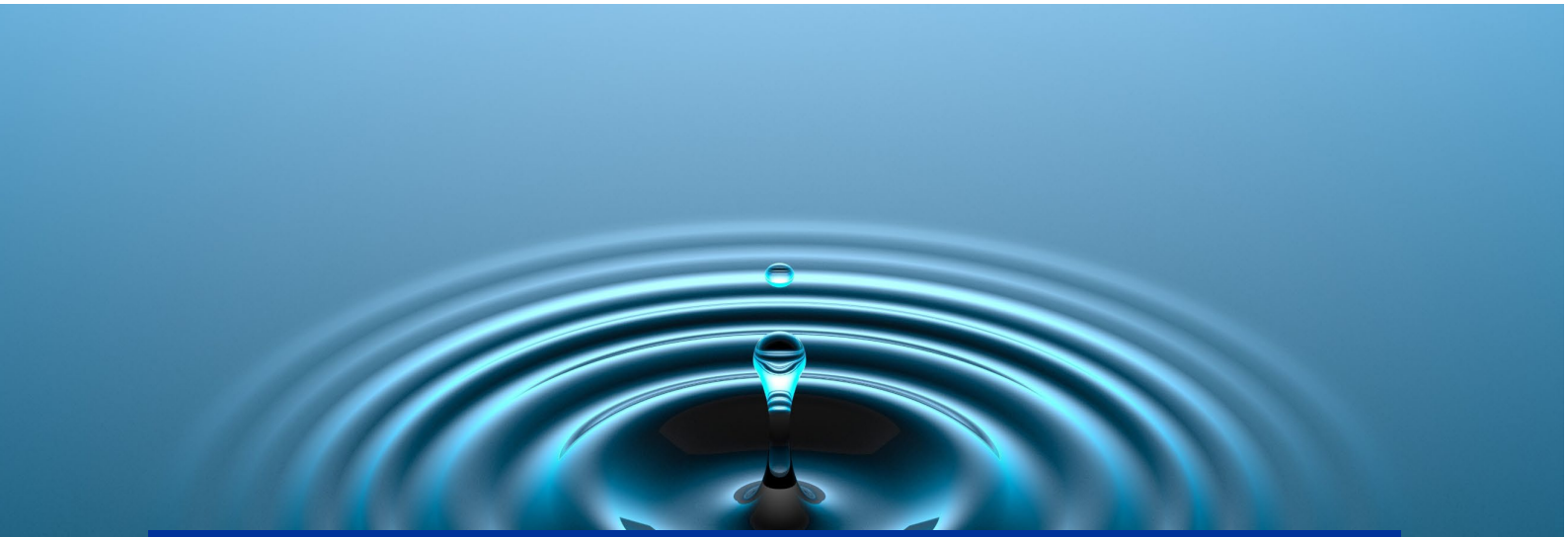
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



EMA/HMA European Platform for Regulatory Science Research

Platform meeting - Agenda

30 April 2026, 13:00 – 17:00 (CEST)
Virtual meeting / EMA, Amsterdam

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 meeting aims to:

- Support scientists and researchers interested in activities that could help address regulatory science research needs
- Share best practices, discuss emerging methodologies and foster translation of research outcomes into useful solutions for developers and regulators
- Grow the community of researchers whose work contributes to advance regulatory science

Contact point: regulatory.science@ema.europa.eu | Platform web page | Platform meeting web page |

European Platform for Regulatory Science Research meeting - Agenda

Thursday 30 April 2026, 13:00 – 17:00 (CEST)

12:45 Technical checks

13:00 Welcome and introduction (20 min)

Welcome and introduction to the meeting purpose and agenda **10 min**
Ralf Herold

Platform discussion topics and activities in 2026 **10 min**
Liese Barbier

13:20 Clinical trial registers and research use (60 min)

Public registers hold detailed data on clinical trials, including their design and results. The session is about how such data can be used to inform subsequent trials and to conduct research of interest to platform participants and regulators, e.g. of analytical methods used, for reviewing and simulating efficient designs, for identifying special features and more.

Introduction and moderation: Pieter Vankeerberghen & Giacomo Capone

International clinical trials registers and CTIS **10 min**
Jacobus van Wyk

Research case examples and learnings on how to use register data **25 min**
Tiago Machado (methodological approaches for using registers for research)
Helen Fagerlind (methodological approaches for using registers for research)
Ralf Herold (results data for safety analysis across registers)

Open discussion and questions **25 min**
The discussion will cover: researcher questions and experience, state of the art, challenges, collaboration opportunities, funded projects or funding opportunities

All participants invited

14:20 Research and evidence generation for medicines including new uses (80 min)

The session is about research and data that can contribute to establish a new medicine or a new use of an established medicine (sometimes called 'repurposing') in healthcare. Medicine regulators support developers with orientation about possible pathways and recommendations about how to generate data.

Introduction and moderation: Marjon Pasmooij & Ralf Herold

Evidence generation pathway and support at EU level **10 min**
Ralf Herold

Learnings from a researcher case **15 min**
Markus Schülke

Open discussion and questions **15 min**
The discussion will cover: researcher questions and experience, state of the art, challenges, collaboration opportunities, funded projects or funding opportunities

New uses landscape and interactions with regulators **10 min**
Marjon Pasmooij

Support for and experiences with researcher evidence generation **15 min**
Donald Lo, Harald Schmidt & Christelle Bouygues

Open discussion and questions **15 min**
The discussion will cover: researcher questions and experience, state of the art, challenges, collaboration opportunities, funded projects or funding opportunities

All participants invited

15:40 Break (10 min)

15:50 HMA-EMA Catalogues of real-world data sources and studies and use by researchers (60 min)

This session, in the series about data provided by regulators for researchers, is about these living catalogues or real-world data sources, studies, institutions and networks that were published and are growing since 2024, and how these can be used to support research into medicines.

Introduction and moderation: Adam Hacker & Paolo Alcini

Introduction and demo of data catalogues **15 min**
Katerina-Christina Deli

Researcher use of the catalogues **15 min**
Helga Gardarsdottir

Open discussion and questions **30 min**
The discussion will cover: researcher questions and experience, state of the art, challenges, collaboration opportunities, funded projects or funding opportunities
All participants invited

16:50 Meeting close (10 min)

Liese Barbier & Ralf Herold **10 min**

List of speakers

Ralf Herold	European Medicines Agency (EMA)
Liese Barbier	European Medicines Agency (EMA)
Pieter Vankeerberghen	European Medicines Agency (EMA)
Giacomo Capone	European Medicines Agency (EMA)
Jacobus van Wyk	European Medicines Agency (EMA)
Tiago Machado	Faculdade de Medicina da Universidade de Lisboa, Portugal
Helen Fagerlind	Sahlgrenska University Hospital, Sweden
Marjon Pasmooij	Medicines Evaluation Board (MEB), The Netherlands
Markus Schülke	Charité – Universitätsmedizin Berlin, Germany
Donald Lo	EATRIS, REMEDi4ALL
Harald Schmidt	REPO4EU, Maastricht University
Christelle Bouygues	European Medicines Agency (EMA)
Adam Hacker	Coalition for Epidemic Preparedness Innovations (CEPI)
Paolo Alcini	European Medicines Agency (EMA)
Katerina-Christina Deli	European Medicines Agency (EMA)
Helga Gardarsdottir	Utrecht University, The Netherlands