

Time	Activity	Content
8:45-9:25	Welcome & coffee	
9:25-9:45	Opening	• Introduction • Brief overview of AI evaluation landscape and REALM • Objectives/structure of today
9:45-10:15	Expert insight	MDR/IVDR landscape • Tom Melvin (regulatory expert) gives context on current regulatory framework for AI medical devices • Open Q&A
10:20-10:40	Coffee break	
10:40-11:25	Activity 1	Stakeholder pain points mapping • Structured template exercise: Participants document challenges from their role's perspective • Plenary mapping: Visualize how challenges interconnect across stakeholder types • Output: Documented barriers by stakeholder type, identification of where one group's constraints create challenges for others
11:30-12:30	Activity 2	Case-based evaluations • Case 1: PulmoDetect ○ Background, real-world use, missing data etc ○ Participants individually evaluate using a template form (Would you approve/recommend? What evidence is sufficient/insufficient?) • Case 2: OncoPath ○ Background, real-world use, missing data etc ○ Participants individually evaluate using a template form (Would you approve/recommend? What evidence is sufficient/insufficient?) • Group discussion of how/why evaluations diverge • Output: Documentation of different evaluation criteria and decision thresholds by stakeholder type
12:30-13:30	Lunch	
13:30-14:00	Activity 3	Prioritizing solutions

14:00-14:30	Wrap-up	• Summarizing main points • Next steps regarding workshop outputs
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