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EUROPEAN MEDICINES AGENCY

The ISG Focus Group on Regulatory Science Research Translation

Industry Standing Group (ISG) meeting, 30 September 2025

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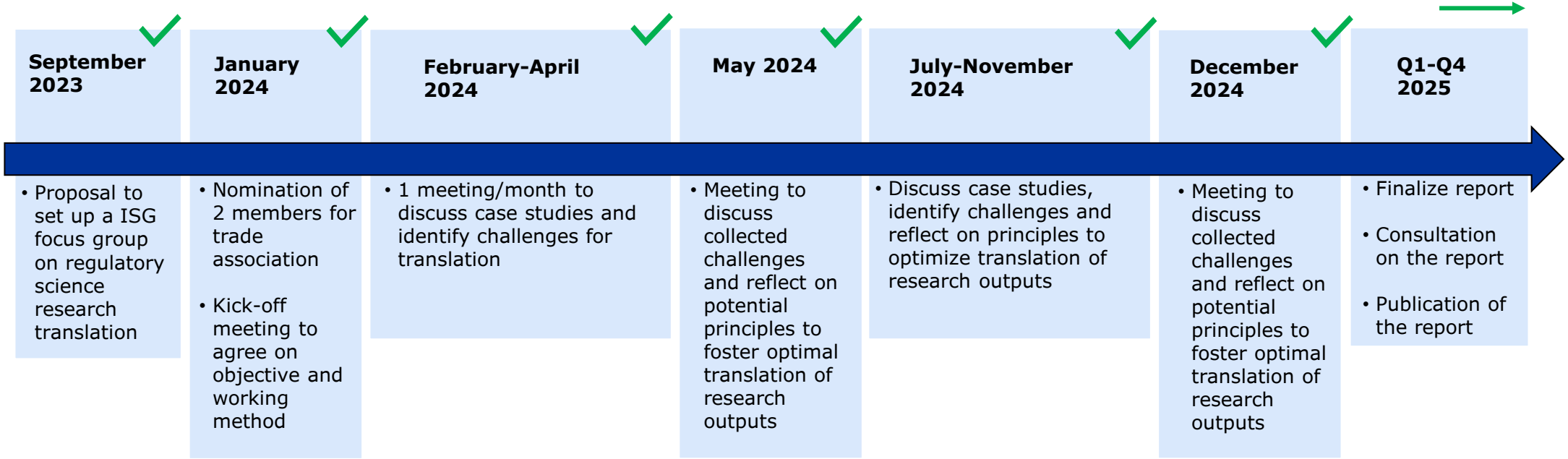
Regulatory Science and Academia Workstream

Task Force Regulatory Science & Innovation

FG timeline and milestones



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

Consortia/RSRN

- Objectives
- Expected impact

Selection of case studies by:

- Designated members from industry
- EMA members

Case studies
(1 meeting/month; 1 case/meeting)

- Presentation of research outcomes (data and results)
- Define category of research outcomes
- Define strength/maturity of research outcomes
- Discuss gaps of research translation

Meetings involving:

- Designated members from industry
- Academic members
- DG-RTD members
- EMA members

Summary of focus areas discussed

- 3 projects on *Biomarkers*
- 2 projects on *Clinical trial methodologies / design*
- 1 project on *RWD / PROs*
- 1 project on *3Rs / non-clinical*

Drafting of recommendations and principles by:

- Designated members from industry
- EMA members
- Feedback and comments from ad-hoc participants
- Feedback and comments from DG-RTD and IHI

Report…

Report on regulatory science research translation

5 June 2025

European Medicines Agency

EMA Industry standing group – Focus Group Regulatory Science Research Translation

Draft output report and recommendations

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Priorities and approaches for consortia to accelerate translation of research outputs

… to ensure projects adopt and resource a **change management** approach for their activities and deliverables

Priorities related to regulatory preparedness

- To ensure the development of a regulatory strategy and implementation plans

Priorities specific to project deliverables

- To ensure project deliverables are thought and achieved with a view on regulatory aspects and as much ready as possible to comply with regulatory requirements

Priorities related to regulatory awareness and engagement

- To ensure communication line and transfer of information can be optimally maintained with the different stakeholders

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SCIENCE MEDICINES HEALTH

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Key recommendations

… for consideration by EMA, industry, academic researchers and their organisations, multiple stakeholders.

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- Increase capacity to support relevant research projects,
- Establish framework for regulatory reflections on projects, guidance for types of drug development tools, foster NCA involvement
- Make use of European platform for regulatory science research to continually discuss translation

Industry

- Maximise contribution of companies in providing regulatory expertise for collaborative projects, contribute to training and education of academic partners
- Facilitate alignment on evidence required towards regulatory acceptance

Academic researchers and organisations

- Promote alliances across disease-focused societies and working groups at universities

Multi-stakeholder

- Enhance management, sharing, access of data, project protocols, agreements, outputs, knowledge
- Maximise training and access to expertise through competence centres, learning offerings
- Maximise dissemination and adoption of research outputs and tracking of their implementation

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Summary

- Focus group participants from industry were experts in pre-competitive collaboration and provided excellent contributions concerning project interests, conduct and output use
- Instructive discussions informed by excellent insights of academic leads of selected projects
- Outputs of diverse projects led to identify broad set of actors and activities
- Report and recommendations cover
  - Elements to be embedded in the different stages of a research project, from design to dissemination, with a particular focus on change management and regulatory strategy
  - Recommendations for EMA and stakeholders to improve the research and translation environment

Next steps

- Report publication on EMA website
- Additional publication lead by Industry
- EMA's Collaboration Management meetings and European Platform for Regulatory Science Research may be used to engage on translation of specific research outputs from selected consortia

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Thank you

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