



Outline for in-person REALM workshop

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

Date: 19th March 2026

Location: Brussels, Belgium

Venue: TRACK [<https://www.track.brussels/fr-be>]

Rue du Progrès 76, 1030 Schaerbeek (adjacent to Bruxelles Gare du Nord)

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

Timetable

Time	Activity	Content	Lead
09.30 -10.00	Welcome & coffee		
10.00 -10.45	Introduction	<ul style="list-style-type: none">• Overview of the workshop schedule• Introduction to the REALM project:<ul style="list-style-type: none">◦ 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	Michael
10.45 – 11.00	Q&A	<ul style="list-style-type: none">• Short Q & A for immediate queries and clarifications	Michael Dominika Tomasz Janaki Zita
11.00-11.15	Coffee break		



11.15-11.45	Presentation	<ul style="list-style-type: none"> REALM Use case 1#: Pharmacogenomics Passports to Practice (PGx2P) AI tool that utilizes data from predictive genetic tests to support doctors in making prescribing decisions for common medications with the aim of reducing adverse drug responses. <ul style="list-style-type: none"> ○ What is PGx2P and how does it work? ○ How can PGx2P help patients and physicians? ○ How does the REALM architecture help to assess the performance of PGx2P? 	VITO
11.45-12.10	Q&A	<ul style="list-style-type: none"> Participant questions on use case 1#, all aspects of REALM , and any general questions 	VITO, ALL
12.10-13.10	Lunch		
13.10-13.40	Presentation	<ul style="list-style-type: none"> REALM use case 2#: COPowereD AI tool for predicting hospitalization in patients with chronic obstructive pulmonary disease <ul style="list-style-type: none"> ○ 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? 	COMUNICARE
13.40-14.10	Q&A	Opportunity to ask questions about use case 2#, all aspects of REALM and any general questions not covered by the previous Q&A (including follow up questions)	COMUNICARE, ALL
14.10 -14.55	Group discussion (x3)	<ul style="list-style-type: none"> 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 20 minutes plus 15 minutes for reporting and discussions after each topic 	Michael Dominika Tomasz Janaki Zita



		<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Trust in medical AI ○ Timely access and the appropriate degree of regulatory oversight ○ What matters in evaluating medical AI: 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 	
14.55-15.10	Coffee break		
15.10- 16-25		<ul style="list-style-type: none"> • Small group discussion resumes for topics 2 and 3 	
16.25- 16.40	Wrap-up & close	<ul style="list-style-type: none"> • Summarizing main points • Next steps regarding workshop outputs • Thanks to participants 	Michael

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/>