

Responsible AI Implementation in Pharmacy Practice:

Ethical and Legal Considerations

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Conflicts of Interest

- I have no conflicts of interest with ineligible companies to disclose.



Learning Objectives

1. Describe key ethical and legal considerations related to AI implementation.
2. Apply ethical and legal principles to an AI use case.
3. Analyze potential risks of AI implementation related to bias, privacy, accountability, and human oversight.
4. Evaluate strategies for responsible, transparent, and legally sound AI adoption.



How does generative AI work?

How an LLM Generates a Response

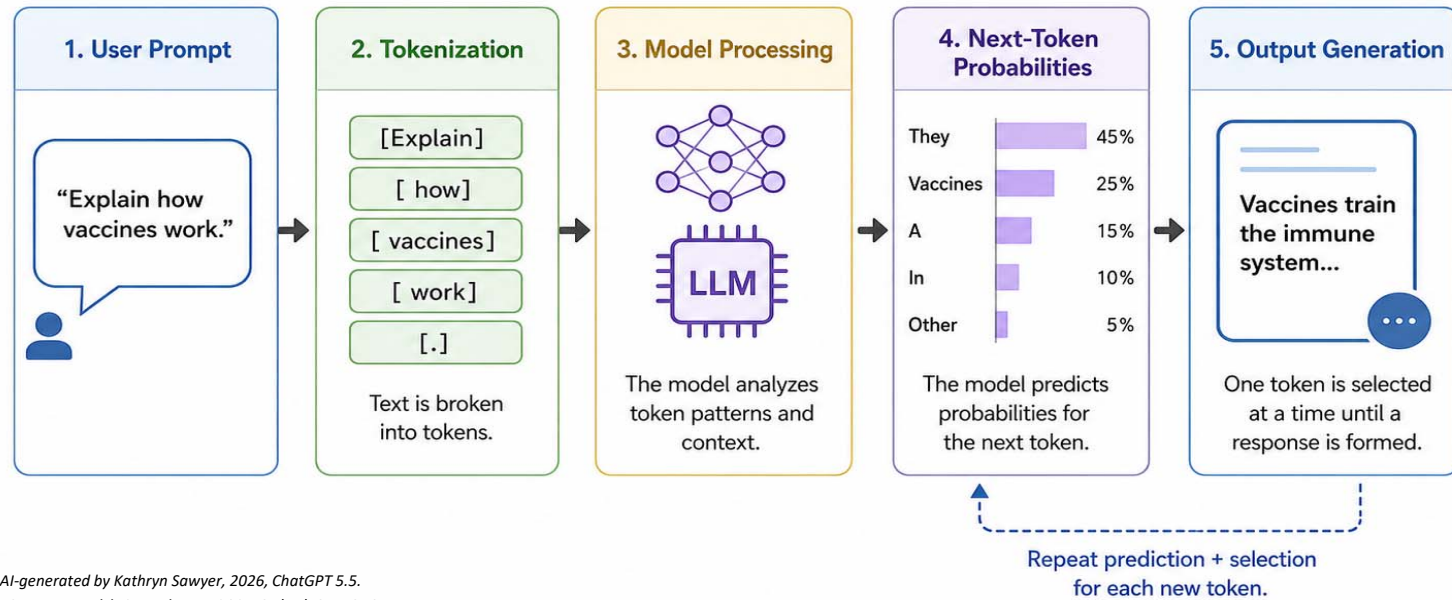


Image AI-generated by Kathryn Sawyer, 2026, ChatGPT 5.5.
Smoke S. Am J Health Syst Pharm. 2024;81(14):641-646

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What are the ethical considerations?

Informed
consent

Safety and
transparency

Algorithmic
fairness and
biases

Data privacy



Gerke S, Minssen T, Cohen G. Artificial Intelligence in Healthcare. 2020;295-336

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Informed consent

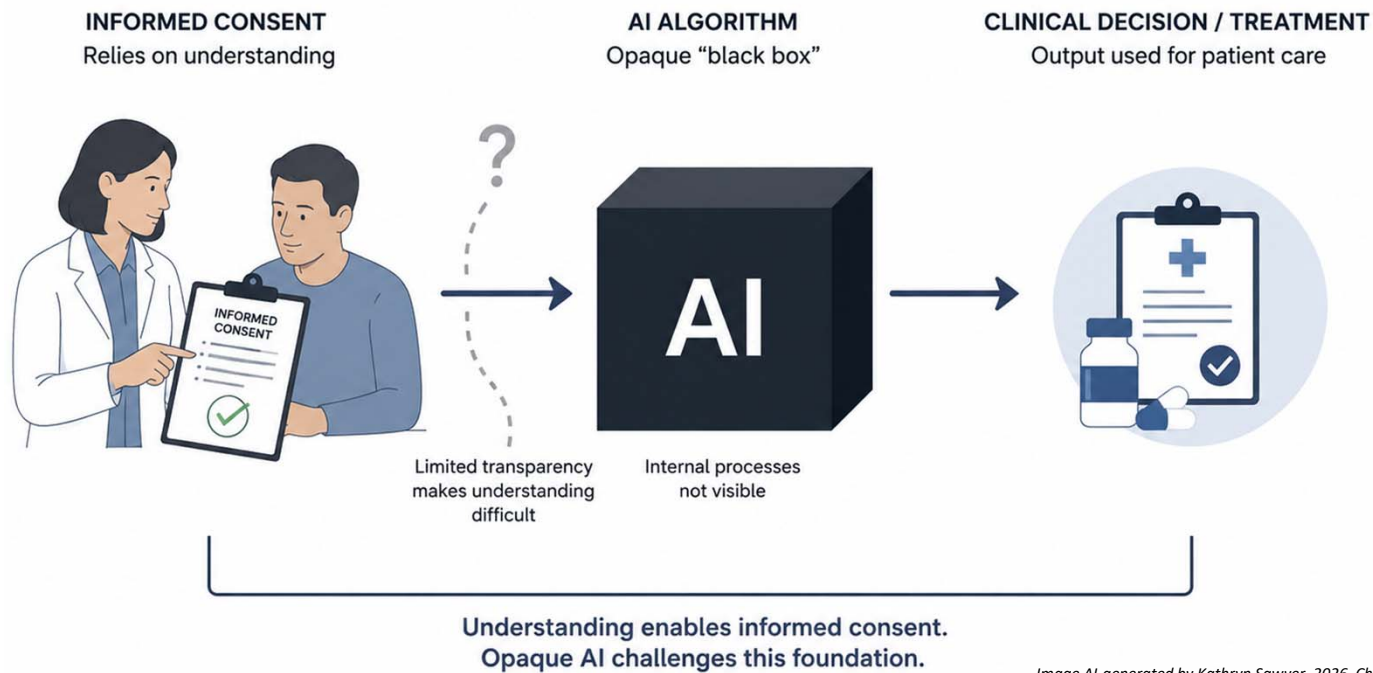


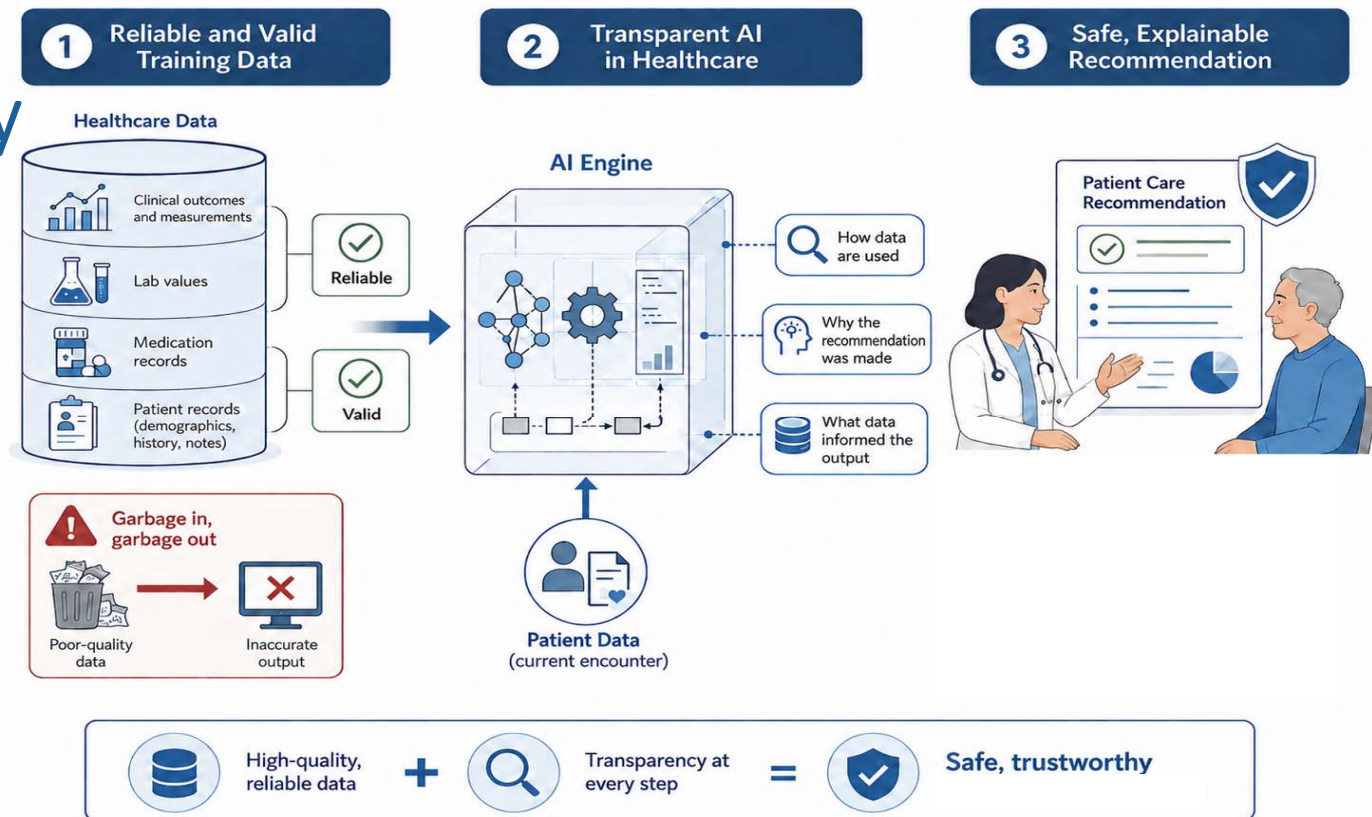
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Safety and transparency



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Algorithmic fairness and biases

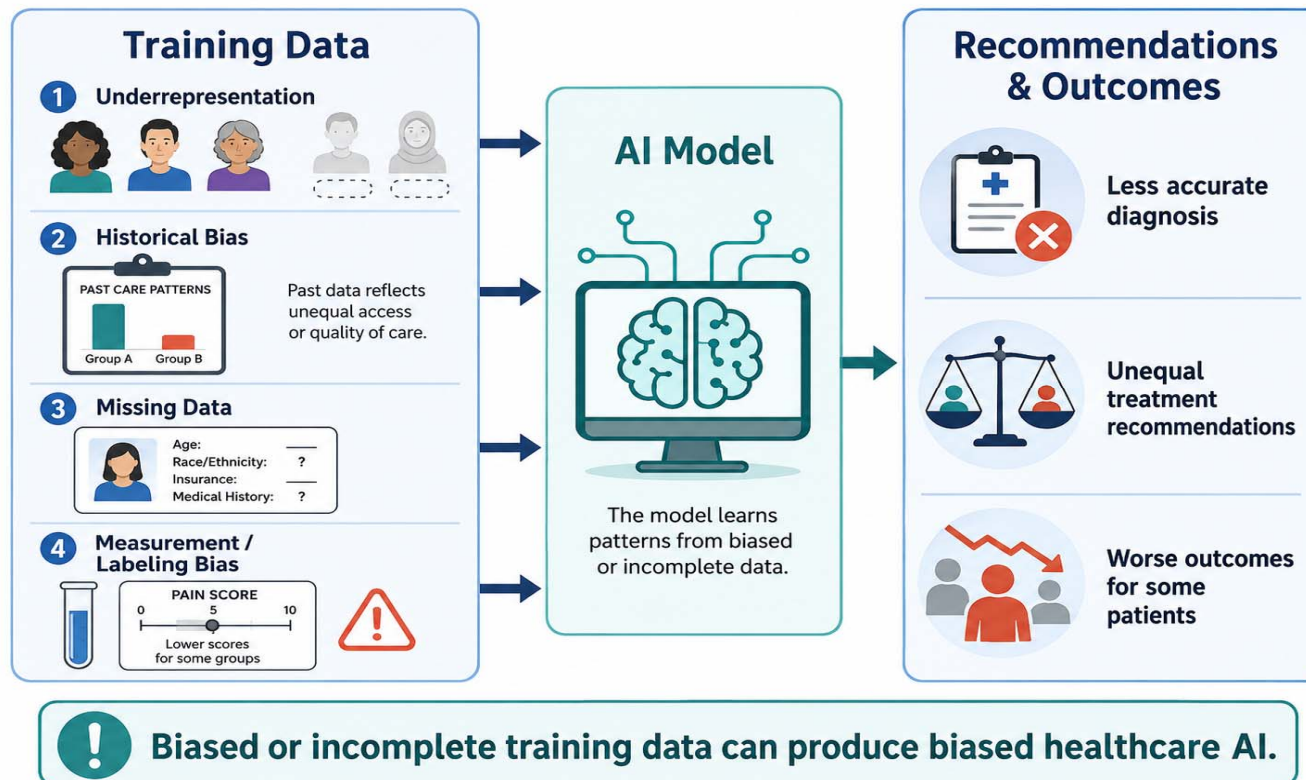


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Data privacy

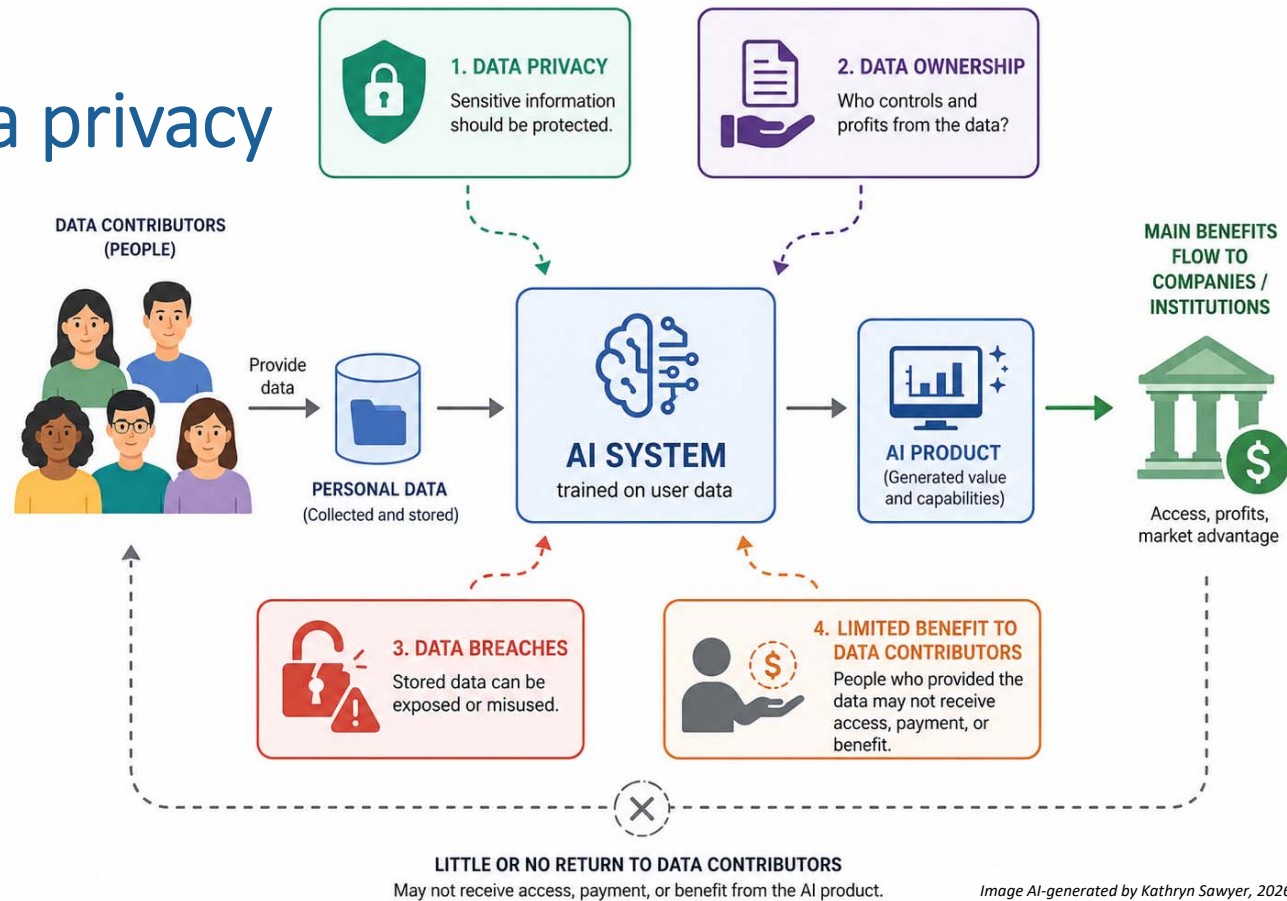


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What are the legal considerations?

Safety and
effectiveness

Liability

Data
protection and
privacy

Cybersecurity

Intellectual
property law



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Safety and effectiveness

How the FDA Approaches Software Regulation

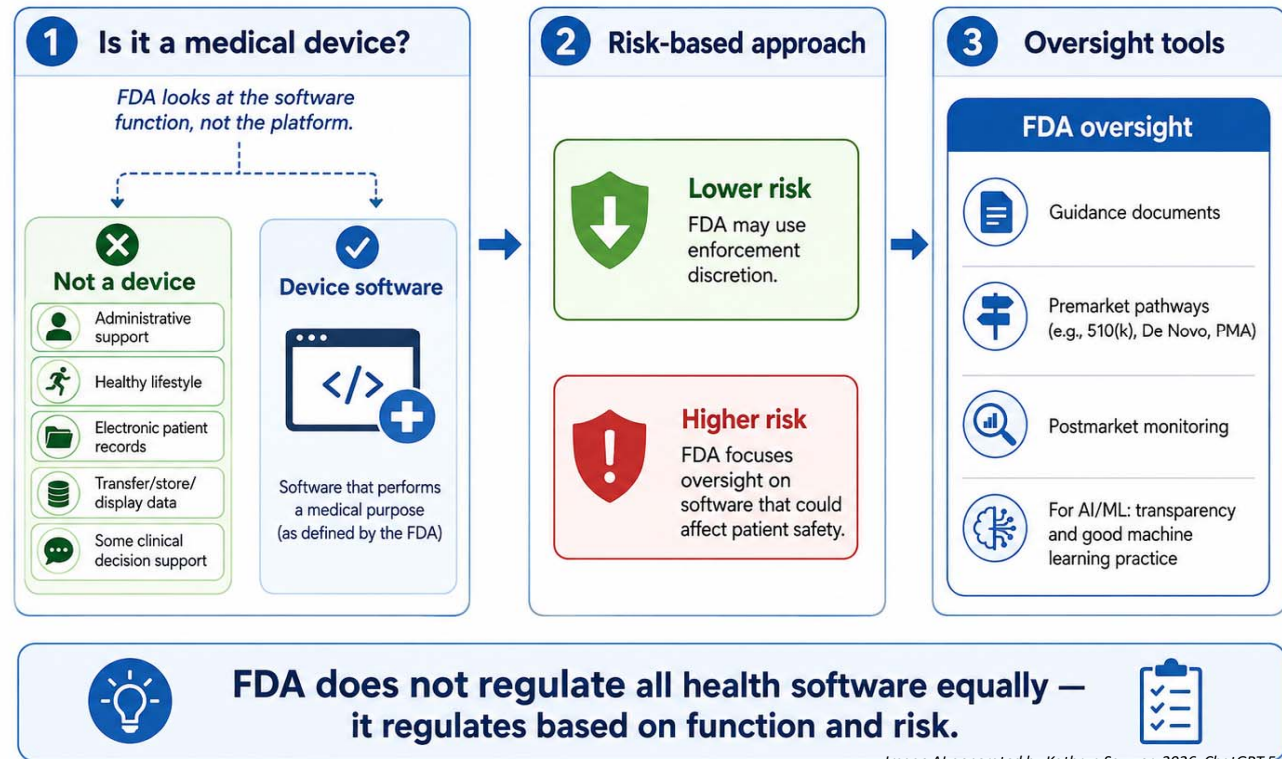


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Gerke S, Minssen T, Cohen G. Artificial Intelligence in Healthcare. 2020;295-336; Federal Food, Drug, and Cosmetic Act § 520(o)(1)(A)-(D), 21 USC § 360j(o)(1)(A)-(D).; US Food and Drug Administration. *Clinical Decision Support Software*. January 2026.

Liability



It is the provider who is liable for medical malpractice when AI outputs lead to patient harm!



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Gerke S, Minssen T, Cohen G. Artificial Intelligence in Healthcare. 2020;295-336

Data protection and privacy

HIPAA Applies Only to Covered Entities

Covered by HIPAA

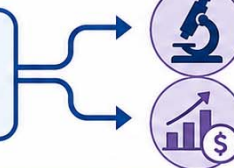


(and their business associates)

Not Automatically Covered by HIPAA



i These industries may generate health information, but HIPAA usually does not apply to them.



Research

Commercial uses



Under HIPAA, de-identified information may be used or disclosed without patient authorization.



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Cybersecurity



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Intellectual property law

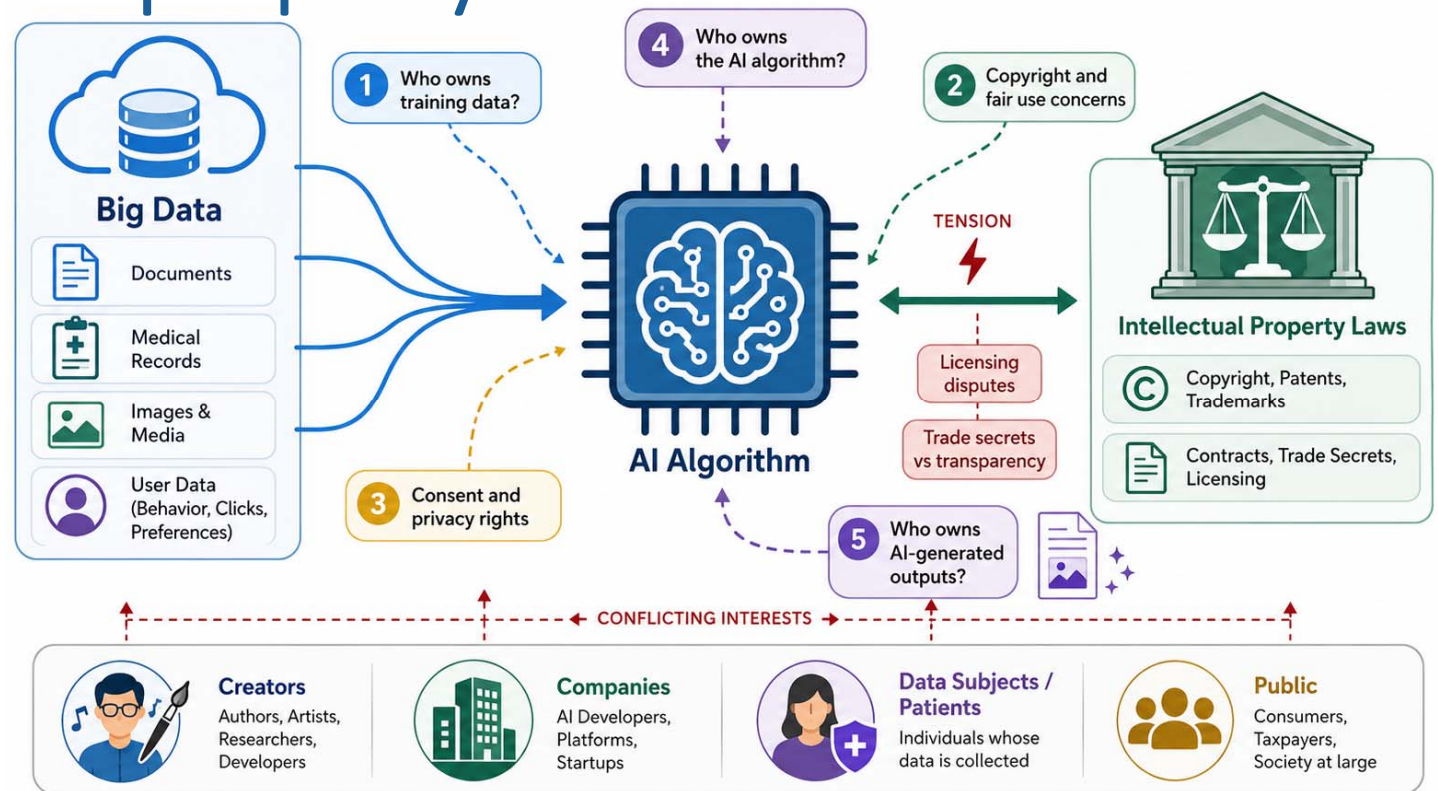


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AI use case: DivertDetect v. Jordan

A large academic medical center implements **DivertDetect**, an AI-based tool designed to identify healthcare workers who may be diverting controlled substances. The algorithm analyzes automated dispensing cabinet transactions, medication administration records, waste documentation, patient pain scores, employee schedules, and patterns of activity compared with peers. Each employee receives a **diversion-risk score**, and individuals exceeding a predefined threshold are automatically referred to the pharmacy-led diversion committee for review.

Six weeks after implementation, the system identifies **Jordan, an ICU nurse, as “high risk.”** Jordan has frequently accessed controlled substances near the end of shifts and has a higher-than-average number of medication waste transactions. Jordan is not told how the score was calculated because the vendor considers the algorithm proprietary.



Wolters Kluwer. *Utilizing advanced technology to detect drug diversion.* 2025.

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Q1: Which response best reflects the principles of safety, transparency, and algorithmic fairness?

- A. Treat the score as sufficient evidence of diversion
- B. Suspend Jordan immediately
- C. Use the score as one component of an investigation
- D. Ignore the score because you know Jordan



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Q2: Which issue raises concerns related to informed consent, data privacy, and data protection?

- A. Jordan works in a high-acuity ICU
- B. Will employee-level data be reused to improve the vendor's algorithm
- C. The algorithm compares Jordan's activity with that of other employees
- D. The diversion committee includes pharmacists



Q3: If Jordan is terminated because of an AI-generated diversion risk score, but a later investigation determines that no diversion occurred, the most important legal issue is determining whether responsibility and liability for the wrongful termination and resulting harms rests with the hospital, managers who relied on the score, the software vendor, or some combination of these parties.

- A. True
- B. False



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Q4: The hospital wants to continue using DivertDetect. Which set of actions best addresses the remaining legal and ethical concerns?

- A. Increase the alert threshold and allow the vendor to manage all employee investigations
- B. Validate the tool locally, establish monitoring, limit data collection and vendor reuse
- C. Inform employees that AI is being used but make no other changes
- D. Require the vendor to disclose its source code publicly



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What are humanistic considerations?

Automation
bias

Deskilling



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Nelson, Wright A. *Am J Health Syst Pharm.* 2026.; Vasconcelos et al, *Proceedings of the ACM on human-computer interaction.* 2023;7(CSCW1):129.

Automation bias (overreliance)

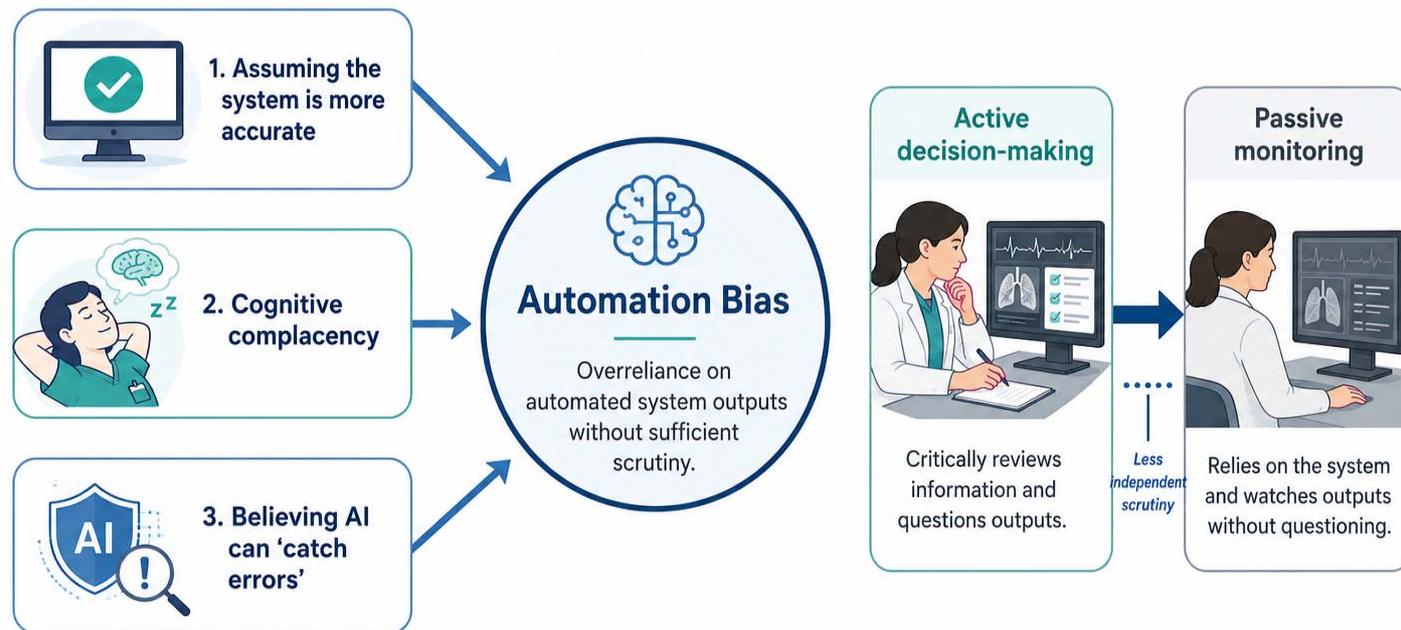


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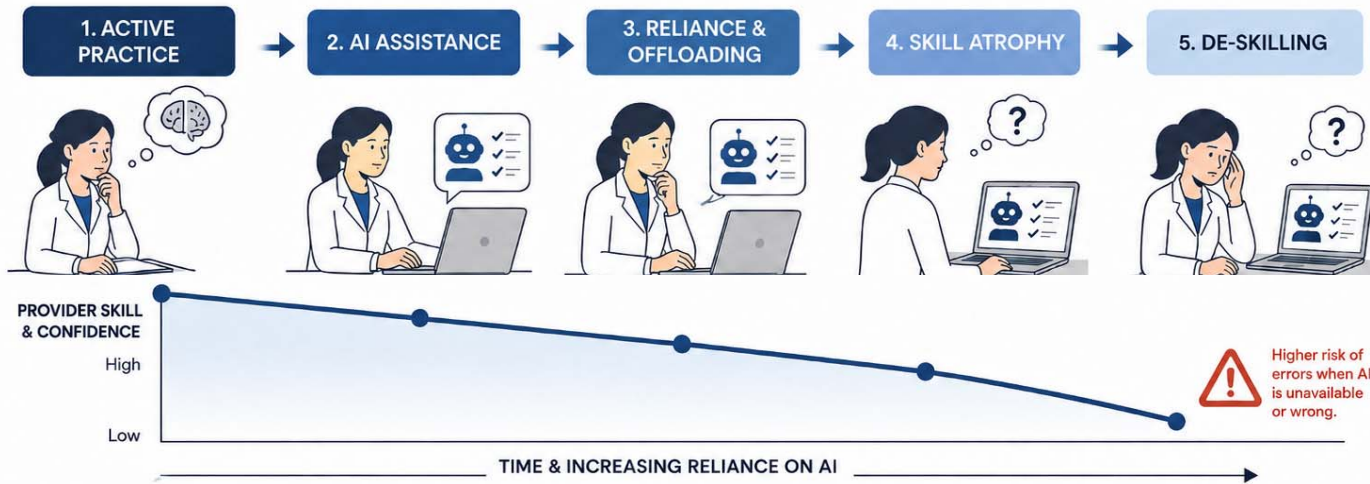


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Deskilling (erosion)

De-Skilling: Erosion of Manual and Cognitive Skills

When Clinical Reasoning is Offloaded to AI



Use it or lose it. The more we offload thinking, the more we lose the ability to think independently.

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How do you
reduce
automation bias
and prevent
deskilling?

Framework to Reduce Automation Bias and Deskilling

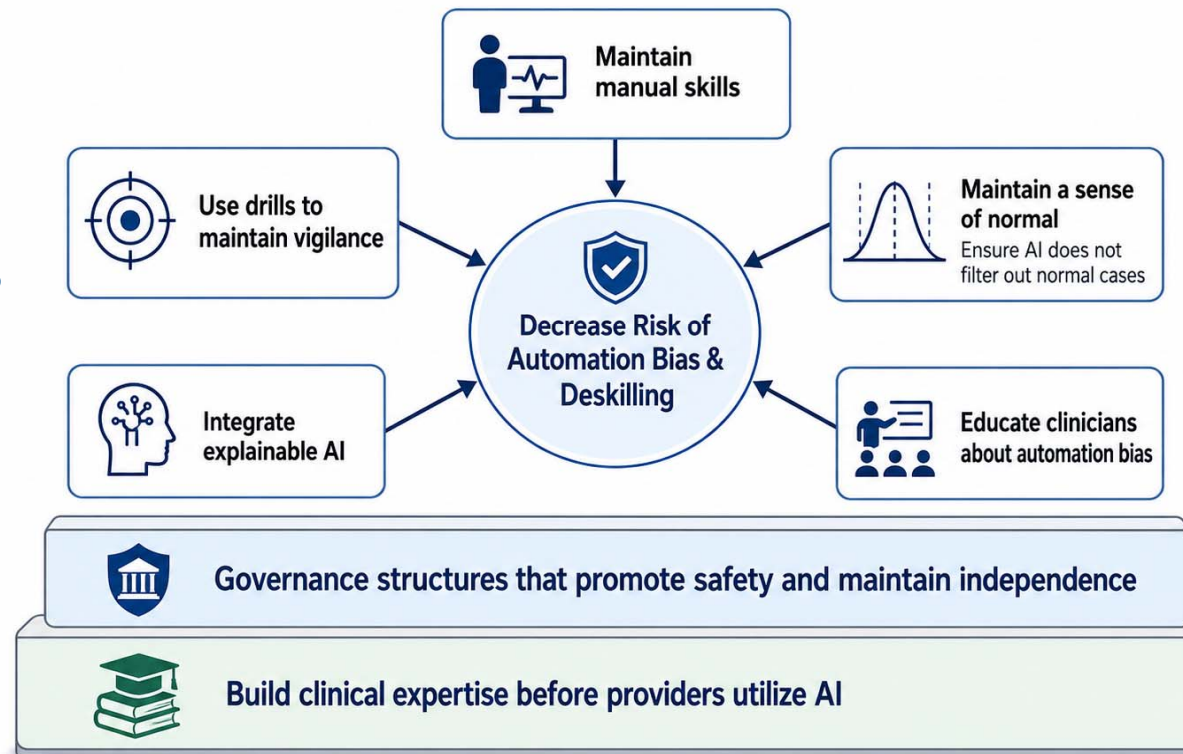


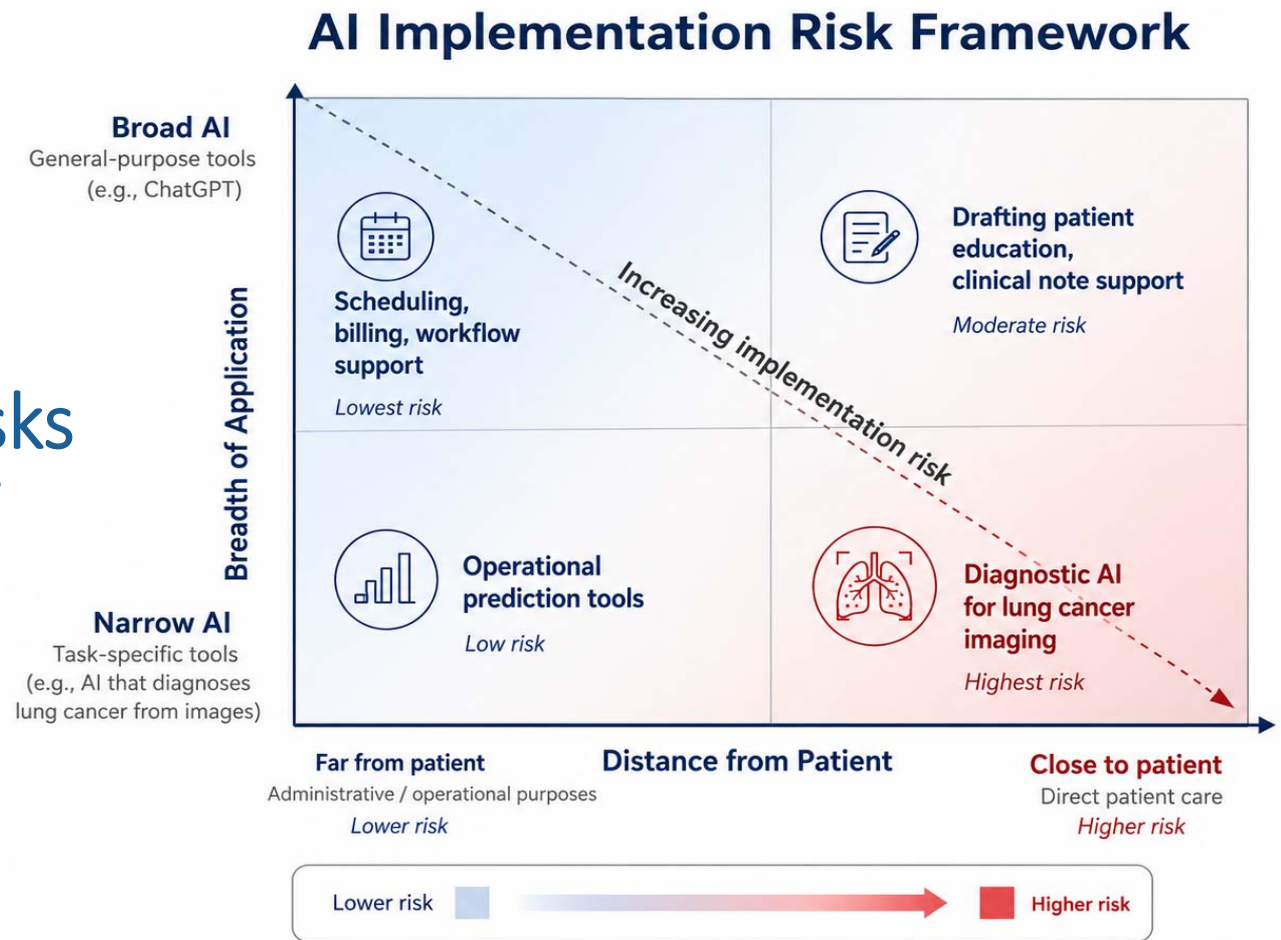
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How can you evaluate the risks and benefits of using AI?



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Smoke S. Am J Health Syst Pharm. 2025;82(3):e113-e116.

To use or not to use?

A technology vendor approaches your health system with a new AI-based clinical decision support tool designed to help clinicians select an **anti-seizure medication (ASM) for adults with newly diagnosed epilepsy**. The vendor claims that its model uses patient characteristics, medical history, laboratory values, seizure characteristics, and concomitant medications to identify the ASM most likely to result in successful treatment for an individual patient.

What ethical and legal consideration questions do you have?

How might humanistic concerns do you have?

What is the risk versus benefit of implementing?

Nelson et al. *Am J Health Syst Pharm.* 2020;77(19):1556-1570.



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Key Takeaways

- Implementing AI requires addressing issues throughout the AI lifecycle
- AI should augment and not replace clinical judgment
- AI risk increases when close to a patient and a broad AI system is used
- You must consider the human in the system



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Questions?



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