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Executive Summary

We are pleased to share the tremendous accomplishments of the Data Science Institute (DSI) over the past calendar year.

Artificial intelligence (AI) in healthcare shows tremendous promise to improve the care physicians provide, and the need to harness AI in radiology for the benefit of our patients, society and our profession is paramount. The DSI is providing a framework for the implementation of artificial intelligence to help ensure that AI benefits patients and improves medical care.

- In October 2018, the DSI successfully launched the Technically Oriented Use Cases for Healthcare-AI (TOUCH-AI) Directory, which includes our initial offering of 50 freely available structured AI use cases. These use cases represent scenarios where the use of AI might help improve medical imaging care and were created under the guidance of our 16 DSI Subspecialty Data Science panels to empower AI developers to produce algorithms that are clinically relevant, safe and effective; free of unintended bias; and can be readily integrated into exiting clinical workflows. As the TOUCH-AI Directory expands with hundreds of structured AI use cases, the DSI will enable efficient creation, implementation and ongoing improvement of radiological AI tools.
- Over the past year, DSI worked with AI stakeholders at several events to address challenges facing AI developers. In May, the DSI and the Society for Imaging Informatics in Medicine (SIIM) co-hosted the Spring 2018 Data Science Summit: Economics of Artificial Intelligence in Health Care at the SIIM 2018 Annual Meeting to explore the opportunities and issues associated with integrating AI into the economics of health care. In August, DSI co-sponsored the National Institute of Biomedical Imaging and Bioengineering (NIBIB)'s Workshop on Artificial Intelligence in Medical Imaging to clarify the needs in foundational and translational research for AI in medical imaging, with two papers reporting the proceedings submitted for publication early this year.
- The DSI continued to work with the Food and Drug Administration (FDA) on several projects to develop validation and monitoring tools AI developers can use to ensure AI algorithms are safe and effective.
- In order to test and demonstrate the effectiveness of our DSI tools, we have established a number of collaborations among the DSI and a broad set of industry partners and other radiological and informatics societies.

As we continue to assist AI developers by defining the most important problems to solve and provide services to ensure algorithms are safe, effective and can be integrated into clinical workflows, there will be other exciting DSI releases in the coming months. I hope you will continue to follow the collaboration among our DSI staff, radiology professionals, industry leaders, government agencies, patients and other stakeholders as we promote and foster an AI ecosystem for the radiological sciences. More information about the DSI's work can be found at acrdsi.org. It is truly an honor and privilege for us to serve the ACR during this pivotal time, 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 Data Science Institute

Chief Medical Officer Bibb Allen, Jr., MD, FACR and Chief Science Officer, Keith J. Dreyer, DO, PhD, FACR are supported by a robust DSI staff of informatics and communications specialists. ACR Informatics Senior Director, Laura Coombs, and ACR Chief Information Officer, Mike Tilkin, continue to provide excellent leadership for the ACR DSI team. In addition to Chris Tremel, who joined as DSI Director of Operations in January 2018, staff now includes a clinical informatics analyst, two data science analysts, two data engineers and a communications specialist.



Mike Tilkin
ACR Chief Information Officer

Laura Coombs
ACR Informatics Senior Director

Chris Tremel
DSI Director of Operations

A robust team of volunteers supports and helps to lead DSI efforts. The ACR AI Advisory Group, which includes international members, has been instrumental in advising the DSI over the past year and is both an ongoing source of ideas and a sounding board for the evaluation of DSI programs.

DSI Senior Scientists provide specific expertise related to data science, methodology, framework, terminology, diversity and clinical integration as well as for research, outside collaborations and education. In addition, Data Science Subspecialty Panels support use case development.



Developing a Robust Artificial Intelligence Ecosystem

A significant challenge facing rapid implementation of AI tools in clinical practice is the lack of a well-developed ecosystem for AI in radiology. Initially, AI algorithms are being developed primarily in single institutions, using single institution data and solving problems specific to that institution. While solutions are integrated into that institution's workflow, there is no assurance that the algorithms developed will be able to be generalized to widespread clinical practice.

A major effort of the DSI has been to define a process for radiologist input into the AI development process.

An important role of the DSI is to help change this paradigm by developing opportunities for the development of AI tools using data from multiple institutions for training, testing and validation. DSI is collaborating with radiology professionals, industry leaders, government agencies, patients, and other stakeholders to facilitate the development and implementation of an AI ecosystem that will ensure AI applications go beyond single institutions and enable radiology professionals to provide improved medical care.

Without input from radiology professionals, AI algorithms might provide no value to radiologists. Physician input is critical to ensuring AI algorithms are both clinically useful, safe and effective for patients, and interoperable across electronic resources such as PACS, EHRs and reporting software. The opportunity to develop AI use cases for the radiological professions is almost endless, and prioritization of the many opportunities will be important to ensure that the AI products coming to market are ones that will enhance the care radiology professionals provide their patients.

A major effort of the DSI has been to define a process for radiologist input into the AI development process. Creating structured AI use cases enables radiologists to play a leading role in assisting developers in creating algorithms that will be useful, effective and safe in clinical practice and enhance the value radiology professionals provide to their patients and health systems.

Bringing the Medical, Developer, Research and Regulatory Communities Together

The DSI's mission has become well known in the medical, developer, research and regulatory communities. Our co-hosted and co-sponsored events for developers and regulators are well attended, and DSI receives invitations to speak to radiology and other healthcare organizations throughout the year. Some of the highlights include:



Keith J. Dreyer, DO, PhD, FACR presents at the Workshop on Artificial Intelligence in Medical Imaging at NIH in August.

Spring 2018 Data Science Summit: Economics of Artificial Intelligence in Health Care

DSI helped AI developers to take a closer look at the opportunities and challenges associated with integrating AI into the economics of healthcare during a full-day event led by expert DSI facilitators. The sessions enabled AI algorithm developers to better understand the reimbursement, regulatory and implementation issues that will influence payment. DSI and the SIIM co-hosted the event at the SIIM 2018 Annual Meeting.

Workshop on Artificial Intelligence in Medical Imaging at NIH

DSI is playing a key role in providing a roadmap for future research in AI for medical imaging. In collaboration with the NIBIB, the Radiological Society of North America (RSNA) and the Academy for Radiology & Biomedical Imaging Research (The Academy), DSI hosted a two-day workshop to discuss needs for foundational research in AI as well as the translational research in AI necessary for advancing AI algorithms into clinical practice. The findings are to be published in two white papers as a research roadmap to be shared with health professionals in academia, industry and government early this year.

ACR Annual Quality and Safety Meeting

At the most recent ACR Data Quality and Safety meeting, data science experts came together with health professionals to deliver the latest quality tools and insights on how artificial intelligence can best be applied for optimal patient care. A series of presentations by DSI leadership and others with AI backgrounds shared high-value strategies for harnessing the power of artificial intelligence, new informatics technology and decision support solutions.

Collaborating with Outside Organizations

Promoting an AI ecosystem for the radiological community has entailed collaborating with medical, developer, research and regulatory communities. During the course of 2018, DSI collaborated with a variety of national and international organizations to advance AI for the benefit of radiologists and our patients:

- Presentations for the RSNA, The American Roentgen Ray Society (ARRS), SIIM, and the European Society for Radiology (ESR). This included a special summit for developers, “The Economics of Healthcare AI,” held during the 2018 SIIM meeting.
- Textbook chapter, “The Role of an AI Ecosystem” in Springer Artificial Intelligence in Medical Imaging: Opportunities, Applications and Risks, edited by Erik Ranschaert and Sergey Morozov, which will be published in the first quarter of 2019.
- Memorandums of Understanding (MOUs) with NVIDIA and Medical Image Computing and Computer Assisted Intervention (MICCAI) to provide educational content and support for activities such as AI challenges, including a keynote address by Dr. Geraldine McGinty, MD, MBA, FACR, ACR Board Chair, for the MICCAI on September 17, 2018.
- Agreements with MICCAI to collaborate on three end-to-end AI challenges based on TOUCH-AI use cases for MICCAI 2019.
- International collaborations for promoting safe and effective clinical AI between major international radiology organizations:
 - ◆ With RSNA, ESR, Royal Australian and New Zealand College of Radiologists (RANZCR), Canadian Association of Radiologists (CAR), and other organizations on developing joint statements and other position papers, as well as on shared activities to advance AI for the benefit of radiologists and our patients
 - ◆ Presentation by Keith Dreyer at the 2018 European Congress of Radiology (ECR)

DSI’s reputation as a thought leader in AI is further demonstrated by reference to DSI in articles written for the imaging press, attendance at DSI events for developers and regulators and frequent invitations to speak to radiology organizations.

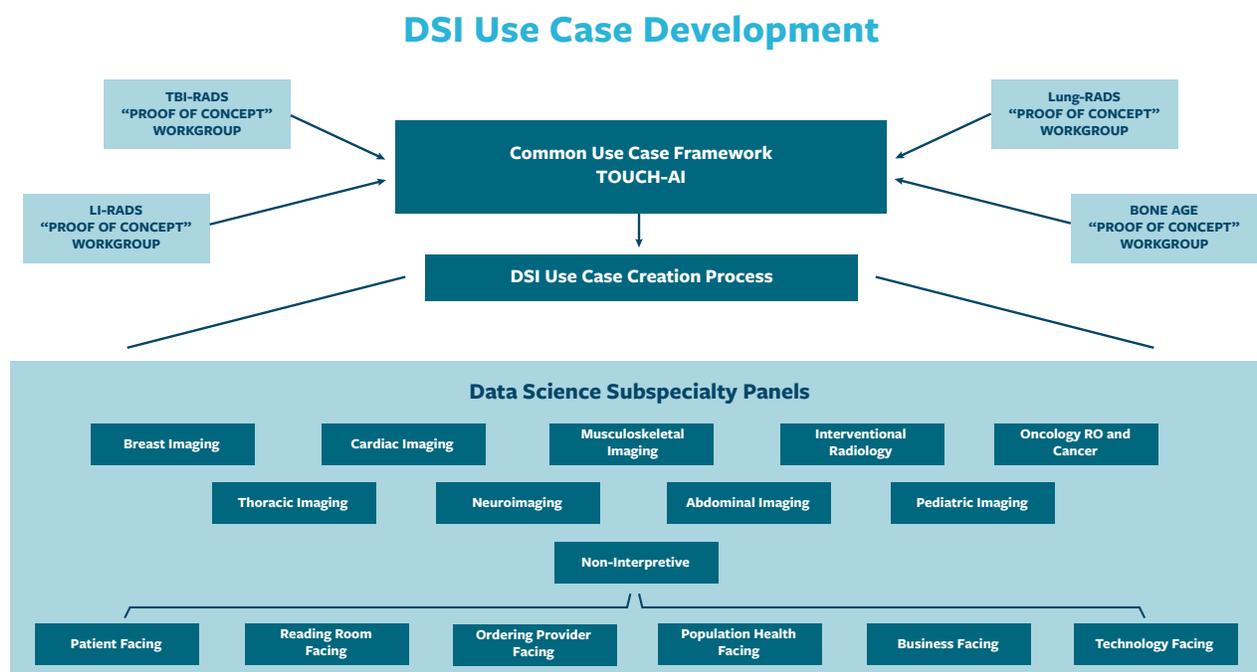


TOUCH-AI's Role in the AI Ecosystem

In October 2018, DSI released 50 structured use cases for the inaugural edition of the TOUCH-AI Directory. These impactful use cases are scenarios where use of AI will accelerate medical imaging AI adoption by providing structured data elements for training, testing, validation and monitoring, so that algorithms:

- Address relevant clinical questions to improve patient care
- Can be implemented across multiple electronic workflow systems
- Enable ongoing quality assessment and performance monitoring
- Comply with legal, regulatory and ethical requirements

Eighty-five volunteers in 16 subspecialty panels worked with DSI to build these high-impact, solvable radiology problems to guide the AI development process. Their work provided guidance on the inputs and outputs for researchers and industry developers of deep learning software and will help identify and prioritize development, so that AI tools will help radiologists provide the highest value for their patients.



Those developing AI have this to say about DSI's use cases and how they impact AI for medical imaging:

“For AI to deliver on its promise to advance medical imaging, a sustained collaborative effort is required between patients, providers, professional associations, regulators, developers and industry. Working closely with an organization like the ACR Data Science Institute helps us to identify and prioritize the right conditions for use cases most valuable to patient care and greatly amplifies the voice of the customer.”

- Thierry Verstraete, Global Product Manager for Analytics & AI, Carestream

“The ACR DSI use cases provide a previously missing understanding with end users on what an AI solution is to deliver by providing functional requirements and enabling better analysis and test models. This makes it easier for developers to develop algorithms that provide specific information medical professionals need and can be efficiently implemented into clinical practice.”

- Rik Primo, Manager of Imaging Informatics Strategic Relationships, Siemens Medical Solutions USA, Inc.

“At Arterys, we are excited to see the TOUCH-AI use cases. Clinical insight from the ACR validates the impact AI can have on radiology. The use cases highlight a number of specific opportunities that are supported by value proposition, workflow, and dataset details.”

- John Axerio-Cilies, Chief Technology Officer, Arterys

Working closely with an organization like the ACR Data Science Institute helps us to identify and prioritize the right conditions for use cases most valuable to patient care.



Providing Independent Testing and Validating Performance

Algorithms that are tested solely against single-source training data might fail when presented with data from other sources or institutions. By combining a clearly defined use case such as those found in the TOUCH-AI Directory with a well-curated, “ground truth” reference standard dataset, Certify-AI independently evaluates algorithm performance to safeguard against results that are not able to be generalized in routine clinical practice.

Verifying that an algorithm not only works well in a single institution, but is able to be generalized to routine practice, presents unique challenges for AI developers.

Datasets for Certify-AI are currently under development and being piloted in a number of projects for the FDA, and more datasets for algorithm validation are expected to be available in the coming year. These unique databases are being built from data gathered from multiple institutions to include cases spanning the range of known sources of variability. Once created, they will offer developers an opportunity to validate algorithms that is not available from any other source. By ensuring these validation datasets are technically, demographically and geographically diverse, we can help mitigate unintended bias that can be introduced from single-site data.

Evaluation of each AI algorithm’s performance will also entail defining the appropriate statistical performance metrics and minimal acceptable criteria for formal statistical testing, a measurement that DSI is better able to evaluate than any other organization as a result of ACR’s long-standing track record in this area. Because Certify-AI offers both rigorous independent testing and guidance on algorithm performance, evaluating algorithms through Certify-AI is a means of demonstrating performance to the FDA.

Verifying that an algorithm not only works well in a single institution, but is able to be generalized to routine practice, presents unique challenges for AI developers.

Monitoring the performance of AI algorithms after they are deployed in clinical practice will also be important to ensure AI algorithms are able to be generalized across multiple institutions and practice settings. Assess-AI allows collection of real world data about algorithm performance in actual clinical practice and collects those data in AI-Assess registries as part of the ACR National

Radiology Data Registry program. In November 2018, DSI announced a demonstration project with Aidoc and Nuance Healthcare on a combined solution that is now in full use at the University of Rochester Medicine. The jointly developed project enables radiologists to assess the performance of this prioritization tool in routine clinical practice and capture that performance data in an AI data registry.

Several other pilots for Assess-AI are expected to launch next year. By monitoring algorithm performance in clinical practice and capturing real-world data during clinical use in a clinical data registry, Assess-AI provides developers with longitudinal algorithm performance data. It thus paves a pathway for using real-world evidence to meet any FDA post-market surveillance requirements.

For both Certify-AI and Assess-AI, DSI is working closely with the FDA to ensure that our tools will be helpful to both developers and the agency to streamline the FDA review process and speed the development and implementation of AI applications with the potential to provide improved medical care.

The Radiology AI Ecosystem: Ideas to Clinical Practice



Algorithm Clinical Performance Assessment

Just as there are many paths to selecting a problem to solve and developing an AI algorithm, choices must also be available for assessing algorithms to measure performance. Without them, these potentially groundbreaking technologies are unlikely to move forward and provide solutions for radiologists to implement in clinical practice.

In the U.S. market, no matter the path for developing an algorithm, FDA approval will be necessary to move forward. Some developers will find they need to perform a clinical performance assessment study for FDA Premarket Approval (PMA) or Premarket Notification [510(k)] Submissions.

When developers need an option for algorithm testing, DSI offers solutions.

DSI offers developers special services for clinical performance assessment for algorithms that are not based on TOUCH-AI use cases. Based on years of ACR experience in testing and validation, these offer a good alternative to Certify-AI and will ensure that algorithms have a path to move forward and meet FDA regulatory requirements.

Depending on the need, several different levels of support are available for imaging algorithm assessment. These range from well-designed reader studies that rely on radiology experts to establish ground truth to end-to-end coordination of multi-center clinical trials. As with all ACR clinical trials, the technology for these assessments includes an informatics core, protocol and study design, and site management and qualification to ensure that the trial is completed on schedule and that the results are accurate, reproducible, and generalized to the population at large.

As with Assess-AI, documenting the longitudinal performance of AI in clinical practice will benefit both developers looking for a path to regulatory approval and radiologists who deploy AI to benefit patient care.

Datasets for AI Training

Well-annotated data is indispensable for developing effective AI tools for the clinical environment. DSI's free publically available Dataset Directory was released in October 2018 to connect machine learning researchers and developers with accessible and meaningful datasets for their projects in order to enable more individuals and institutions to participate in AI development. With the Dataset Directory, we are alleviating some of the burden from industry by connecting machine learning practitioners with accessible and meaningful datasets for their projects.

Significant work goes into creating annotated datasets for algorithm training and testing, but many datasets are not shared. Even when datasets are made available, without standardized definitions and data elements, they are of limited use. The DSI offers our detailed TOUCH-AI use cases to establish standards for annotating training data, and is working to develop a set of annotation utilities and make them available to institutions and radiology practices for creation of annotated datasets for training and testing.

When these datasets are complete, DSI will maintain a directory of sites that have developed training sets around TOUCH-AI use cases to make them available to developers in need of training sets. Developers can then partner with the sites in ways that allow patient datasets to stay onsite (on the premises) while providing developers with access to high-quality training datasets. Access to processes for creating training datasets will always be freely open to institutions, developers and the public. This provides a diverse range of structured data available for algorithm training and testing to reduce potential algorithm bias and help ensure AI algorithms can be made widely available to clinical practice.

Using Representative/Diverse Training Data: Multiple Dimensions of Image Variation



Anatomy
(e.g., body part)



Patient demographics
(e.g., gender, age)



Pathology
(e.g., degree of tear)



Modality
(e.g., X-Ray, MRI, CT,
PET, Ultrasound)



Working with Regulatory Agencies on Pathways for Algorithm Approval

The 21st Century Cures Act of 2016 clarified FDA regulations on medical software, excluding some software functions from classification as a medical device. This opened the door for the FDA to evaluate a number of programs designed to facilitate software clearance processes. One opportunity for physician, developer and FDA collaboration is around the FDA's Medical Device Development Tools (MDDT) initiative.

This year, DSI held several meetings with FDA officials about ways to facilitate algorithm approvals, including a September 4, 2018 meeting to discuss pathways for clearing AI algorithms. The goal is to move products into clinical implementation more quickly, while protecting all aspects of patient safety, including an algorithm's accuracy, reliability and privacy protections.

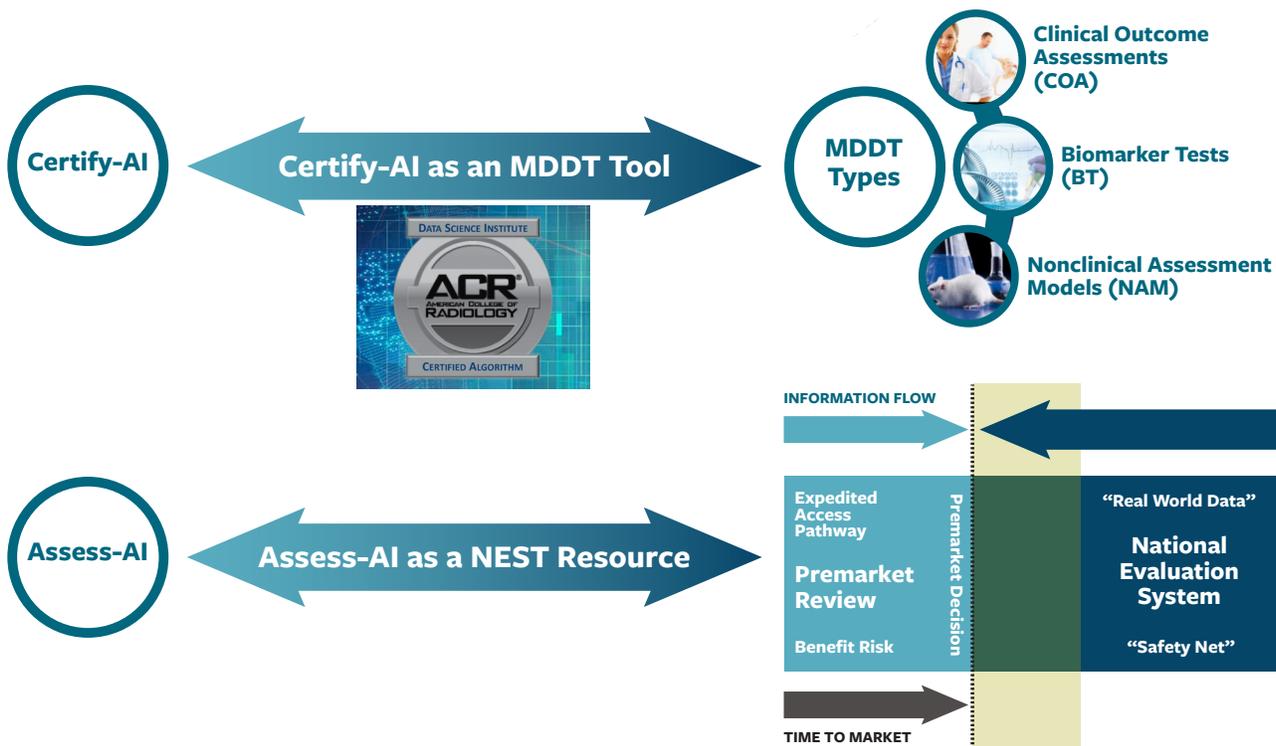
Presently, DSI is working with the FDA to create an MDDT tool set built around the TOUCH-AI use cases and the Certify-AI process for validation certification of AI algorithms. We anticipate the data collected during the validation process will help algorithm developers in their submissions to the FDA and supply the FDA with information on how an algorithm meets benchmarks for algorithm performance set forth in one of the TOUCH-AI use cases.

DSI is working with the FDA to create a tool set for developers built around the TOUCH-AI use cases and the Certify-AI process.

The Center for Devices and Radiological Health (CDRH) at the FDA is in the process of building the National Evaluation System for Health Technology (NEST). The FDA intends to use NEST to combine post-market surveillance with real-world data and shorten the time to market for new technology healthcare products. Because of its potential to be useful in this process, the NEST Coordinating Center chose DSI's Lung-RADS Assist: Advanced Radiology Guidance, Reporting and Monitoring, as one of their early demonstration projects for AI algorithms. The demonstration will use real-world data to assess 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.

This example of a public-private partnership might serve as a model for how AI algorithms can be monitored in clinical practice to ensure ongoing patient safety—while establishing a pathway to increase the efficiency of the FDA pre-market review process. Both Certify-AI and Assess-AI have the potential to streamline the FDA pre-market reviews and establish a robust solution for FDA post-market surveillance on a national scale based on real-world experience.

FDA Collaboration



What's Next for the DSI

For 2019, we are moving even closer to the future of patient-centered, technology-driven medical imaging. The DSI is creating a framework for coordinated development of AI algorithms that can propel the specialty forward and achieve the vision of improved quality of care for our patients.

Connecting radiologists with data scientists, developers and other experts enables us to leverage expertise from other sectors, while injecting new ideas into the healthcare AI community. Potential collaborators from around the world have expressed interest in working with the DSI. While our tools and services are primarily designed for the U.S. healthcare market, the DSI is poised to serve a worldwide market, attracting new ways of thinking and partners from across the international community.

The initial 50 use cases in the TOUCH-AI Directory are the starting point to facilitate development and implementation of AI applications that will help radiology professionals in disease detection, characterization and treatment. Many more use cases, including non-interpretive applications of AI in our specialties, will soon follow. These detailed use cases will enable development of training data across multiple institutions—which will, in turn, help ensure algorithms are able to be generalized for clinical practice and free of unintentional bias.

Beyond our TOUCH-AI use cases, rolling out the Certify-AI and Assess-AI services will require even more collaborations and partnerships. And many academic institutions have expressed interest in helping us take these services to the next level. We will work with stakeholders to create standards to facilitate seamless integration of AI algorithms into clinical workflows. Additional collaborations will focus on building out the Assess-AI process and registry, and piloting collaborations with AI vendors.

In the coming year, the DSI plans to focus on numerous AI projects designed to impact care for critical diseases, such as liver cancer and tuberculosis. We will also foster non-interpretive uses for AI to ensure our follow-up recommendations are adopted in clinical care.

Finally, we believe the DSI can support and empower radiology professionals who are engaged in AI development, and we will coordinate a process where algorithms can be built onsite to address problems of interest to a particular facility or individual radiologist. Look for more information around this effort to be released in 2019.

The DSI was created to guide the advancement of innovative AI solutions in the radiological sciences. To address current challenges, capitalize on opportunities to advance AI solutions and continuously improve healthcare for patients, the DSI team will continue to engage with stakeholders to align our priorities and goals with a rapidly changing AI landscape.

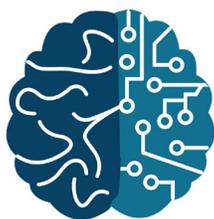
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