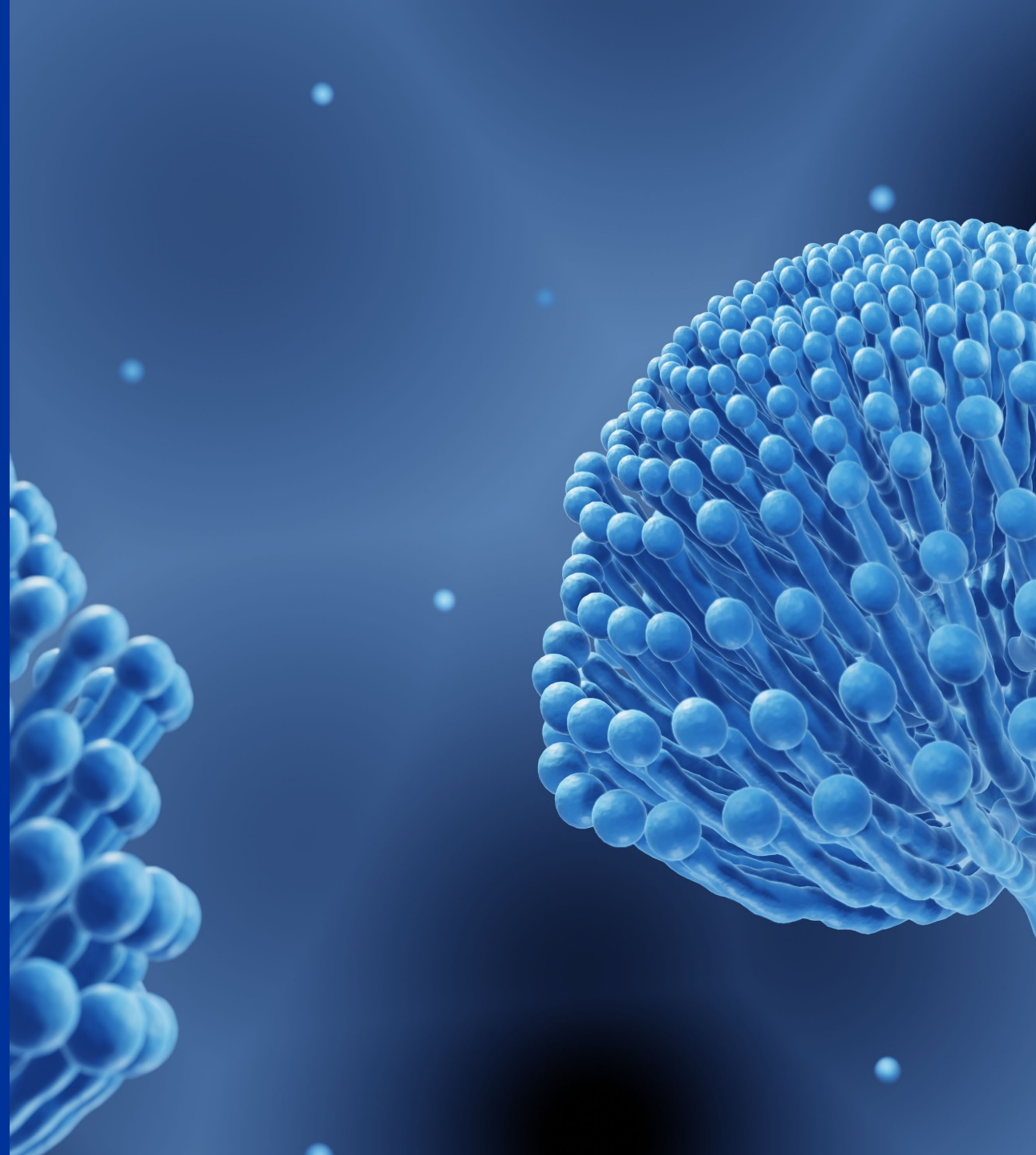


EMA/HMA European Platform for Regulatory Science Research - Call for expression of interest

30 September 2025

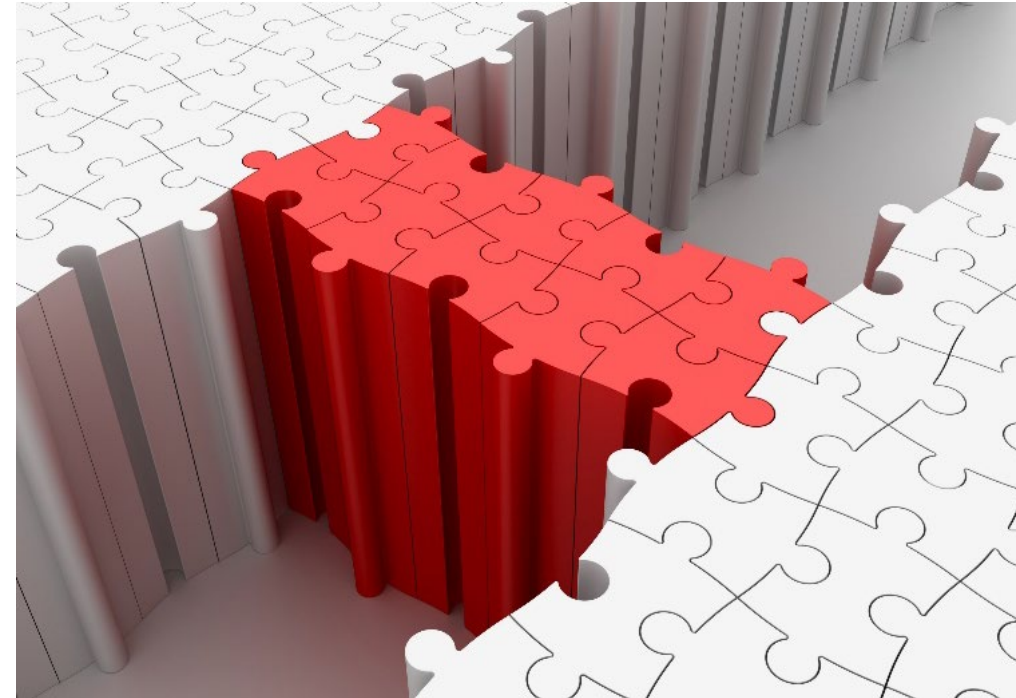
ISG meeting

Liese Barbier and Ralf Herold
Regulatory Science and Academia
Regulatory Science and Innovation Task Force

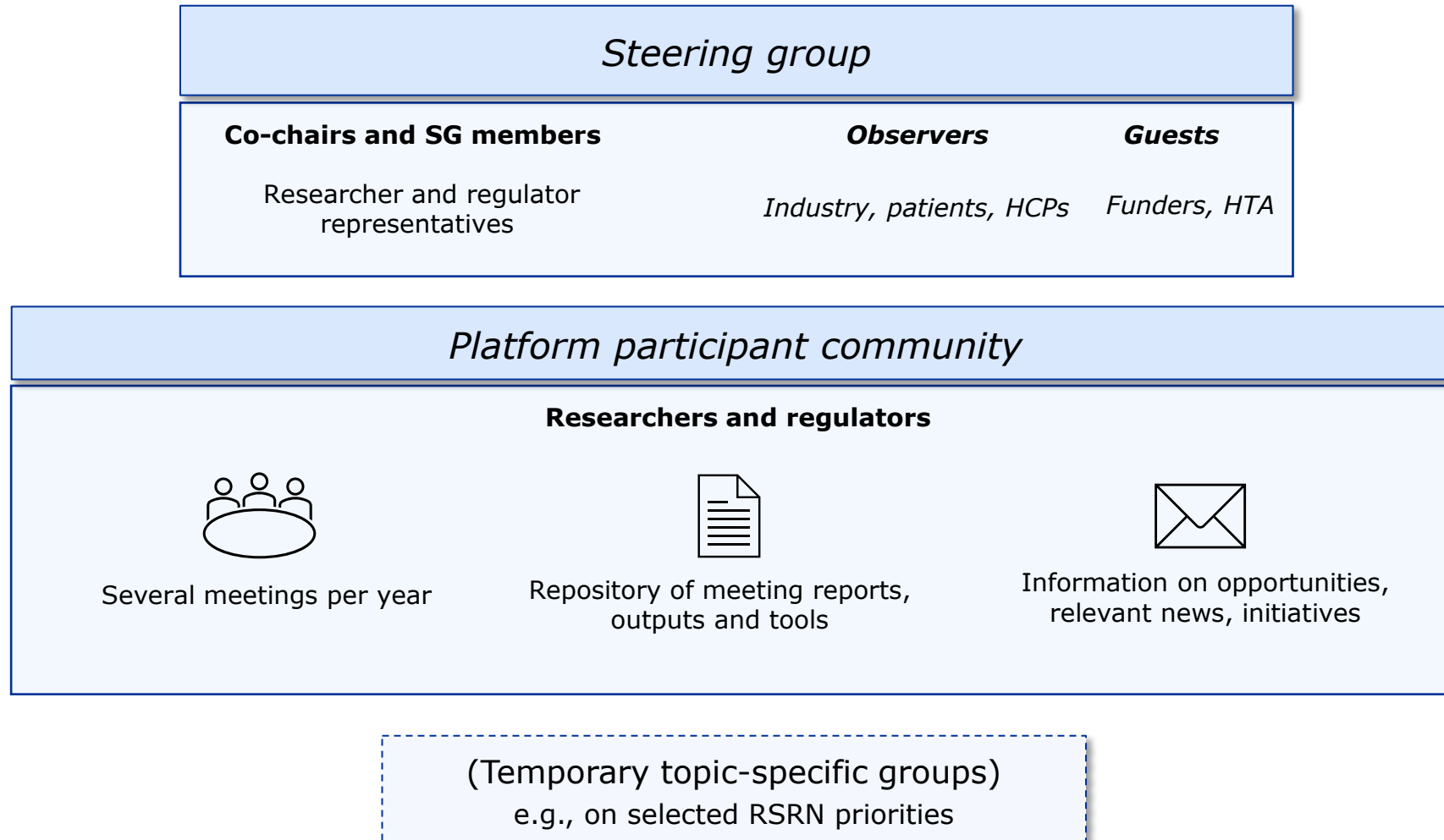


European platform for regulatory science research

- Advancing *research* in regulatory science for improving the development and evaluation of medicines
- A Platform as mechanism for dialogue and collaboration between academic, public and not-for-profit regulatory science researchers and regulators, to
 - foster *collaboration* among and between *academic researchers and regulatory scientists* from Europe and beyond on key topics in regulatory science research
 - *accelerate research*, focusing on questions of common interest, informing research and *funding* on these key questions, increasing the *usefulness and translation of research solutions* in the work of regulators and developers
 - support *growth of research community* engaging on regulatory science



Working model



Call for expression of interest

- Call to invite **one observer** representing **industry stakeholders** in the Steering Group
- Similar call open to involve a patient and an HCP representative
- **Criteria** for the nomination of an industry observer to the Steering Group
 - Sector to be represented: medicine developers
 - Expertise and experience required:
 - Experience in regulatory science and regulatory science research
 - Leadership experience
- **Time and contribution** expected
 - Sought commitment: active engagement, regular participation in Steering group meetings (6 - 8 times/year) and Platform meetings (approximately 4 times /year)
 - Providing input on tasks and topics for discussion, workplans, ...
- In addition to participation of one industry observer in the Steering group, **industry scientists** can be invited and participate **ad hoc** in **Platform meetings** based on the topic scheduled for discussion

Call for expression of interest

- We invite a cross-industry nomination by *Tuesday 28 October 2025*
- By writing to regulatory.science@ema.europa.eu with the emaindustryliasion@ema.europa.eu in CC
- Please mention in the header of your email “European Platform for Regulatory Science Research”.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

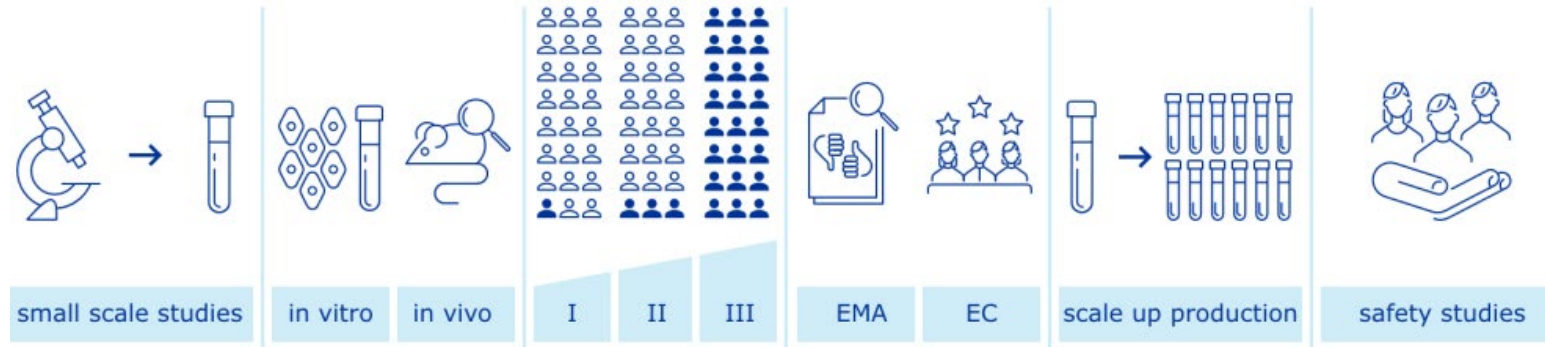
liese.barbier@ema.europa.eu
regulatory.science@ema.europa.eu

European Platform for Regulatory Science
Research | European Medicines Agency (EMA)

Evidence is needed...

...on the particular medicine under investigation

Product R&D development



...on methods and their application in developments

Regulatory science R&D

Investigating and establishing tools and methods for specific activities in drug development

Investigating and establishing approaches for optimising the evidence generation

Investigating and evolving the regulatory activities and system

What do we mean with...

Regulatory science

- applying various scientific disciplines to the quality, safety, and efficacy assessment of medicines
- informing decision-making throughout the lifecycle of the medicine
- evaluating existing, and development of new regulatory standards, tools, methods as well as principles used for developing medicines

Research into regulatory science

- addressing cross-cutting issues in development and gaps that hinder regulatory advancement
- for horizontal questions on medicines and evidence gaps that cannot be addressed through EMA data
- multidisciplinary field using a diverse range of methods, from wet lab to desktop

Regulatory science research needs

 EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH  Regulatory Science Research Needs 2025 update	14 July 2025 EMA/510633/2024																														
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Official address Domenico Sciarlattaan 6 • 1083 HS Amsterdam • The Netherlands Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union © European Medicines Agency, 2025. Reproduction is authorised provided the source is acknowledged.	Regulatory Science Research Needs EMA/510633/2024 Page 2/31																														

Regulatory science research needs



to improve clinical research

- Statistical analysis in clinical trials
- Innovative approaches in clinical trials design
- Clinical trials optimization in specific therapeutic areas



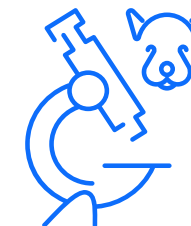
to improve regulatory system evolution

- Going beyond current regulatory pathways
- Shortages
- Communication
- Data management



to foster technologies for development of specific types of medicines

- Platform technologies and vaccines
- Antimicrobial resistance
- Non-animal models / 3Rs
- Non-animal models / ATMPs
- Real-world data / real-world evidence
- Biomarkers



to advance specifically animal health and the regulation of veterinary medicines

- Non-animal models / 3Rs
- Environmental risk assessment
- Antiparasitic resistance
- Pharmacovigilance
- Novel therapies and innovation
- Vaccines
- Antimicrobial resistance
- Veterinary big data