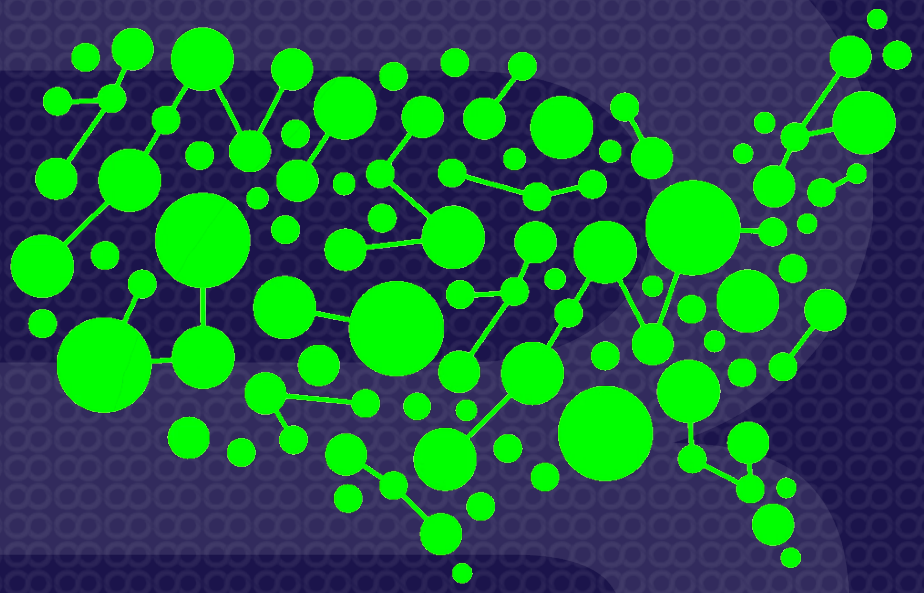
American College of Radiology Assess-AI



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Digital Health Advisory Committee Meeting

Total Product Lifecycle Considerations for Generative AI-Enabled Devices

Bernardo Bizzo, MD, PhD

Associate Chief Science Officer, American College of Radiology - Data Science Institute

Senior Director, Mass General Brigham AI - Harvard Medical School

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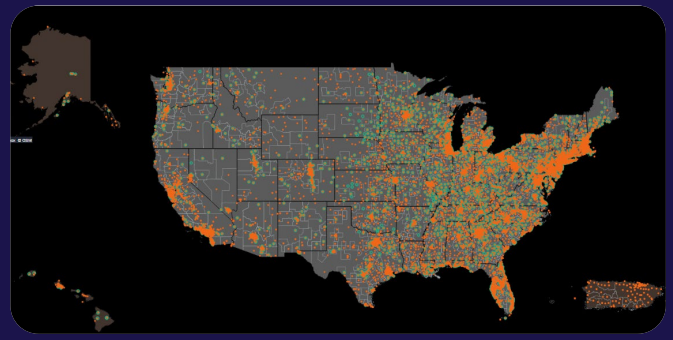
ACR Recognized Center for Healthcare-AI
ARCH-AI

- The ACR exchanges images and data with over 40,000 Imaging entities through ACR Connect for Accreditation, Registries, Research, Education, and AI Programs



ACR facilities network

- The first National AI quality assurance program for radiology facilities:
  - 18 Recognized Centers
  - 48 in the pipeline
  - 2 in submission process
  - 16 International

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ACR Recognized Center for Healthcare-AI
Assess-AI

- Assess-AI is a registry that provides real-world monitoring of imaging-based AI models deployed in a clinical workflow.
- It allows the comparison of local performance metrics to national benchmarks and facilities with similar characteristics (region, facility type, trauma level, urban/rural).
- Piloting with 15 sites, 4 AI vendors/platforms engaged for 2 CNN clinical use cases (intracranial hemorrhage and pulmonary embolism)

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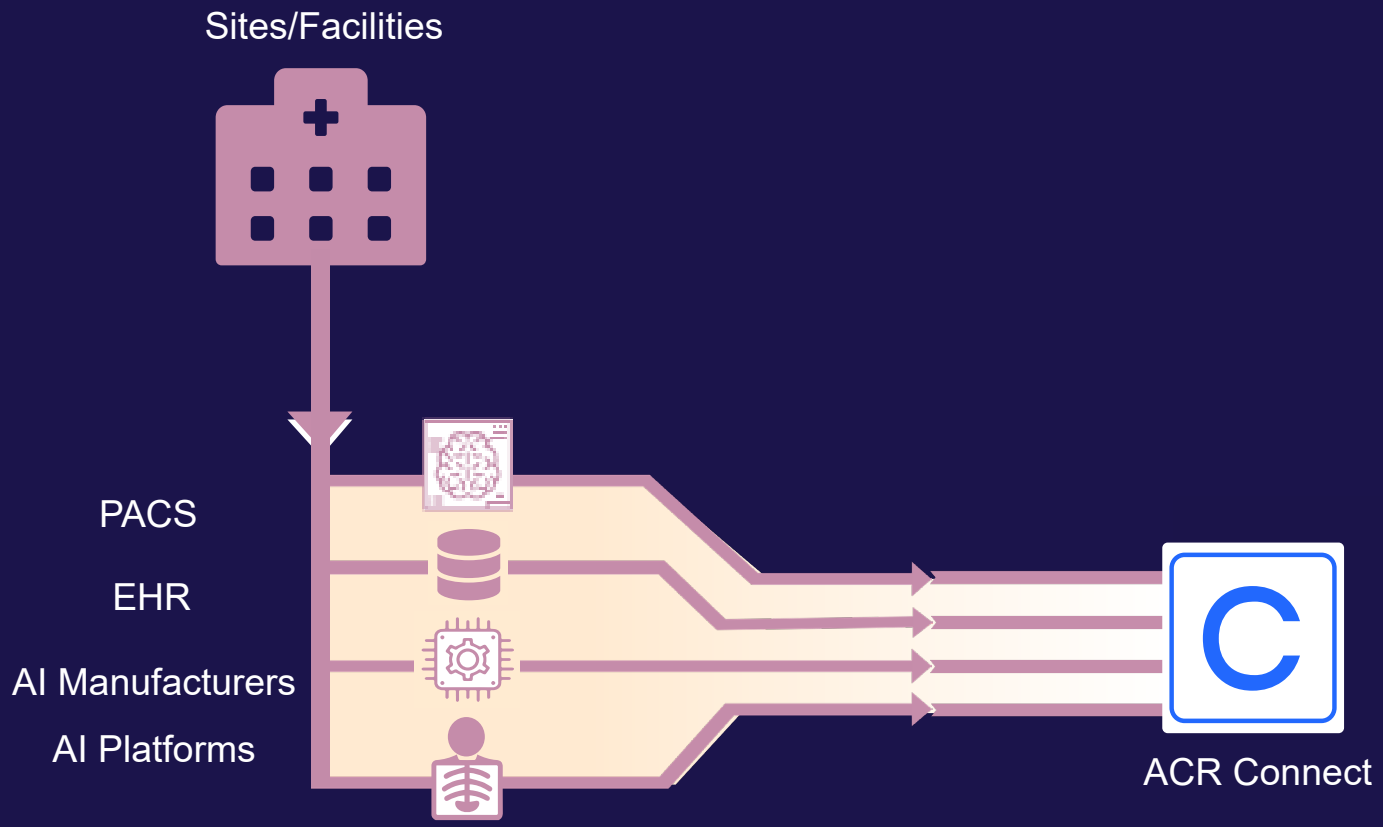
Current state
In use for AI monitoring



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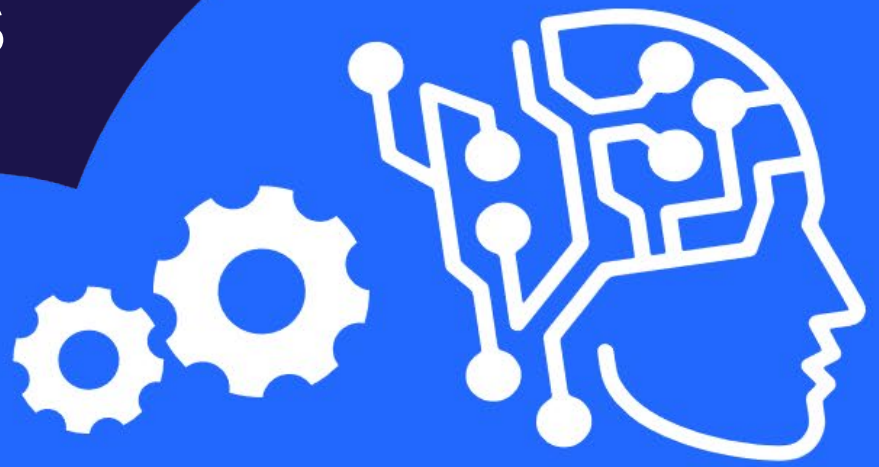
Current state

Narrow AI use cases

ICH, PE, others



Site Information

Final Radiology Report

AI Model (CNN) Information
- Developer
- Version
- Output (positive/negative)

Case Information
- Facility
- Patient age, sex, ethnicity
- DICOM header metadata

ACR Data Science Institute

Large Language Model Prompts
- SME prompting to extract report information
  - Positive or negative for use cases
  - Adequate or suboptimal quality
  - High or low certainty

Analytics and Reporting
- Compare report information to model output
- Dashboards with subgroup analyses, e.g.,
  - Demographics
  - Technical parameters
  - National incidence of finding

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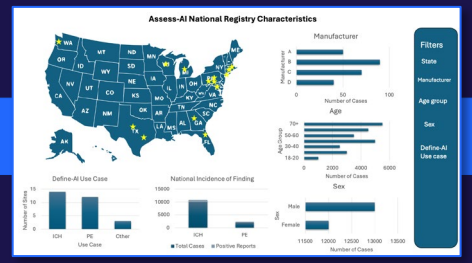
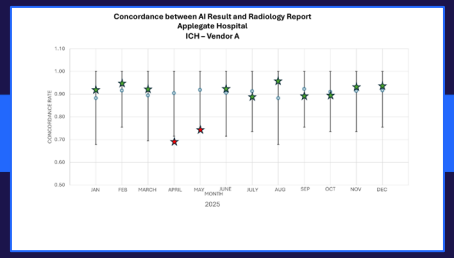
Current state
In use for AI monitoring

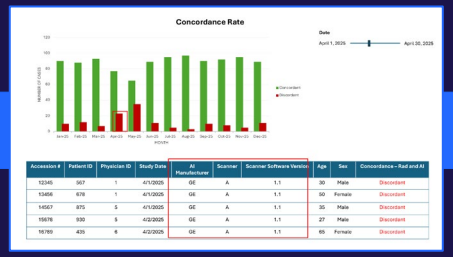
Sites/Facilities



National Registry



Benchmark Reports



Local Performance

PACS

EHR

AI Manufacturers

AI Platforms

ACR Connect

ACR Assess-AI

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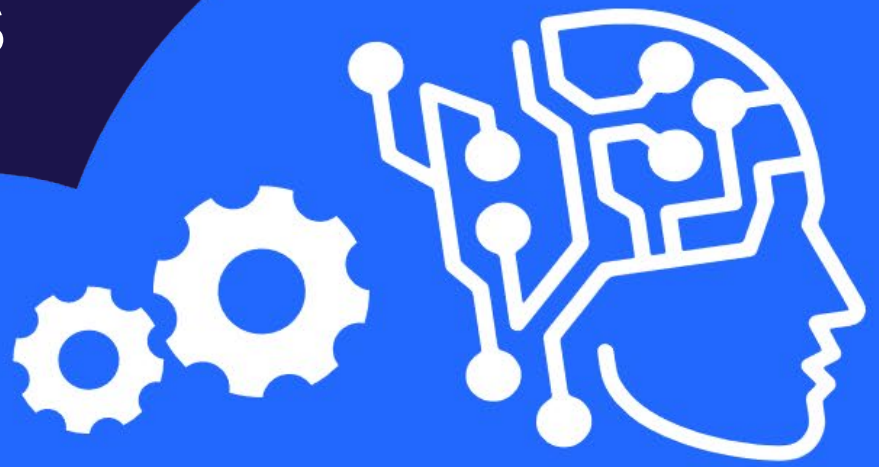
Current state
Gen AI use cases
Draft Reporting



Site Information

Final Radiology Report

AI Model (VLM) Information
- Developer
- Version
- Output (**draft report**)

Case Information
- Facility
- Patient age, sex, ethnicity
- DICOM header metadata

ACR Data Science Institute

Large Language Model Prompts
- SME prompting to extract report information
  - Identify and count clinically relevant findings in **draft report** and **final report**

The Healthcare AI Arena
A Collaborative Community for Healthcare AI Validation and Monitoring

Analytics and Reporting
- **Differences between draft and final report**
- Dashboards with subgroup analyses, e.g.,
  - Demographics
  - Technical parameters
  - National incidence of finding

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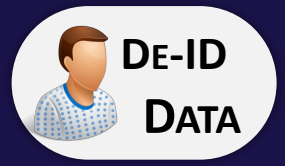
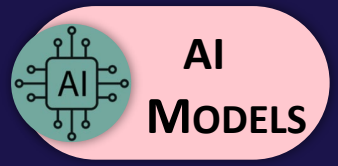
The Healthcare AI Arena

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





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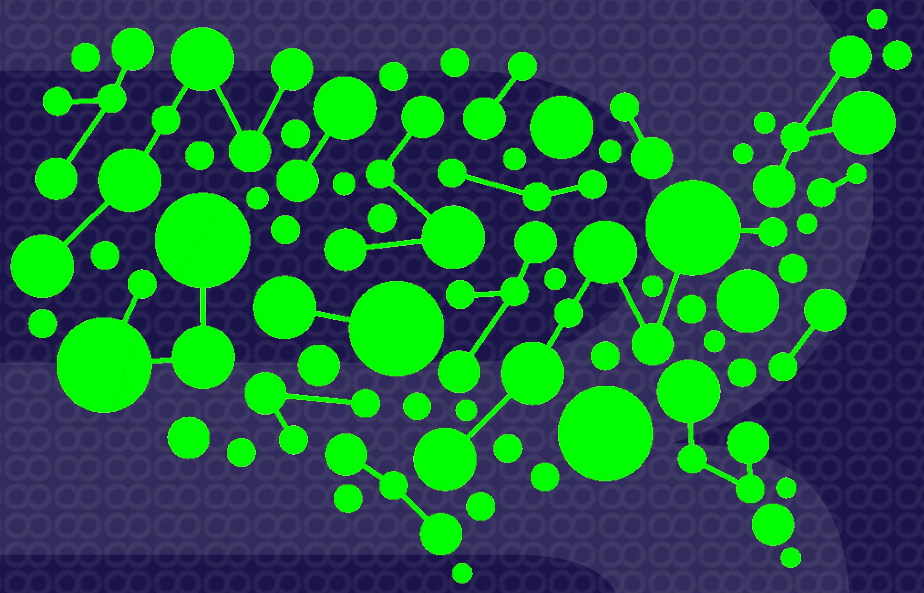
American College of Radiology Assess-AI



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