



The European Platform for Regulatory Science Research brings together academic researchers and regulatory scientists to advance research in regulatory science. Research in this field supports the development and evaluation of medicines.

The European Platform Regulatory Science Research Participant meeting aims to:

- Support scientists and researchers who are interested in activities that could help address regulatory science research needs
- Share best practices, emerging methodologies, and foster translation of research outcomes into useful solutions for developers and regulators
- Grow the community of researchers engaging on regulatory science research topics

Contact point : <u>regulatory.science@ema.europa.eu</u>. Event web page : <u>European Platform for Regulatory</u> Science Research meeting September 2025 | European Medicines Agency (EMA)

European Platform for Regulatory Science Research meeting - Agenda

Monday 29 September 2025, 14:00 - 17:30 (CEST)

13:45	Technical checks	
14:00	Welcome and introduction (10 min)	
	Welcome and introduction to the meeting and agenda Ralf Herold	10 min
14:10	Working on biomarkers – research landscape and evidence generation (80 min)	
	Co-moderators: Marjon Pasmooij & Günter Waxenecker	
	Introduction and topic mapping Marjon Pasmooij	10 min
	Researcher perspective on state, gaps and opportunities Chantal Mathieu	15 min
	Open discussion and questions All participants invited	55 min
15:30	Showcasing EMA's Clinical Data Publication and use by researchers (60 min)	
	Co-moderators: Adam Hacker & Liese Barbier	
	Introduction and demo to EMA's Clinical Data Publication Anne-Sophie Henry-Eude & Karen Quigley	20 min
	Learnings from a researcher case example David Byrne	10 min
	Open discussion and questions All participants invited	30 min
16:30	Spotlight on funding at EU level and ways of involving regulators in scientific projects (55 min)	
	Co-moderators: Madeline Pe & Ralf Herold	
	Introduction and topic mapping Ralf Herold	10 min
	Funder perspectives and insights Tomasz Dylag Nathalie Seigneuret Christine Hasenauer	20 min

All participants invited

17:25 Next steps and meeting close (5 min)

Liese Barbier 5 min

List of speakers

Liese Barbier European Medicines Agency (EMA), Lead European Platform for

Regulatory Science Research

David ByrneUniversity of Medicine and Health Sciences, Royal College of Surgeons in

Ireland (RCSI)

Tomasz Dylag European Commission

Adam Hacker Coalition for Epidemic Preparedness Innovations (CEPI), Academic Co-

chair European Platform for Regulatory Science Research

Christine Hasenauer EP PerMed, DLR Projektträger

Anne-Sophie Henry-Eude European Medicines Agency (EMA)

Ralf Herold European Medicines Agency (EMA), EMA Co-chair European Platform for

Regulatory Science Research

Chantal Mathieu Catholic University of Leuven (KU Leuven), University Hospitals Leuven

(UZ Leuven), INNODIA

Marjon Pasmooij Dutch Medicines Evaluation Board (MEB), NCA Co-chair European

Platform for Regulatory Science Research

Madeline Pe EORTC, Steering group member European Platform for Regulatory

Science Research

Karen Quigley European Medicines Agency (EMA)

Nathalie Seigneuret Innovative Health Initiative (IHI)

Günter Waxenecker Austrian Agency for Health and Food Safety (AGES), Steering group

member European Platform for Regulatory Science Research