-based federal registry of information about clinical trials was first made available to the public. This registry, ClinicalTrials.gov, provided descriptive information about interventional trials performed under US regulatory oversight. Now, in 2024, such registration is a necessary step in the development of AI-based clinical trials, and multiple tools facilitate analysis



**JAMA Health Forum**

**Viewpoint**  
**Artificial Intelligence Can Be Regulated Using Current Patient Safety Procedures and Infrastructure in Hospitals**  
Lee A. Fleisher, MD; Nicoleta J. Economou-Zavlanos, PhD

Artificial intelligence (AI) has the potential to transform health care decision-making, yet the technology risks augmenting and introducing novel challenges in patient safety. AI embedded in clinical decision support (CDS)



# Thank you





# Moderated Discussion

# Moderated Q & A

# TAKE OUR SURVEY

Please fill out the evaluation survey by using the link in the chat or via email this afternoon!

[www.allhealthpolicy.org](http://www.allhealthpolicy.org)



# UPCOMING EVENTS

**2024 Signature Series Public Congressional Briefing:  
Navigating AI in Health Care Policy: How Are Standards  
Evolving?**

October 2, 2024

Hart Senate Office Building (Room 902) in Washington DC

**Post-Election Symposium**

November 13, 2024

Barbara Jordan Conference Center in Washington DC

[allh.us/events](https://allh.us/events)

THANK YOU FOR  
ATTENDING!