EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# EMA/HMA European Platform for Regulatory Science Research

## Platform Participant meeting - Agenda

20 May 2025, 14:00 – 16:30 (CEST)
**Virtual meeting / EMA, Amsterdam**

Advancing regulatory science can aid in improving medicine development and evaluation, enabling patient access to medicines that better meet their needs. Collaboration and dialogue between regulators and researchers are crucial to keep regulatory science in step with innovation and to enhance its impact on the regulatory system.

The European Platform Regulatory Science Research Participant meeting aims to:

- Grow the community of researchers engaging on regulatory science research topics
- 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 results into solutions
- Highlight opportunities for academia to collaborate with regulators on regulatory science research

Contact point: regulatory.science@ema.europa.eu

# European Platform for Regulatory Science Research meeting - Agenda

**Tuesday 20 May 2025, 14:00 – 16:30 (CEST)**

## 13:45 Technical checks

## 14:00 Welcome and introduction (25 min)

**Welcome and introduction to the strategic approach to regulatory science research** — **10 min**
*Ralf Herold & Marjon Pasmooij*

**Introduction to the Platform and agenda topics** — **10 min**
*Liese Barbier*

**Platform participant engagement** — **5 min**
*Adam Hacker & all Platform participants invited*

## 14:25 Within the broad research need '*Perform studies to develop optimal PK (and PD) designs in children to support extrapolation from adults*': starting point pharmacological modelling research (60 min)

*Co-moderators: Andrew Thomson & Ralf Herold*

**Topic mapping and introduction** — **5 min**
*Andrew Thomson*

**Researcher perspective on state, gaps and opportunities** — **10 min**
*Saskia De Wildt*

**Open discussion and questions** — **40 min**
*All Platform participants invited*

## 15:25 Use of regulatory data in research projects: spotlight on the assessment report (60 min)

*Co-moderators: Marjon Pasmooij & Adam Hacker*

**Topic mapping and introduction** — **5 min**
*Marjon Pasmooij*

**Methodological learnings from case examples** — **15 min**
*Florian Klinglmüller & Tobias Fellinger*
*Vincent Haverhoek*

**Open discussion and questions** — **40 min**
*All Platform participants invited*

## 16:25 Collecting feedback and anticipating next meeting (5 min)

*Liese Barbier* — **5 min**

## List of speakers

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|---|---|
| **Ralf Herold** | European Medicines Agency (EMA), EMA Co-chair European Platform for Regulatory Science Research |
| **Marjon Pasmooij** | Dutch Medicines Evaluation Board (MEB), NCA Co-chair European Platform for Regulatory Science Research |
| **Liese Barbier** | European Medicines Agency (EMA), European Platform for Regulatory Science Research Lead |
| **Adam Hacker** | Coalition for Epidemic Preparedness Innovations (CEPI), Academic Co-chair European Platform for Regulatory Science Research |
| **Andrew Thomson** | European Medicines Agency (EMA) |
| **Saskia De Wildt** | Radboud University Medical Center (Radboudumc) |
| **Florian Klinglmüller** | Austrian Federal Office For Safety In Health Care (AGES) |
| **Tobias Fellinger** | Austrian Federal Office For Safety In Health Care (AGES) |
| **Vincent Haverhoek** | Utrecht University (UU) |