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European Platform for Regulatory Science Research

Concept paper – DRAFT

Start of public consultation	14 November 2024
End of public consultation	18 December 2024
Please provide comments using this template. The completed comments form should be sent to regulatory.science@ema.europa.eu.	

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1. Purpose

This concept paper presents a proposal for creating a European Platform for Regulatory Science Research. The purpose of the concept paper is to outline the proposal and principles for the platform. The public consultation of this document aims to generate interest and comments from the public, to refine the scope and development of the platform. The concept paper will be the basis for the platform's terms of reference.

The aims of the European Platform for Regulatory Science Research are, advancing and accelerating regulatory science research, addressing regulatory science research questions and increasing the quality and impact of research to improve regulatory practices and medicines development, by promoting dialogue and fostering collaboration among academic regulatory science researchers and with regulators across Europe and beyond.

2. Background and strategic context

Regulators and developers[1] need high-quality tools to keep pace with scientific and technological advances and particularly to ensure the robust assessment of therapies and outcomes fitting patients' needs. Innovative tools and assessment methods can be enablers for novel medicines.

Regulatory science encompasses a variety of scientific disciplines that are used to evaluate the quality, safety, and efficacy assessment of medicines and that inform decision-making throughout the lifecycle of a medicine. It encompasses basic and applied biomedical and social sciences and contributes to the evaluation of existing, and development of new, regulatory standards, tools, methods, and principles used for developing medicines, as well informing requirements for their evaluation.

Research into regulatory science aims to address cross-cutting issues in development and gaps that hinder regulatory advancement. This multidisciplinary field often involves various stakeholders (such as researchers, patients and developers), and research outcomes enhance understanding of medicines development methods and provide solutions to support and advance regulatory decision-making (Figure 1, Table 1). It draws from a diverse range of methods, including wet lab research, text and data analysis, literature reviews, and techniques from mathematical and social sciences[2,3].

[1] Including non-for-profit, for profit and academic developers
[2] Pasmooij M et al. Clin Pharmacol Ther. 2024 Jul;116(1):64-71
[3] Saesen R et al. Front. Med. 2023 10:1181702.

Table 1. Regulatory science and regulatory science research
Regulatory science: • A range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision making throughout the lifecycle of a medicine. It also contributes to developing regulatory standards and tools.
Regulatory science research: • To investigate and create new tools for developing and evaluating medicinal products • To investigate and create new methods to generate and optimize evidence generation for decision-making • To investigate and systematically identify and address gaps in evolving regulatory activities and system

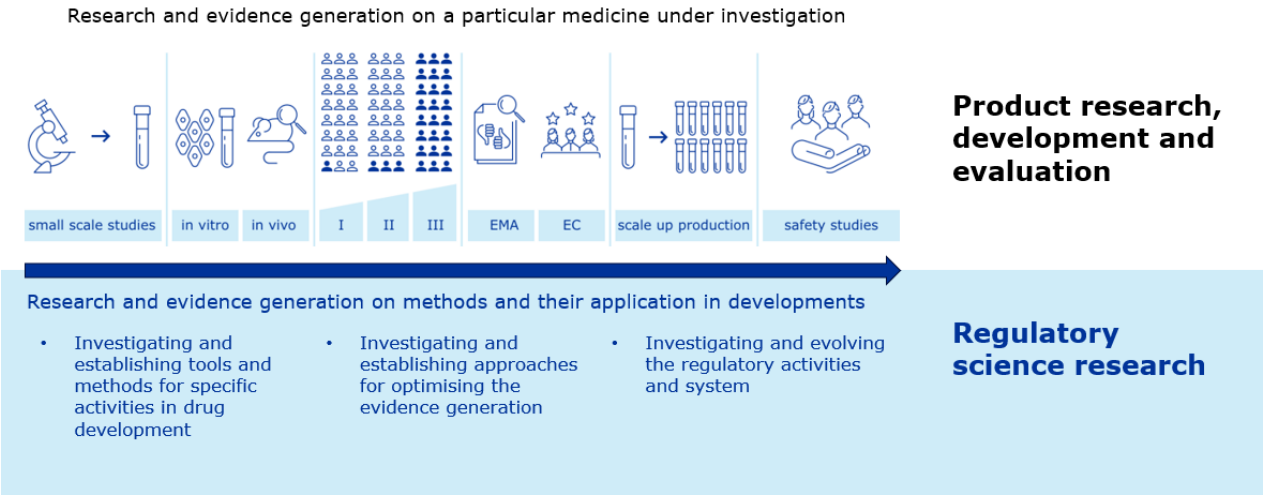

Figure 1: Regulatory science research depicted across the R&D and evaluation pathway of a medicine

Advances in basic and translational science, and the quickening pace of innovation, are drivers for finding ways to ensure regulatory science is prepared and available to be applied by regulators. Conversely, decisions and examples from the operational regulatory work, including of submissions that did not succeed, may contain valuable feedback on what has an impact on regulatory decision-making. This may help refine the focus of research or could help to increase chances of a successful transition from research to regulatory and clinical use. Collaboration and dialogue between regulators and researchers is therefore crucial to keep regulatory science in step with innovation and to enhance its impact in the regulatory system. As recognized in the EMA Regulatory Science Strategy to 2025[4] as a key goal and as underlined by the Framework of collaboration between the EMA and academia[5], there is an important need to further develop interactions and leverage collaborations between regulators and academia to address such rapidly emerging regulatory science research questions.

To advance regulatory science through research and collaboration, the Agency committed in its Regulatory Science to 2025 Strategy to "*Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science*" and to "*Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research*

[4] EMA Regulatory Science to 2025 – Strategic reflection
[5] EMA/125511/2017 Framework of collaboration between the European Medicines Agency and academia

questions" and this was subsequently reinforced in the European Medicines Regulatory Network (EMRN) Strategy to 2025[6]. Also, the HMA EU-Innovation Network (EU-IN) published principles for collaboration between researchers and national regulators[7].

The draft European Medicines Regulatory Network Strategy to 2028 (EMANS 2028)[8] is a successor to previous strategies and underscores regulatory science as a continued focus area, highlighting the critical role regulatory science has in public health by bridging the gap between scientific research and the application of that research in regulatory decision-making. To bridge that gap, the network is aware it needs to help create a conducive regulatory and research environment. Developing partnerships with academia and other stakeholders is needed in this regard to help deliver impactful progress in regulatory science.

Concerning *topics* of regulatory science research, EMA first published in December 2021 a list of regulatory science research needs (RSRN), with the aim of stimulating researchers and funding organisations to consider these needs in their work and programmes.[9] This list is periodically updated with new topics, and the EMA 2024 update of the RSRN is open for public consultation in parallel of this draft concept paper[10].

Establishing a mechanism for regular and iterative engagement between regulators and academic research centres will be crucial to foster collaboration in identifying and tackling pressing needs in regulatory science and key research questions of common interest and develop collaborations to address these needs in important areas of regulatory science.

3. Proposal for a European Platform for Regulatory Science Research

3.1. Scope

The platform aims to advance and accelerate regulatory science research, to increase the quality and impact of research and outcomes, thereby improving regulatory practices, standards, development and use of medicines and relevant devices or other technologies. This includes contributing to identifying new and recurring issues in medicines development, medicines development tools and methods, and regulatory decision-making which would benefit from research, informing research on these regulatory science research needs, exchanging experience on methodology and best practices, and fostering translation of results into practical solutions. This will help the system address gaps and research needs in regulatory science. It will also help improve the usefulness of outputs, and it will support the translation of solutions into the work of regulators and developers. The platform is also intended to promote dialogue and foster collaboration between regulatory science researchers and regulators across Europe and beyond.

The platform will provide a unique systematic approach, acting as mechanism among academic and non-for-profit research organisations[11] and regulators working on regulatory science research to discuss and collaborate on important regulatory science research needs with regulators, and optimise research outcomes and impact on regulatory practices, standards, medicines development and use.

The focus in the platform shall be on horizontal research questions regarding the development and evaluation of medicines, classes of medicines, and tools and methods for medicines development (Figure

[6] EMA/85501/2020 European medicines agencies network strategy to 2025
[7] EMA/38599/2023 Considerations for research / project teams seeking competent authority participation in externally funded regulatory science and public health research projects related to medicinal products
[8] EMA/376542/2024 EMANS 2028
[9] EMA/705364/2021 Regulatory Science Research Needs version 1.0
[10] Open consultations | European Medicines Agency (EMA)
[11] EMA/125511/2017 Framework of collaboration between the European Medicines Agency and academia

1, Figure 2). Not in scope are discussions on individual medicines or evidence generation for specific medicines. It is also not meant to replace support offers for individual development programmes of medicines or tools offered by EMA (such as Scientific advice, Innovation taskforce or Academia briefing meetings).[12,13]

The topics and discussions within the platform will consist of a combination of horizontal/cross-cutting topics, which are expected to be of interest and benefit to a wide group of researchers and regulators, regardless of their specific field of expertise and research. This will include discussions on identifying regulatory science research gaps and finding topics of common interest, discussions on methods and best practices for doing regulatory science research, and discussions on how to improve translation and impact of research results. These horizontal/cross-cutting topics will be combined with discussions on specific research topics ("research topic specific discussions"), and projects, as case studies, with the aim of informing the horizontal topic discussion and generating learnings, best-practices, and take aways that are of use and value for a wider group of researchers and regulators (Figure 2). Discussion topics will range across the spectrum of types of research gaps including knowledge gaps, conceptual / theoretical gaps, methodological gaps, empirical gaps, practical gaps, and population gaps. Topics for human as well as veterinary domains are in scope of the proposal and platform.

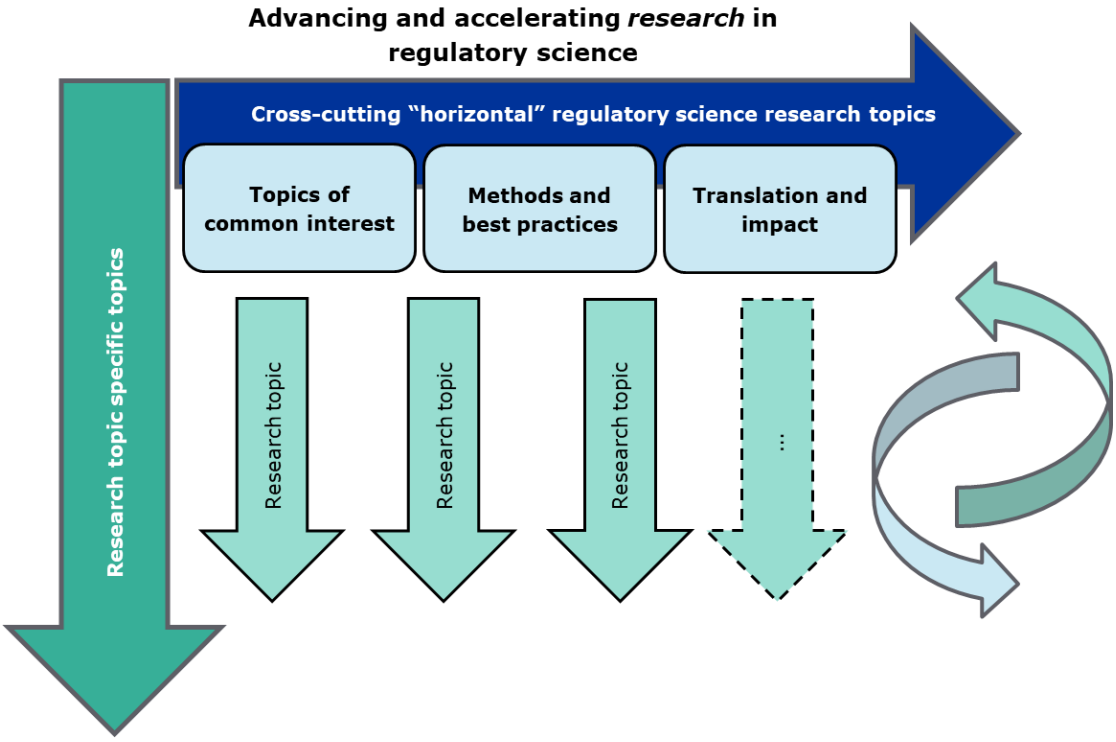

Figure 2 Platform topic framework consisting of an interplay between cross-cutting regulatory science research topics and research topic-specific discussions

[12] Supporting innovation | European Medicines Agency (EMA)
[13] Academia | European Medicines Agency (EMA)

The strategic objectives of the platform aims are:

1. To advance and accelerate research addressing regulatory needs
2. To refine and enrich regulatory research topics with academic interests and research methods expertise
3. To disseminate information on recent regulatory decisions and initiatives that may highlight particular needs for research and that may support fine-tuning of research objectives and projects in the academic researcher community
4. To progress methodological standards and to increase the relevance of research outputs
5. To accelerate translation of outputs into improved medicines R&D and regulatory practices
6. To support growth of the academic researcher community engaging on regulatory issues collaborating with regulators

Proposed performance indicators can be found in section 4.6.1.

The platform will consist of a Steering group and a Platform Participant group. There will be steering group, platform participants, and optional topic-specific meetings.

3.2. Expected benefits

Establishing the proposed platform is expected to yield relevant benefits for regulators and for researchers, and consequently also for other stakeholders (e.g., research funders, developers, healthcare professionals) involved in regulatory science research – ultimately and most importantly to the benefit of patients and public health. These benefits may include:

- Enhanced collaboration and knowledge exchange among academic researchers and regulators
- Streamlined research efforts, increased efficiency, and outputs consolidation
- Strengthened impact and accelerated translation of outputs into practical application
- Support the implementation of the European Medicines Agencies Network Strategy to 2028 (EMANS 2028 draft), especially section 3 *Regulatory science, innovation and competitiveness*[14]

For researchers in particular, benefits motivating to participate are thought to include:

- Inform own research agenda with needs from regulators
- Opportunity to establish collaborations with researchers from other groups and regulators
- Awareness and familiarity of researchers with initiatives and support of European regulators
- Increase visibility and exchange on regulatory science activities at European level
- Increased capacity and competencies for regulatory science research
- Exchange on methodology and regulatory science research best practices
- Facilitate projects and information on formalizing collaborations with regulators (e.g., collaborating or seconded national experts, partnerships with EMA and/or National Competent Authority (NCA) involvement)

[14] EMA/376542/2024 Seizing opportunities in a changing medicines landscape: The European medicines agencies network strategy 2028 (draft)

- Increase translational value of research through early and recurring regulatory input and exchange
- Increase awareness on regulatory science research within researchers' institutions
- Promote and establish (as multiplier and ambassadors) education on regulatory science within researchers' own institutions (e.g., dedicated pre- or postgraduate programmes).

For the medicines' regulatory system, benefits include:

- Enrich regulatory science needs with views from other stakeholders including researchers
- Stimulate researchers to address and take up regulatory science research questions deemed important by regulators into their work (e.g., in grant proposals, PhD programs, …)
- Have research outputs with increased translational value and impact on regulatory practice, through early dialogue and exchange with researchers
- Facilitate formalized expert collaboration with researchers (e.g., collaborating expert projects, seconded national experts, public private partnership with EMA involvement)
- Start developing a mechanism and community for exchange with researchers on issues of common interest (e.g., academia training strategy, tailored scientific, regulatory, and procedural support and interaction for academia and non-for-profit developers, …)

4. Operational aspects

The proposed platform will primarily work as a mechanism for dialogue and collaboration between academic and non-for-profit regulatory science researchers and regulators across Europe and beyond. The platform seeks to engage its participants to foster collaborations. Events convening the platform participants will be organized as two to three meetings per year to discuss selected horizonal questions, case studies, research gaps, and priority topics. In addition, topic-centric discussions (see section 4.1.3) can be organized.

4.1. Governance and structure

The European Platform for Regulatory Science Research will be established to facilitate discussion, understanding and opportunities for collaboration on important regulatory science research needs between academic researchers with regulators, and to optimise research outcomes and impact on regulatory practices, standards, and medicines development and use.

This proposal should be understood as a foundation that will evolve and possibly expand over time to meet emerging needs and opportunities. This draft concept paper will form the basis for the terms of reference/mandate for the platform.

4.1.1. Platform chairs and Steering Group

The platform will initially be co-chaired by a representative of EMA and of an NCA endorsed by HMA and the EMA Scientific Coordination Board, later to be rotated between NCAs. The co-chairs will support the platform by curating topics for discussion, supporting topic-specific groups, organising and moderating platform meetings, and producing meeting reports. A call for expression of interest will be launched to invite and select a researcher of an academic or non-for-profit research centre as third co-chair (also to be rotated).

The members of the Steering group will initially consist of EMA and NCA platform chairs and expanded to include academic and non-for-profit regulatory science researcher and regulators.

The Steering group is responsible for:

- identifying priority tasks and topics for discussion, drafting workplans (meeting topics and frequency), and define ways of working on priority topics
- reviewing the platform organisation and resourcing, resolving operational and scientific matters
- guiding the interaction with stakeholders

The composition of the Steering group will be determined following a public call for expressions of interest. Following this, organisations will be selected and invited to join the Steering group.

Patient, healthcare professional, industry, and health technology assessment (HTA) representatives, and EU and national research funders will be invited to participate to Steering group meetings as observers. Stakeholders will be invited to express their interest to a public call for expressions of interest.

Depending on the topic under discussion, additional participants can be invited to attend the Steering groups meetings. Also, international partner organisations or authorities can be invited to participate as observer (standing invitee) or guest (ad hoc invitee).

Steering group meetings will be organised quarterly to develop platform topics, meetings and relations to stakeholders.

4.1.2. Platform participant group

The platform aims to bring together and foster collaboration with and between researchers engaged in regulatory science research (i.e., those researchers who conduct basic and applied biomedical and social sciences research that aims to inform R&D and regulatory decision-making through the evaluation and development of regulatory standards and tools), under the EMA framework for collaboration with academia.[15] The participants are from the academic sector as defined in the EMA framework for collaboration with academia.

These include:

- EU academic research groups and individual researchers from the academic sector working on regulatory science research, developing novel medicines with product-independent regulatory science issues, enabling technologies, tools, or methods.
- EU non-for-profit research organisations / EU public research organisations conducting regulatory science research, developing or evaluating novel medicines with product-independent regulatory science issues, enabling technologies, tools, or methods.
- Also, non-EU academic and non-for-profit research organisations conducting regulatory science research are welcomed to participate in the platform meetings.

Regulatory participants can include regulatory scientists from:

- European Medicines Agency (EMA)
- EU National Competent Authorities (NCAs)
- International regulatory agencies

[15] EMA/125511/2017 Framework of collaboration between the European Medicines Agency and academia

Participants will be invited to participate in the platform through a first public call for expressions of interest (Q4 2024 – Q1 2025) and will have the opportunity to express their interest to participate in the platform also later via contact details on the platform's webpage.

It is acknowledged that researchers not only from the academic sector and within regulatory agencies conduct relevant regulatory science research. Also, other stakeholders, such as in the for-profit-sector and healthcare professional or patient organizations, are engaged in such activities. Additional types of interested parties (see below) may become involved in the platform participant group over time, also from outside the EU, such as international partner organisations or authorities:

- National and EU-level research funders
- Industry trade organizations
- Patient organisations
- Healthcare professional organisations
- HTA bodies
- Policy makers

After the one-year pilot phase, it will be assessed how to involve additional types of interested parties.

Steering group reports and calls for expressions of interest to join topic centric discussions will be made publicly available via the platform's webpage and circulated to platform participants via email or newsletter.

4.1.3. Optional topic-specific meetings

Topic centric meetings might be held on selected priority regulatory science research needs. The Steering Group will be tasked with selecting these topics based on priority needs (in line with the Regulatory Science Research Needs initiative)[16], considering feedback from the platform participant group, and in alignment/collaboration with existing groups and initiatives.

4.2. Topic repository

It is planned to create a collaborative topic repository, an Agile backlog of topics, from various inputs, including topics from the Regulatory Science Research Needs[17]. From these, the steering group can select, prioritise and refine topics and populate agendas.

This topic repository will consist of horizontal, cross-cutting topics and questions, as well as topic-specific ones and case studies.

For illustration, examples of possible topics are:

- Research into methods to improve acceptance and efficiency of platform trials
- Approaches for establishing biomarkers ("validation") for different purposes
- The European Public Assessment Report (EPAR) as a research tool (method discussion)
- Showcasing and expanding researchers' use of EMA Clinical data publication (policy 70)
- Complementary pathways for translating tools and methods into R&D of health interventions

[16] EMA/705364/2021 Regulatory science research needs (version 1.0)
[17] Regulatory Science Research Needs

- Discussion on strategies for translation into medicines' R&D and use
- Spotlight information on funding opportunities or proposals

4.3. Operation

The platform will primarily operate virtually, with the option for face-to-face meetings as needed. It will use off the shelf IT tools and seeks to have its own webpages on EMA's and HMA's website.

Meeting topics and frequency (e.g., quarterly) will be decided by the Steering group in a workplan. Two to three times a year, the platform will hold a meeting convening the platform participants, to enable exchange, and gathering stakeholder input and setting of priority tasks for the following year. In addition, ad-hoc and topic specific workshops, in line with regulatory science research priorities, can be organised (see Section 8 for a tentative platform schedule).

4.3.1. Resourcing

The platform is proposed to initially be organised by EMA. This will be assessed after the proposed one-year pilot phase.

Resource contributions from each co-chair's organisation (EMA, NCA, and research centre) will be discussed in the Steering group.

4.4. Funding support for conducting research

The platform cannot offer or facilitate funding to researchers. Funders may be wish to present funding opportunities in platform meetings for awareness of participants.

Different levels of engagement with funders are foreseen to raise awareness about regulatory science research topics to support the uptake of relevant topics in considerations for funding calls, and increase awareness among academic partners about funding opportunities:

- EU and national research funders will be invited to participate to Steering group meetings as Observer (described in Section 4.1.1. Platform chairs and Steering Group)
- Funders will be invited to present in Platform meetings to present funding opportunities to researchers (described in Section 4.2. Topic repository)
- Funders will be consulted with the aim of promoting and further developing best practices of interaction with regulators in funded research projects, and to stimulate uptake of research needs in funding calls (described in section 6. Relations with existing groups)

These points might be refined during the pilot phase of the platform.

Outside of the platform, EMA invites tenderers for a framework contract on quality, efficacy and safety studies on medicines[18] which can cover a variety of research in RSRN focus areas to support the delivery of relevant research outputs.

4.5. Practical outputs

Meeting reports will be published under the responsibility of the Chairpersons and made publicly available on EMA's and HMA's websites. In addition, reports will be disseminated to the regulatory network and to

[18] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/72456246-9cd8-4978-9703-f90cf4e86227-PIN

the group of platform participants. The platform sets out to also publish the outcomes of its discussions by preparing recommendations and scientific papers on specific topics of meetings.

The views expressed in the meetings and reports should not be understood as expert advice given by the Agency, or as representing the views of the Agency.

4.6. Evaluation

4.6.1. Key performance indicators

The proposed key performance indicators include:

- Number of participants joining the platform (year 1) / increase in number of platform participants and collaborations fostered compared to proceeding year
- Satisfaction of participants
- Number of meetings carried out/number of meetings planned (ratio)
- Number of research projects initiated
- Number of research projects completed
- Number of regulatory science research needs identified
- Number of regulatory science research needs (EMA RSRNs)[19] addressed
- Number of research results translated into regulatory practice, methods and tools or medicines development
- Number of EMA procedures for human and veterinary medicines where information from this initiative was included in regulatory decision making

The proposed key performance indicators are intended to measure the platform's overall success and impact. Several indicators (e.g., number of completed research projects) are for assessing performance in the longer run and may not be reported after the one-year pilot phase due to the time required to achieve them. A tailored subset of KPIs specific to the first year will be developed and included in the platform's terms of reference.

4.6.2. Pilot phase

The platform is proposed to undergo a one-year pilot phase. Upon conclusion of the pilot phase, the working procedures of the platform will be assessed. Achievements and experiences will be summarized and reported upon conclusion of the pilot phase.

4.7. Reporting

The platform performance and the progress on its business case will be reported to EMA's Management Board and the HMA Management group. In addition, reporting under the form of public reports on EMA's and HMA's website and as part of scientific publications will be considered.

[19] EMA/705364/2021 Regulatory science research needs (version 1.0)

5. Activities for advancing regulatory science research

In 2020, the EMA Regulatory Science Strategy to 2025[20] set the foundation for several initiatives and actions aiming at ensuring that the EU Medicines regulatory network has the regulatory tools to fulfil its mission in face of new scientific challenges. The emergence of new types of medicines, innovations in research and development, novel methods to perform clinical trials and experiments are examples of opportunities but also of challenges from a regulatory perspective.

Among other activities, EMA supports a large number of pre-competitive consortia through staff members in advisory roles and through direct contribution of efforts, in addition to engaging in further ways with externally-funded regulatory science and process improvement activities as well as with researchers from the academic sector as collaborating or seconded experts.[21,22] At National competent authorities (NCAs), regulatory science activities are being conducted, in particular through projects with regional researchers and through participation in externally funded projects. Some NCAs have long-standing interactions with academia and systematically engage with universities to leverage PhD work for increasing regulatory readiness, building capacity of the agency for assessment and fostering good regulatory practices.[23] NCAs also participate as partners in externally funded research, conduct their own research and development subprojects, to provide regulatory expertise to externally-funded projects on a national, European or international basis.[24]

The European Platform for Regulatory Science Research initiative is part of EMA's and the European regulatory network's activities to systematically advance regulatory science through research in a concept of a life cycle that has the following steps as depicted in Figure 3.

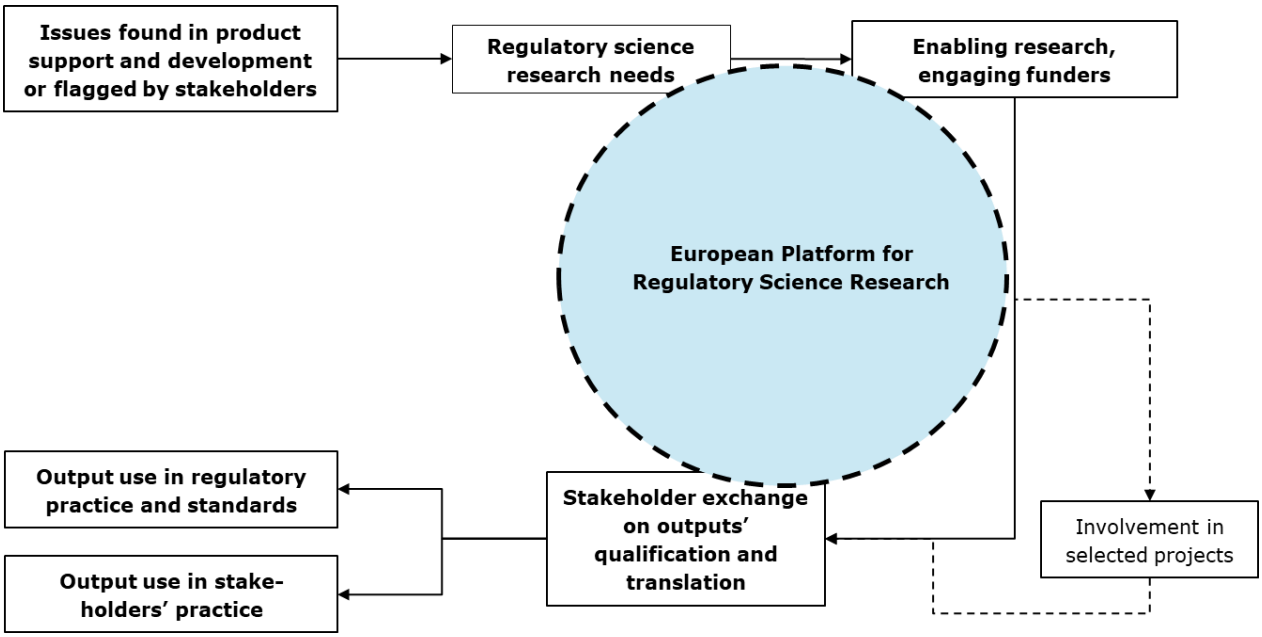

Figure 3: Activities to advance regulatory science research; the regulatory science lifecycle

[20] EMA Regulatory Science to 2025 – Strategic reflection
[21] https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/support-research
[22] https://www.ema.europa.eu/en/documents/other/european-medicines-agency-process-engaging-externally-funded-regulatory-sciences-and-process-improvement-research-activities-public-and-animal-health_en.pdf
[23] https://doi.org/10.1002/cpt.3275
[24] https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/EU-IN/2023_02_EU-IN_Involvement_of_competent_authorities_in_externally_funded_projects.pdf

The Platform will provide a unique mechanism for structured, systematic and pro-active dialogue among academic researchers with regulators on regulatory science research, with the aim of informing, advancing, and accelerating the different components of the regulatory science life cycle; i.e. identifying research gaps and needs, enabling of research, translation of research results in practice, use of outputs in regulatory and stakeholders' practice. Complementary descriptions of the different components depicted in the boxes in Figure 3 can be found in the Regulatory Science Research Needs 2024 update, section 1.1.[25]

6. Relations with existing groups

The following section provides a preliminary overview on how the platform envisions to interact on regulatory science research with existing groups and initiatives.

The platform will seek interaction and engage with existing initiatives and groups active in the field of regulatory science within the remit of regulatory authorities, academic and non-for-profit, and funder organisations, to maximize synergies, avoid overlap and duplication of efforts, and enhance the visibility of its activities and outputs. These interactions will be important to foster collaboration and ensure a cohesive approach to regulatory science research across Europe.

In the following, the anticipated interactions with existing groups or selected members of these groups are described with respect to type of interaction and objectives.

Key groups and initiatives:

- The Methodology Working Party (MWP) and veterinary counterpart: strategic aspects of agenda setting and handling research topics and methods, identification and collaboration on new regulatory issues and needs, individuals to potentially volunteer as collaborator.
- Therapeutic area European specialised expert communities (ESECs)[26] (e.g., haematology, oncology, cardiovascular diseases, others forthcoming): identification and collaboration on new regulatory issues and needs, individuals to potentially volunteer as collaborator, to increase relevance of research outputs, to accelerate translation.
- Methodology-oriented ESECs (e.g., the non-clinical and new approach methodologies ESEC, methodology ESEC, Environmental Risk Assessment ESEC) and Quality Innovation Expert Group (QIG): identification of regulatory issues and needs, to engage academic expertise on these needs, individuals to potentially volunteer as collaborator, to increase relevance of research outputs, to accelerate translation.
- Committee for Medicinal products for Human Use (CHMP), Committee for Veterinary Medicinal Products (CVMP), Committee for Orphan Medicinal Products (COMP), Committee for Advanced Therapies (CAT), Committee on Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), Pharmacovigilance Risk Assessment Committee (PRAC), Scientific Advice Working Party (SAWP), SAWP-V: for expert input and output review on relevant regulatory science research needs, progress, and outcomes, to increase relevance of research outputs, to accelerate translation.

[25] EMA/51138/2023 EMA 2024 update of the Regulatory Science Research Needs – public consultation
[26] ESEC refers to European Specialized Expert Community, which is a community of experts with special knowledge and/or strong interest in the ESEC that are part of the European Regulatory Network.

- EMA Academia Collaboration Matrix: to identify and contribute new topics, to contribute to monitorization of academic stakeholders working on regulatory science research, to foster integration of relevant results into regulatory practice.
- Healthcare Professionals Working Party (HCPWP), Patients' and Consumers' Working Party (PCWP): to accelerate translation into clinical application, to build and grow the academic (researcher) community collaborating with regulators.
- Other Working Parties, or experts identified by WPs, depending on the research topic (3Rs Working party (3RsWP); Non-clinical Working Party (NcWP); Biologics Working party (BWP); Biosimilar Medicinal Products Working Party (BMWP), Quality Working Party (QWP), therapeutic area WPs), and Committee for Veterinary Medicinal Products (CVMP) WPs: for expert input and output review on relevant regulatory science research needs, progress, and outcomes, to increase relevance of research outputs, to accelerate translation.
- HMA-EMA joint Big Data Steering Group: identification and collaboration on new regulatory issues and needs, to identify synergies.
- The Cancer Medicines Forum (CMF): mutual exchange with CMF secretariat about agendas and research topics.
- The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA): mutual exchange with Enpr-EMA secretariat about agendas and research topics.
- The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP): mutual exchange with ENCePP secretariat about agendas and research topics.
- Accelerating Clinical Trials in the EU (ACT EU): mutual exchange with ACT EU secretariat about agendas and research topics.
- ATMP and medicine repurposing pilots to support non-profit organisations and academia: mutual exchange between EMA leads.
- International Coalition of Medicines Regulatory Authorities (ICMRA): for expert input and output review on relevant regulatory science research needs, progress, and outcomes.
- Funders: to promote and further develop best practices of interaction with regulators in EU-funded research projects, to stimulate uptake of research needs in funding calls (e.g., European Innovation Council, Directorate-General Research and Innovation (DG RTD), Directorate-General Health and Food Safety (SANTE), EU4Health, Horizon Europe, Innovative Health Initiative (IHI), national funders)
- Relevant HMA groups, including the EU-Innovation Network (EU-IN): to inform on the activities of the platform, to co-develop activities fostering the involvement and collaboration of competent authorities in relevant regulatory science research projects.
- Optionally, groups that have formed to bring together relevant regulatory science stakeholders, such as the European Federation for Pharmaceutical Sciences (EUFEPS) Regulatory Science Network, Regulatory Science Network Netherlands (RSNN), Critical Path Europe, and the Centre for Innovation in Regulatory Science, among others.

7. Further development to inform and launch the platform

This section describes how the development of the platform proposal was informed and which further activities and steps are planned to further inform the focus, scope, and operation.

7.1. Mapping of academic and non-for-profit regulatory science research groups

A systematic mapping of academic and non-for-profit regulatory science research groups is ongoing to ensure a broad understanding of the existing regulatory science research landscape, to identify potential participants, and to integrate a broad range of expertise into the platform. The mapping and landscape analysis involves a screening of publications in a selection of regulatory science research focused journals and conferences, of EMA Academia briefing meeting applicants, and researchers who contacted EMA on the Regulatory Science Research Needs list, as well as targeted searches and snowballing. Both centres and organisations have been mapped, at national, European and international level. This is an ongoing activity.

7.2. Consultations within EMA and the regulatory network

Interviews with colleagues (n=15) within EMA were conducted between February and July 2024 to obtain input. These internal consultations provided valuable insights from colleagues across offices, taskforces and academia-oriented initiatives (including Enpr-EMA (European network of paediatric research at EMA), ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance), ACT EU (Accelerating Clinical Trials in the European Union), CMF (Cancer Medicines Forum)) to inform the concept and operation of the proposed Platform. In addition, the HMA EU-Innovation Network (EU-IN), the EMA Scientific Coordination Group (SCG), the EMA Scientific Coordination Board (SciCoBo), the HMA Management Group and HMA were consulted. Interviews and presentations were combined with review and revisions of the draft concept paper.

7.3. Academia interviews

Interviews with academic and non-for-profit regulatory science researchers and funders (also involving (former) HCPWP and PCWP chairs) are envisaged in order to gather expert views and suggestions on the proposed Platform. This will facilitate to obtain in-depth views and suggestions on the proposed way of collaboration between academic regulatory science researchers and regulators within the platform. The interviews will address questions regarding sustaining buy-in of researchers, incentives, involvement in governance, identifying researchers to grow platform contacts. The researchers for the interviews will be selected to ensure broad European input. The interviews will be semi-structured with a topic guide.

7.4. Public consultation

A public consultation[27] is open (14 November 2024 – 18 December 2024) to invite feedback from a wider audience, and across stakeholder groups on this proposal.

7.5. Public Event Advancing Regulatory Science Research

A public Event Advancing Regulatory Science Research[28] will take place on 18 November 2024 (13:30-17:30 CET) to introduce the platform and its objectives, invite feedback on the draft concept paper from the public, and invite stakeholders to express their interest to participate.

During this event, also the EMA 2024 update of the Regulatory Science Research Needs[29] will be presented which is also open for public consultation.

[27] EMA/HMA Draft concept paper European Platform for Regulatory Science Research
[28] EMA 2024 Public Event Advancing Regulatory Science Research
[29] EMA/51138/2023 EMA 2024 update of the Regulatory Science Research Needs – public consultation

7.6. Call for expression of interest

A call for expression of interest to participate in the platform will be opened (Q4 2024 – Q1 2025) to invite collaborators to the platform.

8. Next steps and tentative platform schedule

Tentative date /period	Activity
14 November 2024 – 18 December 2024	Public consultation on the draft concept paper
18 November 2024	Public event Advancing Regulatory Science Research Advancing regulatory science research | European Medicines Agency (EMA)
Q4 November 2024 – Q1 2025	Call for expression of interest
January – February 2025	Publication of the final concept paper
February 2025	Steering Group meeting I
March 2025	Platform meeting I
April 2025	Steering Group meeting II
June 2025	Platform Meeting II
June 2025	Steering Group meeting III
September 2025	Steering Group meeting IV
November 2025	Platform Meeting III