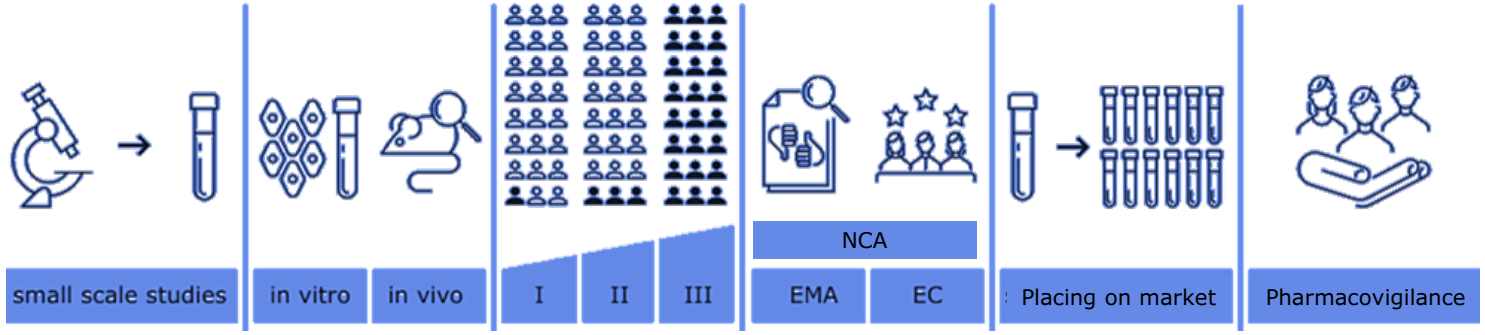
European Platform for Regulatory science research

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

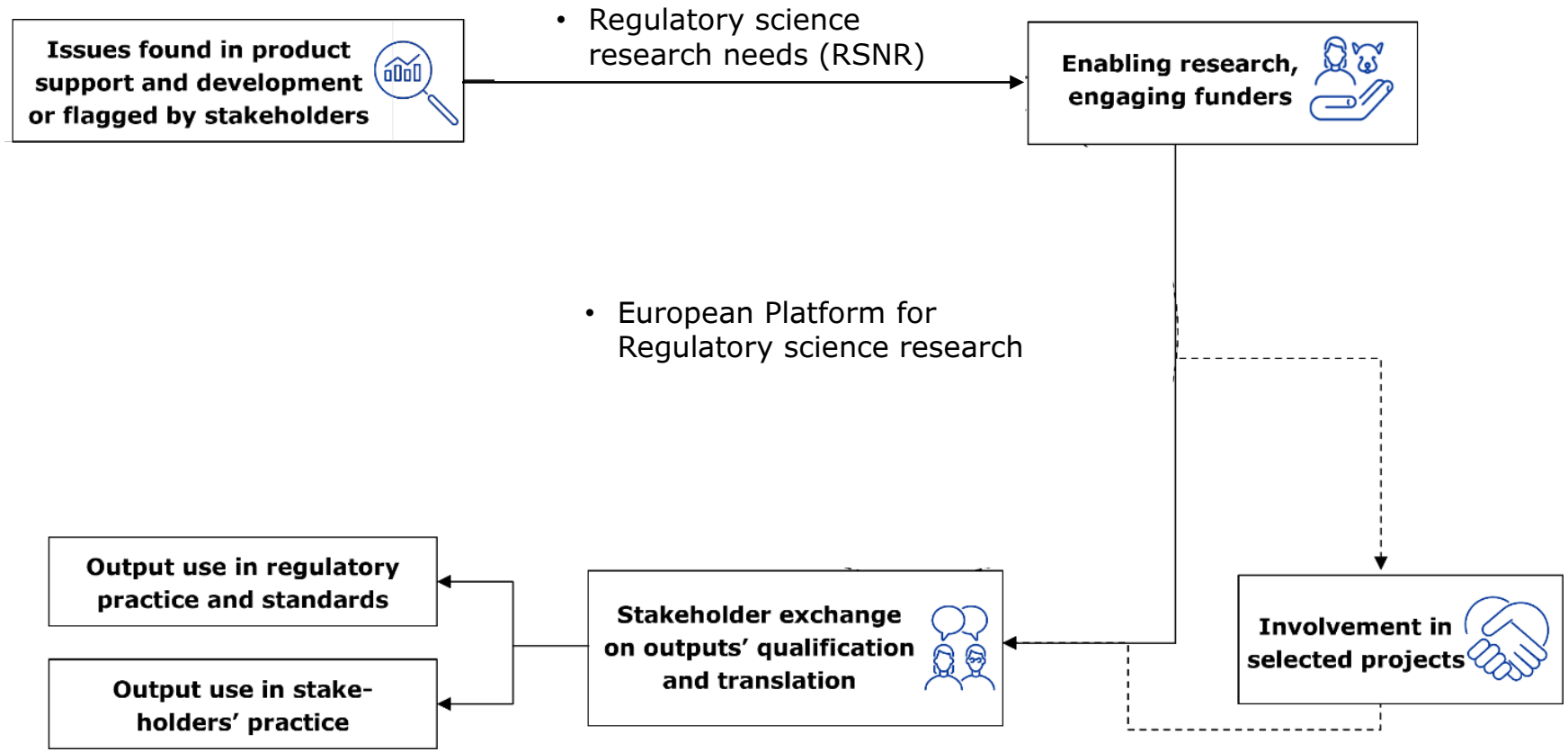
Domain II:
Investigating and establishing approaches for optimising evidence generation

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

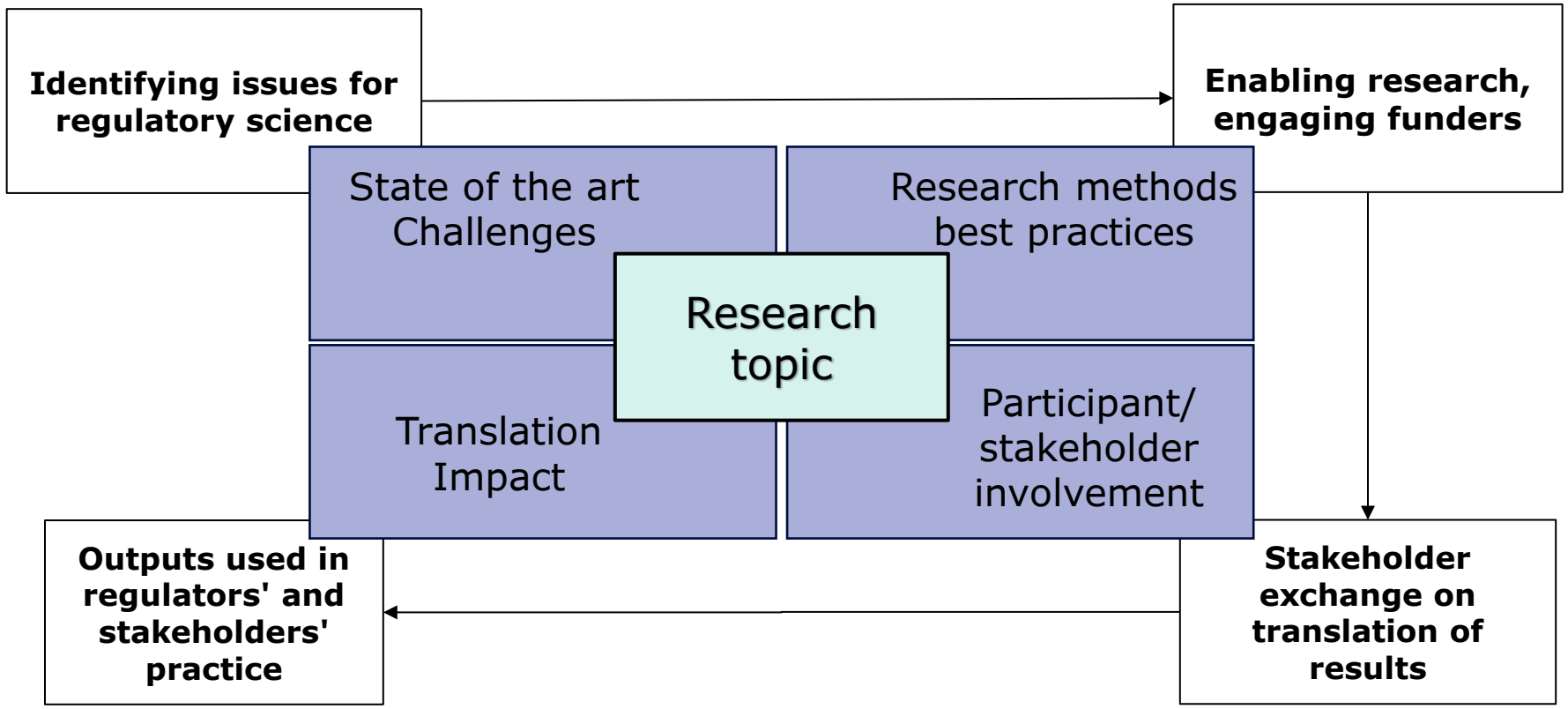


Regulatory science research needs

Word cloud from keywords across all research needs

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

A structured discussion approach



Platform working model

Steering group

Co-chairs and SG members	**Observers**	**Guests**
Researcher and regulator representatives	Industry, patient, HCP representatives	Funders, HTA bodies

Platform participant community

Researchers and regulators, ad hoc participation other stakeholders

Several meetings per year

Repository of meeting reports, outputs and tools

Information on opportunities, relevant news, initiatives

Temporary topic-specific working groups

on selected RSRN priorities, Platform discussion topics

- EPAR Best-practice guide drafting group
- Clinical data for research purposes
- Pharmacological modelling
- Biomarker research
- …

Expansion of Platform's Steering Group

Adam Hacker (CEPI) (Co-chair)
Ronette Gehring (UU)
Madeline Pe (EORTC)

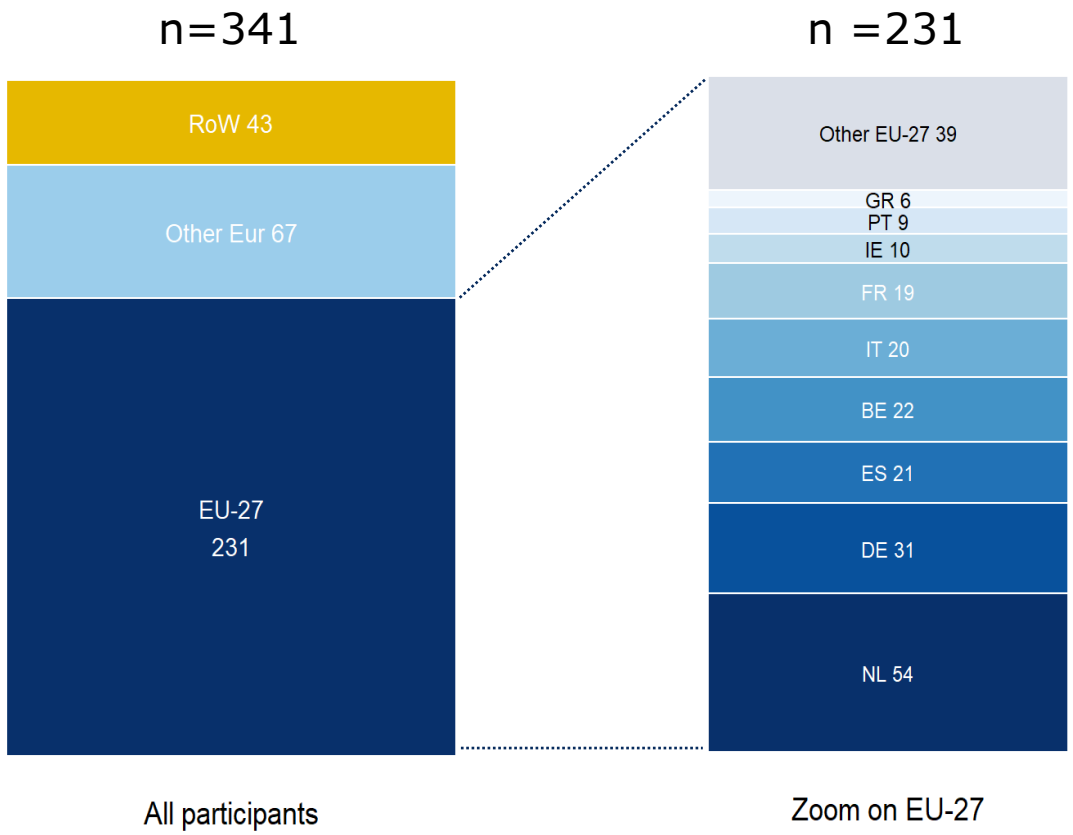
Marjon Pasmooij (MEB, Co-chair)
Kit Roes (MEB, Methodology WP)
Günter Waxenecker (AGES)

Ralf Herold (EMA, Co-chair)
Liese Barbier (EMA, Lead)
Ivana Silva (EMA)
Frank Pétavy (EMA)
Steffen Thirstrup (EMA)

Anja Minheere (EFNA)
Alexander Mathioudakis (HCPWP, ERS)
Nick Sykes (EFPIA)

The Platform’s growing community

Over 300 researchers and scientists and counting



Pharmacometrics
Regulatory – academic collaboration
Platform trials
Regulatory sandbox
Funding opportunities
Medical devices
Digital technologies
Modelling
Patient experience data
ATMPs
Rare diseases
Real world data
Accelerated pathways
Clinical trial methodology
New approach methodologies
Nanomedicines
Academic drug development
Regulatory – HTA interface
AI & machine learning
Uncertainty communication
Drug repurposing
Pharmacovigilance
Benefit risk methodologies
Antimicrobial resistance
Vaccines
Data availability and sharing
...
Biomarker validation

Platform meetings 2026

30 April 2026

13 – 17:00 CEST , online

16 June 2026

14 – 18:00 CEST, online

22 October 2026

10 – 17:00 CEST, hybrid

Platform meeting discussion topics 2026

30 April 2026

13 – 17:00 CEST , online

- Clinical trial registers and researcher use
- Research and evidence generation for medicines incl new uses
- HMA/EMA RWD catalogues

16 June 2026

14 – 18:00 CEST, online

- Research for AI regulatory science research needs
- Advancing research for new approach methodologies
- Achieving regulatory impact for your research project

22 October 2026

10:00 – 17:00 CEST, hybrid

- To be announced later

Platform meeting discussion topics 2026

30 April 2026

13 – 17:00 CEST , online

16 June 2026

14 – 18:00 CEST, online

22 October 2026

10:00 – 17:00 CEST, hybrid

EMA's Regulatory Science Research Needs

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Suggestions by platform participants

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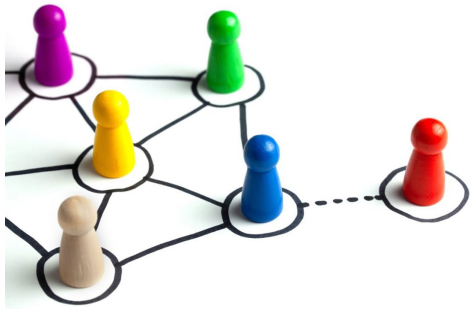
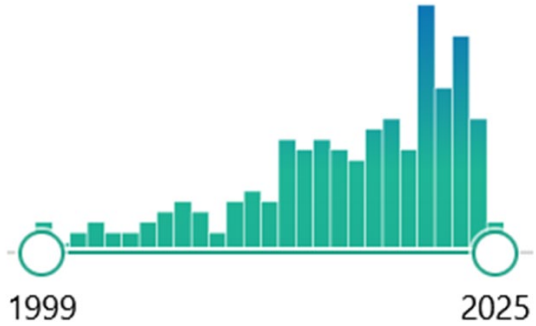
Prioritisation by platform steering group

EPAR best-practice guide drafting group

Starting point: Platform meeting May 2025, session *Use of regulatory data in research: spotlight on the EPAR*





Best-practice guide drafting group

- What is an EPAR
- Use and value of using EPARs in research
- Methodological approaches
- Other types of regulatory documents and data

Research project

- Scoping literature review
- Survey on experiences of first authors

Alessandro Lazdins, Odidison Philbeth, Marieke De Bruin, Malgorzata Kujawska, Christine Hallgreen, Ronette Gehring, Lourens Bloem, Caridad Pontes Garcia, Chera Kurdi, Andreas Kouroumalis, Carmen María González Domenech, John Liddicoat, Maribel Rico Salas, Maria Dul, Diogo Almeida, Maria Teixeira, Amanda Klein, Weam Fageera, Radu Popescu, Frank Petavy, Madeline Pe, Lucina Nollen, Elena Guillen, Fabio Borges, Liese Barbier, Marjon Pasmooij

Agenda for today

13:00 – 13:20	Welcome and introduction
13:20 – 14:20	**Clinical trial registers and research use (60 min)**
14:20 – 15:40	Research and evidence generation for medicines including new uses (80 min)
15:40 – 15:50	*Break*
15:50 – 16:50	HMA-EMA Catalogues of RWD sources and studies and use by researchers (60 min)
16:50 – 17:00	Meeting close