

EMA/HMA European Platform for Regulatory Science Research

Platform meeting

16 June 2026 14:00 – 18:00 CEST

Join at
slido.com
#RSR26

 Passcode: **RSR26**



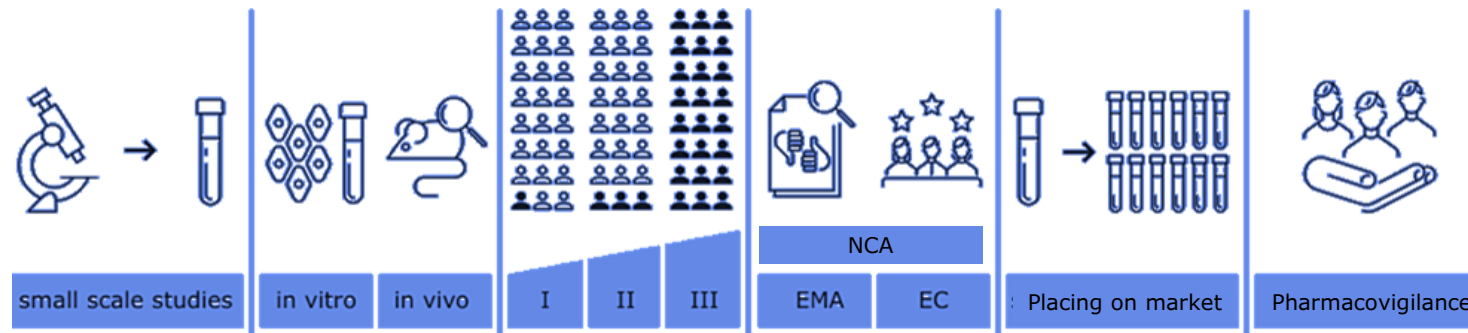
European Platform for Regulatory science research

A mechanism for dialogue and collaboration between academic, public and non-for-profit regulatory science researchers and regulators

- To systematically **advance and accelerate research** addressing regulatory needs
- To refine and enrich regulatory topics with **research interests** and **methods expertise**
- To progress methodological standards and to increase the **quality and relevance** of research outputs for regulatory implementation
- To accelerate **translation of outputs** into improved R&D and regulatory practices
- To support **growth of academic researcher community** engaging on regulatory issues

Need for generating evidence...

...on a particular medicine under investigation



**Medicinal product
research, develop-
ment and evaluation**

...on methods and their application in developments

Domain I:
Investigating and
establishing tools and
methods for specific
activities in drug
development

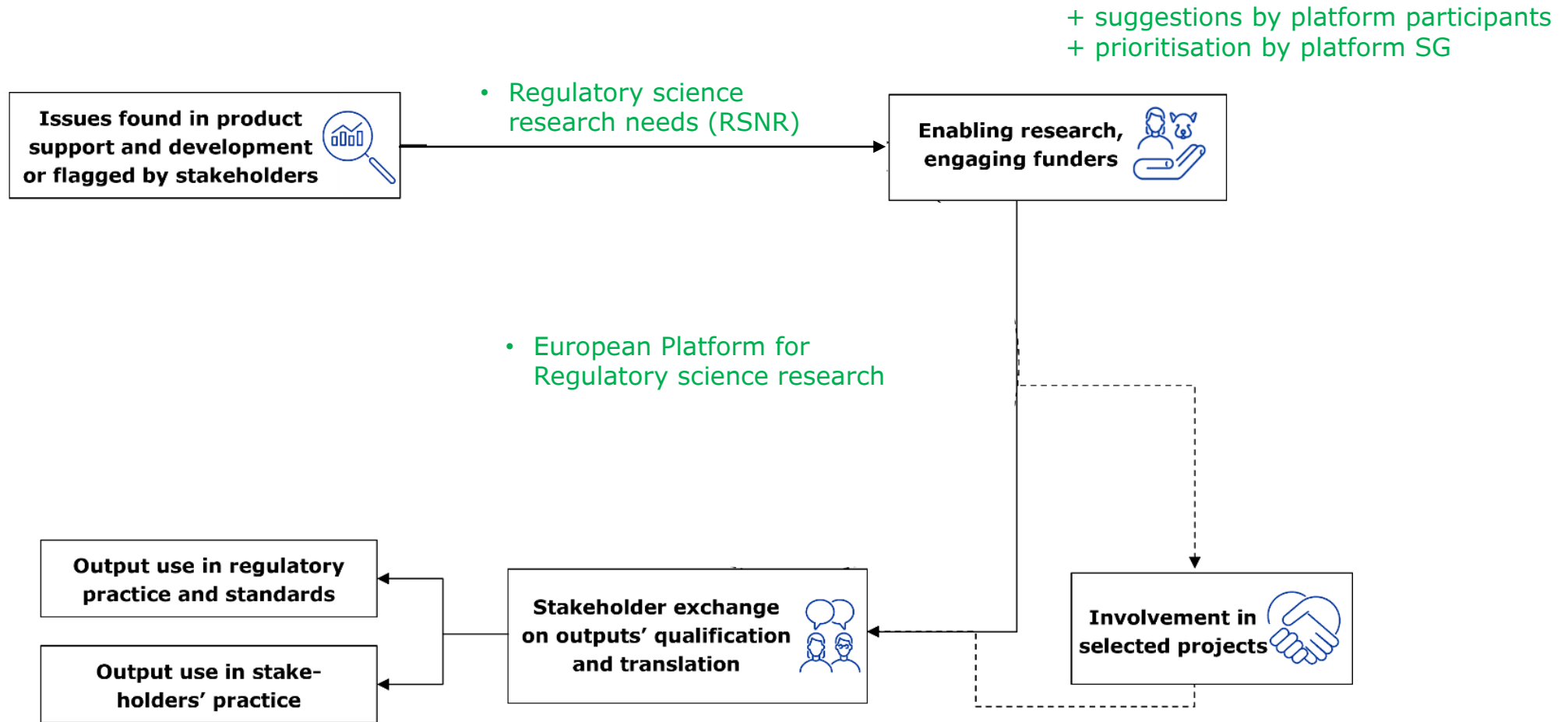
Domain II:
Investigating and
establishing approaches
for optimising evidence
generation

Domain III:
Investigating and
evolving the regulatory
activities and system

**R&D of regulatory
science**

- **Pre-competitive**
- **Product-independent**
- Open science approach
- Often academia leading
- Often multiple stakeholders
- Often publicly financed

A systematic and strategic approach to advancing regulatory science



<https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/regulatory-science-research-needs>

Agenda for today

- 14:00 – 14:10 Welcome and introduction (10 min)
- 14:10 – 15:30 New approach methodologies (NAMs): Understanding academic research for NAMs and how to investigate applications of NAMs in medicine development (80 min)
- 15:30 – 16:30 Researching AI to advance the AI regulatory research needs for medicines (60 min)
- 16:30 – 16:45 *Break (15 min)*
- 16:45 – 17:45 Translating research into impact (60 min)
- 17:45 – 18:00 Meeting close (15 min)