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

Regulation, Payment And The AI Ecosystem

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DATA SCIENCE INSTITUTE™
AMERICAN COLLEGE OF RADIOLOGY



DATA SCIENCE AND ARTIFICIAL INTELLIGENCE: HYPE VERSUS REALITY



ORIGINAL ARTICLE

ACR 2016



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 decrease in demand for imaging. More care in patients' homes and in other nonhospital settings means fewer medical tests, including imaging. Second, payment reform and, in particular, bundled payments and capitation mean that imaging will become a cost rather than a revenue source. 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. Copyright © 2016 American College of Radiology





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: "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."



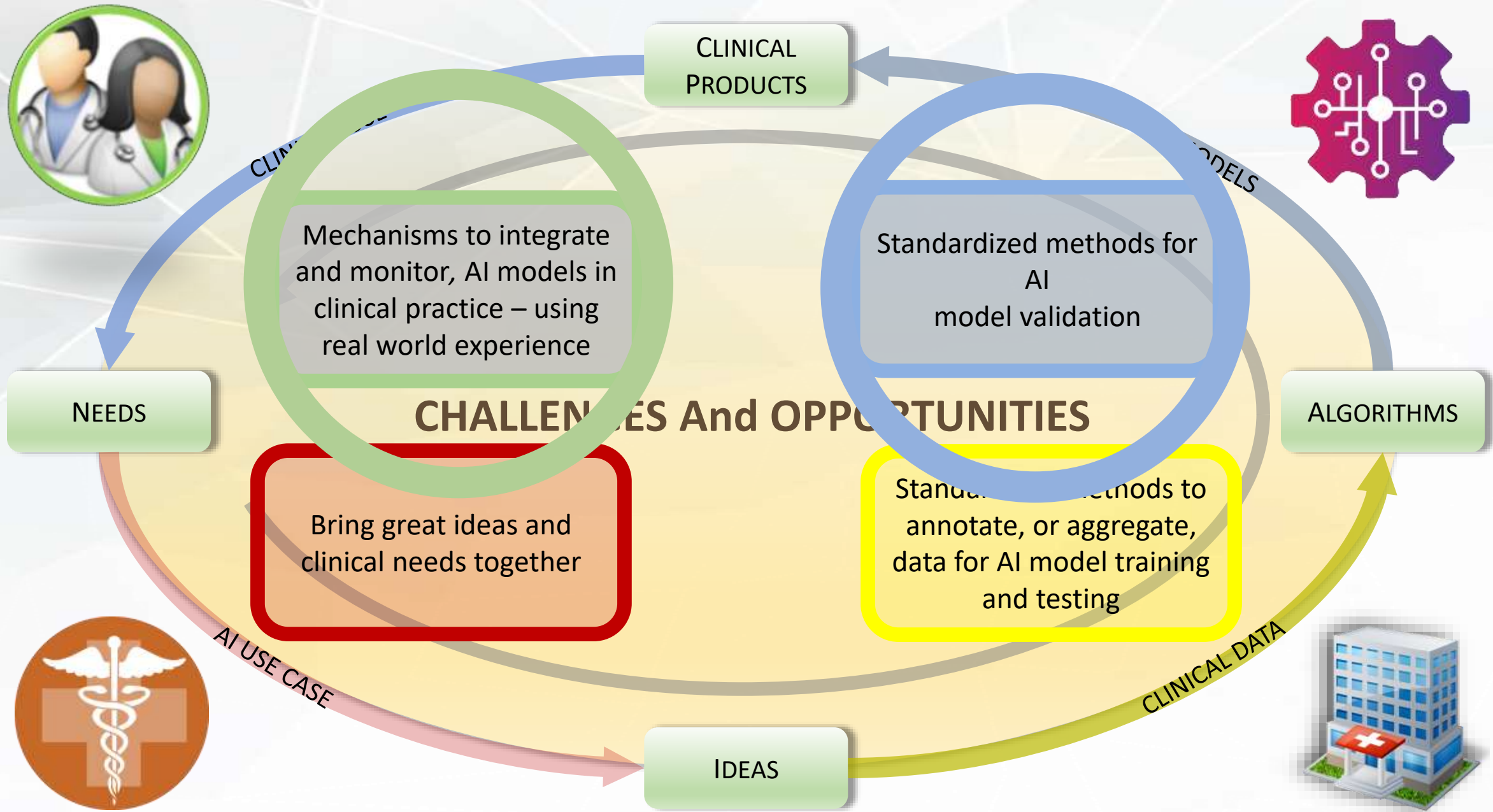
DATA SCIENCE AND ARTIFICIAL INTELLIGENCE: A RAPIDLY EMERGING MEGATREND IN BUSINESS AND SOCIETY

Hype?
Yes.



Real Substance
and Impact?
Yes.

MOVING AI TOOLS TO CLINICAL PRACTICE: DEFINING A RADIOLOGY AI ECOSYSTEM



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

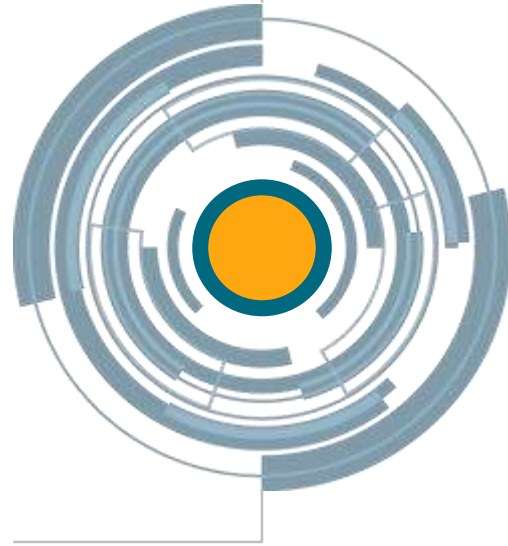
- Algorithms useful, safe and effective
- Clinically validated
- Transparency in algorithm output
- Monitored in practice
- Free of unintended bias
- Medicare and insurance coverage issues

- **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

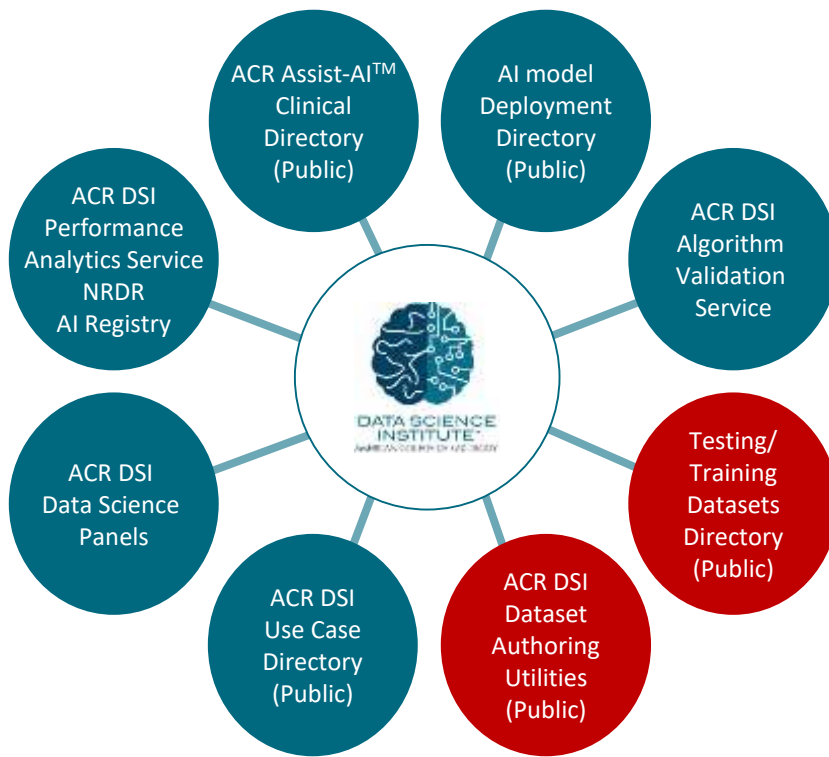
- Trusted partnerships with industry and regulators
- Ensure patient safety
- Increase radiology professionals' value in healthcare



Use Case Development

- Use case authoring platform
- Human language to machine language

Making Datasets For AI Training Available To Developers



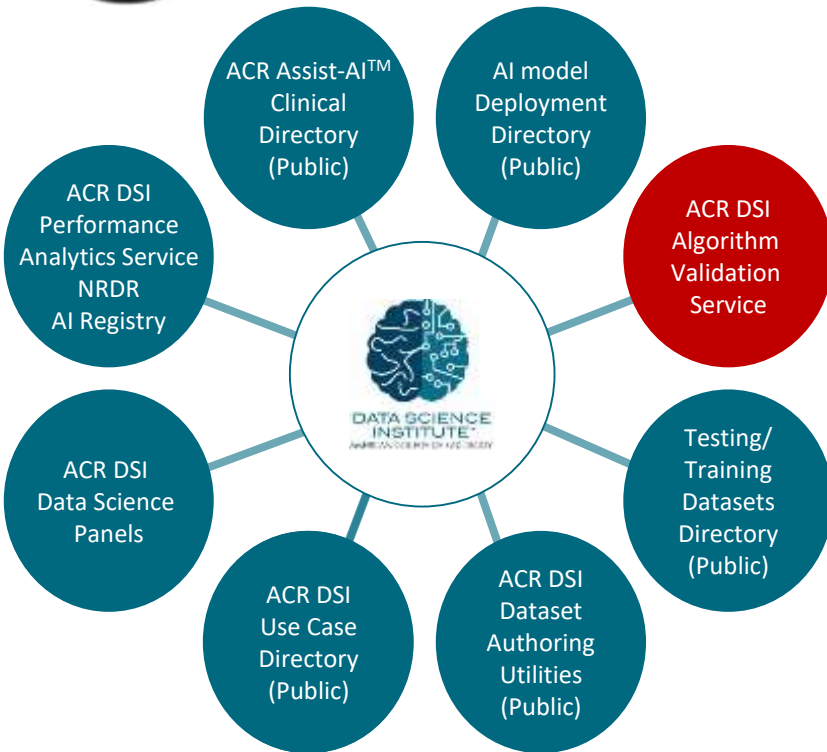
ACR DSI Data Access Directory

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.



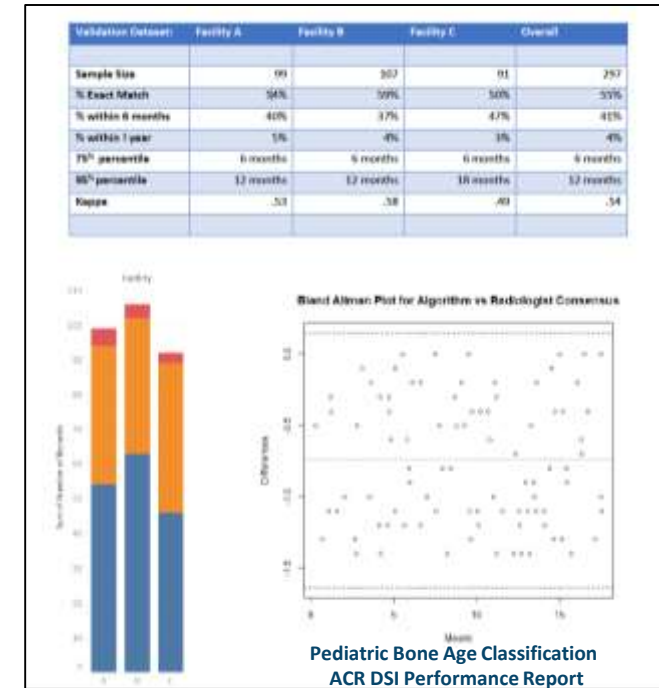
ACR Data Science Institute Certified Algorithms

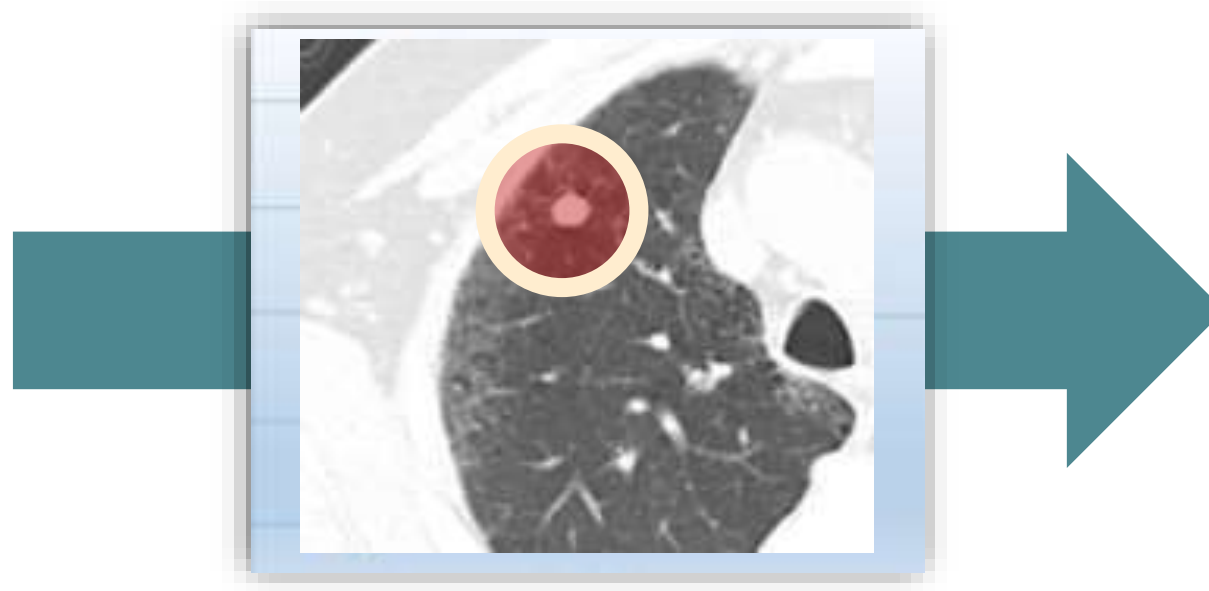


Specialty society certification of AI algorithms provides an “honest broker” partnership with radiology, developers and government regulators.

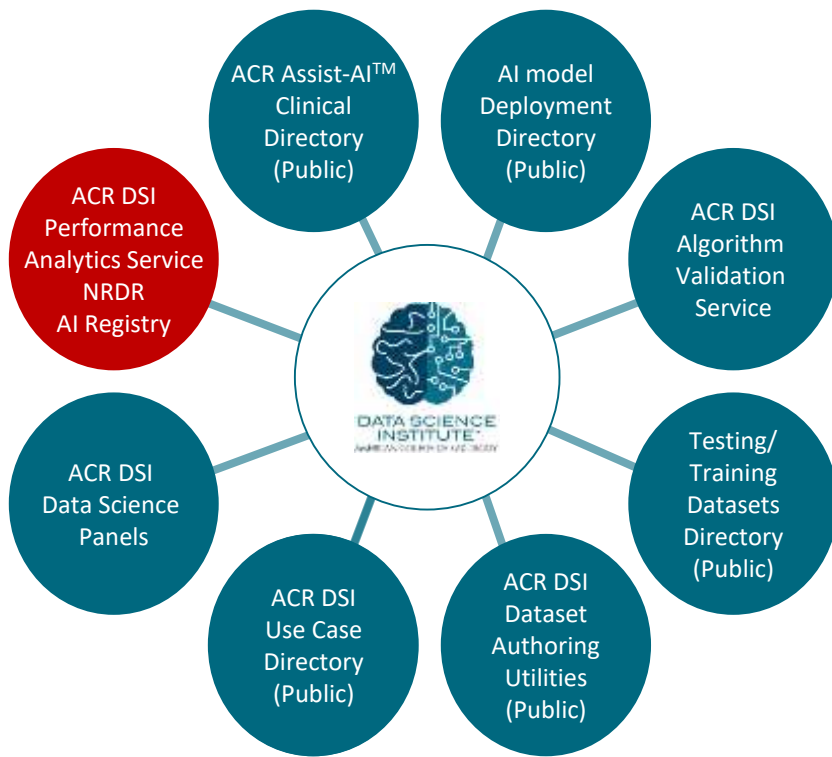
Specifications For Algorithm Validation

- 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.





LEVEL	IMAGE ID	LEVEL	IMAGE	DESCRIPTION	NUMBER OF LESIONS	ACCURACY
1	1	1	1	1	1	1
2	2	2	2	2	2	2
3	3	3	3	3	3	3
4	4	4	4	4	4	4
5	5	5	5	5	5	5
6	6	6	6	6	6	6
7	7	7	7	7	7	7
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9	9	9	9	9	9	9
10	10	10	10	10	10	10



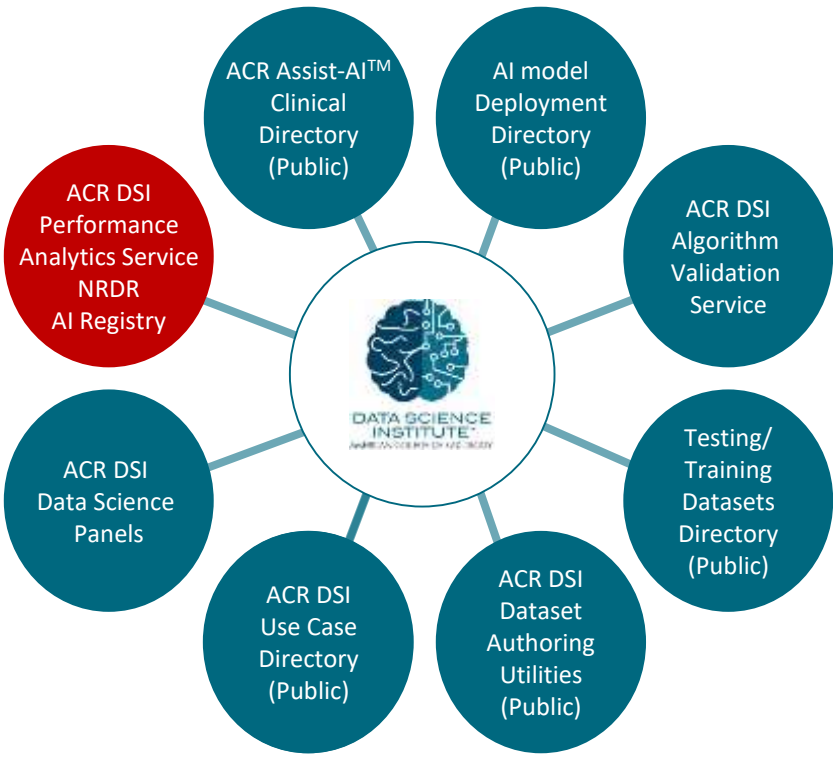
AI Monitoring Program

- 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.**

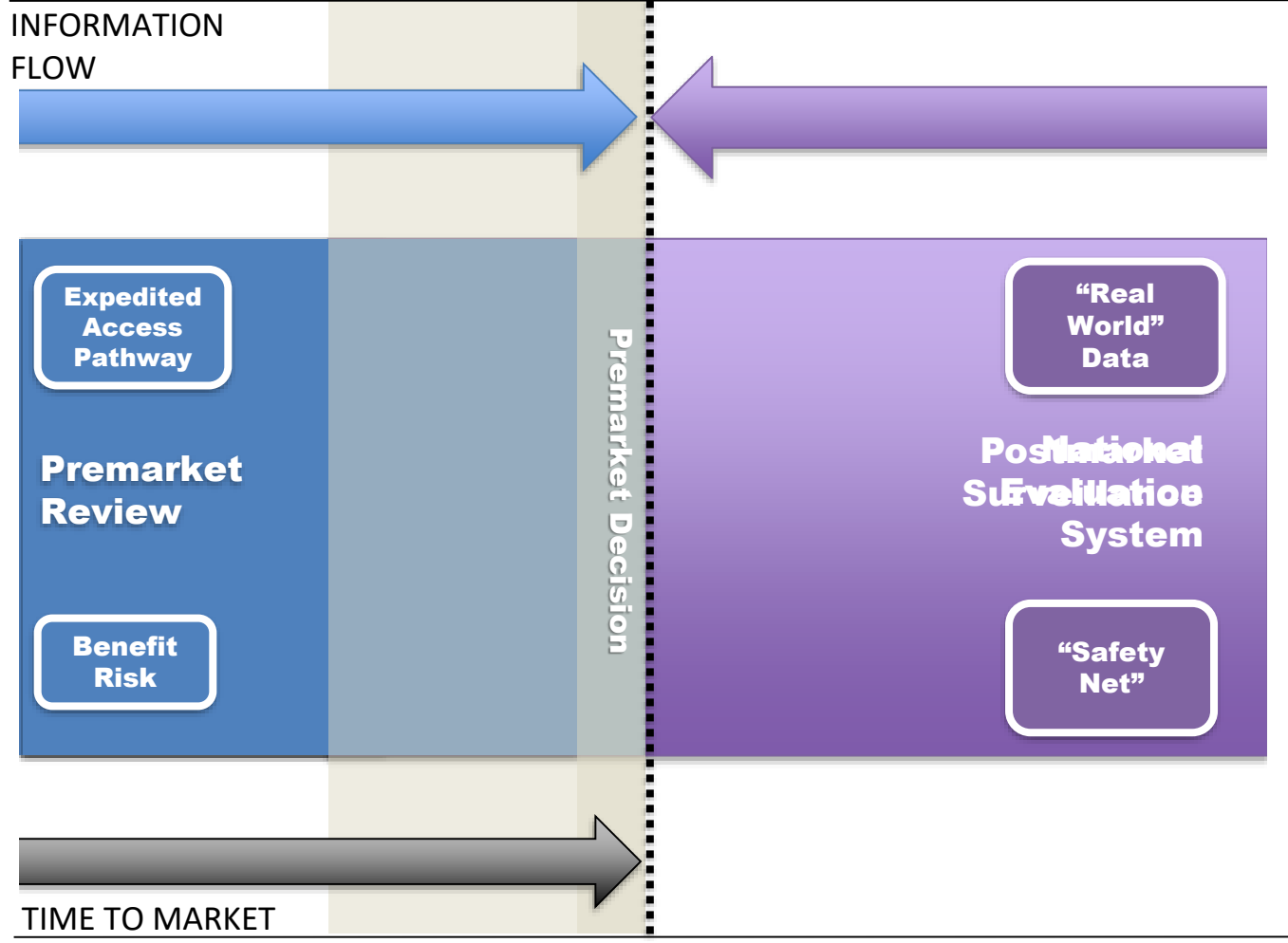
MONITORING ALGORITHM PERFORMANCE IN CLINICAL PRACTICE



AI Monitoring Program

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

Specifications For Monitoring In Clinical Practice



Courtesy Greg Pappas, FDA

FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



About FDA

Home > About FDA > FDA Organization > Office of Medical Products and Tobacco > About the Center for Devices and Radiological Health > CDRH Offices

CDRH Offices

- Office of the Center Director
- CDRH Offices: Office of Communication and Education
- CDRH Offices: Office of Compliance
- CDRH Offices: Office of Management
- CDRH Offices: Office of Science and Engineering Laboratories
- Office of Device Evaluation
- Office of In Vitro Diagnostics and Radiological Health
- Office of Surveillance and Biometrics

Division of Imaging, Diagnostics, and Software Reliability

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Phone: (301) 796-2767
Email: CDRH-OSEL-DIDSR-VMAIL@fda.hhs.gov

The Division of Imaging, Diagnostics and Software Reliability (DIDSR) participates in the Center's mission of protecting and promoting public health by identifying and investigating issues related to medical imaging, computer-assisted diagnostics, and software reliability. The division accomplishes this through activities supporting the OSEL mission.



Resources for You



About FDA

Home > About FDA > FDA Organization > Office of Medical Products and Tobacco > About the Center for Devices and Radiological Health > CDRH Offices

CDRH Offices

- Office of the Center Director
- CDRH Offices: Office of Communication and Education
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- Office of Device Evaluation
- Office of In Vitro Diagnostics and Radiological Health
- Office of Surveillance and Biometrics

Office of Device Evaluation

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What We Do

- Premarket Notifications (510(k))
- Premarket Approval Applications (PMAs) and Supplements
- Humanitarian Device Exemptions (HDEs)
- Investigational Device Exemptions (IDEs), Amendments and Supplements
- Product Development Protocols (PDPs)

ODE is responsible for the program area through which medical devices are evaluated or cleared for clinical trials and marketing. This page provides summary information about the major programs administered by ODE and includes a brief description of the premarket approval, product development protocol, humanitarian device exemption, investigational device exemption, and premarket notification programs.

Premarket Notifications (510(k))

At least 90 days before placing a medical device into commercial distribution, a person required to register must submit to FDA a premarket notification, commonly known as a "510(k)." The exception to this is if the device is exempt from the 510(k) requirements of the Act by statute or regulation. In addition to other information concerning the device, e.g., a description of the device, a 510(k) summary or a 510(k) statement, the 510(k) submitter must include information to substantiate that the device is "substantially equivalent" to a legally marketed device that is not subject to premarket approval. A substantially equivalent device is marketed subject to the same regulatory controls as the device to which it is found to be substantially equivalent. A device may not be marketed pursuant to a 510(k) until the submitter receives written clearance from FDA.

Top

Premarket Approval Applications (PMAs)

Under the Federal Food, Drug, and Cosmetic Act (the Act) and the FDA regulations, Code of Federal Regulations, Title 21 (the Regulations), a manufacturer or others must submit a PMA for FDA review and approval before marketing certain new Class III devices. The PMA submitter must provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufactured in accordance with current good manufacturing practices. As part of the review process, FDA may present the PMA to an expert advisory panel for its recommendations. After obtaining the panel recommendations, the agency makes a determination to approve the PMA, deny it, or request additional information. When the FDA either approves or denies the PMA, it must publish a notice in the Federal Register to inform the public of the decision and make available a summary of the safety and effectiveness data upon which the decision is based. This publicly available summary does not include proprietary data or confidential information submitted by the applicant.

Office of Science And Engineering Labs



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

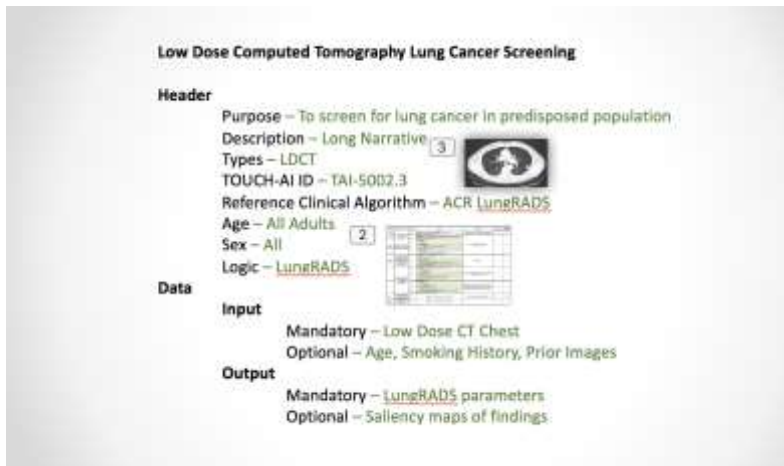
- **National Evaluation System For Health Technology (NEST)**

- 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”

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)



Key Takeaways

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- FDA-funded NESTcc program has chosen the Lung-RADS Assist: Advanced Radiology Guidance, Reporting and Monitoring use case among its first demonstration projects.
- This ACR Data Science Institute™ (DSI) use case will determine the end-to-end workflow from deployment of an AI algorithm in a radiology reporting system through capture of performance metrics within a national registry.
- Use cases are clinical scenarios in which artificial intelligence (AI) use may improve care. Medical Imaging AI use case development is an initial focus of the ACR DSI.

February 02, 2018

FDA-Funded NEST Program Names ACR Data Science Institute AI Use Case as Demonstration Project

Designation Boosts National Efforts to Improve Medical Imaging Care Using Artificial Intelligence

A U.S. Food and Drug Administration (FDA)-funded program to speed safe and effective medical device technologies to market has chosen an ACR Data Science Institute™ (DSI) use case among its first demonstration projects.

The National Evaluation System for Health Technology Coordinating Center (NESTcc) selected the "Lung-RADS® Assist: Advanced Radiology Guidance, Reporting and Monitoring" use case. The center supports timely, reliable and cost-effective evidence development regarding FDA medical device pre- and post-market requirements.

"We are proud that the NEST program recognizes the value of the ACR Data Science Institute's groundbreaking work. The ACR DSI will employ our open framework, TOUCH AI (Technology Oriented Use Cases for Healthcare Artificial Intelligence), to provide infrastructure for ongoing longitudinal AI algorithm verification pre- and post-FDA approval. This can help bring better medical care to patients more quickly," said ACR DSI Chief Medical Officer Bob Allen Jr., MD, FACR.

Lung-RADS Assist: Advanced Radiology Guidance, Reporting and Monitoring will determine the end-to-end workflow from deployment of an AI algorithm in a radiology reporting system through capture of performance metrics within a national registry. It will:

- Utilize existing ACR technology to demonstrate the ability to collect validation data and perform local algorithm testing prior to market approval
- Utilize existing ACR technology to facilitate interoperability between reporting and AI vendors to generate standardized data in a real-world setting
- Capture validation data and real-world events in a national registry to enable both facility-level and cross-facility reporting

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

Use Cases	Content	Validation	Implementation	Regulatory	Safety
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!