Scientific, Clinical & Regulatory Challenges for Radiological AI Software

Risk vs. Benefit

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What we do: DS (decision support) for ultrasound
Challenges & Risks

**SCIENTIFIC**

- Privacy
- Quality image + meta data
- Generalizable models
- Complex deployment

**risks**

- Accuracy
- Errors
## Challenges & Risks

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<tr>
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**Risks:**
- Patient Harm
- Physician Adoption
- Business Continuity
Challenges & Risks

**SCIENTIFIC**
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**CLINICAL**
- Workflow integration
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- Liability
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- Diagnostic performance

**REGULATORY**
- Documentation/QMS
- Continuous Algorithmic Improvement

- **risks**
  - Non-Conformance
  - Penalties
MASSIVE Need & Benefits

Radiologists with comparable training and experience disagreed with each other 25% of the time by rendering different diagnoses.

When presented with the same case a month later, they disagreed with themselves almost 20% of the time.

Every day in the US, physicians order over 4,000 breast tissue biopsies, of which 80% are benign — false positives. Still, over 350 cancers are missed daily . . .

130,000 false negatives each year.
THANK YOU!

Save Time, Save Lives
Be Koios Confident