

Introducing the European Platform for Regulatory Science Research

An EMA – HMA initiative

Liese Barbier

Regulatory Science and Academia workstream
European Medicines Agency

18 November 2024 – Advancing Regulatory Science Research

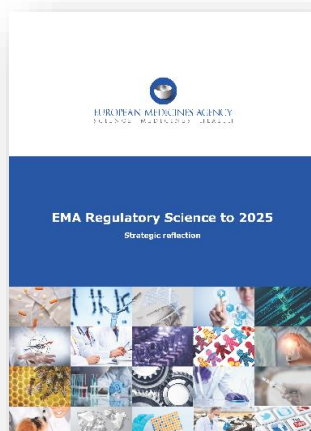


Regulatory science strategy

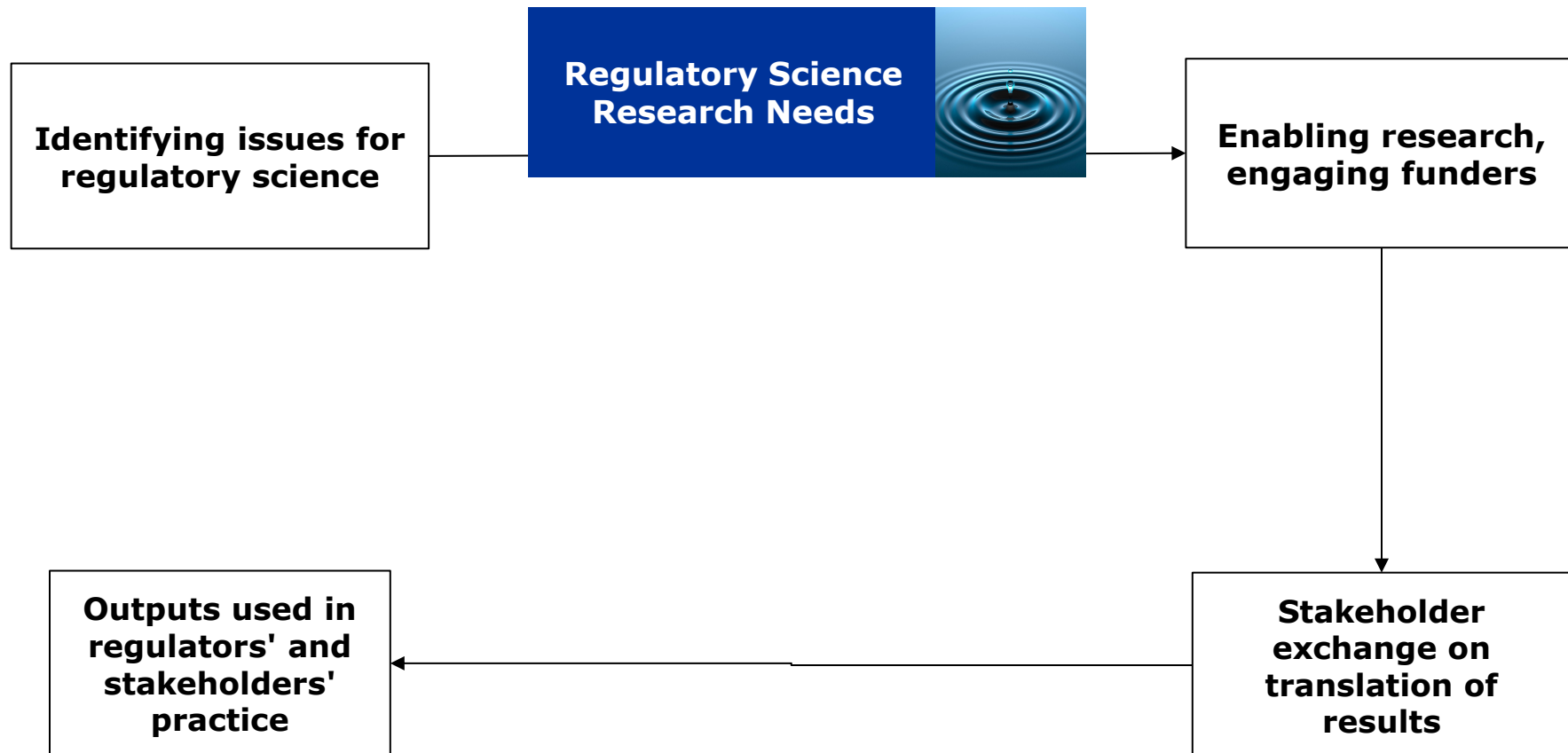
- Develop partnerships with academic / research centers to undertake research in strategic areas of regulatory science
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

Examples of progress so far

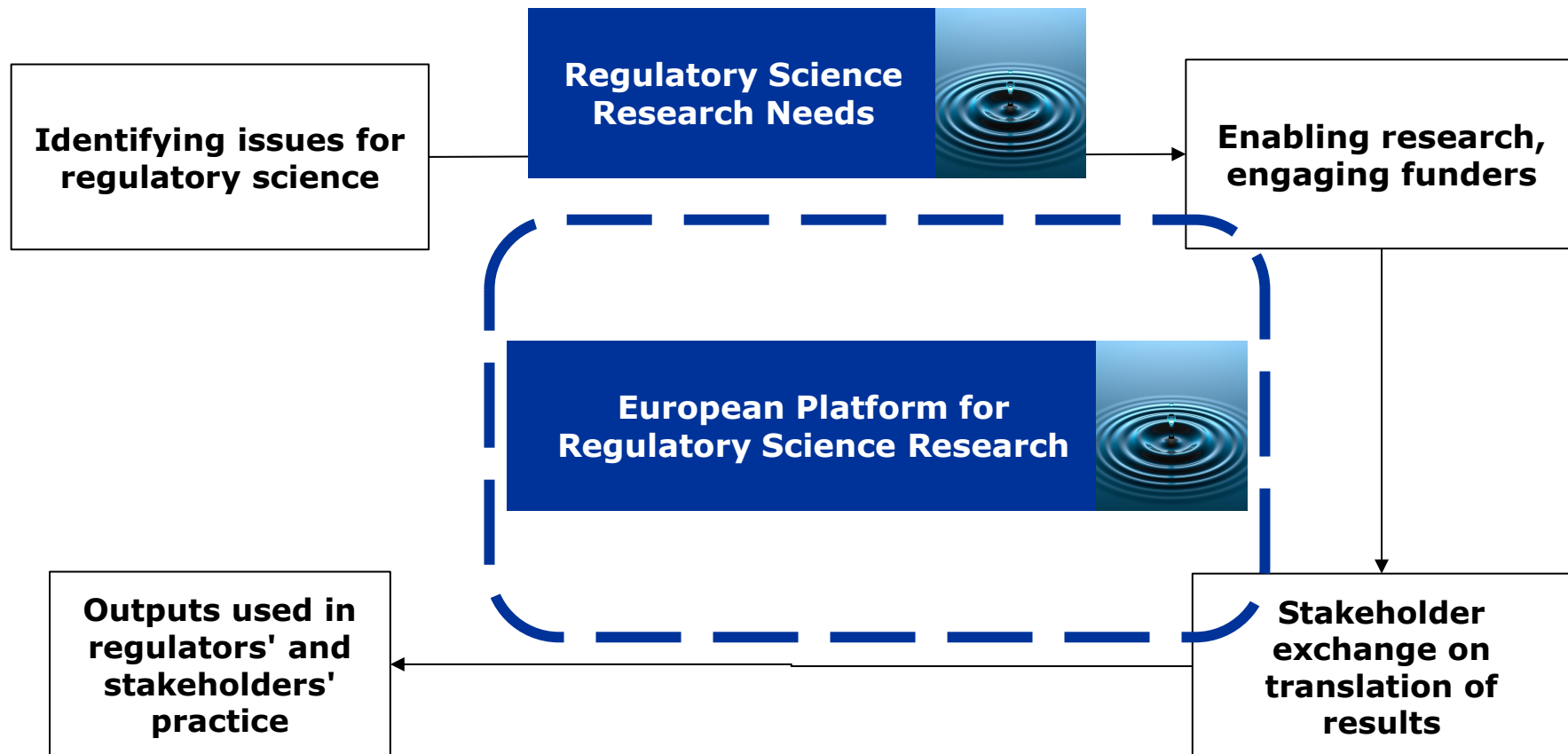
- Various agency collaborations with academia
- Regulatory science research needs
- EMA and NCA involvement in PPPs
- Academia briefing meetings



A strategic approach to Advancing regulatory science research



A strategic approach to Advancing regulatory science research

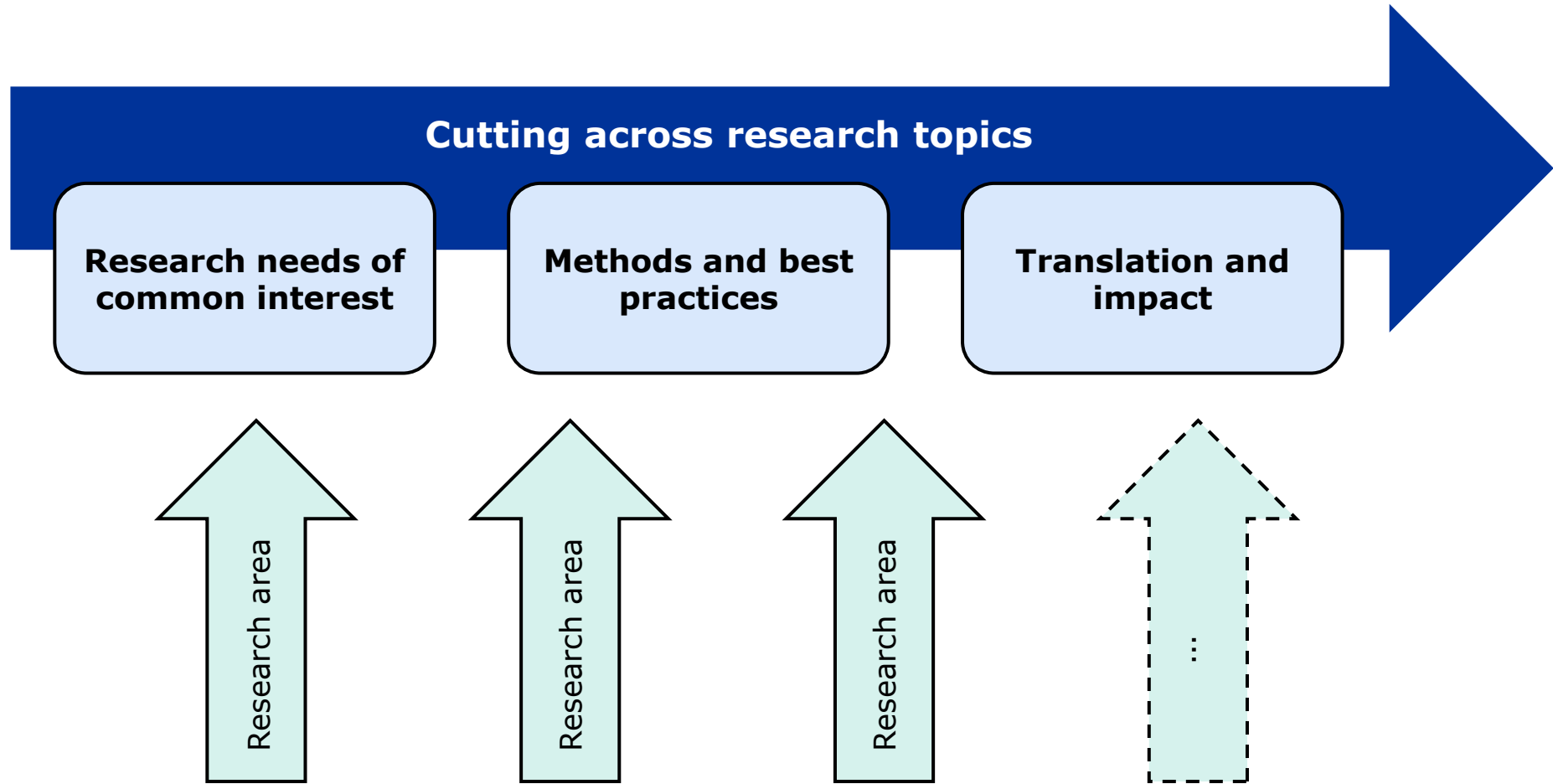


European Platform for Regulatory Science Research

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

Advancing and accelerating research in regulatory science



Opportunities for researchers

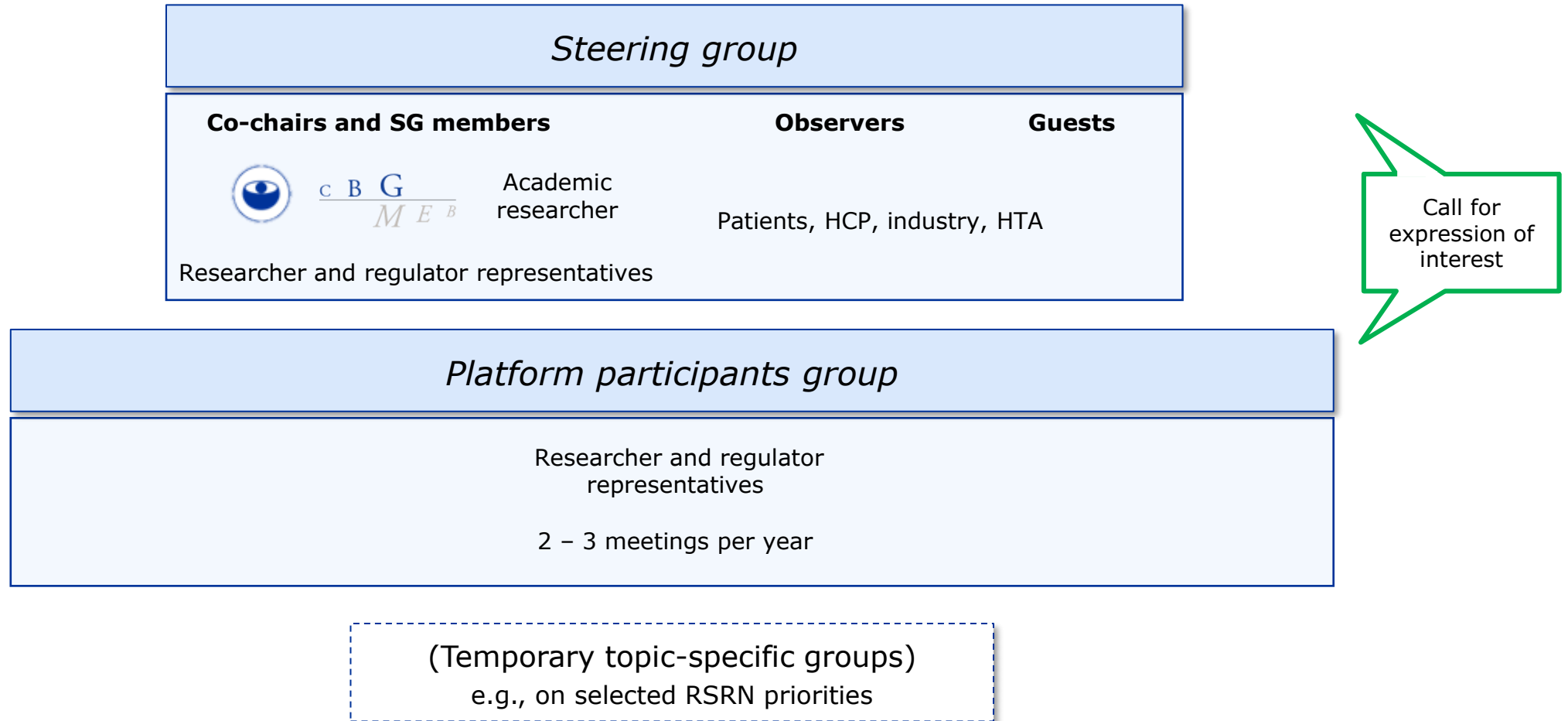
- Inform **research agenda** with needs from regulators
- Facilitate **projects and collaborations** with researchers from other groups and regulators
- **Awareness and familiarity** with initiatives and support of European regulators
- Increase **visibility** and exchange on regulatory science activities at EU level
- Increase **awareness** on regulatory science research **within researchers' institutions**
- Increased **capacity and competencies** for regulatory science research

Benefits for the regulatory system

- Enrich regulatory science needs with **views** from **other stakeholders** including researchers
- Stimulate researchers to address and take up **regulatory science research questions deemed important by regulators** into their work (e.g., in grant proposals, PhD programs, ...)
- **Streamlined** research **efforts**, increased efficiency, and outputs consolidation

Research outputs with increased translational value and impact on regulatory practice

Proposed working model – one year pilot phase



Timeline and next steps



Q1 – Q3 2024

Q4 2024

As of 2025

Ideation, design and development of Platform proposal

Draft concept paper and public consultation

Launch of pilot year

- EMA and network alignment ✓
- Draft concept paper development ✓
- Profiling of academic and non-for-profit organisations ✓
- Public event 18 November 2024
- Jointly with updated RSRN list
- Call for Expression of Interest
- Publication of final concept paper
- Nomination and invitation to participate
- First meetings

A vertical blue bar on the left side of the slide features a high-speed photograph of a water droplet hitting a surface, creating concentric ripples.

The draft concept paper on the Platform is open for your comments and we are very interested to hear from you



QR code to
public
consultation

Open for comments until 18 December 2024



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

regulatory.science@ema.europa.eu

Follow us

