

The Regulatory Science Research Needs

2024 update

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Regulatory science and Academia Workstream



EMA Regulatory Science to 2025

Strategic reflection



EMA Regulatory Science Strategy to 2025

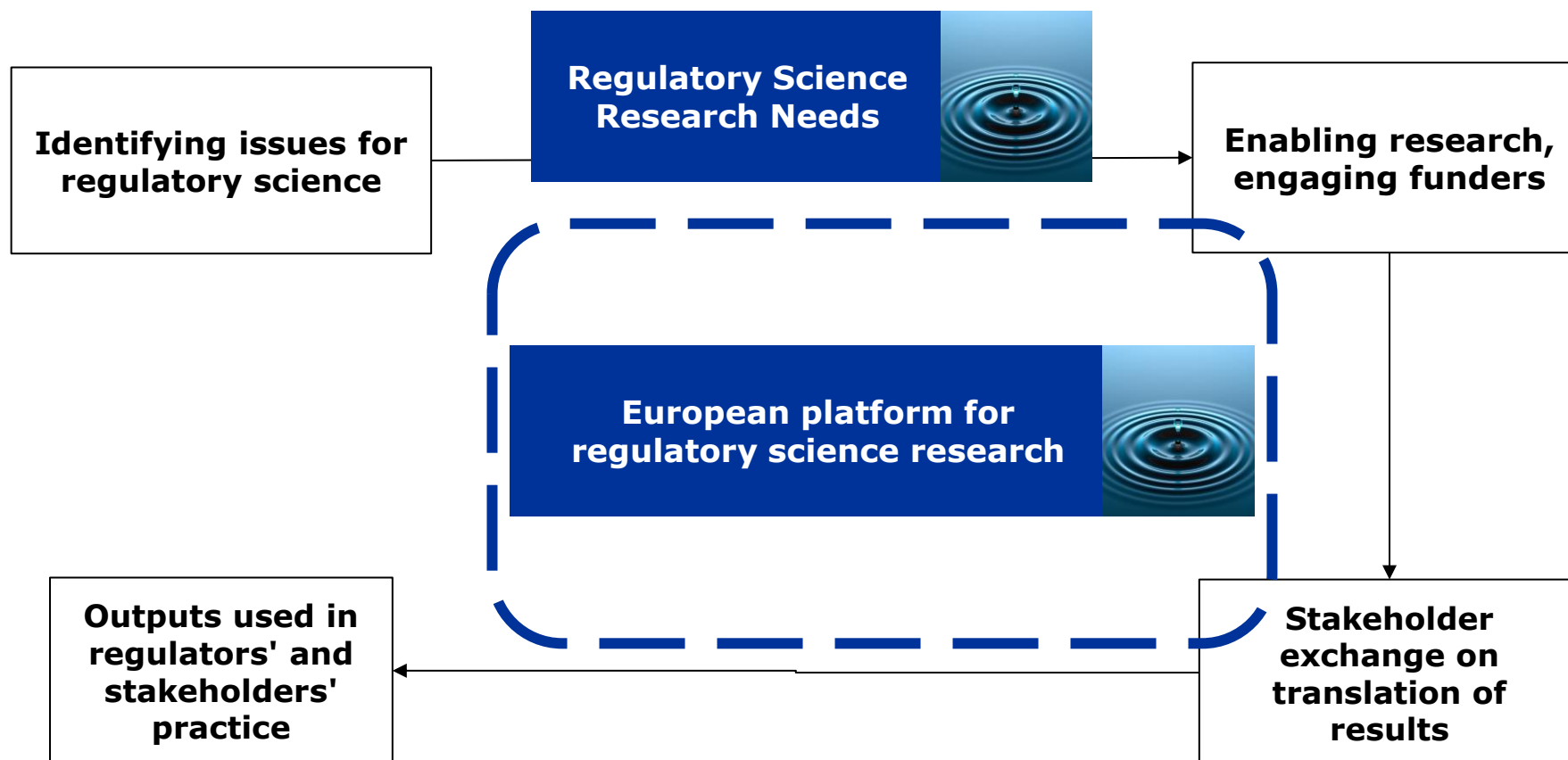


- How ready are we to engage with emerging science and technological innovations?
- Do we have the necessary skills and competencies, or indeed access to the specific expertise required?
- Are we generating new guidance or providing sufficient levels of advice to facilitate the utilisation and translation of these innovations?



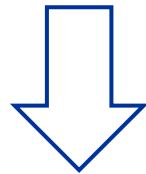
➔ Enabling innovation through advanced regulatory standards and practices

A strategic approach to Advancing regulatory science research



Identifying issues for regulatory science and translating them into RSRN

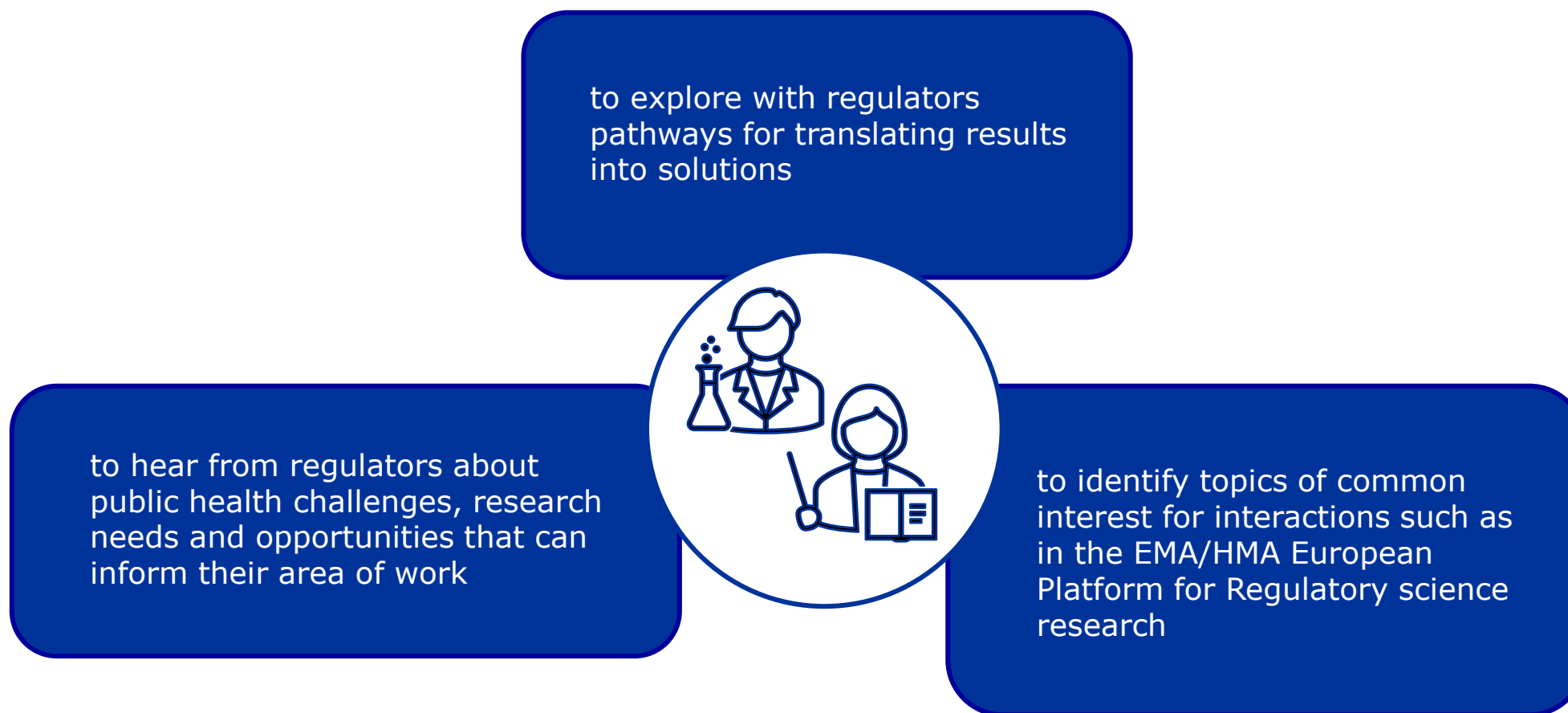
- Interviews with EMA scientific and topic leads
- Procedure reviews
- Horizon scanning activities
- Regulatory interactions at early stages
- Enquiries from academia



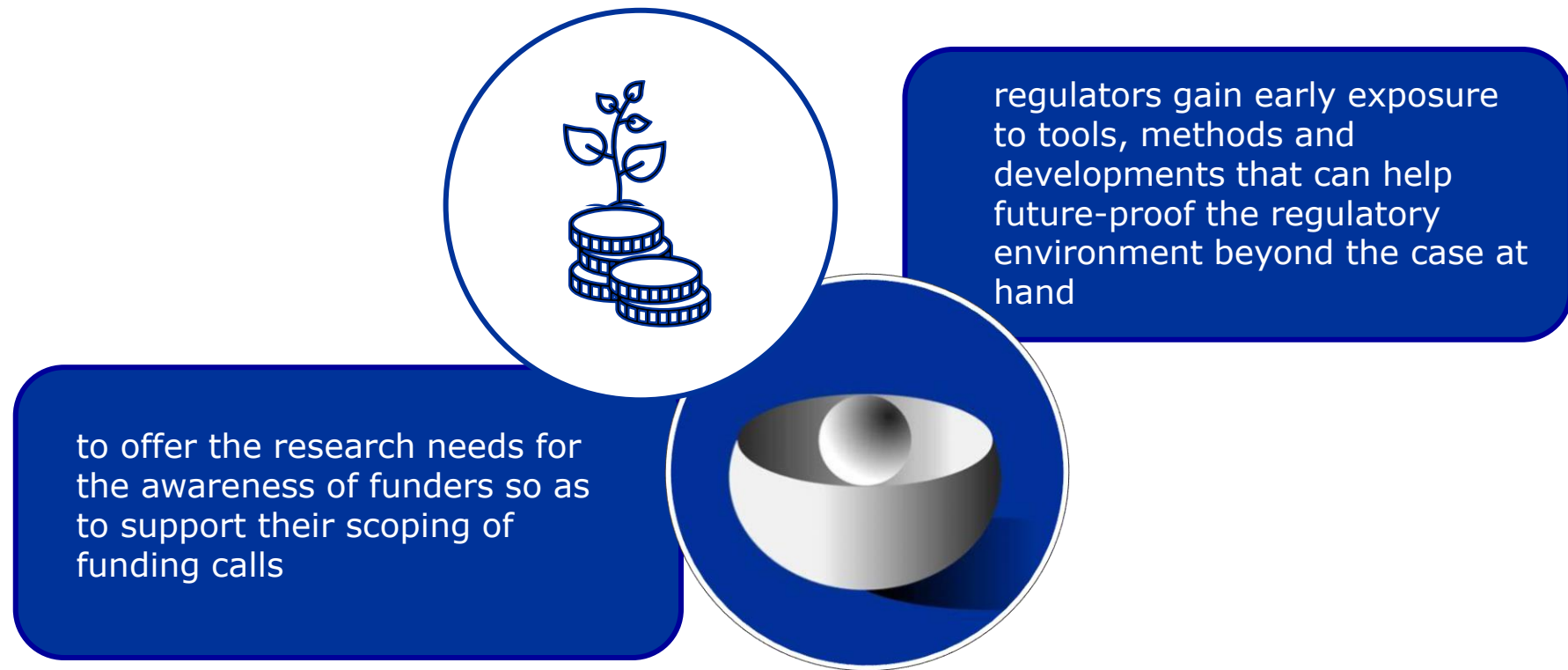
**Regulatory Science
Research Needs**



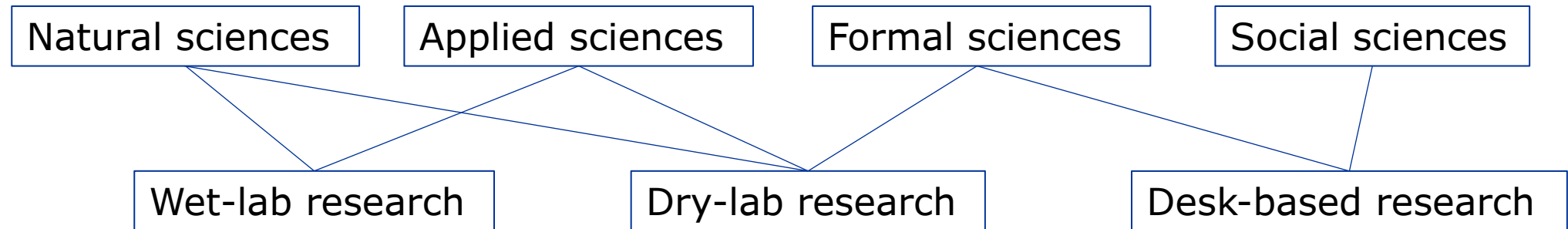
Opportunities for researchers



Opportunities for regulators and funders



Research types sought for addressing regulatory science research needs



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 inform the 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 with available data
- multidisciplinary field using a diverse range of methods, from wet lab to desktop

Updated Regulatory Science Research Needs

1. Research needs to **improve clinical research**

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

2. Research needs to **improve regulatory system evolution**

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

3. Research needs 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

4. Research needs 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



The updated list of regulatory science research needs is open for consultation and we are very interested to hear from you about:

- The structure
- Any important existing regulatory science gap you would like to flag to us



QR code to
RSRN public
consultation

Open for comments until 18 December 2024



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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