Evolving Role of Artificial Intelligence in Radiological Imaging

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Welcome!

- Who's here?
  - 500 onsite attendees
    - Registration full within ~1 month
    - Nearly 100 waitlisted before closing onsite registration
    - Over 80 presentation requests for ~20 5-minute timeslots
    - ~60 presenters, panelists, and moderators
    - ~217 industry, 20 clinical, 47 regulatory, 5 patient advocates, 86 government, 37 consultants, 68 academia
  - 830 webcast attendees (2/10/2020)
    - Webcast will be available online for up to 1 year after the event

Welcome!

- Significant interest in Artificial Intelligence (AI) and Machine Learning (ML)

  - 3rd most trafficked device site on fda.gov

While you're here…

- Please keep the aisles clear
  - Move in toward the center of each row, please
- Coat racks are underneath the stairs outside the auditorium
- Cafeteria and convenience store upstairs
- Pre-ordered lunch should arrive before noon.
- Reserved seating in front for FDA management, moderators, and presenters/panelists.

The workshop is about…

- Autonomous AI and AI-guided imaging
  - Day 1: Software in which AI/ML is being used to automate some portion of the radiological imaging workflow (e.g. detection, diagnosis, reporting)
  - Day 2: Software used in conjunction with imaging hardware such that AI/ML driven real-time feedback guides a non-expert user to acquire their own images to aid in or provide diagnostic or treatment decisions including in special environments
- What does this mean for the radiological imaging workflow, patients, and healthcare providers?
- Regulatory considerations

AI used throughout the day likely means AI/ML for brevity

The workshop is not about….

- CAD – detection, diagnosis, or triage
- Quantitative imaging
- Pathology / IVDs
- AI as an alternative technical method

…but we can certainly learn from these!

A Prospective Approach…

- Fully autonomous AI systems and AI-guided image acquisition offer many benefits but could:
  - Change or challenge the standard of care
  - Introduce new questions of safety and effectiveness into an established radiological imaging workflow
  - New intended use including user and/or environment

A Prospective Approach…

- Allows the Agency to engage the public early to promote consistency and fairness
- Community approach to identifying benefits and risks needed to ensure safety, build trust
- Develop approaches that ensure scientific integrity and data quality while allowing flexibility for algorithm change/development

A Prospective Approach…

- Inspire confidence through collaborative solutions
  - No human (or experienced human) in the loop serving as mitigation? Let's get it right the first time.
  - Applications in radiology can impact a wide population of providers and patients.
- Q-submission process
- Important precedent set in first submission(s) for a particular device classification regulation

Agenda = Major Submission Decisions

- How and why do you bring an entire community including patients, healthcare providers, regulators, manufacturers, and advisors along in the decision-making process for novel, high-risk devices?
  - Agenda structure
  - Large community with complicated ecosystem
  - Facilitate efficient, effective approval/classification
  - Challenging task faced by workshop participants

Agenda Day 1

8:00 Welcome

8:15 Responsible Innovation and Regulation of AI/ML in Radiological Imaging

9:15 Emerging Trends in Radiological AI Software – Exploring Benefits and Risks

10:15: 15-minute break

10:30 Emerging Trends in Radiological AI Software – Discussion Panel

12:00 Lunch

1:00PM Public Presentations

2:00PM Evaluation of AI Software for Radiological Applications

3:25PM 15-minute break

3:40PM Evaluation of AI Software for Radiological Applications – Discussion Panel

5:20PM Closing Remarks

Agenda Day 2

9:00AM Welcome

9:10AM Opportunities and Challenges in AI-Enabled Healthcare

9:50AM Innovation in AI-Guided Image Acquisition

10:50AM 10-minute break

11:00AM AI-Guided Image Acquisition: Clinical and Patient Perspectives

11:45AM AI-Guided Image Acquisition – Discussion Panel

12:45PM Lunch

1:45PM Public Presentations

2:45PM Regulation of Imaging Devices Containing AI Software

4:00PM Public Health and Regulation of Imaging Devices Containing AI Software – Discussion Panel

4:45PM: Conclusion

Discussion Panels

- Panel discussions are led morning and afternoon each day of the workshop
- Pre-selected questions from the panel members and audience
- Audience members whose questions were selected in advance will be called to the aisle mics by the session moderators – you must be at the session in order to read your question

Next Steps and the Public Docket

- Next steps – one part of an ongoing national discussion
- Public docket- One way to discuss next steps and relevant scientific and regulatory matters is through the public docket

Featured Result - Docket ID: FDA-2019-N-5592 Open Docket Folder

Public Workshop - Evolving Role of Artificial Intelligence in Ra…

Agency: Food and Drug Administration (FDA)

regulations.gov

Your Voice in Federal Decision-Making

SUBMIT COMMENTS

Please submit your comments regarding the workshop to https://www.regulations.gov/, Docket No. FDA-2019-N-5592 by March 26, 2020.

Please refer to the instructions for submitting comments to the docket to ensure that your feedback is received.

Please be advised that as soon as a transcript is available, it will be posted in the Dockets and accessible at http://www.regulations.gov.

Presenter Requests

- CDRH Speaker Liaison
  - Many emails about having FDA staff present at your events, please send these requests using the instructions found on FDA's website
  - https://www.fda.gov/about-fda/center-devices-and-radiological-health/requesting-speakers-cdrh

Disclaimer: Devices may be used as regulatory examples in presentations given by the Agency. FDA does not endorse any particular device or product.

Acknowledgements

Organizers and Moderators

Day 1

Berkman Sahiner, PhD

Subok Park, PhD

Alex Cadotte, PhD

Yanna Kang, PhD

Jessica Lamb, PhD

Day 2

Shahram Vaezy, PhD

Marjan Nabili, PhD

Tracy Gray

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