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SCIENCE MEDICINES HEALTH

The ISG Focus Group on Regulatory Science Research Translation

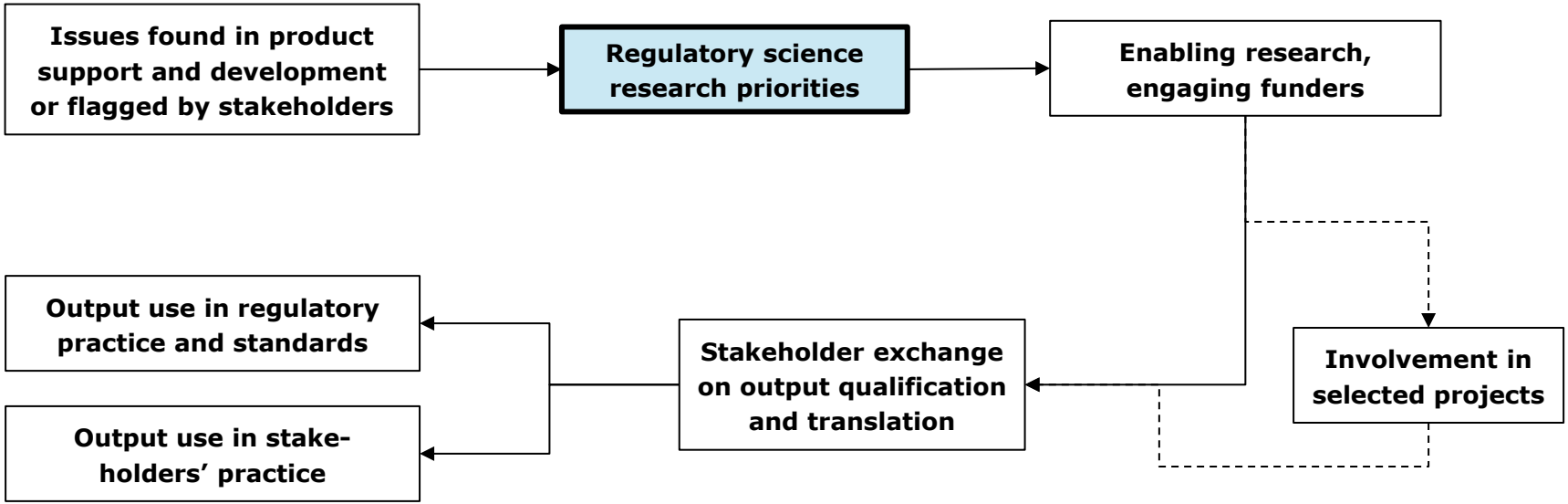
Industry Standing Group (ISG) meeting, 28 June 2024

Ralf Herold and Pierpaolo Moscariello
Regulatory Science and Academia Workstream
Task Force Regulatory Science & Innovation

The regulatory science research landscape

1 The ISG Focus Group on Regulatory Science Research Translation

EMA advancing regulatory science research



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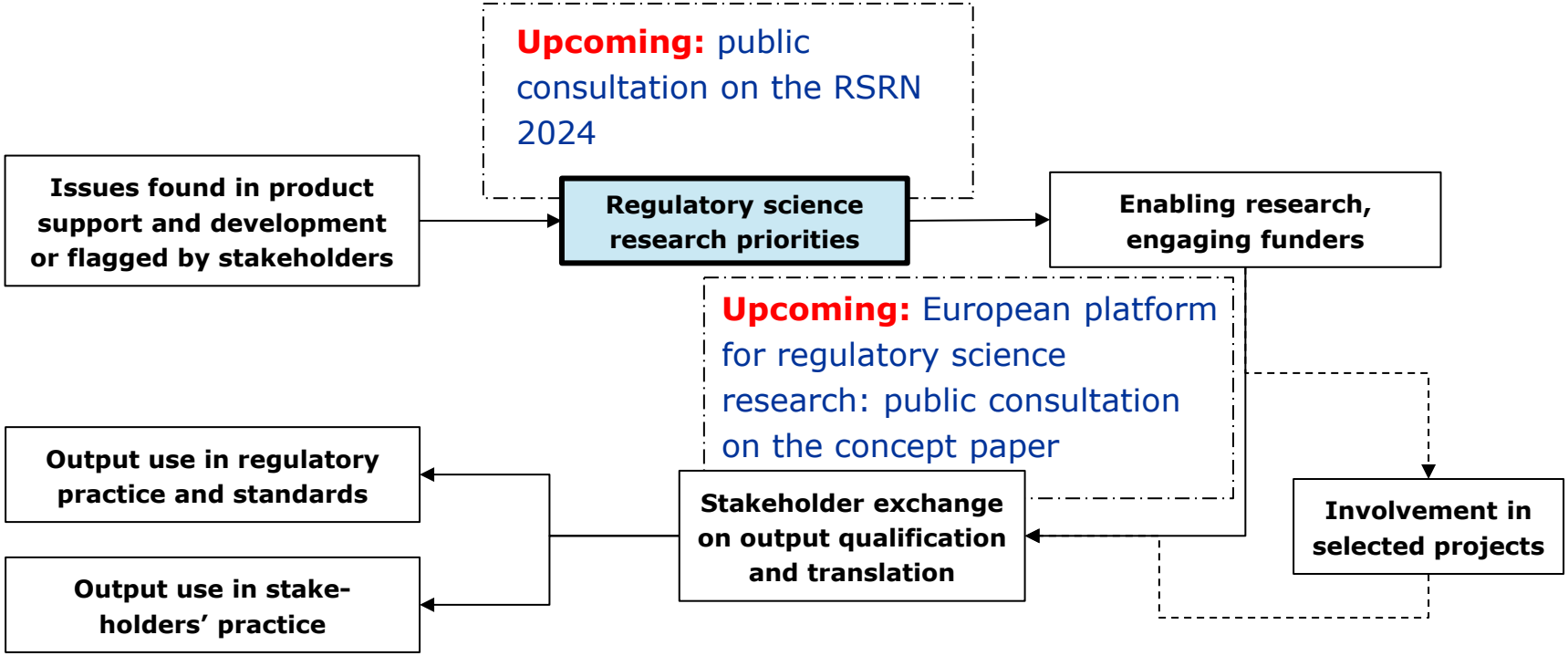

FG timeline and milestones

September 2023

- Proposal to set up a ISG focus group on regulatory science research translation

Proposal to set up a FG

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19 December 2023
EMA/423751/2023

Highlights - 6th Industry Standing Group (ISG) meeting

21st September 2023 – chaired by Marie-Hélène Pinheiro

7. EMA Regulatory Science and use of public private partnerships' results to address Regulatory Science Needs

EMA provided an overview of the work being done by EMA on identifying the progress and updating the Regulatory science research needs (RSRN), which were published end 2021 and are linked to the Strategic goal 5 in the EMA Regulatory Science Strategy to 2025. The RSRN includes a lifecycle approach where the goal is to close regulatory gaps through translation of results, for example by updating the regulatory standards and guidelines, informing scientific advice to developers and improving medicines development and assessment, and additional ways to translate to achieve visible impact that should be explored and established. A public consultation is considered for the draft updated RSRN.

EFPIA presented a summary of their mapping analysis of EMA's published RSRN against completed or ongoing projects under the IMI/IHI Partnerships, highlighting areas of potential high public health impact and the need for accelerating getting to regulatory acceptance. Industry proposed to set up a focus group aiming to reflect on mechanisms for efficiently translating results coming from such public-private undertakings, on optimising how to establish regulatory acceptance, and on creating impact through use in research and regulatory practice.

Actions arising:

- EMA to further reflect on the proposal to set up a focus group to continue the dialogue with relevant Industry stakeholders.

Link to EMA presentation.

5 The ISG Focus Group on Regulatory Science Research Translation

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EFPIA (coordination)
Eucope
EuropaBio
Vaccines Europe

Objectives of the Focus Group

The objective of this group is to **develop recommendations, priorities and approaches** for enhancing the translation of regulatory science research outputs into practical application in research and development and in improved regulatory standards and practices.

Translation includes advancing the regulatory framework for the development, evaluation and use of medicines and drug development tools, as well as maximising the uptake and application of research outputs by relevant stakeholders.

In addition to nominated members from industry organisations, a multistakeholder approach will be used by involving relevant academic stakeholders, researchers, funders, and the European Commission.

The following outcomes are expected:

- **Define relevant actors** for initiating and progressing the translation of regulatory science research outputs.
- **Describe relevant existing and any newly required translation approaches**, including criteria, governance, milestones and deliverables (e.g., training and competency building, stakeholders needed, type of regulatory endorsement needed, requirements for raising awareness and for availability of tools).
- **Define key elements** to be considered when establishment and running of private-public partnerships **to ensure early embedding of relevant translation approaches** to obtain regulatory support and practical application.
- **Develop reflections** on what is needed to **accelerate the process of translation of research outputs**, and to **maintain acceleration and efficiency of translation** of regulatory science research outputs for the benefit of patients and public health.

Proposed 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
  ➔ problem identified ➔ new datasets
  ➔ solutions/recommendations
- Discuss gaps of research translation

Meetings prepared by:

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

Drafting of recommendations and principles by:

- Designated members from industry
- EMA members
- Academic members
- Feedback and comments from DG-RTD

Principles

- Possible translational pathways
- Elements for highest possible impact and translation
- Key actors involved in the relevant identified translational pathways
- Reflections on needed elements for acceleration of the translation process
- Recommendations for key stakeholders

FG timeline and milestones

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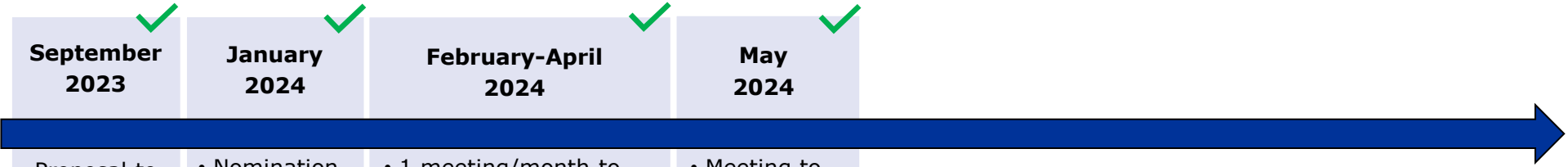

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February-April 2024

- 1 meeting/month to discuss case studies and identify challenges for translation

May 2024

- Meeting to discuss collected challenges and reflect on potential principles to foster optimal translation of research outputs

Overview on cases agreed by FG for discussion

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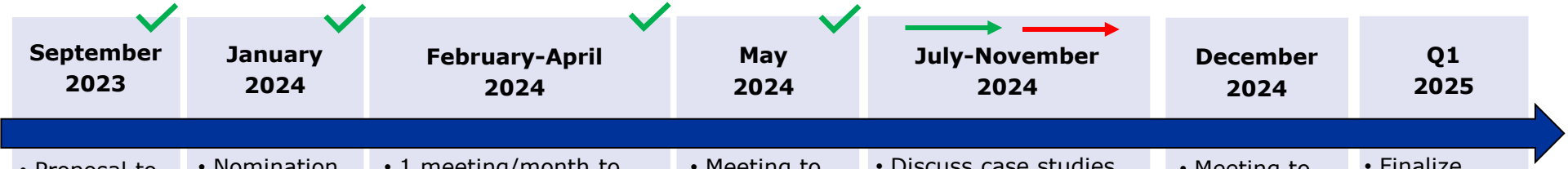
Clusters

1. Biomarkers
2. Clinical research methodologies
3. 3Rs-related methods

Examples of gaps and steps for further translation

- Dissemination and adoption of research outputs
- Tracking of adoption and implementation of developed models
- Regulatory interactions and flexibility of current system
- Protocols optimization
- Data sharing and accessibility
- Training of academia
- Beyond qualification procedure
- Future fundings
- Priorities of academia and Industry
- Resources availability and sharing
- Fragmentation of regulatory pathway

FG timeline and milestones



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July-November 2024

- Discuss case studies, identify challenges and reflect on principles to optimize translation of research outputs

1 x Biomarkers
1 x Clinical research methodologies

December 2024

- Meeting to discuss collected challenges and reflect on potential principles to foster optimal translation of research outputs

Q1 2025

- Finalize inputs on principles and recommend ations
- Report FG outcomes

Summary

- Focus group had instructive discussions on factors influencing translation of outputs
- Outputs of diverse cases projects led to identify broad set of actors and activities
- Some more cases sought to be discussed, while drafting recommendations
- Report and recommendations anticipated to cover, e.g.,
  - Types of gaps to be filled for adopting and translating research outputs
  - Opportunities for accelerating translation through multiple stakeholders' coordinated action
  - Principles and recommendations to engage with consortia on translation

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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