AI In Radiology: Now and in the Future

Toward an Integrated AI Ecosystem

AAPM
July 2018

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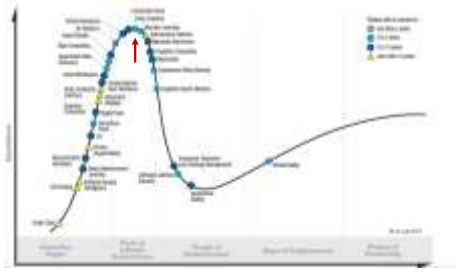
EVP for Technology

DATA SCIENCE INSTITUTE
AMERICAN COLLEGE OF RADIOLOGY

CURRENT LANDSCAPE

Gartner Hype Cycle - 2017



Artificial Intelligence


ORIGINAL ARTICLE

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

OBAMA RECKONS WITH A TRUMP PRESIDENCY

By David Remnick

All of these 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, to 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.**

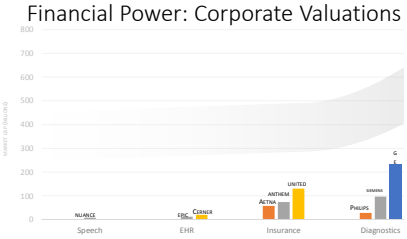
People should stop training radiologists now. It's just completely obvious that within 5 years deep learning is going to do better than radiologists, because it's going to be able to get a lot more experience.

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

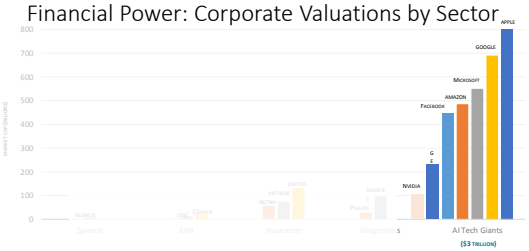
"The role of radiologists will evolve from doing perceptual things that could probably be done by a highly trained pigeon to doing far more cognitive things."

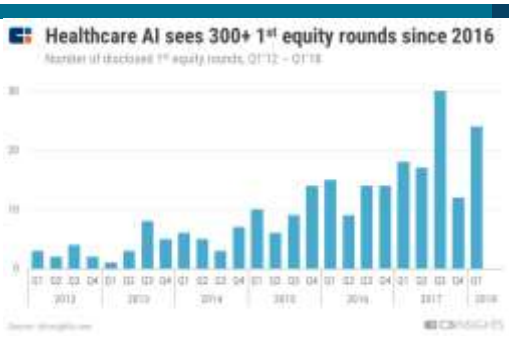
Data Science and Artificial Intelligence: A Rapidly Emerging Megatrend in Business and Society

Financial Power: Corporate Valuations



Financial Power: Corporate Valuations by Sector





Examples of Recent FDA Clearances

Company	Software	Purpose	Month Approved
Arterys	Cardio DL	perform editable ventricle segmentation (cardiac MRI)	Jan-17
iCAD	PowerLook Tomo Detection	tomosynthesis breast cancer detection and workflow solution	Mar-17
EnsoData	EnsoSleep	analyze sleep quality and aide in diagnosis of sleep or respiratory-related sleep disorders	Apr-17
Quantitiative Insights	QuantX	evaluation of breast abnormalities	Jul-17
Butterfly Network	Butterfly iQ	Provide ultrasound imaging by way of Iphone application	Oct-17
Arterys	Oncology AI suite	Measure and track tumors or potential cancers in liver (MRI and CT) and lung (CT)	Feb-18
Viz.ai	Proactive Stroke Pathway	Detect and directly alert the on-call stroke physicain about suspected large vessel occulusions (CTA)	18-Feb
IDx	Idx-DR	Identify patients with "more than mild" diabetic retinopathy	Apr-18
Densitas	DENSITAS|density	produce breast density reports (digital mammo)	Apr-18
Imagen	OsteoDetect	Detect wrist fractures in adult patients (XRAY)	May-18
Zebra Medical Vision	Cardiovascular	Automate coronary calcium scoring (Chest CT)	Jul-18

AI

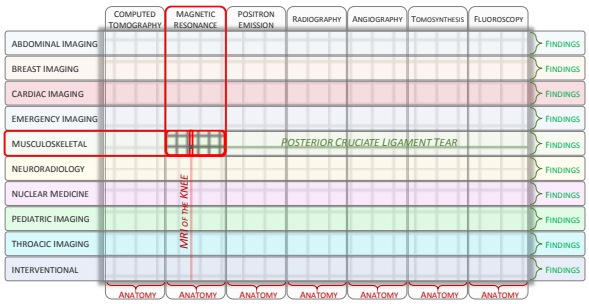
What's fueled the growth in AI applications in the last 5 years?

These advances in technologies and growth in data have spurred:

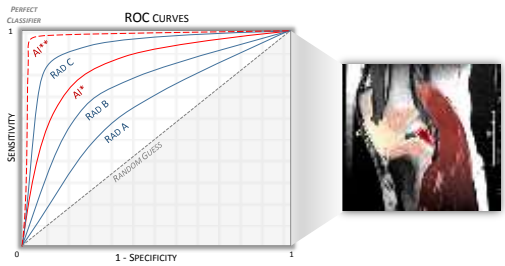
- Powerful new applications for established and evolving AI techniques (e.g., deep learning)
- Advances in hardware led by GPU Computing
- A global, online community of AI practitioners sharing advances *(e.g. ImageNet)*
- Open source software from the community and tech giants (e.g., Google's TensorFlow, Amazon/Microsoft's Gluon)
- *Huge* AI spending by investors and tech companies who see AI as a significant disruptor

CHALLENGES

AI IN DIAGNOSTICS



AI IN DIAGNOSTICS



AI IN DIAGNOSTICS

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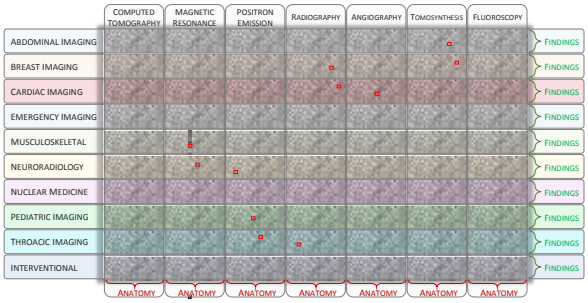
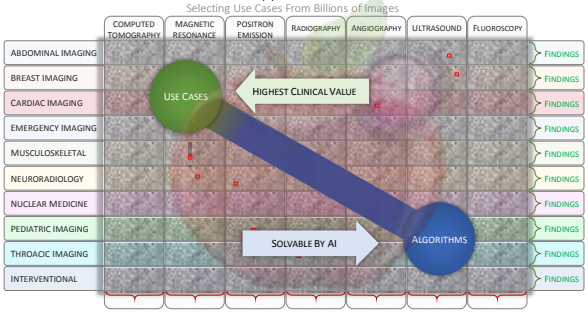


Endless Opportunities For AI

Selecting Use Cases From Billions of Images



Well Characterized Data Sets

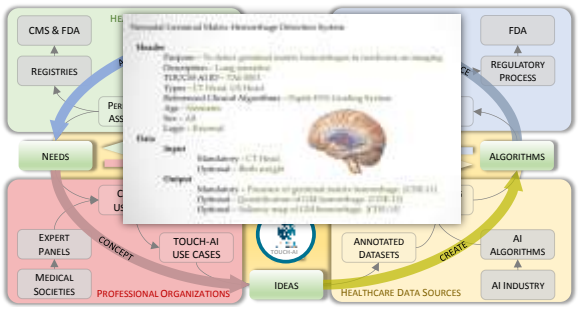
The Future of AI Depends on a Huge Workforce of Human Teachers

*The market for humans training AI could hit **$5 billion** in five years.*

– McKinsey Global Institute

$5B/Year just for tagging!

AI Ecosystem



ACR DATA SCIENCE INSTITUTE

The Role of the ACR

- Founded in 1924, the American College of Radiology has been at the forefront of radiology evolution
- More than 38,000 radiologists, radiation oncologists, nuclear medicine physicians and medical physicists.
- Core Purpose:

  To serve patients and society by empowering members to advance the practice, science and professions of radiological care.

QUALITY AND SAFETY
REGISTRIES AND ACCREDITATION
APPROPRIATENESS CRITERIA
TECHNICAL STANDARDS AND PRACTICE PARAMETERS

EDUCATION
AMERICAN INSTITUTE FOR RADIOLOGIC PATHOLOGY
ACR EDUCATION CENTER
ONLINE LEARNING

INFORMATICS
TECHNOLOGY STANDARDS - DICOM
CLINICAL DECISION SUPPORT
COMPUTER ASSISTED REPORTING

ECONOMICS
CPT CODING
VALUATION OF PHYSICIAN SERVICES AND PRACTICE EXPENSE
MACRA METRICS AND PAYMENT MODELS

GOVERNMENT RELATIONS
CONGRESS
HHS

Radiology- Leading Technology Innovation

Improving care for 100+ years by embracing new technologies and approaches to medicine.

Since 1895, to name just a few innovations we've adopted…

- X-Ray
- Contrast Agents
- Ultrasound
- Nuclear Medicine
- Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Interventional Radiology (IR)
- Evidence-Based Clinical Guidelines
- Picture Archiving and Communications Systems (PACS)
- Computerized Voice Recognition and Transcription
- Electronic Health Records
- Value-Based Medicine
- *Artificial Intelligence & Data Science*

AI and Next Generation Technology

- The ACR Data Science Institute established May 2017
- Core Purpose:

  ACR Data Science Institute (DSI) empowers the advancement, validation, and implementation of artificial intelligence in medical imaging and the radiological sciences for the benefit of our patients, society, and the profession

DATA SCIENCE INSTITUTE
AMERICAN COLLEGE OF RADIOLOGY

ACR DSI Mission

Ensure the value of medical imaging 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 validation of algorithms

Educate radiologists, other physicians and all stakeholders about AI and the ACR's role in data science for the good of our patients

ACR Data Science Institute

Possible Applications of AI in Medical Imaging

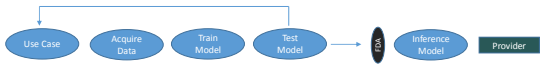
- Image interpretation
  - Quantification of findings
  - Quantified comparison between multiple studies
  - Multiparametric analysis across multiple modalities
  - Volumetric analysis
  - Textural analysis
  - Automation of Region Of Interest targeting and measuring
- Patient care and safety
  - Detection 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

- Imaging Physician and 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

Challenges – AI at Scale

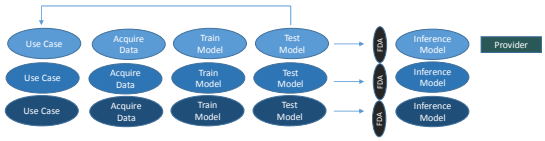
Considerations

Challenges in the AI Life Cycle



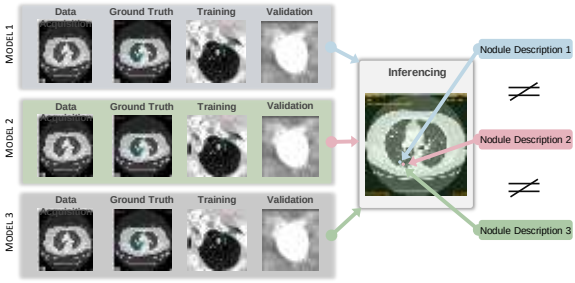
- How generalizable is the inference model?
- Is there hidden sample bias?
- What is the appropriate threshold for clinical use?
- How do we ensure ongoing performance?
- How robust is the model to changes in the environment?

Challenges in the AI Life Cycle

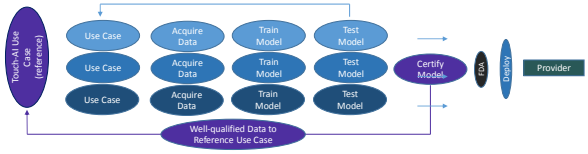


- Do models solving the same problem yield consistent, comparable outputs?
- Does the customer understand potential differences in the implicit use cases?
- How do we establish standard, consistent performance metrics?

Lung Nodule Detection Algorithms

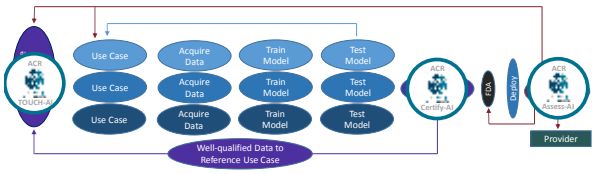


Establish Standards & Certification Criteria



- Establish common expectations for addressing specific clinical scenarios (e.g. BI-RADS)
- Create well-qualified data sets that address explicit concerns about bias
- Define standard performance metrics that establish a quality threshold
- Validate models that address a specific clinical condition against these standards

Establish Standards & Certification Criteria



- Monitor Ongoing Performance to Ensure Ongoing Quality and Safety
- Provide Monitoring for Regulators
- Continuous Feedback Loop to Vendors and Content Creators
- Match continuous learning with continuous assessment, monitoring, and feedback

TOUCH-AI

Detecting Lisfranc Joint Injury

Lisfranc joint injury is common and easily missed. AI that segments and detects abnormality would prove valuable and help reduce false negative rate, patient risk, and medical-legal risk for the radiologists.

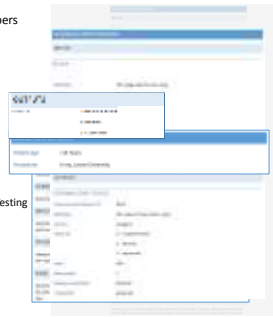
DSI Use Cases Clinical Guidance for Developers

Example: Lisfranc Joint Injury

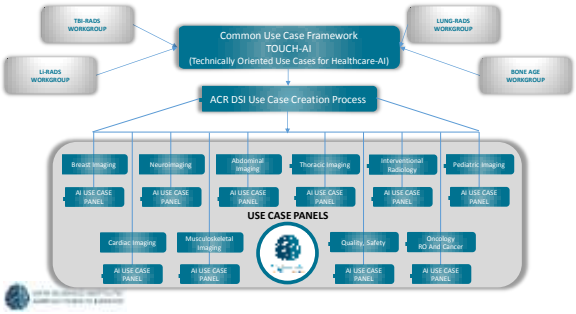
Expected Clinical Inputs/Outputs

Conditions for launch

Data Considerations for Training/Testing

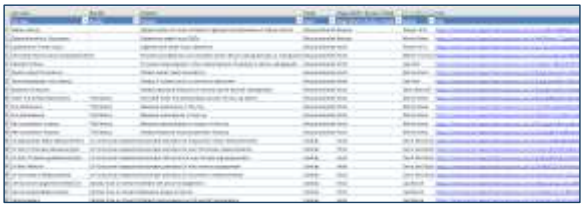


ACR DSI Use Case Development – ACR DSI Use Case Panels



TOUCH-AI USE CASES

- Approximately 50 Use Cases in Draft Form
- Currently Under Industry Review
- Anticipated Release Fall 2018



VALIDATION & REGULATORY CONSIDERATIONS

REGULATORY CONSIDERATIONS (FDA)

- Objectives
  - Protect the public health
  - Help speed safe and effective innovation
- Medical Device Classification
  - Based on Risk
  - Based on Intended Use (what does your label say)
  - Based on Indications for Use (under what conditions will the product be used)

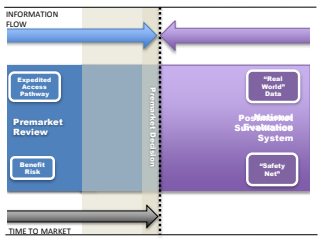
Where Does AI fall?

- CADe - Detection
  Devices intended to identify, mark, highlight, or in any other manner direct attention to portions of an image, or aspects of radiology device data, that may reveal specific abnormalities during interpretation of patient radiology images or patient radiology device data by the clinician
- CADx – Diagnosis
  Devices go beyond CADe and include those that are intended to provide an assessment of disease or other conditions in terms of the likelihood of the presence or absence of disease, or are intended to specify disease type (i.e., specific diagnosis or differential diagnosis), severity, stage, or intervention recommended
- 9/17 – Ruling classified CADx with AI as Class II. Vendors with similar products can apply for 510k clearance and avoid Pre-Market Approval (PMA)
- 6/18 – Request for Comment on Plan to Move Remaining CADe devices to Class II

Opportunities to Accelerate the Process

- Software as a Medical Device (SaMD)
  - 21st Century Cures Act provides guidance of medical device software
  - FDA is developing guidance for implementation
- Medical Device Development Tools
  - Promotes innovation in medical device development and regulatory science to help bridge the gap between research of medical devices and the delivery of devices to patients.
- 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

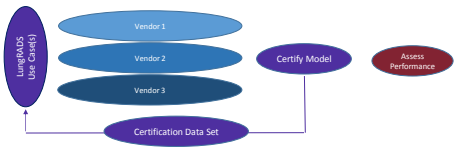
Establishing NEST Will Enable The Pre-Post Market Shift



Graphic courtesy of Greg Pappas, Assistant Director FDA NEST

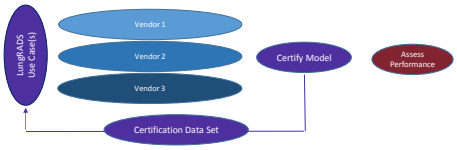
NEST Demonstration Project: Lung-RADS Assist

LungRads Assist - Demonstration Project



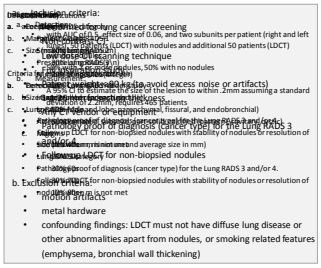
Use Case

LungRads Assist - Demonstration Project

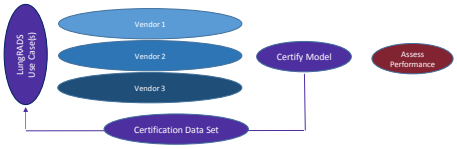


Certification Data Sets (e.g. LDCT for Lung Screening)

- Inclusion/Exclusion Criteria
- Sample Size (number of cases, % positive)
- Data Dictionary
- Dataset Stratifications
- Annotation



LungRads Assist - Demonstration Project



Threshold Considerations for Certification

Evaluation Method

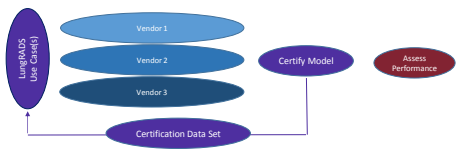
Algorithm	Examples	Eval Method
Classification	*RADS, Nodule Type	AUC, logloss, MeanFScore
Segmentation	Nodule or organ seg.	DICE Coefficient
Estimation	Nodule Size, #, midline Shift	RMSE, RMSLE, NWRMSLE
Location	Nodule Detection	Dice Coefficient

Risk Assessment

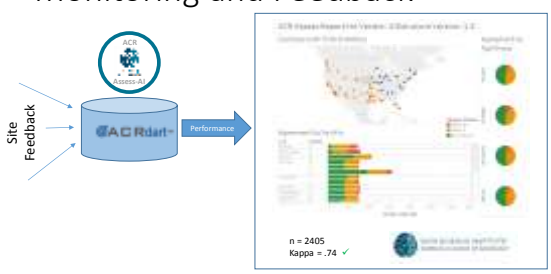
Clinical Use	Risk
Prioritization in Work list	Low
Detection and Classification	Med
Diagnosis	High

Use Case	Evaluation Method	Possible Evaluation Outcome	Certified Use (FDA)	Possible Result
Location of nodule	Dice Coefficient	.90	Detection	Pass
Size of nodule	RMSE	5.6%	Detection	Pass
Attenuation of nodule	ROC AUC	.85	Detection	Pass
Lung-RADS category	ROC AUC	.80	Detection	Pass

LungRads Assist - Demonstration Project

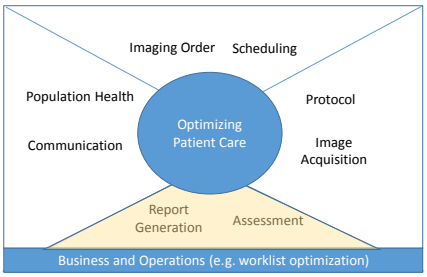


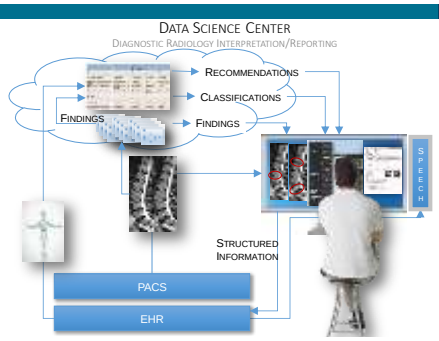
Monitoring and Feedback



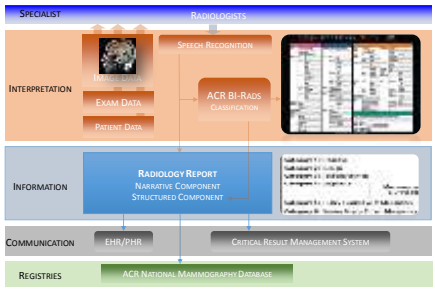
WORKFLOW INTEGRATION

AI Opportunities Across the Imaging Life Cycle

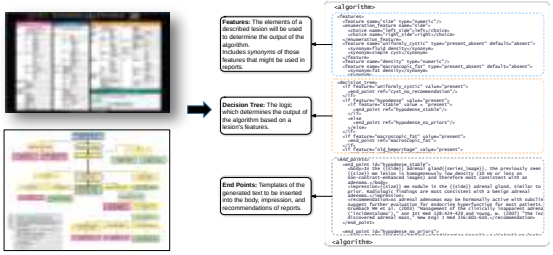




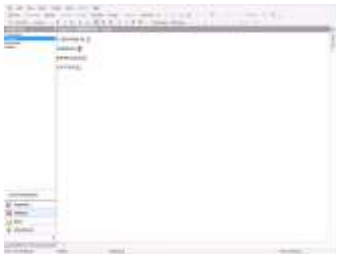
Radiology Reporting Without Integrated CDS

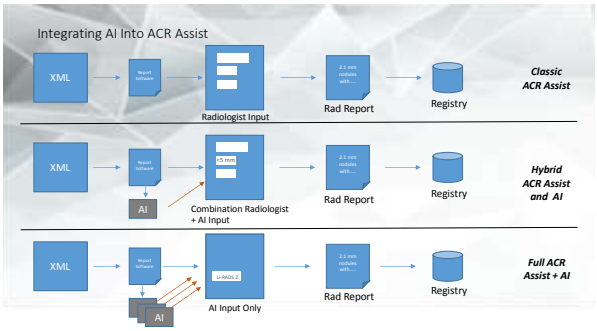


Encode Content via Open CAR/DS



Radiology Reporting with CDS/AI





Summary

- **AI will persistently and pervasively enhance all aspects of radiology**
  - It's *not* about Human vs AI.
  - It is about Human augmented by AI vs. Human working *without* AI
- **AI will expand today's decision-making capabilities**
  - Earlier and better detection leads to better treatment options and improved outcomes
- **Meaningful AI will improve quality, efficiency and outcomes**
  - Utilizing all available data to optimize patient care

2018

Combined
Quality and Safety
And
Artificial Intelligence
Meeting

- Practicing Physicians
- Radiology Informaticians
- Developers

THANK YOU!

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Thank You!