

Agenda for 2nd in-person REALM workshop

Title: REALM stakeholder workshop: patient group and medical charity perspectives on evaluation of medical AI

Date: 16 January 2026

Location: Brussels, Belgium

Venue: HOEK 38

<u>Leuvenseweg 38</u>, 1000 Brussels

Room: MALACHIET

Target group: Representatives of patient organizations and medical charities based in European countries

Time	Activity	Content
10:00 -10.15		Welcome & coffee
10.15 -11.00	Introduction	Overview of the workshop schedule
		Introduction to the REALM project:
		 What are the goals of REALM?
		 What is the REALM architecture and what is it going to do?
		 Why stakeholder input matters: the REALM living labs and improved medical
		device software guidelines
11.00 – 11.15	Brief Q&A	Q & A for immediate queries and clarifications
11.15-11.35	Coffee break	
11.35-12.20	Presentation	REALM Use case: COPowereD AI tool for predicting hospitalization in patients with chronic obstructive pulmonary disease



		 What is COPowereD and what is it intended to do? How can COPowereD help patients and physicians? How does the REALM architecture help to assess the performance of COPowereD?
12.20-12.45	Q&A	Opportunity to ask questions about the COPowereD use case
12.45-13.30	Lunch	
13.30 -14.35		 Small group discussion structured around three themes Participants divide into small groups of 2-5 persons Each group has one REALM member present to respond to questions and take notes Discussion on each theme lasts for 15 minutes All participants have a copy of pre-prepared background material outlining an issue for discussion and suggesting relevant questions to discuss within the group. The three themes for discussion are Trust in medical Al Timely access and the appropriate degree of regulatory oversight What matters in evaluating medical Al: what counts and what ought to be counted? Each small group then nominates one person to report the key ideas from the discussion to all participants so everyone gets to hear and respond to the main points from each group. We then move on to the next theme for discussion
14.45-15.00	Wrap-up &	Summarizing main points
	close	Next steps regarding workshop outputs



About REALM

REALM (*Real-World Data and Evidence for Regulatory Assessment of Artificial Intelligence–Based Medical Devices*) is an **EU-funded Horizon Europe project** that brings together academic, clinical, regulatory, and industry partners across Europe. The consortium is developing a shared European framework — a *regulatory sandbox* — to improve how **AI-driven medical device software** is evaluated, benchmarked, and regulated. By creating tools, data standards, and collaborative processes for assessing real-world performance, REALM aims to make the development and oversight of medical AI more transparent, trustworthy, and aligned with patient and societal needs.

Learn more at https://realm-ai.eu/