



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7. EMA Regulatory Science and use of public private partnerships to address Regulatory Science Research Needs (RSRN)

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An agency of the European Union





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?
- ➔ Keep pace with innovation while innovating regulatory standards and practices





Research topics in regulatory science needs list

Number RSRN topics

12 H + 9 V



Regulatory Science Strategy (RSS) to 2025 goals

Goal 1: Catalysing the integration of science and technology in medicines development

25 H + 16 V



Goal 2: Driving collaborative evidence generation improving the scientific quality of evaluations

23 H



Goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems

12 H + 11 V



Goal 4 (H) / 3 (V): Addressing emerging health threats and availability/therapeutic challenges

2 H + 1 V



Goal 5 (H) / 4 (V): Enabling and leveraging research and innovation in regulatory science

Total: 111



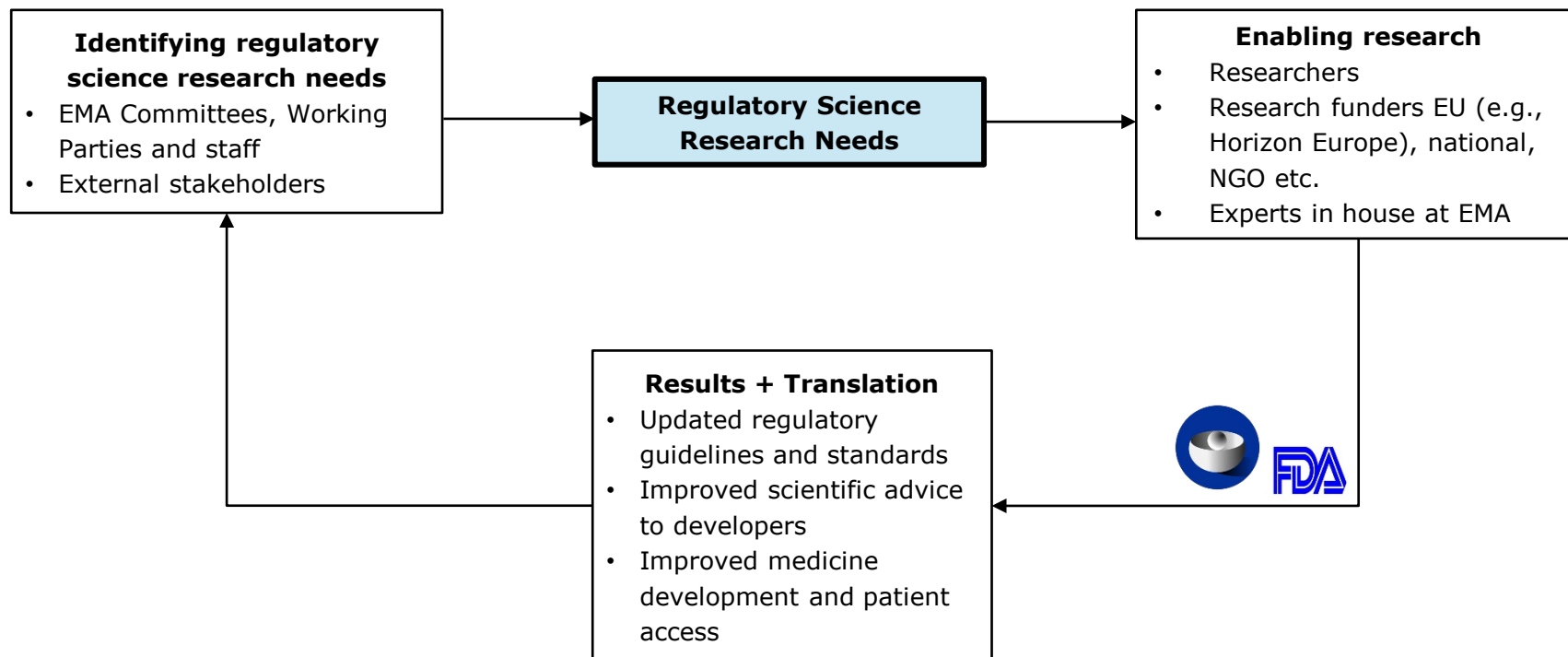


Regulatory Science Research Needs (RSRN) Example

Number (click to send email)	Research topic	Objectives	Expected impact
H2.5.4	Identify areas of highest unmet needs where real-world evidence (RWE) can supplement clinical trial data in regulatory decision-making. Investigate corresponding methodological approaches.	To define the most promising special populations and data for which RWE can be utilised to supplement RCT data and enhance regulatory decision-making. Define the sources of data and methods for using such RWE.	Enhanced regulatory decision making for special populations.



Lifecycle of the RSRN





Roadmap updating EMA Regulatory Science Research Needs (RSRN)

- Targeted gathering of regulatory science research (RSRN) priorities
- Complete progress review of RSRN v1.0
- Consideration of public consultation
- Publication RSRN v1.1 or v2.0
- Webinar RSRN
- Explore new strategies to engage with stakeholders



Open for discussion

- Open to public consultation of Stakeholders including Industry on the new version of RSRN
- Interest in understanding how Industry Stakeholders systematically identify and prioritize regulatory gaps
- Open to consider the development of efficient translation pathways in relevant EMA/industry stakeholders focus group.



Any questions?

Further information

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