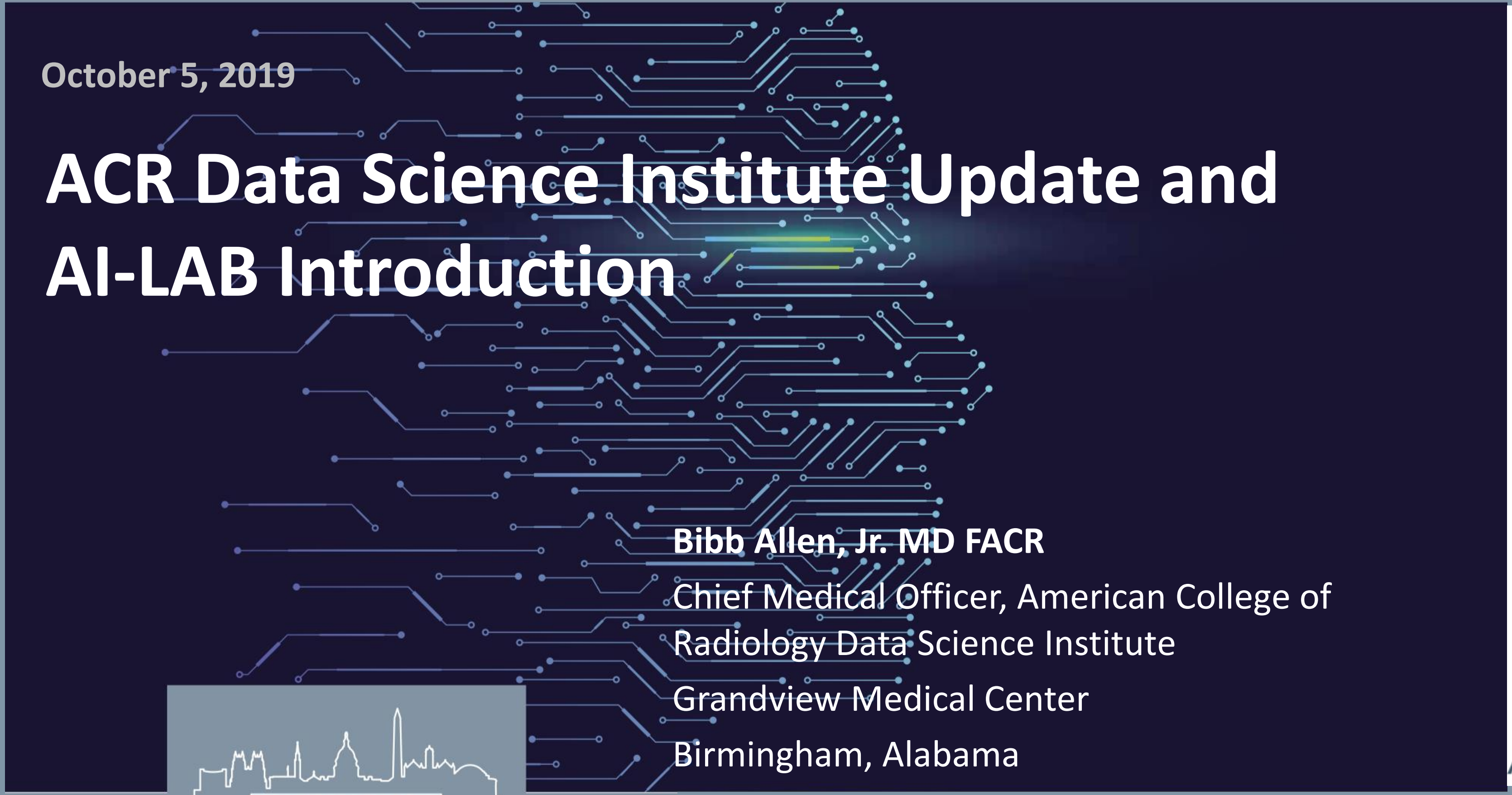
2019 IMAGING INFORMATICS SUMMIT



October 5, 2019

# ACR Data Science Institute Update and AI-LAB Introduction

**Bibb Allen, Jr. MD FACR**
Chief Medical Officer, American College of Radiology Data Science Institute
Grandview Medical Center
Birmingham, Alabama

WASHINGTON
OCTOBER 5–6, 2019
Ronald Reagan Building/
International Trade Center
Washington, DC

DATA SCIENCE INSTITUTE™
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# CONFLICTS AND ACKNOWLEDGEMENTS

## No Commercial Conflicts Of Interest

Neither I nor my immediate family have a financial relationship with a commercial organization that may have a direct or indirect interest in the content of this presentation

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# CONFLICTS AND ACKNOWLEDGEMENTS

## No Commercial Conflicts Of Interest

- Chief Medical Officer American College of Radiology Data Science Institute
- Former Board Chair and President ACR

# Objectives

- Artificial intelligence will be transformational technology for improving how we care for our patients

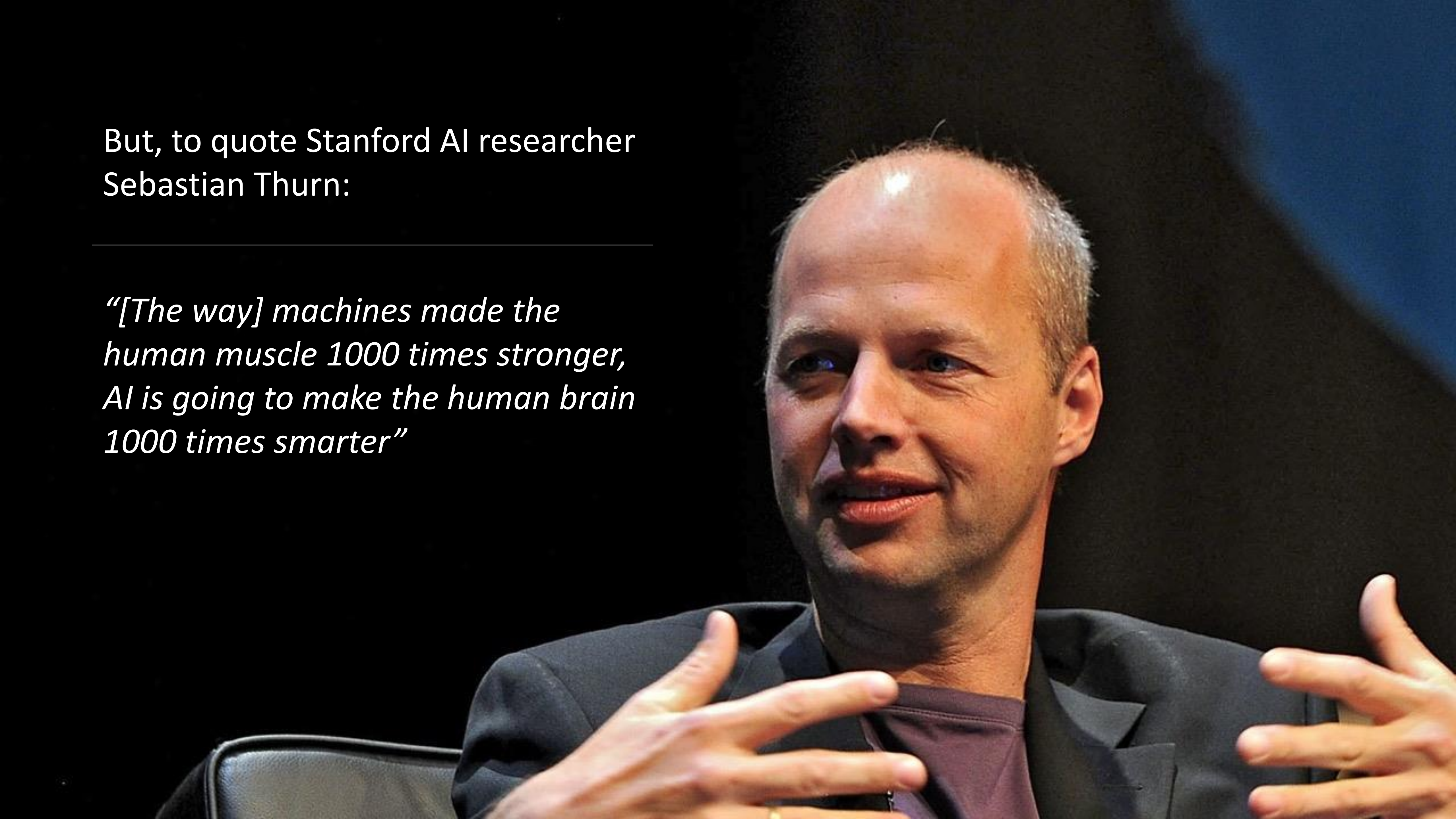
- Radiologists and radiology organizations can facilitate the development, deployment and clinical use of AI by fostering an ecosystem between disparate stakeholders

- The democratization of AI will accelerate the advancement of AI in healthcare and radiologists should play a leading role

AI presents a once-in-a-generation opportunity to dramatically improve patient care and lower the costs of high quality healthcare

Something on the order of the huge forward leap in diagnosis from X-ray to PET-MRI

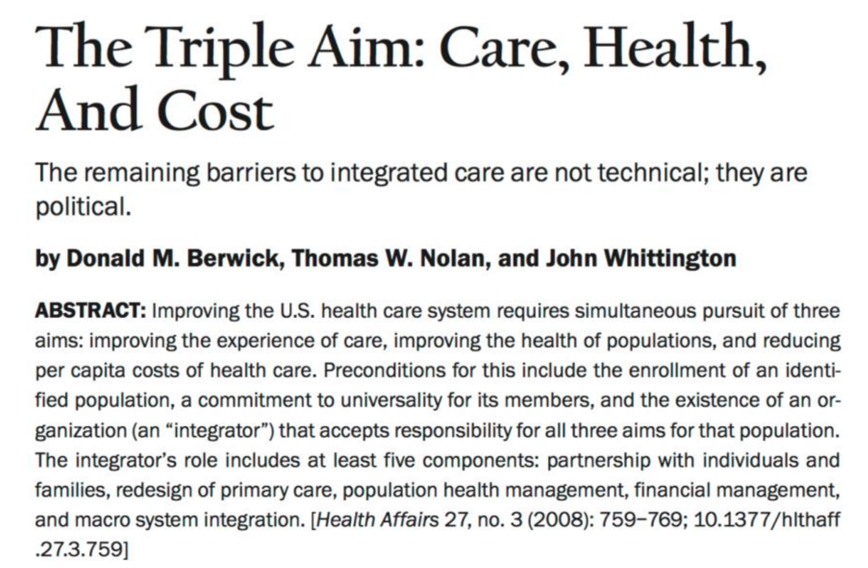
Not because AI is going to create a genius robot that is a far superior replacement to the radiologist



But, to quote Stanford AI researcher Sebastian Thurn:

*"[The way] machines made the human muscle 1000 times stronger, AI is going to make the human brain 1000 times smarter"*

# The Quadruple Aim



### The Triple Aim: Care, Health, And Cost

The remaining barriers to integrated care are not technical; they are political.

**by Donald M. Berwick, Thomas W. Nolan, and John Whittington**

**ABSTRACT:** Improving the U.S. health care system requires simultaneous pursuit of three aims: improving the experience of care, improving the health of populations, and reducing per capita costs of health care. Preconditions for this include the enrollment of an identified population, a commitment to universality for its members, and the existence of an organization (an "integrator") that accepts responsibility for all three aims for that population. The integrator's role includes at least five components: partnership with individuals and families, redesign of primary care, population health management, financial management, and macro system integration. [*Health Affairs* 27, no. 3 (2008): 759–769; 10.1377/hlthaff.27.3.759]

Improving the individual experience of care

Improving the health of populations

Improving the work life of those who deliver care

Reducing the per capita costs of care

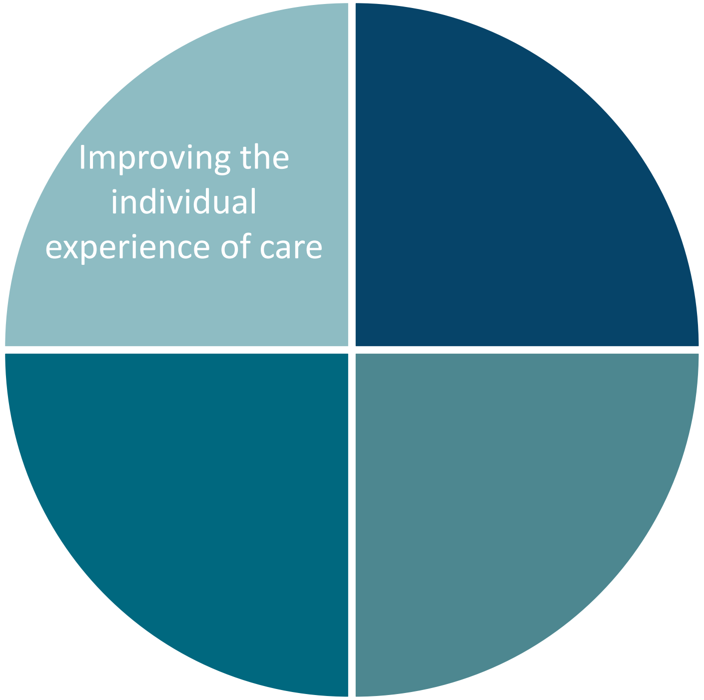
AI WILL ADD VALUE FOR EACH GOAL

Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. Health affairs. 2008 May;27(3):759-69.

Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. The Annals of Family Medicine. 2014 Nov 1;12(6):573-6.

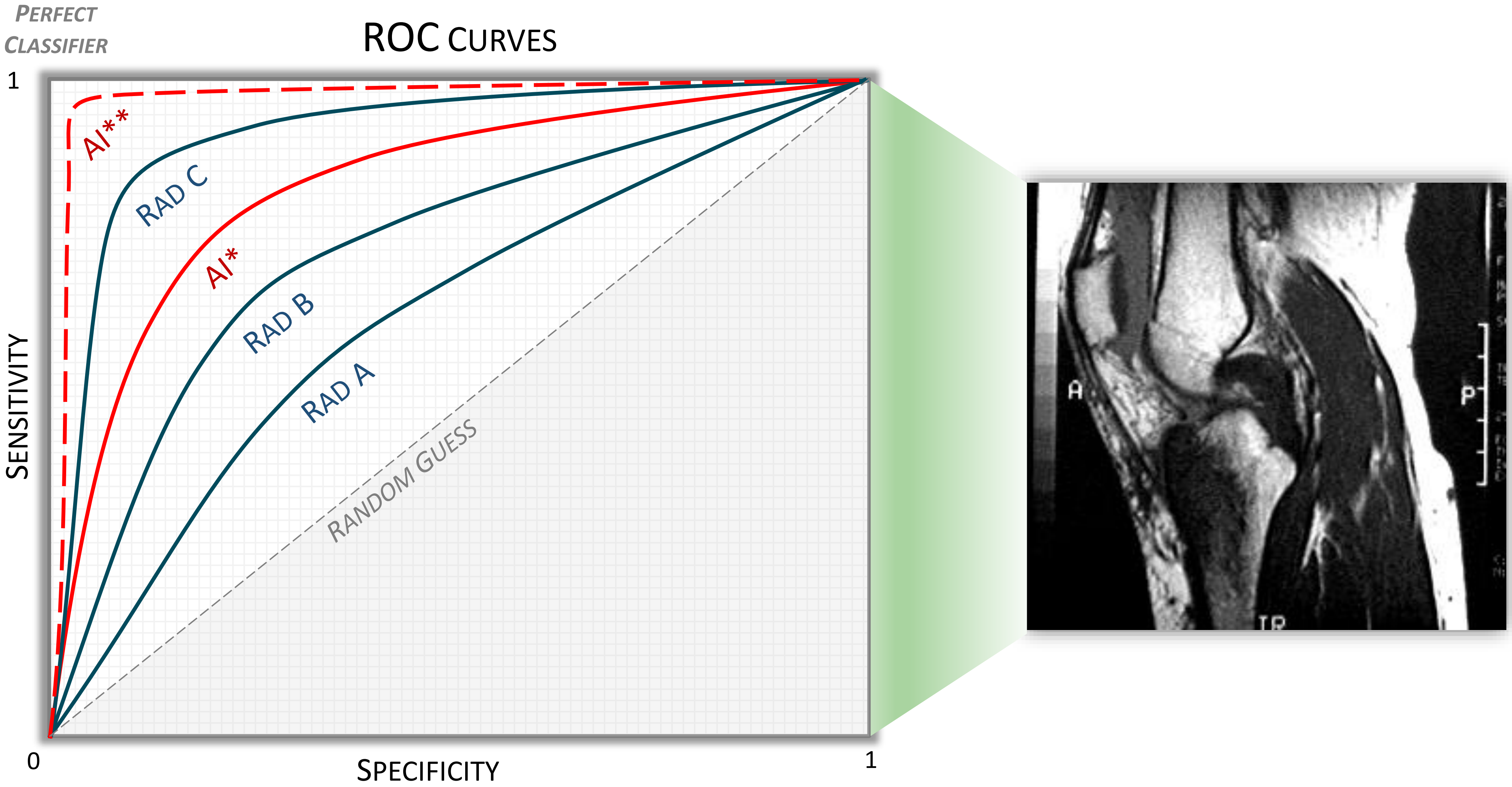
WHY DO AI IF NOT TO IMPROVE QUALITY AND VALUE?

# IMPROVING THE INDIVIDUAL CARE EXPERIENCE



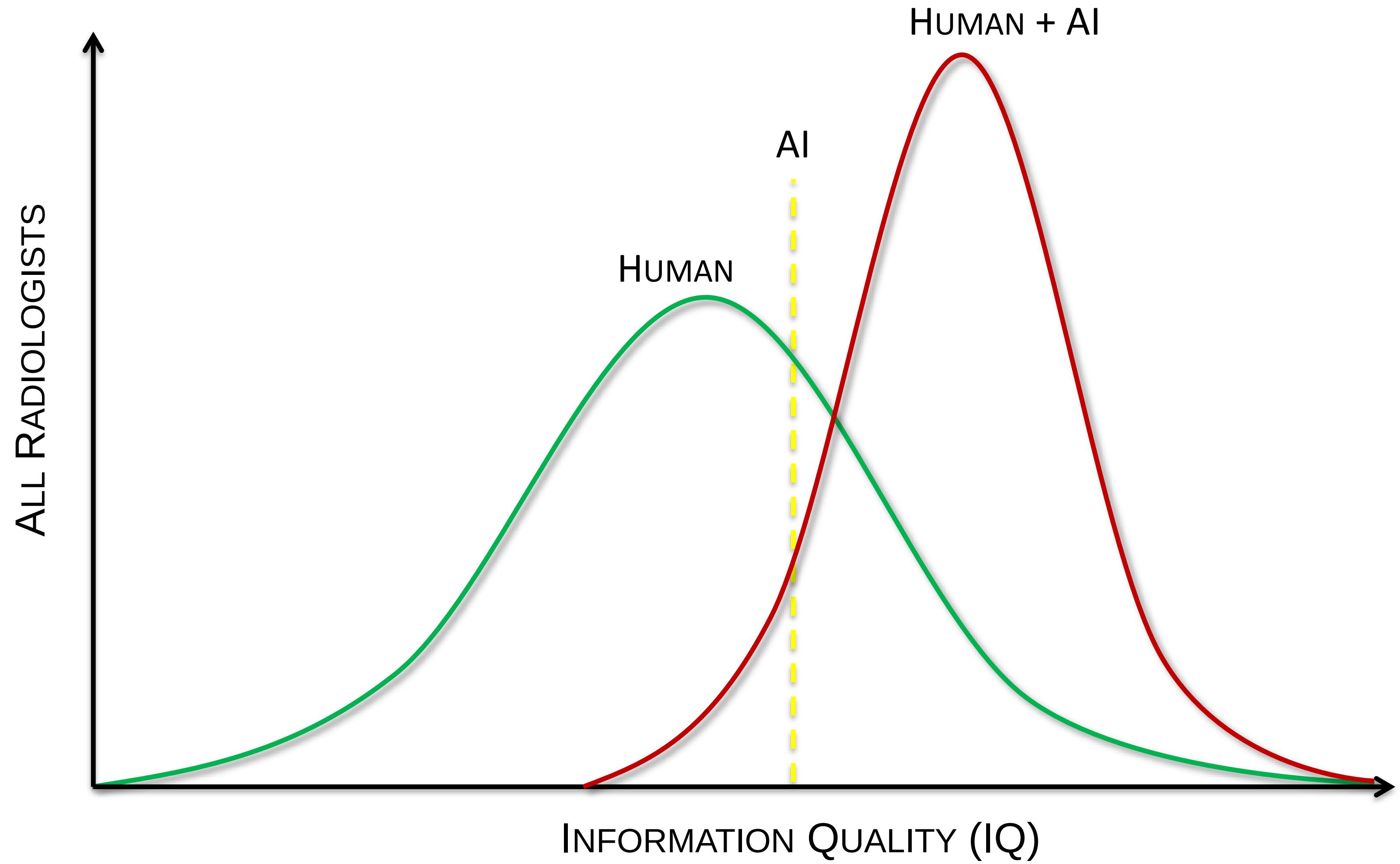
## Improving The Individual Care Experience

# THE HUMAN AI INTERFACE – DOES AI HAVE TO BE PERFECT?



# IMPROVING INDIVIDUAL CARE EXPERIENCE

## CREATES AN AI QUALITY THRESHOLD DEMONSTRATING AI + HUMAN > HUMAN OR AI ALONE



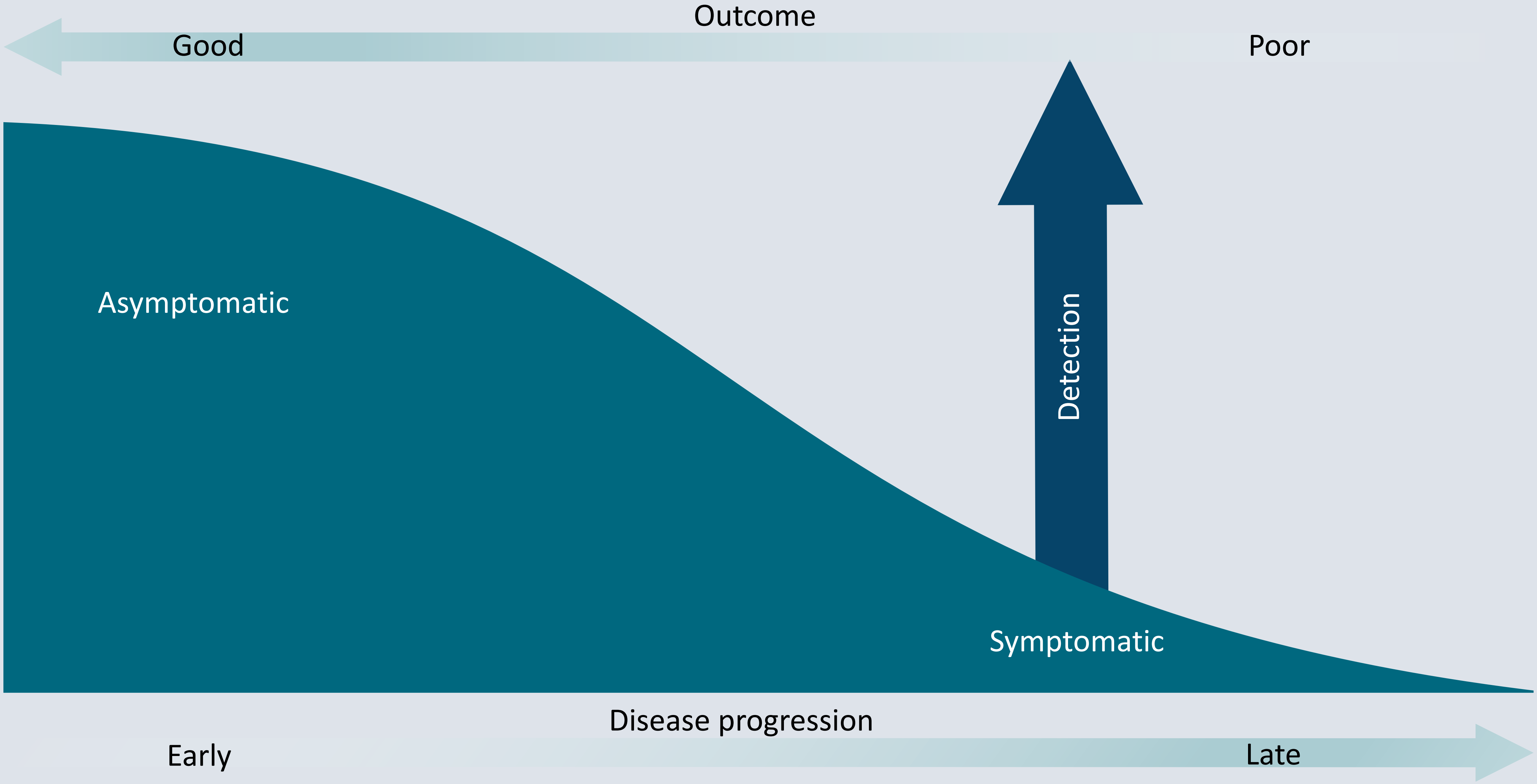
# IMPROVING THE HEALTH OF POPULATIONS

Improving the individual experience of care

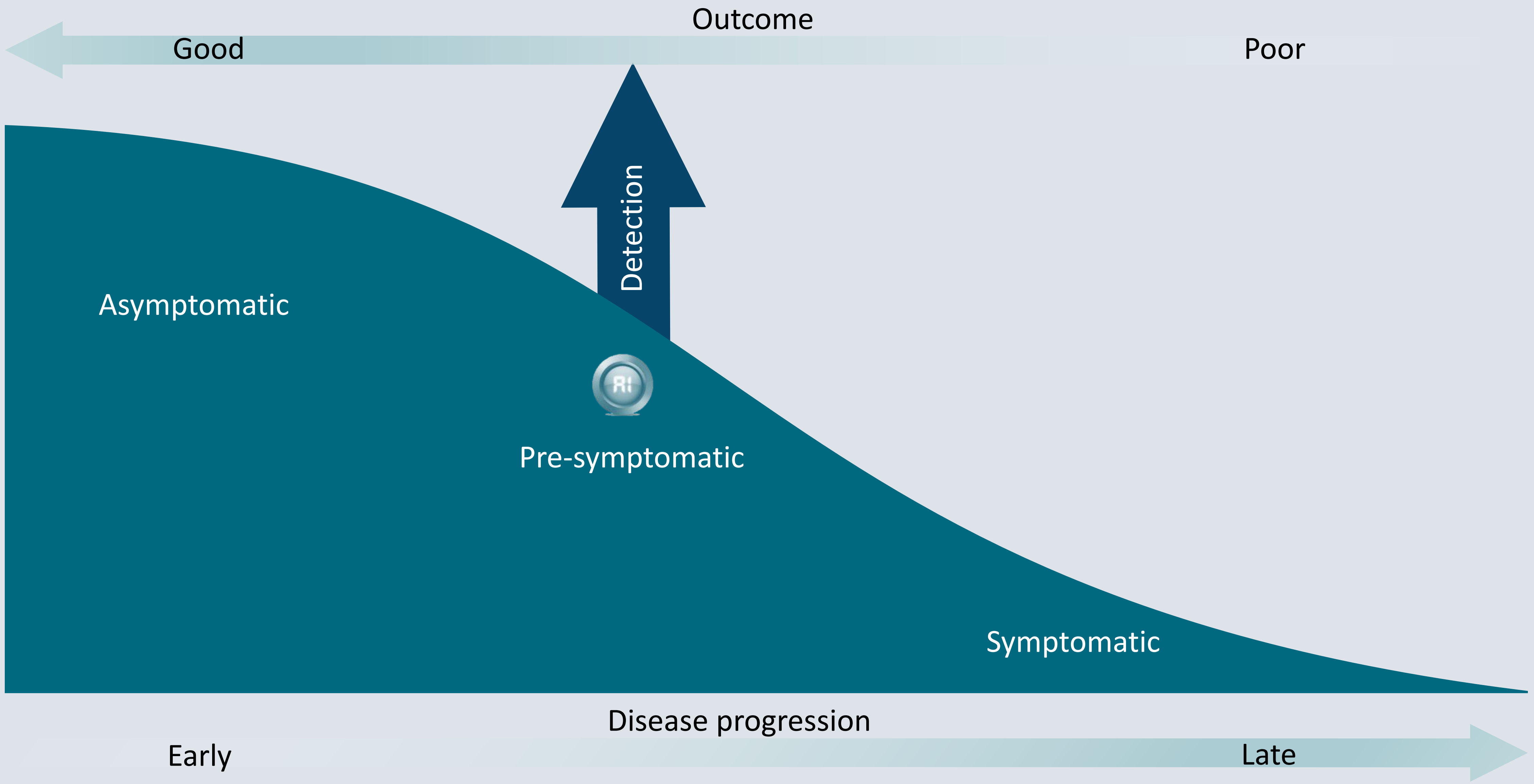
Improving the health of populations

## Improving The Health Of Populations

# DIAGNOSTIC IMAGING, AI & POPULATION HEALTH



# DIAGNOSTIC IMAGING, AI & POPULATION HEALTH



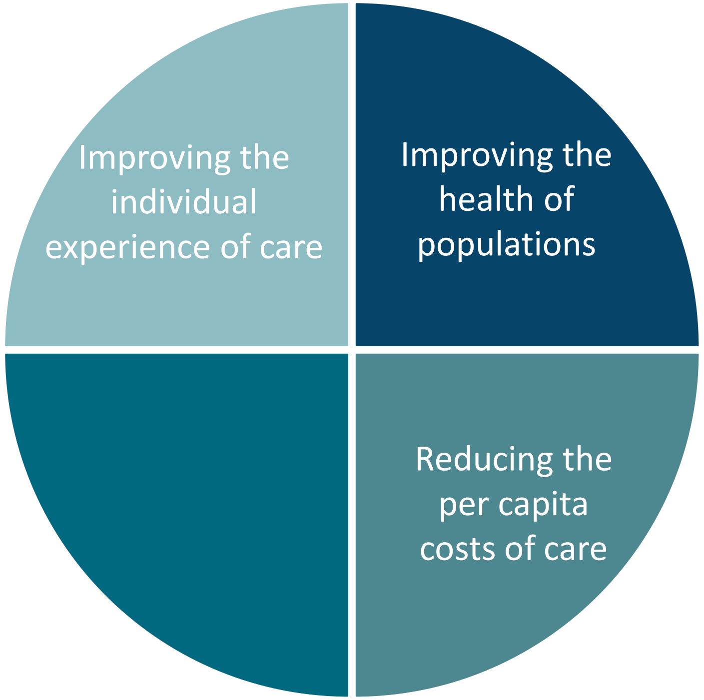
# Improving The Health Of Populations

Genomics
Radiomics

Precision
Medicine

Personalized
Medicine

# REDUCING PER CAPITA COSTS OF CARE



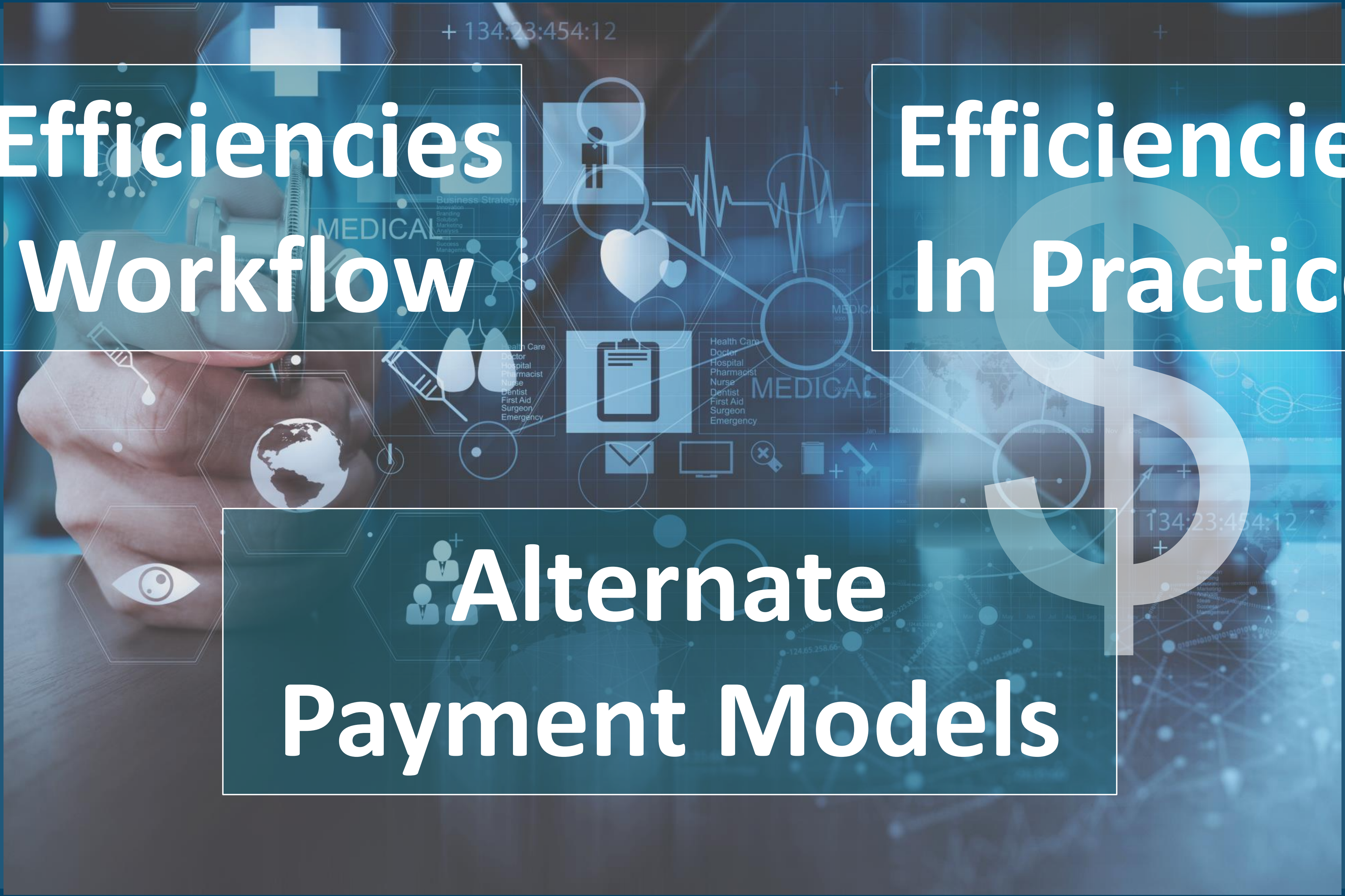
Improving the individual experience of care

Improving the health of populations

Reducing the per capita costs of care

## Reducing The Per Capita Costs Of Care

# REDUCING THE PER CAPITA COSTS OF CARE



Efficiencies
Workflow

Efficiencies
In Practice

Alternate
Payment Models

# IMPROVING THE WORK LIFE OF THOSE WHO DELIVER CARE

Improving the individual experience of care

Improving the health of populations

Improving the work life of those who deliver care

Reducing the per capita costs of care

## Improving The Work Life Of Those Who Deliver Care

# IMPROVING THE THE WORK LIFE OF HEALTH CARE PROVIDERS

# REALITY SETTING IN – CONSEQUENCES OF UNREALISTIC EXPECTATIONS

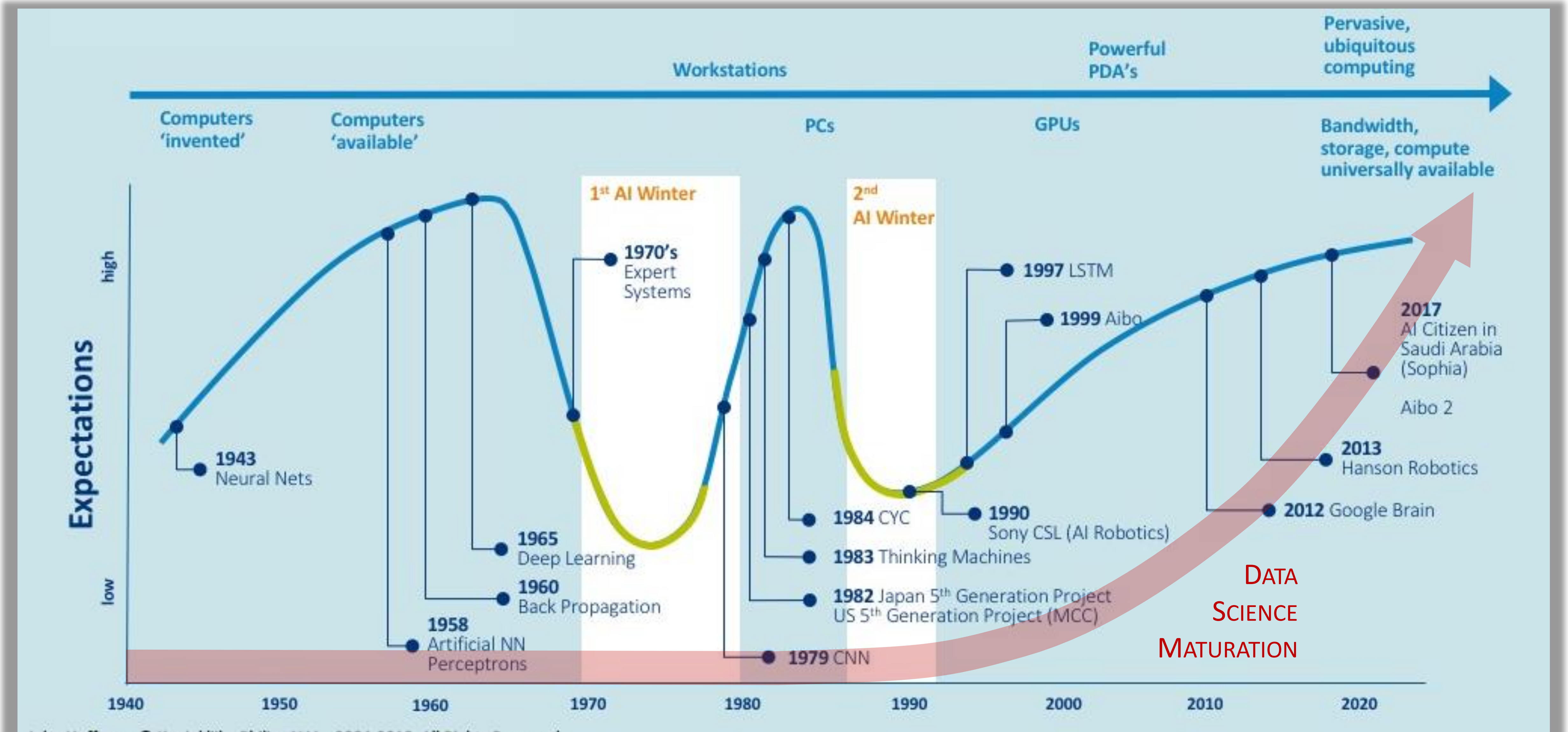
## Big Data Bust: MD Anderson-Watson Project Dies

### Top Cancer Center Spent $62M

Nick Mulcahy
February 22, 2017

After 4 years of spiralling costs that now total at least $62 million, a grandiose big-data project that was a collaboration between MD Anderson Cancer Center and IBM's Watson artificial intelligence system is over. The details emerged in a 48-page audit report from the University of Texas System that surfaced last week in news stories.

# THE HISTORICAL EFFECTS OF AI OVERHYPE



John Huffman, © Koninklijke Philips N.V., 2004-2018. All Rights Reserved

**Can maturing data science eliminate the next AI winter?**

# TECHNOLOGY INDUSTRY ECOSYSTEM

## Apple Ecosystem

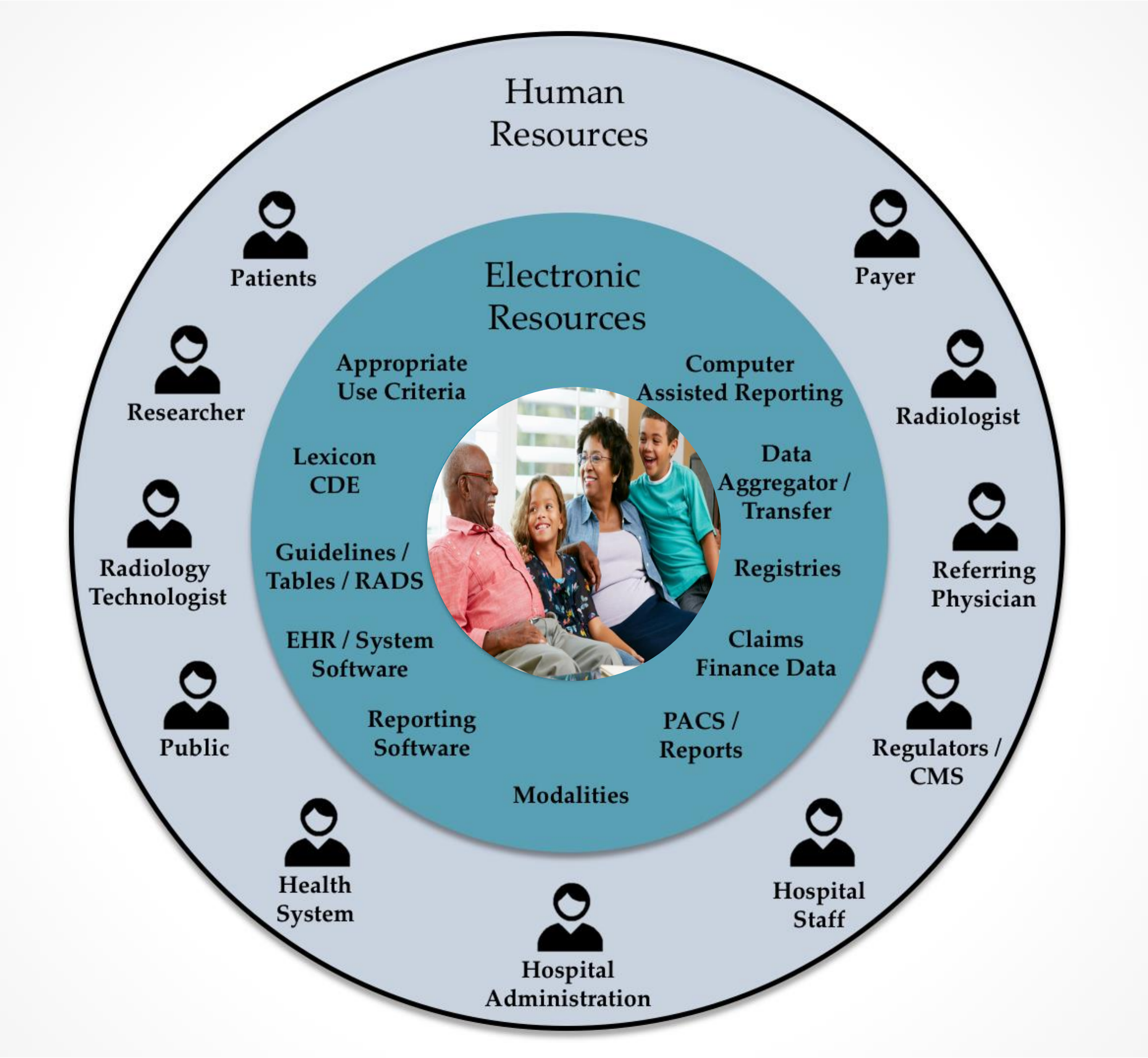
Infrastructural Components

Third-party Applications and Services

Applications and Services

# HEALTHCARE ECOSYSTEM

## Healthcare Ecosystem



## Radiology AI Ecosystem

- Patients
- Radiology professionals
- Researchers and academic centers
- Industry developers
- Governmental agencies
- Hospitals and health systems
- Insurers and third-party payers

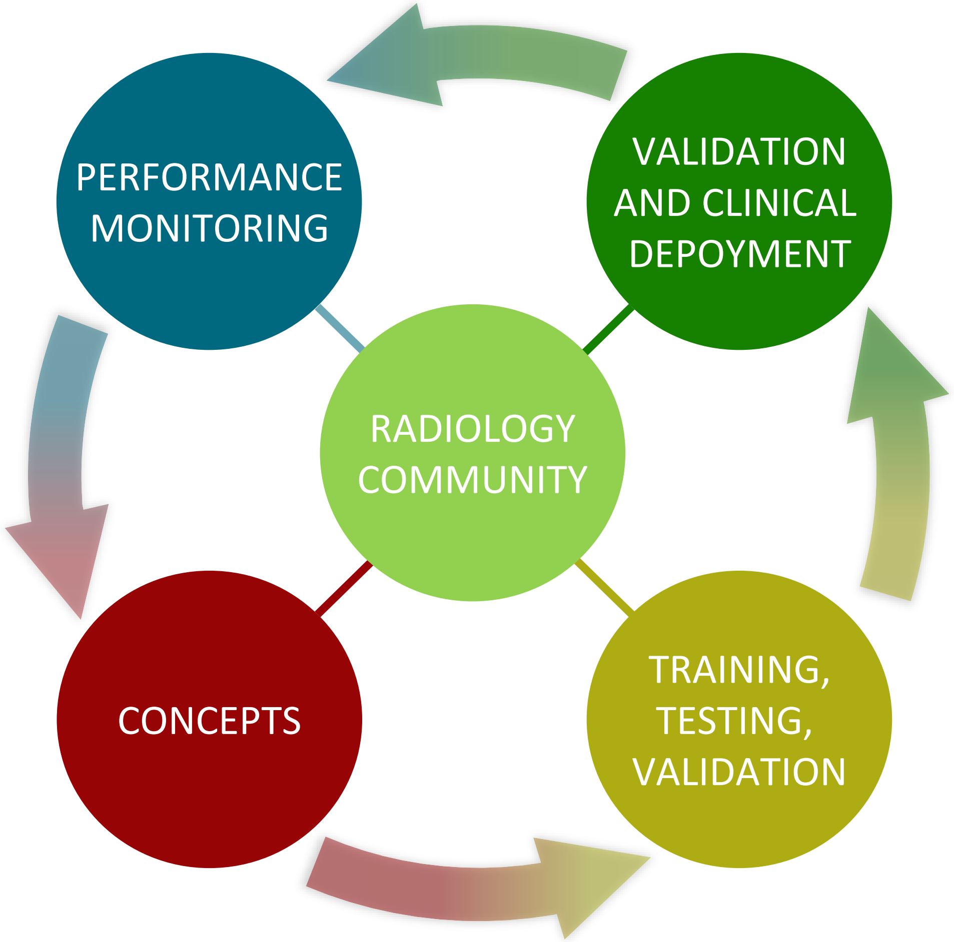
# CONCEPT TO CLINICAL PRACTICE – RADIOLOGY AI ECOSYSTEM

## The Radiology AI Ecosystem

Ideas to Clinical Practice

**Define standard methods to integrate and monitor, AI models in clinical practice using real world evidence**

**Define standards for use cases considering clinical needs and technical capabilities**



PERFORMANCE MONITORING

VALIDATION AND CLINICAL DEPOYMENT

RADIOLOGY COMMUNITY

CONCEPTS

TRAINING, TESTING, VALIDATION

**Define standardized methods for AI model validation consistent with regulatory processes**

**Define standard methods to aggregate and annotate data for AI model training and testing**

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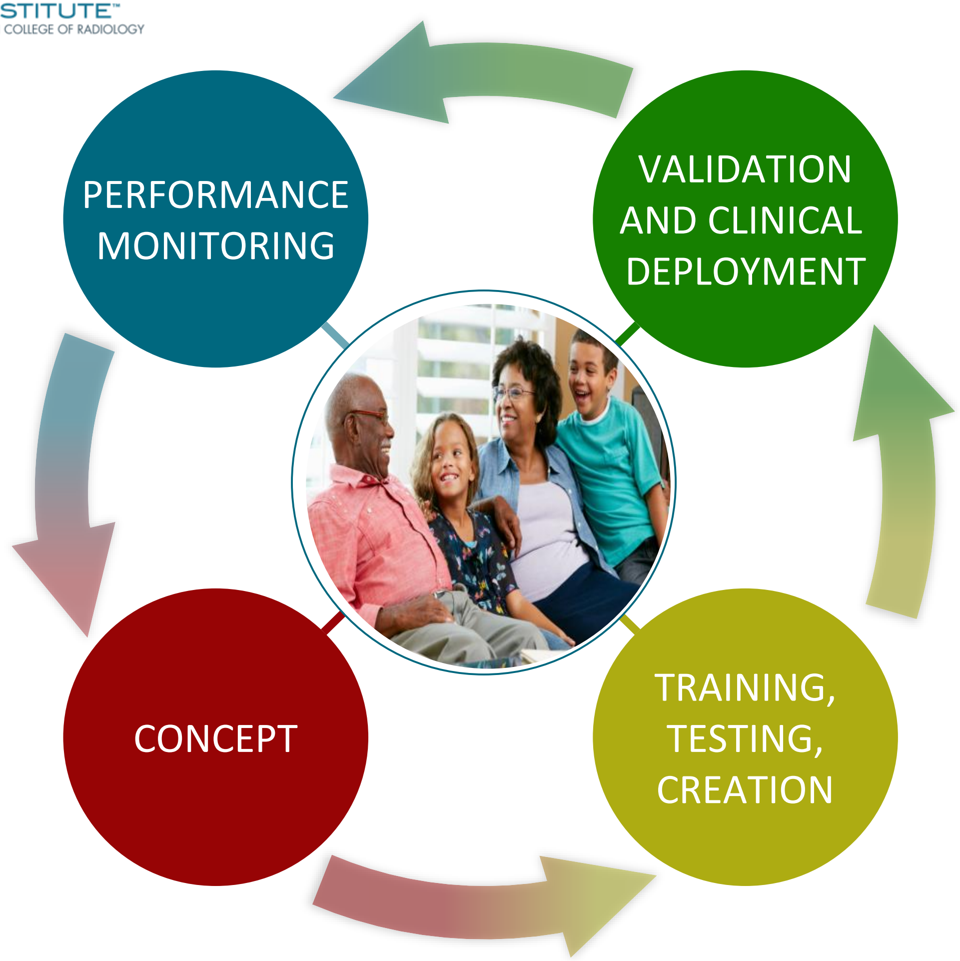
# The Radiology AI Ecosystem

## Ideas To Clinical Practice



CONCEPT

TRAINING, TESTING, CREATION

VALIDATION AND CLINICAL DEPLOYMENT

PERFORMANCE MONITORING

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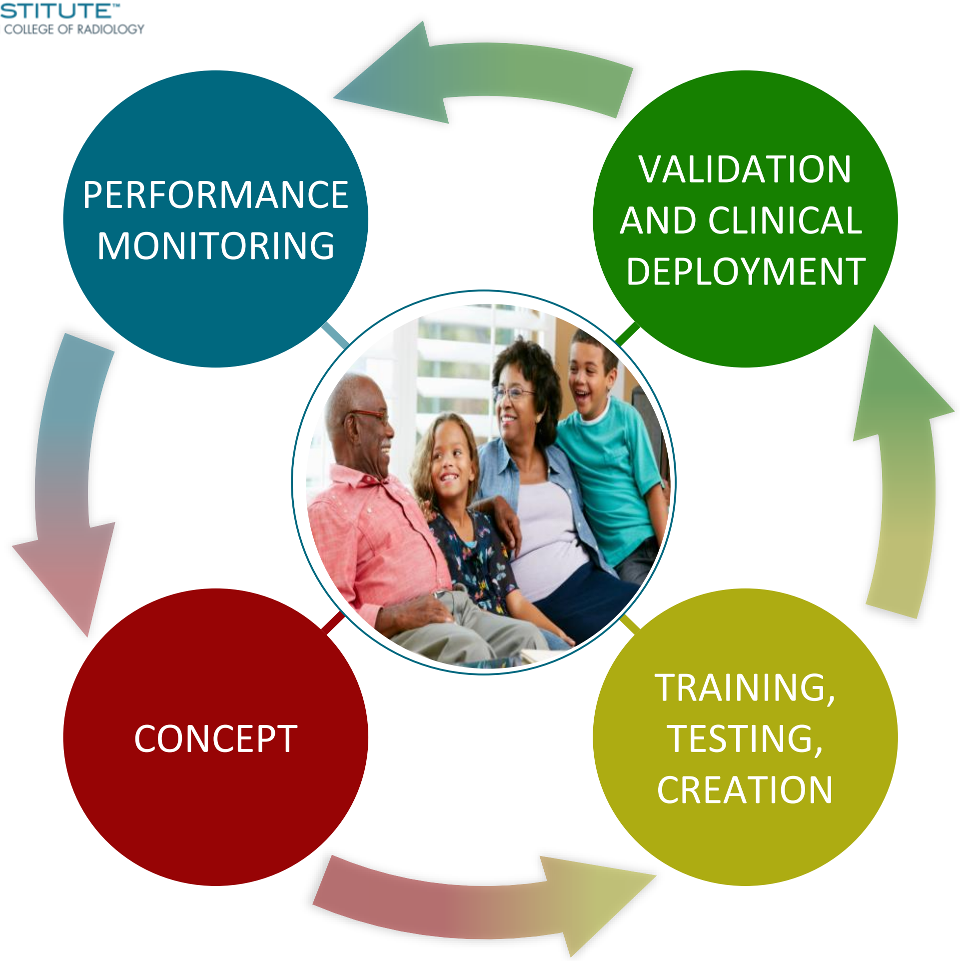
## The Radiology AI Ecosystem

Ideas To Clinical Practice



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## ACR Strategic Plan For Data Science

***Advance data science as core to clinically relevant, safe and effective radiologic care***

- Educate on the appropriate use and ethical issues for AI in radiology
- Define the appropriate uses of AI in radiology
- Help radiologists become global leaders in data science

# ACR DSI Mission

http://acrdsi.org/media-library/pdf/Strategic-Plan-Final.pdf

**Leverage the value of radiology professionals as AI evolves** through the development of appropriate use cases and workflow integration

**Establish industry relationships** by providing credible use cases, help with FDA and other government agencies, and pathways for clinical integration

AI ECOSYSTEM

EDUCATION

**Protect patients** through leadership roles in the regulatory process with government agencies and verification of algorithms

**Educate** radiology professionals, other physicians and all stakeholders about AI and the ACR’s role in data science for the good of our patients

# Radiology's Value Proposition

**RADIOLOGIST**

**REFERRING PHYSICIAN**

**Government**

**HOSPITAL FINANCE**

IMAGING3.0™

## Part Of The Solution

# IMAGING 3.0: VALUE-BASED RADIOLOGY

**Clinical Decision Support for Ordering Physicians**
*Providing >24 Million examinations per month*

IMAGING3.0™

Imaging 3.0 is a vision
for providing optimal i

**Image Sharing**
*RSNA / NIH / Vendors*

**Structured Reporting**
*Incorporated in all VR reporting platforms*

3 Key Actions:

**Registries**
*Radiation Exposure / Patient Outcomes / Quality*

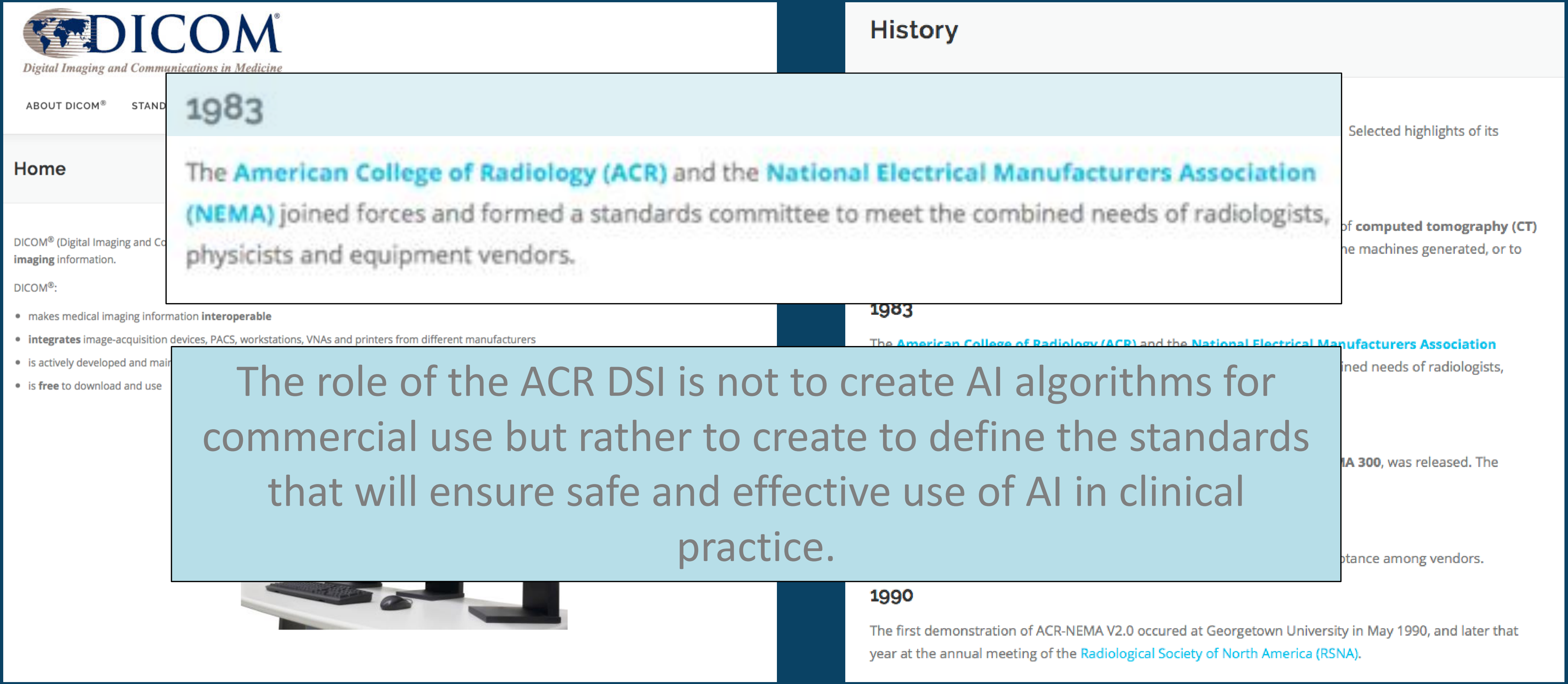
ent of
tives

Portfolio
of IT Tools

**Clinical Decision Support for Image Interpretation**
*Integrated into >75% of radiologists desktops*

**Artificial Intelligence**

# ACR DSI – Developing Standards For Industry And Institutions



DICOM®

Digital Imaging and Communications in Medicine

ABOUT DICOM® STAND

## Home

DICOM® (Digital Imaging and Co
**imaging** information.

DICOM®:

- makes medical imaging information **interoperable**
- **integrates** image-acquisition devices, PACS, workstations, VNAs and printers from different manufacturers
- is actively developed and mai
- is **free** to download and use

## History

Selected highlights of its

of **computed tomography (CT)**
he machines generated, or to

### 1983

The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) joined forces and formed a standards committee to meet the combined needs of radiologists, physicists and equipment vendors.

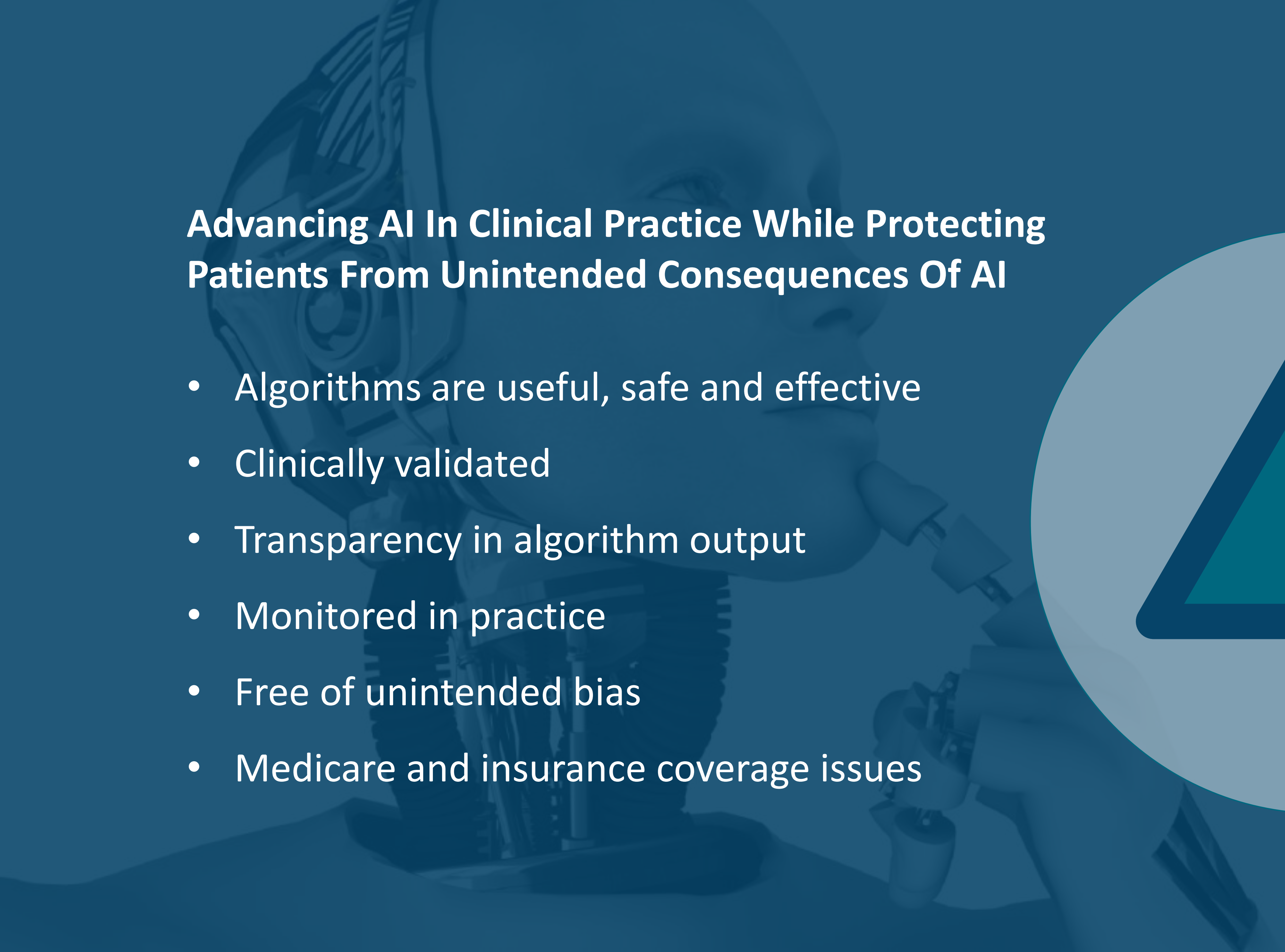
A 300, was released. The

otance among vendors.

### 1990

The first demonstration of ACR-NEMA V2.0 occured at Georgetown University in May 1990, and later that year at the annual meeting of the Radiological Society of North America (RSNA).

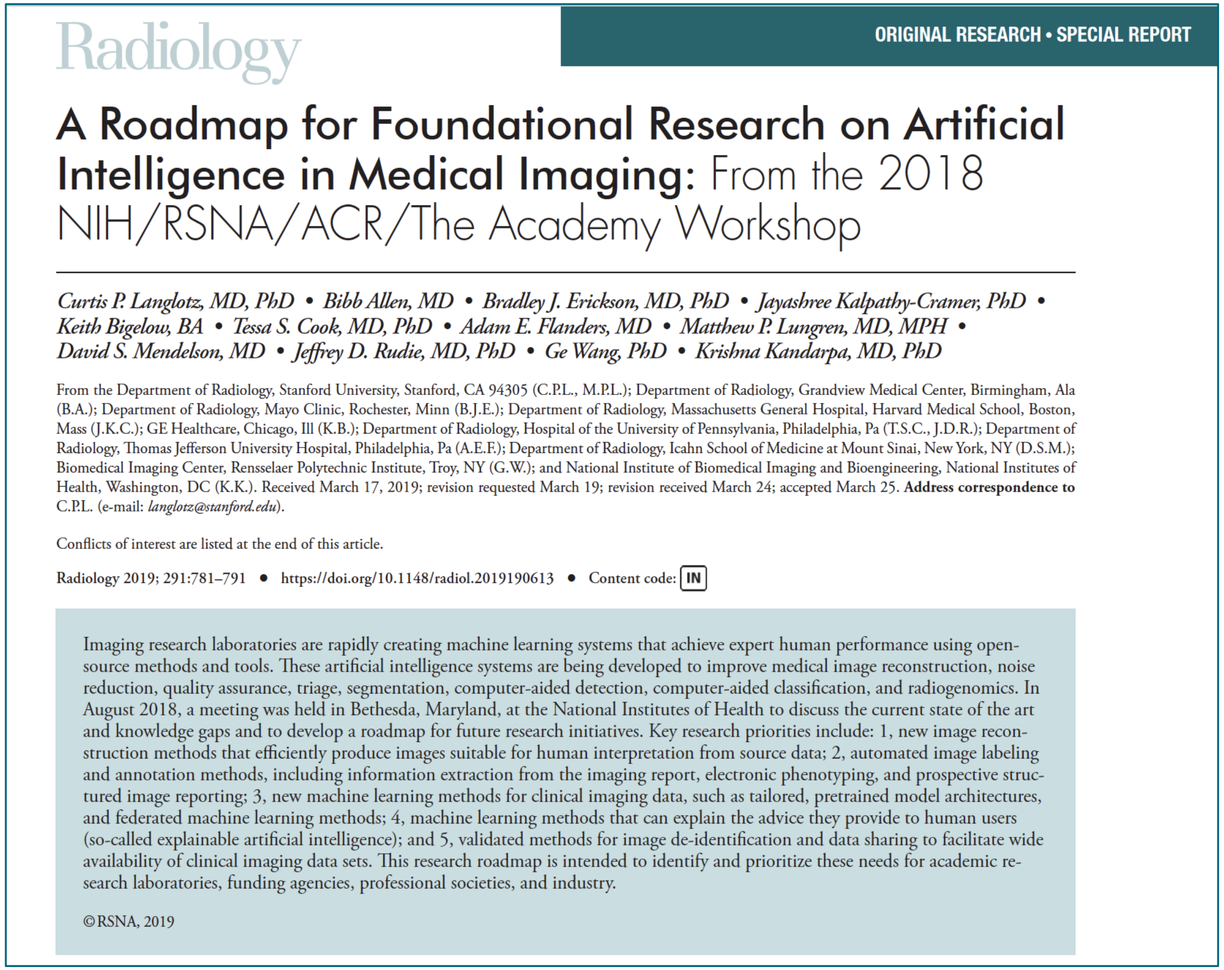
The role of the ACR DSI is not to create AI algorithms for commercial use but rather to create to define the standards that will ensure safe and effective use of AI in clinical practice.



## Advancing AI In Clinical Practice While Protecting Patients From Unintended Consequences Of AI

- Algorithms are useful, safe and effective
- Clinically validated
- Transparency in algorithm output
- Monitored in practice
- Free of unintended bias
- Medicare and insurance coverage issues

# RESEARCH NEEDS TO ADVANCE AI IN CLINICAL PRACTICE



Radiology

ORIGINAL RESEARCH • SPECIAL REPORT

## A Roadmap for Foundational Research on Artificial Intelligence in Medical Imaging: From the 2018 NIH/RSNA/ACR/The Academy Workshop

*Curtis P. Langlotz, MD, PhD • Bibb Allen, MD • Bradley J. Erickson, MD, PhD • Jayashree Kalpathy-Cramer, PhD • Keith Bigelow, BA • Tessa S. Cook, MD, PhD • Adam E. Flanders, MD • Matthew P. Lungren, MD, MPH • David S. Mendelson, MD • Jeffrey D. Rudie, MD, PhD • Ge Wang, PhD • Krishna Kandarpa, MD, PhD*

From the Department of Radiology, Stanford University, Stanford, CA 94305 (C.P.L., M.P.L.); Department of Radiology, Grandview Medical Center, Birmingham, Ala (B.A.); Department of Radiology, Mayo Clinic, Rochester, Minn (B.J.E.); Department of Radiology, Massachusetts General Hospital, Harvard Medical School, Boston, Mass (J.K.C.); GE Healthcare, Chicago, Ill (K.B.); Department of Radiology, Hospital of the University of Pennsylvania, Philadelphia, Pa (T.S.C., J.D.R.); Department of Radiology, Thomas Jefferson University Hospital, Philadelphia, Pa (A.E.F.); Department of Radiology, Icahn School of Medicine at Mount Sinai, New York, NY (D.S.M.); Biomedical Imaging Center, Rensselaer Polytechnic Institute, Troy, NY (G.W.); and National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Washington, DC (K.K.). Received March 17, 2019; revision requested March 19; revision received March 24; accepted March 25. **Address correspondence to** C.P.L. (e-mail: *langlotz@stanford.edu*).

Conflicts of interest are listed at the end of this article.

Radiology 2019; 291:781–791 • https://doi.org/10.1148/radiol.2019190613 • Content code: IN

Imaging research laboratories are rapidly creating machine learning systems that achieve expert human performance using open-source methods and tools. These artificial intelligence systems are being developed to improve medical image reconstruction, noise reduction, quality assurance, triage, segmentation, computer-aided detection, computer-aided classification, and radiogenomics. In August 2018, a meeting was held in Bethesda, Maryland, at the National Institutes of Health to discuss the current state of the art and knowledge gaps and to develop a roadmap for future research initiatives. Key research priorities include: 1, new image reconstruction methods that efficiently produce images suitable for human interpretation from source data; 2, automated image labeling and annotation methods, including information extraction from the imaging report, electronic phenotyping, and prospective structured image reporting; 3, new machine learning methods for clinical imaging data, such as tailored, pretrained model architectures, and federated machine learning methods; 4, machine learning methods that can explain the advice they provide to human users (so-called explainable artificial intelligence); and 5, validated methods for image de-identification and data sharing to facilitate wide availability of clinical imaging data sets. This research roadmap is intended to identify and prioritize these needs for academic research laboratories, funding agencies, professional societies, and industry.

JACR Journal of the American College of Radiology
Health Services Research & Policy ▪ Clinical Practice Management ▪ Data Science ▪ Training & Education ▪ Leadership

## A Road Map for Translational Research on Artificial Intelligence in Medical Imaging: From the 2018 National Institutes of Health/RSNA/ACR/The Academy Workshop

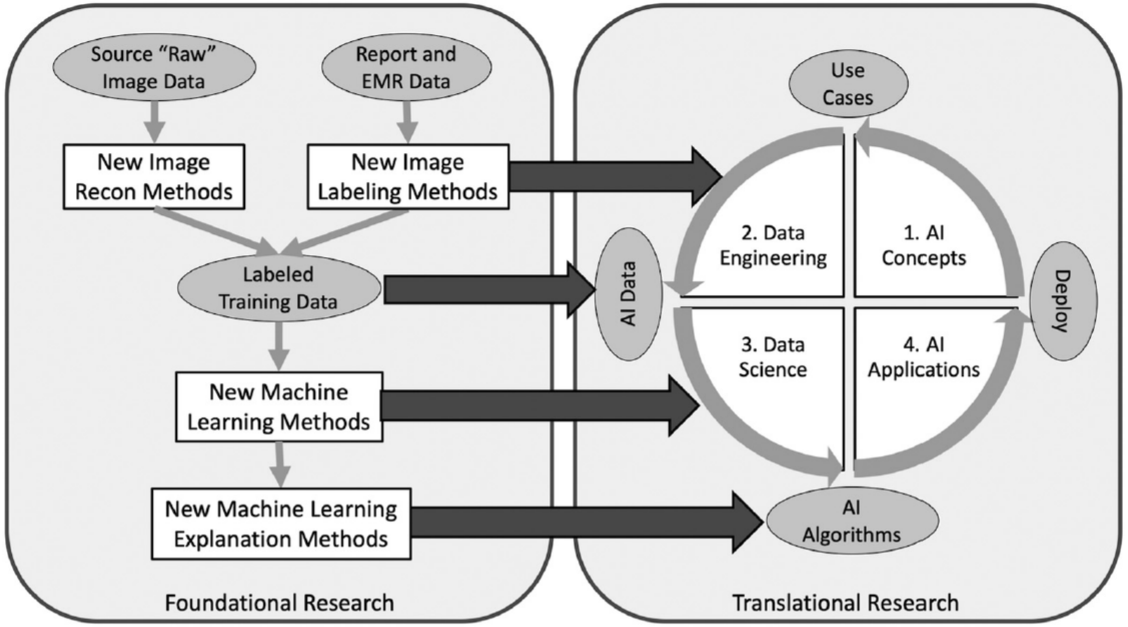
*Bibb Allen Jr, MD[a], Steven E. Seltzer, MD[b,c], Curtis P. Langlotz, MD, PhD[d], Keith P. Dreyer, DO, PhD[e], Ronald M. Summers, MD, PhD[f], Nicholas Petrick, PhD[g], Danica Marinac-Dabic, MD, PhD, MMSC[h], Marisa Cruz, MD[i], Tarik K. Alkasab, MD, PhD[e], Robert J. Hanisch, PhD[j], Wendy J. Nilsen, PhD[k], Judy Burleson, BSW, MHSA[l], Kevin Lyman, BS[m], Krishna Kandarpa, MD, PhD[n]*

### Abstract

Advances in machine learning in medical imaging are occurring at a rapid pace in research laboratories both at academic institutions and in industry. Important artificial intelligence (AI) tools for diagnostic imaging include algorithms for disease detection and classification, image optimization, radiation reduction, and workflow enhancement. Although advances in foundational research are occurring rapidly, translation to routine clinical practice has been slower. In August 2018, the National Institutes of Health assembled multiple relevant stakeholders at a public meeting to discuss the current state of knowledge, infrastructure gaps, and challenges to wider implementation. The conclusions of that meeting are summarized in two publications that identify and prioritize initiatives to accelerate foundational and

# Radiology AI Ecosystem

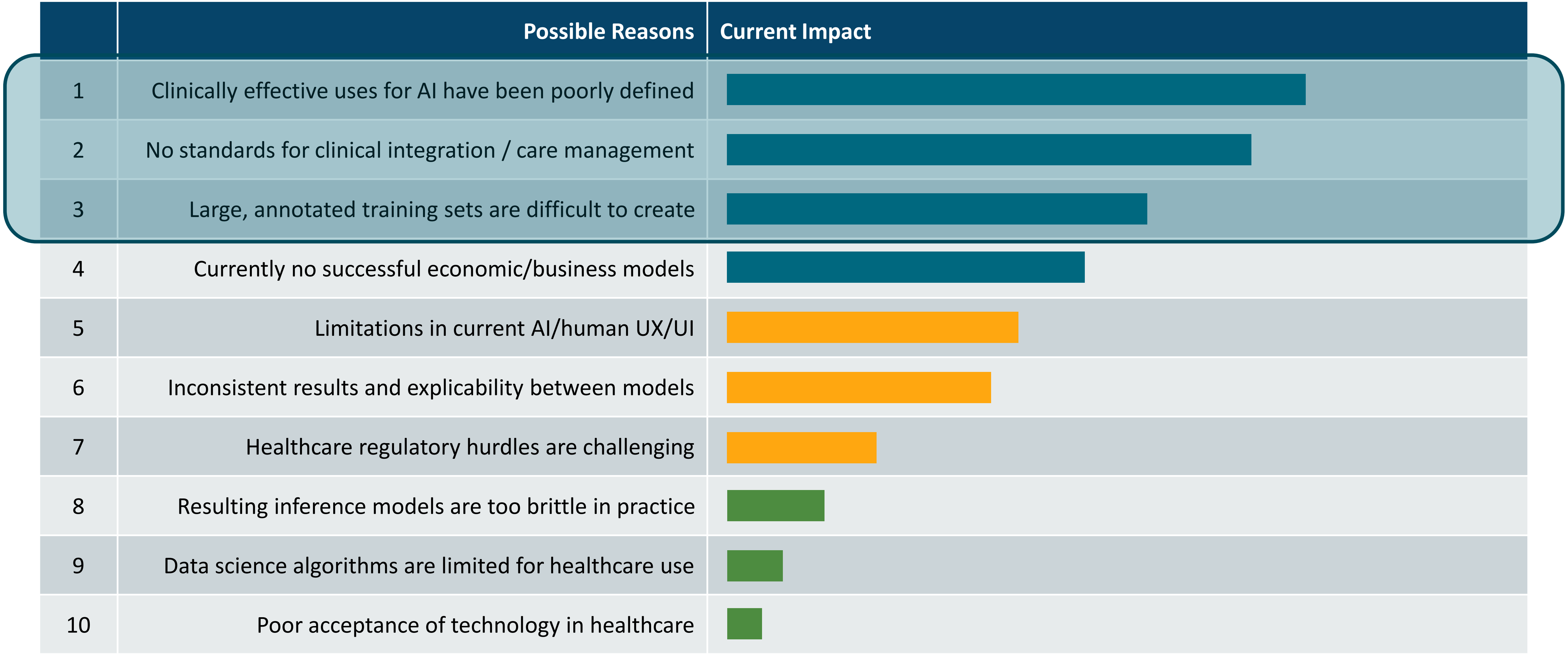
- Structured use cases
- Data access
- Patient safety
- Clinical integration



AI DEVELOPMENT IN MEDICAL IMAGING

**Fig 1.** As in other industries, AI development in medical imaging includes both foundational and translational research activities. The foundational portion of the National Institutes of Health Workshop considered research priorities to accelerate and improve the development of AI algorithms for medical imaging [8]. The translational portion of the workshop considered medical imaging use cases for algorithm development and how these applications will be validated, deployed, and monitored in routine clinical practice. The diagram shows how foundational and translational research activities are connected. Foundational research leads to new image reconstruction and labeling methods, new machine learning algorithms, and new explanation methods, each of which enhance the data sets, data engineering, and data science that lead to the successful deployment of AI applications in medical imaging. AI = artificial intelligence; EMR = electronic medical record; Recon = reconstruction. The figure was developed by the authors for publication in both *Radiology* and *JACR*. This figure also published in reference 8.

# HEALTHCARE AI CHALLENGES



|  | Possible Reasons | Current Impact |
|---|---|---|
| 1 | Clinically effective uses for AI have been poorly defined |  |
| 2 | No standards for clinical integration / care management |  |
| 3 | Large, annotated training sets are difficult to create |  |
| 4 | Currently no successful economic/business models |  |
| 5 | Limitations in current AI/human UX/UI |  |
| 6 | Inconsistent results and explicability between models |  |
| 7 | Healthcare regulatory hurdles are challenging |  |
| 8 | Resulting inference models are too brittle in practice |  |
| 9 | Data science algorithms are limited for healthcare use |  |
| 10 | Poor acceptance of technology in healthcare |  |

# ARTIFICIAL INTELLIGENCE: SCIENCE TO CLINICAL PRACTICE

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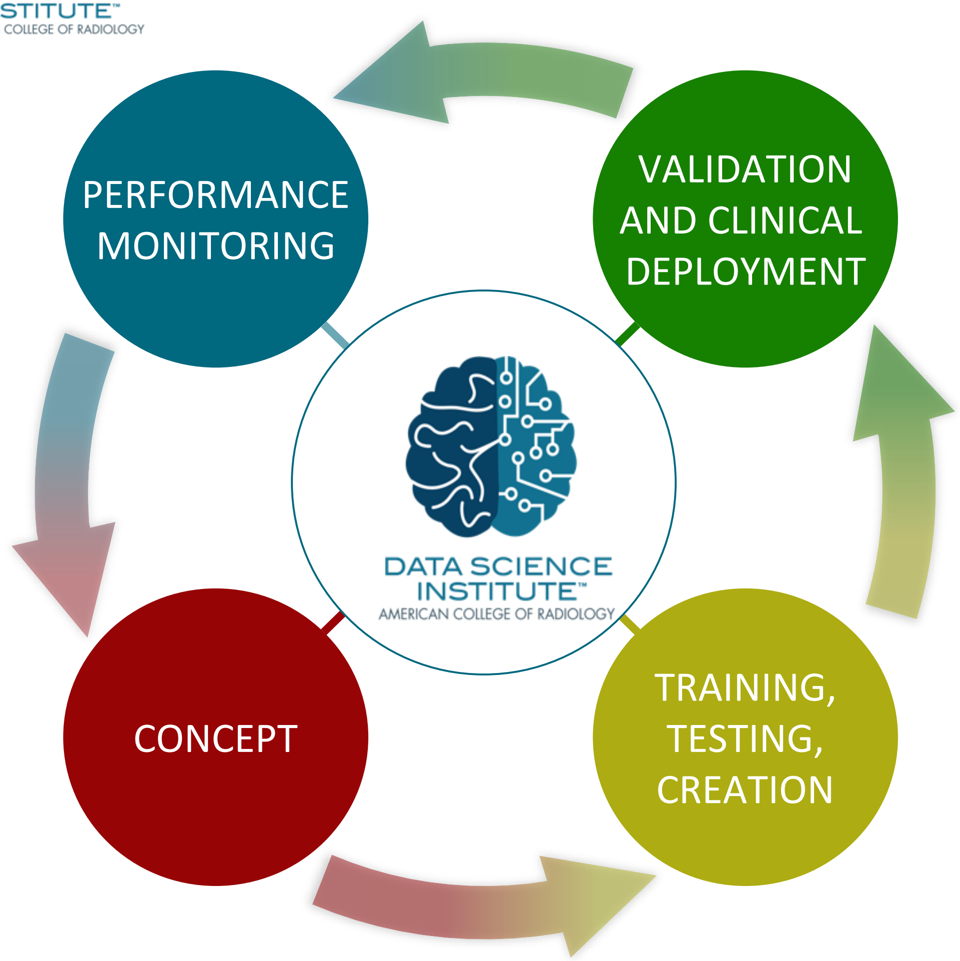
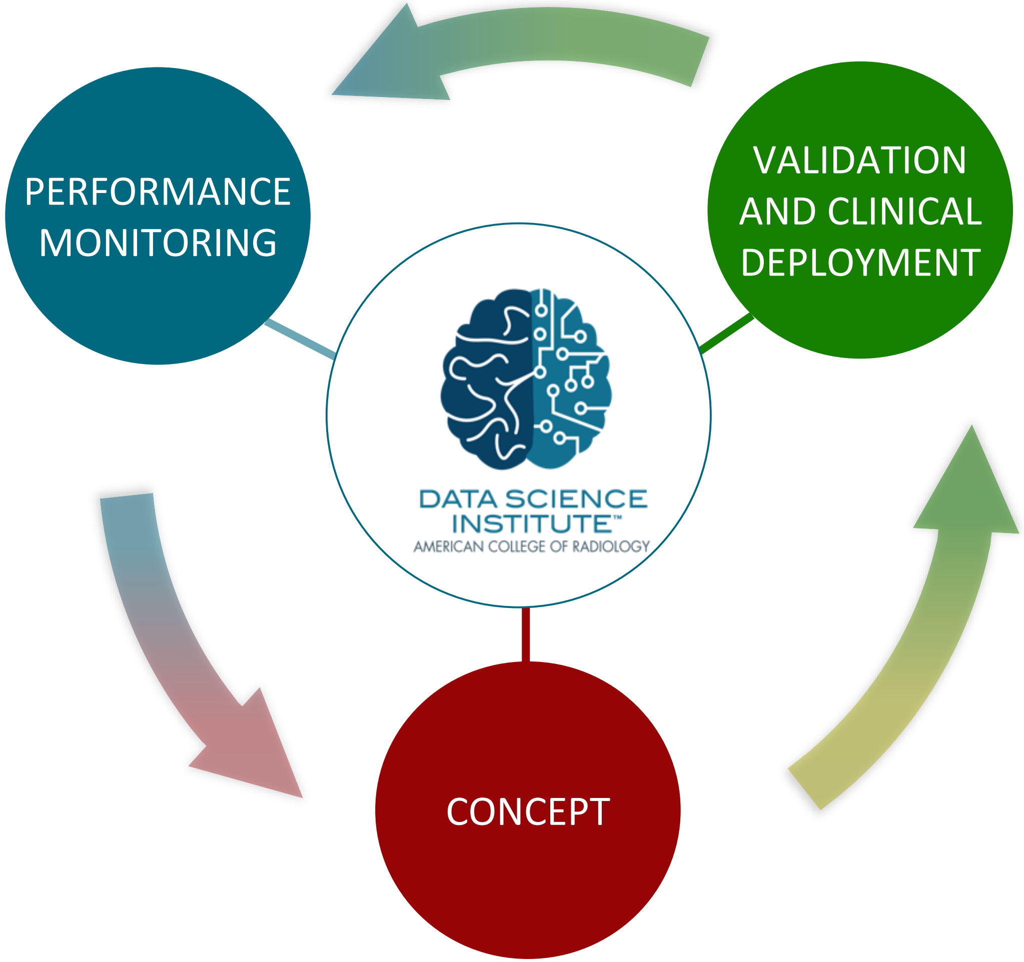
## The Radiology AI Ecosystem

### Ideas to Clinical Practice



# ARTIFICIAL INTELLIGENCE: CONCEPT TO CLINICAL PRACTICE

***HOW DO WE MAKE SURE AI IS WORKING IN THE REAL WORLD?***



PERFORMANCE MONITORING

VALIDATION AND CLINICAL DEPLOYMENT

CONCEPT

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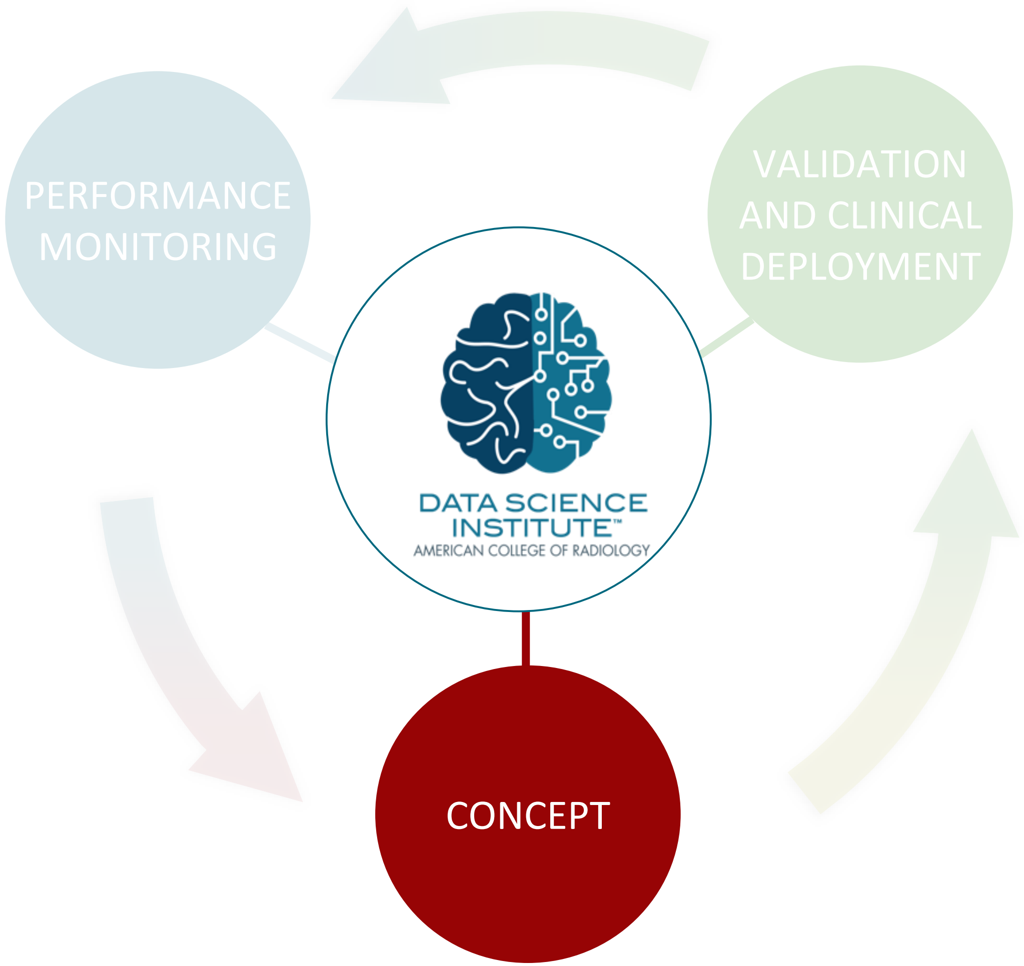
***HOW DO WE VALIDATE AI ALGORITHMS FOR CLINICAL PRACTICE?***

***WHAT ARE THE MOST IMPORTANT CLINICAL TASKS FOR AI?***

# Artificial Intelligence: Concept To Clinical Practice



*How Do We Make Sure AI Is Working In The Real World?*

PERFORMANCE MONITORING

VALIDATION AND CLINICAL DEPLOYMENT

*How Do We Validate AI Algorithms For Clinical Practice?*

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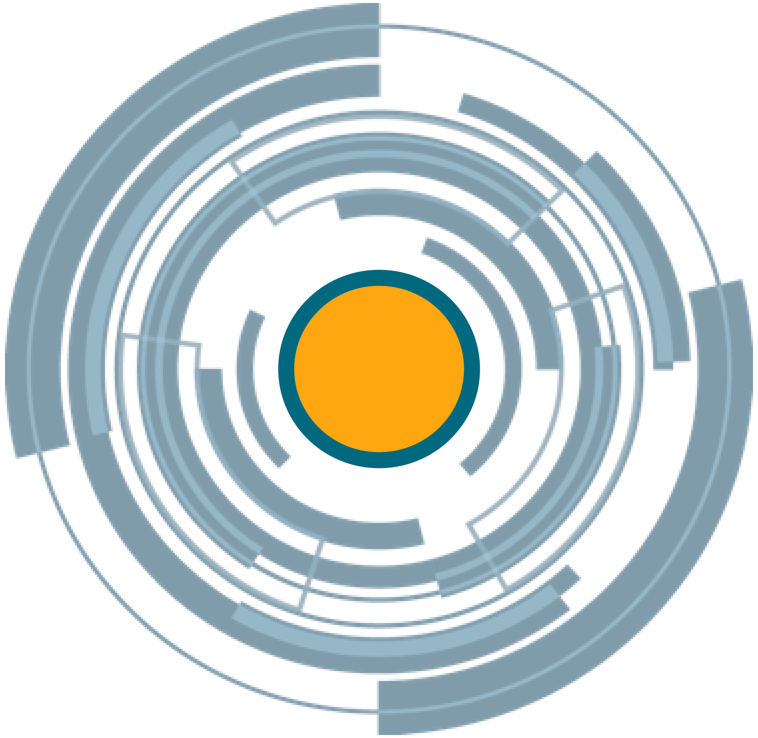
CONCEPT

***What Are The Most Important Clinical Tasks For AI?***

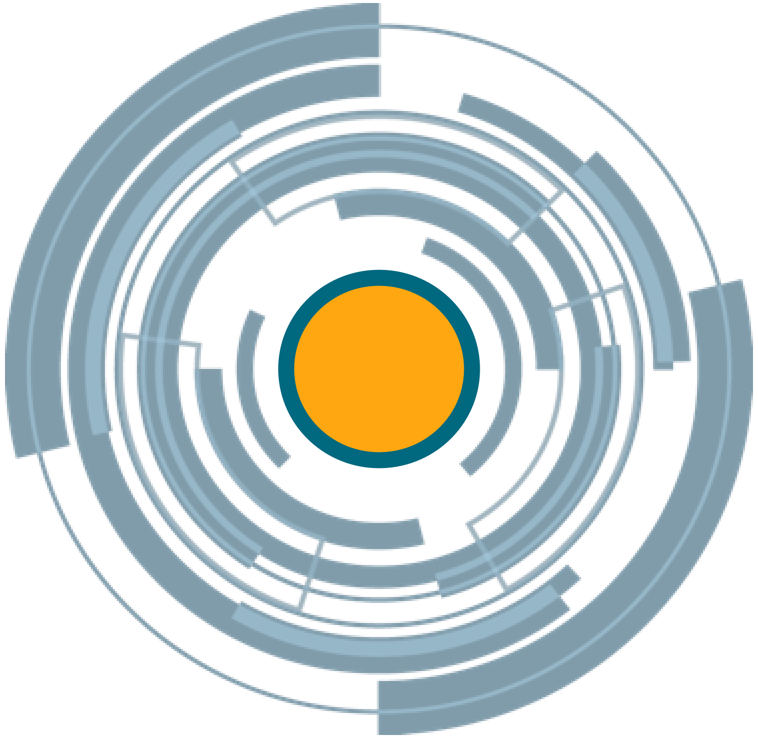
# POSSIBLE APPLICATIONS OF AI IN MEDICAL IMAGING



## Image interpretation

- Quantification of findings
- Quantified comparison between multiple studies
- Multiparametric analysis across multiple modalities
- Volumetric analysis
- Textural analysis
- Automation of Region Of Interest targeting and measuring

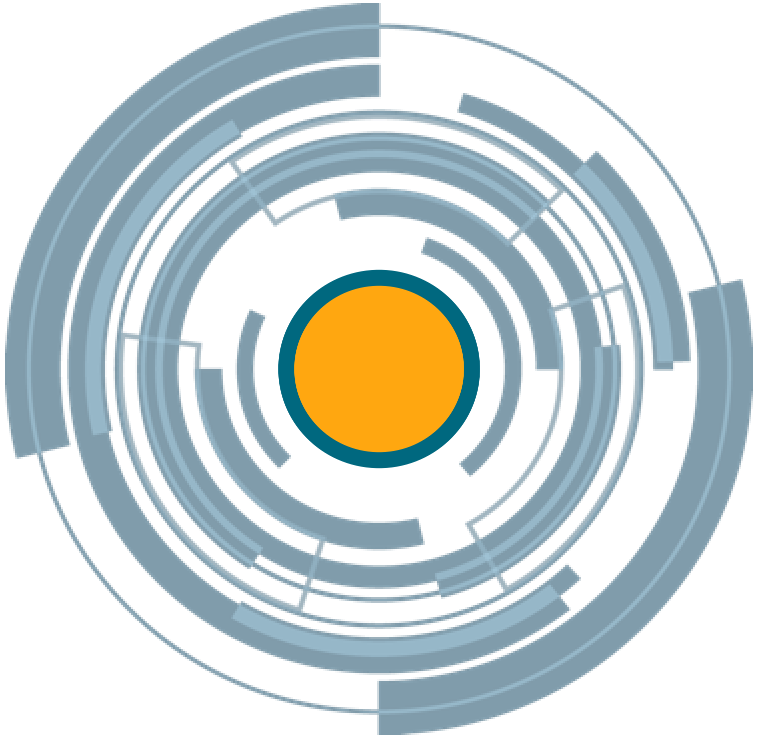
# POSSIBLE APPLICATIONS OF AI IN MEDICAL IMAGING



## Patient care and safety

- Detection and prioritization of potentially critical results
- Radiation dose optimization
- Pre-test probability assessment of patient risk of positive findings and contrast reactions
- Cancer and mammography screening
- Automatic protocoling of studies from EMR data

# POSSIBLE APPLICATIONS OF AI IN MEDICAL IMAGING



## Practice optimization for productivity and quality

- Automated transcription of audio narration
- Automated population of structured reports
- Optimization for case assignment across teams
- Increased accuracy of coding
- Smarter PACS hanging protocols and synchronization protocols
- Communication and tracking of primary and incidental findings
- Decreased patient waiting times
- Quality improvement in scanning
- Prediction and prevention of missed patient appointments
- Preventing imaging machine outages

# ARTIFICIAL INTELLIGENCE: CONCEPT TO CLINICAL PRACTICE

*HOW DO WE MAKE SURE AI IS WORKING IN THE REAL WORLD?*

PERFORMANCE MONITORING

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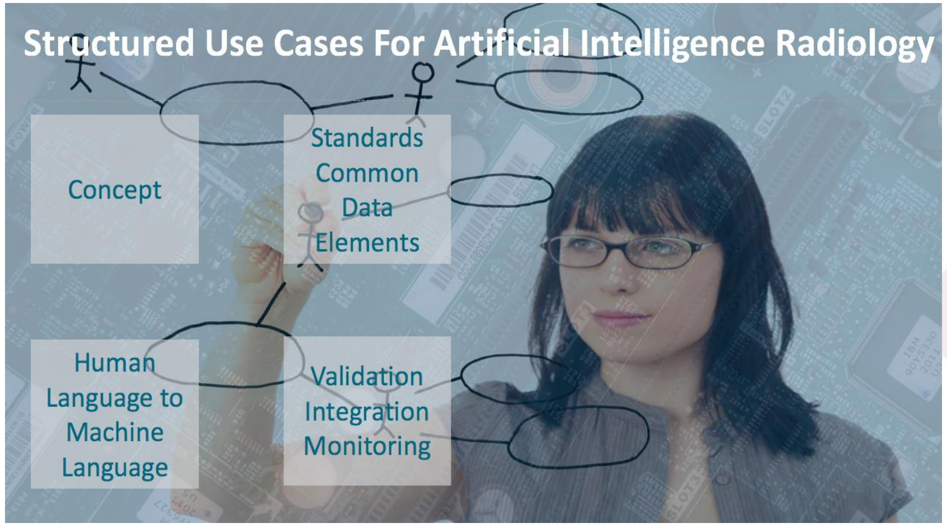
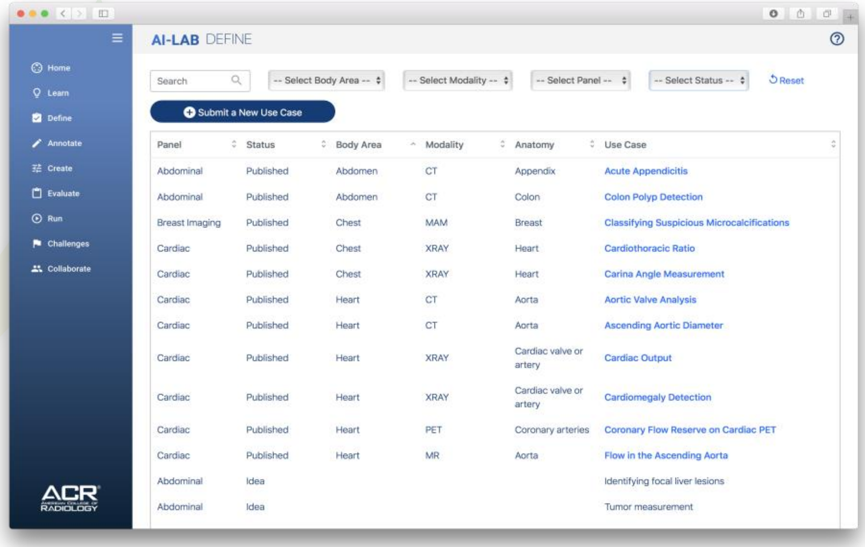
VALIDATION AND CLINICAL DEPLOYMENT

*HOW DO WE VALIDATE AI ALGORITHMS FOR CLINICAL PRACTICE?*



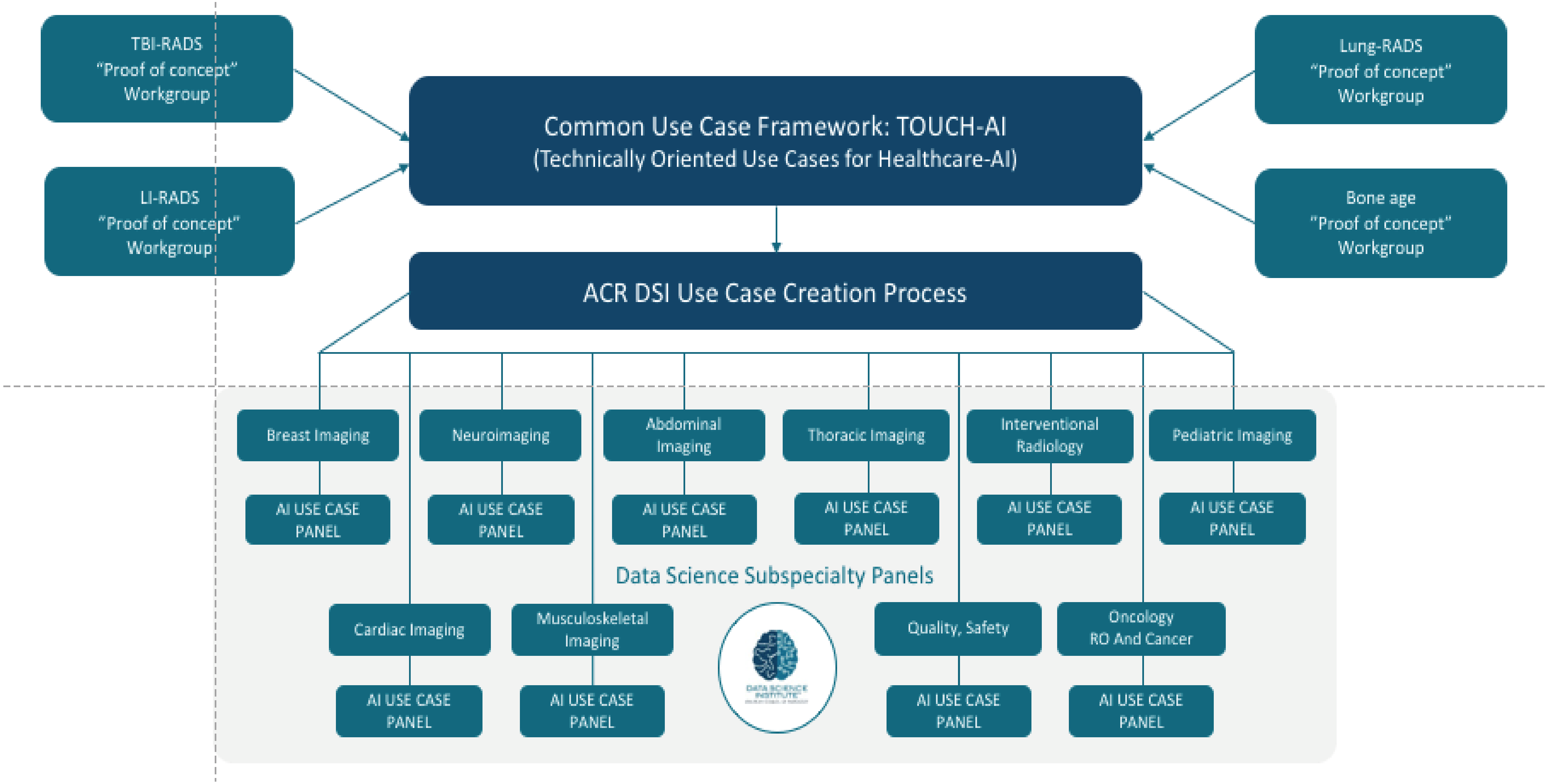
ACR DSI STRUCTURED AI USE CASES



| Panel | Status | Body Area | Modality | Anatomy | Use Case |
|---|---|---|---|---|---|
| Abdominal | Published | Abdomen | CT | Appendix | Acute Appendicitis |
| Abdominal | Published | Abdomen | CT | Colon | Colon Polyp Detection |
| Breast Imaging | Published | Chest | MAM | Breast | Classifying Suspicious Microcalcifications |
| Cardiac | Published | Chest | XRAY | Heart | Cardiothoracic Ratio |
| Cardiac | Published | Chest | XRAY | Heart | Carina Angle Measurement |
| Cardiac | Published | Heart | CT | Aorta | Aortic Valve Analysis |
| Cardiac | Published | Heart | CT | Aorta | Ascending Aortic Diameter |
| Cardiac | Published | Heart | XRAY | Cardiac valve or artery | Cardiac Output |
| Cardiac | Published | Heart | XRAY | Cardiac valve or artery | Cardiomegaly Detection |
| Cardiac | Published | Heart | PET | Coronary arteries | Coronary Flow Reserve on Cardiac PET |
| Cardiac | Published | Heart | MR | Aorta | Flow in the Ascending Aorta |
| Abdominal | Idea | | | | Identifying focal liver lesions |
| Abdominal | Idea | | | | Tumor measurement |

*WHAT ARE THE MOST IMPORTANT CLINICAL TASKS FOR AI?*

# ACR DSI Data Science Subspecialty Panels: ACR DSI Use Case Creation



TBI-RADS
"Proof of concept"
Workgroup

LI-RADS
"Proof of concept"
Workgroup

Lung-RADS
"Proof of concept"
Workgroup

Bone age
"Proof of concept"
Workgroup

Common Use Case Framework: TOUCH-AI
(Technically Oriented Use Cases for Healthcare-AI)

ACR DSI Use Case Creation Process

Data Science Subspecialty Panels

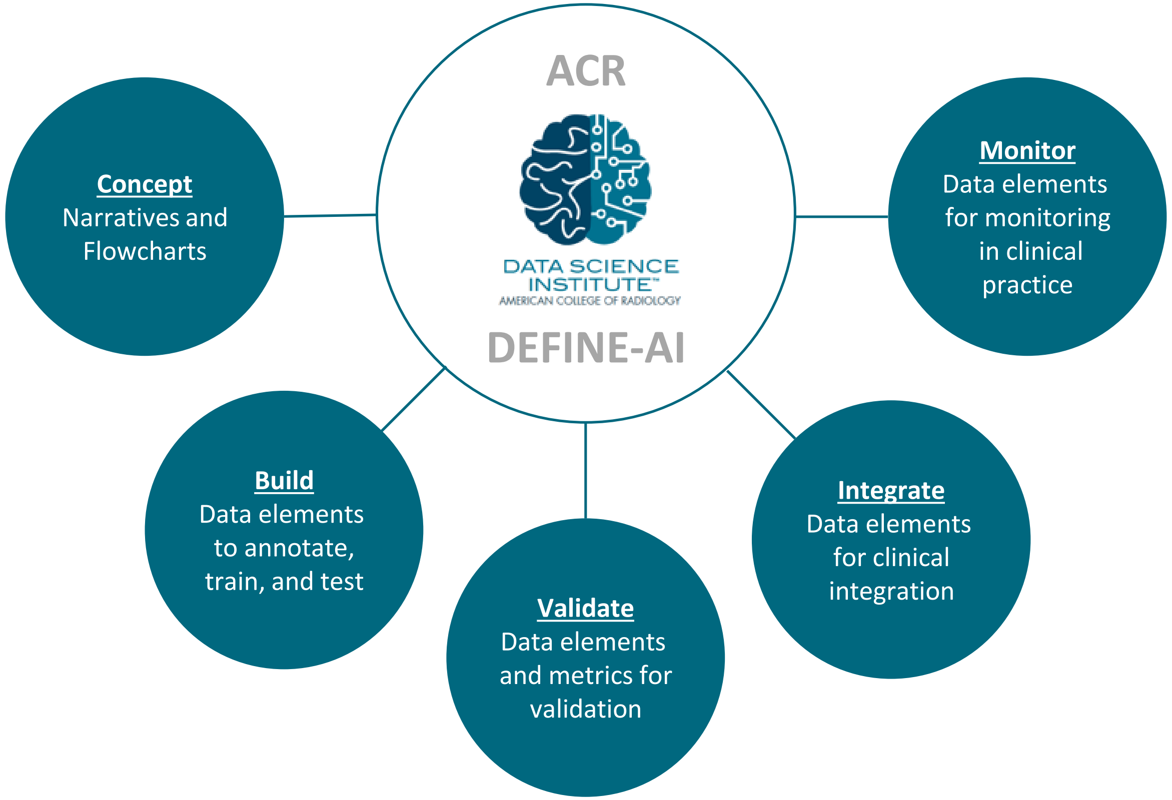
- Breast Imaging – AI USE CASE PANEL
- Neuroimaging – AI USE CASE PANEL
- Abdominal Imaging – AI USE CASE PANEL
- Thoracic Imaging – AI USE CASE PANEL
- Interventional Radiology – AI USE CASE PANEL
- Pediatric Imaging – AI USE CASE PANEL
- Cardiac Imaging – AI USE CASE PANEL
- Musculoskeletal Imaging – AI USE CASE PANEL
- Quality, Safety – AI USE CASE PANEL
- Oncology RO And Cancer – AI USE CASE PANEL

**Expert Panels, Prioritize Clinical Needs, Technical Specs, Data Parameters, Public Input**

# Common Data Elements (CDE) and RadElements

## AI Data Elements

RadElement.org



ACR

DEFINE-AI

**Concept**
Narratives and Flowcharts

**Build**
Data elements to annotate, train, and test

**Validate**
Data elements and metrics for validation

**Integrate**
Data elements for clinical integration

**Monitor**
Data elements for monitoring in clinical practice

# Data Availability For AI Development

- Single institution data
- Diversity and bias

# FACIAL RECOGNITION UNDERPERFORMS IN WOMEN AND WOMEN AND MEN OF COLOR

June 26, 2018, 4:00 AM CDT

Corrected June 26, 2018, 10:20 AM CDT

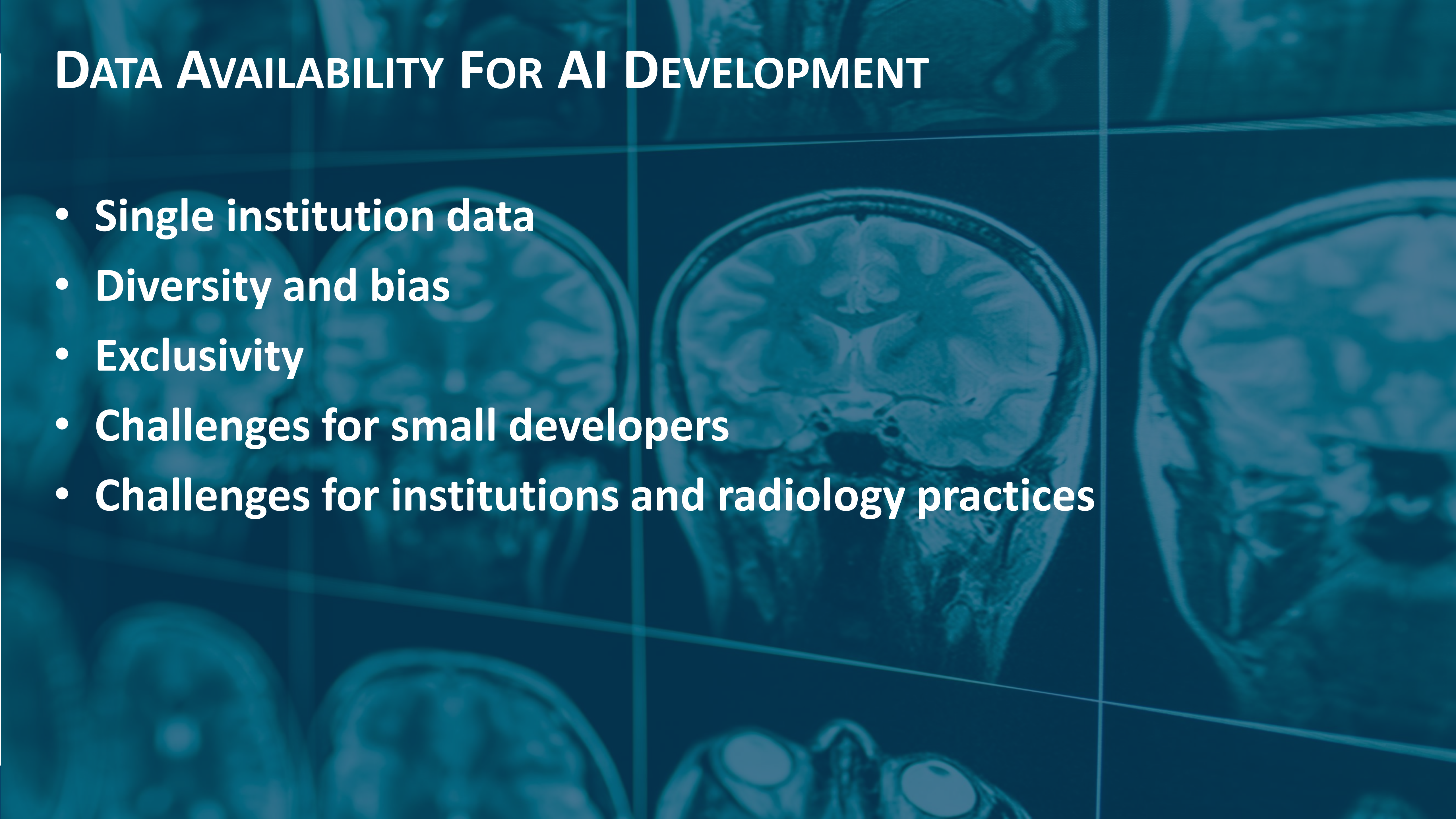
## A.I. Has a Race Problem

- Facial recognition software still gets confused by darker skin tones.

By Lizette Chapman and Joshua Brustein

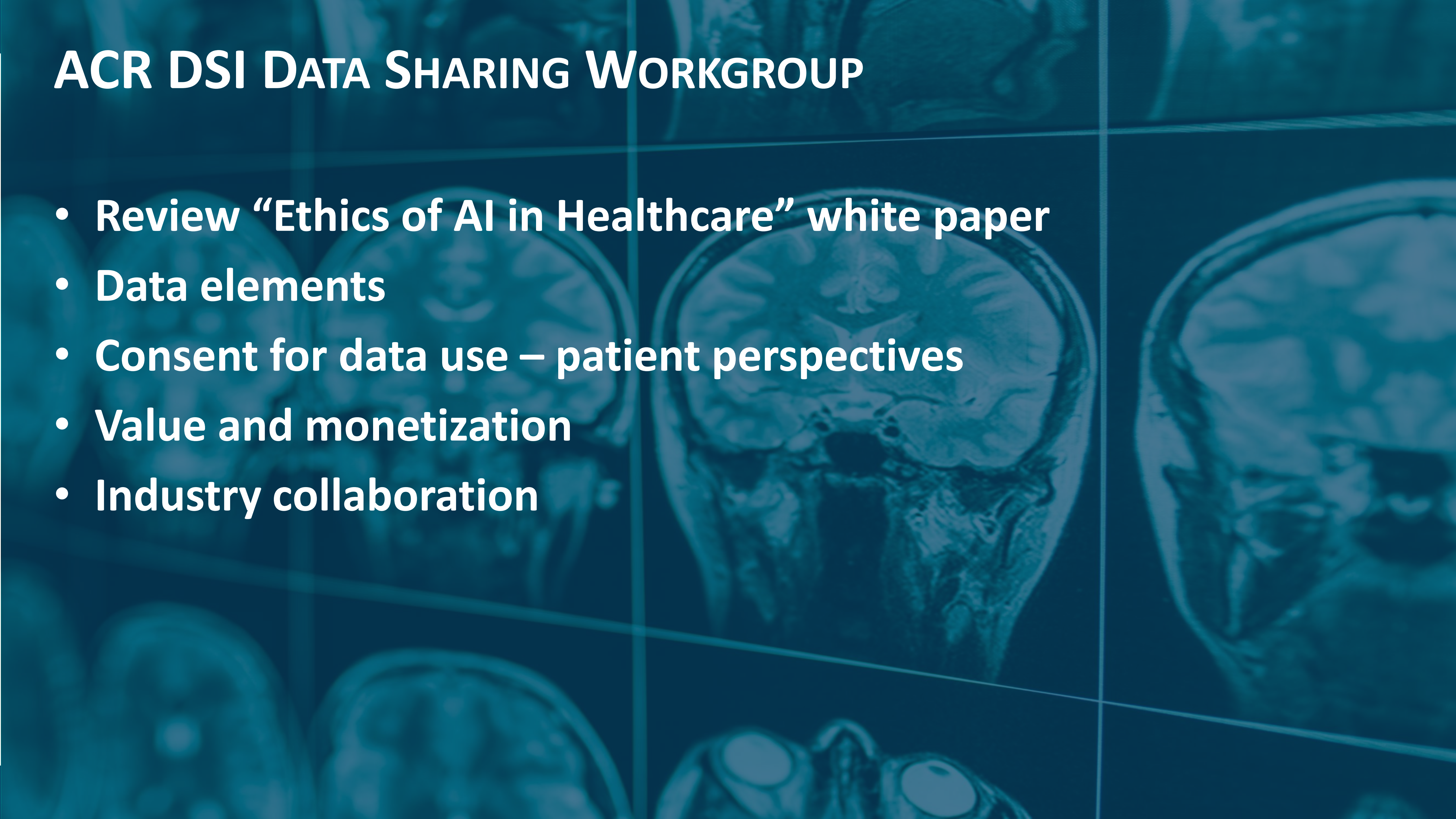
## MIT Researcher: Artificial Intelligence Has a Race Problem, and We Need to Fix It

The next generation of AI is poisoned with bias against dark skin, Joy Buolamwini says.



# Data Availability For AI Development

- Single institution data
- Diversity and bias
- Exclusivity
- Challenges for small developers
- Challenges for institutions and radiology practices

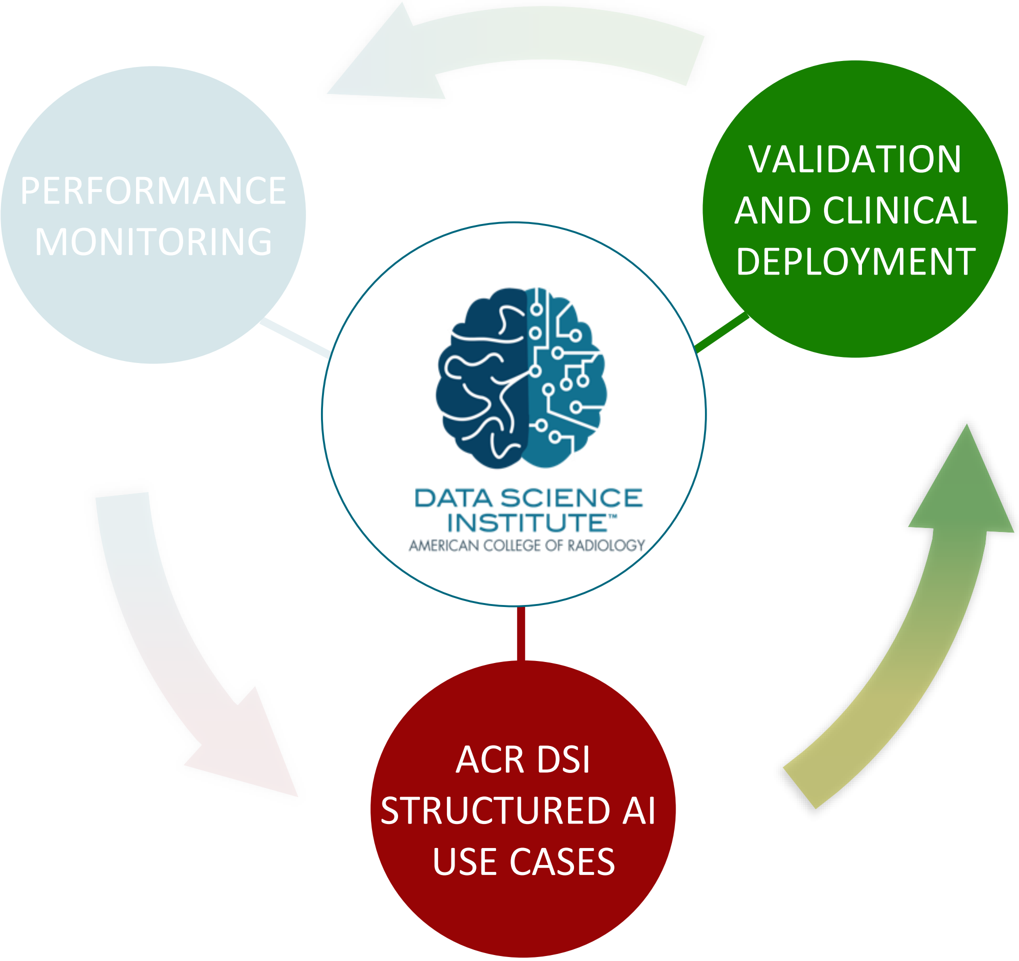


# ACR DSI Data Sharing Workgroup

- Review “Ethics of AI in Healthcare” white paper
- Data elements
- Consent for data use – patient perspectives
- Value and monetization
- Industry collaboration

# ARTIFICIAL INTELLIGENCE: PROTECTING PATIENTS AND THE PUBLIC

*HOW DO WE MAKE SURE AI IS WORKING IN THE REAL WORLD?*



PERFORMANCE MONITORING

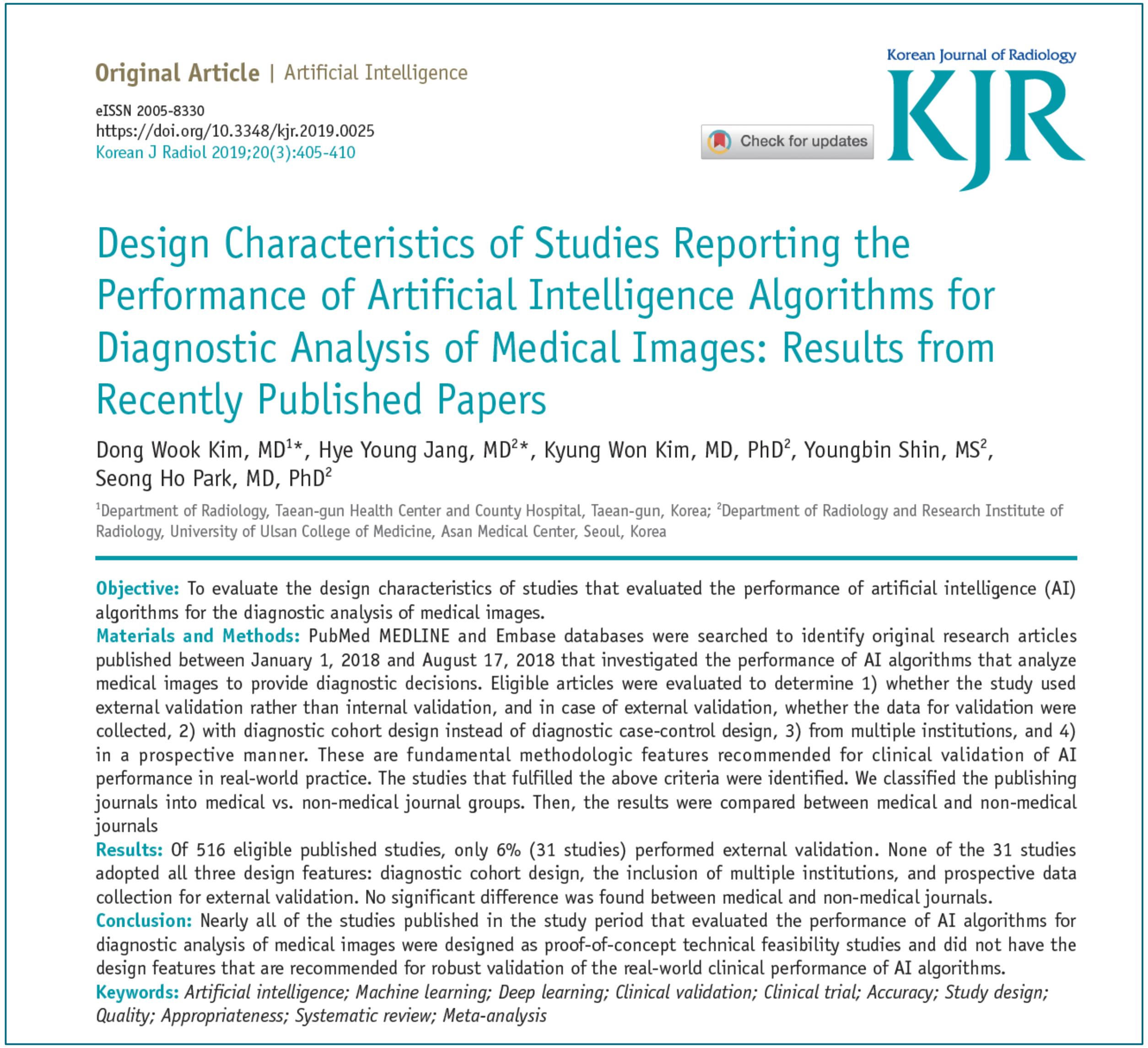
VALIDATION AND CLINICAL DEPLOYMENT

ACR DSI STRUCTURED AI USE CASES

*HOW DO WE VALIDATE AI ALGORITHMS FOR CLINICAL PRACTICE?*

*WHAT ARE THE MOST IMPORTANT CLINICAL TASKS FOR AI?*

# VALIDATING AI FOR CLINICAL USE



**Original Article** | Artificial Intelligence

eISSN 2005-8330
https://doi.org/10.3348/kjr.2019.0025
Korean J Radiol 2019;20(3):405-410

Korean Journal of Radiology
KJR

## Design Characteristics of Studies Reporting the Performance of Artificial Intelligence Algorithms for Diagnostic Analysis of Medical Images: Results from Recently Published Papers

Dong Wook Kim, MD[1]*, Hye Young Jang, MD[2]*, Kyung Won Kim, MD, PhD[2], Youngbin Shin, MS[2], Seong Ho Park, MD, PhD[2]

[1]Department of Radiology, Taean-gun Health Center and County Hospital, Taean-gun, Korea; [2]Department of Radiology and Research Institute of Radiology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea

**Objective:** To evaluate the design characteristics of studies that evaluated the performance of artificial intelligence (AI) algorithms for the diagnostic analysis of medical images.
**Materials and Methods:** PubMed MEDLINE and Embase databases were searched to identify original research articles published between January 1, 2018 and August 17, 2018 that investigated the performance of AI algorithms that analyze medical images to provide diagnostic decisions. Eligible articles were evaluated to determine 1) whether the study used external validation rather than internal validation, and in case of external validation, whether the data for validation were collected, 2) with diagnostic cohort design instead of diagnostic case-control design, 3) from multiple institutions, and 4) in a prospective manner. These are fundamental methodologic features recommended for clinical validation of AI performance in real-world practice. The studies that fulfilled the above criteria were identified. We classified the publishing journals into medical vs. non-medical journal groups. Then, the results were compared between medical and non-medical journals
**Results:** Of 516 eligible published studies, only 6% (31 studies) performed external validation. None of the 31 studies adopted all three design features: diagnostic cohort design, the inclusion of multiple institutions, and prospective data collection for external validation. No significant difference was found between medical and non-medical journals.
**Conclusion:** Nearly all of the studies published in the study period that evaluated the performance of AI algorithms for diagnostic analysis of medical images were designed as proof-of-concept technical feasibility studies and did not have the design features that are recommended for robust validation of the real-world clinical performance of AI algorithms.

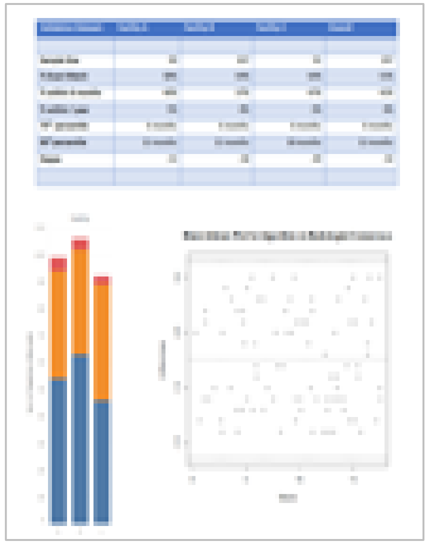
**Keywords:** *Artificial intelligence; Machine learning; Deep learning; Clinical validation; Clinical trial; Accuracy; Study design; Quality; Appropriateness; Systematic review; Meta-analysis*

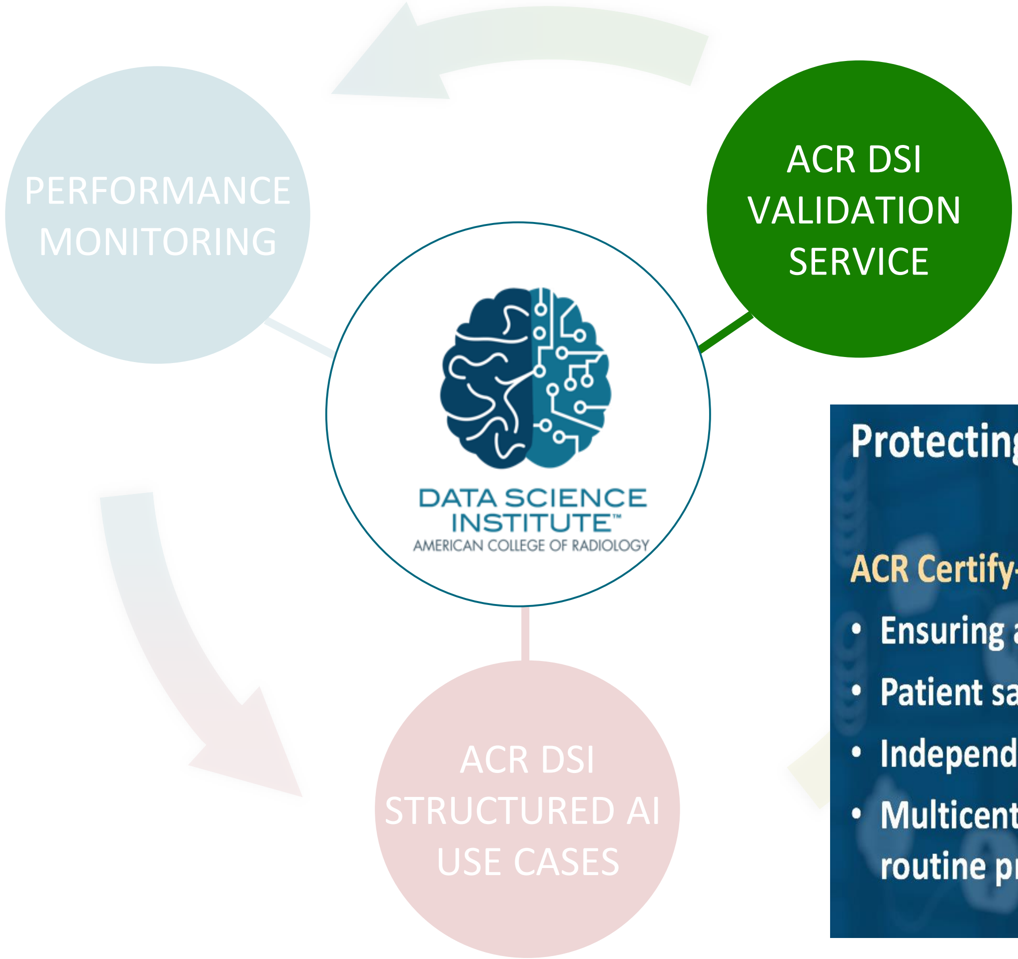
## Validating AI For Clinical Use

- 516 eligible studies from the literature
- 6% performed external validation

# Artificial Intelligence: Concept To Clinical Practice

*How Do We Make Sure AI Is Working In The Real World?*





## *How Do We Validate AI Algorithms For Clinical Practice?*

**Protecting Patients And The Public**

**ACR Certify-AI**

- Ensuring algorithms perform as expected
- Patient safety – FDA and regulatory issues
- Independent validation of algorithm performance
- Multicenter data to ensure diversity and generalizability to routine practice

*What Are The Most Important Clinical Tasks For AI?*

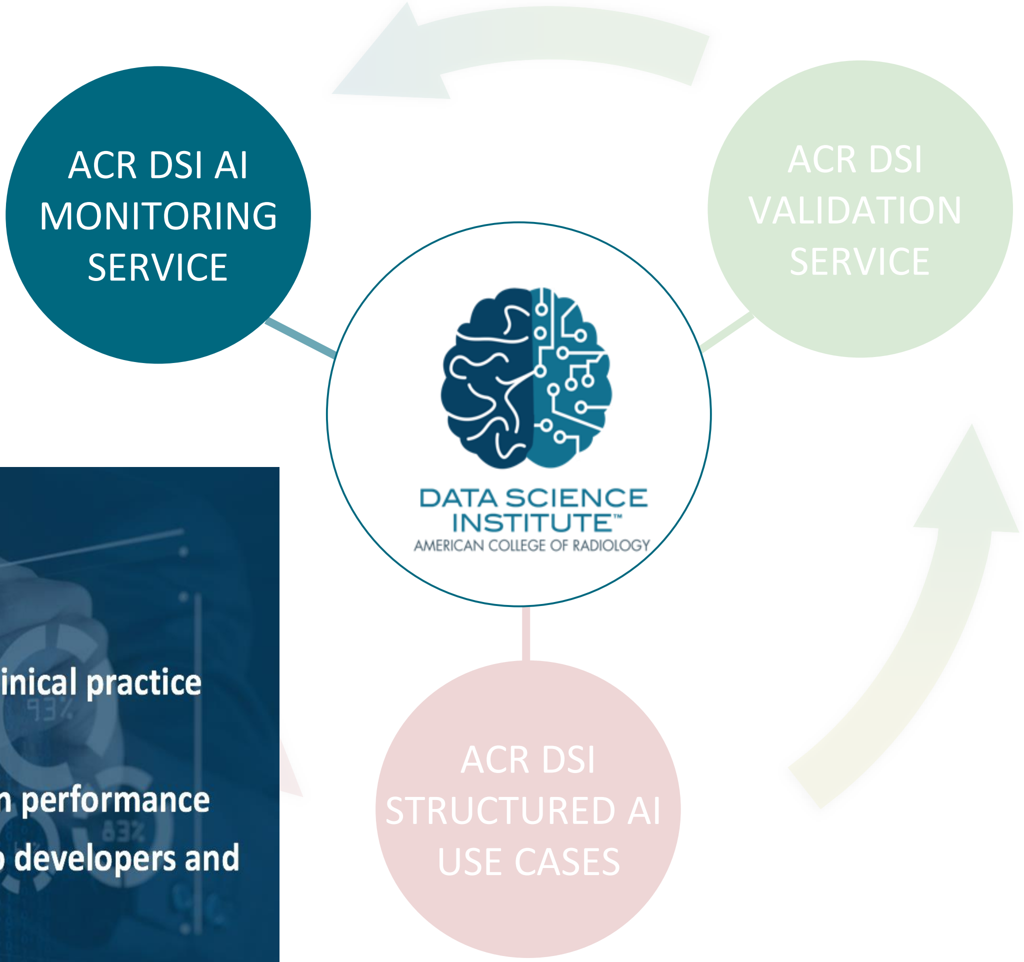
# ARTIFICIAL INTELLIGENCE: CONCEPT TO CLINICAL PRACTICE

## *HOW DO WE MAKE SURE AI IS WORKING IN THE REAL WORLD?*

### Protecting Patients And The Public

**ACR Assess-AI**

- Ensuring algorithms perform as expected in clinical practice
- Patient safety – FDA and regulatory issues
- Real world / real time monitoring of algorithm performance
- Radiology professionals providing feedback to developers and regulatory agencies to ensure safe use of AI



ACR DSI AI MONITORING SERVICE

ACR DSI VALIDATION SERVICE

ACR DSI STRUCTURED AI USE CASES

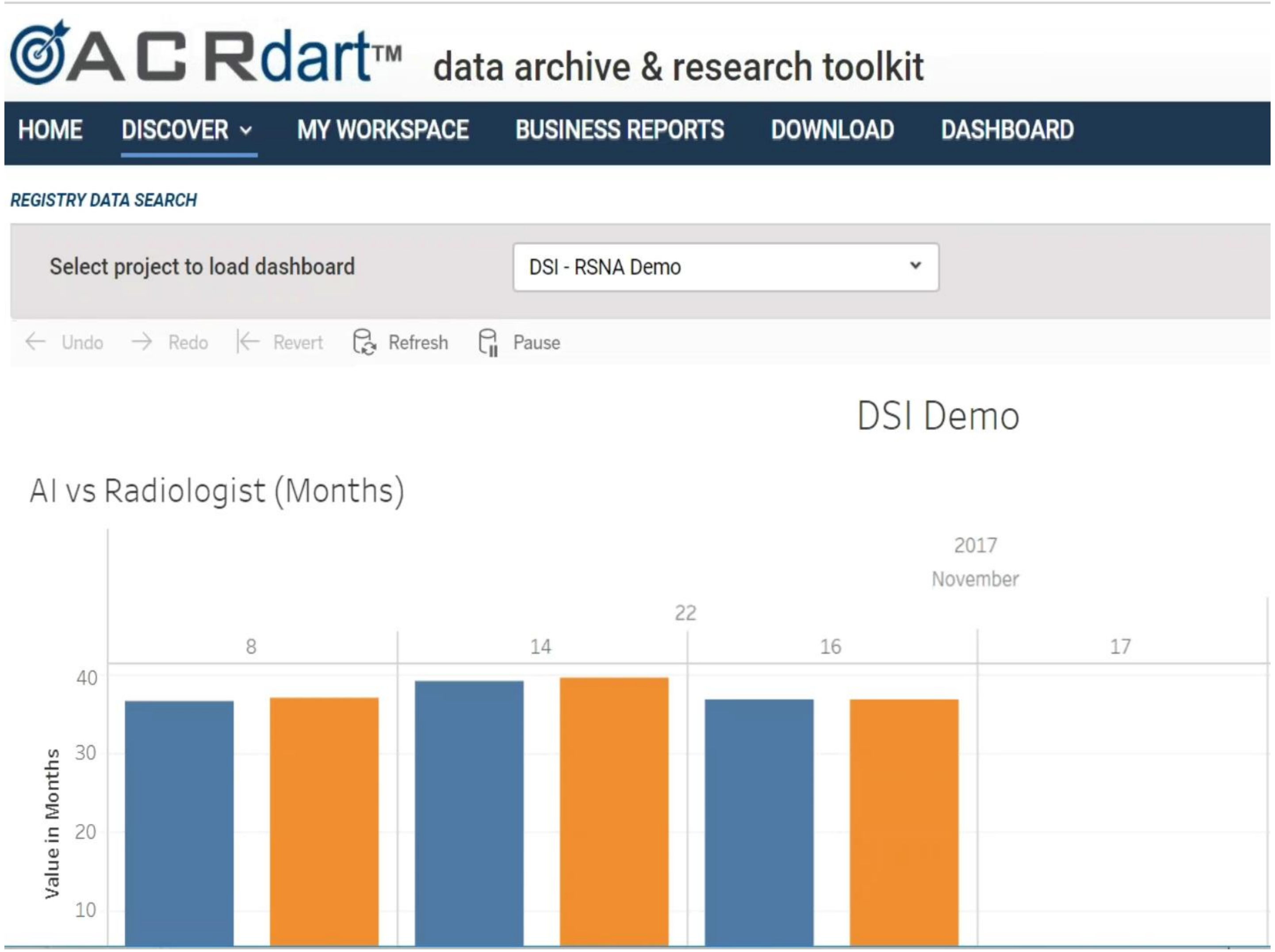
DATA SCIENCE INSTITUTE™
AMERICAN COLLEGE OF RADIOLOGY

## *HOW DO WE VALIDATE AI ALGORITHMS FOR CLINICAL PRACTICE?*

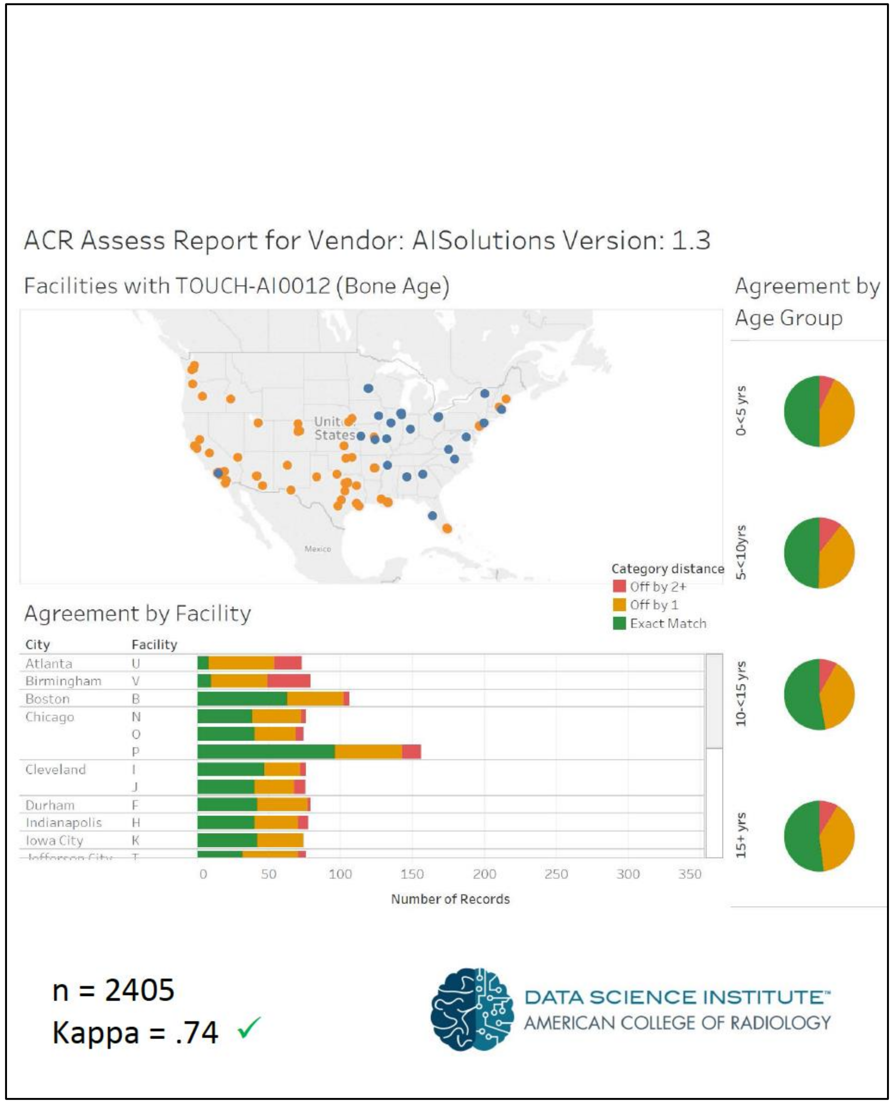
## *WHAT ARE THE MOST IMPORTANT CLINICAL TASKS FOR AI?*

NRDR
AI
ARTIFICIAL INTELLIGENCE
REGISTRY™
AMERICAN COLLEGE OF RADIOLOGY
DATA SCIENCE INSTITUTE

# MONITORING ALGORITHM PERFORMANCE IN CLINICAL PRACTICE – REAL WORLD DATA



Select project to load dashboard: DSI - RSNA Demo



n = 2405

Kappa = .74 ✓

# AI DATA ELEMENTS AND ASSETS FOR CLINICAL INTEGRATION AND PERFORMANCE MONITORING

RSNA Informatics™

## AI Data Elements

**Concept**
Narratives and Flowcharts

**Build**
Data elements to annotate, train, and test

**Validate**
Data elements and metrics for validation

**Integrate**
Data elements for clinical integration

**Monitor**
Data elements for monitoring in clinical practice

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QUALITY IS OUR IMAGE

DATA SCIENCE INSTITUTE™
AMERICAN COLLEGE OF RADIOLOGY

RSNA Informatics™
RadLex®

**Radreport.org**
Structured Reporting Templates

**RadElement.org**
Common Data Elements

**Reporting And Data Systems (RADS)**

**Management Of Incidental Findings**

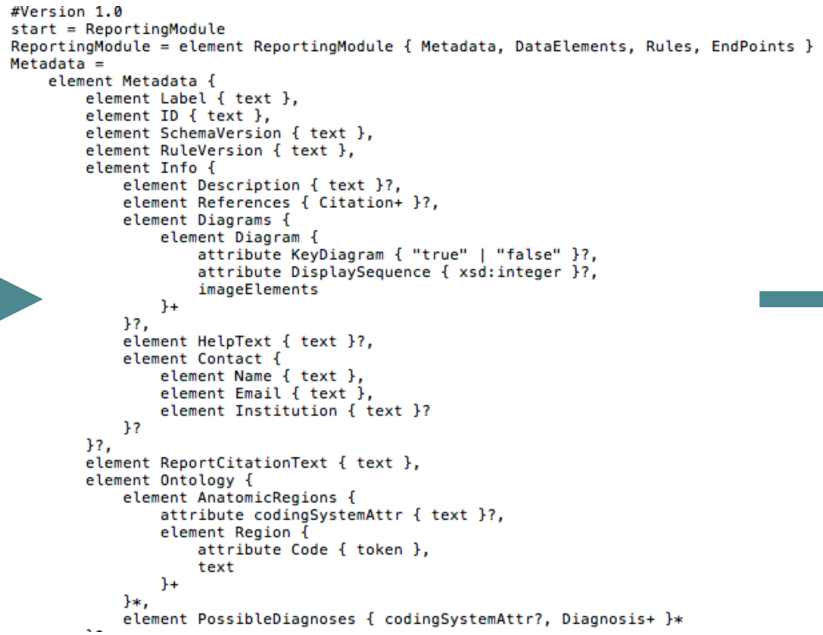
**DSI Structured AI Use Cases**
Technically Oriented Use Cases for Healthcare AI

**National Radiology Data Registry**

# Clinical Integration Of AI

## Computer Assisted Reporting – Decision Support (CARDS)

**Existing Assets**



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        element Label { text },
        element ID { text },
        element SchemaVersion { text },
        element RuleVersion { text },
        element Info {
            element Description { text }?,
            element References { Citation+ }?,
            element Diagrams {
                element Diagram {
                    attribute KeyDiagram { "true" | "false" }?,
                    attribute DisplaySequence { xsd:integer }?,
                    imageElements
                }+
            }?,
            element HelpText { text }?,
            element Contact {
                element Name { text },
                element Email { text },
                element Institution { text }?
            }?
        }?,
        element ReportCitationText { text },
        element Ontology {
            element AnatomicRegions {
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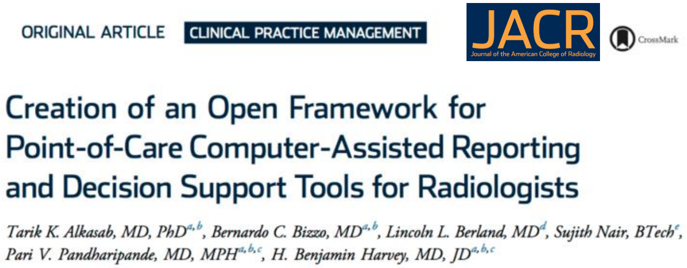
                element Region {
                    attribute Code { token },
                    text
                }+
            }*,
            element PossibleDiagnoses { codingSystemAttr?, Diagnosis+ }*
```



ORIGINAL ARTICLE CLINICAL PRACTICE MANAGEMENT

JACR Journal of the American College of Radiology

Creation of an Open Framework for Point-of-Care Computer-Assisted Reporting and Decision Support Tools for Radiologists

*Tarik K. Alkasab, MD, PhD[a,b], Bernardo C. Bizzo, MD[a,b], Lincoln L. Berland, MD[d], Sujith Nair, BTech[e], Pari V. Pandharipande, MD, MPH[a,b,c], H. Benjamin Harvey, MD, JD[a,b,c]*

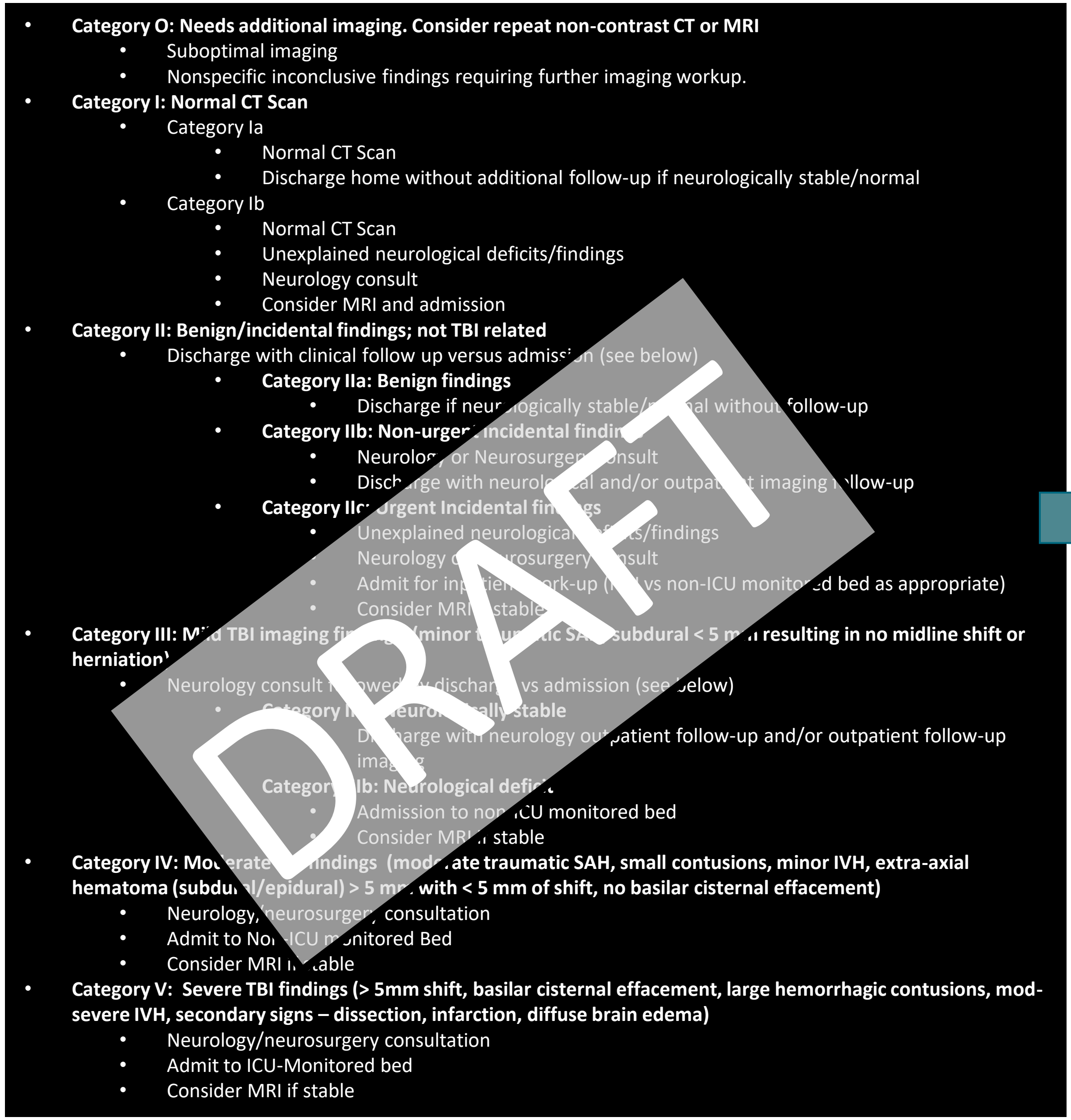
ACR Rassist™

- Raw clinical content
- An encoding scheme that allows this content to be consumed by commercial applications
- Communication framework that facilitates content delivery
- Available at no cost

ACR Assist Modules Can Serve As Containers For Output From AI Algorithms

XML / JSON Imaging Reporting Framework / Template

# ACR HEAD INJURY INSTITUTE – TBI-RADS DEVELOPMENT



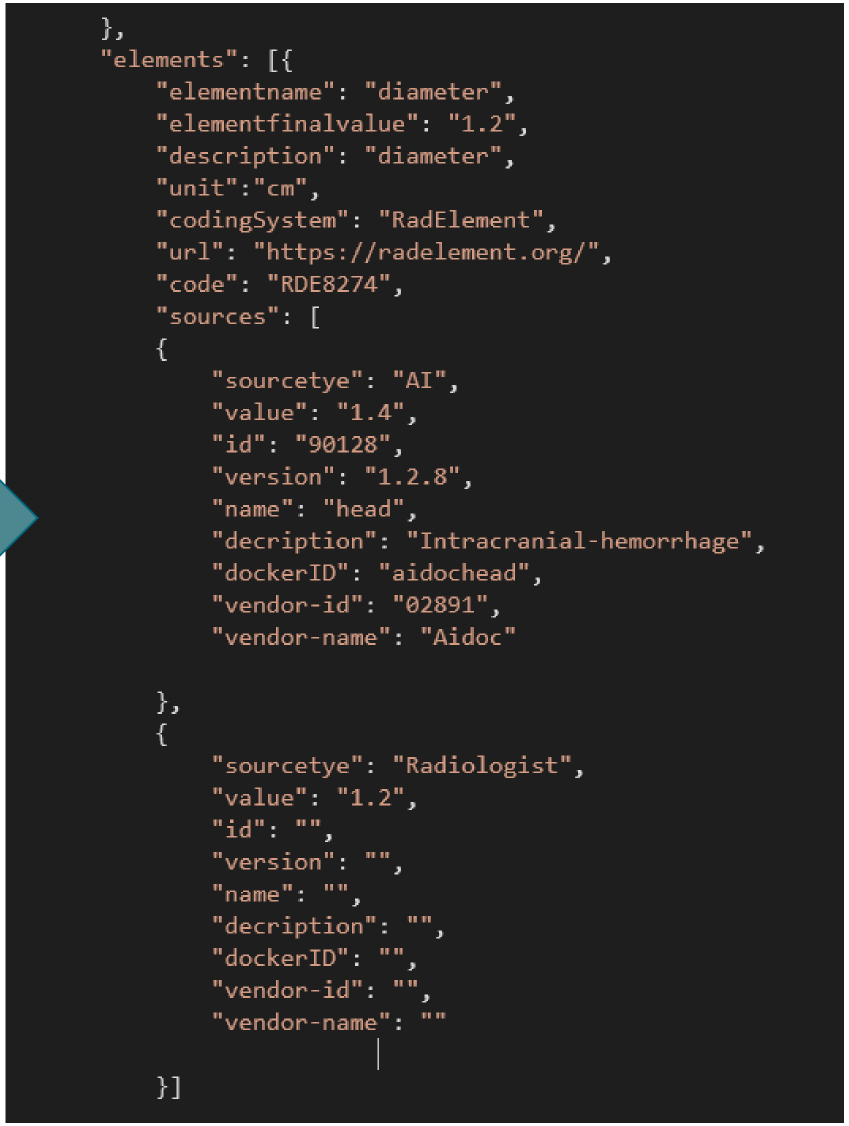
- **Category O: Needs additional imaging. Consider repeat non-contrast CT or MRI**
    - Suboptimal imaging
    - Nonspecific inconclusive findings requiring further imaging workup.
- **Category I: Normal CT Scan**
    - Category Ia
        - Normal CT Scan
        - Discharge home without additional follow-up if neurologically stable/normal
    - Category Ib
        - Normal CT Scan
        - Unexplained neurological deficits/findings
        - Neurology consult
        - Consider MRI and admission
- **Category II: Benign/incidental findings; not TBI related**
    - Discharge with clinical follow up versus admission (see below)
        - **Category IIa: Benign findings**
            - Discharge if neurologically stable/normal without follow-up
        - **Category IIb: Non-urgent incidental findings**
            - Neurology or Neurosurgery consult
            - Discharge with neurological and/or outpatient imaging follow-up
        - **Category IIc: Urgent Incidental findings**
            - Unexplained neurological deficits/findings
            - Neurology or Neurosurgery consult
            - Admit for inpatient work-up (ICU vs non-ICU monitored bed as appropriate)
            - Consider MRI if stable
- **Category III: Mild TBI imaging findings (minor traumatic SAH, subdural < 5 mm resulting in no midline shift or herniation)**
    - Neurology consult followed by discharge vs admission (see below)
        - **Category IIIa: Neurologically stable**
            - Discharge with neurology outpatient follow-up and/or outpatient follow-up imaging
        - **Category IIIb: Neurological deficit**
            - Admission to non-ICU monitored bed
            - Consider MRI if stable
- **Category IV: Moderate TBI findings (moderate traumatic SAH, small contusions, minor IVH, extra-axial hematoma (subdural/epidural) > 5 mm with < 5 mm of shift, no basilar cisternal effacement)**
    - Neurology/neurosurgery consultation
    - Admit to Non-ICU monitored Bed
    - Consider MRI if stable
- **Category V: Severe TBI findings (> 5mm shift, basilar cisternal effacement, large hemorrhagic contusions, mod-severe IVH, secondary signs – dissection, infarction, diffuse brain edema)**
    - Neurology/neurosurgery consultation
    - Admit to ICU-Monitored bed
    - Consider MRI if stable

Text Based Guidelines

Hunan Language To Machine Language

ACRassist™

**Assess-AI Demonstration Project**



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        }]
```

XML and JSON Schema For Reporting And Capturing Registry Data

# ACR HEAD INJURY INSTITUTE – TBI-RADS DEVELOPMENT

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        },

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            "vendor-name": ""
```

XML and JSON Schema For Reporting And Capturing Registry Data

AI Inferences Presented To Radiologists

PACS
Reporting
Other

**Assess-AI Demonstration Project**

## Developer Built UI/UX For Revealing AI Inferences

Back to List  Demo User  1294962652  4015005756729  Logout

Finding : Hyperdense (38)

Shape: Crescentic
Location: Unilateral
Dendity: High homogeneous
Septations: No
Size: 3.2 Volume mm
Size: 3.0 Diameter mm³

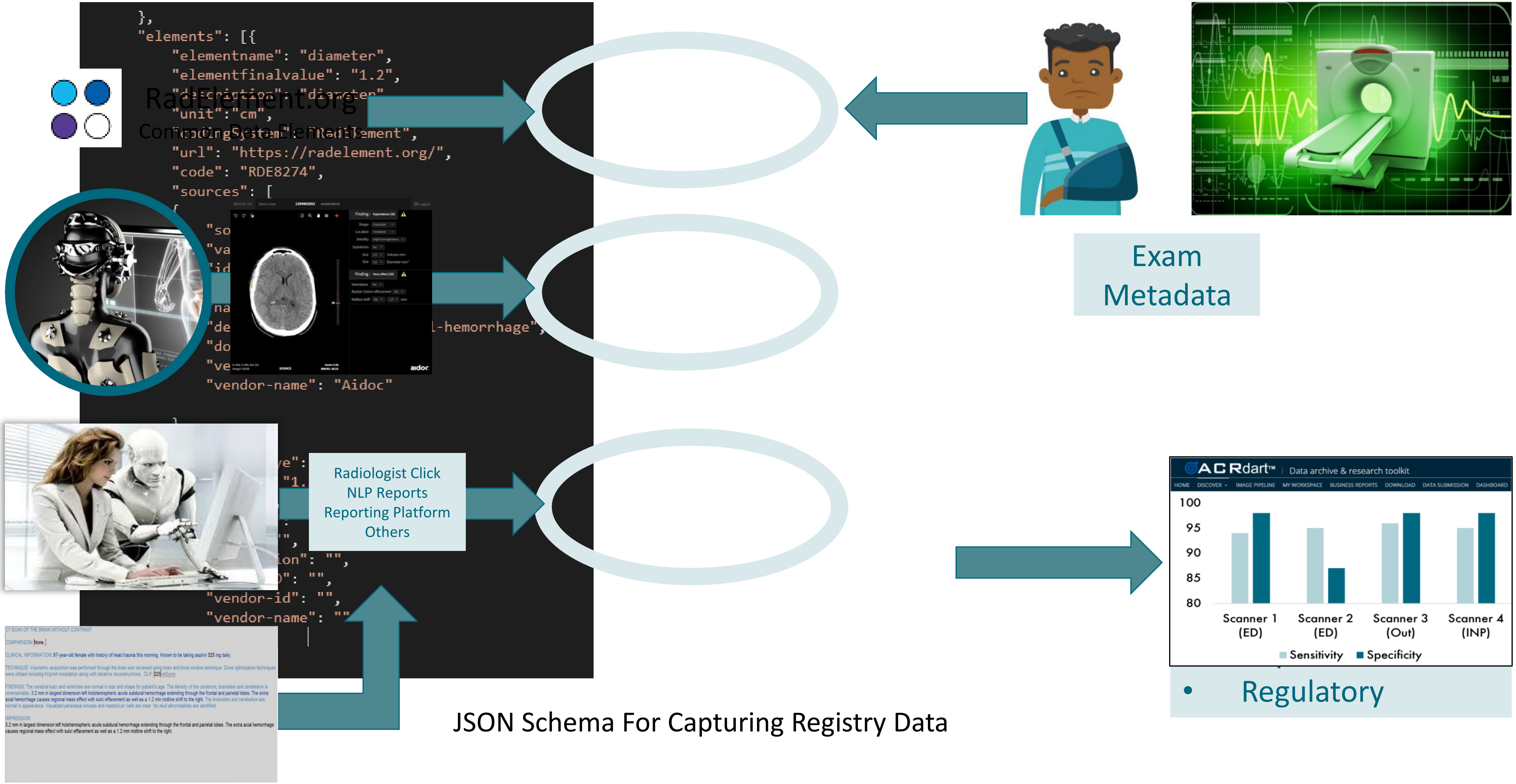
Finding : Mass effect (38)

Herniation: No
Basilar Cistern effacement: No
Midline shift: Yes 1.9 mm

X: 298, Y: 260, Val: 511
Image # 38/56
SOURCE
Zoom: 0.98
WW/WL: 80/35

Includes Elements For Interface With Radiologists and Reporting Platforms

# ASSESS-AI REGISTRY WORKFLOW



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    }


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```

CT SCAN OF THE BRAIN WITHOUT CONTRAST

COMPARISON: None.

CLINICAL INFORMATION: 87-year-old female with history of head trauma this morning. Known to be taking aspirin 325 mg daily.

TECHNIQUE: Volumetric acquisition was performed through the brain and reviewed using brain and bone window technique. Dose optimization techniques were utilized including kVp/mA modulation along with iterative reconstructions. DLP: 325 mGycm

FINDINGS: The cerebral sulci and ventricles are normal in size and shape for patient's age. The density of the cerebrum, brainstem and cerebellum is unremarkable. 3.2 mm in largest dimension left holohemispheric acute subdural hemorrhage extending through the frontal and parietal lobes. The extra axial hemorrhage causes regional mass effect with sulci effacement as well as a 1.2 mm midline shift to the right. The brainstem and cerebellum are normal in appearance. Visualized paranasal sinuses and mastoid air cells are clear. No skull abnormalities are identified.

IMPRESSION:
3.2 mm in largest dimension left holohemispheric acute subdural hemorrhage extending through the frontal and parietal lobes. The extra axial hemorrhage causes regional mass effect with sulci effacement as well as a 1.2 mm midline shift to the right.

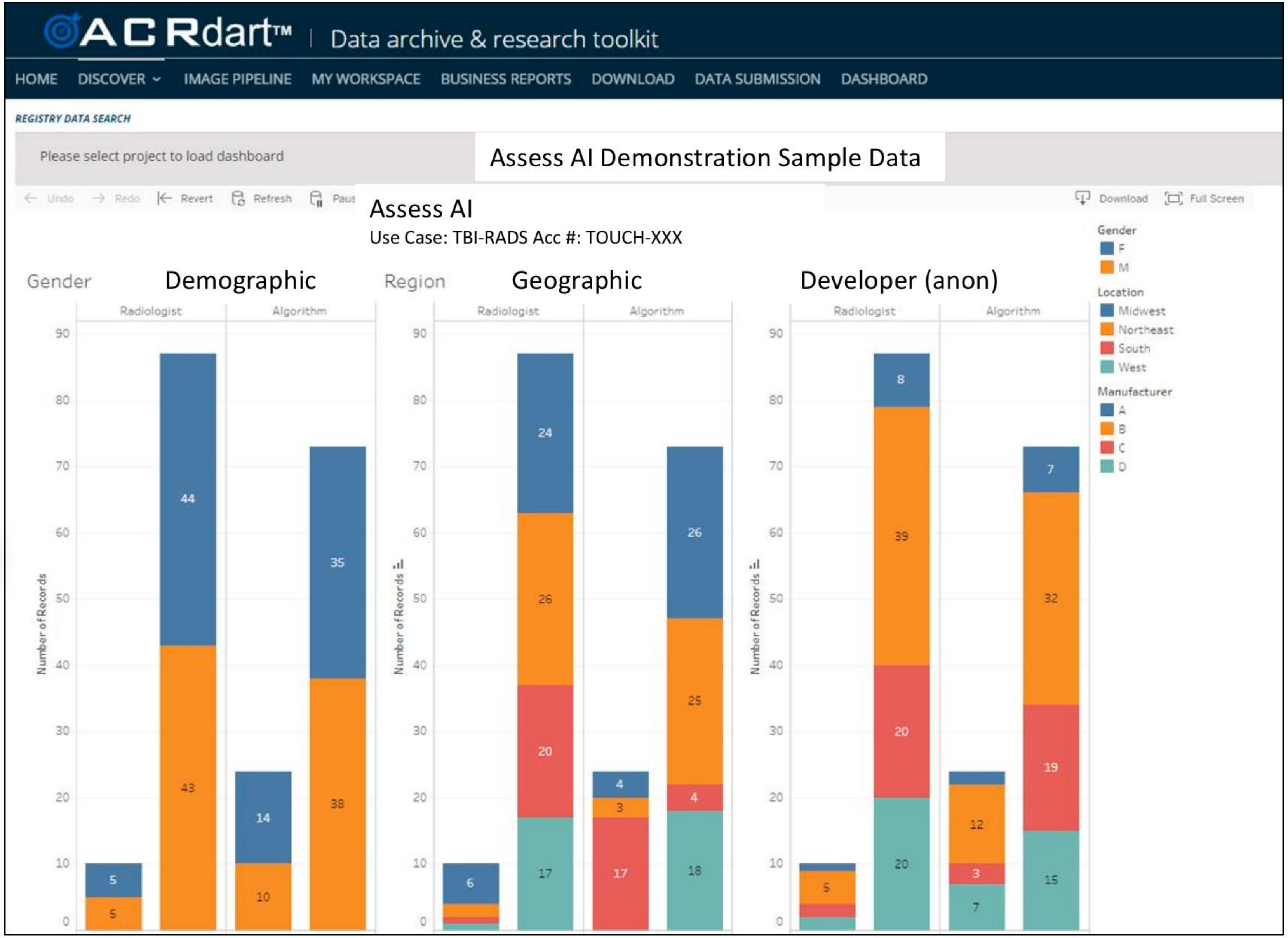
Radiologist Click
NLP Reports
Reporting Platform
Others

Exam Metadata

- Regulatory

JSON Schema For Capturing Registry Data

# SAMPLE ASSES-AI REPORT



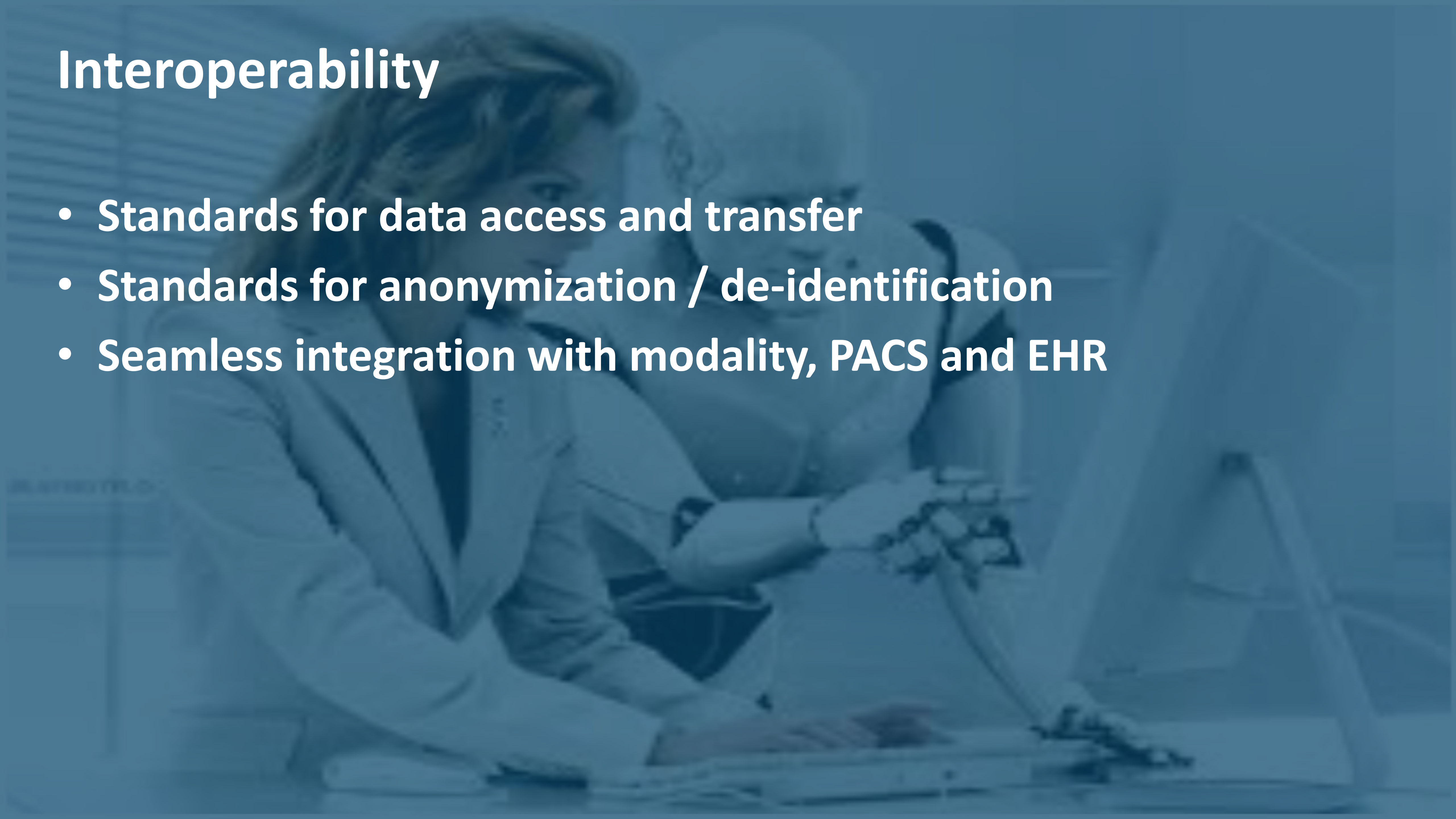
Please select project to load dashboard

Assess AI Demonstration Sample Data

Assess AI

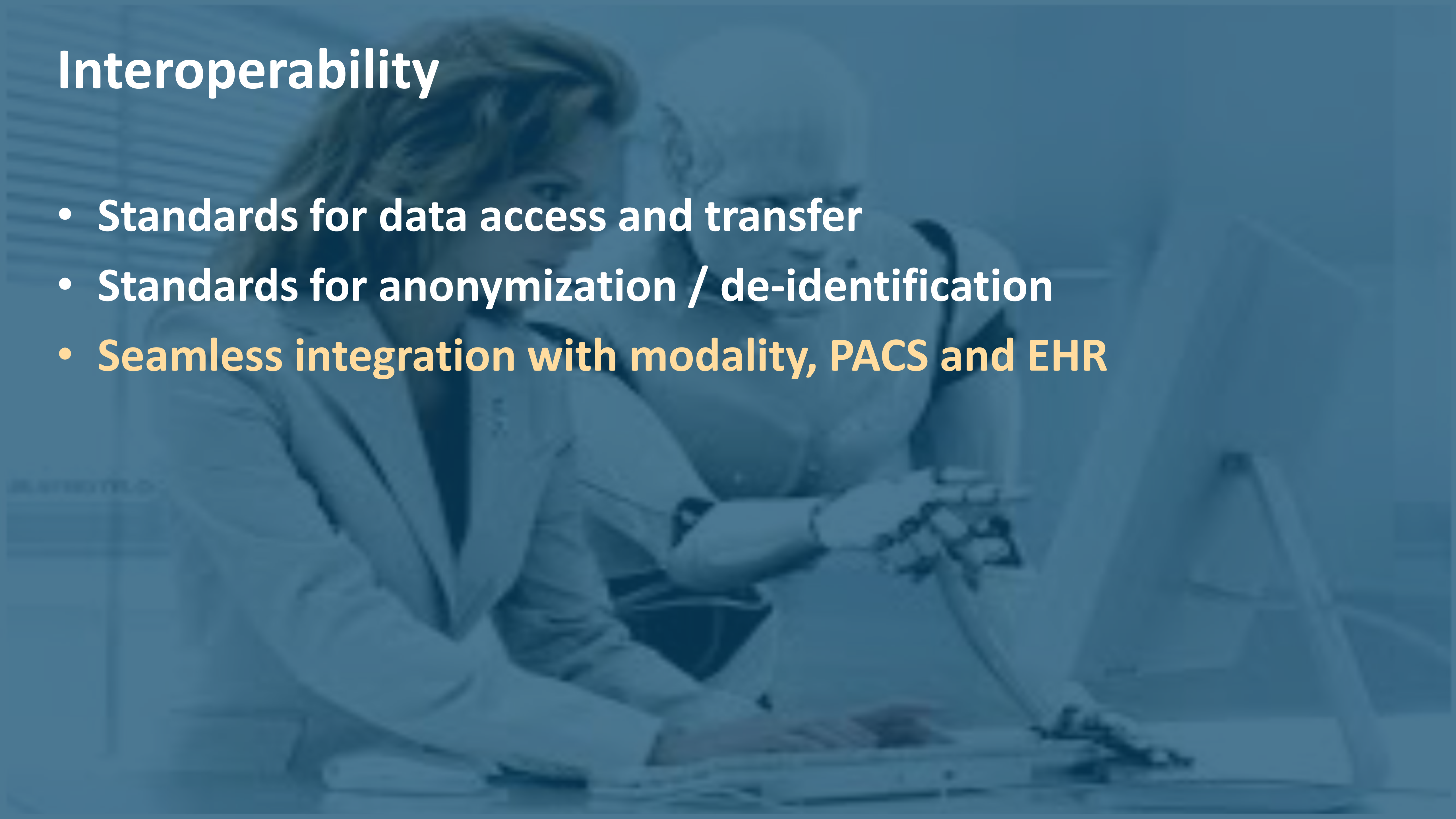
Use Case: TBI-RADS Acc #: TOUCH-XXX

# Interoperability



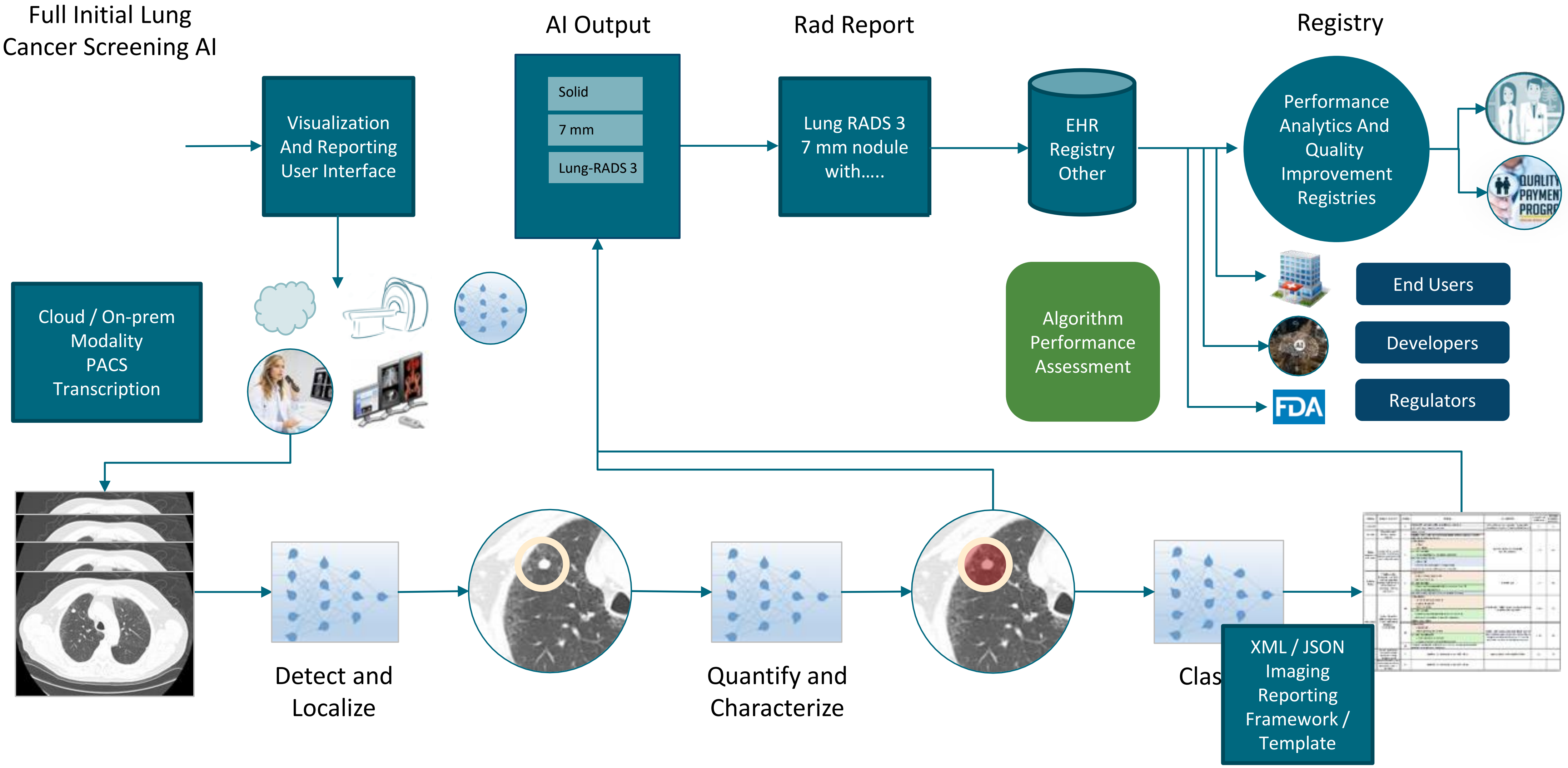
- Standards for data access and transfer
- Standards for anonymization / de-identification
- Seamless integration with modality, PACS and EHR

# Interoperability



- Standards for data access and transfer
- Standards for anonymization / de-identification
- Seamless integration with modality, PACS and EHR

# Integrating AI Into Routine Clinical Practice



Full Initial Lung Cancer Screening AI

Visualization And Reporting User Interface

Cloud / On-prem
Modality
PACS
Transcription

AI Output

Solid

7 mm

Lung-RADS 3

Rad Report

Lung RADS 3
7 mm nodule with.....

EHR
Registry
Other

Registry

Performance Analytics And Quality Improvement Registries

Algorithm Performance Assessment

End Users

Developers

Regulators

Detect and Localize

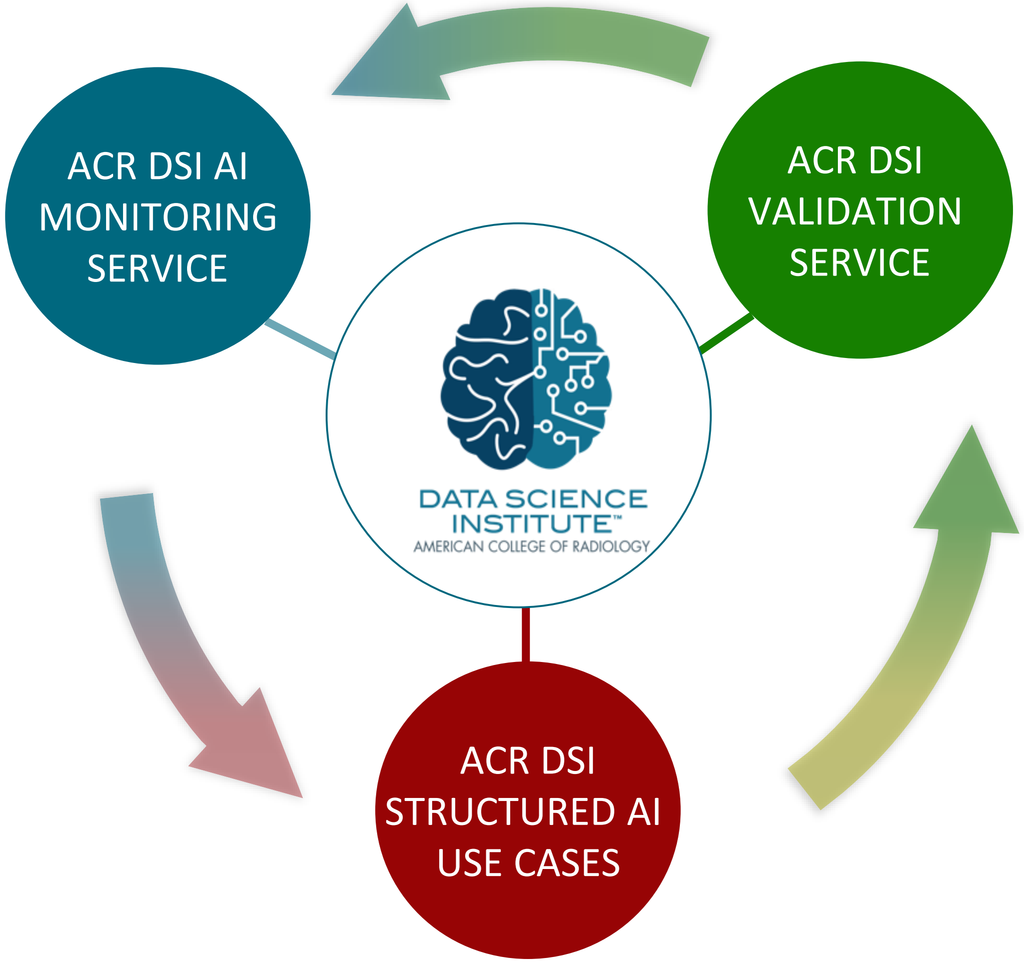
Quantify and Characterize

Clas

XML / JSON Imaging Reporting Framework / Template

## AI In Clinical Practice With Registry Reporting For Monitoring With Real-World Data

# ARTIFICIAL INTELLIGENCE: CONCEPT TO CLINICAL PRACTICE



ACR DSI AI MONITORING SERVICE

ACR DSI VALIDATION SERVICE

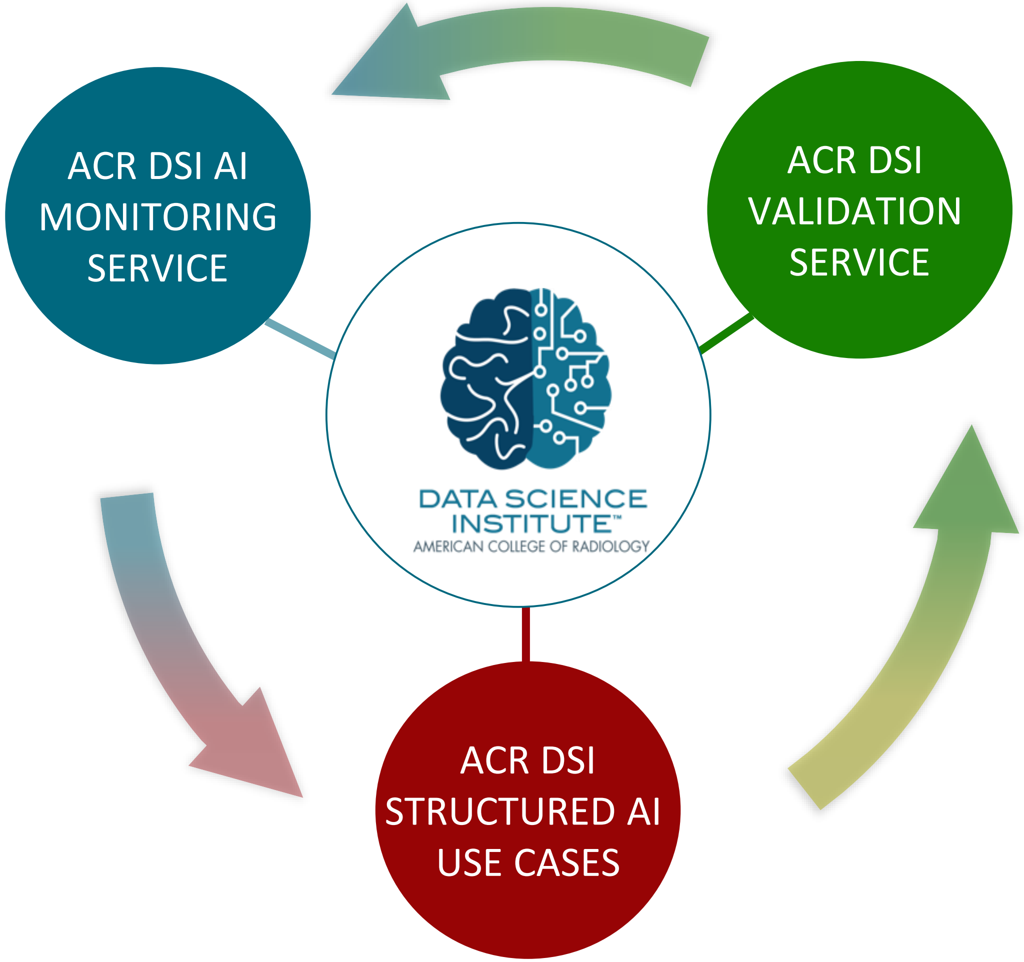
ACR DSI STRUCTURED AI USE CASES

***HOW DO WE MAKE SURE AI IS WORKING IN THE REAL WORLD?***

***HOW DO WE VALIDATE AI ALGORITHMS FOR CLINICAL PRACTICE?***

***WHAT ARE THE MOST IMPORTANT CLINICAL TASKS FOR AI?***

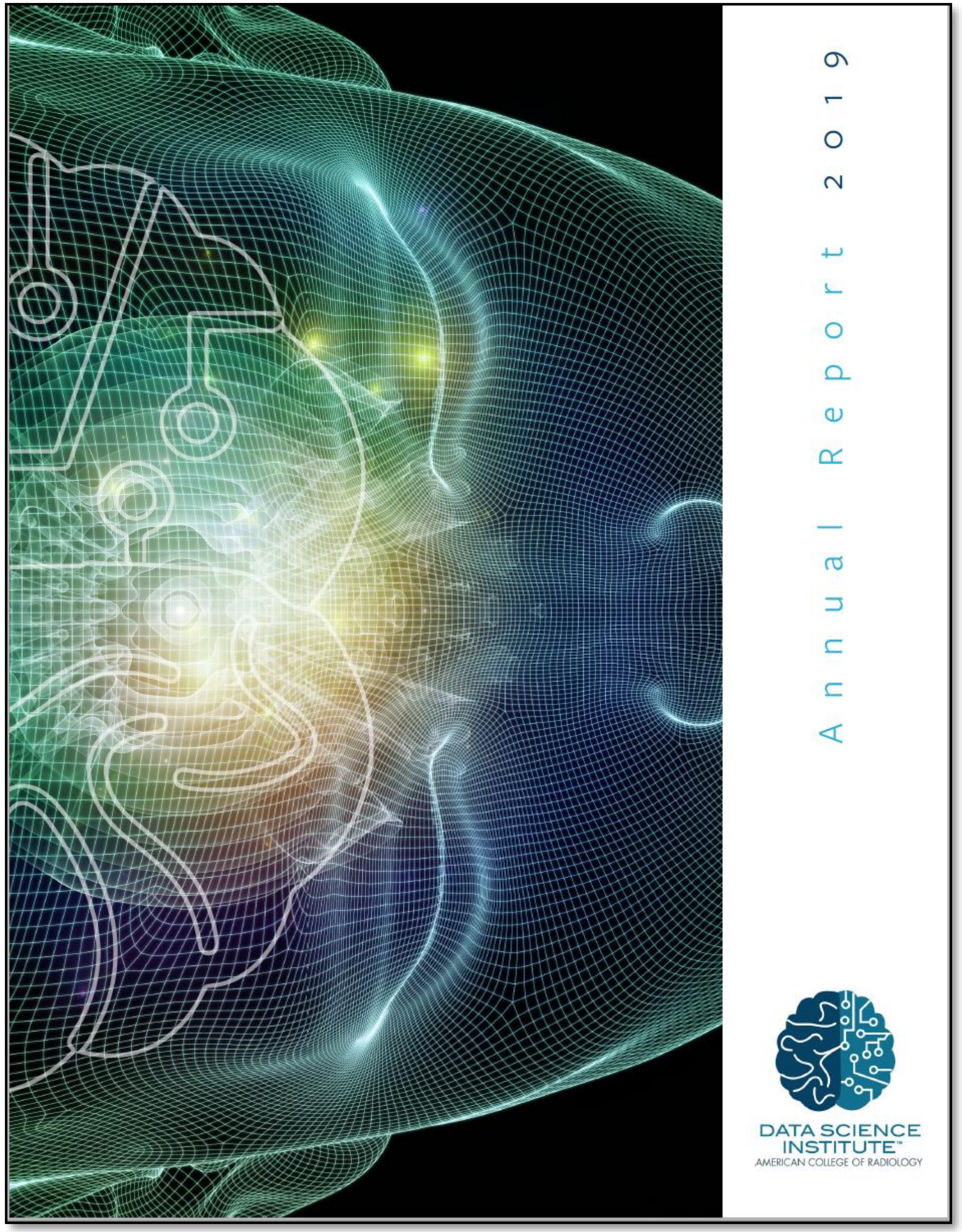
# DEMOCRATIZE AI: ENABLE ALL RADIOLOGIST, PATIENT (DATA) AND DATA SCIENTIST PARTICIPATION



ACR DSI AI MONITORING SERVICE

ACR DSI VALIDATION SERVICE

ACR DSI STRUCTURED AI USE CASES



Annual Report 2019

DATA SCIENCE INSTITUTE™
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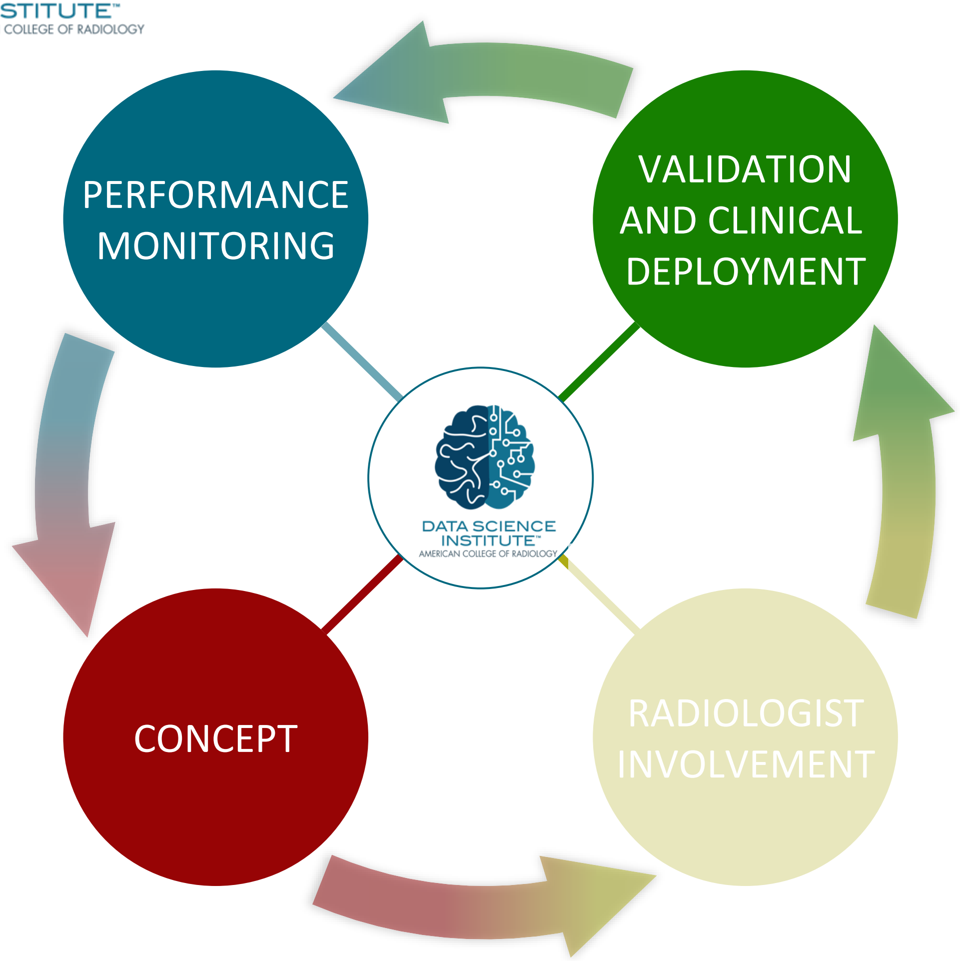
## The Radiology AI Ecosystem

Ideas To Clinical Practice



## Radiology AI Ecosystem

- Radiology professionals
- Researchers
- Industry developers
- Government agencies
- Patients

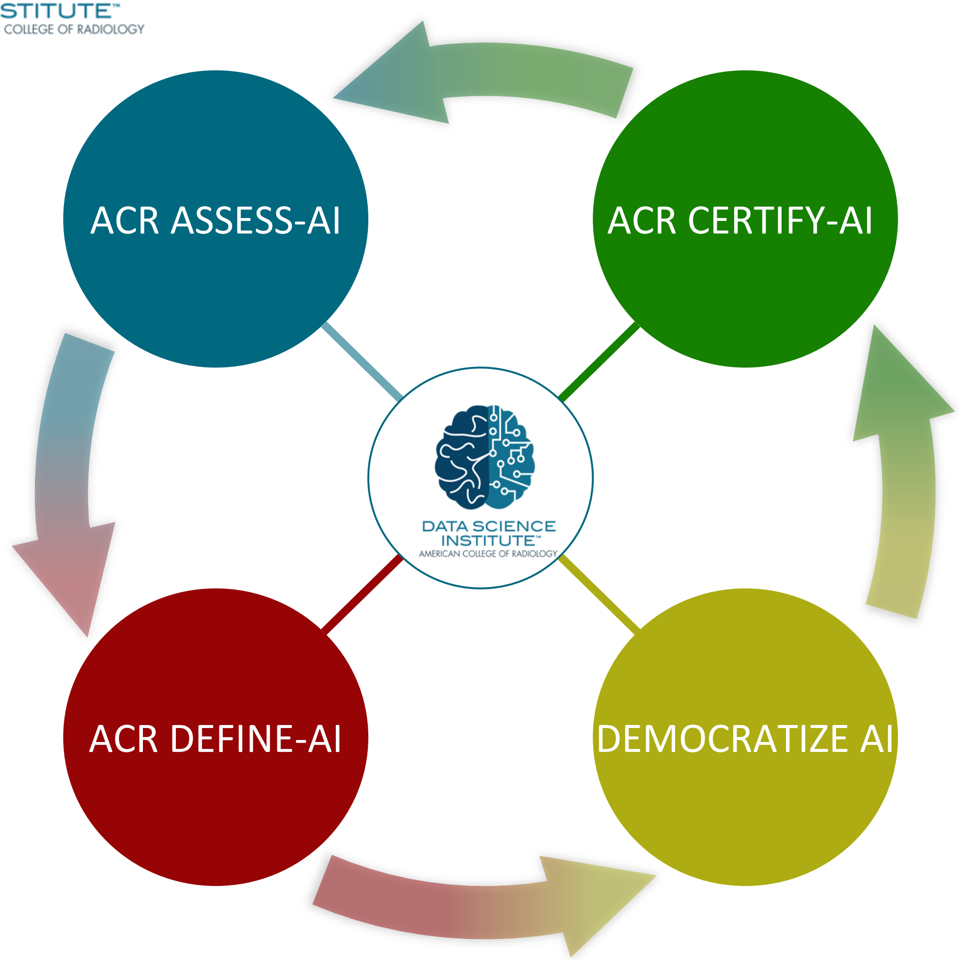
## Radiology's Value Proposition

- Trusted partnerships with industry and regulators
- Ensure patient safety and minimize disparities
- Increase radiology professionals' value in healthcare

# THE MISSING PIECE….

**The Radiology AI Ecosystem**

Ideas To Clinical Practice



## *WHAT WERE WE MISSING?*

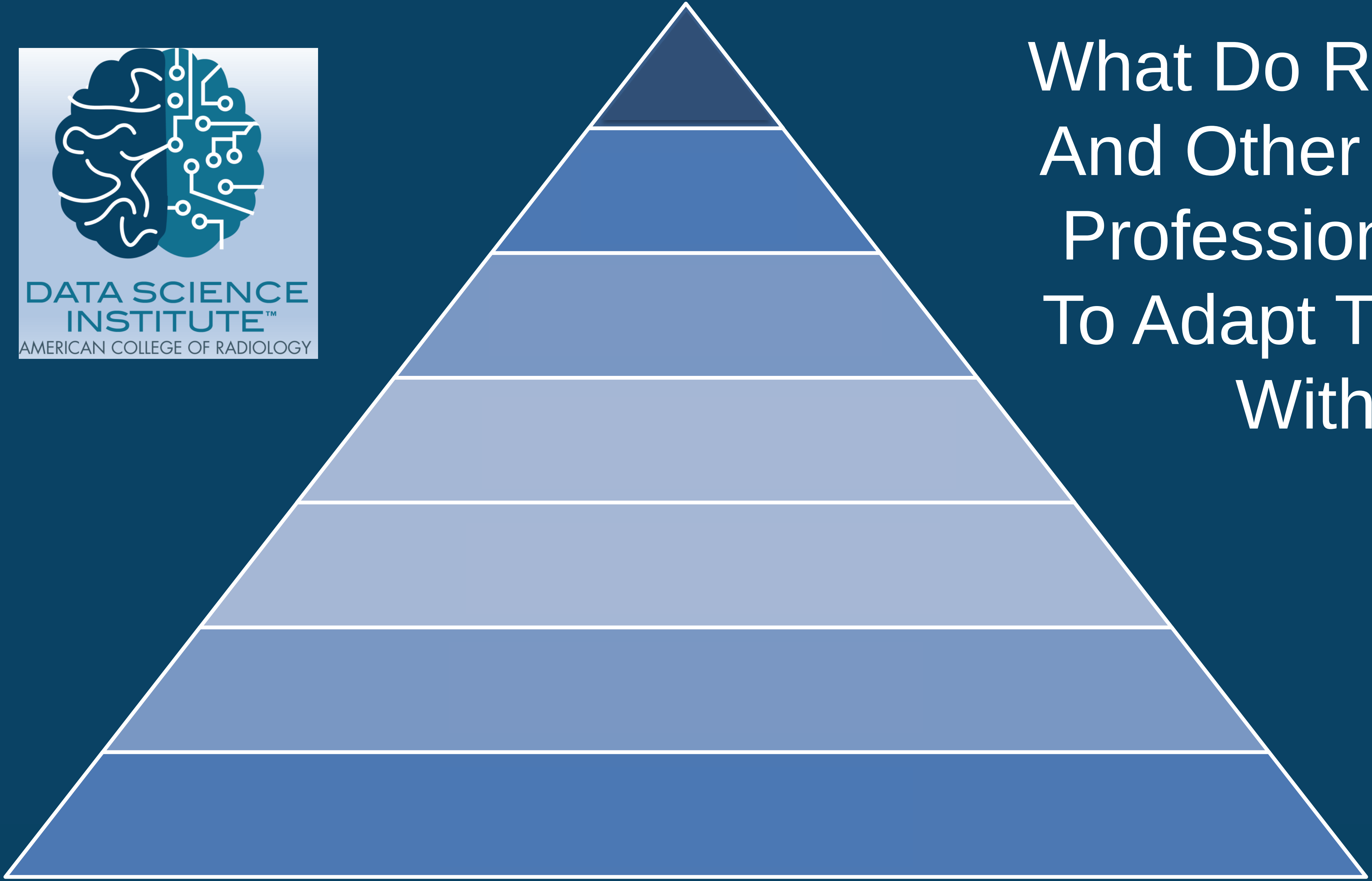
**If we want AI to be useful in clinical practice….**

**How do we accelerate the creation of AI?**

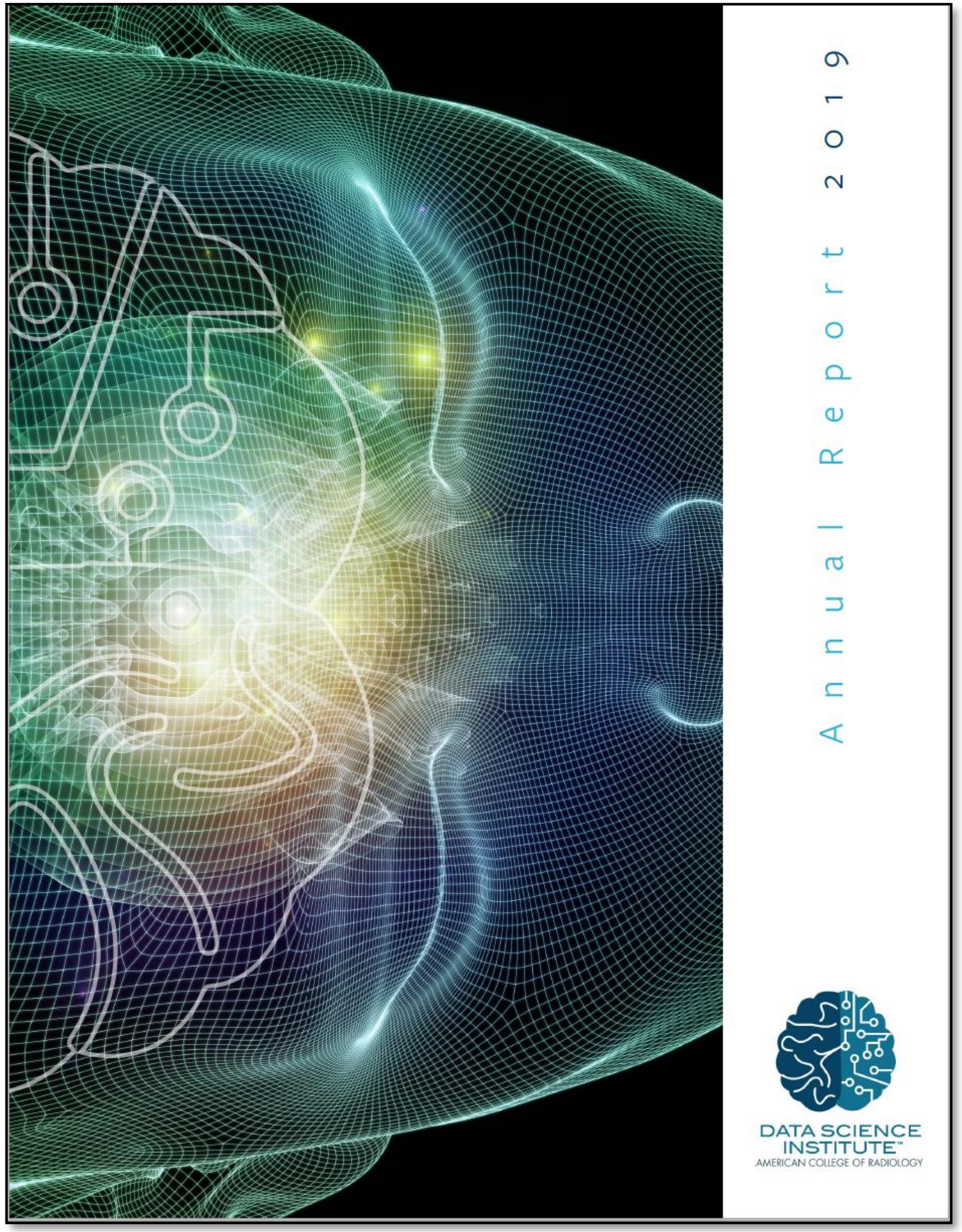
- ✓ **Radiologists**
- ✓ **Patient data**
- ✓ **Data scientists**
- ✓ **Commercial developers**

## DEMOCRATIZATION OF AI

# What Do Radiologists And Other Radiology Professionals Need To Adapt To A Future With AI?



# DEMOCRATIZE AI: ENABLE ALL RADIOLOGIST, PATIENT (DATA) AND DATA SCIENTIST PARTICIPATION



Annual Report 2019

DATA SCIENCE INSTITUTE™
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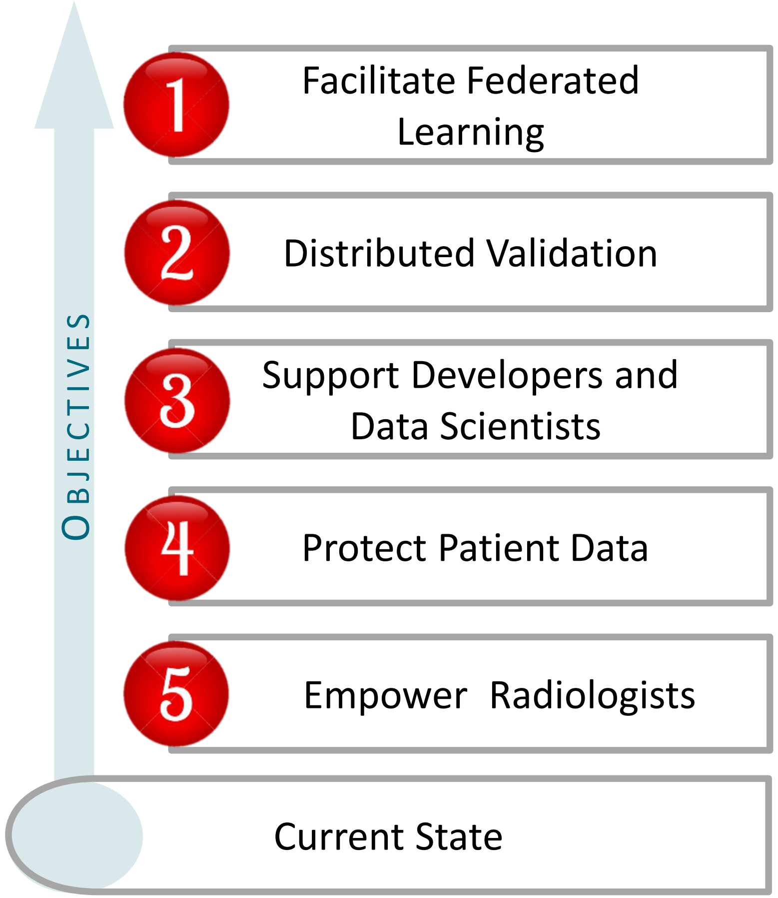
## ACR DSI STRATEGY FOR 2020



OBJECTIVES

1 Facilitate Federated Learning

2 Distributed Validation

3 Support Developers and Data Scientists

4 Protect Patient Data

5 Empower Radiologists

Current State

# ACR DATA SCIENCE INSTITUTE

## AI-LAB

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QUALITY IS OUR IMAGE

## CONNECTING THE AI ECOSYSTEM