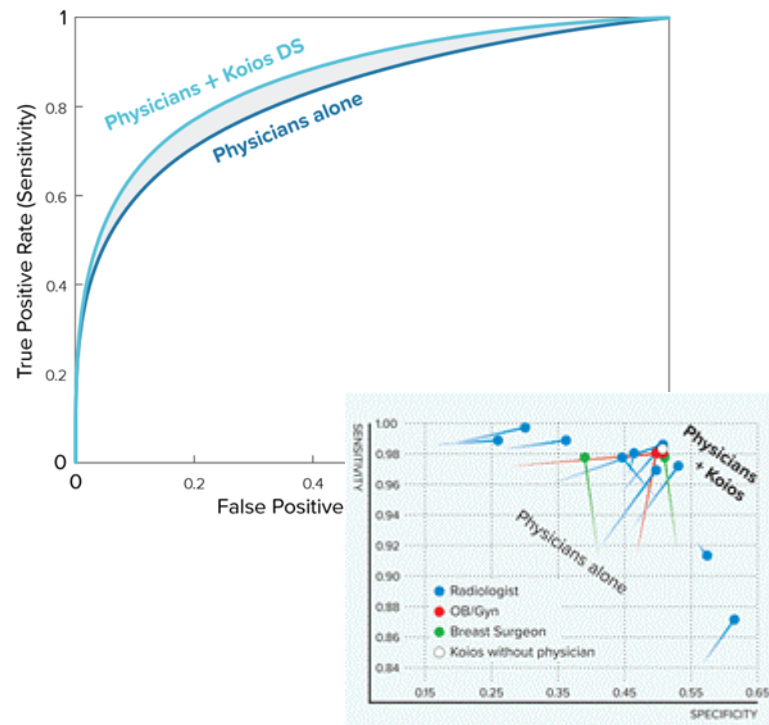
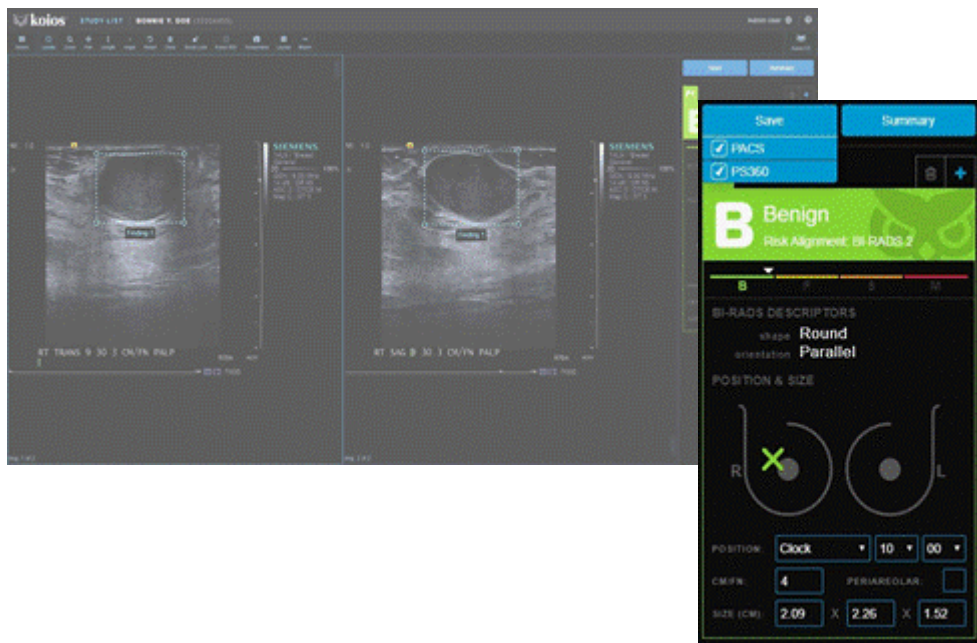


# Scientific, Clinical & Regulatory Challenges for Radiological AI Software

**Risk** vs. **Benefit**

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President & CEO

# 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

## SCIENTIFIC

- Privacy
- Quality image + meta data
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## CLINICAL

- Workflow integration
- Physician trust
- Compelling value proposition
- Liability
- Reimbursement
- Diagnostic performance

### risks

- ☒ Patient Harm
- ☒ Physician Adoption
- ☒ Business Continuity

# Challenges & Risks

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## 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 . . .

**130,00 false negatives** each year.



THANK YOU!



Save Time, Save Lives

Be Koios Confident