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AMERICAN COLLEGE OF RADIOLOGY



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# Executive Summary

In this year's annual report, we are pleased to share the tremendous accomplishments of the ACR Data Science Institute® (ACR DSI) over the past calendar year.

This past year, we conducted a survey of ACR® members to assess the penetration of AI in the market and barriers to deploying AI in clinical practice. The survey found that approximately 30% of practices are using some type of AI in the clinical workflows, although the number of models being used in each practice was small. While uncertain reimbursement was considered a potential issue, the trustworthiness of AI was also an important issue impeding deployment.

While 93% of the respondents using AI found the models they are using are inconsistent and 95% would not trust AI to work autonomously, those using AI believe it is adding value to their practices. A potential barrier to AI deployment is being able to evaluate an algorithm's trustworthiness prior to purchase, and many survey participants suggested that the ACR provide resources to help evaluate AI models and monitor their performance in clinical use.

## The Role of the ACR DSI in AI

The survey confirmed that the role of the ACR DSI in helping the medical imaging community bring AI to patient care is vital. There is a great need to develop standards for AI, create and deploy resources to evaluate and monitor AI, and share best practices — and the ACR DSI continues to foster an AI ecosystem that ensures AI will benefit patients and improve medical care, and increase the value radiologists bring to the healthcare system.

- AI Central, our new FDA-cleared AI algorithms catalog, collates commercially available algorithms to make them searchable by company, radiological subspecialty and modality. Our summary of each AI product tracks the number of examinations in the validation data sets, as well as other parameters, to assist members in evaluation the FDA-cleared models.
- Our successful [ACR AI-LAB™](#) pilot projects have shown that the [ACR Connect®](#) technology employed by the ACR AI-LAB can be used to successfully transfer models among institutions for federated learning, local evaluation of models using enriched datasets, and multicenter validation of AI models (distributed validation) — while keeping data safe at the original institution.
- The ACR DSI has increased the number of freely available, structured AI use cases in our [Define-AI Directory](#) to 160 to empower AI developers to produce algorithms that are clinically relevant and contain structured data elements for integration into exiting clinical workflows.
- The ACR DSI continues to collaborate with radiology subspecialty societies, industry, and governmental regulatory agencies to evaluate ACR resources for developing, evaluating, validating, and monitoring AI algorithms. We are also working with other medical specialty societies to enhance the leadership position of the ACR in healthcare AI.

The AI future we imagined at the inception of the ACR DSI has begun to take shape. We are beginning to see some penetration of AI into clinical practice, and we look forward to continuing to empower the advancement, validation and implementation of AI in medical imaging.

Sincerely,

Bibb Allen Jr., MD, FACR and Keith Dreyer, DO, PhD, FACR

# Leadership of the ACR Data Science Institute

Chief Medical Officer Bibb Allen Jr., MD, FACR, and Chief Science Officer, Keith J. Dreyer, DO, PhD, FACR, continued to lead the ACR DSI in 2020. Our support staff is expertly led by Mike Tilkin, ACR Chief Information Officer; Laura Coombs, VP of ACR DSI and Informatics; and Chris Trembl, ACR DSI Director of Operations. And the full team of ACR DSI professionals does a phenomenal job of supporting our volunteers.



Mike Tilkin  
ACR Chief Information Officer

Laura Coombs  
ACR Informatics Senior Director

Chris Trembl  
ACR DSI Director of Operations

The most important feature of the ACR DSI is the people. We continue to maintain and add to the hundreds of volunteers working as senior scientists and members of our data science panels, serving on the ACR AI Advisory Group and the Commission on Informatics, and supporting the AI Journal Advisor and the Informatics Advisory Council.

With these staff and volunteer resources, the ACR DSI remains well positioned to continue to implement the goals and objectives of our strategic plan, empowering our members to be ready to embrace AI in their practices.

# Getting Connected: Federated Learning, Distributed Validation and the ACR AI-LAB

Algorithms developed at single institutions often have limited diversity in equipment type and patient demographics, restricting their ability to be generalized for routine clinical practice. An important role of the ACR DSI is to change the paradigm of AI algorithms developed at a single institution to one that favors development of models using data from multiple institutions for training, testing and validation.

The ACR AI-LAB will provide resources for practices of all sizes and types (academic or community) to not only participate in federated AI research but also run and evaluate commercial AI models — using their own data — before purchase.

In April 2019, the ACR DSI launched a cloud-based version of the [ACR AI-LAB](#), a free, vendor-neutral software platform that allows radiologists to learn AI and participate in use case development. In addition, the ACR AI-LAB allows for the creation, validation and use of AI models using cloud-based data.

In 2020, we deployed an on-premises version of the ACR AI-LAB to pilot sites using technology from [ACR Connect](#) — the updated image and data transfer platform. The on-premises version of the ACR AI-LAB allows AI models to be transferred and run while patient data at the participating sites remains on premises, safely behind their institutions' firewalls.

As such, the institutions are able to securely use their own patient data to build an enriched local dataset and run the model against a dataset with local cases specific to the algorithm, without the logistical hurdles of moving data to a centralized site. Models can be shared and trained using data from multiple sites creating more diverse algorithms that might be more generalizable to widespread clinical use.

Democratizing AI for radiology requires making AI accessible to institutions of all sizes. During the pilot, we found that even the institutions without a high degree of system IT support for AI were able to solve the logistical challenges in bringing in the ACR AI-LAB to their organizations.

Over several months, the pilot sites were able to successfully share research algorithms and collaborate with other sites in federated learning demonstration projects and distributed validation of algorithms created elsewhere.



There has been incredible interest from both academic and community practices in federated AI models around AI. The second wave of pilot testing will include a large variety of practice sizes and types that will participate in federated learning and local evaluation of AI models prior to purchase.

In the months ahead, we will use our COVID-19 AI uses cases to build, train and test federated AI models using data from the expanded group of participating sites. Once this testing is complete, we will be ready to deploy the ACR AI-LAB to the more than 18,000 facilities in our ACR Connect network. This expansion will not only facilitate the democratization of AI by allowing more radiologists to participate in AI development and/or the distributed validation of AI models, but also provide resources for practices of all sizes to run and evaluate commercial AI models using their own data prior to purchase.

# Bringing the Medical, Developer, Research and Regulatory Communities Together

Educating radiology professionals and non-radiology stakeholders about the uses of AI in medical imaging and role of the ACR in using data science to advance the welfare our patients and the public is an intrinsic part of our mission. To that end, the ACR DSI has been invited to participate in national and international symposia on AI, and our volunteers and staff helped develop numerous white papers, textbook chapters and journal articles highlighting the activities of the ACR DSI.

In addition, despite our inability to conduct face-to-face meetings during 2020, we held two virtual radiology AI summits and one hackathon event directed at developing industry standards.

## **Virtual 2020 Data Science Summit**

In conjunction with the Society for Imaging Informatics in Medicine (SIIM) Virtual Annual Meeting in June, the ACR DSI held a virtual version of its annual Data Science Summit. The half-day event focused on Monitoring and Evaluating AI: Challenges and Practical Implications and was well attended, with over 140 registrants. We recorded six informative sessions, which are now available for continuing education.

## **ACR Virtual 2020 Imaging Informatics Summit**

On October 27–28, 2020, a virtual informatics summit brought together 265 attendees for two days of expert-led talks on how to make AI projects successful. The program included an update on ACR Informatics™ initiatives and sessions covering workflow-based AI, data sharing for AI development, the economics of AI, regulatory issues related to AI, and algorithm training and evaluation with the ACR AI-LAB.

## **ACR Hackathon on AI Model API**

The ACR hosted an October Hackathon to test the AI model API, a technology innovation facilitated by the ACR to drive development of a standard interface by which AI algorithms communicate with radiology production systems (e.g., PACS or speech recognition systems).

Over 30 developers and researchers participated, with seven different production systems registered. At the event, organizers issued congratulations to the development teams from Fuji and GE Healthcare for their success. The ACR partnered with SIIM to produce the hackathon.



# Collaborating With AI Resources and Standards

To facilitate the implementation of AI applications, the ACR DSI is involved with developing a framework to implement AI in the radiological professions. Our work includes providing comprehensive resources and setting standards for AI integration and data sharing — all based on the expertise of radiology professionals who enable AI models to function seamlessly in the clinical workflow.

## **Medical Imaging and Data Resource Center (MIDRIC)**

The ACR DSI is participating with the ACR Center for Research and Innovation™ (CRI) in a multisociety (Radiological Society of North America and American Association of Physicists in Medicine) project to develop the Medical Imaging and Data Resource Center (MIDRIC) within the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the National Institutes of Health (NIH).

The project is funded through an NIH grant, and the ACR is leveraging its expertise in image and data transfer, as well as in registry development, to create an open access platform that will collect, annotate, store and share COVID-related medical images. While initially the MIDRIC will focus on COVID, the project could serve as a model for a more comprehensive centralized data source for AI research in the future.

## **DICOM Standards**

To streamline the expansion of AI into the healthcare arena and radiology, standards bodies such as Integrating the Healthcare Enterprise (IHE), Digital Imaging and Communications in Medicine (DICOM) and HL7/Fast Healthcare Interoperability Resource (FHIR) are actively defining and maintaining standards to enable the integration of AI into healthcare. ACR member volunteers bring their own expertise and views to these groups.

In 2020, the IHE organization published a white paper, “[AI Interoperability in Imaging](#),” that maps out AI challenges from dataset creation through model results feedback. The DICOM Standards Committee is working to define the need for application hosting with a supplement for service discovery and control. The HL7/FHIR community is mapping radiology reporting content for easier tracking and transfer between radiology systems and the EHR.

## **ACR DSI Data Sharing Workgroup**

The Data Sharing Workgroup has produced a two-part white paper submitted for publication in the Journal of the American College of Radiology that defines issues and standards for data sharing in AI development. Expanding on the 2019 multisociety “[Ethics of Artificial Intelligence in Radiology](#),” these white papers define standards that can be applied to AI development to ensure public trust and encourage responsible data use in development of AI for healthcare.



# AI Assessment, Monitoring, and Standards for the Developer and Medical Communities

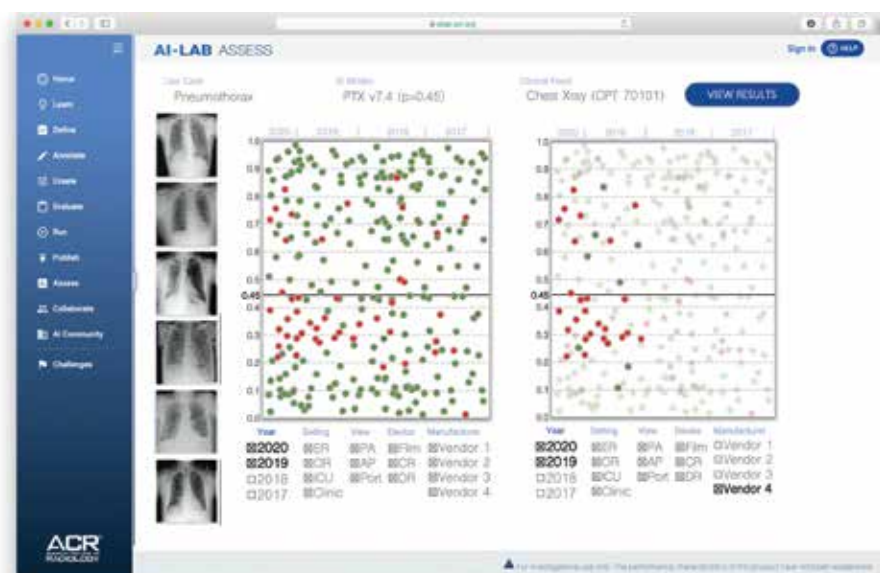
A key goal of the ACR DSI is to facilitate the development of clinically relevant algorithms that will benefit radiology and improve healthcare. As such, we provide services to help developers and institutions evaluate AI products and ensure they are useful in a clinical setting.

## Assess-AI Data Registry

The [Assess-AI](#) tool within the ACR National Radiology Data Registry (NRDR) is now up and running at the University of Rochester, providing real-world continuous assessment of model accuracy and longitudinal performance monitoring.

Assessment of model performance by the interpreting radiologist — along with the demographic, equipment and imaging protocol meta data we are collecting in the registry — gives us a powerful tool to assist practices in identifying when a particular algorithm experiences a drop in performance, as well as the specific conditions associated with the failure.

If a failure occurs, the registry data can be analyzed to determine if false positives or false negatives are coming from a specific piece of equipment at the site or from a change in protocol. The data can also be filtered down to the exam level to identify whether the model or the interpreting radiologist was the source of the error. In the aggregate, the registry can provide real-world performance data that developers can use to improve the algorithm or provide post-market surveillance data to regulatory agencies such as the FDA.



## Certify-AI Centralized or Distributed AI Validation

The ACR DSI remains on track to offer validation services for AI developers. Leveraging the resources of the ACR CRI, developers can perform multisite AI validation using traditional reader studies and centralized data from multiple institutions. We are also working with institutions, developers, and the FDA to assess the accuracy of distributed validation, where the AI model is disseminated among numerous sites for evaluation of sequestered datasets, as well as to evaluate more traditional centralized validation.

The ACR DSI is working closely with the FDA to ensure our processes meet or exceed their standards for model validation, and we expect the Certify-AI distributed validation program will be able to streamline the FDA clearance process for developers, while ensuring AI is safe and effective for widespread clinical use.

*The ACR DSI provides services to help developers and institutions evaluate AI products and ensure they are useful in a clinical setting.*

## Define-AI Use Cases

The ACR DSI had published more than [160 freely available use cases](#) by 2020 to help ensure that AI algorithms will be useful in a clinical setting. The use cases provide structured data elements for training, testing, and monitoring algorithms.

As part of our standardization efforts to integrate AI into clinical workflow, we have begun linking the ACR DSI use cases to ACR Assist<sup>®</sup>. As new decision support tools for radiologists (assistants) are developed, we will incorporate them into all of the ACR DSI use cases, so that output of the AI models are automatically ingested into radiology reports.

# Leveraging AI Resources to Battle COVID-19

Our Pandemic AI Response (PAIR) community was created to develop a framework to prepare our clinical radiologists and researchers to combat potential future infectious disease outbreaks. The new PAIR community is intended to foster and disseminate knowledge mobilized in response to COVID-19.

## Case Repository

The PAIR community created a real-time COVID-19 case repository for facilities throughout the United States to submit and review COVID-19 cases. PAIR was developed to leverage ACR resources in the battle against COVID-19 and to prepare our clinical radiologists and researchers to combat potential future infectious disease outbreaks. The [COVID-19 case repository](#) is freely available to all and will be coordinated with resources of the NIH MIDRIC project.

## ACR Assist Module for COVID-19 Reporting

A structured reporting module for COVID-19 was developed to establish consistent reporting of radiographic findings of COVID-19 and make the data useful to researchers. It also aids radiologists in communication with other healthcare providers. An initial example was based on the RSNA Consensus Statement on Reporting Chest CT Findings Related to COVID-19, endorsed by the ACR. The ACR Assist team developed an assistant for COVID-19 reporting, which has been incorporated into our DSI structured use cases for COVID-19.

PAIR was created to foster and disseminate knowledge mobilized in response to COVID-19.

## AI Algorithm Repository and Local Algorithm Evaluation

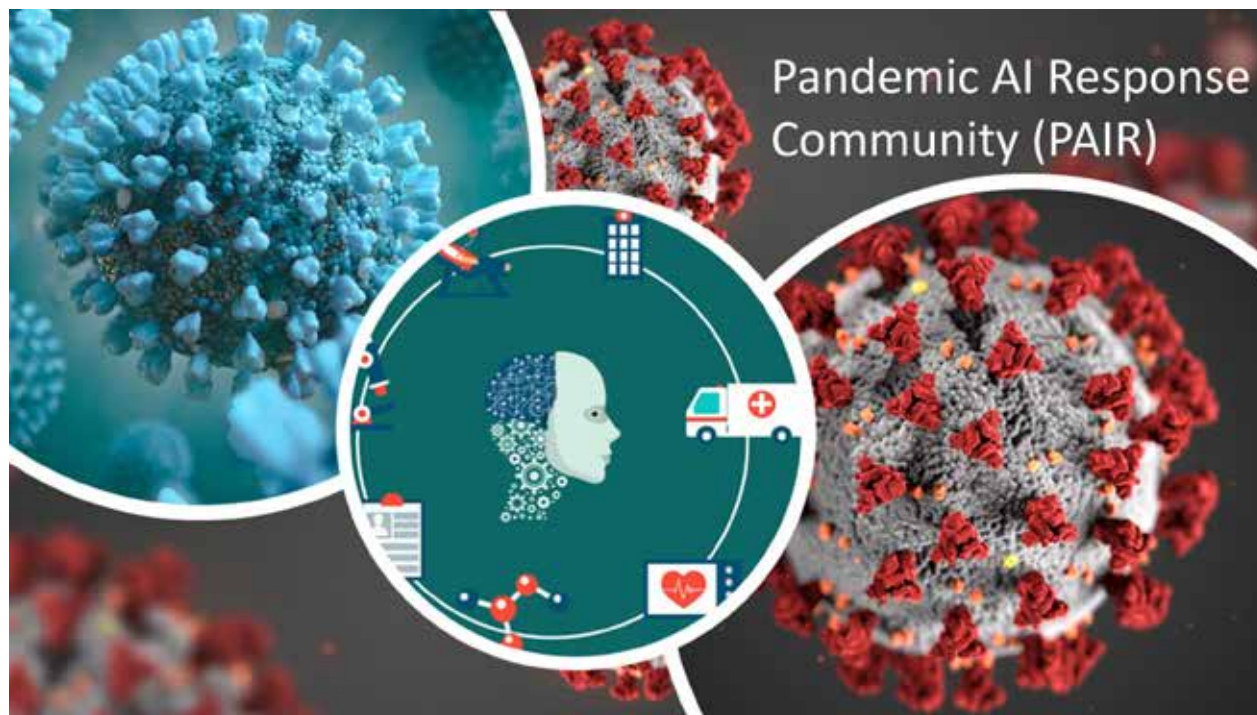
Organizations around the world are creating AI algorithms to solve COVID-19 challenges. The growing list of algorithms can be found in the [ACR AI-LAB](#). The ACR AI-LAB provides free hosting of relevant COVID-19

AI algorithms for evaluation by any facility in the United States. In addition to using the ACR AI-LAB to evaluate algorithms using local data, facilities can also provide feedback to the ACR AI-LAB about algorithm performance in their patient populations.



## AI Use Case Development

The ACR DSI Thoracic Radiology Data Science Panel has developed freely available structured AI use cases, where AI might impact clinical care of COVID-19 patients. These use cases enable AI developers to create algorithms with the greatest potential to assist patients and help the medical community during the ongoing COVID-19 pandemic. To facilitate standardization of interpretation and workflow integration, an ACR Assistant has been developed for the [COVID-19 Compatible Chest CT Pattern](#) use case.



# AI Central: Creating Awareness of the Latest AI Tools

Our ACR data scientists are continuously reviewing AI models and have developed the ACR DSI [AI Central](#), which includes a catalog of FDA-cleared medical imaging AI algorithms. This catalog enables the radiology community to easily see the commercially available AI products and dramatically reduces the time required to sort through a growing list of algorithms available to those in medical imaging.

Each model includes a summary with the model manufacturer, FDA product code, body area, modality, predicate device, product testing and evaluation related to product performance, and clinical validation. Searchable fields in the catalog include vendor, radiology subspecialty area and modality, with links to the FDA clearance letter. Many of the models match with the ACR DSI [Define-AI use cases](#) and are linked under related use cases.



The year-old catalog, which now contains over 100 AI algorithms, is a high-traffic area for the ACR DSI website and is growing rapidly. If the clearance rate for AI products continues to follow this trend, we can expect explosive growth of FDA-cleared tools — making AI Central an increasingly important resource for the AI community.

The AI Central Editorial Board guides and reviews the catalog content to ensure it

is useful for the community and potential purchasers of commercial algorithms. Members of the board include Keith J. Dreyer, DO, PhD, FACR and Bibb Allen Jr., MD, FACR, as well as Christoph Wald, MD, PhD, MBA, FACR, Chairman of the Department of Radiology at Lahey Hospital & Medical Center in Boston, MA, and Chair of the ACR Commission on Informatics; Sheela Agarwal, MD, MBA, ACR Senior Scientist and Digital Medical Advisor at Bayer HealthCare; Judy Gichoya, MD, MS, Assistant Professor, Interventional Radiology and Informatics at Emory University; and Jay W. Patti, MD, Chief Radiology Informatics Officer at Mecklenburg Radiology Associates.

In coming months, the current catalog of commercially available algorithms will be expanded to include publicly available AI algorithms for medical imaging, with the goal of making the latest AI tools available to help improve patient care.

# Next Steps

In 2021, we are enthusiastic about using our momentum to create a framework for development of AI that will benefit the medical imaging community. Our ACR DSI AI survey confirmed that by providing radiologists with the tools they need to evaluate and monitor AI algorithms for their practices, we are moving the medical imaging toward a more patient-centered, technology-driven future — where radiologists using AI will continue to improve patient care and increase our value to healthcare systems.

We found our current survey indispensable in establishing our goals and direction for the coming year, and plan to conduct a new survey each year to ensure we continue to meet the needs of the medical imaging community.

Seeking input from the industry and government at regular intervals has also been beneficial in providing guidance for the ACR DSI and allows us to continue to connect radiologists with data scientists, developers, and other experts to develop and implement AI applications to help radiology professionals in the areas of greatest need. We have had input from around the world, and excitement continues to build for collaborating with us on standards, tools for evaluation and assessment, and products that will benefit the medical imaging community in the new data-driven era.

In the months ahead, work on our AI Central FDA-cleared algorithm catalog will continue with enhancements to include freely available algorithms and commercial AI products, so that the radiology community is aware of the range of AI products available to them.

We will also provide radiologists with tools to evaluate algorithms and monitor longitudinal performance. And we will provide AI developers with validation and post-market surveillance services, while continuing to build tools for clinical workflow integration. The need for these services is growing as we work to ensure that AI performs as expected across a wide range of clinical practice types and is free of any unintended bias that might be introduced during single site AI development and validation.

Establishing standards and best practices is at the core of the ACR DSI mission. In the year ahead, we will collaborate on additional white papers to recommend best practices in AI development and clinical use. By addressing current challenges and seeking out opportunities to advance AI, the ACR DSI will continue to guide the growth of AI in medical imaging to improve the quality of life of our patients.

**Bibb Allen Jr., MD, FACR**

*Chief Medical Officer*

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