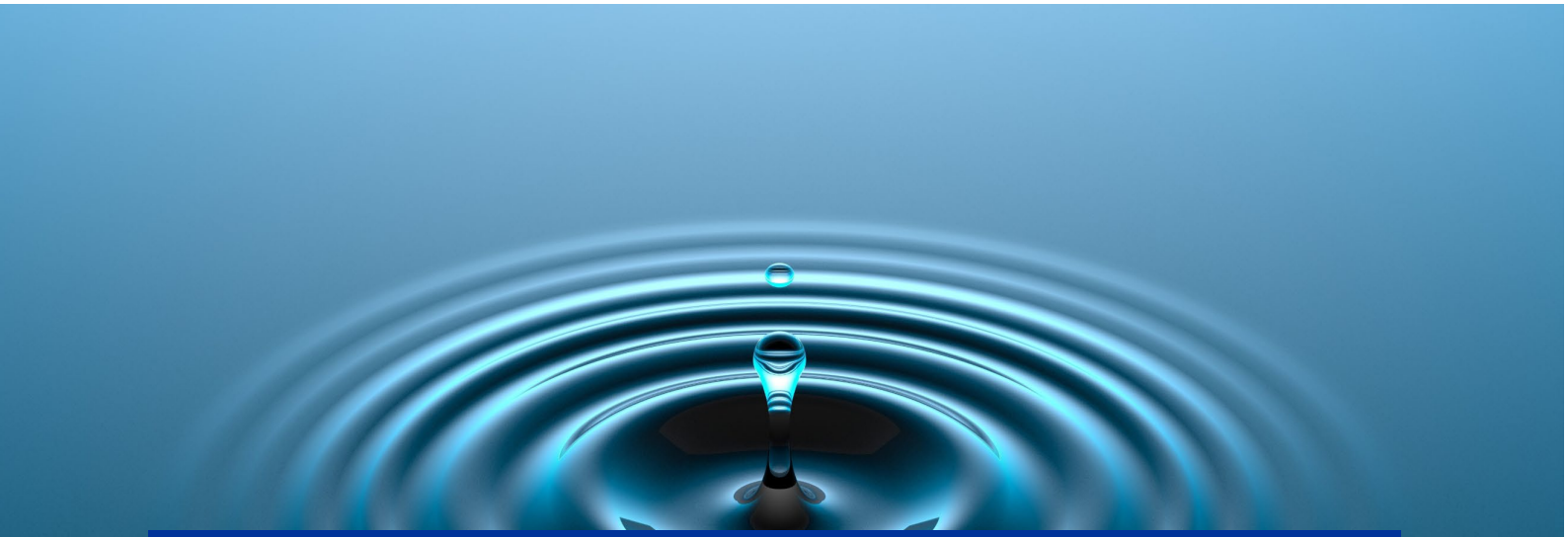
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



EMA/HMA European Platform for Regulatory Science Research

Platform meeting – Draft Agenda

16 June 2026, 14:00 – 18:00 (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, foster collaboration and 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 | Participate in Platform and meetings : registration

European Platform for Regulatory Science Research meeting - Agenda

Tuesday 16 June 2026, 14:00 – 18:00 (CEST)

13:45 Technical checks

Slido used throughout the meeting: link, passcode RSR26

14:00 Welcome and introduction (10 min)

Welcome and introduction – platform background, meeting purpose and agenda **10 min**

Marjon Pasmooij & Liese Barbier

14:10 New approach methodologies (NAMs): Understanding academic research for NAMs and how to investigate applications of NAMs in medicine development (80 min)

New approach methodologies (NAMs) are being broadly researched and can be developed to have utility as innovative methods that improve the scientific basis for evaluating and decision-making for medicinal products while reducing or replacing animal use. This session will explore the state of play in academic NAMs research and how research can be supported to work towards acceptance and use of these methodologies in medicine development and evaluation.

Background: Regulatory acceptance of new approach methodologies (NAMs) to reduce animal use testing | European Medicines Agency (EMA)

Introduction and moderation: Stefano Ponzano & Ronette Gehring **5 min**

From research to application: insights from organoid research field **15 min**
Jürgen Knoblich

What I as a regulator think about when we talk about NAMs: considerations on evidence generation for achieving regulatory acceptance for NAMs **15 min**
Peter van Meer

Open discussion and questions **40 min**
All participants invited
Discussion will invite researcher questions and experience, best practices considered by the field, common challenges, collaboration opportunities, interests in potential follow-up activities

Session close **5 min**
Stefano Ponzano

15:30 Researching AI to advance the AI regulatory research needs for medicines (60 min)

The starting point of this session are the new regulatory research needs related to the use of AI in the medicine lifecycle. The discussion will focus on advancing research to make progress on these needs, such as approaches for generating evidence on methodologies that enable safe and reliable AI integration. Epistemological approaches, how knowledge is created and validated in this field, will be discussed so that activities can build on them for addressing the AI research needs. Not in focus will be specific applications of AI.

Background: AI regulatory research needs (Annex below and pre-print available here) | AI observatory reports | European Medicines Agency (EMA)

Introduction and moderation: Luis Pinheiro & Adam Hacker **5 min**

Regulatory research priorities for AI use in the medicine lifecycle **10 min**
Amanda Langston

Academic perspective: developing and validating methods for AI **10 min**
Maarten van Smeden

Open discussion and questions **30 min**
All participants invited
The discussion will invite researcher questions and experience, state of the art, challenges, collaboration opportunities, funded projects or funding opportunities, interests in potential follow-up activities

Session close **5 min**
Luis Pinheiro

16:30 Break (15 min)

16:45 Translating research into impact (60 min)

This session builds on recent findings of a focus group on regulatory science research translation, involving consortia and trade associations. It will highlight best practices and practical guidance for developing regulatory strategies and integrating change management into research projects to support downstream impact. This includes uptake by different stakeholders in the health system, such as medicines R&D and evaluation. The session will also facilitate discussion of selected recommendations by the focus group, exploring how actors in the field and platform members could articulate their needs and collaborate.

Background: Report Focus Group Regulatory Science Research Translation | European Medicines Agency (EMA)

Introduction and moderation: Ralf Herold & Liese Barbier **5 min**

Focus group report: practical recommendations for implementing change management and regulatory strategy in projects **10 min**
Pierpaolo Moscariello

Open discussion and questions **20 min**
All participants invited
The discussion will invite researcher questions and experience, best-practices and challenges

Exploring needs for, and interests in a curated knowledge base, pool of experienced project participants and repository of project outputs as per Focus group recommendations **5 min**
Ralf Herold

Open discussion and questions **20 min**
All participants invited

The discussion will cover what is already available, experience with curating and sharing, challenges, collaboration opportunities, funded projects or funding opportunities, interests in potential follow-up activities

Session close **5 min**
Liese Barbier

17:45 Meeting close (10 min)

Ralf Herold **10 min**

List of speakers

Ralf Herold	European Medicines Agency (EMA)
Marjon Pasmooij	Medicines Evaluation Board (MEB), The Netherlands
Liese Barbier	European Medicines Agency (EMA)
Stefano Ponzano	European Medicines Agency (EMA)
Peter Van Meer	Dutch Medicines Evaluation Board (MEB), EMA 3R Working Party, EMA Non-clinical Working Party
Jürgen Knoblich	Research Institute of Molecular Pathology, Austria
Luis Pinheiro	European Medicines Agency (EMA)
Adam Hacker	Coalition for Epidemic Preparedness Innovations (CEPI)
Amanda Langston	European Medicines Agency (EMA)
Maarten van Smeden	UMC Utrecht, Netherlands
Pierpaolo Moscariello	European Medicines Agency (EMA)

Annex

AI regulatory research needs

From *Pinheiro, L., Langston, A., Orre, M., Zinserling, J., Boumaki, K., Hornung, B., O'Sullivan, S., Westman, G., Broich, K., & Arlett, P. (2026). Regulatory research priorities for AI use in the medicine lifecycle: a European perspective with global relevance. Zenodo. https://doi.org/10.5281/zenodo.20554817*

Pre-print available here

<<< Accuracy and reliability

1. How can the accuracy and reliability of AI models be ensured when they are used to generate clinical evidence and inform regulatory decisions, and how can limitations of AI for these purposes be identified?
2. How can AI systems used in the medicines lifecycle and regulatory review remain robust and trustworthy when they face challenges like changing data, reduced performance over time, incomplete information, or misleading inputs?
3. When is it important for AI models to be explainable in regulatory decision-making, and what methods best achieve that without affecting their performance?

Data governance, confidentiality and consent

4. What models of informed consent or other legal basis are most appropriate when using health data for AI research beyond the original purpose the data were collected for?
5. How can data used in AI-based medicines development be made more secure and easier to audit or track?

Ethics, fairness, and bias prevention

6. What methods are most effective for spotting and reducing bias in AI models for use in medicines development and evaluation?
7. What kind of transparency measures are necessary to clearly explain the limits and uncertainties of AI use in the medicines' lifecycle?

Regulation and oversight

8. What gaps exist in current guidance for AI use in areas like benefit-risk assessment, monitoring medicine safety (pharmacovigilance), and clinical evidence generation?

Research integrity and intellectual property

9. How can transparency and reproducibility of results be strengthened in AI-enabled medicine development?

Resources and support for AI use

10. Which technical checks and quality controls are essential to ensure that AI systems used in clinical trials, manufacturing, safety monitoring, and regulatory submissions are properly validated, secure, and reliable? **>>>**