The ACADEMY for Radiology & Biomedical Imaging Research

FDA Workshop:
"Evolving Role of Artificial Intelligence in Radiological Imaging"

February 25 and 26, 2020

On February 25-26, 2020, the U.S. Food & Drug Administration (FDA) hosted a public workshop on ***"Evolving Role of Artificial Intelligence in Radiological Imaging"***. The workshop was designed to identify and discuss benefits and risks associated with emerging applications of AI software in radiological imaging, evaluate AI software applications, and examine innovation in AI Image -Guided Image application. Presentations were made on regulatory issues in AI innovation and imaging devices containing AI software as well as on AI devices intended to automate the diagnostic radiology workflow. Also discussed were best practices for the validation of AI-automated radiological imaging software and image acquisition devices to appropriately assess safety and effectiveness. Participants in the workshop included academia, imaging societies, industry and government agencies.

As stated by the FDA, artificial intelligence (AI), including machine learning technologies, has the potential to transform healthcare by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Radiological applications of AI-based technologies are numerous and expanding. These applications aim to automate and streamline tasks to improve efficiency, accuracy, and consistency.

Large sets of widely available imaging data across imaging modalities have supported the development of AI based algorithms for these devices. While historically the information provided by these algorithms has augmented the tasks performed by radiologists, software developments now can enable the devices to perform certain tasks autonomously. The potential for independent action by these devices to bypass human clinical review is an important factor in their benefit-risk profile, and it heightens expectations for the safety and effectiveness of these devices.

Another area of growth is the use of AI to provide prescriptive guidance for the operator to acquire optimal images. The image quality of ultrasound imaging can be greatly influenced by how the operator uses a handheld probe. Clinical AI applications may assist the acquisition of standardized images independent of the operator, guiding both sonographers and non-experts in sonography, potentially including lay users, to acquire images with equivalent diagnostic quality. The addition of such clinical AI applications and the potential for new users of these devices, similarly affect the benefit risk profiles for these devices and the expectations for the safety and effectiveness of these devices.

Through the workshop, FDA sought to engage with stakeholders to explore benefits and risks of these evolving applications of AI in radiology. As the benefit-risk profile changes, it is critical to adapt the methods used to evaluate and characterize their performance. The FDA workshop sought innovative and consistent ways to leverage existing methods and to develop new methods for validation of these AI-based algorithms and explore opportunities for stakeholder collaboration in these efforts.

The Academy was delighted to be a part of the workshop and to facilitate the ongoing momentum and collaboration between the federal agencies, academia, imaging societies and industry to appropriately address the AI and ML in radiological imaging.

Many of the **Academy's members** were participants in the well-attended FDA Workshop. Here is a list of those Academy members who made presentations:

Academic Members:

- Harvard, MGH: Constance Lehman, MD, PhD and Anthony Samir, MD
- B&W/MGH: Behrooz Hashemain, PhD
- Mayo Clinic: Cynthia McCullough, PhD
- Univ. of Washington: Paul Kinahan, PhD
- Univ. of Chicago: Maryellen L. Giger, PhD
- Stanford: David Larson, MD, MBA and Greg Zaharchuk, MD PhD
- Univ. of Wisconsin, Madison: Helen Feltovich, MD, MS
- Univ. of Pennsylvania: Hersh Sagreiya, MD
- Univ. of Pittsburgh: Shandong Wu, PhD

Imaging Societies:

- RSNA: Timothy J. Hall, VC RSNA-QIBA
- ACR: Bibb Allen, MD, Laura Coombs, PhD and Keith Dreyer, DO, PhD
- AAPM: Paul Kinahan, PhD

CIBR Industry Partners:

- Hologic: Nikos Ghanatsios, PhD
- Siemens Healthineers: Richard Frank, PhD and Andy Milkowski, PhD
- Canon Medical Research USA: Kevin O'Donnell
- GE Healthcare: Marc Edgar, MS, Mike Washburn, MS, and Tony Roder, MS
- Philips Healthcare: Benny Lam, PhD and Rob Trahms, MS, PMP
- Fujifilm: Scott Paulson

Early Career Investigators:

- Washington Univ. in St Louis: Abhinav K. Jha, PhD – (Academy CECI 2019)
- UC, Irvine: Peter Chang, MD – (Academy CECI 2020)

The Academy is grateful to the FDA for hosting and facilitating this important workshop, helping to maintain important momentum on the issue of AI in radiological imaging. **More information on the workshop, including links to presentations and archived webcast links can be found at this webpage.**

The webcast links will be available for up to 1-year of the workshop.

Participants discussed public-private collaboration to address the expressed needs of the medical imaging community for advancing related machine intelligence systems by accelerating founda-tional and transactional research to develop critically validated applications that improve patient management and clinical outcomes.