



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Research and Innovation (TRS-RNI)

Academia Collaboration Matrix action plan (2021 – 2023)

Introduction

The European Medicines Agency (EMA) is committed to maintaining a strong working relationship with European academics and researchers. Collaboration with academia is necessary for the Agency to be prepared for future challenges as well as opportunities offered by advances in science and technology. The Agency has targeted engagement with academia, learned societies and research groups in a range of areas.

This Academia Collaboration Matrix action plan was conceived as a tool to deliver on activities identified in EMA strategic plans while giving due consideration to the environment in which the Agency operates, including resources availability.

The [EMA programming document 2021-2023](#) states as an objective for the Regulatory Science and Innovation (TRS) Task Force to “Leverage collaborations between academia and network scientists to prepare for engagement with [Horizon Europe](#) and [Innovative Health Initiative](#) (IHI), define EMA's regulatory science research agenda and enable exchange of knowledge and expertise.” Specifically the programming document refers to “an Agency-wide plan for interaction with academia is being developed, which aims (1) to support governance and oversight of interactions with externally funded research and networks; (2) identify academic disciplines/research topics; (3) support the establishment of staff-exchange programmes and placements; (4) create academia-targeted materials to promote existing regulatory tools; (5) set up a communication strategy.”

This action plan is in line with the [EMA programming document 2021-2023](#) and the [Regulatory Science Strategy to 2025](#) (RSS 2025), and captures the objectives the Agency must pursue in order to achieve an optimal collaboration with Academia:

- Develop network-led partnerships with Academia / research centres to undertake research in strategic areas of regulatory science;
- Leverage collaborations between Academia and network scientists to address rapidly emerging regulatory science research questions;
- Identify and enable access to the best expertise across Europe and internationally;
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.

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The implementation of these actions calls for a cross-Agency approach to ensure that the collaboration with Academia is coordinated, builds on knowledge-sharing, and empowers the different Agency departments to progress on their collaboration with Academia.

Academia Collaboration Matrix action plan outline

This Academia Collaboration Matrix action plan has been developed taking into consideration the feedback received from both internal and external stakeholders.

The plan outlines a series of actions for the coming 2.5 years with a view to maintaining a strong engagement with academia, learned societies and research groups, and to be prepared for future challenges as well as opportunities offered by advances in science and technology.

This action plan is presented according to the five themes of RSS 2025 goal 5, namely

- Theme 1: Regulatory science and partnerships;
- Theme 2: Innovation and support to academia;
- Theme 3-4-5: Communication, events strategy and training.

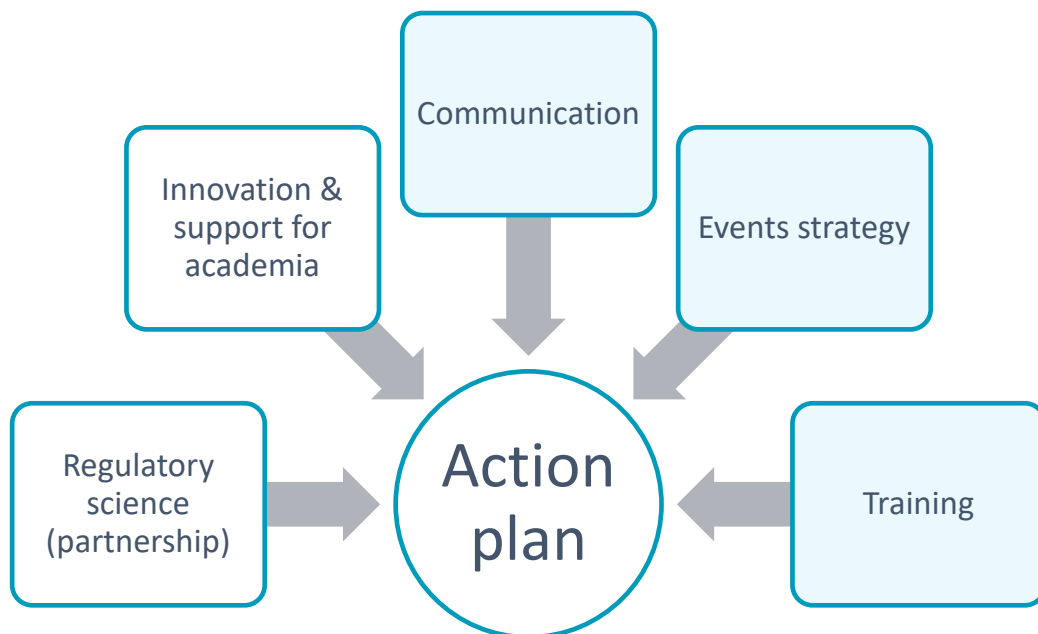


Figure 1: Five themes of the 5th goal of the Regulatory Science Strategy 2020-2025

Theme 1: Regulatory science and partnerships – 2021-2023 Q1/Q2

Action	Start	Finish	Deliverables
1. Assess EMA involvement in externally funded regulatory science projects	Q1 2021	Q3 2021	EMA report on EMA involvement in externally funded regulatory science projects. Disseminate report to stakeholders (e.g. STARs consortium).
2. Develop EMA's Regulatory Science Research Agenda.	Q1 2021	Q4 2021	Develop and implement a process for EMA's Regulatory Science Research Agenda, including assessment, prioritisation of questions. Publish EMA living Regulatory Science Research Agenda.
3. Proactively engage with DG Research & Innovation, DG-SANTE, IHI, international regulators (e.g. FDA), other public-private partnerships, Member States, funding agencies and other relevant bodies to explore research topics of mutual interest and propose calls to establish research collaborations.	Q2 2021	Q4 2021	Summarise areas of common interest into international collaboration regulatory research agenda. Organise meetings to identify areas of common interest.
4. Explore with the EU network, opportunities for engaging with healthcare professionals working at the interface of clinical research and clinical practice on areas such as clinical trial design, personalised medicine and use of real-world evidence.	Q1 2022	Q4 2022	EMA report to identify experts according to research collaborating fields.
5. Develop a roadmap that clarifies, where and how partnerships with academia can best contribute to EMA work and delivering the RSS 2025.	Q1 2022	Q4 2022	Optimized academia stakeholder database showing the first-line experts in each collaborating research field Optimized process to register and document academia stakeholders.
6. Investigate other potential funding schemes to build (public-private) partnerships.	Q1 2023	Q4 2023	EMA report of identified novel funding mechanism, by research fields.
7. Validate academia status and ensure a rigorous conflict of interests-assessment for academia stakeholders.	Q2 2023	Q4 2023	Validation and assessment mechanism for academia status and Conflict of Interests.

Theme 2: Innovation and support to academia - 2021-2023 Q1/Q2

Action	Start	Finish	Deliverables
8. Improve awareness of Agency's tools to support academia developers	Q1 2021	Q4 2021	<p>Survey to academia focused on communication expectations and needs and current performance of support tools from the Agency.</p> <p>Enhance Agency's website to raise awareness of regulatory support and tools available to academia along a medicinal product lifecycle.</p> <p>Participate to events to improve awareness of regulatory support and tools (e.g. DIA conferences), including follow up events' actions such as publications and commentaries.</p>
9. Engage with academia on Horizon Scanning	Q2 2021	Q4 2021	<p>EU-IN/EMA HS report academia collaboration opportunities.</p> <p>Relate information HS activities with academia.</p>
10. Engage with EMA's Scientific Committees to enhance their external engagement and communications with academia directly and via national competent authorities (NCAs).	Q2 2021	Q4 2021	Report on identified areas of mutual interest and defined collaborative actions.
11. Develop technology platforms in key areas of innovation in close collaboration with academic medicines developers.	Q4 2021	Q2 2022	<p>Platforms organized.</p> <p>Events reports / communication, and feedback from developers.</p>
12. Explore widening the scope of Executive Director-decision on academia fee waiver for protocol assistance.	Q1 2022	Q4 2022	Internal report on uptake of policy and highlighting need for revision, if any.
13. Reflect on PRIME to improve usability of the incentives for academic medicines developers.	Q3 2022	Q1 2023	Report on approaches and results to improve the awareness of the incentives to academia.
14. Promote technology platforms and ensure academic representation.	Q4 2022	Q4 2023	<p>Planned events.</p> <p>Event reports and feedback from academia.</p>
15. Intelligence gathering from knowledge management system to manage academic topics.	Q1 2023	Q3 2023	EMA report on intelligence systems.

**Theme 3-4-5: Communication, events strategy and training - 2021-2023
Q1/Q2**

	Action	Start	Finish	Deliverables
16.	Set out reporting activities on EMA's engagement with academia.	Q3 2021	Q2 2022	EMA annual report; Academia info day.
17.	Define an annual events planner for EMA engagement with academia (e.g. EMA-Academia symposia, information days for young researchers, multi-stakeholder awareness conferences).	Q1 2022	Q3 2022	EMA academia Event planner. Planned meetings / events. Reports and feedback.
18.	Launch a bulletin dedicated to academia.	Q1 2022	Q3 2022	Communication needs defined based on analysis of Academia survey results (see action 8). Based on survey results, adopt decision on the launch of an Academia Bulletin (if positive decision, bulletin launched).
19.	Enable Agency staff to develop profiles to supervise academic researchers at the Agency (e.g. supervisor, PhD, trainer).	Q1 2023	Q3 2023	EMA report delineating roles of EMA staff for supervision, by research topic.