

# NARROW VS GENERATIVE AI

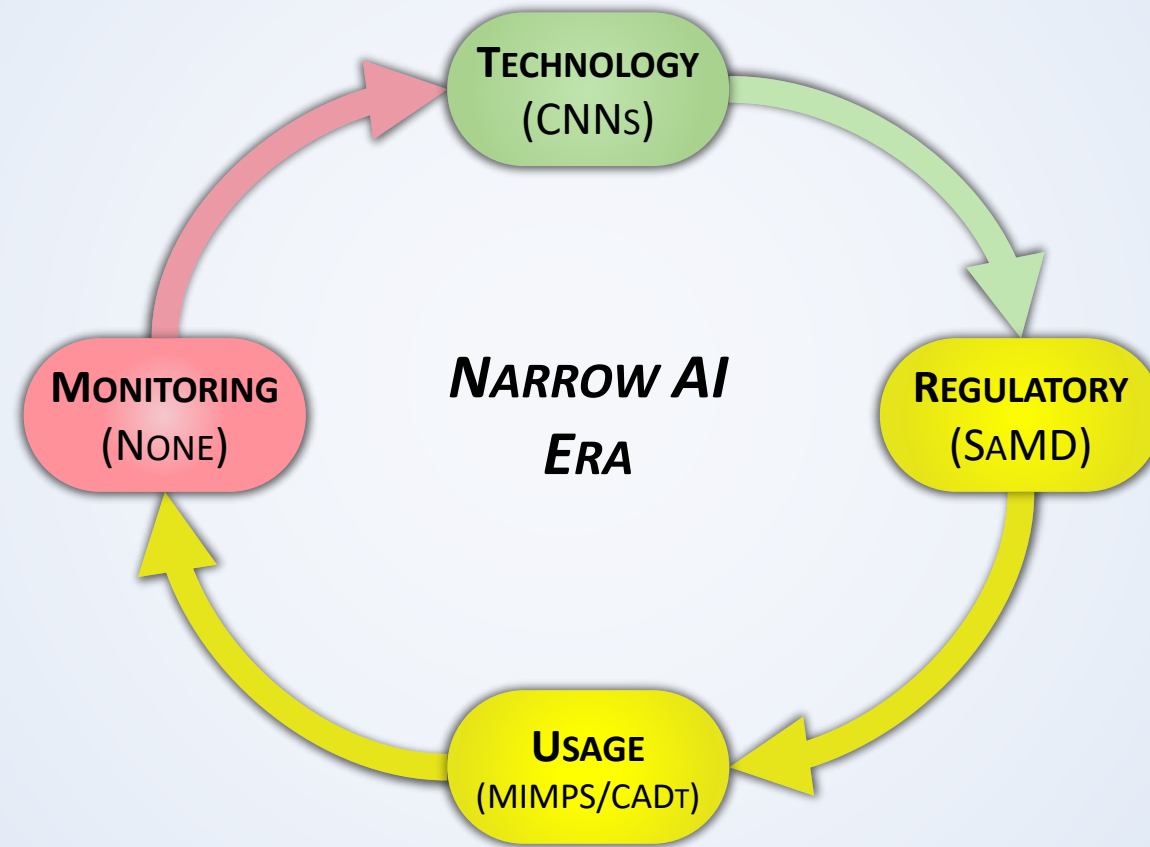
RISK DETERMINATION > CONTROLS => SAFE INNOVATION

*KEITH DREYER, DO, PHD, FACR, FSIIM*

*CHIEF DATA SCIENCE OFFICER, MASS GENERAL BRIGHAM - HARVARD MEDICAL SCHOOL*

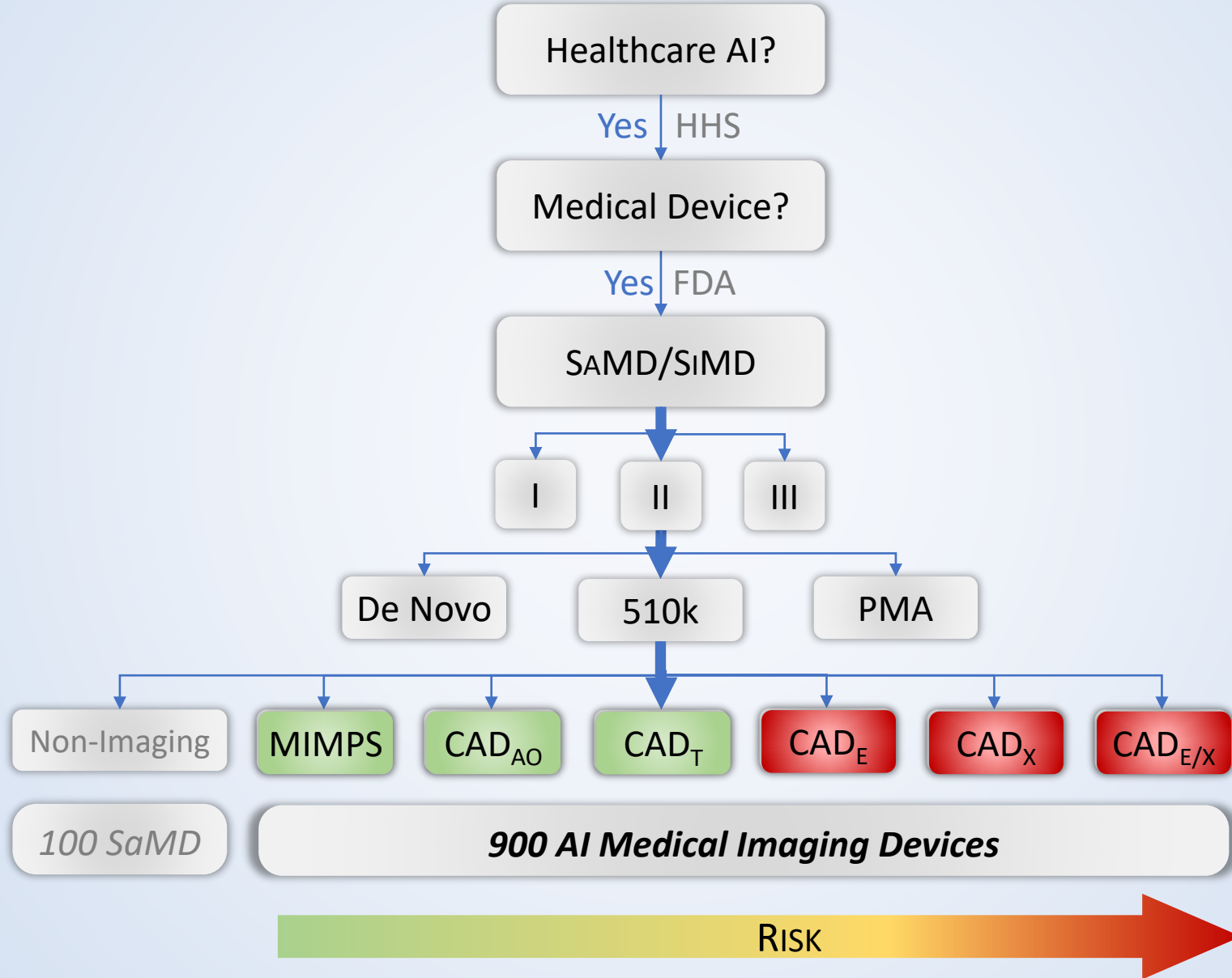
*CHIEF SCIENCE OFFICER, AMERICAN COLLEGE OF RADIOLOGY - DATA SCIENCE INSTITUTE*

# HEALTHCARE AI LIFE CYCLE



**REGULATORY  
(SaMD)**

# THE ERA OF NARROW AI

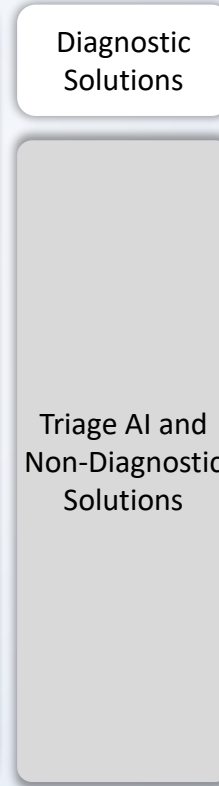
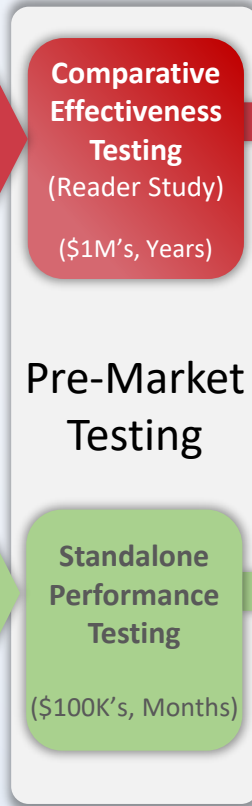
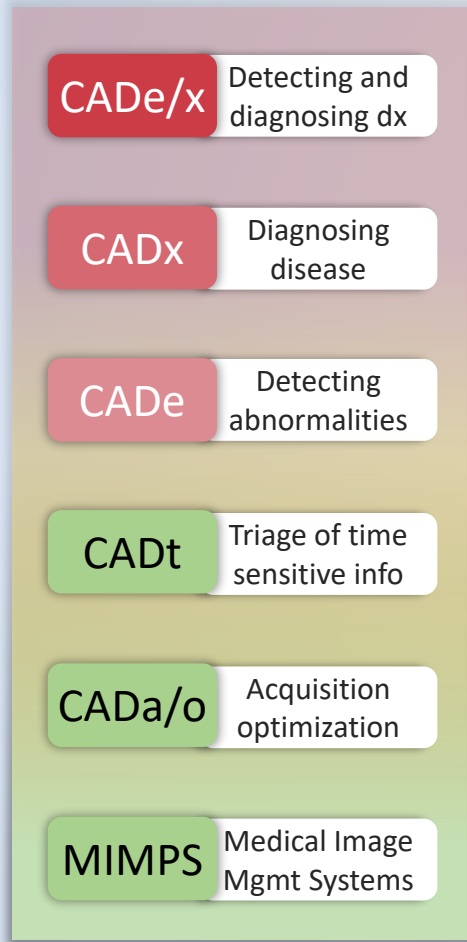


REGULATORY  
(SAMd)

# THE ERA OF NARROW AI

900 AI Medical Imaging Devices

RISK



**<2% Adoption Rate**  
(ACR Survey)

**Physician Value**

- FDA requires Triage AI to not show image results
- However, since all AI products require human oversight
- Triage AI makes workforce burnout worse
- Therefore, many experts won't use this type of AI

**Payer Value**

- CMS has created fewer than 5 CPT codes for AI payment
- No commercial coverage for FDA cleared AI products

**Patient Value**

- These same products in other countries are considered diagnostic solutions, providing improved patient care
- The AI coverage of diagnostic tasks in the US is about 1%

CLAIMS

RISK

CATEGORY

CONTROLS

CLEARANCE

PRODUCTS

PROVIDERS, PAYERS AND PATIENTS

**REGULATORY  
(SAMd)**

# THE ERA OF NARROW AI

*The AI coverage of diagnostic tasks in the US is about 1%*

Potential AI Findings	Modalities	Computed Tomography	Magnetic Resonance	Nuclear Medicine	Radiography/ Mammography	Angiography	Ultrasound	Interventional
Organ Systems	3,581 (42)	828 (9)	690 (3)	318	687 (27)	417	410 (3)	231
Abdominal	449 (2)	186	60 (2)	40	40	35	65	23
Breast	164 (10)	30	25 (1)	25	55 (8)	0	25 (1)	4
Cardiovascular	276 (1)	55	45	55	7	55	45 (1)	14
Emergency	364	105	35	2	105	45	55	17
Musculoskeletal	529 (4)	135	165	12	157 (4)	14	25	21
Neuroradiology	595 (5)	87 (3)	175	54	19 (2)	155	25	80
Pediatric Imaging	584 (6)	105	155	25	84 (6)	73	105	37
Thoracic Imaging	620 (14)	125 (6)	30	105	220 (7)	40	65 (1)	35

*Chest Xray*

*The same AI products in UK, EU and Asia provide full diagnostic coverage*

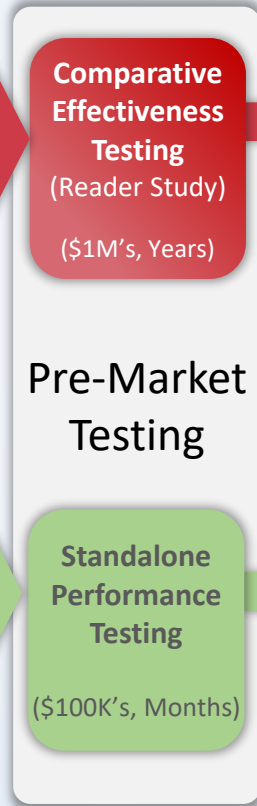
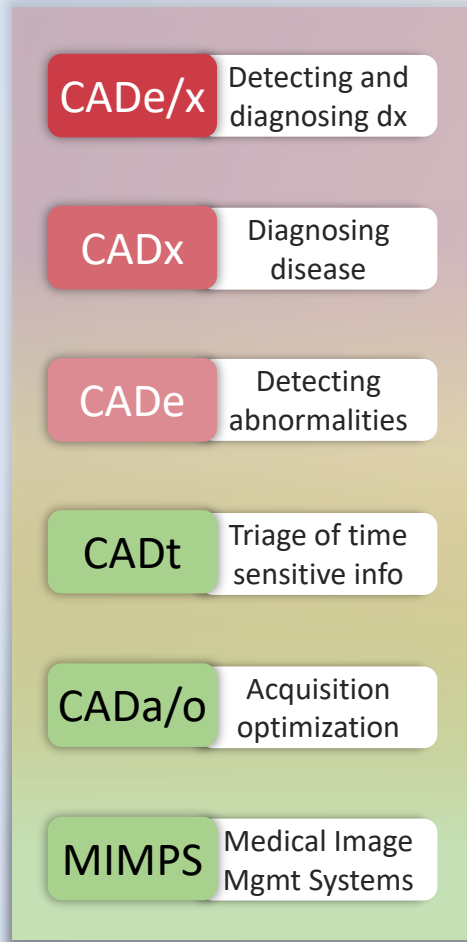
REGULATORY  
(SAMd)

# THE ERA OF NARROW AI

**LIMITATIONS IN SAMd RISK CLASSIFICATION ARE PREVENTING AI FROM PROVIDING PATIENT BENEFIT**

900 AI Medical Imaging Devices

RISK



**<2% Adoption Rate (ACR Survey)**

**Physician Value**

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- Triage AI makes workforce burnout worse
- Therefore, many experts won't use this type of AI

**Payer Value**

- CMS has created fewer than 5 CPT codes for AI payment
- No commercial coverage for FDA cleared AI products

**Patient Value**

- These same products in other countries are considered diagnostic solutions, providing improved patient care
- The AI coverage of diagnostic tasks in the US is only 1%
- **All AI requires human oversight... but not by an expert**

CLAIMS

RISK

CATEGORY

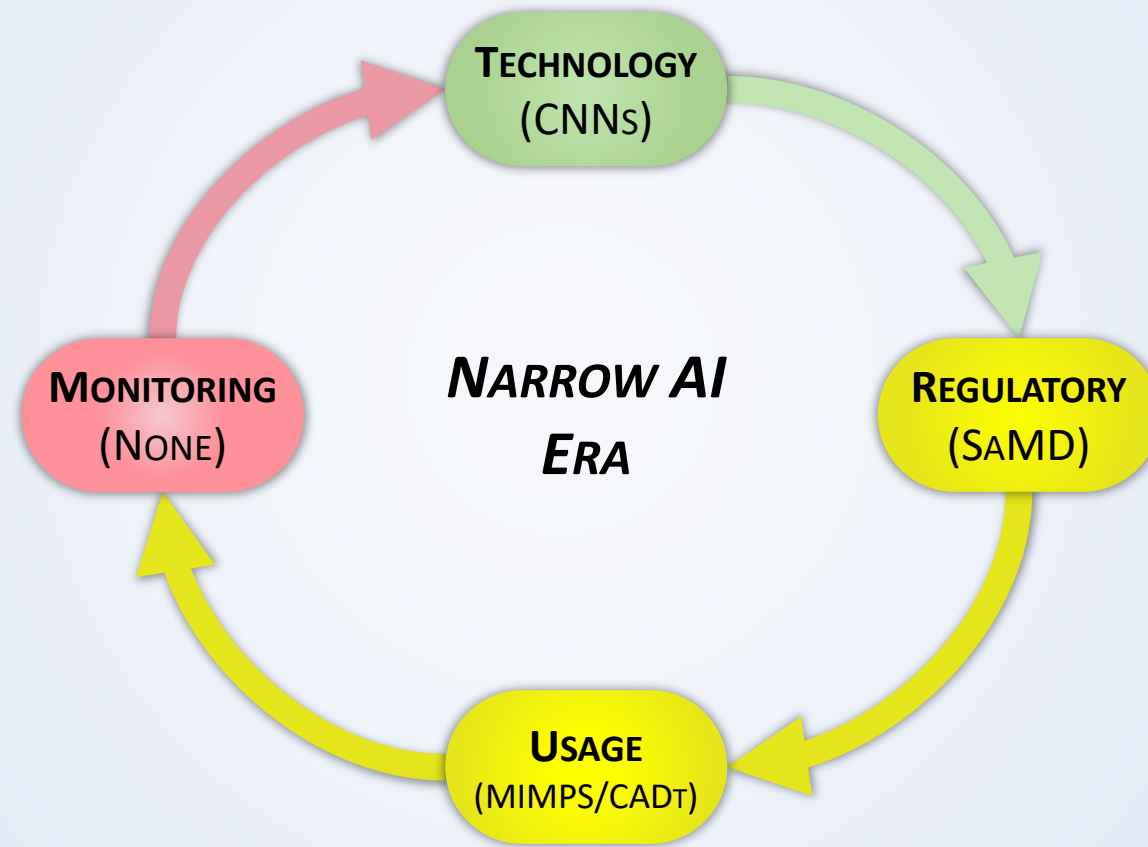
CONTROLS

CLEARANCE

PRODUCTS

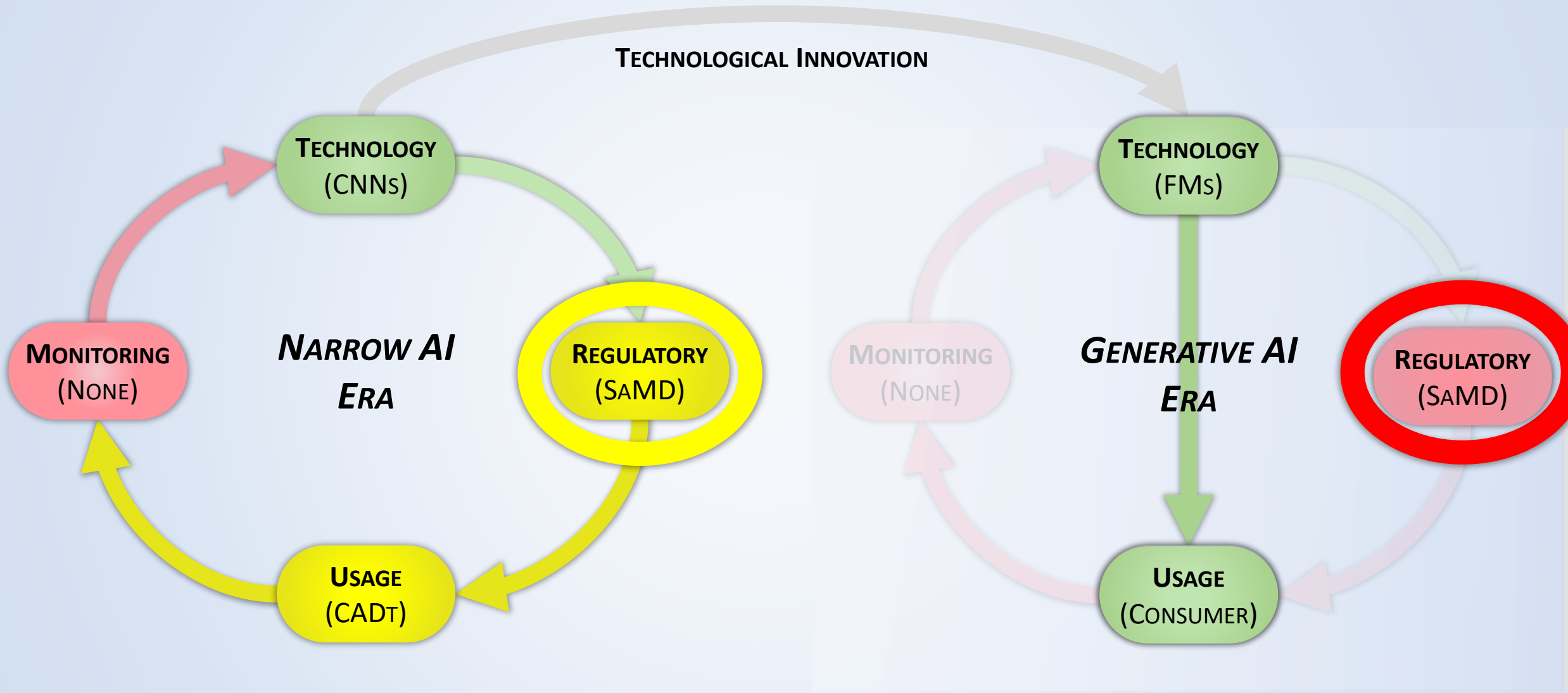
PROVIDERS, PAYERS AND PATIENTS

# HEALTHCARE AI LIFE CYCLE





# HEALTHCARE AI LIFE ~~CYCLE~~ LINE



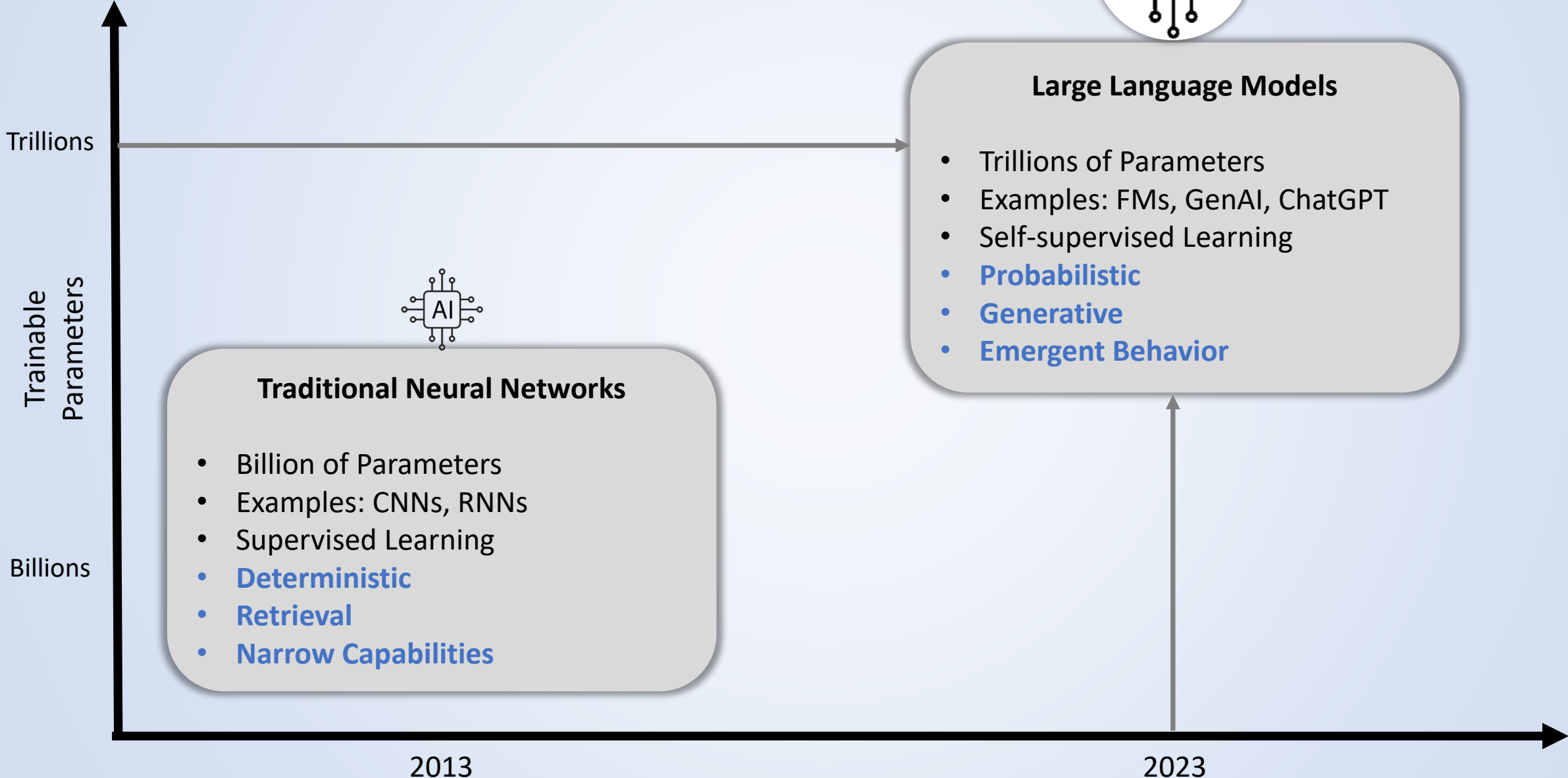
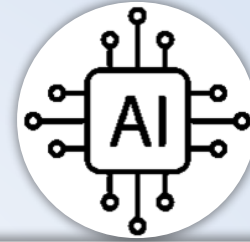
*How can these regulatory issues be addressed?*



# REGULATING GEN AI

REGULATORY  
(SAMD)

REGULATORY  
(SAMD)



## Large Language Models

- Trillions of Parameters
- Examples: FMs, GenAI, ChatGPT
- Self-supervised Learning
- **Probabilistic**
- **Generative**
- **Emergent Behavior**

## Traditional Neural Networks

- Billion of Parameters
- Examples: CNNs, RNNs
- Supervised Learning
- **Deterministic**
- **Retrieval**
- **Narrow Capabilities**

2013

2023

# REGULATING GEN AI

REGULATORY  
(SAMd)

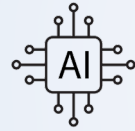
REGULATORY  
(SAMd)

*Narrow AI Medical Devices*



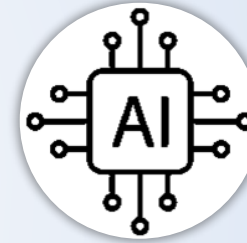
*Stand alone  
Performance Test*

*Comparative  
Effectiveness Test*



- Deterministic
- Retrieval
- Narrow Capabilities

*Gen AI Medical Devices*

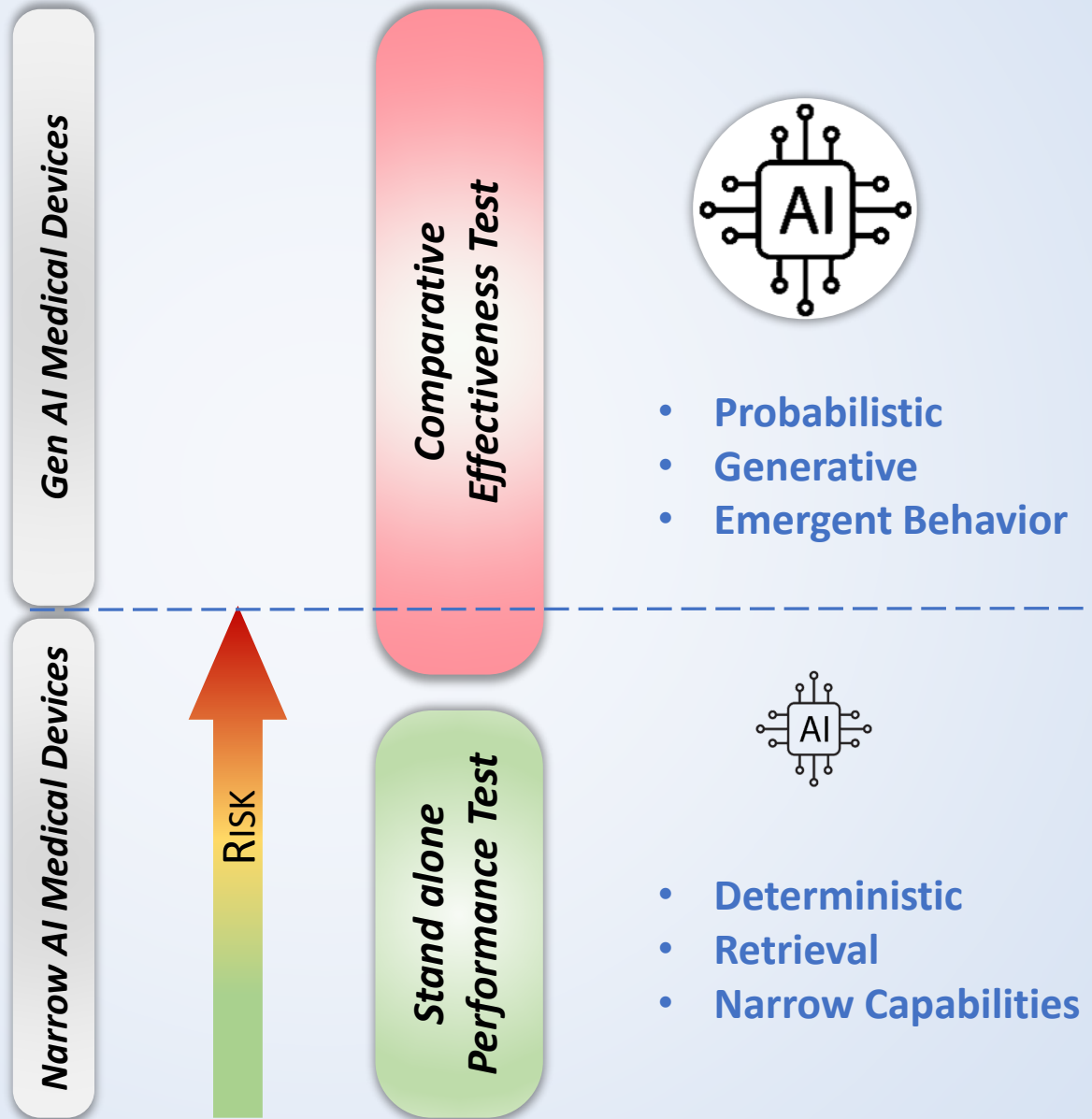


- Probabilistic
- Generative
- Emergent Behavior

**REGULATORY  
(SAMd)**

# REGULATING GEN AI

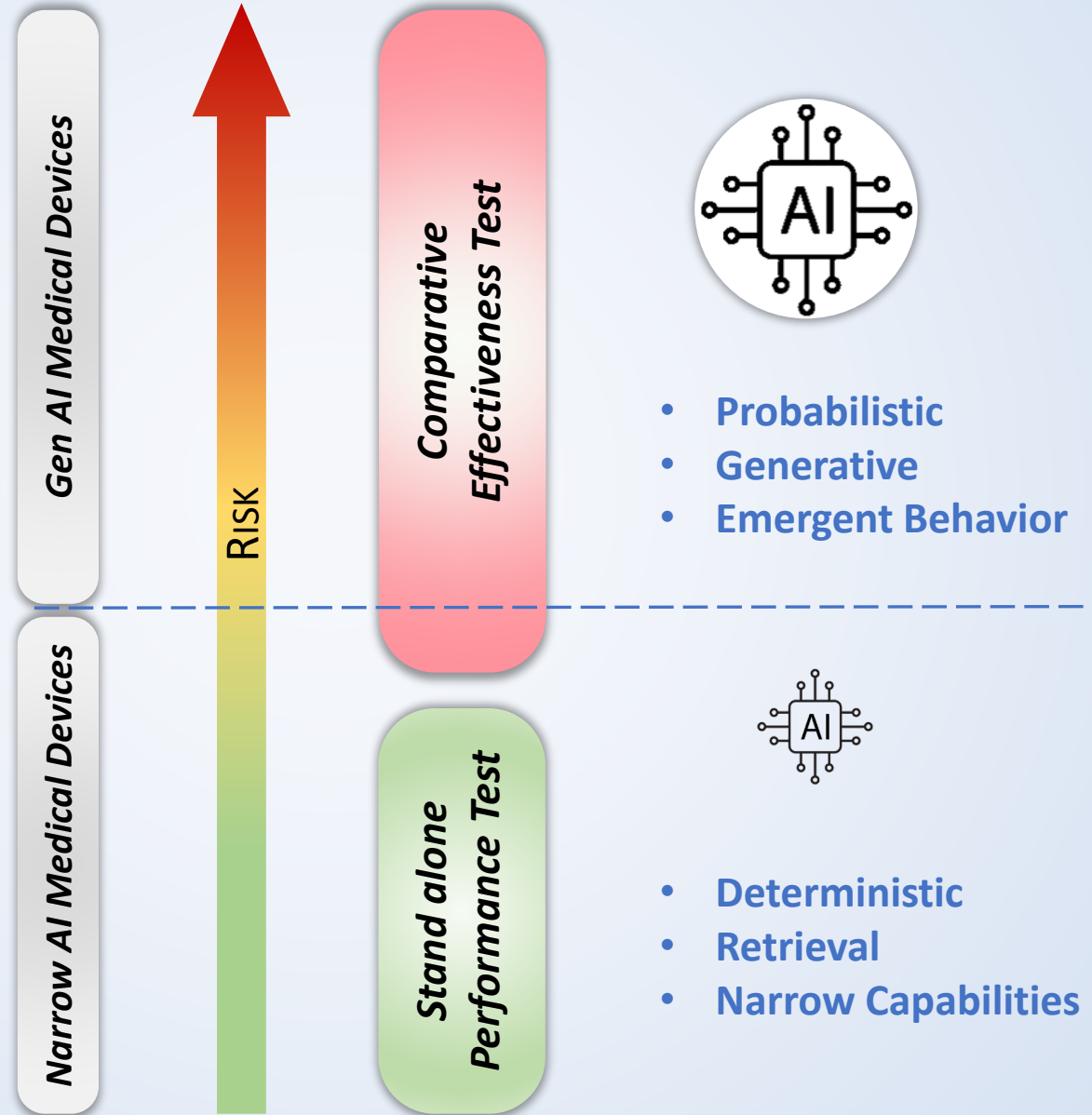
**REGULATORY  
(SAMd)**



**REGULATORY  
(SAMd)**

# REGULATING GEN AI

**REGULATORY  
(SAMd)**



**REGULATORY  
(SAMd)**

# REGULATING GEN AI

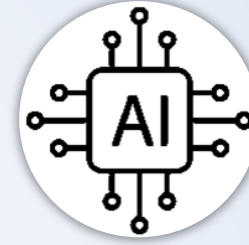
**REGULATORY  
(SAMd)**

*AI Medical Devices*



*Comparative  
Effectiveness Test*

*Stand alone  
Performance Test*



- Probabilistic
- Generative
- Emergent Behavior



- Deterministic
- Retrieval
- Narrow Capabilities

REGULATORY  
(SAMd)

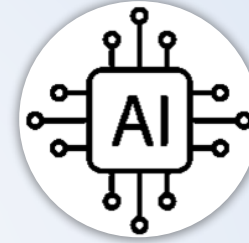
# REGULATING GEN AI

REGULATORY  
(SAMd)

*AI Medical Devices*

RISK

*Stand alone  
Performance Test*



- Probabilistic
- Generative
- Emergent Behavior



- Deterministic
- Retrieval
- Narrow Capabilities

REGULATORY  
(SAMD)

# REGULATING GEN AI

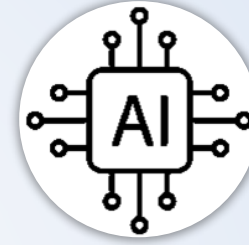
REGULATORY  
(SAMD)

*AI Medical Devices*

RISK

*Stand alone  
Performance Test*

*Clinical Validation*



- Probabilistic
- Generative
- Emergent Behavior



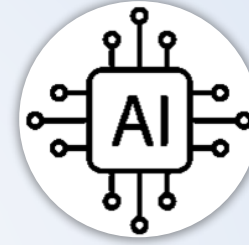
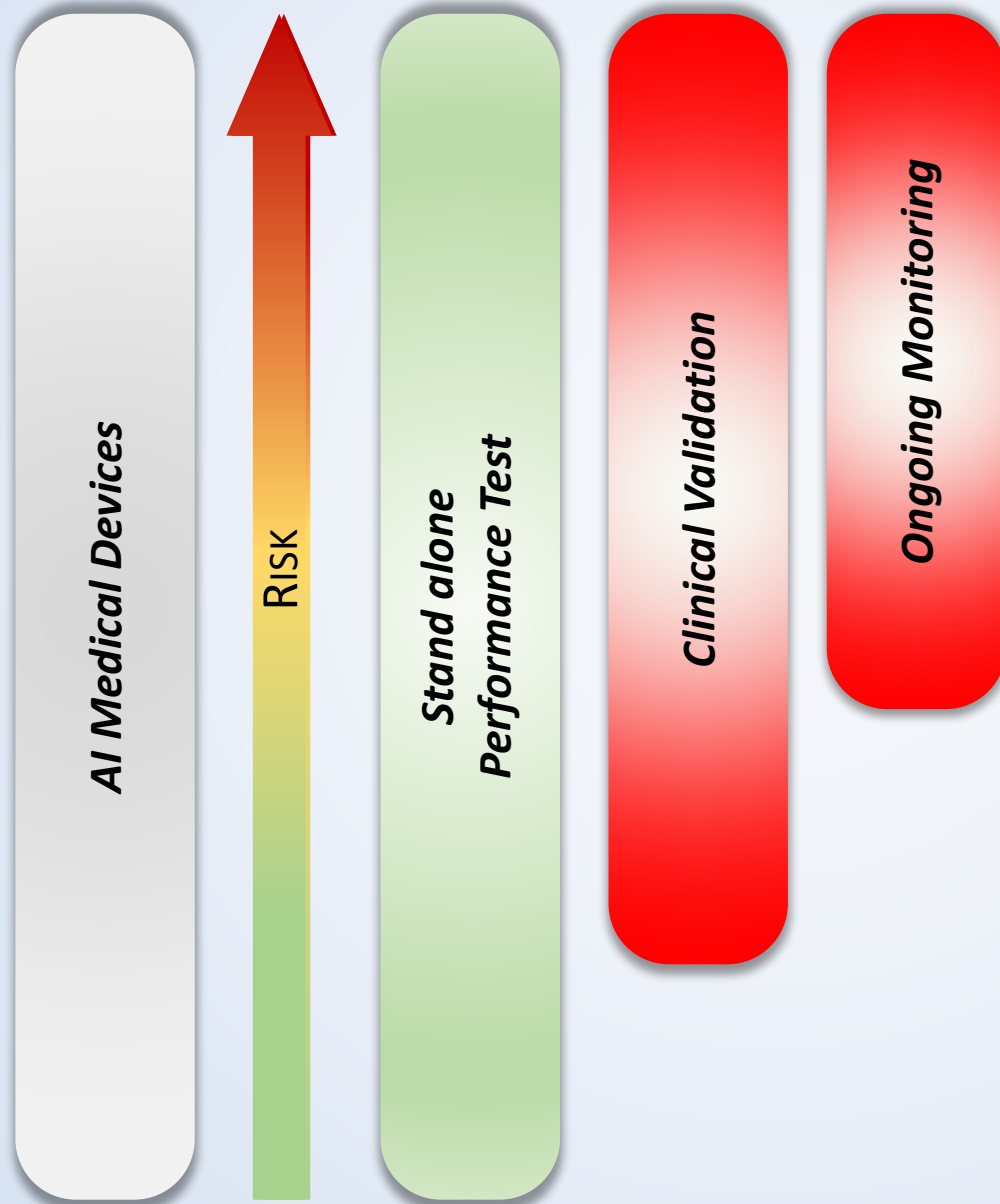
- Deterministic
- Retrieval
- Narrow Capabilities



REGULATORY  
(SAMd)

# REGULATING GEN AI

REGULATORY  
(SAMd)



- Probabilistic
- Generative
- Emergent Behavior



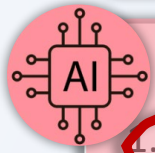
- Deterministic
- Retrieval
- Narrow Capabilities

# REGULATING GEN AI



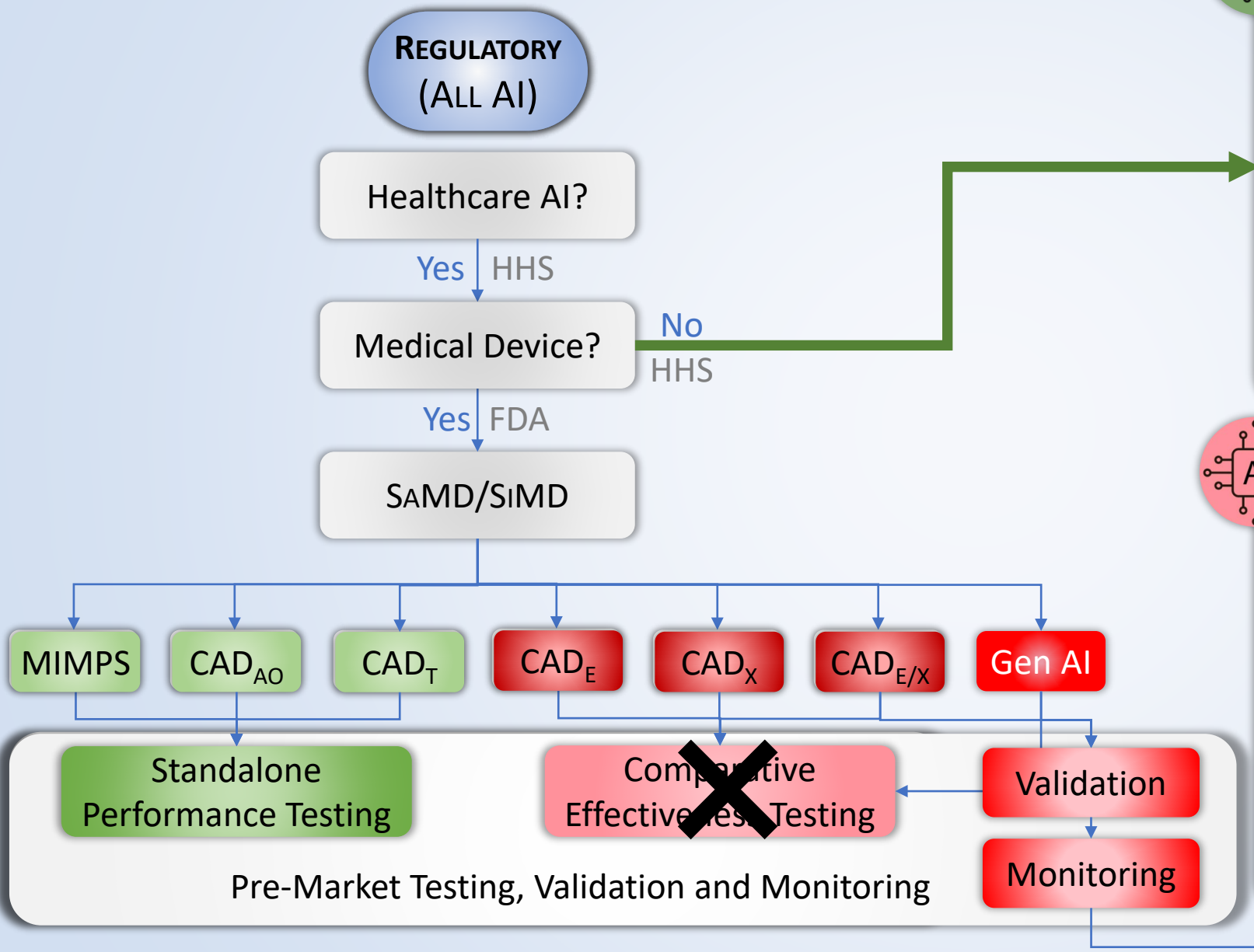
## AGI Non-Device Applications

- Voice-to-Text Transcription
- Automated Clinical Note Generation
- Clinical Documentation Enhancement
- NLU for EHR Notes
- Patient Interaction Summarization
- Patient Sentiment Analysis
- Clinical Note Auto-Coding
- Clinical Note Translation
- Personalized Patient Education
- Clinical Decision Support in EHRs



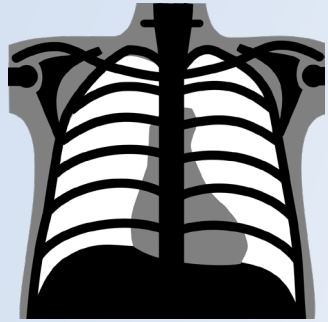
## AGI Medical Device Applications

- Diagnostic Draft Reporting from Imaging
- Data-Driven Treatment Recommendations
- AI-Powered Pathological Diagnosis
- Image-Guided Surgical Assistance
- Predictive Disease Progression Modeling
- Personalized Drug Response Prediction
- Genomic Data Interpretation Tools
- AI-Enhanced Medical Imaging
- Virtual Tumor Board Decision Support
- Real-Time Clinical Decision Assistance



# REGULATING GEN AI

## Voice to Text Transcription



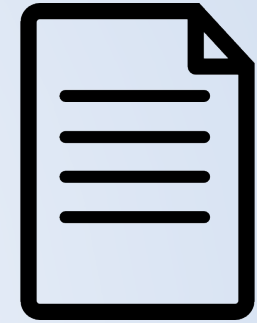
Image



Interpretation

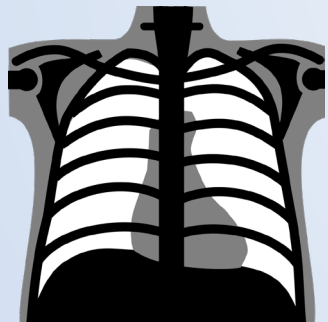


Voice to Text  
*(Transcription)*



Report

## Diagnostic Draft Reporting



Image

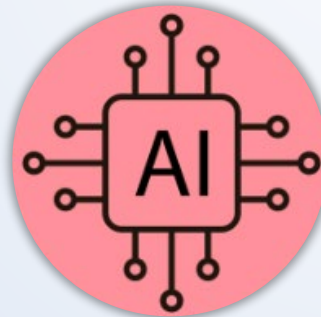
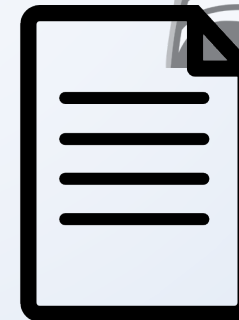
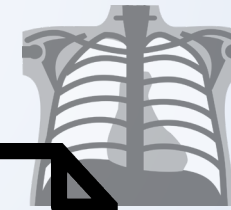


Image to Text  
~~*(Transvision)*~~



Draft



Image



Interpretation



# REGULATING GEN AI



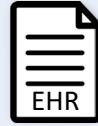
**Transcription**  
(Non Medical Device)

**Transvision**  
(Medical Device)

**Summarization**  
(Medical Device?)

**Quality Checking**  
(Medical Device?)

**Consumer Usage**  
(No Claims, no Regs)



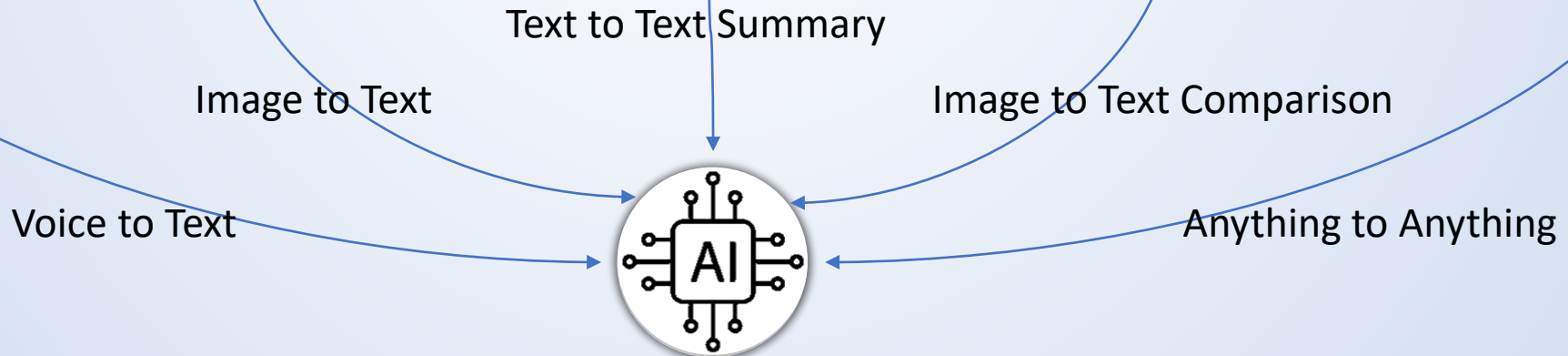
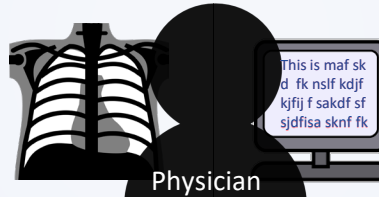
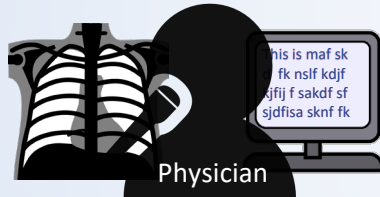
Text ↑

Text ↑

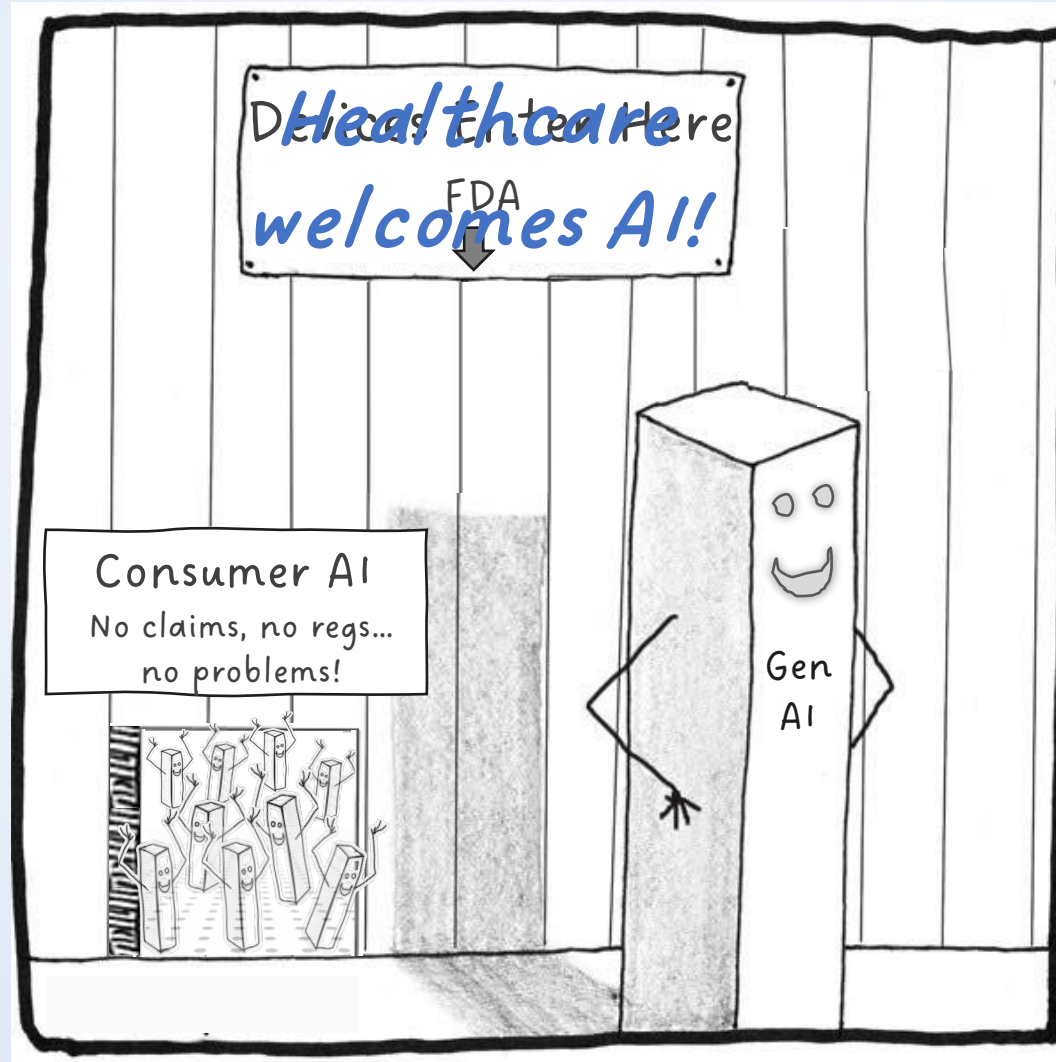
Text ↑

Text ↑

Text ↑



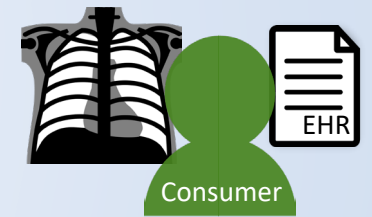
# REGULATING GEN AI



**Consumer Usage**  
(No Claims, no Regs)



Text ↑



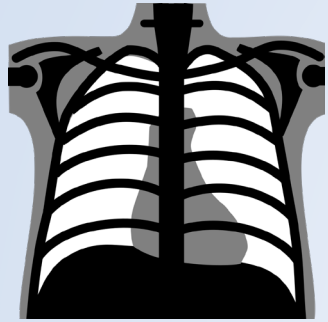


# **DIAGNOSTIC DRAFT REPORTING**

## **A GEN AI CASE STUDY**

# DIAGNOSTIC DRAFT REPORTING

## Voice to Text Transcription



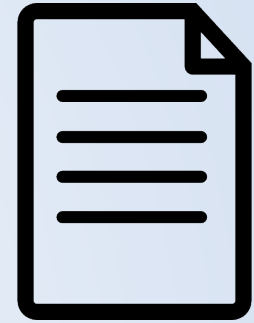
Image



Interpretation

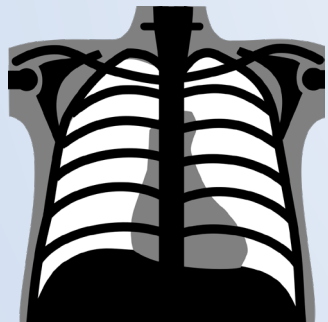


Voice to Text  
*(Transcription)*



Report

## Diagnostic Draft Reporting



Image

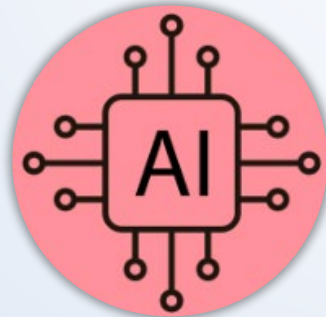
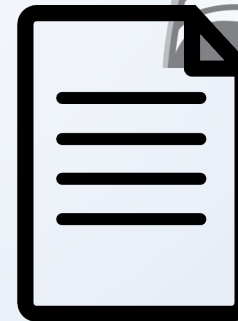
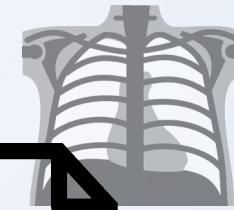


Image to Text  
~~*(Transvision)*~~



Draft



Image



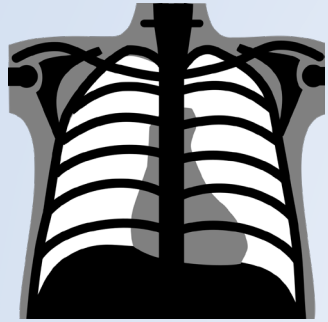
Interpretation





# DIAGNOSTIC DRAFT REPORTING

## Voice to Text Transcription



Image



Interpretation

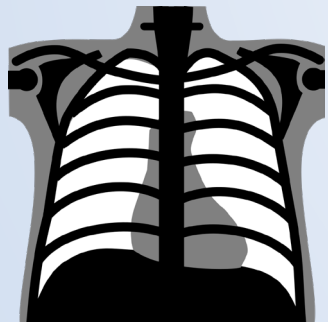


Voice to Text  
*(Transcription)*



Report

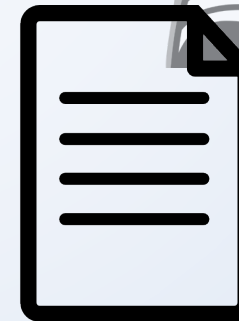
## Diagnostic Draft Reporting



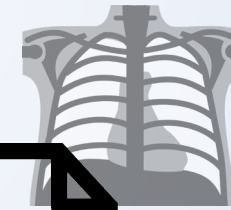
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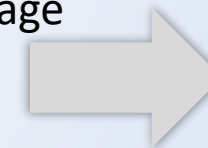
Image to Text  
*(Transvision)*



Draft



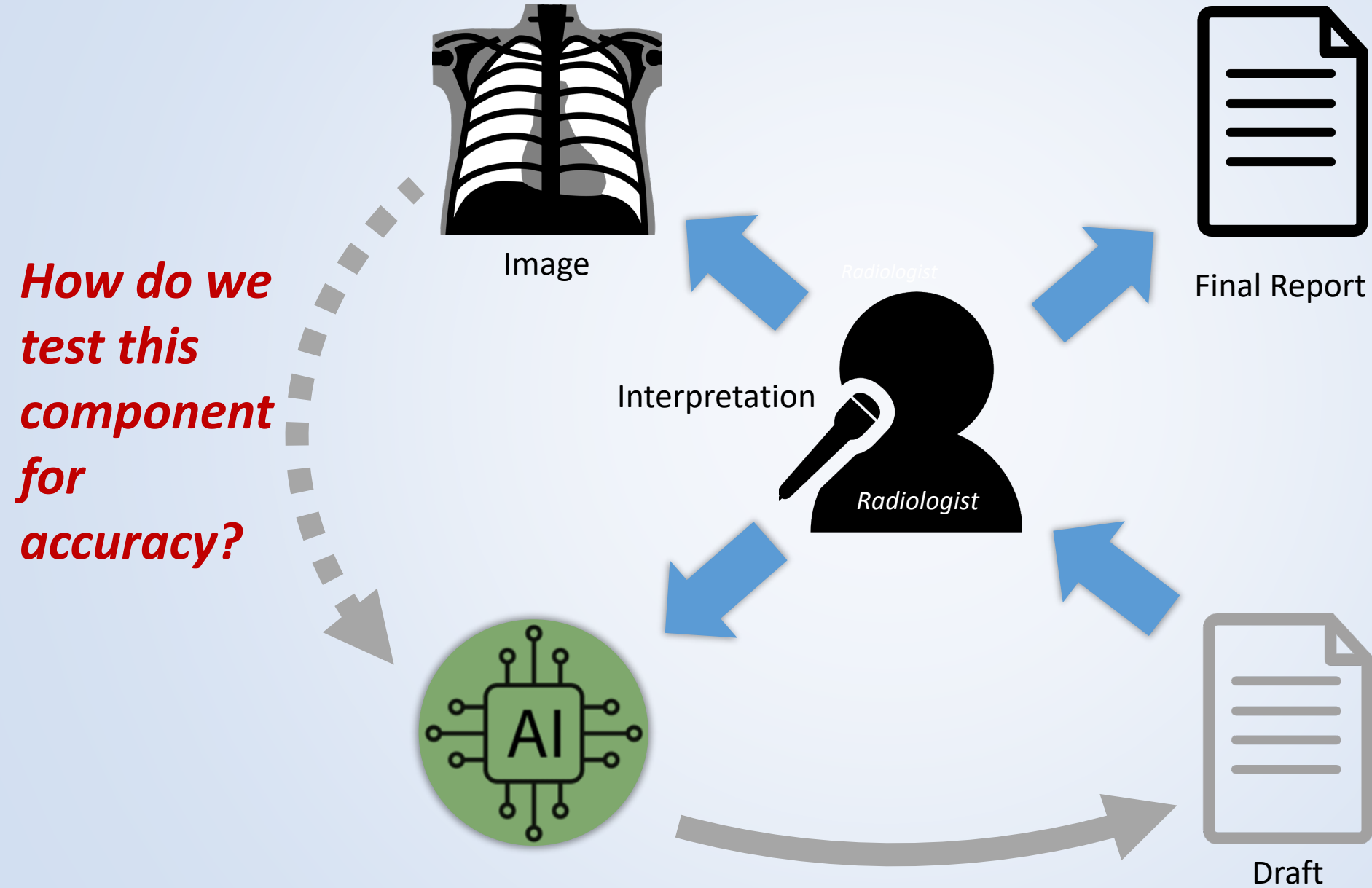
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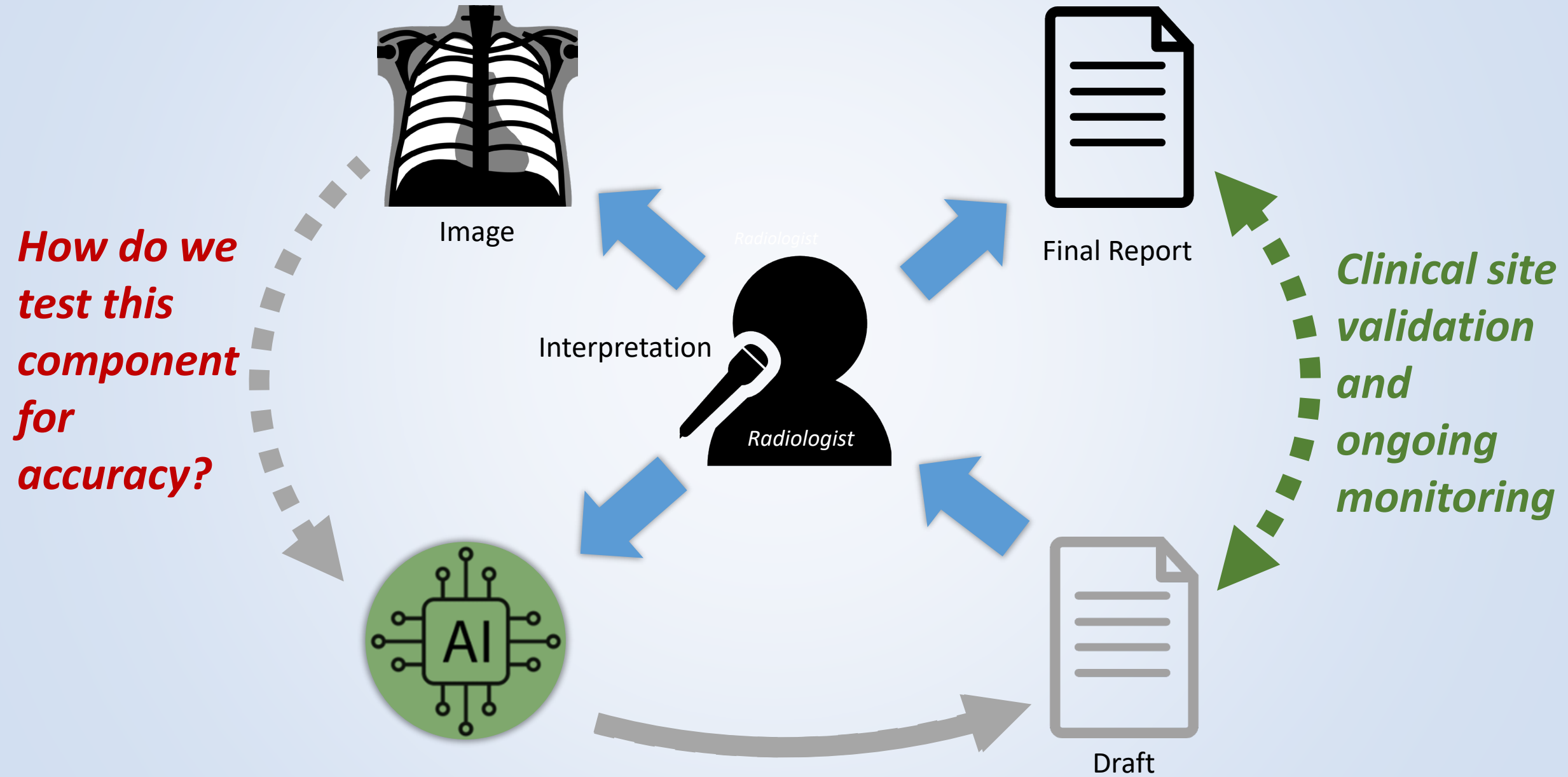
# DIAGNOSTIC DRAFT REPORTING



*How do we test this component for accuracy?*

*If accurate, this addition would improve diagnostic efficiency by ~150%*

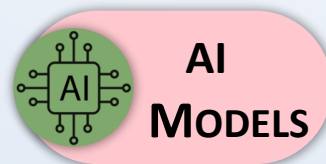
# DIAGNOSTIC DRAFT REPORTING



# THE HEALTHCARE AI ARENA

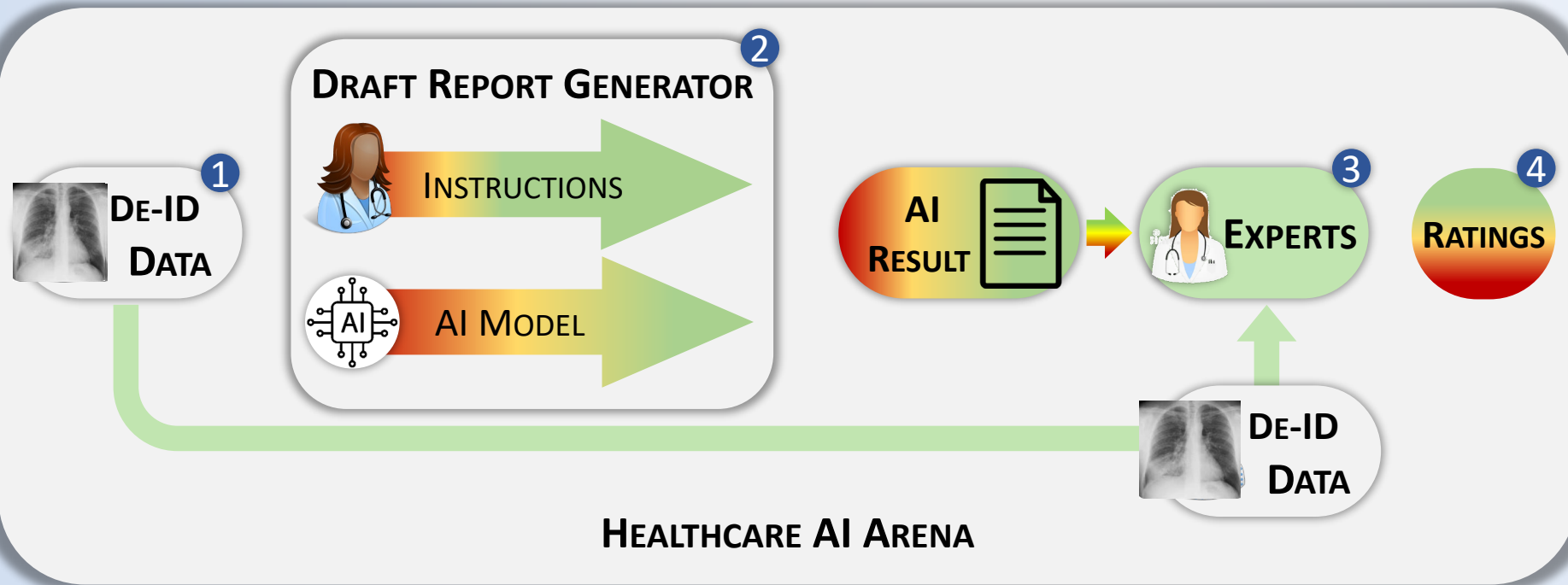
*A Collaborative Community for Healthcare AI Validation and Monitoring*

American College of Radiology  
Emory Healthcare  
Mass General Brigham  
The University of Washington  
The University of Wisconsin

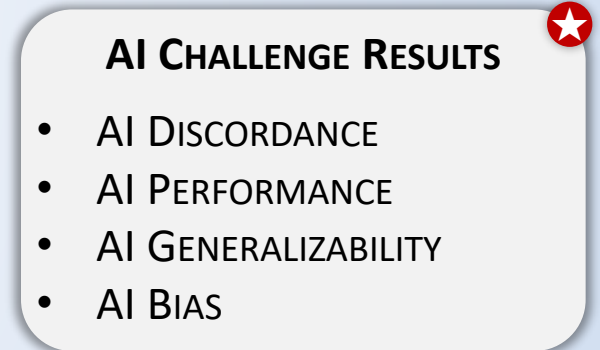


## HEALTHCARE AI ARENA

- 1 Geographically & Demographically Diverse, Embargoed Data
  - 2 Unlimited Clinical Use Cases (e.g. Draft Report Generation)
  - 3 Geographically & Institutionally Diverse Experts
  - 4 Expert evaluation of AI Agents with Input Data
- 
- ★ Analytic Evaluation of AI Agents in Real-World Environment



**AI PERFORMANCE RATINGS  
(PUBLIC FORUM)**



**AI DECISION MAKING  
(INSTITUTIONAL)**

# THE HEALTHCARE AI ARENA

Healthcare AI Challenge

Challenge About My Account [kdreyer@mgb.org](mailto:kdreyer@mgb.org)

Description Rules

A placeholder for the Description tab

Challenges

Radiology XR Radiology Chest EHR Data

Use Cases

- Describe the findings of this x-ray exam
- What are the most clinically relevant differential diagnoses
- What would be the appropriate follow-up recommendation for the most clinically relevant diagnosis?
- What would be the appropriate treatment for the most clinically relevant diagnosis?
- Create a draft report

Specialty Select one or more Specialties - default is all

Cardiology Emergency Endocrinology Gastroenterology General Medicine Neurology

Oncology Orthopedics Pulmonology Rheumatology Surgery Urology


Run Challenge

# THE HEALTHCARE AI ARENA

Healthcare AI Challenge

Challenge About My Account [kdreyer@mgb.org](mailto:kdreyer@mgb.org)

Create a draft report Use Case 1 of 1



**Reason for Exam:**

The patient presented with pain and swelling in the right lower leg following a recent fall. There is a concern for possible fracture.

**Findings:**

The X-ray images of the right lower leg show a transverse fracture of the midshaft of the fibula. The fracture appears to be non-displaced. The tibia is intact with no evidence of fracture. Soft tissue swelling is noted around the fracture site.

**Impression:**

Transverse non-displaced fracture of the midshaft of the right fibula. No tibial fracture identified. Recommend orthopedic consultation for management.




# THE HEALTHCARE AI ARENA

Healthcare AI Challenge

Challenge About My Account [kdreyer@mgb.org](mailto:kdreyer@mgb.org)

Create a draft report Use Case 1 of 1



**Reason for Exam:**  
Patient presents with left hand pain and reduced range of motion following a recent fall. Previous imaging suggested possible fracture.

**Findings:**  
Three views of the left hand are provided: anteroposterior (AP), oblique, and lateral projections. The bony structures demonstrate normal alignment and mineralization. No acute fractures or dislocations are identified. The joint spaces are well-maintained throughout. Soft tissues appear normal without significant swelling. There is no evidence of foreign bodies or radiopaque lesions.

**Impression:**  
No acute osseous abnormality of the left hand. The previously suspected fracture is not evident on these images. Consider clinical correlation and follow-up if symptoms persist. Additional imaging such as MRI may be warranted if there is concern for soft tissue injury not visible on plain radiographs.

**Radiologist** Fellow Resident Med Student Unacceptable

Next Case

# THE HEALTHCARE AI ARENA

Healthcare AI Challenge

Challenge About My Account [kdreyer@mgb.org](mailto:kdreyer@mgb.org)

Create a draft report Use Case 1 of 1

**Reason for Exam:**  
The patient presented with left arm pain and limited range of motion following a recent fall.

**Findings:**  
The X-ray images of the left humerus demonstrate a mid-shaft fracture with mild displacement. There is no evidence of additional fractures or dislocations in the shoulder or elbow joints. The surrounding soft tissues appear unremarkable, with no significant swelling or hematoma noted.

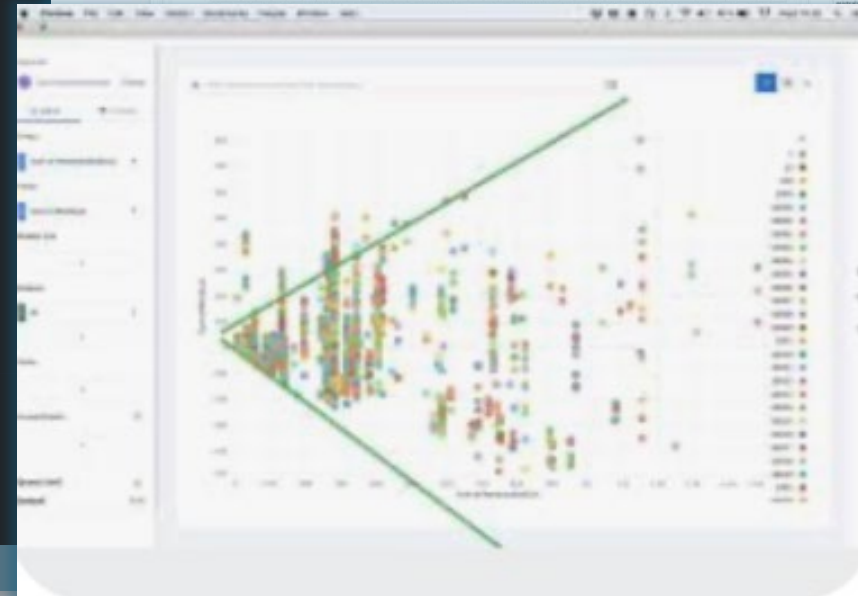
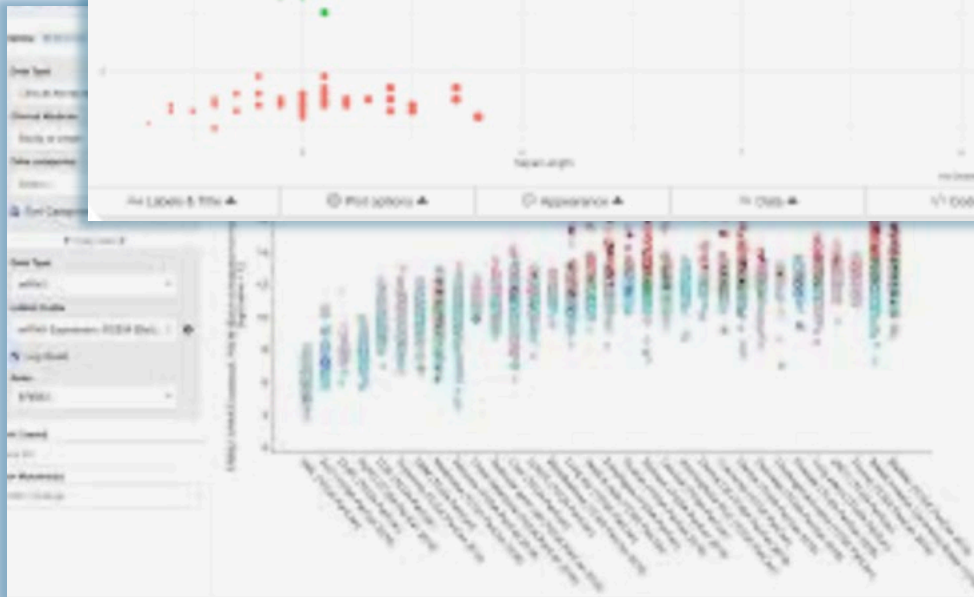
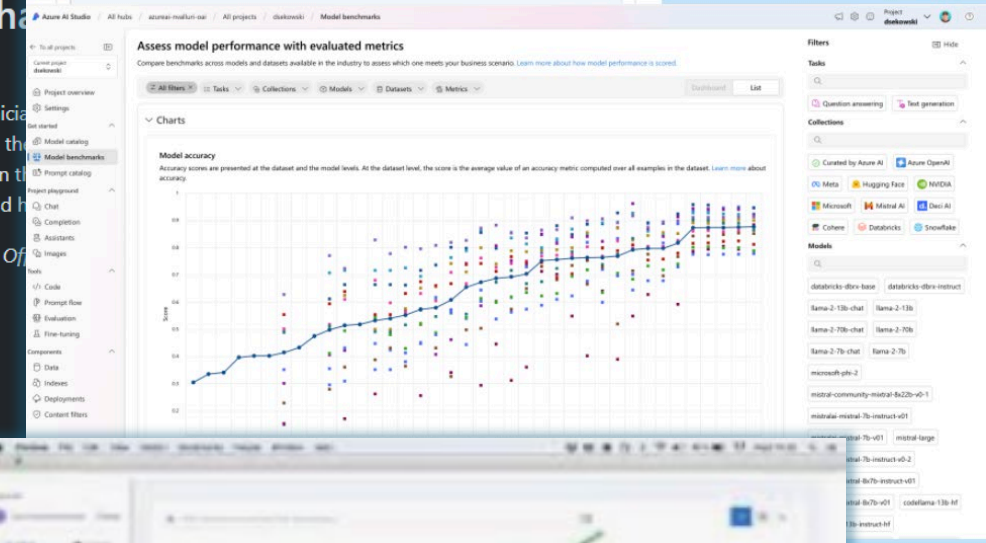
**Impression:**  
Mid-shaft fracture of the left humerus with mild displacement. Recommend orthopedic consultation for further management and possible immobilization. Follow-up imaging may be necessary to assess healing progress.



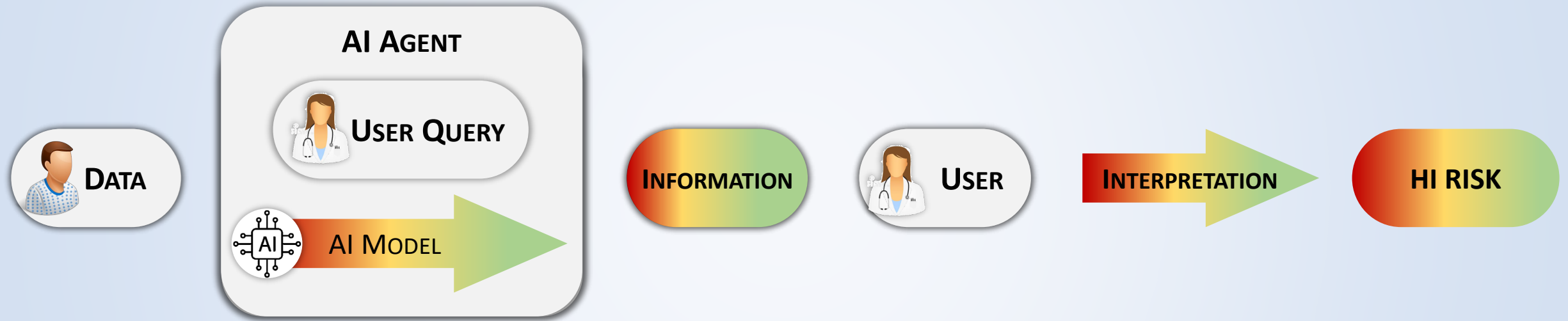
# THE HEALTHCARE AI ARENA

Bright

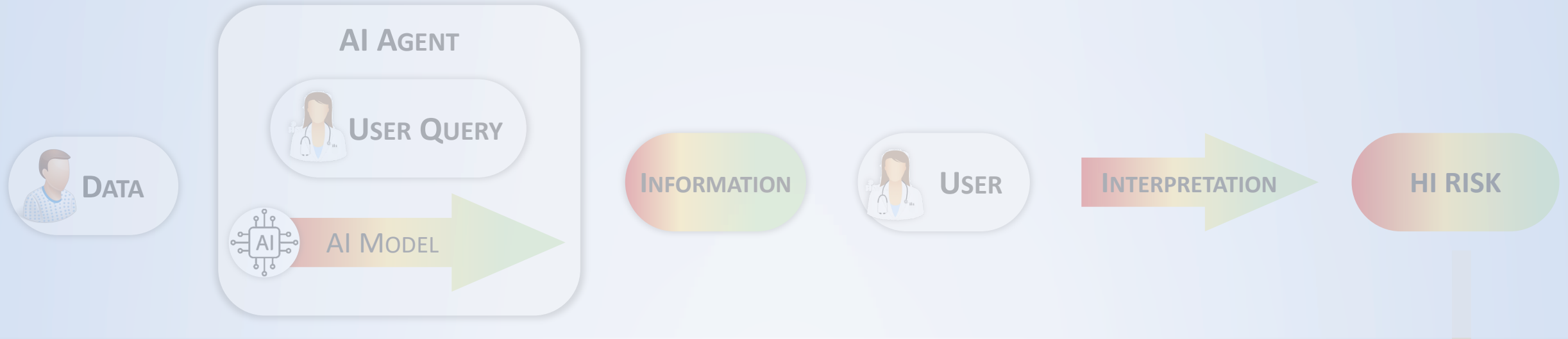
enable clinicians  
furthering the  
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providers, and H  
Academic Of



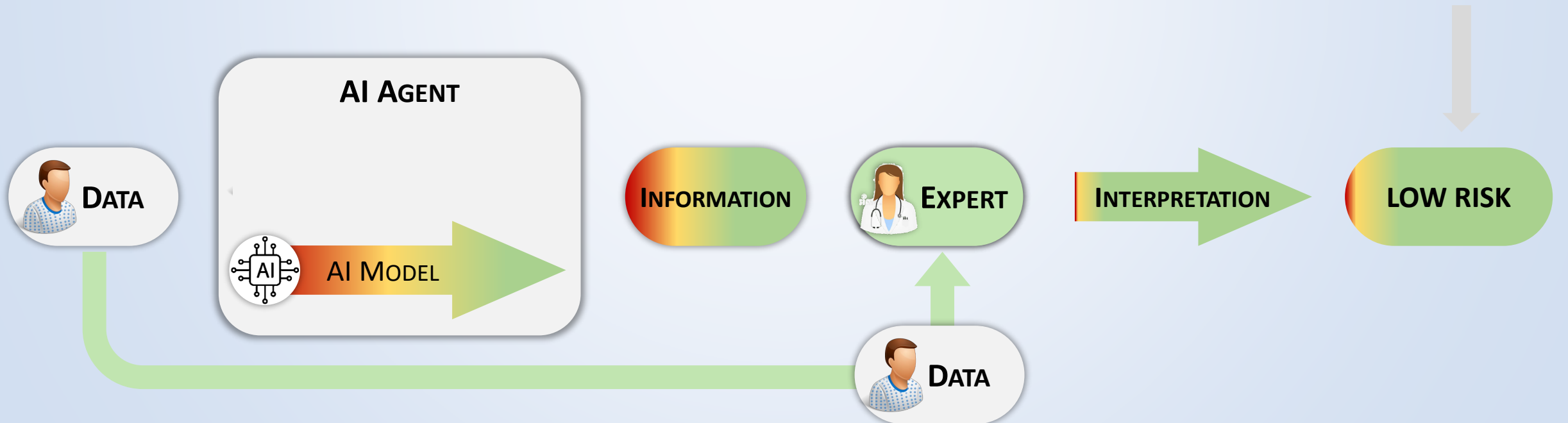
# USING AI HEALTHCARE ARENA TO REDUCE RISK



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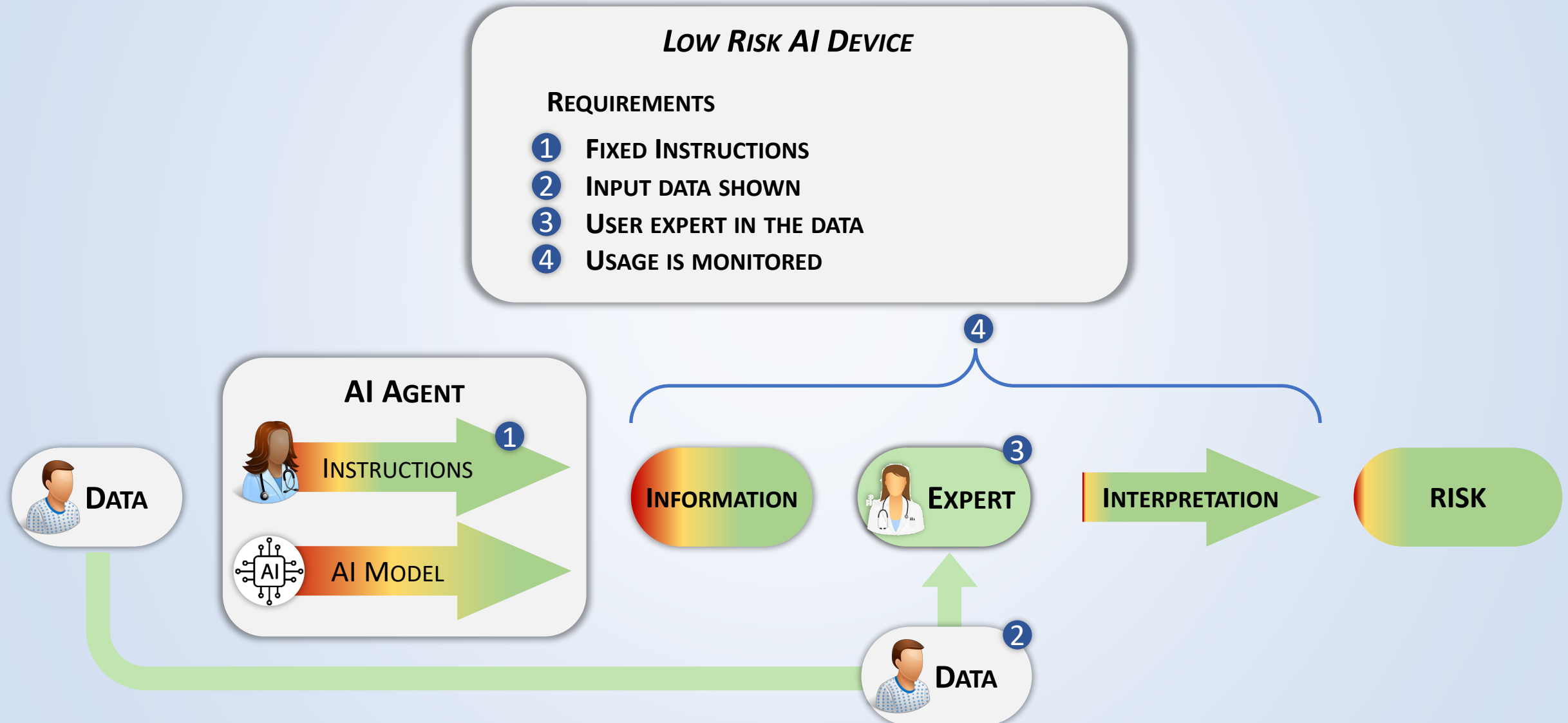


***FIXED INSTRUCTION PROMPT, INPUT DATA SHOWN, USER EXPERT IN THE DATA, AND USAGE IS MONITORED > LOW RISK***



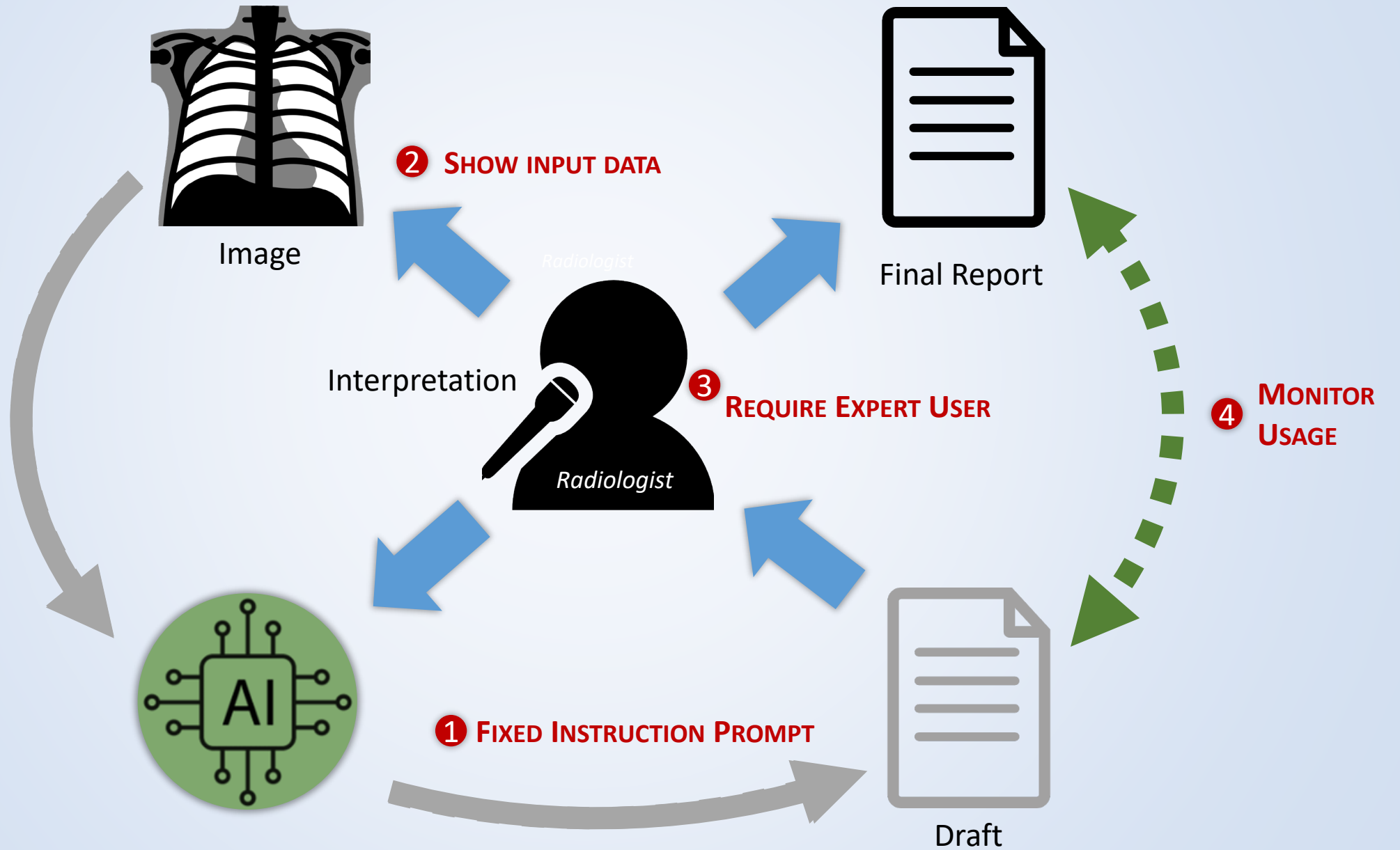
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# DIAGNOSTIC DRAFT REPORTING





# THE HEALTHCARE AI ARENA

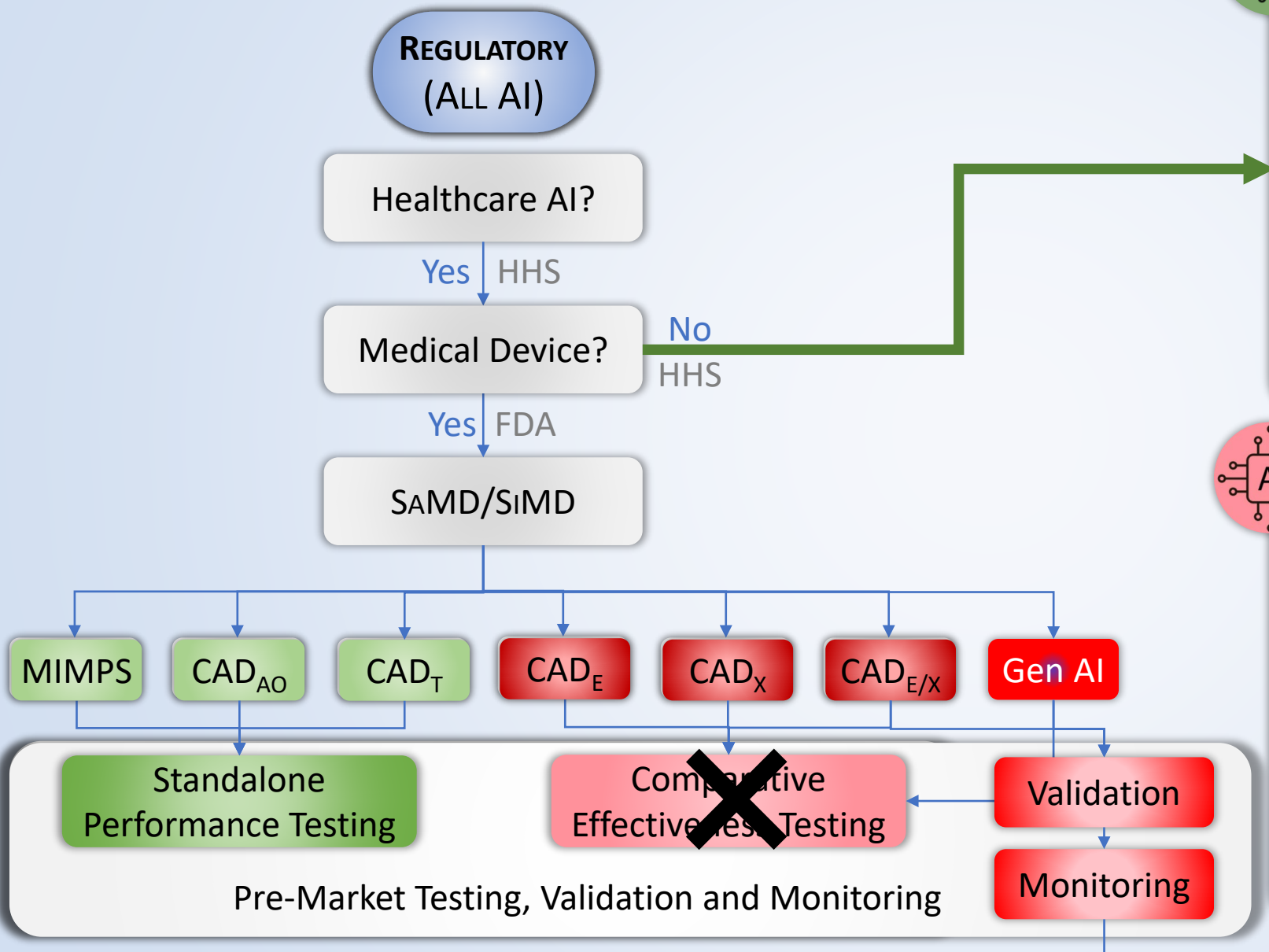
## AI Validation

- Informs Manufacturers of Potential Defects
- Determines Site Accuracy and Generalizability
- Lowers Risk of Failure on Site
- Promotes Early and Safe Innovation
- Provides a Mechanism for Ongoing Monitoring

# THE FUTURE OF HEALTHCARE AI REGULATIONS

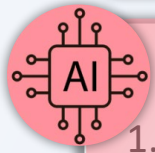
***IS THERE A THOUGHTFUL WAY TO REGULATE HEALTHCARE AI  
BEYOND A MEDICAL DEVICE DEFINITION?***

# THE FUTURE OF HEALTHCARE AI REGULATIONS



## AGI Non-Device Applications

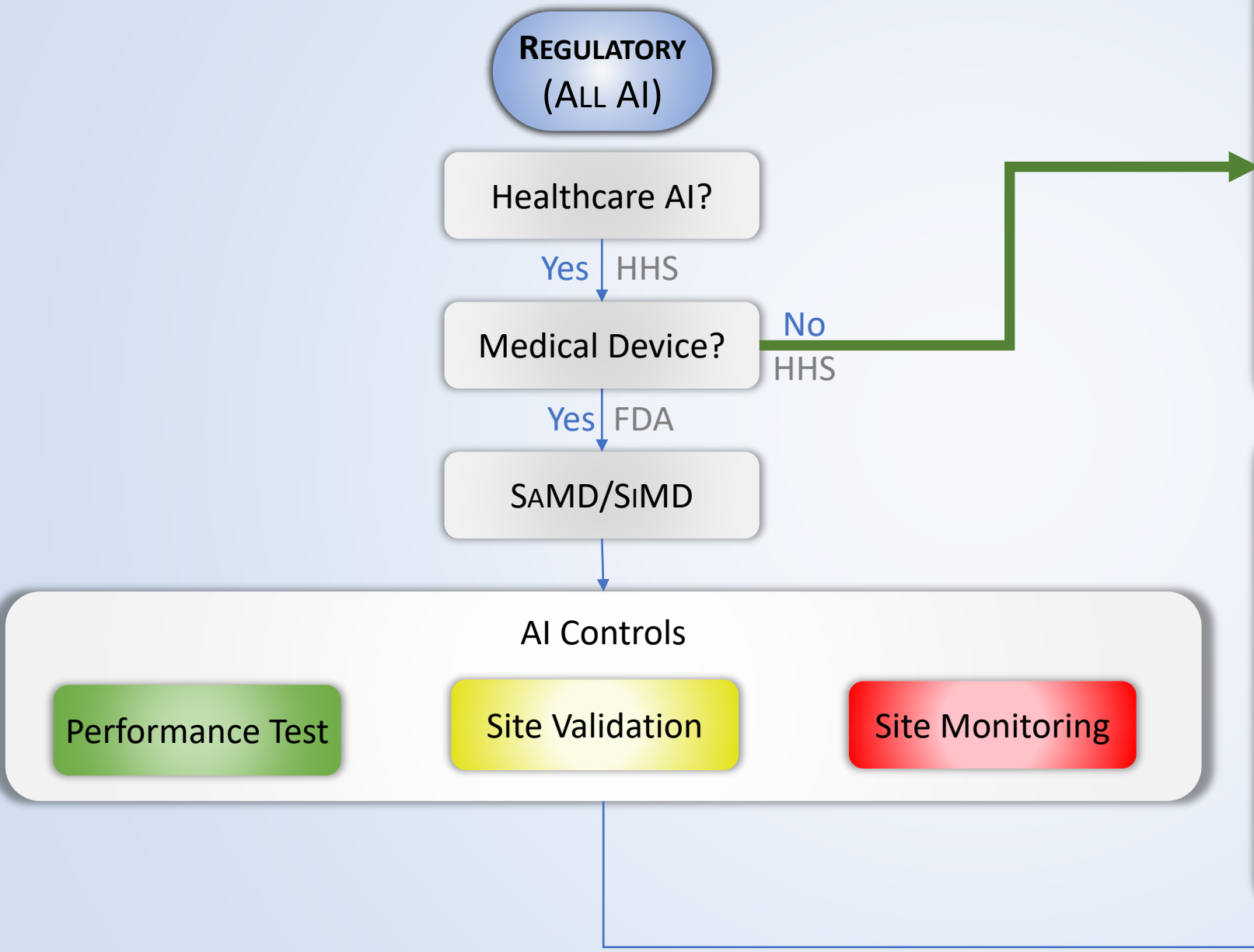
1. Voice-to-Text Transcription
2. Automated Clinical Note Generation
3. Clinical Documentation Enhancement
4. NLU for EHR Notes
5. Patient Interaction Summarization
6. Patient Sentiment Analysis
7. Clinical Note Auto-Coding
8. Clinical Note Translation
9. Personalized Patient Education
10. Clinical Decision Support in EHRs



## AGI Medical Device Applications

1. Diagnostic Draft Reporting from Imaging
2. Data-Driven Treatment Recommendations
3. AI-Powered Pathological Diagnosis
4. Image-Guided Surgical Assistance
5. Predictive Disease Progression Modeling
6. Personalized Drug Response Prediction
7. Genomic Data Interpretation Tools
8. AI-Enhanced Medical Imaging
9. Virtual Tumor Board Decision Support
10. Real-Time Clinical Decision Assistance

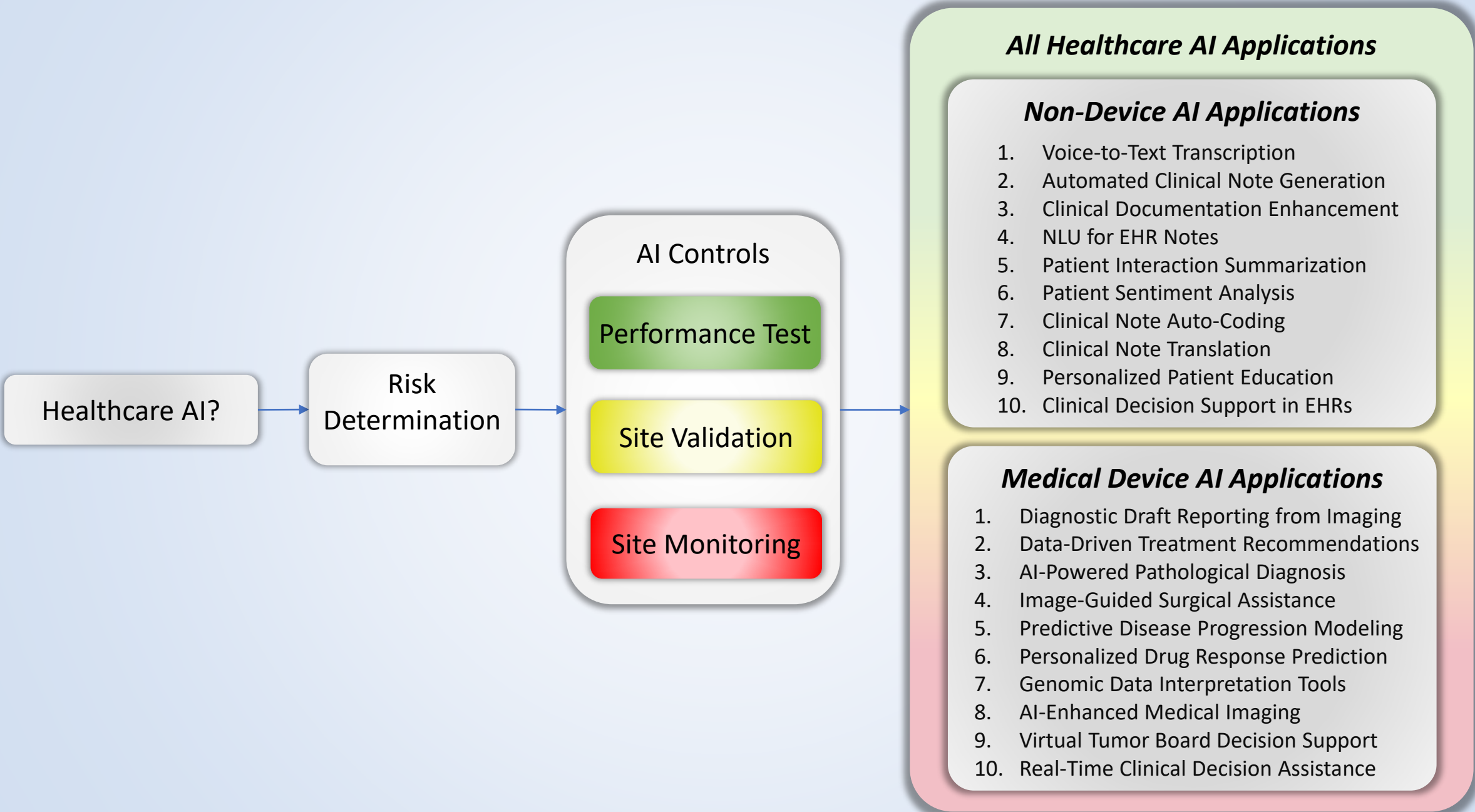
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# THE FUTURE OF HEALTHCARE AI REGULATIONS



Healthcare AI?

Risk Determination

AI Controls

Performance Test

Site Validation

Site Monitoring

## ***All Healthcare AI Applications***

### ***Non-Device AI Applications***

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### ***Medical Device AI Applications***

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# NARROW VS GENERATIVE AI

RISK DETERMINATION > CONTROLS => SAFE INNOVATION

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