May 30, 2018

# 2018 Data Science Summit: The Economics Of Artificial Intelligence In Healthcare

## Regulation, Payment And The AI Ecosystem

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# Data Science and Artificial Intelligence: Hype Versus Reality

# Will AI Be The Demise Of Radiologists?

ORIGINAL ARTICLE ACR 2016

CrossMark

## The End of Radiology? Three Threats to the Future Practice of Radiology

*Katie Chockley, BA*[a], *Ezekiel Emanuel, MD, PhD*[a]

**Abstract**

Radiology faces at least three major, potentially fatal, threats. First, as care moves out of the hospital, there will be a
for imaging. More care in patients' homes and in other nonhospital settings means fewer medical tests, including
payment reform and, in particular, bundled payments and capitation mean that imaging will become a cost rather than a
These shifts in provider payment will decrease the demand for imaging and disrupt the practice of radiology. Potentially, the ultimate
threat to radiology is machine learning. Machine learning will become a powerful force in radiology in the next 5 to 10 years and could
end radiology as a thriving specialty.

**Key Words:** Machine learning, payment reform, technology, future of health care

*J Am Coll Radiol 2016;13:1415-1420.* 

# Will AI Be The Demise Of Radiologists?

THE POLITICAL SCENE NOVEMBER 28, 2016 ISSUE

## OBAMA RECKONS WITH A TRUMP PRESIDENCY

*Inside a stunned White House, the President considers his legacy and America's future.*

**By David Remnick**

All of those things accelerate growth, give you more of a runway. But at some point, when the problem is not just Uber but driverless Uber, when radiologists are losing their jobs to A.I., then we're going to have to figure out how do we maintain a cohesive society and a cohesive democracy in which productivity and wealth generation are not automatically linked to how many hours you put in, where the links between production and distribution are broken, in some sense. Because I can sit in my office, do

# Geoff Hinton - October, 2016: "What do you think is the most exciting work to come?"

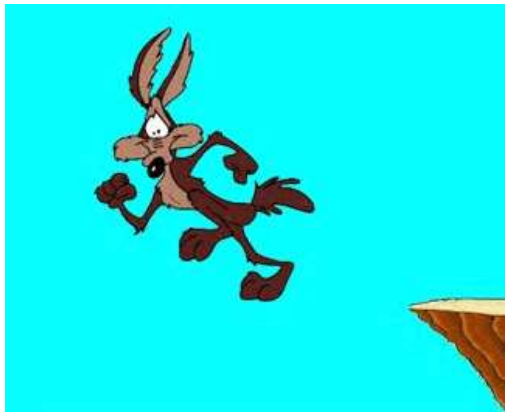
## Geoff Hinton: "The Father of Deep Learning"

"Let me start by just saying a few things that seem obvious.

I think **if you work as a radiologist, you're like the coyote that's already over the edge of the cliff that hasn't yet looked down, so he doesn't yet realize there's no ground underneath him.**

**People should stop training radiologists now. It's just completely obvious that within 5 years deep learning is going to do better than radiologists**, because it's going to be able to get a lot more experience.

It might be 10 years, but we've got plenty of radiologists already."




"The role of radiologists will evolve from doing perceptual things that could probably be done by a highly trained pigeon to doing far more cognitive things."

# Data Science and Artificial Intelligence: A Rapidly Emerging Megatrend in Business and Society


Hype?

**Yes.**

Real Substance and Impact?

**Yes.**

# Moving AI Tools To Clinical Practice: Defining A Radiology AI Ecosystem

CLINICAL PRODUCTS

Mechanisms to integrate and monitor, AI models in clinical practice – using real world experience

Standardized methods for AI model validation

NEEDS

CHALLEN ES And OPPO TUNITIES

ALGORITHMS

Bring great ideas and clinical needs together

Standa ethods to annotate, or aggregate, data for AI model training and testing

AI USE CASE

CLINICAL DATA

IDEAS

# ACR DSI Mission

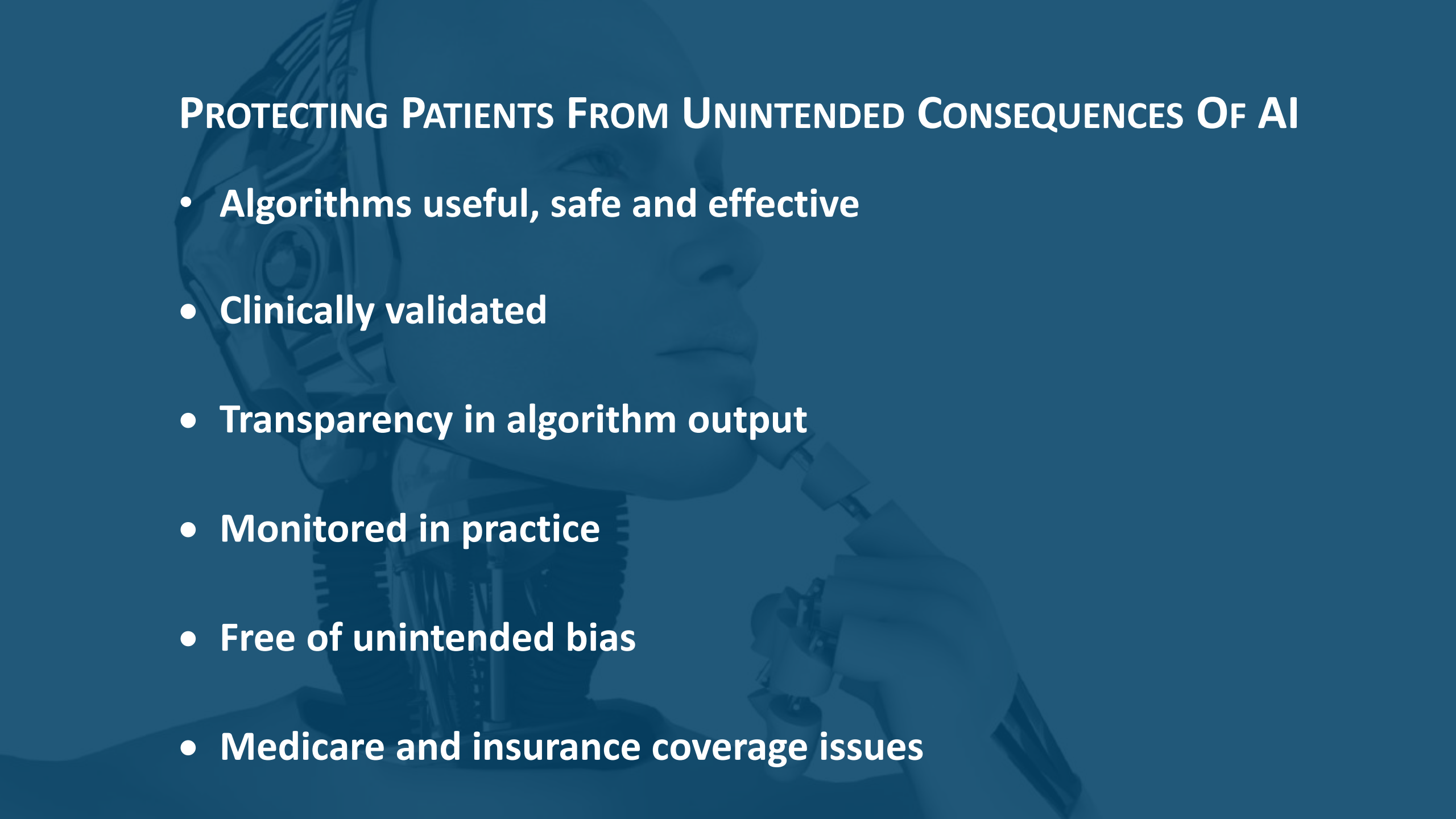
http://acrdsi.org/media-library/pdf/Strategic-Plan-Final.pdf

**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

**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



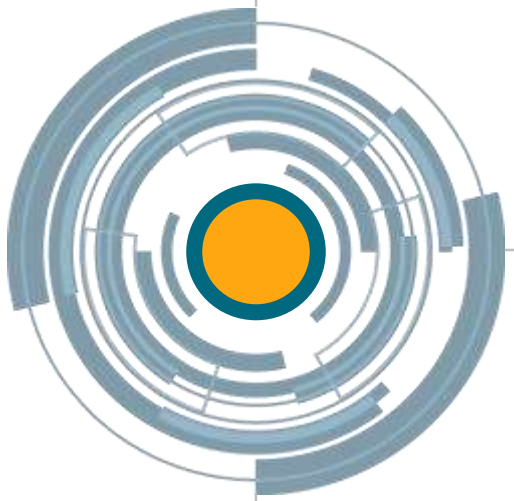
# Protecting Patients From Unintended Consequences Of AI

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

# 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

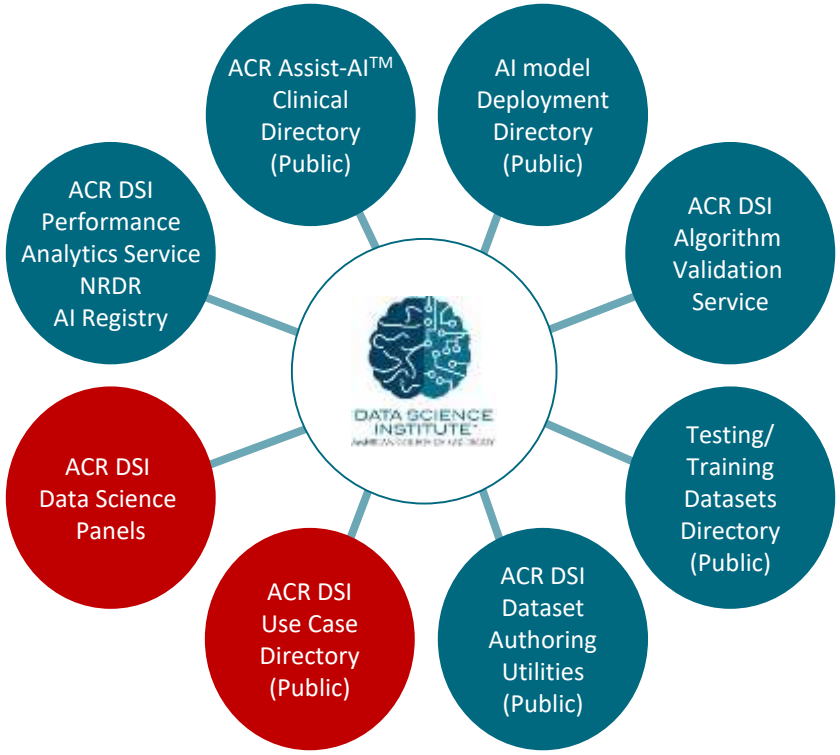
- Patient care and safety
  - Detection and prioritization of potentially critical results
  - Radiation dose optimization
  - Pre-test probability assessment of patient risk of positive findings and contrast reactions
  - Cancer and mammography screening
  - Automatic protocoling of studies from EMR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



- Radiologist and practice optimization for productivity and quality
  - Automated transcription of audio narration
  - Automated population of structured reports
  - Optimization for case assignment across teams
  - 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

## The Radiology AI Ecosystem

### Ideas To Clinical Practice




## Radiology's Value Proposition

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

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DATA SCIENCE INSTITUTE™
TOUCH-AI

### Use Case Development

- Use case authoring platform
- Human language to machine language

# The United States Regulatory Process: Challenges For Artificial Intelligence

AuntMinnie.com

C-MIMI: FDA decision paves the way for imaging AI

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956.96 0.37% S&P 500 ▲ 2557.64 0.18% Nasdaq ▲ 6624.00 0.28% U.S. 10 Yr ▼ -7/32 Yield 2.301% Crude Oil ▲

THE WALL STREET JOURNAL.

THE EXPERTS | HEALTH

## How the FDA Should Regulate Medical AI Systems

IEEE SPECTRUM

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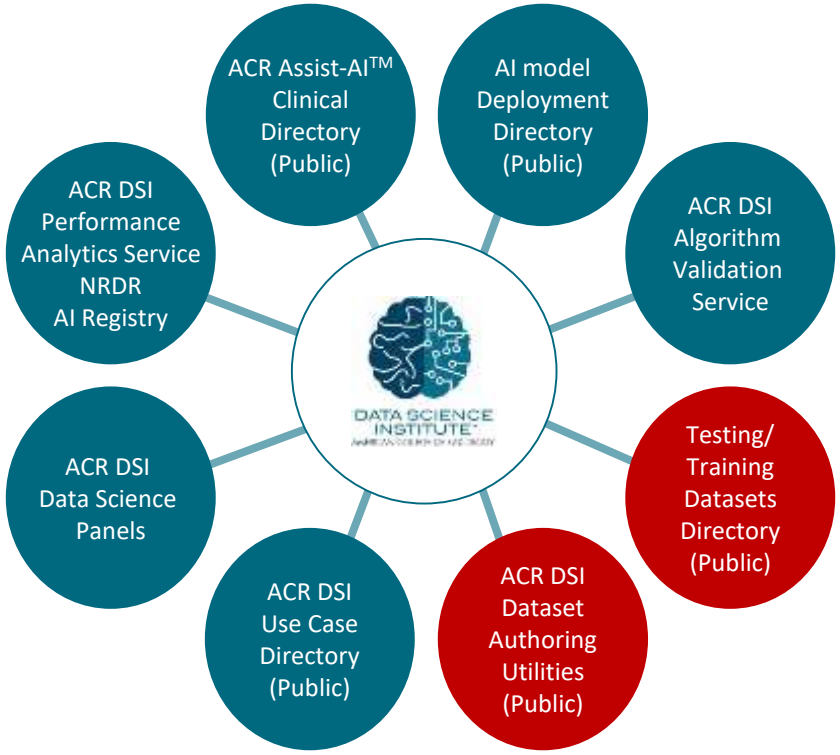
## FDA Assembles Team to Oversee AI Revolution in Health

By Jeremy Hsu

Posted 29 May 2017 | 13:00 GMT

## Making Datasets For AI Training Available To Developers



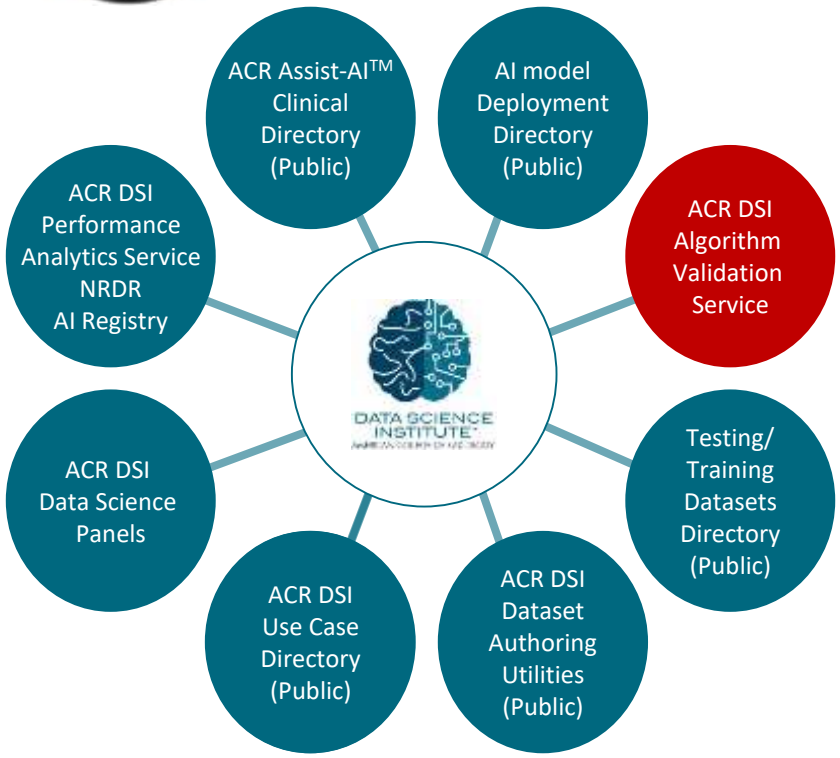

## ACR DSI Data Access Directory

## Specifications For Data Access

- **Standardized definitions and data elements allow multiple institutions to use these standards to create datasets that developers can use for algorithm training and testing.**
- Specifications include standardized tools and methods for image annotation.
- **Using multiple sites as data sources for these datasets provides technical, geographic and patient diversity to prevent unintended bias in algorithm development.**
- Allows more individuals and institutions to participate in AI development.
- The ACR DSI will house a freely available **public directory** of institutions that have created these datasets around ACR DSI Use Cases to inform the developer community.

# Validating AI Algorithms

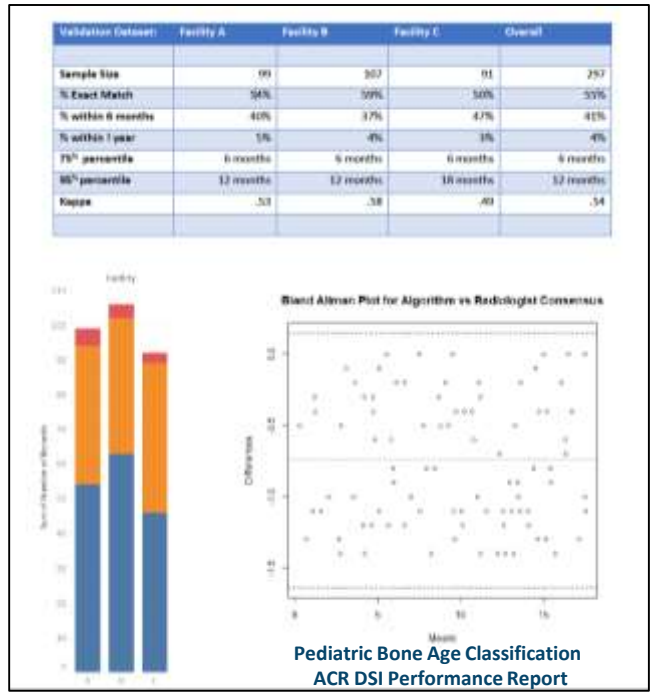
## ACR Data Science Institute Certified Algorithms



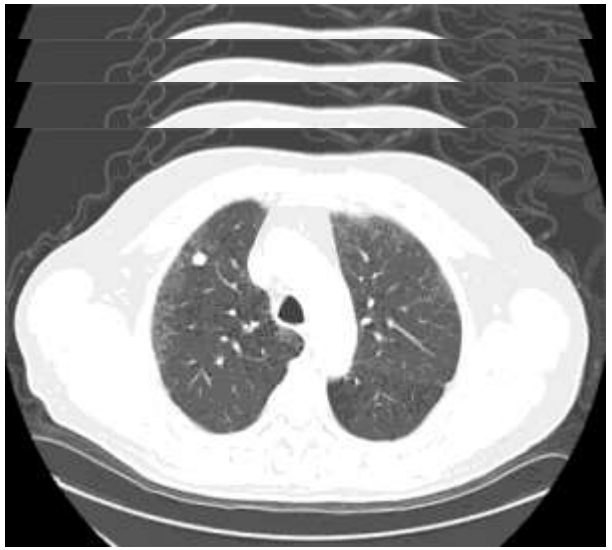

**Specialty society certification of AI algorithms provides an "honest broker" partnership with radiology, developers and government regulators.**

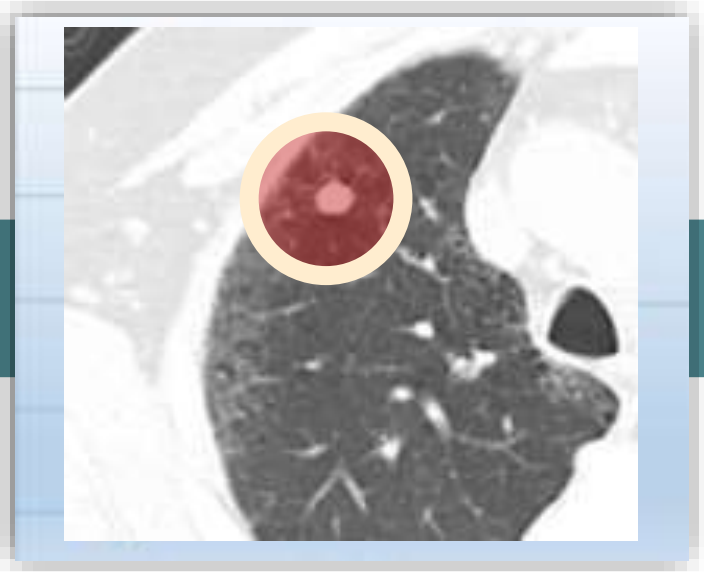
## Specifications For Algorithm Validation

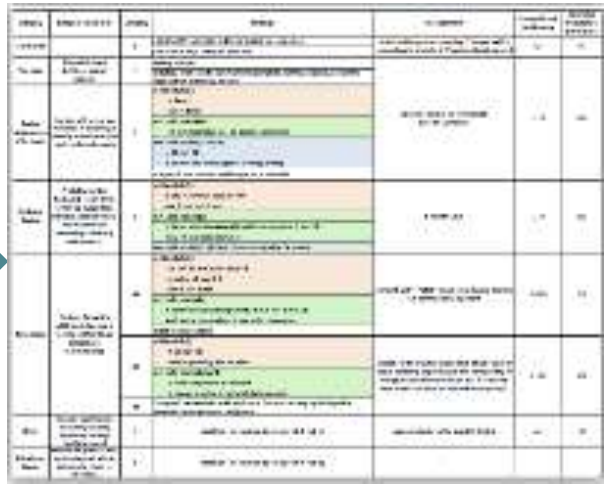
- Centralized assessment of algorithm performance will be performed according to the statistical metrics metrics specified in the use case using **novel datasets**.
- These validation datasets are created at **multiple institutions to ensure geographic, technical and patient diversity** within the validation dataset.
- **Multiple readers and guidelines for data quality to ensure "ground truth"** consistency between sites, consistent metrics for measuring performance across sites and standards to **protect developers' intellectual property, ensure patient privacy and diminish bias.**
- Reports are generated for developers to use in the FDA pre-market process.


Pediatric Bone Age Classification
ACR DSI Performance Report

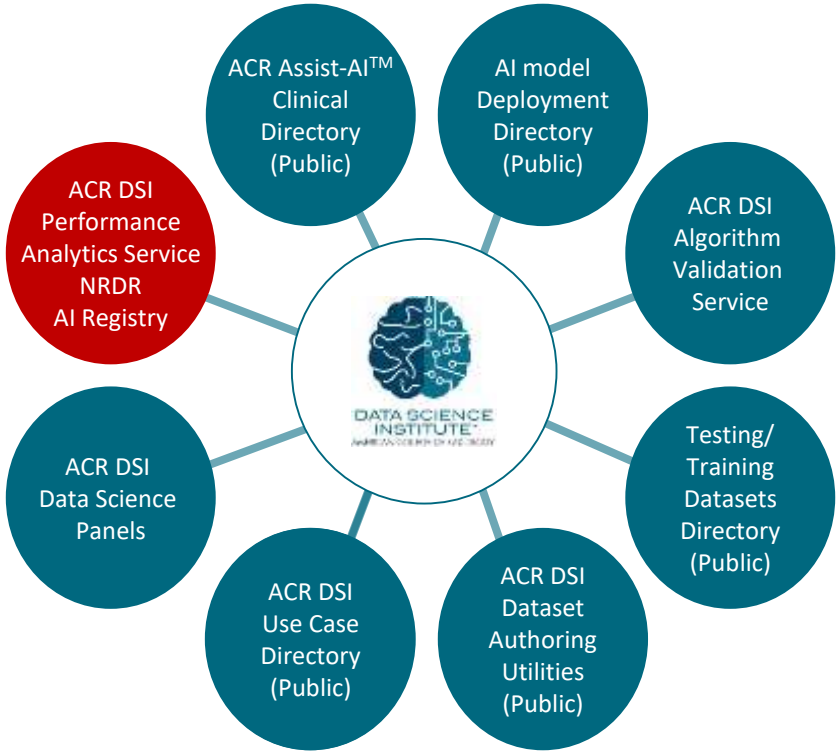
# The Importance Of Transparency







# Monitoring Algorithm Performance In Clinical Practice




**AI Monitoring Program**

- Patient safety and FDA surveillance
- Algorithm transparency and radiologist acceptance
- Developer improvements

## Specifications For Monitoring In Clinical Practice

- Data elements in each use case specify how the algorithm will be monitored in clinical practice.
- **Radiologist input is gathered as the case is being reported**, and if the radiologist does not incorporate the algorithm inferences into the report, this change is captured in the background by the reporting software. If the radiologists agrees changes the output of the agrees with algorithm, this is also noted and transmitted to the registry.
- **Specified metadata about the exam such as equipment vendor, slice thickness and exposure exposure are also transmitted to the registry.**
- Algorithm assessment **reports include algorithm performance metrics** and the exam parameters affecting the algorithms' performance.
- These reports are used by the **developers to report to the FDA and for algorithm improvement.**

# Monitoring Algorithm Performance In Clinical Practice


## AI Monitoring Program

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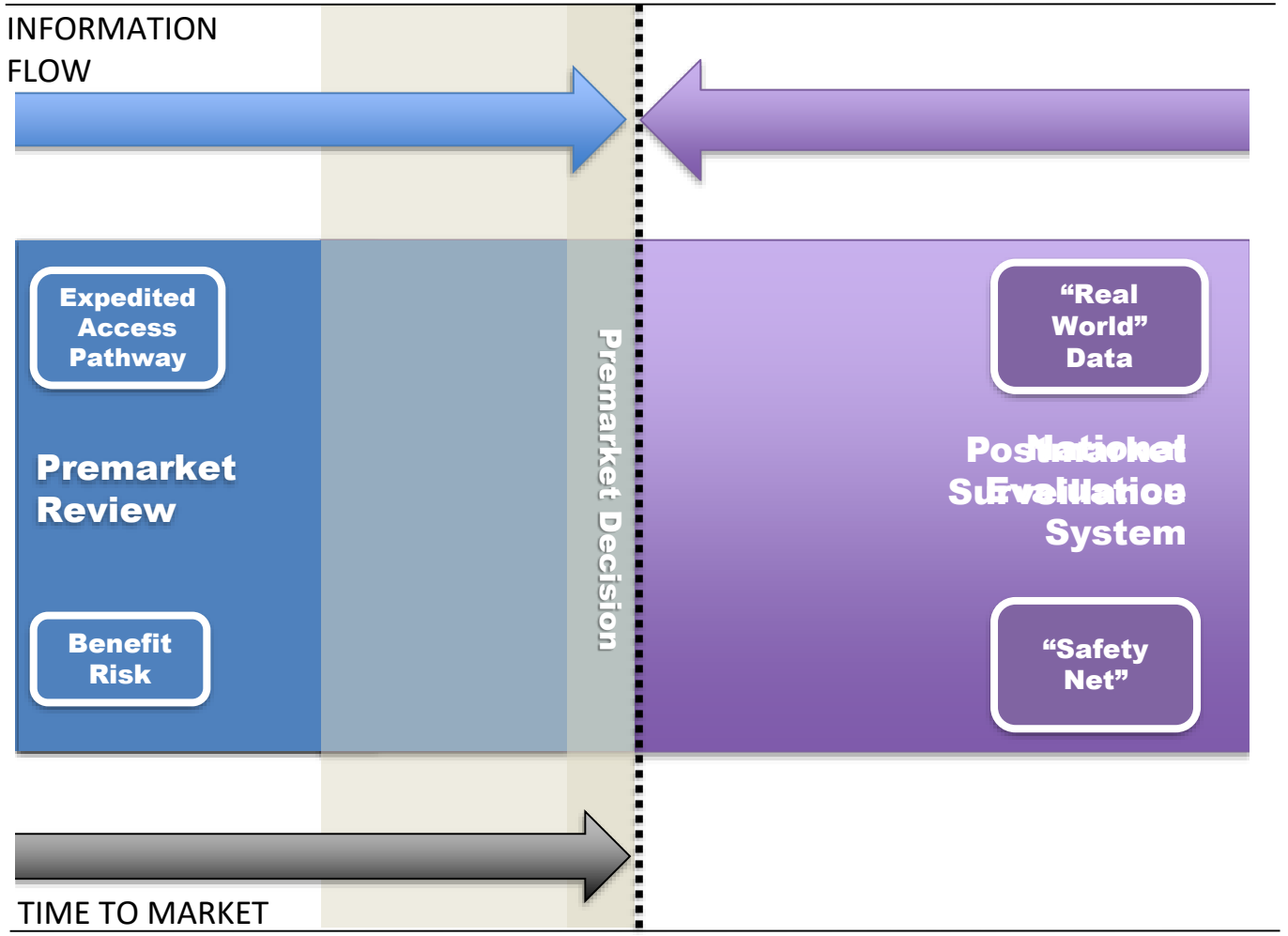
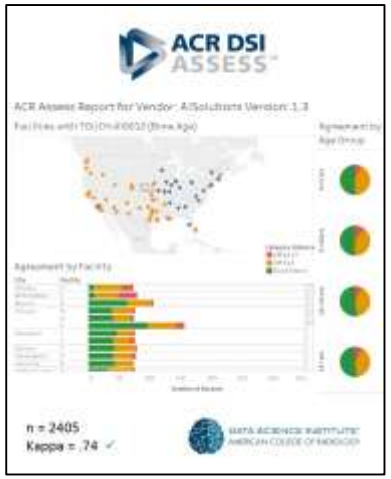
## Specifications For Monitoring In Clinical Practice




Courtesy Greg Pappas, FDA

# Monitoring Algorithm Performance In Clinical Practice






**Raw Data Captured In Reporting Software And Transmitted To AnAI Registry**

**Raw Data From Reports And Modalities Aggregated In Registry**

**AI Algorithm Assessment Reports For Each Developer And Site**

## Working Example of Monitoring Algorithm Performance Using An AI Data Registry

- This example is from a pediatric bone age classification algorithm. **The reporting software, PACS or the modality transmits information about the radiologist's agreement or disagreement with the algorithm along metadata about the examination to the AI data registry.**
- The raw data are complied in the registry and reports are aggregated and **developer specific reports** are generated for developers for use in FDA post-market surveillance reports and to improve the algorithm.
- **Site reports** are provided to provide AI performance metrics to the clinical practices.

# FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



## Office of Science And Engineering Labs

ACR DATA SCIENCE INSTITUTE Certify-AI

ACR DATA SCIENCE INSTITUTE Assess-AI

# Novel / Future Pathways For FDA Approval Of Software Devices

- **Software as a Medical Device (SaMD)**
  - 21st Century Cures Act provides guidance of medical device software
  - Some software applications may not require FDA regulation
  - FDA is developing guidance for implementation and will that guidance include AI?
- **Medical Device Development Tools Initiative (MDDT)**
  - Recent FDA Guidance August 2017
  - "Method, material, or measurement used to assess the effectiveness, safety, or performance of a medical device… qualified for use in device evaluation and to support regulatory decision-making within a specified context of use"

# Novel / Future Pathways For FDA Approval Of Software Devices

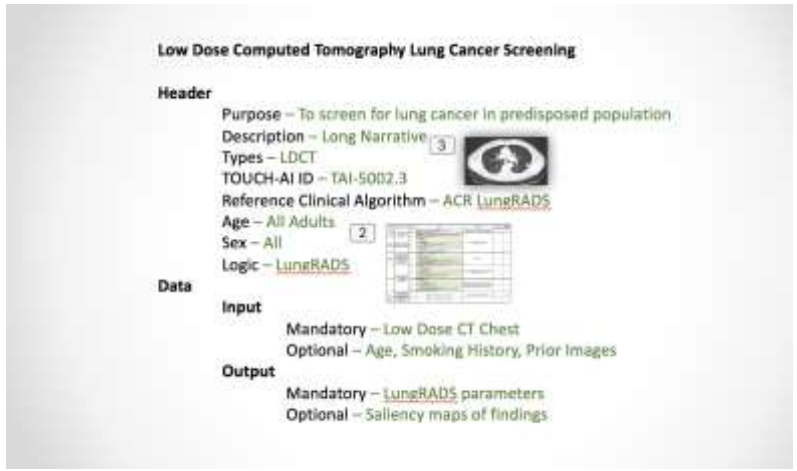
- **National Evaluation System For Health Technology (NEST)**
  - Intended to shorten the time to market for new technology health care products by developing a system for more robust post-market surveillance
  - "Bring life sustaining, health promoting devices to patients more quickly"
  - "Improve the ability to detect safety issues by moving to more active surveillance"
  - "Successfully and efficiently harness data from the diverse set of real-world evidence – digital information collected from clinical experience in registries and similar tools – creating the necessary infrastructure for a national evaluation system for medical devices"

**"By leveraging real world data collected as part of routine clinical care, our nation and the public will more fully realize the potential of the digital revolution for the device space"**

# ACR DSI Activities And Relationships: Industry

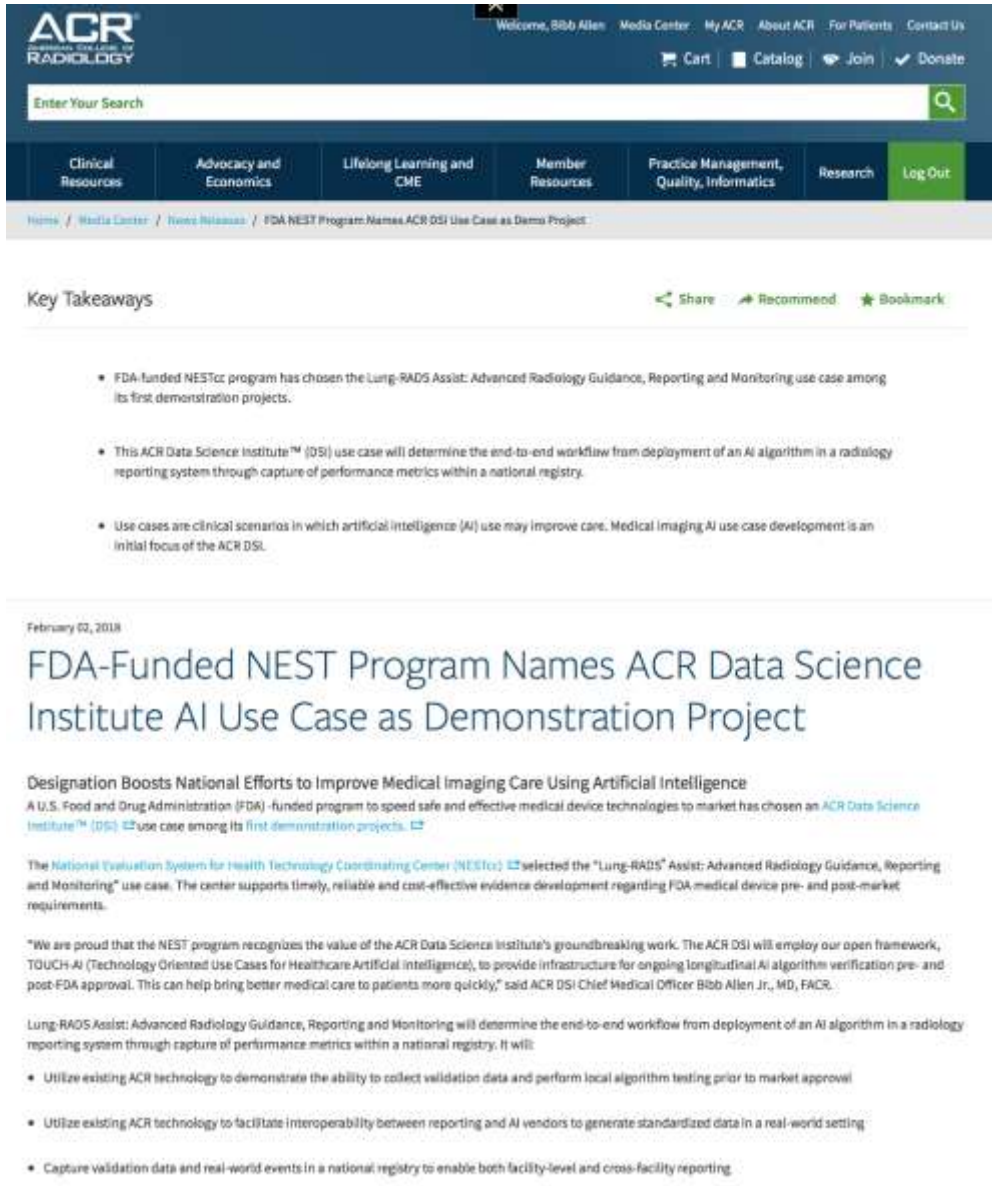
| | | | | | |
|---|---|---|---|---|---|
| Use Cases | Content | Validation | Implementation | Regulatory | Safety |
| Economics | Standards | Education | Facilitation | Legal | Ethical |

## Food and Drug Administration




**ACR DSI and FDA NEST Demonstration Project**

- Pre-market review
  - ACR CERTIFY-AI as a Medical Device Development Tool (MDDT)
- Post-market surveillance
  - ACR ASSESS-AI as a National Evaluation System for Health Technology (NEST)




# Academic Partners And Industry Partners

NESTcc will evaluate program for using real word data to assess AI algorithms

Individual components of the validation process will support applications for MDDT

# ACR DSI Activities And Relationships: Industry

| | | | | | |
|---|---|---|---|---|---|
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| Economics | Standards | Education | Facilitation | Legal | Ethical |

## Moving AI From Concept To Clinical Practice

**DSI and Healthcare AI Industry**

Services to assist industry deliver successful AI solutions to clinical practices

- AI Use Case Development (ACR TOUCH-AI)
- AI model Certification (ACR CERTIFY-AI)
- AI model Integration (ACR ASSIST)
- AI model Assessment (ACR DSI ASSESS and ACR AI REGISTRY)

## SUMMARY

- Useful
- Safe and effective in clinical practice
- Performance monitored and improvements made based on real world data
- Transparency
- Ensuring diversity and preventing unintended bias

# THANK YOU!