

Practical recommendations for implementing change management and regulatory strategy in projects

Focus group report

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Regulatory Science and Academia work stream

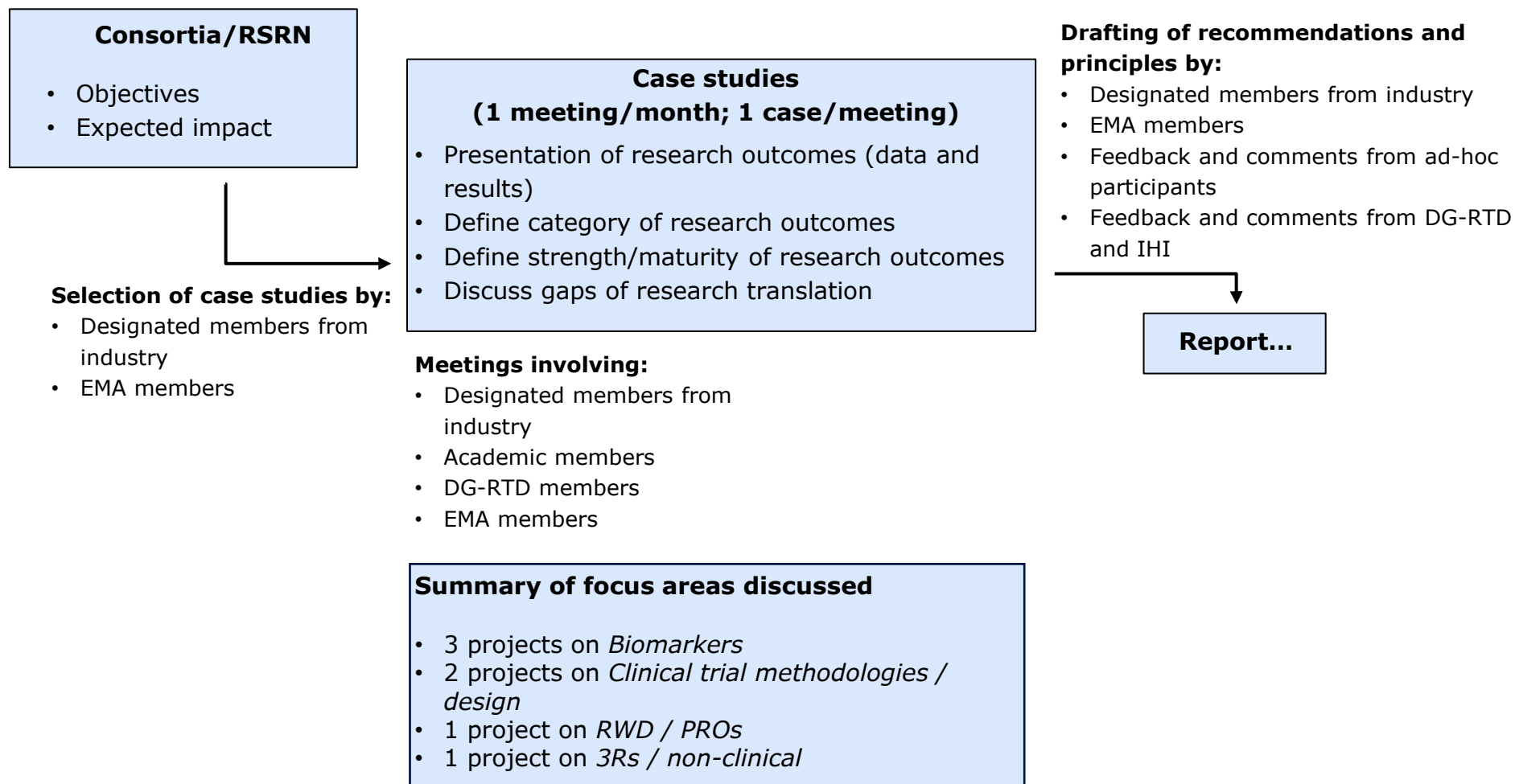
European Medicines Agency



Why was the Focus Group needed?

There is a gap in translating promising research outputs from consortia into practical applications that deliver concrete and impactful solutions for public health

Working method of the Focus Group



Report on regulatory science research translation



17 March 2026
EMA/63729/2026
European Medicines Agency

EMA Industry standing group – Focus Group Regulatory Science Research Translation

Output report and recommendations



Priorities and approaches for consortia to accelerate translation of research outputs

Pursuing change management in a well-informed way and with competent resources is foundational for the success of a PPP and for the impact of translation of its outputs.

Priorities related to regulatory preparedness

- Start developing a regulatory strategy during the project design phase
- Link the regulatory strategy with the implementation work plan and identify potentially critical paths as well as any potential impediments or blockers for regulatory acceptance
- Build into the project the regulatory expertise
- Seek to get into contact with partners in related ongoing or previous projects and build on their expertise
- Identify the various different regulators involved in the translational process of the technology/method in development and the needed interactions

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Priorities specific to project deliverables

- Identify at an early stage the potential outputs and use them for stakeholder identification and mapping to plan engaging them appropriately
- Define which outputs will be disease- or product-specific and which will be independent, what is their added value and how their utility or value can be maximised for relevant stakeholders
- conduct and maintain a gap analysis comparing current international regulators views and current activities
- Identify relevant deliverables, draft and refine a 'context of use' (CoU)

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Priorities related to regulatory awareness and engagement

- Pro-actively seek discussions with regulators
- Review EMA's Regulatory science research needs
- Maintain awareness on regulators' activities, initiatives and opportunities
- Maintain awareness on technical guidelines within the working area
- Ensure that project partners representing different groups of stakeholders consult and involve their organisations internally on evolving outputs