



**DUKE University**  
School of Medicine

**DUKE Institute for  
Health Innovation**

# Organizational Governance of AI

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# Learning Objectives

1. Define common terminologies and lay the foundations related for healthcare AI
2. Identify common stages and decision points that healthcare organizations navigate along the AI product lifecycle.
3. Describe the implementation of best practices throughout the AI product lifecycle at Duke Health.
4. Specify organizational capabilities and processes required to govern the use of AI products.
5. Lay out the technical infrastructure, personnel requirements, and frontline clinician support required to implement AI products within clinical care



Duke Institute for Health Innovation

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2 mins

Terminology

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3 mins

Big data and AI in healthcare

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2 mins

Health AI Partnership (HAIP)

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3 mins

Key Decision Points in AI Adoption

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15 mins

Organizational Governance of AI

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15 mins



Duke Institute for Health Innovation

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15 mins



# Duke Institute for Health Innovation





# Duke Institute for Health Innovation (DIHI)

## **Our mission: Catalyze innovations at Duke**

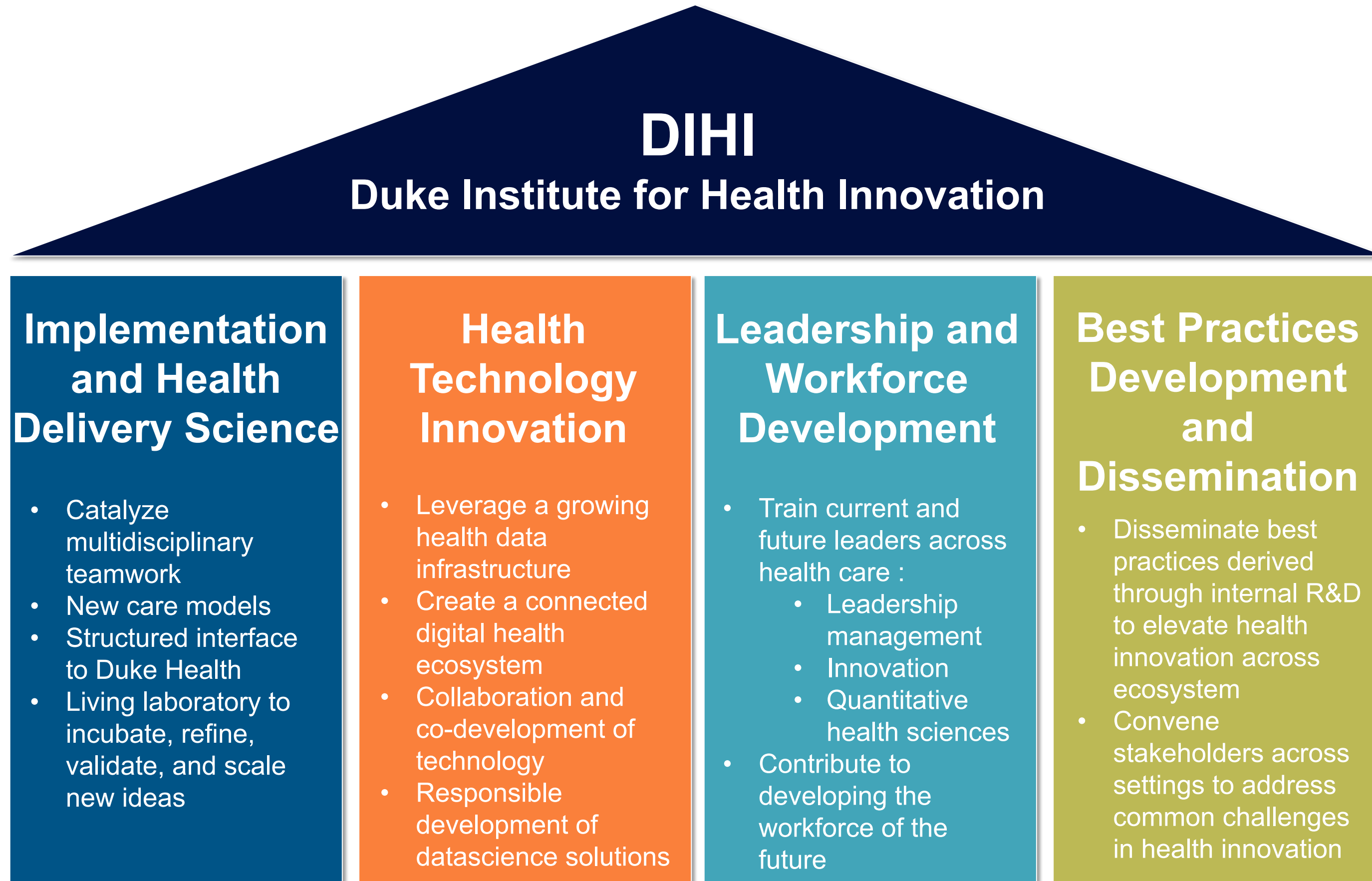
Catalyze **transformative innovation in health and healthcare** through high-impact research, leadership development and workforce training and the cultivation of a community of entrepreneurship

## **Our approach: Innovation by design**

Understand **user workflow**, desired **outcomes** and **problems (needs)** and then collaboratively develop concepts and prototypes, and **iterate** through to **finalize solution**



# DIHI domains of innovation





# Industry best-practice approach in catalyzing innovation

## RFA

### DIHI RFA approach

#### “Top-down + Bottom-Up” approach to sourcing innovations

- Duke Health leadership develops mission-aligned strategic themes for innovation
- Front-line faculty and staff propose “problems” aligned with strategic themes and novel solutions
- Systematic review and due diligence: Assessments on team, feasibility, resource needs, impact and value to patients
- Operational Lead engaged right from the proposal stage
- 8-12 innovations funded each year; Duration: 12-15 months
- DIHI members embedded within project innovation teams to rapidly catalyze the innovations
- Pivots as needed to support rapid evolution to create value
- Metrics: clinical utility, economic utility, cultural impact, IP and academic outputs

**11** Years  
Catalyzing  
Innovations

**90+**  
Innovation Projects

**740+**  
Proposals

## IJ

### DIHI Innovation Jam

#### A Health focused **Shark Tank** at Duke

- Solicits and identifies high-potential healthcare and health **innovations ready for commercialization**
- **Duke Leadership as Sharks:**
  - DUHS leaders, Department Chairs, Deans of School of Medicine, Nursing, Engineering, OLV, I&E, MedBlue, Center and Institute Directors
- Innovation proposals from students, faculty, trainees and staff across campus
- **Funding** to support entrepreneurship / **formation of company** and also **develop the product/service** etc.
- Inventors offer portion of their share of Duke internal returns for investment from the sharks
- Internal syndicated investment agreements documented through MOUs.

**6** Years  
of Jamming

**30+**  
Pitches

**12** Companies  
Incubated





# Industry best-practice approach in catalyzing innovation



 **Duke Institute**  
for Health Innovation

# RFA 2024

We invite you to submit your novel ideas supporting

**Generative AI & Large Language Models: AI solutions to improve staff and clinician efficiency, patient journey and outcomes**

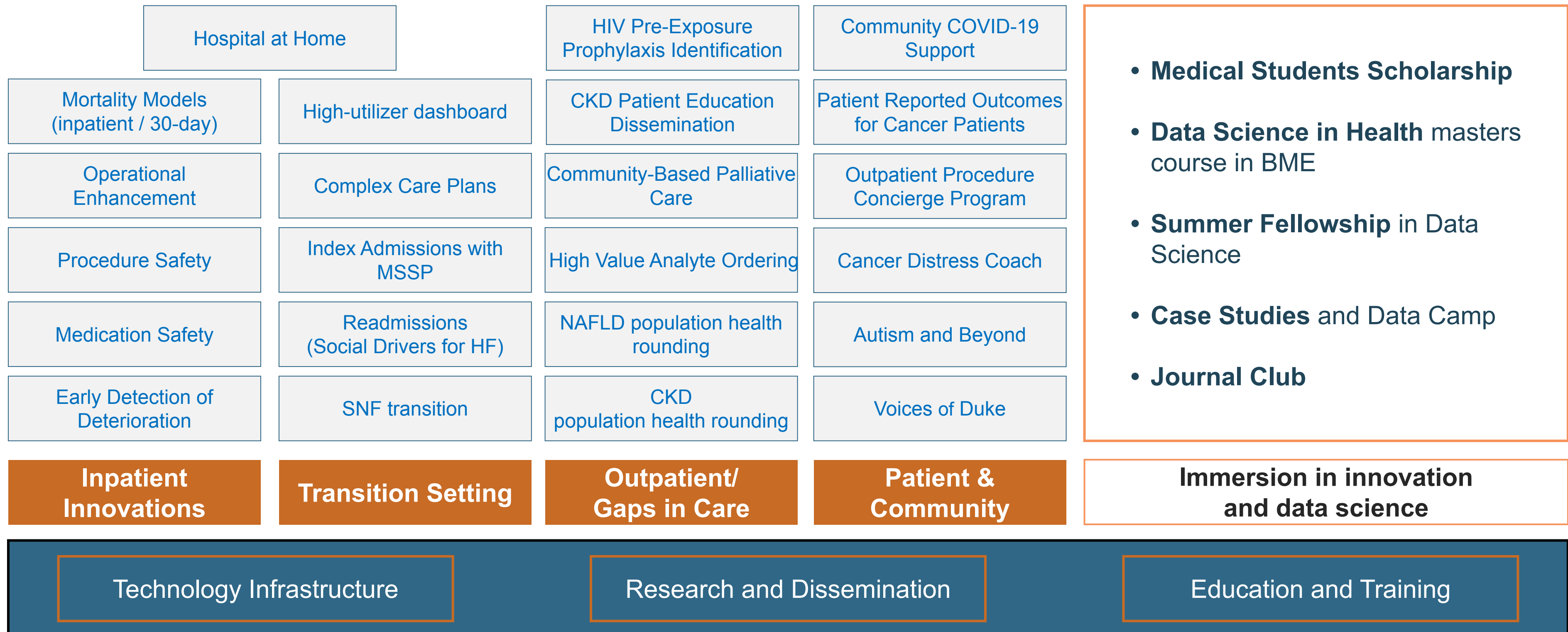
Visit: [dihi.org/events/rfa](https://dihi.org/events/rfa)  
email: [dihi-rfa@duke.edu](mailto:dihi-rfa@duke.edu)

 @dukeinnovate

Proposals due: **NOVEMBER 3, 2023**



# DIHI spectrum of value creation



Duke Institute for Health Innovation [ DIHI ] – Spectrum of value creation across the ecosystem



Duke Institute for Health Innovation

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2 mins

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Key Decision Points in AI Adoption

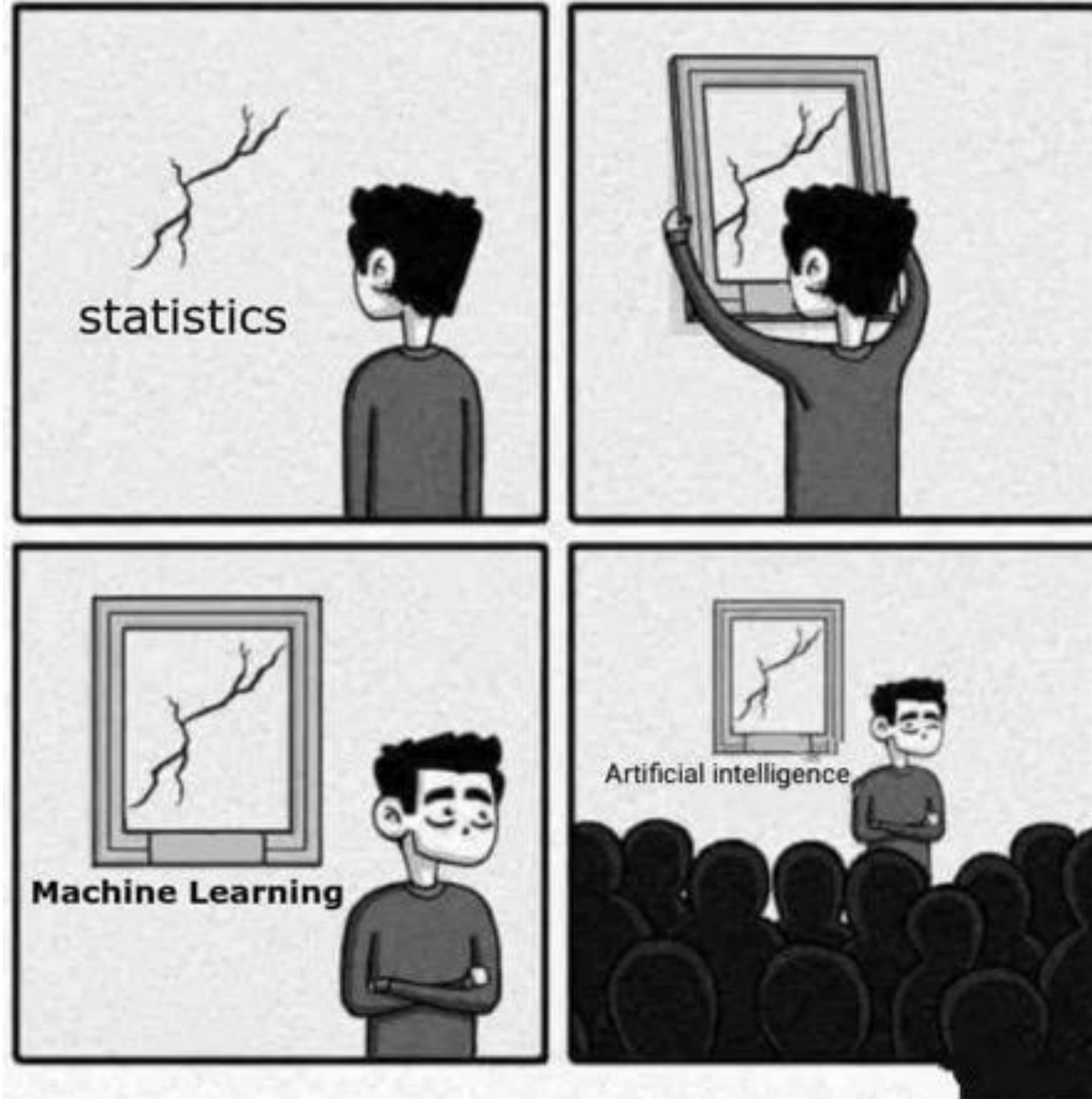
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15 mins

Organizational Governance of AI

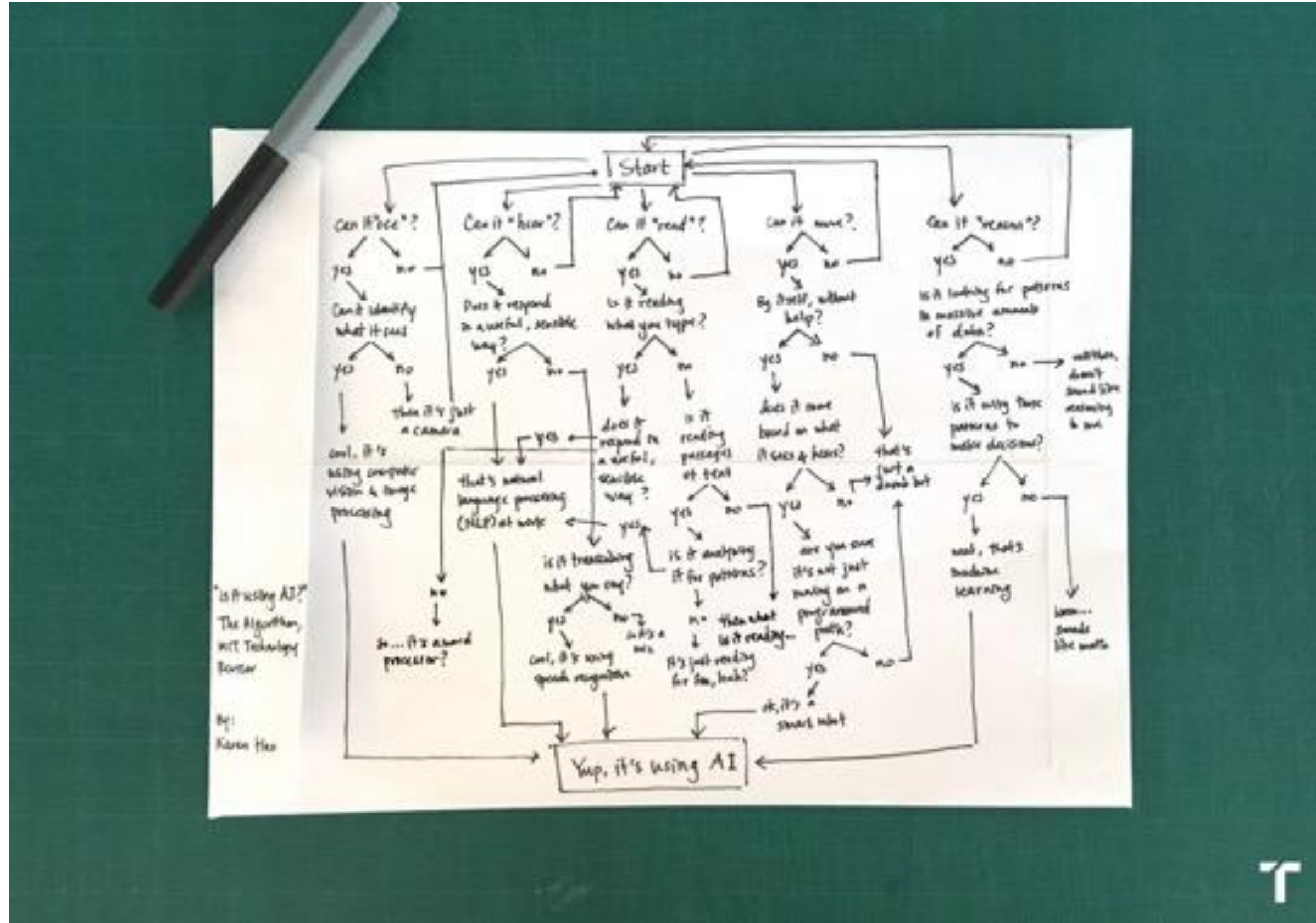
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15 mins





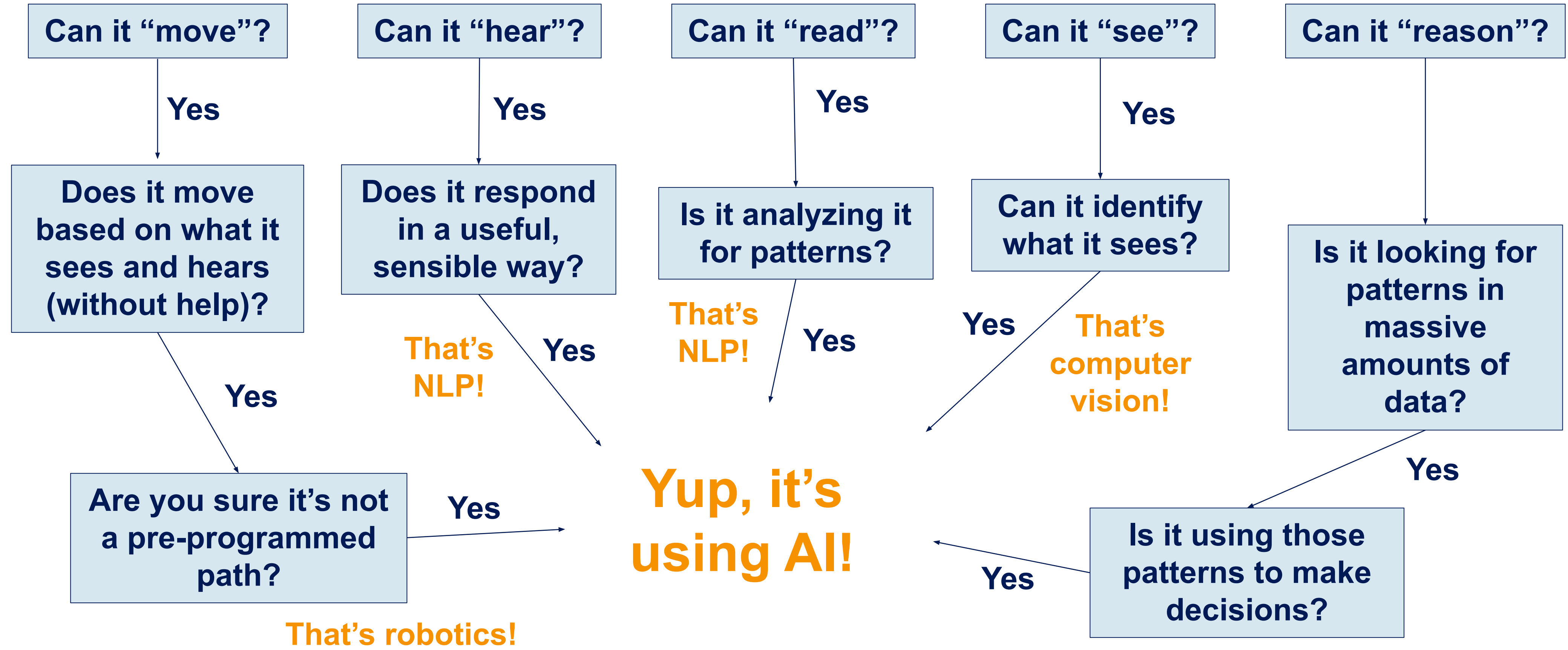
# What is AI?



<https://www.technologyreview.com/2018/11/10/139137/is-this-ai-we-drew-you-a-flowchart-to-work-it-out/>



# What is AI?

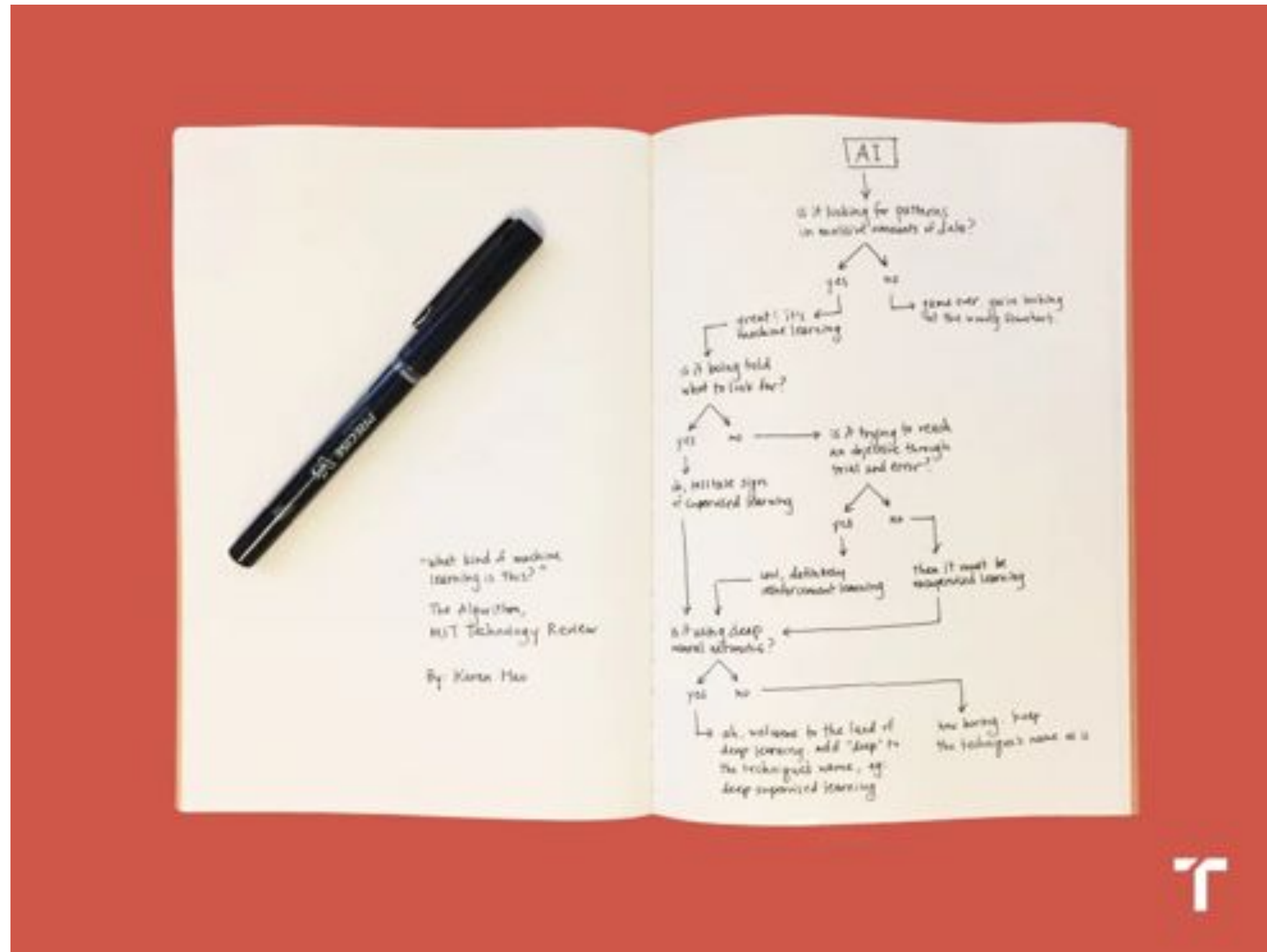


**That's robotics!**

**Yup, it's using AI!**



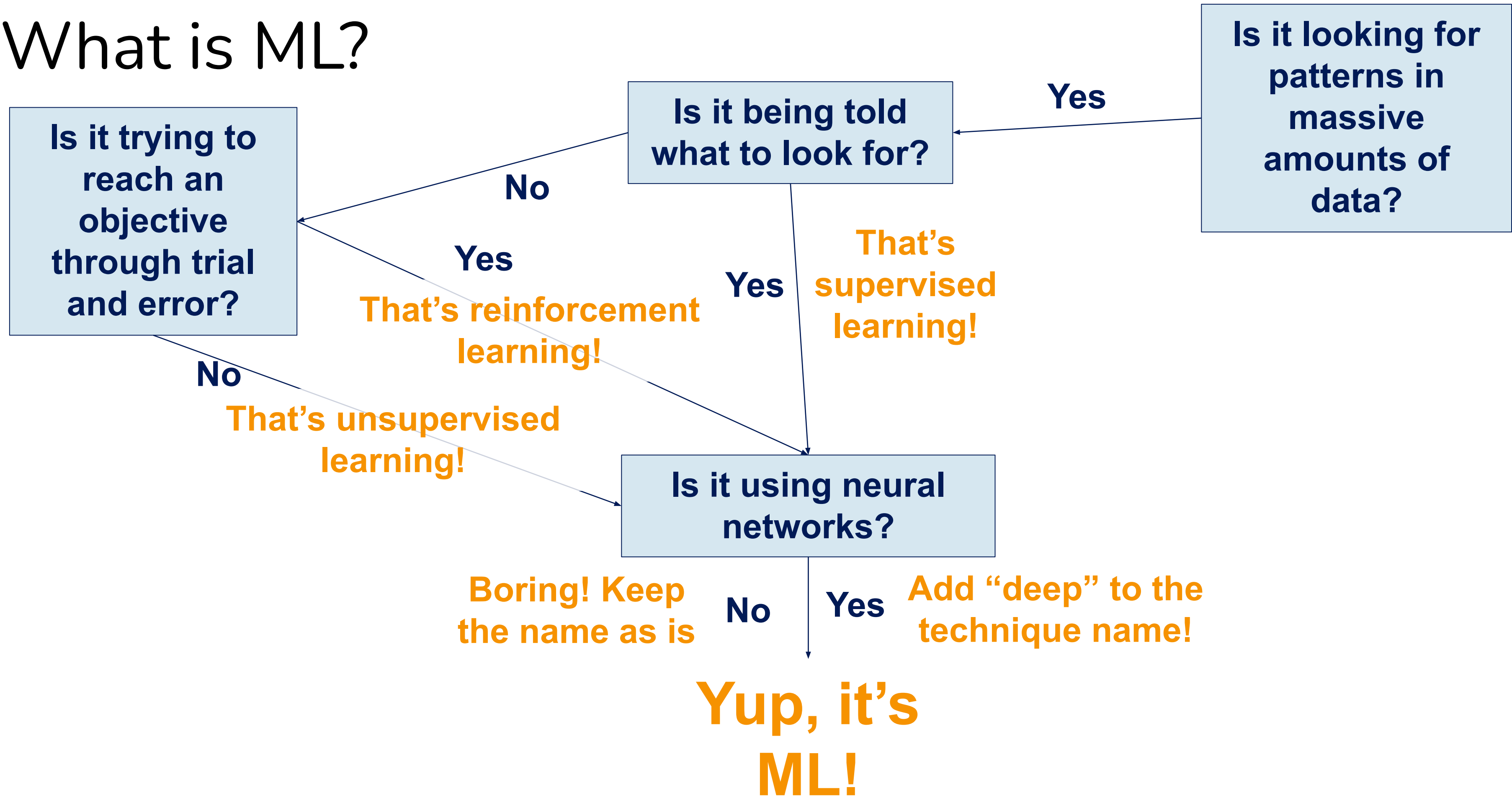
# What is Machine Learning (ML)?



<https://www.technologyreview.com/2018/11/17/103781/what-is-machine-learning-we-drew-you-another-flowchart/>



# What is ML?







# What is Generative AI

Generative AI refers to a type of deep-learning artificial intelligence technology that can generate new content, from text to images, sound, and videos, based on the data it has learned from.

It uses patterns and information from vast amounts of data to create new, similar data.

**Examples:** Chatbots, image generators, music composition.

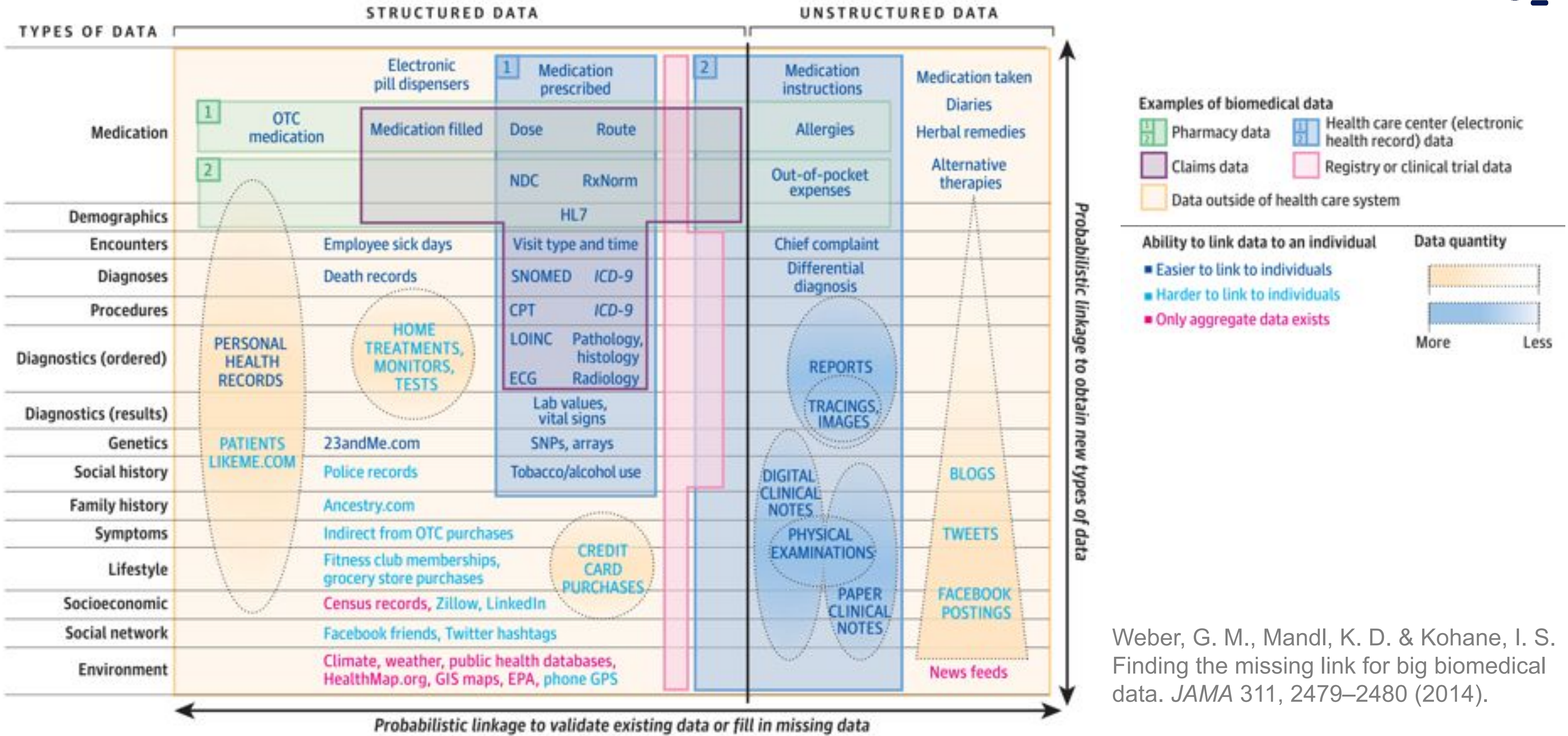


# Artificial Intelligence vs. Traditional Machine Learning, Generative AI

| Characteristic   | AI   | Traditional ML  | Generative AI  |
|------------------|--|---|--|
| Purpose          | Develop computer systems that can perform tasks that typically require human intelligence.                             | Make predictions or decisions based on given data.                          | Generate new data samples that resemble a given set of training data.                                |
| Data Interaction | Models use various techniques and strategies designed to mimic human intelligence across a wide range of applications. | Models learn from data to make predictions or decisions on new unseen data. | Models produce new data that weren't part of the original dataset but share similar characteristics. |



# What is data?



Weber, G. M., Mandl, K. D. & Kohane, I. S. Finding the missing link for big biomedical data. *JAMA* 311, 2479–2480 (2014).



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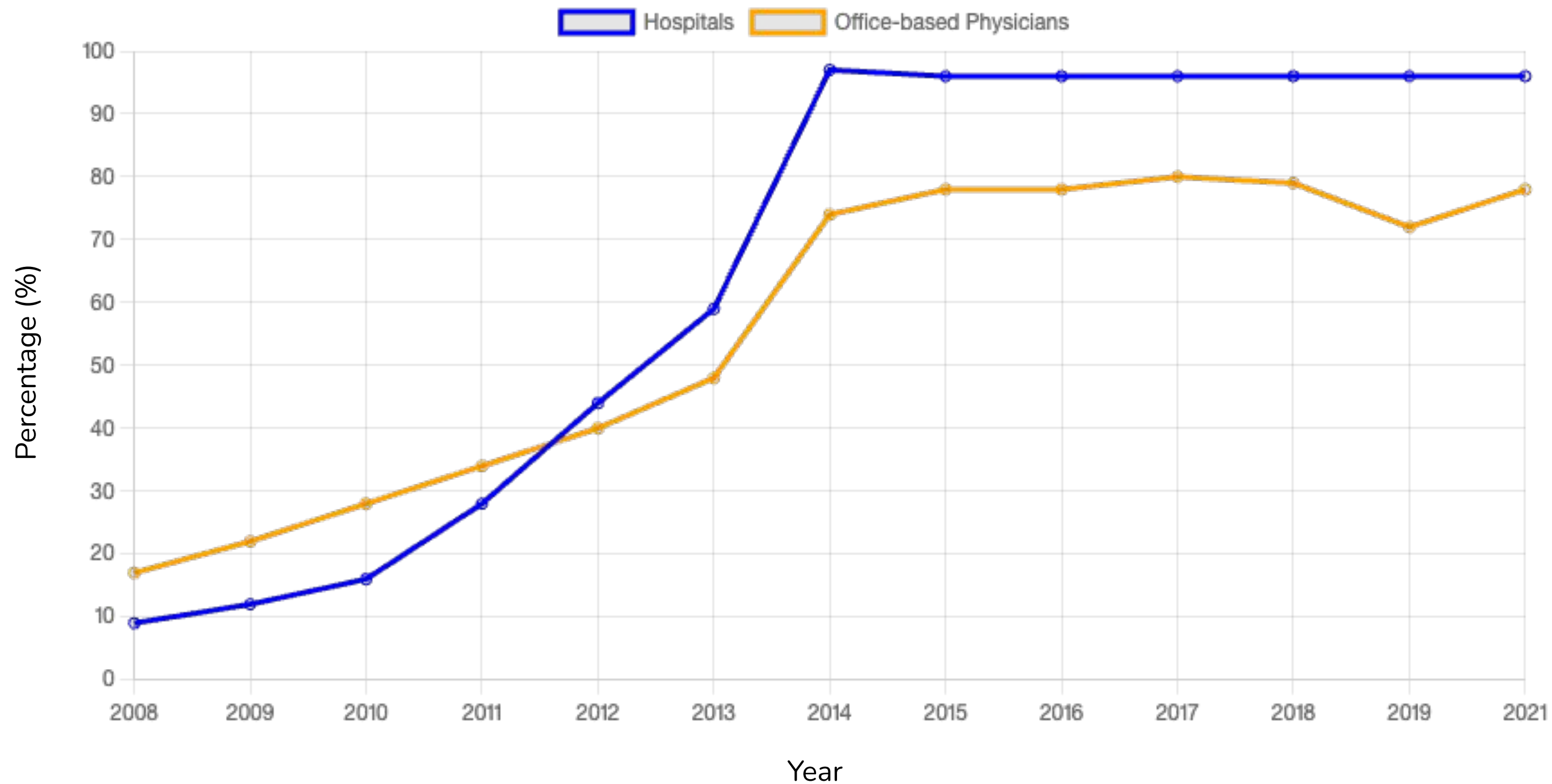
Organizational Governance of AI

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15 mins



# Adoption of Electronic Health Records (EHR) in US



[Data from HealthIT.gov](https://www.healthit.gov)



# Excitement about using AI in healthcare delivery



**500+ medical AI systems**  
July 2022



**3,569** → **50,000+**  
in 2010                      in 2022

de Hond AAH, Leeuwenberg AM, Hooft L, Kant IMJ, Nijman SWJ, van Os HJA, et al. Guidelines and quality criteria for artificial intelligence-based prediction models in healthcare: a scoping review. NPJ Digit Med. 2022;5(1):2.

Jungblut L, Blüthgen C, Polacin M, Messerli M, Schmidt B, Euler A, et al. First Performance Evaluation of an Artificial Intelligence-Based Computer-Aided Detection System for Pulmonary Nodule Evaluation in Dual-Source Photon-Counting Detector CT at Different Low-Dose Levels. Invest Radiol. 2022;57(2):108-14.



# AI in healthcare delivery

- Informing therapeutic and diagnostic decisions [1-2]
- Prioritizing healthcare resources
  - Enrollment in care management programs [3]
  - Surgery scheduling [4]
  - Organ transplantation [5]

[1] Badgeley MA, Zech JR, Oakden-Rayner L, et al. Deep learning predicts hip fracture using confounding patient and healthcare variables. NPJ digital medicine. 2019;2:31.

[2] Zech JR, Badgeley MA, Liu M, Costa AB, Titano JJ, Oermann EK. Confounding variables can degrade generalization performance of radiological deep learning models. arXiv preprint 2018;arXiv:1807.00431v2.

[3] Rumsfeld JS, Joynt KE, Maddox TM. Big data analytics to improve cardiovascular care: promise and challenges. Nature Reviews Cardiology. 2016;13(6):350-9.

[4] Murray SG, Wachter RM, Cucina RJ. Discrimination by artificial intelligence in a commercial electronic health record—a case study. Health Affairs Forefront. January 2020. (<https://www.healthaffairs.org/content/forefront/discrimination-artificial-intelligence-commercial-electronic-health-record-case-study>.)

[5] Clement J, Maldonado AQ. Augmenting the transplant team with artificial intelligence: Toward meaningful AI use in solid organ transplant. Frontiers in immunology. 2021;12:694222.



# Benefits of using AI in healthcare delivery

- Operational benefits
  - Cost savings by USD 150 billion in 2026
- Care delivery benefits from proactive (vs. reactive) health management
  - Earlier diagnosis
  - Tailored treatments
  - More efficient follow-ups
  - Fewer hospitalizations
  - Less doctor visits
  - Less treatments





# AI adoption in healthcare delivery

However, few AI tools are used in clinical care in reality.

## Census data (2022)

- Less than 5% of healthcare organizations in the US are using AI tools.
- Fewer than 1,000 jobs in healthcare are related to machine learning and AI.

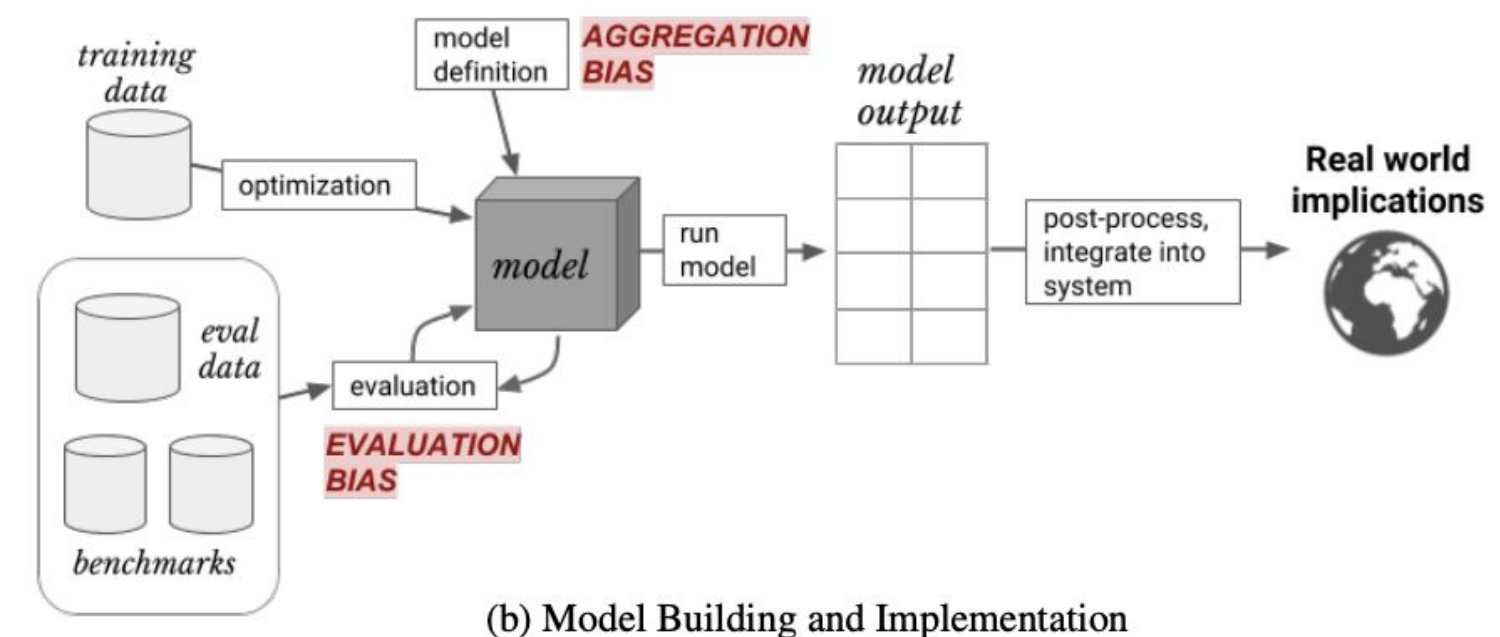
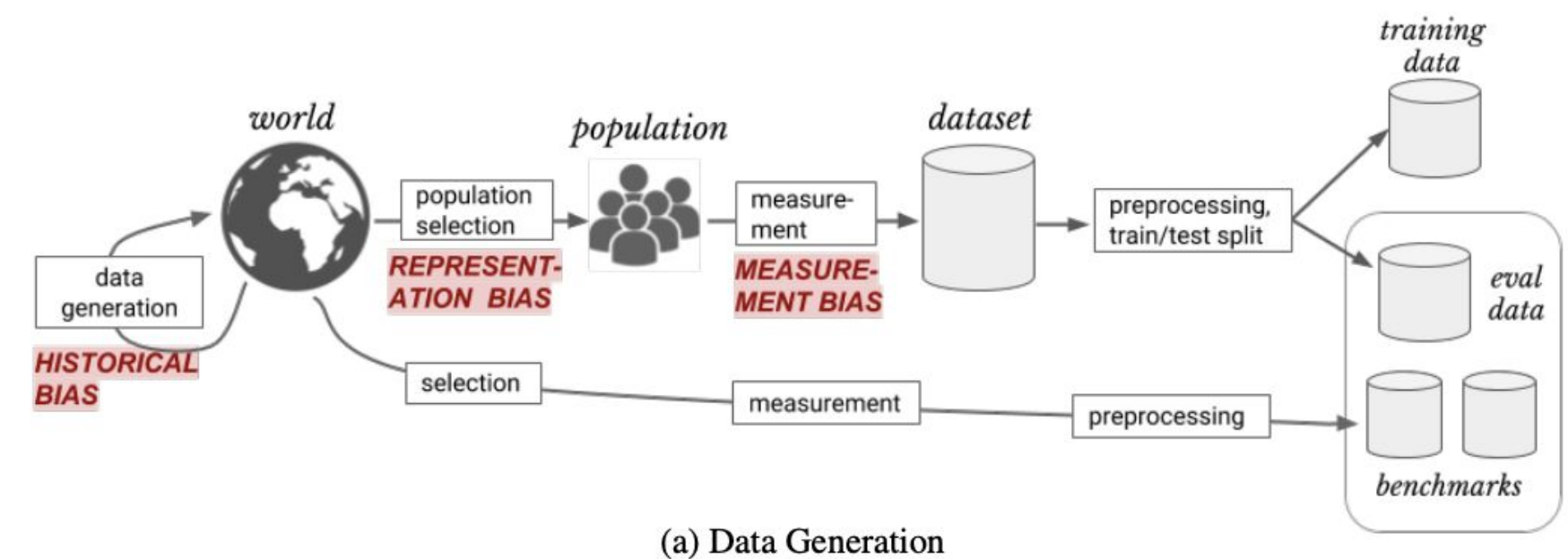
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# Challenges of AI adoption in healthcare delivery

- Lack of trust in AI solutions
- Bias in medical AI
- Lack of systematic implementation approach
- Compliance with regulation
- Lack of governance processes and maintenance and monitoring infrastructure



Wu E, Wu K, Daneshjou R, Ouyang D, Ho DE, Zou J. How medical AI devices are evaluated: limitations and recommendations from an analysis of FDA approvals.

Suresh H, Gutttag JV. A framework for understanding unintended consequences of machine learning. arXiv preprint arXiv:1901.10002. 2019 Dec 30;2(8):73.



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# Health AI Partnership (HAIP)

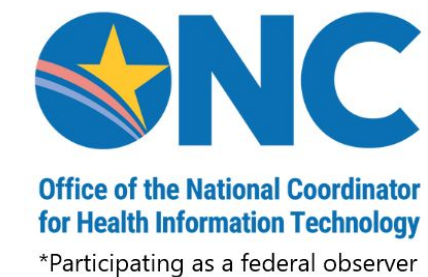
## Health Systems



## Ecosystem Partners



## Federal Agencies





# Health AI Partnership

**Our mission:** Empowering healthcare professionals to use AI effectively, safely, and equitably through community-informed up-to-date standards

## Our values:

### advance health equity

prioritize solutions that advance health equity and eliminate the AI digital divide

### improve patient care

ensure that AI adoption is driven by patient care needs, not technical novelty

### improve the workplace

surface socio-technical challenges in AI use and foster a positive work environment

### build community

create safe spaces to share learnings and consult peers



# Milestones of phase 1 (April 22 - August 23, 2023)

## Standard AI Solution Procurement Milestones

- Best practices sourced from across the HAIP organizations
- Co-design workshops with IDEO.org
- Focused on AI solutions used for:
  - Diagnosis or treatment decisions for patients
  - Prioritization of patients for healthcare services (e.g., surgery scheduling, care management prioritization, ED triaging)

## Health Equity Across the AI Lifecycle (HEAAL) Framework

- Developed detailed procedures for healthcare organizations to follow for AI procurement
- Developed to answer the question: “Our health system is considering adopting a new solution that uses AI; how do we assess the potential future impact on health inequities?”
- Multi-stakeholder workshop featuring case studies, expert discussants, and framework developers

**8** Key  
Decision  
Points

**85+**  
Interviews

**31** Topic  
Guides

**3** Case  
Studies

**75+**  
Participants

**37**  
Procedures



# Crowded Ecosystem of AI Conveners

| Organization  | Description   |
|---|---|
| Health AI Partnership (HAIP)                                  | A multi-stakeholder collaborative who seeks to empower healthcare organizations to use AI safely, effectively, and equitably. Vision is to be the trust partner and up-to-date source of actionable guidance for healthcare professionals using AI. |
| Coalition for Health AI                                       | A community of academic health systems, organizations, and expert practitioners of artificial intelligence (AI) and data science.   |
| Valid AI  | A collaborative community to advance generative AI in a responsible manner to improve health care and research  |
| HIMSS (Healthcare Information and Management Systems Society) | A member-based society that covers a large part of health technology ecosystem. This society offers educational resources such as course materials, guides, webinars, and certifications on a range of health information and technology subjects.  |
| HLTH  | Community for innovators in the healthcare ecosystem. Has a heavy industry focus. Hosts conferences and creates digital content like webinars, podcasts, and blogs.   |
| Alliance for AI in Healthcare                                 | An international multi-stakeholder membership-based advocacy group organized to influence regulatory principles for development and implementation of AI in healthcare.   |
| AI Healthcare Coalition                                       | An industry advocacy group to influence on health care AI policy and law.   |
| Healthcare Products Collaborative                             | Promotes discussion and innovation in the healthcare products community, bringing together regulators, professionals, academics, and thought leaders to tackle industry challenges.   |
| Connected Health Initiative                                   | A multi stakeholder coalition that advocates for policies and laws related to AI in healthcare. They educate regulators and lawmakers and publish white papers that define industry best practices.   |
| The AI Collaborative (Nuance + The Academy)                   | A peer learning and consulting services to clinical and operational executives who oversee their organization's investment in AI tools for healthcare.  |
| KLAS Research   | A consulting services that evaluates digital products by aggregating and synthesizing feedback about vendor products.   |
| Machine Learning for Healthcare                               | Academic publishing and dissemination of scientific work  |
| Association for Health Learning and Inference                 | Academic publishing and dissemination of scientific work  |

| Organization                                       | Description  |
|--|--|
| American Medical Informatics Association (AMIA)    | A society for health informatics professionals that offers education, training, accreditation, and certifications.   |
| Society for Imaging Informatics in Medicine (SIIM) | Healthcare professional organization for those interested in use of informatics in medical imaging.  |
| National Academies of Medicine AI Code of Conduct  | Aimed at providing a guiding framework to ensure that AI algorithms and their application in health, health care, and biomedical science perform accurately, safely, reliably, and ethically in the service of better health for all.  |
| Digital Health Collaborative                       | The Digital Health Collaborative is a group of leading healthcare and consumer organizations that share a commitment to “raising the bar” for evidence and value in digital health technology.   |
| The AI Alliance                                    | A community of technology creators, developers and adopters collaborating to advance safe, responsible AI rooted in open innovation.   |
| Trustworthy & Responsible AI Network (TRAIN)       | Through collaboration, TRAIN members will help improve the quality and trustworthiness of AI by: <ul style="list-style-type: none"> <li>- Sharing best practices related to the use of AI in healthcare settings</li> <li>- Enabling registration of AI used for clinical care or clinical operations</li> <li>- Providing tools to enable measurement of outcomes associated with the implementation of AI</li> <li>- Facilitating the development of a federated national AI outcomes registry for organizations to share among themselves.</li> </ul> |
| Collaborative Community on Ophthalmologic Imaging  | A collaborative of academic institutions, government agencies, private businesses, and professional organizations dedicated to establishing standards of practice for innovative ophthalmic imaging.   |
| Center for AI Policy (CAIP)                        | The Center for AI Policy (CAIP) is a nonpartisan research organization dedicated to mitigating the catastrophic risks of AI through policy development and advocacy.   |
| Center for Public Sector A.I.                      | The Center' firmly believes that, if managed carefully and prudently by the right leaders, technology like generative AI can significantly improve government agencies' ability to serve the public.   |



# Crowded Ecosystem of AI Conveners

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| Coalition for Health AI                                       |   |  | se of informatics in   |
| Valid AI  |   |  | gorithms and their form accurately, all.   |
| HIMSS (Healthcare Information and Management Systems Society) |   |  | are and consumer evidence and value  |
| HLTH  |   |  | s collaborating to   |
| Alliance for AI in Healthcare                                 |   |  | e quality and  |
| AI Healthcare Coalition                                       |   |  | settings operations ated with the  |
| Healthcare Products Collaborative                             |   |  | omes registry for  |
| Connected Health Initiative                                   |   |  | s, private   |
| The AI Collaborative (Nuance + The Academy)                   |   |  | ublishing standards of   |
| KLAS Research   |   |  | ganization dedicated pment and   |
| Machine Learning for Healthcare                               | Academic publishing and dissemination of scientific work  | Center for AI Policy (CAIP)              | advocacy.  |
| Association for Health Learning and Inference                 | Academic publishing and dissemination of scientific work  | Center for Public Sector A.I.            | The Center' firmly believes that, if managed carefully and prudently by the right leaders, technology like generative AI can significantly improve government agencies' ability to serve the public. |

**Organizations vary significantly across:**

- Types of content produced (e.g., academic manuscripts, actionable guidance, technical standards)
- Frequency of content updates
- Types of convenings (e.g., public conferences, closed-door workshops)
- Primary target audience (e.g., academic, practitioner, government)
- Business model (e.g., pay for content, pay for events, pay for certification)
- Organization structure (e.g., housed within AMCs, 501(c)3, 501(c)6, for-profit companies)
- Level of industry participation
- Focus on government advocacy

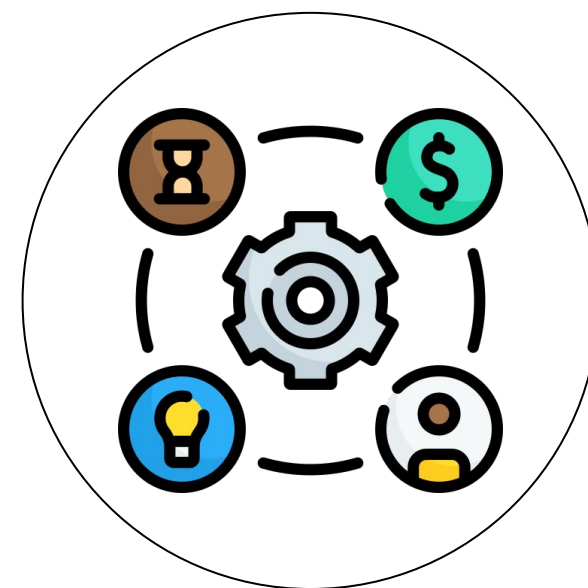




# Differentiators of HAIP



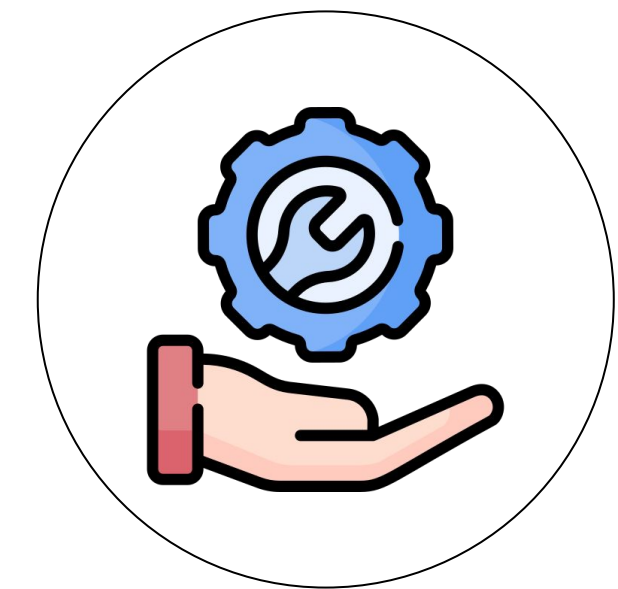
Voice of healthcare  
organizations



Support high- and  
low-resource  
environments



Team of clinical,  
technical, operational,  
strategic, and  
regulatory  
stakeholders



Provider of technical  
assistance for AI  
implementation



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**Key Decision Points in AI Adoption**

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**15 mins**

Organizational Governance of AI

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15 mins



# Building “practical” standards for AI adoption



## Design research

Design prototype of the AI adoption standards that health system leaders find immediately useful in practice



## Qualitative research

Understand the current and aspirational state of AI adoption in healthcare organizations and surface content to be included in the standards



# Qualitative research

- **Results:** 8 key decision points in the AI adoption process



- 1 Identify and prioritize a problem
- 2 Identify requirements for an AI product as a viable component of the solution
- 3 Develop measures of outcomes and success of the AI product
- 4 Design a new optimal workflow to facilitate integration
- 5 Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use
- 6 Execute AI product roll out, workflow integration, communication, education, and scaling
- 7 After operationalization, monitor and maintain the AI product and work environment
- 8 Update or decommission the AI product and work environment

Kim JY, Boag W, Gulamali F, Hasan A, Hogg HD, Lifson M, Mulligan D, Patel M, Raji ID, Sehgal A, Shaw K. Organizational Governance of Emerging Technologies: AI Adoption in Healthcare. In Proceedings of the 2023 ACM Conference on Fairness, Accountability, and Transparency 2023 Jun 12 (pp. 1396-1417).



# Decision point 1

Problem Identification and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

**1 Identify and prioritize a problem**

3 Develop measures of outcomes and success of the AI product

6 Execute AI product roll out, workflow integration, communication, education, and scaling

7 After operationalization, monitor and maintain the AI product and work environment

2 Identify requirements for an AI product as a viable component of the solution

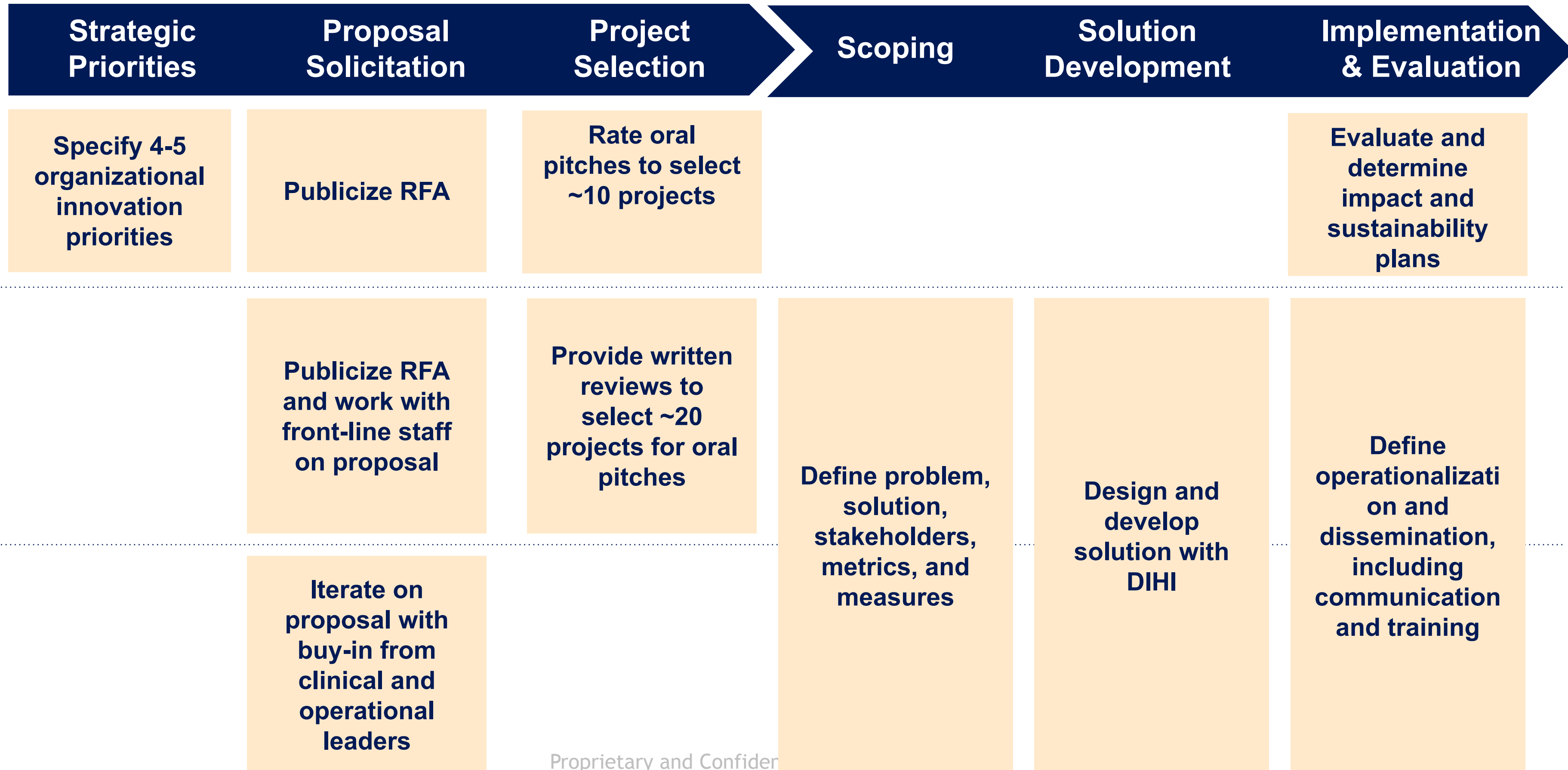
4 Design a new optimal workflow to facilitate integration

8 Update or decommission the AI product and work environment

5 Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use



Create alignment with frontline staff and organizational leaders throughout project selection





# Decision point 2

Problem Identification and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

1 Identify and prioritize a problem

3 Develop measures of outcomes and success of the AI product

6 Execute AI product roll out, workflow integration, communication, education, and scaling

7 After operationalization, monitor and maintain the AI product and work environment

2 **Identify requirements for an AI product as a viable component of the solution**

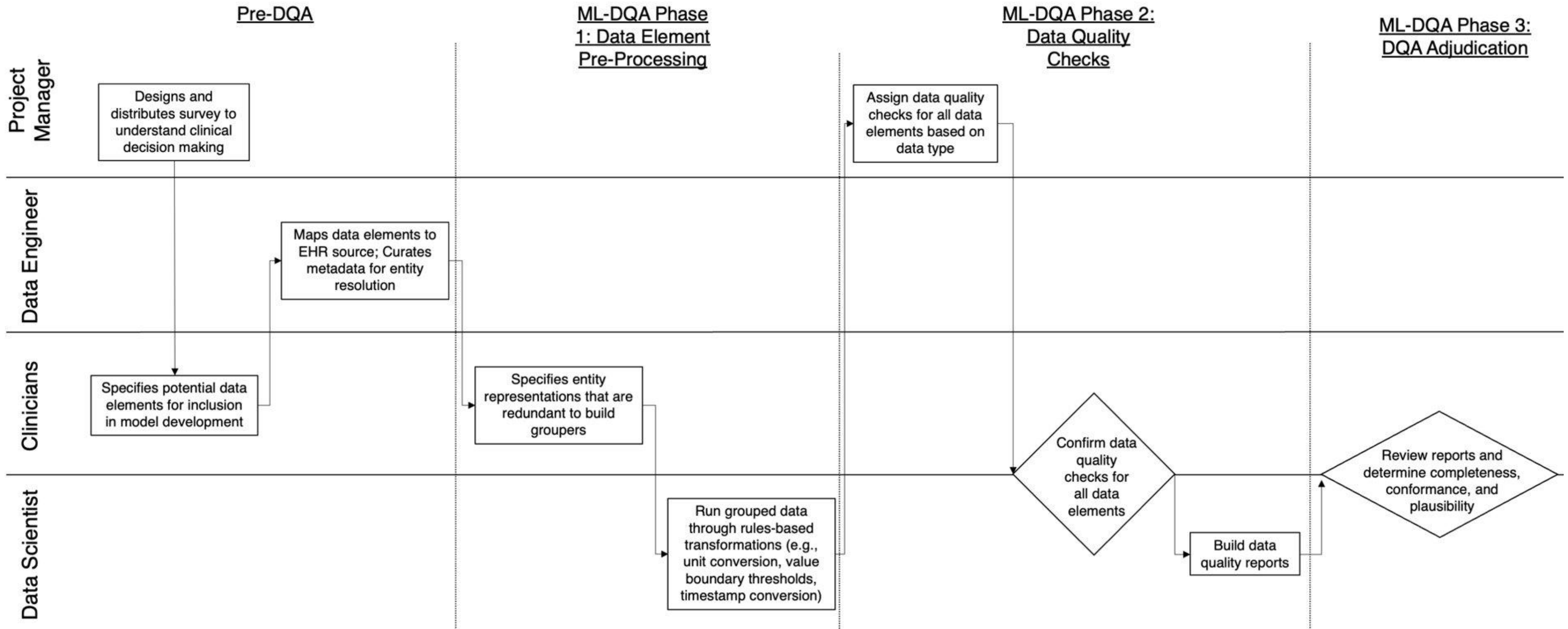
4 Design a new optimal workflow to facilitate integration

8 Update or decommission the AI product and work environment

5 Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use



# Conduct data quality assurance (DQA) and create groupers

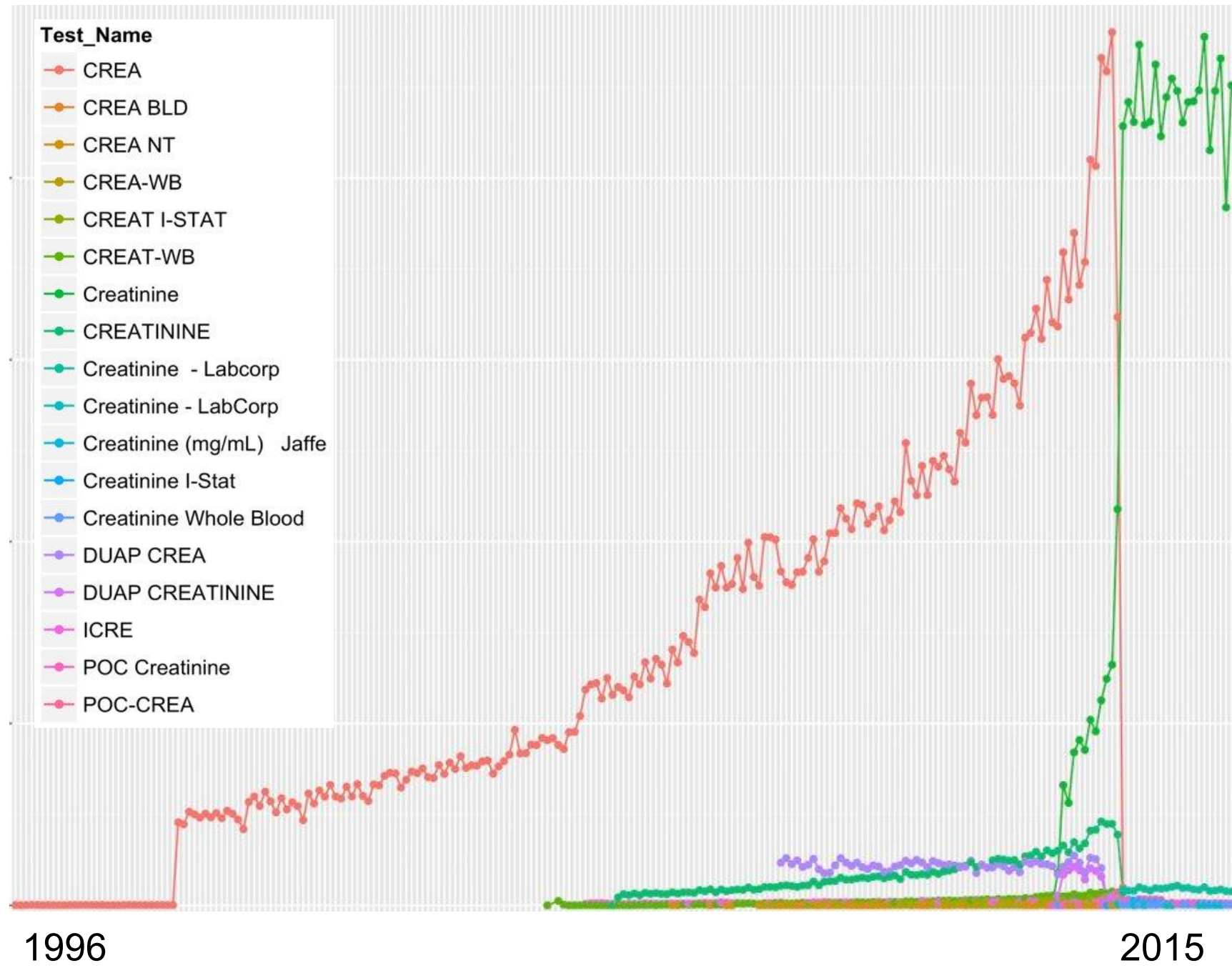






# Conduct data quality assurance (DQA) and create groupers

## Which Creatinine?



|   | Pediatric Sepsis Prediction | Immune-Related Adverse Event Prediction | Maternal Morbidity and Mortality Prediction |
|---|-----------------------------|---|---|
| <b>Phase I: Data Element Pre-Processing</b> |                             |   |   |
| Pre-existing groupers                       | 108                         | 39                                      | 310   |
| Project-specific groupers                   | 73                          | 41                                      | 12  |
| <b>Phase II: ML-DQA Checks</b>              |                             |   |   |
| Completeness checks                         | 144                         | 508                                     | 404   |
| Conformance checks                          | 122                         | 225                                     | 69  |
| Plausibility checks                         | 123                         | 301                                     | 404   |
| <b>Total quality checks</b>                 | <b>389</b>                  | <b>1,034</b>                            | <b>877</b>                                  |



# Decision point 3

Problem Identification  
and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

- 1 Identify and prioritize a problem
- 2 Identify requirements for an AI product as a viable component of the solution
- 3 Develop measures of outcomes and success of the AI product**
- 4 Design a new optimal workflow to facilitate integration
- 5 Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use
- 6 Execute AI product roll out, workflow integration, communication, education, and scaling
- 7 After operationalization, monitor and maintain the AI product and work environment
- 8 Update or decommission the AI product and work environment



## Define categories of measures

| Category               | Definition   | Example Metrics  |
|------------------------|--|--|
| Model performance      | <b>Effectiveness, accuracy, and reliability of the AI model</b> or algorithm in fulfilling its intended tasks within the clinical or healthcare context. | Sensitivity (recall, true positive rate), Specificity (true negative rate), Area Under the ROC Curve (AUC-ROC), F1 Score, Precision (positive predictive value). |
| Software performance   | <b>Efficiency and responsiveness of processing tasks</b> , delivering results, and overall performance of the software components and its interactions.  | Inference time, throughput, model latency, response time, resource utilization, scalability.   |
| Clinical effectiveness | Assessment of impact of product use on healthcare outcomes.  | <b>Mortality rate, intensive care unit requirement, complication rate</b>  |
| Usability              | <b>Quality of users' interactions with the AI-based medical software.</b>  | Clinician satisfaction, user error rates, ease of use.   |
| Safety and security    | Safe and secure operating software, evaluating harm to patients and protection against unauthorized access, data breaches, and cyber threats.            | Number of identified safety risks and mitigations, adherence to cybersecurity standards, detection of adversarial attacks, incident response time.               |
| Business               | Business objectives and outcomes   | <b>Reduction in diagnostic time, cost savings.</b>   |

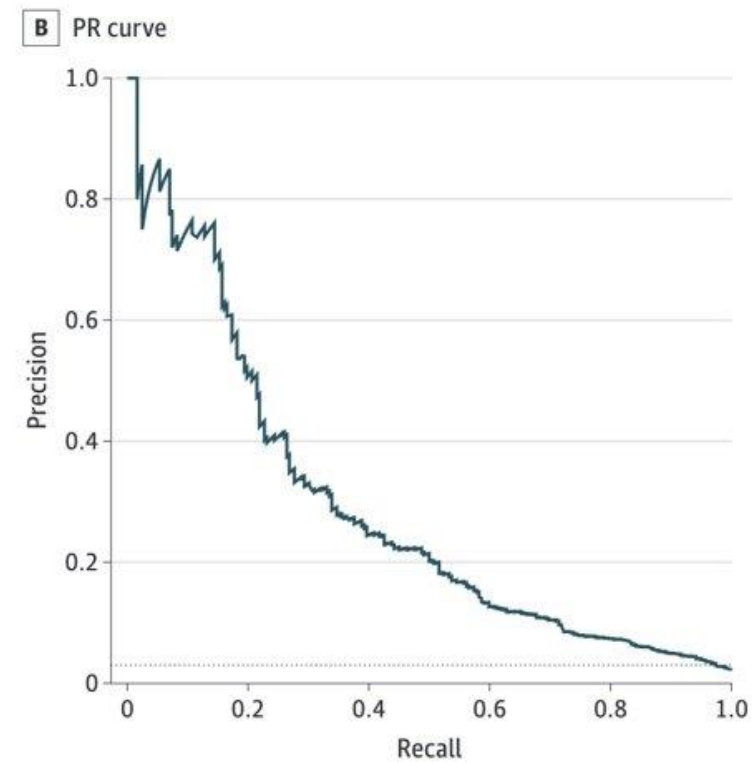
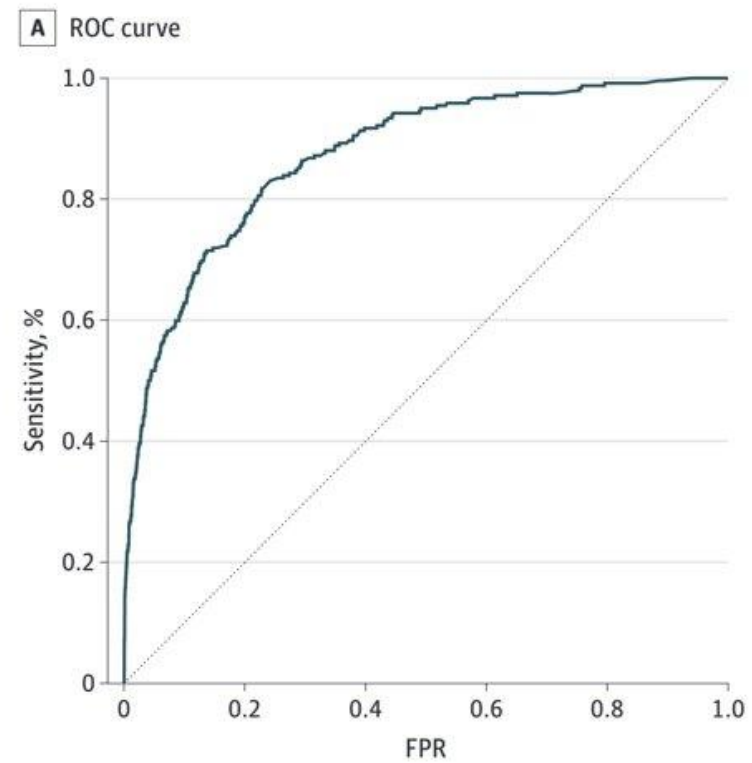


# Evaluate model performance against defined measures

## Mortality model performance measures

Table 2. Prediction Accuracy by Evaluation Method, Location, and Time

| Evaluation Method | Location   | Time      | AUROC (95% CI)   | AUPRC (95% CI)   |
|-------------------|------------|-----------|------------------|------------------|
| Retrospective     | Hospital A | 2014-2015 | 0.87 (0.83-0.89) | 0.29 (0.25-0.37) |
| Retrospective     | Hospital A | 2018      | 0.85 (0.83-0.87) | 0.17 (0.13-0.22) |
| Retrospective     | Hospital B | 2018      | 0.89 (0.86-0.92) | 0.22 (0.14-0.31) |
| Retrospective     | Hospital C | 2018      | 0.84 (0.80-0.89) | 0.13 (0.08-0.21) |
| Prospective       | Hospital A | 2019      | 0.86 (0.83-0.90) | 0.14 (0.09-0.21) |



| Threshold | Sensitivity | Specificity | PPV  | Alerts, No./d |       |      |
|-----------|-------------|-------------|------|---------------|-------|------|
|           |             |             |      | Total         | False | True |
| 0.01      | 0.88        | 0.66        | 0.05 | 39.9          | 37.8  | 2.1  |
| 0.02      | 0.76        | 0.81        | 0.08 | 23.3          | 21.5  | 1.8  |
| 0.03      | 0.68        | 0.88        | 0.11 | 15.3          | 13.6  | 1.7  |
| 0.04      | 0.61        | 0.91        | 0.12 | 11.9          | 10.4  | 1.5  |
| 0.05      | 0.57        | 0.93        | 0.15 | 9.1           | 7.7   | 1.4  |
| 0.06      | 0.54        | 0.95        | 0.18 | 7.4           | 6.1   | 1.3  |
| 0.07      | 0.52        | 0.95        | 0.19 | 6.5           | 5.3   | 1.3  |
| 0.08      | 0.50        | 0.96        | 0.21 | 5.8           | 4.5   | 1.2  |
| 0.09      | 0.48        | 0.96        | 0.22 | 5.2           | 4.1   | 1.2  |
| 0.10      | 0.44        | 0.97        | 0.22 | 4.8           | 3.7   | 1.1  |
| 0.11      | 0.43        | 0.97        | 0.24 | 4.4           | 3.4   | 1.0  |
| 0.12      | 0.41        | 0.97        | 0.24 | 4.1           | 3.1   | 1.0  |
| 0.13      | 0.39        | 0.98        | 0.26 | 3.7           | 2.7   | 1.0  |
| 0.14      | 0.39        | 0.98        | 0.27 | 3.5           | 2.6   | 0.9  |
| 0.15      | 0.36        | 0.98        | 0.27 | 3.2           | 2.3   | 0.9  |
| 0.16      | 0.35        | 0.98        | 0.28 | 3.1           | 2.2   | 0.9  |
| 0.17      | 0.34        | 0.98        | 0.30 | 2.8           | 2.0   | 0.8  |
| 0.18      | 0.33        | 0.98        | 0.32 | 2.6           | 1.7   | 0.8  |
| 0.19      | 0.31        | 0.99        | 0.32 | 2.4           | 1.6   | 0.8  |
| 0.20      | 0.29        | 0.99        | 0.33 | 2.2           | 1.5   | 0.7  |
| 0.21      | 0.28        | 0.99        | 0.33 | 2.0           | 1.4   | 0.7  |
| 0.22      | 0.28        | 0.99        | 0.35 | 1.9           | 1.3   | 0.7  |
| 0.23      | 0.27        | 0.99        | 0.36 | 1.8           | 1.2   | 0.7  |
| 0.24      | 0.26        | 0.99        | 0.38 | 1.7           | 1.1   | 0.6  |
| 0.25      | 0.26        | 0.99        | 0.41 | 1.5           | 0.9   | 0.6  |

Abbreviation: PPV, positive predictive value.

Number needed to evaluate = 1 / PPV



# Decision point 4

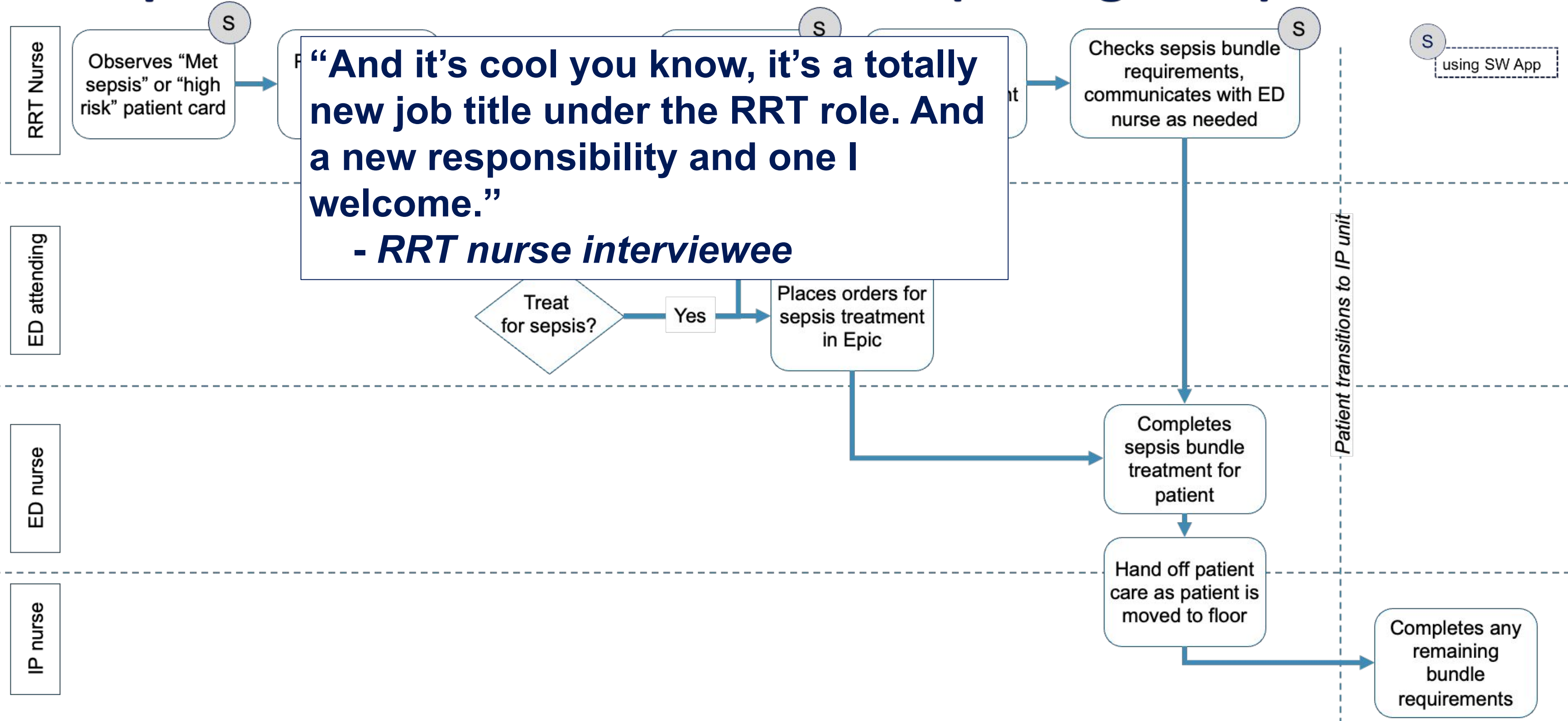


- 1 Identify and prioritize a problem
- 2 Identify requirements for an AI product as a viable component of the solution
- 3 Develop measures of outcomes and success of the AI product
- 4 **Design a new optimal workflow to facilitate integration**
- 5 Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use
- 6 Execute AI product roll out, workflow integration, communication, education, and scaling
- 7 After operationalization, monitor and maintain the AI product and work environment
- 8 Update or decommission the AI product and work environment



Adapt workflows, roles, and organization to solve problems:  
Don't rely on existing workflows

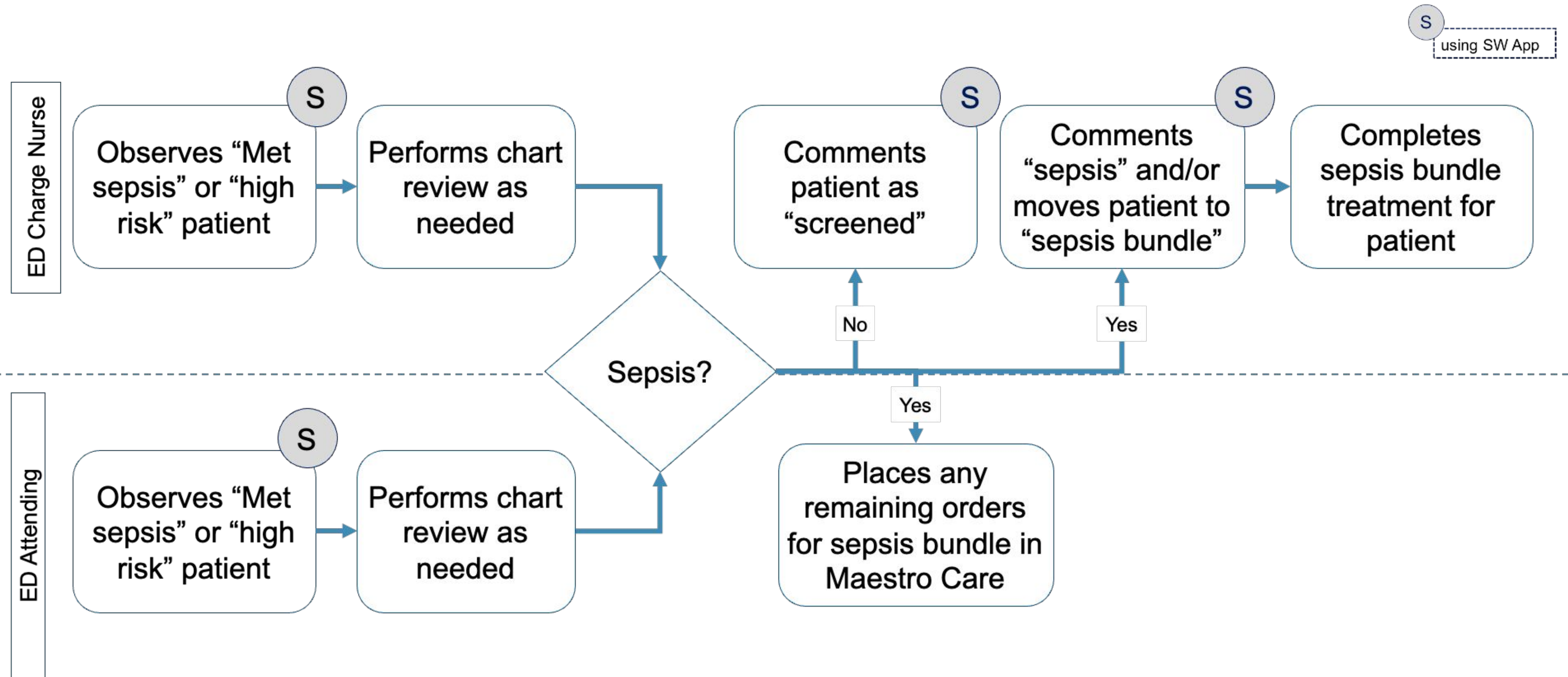
## Sepsis Watch ED Workflow at DUH (2018 go live)





Adapt workflows, roles, and organization to solve problems:  
Don't rely on existing workflows

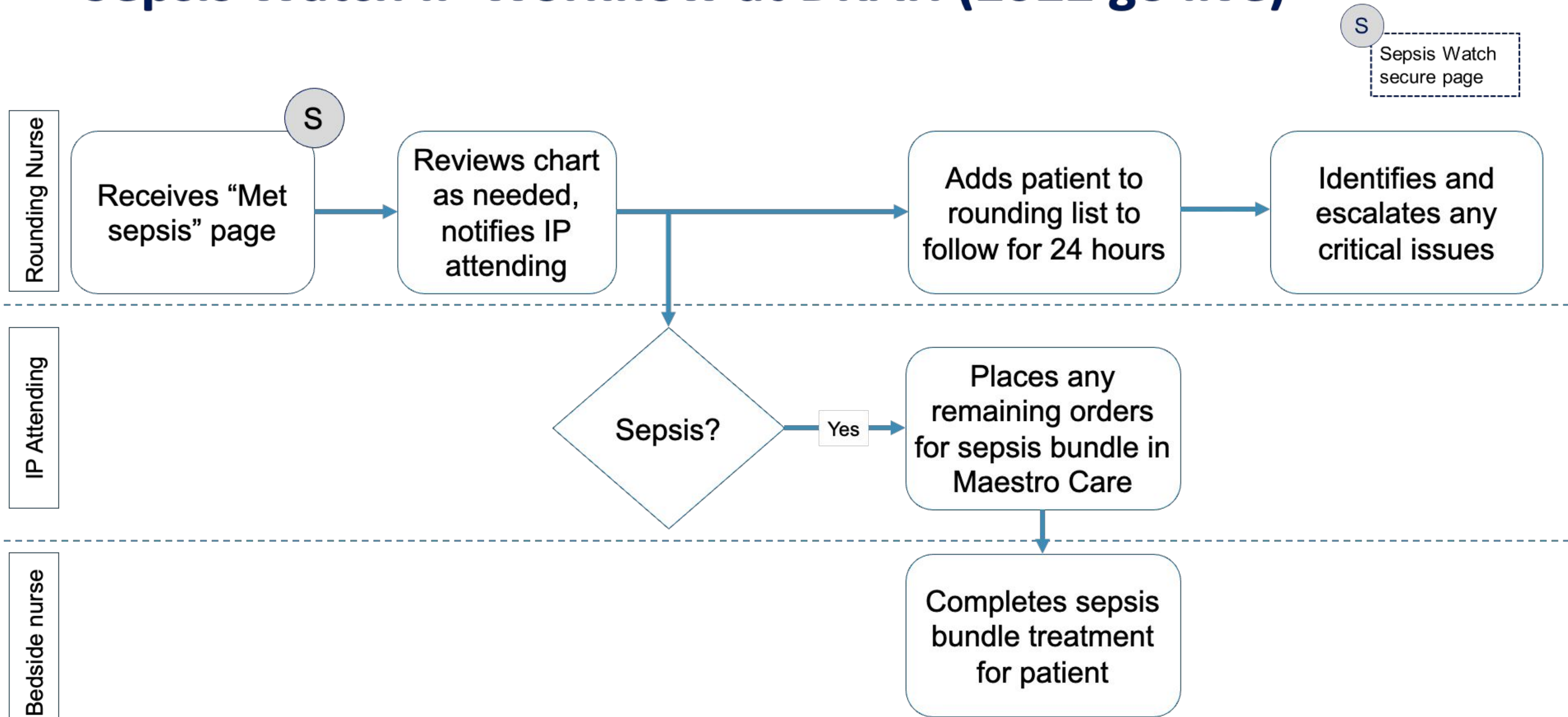
## Sepsis Watch ED Workflow at DRAH (2019 go live)





Adapt workflows, roles, and organization to solve problems:  
Don't rely on existing workflows

## Sepsis Watch IP Workflow at DRAH (2022 go live)







# Decision point 5



- 1 Identify and prioritize a problem
- 2 Identify requirements for an AI product as a viable component of the solution
- 3 Develop measures of outcomes and success of the AI product
- 4 Design a new optimal workflow to facilitate integration
- 5 **Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use**
- 6 Execute AI product roll out, workflow integration, communication, education, and scaling
- 7 After operationalization, monitor and maintain the AI product and work environment
- 8 Update or decommission the AI product and work environment



Identify label leakage during a silent trial

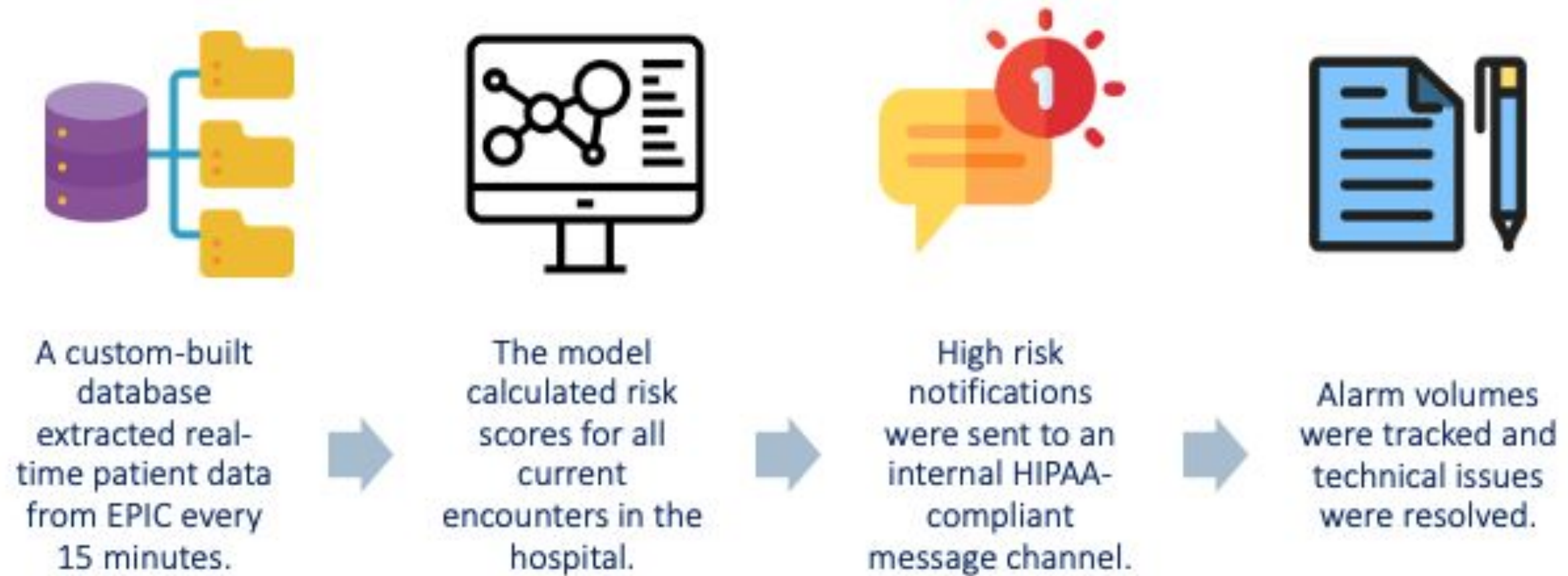
### **Pediatric sepsis prediction**

- Outcome definition: Blood Culture  $\cap$  Antibiotics for 4 days  $\cap$  Acute organ dysfunction
- LSTM with 6-hour prediction window and 3-hour snooze
- Retrospective training set:
  - 17,491 unique encounters for children between 30 days old and 18 years old
  - Between November 1, 2016 – December 31, 2020
- Temporal validation set:
  - 6,545 unique encounters for children between 30 days old and 18 years old
  - Between January 1, 2021 – June 30, 2022



# Identify label leakage during a silent trial

## Silent Trial Design



|                               | AUROC | AUPRC | PPV at 20% sensitivity (with 3hr snooze) | PPV at 50% sensitivity (with 3hr snooze) |
|-------------------------------|-------|-------|--|--|
| <b>Retrospective test set</b> | 0.816 | 0.483 | 0.769                                    | 0.612                                    |
| <b>Temporal validation</b>    | 0.862 | 0.386 | 0.851                                    | 0.611                                    |



Identify label leakage during a silent trial

### **Silent trial results**

- Model ran on 1,475 unique encounters over 2 months
- Model generated 30 alarms per day >> 2 alarms per day expected
- Model fired alarm on almost all patients in ED within first hour of arrival



Identify label leakage during a silent trial

**Retrained LSTM without layer normalization using the same hyperparameters**

|  | AUROC | AUPRC |
|--|-------|-------|
| Retrospective test set (with layer normalization)    | 0.816 | 0.483 |
| Temporal validation (with layer normalization)       | 0.862 | 0.386 |
| Retrospective test set (without layer normalization) | 0.782 | 0.01  |



# Decision point 6

Problem Identification  
and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

1 Identify and prioritize a problem

3 Develop measures of outcomes  
and success of the AI product

6 **Execute AI product roll out,  
workflow integration,  
communication, education,  
and scaling**

7 After operationalization, monitor  
and maintain the AI product and  
work environment

2 Identify requirements for an AI  
product as a viable component  
of the solution

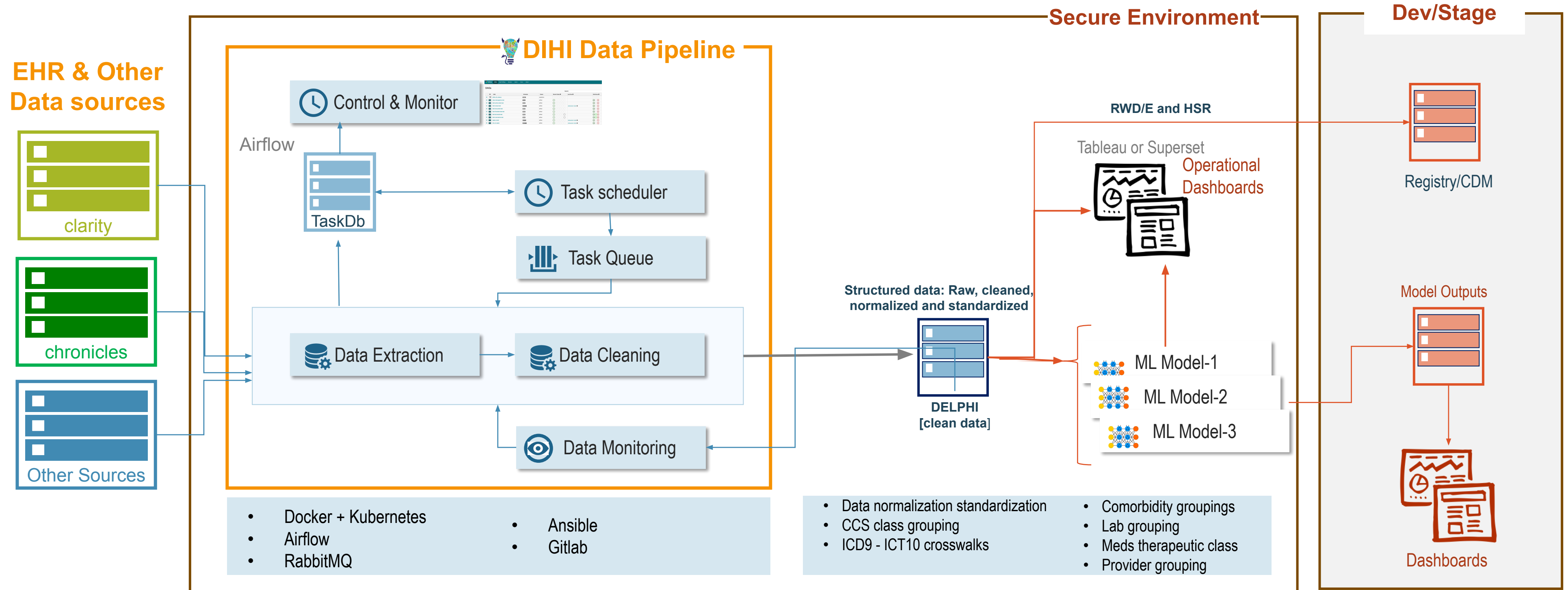
4 Design a new optimal  
workflow to facilitate  
integration

8 Update or decommission the AI  
product and work environment

5 Evaluate safety, effectiveness,  
and equity concerns of the AI  
product in the intended setting  
prior to clinical use



# Build modular infrastructure to support many projects: Flexible data pipeline technology infrastructure





# Create model facts labels and share with end users and affected stakeholders

|  |                                 |   |                                 |                                 |
|--|---------------------------------|---|---------------------------------|---------------------------------|
| <b>Model Facts</b>   | <b>Model name:</b> Deep Sepsis  | <b>Locale:</b> Duke University Hospital |                                 |                                 |
| <b>Approval Date:</b> 09/22/2019   | <b>Last Update:</b> 09/24/2019. | <b>Version:</b> 1.0                     |                                 |                                 |
| <b>Summary</b><br>This model uses EHR input data collected from a patient's current inpatient encounter to estimate the probability that the patient will meet sepsis criteria within the next 4 hours. It was developed in 2016-2019 by the Duke Institute for Health Innovation. The model was licensed to Cohere Med in July 2019.  |                                 |   |                                 |                                 |
| <b>Mechanism</b>   |                                 |   |                                 |                                 |
| <ul style="list-style-type: none"> <li>▪ <b>Outcome</b> .....sepsis within the next 4 hours, see (1) for sepsis criteria</li> <li>▪ <b>Output</b> .....0% - 100% probability of sepsis occurring in the next 4 hours</li> <li>▪ <b>Patient population</b> .....all adult patients &gt;18 y.o. presenting to DUH ED and admitted</li> <li>▪ <b>Time of prediction</b> .....every hour of a patient's encounter</li> <li>▪ <b>Input data source</b>.....electronic health record (EHR)</li> <li>▪ <b>Input data type</b> .....demographics, analytes, vitals, medication administrations</li> <li>▪ <b>Training data location and time-period</b> .....DUH, 10/2014 – 12/2015</li> <li>▪ <b>Model type</b>..... Recurrent Neural Network</li> </ul>  |                                 |   |                                 |                                 |
| <b>Validation and performance</b>  |                                 |   |                                 |                                 |
|  | <b>Prevalence</b>               | <b>AUC</b>                              | <b>PPV @ Sensitivity of 60%</b> | <b>Sensitivity @ PPV of 20%</b> |
| <b>Local Retrospective</b>   | 18.9%                           | 0.88                                    | 0.14                            | 0.50                            |
| <b>Local Temporal</b>  | 6.4%                            | 0.94                                    | 0.20                            | 0.66                            |
| <b>Local Prospective</b>   | TBD                             | TBD                                     | TBD                             | TBD                             |
| <b>External</b>  | TBD                             | TBD                                     | TBD                             | TBD                             |
| <b>Uses and directions</b>   |                                 |   |                                 |                                 |
| <ul style="list-style-type: none"> <li>▪ <b>Operational use case(s):</b> Every hour, data is pulled from the EHR to calculate risk of sepsis for every patient at the DUH ED. A rapid response team nurse reviews every high-risk patient with a physician in the ED to confirm whether or not to initiate treatment for sepsis.</li> <li>▪ <b>General use:</b> This model is intended to be used to by clinicians to identify patients for further assessment for sepsis. The model is not a diagnostic for sepsis and is not meant to guide or drive clinical care. This model is intended to complement other pieces of patient information related to sepsis as well as a physical evaluation to determine the need for sepsis treatment.</li> <li>▪ <b>Examples of appropriate decisions to support:</b> Patient X has a high risk of sepsis according to the model. A rapid response team nurse discusses the patient with the ED physician caring for the patient and they agree the patient does not require treatment for sepsis.</li> <li>▪ <b>Before using this model:</b> Test the model retrospectively and prospectively on local data to confirm generalizability of the model to the local setting.</li> <li>▪ <b>Safety and efficacy evaluation:</b> Analysis of data from clinical trial (NCT03655626) underway. Preliminary data shows rapid response team, nurse-driven workflow was effective at improving sepsis treatment bundle compliance.</li> </ul> |                                 |   |                                 |                                 |

Comment | [Open Access](#) | [Published: 23 March 2020](#)

## Presenting machine learning model information to clinical end users with model facts labels

Mark P. Sendak , Michael Gao, Nathan Brajer & Suresh Balu

*npj Digital Medicine* **3**, Article number: 41 (2020) | [Cite this article](#)

5222 Accesses | 9 Citations | 73 Altmetric | [Metrics](#)

### Warnings

- **General warnings:** This model was not trained or evaluated on patients receiving care in the ICU. Do not use this model in the ICU setting without further evaluation. This model was trained to identify the first episode of sepsis during an inpatient encounter. During long inpatient stays with multiple sepsis episodes, model accuracy needs to be further evaluated. The model is not interpretable and does not provide rationale for high risk scores. Clinical end users are expected to place model output in context with other clinical information to make final determination of diagnosis.
- **Examples of inappropriate decisions to support:** This model may not be accurate outside of the target population, primarily adults in the non-ICU setting. This model is not a diagnostic and is not designed to guide clinical diagnosis and treatment for sepsis.
- **Discontinue use if:** Clinical staff raise concerns about utility of the model for the indicated use case or large, systematic changes occur at the data level that necessitates re-training of the model.

### Other information:

- **Outcome Definition:** <https://doi.org/10.1101/648907>
- **Related model:** <http://doi.org/10.1001/jama.2016.0288>
- **Model development & validation:** [arxiv.org/abs/1708.05894](https://arxiv.org/abs/1708.05894)
- **Model implementation:** [jmir.org/preprint/15182](https://jmir.org/preprint/15182)
- **Clinical trial:** [clinicaltrials.gov/ct2/show/NCT03655626](https://clinicaltrials.gov/ct2/show/NCT03655626)
- **Clinical impact evaluation:** TBD
- **For inquiries and additional information:** please email [mark.sendak@duke.edu](mailto:mark.sendak@duke.edu)





# Decision point 7

Problem Identification  
and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

1 Identify and prioritize a problem

3 Develop measures of outcomes  
and success of the AI product

6 Execute AI product roll out,  
workflow integration,  
communication, education, and  
scaling

7 **After operationalization,  
monitor and maintain the AI  
product and work environment**

2 Identify requirements for an AI  
product as a viable component  
of the solution

4 Design a new optimal  
workflow to facilitate  
integration

8 Update or decommission the AI  
product and work environment

5 Evaluate safety, effectiveness,  
and equity concerns of the AI  
product in the intended setting  
prior to clinical use



## Monitor AI system at DIHI

Effective monitoring of AI/ML solutions also requires multidisciplinary combination of technical and human capabilities, including expertise in engineering, data analysis, AI/ML, and clinical domain knowledge employed during the solution development phase.

### Model Monitoring

- Data quality monitoring
  - Input data accurate, complete, and up-to-date
  - Entity/grouper monitoring
  - Continuous monitoring
- Performance comparison
  - auroc, auprc wrt. training
  - Analysis cadence: M/Q/Y
- Output drift monitoring
  - Data distribution
  - Category distribution

### Solution Monitoring

- Outcome monitoring
  - Project specific measures
  - Bi-annual for most solutions
- Workflow changes
  - Observation / documentation
- Usage monitoring
  - UI tools/dashboard usage
  - Secondary data analysis
- User feedback
  - Survey for model & solution usability and refinements

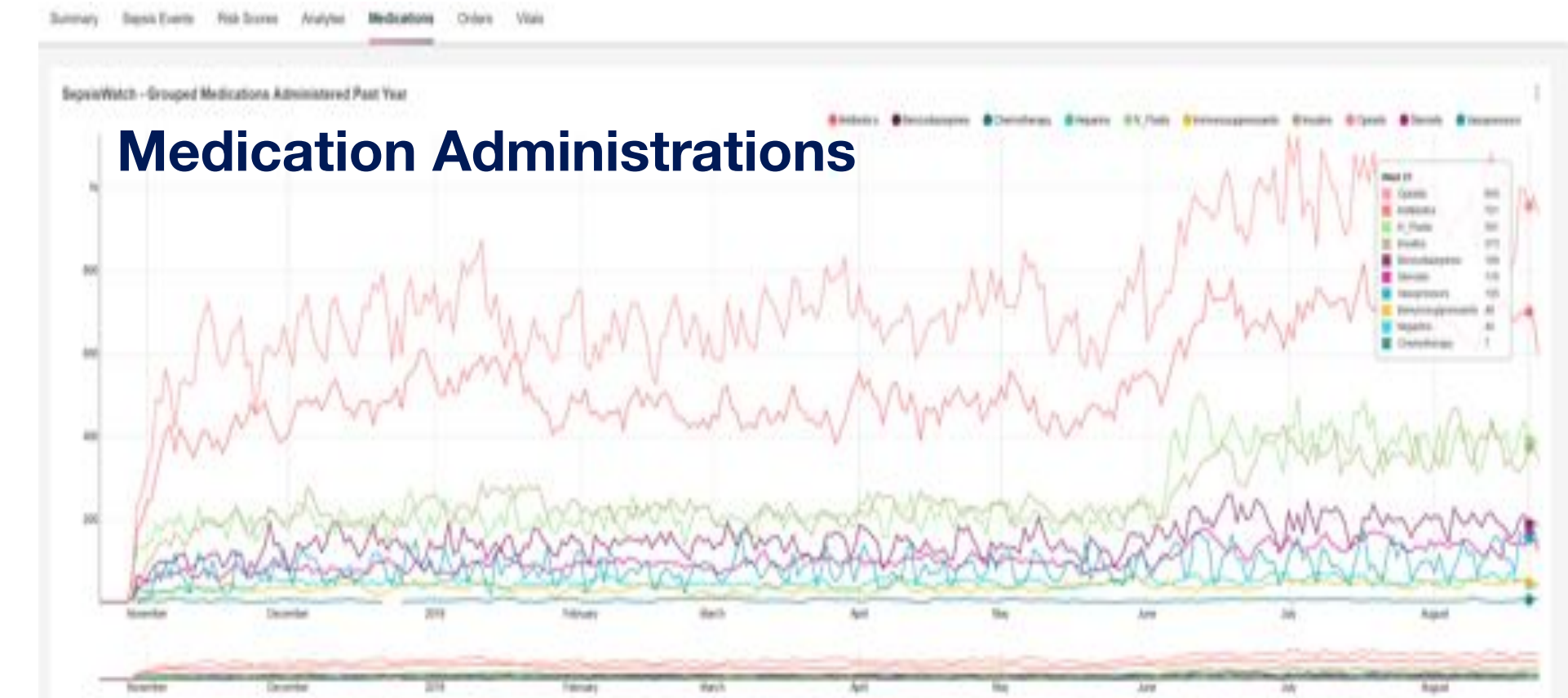
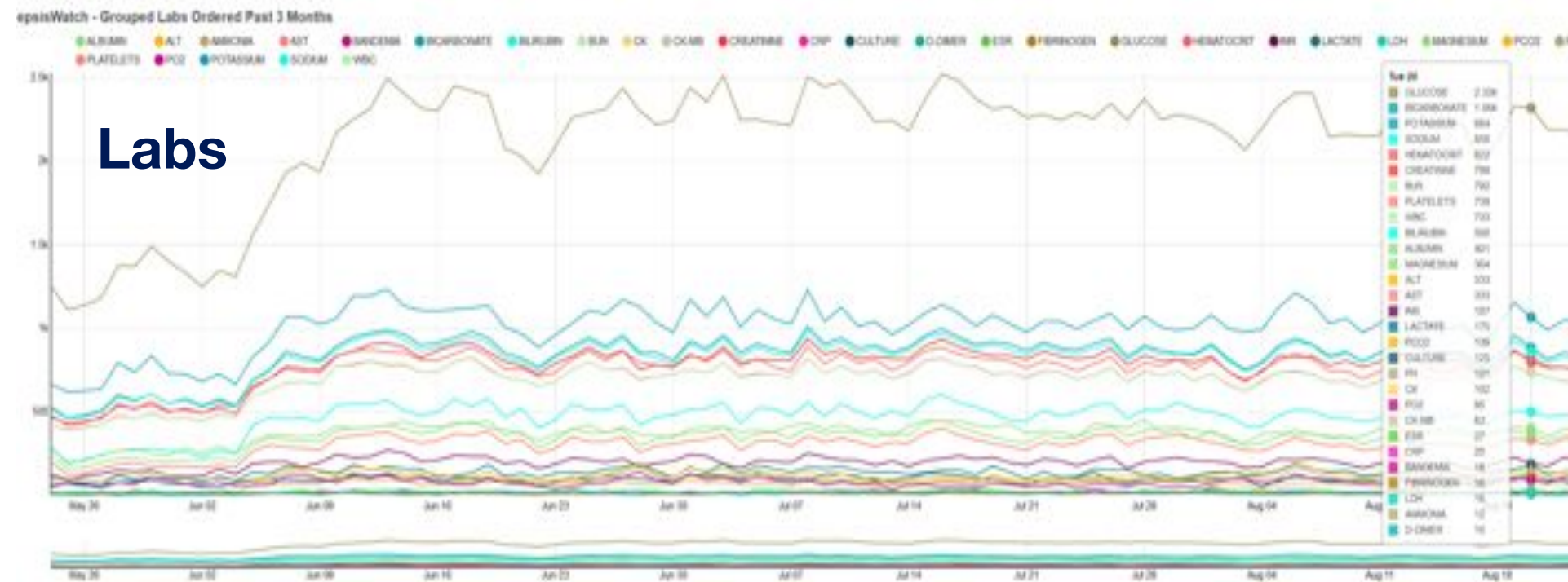
### Operations Monitoring

- Alerting & notification
  - Flexible rules-based engine for alerting
  - Used in clinical workflow
  - Email/page/spok/sms etc.
- Technical monitoring
  - Model run times, failures etc.
  - Service level monitoring
- Regulatory & Policy
  - Compliance monitoring for regulation & Duke policies
  - Ethical and legal standards

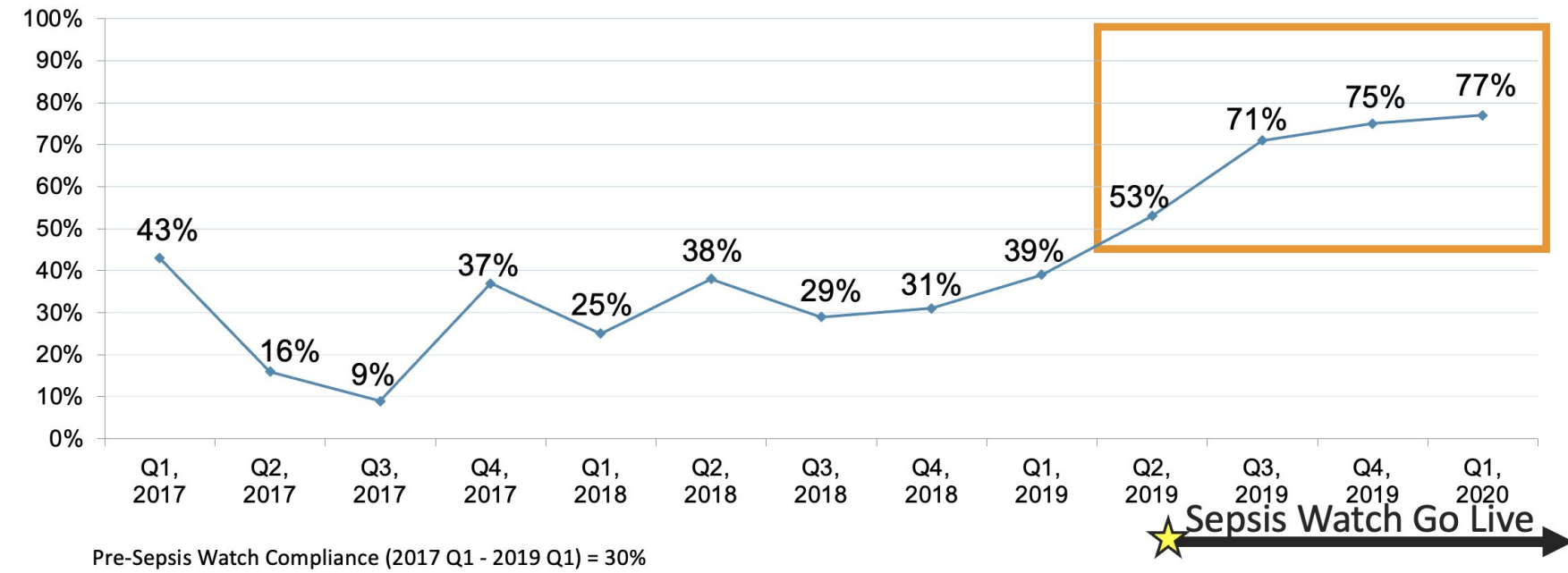


# Solution and Input Data Monitoring

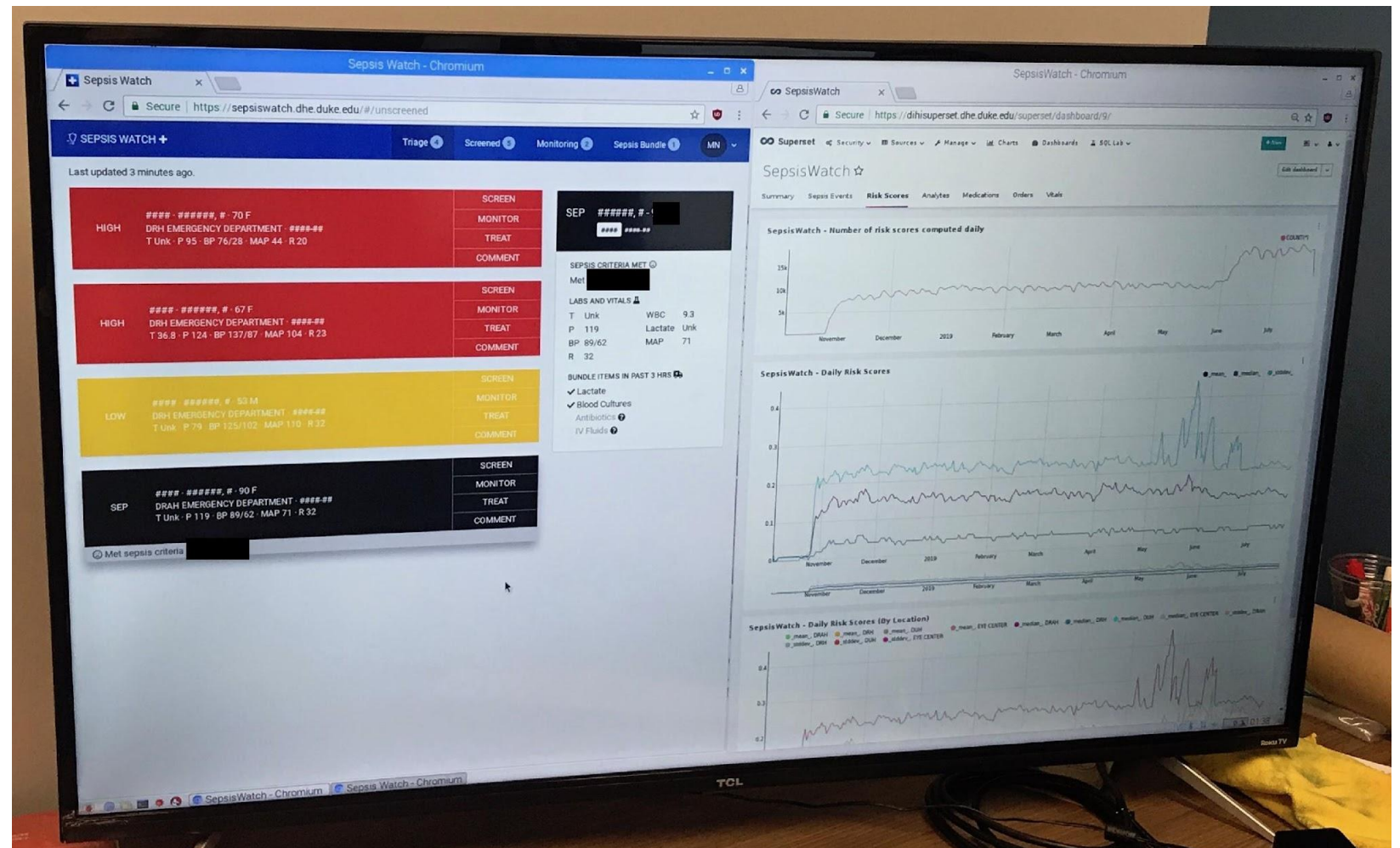
Continuous monitoring to ensure safety and quality of data used in model inputs



## SEP-1 bundle compliance | Sepsis Watch model



Pre-Sepsis Watch Compliance (2017 Q1 - 2019 Q1) = 30%  
 Post-Sepsis Watch Compliance (2019 Q2 - 2020 Q1) = 70%





# Decision point 8

Problem Identification and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

1 Identify and prioritize a problem

3 Develop measures of outcomes and success of the AI product

6 Execute AI product roll out, workflow integration, communication, education, and scaling

7 After operationalization, monitor and maintain the AI product and work environment

2 Identify requirements for an AI product as a viable component of the solution

4 Design a new optimal workflow to facilitate integration

5 Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use

8 **Update or decommission the AI product and work environment**



# Manage lifecycle of AI after clinical integration

## Sepsis Watch post-integration lifecycle management

|                       | Monitoring & Evaluation   | Update  | Operational Management   |
|-----------------------|---|---|--|
| <b>Event based</b>    | <ul style="list-style-type: none"> <li>• Debug issues that arise (e.g., data endpoint unexpectedly goes down)</li> </ul>  | <ul style="list-style-type: none"> <li>• Customize the UI for different user groups</li> <li>• Train new versions of the model for new clinical settings</li> </ul> | <ul style="list-style-type: none"> <li>• Update user access</li> <li>• Update reporting functionalities to support clinician management</li> </ul> |
| <b>Recurring</b>      | <ul style="list-style-type: none"> <li>• Monitor technical elements of the model and source data in pipeline</li> <li>• Monitor changes that affects work environment and use of model</li> </ul> | <ul style="list-style-type: none"> <li>• Regularly scheduled maintenance (e.g., update groupers every 6 months)</li> </ul>  | <ul style="list-style-type: none"> <li>• Conduct bi-annual end user training to ensure baseline knowledge of AI system</li> </ul>                  |
| <b>Semi-Recurring</b> | <ul style="list-style-type: none"> <li>• Audit the solution for impact on clinical and operational outcomes and impact on work environment</li> </ul>   | <ul style="list-style-type: none"> <li>• Improve the UI (e.g., add comment feature, automatically check boxes)</li> <li>• Scale to different use cases</li> </ul>   | <ul style="list-style-type: none"> <li>• Convene governance committee monthly</li> <li>• Secure ongoing funding for AI system use</li> </ul>       |
| <b>One-off</b>        | <ul style="list-style-type: none"> <li>• Create channels for end users to report issues and provide user support services</li> </ul>  | <ul style="list-style-type: none"> <li>• Create process and criteria to scope responses to user requests</li> </ul>   | <ul style="list-style-type: none"> <li>• Determine ownership of model (e.g., clinical lead, technical lead)</li> </ul>                             |



Duke Institute for Health Innovation

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2 mins

Terminology

---

3 mins

Big data and AI in healthcare

---

2 mins

Health AI Partnership (HAIP)

---

3 mins

Key Decision Points in AI Adoption

---

15 mins

**Organizational Governance of AI**

---

**15 mins**



# AI Systems Monitoring Vs Governance

## Monitoring

Purpose: To ensure the safety, effectiveness, and reliability of an AI applications in clinical settings.

Monitor:

- the Model
- the solution
- the operations

Activities:

- Continuous data quality monitoring
- Continuous assessment of accuracy of the outcome
- Real-time tracking of AI performance against medical standards.

## Governance

Purpose: To establish broad oversight over the development, deployment, and general use of AI across the institution

Govern:

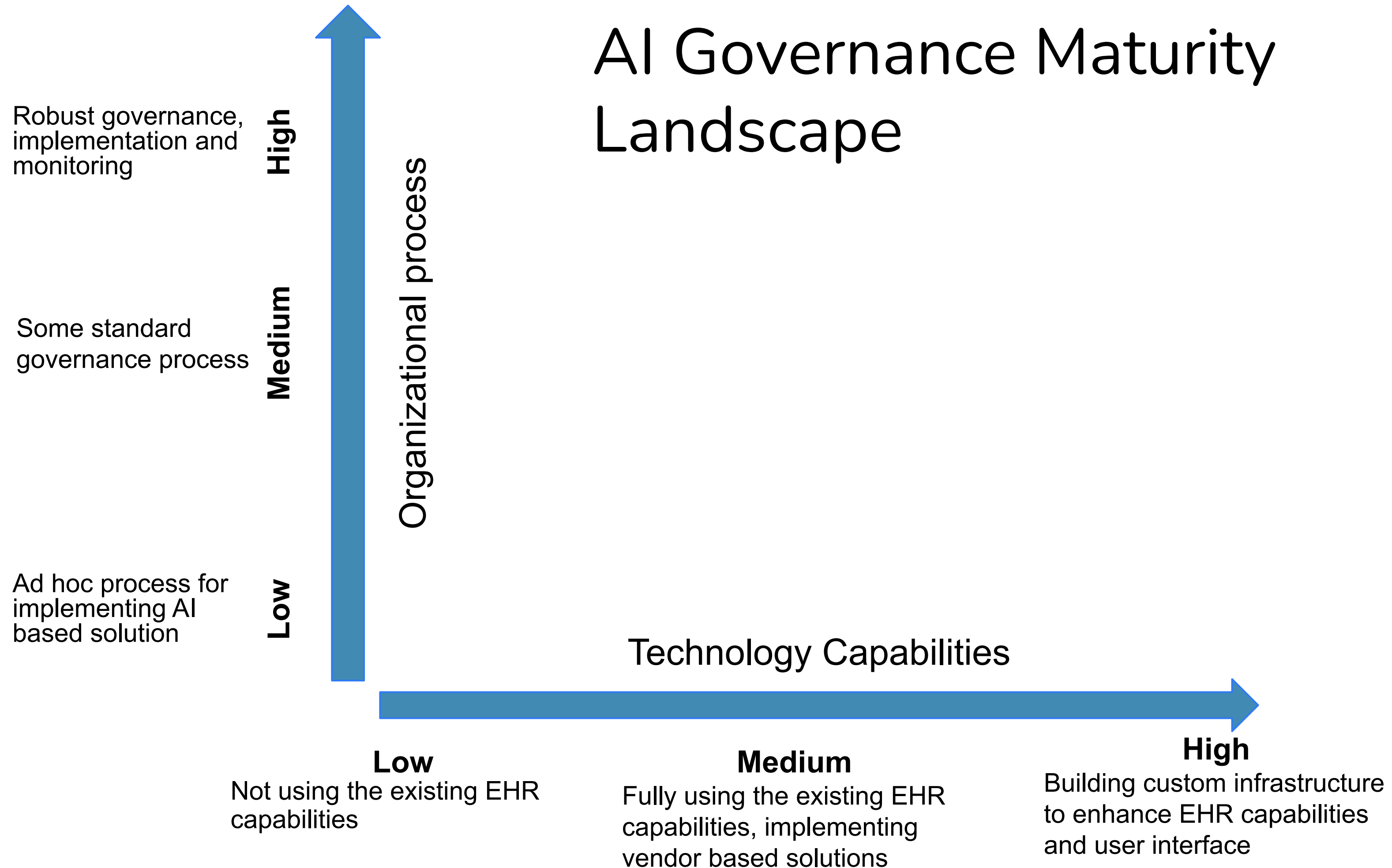
- need and impacts of AI
- Risk Mitigation
- legal, regulatory and ethical compliance,

Activities:

- Formulating policies and regulations for AI use.
- Promoting transparency and accountability in AI systems. Regular governance oversight
- Addressing ethical concerns like bias, fairness, and human oversight.



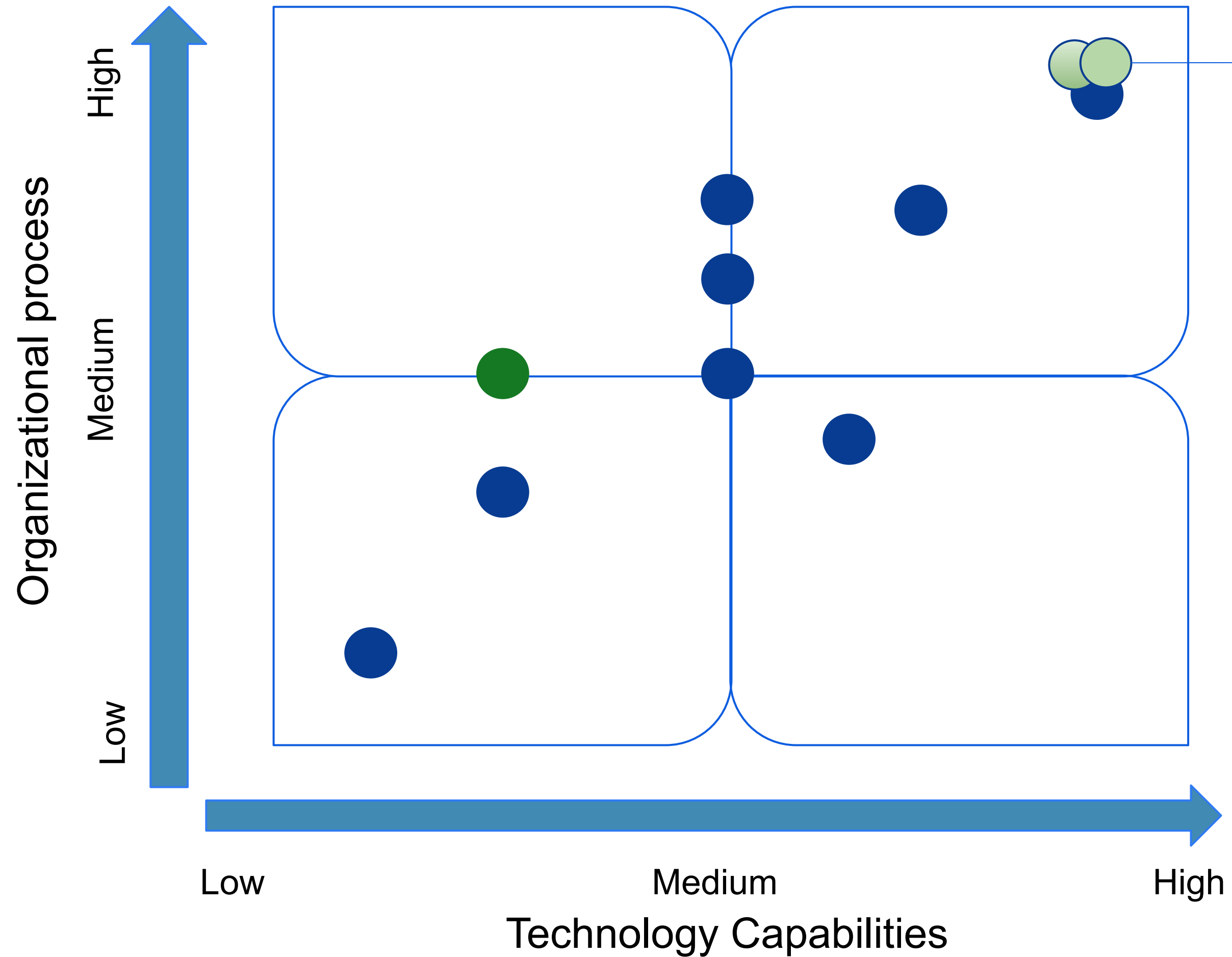
# AI Governance Maturity Landscape







# AI Governance Maturity Landscape



DukeHealth

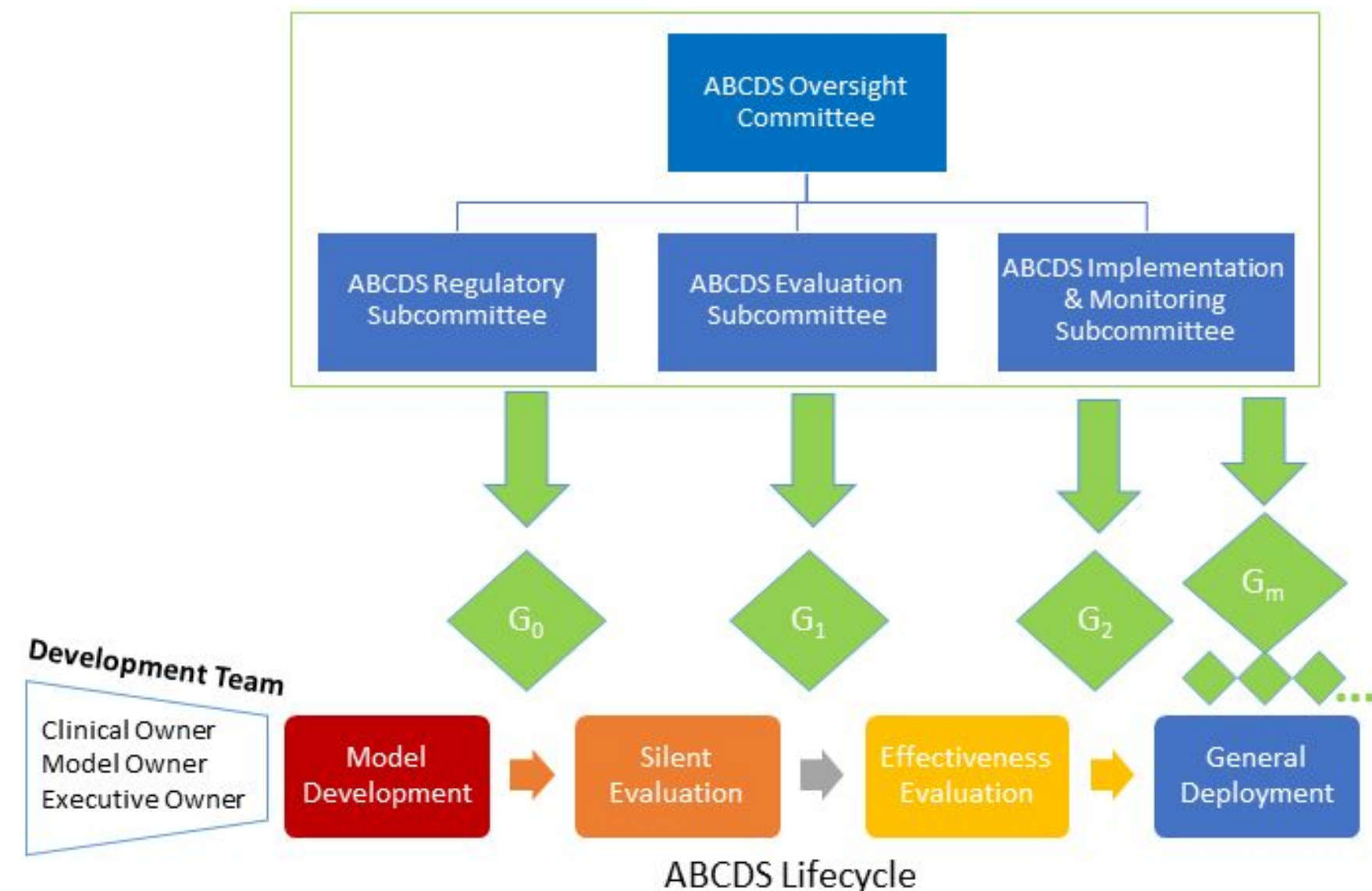
|  |  |
|--|--|
|  | Institutions developing and procuring solutions for internal use   |
|  | Institutions commercializing the internally developed solutions  |
|  | Institutions building solutions for internal use and also commercializing the internally developed solutions |



# AI Governance at Duke Health

**Algorithm-Based Clinical Decision Support (ABCDS) Oversight** is a “people-process-technology” framework established in January, 2021 to provide governance, evaluation, and monitoring of algorithms used in clinical care and/or operations at Duke Health.

- The ABCDS lifecycle consists of 4 distinct phases with evaluation “checkpoints” placed at the transition points and at regular intervals in deployment.
- Readiness to proceed to the next ABCDS lifecycle phase is evaluated according to our 5 guiding principles:
  1. Transparency & Accountability
  2. Clinical Value & Safety
  3. Fairness & Equity
  4. Usability, Reliability & Adoption
  5. Regulatory Compliance



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# Definition of AI at Duke Health

## **A data-driven model (non-standard of care):**

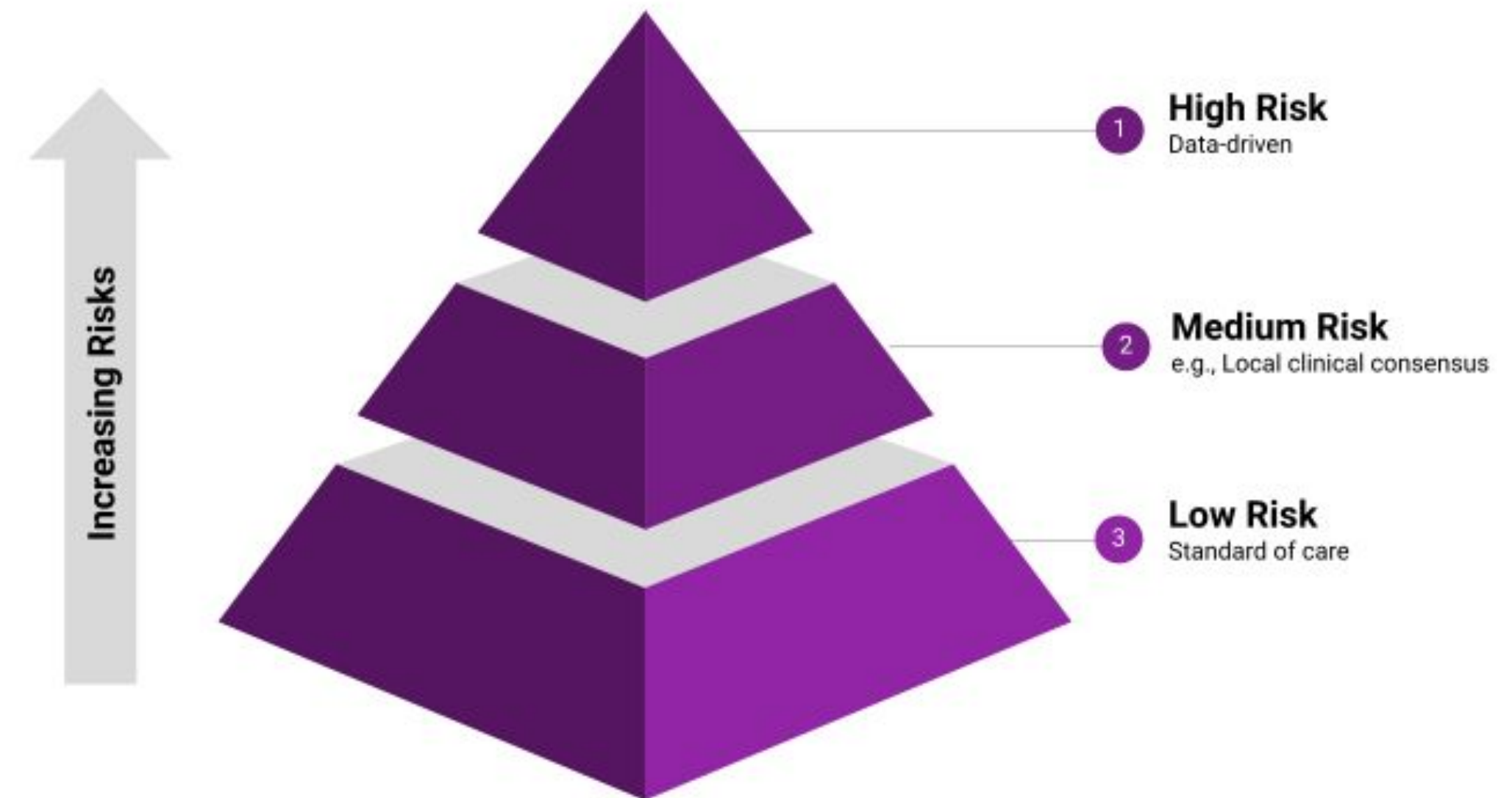
*A model that builds relationships between input and output data using statistical/machine learning techniques.*

## **A clinical consensus-based (knowledge-based) model:**

*A formula or set of rules that were derived based on clinical acumen and consensus, the literature, and/or expert recommendations. These algorithms provide the same results on the same inputs.*

## **A 'standard of care' tool or model:**

*A tool or model used to guide standard-of-care and would be supported by evidence in the medical literature, recommended by medical societies, or incorporated into clinical practice guidelines.*



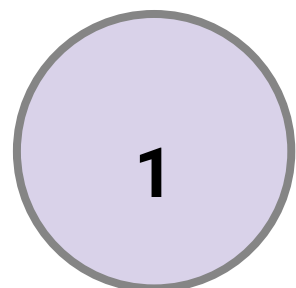
**ABCDS Tool = Algorithm(s) + Interface Algorithms**



# Customizing AI Governance Practices at for an Institution

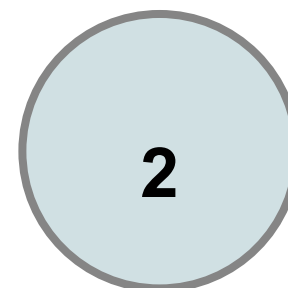


# Method



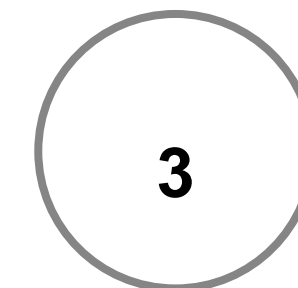
## Interview and Discovery

- Interviewed 12 stakeholders
- To analyze the current state of AI governance
- To surface needs for future AI governance



## Algorithm Journey Mapping

- Interviewed the site lead
- To identify key stakeholders for future AI governance
- To map out process for future AI governance



## Finalize Outputs and Share Back

- Finalize future AI governance process
- Help implementing the new AI governance in practice



# Status Quo Governance process

Good practices

Gaps and opportunities for improvement

## Procurement

- **Problems are identified across the organization.**
- **Feasibility of adoption is assessed.**
- No clear evidence-based reason for AI adoption
- No sufficient time and transparency for assessing a problem and a solution
- Lack of relevant key stakeholders' involvement in the procurement process

## Development or Adaptation

- **Strong data infrastructure and capabilities**
- **Active engagement of a clinical team in designing a new workflow**
- Heavily dependent on the vendor (variability)
- Ad hoc sessions to design and test UI/UX with end users
- Limited discussion of success measures for projects
- Lack of internal validation and evaluation
- No systematic decision process for rollout

## Clinical Integration

- **Established communication channels**
- Heavily dependent on the vendor (variability)
- No sufficient education about the AI solution provided to those affected by the solution adoption

## Lifecycle Management

- **Established end user support channels for EHR software**
- No systematic approach to gather feedback from end users
- Insufficient monitoring
- No systematic approach for updating or decommissioning the AI solution or its ecosystem



“A lot of times, the problem is not clear. We’re already jumping to the solution and going out to look for something or purchase something without even understanding the problem.”

- Technical Stakeholder

“As a clinician, there needs to be value that feels safe. There needs to be proper understanding of what is the role of the tool and what is my role and what’s affecting who and what degree.”

- Operational Stakeholder

“We work in silos.”

- Operational Stakeholder

The presentation of performance metrics for all these algorithms by the vendors is completely different. There’s no way to standardize them. It’s very difficult. So we need to do this evaluation in house.”

- Technical Stakeholder

Procurement

Development

Integration

Lifecycle Management

“Why are you selecting this when there's knowledge that there's three or four others? We want to know their vetting process. Did you look at all the different tools? What was your decision making process for selecting this one?”

- Operational Stakeholder

“The project team has been running the whole thing. Ideally, maybe it should be the clinical operations stakeholders to define a clinical problem who define what the benchmark for success should be. And the project team is more about execution, but that's not how it played out in this instance.”

- Clinical Stakeholder

“Performance dropped by 5%. What should we do? No, that doesn’t exist today.”

- Clinical Stakeholder



# Recommendations

## 1 People

- Define roles and responsibilities of key stakeholders who are responsible for implementing unified AI governance.
- Create education and training programs for the key stakeholders.

## Process 2

- Adapt and institutionalize a unified governance process for AI lifecycle management, using a 8 key decision points framework.
- Document internal AI governance policies.



## 3 Technology

- Develop technical capabilities and infrastructures to build, implement, evaluate, monitor and maintain algorithms.
- Align with an IT roadmap.

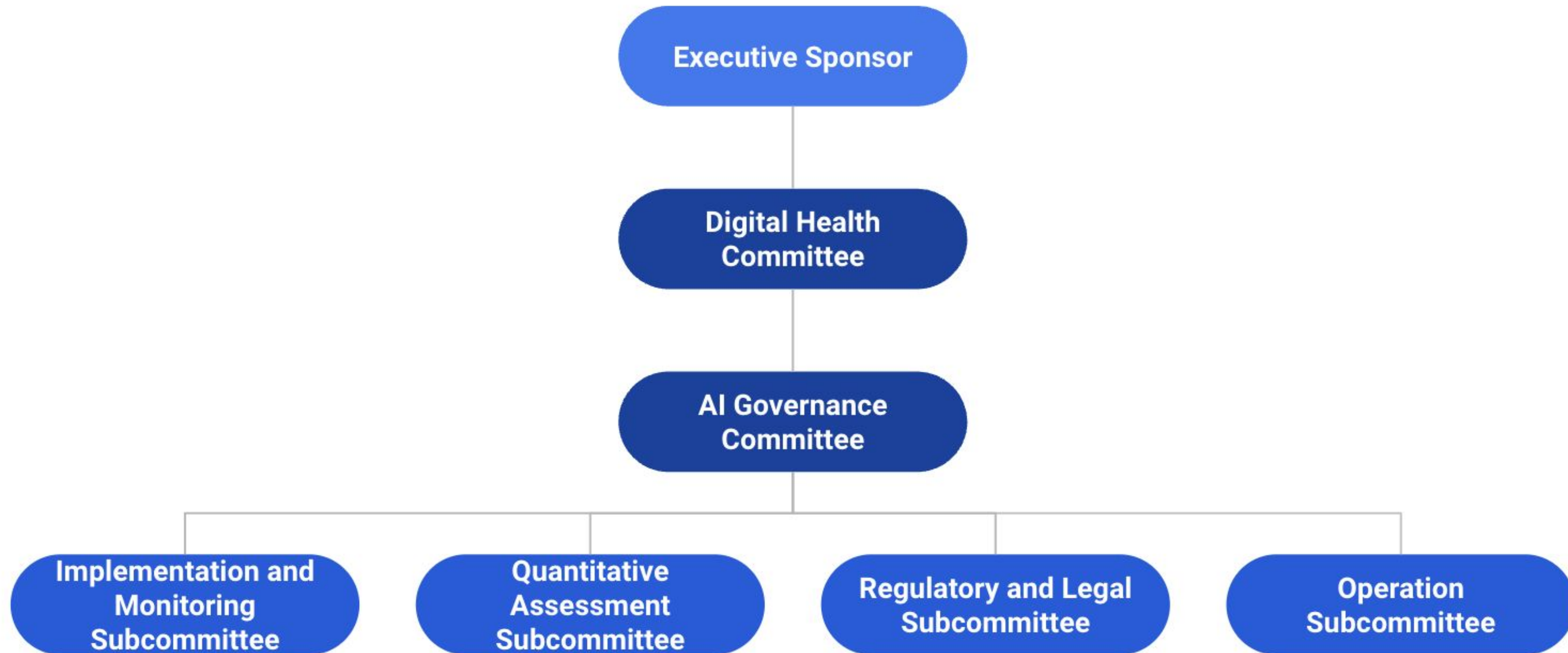
## Operation 4

- Establish business plans and operations.
- Secure resources to put AI governance in place.
- Establish impact measures.



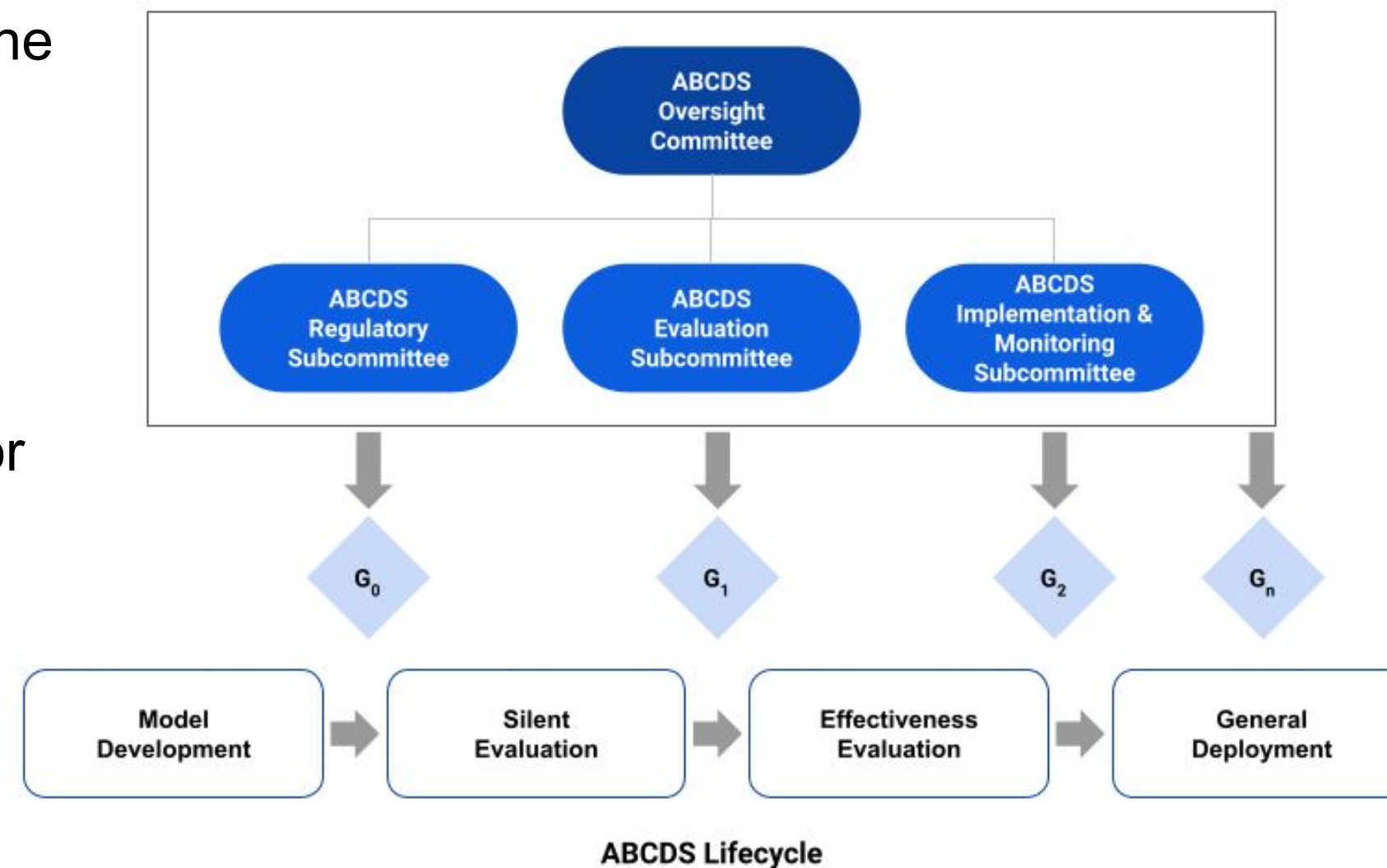
# People

Who should oversee AI governance?



# For Example: Membership of ABCDS at Duke

- **Co-Chair (clinical/operational):** Chief Health Information Officer (Primary care internal medicine)
  - Responsible for overseeing the operation of EHR and clinical and analytic information systems
- **Co-Chair (technical):** Vice dean of data science (Professor of Biostatistics and Bioinformatics)
  - Responsible for assessing performance and quality of implementation plans
- **Program Director**
  - Responsible for leading the operations for the governance, evaluation, and monitoring of ABCDS software



- **Subcommittee chairs and committee members**
  - Regulatory expertise
  - Clinical knowledge
  - Operational experience
  - Quantitative sciences and informatics knowledge
  - Innovation

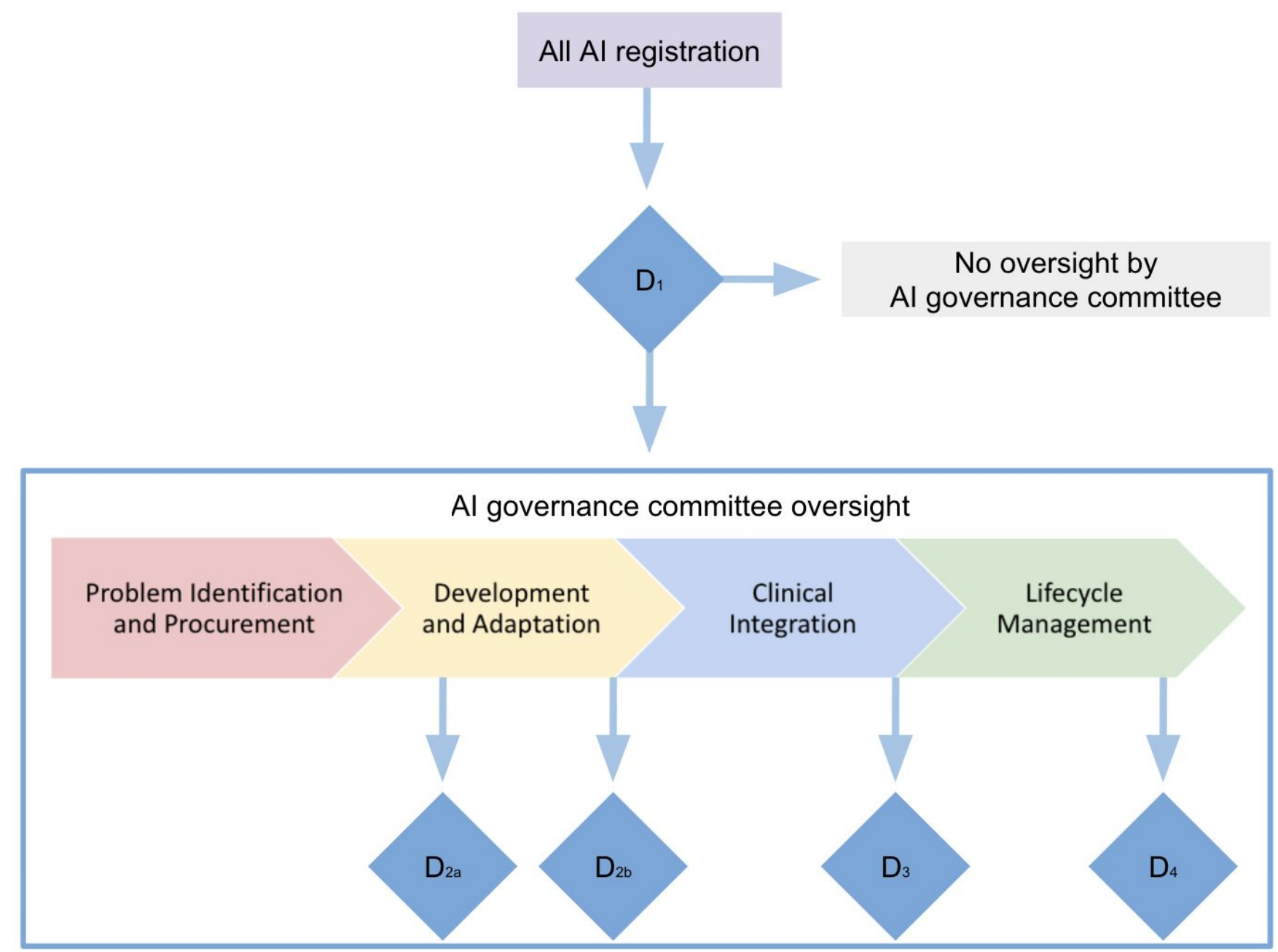
# Expertise & Responsibilities

| Domain               | Skills and expertise   | Responsibilities   |
|----------------------|--|--|
| Clinical and medical | Clinical knowledge, frontline care, patient needs, Epic, socio technical expertise as end users (i.e., human-computer interaction)   | Advise on clinical risks of use and operational value  |
| Technical            | Data engineering, data quality, building and evaluating AI, statistics, AI technology, UI/UX, product and solution management  | Evaluate the proposed AI implementation by assessing model performance, UI/UX, and solution performance  |
| Social               | User research, human-computer interaction, ethnography, critical data studies, science and technology studies  | Advise on workflow<br>Identify potential risks of implementation   |
| Informatics          | Data quality, data preparation, equity data (i.e., demographic data), software systems, technical systems, technical integration and needs, Epic, security, informatics, strategy                | Advise on data quality and availability  |
| Operational          | Business strategy, change management and communication, business (e.g., financial, HR, procurement), Epic, operational governance, equity data (i.e., demographic data), patient care operations | Ensure strategic alignment<br>Ensure appropriate engagement and change management plans are in place   |
| Regulatory and legal | Risk management, ethics, technology policy, legal expertise, security, data privacy, compliance  | Ensure AI implementation complies with internal policies, procedures, and governance, follows legal requirements and privacy laws and follows ethical principles |

# Defining a scope of AI governance

- All AI products should be registered

| Full governance  | Limited governance  |
|--|---|
| <ul style="list-style-type: none"> <li>AI products that interface directly with patients</li> <li>AI products used for clinical documentation (e.g., drafting patient messages and visit notes)</li> <li>AI products used for non-clinical tasks that may limit access to care services (e.g., patient scheduling)</li> <li>Assistive AI products that detect data to aid care provider without analysis or generated conclusions (e.g., rule-based non-ML product)</li> <li>Augmentative AI products that analyze data in a clinically meaningful way</li> <li>Autonomous AI products that interpret data and generate clinically meaningful conclusions without care provider input</li> </ul> | <ul style="list-style-type: none"> <li>AI products focused on billing of clinical services</li> <li>AI-driven robotics or automation products used for non-medical purposes (e.g., facility maintenance or logistics management)</li> <li>AI products used for clinical research</li> <li>AI products embedded in regulated hardware devices</li> </ul> |



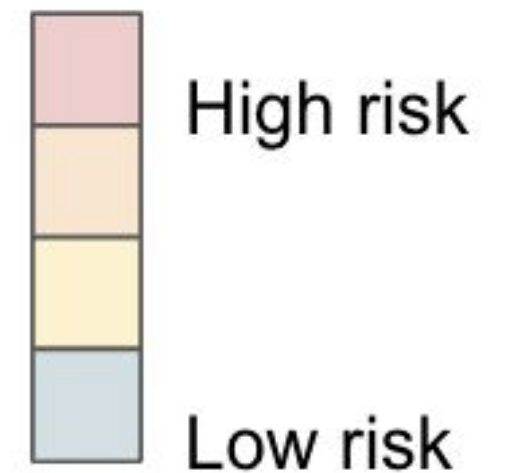
# Defining a Documentation Requirements

| AI lifecycle stage                     | Information to collect and document  | Decision to make  |
|--|--|---|
| Problem identification and procurement | <ul style="list-style-type: none"> <li>• Description of the identified problem</li> <li>• Descriptions of scope and intended use of the AI solution</li> <li>• Documentation of equity consideration for procurement</li> </ul>  | Decision 1: Decide which AI products to fully govern and provide recommendations to project teams for mandatory next steps. |
| Development and adaptation             | <ul style="list-style-type: none"> <li>• Model performance targets and measures of successful use</li> <li>• Method and results of retrospective evaluation</li> <li>• Plans for technical and clinical integration</li> </ul>   | Decision 2a: Approve progressing to a prospective evaluation.   |
|  | <ul style="list-style-type: none"> <li>• Results of prospective silent trial evaluation</li> <li>• Model configuration (Threshold selection, Snoozing window)</li> </ul>   | Decision 2b: Approve progressing to clinical integration.   |
| Clinical integration                   | <ul style="list-style-type: none"> <li>• User feedback collected via interviews and shadowing and Solution impact</li> <li>• Plans for post-integration monitoring and surveillance</li> <li>• Plans for ongoing education and training for end users and affected stakeholders</li> </ul> | Decision 3: Approve sustaining the use of the AI solution.  |
| Lifecycle management                   | <ul style="list-style-type: none"> <li>• Ownership of the model</li> <li>• Scope of continuous monitoring</li> <li>• Cadence of periodic audits</li> <li>• Feedback from end users and affected patients</li> <li>• Needs for update or decommission</li> <li>• Solution impact</li> </ul> | Decision 4: Approve sustaining or decommissioning the use of the AI solution.   |

# Risk Based AI Governance

- Different clinical AI products may be associated with varying levels of risk.
- The AI governance committee can determine the level of risk for each AI product and impose different levels of oversight based on its risk level.

| State of healthcare situation or condition | Significance of information provided to healthcare decision |                 |              |
|--|---|-----------------|--------------|
|  | Autonomous AI   | Augmentative AI | Assistive AI |
| Critical                                   | 4   | 3               | 3            |
| Serious                                    | 3   | 2               | 1            |
| Non-serious                                | 2   | 1               | 1            |



Reference: IMDRF SaMD Working Group. Software as a medical device: possible framework for risk categorization and corresponding considerations. In International Medical Device Regulators Forum 2014. <https://www.imdrf.org/documents/software-medical-device-possible-framework-risk-categorization-and-corresponding-considerations>

# Bounds of Enforcement of AI governance

Division of responsibility between the AI governance committee and the department.

| AI governance committee   | Department or program  |
|---|--|
| <ul style="list-style-type: none"> <li>● Approval of use case specific solution and its workflow</li> <li>● Efficacy (i.e., solution performance)</li> <li>● Safety</li> <li>● Equity</li> <li>● Security and privacy</li> <li>● Regulatory compliance</li> <li>● Alignment with IT roadmap</li> <li>● Interoperability with existing enterprise (non-department) software</li> <li>● Monitoring and reporting requirements</li> <li>● Monitoring threshold settings</li> </ul> | <ul style="list-style-type: none"> <li>● Clinical need</li> <li>● Patient needs</li> <li>● Business problem that will be addressed</li> <li>● Feasibility assessment</li> <li>● Budget</li> <li>● Cost effectiveness</li> <li>● Interoperability with existing department-specific software</li> <li>● Workforce and workflow burden</li> <li>● Clinician satisfaction</li> <li>● Accountability (i.e., clear product ownership and management)</li> </ul> |

# Technical Capabilities and Infrastructure Needs

Problem Identification  
and Procurement

Development and Adaptation

Clinical Integration

Lifecycle Management

- A tool for clinicians and researchers to register solution requirements and specifications
- A tool to manage and track internal AI governance submissions
- A system to manage model fact sheets and solution artifacts
- Secure computing environment for development and retrospective validation of algorithms
- Real-time validation environment for prospective validation of solution and lifecycle management
  - Data quality monitoring
  - Metadata management
  - Notification and alerting system
  - Outcomes monitoring
  - Operational monitoring
- Registry to store documentation of analyses conducted throughout development, silent validation, and monitoring
- A tool to record education and training of end users



# Define Resources Needs for AI Governance

- Establish business plans and operations.
  - Develop detailed plans for operationalizing AI governance.
  - Establish a structure for AI governance.
  - Establish communication plans.
- Secure necessary resources to implement AI governance.
  - Personnel
  - Budget
- Establish impact measures and evaluate the success of implementing AI governance.
- Seek feedback from local clinical, regulatory, and patient community members.



# Engage with our community of practice!

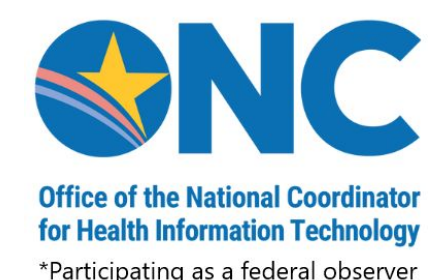
## Health Systems



## Ecosystem Partners



## Federal Agencies





# Thank you

- Gordon and Betty Moore Foundation
- Health AI Partnership leadership team & Corps Sites
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- Jee Young Kim
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- Suresh Balu
- Freya Gulamali
- Jeffry Hogg
- Joanne Kim
- Claire Carroll
- Shira Zilberstein



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