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
Public Workshop - Evolving Role of Artificial Intelligence in Ra
Agency: Food and Drug Administration (FDA)

SUBMIT COMMENTS


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

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

**Day 1**
Berkman Sahiner, PhD
Subok Park, PhD
Alex Cadotte, PhD
Yanna Kang, PhD
Jessica Lamb, PhD

**Day 2**
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